



Instruction For Use

Vi-CELL MetaFLEX

Bioanalyzer



PN B95790AE
January 2025



Beckman Coulter, Inc.
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Brea, CA 92821 U.S.A.



Vi-CELL MetaFLEX

Bioanalyzer

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*May be covered by one or more pat. - see
www.beckman.com/patents*

Glossary of Symbols is available at
beckman.com/techdocs (PN C24689).

Original Instructions

Revision History

This document applies to the latest software listed and higher versions. When a subsequent software version affects the information in this document, a new issue will be released to the Beckman Coulter Web site. For labeling updates, go to www.beckman.com/TechDocs and download the latest version of the manual or system help for your instrument.

Initial Issue, September 2016

Software version 3.1

Issue AB, May 2017

Software version 3.1

Updates were made to the following sections:

Conventions Used, Product Description, Metabolite Sensors, Long-Term Shutdown of the Analyzer, Maximum Sample Age, Automatically Change the Temperature Units, Replacing the Fuse, Overview, and Cleaning Products - Part Numbers.

Issue AC, September 2021

Software version 3.1

Updates were made to the following sections:

Ranges of Indication, Quality Control Products - Part Numbers

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Updates were made to the following sections:

Symbol Explanations, Figure 9.1, and Figure 9.2

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Updates were made to the following sections:

[CHAPTER 9, Precautions/Hazards](#)

[CHAPTER 9, Hazard Labels and Locations](#)

Note: Changes that are part of the most recent revision are indicated by a bar in the left margin.

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Safety Notice

Read all product manuals and consult with Beckman Coulter-trained personnel before attempting to operate instrument. Do not attempt to perform any procedure before carefully reading all instructions. Always follow product labeling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, contact your Beckman Coulter representative.

Beckman Coulter, Inc. urges its customers and employees to comply with all national health and safety standards such as the use of barrier protection. This may include, but it is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

Alerts for Warning and Caution



WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

In this document the signal word WARNING is only used to indicate the possibility of personal injury. It is not used to indicate the possibility of erroneous data.



CAUTION indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.

In this document the signal word CAUTION is only used to indicate the possibility of damage to the instrument or of erroneous data.

Safety Precautions

WARNING

Risk of operator injury if:

- All doors, covers and panels are not closed and secured in place prior to and during instrument operation.
- The integrity of safety interlocks and sensors is compromised.
- Instrument alarms and error messages are not acknowledged and acted upon.
- You contact moving parts.
- You mishandle broken parts.
- Doors, covers and panels are not opened, closed, removed and/or replaced with care.
- Improper tools are used for troubleshooting.

To avoid injury:

- Keep doors, covers and panels closed and secured in place while the instrument is in use.
- Take full advantage of the safety features of the instrument.
- Acknowledge and act upon instrument alarms and error messages.
- Keep away from moving parts.
- Report any broken parts to your Beckman Coulter Representative.
- Open/remove and close/replace doors, covers and panels with care.
- Use the proper tools when troubleshooting.

CAUTION

System integrity could be compromised and operational failures could occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the product manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's software with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

CAUTION

If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, contact your Beckman Coulter Representative.

General Warning and Cautions

WARNING

Risk of infection. Dispose and handle all used sampling devices, quality control (QC) ampoules, Solution Packs, Sensor Cassettes, Inlet Probes, Inlet Gasket Holders, Inlet Connector Gaskets and Inlet Modules as biohazardous waste.¹ Follow your local regulations.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

CAUTION

Risk of operator injury. The sensor cassette door and sample inlet probe are automated moving parts. Use caution around these areas to avoid injury.

CAUTION

Risk of instrument damage. This device is intended for indoor use only. To avoid device damage, do not install the instrument outdoors.

WARNING

Risk of personal injury. Safety protection can be impaired if used in a manner not specified by the manufacturer. To avoid personal injury, use the instrument according to the manufacturer's instructions only.

Symbol Explanations

These are the symbols and icons you may find on the analyzer and the consumable products used with it.

Symbol/icon	Explanation
	Caution / Warning
	Biohazard
	Possible laser radiation inside.

Symbol/icon	Explanation
	Sample mixer
	Keep dry
	Do not use if package is damaged
	Do not re-use
	Use by
	Contains sufficient for <n> tests
	Temperature limit
	Lot no.
	Catalog no. (product code)
	Consult instructions for use
	Manufacturer
	Keyboard
	CE = Conformité Européenne A “CE” mark indicates that a product has been assessed before being placed on the market, and has been found to meet European Union safety, health, and/or environmental protection requirements. It is a mandatory marking for various product categories that are placed into service within the European Economic area.
	A “UKCA” mark indicates that a product has been assessed before being placed in the UK market, and has been found to meet UK safety, health, and/or environmental protection requirements.
	COM gate (scanner/barcode reader)
	VGA (monitor)
	Mouse

Symbol/icon	Explanation
	Network
	Off
	On
	cNRTLus certification
	The RCM mark is for products that comply with Australian Communications Media Authority (ACMA) EMC requirements.
	Fuse symbol
	USB
	This symbol indicates that Beckman Coulter Medical ApS and its distributors within the European Union (EU) and associated states have taken the necessary steps to comply with the "DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste of electrical and electronic equipment (WEEE)". Equipment marked with this symbol must not be disposed of as household waste but as electronic waste in accordance with local legislation. Please note that equipment contaminated with potentially infectious substances, such as body fluids, must be decontaminated before recycling. If this is not possible, the equipment must be disposed of as biohazardous material. Contact your local Beckman Coulter representative for instructions.
	Marks compliance with SJ/T 11363-2006 (China RoHS). The number in the symbol shows the environmentally friendly use period in years.
	Marks compliance with SJ/T 11363-2006 (China RoHS). The product contains no restricted substances above the prescribed thresholds.

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Introduction

How to Use Your Manual

Your Vi-CELL MetaFLEX Bioanalyzer includes the manuals listed below:

- Use this **Instructions for Use** manual for information on the day-to-day operation of your Vi-CELL MetaFLEX Bioanalyzer. You can find detailed step-by-step procedures for Daily Startup and Quality Control, sample analysis, data review, and Shutdown. This manual also contains physical and system specifications, safety and troubleshooting information, as well as information about what your Vi-CELL MetaFLEX Bioanalyzer does and the methods it uses. It also contains procedures for cleaning and replacement.
- Use the **Vi-CELL MetaFLEX Safety Notices and Basic Troubleshooting** insert for safety notices and basic troubleshooting.

About this Manual

This document tells you what the analyzer can do and how to use it. The analyzer has a default set up that can be customized. Some topics in this document may therefore not be relevant to your analyzer.

The information in your Instructions for Use manual is organized as follows:

CHAPTER 1, System Overview

Provides information regarding the individual components of the Vi-CELL MetaFLEX analyzer and the corresponding functions of these components.

CHAPTER 2, Operation Principles

Describes the basic operation principles related to the instrument and data collection.

CHAPTER 3, Daily Startup

Provides instructions for starting your Vi-CELL MetaFLEX analyzer.

CHAPTER 4, Quality Control

Provides instructions for performing daily quality control (QC) on your Vi-CELL MetaFLEX analyzer to confirm the instrument is working correctly and to ensure accurate experimental data.

CHAPTER 5, Sample Analysis

Provides instructions for operating your Vi-CELL MetaFLEX analyzer to collect sample data.

[CHAPTER 6, Data Review](#)

Describes how to analyze data that has already been acquired through the instrument.

[CHAPTER 7, Shutdown](#)

Describes how to shutdown the Vi-CELL MetaFLEX analyzer.

[CHAPTER 8, Setup](#)

Describes how to carry out various procedures to setup your Vi-CELL MetaFLEX analyzer for use.

[CHAPTER 9, Troubleshooting](#)

Describes some common problems and their solutions.

[CHAPTER 10, Calibration](#)

Provides instructions for performing instrument calibration on your Vi-CELL MetaFLEX analyzer to ensure the instrument is working correctly and to ensure accurate experimental data.

[CHAPTER 11, Cleaning Procedures](#)

Describes how to carry out various cleaning procedures.

[CHAPTER 12, Replacement/Adjustment Procedures](#)

Describes how to carry out various replacement and adjustment procedures.

[APPENDIX A, Installation](#)

Provides the instrument installation procedures for your Vi-CELL MetaFLEX analyzer.

[APPENDIX B, Derived and Input Parameters](#)

This section describes the different types of parameters available on the Vi-CELL MetaFLEX instrument. Some parameters are measured by the analyzer, others are calculated from equations that use measured / keyed-in / default values of other parameters.

[APPENDIX C, Ordering Information](#)

Lists orderable parts and the associated part numbers.

Conventions Used

This document uses the following conventions:

- **Bold face** font indicates buttons or selections that appear on the workstation screen.
- When the word "select" is used in conjunction with a screen and the associated buttons on the screen, you are to press the buttons on the touch screen or click on the buttons with the mouse, as necessary, to display the desired screen or to initiate the desired function.

NOTE The verb "press" is reserved for mechanical buttons, such as keys on the keyboard.

- The software path to a specific function or screen appears with the greater than (>) symbol between screen options.
- Links to information in another part of the document for additional information are in blue and are underlined. To access the linked information, select the blue, underlined text.
- The Vi-CELL MetaFLEX technology is developed from a blood gas analyzer for clinical diagnostics. There will be areas in the software that reference patient. Patient and sample are used interchangeably in displays and reporting.

NOTE The Vi-CELL MetaFLEX system is not intended to be used in the diagnosis of disease or other conditions.

IMPORTANT IMPORTANT is used for comments that add value to the step or procedure being performed. Following the advice in the IMPORTANT adds benefit to the performance of a piece of equipment or to a process.

NOTE NOTE is used to call attention to notable information that should be followed during use, or maintenance of this equipment.

Graphics

All graphics, including screens and printouts, are for illustration purposes only and must not be used for any other purpose. For example, software screens that show the Vi-CELL MetaFLEX system in the background may not depict the latest production version of the system.

CHAPTER 1

System Overview

Overview

This manual is intended to provide the user with information needed to operate and maintain the Vi-CELL MetaFLEX system safely and effectively.

This chapter describes the individual components of the Vi-CELL MetaFLEX Bioanalyzer and the corresponding functions of these components.

This chapter contains information on:

- [Product Description](#)
- [Main Components](#)
- [Consumables](#)
- [Software Menu](#)
- [Operational Checks](#)
- [Common Tasks](#)
- [Analyzer Specifications](#)
- [Consumables Specifications](#)
- [Material Safety Data Sheets \(SDS/MSDS\)](#)

Product Description

The Vi-CELL MetaFLEX analyzer is an automated biochemistry analyzer intended for use in the biochemical analysis of cell culture media, and in the biochemical analysis of whole blood in research applications.

The Vi-CELL MetaFLEX analyzer is not intended to be used in the diagnosis of disease or other conditions.

[Table 1.1](#) shows the measured parameters.

Table 1.1 Measured Parameters

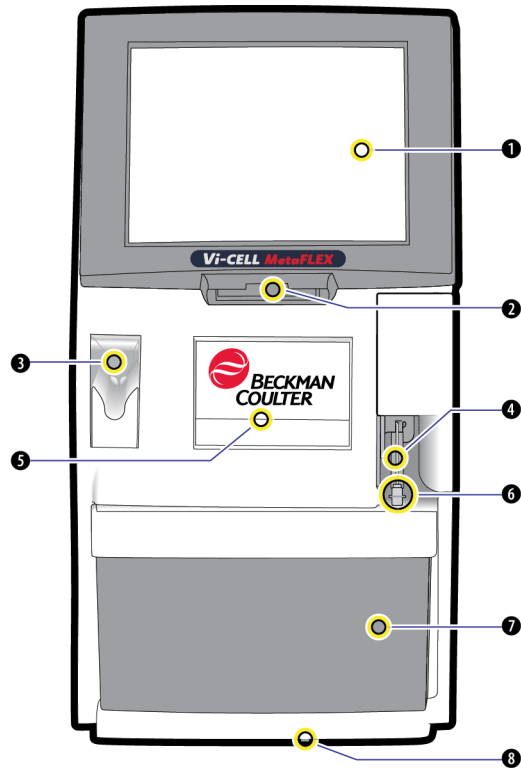
Parameter group	Parameter
Default Cell Media Parameters	
pH/dissolved gas:	pH (acidity)
	$p\text{CO}_2$ (carbon dioxide tension)
	$p\text{O}_2$ (oxygen tension)
Electrolytes:	$c\text{K}^+$ (potassium ion concentration)
	$c\text{Na}^+$ (sodium ion concentration)
	$c\text{Ca}^{2+}$ (calcium ion concentration)
Metabolites:	$c\text{Glu}$ (D-glucose concentration)
	$c\text{Lac}$ (L(+)-lactate concentration)
Additional Parameters	
Oximetry:	ctHb (total hemoglobin concentration)
	$s\text{O}_2$ (oxygen saturation)
	FO_2Hb (fraction of oxyhemoglobin in total hemoglobin)
	FCOHb (fraction of carboxyhemoglobin in total hemoglobin)
	FHHb (fraction of deoxyhemoglobin in total hemoglobin)
	FMetHb (fraction of methemoglobin in total hemoglobin)
	FHbF (fraction of fetal hemoglobin)
	ctBil (concentration of total bilirubin in plasma)
Electrolytes:	$c\text{Cl}^-$ (chloride ion concentration)



Risk of erroneous results. Low $p\text{O}_2$ levels can have an effect on the linearity of glucose measurements. This can lead to incorrect low glucose results. Note that $c\text{Glu}$ linearity is not specified when the $p\text{O}_2$ level is less than 10 mmHg (1.3 kPa).

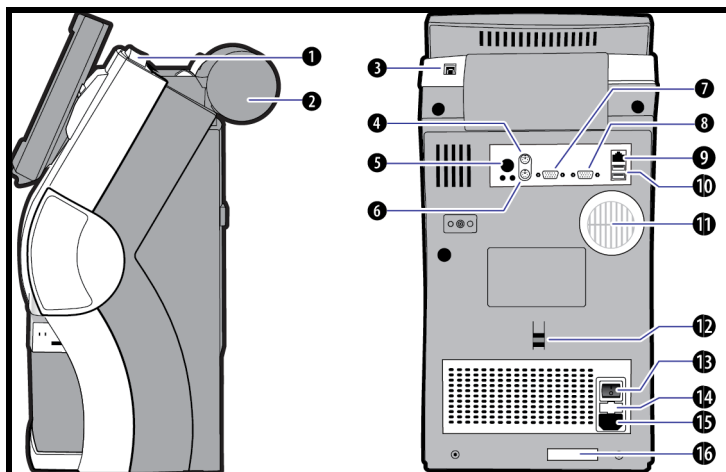
Main Components

Figure 1.1 Front View



1. Touch screen	5. Compartment for the Sensor Cassette
2. Barcode reader	6. Inlet gasket (for sample aspiration)
3. Sample mixer (when working with whole blood)	7. Solution Pack
4. Inlet Gasket Holder	8. Battery indicator light (if the optional battery is installed)

Figure 1.2 Side and Back View

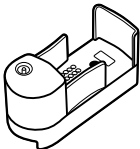
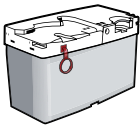


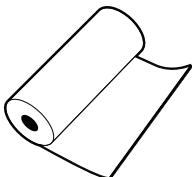
1. Handle
2. Thermal printer
3. USB port
4. Mouse port
5. Standby button
6. External keyboard port
7. External monitor port
8. COM port

9. Network cable port
10. USB ports
11. Ventilator grid
12. Latch for manual release of a Solution Pack
13. Power switch ON (I) and OFF (O)
14. Mains power fuse
15. Mains power socket
16. Serial number

Consumables

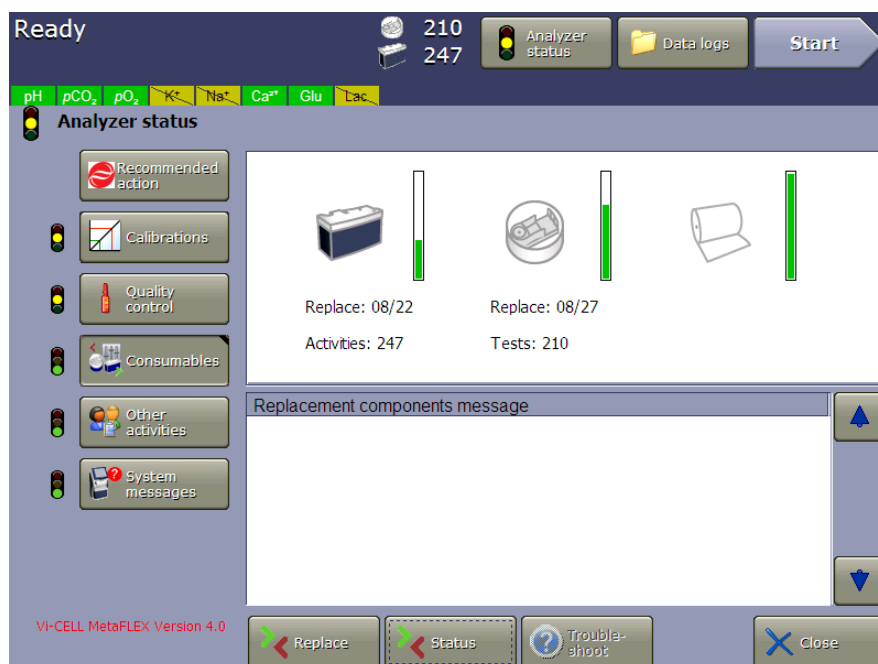
Consumables are parts of the analyzer. The consumables have to be replaced at different times. With the exception of the printer paper, the analyzer tells you when consumables must be replaced.

Consumables	Description
Sensor Cassette 	Contains sensors for the tests (except for the oximetry and bilirubin tests)
Solution Pack 	Contains pouches with QC and calibration material, rinse solution, a gas mixture and closed containers to hold liquid and waste

Consumables	Description
Inlet Gasket Holder 	Holds the inlet gasket (1). This is where you put your sampling device for sample aspiration.
Printer paper 	Paper for the thermal printer

Viewing Details About Installed Consumables

- 1 Select **Menu > Analyzer status > Consumables**. The Consumable Details screen appears.



- 2 Choose an option and follow the steps for it.

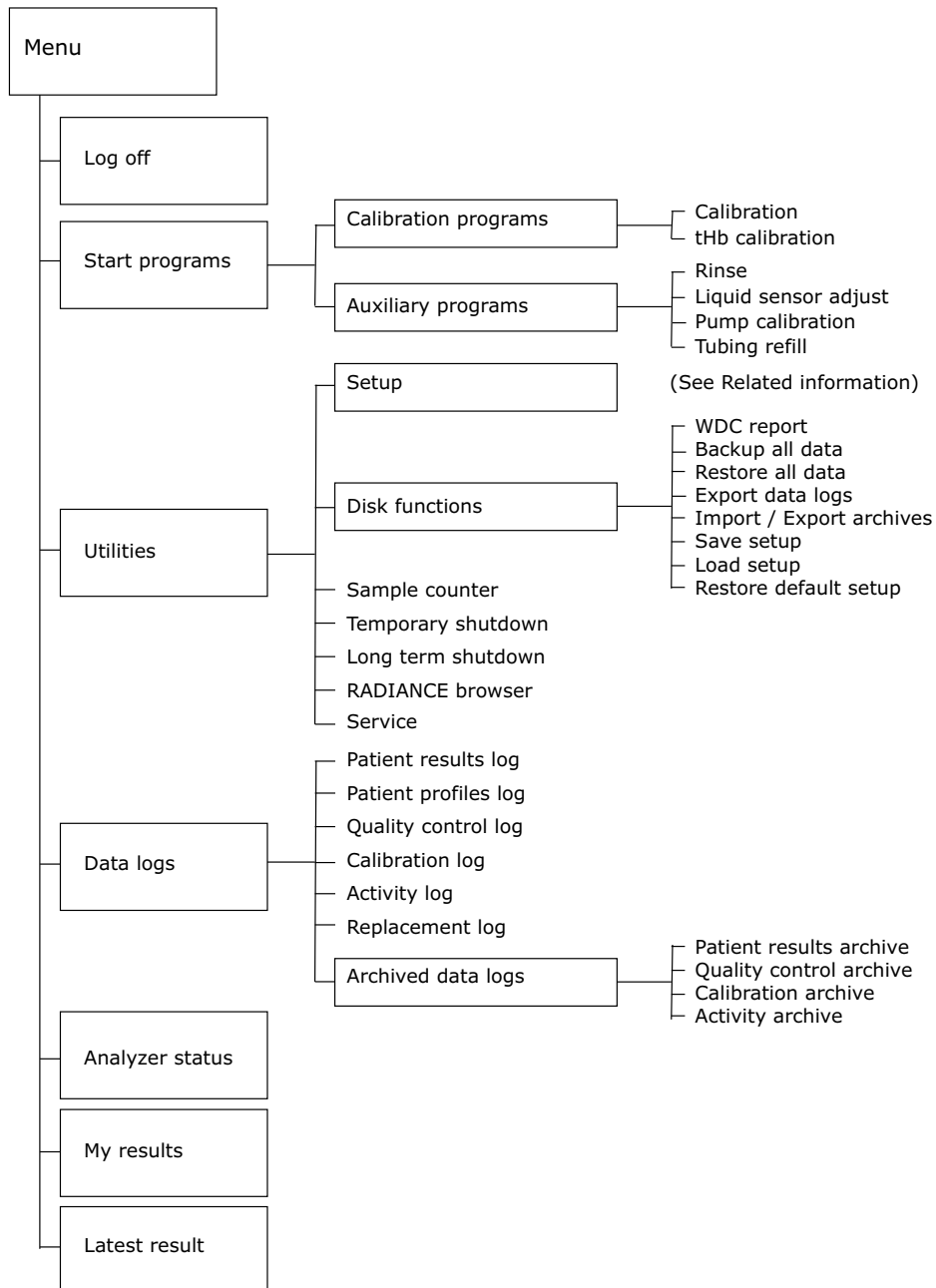
Option	Steps
To see more data about the Solution Pack	Select Status > Solution Pack
To see more data about the Sensor Cassette	Select Status > Sensor Cassette

Software Menu

Menu structure

The Vi-CELL MetaFLEX software contains the following selectable menu items:

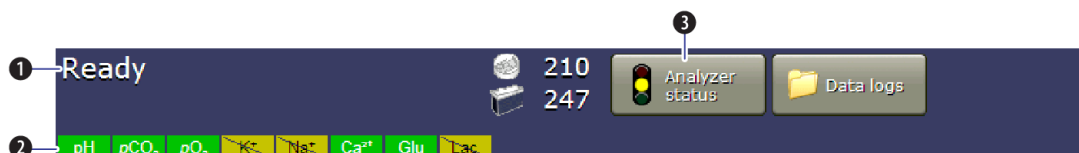
Figure 1.3 Software Menu Tree

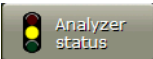


Operational Checks

Three Important Conditions

The analyzer is ready for use when three conditions are present.



1. The analyzer displays *Ready* in the top left corner of the screen.
2. The color of the parameters tab you want to get a result for is green or yellow.
3. The color of the traffic light in the  button is green or yellow.

Parameter Tab Colors

Parameter tab color	Indication
Green	You will get a result for the parameter.
Yellow with one line crossing	• A QC or calibration error was found for the parameter, but you will get a result. • There is an error associated with the given parameter during the last calibration or quality control measurement. The parameter is unreliable and will display a "?" in front of the result.
Red with two lines crossing	No result will be reported for the parameter. The conditions that may cause a parameter tab to be red are as follows: • There is a serious error associated with the given measuring channel. • An operator has locked the parameter in the Parameter setup screen. • An operator has locked the analyzer (all parameter tabs will change to red) • Parameter repression was enabled for the parameter and a QC and/or calibration error is present. • Ampoule-based QC measurements are pending. The analyzer was set up to lock after a Solution Pack and/or Sensor Cassette replacement until the QC measurements are completed.

Analyzer Status Screen

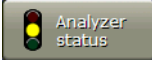
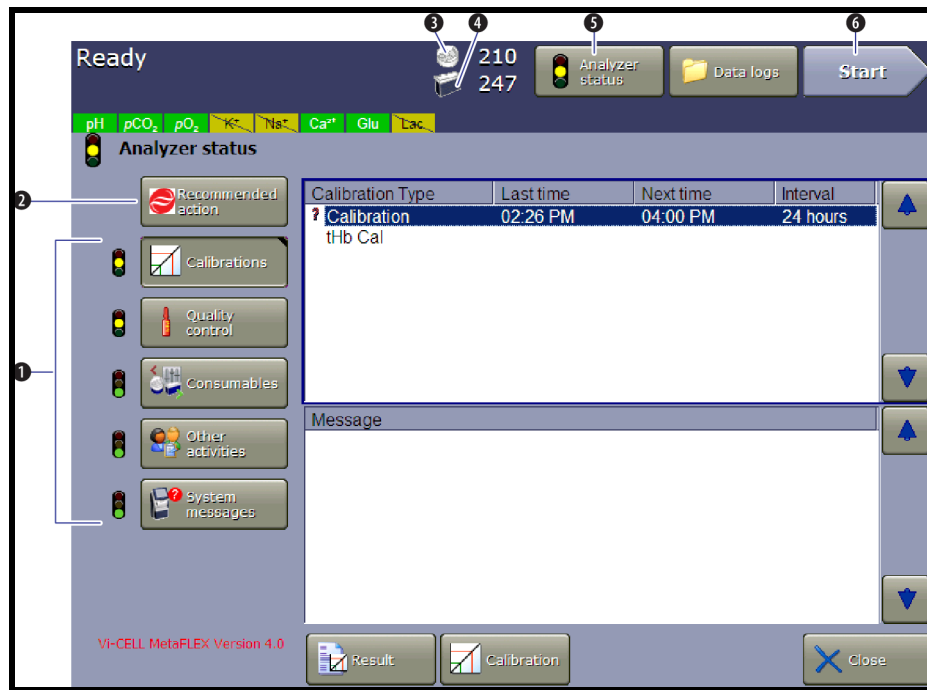
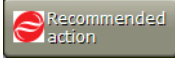
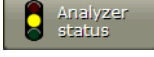
Select **Menu > Analyzer status** or, if available on the screen, select . The Analyzer status screens appears. Refer to [Figure 1.4](#).

Figure 1.4 Analyzer Status Screen



1. Activity buttons – the color of the traffic lights adjacent to each button shows the overall status of various activities within the analyzer. The buttons give access to details and activities. Refer to [Analyzer Status - Traffic Light Colors](#).
2.  – if there are any recommended actions, they are shown here when the Analyzer Status screen is opened.
3.  – the number adjacent to the icon shows the number of tests that are left on the sensor cassette.
4.  – the number adjacent to the icon displays the number of activities remaining on the solution pack.
5.  – the color of the traffic light on the button displays the overall status of the analyzer.
6.  – Gives you quick access to the start screen. The start screen is where most measurements can be started.

Analyzer Status - Traffic Light Colors

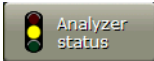
Traffic light color	Indication	Consequences
Green	No condition exists that requires action.	All operations are possible
Yellow	One or more messages indicate a condition that requires action, but not immediate action.	All operations are possible
Red	One or more messages indicate a condition that requires immediate action.	Only actions that are necessary to remove the reported conditions can be done.

Messages

The analyzer shows different types of messages.

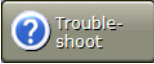
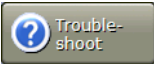
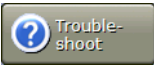
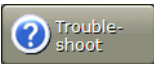
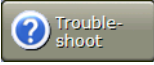
Message type	Where messages are shown
Status	In the Analyzer status screens. Refer to Figure 1.4 .
Feedback	In the space above the parameter bar. NOTE Feedback messages tell operators something about an action that they have just done or about measurements and calibrations in progress. Feedback messages are shown for a short period of time.
Pop-up	In pop-up windows
Result	In result message screens
Activity	In the Activity log

To find and troubleshoot messages in the Analyzer status screen

If the traffic light in the  button is yellow or red, follow the steps below.

- 1 Select **Menu > Analyzer status**. The Analyzer Status screen appears. Refer to [Figure 1.4](#).
- 2 Select the activity button adjacent to a yellow or red traffic light. Refer to [Figure 1.4](#).

3 Choose an option and follow the steps for it.

Option	Steps
To troubleshoot a Recommended action	Follow the instructions on the screen.
To troubleshoot Quality control messages	To troubleshoot errors in the Built-in QC and Ampoule-based QC fields: 1. Select the quality control measurement marked by a ,  or  symbol. 2. Select . 3. Select . 4. Select the message. 5. Select . 6. Follow the instructions on the screen. To troubleshoot messages in the QC Messages field: 1. Select the message. 2. Select . 3. Follow the instructions on the screen.
To troubleshoot Calibrations messages	To troubleshoot calibrations marked by a ,  or  symbol. 1. Select the marked calibration. 2. Select . 3. Select . 4. Select the message. 5. Select . 6. Follow the instructions on the screen. To troubleshoot messages in the Message field: 1. Select the message. 2. Select . 3. Follow the instructions on the screen.
To troubleshoot Consumables or System messages	1. Select the message. 2. Select . 3. Follow the instructions on the screen.

Power Supply Indicator

If a battery is installed in the analyzer, the battery indicator light will be on and a symbol in the lower right corner of the screen shows which power supply is in use.

NOTE The analyzer can operate on battery power for a limited period of time. The age and charge level of the battery and the number of activities that are done limit this period.

Symbol	Battery indicator	Indication
	Yellow light that blinks slowly	Only battery power is in use.
	Yellow light that blinks fast	Only battery power is in use. The analyzer must be connected to the mains power supply to prevent analyzer shutdown. NOTE The color of the battery in the symbol changes to red when the level falls below 14%. The analyzer shuts down when the level falls below 11%.
	Green light	Only the mains power supply is in use.
	Green light that blinks slowly	Only the mains power supply is in use. It supplies power to the analyzer and recharges the battery at the same time. NOTE The number indicates the charge level of the battery.

Common Tasks

Scanning a Barcode

To scan a barcode using the barcode reader, hold the barcode parallel to the barcode reader and no more than 7 cm from it.

Using the External or Onscreen Keyboard

Option	Steps
To use the keyboard on the screen	1. Select . 2. Enter the text. 3. Select .
To use an external keyboard	1. Enter the text. 2. Select the Enter key.

Selecting/Deselecting a Check Button

To select/deselect a check button, choose an option and follow the steps for it.

Option	Steps
To select a check button	Select  to check the button.
To deselect a check button	Select  to uncheck the button.

Saving Changes

To save changes, choose an option and follow the steps for it.

Option	Steps
To save changes and go to the previous screen	Select the Back 
To save changes and close the screen	Select the Close 

Analyzer Specifications

Ranges of Indication

Parameter	Unit	Range of indication	Reportable Range
pH	pH scale	6.3-8.0	6.300-8.000
pCO ₂	mmHg; Torr	5-250	5.0-250
	kPa	0.67-33.3	0.67-33.3
pO ₂	mmHg; Torr	0-803	0.0-803
	kPa	0-107	0-107
cK ⁺	mmol/L; meq/L	<0.1-25	<0.1-25.0
cNa ⁺	mmol/L; meq/L	<0.1-350	<0.1-350

Parameter	Unit	Range of indication	Reportable Range
cCa ²⁺	mmol/L	<0.1-9.99	<0.1-9.99
	meq/L	<0.1-19.98	<0.1-19.98
	mg/dL	<0.1-40.04	<0.1-40.04
cGlu	mmol/L	0-60	0.0-60
	mg/dL	0-1081	0.00-1081
	g/L	0-10.81	0.00-10.81
cLac	mmol/L; meq/L	-0.1-31	-0.1-31
	mg/dL	-1-279	-1-279
	g/L	-0.01-2.79	-0.01-2.79
ctHb	g/dL	-0.48-27.7	-0.19-27.1
	g/L	-4.8-277	-1.9-271
	mmol/L	-0.30-17.2	-0.12-16.8
sO ₂	%	-2-102	-2.0-102.0
	Fraction	-0.02-1.02	-0.020-1.020
FO ₂ Hb	%	-2-103	-2-103.0
	Fraction	-0.02-1.03	-0.020-1.030
FCOHb	%	-2-103	-2.0-103.0
	Fraction	-0.02-1.03	-0.020-1.030
FHHb	%	-2.0-102	-2.0-102.0
	Fraction	-0.02-1.02	-0.020-1.020
FMetHb	%	-2-103	-2.0-103.0
	Fraction	-0.02-1.03	-0.020-1.030
FHbF	%	-25-121	-25-121
	Fraction	-0.25-1.21	-0.25-1.21
ctBil	μmol/L	-20-1000	-20-690
	mg/dL	-1.2-58.5	-1.2-40.4
	mg/L	-12-585	-12-404
cCl ⁻	mmol/L; meq/L	<0.1-350	<0.1-350



Risk of erroneous results. Low pO_2 levels can have an effect on the linearity of glucose measurements. This can lead to incorrect low glucose results. Note that cGlu linearity is not specified when the pO_2 level is less than 10 mmHg (1.3 kPa).

Parameter	Unit	Reportable range	Range of Indication
ctHb	g/dL	-0.19-27.1	-0.48-27.7
	g/L	-1.9-271	-4.8-277
	mmol/L	-0.12-16.8	-0.30-17.2
FO_2Hb , $FCOHb$, $FMetHb$	%	-2.0-103.0	-2-103
	Fraction	-0.020-1.030	-0.02-1.03
sO_2 , $FHHb$	%	-2.0-102.0	-2-102
	Fraction	-0.020-1.020	-0.02-1.02
FHbF	%	-25-121	-25-121
	Fraction	-0.25-1.21	-0.25-1.21
ctBil	$\mu\text{mol/L}$	-20-690	-20-1000
	mg/dL	-1.2-40.4	-1.2-58.5
	mg/L	-12-404	-12-585

Product Specifications

Specification	Value
Height	470 mm with the screen in a vertical position
Width	250 mm
Depth	290 mm
Weight	<12 kg
Acoustic noise	In front of the analyzer, when no activities are done: >27 dB. During automatic activities: >36 dB. During measurements and when data is printed: >55 dB.
Volume of sample necessary for aspiration	For the capillary 45 μL mode: 45 μL . For the syringe mode: 65 μL .
Measuring time	For the capillary 45 μL mode: ≤ 60 seconds from the time the sample is aspirated until the results are shown. For the syringe mode: 35 seconds from the time the sample is aspirated until the results are shown.

Specification	Value	
Measurement cycle time	For the capillary 45 µL mode: 85 seconds from the time the sample is aspirated until the analyzer is ready to analyze the next sample. For the capillary 45 µL and syringe 65 µL modes: 60 seconds from the time the sample is aspirated until the analyzer is ready to analyze the next sample. The time may be different during Start up .	
Number of samples per hour	For the capillary 45 µL mode ≤35 samples per hour. For the syringe 65 µL modes: ≤44 samples per hour. During Start up : For the capillary 45 µL mode: ≤13 samples per hour. During Start up : For the capillary 45 µL and syringe 65 µL modes: ≤15 samples per hour.	
Data storage capacity	Patient profiles log Maximum 2000 profiles. NOTE This number can be increased. Contact us to request this option.	
	Sample results log	Maximum 2000 results
	Activity log	Maximum 5000 activities
	Calibration log	Maximum 1000 results
	Quality control log	Maximum 2000 results
	Replacements log	This log is part of the Activity log
	Archived data logs	500 results from each log and 2000 activities from the Activity log
	System messages	This log is part of the Activity log
External serial port	1 × RS-232 (9-pin) connector. Baud rate: 1200, 2400, 4800, 9600, 14400, 19200, 38400.	
USB ports	3 (1 at the top and 2 in the back of the analyzer). NOTE Only the USB port at the top of the analyzer can be used for the WIFI Adapter.	
Ethernet	1 × RJ45 connector, 100Base-Tx Fast Ethernet	
Keyboard/mouse port	PS/2	
External VGA screen port	Connector for VGA screen (disabled in BIOS setting)	

Specification	Value	
External communication protocols	High-level protocols:	
	• ASTM • ASTM6xx • HL7 ver. 2.2 • HL7 ver. 2.5 • POCTDML1A	
	Low-level protocols:	
	• Serial • Serial(Raw) • Network(TCP/IP) • Network(TCP/IP)(RAW) • Network(TCP/IP)(ASTM)	
Display	• 8" TFT-LCD, resolution 800 x 600 VGA • Resistive touch screen	
Built-in printer	Thermal printer	
Built-in bar code reader (under the screen)	• Reading distance: 0-70 mm • Bar code width: $\geq 127 \mu\text{m}$ • Number of characters: < 62 • Accepted codes: Code 128, Code 39, Code 93, Interleaved 2 of 5, Codabar	
Laser specifications	Contains 1 laser that is in compliance with international standard (IEC 60825-1 Safety of laser products) and US requirements (21 CFR 1040.10 - LASER PRODUCTS). 	
Thermostat	Solid state, $37.0 \pm 0.15 \text{ }^{\circ}\text{C}$ (Oxi: $\pm 0.3 \text{ }^{\circ}\text{C}$)	
Battery pack	Operation time:	Approximately 45 minutes including 10 measurements
	Charge time:	Approximately 90 minutes to fully charge a flat battery
	Voltage:	24 V
	Power consumption:	49 W/hour
Fuses	Main fuse has two protective fuses: 5 x 20 mm, 2.5A HRC (F) 250 VAC	

Specification	Value	
WiFi	Supported connector	Belkin Surf N150 Micro WLAN USB Adapter, (code number F7D1102)
	Data transfer rate	Up to 150 Mbit/s
	Data link protocols/standards	• IEEE 802.11b • IEEE 802.11g • IEEE 802.11n
	Supported authentication	• Open • WPA/WPA2
	Supported encryption settings	• None/WEP • TKIP/AES
	Contact us to request this option.	
Operating temperature	15-32°C (59-89.6°F).	

Environmental Specifications

Specification	Value	
Location	Intended for indoor use	
Maximum altitude	3000 m	
Ambient temperature	15-32 °C	
Relative humidity	20-80%	
Barometric pressure	At 15-30 °C:	525-800 mmHg
		70.0-106.7 kPa
		0.700-1.067 bar
		525-800 Torr
	At 30-32 °C	600-800 mmHg
		80.0-106.7 kPa
		0.800-1.067 bar
		600-800 Torr
Mains power supply	Rated voltage: 100-240 V ±10%; 50/60 Hz. Average power consumption: <60 W Maximum power consumption: 90 W (during Start Up <106 VA for less than a second) Maximum voltage fluctuations: ±10% Class 1 power supply	
Installation category	Installation category II	
Pollution degree	2 (occasional/temporary conductivity caused by condensation)	
Heat dissipation	<60 W	

Specification	Value
Start Up	Without the metabolite sensors: Up to 2 hours. With the metabolite sensors: Up to 4 hours. Start up is the period of time from when the Sensor Cassette was installed and 3 levels of automatic QC are done. It includes the conditioning of the Sensor Cassette, calibration and QC cycles.
Ventilation	The analyzer must be put in a well-ventilated room to get a proper calibration of pO_2 . Make sure that the ventilation creates an environment that is as close as possible to a normal outdoor environment, so that the effect from devices that release gases to the environment is kept to a minimum.
EMC (Emissions and Immunity)	The equipment complies with the emission requirements for Class A equipment and the immunity requirements as specified in IEC/EN 61326-1: Electrical equipment for measurement, control and laboratory use - EMC requirements part 1: General requirements.
Space requirement	Sufficient space in front and on the sides of the analyzer to prevent it overheating. Do not put the analyzer in an enclosure. Easy access to the mains power switch that connects the analyzer to the mains.
Storage temperature	-20 °C to 60 °C

Power-Supply Cords

Country	Power-supply cord specifications
For USA and Japan (125 VAC)	UL listed and KAM cord, min. type SV, min. 18 AWG, 3 conductors. Rated min. 60 C. Provided with a molded grounding-type (NEMA 5-15P) attachment plug rated 125 VAC, min. 2.5 A. Opposite end terminates in molded IEC 320 style connector rated 125 VAC, min. 2.5 A.
For Europe (265 VAC)	Cord type min. H05RR-F or min. H05VV-F or min. H05VVH2-F, rated min. 60 C, $2 \times 0.75 \text{ mm}^2$. Provided with a molded grounding-type attachment plug rated min. 250 VAC, min. 2.5 A. Opposite end terminates in molded IEC 320 style connector rated min. 250 VAC, min. 2.5 A.



The power-supply cord and plug of the analyzer must comply with national regulations. If the regulations are not complied with, the equipment may be damaged.

External devices connected to the analyzer must be in compliance with the standard UL 60950 for US and IEC 60950 for Europe. If you do not do this, the equipment may be damaged.

Consumables Specifications

Solution Pack

Product Description

The Vi-CELL MetaFLEX solution pack supplies the solutions for calibration, quality control, cleaning and collection of waste from the VI-CELL MetaFLEX. The solution pack also includes a memory chip for part/lot number recognition and keeping track of number of tests and expiration date.

Specifications

Specification	Details
Number of activities	680. An activity can be a sample or QC measurement, a calibration or a rinse.
Storage temperature	2-25 °C
Storage humidity	20-80%
Shelf life	Stable until the expiration date printed on the Solution Pack label
On-board stability	30 days
Expiration date	See the date printed on the Solution Pack label
Contents	• 3 pouches with quality control material • 3 pouches with calibration material • 1 pouch with gas mixture • 2 pouches to hold waste
Chemical composition	Reactive ingredients: See the table below. Other ingredients: Biological buffers, salts, enzyme, heparin, surfactant, preservative
Certificates of traceability	Contact us to request certificates of traceability.
Material safety data sheet (MSDS)	Contact us to request a material safety data sheet (MSDS).

Volume of Solutions in the Solution Pack		
Solution name	Solution type	Volume (mL)
QC 1	S9030	200
QC 2	S9040	100
QC 3	S9050	100
CAL 1	S1920	200
CAL 2	S1930	100
CAL 3	S1940	100

Approximate Levels of Measurands in the Solution Pack										
Solution type	pH	pCO ₂ mmHg	pO ₂ mmHg	cNa ⁺ ^a	cK ⁺ ^a	cCl ⁻ ^a	cCa ²⁺ ^a	cGlu ^a	cLac ^a	ctHb ^a
S9030	7.2	30	180	140	4	105	0.8	0	0	0
S9040	6.8	67	N/A	118	7	95	1.65	15	8	8
S9050	7.5	20	20	175	1.8	125	0.3	7	4	12
S1920	7.30	35	180	150	4	95	0.5	0	0	N/A
S1930	6.8	N/A	N/A	70	10	50	2.3	N/A	N/A	N/A
S1940	N/A	80	N/A	N/A	N/A	N/A	N/A	10	10	0

a. Measured in mmol/L

Chemical composition of the gas mixture in the Solution Pack			
Volume (mL)	Reactive ingredients		
	O ₂ %	CO ₂ %	N ₂
150 (at sea level)	42.07	5.61	52.32

Sensor Cassette

Product Description

The sensor cassette is the measuring device of the Vi-CELL MetaFLEX. The sensor cassette is based on thick-film technology, composed of many layers of ceramic slabs, microelectrodes and membranes similar to conventional electrodes. The sensor cassette also includes a memory chip for part/lot number recognition and keeping track of number of tests and expiration date.

Sensor Cassette Specifications

Specification	Details
Number of tests	Varies depending on the sensor cassette version
Storage temperature	2-8 °C
Storage humidity	20-80%
Shelf life	When kept in its sealed container, the Sensor Cassette is stable until the expiration date printed on the label of the pack
On-board stability	30 days
Expiration date	See the date printed on the label of the pack
Contents	One Sensor Cassette in a sealed container

Material Safety Data Sheets (SDS/MSDS)

To obtain an SDS or MSDS for Vi-CELL MetaFLEX reagents used on the Vi-CELL MetaFLEX system:

- On the Internet, go to www.beckmancoulter.com:
 1. Select **Safety Data Sheets (SDS/MSDS)** from the Support menu.
 2. Follow the instructions on the screen.
 3. Contact your Beckman Coulter Representative if you have difficulty locating the information.
- If you do not have Internet access contact your Beckman Coulter Representative.

System Overview

Material Safety Data Sheets (SDS/MSDS)

CHAPTER 2

Operation Principles

Overview

This chapter explains how the analyzer measures various parameters.

This chapter contains information on:

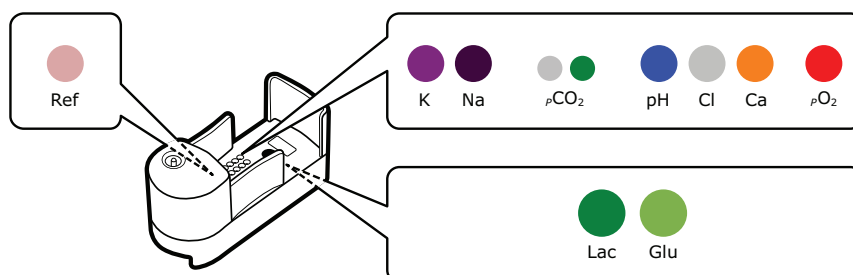
- [General Construction](#)
- [General Measurement Principles](#)
- [Calibration](#)
- [The Calibration Equation](#)
- [Sensitivity, Status, and Drift](#)
- [Reference Electrode](#)
- [pH and Electrolyte Sensors](#)
- [pCO₂ Sensor](#)
- [pO₂ Sensor](#)
- [Metabolite Sensors](#)
- [ctHb and Derivates](#)

General Construction

Sensors

In this manual, the term sensor refers to an individual sensor as part of the sensing array within a Sensor Cassette. The electrical signal from each sensor is measured by proprietary analog electronics contained within the analyzer unit.

The sensors are located on sensor boards in the Sensor Cassette.



General Measurement Principles

Introduction

There are four different measuring principles employed in the sensors in the Vi-CELL MetaFLEX analyzer.

- **Potentiometry:** The potential of an electrode chain is measured by a voltmeter, and related to the concentration of the sample (the Nernst equation). The potentiometric measuring principle is applied in the pH, $p\text{CO}_2$, K^+ , Na^+ , Ca^{2+} and Cl^- sensors.
- **Amperometry:** The magnitude of an electrical current that flows through an electrode chain is proportional to the concentration of the substance that is oxidized or reduced at a electrode in the chain. The amperometric measuring principle is applied in the cGlu and cLac sensors.
- **Optical $p\text{O}_2$:** The optical system for $p\text{O}_2$ is based on the ability of O_2 to reduce the intensity and time constant of the phosphorescence from a phosphorescent dye that is in contact with the sample. This measuring principle is applied in the $p\text{O}_2$ sensor.
- **Spectrophotometry:** Light passes through a cuvette that contains a hemolyzed blood sample. The absorption spectrum is used to calculate oximetry parameters. This measuring principle is used for ctHb, $s\text{O}_2$, FO_2Hb , FCOHb , FHHb , FMetHb , FHbF and ctBil.

Activity vs. Concentration

In potentiometry, the potential of an electrode chain is related to the activity of a substance not its concentration.

The activity of a substance can be considered the effective concentration of a species that takes non-ideality of the medium into account.

Activity and concentration are related by the following equation:

$$a_x = \gamma c_x$$

where:

a_x = the activity of the species x

γ = the activity coefficient of species x under the measurement conditions (for ideal systems $\gamma = 1$)

c_x = the concentration of species x (mol/L)

NOTE Activity is related to the molality of species x (the amount of substance of the solute (in mol), divided by the mass of the solvent (in kg)). However, molality is converted to concentration (molarity).

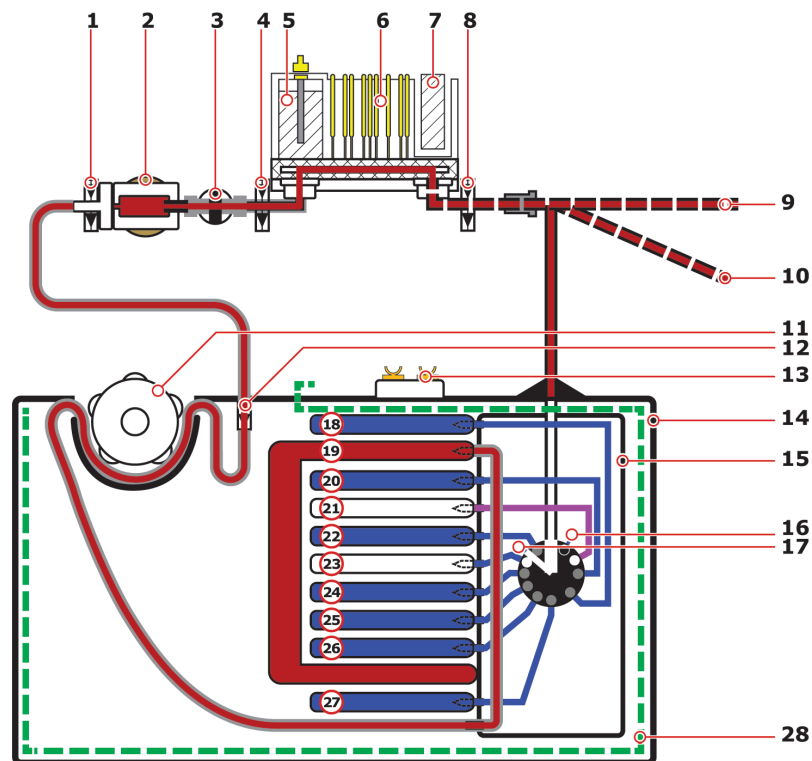
The analyzer automatically converts activities into concentrations. The term concentration is therefore used in explanations of the measuring principles for each of the sensors.

Fluid Transport System

Samples and solutions necessary for calibration, QC measurements, and other procedures are transported through the fluid transport system of the analyzer. Figure 2.1 shows the fluid transport system. The sample is aspirated from the inlet, transported through the Sensor Cassette and the oximetry module and into the waste pouch of the Solution Pack.

After a sample analysis the system is rinsed. The CAL 1 solution from the Solution Pack is used.

Figure 2.1 Fluid Transport System



1. Liquid sensor 3	15. Flow selector (to select a solution/gas)
2. Hemolyzer	16. Closed position (nothing selected)
3. Oximetry valve	17. Position to select air
4. Liquid sensor 2	18. Pouch not in use
5. Reference electrode	19. Pouch to hold waste
6. Sensor Cassette	20. Pouch with CAL 3 solution
7. Optical pO_2 sensor	21. Pouch to hold clot waste
8. Liquid sensor 1	22. Pouch with CAL 1 solution
9. Sample inlet (position for capillary tubes)	23. Pouch with gas mixture
10. Sample inlet (position for syringes and test tubes)	24. Pouch with QC 1 solution
11. Peristaltic pump	25. Pouch with CAL 2 solution
12. Waste valve	26. Pouch with QC 3 solution
13. Smart chip	27. Pouch with QC 2 solution
14. Solution Pack	28. Electrical shield

Measurement Process

The measurement process is similar for all types of measurement, sample analysis, built-in QC measurements, ampoule-based QC measurements, calibration-verification measurements, and calibration measurements.

1. The sample (sample, QC solution or calibration solution) is aspirated or drawn into the sensor measurement chamber and the oximetry measurement chamber.
2. Measurements are done as soon as the sample is in the chambers. Liquid sensors control the process and can detect sample inhomogeneity and air bubbles in the sample. If any problems are found or the sample volume is too low, the measurement is aborted and the problem is reported in a message attached to the result.
3. A rinse is done.
4. A status calibration is done for all parameters.

Rinse Process

A rinse is done after a measurement is completed.

1. The sample is removed.
 2. The system is rinsed with a mixture of solution and air/gas.
 3. The system is filled with CAL1 to prepare for next sample.
- During the rinse procedure, a check of the fluid transport system is done.

Calibration

Calibration is the process that relates the sensor signals during the calibration sequence to the values of the calibrating solutions and air. Calibration enables the sensor signals to be converted to the accurate values for an unknown sample.

Frequency

Automatic calibrations are scheduled by default to be done at regular intervals. This is necessary to compensate for small changes in the behavior of the sensors in the Sensor Cassette.

Calibration Solutions

CAL 1, CAL 2, and CAL 3 solutions are used for the calibration of sensors. Air is used for the calibration of the pO_2 sensor.

The calibration solutions contain known concentrations of the parameters to be measured. These concentrations are necessary to determine the measurement results. The concentrations are automatically read from a chip on the Solution Pack when the Solution Pack is installed.

The Calibration Equation

The calibration equation expresses the relationship between the electrical measurement at a sensor and the concentration of the parameter specific to the sensor.

Plotting a Calibration Line

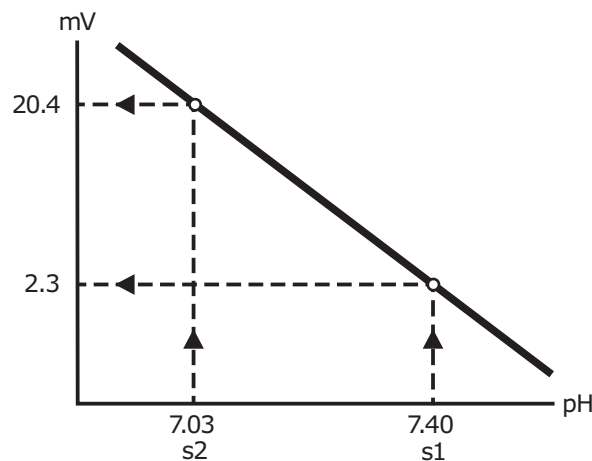
The calibration equation for each sensor is established during sensor calibration.

For the pH sensor, the relationship between potential and pH is linear. Thus, this type of sensor can be calibrated from the measurement of two solutions of known concentration. The measured potentials are plotted against the known concentrations and a line is drawn between them.

The calibration of the pH sensor shows how this equation is established.

- Solution 1 (s1), which has a pH of **7.40**, gives a measured potential of **2.3 mV**.
- Solution 2 (s2), which has a pH of **7.03**, gives a measured potential of **20.4 mV**.

These points are plotted on a graph and a line is drawn between them.



The calibration line is used to convert the potential measured at the pH sensor during sample analysis to an actual pH value.

For electrolyte sensors, ion concentrations are plotted on a log scale ($\log_{10}(a_{\text{ion}})$).

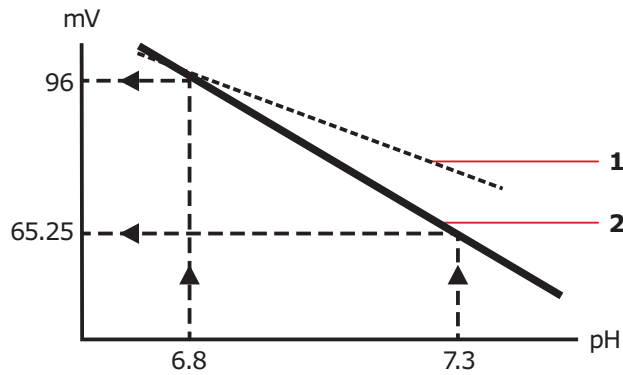
Sensitivity, Status, and Drift

Sensitivity

The sensitivity value shown in calibration results shows how much the sensitivity of a sensor differs from the sensitivity of a theoretical sensor.

The sensitivity of a theoretical sensor is 100%. If a sensor sensitivity is reported to be 95%, its sensitivity is 5% less than the theoretical sensor sensitivity.

The sensitivity of a sensor is the slope of its calibration line.



1. Calibration line for the sensor
Slope = -58.4 mV/pH
Sensitivity = 95%
2. Calibration line for a theoretical sensor
Slope = -61.5 mV/pH
Sensitivity = 100%

The sensitivity of a sensor is calculated as:

$$\text{Sensitivity} = \frac{\text{Potential at 6.8} - \text{Potential at 7.3}}{61.5 \times (7.3 - 6.8)} \quad (\%)$$

Where 61.5 = sensitivity of theoretical sensor.

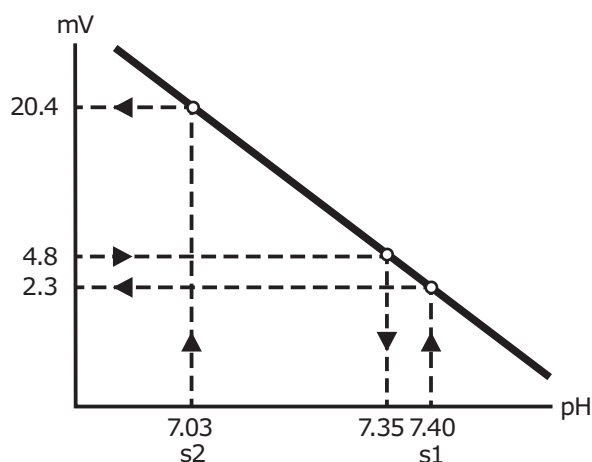
Each sensor has its own sensitivity limits.

The sensitivities are range checked:

	pH	pCO ₂	pO ₂	cK ⁺	cNa ⁺	cCa ²⁺	cCl ⁻	cGlu	cLac
	%	%	%	%	%	%	%	pA/mmol/L	pA/mmol/L
Min.	85	60	85	85	85	85	75	100	100
Max.	105	105	110	105	105	105	105	2000	2000

The calibration line slope is re-established with every calibration.

A blood sample gives a measured potential of 4.8 mV at the pH sensor. This potential corresponds to a pH of 7.35 (see the diagram below).



To compensate for deviations from ideal conditions (for example, residual rinse solution that dilutes a sample), a correction is applied to measurement results. Applied corrections are usually linear corrections.

Status

The calibration status values are, in general, defined as the sensor signals of CAL 1 except for pO_2 , which is only calibrated in one point (pO_2 status reflects the cal check).

Drift

Drift describes the variation in location of the calibration line between consecutive calibrations. A Status calibration is done with every measurement. This lets the analyzer automatically compensate for status drifts. Sensitivity drift is usually insignificant in comparison with status drift.

Reference Electrode

Background Information - Reference Electrode

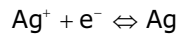
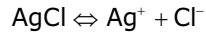
Purpose

The purpose of the reference electrode is to provide a stable, fixed potential, against which the potential differences can be measured.

The potential of the reference electrode is not changed by the sample composition.

Fixed Potential

A fixed potential is maintained at the reference electrode by these equilibrium reactions:



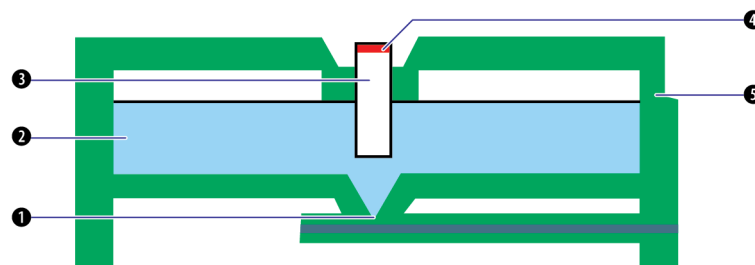
These reactions are possible because the electrode is made of an Ag rod coated with AgCl to provide the Ag/Ag⁺ equilibrium in a solution with constant Cl⁻ concentration and thus determining the reference potential.

Use

The reference electrode is used in the measurement of pH and electrolyte concentrations. Contact with the sample is made via a membrane junction between the reference electrode liquid chamber and the measuring chamber.

Construction - Reference Electrode

Construction



1. Membrane – Interface to the sample
2. Electrolyte solution – Acts as a salt-bridge solution that maintains an electrical contact between the electrode and the sample
3. Electrode – Provides the contact between the electrolyte solution and the electrical contact
4. Electrical contact – The point of electrical contact between the electrode and the analyzer
5. Housing – Sensor Cassette housing with integrated reference electrode

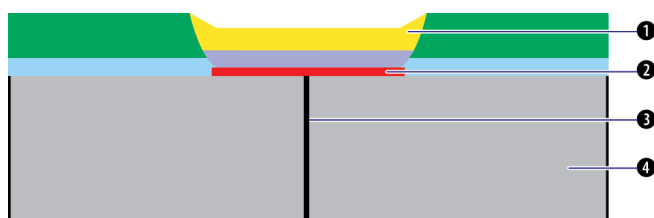
pH and Electrolyte Sensors

Construction - pH and Electrolyte Sensors

Construction

The pH and electrolyte sensors are of solid-state design with a H^+ , K^+ , Na^+ and Ca^{2+} sensitive PVC membrane. The Cl^- sensor is of solid-state design with a Cl^- sensitive epoxy membrane.

The pH sensor is used as an example:



1. Membrane – Ion-selective membrane that is in direct contact with the sample or calibration solution and that is sensitive to a specific ion, e.g. the H^+ ions
2. Solid-state contact – The point of electrical and ionic contact with the membrane
3. Electrical contact – The point of electrical contact between the sensor and the analyzer
4. Sensor base – The structural platform on which the sensor is formed

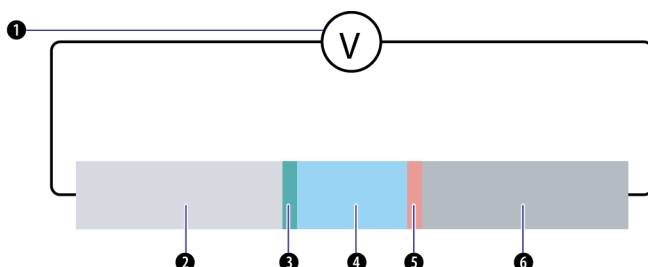
Measurement Principles - pH and Electrolyte Sensors

Potentiometric Measurement Principle

The pH and electrolyte sensors are measured according to the potentiometric measurement principle, where the potential of an electrode chain recorded at a voltmeter is related to the concentration of a substance via the Nernst equation (refer to [Nernst Equation](#)).

Electrode Chain

The electrode chain (or electrical circuit) set up to measure pH/electrolytes is shown in this diagram:



1. Voltmeter – measures the potential in the circuit.
2. Reference electrode – provides electrical connection to the voltmeter.
3. Liquid junction – point of contact between the reference electrode and the sample.
4. Sample – the unknown liquid that is measured.
5. Membrane – an ion-sensitive membrane, which is sensitive to H^+ /electrolyte ions.
6. Solid-state contact – provides electrical connection to the voltmeter.

Electrode Chain Potential

Every element in the electrode chain contributes a voltage to the total potential drop through the chain.

The total potential across the electrode chain, therefore, is the sum of these separate potentials, all but one of which are known and constant, as outlined in the table:

Element	Potential	Symbol
Reference electrode	Known and constant when the Ag/AgCl is immersed in the electrolyte solution	E_{ref}
Liquid junction between the electrolyte solution in the reference electrode and the sample	Known and constant. Independent of sample composition.	E_{LJ}
Ion-sensitive membrane that separates the sample and the pH sensor	Unknown. Dependent on sample composition.	E_{Sample}
Solid-state contact	Known and constant	E_E
Total potential	Measured by the voltmeter	E_{tot}

Unknown Potential

The unknown potential difference across the ion-sensitive PVC membrane is the difference between the measured total potential and the sum of the known potentials:

$$E_{sample} = E_{total} - (E_{ref} + E_{LJ} + E_E)$$

Ion-sensitive Membrane

The potential difference across the membrane arises as a consequence of a change in the charge balance at the membrane.

The membrane is sensitive to H^+ /electrolyte ions in that it has an ion-exchange ability. The internal solid-state reference electrode maintains the internal potential at the same level. Changes in the H^+ /electrolyte ions of the sample cause measurable changes in the overall potential.

Nernst Equation

The potential difference across the membrane in the sensor can be expressed by the Nernst equation:

$$E_{\text{sample}} = E_0 + \frac{RT}{nF} \times \ln a_x$$

Where:

E_{Sample} = Potential between the reference electrode and the ion-sensitive membrane

E_0 = Reference electrode potential

R = Gas constant (8.3143 J/°K-mole)

T = Absolute temperature (°K)

n = Charge on the ion

F = Faraday constant (96487 C/mole)

a_x = Activity of the species x

Activity and Concentration

The Nernst equation lets you calculate the activity of known concentrations of samples (pH and electrolytes).

The measured activities are used to calculate the concentrations by the use of the calibration results of the analyzer.

Calibration - pH and Electrolyte Sensors

Calibrations of pH and Electrolyte Sensors

The sensitivity calibration of the pH and electrolyte sensors gives the slopes of the calibration lines. Status calibrations are done with every measurement to compensate for small variations in sensor performance between calibrations.

Calculation of pH and Electrolytes Sensitivity

The sensitivity value shown in calibration results shows how much the sensitivity of a sensor differs from the sensitivity of a theoretical sensor.

The sensitivity is calculated as follows:

pH sensor sensitivity:

$$S = \frac{mV_{cal2} - mV_{cal1}}{-61.5mV \times (pH_{cal2} - pH_{cal1})}$$

Electrolyte sensor sensitivity:

$$S = \frac{n(mV_{cal2} - mV_{cal1})}{61.5mV \times \log_{10} \left(\frac{C_{cal2}}{C_{cal1}} \right)}$$

Where:

- S is the sensitivity
- mV_{cal1} and mV_{cal2} are the signals measured by the sensor and when CAL1 and CAL2 solutions are used
- c_{cal1} and c_{cal2} are the concentrations of the electrolyte in the CAL1 and CAL2 solutions
- n is the ionic charge

Status is defined as the sensor signal when CAL 1 solution is used.

Measurement - pH and Electrolyte Sensors

Calculation of pH and Electrolyte Values

The pH value measured from the sample is calculated as follows, from the sensor signal of the sample mV_{sample} :

$$pH = pH_{cal1} = \frac{mV_{sample} - mV_{cal1}}{-61.5mV \times S}$$

The electrolyte concentration in a sample is calculated from this equation:

$$c = c_{cal1} \times 10^{\frac{n(E_{sample} - E_{cal1})}{61.5mV \times S}}$$

where n is the ionic charge. The measured value is applied a linear correction:

$$c_{displayed} = k_1 \times c + k_2$$

NOTE cCl^- is compensated for $cHCO_3^-$ interference by the use of the measured pH and pCO_2 , before the linear correction is applied.

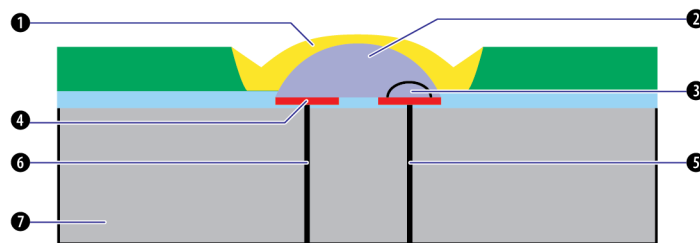
Sensor Response Stability

The sensor response stability is the standard deviation of the last 5 calculated status calibration values.

pCO₂ Sensor

Construction - pCO₂ Sensor

Construction

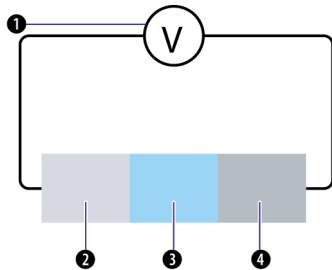


1. Silicone membrane – A membrane that separates the sample and the electrolyte solution. Is only permeable to CO₂ and H₂O
2. Electrolyte solution – A bicarbonate buffer that changes pH upon absorption/desorption of CO₂ from the sample
3. pH membrane – H⁺ sensitive membrane
4. Reference electrode – Ag/AgCl electrode
5. Solid-state contact for the pH system. The point of electrical contact between the pH membrane and the analyzer.
6. Electrical contact between the reference electrode and the analyzer
7. Sensor base – The structural platform on which the sensor is formed

Measurement Principle - pCO₂ Sensor

Electrode Chain

The electrode chain (or electrical circuit) set up to measure pCO₂ is shown in the diagram:



1. Voltmeter – Measures the voltage potential in the circuit
2. pH electrode – Provides electrical connection to the voltmeter
3. Electrolyte solution – Medium for connection
4. Internal reference electrode (Ag/AgCl) – Provides electrical connection to the voltmeter

Electrode Chain Potential

The potential differences at all the junctions in the electrode chain are known and constant, except that at the pH-sensitive membrane. Refer to [pH and Electrolyte Sensors](#) for a full explanation.

The potential difference at the pH-sensitive membrane depends on the pH of the electrolyte solution, which in turn depends on the CO₂ content of the sample. This is explained in the *Measuring process* topic.

Measurement Process in the pCO₂ Sensor

This is an account of the measurement process in the pCO₂ sensor.

Part	Function
Transport of CO ₂	CO ₂ from the sample permeates the membrane
Dissolution of CO ₂	The CO ₂ dissolves in the electrolyte solution. This produces carbonic acid: $\text{H}_2\text{O} + \text{CO}_2 \rightleftharpoons \text{H}_2\text{CO}_3$
Dissociation of carbonic acid	Carbonic acid dissociates according to the this equilibrium reaction: $\text{H}_2\text{CO}_3 \rightleftharpoons \text{H}^+ + \text{HCO}_3^-$
pH change	The release of H ⁺ ions changes the H ⁺ concentration, and thus the pH of the inner buffer solution on one side of the pH-sensitive membrane

Part	Function
Measurement of potential	The concentration gradient of H⁺ ions across the membrane creates a potential difference across the membrane. This change in potential across the membrane is measured by the voltmeter.
Relation of pH to pCO ₂	The pH value is related to the partial pressure of CO₂ in the sample by this equation: $\text{pH} = \text{pK}_a + \log \frac{[\text{HCO}_3^-]}{\alpha \times \text{pCO}_2}$ Where: pK_a = -log K_a, the equilibrium constant for the dissociation of carbonic acid in water α = solubility coefficient for CO₂ in water The structure of the pCO₂ sensor is similar to the pH sensor, including the presence of a pH-sensitive membrane. The major difference is in the internal electrolyte solution present in the pCO₂ sensor which allows the dissolution of CO₂ and ultimate dissociation of carbonic acid mentioned above. If [cHCO₃⁻] and α in the electrolyte solution are constant, it results in this equation: pH = K - log pCO₂ Where K contains the equilibrium constant pK_a, the solubility coefficient α and the concentration of bicarbonate [cHCO₃⁻]. E = E'₀ - 61.5 × pH = E₀ + 61.5 × log pCO₂.

Calibration - pCO₂ Sensor

Calibrations of the pCO₂ Sensor

The sensitivity calibration of the pCO₂ sensor gives the slope of the calibration line. Status calibrations are done with every measurement to compensate for small variations in sensor performance between calibrations.

Calibration Levels

The Vi-CELL MetaFLEX analyzer is equipped with a Solution Pack. This pack contains precision-tonometered fluids. The tonometry calibration gas mixture is of a known composition.

The partial pressure of CO₂ (pCO₂) and the solution pH values are known and contained in the Solution Pack smart chip.

Calculation of pCO₂ Sensitivity

The sensitivity value shown in calibration results shows how much the sensitivity of a sensor differs from the sensitivity of a theoretical sensor.

The sensitivity is calculated as follows:

$$S = \frac{mV_{cal2} - mV_{cal1}}{61.5mV \times \log_{10} \left(\frac{pCO_2(cal2)}{pCO_2(cal1)} \right)}$$

Where

- S is the sensitivity
- mV_{cal1} and mV_{cal2} are the signals measured by the sensor when CAL1 and CAL2 solutions are used
- $pCO_2(cal1)$ and $pCO_2(cal2)$ are the concentrations of pCO_2 in the CAL1 and CAL2 solutions

Status is defined as the sensor signal when CAL 1 solution is used.

Measurement - pCO_2 Sensor

Calculation of pCO_2 Values

The pCO_2 value measured from the sample is calculated as follows, from the sensor signal of the sample mV_{sample} :

$$pCO_2 = pCO_2(cal1) \times 10^{\frac{E_{sample} - E_{cal1}}{61.5mV \times S}}$$

The measured value is applied as a linear correction:

$$C_{displayed} = k_1 \times C + k_2$$

Sensor Response Stability

The sensor response stability is the standard deviation of the last 5 calculated status calibration values.

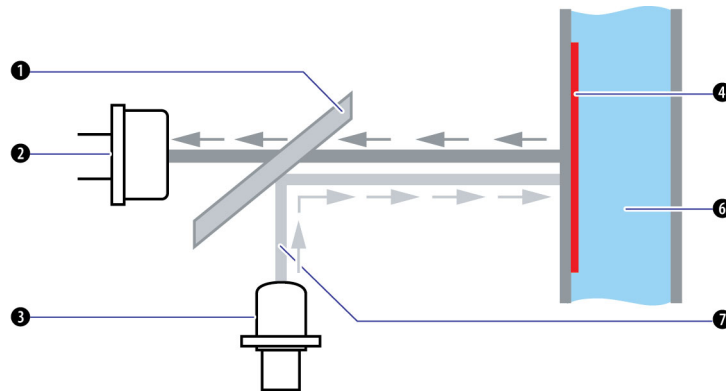
pO_2 Sensor

Measurement Principle - pO_2 Sensor

Optical System for pO_2

The optical system for pO_2 is based on the ability of O_2 to reduce the intensity and time constant of the phosphorescence from a phosphorescent dye that is in contact with the sample.

The optical system for pO₂ is shown in the diagram:



1. Dichroic mirror
2. Photodetector
3. Green LED
4. pO₂ sensor
5. Phosphorescence
6. Sample
7. Excitation light

Measurement Sequence

The green LED emits light, which is reflected by a dichroic mirror onto the pO₂ sensor. Due to the phosphorescence, red light is emitted back through the dichroic mirror and onto a photo detector. The photo detector sends the electrical signals, proportional to the light intensity, to the analog/digital converter and the data processing unit that calculates the pO₂ concentration.

Calculations

The pO₂ is calculated on the basis of the Stern-Volmer equation, which describes the relationship between the phosphorescence intensity/time constant (τ) and the pO₂ value in a sample:

$$pO_2(\tau) = k \times \left(\frac{\tau_0}{\tau} - 1 \right)$$

Where k and τ_0 are constants.

Calibration - pO₂ Sensor

Overview of pO₂ Calibrations

CAL 1 solution and ambient air are used to do a sensitivity calibration of the pO₂ sensor. A status calibration is done before every measurement to check the performance of the sensor between sensitivity calibrations.

Sensitivity

The sensitivity is defined as the percentage of the measured pO₂ on ambient air compared to the reference value:

$$S = \frac{pO_2(\text{meas})}{pO_2(\text{ref})}$$

Where pO₂(ref) is the pO₂ tension in ambient air saturated with water vapor:

$$pO_2(\text{ref}) = FO_2 \cdot (p(\text{amb}) - p_{H_2O})$$

where FO₂ is the pO₂ fraction in ambient air, and p_{H₂O} is the partial water vapor pressure of saturated air at 37 °C, and p(amb) is the barometric pressure.

Status

In connection with the sensitivity calibration done on ambient air, the CAL 1 solution is also measured to obtain a status. This status aims to check the performed calibration. This is done by a comparison of the measured value of the CAL 1 solution to the reference value of CAL 1, given by the smart chip:

$$pO_2(\text{status,cal}) = pO_2(\text{CAL 1, cal}) - pO_2(\text{CAL 1, ref})$$

For every measurement, the pO₂ calibration is checked by a comparison of the measured value of CAL 1 solution to the value obtained on the CAL 1 solution of the last calibration (CAL 1, cal):

$$pO_2(\text{status, meas}) = pO_2(\text{CAL 1, meas}) - pO_2(\text{CAL 1, cal})$$

The CAL 1 solution is used to do a status calibration of the pO₂ sensor. The measured value of the CAL 1 solution is compared to the reference value of the CAL 1 solution that is read from the smart chip of the Solution Pack.

$$pO_2(\text{status,cal}) = pO_2(\text{CAL 1, meas}) - pO_2(\text{CAL 1, ref})$$

The status calibration of the pO₂ sensor is done before every measurement. The measured value of the CAL 1 solution is compared with the value obtained during the previous status calibration to determine the status drift:

$$pO_2(\text{status,drift}) = pO_2(\text{CAL 1, meas}) - pO_2(\text{CAL 1, prev cal}).$$

Measurement - pO₂ Sensor

Calculation of pO₂ Values

Blood, pO₂ is adjusted with the sensitivity value and the measured pO₂ is therefore determined as follows:

$$pO_2(\text{sens,adjusted}) = \frac{pO_2(\text{meas})}{S}$$

The measured value is applied as a second-order blood correction, to compensate for the varying buffer value of blood, as a function of pO₂ tension. A second-order correction is applied:

$$pO_2(\text{display}) = k_1 pO_2^2 + k_2 pO_2 + k_3$$

NOTE Air bubbles in samples may collect in front of the pO₂ sensor and cause incorrect results. However, the analyzer detects them and attaches a message to the results.

Metabolite Sensors

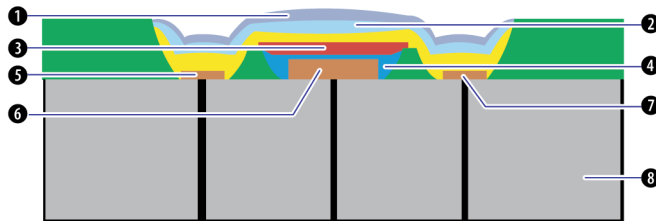
Construction - Metabolite Sensors



Risk of erroneous results. Low pO_2 levels can have an effect on the linearity of glucose measurements. This can lead to incorrect low glucose results. Note that cGlu linearity is not specified when the pO_2 level is less than 10 mmHg (1.3 kPa).

Construction

The cGlu and cLac sensors are three-electrode sensors which consist of an internal silver/silver chloride reference electrode, a platinum auxiliary electrode, and a platinum anode. The sensors are covered by a multi-layer membrane bound to the sensor board.



1. Biocompatible layer – Biocompatible layer
2. Outer membrane – Outer membrane permeable to glucose/lactate – diffusion control
3. Enzyme layer – Contains glucose/lactate oxidase
4. Inner membrane – Cellulose acetate
5. Reference – Ag/AgCl electrode
6. Anode – Platinum electrode
7. Cathode – Platinum electrode
8. Sensor base – The structural platform on which the sensor is formed

Zero Current

The zero current is a small background current measured at the electrode when no cGlu/cLac is present in a solution. As CAL 1 solutions contain no cGlu/cLac, a baseline that represents the zero current, I_0 as a function of time ($I_0 = f(t)$), is obtained from continuous measurements on CAL 1 solutions.

This I_0 baseline is obtained as follows:

- At the end of a rinse, with CAL 1 solution in the measuring chamber, the zero current of the metabolite electrodes is measured periodically.
- The previous N ($N = 8$) measurements on the CAL 1 solution - before a calibration or a sample measurement starts - are used to obtain a baseline that represents the time function of I_0 .

- The baseline is extrapolated throughout the whole electrode calibration or sample measurement period, and represents the zero current time function.
- The I_0 baseline is used in the determination of the sensitivity of the cGlu/cLac sensor.

Calibration - Metabolite Sensors

Calculation of Sensitivity

The sensitivity of the cGlu and cLac sensors is calculated by measuring the current from CAL 3 solution, then subtracting the zero current as measured from CAL 1 solution. CAL 3 solution has a nominal glucose concentration of 10 mmol/L and a nominal lactate concentration of 10 mmol/L. The precise values are specific to the individual lot of the Solution Pack and are contained in the Solution Pack smart chip.

The current at the cGlu and cLac sensors with CAL 3 solution in the measuring chamber is measured at regular intervals after the chamber is filled with solution. The current, when signal stability is reached, is used to determine the sensitivity of the cGlu or cLac sensor.

The sensitivity of the cGlu or cLac sensor is calculated as follows:

$$S = \frac{I_{\text{cal3}} - I_0}{C_{\text{cal}}}$$

where I_0 is the zero current extrapolated to the time of measurement from the 8 samples taken on CAL 1 solution.

Status is defined as I_0 .

Measurement - Metabolite Sensors

Calculation of Metabolite Values

The glucose or lactate concentration in a sample is calculated from the equation shown below, where the difference between the current in the sample and the extrapolated zero current from the rinse solution is used:

$$C = \frac{I_{\text{sample}} - I_0}{S}$$

The measured value is found after this linear correction has been applied:

$$C_{\text{displayed}} = k_1 \times C + k_2$$

NOTE cLac is compensated for the dependence of the ionic composition by the use of the measured electrolyte values before the linear correction is applied. If the electrolytes are not measured, default values are used.

Sensor Response Stability of the Metabolite Sensors

For CAL 1 solution, the sensor response stability is defined as the standard deviation of the last 5 calculated status calibration values.

For CAL 3 solution, the sensor response stability is defined as the standard deviation of a linear regression for the last 5 calculated status calibration values, normalized with the signal magnitude.

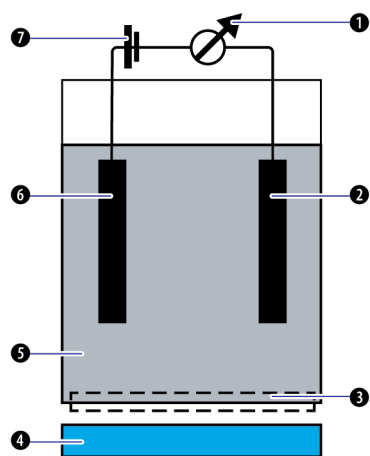
Measurement Principle - Metabolite Sensors

Amperometric Measurement Principle

The cGlu and cLac sensors are measured according to the amperometric measurement principle, in which the magnitude of an electrical current that flows through an electrode chain is related to the concentration of a substance that is oxidized or reduced at an electrode in the chain.

Electrode Chain

The electrode chain set up to measure glucose/lactate is illustrated in the diagram:



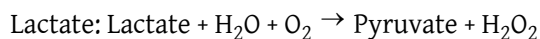
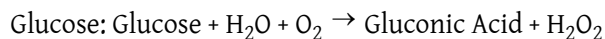
1. Amperemeter – Measures the current that flows through the circuit in nanoamperes
2. Cathode – Negative electrode where a reduction reaction occurs and electrons are consumed
3. Membrane – Lets the appropriate molecules to pass through from the sample
4. Sample – Contacts the membrane
5. Electrolyte – Provides electrical contact between the anode and cathode
6. Anode – Positive electrode where an oxidation reaction occurs and electrons are released
7. Applied voltage – Applies the necessary potential for the reduction or oxidation reaction under study

NOTE Note that polarization voltage is applied between the anode and the reference electrode (not shown). The current runs through the anode and cathode chain.

Measurement Process

A constant polarization voltage is applied to the electrode chain. The current through this chain is measured by an amperemeter.

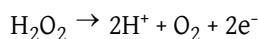
Glucose or lactate molecules, in solution, are transported across the outer layer of a multilayer membrane system. The enzymes glucose oxidase or lactate oxidase, immobilized between the outer and inner layers, converts glucose/lactate according to these reactions:



The oxygen for this reaction is supplied by the membrane system as well as by the oxidation of H_2O_2 at the platinum anode.

The H_2O_2 produced by the enzyme reaction is transported across the inner membrane to the platinum anode.

When a potential is applied to the electrode chain, the oxidation of H_2O_2 produces an electrical current proportional to the amount of H_2O_2 , which in turn is directly related to the amount of glucose/lactate.



At the counter electrode a reduction process that consumes electrons will occur:

1. $\text{H}_2\text{O}_2 + 2\text{e}^- \rightarrow 2\text{OH}^-$ (This process consumes excess H_2O_2 not consumed in the reaction above)
2. $\frac{1}{2}\text{O}_2 + \text{H}_2\text{O} + 2\text{e}^- \rightarrow 2\text{OH}^-$ (This process consumes excess O_2 not consumed in the reaction above)
3. $2\text{H}_2\text{O} + 2\text{e}^- \rightarrow \text{H}_2 + 2\text{OH}^-$ (This process can also occur at the cathode)

Any of these three reactions at the cathode will serve to neutralize the protons generated in the second reaction, so the total change in acidity is caused by the gluconic acid/pyruvate only.

ctHb and Derivates

Description of the Optical System

Measured Parameters

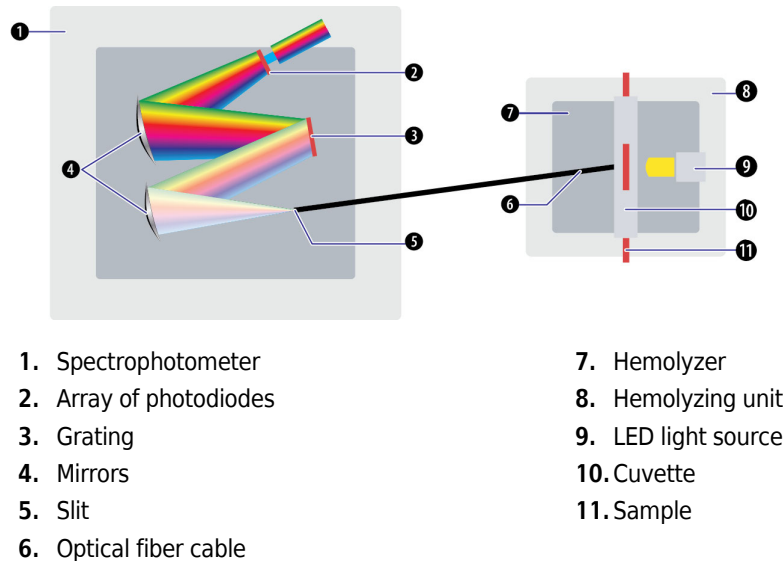
The optical system of the MetaFLEX analyzer is designed to measure these parameters:

Parameter	Description
ctHb	Concentration of total hemoglobin
sO ₂	Oxygen saturation
FO ₂ Hb	Fraction of oxyhemoglobin
FCOHb	Fraction of carboxyhemoglobin
FHHb	Fraction of deoxyhemoglobin
FMetHb	Fraction of methemoglobin
FHbF	Fraction of fetal hemoglobin
ctBil	Concentration of total bilirubin (the sum of unconjugated and conjugated bilirubin) in plasma

NOTE ctBil can be measured on blood or plasma samples. Plasma samples provide the optimal measurement performance. To obtain optimal accuracy when following a trend in ctBil, use the same sample type and the same analyzer.

Construction

The optical system is based on a 256-wavelength spectrophotometer with a measuring range of 467-672 nm. The spectrophotometer is connected via an optical fiber to a combined hemolyzer and measuring chamber.



Measurement Cycle

The method used in the analyzer's optical system is visible absorption spectroscopy. The measurement cycle is as follows:

1. The blood sample is transported to the cuvette in the hemolyzer unit. The temperature of the cuvette is adjusted to 37 °C.
2. A back pressure is exerted on the sample. This one atmosphere over-pressurization is maintained during the hemolization and measurement to remove air bubbles in the sample and to enhance the hemolization process.
3. The 1-μL sample in the cuvette is ultrasonically hemolyzed at a frequency of about 30 kHz. This hemolization process ruptures the walls of the red blood cells and the content of the red blood cells is evenly mixed with the plasma and an optically clear solution is produced.
4. Light from a white LED is sent into the cuvette and the light is transmitted through the cuvette via an optical fiber to the spectrophotometer.
5. The light passes through a slit that points the light towards an arrangement of mirrors and a grating.
6. The grating divides the light into the colors of the rainbow and the mirror focuses the light on a photodiode array.
7. The photodiode array, which has 256 diodes or pixels, one for each wavelength, converts the monochromatic light signals to currents.
8. The currents are measured at each of the 256 diodes. The currents form the basis for the absorption spectrum for a particular sample.
9. The spectrum is sent to the analyzer, which calculates the oximetry parameter values.

Lambert-Beer's Law

Absorption spectroscopy is based on Lambert-Beer's law, which states that the measured absorbance for a single compound is directly proportional to the concentration of the compound and the length of the light path through the sample²:

$$A_y^\lambda = \varepsilon_y^\lambda \times c_y \times l$$

Where:

A_y^λ = absorbance of compound y at wavelength λ

ε_y^λ = extinction coefficient of compound y at wavelength λ (a constant, characteristic of the compound)

c_y = concentration of compound y in sample

l = length of the light path

Absorbance

The absorbance (A) of a compound is defined as the logarithm of the ratio of the light intensity before and after transmission through the compound.

In practice it is the logarithm of the ratio of the light intensity transmitted through water to the light intensity transmitted through the compound.

$$A = \log \frac{I_0}{I}$$

Where:

I_0 = intensity of light transmitted through water (I_0 is measured as the intensity of light transmitted through CAL 3 solution)

I = intensity of light transmitted through the compound

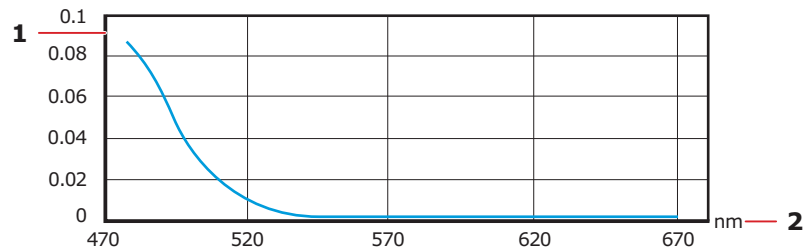
Total Absorbance

For samples that contain more than one optically active compound, the total absorbance (A_{total}) is the sum of the individual compounds' absorbance, since absorbance is an additive quantity.

For example, if a sample contains six compounds $y_1, y_2, \dots, y_6$, the total absorbance measured for that sample at wavelength λ_1 is:

$$\begin{aligned} A_{\text{total}}^{\lambda_1} &= A_{y_1}^{\lambda_1} + A_{y_2}^{\lambda_1} + A_{y_3}^{\lambda_1} + A_{y_4}^{\lambda_1} + A_{y_5}^{\lambda_1} + A_{y_6}^{\lambda_1} \\ &= l \left(\varepsilon_{y_1}^{\lambda_1} c_{y_1} + \varepsilon_{y_2}^{\lambda_1} c_{y_2} + \varepsilon_{y_3}^{\lambda_1} c_{y_3} + \varepsilon_{y_4}^{\lambda_1} c_{y_4} + \varepsilon_{y_5}^{\lambda_1} c_{y_5} + \varepsilon_{y_6}^{\lambda_1} c_{y_6} \right) \end{aligned}$$

Example of the spectrum obtained from unconjugated bilirubin at a concentration of 200 µmol/L.



1. Absorption
2. Wavelength (nm)

The spectrum of conjugated bilirubin is slightly different.

Determining Concentrations

In the measured spectrum of a sample, the absorption recorded at each wavelength contains contributions from each of the compounds in the sample. The task then is to determine the magnitude of that contribution and thereby the concentration of each compound in the sample.

The concentrations are determined as follows:

$$c_y = \sum_{n=1}^{138} K_y^{\lambda_n} A_{\text{total}}^{\lambda_n}$$

Where $K_y^{\lambda_n}$ = a constant specific to compound y at wavelength λ_n .

Matrix of Constants

The constants ($K_y^{\lambda_n}$) are determined by the use of the Multivariate Data Analysis² where the spectra of the calibration compounds are considered together with the reference values of the calibration compounds. The essential interfering substances (intralipids and sulfhemoglobin) were also taken into account.

Calibration of the Optical System

Calibration Materials

The optical system is calibrated at two points by the use of these solutions:

- The S7770 ctHb Calibration Solution with a known dye concentration to determine the cuvette path length, l .
- A transparent solution from the Solution Pack in the analyzer to determine the zero point, I_0 .

Zero Point

The zero point, I_0 , is the current (or intensity) measured by the photodiode array on the transparent solution in the cuvette. During this blank calibration the ctHb is calibrated to this zero point.

I_0 is measured automatically during system start up and during calibrations.

Cuvette Path Length

The cuvette path length (for example, the length of the light path) is determined from Lambert-Beer's Law by measuring the absorbance of the colored dye present in the tHb Calibration Solution (S7770), which has a known equivalent hemoglobin concentration.

Beer's Law: $A = \epsilon \times C_{\text{dye}} \times l$

Where

A = absorbance

ϵ = extinction coefficient

C_{dye} = concentration of colored dye

l = length of light path

Correcting for Interferences

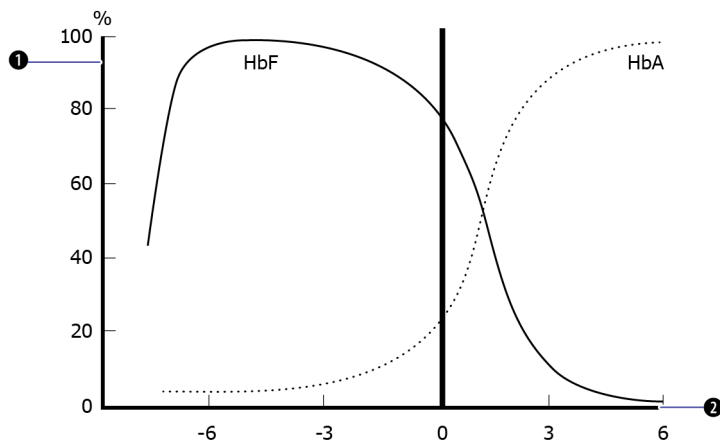
HbF versus HbA

Fetal hemoglobin (HbF) does not have the same spectrum as adult hemoglobin (HbA) due to a slight variation in molecular structure. The presence of HbF in a sample will interfere with the result if a correction is not made.

Therefore, when hemoglobin levels are measured in samples from premature neonates and neonates aged 0-3 months, as well as from adults who suffer from e.g. thalassemia, it is important to take into account this difference³, and to make sure that the analyzer automatically corrects for HbF.

NOTE The analyzer only compensates for interference caused by the presence of HbA and HbF.

The diagram shows the transition from fetal hemoglobin to adult hemoglobin.



1. Hemoglobin

2. Months

NOTE This graph is only schematic and cannot be used to determine *FHbF*.

Deviation of Results

If the difference between the adult and fetal types of hemoglobin is not taken into account in measurements on samples that contain HbF (e.g. from premature neonates and neonates aged 0-3 months) then a deviation in the measurement will occur.

The deviation is most important for measurements of oxygen saturation (sO_2 and FO_2Hb) and the fraction of carboxyhemoglobin ($FCOHb$), since inaccurate measurements of these parameters can lead to incorrect interpretations of the results.

Detecting HbF

The presence of HbF in a sample is detected by measuring the difference between the spectra of fetal and adult oxyhemoglobin. Fetal oxyhemoglobin, cO_2HbF , is determined by the difference.

Correcting for HbF

The amount of cO_2HbF that exceeds a certain level indicates HbF interference. The analyzer automatically corrects for this interference by subtracting the difference spectrum of fetal oxyhemoglobin from the measured spectrum.

Repressing Spectra

Repressing the spectra of the likely interfering substances is done in two ways depending on the substance:

- **Either** the substance is taken account of in the calculation of the matrix of constants, K. This applies to Intralipids and Sulfhemoglobin.
- **Or** the substance is detected, and the measured spectrum is corrected accordingly. This applies to HbF.

Residual Spectrum

The measured spectrum is compared to a model spectrum calculated from the determined concentrations. The difference between these two spectra is called the residual spectrum. If this residual spectrum is too high, the oximetry module parameters ctHb, sO₂, FO₂Hb, FCOHb, FMetHb, FHHb, FHbF and ctBil will be flagged with a warning.

In addition, a warning will accompany the results if any of these conditions exist:

- ctHb <-0.1 mmol/L or ctHb >25 mmol/L
- FHb(deriv) <-2% or FHb(deriv) >102% where FHb(deriv) is defined as sO₂, FO₂Hb, FCOHb, FMetHb, FHHb
- SHb <-2% or SHb >10%
- Value of turbidity <- 0.5% or > 5%

Measurement and Corrections

Calculation of the Values of the Oximetry Parameters

The oximetry parameters are calculated as follows:

Parameter	Equation
ctHb(meas)	$= cO_2Hb + cCOHb + cHHb + cMetHb$
sO ₂	$= \frac{cO_2Hb}{ceHb}$ ceHb = cHHb + cO ₂ Hb (effective hemoglobin)
FO ₂ Hb	$= \frac{cO_2Hb}{ctHb}$
FCOHb	$= \frac{cCO_2Hb}{ctHb}$
FHHb	$= \frac{cHHb}{ctHb}$

Parameter	Equation
<i>F</i> MetHb	$= \frac{c_{\text{MetHb}}}{ctHb}$
<i>F</i> HbF	$= \frac{c_{\text{HbF}}}{ctHb}$

Bilirubin

Bilirubin is calculated as follows:

$$ctBil(P) = \frac{ctBil(B)}{1 - Hct(calc)}$$

Where:

ctBil(P) = concentration of total bilirubin in plasma

ctBil(B) = concentration of diluted plasma bilirubin after sample hemolyzation

Hct(calc) = calculated hematocrit (a fraction):

$$Hct(calc) = \frac{0.0301}{g/dl} \times ctHb$$

For further details on Hct(calc) please refer to Interference Tests and the explanation of MCHC (Mean Corpuscular Hemoglobin Concentration) in this manual.

Restrictions

These parameters will not be calculated:

Parameter	Is not calculated if...
<i>s</i> O ₂ , <i>F</i> COHb, <i>F</i> MetHb, <i>F</i> Hb, <i>F</i> O ₂ Hb	ctHb < 1 mmol/L
<i>s</i> O ₂	ceHb = cHHb + cO ₂ Hb < 0.75 mmol/L
ctBil	ctHb > 14.27 mmol/L

To correct for the presence of HbF in a sample, these conditions are required:

Parameter or settings	Conditions
ctHb	Concentration > 5 mmol/L
<i>F</i> COHb	Concentration < 20%
<i>F</i> MetHb	Concentration < 10%
HbF correction setting - "Enabled for levels > 20%"	cO ₂ HbF/ctHb should be more than 0.2

Parameter or settings	Conditions
HbF correction setting - "Enabled for all levels"	No lower limit value for cO_2HbF is required. Even adult blood samples will be corrected for HbF. This setting may be of value when you analyze blood samples from newborns who have received adult blood transfusion. In these cases $FHbF$ can be lower than 20% and significant deviations of oximetry parameters and bilirubin can occur.
HbF correction setting - "Disabled"	No HbF corrections are made
HbF correction has been enabled	The message "Oxi compensated for HbF" is attached to the result
$sO_2 < 50\%$	The message "FHbF measurement not possible" is shown by the analyzer, if a HbF suppression has been activated, and the $FHbF$ estimation from cO_2HbF is too uncertain

Corrections for ctHb

The uncorrected hemoglobin concentration, $ctHb(\text{sample})$, measured on capillary or syringe samples is corrected as follows:

$$ctHb(\text{sample}, \text{corr}) = \frac{ctHb(\text{sample})}{F_{\text{cuV}}}$$

Where:

$ctHb(\text{sample}, \text{corr})$ = corrected ctHb

F_{cuV} = analyzer-dependent cuvette path length constant determined at tHb calibrations and automatically saved by the analyzer

Corrections for ctBil

The uncorrected total bilirubin concentration, $ctBil(\text{sample})$, measured on capillary or syringe samples is corrected as follows:

$$ctBil(\text{sample}, \text{corr}) = \frac{ctBil(\text{sample})}{F_{\text{cuV}}}$$

F_{cuV} is the same as for tHb.

Overview

This chapter describes the instrument startup procedure.

This chapter contains information on:

- [Pre-Startup Inspection](#)
- [Turning On the Instrument](#)
- [Logging On and Off of the Software](#)

Pre-Startup Inspection

Before using the Vi-CELL MetaFLEX instrument, perform the following system checks:

Power Source Inspection

Check the power cable located on the back of the instrument, and verify it is securely connected to both the instrument and the power source.

Peripherals Connection Inspection

Check that the optional peripherals including mouse, keyboard, and external printer are properly connected to the instrument.

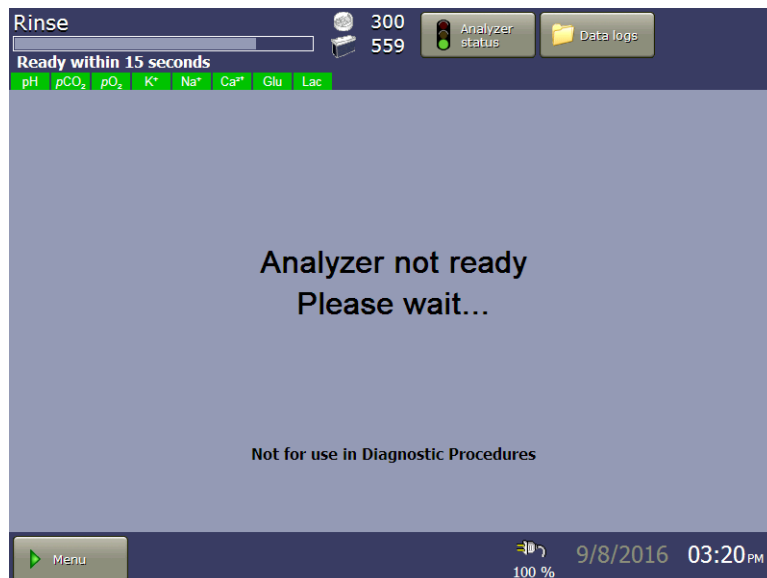
Turning On the Instrument

 CAUTION

1. If the system fails to start properly, check first to see whether the power cable and connection cables are properly connected.
2. Never shut off the power or disconnect a data cable while the system is performing a task. Doing so can result in data loss or damage to the system.

-
- 1 Turn on the main power switch located on the back cover of the instrument. Refer to [Figure 1.2](#)

- 2 Wait for the startup procedure to finish.



When the startup procedure is finished, the system displays *Ready* in the top left corner of the screen.



Logging On and Off of the Software

Dependent on how your analyzer is set up, you may have to log on to the analyzer to get access to menus or buttons.

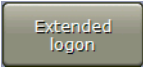
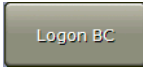
If it is necessary to log on to the analyzer, follow the steps below.

NOTE It is not necessary to log on to an analyzer that is set up for anonymous use.

Logging On

1 Select **Menu > Log on**.

2 Enter or scan data into the fields.

NOTE If that is not possible, select  or  and enter or scan data into the fields.

Logging Off

To log out of the software, select **Menu > Log Off**.

Overview

Quality control management is important as it evaluates the performance of the analyzer to make sure that the results are accurate and precise.

The analyzer manages quality control automatically, but if local regulations or laboratory processes require additional quality control procedures, operators can do them.

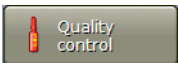
NOTE Beckman Coulter recommends performing QC on a daily basis.

This chapter contains information on:

- [Finding the Status of QC Measurements](#)
- [QC Status Symbols](#)
- [Automatic Quality Control Management](#)
- [Manual Quality Control Management](#)
- [Reviewing QC Statistics](#)
- [Analyzing QC Solutions in Other Modes](#)

Finding the Status of QC Measurements

- 1 Select **Menu > Analyzer status**.

- 2 Select .

NOTE A symbol in the **Solution** column shows the status of a QC measurement. Refer to [QC Status Symbols](#).

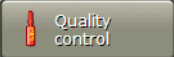
QC Status Symbols

Symbol	Indication
✓	The QC measurement was completed successfully
?	An error was found on one or more QC result

Symbol	Indication
	A scheduled QC measurement is pending. The last QC was completed successfully.
	A scheduled QC measurement is pending. The last QC was not completed successfully.

Automatic Quality Control Management

Automatic quality control management (AQM) is the name given to quality control procedures that the analyzer is programmed to do automatically.

Automatic Quality Control Management	
Name of the Procedure	Description
System checks	Automatic test sequences done with each measurement and at other times to make sure that all parts of the analyzer operate within specifications.
Built-in QC	These are liquid QC measurements that are automatically done by the analyzer. The 3 QC solutions in the Solution Pack are used for these measurements.
Apply statistical rules to QC results.	Helps operators find errors, shifts, and trends. Symbols on results show when rules are violated. For example: Westgard Rules and RiLiBÄK rules (used in Germany). NOTE The analyzer must be set up to do this.
Apply corrective action for QC errors	The default corrective action for QC errors: - The color of the traffic light adjacent to the  button in the Analyzer status screen changes to yellow - The parameter tab changes to yellow - The ? symbol will be shown on the parameter in sample results NOTE The default settings can be changed.
Repress a parameter if there are any problems	NOTE The analyzer must be set up to do this. - Sample results will not include results for parameters with QC errors - The parameter tab changes to red
Lock the analyzer until requested ampoule-based QC measurements are done after a Solution Pack and/or Sensor Cassette replacement	NOTE The analyzer must be set up to do this. NOTE Samples cannot be analyzed while the analyzer is locked.

About System Checks

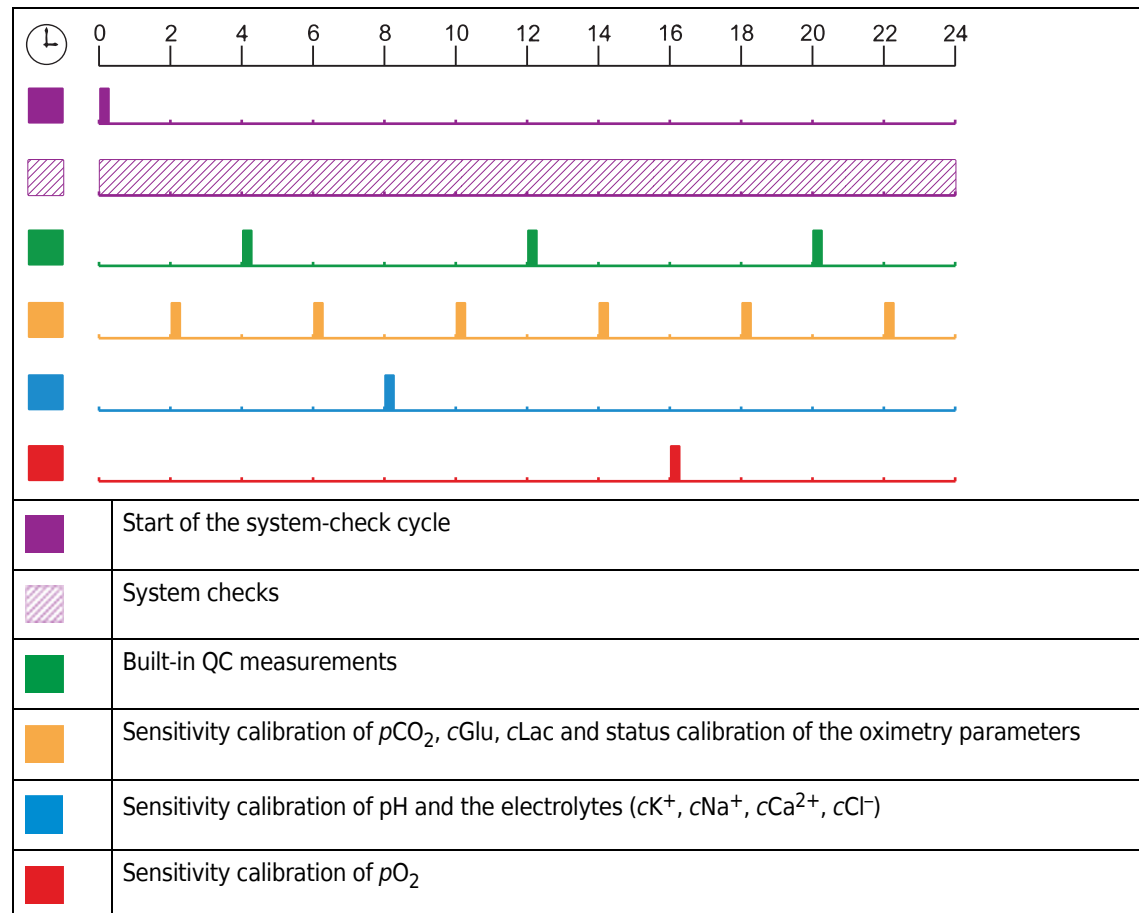
Automatic test sequences done with each measurement and at other times to make sure that all parts of the analyzer operate within specifications.

The analyzer automatically takes action to correct a problem it finds. If the action fails, a message is shown and the analyzer goes into the **Operator Action Needed, Troubleshooting needed** or **Intervention Required** mode. In these modes, operators are given on-screen instructions about what to do.

Results of failed system checks are recorded in the **Activity log**.

Overview of Automatic Quality Management

Here is an overview of the default schedule for system checks, QC, and calibration measurements that the analyzer does to make sure that sample results are accurate, precise, and reliable.



A status calibration of all parameters (except the oximetry parameters) is done before every sample, QC, and sensitivity calibration measurement.

About Built-In QC Measurements

The analyzer uses the three levels of QC solution contained in the Solution Pack to do built-in QC measurements. These QC solutions are automatically registered in slots A, B and C when a Solution Pack is installed.

NOTE The solution in slot A is S9030, the solution in slot B is S9040 and the solution in slot C is S9050.

Built-In QC Measurement Frequency

A built-in QC measurement is scheduled by default to be done every 8 hours. One measurement a day is done with each QC solution. Built-in QC measurements are also scheduled by default to be done in connection with the following activities:

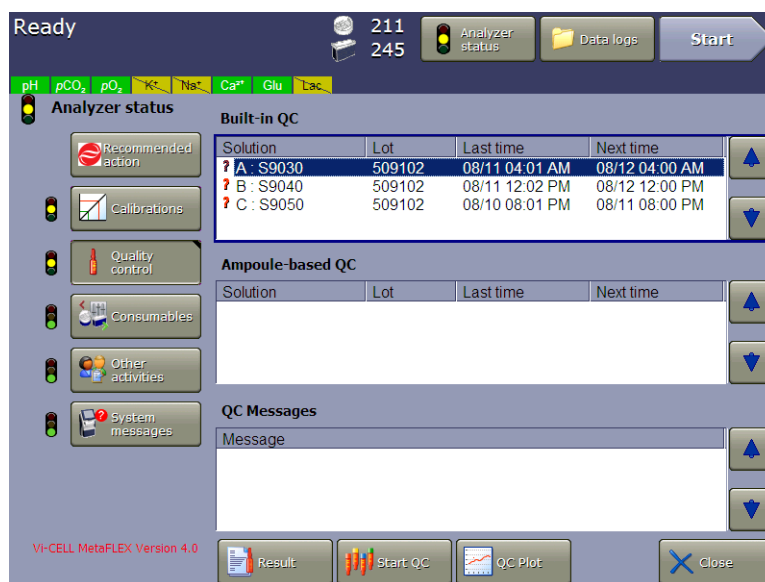
- Replacing the Solution Pack
- Replacing the Sensor Cassette
- Startup

You can edit the schedule for built-in QC measurements. Refer to [Requesting an Unscheduled Built-In QC Measurement](#).

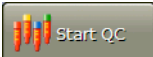
Requesting an Unscheduled Built-In QC Measurement

Prerequisite — The analyzer must state **Ready** in the to left corner of the screen.

- 1 Select **Menu > Analyzer status > Quality control**. The Analyzer Status Quality Control screen appears.



2 Select a QC solution in the **Built-in QC** field.

3 Select .

The result of the QC measurement is saved in the **Quality control log**.

Built-In QC Results

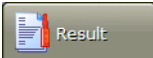
Status of Built-In QC Measurements

The symbols in the **Solution** column of the **Quality control** section of the **Analyzer status** screen shows the overall status of each QC measurement.

Symbol	Description
✓	The QC measurement was successful.
?	An error was found on one or more parameter result.

Finding a Built-In QC Result

Choose an option and follow the steps for it.

Option	Steps
To find a result in the data log	1. Select Menu > Data logs > Quality control log. 2. Select the measurement. NOTE Built-in QC measurements are done with solutions in slots A, B and C. 3. Select .
To find a number of results in the data log	1. Filter the data from the Quality control log.
To find the latest result	1. Select Menu > Analyzer status > Quality control. 2. In the Built-in QC field, select the measurement. 3. Select .

Built-In QC Results Symbols

Problems with built-in QC results are marked with one or more symbols shown in the table below.

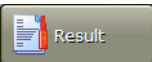
Symbol	Description
	An error was found. A message attached to the result describes the error.
	The result is outside the control range, but inside the statistical range. Results inside the statistical range are included in statistics.
	The result is outside the statistical range. The result is not included in statistics
	The result is outside the range of indication. The result is not included in statistics
.....	The result could not be calculated. When possible, an interpretation of the message is attached.
*	Operator-defined slope/offset corrections were used to calculate the result
W	The result violates a Westgard rule
R	The result violates a RiliBÄK rule

Viewing Built-In QC Results Messages

1 Select **Menu > Data logs > Quality control log**.

2 Select the measurement.

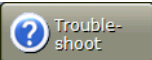
NOTE QC solutions used for built-in QC measurements are automatically registered in slots A, B and C.

3 Select .

4 Select .

Troubleshooting Built-In QC Results Messages

1 Select the message.

2 Select .

- 3 Follow the on-screen instructions.

Manual Quality Control Management

The analyzer manages quality control automatically, but if your laboratory procedures require additional quality control (QC) procedures, quality control can be done manually through ampoule-based QC measurements.

QC procedures	Description
Ampoule-based QC measurements	Manual QC measurements done with QC ampoules NOTE If your laboratory procedures require that analyzer-specific control ranges be established for the QC solutions used for ampoule-based QC measurements, it can be done.
Ampoule-based QC measurements after Solution Pack and/or Sensor Cassette replacements	The analyzer is locked until requested ampoule-based QC measurements are done. NOTE The analyzer must be set up to do this.
Calibration verification measurements (for example in the USA).	Measurements that let you verify the calibration and reportable range of measured parameters NOTE This procedure requires control material to be analyzed as samples.

Ampoule-Based QC Measurements

QC Solutions for Ampoule-Based Measurements

Beckman Coulter recommends that QUALICHECK5+ solutions are used for ampoule-based QC measurements. Four levels of QUALICHECK5+ solutions are available. Refer to [Table 4.1](#) for QUALICHECK5+/AutoCheck5+ expected midpoints.

Table 4.1 QUALICHECK5+/AutoCheck5+ Expected Midpoints

QUALICHECK5+/AutoCheck5+					
QUALICHECK5+ Type		S7730 Level 1	S7740 Level 2	S7750 Level 3	S7760 Level 4
AutoCheck5+ Type		S7735 Level 1	S7745 Level 2	S7755 Level 3	S7765 Level 4
Parameter	Unit				
pH		7.1	7.4	7.6	6.8
pCO ₂	mmHg	70	45	21	100
	kPa	9.3	6.0	2.8	13.3
pO ₂	mmHg	150	105	60	300
	kPa	20.0	14.0	8.0	40.0
ctHb	g/dL	7.8	13.0	19.5	2.6
	mmol/L	4.8	8.1	12.1	1.6
sO ₂	%	50	97	70	5
	fraction	0.50	0.97	0.70	0.05
FO ₂ Hb	%	44	91	49	3
	fraction	0.44	0.91	0.49	0.03
FCOHb	%	6	4	20	10
	fraction	0.06	0.04	0.20	0.10
FMetHb	%	5	2	10	20
	fraction	0.05	0.02	0.10	0.20
FHbF	%	29	83	55	-
	fraction	0.29	0.83	0.55	-
cK ⁺	mmol/L	2.3	3.5	5.5	6.0
cNa ⁺	mmol/L	155	135	125	120
cCa ²⁺	mmol/L	1.1	0.5	0.4	1.6
	mg/dL	4.5	2.0	1.4	6.4
	meq/L	2.2	1.0	0.7	3.2
cCl ⁻	mmol/L	120	95	65	35 (QUALICHECK5+) 90 (Autocheck5+)
cGlucose	mg/dL	36	90	234	0
cLactate	mmol/L	4.5	1.6	10.5	0
	mg/dL	4.1	14	95	0
	meq/L	4.5	1.6	10.5	0
ctBil	μmol/L	180	300	450	60
	mg/dL	10.5	17.5	26.3	3.5

NOTE If non-QUALICHECK QC solutions are used, Beckman Coulter cannot guarantee accurate, valid QC results.

Obtaining Good Ampoule-Based QC Measurement Results

To obtain good ampoule-based QC measurement results, follow the listed advice.

- For QUALICHECK solutions only:
 - Check that there are no calibration errors before you perform an ampoule-based QC measurement.
 - Keep the QC solution under the correct storage conditions. Refer to the product-specific package insert.
 - Hold the ampoule between your thumb and first finger when you shake it.
 - Shake the ampoule vigorously for 15 seconds before it is opened.
 - Use the Beckman Coulter QUALICHECK adapter to hold the ampoule during the QC measurement.
 - Use the prepared QC solution immediately after the ampoule is opened.
 - Use the ampoule for one QC measurement only.
 - Enter the correct ampoule temperature in the **Quality control identification** screen during the QC measurement.
- For non-QUALICHECK QC solutions:
 - Check that there are no calibration errors before you perform an ampoule-based QC measurement.
 - Keep the QC solution under the correct storage conditions. Refer to the product-specific package insert.
 - Prepare the QC solution for use correctly. Follow the manufacturer's instructions.

Preparing a QUALICHECK QC Ampoule for Use

Tools/Supplies Needed:



A QUALICHECK5+ ampoule



An Ampoule Opener



A QUALICHECK Adapter

NOTE The QUALICHECK5+ box that contains the QC ampoules has been stored at a constant temperature (18-32 °C) for 5 hours.

NOTE If there are errors on calibration results, they will be shown on the ampoule-based QC results.

1 Remove a QC ampoule from its box.

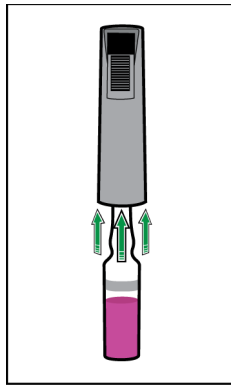
IMPORTANT The ampoules are sensitive to light.

2 Put the lid back on the box.

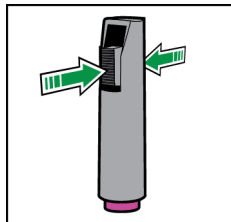
3 Hold the ampoule between your thumb and first finger and shake it vigorously for a minimum of 15 seconds.

4 Hold the ampoule neck-side up and tap the top until all the solution collects in the lower part of the ampoule.

5 Put the ampoule in the Ampoule Opener.

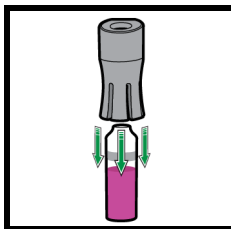


6 Use your fingers to apply pressure in the directions shown, to break off the neck of the ampoule.



7 Gently pull the ampoule out of the Ampoule Opener.

8 Put the QUALICHECK Adapter over the open end of the ampoule.



- 9 Perform an ampoule-based QC measurement immediately. Refer to [Performing a QUALICHECK Ampoule-Based QC Measurement from the Analyzer Status Screen](#) or [Performing an Ampoule-Based QC Measurement from the Start Screen](#).

Performing a QUALICHECK Ampoule-Based QC Measurement from the Analyzer Status Screen

Prerequisites:

- An **Ampoule - QC** mode is set up. Refer to [Setting Up Ampoule QC Mode](#) in CHAPTER 8, Setup.
- The QUALICHECK5+ solution is registered for use on the analyzer. Refer to [Registering a Beckman Coulter QC Solution for Ampoule-Based QC Measurements](#).
- The QUALICHECK5+ ampoule is prepared for use. Refer to [Preparing a QUALICHECK QC Ampoule for Use](#).
- Verify that the analyzer displays **Ready** in the top left corner of the screen.

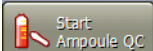
NOTE If there are errors on calibration results, they will be shown on the ampoule-based QC results.

NOTE Beckman Coulter QC ampoules are for single-use only.

- 1 Select **Menu > Analyzer status > Quality control**.

- 2 Select the correct lot of QC solution in the **Ampoule-based QC** field.

NOTE QC solutions are identified by a **Solution** name (for example S7730) and a **Lot** number.

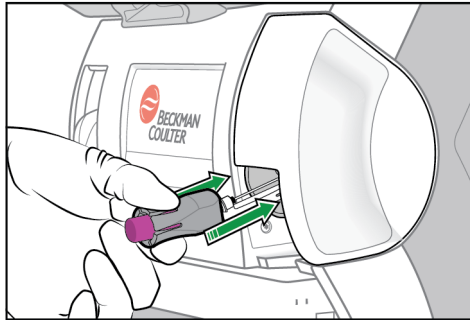
- 3 Select .

The analyzer opens the inlet.

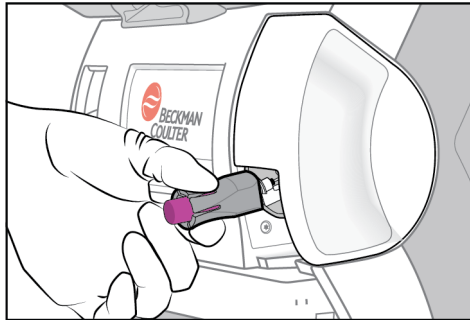
- 4 Turn the QUALICHECK Adapter with the ampoule so the logo faces upwards.

- 5 Put the QUALICHECK Adapter with the ampoule over the inlet gasket.

-
- 6 Push the adapter with the ampoule into the analyzer as far as it will go and hold it there.



-
- 7 Hold the adapter with the ampoule in the pushed-in position until the analyzer prompts you to remove it.

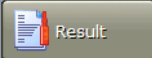


-
- 8 Remove the QUALICHECK adapter with the ampoule when the analyzer prompts you.
The analyzer closes the inlet.

IMPORTANT The insert control ranges of Beckman Coulter QC solutions are determined at a reference temperature of 25 °C. It is therefore important to enter the correct ampoule temperature during QC measurements so the analyzer can temperature-correct QC results.

If the correct temperature is not entered, this will have an effect on pH, $p\text{CO}_2$ and $p\text{O}_2$ results. At temperatures above 25 °C, pH results will be too high and $p\text{CO}_2$ and $p\text{O}_2$ results will be too low. At temperatures below 25 °C, pH results will be too low and $p\text{CO}_2$ and $p\text{O}_2$ results will be too high.

-
- 9 Enter the ampoule temperature.
-
- 10 Enter other necessary data in the **Quality control identification** screen as needed.
-

- 11 Select .



WARNING

Risk of biohazardous contamination if you have skin contact with the ampoule and its contents. The ampoule could contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the ampoule in accordance with your local regulations and acceptable laboratory procedures.

- 12 Remove the ampoule from the adapter and discard it as biohazardous waste.

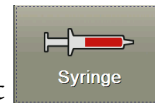
Performing an Ampoule-Based QC Measurement from the Start Screen

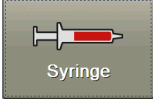
Prerequisites:

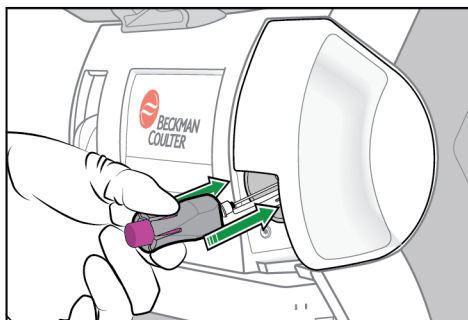
- The QC solution is registered for use on the analyzer. Refer to [Registering a Beckman Coulter QC Solution for Ampoule-Based QC Measurements](#) or [Registering a Non-QUALICHECK QC Solution](#).
- The QC ampoule is prepared for use. Refer to [Preparing a QUALICHECK QC Ampoule for Use](#).
- Verify that the analyzer displays **Ready** in the top left corner of the screen.

NOTE If there are errors on calibration results, they will be shown on the ampoule-based QC results.

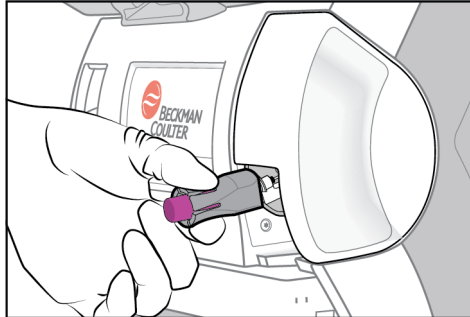
NOTE Beckman Coulter QC ampoules are for single use only.



- 1 Hold the QC adapter with the QC ampoule and select . The analyzer opens the inlet.
- 2 Turn the QUALICHECK Adapter with the ampoule so the logo faces upwards.
- 3 Put the QUALICHECK Adapter with the ampoule over the inlet gasket.
- 4 Push the adapter with the ampoule into the analyzer as far as it will go and hold it there.



-
- 5 Hold the adapter with the ampoule in the pushed-in position until the analyzer prompts you to remove it.



-
- 6 When the analyzer prompts you to, remove the QUALICHECK adapter with the ampoule. The analyzer closes the inlet.

-
- 7 Ensure that the **Solution:** field is selected.

-
- 8 Ensure that there is only one lot of the QC solution.

NOTE QC solutions are identified by a **Solution** name (for example S7730) and a **Lot** number.

-
- 9 If there is only one lot, go to step 11.

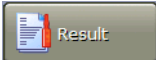
-
- 10 If there is more than one lot, select the correct lot of QC solution.

IMPORTANT The insert control ranges of Beckman Coulter QC solutions are determined at a reference temperature of 25 °C. It is therefore important to enter the correct ampoule temperature during QC measurements so the analyzer can temperature correct QC results.

If the correct temperature is not entered, this will have an effect on pH, $p\text{CO}_2$ and $p\text{O}_2$ results. At temperatures above 25 °C, pH results will be too high and $p\text{CO}_2$ and $p\text{O}_2$ will be too low. At temperatures below 25 °C, pH will be too low and $p\text{CO}_2$ and $p\text{O}_2$ results will be too high.

-
- 11 Enter the ampoule temperature.

-
- 12 Enter other necessary data in the **Quality control identification** screen.

-
- 13 Select  .



WARNING

Risk of biohazardous contamination if you have skin contact with the ampoule and its contents. The ampoule could contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the ampoule in accordance with your local regulations and acceptable laboratory procedures.

- 14 Remove the ampoule from the adapter and discard the ampoule as biohazardous waste.

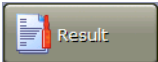
Editing QC Identification Data

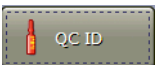
NOTE You can only edit the **Department**, **Operator** and **Note** fields.

- 1 Select **Menu > Data logs > Quality control log**.

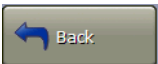
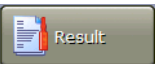
- 2 Select a measurement done with the QC solution you want to edit.

NOTE QC solutions are identified by a **Solution** name (for example, S7730) and **Lot** number.

- 3 Select .

- 4 Select .

- 5 Edit the necessary data.

- 6 Select  or  to automatically save your changes.

Ampoule-Based QC Results

Status of ampoule-based QC measurements

The symbols in the **Solution** column of the **Quality control** part of the **Analyzer status** screen shows the overall status of each QC measurement.

Symbol	Description
✓	The QC measurement was successful
?	An error was found on one or more parameter result.

Finding an Ampoule-Based QC Result

1 Select **Menu > Data logs > Quality control log**.

2 Select the solution.

3 Select  .

Ampoule-Based QC Results Symbols

Problems on ampoule-based QC results are marked with one or more symbols shown in the table below.

Symbol	Description
?	An error was found. A message attached to the result describes the error.
↑↓	The result is outside the control range, but inside the statistical range. Results inside the statistical range are included in statistics.
↑↑↓↓	The result is outside the statistical range. The result is not included in statistics.
↑↑↓↓	The result is outside the range of indication. The result is not included in statistics.
....	The result could not be calculated. When possible, an interpretation of the message is attached.
*	Operator-defined slope/offset corrections were used to calculate the result
W	The result violates a Westgard rule
R	The result violates a RiliBÄK rule

Viewing Ampoule-Based QC Results Messages

1 Select **Menu > Data logs > Quality control log.**

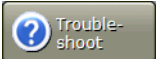
2 Select the solution.

3 Select .

4 Select .

Troubleshooting Results Messages

1 Select the message.

2 Select .

3 Follow the instructions on the screen.

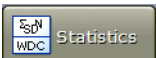
Reviewing QC Statistics

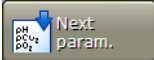
Finding and Printing QC Statistics

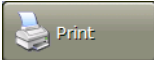
Only QC results that are within the statistical range are included in the QC statistics.

NOTE You can only print QC statistics for one month at a time.

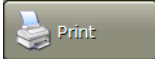
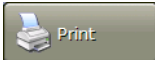
1 Select **Menu > Data logs > Quality control log.**

2 Select .

3 Select  or  to see statistics for other parameters.

4 Select .

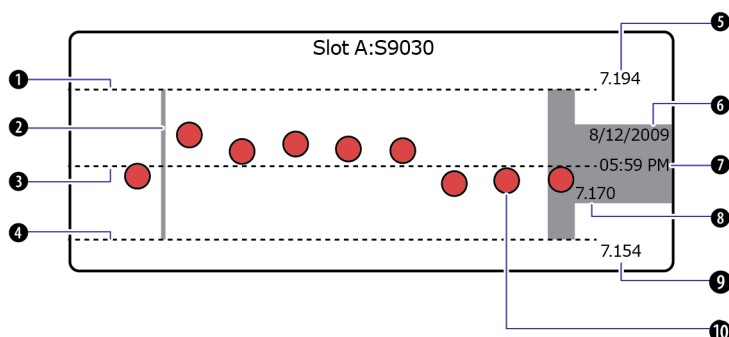
5 Choose an option and follow the steps for it.

Option	Steps
To print statistics for the lot to date	- Select the Print lot-to-date check button. - Select . NOTE This option is only available when a minimum number of QC measurements have been done.
To print statistics for a period	- Select the Print for period check button. - Select the calendar month period in the Print for period frame. - Select .

NOTE QC statistics are printed for all parameters.

QC Plots

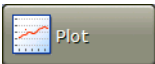
QC plots are Levey-Jennings plots that show QC results done with registered QC solutions. The results are shown on a horizontal time axis.



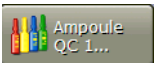
1. Line to show the upper limit of the control range of the solution
2. Line to show when the current control range of the solution was changed, or a new lot of the QC solution was registered
3. Mean value of the control range of the solution
4. Line to show the lower limit of the control range of the solution
5. The absolute value of the upper limit of the control range of the solution
6. Date that the highlighted QC measurement was done
7. Time that the highlighted QC measurement was done
8. QC result for the selected QC measurement
9. The absolute value of the lower limit of the control range of the solution
10. A previous QC measurement done with the solution

Finding a QC Plot

- 1 Select **Menu > Data logs > Quality control log.**

- 2 Select  **Plot**.

- 3 Select a parameter.

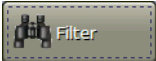
- 4 Select  **Ampoule QC 1...** to see plots for ampoule-based QC measurements.

- 5 Select within the plot for a specific QC solution.

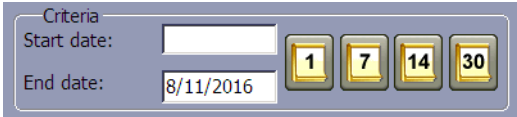
-
- 6 Use the scroll buttons ( ) to select and see details about specific QC measurements.
-

Filtering Data from the Quality Control Log

-
- 1 Select **Menu > Data logs > Quality control log**.
-

- 2 Select  .
-

- 3 In the **Criteria** frame, choose an option and follow the steps for it.

Option	Action
To select a time period prior to today's date	Select the number button for the number of days you want. 
To select a start and end date	Enter data in the Start date: and End date: fields.

4 Select the **Solution**.

5 Select .

6 Select **Lot** and enter the Lot number.

7 If necessary, select other criteria.

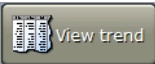
8 Select .

Viewing Trends in QC Results

Prerequisites — You have filtered the QC results from the **Quality control log**. Refer to [Filtering Data from the Quality Control Log](#).

1 Select .

- 2 Select check buttons for the parameters you want to see trends of.

- 3 Select .

Analyzing QC Solutions in Other Modes

QC solutions may be analyzed in other modes than the **Ampoule - QC** mode. However, when this is done, the results must be temperature-corrected manually.

Temperature Correcting Results Based on QUALICHECK5+ Solutions

NOTE Results for pH, $p\text{CO}_2$ and $p\text{O}_2$ must be corrected if the temperature of the ampoule during measurements was above or below 25 °C.

- 1 Find the temperature constant (A) in the table.

QUALICHECK5+ quality control solutions				
Parameter	Temperature constants (A)			
	Level 1 – S7730	Level 2 – S7740	Level 3 – S7750	Level 4 – S7760
pH	0.0018	0.00113	0.000703	0.00163
$p\text{CO}_2$	0.00482	0.00231	0.000676	0.00657
$p\text{O}_2$	0.00982	0.00986	0.00915	0.0107

- 2 Find the temperature constant (B) in the table.

QUALICHECK5+ quality control solutions				
Parameter	Temperature constants (B)			
	Level 1 – S7730	Level 2 – S7740	Level 3 – S7750	Level 4 – S7760
pH	0.0000220	0.0000180	–0.0000260	0.0000209
$p\text{CO}_2$	0.0000617	0.0000394	0.0000195	0.000117
$p\text{O}_2$	–0.0000327	–0.000115	0.0000177	–0.00000876

- 3 Use the equations in the table to correct results for parameters that were measured at temperatures above or below 25 °C.

Parameter	Equation for temperature correction
pH	$\text{pH}_{\text{corrected to 25 °C}} = \text{pH}_{\text{measured}} - A(t - 25) - B(t - 25)^2$
pCO_2	$(\text{pCO}_2)_{\text{corrected to 25 °C}} = (\text{pCO}_2)_{\text{measured}} \times [1 + A(t - 25) + B(t - 25)^2]$
pO_2	$(\text{pO}_2)_{\text{corrected to 25 °C}} = (\text{pO}_2)_{\text{measured}} \times [1 + A(t - 25) + B(t - 25)^2]$

Quality Control

Glossary of Quality Control Terms

Term	Explanation
Accepted result	A QC result that falls within the statistical range
Assigned value	The assigned value is the center value of a control range. NOTE For Beckman Coulter quality control solutions used for ampoule-based QC measurements, control ranges are given in the insert.
Control range	The range within which a QC result should fall. The control range is calculated to be the mean value ± 2 SD. NOTE This range can be set to the lot-to-date range (2 SD) calculated by the analyzer.
Insert range	The upper and lower limits of a control range established for a Beckman Coulter quality control solution. The ranges are calculated from the results of 30-50 QC measurements done on each of 10 analyzers. Measurements are done 2-5 times a day over a period of 1-4 weeks.
Lot-to-date range	A range calculated by the analyzer based on a minimum number of measurements done with a specific lot of a quality control solution. It is the mean value ± 2 SD.
Statistical factor	The factor which a control range is multiplied by to determine the statistical range. The recommended statistical factor is 1.5.
Statistical range	The range within which a QC result must fall in order to be included in the QC statistics. It is determined by multiplying the control range limits by the statistical factor. When the recommended statistical factor of 1.5 is used, the statistical range will be the mean ± 3 SD.

Registering QC Solutions

Why is it Necessary to Register QC Solutions?

When a QC solution is registered, data about the solution is saved on the analyzer. The data is necessary to evaluate QC results. For example, to make sure that the result falls within the specified control range and mark the results that do not. It is only necessary to register a specific lot of a QC solution one time.

About Registration of QC Solutions

QC measurement type	About registration of the QC solutions used
Built-in QC measurements	The QC solutions are automatically registered when the Solution Pack is installed. A chip on the Solution Pack supplies data about the solutions.
Ampoule-based QC measurements	Each lot of each level of QC solution must be manually registered before use. This applies to Beckman Coulter and non-Beckman Coulter QC solutions. The MetaFLEX barcode on the product insert for each level of Beckman Coulter QC solution supplies data about it. The data is saved on the analyzer and used when ampoule-based QC measurements are done with the solution.

Registering a Beckman Coulter QC Solution for Ampoule-Based QC Measurements

Prerequisite — The product insert (the document supplied with the QC solution).

IMPORTANT You must register each level of each lot of QC solution before you can use them.

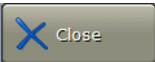
- 1 Select **Menu > Utilities > Setup > QC setup > QC solutions**.

IMPORTANT Risk of calibration data loss if you overwrite the slot.

- 2 Select a **Slot** that contains no data. If you select a slot that contains data, all statistical data related to the QC solution registered in the slot will be irreversibly deleted.

NOTE The number of the slot can be thought of as a registration number.

- 3 Scan or enter the barcode for the MetaFLEX analyzer from the product insert.

- 4 Select .

Post-Requisite — If your laboratory procedures require it, establish analyzer-specific control ranges.

Data Saved During Registration of QUALICHECK QC Solutions

During registration the barcode for the MetaFLEX analyzer is scanned from the product insert. The screen shows the data that is read from the barcode and saved on the analyzer.

Figure 4.1 Quality Control Ranges Setup



- Slot 1** – The slot number tells the analyzer where data for the specific lot of the QC solution is stored
- The generic name of the QC solution – The character S followed by a four digit number. For example, S7750.
- Lot:** – The lot number of the QC solution
- Parameter** – The parameters that can be measured
- Insert range** – The control range given on the product insert for the MetaFLEX analyzer
- Assigned Value** – The center value of the **Insert range**
- Control range** – By default, the control range is given the same values as the **Insert range**.

NOTE If your laboratory procedures require it, control ranges can be changed to analyzer-specific control ranges established by your laboratory.

Registering a Non-QUALICHECK QC Solution

Prerequisite — Control ranges for the parameters to be measured with the QC solution.

NOTE If non-QUALICHECK QC solutions are used, Beckman Coulter cannot guarantee accurate, valid QC results.

NOTE Results of QC measurements done with non-Beckman Coulter QC solutions are not automatically temperature corrected.

- 1 Select **Menu > Utilities > Setup > QC setup > QC solutions**. The QC solutions screen appears.

Ready 211 242 Analyzer status Data logs Start

pH pCO₂ pO₂ K⁺ Na⁺ Ca⁺⁺ Glu Lac

Quality control log - filter

Criteria

Start date: 8/11/2016 1 7 14 30

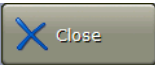
End date: 8/11/2016

Solution	Lot	Department	Operator	Note	Status
S9030					

S7660
S9030
S9040
S9050
S9230
S9240
S9250

Select

Apply Back

- 2 Select a **Slot** that contains no data.
NOTE The number of the slot can be thought of as a registration number.
- 3 Select **Add non-R-**.
- 4 Write down the number of the **Slot**. The number is necessary in step 7 of this procedure.
- 5 Select .

- 6 Select **Menu > Utilities > Setup > QC setup > QC ranges**. The QC ranges screen appears.

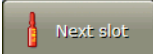
Ready 210 164 Analyzer status Data logs Start

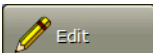
pH pCO₂ pO₂ Na⁺ K⁺ Ca²⁺ Glu Lac

Quality control ranges setup Slot 1: S7730 Lot: 139

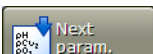
Parameter	Assigned Value	Control range	N	Lot-to-date range (2 SD)	Insert range	Unit
pH	7.070	7.050 7.090	1	7.056 7.056	7.050 7.090	
pCO ₂	71.0	66.0 76.0	1	69.0 69.0	66.0 76.0	mmHg
pO ₂	152	142 162	1	148 148	142 162	mmHg
ctHb	8.0	7.5 8.5	0		7.5 8.5	g/dL
sO ₂	50.0	49.0 51.0	0		49.0 51.0	%
FO ₂ Hb	44.5	43.5 45.5	0		43.5 45.5	%
FCOHb	5.9	4.4 7.4	0		4.4 7.4	%
FMetHb	5.0	4.0 6.0	0		4.0 6.0	%
FHbF	24	9 39	0		9 39	%
cK ⁺	1.8	1.5 2.1	0		1.5 2.1	mmol/L
cNa ⁺	162	158 166	0		158 166	mmol/L
cCa ²⁺	1.00	0.90 1.10	1	1.04 1.04	0.90 1.10	mmol/L
cCl ⁻	124	118 130	0		118 130	mmol/L
cGlu	0.27	0.18 0.36	1	0.27 0.27	0.18 0.36	g/L
cLac	0.38	0.32 0.43	0		0.32 0.43	g/L
ctBil	186	174 198	0		174 198	μmol/L

Next slot Edit Update all Print Close

- 7 Select  to select the number of the slot you wrote down in step 4.

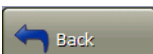
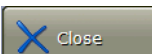
- 8 Select .

- 9 Enter values for the **Current control range** of the parameter shown on the screen.

- 10 Select  to select the next parameter.

- 11 Enter values for the **Current control range** of the parameter shown on the screen.

- 12 Do steps 10 and 11 again for all parameters.

- 13 Select  > .

Data Saved During Registration of QUALICHECK QC Solutions

Here is the data that can be saved during registration of a QUALICHECK QC solution:

- Generic name Non-R-
- **Control range** for each parameter

Quality Control Solutions

Setting Up the Temperature Field for QC Measurements

NOTE QC results are temperature dependent. That is why there is a **Temperature** field in the **Quality control identification** screen that is shown during ampoule-based QC measurements.

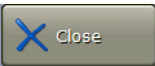
This procedure lets you make it mandatory to enter the room temperature in **Temperature** field, or set a default value in the field.

NOTE If necessary, a set default temperature can be changed during an ampoule-based QC measurement.

1 Select **Menu > Utilities > Setup > QC setup > QC input setup**.

2 Choose an option and follow the steps for it.

Option	Steps
To make the Temperature field mandatory. NOTE When this option is chosen, operators must enter the room temperature before QC results are shown.	Select the Mandatory temperature: check button.
To set a default temperature	Enter a temperature in the Default temperature: field.

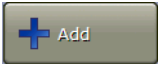
3 Select .

Scheduled QC Measurements

Scheduling Ampoule-Based QC Measurements

Prerequisite — The QC solution is registered.

1 Select **Menu > Utilities > Setup > QC setup > QC schedule**.

2 Select .

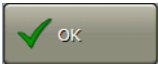
3 Select the registered QC solution, on the right of the screen.

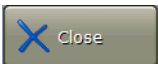
4 Select .

5 Enter a start time.

6 Select a value for the **Repeat:** field, on the right of the screen.

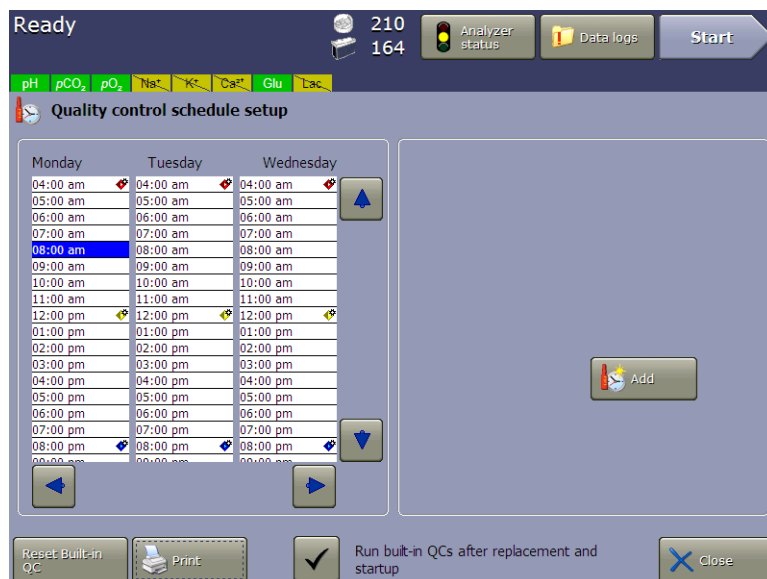
7 If you selected a value less than 24 hours in step 6, select check buttons for the days of the week QC measurements must be done.

8 Select .

9 Select .

Editing the Schedule for Ampoule-Based QC Measurements

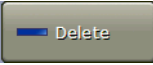
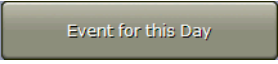
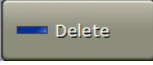
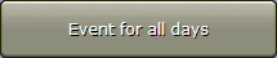
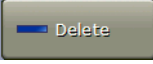
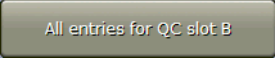
- 1 Select **Menu > Utilities > Setup > QC setup > QC schedule**. The QC schedule screen appears.

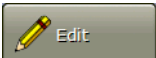
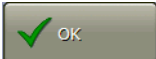
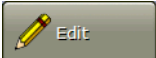
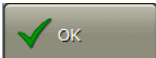
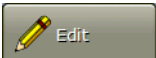
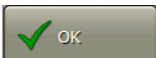


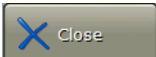
- 2 Select the scheduled measurement you want to edit.

NOTE Scheduled ampoule-based measurements are marked by diamond-shaped icons.

- 3 Choose an option and follow the steps for it.

Option	Steps
To only delete the selected scheduled measurement	1. Select . 2. Select .
To delete all measurements with the selected solution that are scheduled at this time of the day	1. Select . 2. Select .
To delete all scheduled measurements with the selected solution	1. Select . 2. Select . NOTE <n> is a number.

Option	Steps
To change the days of the week measurements must be done	1. Select . 2. Select in the Weekdays: field. 3. Select the check buttons for the days of the week measurements must be done. 4. Select .
To change the start time for measurements	1. Select . 2. Select the Start time: field. 3. Enter a new start time. 4. Select .
To change how frequently measurements must be done	1. Select . 2. Select the Repeat: field. 3. Select a value from the field on the right of the screen. 4. Select .

4 Select .

Built-In QC Measurement Frequency

A built-in QC measurement is scheduled by default to be done every 8 hours. One measurement a day is done with each QC solution. Built-in QC measurements are also scheduled by default to be done in connection with these activities:

- Replacement of the Solution Pack
- Replacement of the Sensor Cassette
- Startup

You can edit the schedule for built-in QC measurements.

Editing the Schedule for Built-In QC Measurements

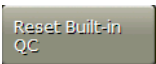
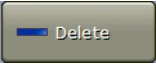
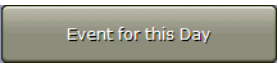
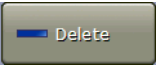
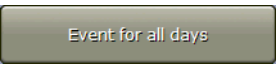
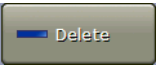
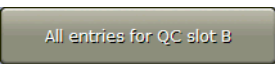
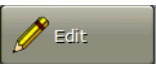
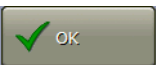
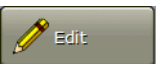
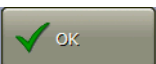
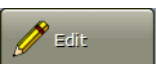
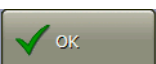
Prerequisite: The schedule for built-in QC measurements is not linked to the calibration schedule.

1 Select **Menu > Utilities > Setup > QC setup > QC schedule.**

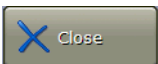
- 2 Select the scheduled built-in QC measurement you want to edit. Scheduled built-in QC measurements are marked by diamond-shaped icons and stars.

NOTE Built-in QC measurements are done with QC solutions registered in slots A, B and C.

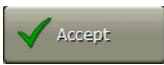
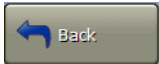
- 3 Choose an option and follow the steps for it.

Option	Steps
To restore the default setup for scheduled built-in QC measurements	Select  .
To only delete the selected scheduled measurement	1. Select  . 2. Select  .
To delete all measurements with the selected solution that are scheduled at this time of the day	1. Select  . 2. Select  .
To delete all scheduled measurements with the selected solution	1. Select  . 2. Select  .
To change the days of the week measurements must be done	1. Select  . 2. Select in the Weekdays: field. 3. Select the check buttons for the days of the week measurements must be done. 4. Select  .
To change the start time for measurements	1. Select  . 2. Select the Start time: field. 3. Enter a new start time. 4. Select  .
To change how frequently measurements must be done	1. Select  . 2. Select the Repeat: field. 3. Select a value from the field on the right of the screen. 4. Select  .

Option	Steps
To schedule built-in QC measurements to be done after replacement and startup procedures	This is the default setting. Beckman Coulter recommends that you do not change this setting.
To remove built-in QC measurements after replacement and startup from the schedule	Beckman Coulter recommends that you do not use this option. Deselect the Run built-in QCs after replacement and startup check button. NOTE If this option is selected, Beckman Coulter recommends that you do ampoule-based QC measurements after replacement and startup procedures.

- 4 Select .

- 5 If a pop-up screen is shown, choose an option and follow the steps for it.

Option	Steps
To accept the new schedule	Select  .
To change the schedule	- Select . - Do steps 3 to 5 again.

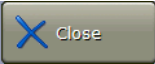
Requesting Ampoule-Based QC Measurements After Replacements

This procedure lets you set up the analyzer to request ampoule-based QC measurements after Sensor Cassette and/or Solution Pack replacements. The analyzer will be locked until the ampoule-based QC measurements are done.

- 1 Select **Menu > Utilities > Setup > QC setup > QC solutions**.
- 2 Select the QC solution to be used for an ampoule-based QC measurement.
- 3 Choose an option and follow the steps for it.

Option	Steps
To request ampoule-based QC measurements after Solution Pack replacements	Select the Request QC after Solution Pack replacement check button.
To request ampoule-based QC measurements after Sensor Cassette replacements	Select the Request QC after Sensor Cassette replacement check button.

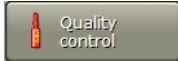
-
- 4** Do steps 2 and 3 again for each QC solution to be used for an ampoule-based QC measurement after a replacement.
-

- 5** Select .
-

Corrective Actions on QC Results

Setting Up Corrective Action for Errors in QC Results

Three corrective actions are available to show errors in QC results.

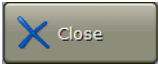
- Attach a question mark symbol to results until the QC error is removed
- Select the color of traffic light shown on the left side of  in the **Analyzer status** screen.
- Do not show results for parameters with QC or other errors.

NOTE A successful QC measurement can remove the error.

- 1** Select **Menu > Utilities > Setup > General setup > Corrective actions**.
-
- 2** Select the condition **QC error(s) present**.
-

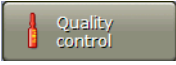
- 3 Choose an option and follow the steps for it.

Option	Steps
To change the traffic light color	1. Make sure the ? on specific parameters check button is deselected. 2. Select the traffic light symbol until it shows the color you want.
To attach a question mark symbol to patient results	Select the ? on specific parameters check button. NOTE This option will also set the traffic light color to yellow.

- 4 Select .

Setting Up Corrective Actions for Overdue Scheduled QC Measurements

Three corrective actions are available to show that scheduled QC measurements are overdue.

- Select the color of traffic light shown on the left side  in the **Analyzer status** screen.
- Attach a message about overdue QC measurements to all results until the measurements are successfully completed.
- Lock the analyzer

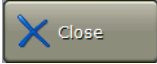
NOTE When the analyzer is locked, no samples can be analyzed until overdue scheduled QC measurements are successfully completed.

- 1 Select **Menu > Utilities > Setup > General setup > Corrective actions**.

- 2 Select the condition **QC schedule reminder(s)**.

- 3 Choose the option you want and follow the steps for it.

Option	Steps
To change the traffic light color	Select the traffic light symbol until it shows the color you want.
To attach a message to subsequent results	Select the Message on next patient result check button.
To lock the analyzer	Select the Lock analyzer when QC overdue check button.

-
- 4 Select .
-

Applying Operator-Defined Corrections to QC Results

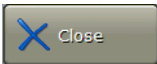
Operator-defined corrections refer to corrections made to the offset and slope for parameters.

-
- 1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**.
-
- 2 Select the **Apply parameter corrections to QC** check button.
-
- 3 Select the **Close** button.
-

Setting Up Corrective Action for Errors in Built-In QC Measurements

This procedure lets you set up the analyzer to do built-in QC measurements again when there are errors in the built-in QC results.

-
- 1 Select **Menu > Utilities > Setup > General setup > Corrective actions**.
-
- 2 Select the condition **Built-in QC error(s) present**.
-
- 3 Select the **Rerun same level once** check button.
-

- 4 Select .
-

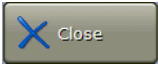
QC Statistics

Setting Up Automatic Print of Built-In QC Statistics

This procedure lets you set up the analyzer to automatically print QC statistics for built-in QC when you start to use a new lot of a QC solution.

-
- 1 Select **Menu > Utilities > Setup > QC setup > QC statistics**.

-
- 2 Select the check button in the **Built-in QC** frame.
-

- 3 Select .
-

Statistical Factor

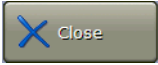
The statistical factor expands the control range to the statistical range, which is the range within which QC results must fall to be included in QC statistics.

NOTE The statistical range = [Control range] × [Statistical factor]. Only QC results that fall within the statistical range are included in QC statistics.

Setting the Statistical Factor

-
- 1 Select **Menu > Utilities > Setup > QC setup > QC statistics**.
-
- 2 If necessary, enter a new value In the **Statistical factor used for value acceptance** field.

NOTE The default value is 1.5.

-
- 3 Select .
-

Westgard Rules

Westgard Rules are a set of control rules that can be applied to QC results to help you do two things:

- Find errors in QC results. The symbol "W" is used to show when QC results have violated applied Westgard Rules.
- Find shifts or trends in QC results. This helps you assess the quality and validity of sample analyses.

Types of Westgard Rule

There are two types of rule.

- Warning rules. Rule 1_{2s} is the only warning rule.
- Rejection rules. Rules 1_{3s} , 2_{2s} , R_{4s} , 4_{1s} and 10_x are rejection rules.

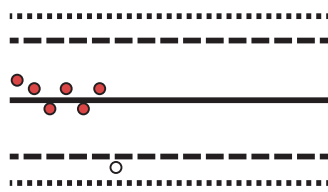
Description of the Lines Used in Westgard Rule Illustrations

Line type	Description
.....	Shows ± 3 SD ranges
---	Shows control ranges (± 2 SD)
—	Shows the mean value

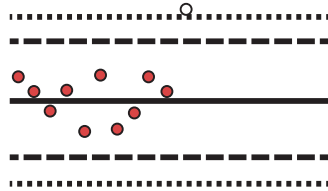
Westgard Rules and Corrective Actions

The 4 Westgard rules (1:3s, 2:2s, R:4s and 4:1s) can be applied to built-in and ampoule-based QC results. Rule 4_{1s} and Rule 10_x can only be applied to ampoule-based QC results.

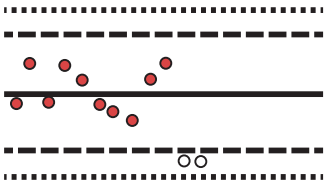
Rule 1:2s (also written 1_{2s}) is a warning rule.

Westgard rule 1_{2s}	Corrective action
The QC result falls outside the mean ± 2 SD range 	Do a new measurement with QC material of the same type, level and lot number. - If the new result does not fall outside the mean ± 2 SD range, the original QC result can be attributed to normal statistical variation. - If the new result falls outside the mean ± 2 SD range, do what is necessary to be in compliance with your local QC regulations.

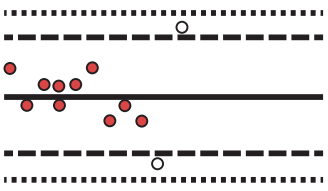
Rule 1:3s (also written 1_{3s}) is a rejection rule.

Westgard rule 1_{3s}	Corrective action
The QC result falls outside the mean ± 3 SD range 	Do a new measurement with QC material of the same type, level and lot number. - If the new result does not fall outside the mean ± 3 SD range, the original QC result can be attributed to normal statistical variation. - If the new result falls outside the mean ± 3 SD range, do what is necessary to be in compliance with your local QC regulations.

Rule 2:2s (also written 2_{2s}) is a rejection rule.

Westgard rule 2_{2s}		Corrective action
Two consecutive QC results fall outside and on the same side of the mean ± 2 SD range		Do what is necessary to be in compliance with your local QC regulations.

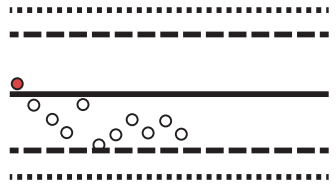
Rule R:4s (also written R_{4s}) is a rejection rule.

Westgard rule R_{4s}		Corrective action
The difference between two consecutive QC results is greater than 4 SD	 This indicates that there is inconsistency in your QC procedures or your analyzer is not stable.	Do what is necessary to be in compliance with your local QC regulations.

Rule 4:1s (also written 4_{1s}) is a rejection rule.

Westgard rule 4_{1s}		Corrective action
Four consecutive QC results are on the same side of the mean ± 1 SD	 This indicates a trend or shift.	Do what is necessary to comply with your local QC regulations. NOTE This rule can only be applied to ampoule-based QC results. Beckman Coulter recommends that this rule is only applied if the parameter control ranges have been changed to analyzer-specific control ranges calculated from a minimum of 20 ampoule-based QC measurements.

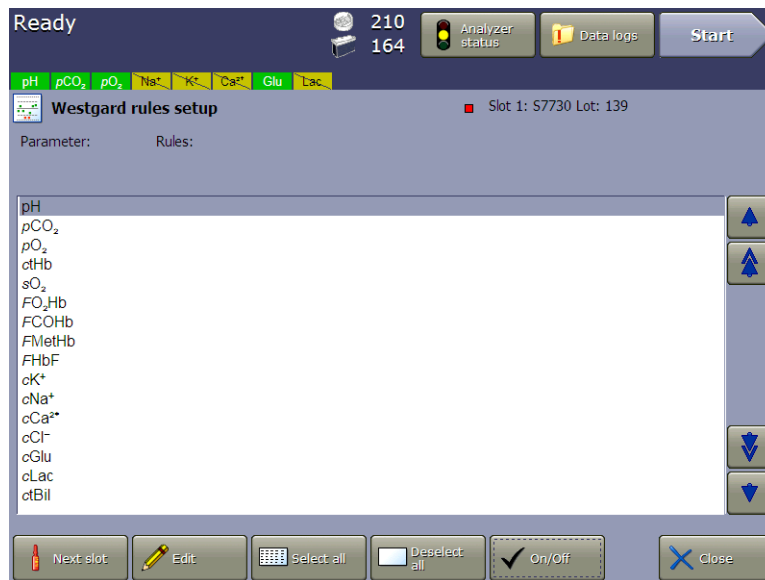
Rule 10:x (also written 10_x) is a rejection rule.

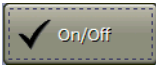
Westgard rule 10 _x	Corrective action
Ten consecutive QC results are on the same side of the mean  This indicates a trend or shift.	Do what is necessary to comply with your local QC regulations. NOTE This rule can only be applied to ampoule-based QC results. Beckman Coulter recommends that this rule is only applied if the parameter control ranges have been changed to analyzer-specific control ranges calculated from a minimum of 20 ampoule-based QC measurements.

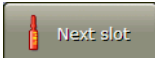
Setting Up and Enabling Westgard Rules

This procedure lets you setup and enable Westgard Rules for selected QC solutions. The rules can be set up for built-in QC solutions and ampoule-based QC solutions.

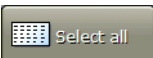
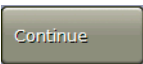
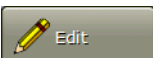
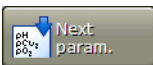
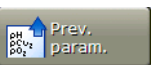
- 1 Select **Menu > Utilities > Setup > QC setup > Westgard Rules**. The Westgard rules setup screen appears.



- 2 Make sure that there is a checkmark on the **On/Off** button . If there is no checkmark, select the button.

- 3 Select  to select the QC solution.

4 Choose an option and follow the steps for it.

Option	Steps
To apply all Westgard rules to QC results for all parameters.	1. Select  . NOTE Rule 4-1S and 10-X cannot be applied to QC solutions in slot A, slot B or slot C. 2. Select  .
To apply some Westgard rules to QC results of some parameters	1. Select a parameter. 2. Select  . 3. Select the check buttons of the rules you want to apply. 4. If necessary, select  or  to select a new parameter and do step c) again.

5 Select > .**Disabling/Enabling Westgard Rules**

Prerequisite — Westgard rules are set up.

This procedure lets you disable/enable the Westgard rules that are set up on all QC solutions.

1 Select **Menu > Utilities > Setup > QC setup > Westgard Rules**.**2** Choose an option and follow the steps for it.

Option	Steps
To disable Westgard rules	Deselect the On/Off check button.
To enable Westgard rules	Select the On/Off check button.

3 Select .

Analyzer-Specific Control Ranges

If your laboratory is required to establish and use analyzer-specific control ranges for the QC solutions used for ampoule-based QC measurements, it can be done.

The analyzer-specific control ranges established in your laboratory must then be used to replace the default **Control range** values given to parameters when QC solutions are registered for use. The default values are the control ranges given on the product insert. These values are shown in the **Insert range** column of the **Quality control ranges setup** screen.

Parameter	Assigned Value	Control range	N	Lot-to-date range (2 SD)	Insert range	Unit
pH	7.093	7.073 7.113	1	7.087 7.087	7.073 7.113	
pCO ₂	68.8	63.8 73.8	0		63.8 73.8	mmHg
pO ₂	151	141 161	0		141 161	mmHg
ctHb	8.1	7.6 8.6	0		7.6 8.6	g/dL
sO ₂	50.0	49.0 51.0	0		49.0 51.0	%
FO ₂ Hb	44.5	43.5 45.5	0		43.5 45.5	%
FCOHb	6.1	4.6 7.6	0		4.6 7.6	%
FMetHb	5.0	4.0 6.0	0		4.0 6.0	%
FHbF	27	12 42	0		12 42	%
cK ⁺	2.3	2.0 2.6	0		2.0 2.6	mmol/L
cNa ⁺	160	156 164	0		156 164	mmol/L
cCa ²⁺	1.03	0.93 1.13	0		0.93 1.13	mmol/L
cCl ⁻	121	115 127	1	128 128	115 127	mmol/L
cGlu	2.3	1.8 2.8	0		1.8 2.8	mmol/L
cLac	4.5	3.9 5.1	1	3.8 3.8	3.9 5.1	mmol/L
ctBil	187	175 199	0		175 199	μmol/L

The control range values given in the insert are not analyzer-specific. They were established as follows: QC measurements were done on a number of MetaFLEX analyzers. Different lots of QC solution were used. Measurements were done by different operators, over several days. Different Solution Packs were also used to take lot-to-lot variations of calibration solutions into account.

How to Establish Analyzer-Specific Control Ranges

Establishment of analyzer-specific control ranges is a 3-stage process:

- Stage 1: Do 20 ampoule-based QC measurements with each level of QC solution.
- Stage 2: Enable the use of **Fixed SD** values to parameters to make sure that the lot-to-date ranges calculated in stage 3 are not made too narrow.
- Stage 3: Use the analyzer to change control ranges to lot-to-date ranges.

Stage 1: To do 20 Ampoule-Based QC Measurements

Prerequisites:

- Beckman Coulter QUALICHECK5+ quality control solutions are registered for use
- The QC ampoules are prepared for use
- Make sure that the analyzer is **Ready**

NOTE This procedure is only necessary if your laboratory requires you to do ampoule-based QC measurements that are based on analyzer-specific control ranges established by your laboratory.

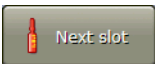
Beckman Coulter recommends that measurements done in this procedure are done by more than one person over a period of 4-5 days. This will take into account sample-to-sample, operator-to-operator and day-to-day variations.

- 1 Do a minimum of 20 ampoule-based QC measurements with each level of QC solution.

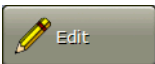
Stage 2: To Enable the Use of Fixed Standard Deviations

You can use this procedure to make sure that the analyzer-specific control ranges calculated in stage 3 of the process are not made too narrow. The **Fixed SD** values enabled for use during this procedure are only used when they are found to be greater than the calculated standard deviations of the measurements made in stage 1 of the process.

- 1 Select **Menu > Utilities > Setup > QC setup > QC ranges**.

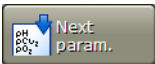
- 2 Select  to find the QC solution you want to edit.

- 3 Select the parameter.

- 4 Select .

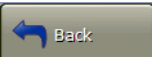
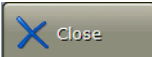
- 5 Select the check button in the **Fixed SD** field.

NOTE The value shown is a Beckman Coulter value.

- 6 Select  or  to select a new parameter.

- 7 Select the check button in the **Fixed SD** field.

8 Do steps 6 and 7 again for each parameter.

9 Select  > .

Stage 3: To Use the Analyzer to Change Control Ranges to Analyzer-Specific Control Ranges

NOTE Beckman Coulter recommends that you do Stage 1 and 2 of the process before you do stage 3.

The analyzer uses all successful QC results to calculate the mean value and standard deviation (SD) values of parameters. The lot-to-date range is calculated as follows:

Lot-to-date range = [Mean value] $\pm$ [2 $\times$ calculated SD value]

The analyzer then updates the **Control range** of parameters. It compares the calculated SD values with the **Fixed SD** values that were enabled for use in stage 2 of the process.

- If a [calculated SD value] > [Fixed SD value], the control range of the parameter is changed to the lot-to-date range
- If a [calculated SD value] < [Fixed SD value], the control range of the parameter is changed to the control range calculated as follows:

Control range = [Mean value] $\pm$ [2 $\times$ Fixed SD value].

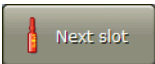
This makes sure that the control ranges are not made too narrow.

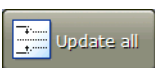
1 Select **Menu > Utilities > Setup > QC setup > QC ranges**. The QC Ranges screen appears.



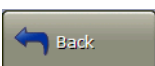
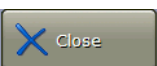
Parameter	Assigned Value	Control range	N	Lot-to-date range (2 SD)	Insert range	Unit
pH	7.070	7.050 7.090	1	7.056 7.056	7.050 7.090	
pCO ₂	71.0	66.0 76.0	1	69.0 69.0	66.0 76.0	mmHg
pO ₂	152	142 162	1	148 148	142 162	mmHg
ctHb	8.0	7.5 8.5	0		7.5 8.5	g/dL
sO ₂	50.0	49.0 51.0	0		49.0 51.0	%
FO ₂ Hb	44.5	43.5 45.5	0		43.5 45.5	%
FCO ₂ Hb	5.9	4.4 7.4	0		4.4 7.4	%
FMetHb	5.0	4.0 6.0	0		4.0 6.0	%
FMetF	24	9 39	0		9 39	%
cK ⁺	1.8	1.5 2.1	0		1.5 2.1	mmol/L
cNa ⁺	162	158 166	0		158 166	mmol/L
cCa ²⁺	1.00	0.90 1.10	1	1.04 1.04	0.90 1.10	mmol/L
cCl ⁻	124	118 130	0		118 130	mmol/L
cGlu	0.27	0.18 0.36	1	0.27 0.27	0.18 0.36	g/L
cLac	0.38	0.32 0.43	0		0.32 0.43	g/L
ctBil	186	174 198	0		174 198	μmol/L

NOTE The number of successful QC measurements are shown in the **N** column.

2 Select  to find the QC solution you want to edit.

3 Select .

NOTE The control ranges of all parameters are now analyzer-specific.

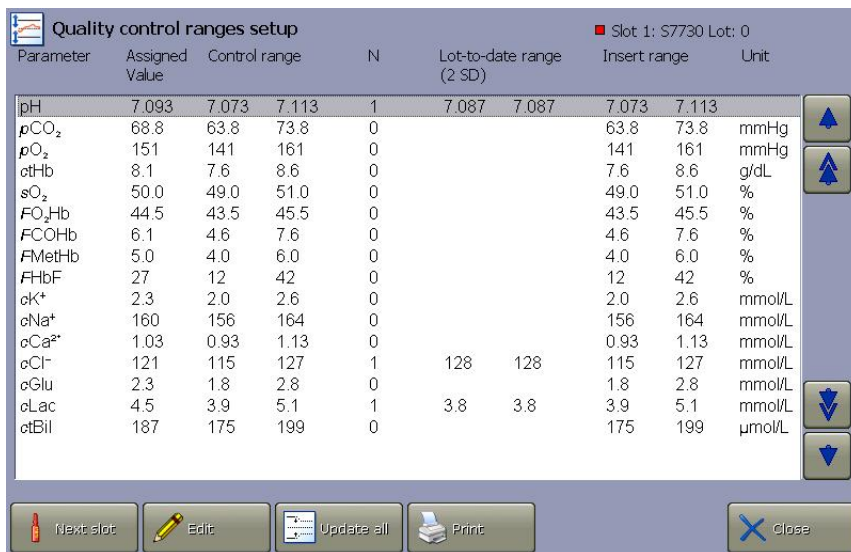
4 Select  > .

Manually Changing Control Ranges to Analyzer-Specific Control Ranges

Prerequisite — Established analyzer-specific control ranges.

NOTE This procedure is only necessary if your laboratory requires you to do ampoule-based QC measurements that are based on analyzer-specific control ranges established by your laboratory. The procedure lets to change the control ranges manually.

1 Select **Menu > Utilities > Setup > QC setup > QC ranges**. The Quality control ranges set up screen appears.

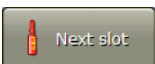


Quality control ranges setup

Slot 1: S7730 Lot: 0

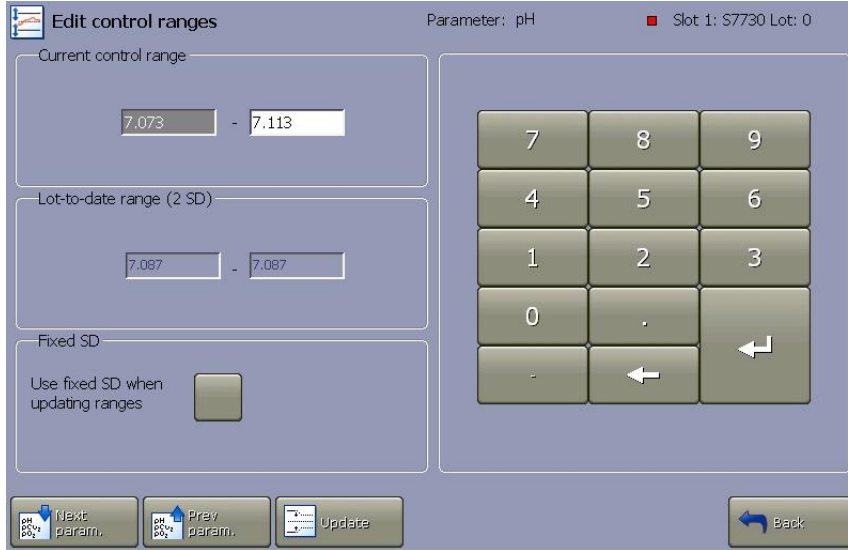
Parameter	Assigned Value	Control range	N	Lot-to-date range (2 SD)	Insert range	Unit
pH	7.093	7.073 7.113	1	7.087 7.087	7.073 7.113	
pCO ₂	68.8	63.8 73.8	0		63.8 73.8	mmHg
pO ₂	151	141 161	0		141 161	mmHg
ctHb	8.1	7.6 8.6	0		7.6 8.6	g/dL
sO ₂	50.0	49.0 51.0	0		49.0 51.0	%
FO ₂ Hb	44.5	43.5 45.5	0		43.5 45.5	%
FCOHb	6.1	4.6 7.6	0		4.6 7.6	%
FMetHb	5.0	4.0 6.0	0		4.0 6.0	%
FHbF	27	12 42	0		12 42	%
cK ⁺	2.3	2.0 2.6	0		2.0 2.6	mmol/L
cNa ⁺	160	156 164	0		156 164	mmol/L
cCa ²⁺	1.03	0.93 1.13	0		0.93 1.13	mmol/L
cCl ⁻	121	115 127	1	128 128	115 127	mmol/L
cGlu	2.3	1.8 2.8	0		1.8 2.8	mmol/L
cLac	4.5	3.9 5.1	1	3.8 3.8	3.9 5.1	mmol/L
ctBil	187	175 199	0		175 199	μmol/L

Buttons: Next slot, Edit, Update all, Print, Close

2 Select  to find the specific lot and level of QC solution you want to edit.

3 Select a parameter.

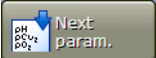
- 4 Select . The Edit control ranges screen appears.



The screenshot shows the 'Edit control ranges' screen for the parameter 'pH'. The screen has a title bar with a small icon, the text 'Edit control ranges', and status information 'Parameter: pH' and 'Slot 1: S7730 Lot: 0'. The main area is divided into three sections on the left and a numeric keypad on the right. The first section, 'Current control range', has input fields showing '7.073' and '7.113'. The second section, 'Lot-to-date range (2 SD)', has input fields showing '7.087' and '7.087'. The third section, 'Fixed SD', has a checkbox labeled 'Use fixed SD when updating ranges' which is currently unchecked. The numeric keypad on the right contains digits 0-9, a decimal point, and left and right arrow keys. At the bottom, there are four buttons: 'Next param.' (with a dropdown arrow), 'Prev param.' (with a dropdown arrow), 'Update' (with a document icon), and 'Back' (with a left arrow icon).

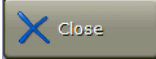
- 5 Enter the values of the analyzer-specific control range in the **Current control range** frame.

- 6 To change the control range of the other parameters, do as follows for each parameter:

- Select .
- Do step 5 again.

- 7 Select the **Back** button.

NOTE The entered values are shown in the **Control range** column of the **Quality control ranges setup** screen.

- 8 Select .

Overview

This chapter contains information on:

- [General Warnings and Cautions](#)
- [Anticoagulants](#)
- [Pre-Registration of Samples](#)
- [Analyzing Samples](#)
- [Entering and Editing Data in the Patient Identification Screen](#)
- [Critical Limit Notification](#)

General Warnings and Cautions

WARNING

Risk of infection. Dispose and handle all used sampling devices, quality control (QC) ampoules, Solution Packs, Sensor Cassettes, Inlet Probes, Inlet Gasket Holders, Inlet Connector Gaskets and Inlet Modules as biohazardous waste.¹ Follow your local regulations.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

WARNING

Risk of infection. Make sure you do not prick or scratch yourself on the Inlet Probe.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Anticoagulants

Most blood sampling devices contain dry, electrolyte-balance heparin. In general, this type of heparin gives good results, because it minimizes the bias on cNa^+ , cK^+ , cCa^{2+} results.

Different types of anticoagulant may change the concentration of some parameters and give false sample results.

Anticoagulant	Possible effect on sample results
Heparin in liquid form	Biased results on all parameters
Anticoagulants with sodium cations (Na^+)	Falsely high cNa^+ results
Anticoagulants with sodium and potassium cations (Na^+ and K^+)	False cNa^+ and cK^+ results
Anticoagulants with Lithium/Zinc heparin	False cCa^{2+} results
Anticoagulants with ammonium heparin	False cCl^- results
Disodium oxalate with sodium fluoride	Falsely high cNa^+ , falsely low cCa^{2+} and false cGlu and cLac results
Trisodium citrate	False cNa^+ , cK^+ , cCa^{2+} , pH, cGlu and cLac results
EDTA	- False pH, pCO_2, cNa^+, cK^+ and cCa^{2+} results - False cCa^{2+} results in subsequent samples

 CAUTION

Risk of erroneous results. Do not use EDTA as an anticoagulant when working with blood samples, as it will cause incorrect pH, pCO_2 , cNa^+ , cK^+ and cCa^{2+} results and have an effect on subsequent cCa^{2+} measurements.

 CAUTION

Risk of instrument damage. Do not use EDTA as anticoagulant as it will decrease the lifetime of the calcium sensor.

 CAUTION

Risk of erroneous results. Low pO_2 levels can have an effect on the linearity of glucose measurements. This can lead to incorrect low glucose results. Note that cGlu linearity is not specified when the pO_2 level is less than 10 mmHg (1.3 kPa).

Pre-Registration of Samples

Sample pre-registration allows operators ensure that the sample data shown on the screen belongs to the sample to be analyzed. This reduces the risk of sample mix-up.

NOTE The analyzer must be set up for sample pre-registration.

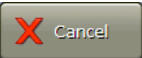
Pre-Registering a Sample

Prerequisites:

- The analyzer is set up for sample pre-registration
- A barcode that identifies the sample

1 Scan the barcode.

2 Make sure the data that is shown on the screen belongs to the sample you want to analyze.

Option	Steps
If the data is correct	Analyze the sample.
If the data is not correct	Select  .

Analyzing Samples

General Information for Obtaining Successful Sample Analyses

The analyzer will guide you through the different steps of the sample analysis process. Depending on the setup, the process will vary. Always follow the on-screen instructions.

Depending on the setup:

- You may be able to select measurement mode during sample analysis. If so, you must select a measurement mode, or the analyzer will automatically select the measurement mode set up as default in the setup.
- In the **Identification** screen, it is mandatory to enter data in fields with this icon: .
The sample will be analyzed, but the results will not be available until data is entered.
- In the **Identification** screen, it is possible to change the report layout during sample analysis.

During sample analysis, make sure that the Inlet Probe does not touch the plunger of or the fiber disk in the syringe as this may cause the sample to be aspirated incorrectly.

To ensure the Inlet Probe does not bend, hold the sampling device still during sample analysis. If the Inlet Probe is bent, do not use the analyzer for sample analysis. Refer to [Replacing the Inlet Probe](#) in [CHAPTER 12, Replacement/Adjustment Procedures](#).

Analyzing a Sample from a Syringe

Prerequisites:

- A good sample (no air bubbles, no exposure to air, and no clots)
- Verify that the analyzer displays **Ready** in the top left corner of the screen.

NOTE Once the inlet is opened, you only have a short time to complete the actions necessary.

- 1 If measurement mode can be selected, select measurement mode. Refer to [Selecting a Default Measurement Mode](#) in [CHAPTER 8, Setup](#).

NOTE If you selected the wrong mode, select **Reselect** and select the correct mode.

NOTE If the **Other modes** button is available, select it to get access to more modes.



- 2 Gently mix the sample to make sure that it is homogeneous.

- 3 Hold the syringe by its barrel.

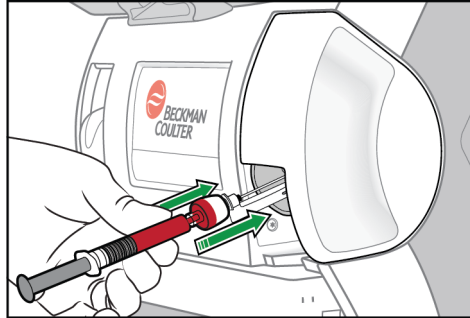
- 4 Select  .

The analyzer opens the inlet.

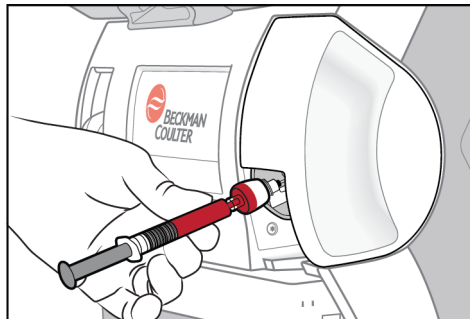
- 5 Follow the instructions on the screen.

6 Place and hold the tip of the syringe in the center of the Inlet Gasket.

7 Push the syringe into the analyzer as far as it will go and hold it there.



8 Hold the syringe in the pushed-in position until the analyzer tells you to remove it.



9 When the analyzer tells you to, remove the syringe.
The analyzer closes the inlet.

10 If necessary, select a different report layout as follows:

- a. Select the current **Report layout** shown on the screen.
- b. Select a new layout from the list.

c. Select .

11 Enter the necessary data in the **Patient Identification** screen.

NOTE It is mandatory to enter data in fields with this icon: 

- 12 If the Patient **Result** screen opens before you have entered the necessary data, select



Analyzing a Sample from a Capillary Tube

Prerequisites:

- A good sample (no air bubbles, no exposure to air, and no clots)
- Verify that the analyzer displays **Ready** in the top left corner of the screen.

NOTE Once the inlet is opened, you only have a short time to complete the actions necessary.

Use this procedure to analyze low volume blood samples.

- 1 If measurement mode can be selected, select measurement mode. Refer to [Selecting a Default Measurement Mode](#) in [CHAPTER 8, Setup](#).

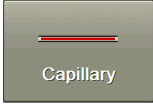
NOTE If you selected the wrong mode, select **Reselect** and select the correct mode.

NOTE If the **Other modes** button is available, select it to get access to more modes.



- 2 Gently mix the sample to make sure that it is homogeneous.
- 3 Move the mixing wire to the end opposite to that from which the sample is to be aspirated.

-
- 4 Remove the end caps of the capillary tube.
-

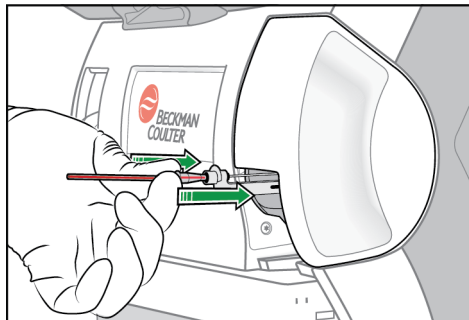
- 5 Hold the capillary tube and select  .
The analyzer opens the inlet.
-

- 6 Follow the on-screen instructions.
-

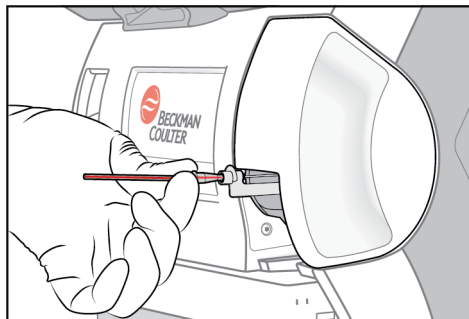
- 7 Place and hold the end with the Clot Catcher in the center of the Inlet Gasket.

NOTE If you turn the capillary tube slightly when you place it in the center, it may be easier to put it in the right place.

- 8 Carefully push the capillary tube into the analyzer as far as it will go and hold it there.



- 9 Hold the capillary tube in the pushed-in position until the analyzer tells you to remove it.



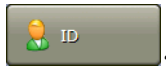
- 10 When the analyzer prompts you, remove the capillary tube.
The analyzer closes the inlet.

-
- 11** If necessary, select a different report layout as follows:
- Select the current **Report layout** shown on the screen.
 - Select a new layout from the list.
 - Select .

-
- 12** Enter the necessary data in the **Identification** screen.

NOTE It is mandatory to enter data in fields with this icon: 

-
- 13** If the **Patient Result** screen opens before you have entered the necessary data, select



Analyzing a Sample from a Test Tube or Vi-CELL Sample Cup

Prerequisites:

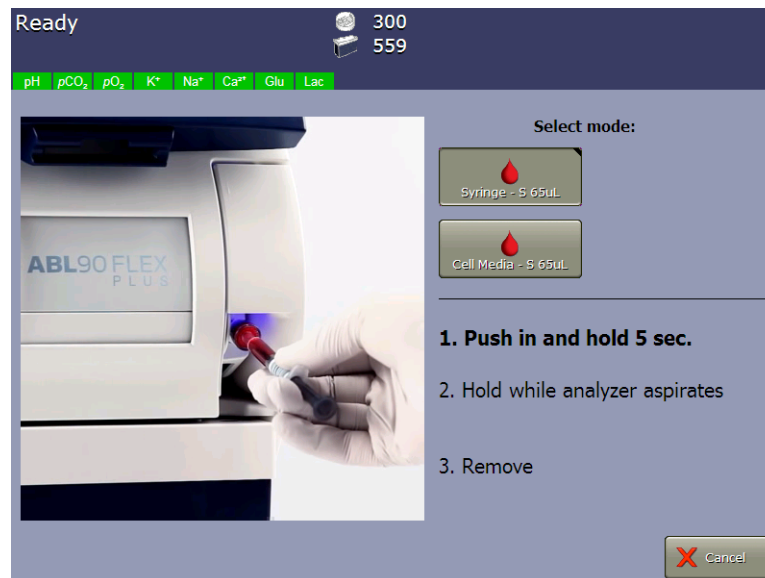
- A good sample (no air bubbles, no exposure to air, and no clots)
- Verify that the analyzer displays **Ready** in the top left corner of the screen.

NOTE Once the inlet is opened, you only have a short time to complete the actions necessary.

- 1 If measurement mode can be selected, select measurement mode. Refer to [Selecting a Default Measurement Mode](#) in [CHAPTER 8, Setup](#).

NOTE If you selected the wrong mode, select **Reselect** and select the correct mode.

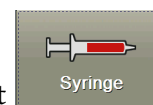
NOTE If the **Other modes** button is available, select it to get access to more modes.



- 2 Gently mix the sample to make sure that it is homogeneous.

- 3 If you are using a test tube, uncap the test tube.

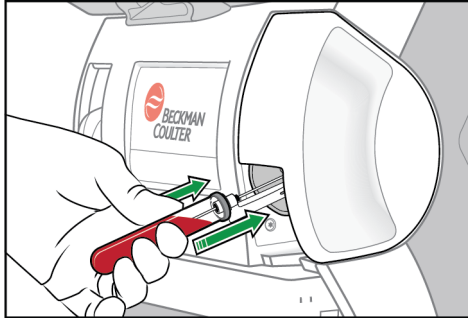
- 4 Hold the test tube or Vi-CELL sample cup and select
The analyzer opens the inlet.



- 5 Follow the on-screen instructions.

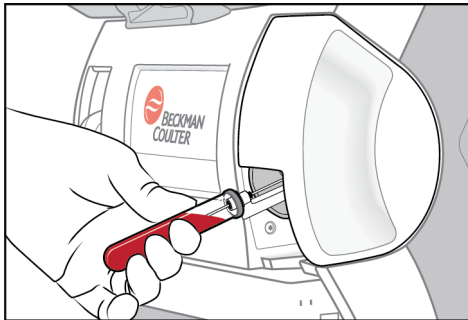
- 6 Place and hold the lip of the test tube or Vi-CELL sample cup against the collar of the Inlet Gasket.

-
- 7 Push the test tube into the analyzer as far as it will go and hold it there.



NOTE Make sure that the probe extends into the sample and stays there during sample aspiration.

-
- 8 Hold the test tube or Vi-CELL sample cup in the pushed-in position until the analyzer tells you to remove it.



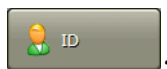
-
- 9 When the analyzer tells you to, remove the test tube.
The analyzer closes the inlet.

-
- 10 If necessary, select a different report layout as follows:
- a. Select the current **Report layout** shown on the screen.
 - b. Select a new layout from the list.
 - c. Select .

-
- 11 Enter the necessary data in the Identification screen.

NOTE It is mandatory to enter data in fields with this icon: 

- 12 If the **Patient Result** screen opens before you have entered the necessary data, select



Entering and Editing Data in the Patient Identification Screen

Patient Identification Screen

The content of the Patient Identification screen shown below shows the items included in the **-R- Default** report layout. Other layouts can be created.

Changing the Report Layout in the Patient Identification Screen

When you change the report layout, data fields in the Patient Identification screen can change.

- 1 Select the current **Report layout**.

- 2 Select a new layout.

- 3 Select .

Requesting Data Automatically when Connected to a LIS/HIS System

Prerequisites:

- The analyzer is connected to a LIS/HIS/data management system. Refer to [Setting up an LIS/HIS Connection](#) in [CHAPTER 8, Setup](#).
- The analyzer is set up to enable automatic requests for sample data. Refer to [Setting Up Automatic Requests for Data](#) in [CHAPTER 8, Setup](#).

- 1 In the Patient Identification screen, enter data in the field that was set up to enable data to be requested automatically.

NOTE It will be one of these fields: **Accession number** or **Patient ID** or **Sampler ID**.

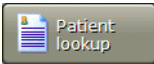
NOTE If no data is transmitted, select the **Request** button.

Request Data Using Patient Lookup

Prerequisites:

- The report includes the **Department (Pat.)** field.
- The analyzer is set up to enable lookup. Refer to [Enabling Manual Data Requests Using Patient Lookup](#) in [CHAPTER 8, Setup](#).

- 1 In the Patient Identification screen, enter data in the **Department (Pat.)** field.

- 2 Select .

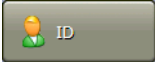
- 3 Select the sample from the list.

- 4 Select .

Based on the Patient ID of the sample you selected, data is requested and downloaded to the **Patient Identification** screen.

Editing Data in the Patient Identification Screen

- 1 Find the result.

2 Select .

3 Edit the necessary data.

Critical Limit Notification

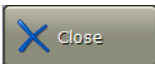
When **Critical limit notification** is enabled, a notification procedure is necessary before results with values outside the critical limit can be transmitted to external systems and printed automatically. The results are pending until a notification procedure is done. The results can be seen in **Pending results log**.

Enabling Critical Limit Notifications

1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**.

2 Select **Enable critical limit notification**.

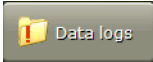
3 Select the check button.

4 Select .

NOTE If a print of the result is needed, you can make a print from the **Notification** screen. The printout will tell you that the notification is pending.

Using Critical Limit Notifications

- 1 Choose an option and follow the steps.

Option	Steps
If a pop-up window notifies you that the result has values that lie outside critical limits.	1. Go to step 2.
If an exclamation mark is shown on the Data logs button. 	1. Select Data logs > Pending results log. 2. Highlight a result. 3. Select . NOTE A pop-up window notifies you that the result has values that lie outside critical limits.

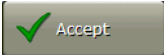
- 2 Select inside the message to close the pop-up window.

- 3 Select **Notification**.

- 4 See the values that are outside critical limits.

NOTE If it is not necessary to notify about the values, select **Not needed** and go to step 6.

- 5 Fill in the data fields on the screen.

- 6 Select .

Pending Results Log

To access the Pending results log, select **Data logs > Pending results log**. The Pending results log screen appears.



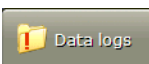
Time	Sample #	Sample type	Status	Patient ID	Last name
8/11/2016 02:26 PM	34	Not specified	?		its so much easier
8/3/2016 01:10 PM	33	Not specified	?	test	
8/3/2016 12:12 PM	32	Not specified	?	testing er...	
8/3/2016 12:01 PM	31	Not specified	?	PC12 day 5	plated 7/18
8/3/2016 12:00 PM	30	Not specified	?	PC12 day 5	plated 7/18
8/3/2016 11:58 AM	29	Not specified	?	PC12 day 4	plated 7/18
8/3/2016 11:57 AM	28	Not specified	?	PC12 day 4	plated 7/18
8/3/2016 11:54 AM	27	Not specified	?	PC12 day 3	plated 7/18
8/3/2016 11:53 AM	26	Not specified	?	PC12 day 3	plated 7/18
8/3/2016 11:52 AM	25	Not specified	?	PC12 day 3	plated 7/18
8/3/2016 11:50 AM	24	Not specified	?	PC12 day 2	plate 7/18
8/3/2016 11:49 AM	23	Not specified	?	PC12 day 2	plate 7/18
8/3/2016 11:47 AM	22	Not specified	?	PC12 day 1	plated 7/18
8/3/2016 11:45 AM	21	Not specified	?	PC12 day 1	plated 7/18
8/3/2016 11:44 AM	20	Not specified	?	SF9 day 12	plated 7/18
8/3/2016 11:42 AM	19	Not specified	?	SF9 day 12	plated 7/18

The **Pending results log** contains the following results:

- Results that someone needs to be notified about
- Results that need to be approved
- Results that need mandatory input

Results in the **Pending results log** are filtered from the **Patient Results log** and remain pending until they have been dealt with. If results are pending, an exclamation mark is shown on the **Data logs**

button.



Input Fields for the Patient Report Layout

The following notification-related input fields can be added to the sample report layout:

- Notified whom
- Notified time
- Notified by
- Notification status
- Notification

NOTE To include these items in a sample report layout, refer to [Reviewing and Editing Results](#) in [CHAPTER 6, Data Review](#).

Overview

This chapter discusses how to analyze the data.

This chapter contains information on:

- [Data logs](#)
- [Patient Results](#)
- [Reviewing and Editing Results](#)

Data logs

Data logs are where sample data and results of measurements and activities are saved.

Overview of Data Logs

Data logs	Content
Patient Results log	• Results of sample analyses • Results of calibration verification measurements
Patient Profiles log	Data that helps to identify samples that have been analyzed
Calibration log	Results of calibrations
Quality control log	Results of QC measurements
Activity log	Activities done on or by the analyzer
Replacement log	Record of replacement activities
Archived data logs	The oldest results/activities from the data logs. NOTE Automatic archiving must be set up.

Accessing Data Logs

- 1 Select **Menu > Data logs**.
- 2 Select the data log you want.

Patient Results

Finding a Result

Choose an option and follow the on-screen instructions.

Option	Steps
To find a result in the data log	1. Select Menu > Data logs > Patient Results log. 2. Select the measurement. 3. Select .
To find a number of results in the data log	Filter the data from the Patient Results log.
To find the latest result	Select Menu > Latest result.
To find a result under My results	1. Select Menu > My results. 2. Select the measurement. 3. Select .

Symbols on Patient Results

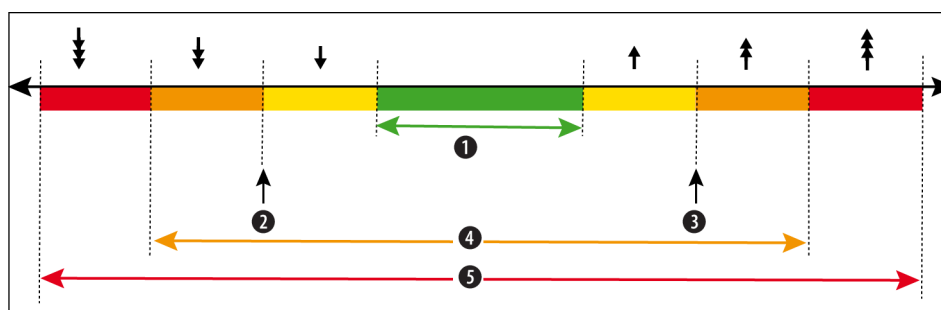
Problems on sample results are marked with one or more of the symbols shown in the table below.

Symbol	Description
	An error occurred. A message attached to the result describes the error.
	Result is above the reference range but below the upper critical limit
	Result is below the reference range but above the lower critical limit
	Result is above the upper critical limit but below the upper limit of the reportable range
	Result is below the lower critical limit but above the lower limit of the reportable range
	No result is shown because it is above the upper limit of the reportable range. NOTE The analyzer can be set up to show the result as greater than the value of the upper limit of the reportable range. For example: All pH results above 7.850 (the upper limit of a pH reportable range) will be shown as >7.850.
	No result is shown because it is below the lower limit of the reportable range. NOTE The analyzer can be set up to show the result as less than the value of the lower limit of the reportable range. For example, all pH results below 6.750 (the lower limit of the pH reportable range) will be shown as <6.750.

Symbol	Description
.....	No result could be calculated
(blank)	No result is shown because it is outside the range of indication of the analyzer.
*	User-defined correction factors were used to calculate the result
c	A subscript of the letter c shows that the value was calculated from measured and/or keyed-in (input) values. Only shown on derived parameters.
e	A subscript of the letter e shows that the value was estimated. Default values were used to replace measured and/or keyed-in (input) values that were not available. Only shown on derived parameters.

Ranges and Critical Limits

Measurement results are marked by symbols to show where they fall in relation to reference ranges, critical limits and reportable ranges. The diagram illustrates these relationships.



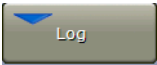
1. Reference range
2. Lower critical limit
3. Upper critical limit
4. Reportable range
5. Range of indication

Status in the Sample Results Log

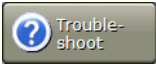
The **Status** column in the **Results log** screen shows the overall status of each sample analysis.

Symbol	Description
OK	The sample analysis was successful
?	An error was found on one or more parameter result.
Aborted	The sample analysis was stopped by the analyzer because it found an error

Viewing Results Messages

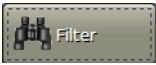
- 1 Select **Menu > Data logs > Patient Results log**.
- 2 Select the measurement.
- 3 Select  .
- 4 Select  or select  >  .

Troubleshooting Results Messages

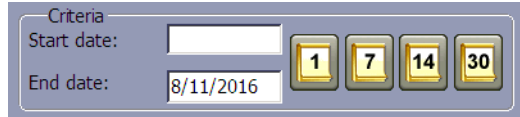
- 1 Select the message.
- 2 Select  .
- 3 Follow the instructions on the screen.

Reviewing and Editing Results

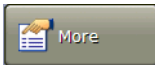
Filtering Data from the Patient Results Log

- 1 Select **Menu > Data logs > Patient Results log**.
- 2 Select  .

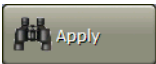
- 3 In the **Criteria** frame, choose an option and follow the steps for it.

Option	Steps
To select a time period prior to today's date	Select the number button for the number of days you want. 
To select a start and end date	Enter data in the Start date: and End date: fields

- 4 Select the next criterion. If necessary, enter or select a value for it.

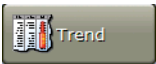
- 5 If more criteria are necessary, select .

- 6 If necessary, do step 4 again.

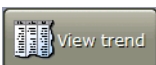
- 7 Select .

Viewing Trends in Sample Results

Prerequisite — You have filtered the sample results from the **Results log**. Refer to [Filtering Data from the Patient Results Log](#).

- 1 Select .

- 2 Select the parameters.

- 3 Select .

Viewing the Audit Trail on a Result

Prerequisite — Changes were made to the result.

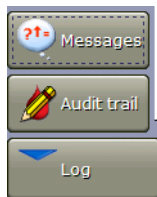
NOTE An audit trail shows the changes made to a result.

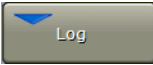
1 Select **Menu > Data logs > Patient Results log**.

2 Select the measurement.

3 Select  **Result** .

4 Select **Log > Audit trail**.



NOTE  **Log** will only be available if changes were made to the sample result.

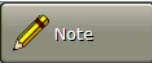
Adding a Note to a Sample Result

1 Select **Menu > Data logs > Patient Results log**.

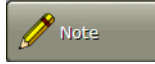
2 Select the measurement.

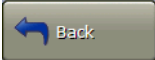
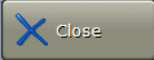
3 Select  **Result** .

4 Select  **Messages** .

5 Select  **Note** .

- 6 Choose an option and follow the steps for it.

Option	Steps
If a pop-up window is shown	To use one of the listed notes: - Select the note - Select the Enter button To enter a new note: - Select  . - Enter the note.
If no pop-up window is shown	Enter a note.

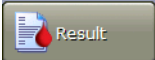
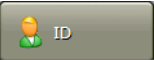
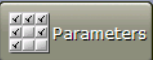
- 7 Select  >  .

Removing a Parameter from a Result

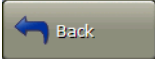
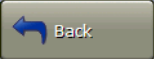
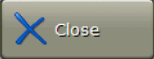
Prerequisite — The result is not approved or rejected.

- 1 Select **Menu > Data logs > Patient Results log**.

- 2 Select the measurement.

- 3 Select  >  >  .

- 4 Deselect the check buttons for the parameter you want to remove.

- 5 Select  >  >  .

NOTE The result of the parameter is removed from the **Patient Results** screen and from printed results.

Viewing a Parameter in a Sample Result

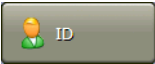
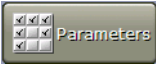
Prerequisites:

- The parameter was removed from the sample result.
- The sample result is not approved or rejected.

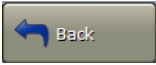
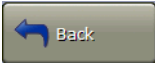
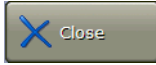
This procedure allows you to see the parameter on the screen and in printed results.

1 Select **Menu > Data logs > Results log**.

2 Select the measurement.

3 Select  **Result** >  **ID** >  **Parameters**.

4 Select the check button for the parameter you want to see.

5 Select  **Back** >  **Back** >  **Close**.

Approval and Rejection of Results

Approval/rejection of results is not set up by default. If it is set up, it can be used to filter results that are transmitted to a LIS/HIS system. Approved results are transmitted, rejected results are not.

NOTE An approved result does not guarantee accuracy of the result.

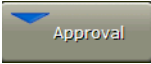
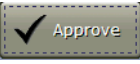
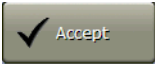
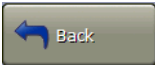
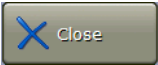
Approval can, for example, be used to make sure that necessary data was correctly entered, for example, that the **Sample type** was "Venous", not "Arterial" and the sample temperature was 42 °C, not 38 °C.

NOTE Approved/rejected results cannot be edited.

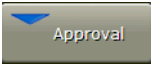
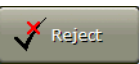
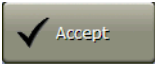
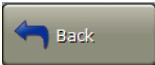
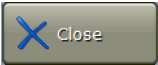
Approving a Sample Result

1 Select **Menu > Data logs > Patient Results log**.

2 Select the measurement.

- 3 Select  .
- 4 Select  >  .
- 5 Select  .
- 6 Select  >  .

Rejecting a Sample Result

- 1 Select **Menu > Data logs > Patient Results log**.
- 2 Select the measurement.
- 3 Select  .
- 4 Select  >  .
- 5 Select  .
- 6 Select  >  .

Overview

This chapter provides procedures for shutting down the Vi-CELL MetaFLEX instrument.

This chapter contains information on:

- [Shutdown](#)
- [Temporary Shutdown of the Analyzer](#)
- [Long-Term Shutdown of the Analyzer](#)
- [Storing the Analyzer](#)
- [Moving the Analyzer](#)
- [Restarting the Analyzer](#)

Shutdown

Shutdown is a safe procedure for you to close down the analyzer. There are 2 procedures a **Temporary shutdown** and a **Long term shutdown**.

NOTE Do not use the power switch to shut down the analyzer.

Temporary Shutdown of the Analyzer

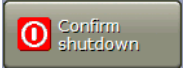
When to do a temporary shutdown

Usually, the analyzer is kept switched on so that it is ready to use at any time. However, in some situations, it is necessary to do a temporary shutdown:

- When an analyzer without a battery must be moved to a new location
- When an analyzer with a low-charge level battery must be moved to a new location
- When the analyzer tells you to do a shutdown (for example, during a troubleshooting procedure)
- After a non-USB keyboard or mouse is connected to an analyzer that is switched on.

NOTE If the analyzer is shut down for more than 2 hours, the Sensor Cassette must be replaced.

Performing a Temporary Shutdown

- 1 Select **Menu > Utilities > Temporary shutdown**.
- 2 Select .
- 3 Wait until the Windows program prompts that it is shutting down.
- 4 When the Windows program has shut down, push the analyzer power switch to the Off position (O).

Long-Term Shutdown of the Analyzer

It is usually only necessary to do a long-term shutdown when the analyzer is stored.

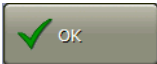
Performing a Long-Term Shutdown

Prerequisites:

- The Inlet Module has been cleaned. Refer to [Cleaning the Inlet Gasket](#) in [CHAPTER 11, Cleaning Procedures](#).
- A syringe filled with Sodium Hypochlorite Solution.
- A syringe filled with distilled water.

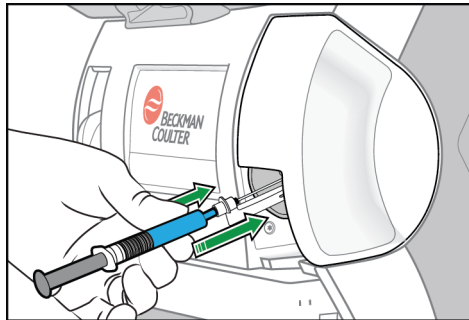
NOTE Approximately 15 minutes are necessary for this procedure.

NOTE The Sensor Cassette used during this procedure must not be used again.

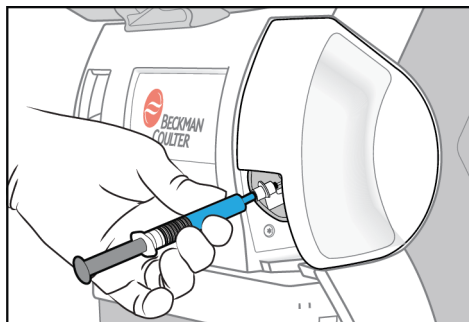
- 1 Select **Menu > Utilities > Long term shutdown**.
- 2 Select .
The analyzer opens the inlet.
- 3 Hold the syringe with the Sodium Hypochlorite Solution by its barrel.

- 4 Follow the instructions on the screen.
- 5 Place and hold the tip of the syringe in the center of the inlet gasket.
- 6 Push the syringe into the analyzer as far as it will go and hold it there.

NOTE Be careful not to bend the Inlet Probe.



- 7 Hold the syringe in the pushed-in position until the analyzer tells you that the aspiration is completed.



- 8 When the analyzer prompts you that the aspiration is completed, remove the syringe. The analyzer closes the inlet.
- 9 Hold the syringe with distilled water by its barrel.
- 10 When the analyzer prompts you, do steps 5 - 8 again.
- 11 Wait until the Sensor Cassette compartment opens.

! WARNING

Risk of biohazardous contamination if you have skin contact with the Sensor Cassette. The Sensor Cassette could contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the Sensor Cassette in accordance with your local regulations and acceptable laboratory procedures.

- 12 Remove the Sensor Cassette and dispose of it as biohazardous waste.



- 13 Select the **Confirm removal** button.

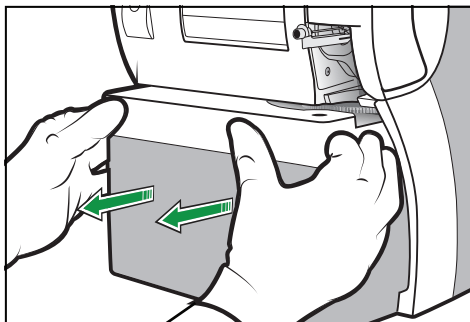
The inlet opens.

- 14 Wait until the Solution Pack is ejected.

! WARNING

Risk of biohazardous contamination if you have skin contact with the Solution Pack and its contents. The Solution Pack could contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the Solution Pack in accordance with your local regulations and acceptable laboratory procedures.

- 15 Remove the Solution Pack and dispose of it as biohazardous waste.



The analyzer closes the inlet.

-
- 16 Wait until the Windows program tells you that it is shutting down.
 - 17 When the Windows program has shut down, push the analyzer power switch to the Off position (O).
-

Storing the Analyzer

- 1 Perform a long-term shutdown. Refer to [Long-Term Shutdown of the Analyzer](#).
 - 2 Put a dust cover on the analyzer.
 - 3 Store the analyzer between -20 °C and 60 °C.
-

Moving the Analyzer

Moving an Analyzer with a Charged Battery

IMPORTANT The charge level of the battery must be high enough to be able to move the analyzer and connect it to the mains power supply before the charge level drops below 11%.

-
- 1 Disconnect the power cable and peripheral devices.
 - 2 Lift the analyzer by its handle, keep it vertical and move it to its new location.
 - 3 Connect the power cable and peripheral devices to the analyzer.
 - 4 Connect the analyzer to the mains power supply before the analyzer battery charge-level falls below 10%.
-

Moving an Analyzer Without a Battery

- 1 Perform a temporary shutdown. Refer to [Temporary Shutdown of the Analyzer](#).
- 2 Disconnect the power cable and peripheral devices.
- 3 Lift the analyzer by its handle, keep it vertical and move it to its new location.
- 4 Connect the power cable and peripheral devices.
- 5 Switch on the mains power supply.
- 6 Push the power switch to the On position (I).
- 7 If the analyzer does not restart, press the standby button on the back of the analyzer. Refer to [Figure 1.2](#)

Restarting the Analyzer

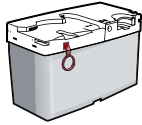
Restart the Analyzer after a Temporary Shutdown

- 1 Push the power switch to the On position (I).
- 2 If the analyzer does not restart, press the standby button on the back of the analyzer. Refer to [Figure 1.2](#)

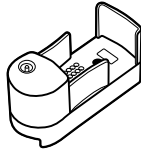
NOTE The analyzer is ready for use it displays **Ready** in the top left corner of the screen.

Restarting the Analyzer After a Long-Term Shutdown

Prerequisites:



A Solution Pack



A Sensor Cassette

- 1 Use the power cable to connect the analyzer to the mains power supply.
- 2 Push the power switch to the On position (I) and wait until the **Operator-intervention required** screen is shown.
- 3 If the analyzer does not restart, press the standby button on the back of the analyzer. Refer to [Figure 1.2](#)
- 4 Install a Solution Pack. Refer to [Replacing the Solution Pack](#) in [CHAPTER 12, Replacement/Adjustment Procedures](#).
- 5 Install a Sensor Cassette. Refer to [Replacing the Sensor Cassette](#) in [CHAPTER 12, Replacement/Adjustment Procedures](#).
- 6 Select **Intervention**.
The analyzer is ready for use when it displays **Ready** in the top left corner of the screen.

Overview

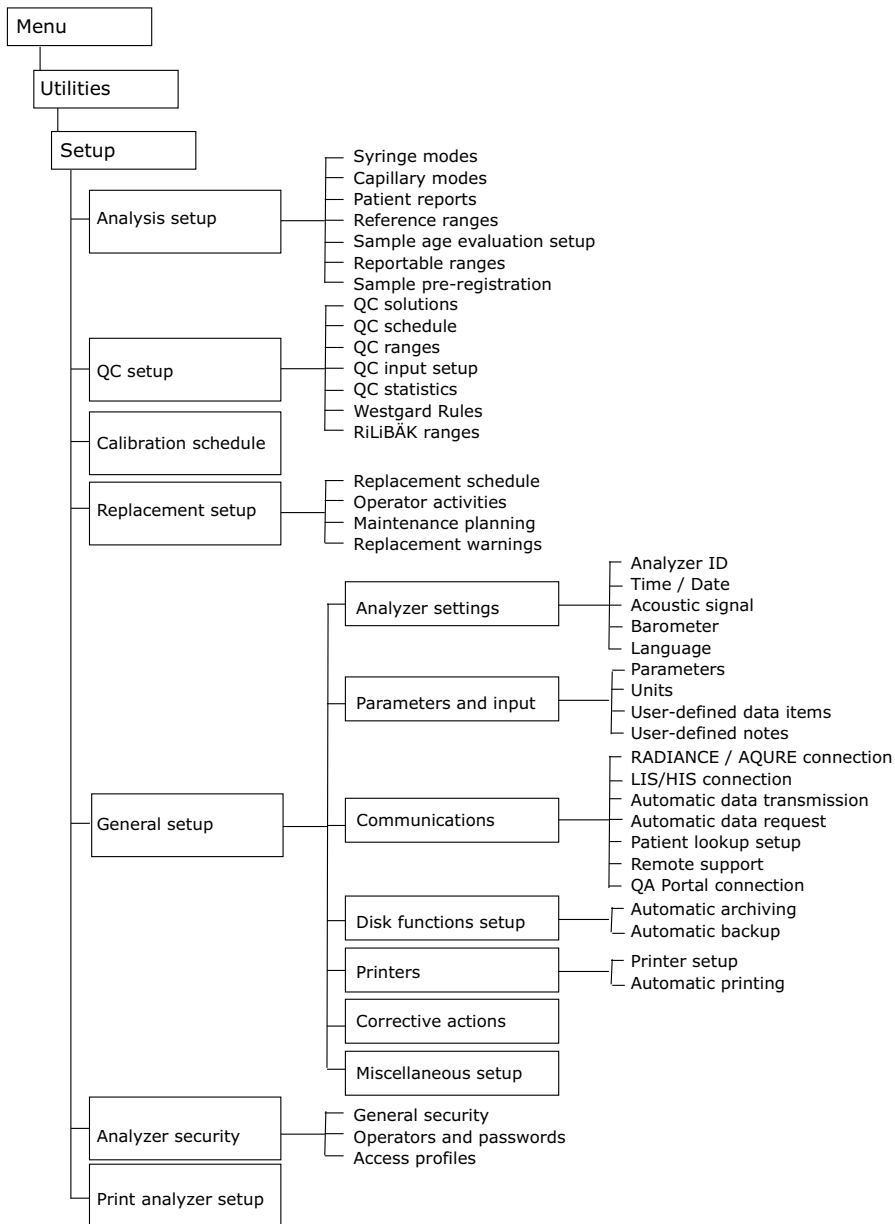
This chapter provides procedures to setup your Vi-CELL MetaFLEX analyzer for use.

This chapter contains information on:

- [Setup Menu Structure](#)
- [Printing Setups](#)
- [Managing Operators](#)
- [Managing Sample Profiles](#)
- [Analyzer Operations](#)
- [Analyzer Settings](#)
- [Analysis Setup](#)
- [Parameter Settings](#)
- [Calibration Settings](#)
- [Maintenance Setup](#)
- [Note Fields](#)
- [Communications](#)
- [Printers](#)
- [Data Logs and Archives](#)
- [Data Backup and Restoration](#)
- [Saving and Loading Setups](#)
- [Beckman Coulter Default Settings](#)

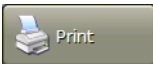
Setup Menu Structure

Figure 8.1 Setup Software Menu Tree

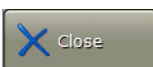


Printing Setups

- 1 Select **Menu > Utilities > Setup > Print analyzer setup**.
- 2 Deselect the check buttons for the setups you do not want to print.

3 Select  .

4 If necessary, select the printer and select **Select printer**.

5 Select  .

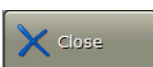
Managing Operators

Select the Logon Procedure

1 Select **Menu > Utilities > Setup > Analyzer security > General security**.

2 In the **Authenticate operator by** field, select the option you want.

Option	Action
To let most operators log on with an Operator name: and Password: , but let some operators log on with a logon barcode	Select <i>Operator ID / password as primary</i>
To let most operators log on with a logon barcode, but let some operators log on with an Operator name: and Password:	Select <i>Logon-barcode as primary</i>
To only let operators log on with an Operator name: and Password:	Select <i>Operator ID / password only</i>
To only let operators log on with a logon barcode	Select <i>Logon-barcode only</i>

3 Select  .

Access Profiles

An access profile specifies what an operator with the given profile can do on the analyzer.

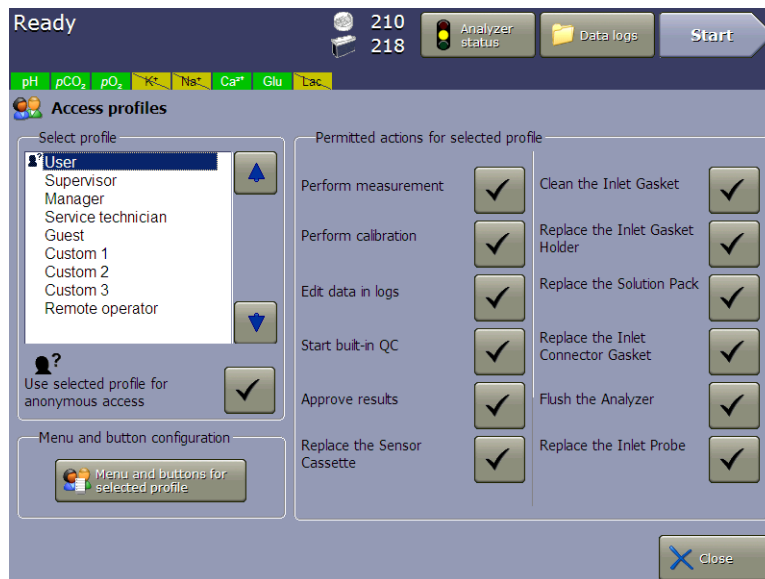
- The operations that can be done
- The menus and screens that can be opened
- The shortcut buttons that are available to operators

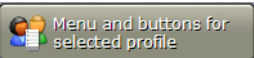
Eight access profiles are available. Access profiles may be edited, but their names cannot be changed. No new access profiles can be created. An access profile must be selected for each operator.

Editing an Access Profile

NOTE All access profiles may be edited, but some only in part.

- 1 Select **Menu > Utilities > Setup > Analyzer security > Access profiles**. The Access profiles screen appears.



- 2 Select the access profile.
- 3 Select the check buttons in the **Permitted actions for selected profile** field.
- 4 Select .

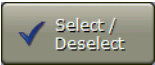
5 To create a shortcut button.

NOTE You can create a shortcut button to six menus.

- a. In the **Available menu items:** field, select the menu you want a shortcut button for.
- b. In the **Button shortcuts** field, select a button position for the shortcut.
- c. Do these steps again for each shortcut button you want to create.

6 To create access to menus.

- a. In the **Available menu items:** field, select the menu that you want to create access to.

- b. Select .

NOTE Make sure a checkmark is shown in the selected check box.

- c. Do these steps again for each menu you want to create access to.

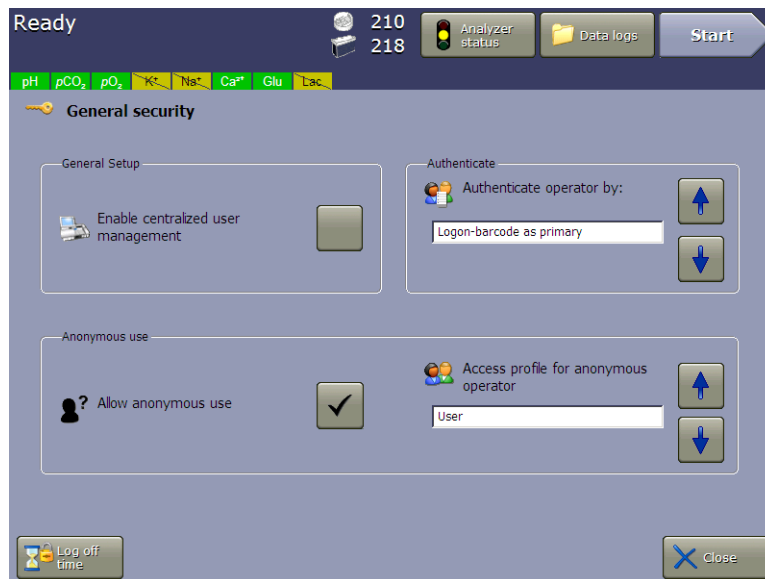
7 Select > .

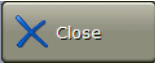
Anonymous Use

Operators do not have to log on to an analyzer that is set up for anonymous use. The access profile selected for anonymous use specifies the shortcut buttons and menus that anonymous operators can use.

Setting Up Anonymous Use

- 1 Select **Menu > Utilities > Setup > Analyzer security > General security**. The General security screen appears.



- 2 Select the **Allow anonymous use** check button.
- 3 Select an access profile for anonymous operators.
- 4 Select .

Default Operators

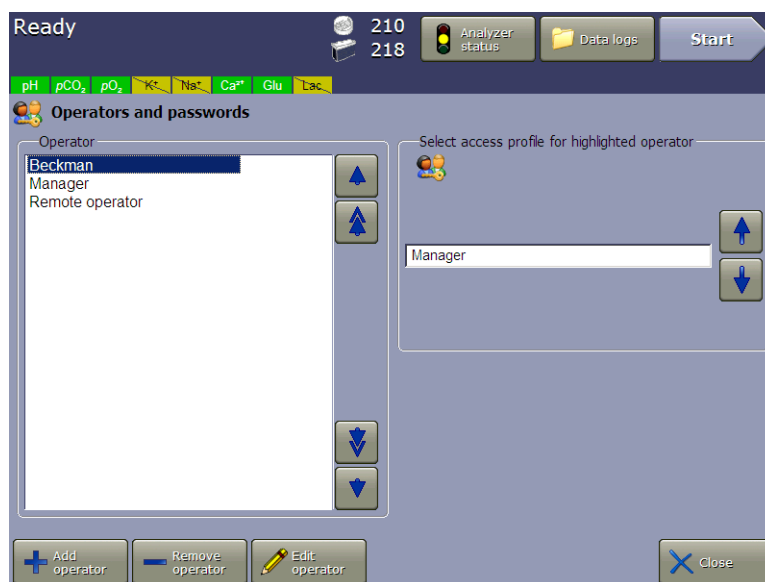
Some operators are set up by default.

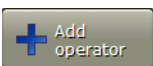
Operator	Default access to menus	Can the operator be deleted?
Manager	See the default "Manager" access profile. NOTE The password 123456 lets you log on to the analyzer the first time the analyzer is used.	Yes

Operator	Default access to menus	Can the operator be deleted?
Beckman Coulter	All operator and service menus.	No
Remote operator	All operator and service menus. NOTE A remote operator cannot by default view data. NOTE This operator is only shown when you have the "Remote support" option. Contact us for details.	No

Adding an Operator

- 1 Select **Menu > Utilities > Setup > Analyzer security > Operators and passwords**. The Operators and passwords screen appears.



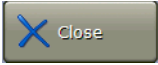
- 2 Select .

3 Choose an option and follow the steps for it.

Option	Steps
To let the operator log on with an Operator name: and a Password:	- Enter a unique ID for the operator. NOTE Only enter 35 characters, so that the complete ID is seen in the Logon screen. NOTE Do not include characters such as apostrophes (') and slashes (/). - Enter the password for the operator. NOTE The password must contain a minimum of 4 characters. - Enter the password again in the Confirm: field below the Password: field.
To let the operator log on with a logon barcode	- Enter or scan in the logon barcode for the operator. NOTE The logon barcode must be unique and contain a minimum of 4 characters. - Enter or scan in the logon barcode again in the Confirm field below the Logon - barcode: field.
To let the operator log on with an Operator name: and a Password: or with a logon barcode	- Enter a unique ID for the operator. NOTE Do not include characters such as apostrophes (') and slashes (/). NOTE Only enter 35 characters, so that the complete ID is seen in the Logon screen. - Enter the password for the operator. NOTE The password must contain a minimum of 4 characters. - Enter or scan in the password again in the Confirm: field below the Password: field. - Enter or scan in the logon barcode for the operator. NOTE The logon barcode must be unique and contain a minimum of 4 characters. - Enter or scan in the logon barcode again in the Confirm field below the Logon - barcode field.

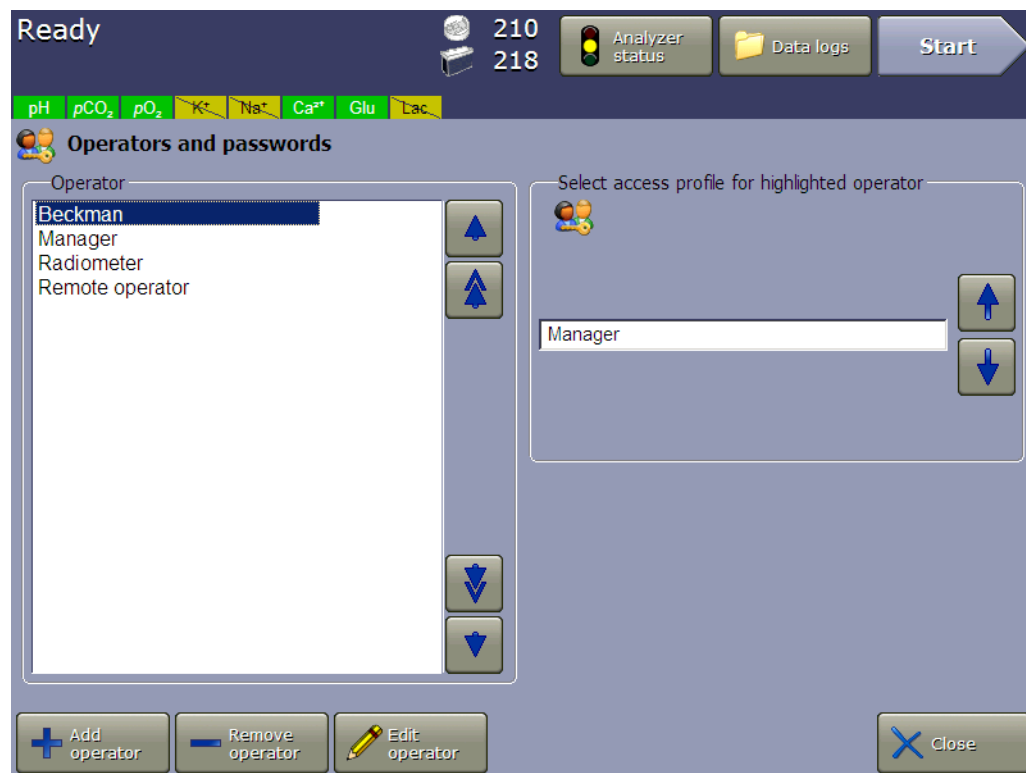
4 Select .

NOTE If data is not valid, a pop-up message is shown and an acoustic signal is sent.

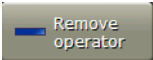
- 5 Make sure that the operator is selected.
- 6 Select an access profile for the selected operator.
- 7 Select .

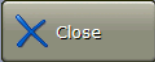
Removing an Operator

- 1 Select **Menu > Setup > Analyzer security > Operators and passwords**. The Operators and passwords screen appears.



- 2 Select the operator.

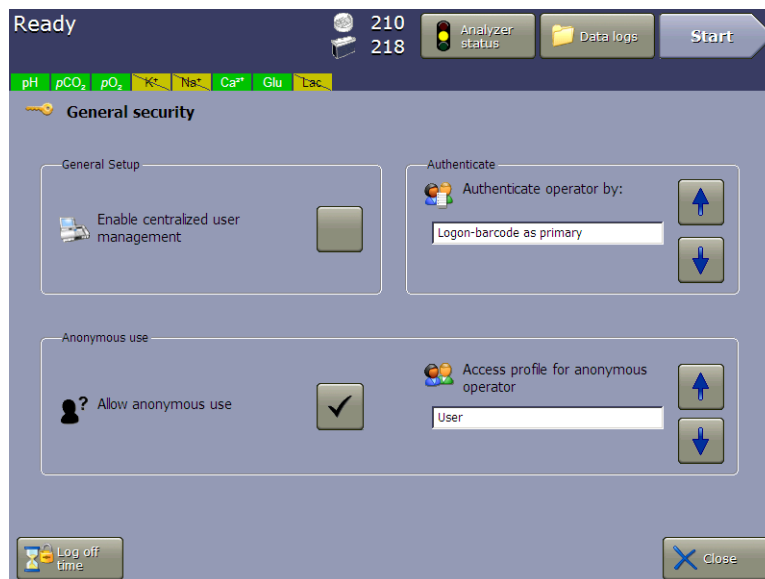
- 3 Select .

- 4 Select .

Setting a Logoff Time for All Operators

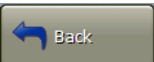
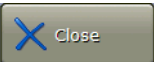
NOTE If no time is set, operators will be automatically logged off after 3 minutes. The maximum logoff time that can be set is 60 minutes and 50 seconds.

- 1 Select **Menu > Utilities > Setup > Analyzer security > General Security**. The General security screen appears.



- 2 Select .

- 3 Set a logoff time in minutes and seconds.

- 4 Select  > .

Centralized User Management

IMPORTANT Centralized User Management is not supported by Beckman Coulter. [Contact us](#) for more information.

Setting Up Centralized User Management

IMPORTANT Centralized User Management is not supported by Beckman Coulter. [Contact us](#) for more information.

Managing Sample Profiles

Patient Profiles Log

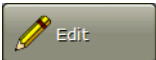
A patient profile contains data that helps to identify a sample. This data is automatically saved in the **Patient profiles log** during sample analysis.

If an **ID** is included in a profile, the analyzer will download all the other patient profile data to the **Identification** screen, when the **ID** field is filled in. If the analyzer is set up to automatically request data from a LIS/HIS system, data received from the LIS/HIS system updates data in the screen and in the log.

Viewing the Data Saved in a Patient Profile

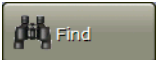
1 Select **Menu > Data logs > Patient profiles log**

2 Select the profile.

3 Select .

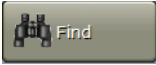
Finding a Patient Profile

1 Select **Menu > Data logs > Patient profiles log**.

2 Select .

3 Select the field of the criterion you want to use to find the profile. For example **Patient ID**.

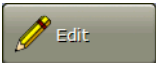
4 Enter data in the field.

5 Select  .

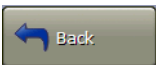
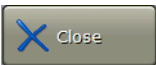
Editing a Patient Profile

1 Select **Menu > Data logs > Patient profiles log**.

2 Select the profile.

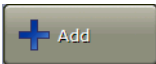
3 Select  .

4 Edit the values you want to edit.

5 Select  >  .

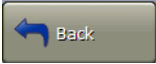
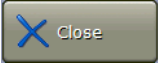
Adding a New Patient Profile

1 Select **Menu > Data logs > Patient profiles log**.

2 Select  .

3 Enter data in the **Patient ID** field.

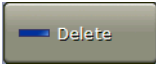
4 Enter data in other fields that help to identify the profile.

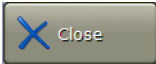
-
- 5 Select  > .
-

Deleting a Patient Profile

-
- 1 Select **Menu > Data logs > Patient profiles log**.
-

- 2 Select the profile.
-

- 3 Select .
-

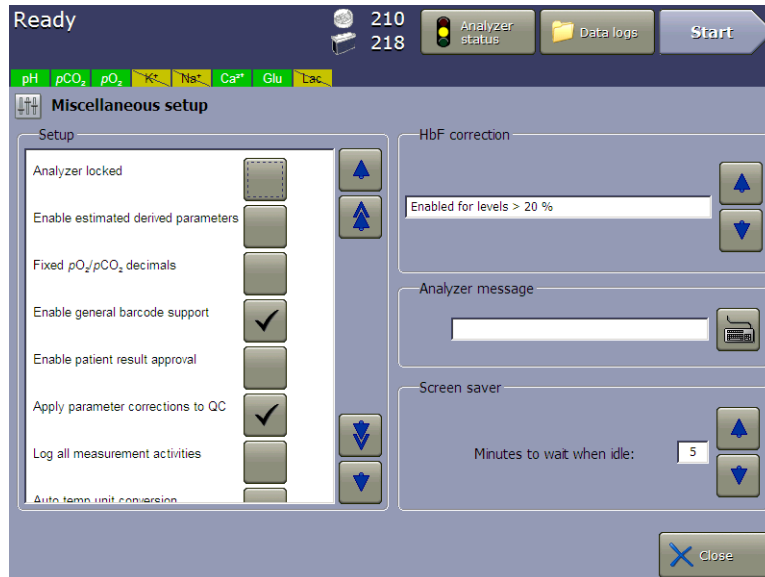
- 4 Select .
-

Analyzer Operations

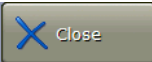
Locking the Analyzer

No samples can be analyzed when the analyzer is locked. However, the analyzer will continue to do automatic calibrations.

- 1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**. The Miscellaneous setup screen appears.



- 2 Select the **Analyzer locked** check button.

- 3 Select .

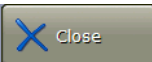
Unlocking the Analyzer

This procedure lets you unlock the analyzer when an operator has locked it.

NOTE To unlock an analyzer that is set up to lock automatically after a Solution Pack and/or Sensor Cassette replacement: Operators must do the requested ampoule-based QC measurements.

- 1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**.

- 2 Deselect the **Analyzer locked** check button.

- 3 Select .

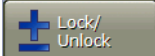
Locking/Unlocking Parameters for Measurement

A locked parameter cannot be measured. When a parameter is locked, the parameter tab changes to red and no values are given for the parameter in result screens or in printouts. However, locked parameters continue to be calibrated.

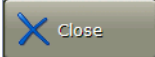
- 1 Select **Menu > Utilities > Setup > General setup > Parameters and input > Parameters**. The Parameters screen appears.

Parameter	Enabled/locked	Repression	Correction slope	Correction offset	Unit	Out-of-range suppression
pH	Yes / No	No	1.000	0.000		
pCO ₂	Yes / No	No	1.000	0.0	mmHg	
pO ₂	Yes / No	No	1.000	0.0	mmHg	
ctHb	No / No	No	1.000	0.00	g/dL	No
sO ₂	No / No	No	1.000	0.0	%	No
FCOHb	No / No	No		0.0	%	No
FMetHb	No / No	No		0.0	%	No
FHbF	No / No	No	1.000	0	%	Yes
FHHb	No / No	No			%	No
cK ⁺	Yes / No	No	1.000	0.0	mmol/L	
cNa ⁺	Yes / No	No	1.000	0	mmol/L	
cCa ²⁺	Yes / No	No	1.000	0.00	mmol/L	
cCl ⁻	No / No	No	1.000	0	mmol/L	
cGlu	Yes / No	No	1.000	0.00	g/L	
cLac	Yes / No	No	1.000	0.00	g/L	
ctBil	No / No	No	1.000	0	μmol/L	Yes

- 2 Select the parameter.

- 3 Select .

NOTE The last value in the **Enabled/locked** column must be "Yes" to lock the parameter, and "No" to unlock it.

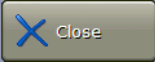
- 4 Select .

Viewing a Message on the Analyzer Screen

The message is shown in the start screen.

- 1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**.

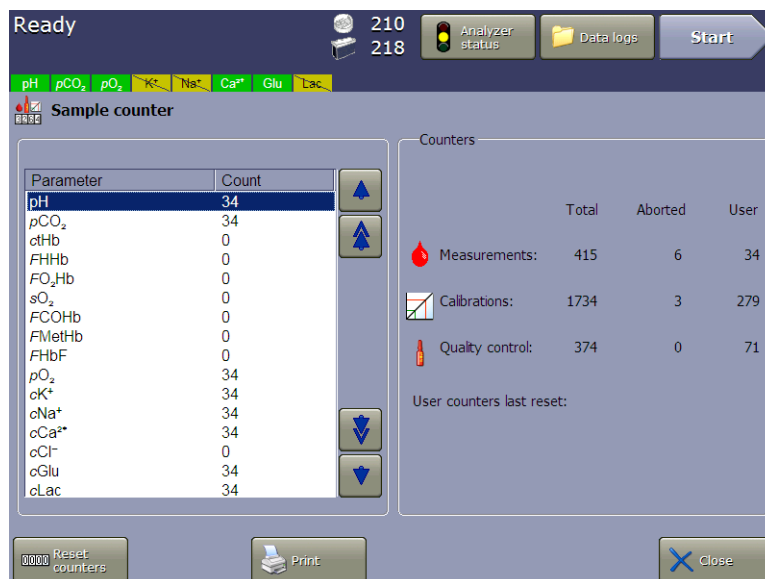
2 Enter a message in the **Analyzer message** frame.

3 Select .

Sample Counter

Viewing an Overview of Measurements and Tests Done on the Analyzer

1 **Menu > Utilities > Sample counter.** The Sample counter screen appears.



Sample Counter

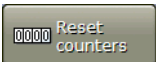
The Sample counter screen gives an overview of the measurements and tests done on the analyzer.

Data	Description
Parameter, Count	Shows the number of tests done for each parameter on samples and QC solutions
Total column	Shows the number of completed sample analyses, calibrations and QC measurements. NOTE Because a parameter can be removed from a measurement, the total number of completed measurements may not be equal to the total number of tests.
Aborted column	Shows the number of measurements stopped by the analyzer because it found an error
User column	The number of measurements done since the user counters were last set to zero
User counters last reset	Shows the date when the counters in the User column were last reset to zero

Resetting the Counters in the User Column

NOTE The counter in the **User** column is the only counter that can be reset (set to zero).

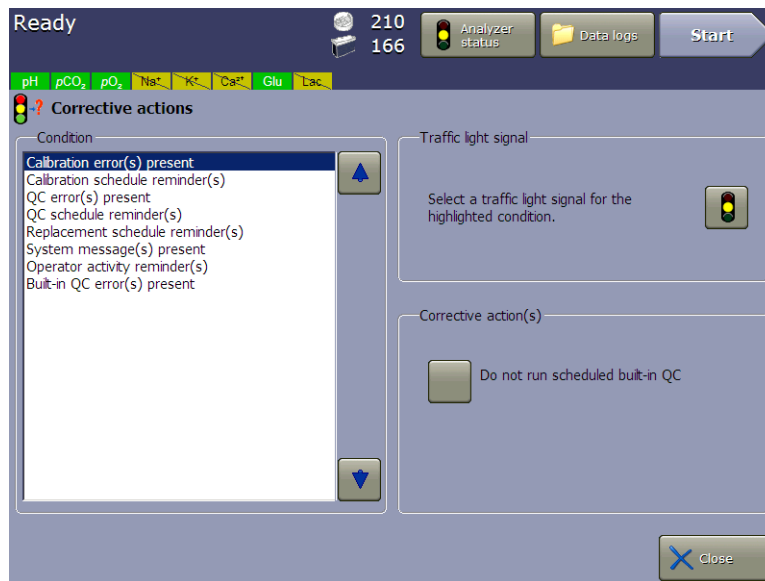
1 Select the **Menu > Utilities > Sample counter**.

2 Select .

Analyzer Settings

Setting Up Corrective Actions on System Messages

- 1 Select **Menu > Utilities > Setup > General setup > Corrective actions**. The Corrective actions screen appears.



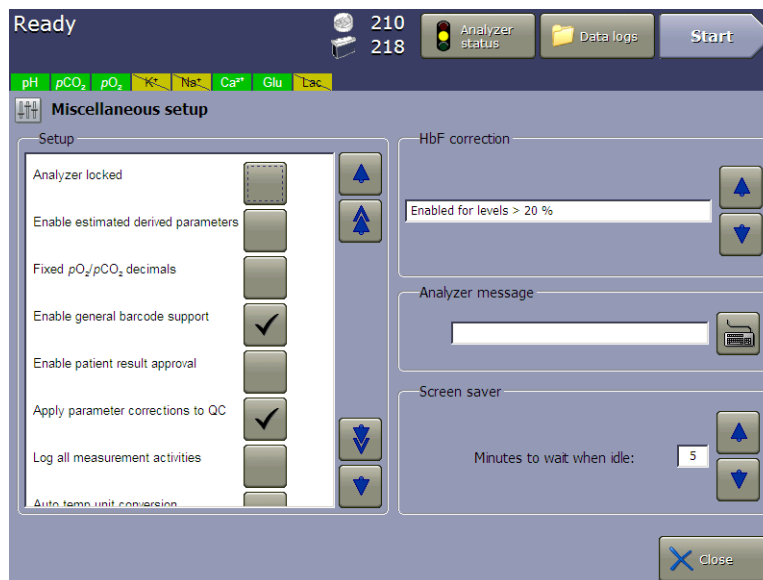
- 2 Select the condition **System message(s) present**.
- 3 Choose an option and follow the steps for it.

Option	Steps
To change the traffic light color	Select the traffic light until it shows the color you want.
To attach a message to the next result	Select the Message on next patient result check button.

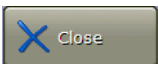
Enabling Data to be Scanned from Barcodes

This procedure lets operators scan barcodes to enter data into more text fields than the **Patient ID**, **Accession no.** and **Sampler ID** text fields.

- 1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**. The Miscellaneous setup screen appears.



- 2 Select the **Enable general barcode support** check button.

- 3 Select .

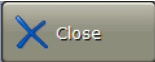
Creating a Heading for Printed Data

NOTE The text you enter in this procedure will be part of the heading that will be shown on all printed data and data sent to LIS/HIS systems. The **Analyzer type:** will also be included.

- 1 Select **Menu > Utilities > Setup > General setup > Analyzer settings > Analyzer ID**. The Analyzer ID screen appears.

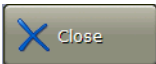
The screenshot shows the 'Analyzer identification' window. At the top, there's a status bar with 'Ready', a traffic light icon, and 'Analyzer status' with a green light. Below that are buttons for 'Data logs' and 'Start'. A row of tabs shows 'pH', 'pCO₂', 'pO₂', 'K⁺', 'Na⁺', 'Ca⁺⁺', 'Glu', and 'Lac'. The main area is titled 'Analyzer identification' and contains a form with the following fields: 'Analyzer type:' with value 'Vi-CELL MetaFLEX', 'Installation No:' with value 'I393-092R0047N0004', 'Analyzer name:' with an empty text box, 'TCP/IP address:' with value '127.0.0.1', and 'Host name:' with value '393-092R047N004'. To the right of the form is a numeric keypad with buttons for digits 0-9, a decimal point, and backspace/arrow keys. A 'Close' button with a blue 'X' icon is at the bottom right.

- 2 Enter the text for the heading (up to 25 characters). For example, a hospital or department name.

- 3 Select .

Enabling the Screen Saver

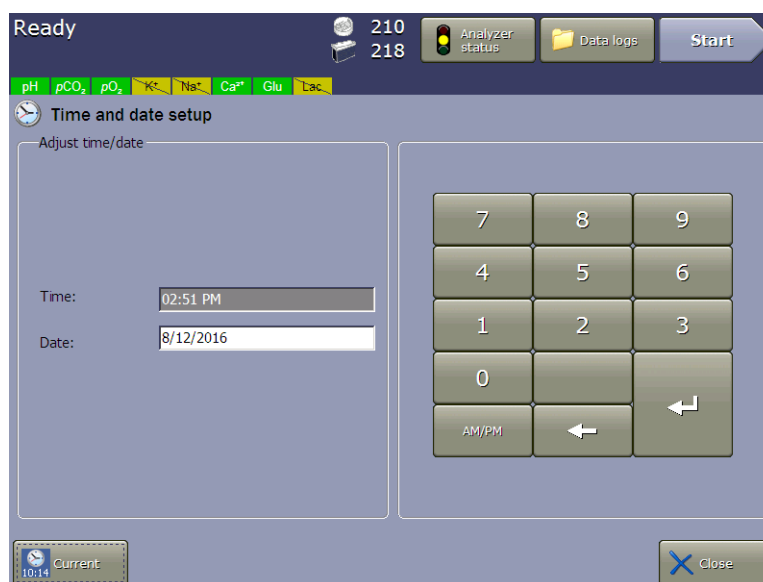
- 1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**.
- 2 Select the **Enable screen saver** check button.
- 3 In the **Screen saver** frame, select the number of minutes the analyzer must not be in use before the screen saver is shown.

- 4 Select .

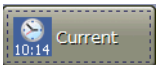
Setting the Time and Date

This procedure sets the time and date on the analyzer clock. The time at which measurements and activities are done are read from this clock. If there is more than 2 hours difference between the time you set and the system time, the activity is recorded in the **Activity log**.

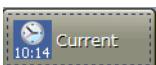
- 1 Select **Menu > Utilities > Setup > General setup > Analyzer settings > Time / Date**. The Time and date setup screen appears.

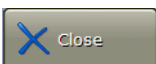


- 2 Enter the time.

NOTE  cancels entered values.

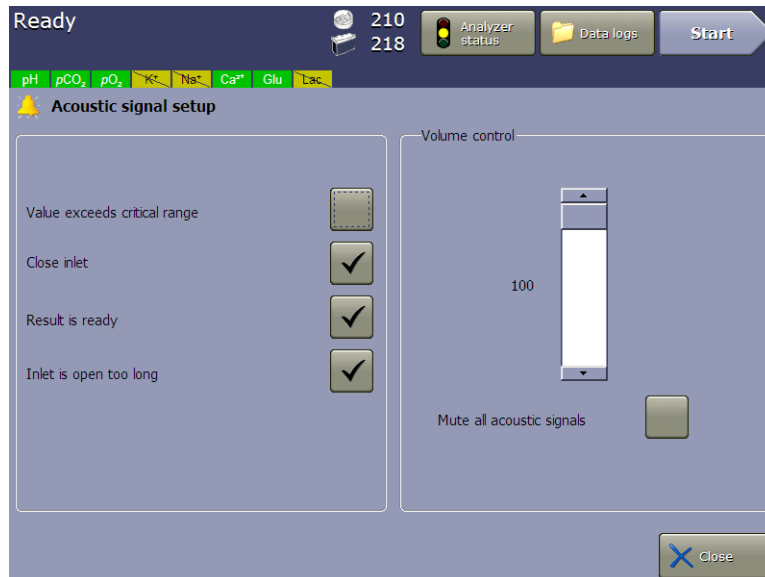
- 3 Enter the date.

NOTE  cancels entered values.

- 4 Select .

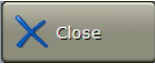
Setting the Acoustic Signals

- 1 Select **Menu > Utilities > Setup > General setup > Analyzer settings > Acoustic signal**. The Acoustic signal setup screen appears.



- 2 Select when you want an acoustic signal to be given.

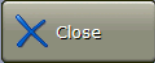
- 3 Use the scroll buttons to select the volume level.

- 4 Select .

Muting All Acoustic Signals

- 1 Select **Menu > Utilities > Setup > General setup > Analyzer settings > Acoustic signal**.

- 2 Select the **Mute all acoustic signals** check button.

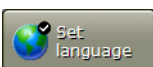
- 3 Select .

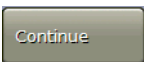
Changing the Screen Language

- 1 Select **Menu > Utilities > Setup > General setup > Analyzer settings > Language**. The Current Language screen appears.

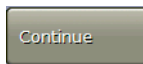
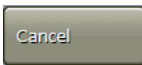


- 2 In the **Select a language from the list** frame, select a language.

- 3 Select .

- 4 Select .

- 5 Choose an option and follow the steps for it:

Option	Steps
To change the language immediately	Select  . NOTE This will restart the analyzer.
To change the language later. For example, if you also want to change regional settings.	1. Select  2. Restart the analyzer later.

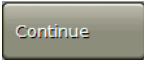
Selecting a Regional Setting

A regional setting includes default values for time and date formats, the separator used for thousands and decimals in numerical values and the layout of the keyboard shown on the analyzer screen.

1 Select **Menu > Utilities > Setup > General setup > Analyzer settings > Language**.

2 In the **Regional settings** frame, select a regional setting.

3 Select .

4 Select .

NOTE This will restart the analyzer.

Setting the Barometric Pressure

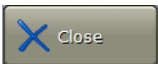
Prerequisite — The value of the barometric pressure in your laboratory.

This procedure makes sure that the analyzer barometer values are adjusted to the room in which the analyzer is used.

- 1 Select **Menu > Utilities > Setup > General setup > Analyzer settings > Barometer**. The Barometer setup screen appears.

- 2 In the **Adjust to:** field, enter the value of the barometric pressure in your laboratory.

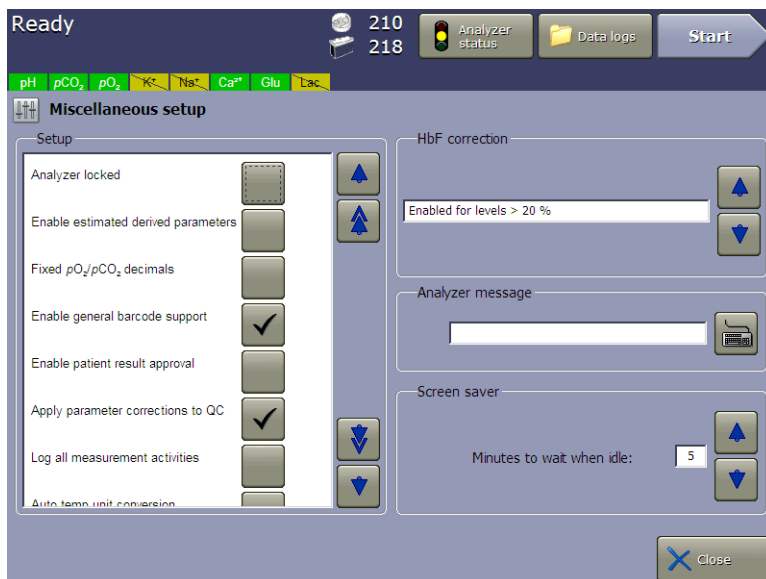
NOTE The maximum difference between the **Measured unadjusted:** and **Adjust to:** values that the analyzer will accept is ± 19 mmHg.

- 3 Select .

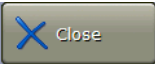
Logging All Measurement Activities

By default not all measurement activities are recorded in the **Activity log**. This procedure sets up the analyzer to record all measurement activities.

- 1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**. The Miscellaneous setup screen appears.



- 2 Select the **Log all measurement activities** check button.

- 3 Select .

Analysis Setup

Analysis Modes

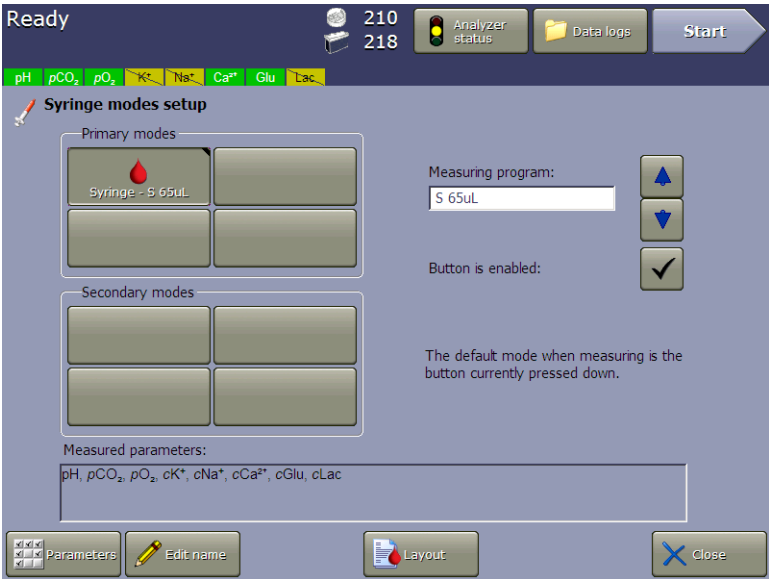
Syringe Modes

Syringe modes refer to the types of analysis that can be done when the inlet is in the syringe position. The syringe mode, **Syringe - S 65µL** is setup by default for the analysis of samples in syringes. This mode can be edited and new syringe modes created.

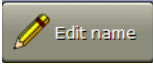
A **Syringe - S 65µL short probe** mode is also available for specific types of syringes where the distance from the tip of the syringe to the barrel of the plunger is short. [Contact us](#) for more information.

Editing a Syringe Mode

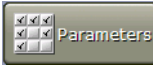
- 1 Select **Menu > Utilities > Setup > Analysis setup > Syringe modes**. The Syringe modes screen appears.



- 2 Select the button for the mode you want to edit in the **Primary modes** or **Secondary modes** field.
- NOTE** The set of modes that holds the default mode is the one first shown during a measurement.

- 3 Select .

- 4 If necessary, edit the name.
- NOTE** The - S 65µL and/or - S 65µL short probe texts cannot be changed.

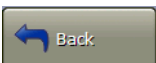
- 5 Select .

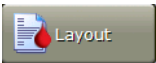
- 6 If necessary, choose another option and follow the steps for it.

Option	Steps
To set up a default parameter profile for the mode	Select the parameters to measure in the mode.

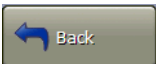
Option	Steps
To let operators select the parameters they want to show in results	Select the Select parameter profile during measurement check button.
To set up a default parameter profile for the mode, but also let operators select the parameters they want to show in results	- Select the parameters to measure in the mode. - Select the Select parameter profile during measurement check button.

7 Make sure the check buttons for parameters you want to measure in this mode are selected.

8 Select .

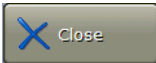
9 Select .

10 If necessary, select another report layout to be shown when you measure in this mode.

11 Select .

12 Select the button for the mode you want to be the default mode.

NOTE The default mode is the mode the analyzer will use if no other measurement mode is selected.

13 Select .

Creating a New Syringe Mode

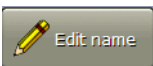
1 Select **Menu > Utilities > Setup > Analysis setup > Syringe modes**.

2 Select a button with no text in the **Primary modes** or **Secondary modes** field.

NOTE The set of modes that holds the default mode is the one first shown during a measurement.

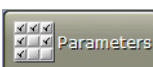
3 Select the **Button is enabled:** check button.

4 Select the  button until the **Measuring program:** field shows the mode you want.

5 Select .

6 Enter a name for the mode.

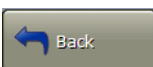
NOTE The - S 65 μ L and/or - S 65 μ L short probe texts cannot be changed.

7 Select .

8 Choose an option and follow the steps for it.

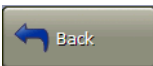
Option	Steps
To set up a default parameter profile for the mode	Select the parameters to measure in the mode.
To let operators select the parameters they want to show in results	Select the Select parameter profile during measurement check button.
To set up a default parameter profile for the mode, but also let operators select the parameters they want to show in results	• Select the parameters to measure in the mode. • Select the Select parameter profile during measurement check button.

9 Make sure the check buttons for parameters you want to measure in this mode are selected.

10 Select .

11 Select .

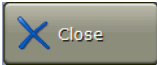
12 If necessary, select another report layout to be shown when you measure in this mode.

13 Select .

-
- 14** Select the button for the mode you want to be the default mode.

A small black mark in the top right-hand corner of the button shows that the mode has been selected as the default.

NOTE The default mode is the mode the analyzer will use if no other measurement mode is selected.

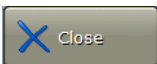
- 15** Select .

Removing a Measurement Mode

-
- 1** Select **Menu > Utilities > Setup > Analysis setup > Syringe modes**.

-
- 2** Select the button for the mode you want to remove.

-
- 3** Deselect the **Button is enabled:** check button.

-
- 4** Select .

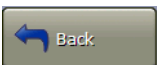
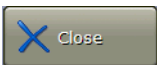
Selecting a Default Measurement Mode

The default measurement mode is the mode the analyzer will use if no other measurement mode is selected.

-
- 1** Select **Menu > Utilities > Setup > Analysis setup > Syringe modes**.

-
- 2** Select the button for the mode you want to be the default mode.

A small black mark in the top right-hand corner of the button shows that the mode has been selected as the default.

-
- 3** Select  > .

Selecting a Specific Report Layout for an Analysis Mode

Prerequisite: There is more than one report layout.

This procedure lets you select the report layout that the analyzer shows during an analysis.

- 1 Choose an option and follow the steps for it.

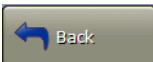
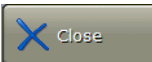
Option	Steps
For analyses done with the inlet in the syringe position	Select Menu > Utilities > Setup > Analysis setup > Syringe modes .
For analyses done with the inlet in the capillary position	Select Menu > Utilities > Setup > Analysis setup > Capillary modes .

- 2 Select the button for the mode in the **Primary modes** or **Secondary modes** field.

- 3 Make sure the **Button is enabled**: check button is selected.

- 4 Select .

- 5 Select the report layout to be automatically shown.

- 6 Select  > .

Setting Up a Calibration-Verification Mode

It is necessary to set up a calibration-verification mode before calibration-verification measurements can be done.

- 1 Select **Menu > Utilities > Setup > Analysis setup > Syringe modes**.

- 2 Select a button with no text in the **Primary modes** or **Secondary modes** field.

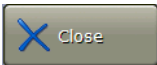
- 3 Select the **Button is enabled**: check button.

- 4 Select  until the button you selected in step 2 is given the name **Cal Verification**.

-
- 5 Select the button for the mode you want to be the default mode.

A small black mark in the top right-hand corner of the button shows that the mode has been selected as the default.

NOTE The default mode is the mode the analyzer will use if no other measurement mode is selected.

- 6 Select .

Setting Up Ampoule QC Mode

This is an optional procedure. It lets you start ampoule-based QC measurements from the same screen as you start sample analyses.

- 1 Select **Menu > Utilities > Setup > Analysis setup > Syringe modes**.

- 2 Select a button with no text in the **Primary modes** or **Secondary modes** field.

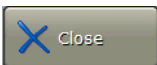
- 3 Select the **Button is enabled:** check button.

- 4 Select the  button until the button you selected in step 2 is given the name **Ampoule - QC**.

- 5 Select the button for the mode you want to be the default mode.

A small black mark in the top right-hand corner of the button shows that the mode has been selected as the default.

NOTE The default mode is the mode the analyzer will use if no other measurement mode is selected.

- 6 Select .

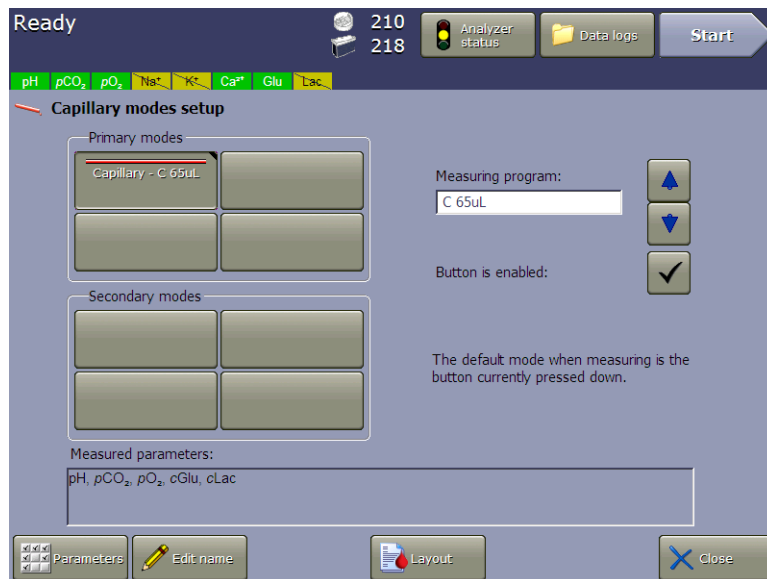
Capillary Modes

Capillary modes refer to the types of analysis that can be done when the inlet is in the capillary position.

The capillary mode **Capillary - C 65µL** is set up by default for the analysis of samples in capillary tubes. The mode can be edited.

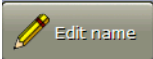
Editing a Capillary Mode

- 1 Select **Menu > Utilities > Setup > Analysis setup > Capillary modes**. The Capillary modes screen appears.



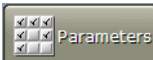
- 2 Select the button for the mode you want to edit in the **Primary modes** or **Secondary modes** field.

NOTE The set of modes that holds the default mode is the one first shown during a measurement.

- 3 Select .

- 4 If necessary, edit the name.

NOTE The text - C 65µL or - C 45µL cannot be changed.

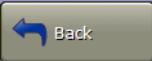
- 5 Select .

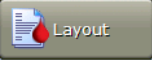
- 6 If necessary, choose another option and follow the steps for it.

Option	Steps
To set up a default parameter profile for the mode	Select the parameters to measure in the mode.

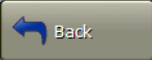
Option	Steps
To let operators select the parameters they want to show in results	Select the Select parameter profile during measurement check button.
To set up a default parameter profile for the mode, but also let operators select the parameters they want to show in results	- Select the parameters to measure in the mode. - Select the Select parameter profile during measurement check button.

7 Make sure the check buttons for parameters you want to measure in this mode are selected.

8 Select .

9 Select .

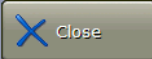
10 If necessary, select another report layout to be shown when you measure in this mode.

11 Select .

12 Select the button for the mode you want to be the default mode.

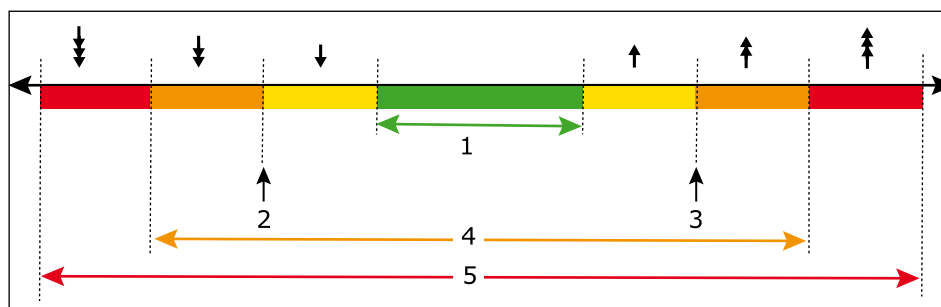
A small black mark in the top right-hand corner of the button shows that the mode has been selected as the default.

NOTE The default mode is the mode the analyzer will use if no other measurement mode is selected.

13 Select .

Ranges and Critical Limits

Measurement results are marked by symbols to show where they fall in relation to reference ranges, critical limits and reportable ranges. The diagram illustrates these relationships.



1. Reference range
2. Lower critical limit
3. Upper critical limit
4. Reportable range
5. Range of indication

About Reference Ranges

Results that lie outside the limits will be marked with the symbols:



Reference ranges are not set up by default. Laboratories must establish their own ranges. If reference ranges are set up, results that lie outside the limits will be marked with the symbols.

About Critical Limits

Critical limits are not set up by default. Laboratories must establish their own critical limits. If critical limits are set up, results that lie outside the limits will be marked with the symbols:



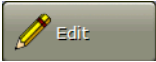
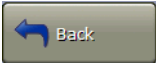
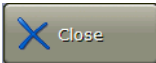
The symbols may be used to indicate when a value is high or low.

Setting Up Reference Ranges and Critical Limits

Prerequisite — Sample age groups have been set

Laboratories should establish their own reference ranges.

- 1 Select **Menu > Utilities > Setup > Analysis setup > Reference ranges**.

- 2 Select a parameter in the **Parameter:** field.
- 3 If the reference ranges of the selected parameter are dependent on a specific type of sample, select the **Sample type** check button.
- 4 If the reference ranges of the selected parameter are dependent on the age of samples, select the **Age group** check button.
- 5 If the reference ranges of the selected parameter are dependent on the sex of samples, select the **Sex** check button.
- 6 Select a setting for each of the buttons selected in steps 3, 4 and 5.
- 7 Select .
- 8 Enter values for the reference range and the critical limits.
If an entered value is not accepted, it will be removed and a message will be shown for a short period of time in a window on top of the screen.
- 9 Select .
- 10 Do steps 6 to 9 again for each of the combinations of sample type, age and/or sex.
- 11 Do steps 2 to 10 again for each parameter.
- 12 Select .

About Reportable Ranges

Reportable range is the range of results from a testing system or method over which analytical performance is claimed.

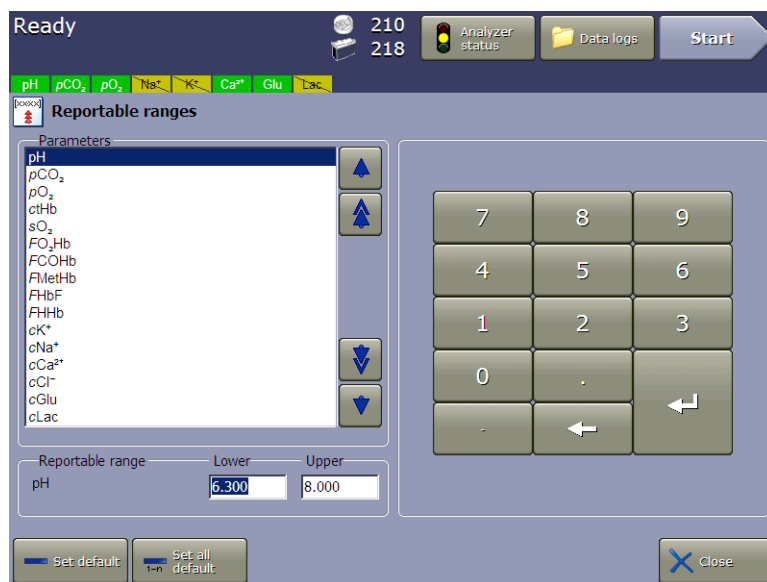
Results that lie outside the limits will be marked with the symbols:



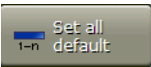
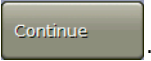
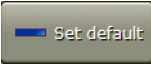
Setting Up Reportable Ranges

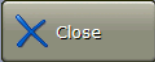
NOTE Symbols are shown on test results that fall outside the reportable range of the measured parameter.

- 1 Select **Menu > Utilities > Setup > Analysis setup > Reportable ranges**. The Reportable ranges screen appears.



- 2 Choose an option and follow the steps for it.

Option	Steps
To set the reportable range of all parameters to the default values	1. Select  . 2. Select  .
To set the reportable range for a parameter to the default value	1. Select a parameter in the Parameters field. 2. Select  .
To set the reportable range for a parameter	1. Select the parameter in the Parameters field. 2. Enter new values for the upper and lower limits of the reportable range.

- 3 Select .

About Range of Indication

The range of indication is the range within which that the analyzer can physically measure.

Sample Pre-Registration

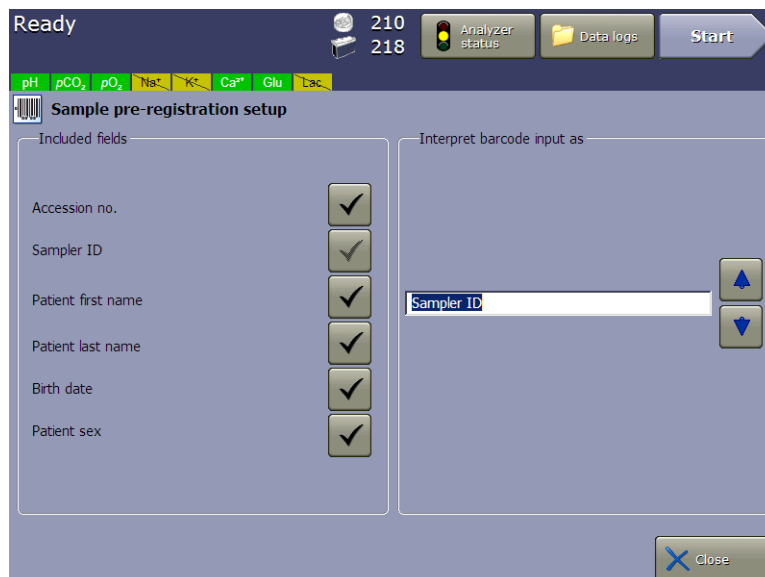
About Sample Pre-Registration

Sample pre-registration lets operators make sure that the data shown on the screen belongs to the sample to be analyzed. This reduces the risk of sample mix-up.

NOTE The analyzer must be set up for sample pre-registration.

Setting Up Sample Pre-Registration

- 1 Select **Menu > Utilities > Setup > Analysis setup > Sample pre-registration**. The Sample pre registration setup screen appears.

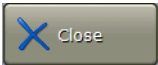


The screenshot shows the 'Sample pre-registration setup' screen. At the top, there's a status bar with 'Ready', '210', '218', 'Analyzer status', 'Data logs', and a 'Start' button. Below this is a menu bar with 'pH', 'pCO₂', 'pO₂', 'Na⁺', 'K⁺', 'Ca⁺⁺', 'Glu', and 'Lac'. The main area is titled 'Sample pre-registration setup'. It has two sections: 'Included fields' on the left and 'Interpret barcode input as' on the right. In 'Included fields', there are six items: 'Accession no.', 'Sampler ID', 'Patient first name', 'Patient last name', 'Birth date', and 'Patient sex', each with a checkmark button. In 'Interpret barcode input as', there is a text input field containing 'Sampler ID' and two arrow buttons (up and down). A 'Close' button is at the bottom right.

- 2 Select a value in the **Interpret barcode input as** field.

-
- 3** Make sure that check buttons are selected for the data fields you want included in the **Patient identification** screen shown during pre-registration.

NOTE A data field is automatically included for the value you selected in step 2.

- 4** Select .
-

Sample Age Evaluation

About Sample Age Evaluation

Sample age evaluation lets the analyzer calculate the age of samples and compare it to the value set in the **Sample age rule in minutes** value. Samples older than this value will be analyzed but a message attached to the result will indicate that the sample was old.

The calculation is based on the sample **Draw time** entered on the **Patient identification** screen:

[Sample age] = [Time the sample aspiration starts] - [Time the sample was collected].

Maximum Sample Age

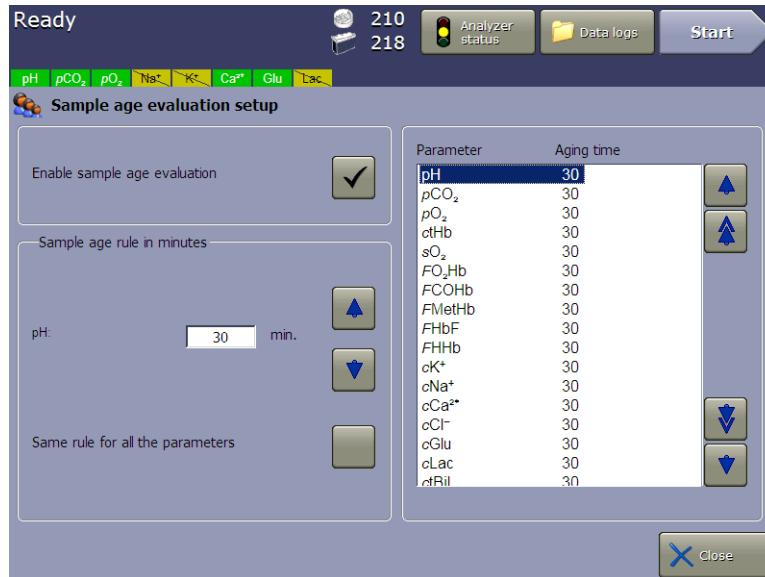
Maximum sample age is the maximum period of time that should elapse between when a sample is collected and when it is analyzed. How the sample is stored and handled after it is collected has an effect on the maximum sample age.

Setting a Maximum Sample Age

The **Sample age rule in minutes** value is set by default to the same value for all parameters. However, a value can be set for each individual parameter.

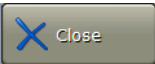
NOTE You must include the **Sample age** item in your report layouts to see calculated values.

- 1 Select **Menu > Utilities > Setup > Analysis setup > Sample age evaluation setup**. The Sample age evaluation setup screen appears.



- 2 Select the **Enable sample age evaluation** check button.
- 3 Choose an option and follow the steps for it.

Option	Steps
To select the same maximum sample age for all parameters	• Select a maximum sample age for the parameter in the Sample age rule in minutes field. • Select the Same rule for all the parameters check button.
To select a maximum sample age for a parameter	• Select a parameter. • Select a maximum sample age for the parameter in the Sample age rule in minutes field.

- 4 Select .

Patient Report Layouts

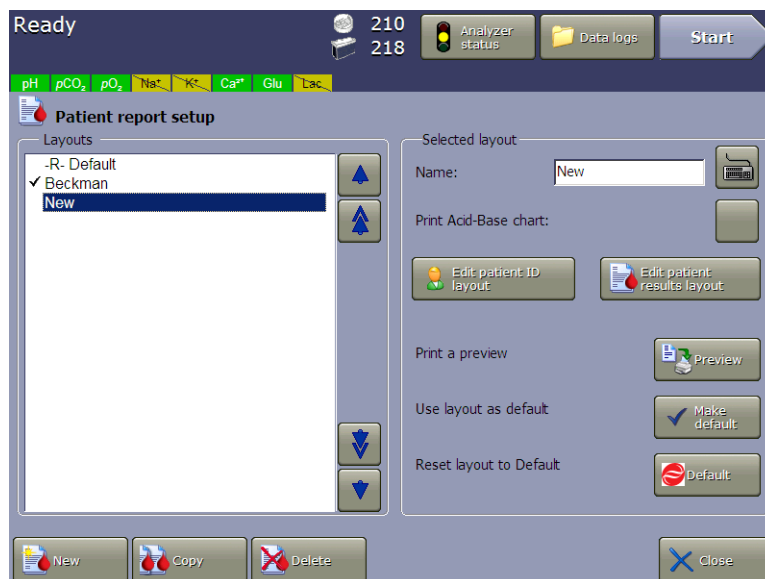
A patient report layout has 2 parts:

- A patient ID part – lets you create the content and layout of the **Patient identification** screen
- A patient results part – lets you create a template for the content and layout of the **Patient results** screen

You can select a default patient report layout. The default report layout is the **Report layout** shown in the **Patient identification** screen when it opens.

Creating a Patient Report Layout

- 1 Select **Menu > Utilities > Setup > Analysis setup > Patient reports**. The Patient report setup screen appears.



- 2 Select .

- 3 Enter a name for the report in the **Name:** field.

- 4 Select .

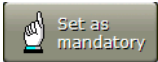
- 5 To add data items to the layout:
- Select a data item In the **Available items** frame.
 - Select the right arrow button.

NOTE Data items are shown in the layout as you add them.

- Do steps a. and b. again for each data item you want to add.

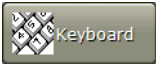
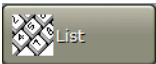
Option	Steps
If data is to be automatically requested from a LIS/HIS system	Add the data item that was selected in the Interpret barcode input as field during the sample pre-registration setup procedure.
If data is to be manually requested from a LIS/HIS system	Add the data field selected in the Request patient demographics frame during the automatic requests for data procedure. It will be one of the items: Sampler ID, Patient ID or Accession no? NOTE If more than one of these items are added, it is the item closest to the top of the Patient identification screen that must be filled before you can manually request data from the LIS/HIS system.
If data is to be looked up, found and requested manually	Add the "Department (Pat.)" data item.

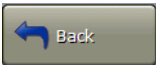
- 6 To make a data item mandatory:
- Select the data item in the **Selected items** frame.

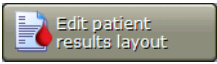
- Select  .

NOTE The mandatory icon is shown adjacent to the data item. 

- 7 To set a default value for a data item, choose an option and follow the steps for it.

Option	Steps
To enter a value	1. Select the data item in the Selected items frame. 2. Select  . 3. Enter a value.
To select a value from a data item list	1. Select the data item in the Selected items frame. 2. Select  . 3. Select a value in the Available values field. 4. Select  .

- 8 Select  .

- 9 Select  .

- 10 To add a heading for a group of parameters:
- a. In the **Available items** frame, select a heading. For example, "Blood gas values".
 - b. Select the right arrow button.

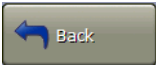
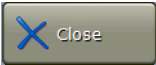
- 11 To add a parameter:
- a. In the **Available items** frame, select a parameter.
 - b. Select the right arrow button.
- NOTE** Parameters will be shown in the results as they are shown in the **Selected items** field.
- c. If necessary, do steps a. and b. again.

- 12 To change the position of an item in the **Selected items** frame:
- a. Select the item.
 - b. Select the left arrow button.
 - c. In the **Selected items** frame, select the item you want the selected item to follow.
In the **Available items** frame, select the item you selected in step a).
 - d. Select the right arrow button.

13 To show the reference range of a parameter with results:

- a. In the **Selected items** frame, select a parameter.
- b. Select **Show ranges**.
- c. If necessary, repeat steps a) and b) again for other parameters.

14 To change the selected data items to the data items in the Beckman Coulter default report layout, select **-R- Default**.

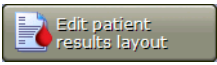
15 Select  > .

To change a patient result layout

This procedure tells you how to change the patient result layout for a selected layout.

1 Select **Menu > Utilities > Setup > Analysis setup > Patient reports**.

2 Select the layout.

3 Select .

4 To add a heading for a group of parameters:

- a. In the **Available items** frame, select a heading. For example, "Blood gas values".
- b. Select the right arrow button.

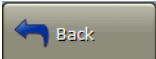
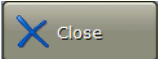
5 To add a parameter:

- a. In the **Available items** frame, select a parameter.
- b. Select the right arrow button.

NOTE Parameters will be shown in the results as they are shown in the **Selected items** field.

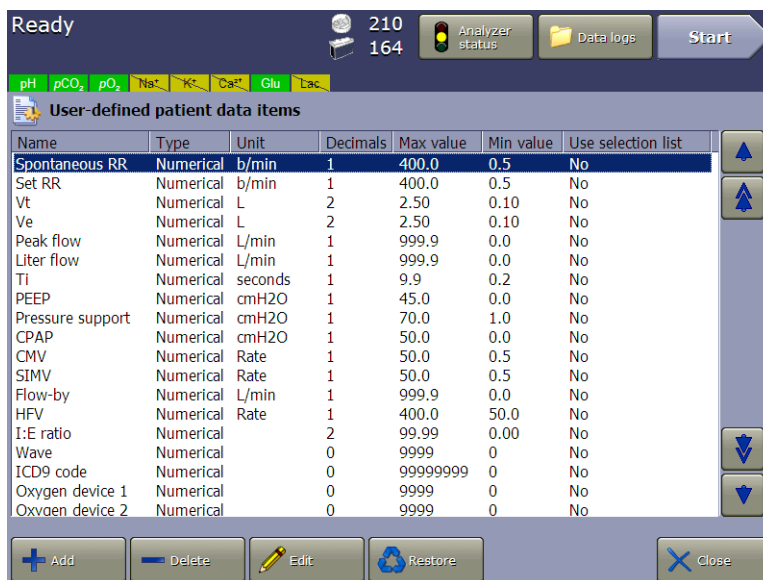
- c. If necessary, do steps a) and b) again.

- 6** To change the position of an item in the **Selected items** frame:
- Select the item.
 - Select the left arrow button.
 - In the **Selected items** frame, select the item you want the selected item to follow.
 - Select the right arrow button.
- 7** To show the reference range of a parameter with patient results:
- In the **Selected items** frame, select a parameter.
 - Select **Show ranges**.
 - If necessary, do steps a) and b) again for other parameters.

8 Select  > .

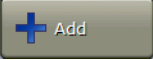
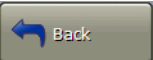
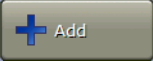
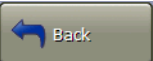
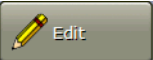
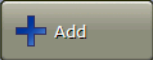
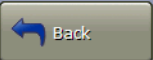
Creating Extra Items for Use in Patient Report Layouts

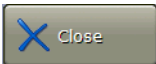
- 1** Select **Menu > Utilities > Setup > General setup > Parameters and input > User-defined data items**. The User-defined patient data items screen appears.



Name	Type	Unit	Decimals	Max value	Min value	Use selection list
Spontaneous RR	Numerical	b/min	1	400.0	0.5	No
Set RR	Numerical	b/min	1	400.0	0.5	No
Vt	Numerical	L	2	2.50	0.10	No
Ve	Numerical	L	2	2.50	0.10	No
Peak flow	Numerical	L/min	1	999.9	0.0	No
Liter flow	Numerical	L/min	1	999.9	0.0	No
Ti	Numerical	seconds	1	9.9	0.2	No
PEEP	Numerical	cmH2O	1	45.0	0.0	No
Pressure support	Numerical	cmH2O	1	70.0	1.0	No
CPAP	Numerical	cmH2O	1	50.0	0.0	No
CMV	Numerical	Rate	1	50.0	0.5	No
SIMV	Numerical	Rate	1	50.0	0.5	No
Flow-by	Numerical	L/min	1	999.9	0.0	No
HFV	Numerical	Rate	1	400.0	50.0	No
I:E ratio	Numerical		2	99.99	0.00	No
Wave	Numerical		0	9999	0	No
ICD9 code	Numerical		0	99999999	0	No
Oxygen device 1	Numerical		0	9999	0	No
Oxvaen device 2	Numerical		0	9999	0	No

2 Choose an option and follow the steps for it.

Option	Steps
To create a text item.	1. Select . 2. Enter the name of the item. NOTE Only enter 20 characters, so that the complete name is seen in the Patient Identification screen. 3. Select "Text" in the field on the right of the screen. 4. Select . 5. Select .
To create a numerical item.	1. Select . 2. Enter the name of the item. NOTE Only enter 20 characters, so that the complete name is seen in the Patient Identification screen. 3. Select "Numerical" in the field on the right of the screen. 4. Select . 5. Enter the name of the unit. 6. If entered numbers must have a fixed number of decimals to be accepted, select the number of decimals. Select . 7. If entered numbers must fall within a range to be accepted, enter the maximum and minimum values of the range. 8. Select .
To create a selection list for an existing text or numerical item. NOTE A minimum of 2 values must be added to create a list.	1. Select the item. 2. Select . 3. Select the Use selection list check button. 4. Select . 5. Enter a value. 6. Do steps d) to e) again for each item you want in the selection list. 7. Select the Use selection list check button. 8. Select .

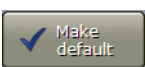
-
- 3 Select  .
-

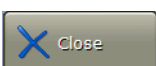
Selecting a Patient Report Layout as Default

The patient report layout you select as default is the one shown in the **Patient identification** screen when it opens.

-
- 1 Select **Menu > Utilities > Setup > Analysis setup > Patient reports**.
-

- 2 Select the layout.
-

- 3 Select  .
-

- 4 Select  .
-

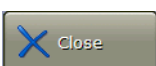
Automatically Change the Temperature Units

The analyzer can be set up to let temperatures be entered in Celsius (°C) or Fahrenheit (°F) degrees. However, this procedure lets the analyzer automatically change the set up temperature unit from °F to °C if an operator enters °C values in a °F temperature field and vice versa.

Examples: If 41 is entered as the temperature in a °F temperature field, the analyzer will automatically change the unit to °C. If 105 is entered as the temperature in a °C temperature field, the analyzer will automatically change the unit to °F.

-
- 1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**.
-

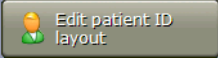
- 2 Select the **Auto temp unit conversion** check button.
-

- 3 Select  .
-

Editing a Patient Report Layout

1 Select **Menu > Utilities > Setup > Analysis setup > Patient reports.**

2 Select the layout.

3 Select  .

4 To add an item to the layout:

- a. Select an item In the **Available items** frame.
- b. Select the right arrow button.

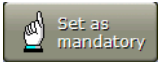
NOTE Items are shown in the layout as you add them.

5 To remove an item from the layout:

- a. Select an item In the **Selected items** frame.
- b. Select the left arrow button.

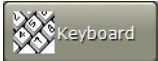
6 To make an item mandatory:

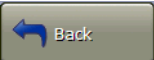
- a. Select the item in the **Selected items** frame.

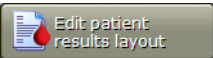
b. Select  .

7 To set a default value for an item:

- a. Select the item in the **Selected items** frame.

b. Select  and enter a value, or: (1) Select the **List** button. (2) Select a value. (3) Select the **Select** button.

8 Select  .

9 Select  .

10 To add a heading for a group of parameters:

- a. In the **Available items** frame, select a heading. For example, "Blood gas values".
- b. Select the right arrow button.

11 To add a parameter:

- a. In the **Available items** frame, select a parameter.
- b. Select the right arrow button.

NOTE Parameters will be shown in the results as they are shown in the **Selected items** field.

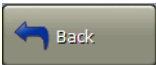
- c. If necessary, do steps a) and b) again.

12 To change the position of an item in the **Selected items** frame:

- a. Select the item.
- b. Select the left arrow button.
- c. In the **Selected items** frame, select the item you want the selected item to follow.
In the **Available items** frame, select the item you selected in step a).
- d. Select the right arrow button.

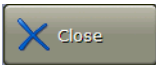
13 To show the reference range of a parameter with results:

- a. In the **Selected items** frame, select a parameter.
- b. Select **Show ranges**.
- c. If necessary, do steps a. and b. again for other parameters.

14 Select .

15 If necessary, enter a new name for the report in the **Name:** field.

16 To change the selected data items to the data items in the Beckman Coulter default report layout, select **-R- Default**.

17 Select .

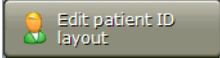
Creating a Patient Report Layout for $FShunt$ and $ctO_2(a-\bar{v})$

1 Select **Menu > Utilities > Setup > Analysis setup > Patient reports.**

2 Select the **-R- Default** layout.

3 Select .

4 Enter a name for the report in the **Name:** field.

5 Select .

6 Select $pO_2(\bar{v})$ in the **Available items** frame.

7 Select the right arrow button.

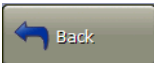
8 Do steps 5 and 6 again for these parameters:

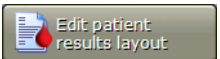
- $sO_2(\bar{v})$
 - $FO_2(I)$
 - RQ
 - T
-

9 If necessary, select another identifier in the **Available items** frame.

10 Select the right arrow button.

11 Do steps 8 and 9 again for each data item you want to add.

12 Select .

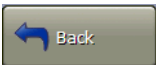
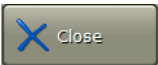
13 Select .

14 Select *FShunt* in the **Available items** frame.

15 Select the right arrow button.

16 Select $\text{ctO}_2(\text{a-v})$ in the **Available items** frame.

17 Select the right arrow button.

18 Select  > .

Patient Result Settings

Setting Up Automatic Printing of Acid-Base Charts

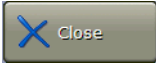
This procedure lets you set up the analyzer to automatically print acid-base charts when a selected report layout is used during a measurement.

1 Select **Menu > Utilities > Setup > Analysis setup > Patient reports**.

2 Select a report layout.

3 Select the **Print Acid-Base chart** check button.

NOTE Acid-base charts are only printed when all necessary parameter values are available.

4 Select .

Approval and Rejection of Sample Results

Approval/rejection of sample results is not set up by default. If it is set up, it can be used to filter sample results that are transmitted to a LIS/HIS system. Approved results are transmitted, rejected results are not.

NOTE An approved sample result does not indicate that the result can be used in a clinical evaluation of the sample.

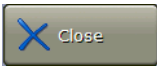
Approval can for example be used to make sure that necessary data was correctly entered, for example, that the **Sample type** was "Venous", not "Arterial" and the temperature was 42 °C, not 38 °C.

NOTE Approved/rejected results cannot be edited.

Enabling Result Approval/Rejection

1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**.

2 Select the **Enable patient result approval** check button.

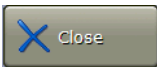
3 Select .

Parameter Settings

Displaying the Parameter Bar

1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**.

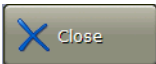
2 Select the **Show parameter bar** check button.

3 Select .

Hiding the Parameter Bar

1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**.

2 Deselect the **Show parameter bar** check button.

-
- 3 Select .
-

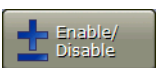
Enabling/Disabling a Parameter

When you disable a parameter, it will not be shown in the parameter bar. You cannot measure the parameter, it will not be calibrated and no built-in QC measurements will be done for it.

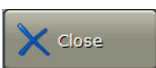
NOTE You cannot disable the pH, pO_2 or pCO_2 parameters.

-
- 1 Select **Menu > Utilities > Setup > General setup > Parameters and input > Parameters**.
-

- 2 Select the parameter.
-

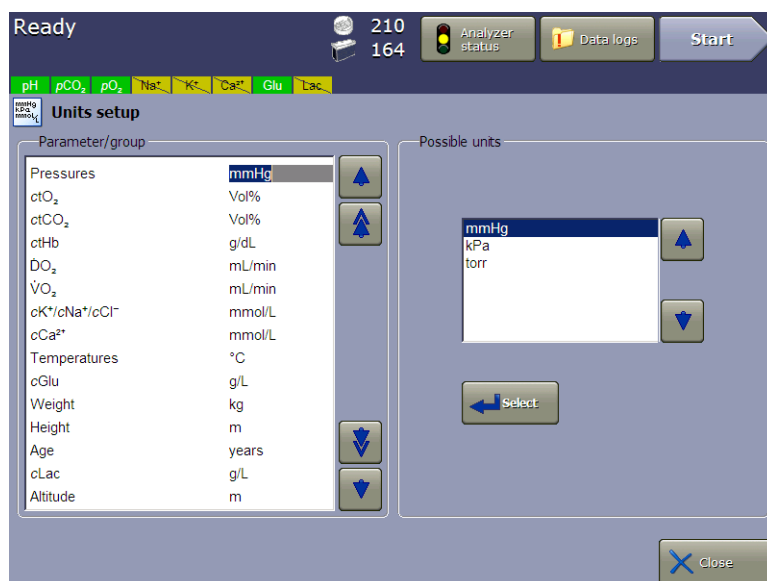
- 3 Select .
-

NOTE The first value in the **Enabled/locked** column must be Yes to enable the parameter, and No to disable it.

- 4 Select .
-

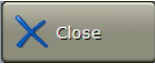
Setting Up Measuring Units for Parameters

- 1 Select **Menu > Utilities > Setup > General setup > Parameters and input > Units**. The Units screen appears.



- 2 Use the scroll buttons to select the field adjacent to the parameter.

- 3 In the **Possible units** frame, select the unit.

- 4 Select .

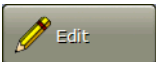
Repressing a Parameter

When you repress a parameter, no value will be given for the parameter in the results if an error occurred during the measurement.

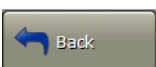
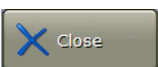
If an QC or calibration problem exists repressing a parameter will change the parameter tab to red and repress that parameter in subsequent results.

- 1 Select **Menu > Utilities > Setup > General setup > Parameters and input > Parameters**.

- 2 Select the parameter.

3 Select .

4 Select the **Repress parameter value in patient result in case of any problems** check button.

5 Select  > .

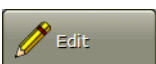
Suppressing Out-of-Range Results

Only out-of-range oximetry and ctBil parameters can be suppressed.

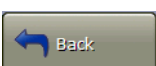
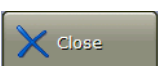
- Suppression causes oximetry results (excluding ctHb) that are within the range of indication and below zero to be shown as zero, and results that are within the range of indication and above 100% to be shown as 100%.
- Suppression of ctHb and ctBil results that are within the range of indication but below zero will be shown as zero.

1 Select **Menu > Utilities > Setup > General setup > Parameters and input > Parameters**.

2 Select the parameter.

3 Select .

4 Select the **Out of range suppression** check button.

5 Select  > .

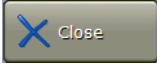
Fixing the Number of Decimals Used in Blood-Gas Results

The analyzer measures the blood gas parameters pO_2 and pCO_2 more precisely in the lower part than in the upper part of ranges. By default, results are shown with a different number of decimal points. For example, in the range 0-99.9 mmHg, $pO_2(T)$ results are shown with one decimal point and in the range 100-750 mmHg, with no decimal points (that is, in whole numbers).

This procedure can be used to make sure pO_2 and pCO_2 results are shown with the same number of decimal points in the whole reportable range.

1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**.

2 Select the **Fixed pO_2/pCO_2 decimals** check button.

3 Select .

Enabling HbF Corrections

Prerequisite — You know if the analyzer is to be used to analyze neonatal samples only, adult samples only, neonatal samples and adult samples or samples that contain hemoglobins that deviate from HbA hemoglobins.

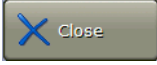
This procedure is necessary to make sure that ctBil, sO_2 , FO_2Hb , $FMetHb$, $FCOHb$ and $FHHb$ results are corrected for the presence of HbF in the sample.

1 Select **Menu > Utilities > Setup > General setup > Miscellaneous setup**.

2 In the **HbF correction** frame, choose an option and follow the steps for it.

Option	Steps
For neonatal samples	Select "Enabled for all levels"
For adult samples	Select "Enabled for levels > 20%"
For neonatal and adult samples	Select "Enabled for levels > 20%"
For adult samples that contain hemoglobins which deviate from HbA hemoglobins	Select "Disabled"

NOTE The "Enabled for all levels" setting will correct ctBil, sO_2 , FO_2Hb , $FMetHb$, $FCOHb$ and $FHHb$ results and show HbF values.

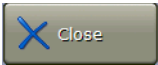
3 Select .

Enabling the Estimation of Derived Parameters

This procedure lets the analyzer replace missing measured values and/or keyed-in values with default values in order to estimate values for derived parameters. Estimated results are marked with the subscript e.

1 Select **Menu > Utilities > General setup > Miscellaneous setup**.

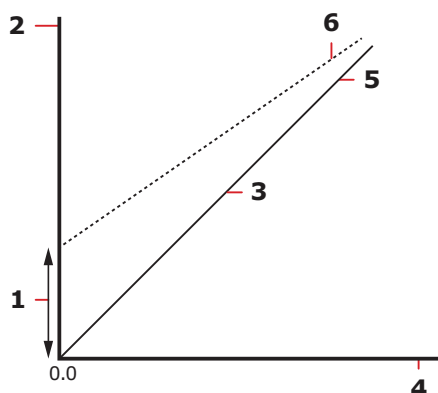
2 Select the **Enable estimated derived parameters** check button.

3 Select .

Editing the Slope and Offset of a Parameter

Operator-Defined Corrections (Offset and Slope)

Operator-defined corrections refer to corrections made to the offset and/or slope of parameters.



1. Offset
2. Shown values (y axis)
3. Slope = 1.0
4. Measured values (x axis)
5. Correction line without operator-defined corrections
6. Correction line with operator-defined corrections

The diagram shows the relation between correction lines with and without operator-defined corrections.

Operator-defined corrections are most commonly applied when the values measured for a parameter by two or more analyzers deviate consistently from each other.

Operator-defined corrections are based on a linear correlation between the measured values (without operator-defined corrections) and the shown values (with operator-defined corrections).

The correction factors for each measured parameter are the slope and the offset of the correction line. With operator-defined corrections it is possible to change the values of the slope and offset or only change the value of one of them. This depends on the parameter.

Corrected value = Slope × Uncorrected value + Offset

Before you enter corrections for a parameter, you must have the reference value for the parameter. Use a procedure accepted in your laboratory to get the reference value.

Here are the other prerequisites:

- Analyses must be done on the analyzer without the use of operator-defined corrections and on one reference analyzer
- Analyses must be done over the full measuring range
- Analyses must be done on the analyzer and on the reference analyzer at the same time, and the samples must be handled correctly
- The slope and the offset must be calculated. You may, for example, make a linear correlation between the values measured on the analyzer and the reference analyzer. The analyzer is then used as an independent variable.
- You must verify the corrections entered.

Recommendations About Samples to Use

Parameter	Sample description
ctHb	Use a SAT100 sample to approximately 15 g/dL (9.3 mmol/L) (which is the maximum uncorrected or corrected point) and pH is approximately 7.4
sO ₂	Set ctHb of gas equilibrated SAT0 and SAT100 sample to approximately 15 g/dL (9.3 mmol/L) and pH is approximately 7.4
FCOHb	The zero point (FCOHb approximately zero) is saturated to approximately SAT100, and ctHb is set to approximately 15 g/dL (9.3 mmol/L) and pH is approximately 7.4
FMetHb	The zero point (FCOHb approximately zero) is saturated to approximately SAT100, and ctHb is set to approximately 15 g/dL (9.3 mmol/L) and pH is approximately 7.4
FHbF	Beckman Coulter recommends that the ctHb in adult samples (with FHbF = 0) and fetal samples (with high FHbF) is set to approximately 15 g/dL (9.3 mmol/L), sO ₂ is approximately 100 % and pH is approximately 7.4
ctBil	Beckman Coulter recommends that human plasma or serum is used with pH = 7.4 (the analyzer reading). Zero point sample could be adult sample (ctBil)

Limits for Slope and Offset Values

The slope and offset value of some parameters can be changed to values that fall within the limits stated in the tables.

- For arterial, venous and a-v̄ samples:

Limits for pH and blood gases		
Parameter	Limits for the slope value	Limits for the offset value
pH	0.95-1.05 (pH unit)	±0.1 (pH unit)
$p\text{CO}_2$	0.95-1.05 kPa	±0.5 kPa
$p\text{O}_2$	0.95-1.05 KPa	±0.5 kPa

Limits for electrolyte parameters		
Parameter	Limits for the slope value (mmol/L)	Limits for the offset value (mmol/L)
cK^+	0.75-1.25	±0.3
cNa^+	0.85-1.15	±5
cCa^{2+}	0.8-1.2	±0.05
cCl^-	0.85-1.15	±5

Limits for metabolite parameters		
Parameter	Limits for the slope value (mmol/L)	Limits for the offset value (mmol/L)
cGlu	0.75-1.25	±0.5
cLac	0.75-1.25	±0.5

Limits for oximetry parameters		
Parameter	Limits for the slope value	Limits for the offset value
ctHb	0.95-1.05 mmol/L	±2 mmol/L
$s\text{O}_2$	0.9-1.1 (fraction)	±0.05 (fraction)
FCOHb	Cannot be changed	±0.05 (fraction)
FMetHb	Cannot be changed	±0.05 (fraction)
FO_2Hb	Cannot be changed	If measurements indicate that it is necessary to change the offset value for $s\text{O}_2$ and/or FCOHb and/or FMetHb , change it. Use the equation: $s\text{O}_2 \times (1 - \text{FCOHb} - \text{FMetHb})$ to calculate FO_2Hb concentrations.

Limits for oximetry parameters		
Parameter	Limits for the slope value	Limits for the offset value
FHHb	Cannot be changed	If measurements indicate that it is necessary to change the offset value for sO_2 and/or FCOHb and/or FMetHb, change it. Use the equation: $(1 - sO_2) \times (1 - FCOHb - FMetHb)$ to calculate FHHb concentrations.
FHbF NOTE Before samples are analyzed, "Enabled for all levels" must be selected for HbF correction in the Miscellaneous setup screen.	0.8-1.2 (fraction)	±0.2 (fraction)
ctBil	0.5-1.5 (μmol/L)	±100 (μmol/L)

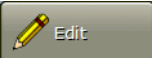
Editing the Offset and Slope for a Parameter

CAUTION

Risk of incorrect measurement results. Changes made to the offset and/or slope of parameters will have an effect on results and change some performance characteristics. If you do not want the changes to have an effect on QC results too, make sure the Apply parameter corrections to QC check button is deselected in the Miscellaneous setup screen.

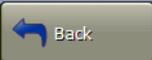
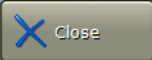
1 Select **Menu > Utilities > Setup > General setup > Parameters and input > Parameters**.

2 Select the parameter.

3 Select .

4 If necessary, enter a new value for **Correction offset**.

5 If necessary, enter a new value for **Correction slope**.

6 Select  **Back** >  **Close**.

Calibration Settings

Details About Calibration Frequency

By default the analyzer is set up to do automatic calibrations and built-in QC measurements at intervals that enable optimum use to be made of materials in the Solution Pack. The table provides details.

NOTE Automatic calibrations are also done when the Sensor Cassette or Solution Pack are replaced, in connection with maintenance and troubleshooting procedures and when the analyzer is restarted.

Calibration identifier (parameters)	Calibration	Calibration material	Default frequency	Default start time
Elec, pH (cK ⁺ , cNa ⁺ , cCa ²⁺ , cCl ⁻ , pH)	Sensitivity	CAL 1 solution CAL 2 solution	Once a day	08:00 hours
	Status	CAL 1 solution	Every measurement	N/A
BG, Met (pCO ₂ , cGlu, cLac)	Sensitivity	CAL 1 solution CAL 3 solution	Every 4 hours	02:00 hours
	Status	CAL 1 solution	Every measurement	N/A
BG (pO ₂)	Sensitivity	CAL 1 solution Ambient air	Once a day	16:00 hours
	Status	CAL 1 solution	Every measurement	N/A
Oxi (Oximetry parameters)	Sensitivity	CAL 1 solution ctHb calibration solution (S7770)	Every 3 months (recommended)	N/A
	Status	CAL 3 solution	• Every 4 hours • When temperature drift in the oximetry optical system is outside specified limits	N/A

NOTE The calibration identifier **BG, Met**, **Oxi** and **BG, Elec, Met, pH** are combinations of those listed in the table.

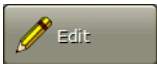
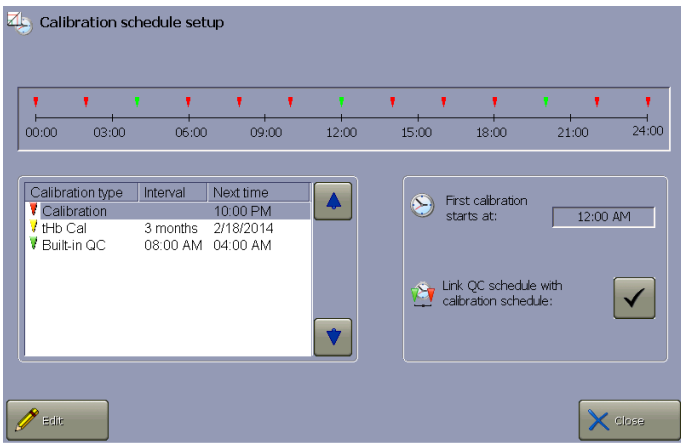
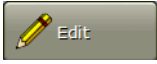
Editing the Calibration Schedule

NOTE Changes made to the default schedule may prevent optimum use of solutions in the Solution Pack. This is because the automatic calibrations and built-in QC measurements are scheduled by default to be done at times that let the analyzer make optimum use of the calibration and QC materials in the Solution Pack.

This procedure lets you change the default schedule for calibrations, (automatic calibrations) and tHb calibrations (sensitivity calibration of oximetry parameters, which is a manual calibration).

1 Select **Menu > Utilities > Setup > Calibration schedule.**

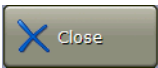
2 Choose an option and follow the steps for it.

Option	Steps
To change the start time for automatic calibrations	1. Select "Calibration" as the Calibration type. 2. Select . 3. Select a new Start time.  NOTE The schedule above shows both the default calibration schedule as well as the default start time for a number of specific system checks that are scheduled to start at 00:00 (24:00) hours. The change you make to the start time in this step will change the start time for both automatic calibrations and other system checks. For example, if the start time is changed from 00:00 to 02:00 hours, automatic calibrations will be delayed by 2 hours.
To change the start time for the next sensitivity calibration of tHb	1. Select "tHb Cal" as the Calibration type. 2. Select . 3. Select a Start time. 4. Select an Interval setting. NOTE The day the next calibration is scheduled = [current date] + [Interval setting].

Linking the Built-In QC Schedule to the Calibration Schedule

This procedure changes the current schedule for built-in QC measurements to the default schedule. This lets the analyzer make optimum use of the solutions in the Solution Pack.

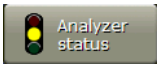
- 1 Select **Menu > Utilities > Setup > Calibration schedule**.
- 2 Select "Calibration" in the **Calibration type** field.
- 3 Select the **Link QC schedule with calibration schedule** check button.

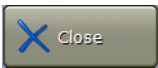
- 4 Select .

Setting Up Corrective Actions for Overdue Scheduled Calibrations

This procedure lets you select what the analyzer must do when scheduled calibrations are overdue.

- 1 Select **Menu > Utilities > Setup > General setup > Corrective actions**.
- 2 Select **Calibration schedule reminder(s)**.
- 3 Choose an option and follow the steps for it.

Option	Steps
To select the color of the traffic light signal on the Analyzer status button 	Select the Traffic light signal check button until it shows the color you want
To attach a message about the overdue scheduled calibration to results	Make sure the check button in the Corrective action(s) frame is selected

- 4 Select .

Maintenance Setup

Mandatory and Operator-Defined Activities

There are 2 types of maintenance activity:

- Mandatory – activities that must be done
- Operator-defined – activities that can be set up by operators

Mandatory Maintenance Activities

Other Activities

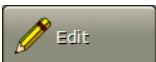
Other activities are mandatory replacement activities that are scheduled or can be scheduled to be run at regular intervals of time. For example, to clean the screen.

Other activities are shown in the **Other activities** part of the **Analyzer status** screen. When a scheduled activity is due, a reminder is shown in the **Analyzer status** screen.

Scheduling Other Activities

1 Select **Menu > Utilities > Setup > Replacement setup > Replacement schedule**.

2 Select the activity in the **Replacements** column.

3 Select  .

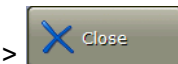
4 Select the frequency for the activity in the **Interval** field.

NOTE The first date for the scheduled activity is shown in the **Next date** field. The time is equal to the current date plus the number of days selected in the **Interval** field.

5 Choose an option and follow the steps for it.

Option	Steps
To change the first date for the scheduled activity	1. Select in the Next date field. 2. Enter a new date.
To accept the first date for the scheduled activity	Go to the next step.

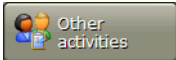
6 Select



Setting Up Corrective Action for Other Activities that are Overdue

Prerequisite — Other activities are scheduled.

Three corrective actions are available to show that scheduled **Other activities** are overdue.

- Select the color of traffic light shown on the left side of the  button in the **Analyzer status** screen.
- Attach a message about overdue scheduled activities to all results until the activities are successfully completed.
- Lock the analyzer when a scheduled activity is more than 10% overdue.

NOTE When the analyzer is locked, no samples can be analyzed until overdue scheduled activities are successfully completed.

For example: If an activity is scheduled to be done every 10 days and the activity is not done [10 days + (10% of 10 = 1) day] = 11 days after the activity was last done, the analyzer locks.

1 Select **Menu > Utilities > Setup > General setup > Corrective actions**.

2 Select the condition "Replacement schedule reminder(s)".

3 Choose the option you want and follow the steps for it.

Option	Steps
To change the traffic light color	Select the traffic light symbol until it shows the color you want.
To attach a message to subsequent results	Select the Message on next patient result check button.
To lock the analyzer when the activity is more than 10% overdue	Select the Lock analyzer when 10% overdue check button.

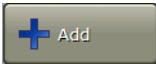
Operator-Defined Activities

Operator Activities

Operator activities are activities you can set up and schedule to be done at regular intervals of time. For example, to clean the touch screen and analyzer exterior. When a scheduled activity is due, a message is sent as a reminder to do the activity.

Setting Up an Operator Activity

1 Select **Menu > Utilities > Setup > Replacement setup > Operator activities**.

2 Select .

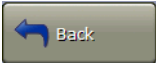
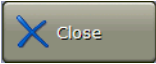
3 Enter a name for the activity.

4 Select the frequency for the activity in the **Interval** field.

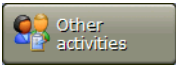
NOTE The first date for the scheduled activity is shown in the **Next date** field. The time is equal to the current date plus the number of days selected in the **Interval** field.

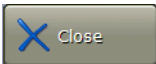
5 Choose an option and follow the steps for it.

Option	Steps
To change the first date for the scheduled activity	1. Select in the Next date field. 2. Enter a new date.
To accept the first date for the scheduled activity	Go to the next step.

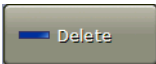
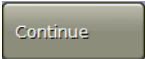
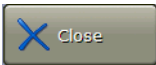
6 Select  > .

Setting Up Corrective Action for Pending Operator Activities

This procedure lets you set up the analyzer to change the color of the traffic light shown on the left side of the  button in the **Analyzer status** screen to remind operators about pending operator activities.

- 1 Select **Menu > Utilities > Setup > General setup > Corrective actions**.
- 2 Select the condition **Operator activity reminder(s)**.
- 3 Select the button with the traffic light symbol to select the color you want to show.
- 4 Select .

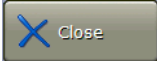
Deleting an Operator Activity

- 1 Select **Menu > Utilities > Setup > Replacement setup > Operator activities**.
- 2 Select the activity.
- 3 Select .
- 4 Select .
- 5 Select .

Maintenance Planning

Planning Maintenance Activities

This procedure lets you enter the periods of time that people who maintain the analyzer are available each day. The analyzer uses this information to send reminders about maintenance activities so they can be done when people who maintain the analyzer are available. This procedure can be used to decrease analyzer down time.

- 1 Select **Menu > Utilities > Setup > Replacement setup > Maintenance planning.**
- 2 Select the check button for the days that people who maintain the analyzer are available.
- 3 Enter the start and end time that people who maintain the analyzer are available.
- 4 Select .

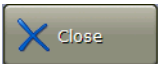
Replacement Warnings

Setting Up Replacement Warnings

Replacement warnings are messages that can be set up to tell operators that installed consumables (Solution Pack/Sensor Cassette) will soon have to be replaced. You can set up two conditions to cause a message to be sent.

- the number of remaining activities/tests falls below a selected value
- the number of hours that remain before a consumable expires falls below a selected value

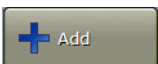
- 1 Select **Menu > Utilities > Setup > Replacement setup > Replacement warnings.**
- 2 Select a number in the **Expected measurements per day** field, so the analyzer can calculate the most probable replacement date.
- 3 Select a number in the **Number of tests before replacement warning** field.
- 4 Select a time period in the **Time before replacement warning** field.

-
- 5 Select .
-

Note Fields

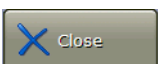
Creating Standard Texts for Use in Note Fields

-
- 1 Select **Menu > Utilities > Setup > General setup > Parameters and input > User-defined notes**.
-
- 2 Select the check button for the screen where you want standard text to be available for use in the **Note** field.
-

- 3 Select .
-

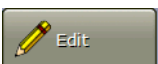
- 4 Enter the standard text.
-

- 5 Do steps 3 and 4 again for each standard text you want to add.
-

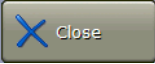
- 6 Select .
-

Editing Standard Texts for Use in Note Fields

-
- 1 Select **Menu > Utilities > Setup > General setup > Parameters and input > User-defined notes**
-
- 2 Select the note you want to edit.
-

- 3 Select .
-

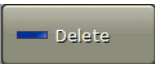
- 4 Edit the note.

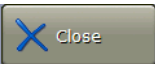
-
- 5 Select .
-

Deleting Standard Texts for Use in Note Fields

-
- 1 Select **Menu > Utilities > Setup > General setup > Paramters and input > User-defined notes.**
-

- 2 Select the note you want to delete.
-

- 3 Select .
-

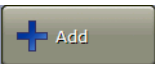
- 4 Select .
-

Communications

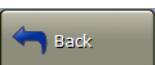
Setting up an LIS/HIS Connection

Prerequisite — Connection to a network.

-
- 1 Select **Menu > Utilities > Setup > General setup > Communications > LIS/HIS connection.**
-

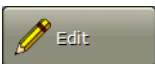
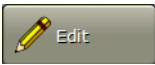
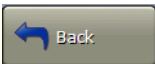
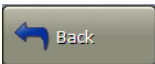
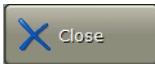
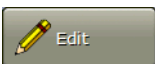
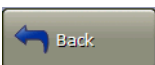
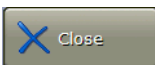
- 2 Select .
-

- 3 Enter a name for the connection.
-

- 4 Select .
-

- 5 Select the high-level protocol used by the LIS/HIS system.
-

6 Choose an option and follow the steps for it.

Option	Steps
To set up a serial low-level protocol	1. Select a serial setting. 2. Select . 3. Select . 4. If necessary, change the settings. 5. Select  >  > .
To set up a network low-level protocol	1. Select a network setting. 2. Select . 3. If necessary, change the settings. 4. Select  > .

Setting Up an AQUIRE/RADIANCE Connection

IMPORTANT AQUIRE/RADIANCE is not supported by Beckman Coulter. [Contact us](#) for more information.

Data from a LIS/HIS System

Data can be downloaded to the analyzer from a connected LIS/HIS system.

You can set up the analyzer to request data automatically from the system, or let operators request data manually. There are 2 options for manual requests:

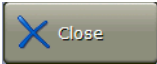
- Fill in the **Accession number**, **Patient ID** or **Sampler ID** field in the **Patient identification** screen and request the data.
- Fill in the **Patient department** field in the **Patient identification** screen, lookup, find and request the data.

NOTE To use this option, you must enable patient lookup.

Setting Up Automatic Requests for Data

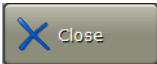
Prerequisite — A connection is set up to the LIS/HIS system that data is to be requested from.

1 Select **Menu > Utilities > Setup > General setup > Communications > Automatic data request**.

- 2 Select the connection to the system that data is to be requested from.
- 3 In the **Request patient demographics** frame, select the check button for the data field in the **Patient identification** screen that when filled in will automatically request data from the system.
NOTE It is possible to select more than one check button, but Beckman Coulter recommends that you only select one.
- 4 Select .

Setting Up Automatic Transmission of Data to a System

Prerequisite — A connection is set up to the LIS/HIS system that data is to be sent to.

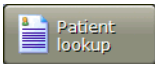
- 1 Select **Menu > Utilities > Setup > General setup > Communications > Automatic data transmission**.
- 2 Select the name of the connection.
- 3 Select the check buttons for the data to be automatically sent.
- 4 Do steps 2 and 3 again for each system that you want to transmit data to.
- 5 Select .

Enabling Manual Data Requests Using Patient Lookup

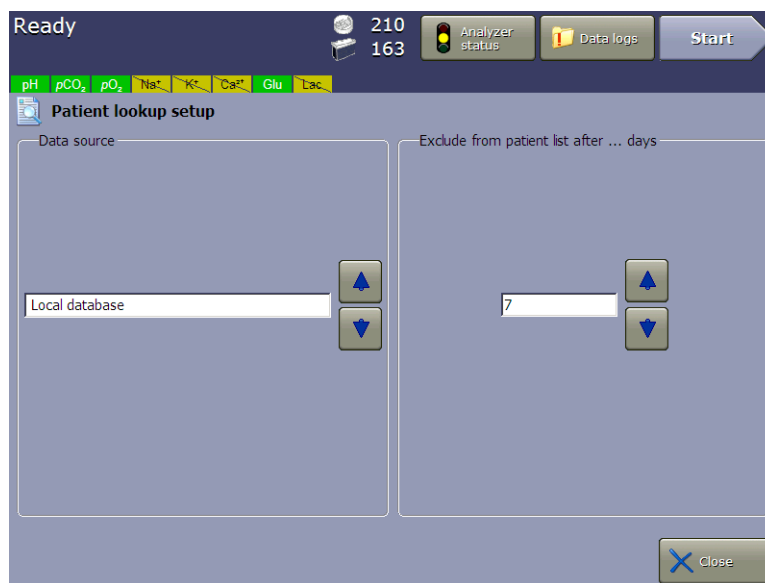
Prerequisites:

- If data is to be requested from an LIS/HIS system, a connection must be set up to the system
- The selected **Patient report** contains the **Department (Pat.)** field

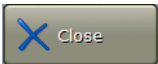
Data can be requested from the analyzer database, a connected LIS/HIS system.

This procedure lets operators request data manually, via  after they have filled in the **Department (Pat.)** field of the **Patient identification** screen.

- 1 Select **Menu > Utilities > Setup > General setup > Communications > Patient lookup setup**. The Patient lookup setup screen appears.



- 2 Select the name of the connection.
- 3 Select the number of days after data is saved in the **Patient profiles log** that it must be available for use. The default is 7 days.

- 4 Select .

Accessing the RADIANCE System from the Analyzer

IMPORTANT RADIANCE is not supported by Beckman Coulter. [Contact us](#) for more information.

Setting Up a QA Portal Connection

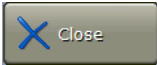
- 1 Select **Menu > Utilities > Setup > General setup > Communications > QA Portal connection**.

2 Enter the TCP/IP address of the QA Portal server the analyzer is connected to.

3 Enter the number of the QA Portal server port the analyzer is connected to.

4 Select the **Communicate with QA Portal** check button.

NOTE The **Connection status** frame shows whether or not there is a connection.

5 Select .

Printers

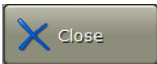
Setting Up Automatic Printing

1 Select **Menu > Utilities > Setup > General setup > Printers > Automatic printing**.

2 Select the check buttons for the data you want to be printed automatically.

NOTE If you select the **QC results** check button, built-in and ampoule-based QC measurement results will be printed.

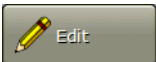
3 Select the number of copies of results that must be printed.

4 Select .

Installing an External Printer for the Analyzer

1 Select **Menu > Utilities > Setup > General setup > Printers > Printer setup**.

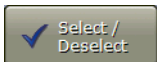
2 Select  and follow the instructions shown on the screen.

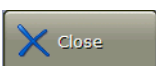
3 If necessary, select  and enter the new name.

4 Do step 2 and 3 again for each printer you want to install.

NOTE Beckman Coulter recommends that a maximum of 10 printers are installed.

5 Choose an option and follow the steps for it.

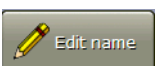
Option	Steps
To print data on the same printers each time	1. Select the printer. 2. Select . 3. Make sure a check mark is shown adjacent to the printer name. 4. Do steps a) to c) again for each printer.
To get a list of the installed printers before you print data	Select the check button in the Manual printing frame.
To print data on all installed printers	Make sure that the check button in the Manual printing frame is deselected.

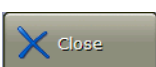
6 Select .

Editing the Name of a Printer

1 Select **Menu > Utilities > Setup > General setup > Printers > Printer setup**.

2 Select the printer.

3 Select , and enter the new name.

4 Select .

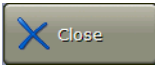
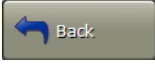
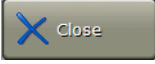
Data Logs and Archives

The analyzer can be set up to automatically save data logs to archives on the analyzer or on an external device. Data is moved to the archives when the data logs are full.

You can export data logs and archived data logs manually and save them on an external device. You can also import archives from other MetaFLEX analyzers.

Setting Up Automatic Archiving

- 1 Select **Menu > Utilities > Setup > General setup > Disk functions setup > Automatic archiving**.
- 2 Select the check buttons for the data logs that you want to be archived.
- 3 Choose an option and follow the steps for it:

Option	Steps
To archive the data logs on the analyzer	1. Select the Store archives on the analyzer check button. 2. Select . NOTE The data is saved on the D: drive.
To archive the data logs to a different destination	1. Deselect the Store archives on the analyzer check button. 2. Select an external drive. 3. Select the button with the folder icon. 4. Select the folder where the data logs must be archived. 5. Select  > .

File Format of Exported Data Logs and Archived Data Logs

Data logs can be exported as compressed Comma Separated Value (CSV) files. The CSV files can be read by database and spreadsheet programs. For example: Microsoft Excel, Access and Lotus 1-2-3.

However, archived data logs can also be exported as .bin files. The .bin files are encrypted. If you want to read them, you must import them to the analyzer.

Exporting Data Logs

This procedure lets you export one or more data log from the analyzer in .csv format.

NOTE Data logs are not removed from the analyzer during this procedure. The exported data logs are only copies.

- 1

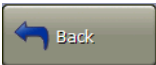
Make sure that there is a connection between the analyzer and the device to which the logs are to be exported.
- 2

Select **Menu > Utilities > Disk functions > Export data logs.**
- 3

Deselect the check buttons for the data logs that you do not want to export.
- 4

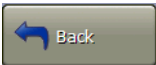
Select the button with the calendar icon in the **Date interval** frame.
- 5

Enter a date in the **From:** and **To:** fields.
- 6

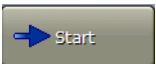
Select .
- 7

Select the check button on the right side of the **Directory:** field.
- 8

Select the folder on the external drive you want to export the data logs to.
- 9

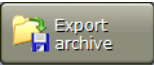
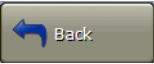
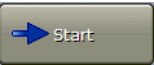
Select .
- 10

Select .
- 11

Select .

Exporting Data from Archived Data Logs

This procedure lets you export part of an archived data log from the analyzer in .csv format.

- 1 Make sure that there is a connection between the analyzer and the device to which the archive is to be exported.
- 2 Select **Menu > Data logs > Archived data logs**.
- 3 Select the archive type.
- 4 Select a date interval.
- 5 Select .
- 6 Select the folder on the external drive that you want to export the archived data log to.
- 7 Select .
- 8 Select .

Creating Disc Space by Exporting and Deleting Archives

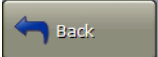
This procedure lets you export archives to an external system and then delete them from the analyzer database to create space. The files are moved in .bin format. They cannot be read by database or spreadsheet programs. They must be imported to the analyzer to be read.

- 1 Make sure that there is a connection between the analyzer and the device to which the archive parts are to be exported.
- 2 Select **Menu > Utilities > Disk functions > Import / Export archives**.
- 3 Select the archive type.

4 Select an archive.

5 Select the button with the folder icon in the **Source/Destination:** frame.

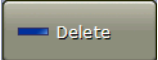
6 Select the folder to export the archive to.

7 Select .

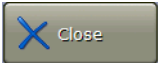
8 Select .

9 In the **Archives stored on analyzer:** frame:

a. Select the archive that you selected in step 4 and have just exported.

b. Select .

10 Do steps 3 to 9 again for each archive you want to export and delete.

11 Select .

Importing Archived Data Logs

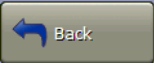
1 Make sure that there is a connection between the analyzer and the device that contains the archives.

2 Select **Menu > Utilities > Disk functions > Import / Export archives.**

3 Select the archive type.

4 Select the button with the folder icon in the **Source/destination** frame.

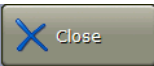
5 Select the folder that contains the archives you want to import.

6 Select  .

7 Select one of the archives in the **Source/destination** frame.

8 Select **Import**.

9 If necessary, do steps 7 and 8 again.

10 Select  .

Data Backup and Restoration

Backup

A backup includes all data logs and system files. Backup can be set up to be done automatically. The backup can also be done manually.

If data is lost or damaged, the backup will restore most of the data and keep data loss to a minimum.

NOTE The customer must make sure that a backup is done regularly.

Destinations for Backup Data

A backup can be saved to these destinations.

- A USB flash drive
- An external CD drive
- A folder on an external network drive

Scheduling Automatic Backups

1 Create a folder for the backup on the device on which the backup is to be saved.

2 Make sure that there is a connection between the analyzer and the device.

3 Select **Menu > Utilities > Setup > General setup > Disk functions setup > Automatic backup.**

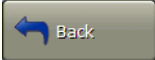
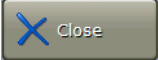
4 Select the **Automatic backup of all data- and system files** check button.

5 Enter the time.

6 Enter the number of days between subsequent backups.

7 Select the button with the folder icon.

8 Select the folder where the backup is to be saved.

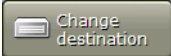
9 Select  Back > .

Performing a Manual Backup

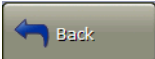
1 Create a folder for the backup on the device on which the backup is to be saved.

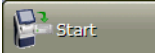
2 Make sure that there is a connection between the analyzer and the device.

3 Select **Menu > Utilities > Disk functions > Backup all data.**

4 Select .

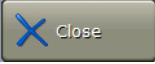
5 Select the folder where the backup is to be saved.

6 Select .

7 Select .

-
- 8 Look at the screen. A message will tell you when the backup is done.

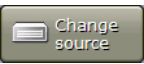
NOTE A message is shown on the screen if the backup cannot be done.

- 9 Select .
-

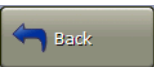
Restoring Data from a Backup

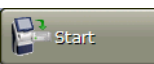
- 1 Make sure that there is a connection between the analyzer and the device that contains the backup.
-

- 2 Select **Menu > Utilities > Disk functions > Restore all data.**
-

- 3 Select .
-

- 4 Select the folder that contains the backup.
-

- 5 Select .
-

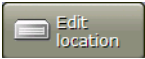
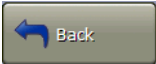
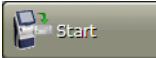
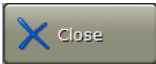
- 6 Select .
-

NOTE When data is restored, the analyzer shuts down and restarts.

Saving and Loading Setups

Saving the Setup

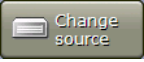
- 1 Create a folder for the setup on the device on which the setup is to be saved.

- 2 Make sure that there is a connection between the analyzer and the device on which the setup is to be saved.
- 3 Select **Menu > Utilities > Disk functions > Save setup.**
- 4 Select .
- 5 Select the folder where the setup is to be saved.
- 6 Select .
- 7 Select .
- 8 Wait until a message tells you that the setup is saved.
- 9 Select .

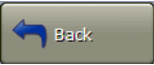
Loading a Setup

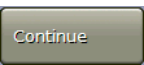
- 1 Make sure that there is a connection between the analyzer and the device from which the setup is to be loaded.
- 2 Select **Menu > Utilities > Disk functions > Load setup.**
- 3 Choose an option and follow the steps for it.

Option+	Steps
To load all parts of the setup	Select the All check box.
To load one or more parts of the setup	1. Deselect the All check box. 2. Select the check boxes of the setups you want to load.

4 Select .

5 Select the folder from which the setup is to be loaded.

6 Select .

7 Select .

NOTE The analyzer will shut down and restart with the new setup.

Beckman Coulter Default Settings

Operators and Profiles - Default Settings

Item	Default setting
Operators	Beckman Coulter, Remote operator, Manager
Access profiles	Service engineer, Remote operator, Manager
Logoff time	3 minutes
Anonymous access enabled	Yes
Access profile for anonymous operator	User
Authenticate operator by	Logon-barcode as primary

Access profile	Access to activities												
	A	B	C	D	E	F	G	H	I	J	K	L	M
Operator	X	X	X	X	X		X	X	X	X	X	X	X
Supervisor	X	X	X	X	X	X	X	X	X	X	X	X	X
Manager	X	X	X	X	X	X	X	X	X	X	X	X	X
Service technician	X	X	X	X	X	X	X	X	X	X	X	X	X
Guest	X		X					X		X	X	X	X
Custom 1			X							X	X	X	X
Custom 2			X							X	X	X	X

Access profile	Access to activities												
	A	B	C	D	E	F	G	H	I	J	K	L	M
Custom 3			X							X	X	X	X
Remote operator	X	X	X	X	X		X	X	X	X	X	X	X

Activity	Description
A	Perform measurements
B	Perform calibrations
C	Perform operator Activities
D	Edit data in logs
E	Perform built-in QC
F	Approve results
G	Replace the Sensor Cassette
H	Clean the Inlet Gasket
I	Replace the Inlet Gasket Holder
J	Replace the Solution Pack
K	Replace the Inlet Connector Gasket
L	Flush the analyzer
M	Replace the Inlet Probe

Alarm Sound (Acoustic Signal) Settings for Events - Default Settings

Event	Default setting
Value exceeds critical range	No
Close inlet	Yes
Result is ready	Yes
Inlet is open too long	Yes

Language - Default Setting

Item	Default setting
Screen language	English

Analysis Setup – Default Settings

Analysis setup	Default setting	
Syringe sample modes	Syringe - S 65 µL NOTE All user-defined modes are removed.	
Capillary sample modes	C 65 µL NOTE All user-defined modes are removed.	
Parameter profiles	All parameters are selected. Use dynamic parameters is off.	
Sample pre-registration setup	- Interpret barcode input as: Sampler ID - Included fields: Sampler ID, Patient first name, Patient last name, Birth date, Patient sex, Accession no?	
Sample age evaluation setup	Enable calculation of sample age: Yes (30 minutes for all parameters)	
Patient report setup	- Layouts: -R- Default - Patient ID layout settings included in the -R- Default layout: — Patient ID — Patient last name — Patient first name — Sample type (Not specified) — Temperature (T), 37.0 °C - Patient result settings included in the -R- Default layout (bold text = a new title; [xxx - xxx] = the reference range for a parameter)	
	Blood gas values	
	pH	[xxx - xxx]
	pCO ₂	[xxx - xxx]
	pO ₂	[xxx - xxx]
	<New line>	
	Oximetry values	
	ctHb	[xxx - xxx]
	sO ₂	[xxx - xxx]
	FO ₂ Hb	[xxx - xxx]
	FCOHb	[xxx - xxx]
	FHHb	[xxx - xxx]
	FMetHb	[xxx - xxx]
	FHbF	[xxx - xxx]
	<New line>	

Analysis setup	Default setting	
	Electrolyte values	
	cK ⁺	[xxx - xxx]
	cNa ⁺	[xxx - xxx]
	cCa ²⁺	[xxx - xxx]
	cCl ⁻	[xxx - xxx]
	<New line>	
	Metabolite values	
	cGlu	[xxx - xxx]
	cLac	[xxx - xxx]
	ctBil	[xxx - xxx]
	<New page>	
	Temperature-corrected values	
	pH(T)	
	pCO ₂ (T)	
	pO ₂ (T)	
	<New group>	
	Oxygen status	
	ctO ₂	
	p50	
	<New line>	
	Acid-base status	
	cBase(Ecf)	
	cHCO ₃ ⁻ (P,st)	

Parameters - Default Settings

The user-defined settings for **Enabled** and **Locked** are saved as the default settings. No parameter is repressed by default.

Measured parameters	Units	Offset	Slope	Out-of-range suppression
pH	N/A	0.000	1.000	N/A
pCO ₂	mmHg	0.0	1.000	N/A
pO ₂	mmHg	0.0	1.000	N/A
ctHb	g/dL	N/A	1.000	No
sO ₂	%	0.0	1.000	No

Measured parameters	Units	Offset	Slope	Out-of-range suppression
FO ₂ Hb	%	N/A	N/A	No
FCOHb	%	0.0	N/A	No
FMetHb	%	0.0	N/A	No
FHHb	%	N/A	N/A	No
FHbF	%	0	1.000	Yes
cK ⁺	mmol/L	0.0	1.000	N/A
cNa ⁺	mmol/L	0	1.000	N/A
cCa ²⁺	mmol/L	0.00	1.000	N/A
cCl ⁻	mmol/L	0	1.000	N/A
cGlu	mmol/L	0.0	1.000	N/A
cLac	mmol/L	0.0	1.000	N/A
ctBil	μmol/L	0	1.000	N/A

Measurement Units - Default Settings

Items	Default setting
Pressure	mmHg
ctBil	μmol/L
ctHb	g/dL
FCOHb	%
FHbF	%
FHHb	%
FMetHb	%
FO ₂ Hb	%
sO ₂	%
Gas fractions	%
FO ₂ (I)	%
Hct	%
pO ₂ (a,A)	%
FShunt	%
RI	%
cK ⁺ /cNa ⁺ / cCl ⁻	mmol/L
cCa ²⁺	mmol/L
cGlu	g/L

Items	Default setting
cLac	g/L
Temperature	°C
ctO ₂	Vol%
ctCO ₂	Vol%
DO ₂	mL/min
VO ₂	mL/min
Age	years
Weight	kg
Height	m
Altitude	m
Birth weight	g

Calibration Schedule - Default Settings

Calibration schedule setup	Default setting
tHb calibration	Interval: 3 months
First calibration starts at:	00:00
Link QC schedule with calibration schedule:	Yes

Quality Control Setups - Default Settings

Setups	Item	Default setting
QC statistics	Statistical factor used for value acceptance:	1.5
	Automatically print QC statistics when lot changes:	Yes
QC input setup	Mandatory temperature:	No
	Default temperature:	25 °C
QC schedule	Built-in QC solutions (S9030, S9040, S9050)	04:00, 12:00, 20:00 (daily)
	Run built-in QCs after replacement and startup	Yes
Westgard rules	Use Westgard Evaluation:	No
RiLiBÄK rules	Use RiLiBÄK rules	No

Replacement Setups - Default Settings

Menu	Item	Default setting - interval
Replacement schedule setup	Inlet Gasket	Never
	Inlet Probe	Never
	Connection gasket	Never
	Clean inlet	Never
Operator activity schedule	None	–
Maintenance planning setup	None	–
Replacement warning setup	Number of activities before replacement warning:	5
	Time before replacement warning:	4 hours
	Expected measurements per day:	10

NOTE A dash (-) indicates there is no default setting.

Communication Setup - Default Settings

Item	Default settings
RADIANCE connection	Not enabled
LIS/HIS connection	-
QA portal	Not enabled
Automatic data request	-
Automatic data transmission	-
Patient lookup setup	On the D:\ drive of the analyzer (local database)
Remote support	Enable remote access: Yes

NOTE A dash (-) indicates there is no default setting.

User-Defined Data Items - Default Settings

NOTE All items have numerical values.

Item	Unit	Number of decimals
Spontaneous RR	b/min	1
Set RR	b/min	2
Vt	L	2
Ve	L	2
Peak flow	L/min	1
Liter flow	L/min	2
Ti	seconds	1
PEEP	cmH ₂ O	1
Pressure support	cmH ₂ O	1
CPAP	cmH ₂ O	1
CMV	Rate	1
SIMV	Rate	1
Flow-by	L/min	1
HFV	Rate	1
I:E ratio	–	2
Wave	–	–
ICD9 code	–	–
Oxygen device 1	–	–
Oxygen device 2	–	–
Diagnostic code	–	–

NOTE – = There is no default setting.

Corrective Actions – Default Settings

Event	Default setting	Traffic light color
Calibration error(s) present	Do not run scheduled built-in QC	Yellow
Calibration schedule reminder(s)	–	Yellow
QC error(s) present	? on specific parameters	Yellow
QC schedule reminder(s)	–	Yellow
Replacement schedule reminder(s)	–	Yellow
System message(s) present	–	Yellow
Operator activity reminder(s)	–	Yellow
Built-in QC error(s) present	–	Yellow

NOTE – = There is no default setting.

Miscellaneous Setup - Default Settings

Item	Default setting
Analyzer locked	Not enabled
Enable estimated derived parameters	Not enabled
Fixed pO_2/pCO_2 decimals	Not enabled
Enable general barcode support	Enabled
Enable result approval	Not enabled
Apply parameter corrections to QC	Enabled
Log all measurement activities	Not enabled
Auto temp unit conversion	Not enabled
Enable screen saver	Enabled
Show parameter bar	Enabled
HbF correction	Enabled for levels > 20%
Analyzer message	–
Enable screen saver (the time period the analyzer must not be in use before the screen saver is shown)	5 minutes

Printer Setup - Default Settings

Item	Default setting
Installed printers	The analyzer printer
Manual printing (to see and select a printer from a list of the installed printers)	Off

Automatic Printing - Default Settings

Item	Default settings
Patient results	On
QC results	Off
Calibration results	Off
Activity log messages	Off
Message level	User
Number of copies (to print)	1

Automatic Archiving - Default Settings

Item	Default setting
Patient results log	On
Calibration log	On
Quality control log	On
Activity log	On
Store archives on the analyzer	On

Automatic Backup - Default Setting

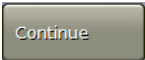
Item	Default setting
Automatic backup	Off

Restoring Beckman Coulter Default Settings

1 Select **Menu > Utilities > Disk functions > Restore default setup.**

2 Choose an option and follow the steps for it.

Option	Steps
To restore all default settings	Select the All check box.
To restore one or more default settings	1. Deselect the All check box. 2. Select the check boxes of the default settings you want to restore.

3 Select .

NOTE The analyzer will shut down and restart with the new setup.

Setups Without Default Settings

- User-defined notes
- Barometer setup
- Time and date setup
- Analyzer identification setup

Setup

Beckman Coulter Default Settings

CHAPTER 9

Troubleshooting

Overview

IMPORTANT In addition to the information stated, never disassemble the instrument or have it repaired by unauthorized personnel. Beckman Coulter bears no responsibility for any problems arising from the unauthorized repair of the instrument.

This chapter introduces solutions to common problems. If there is a problem, follow the information in this chapter to carry out self inspection. If the problem can not be resolved, [contact us](#).

This chapter contains information on:

- [Precautions/Hazards](#)
- [Hazard Labels and Locations](#)
- [RoHS Notice](#)
- [Disposal Precaution](#)
- [Troubleshooting - When is it Necessary?](#)
- [About Guided Troubleshooting](#)
- [Exiting the Operator Action Needed Mode](#)
- [Exiting the Troubleshooting Needed Mode](#)
- [Exiting the Intervention Required Mode](#)
- [Troubleshooting Modes - Causes](#)
- [Finding and Troubleshooting Messages in the Analyzer Status Screen](#)
- [Operator Actions Requested in Analyzer Messages](#)
- [Basic Troubleshooting](#)
- [Troubleshooting Analyzer Messages](#)
- [Activity Log](#)
- [Analyzer Service](#)

Precautions/Hazards

Laser Related Hazards

 WARNING

Risk of personal injury. The laser beam can cause eye damage if viewed either directly or indirectly from reflective surfaces (such as a mirror or shiny metallic surfaces). To prevent eye damage, avoid direct exposure to the laser beam. Do not view it directly or with optical instruments. This product uses a Class I laser to read the bar codes of the samples. This product complies with 21CFR subchapter J, section 1040.12 and IEC 60825-1.

The Vi-CELL MetaFLEX contains a Class 1 laser scan engine. The Vi-CELL MetaFLEX is rated as a Class 1 Laser Product according to IEC 60825-1. The laser scanner is located underneath the display.

Beckman Coulter design and manufacture of the instrument complies with the requirements governing the use and application of a laser specified in regulatory documents issued by the:

- U.S. Department of Health and Human Services
- Center for Devices and Radiological Health (CDRH)
- International Electrotechnical Commission (IEC)

In compliance with these regulatory documents, every measure has been taken to ensure the health and safety of users and laboratory personnel from the possible dangers of laser use.

Use the instrument according to the information in the manuals.

Use controls or adjustments or performance of procedures other than those specified herein might result in hazardous radiation exposure.

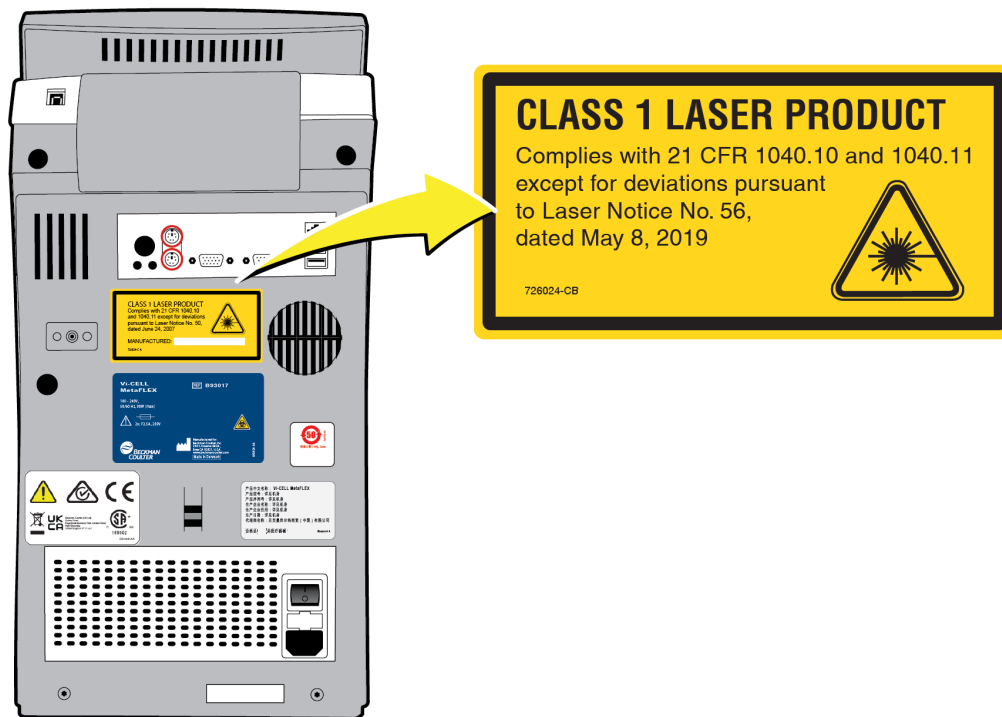
To ensure your safety, the Analyzer lasers are covered with protective shields. Do not remove these shields.

No user-servicable assemblies are accessible. Do not attempt to remove the laser or open it. The instrument has components that are dangerous to the operator. If any attempt has been made to defeat a safety feature, or if the instrument fails to perform as described in its manuals, disconnect the power and contact your Beckman Coulter Representative.

Laser Warning Labels

Refer to [Figure 9.1](#) for the labels and their locations on the Vi-CELL MetaFLEX instrument.

Figure 9.1 Laser Warning and Certification Label



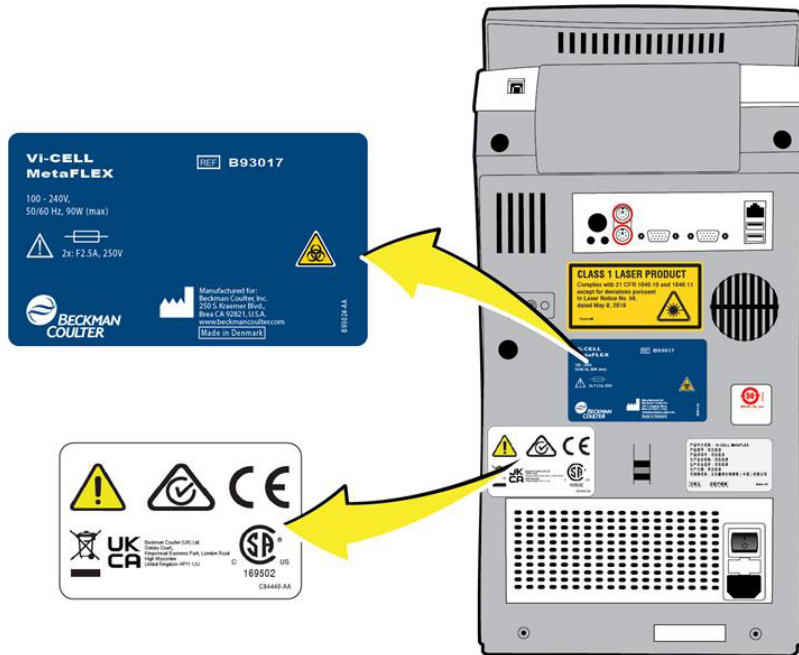
Hazard Labels and Locations

Carefully read the hazard warning labels on the instrument. The hazard labels are located on the instrument as indicated.

NOTE If a label is missing or unclear, contact your Beckman Coulter Representative.

Biohazard and Caution Labels

Figure 9.2 Biohazard and Caution Labels on the Rear Cover



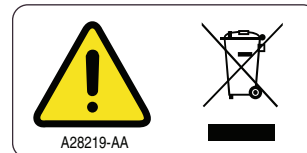
Disposal Of Electrical Instrumentation

It is very important that customers understand and follow all laws regarding the safe and proper disposal of electrical instrumentation.

The symbol of a crossed-out wheeled bin on the product is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates:

- that the device was put on the European Market after August 13, 2005 and
- that the device is not to be disposed via the municipal waste collection system of any member state of the European Union.

For products under the requirement of WEEE directive, please contact your dealer or local Beckman Coulter office for the proper decontamination information and take back program which will facilitate the proper collection, treatment, recovery, recycling, and safe disposal of device.



RoHS Notice

These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) are to meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 "Marking for Control of Pollution Caused by Electronic Information Products" requirements.

RoHS Caution Label

This label indicates that this electronic information product contains certain toxic or hazardous substances. The center number is the Environmentally friendly Use Period (EFUP) date, and indicates the number of calendar years the product can be in operation. Upon the expiration of the EFUP, the product must be recycled. The circling arrows indicate the product is recyclable. The date code on the label or product indicates the date of manufacture.



RoHS Environmental Label

This label indicates that the electronic information product does not contain any toxic or hazardous substances. The center "e" indicates the product is environmentally safe and does not have an Environmentally Friendly Use Period (EFUP) date. Therefore, it can safely be used indefinitely. The circling arrows indicate the product is recyclable. The date code on the label or product indicates the date of manufacture.



Disposal Precaution



Risk of biohazardous contamination if you have skin contact with the Solution Pack and its contents. The Solution Pack could contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the Solution Pack in accordance with your local regulations and acceptable laboratory procedures.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Disposing of the Analyzer

To dispose of the analyzer, [contact us](#).

Troubleshooting - When is it Necessary?

Troubleshooting is necessary when the analyzer goes into a **Operator Action Needed**, **Troubleshooting needed** or **Intervention Required** mode. It may also be necessary to troubleshoot messages in the **Analyzer status** screen.

About Guided Troubleshooting

In the troubleshooting modes, **Troubleshooting needed** and **Operator Action Needed** modes, text and video instructions guide you through each troubleshooting procedure and show you what to do to get out of the troubleshooting mode.

After each troubleshooting procedure, the analyzer makes checks to find out if the issue has been resolved. If not, a new troubleshooting procedure is shown on the screen. If the guided troubleshooting procedures do not resolve the issue, the analyzer will go into the **Intervention Required**.

Troubleshooting Modes - Causes

Troubleshooting mode	Possible causes
Operator Action Needed	A consumable must be replaced
Troubleshooting needed	Fluid transport errors were found
Intervention Required	- If the troubleshooting procedures in the Troubleshooting needed mode did not resolve the issue - All other possible errors

Exiting the Operator Action Needed Mode

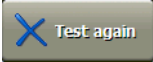
Follow the text and video instructions on the screen.

Exiting the Troubleshooting Needed Mode

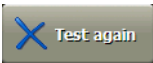
Follow the text and video instructions on the screen.

Exiting the Intervention Required Mode

1 Do the first action shown in the **Suggested actions** frame.

2 Select .

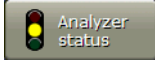
3 If the analyzer does not go out of **Intervention Required** mode, do the next action.

4 Select .

5 If the analyzer does not go out of **Intervention Required** mode, do steps 3 and 4 again.

6 If none of the actions cause the analyzer to go out of **Intervention Required** mode, [Contact us](#).

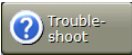
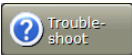
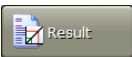
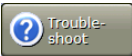
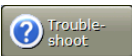
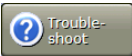
Finding and Troubleshooting Messages in the Analyzer Status Screen

Prerequisite: — The traffic light in the  button is yellow or red.

1 Select **Menu > Analyzer status**.

2 Select the button adjacent to a yellow or red traffic light.

3 Choose an option and follow the steps for it.

Option	Steps
To troubleshoot a Recommended action	Follow the instructions on the screen
To troubleshoot Quality control messages	To troubleshoot errors in the Built-in QC and Ampoule-based QC fields: 1. Select the quality control measurement marked by a ,  or  symbol. 2. Select . 3. Select . 4. Select the message. 5. Select . 6. Follow the instructions on the screen. To troubleshoot messages in the QC Messages field: 1. Select the message. 2. Select . 3. Follow the instructions on the screen.
To troubleshoot Calibrations messages	To troubleshoot calibrations marked by a ,  or  symbol. 1. Select the marked calibration. 2. Select . 3. Select . 4. Select the message. 5. Select . 6. Follow the instructions on the screen. To troubleshoot messages in the Message field: 1. Select the message. 2. Select . 3. Follow the instructions on the screen.
To troubleshoot Consumables or System messages	1. Select the message. 2. Select . 3. Follow the instructions on the screen.

Operator Actions Requested in Analyzer Messages

Requesting a Tubing Refill

Select **Menu > Start programs > Auxiliary programs > Tubing refill**.

Requesting a Liquid Sensor Adjustment

Select **Menu > Start programs > Auxiliary programs > Liquid sensor adjust** to measure and adjust the settings of the liquid sensors.

Requesting a Pump Calibration

Select **Menu > Start programs > Auxiliary programs > Pump calibration** to ensure that the pumps in the analyzer are operating correctly.

Requesting a Rinse

Select **Menu > Start programs > Auxiliary programs > Rinse** to start a rinse process. A rinse is also done after all measurement activities.

Basic Troubleshooting

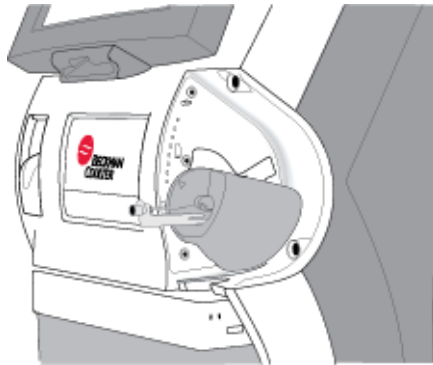
IMPORTANT This section covers basic troubleshooting for the Vi-CELL MetaFLEX instrument. For additional troubleshooting, refer to the Vi-CELL MetaFLEX Bioanalyzer Instruction for Use manual.

Fluid Transport Error

Probable Cause

- Air introduced with the sample
- Inhomogeneous solution
- Unable to pump solution
- Leak detected
- Cal backlog error

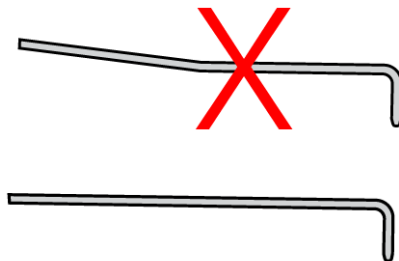
1 Clean the inlet.



Start the video guidance and follow the instructions on the screen.

OR

- a. Select **Analyzer status > Other activities > Inlet check**. The Inlet cleaning screen appears.
- b. Start the guided action.
- c. Check if the probe is bent. If bent, replace it.



- d. Dampen a lint-free tissue with tap water.
 - e. Remove any deposits from the inlet gasket.
 - f. Check the position of the inlet gasket in the Inlet Gasket Holder.
 - g. Select **Action Completed**.
 - h. Select **Test again**.
 - i. Perform a calibration and/or QC, if necessary.
- If the problem persists, proceed to Step 2.

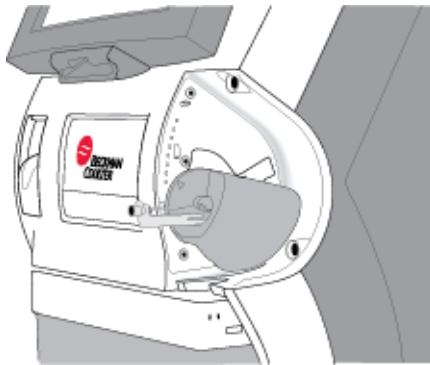
2 Replace Inlet Gasket Holder and Connector Gasket.

Start the video guidance and follow the instructions on the screen.

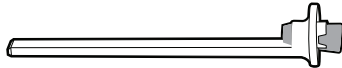
OR

- a. Select **Analyzer status > Other activities > Inlet check**. The Inlet replacement screen appears.

- b. Lift the inlet handle to the capillary position.

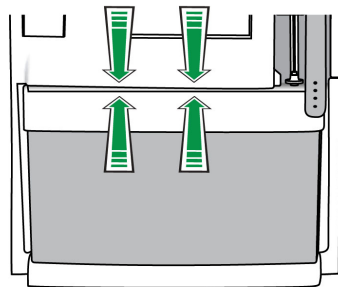


- c. Pull out the Inlet Gasket Holder.



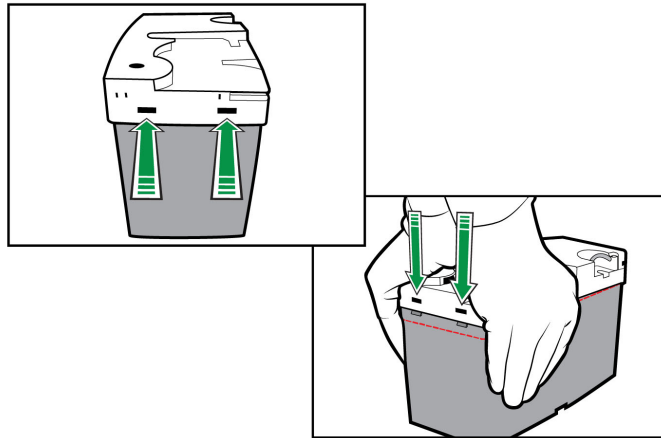
- d. Put a new Inlet Gasket Holder in place.
 - e. Pull off the inlet module.
 - f. Pull out the Connector Gasket.
 - g. Dampen a new Connector Gasket with water.
 - h. Wiggle the Connector Gasket fully into place.
 - i. Put on the inlet module and select **Action Completed**.
 - j. Select **Done**.
 - k. Perform a calibration and/or QC, if necessary.
- If the problem persists, proceed to Step 3.

IMPORTANT The lid on the Solution Pack must be parallel to the top of the compartment that it is placed in.



- 3** Check the Solution Pack.
Start the video guidance and follow the instructions on the screen.
OR

- a. Select **Analyzer status > Consumables > Replace > Replace solution pack**. The Replacing Solution Pack screen appears.
Remove the Solution Pack when ejected.
- b. Verify that the two blue tabs are in the tab holes.
If not, press the lid down with both hands until the tabs click into the holes.



- c. Reinsert the Solution Pack and follow the instructions on the screen. Select **Test again**, if available.
- d. Perform a calibration and/or QC, if necessary.
If the problem persists, proceed to Step 4.

4 Flush the analyzer.

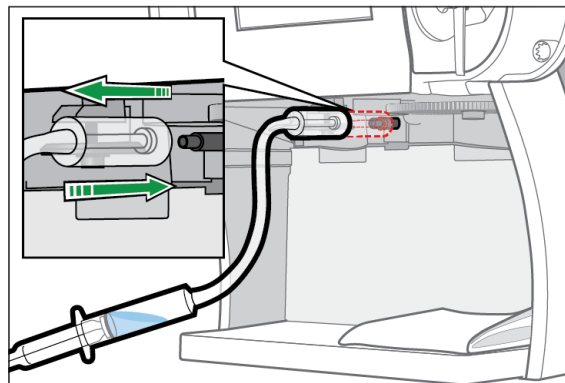
Start the video guidance and follow the instructions on the screen.

OR

- a. Select **Analyzer status > Consumables > Replace > Replace solution pack**. The Replacing Solution Pack screen appears.
Remove the Solution Pack when ejected.
- b. Fill a Flush Device with 50% tap water and 50% air.

IMPORTANT Ensure that the Flush Device is securely connected.

- c. Connect the Flush Device to the waste connector.



- d. Hold the Flush Device with the plunger upwards and inject a little tap water.

NOTE It may be necessary to pull and push the syringe plunger back and forth a couple of times.

- e. Hold the Flush Device with the plunger downwards and inject a little air.

NOTE It may be necessary to pull and push the syringe plunger back and forth a couple of times.

- f. Repeat Steps d and e several times, finishing with tap water.
- g. Push the Inlet Gasket Holder back to expose the probe. Fluidic path is cleaned when an unbroken stream of water comes out of the inlet.
- h. Reinsert the Solution Pack and follow the instructions on the screen. Select **Test again**, if available.
- i. Perform a calibration and/or QC, if necessary.

Single Parameter Error

Probable Cause

- Sensitivity error
- Status error
- Response error
- Impedance error

IMPORTANT Only use the table below if a Fluid transport error has not been reported. If a Fluid Transport error has been reported, refer to [Fluid Transport Error](#).

Use the following table when you troubleshoot single parameter errors after Sensor Cassette start-up.

Parameter	Error reading (Same error on consecutive calibrations or QCs)	Ranges	Corrective Action
pH, K ⁺ , Na ⁺ , Ca ²⁺ , Cl ⁻	Sensitivity error	[85-105%] Cl: [75-105%]	Replace the Sensor Cassette.
	Status error	[-50-250 mV] Cl: [-50-100mV]	Replace the Sensor Cassette.
	Impedance error		Replace the Sensor Cassette.
	Response error		Replace the Sensor Cassette.
pCO ₂	Sensitivity error	[60-105%]	Replace the Sensor Cassette.
	Status error	[-50-250mV]	Replace the Sensor Cassette.
	Impedance error		Replace the Sensor Cassette.
	Response error		Replace the Sensor Cassette.
pO ₂	Sensitivity error	[85-110%]	Replace the Sensor Cassette.
	Status error	[-20-20]	1. Replace the Solution Pack. 2. Replace the Sensor Cassette.
	Substrate thickness		Replace the Sensor Cassette.
	pO ₂ QC error		Replace the Solution Pack.
Glu, Lac	Sensitivity error	[100-2000 pA]	Replace the Sensor Cassette.
	Status error	[0-3000 pA]	1. Replace the Solution Pack. 2. Replace the Sensor Cassette.
	Response error		Replace the Sensor Cassette.

If none of these actions solved your problem, [contact us](#).

Troubleshooting Analyzer Messages

This procedure can be used to find out what operator actions are necessary to troubleshoot messages.

1 Note the message number (on the left of the message).

2 Find the message and operator actions in the *Analyzer messages* table.

NOTE The messages in the table are sorted by number.

NOTE If more operator actions are available, start with the first action listed and see if this resolves the issue. If not, continue with the next action listed.

Analyzer Messages

No.	Message	Interpretation	Action
1	Inconsistent software versions. Contact us.	Inconsistent software versions for different modules. May appear after replacing a complete module or as a result of an incomplete software upgrade.	Contact us.
83	Value above reference range	The parameter value is above the user-defined reference range. This is only a message, not an error.	No action required.
84	Value below reference range	The parameter value is below the user-defined reference range. This is only a message, not an error.	No action required.
85	Value below critical limit	The parameter value is below the user-defined critical limit. This is only a message, not an error.	No action required.
86	Value above critical limit	The parameter value is above the user-defined critical limit. This is only a message, not an error.	No action required.
89	Measured QC value above control range	The measured parameter value is above the control range.	Verify the procedure and repeat the measurement.
90	Measured QC value below control range	The measured parameter value is below the control range.	Verify the procedure and repeat the measurement.
93	Value above reportable range	The parameter value is above the reportable range.	1. Check for and remedy other errors related to the result, system messages or calibration status. 2. Perform QC. If the QC result is accepted, the blood sample may be suspected. 3. Perform measurement on new blood sample.
94	Value below reportable range	The parameter value is below the reportable range.	1. Check for and remedy other errors related to the result, system messages or calibration status. 2. Perform QC. If the QC result is accepted, the blood sample may be suspected. 3. Perform a measurement on new blood sample.
117	LIS/HIS: Invalid connection configuration	The communication configuration or the protocol definition was invalid.	Check the communication parameters specified in Communications Setup.

No.	Message	Interpretation	Action
128	LIS/HIS: Failed to open connection	The communication hardware was busy or the remote system did not respond.	1. Check that the remote system is running, correctly configured and responding. 2. Check communication parameters, e.g. baud rate, parity, IP address, etc., as defined in Communication Setup. 3. Reboot the analyzer.
129	LIS/HIS: Failed to close connection	Messages were queued when the communication channel was closed. Results and other messages sent by the analyzer to a remote system may be lost.	If the problem persists, check the communication hardware. The remote system may lack buffer capacity.
131	LIS/HIS: Failed to send packet	A communication error occurred while sending a message. The message was not sent.	1. Check that the remote system is running and responding. 2. Check the communication hardware, including cables. 3. Repeat sending.
132	LIS/HIS: Failed to receive packet	An error occurred while receiving a message. The analyzer was not able to recognize the received message.	1. Check that protocol types are correctly configured on both the analyzer and the remote system. 2. Contact us.
133	LIS/HIS: Connection lost	A previously established LIS/HIS connection has been lost.	1. Check that the remote system is running and responding. 2. Check cables.
134	LIS/HIS: Connection established	The connection was successfully established.	No action required. For information only.
165	LIS/HIS: High-level protocol could not generate high-level packet	An error occurred while formatting a message.	Check protocol configurations. Contact us .
166	LIS/HIS: General communication error	An internal error occurred in the LIS/HIS communication module.	Contact us if the problem persists.
167	LIS/HIS: High-level protocol received packet in wrong format	An error occurred while parsing (interpreting) a message.	Check protocol configurations. Contact us .
200	Operator msg:	This is only a message. An operator has entered a note in the log.	No action required.
201	Westgard Rule (1.2s) violation	Measured parameter value is outside the mean +/- 2 SD range.	1. Verify procedure and repeat measurement. 2. Check Replacement Status for pending replacements.
202	Westgard Rule (1.3s) violation	Measured parameter value is outside the mean +/- 3 SD range.	1. Verify procedure and repeat measurement. 2. Check Replacement Status for pending replacements including electrodes.

No.	Message	Interpretation	Action
203	Westgard Rule (2.2s) violation	Two consecutive measurements are outside the mean +/- 2 SD range on the same side of the mean. This may indicate a shift.	1. Verify procedure and repeat measurement. 2. Check Replacement Status for pending replacements including electrodes.
204	Westgard Rule (R.4s) violation	The difference between two consecutive measurements exceeds 4 SD. This may indicate an inconsistency in your procedure or an unstable analyzer.	1. Verify procedure and repeat measurement. 2. Check Replacement Status for pending electrode replacements.
205	Westgard Rule (4.1s) violation	Four consecutive measurements are outside the mean +/- 1 SD range on the same side of the mean. A trend or shift is indicated. Results should be considered unreliable until the problem is remedied.	1. Check for excessive electrode sensor calibration drift. 2. Check Replacement Status for pending electrode replacements.
206	Westgard Rule (10.x) violation	Ten consecutive measurements are on the same side of the mean. A trend or shift is indicated. Results should be considered unreliable until the problem is remedied.	1. Check the electrode drift during last calibration. 2. Check Replacement Status for pending electrode replacements.
207	Calibration schedule reminder(s) present	One or more scheduled calibrations are overdue.	Check the Calibration Status and perform any pending calibrations.
208	Quality control schedule reminder(s) present	One or more scheduled QC measurements are overdue.	Check the Quality Control Status and perform the pending quality control.
209	Replacement schedule reminder(s) present	One or more scheduled replacements are overdue.	Check the Replacement Status and perform any pending replacement actions.
210	Calibration error(s) present	An error registered on one or more parameters during the last calibration.	Check Calibration Status for errors in latest calibration results for the given parameter. View calibration error messages and take required corrective action.
211	Quality control error(s) present	One or more errors were registered during last QC measurement on one of the installed QC levels.	Check Quality Control Status for errors. View QC error messages and take required corrective action.
212	System message(s) present	One or more systems errors are present.	Check the System Messages Status for errors. Take corrective required action.
213	Automatic backup failed	An error occurred during the scheduled data backup.	1. Check Automatic Backup Setup. 2. Check network and servers used for the backup. 3. Contact your IT engineer.
214	Automatic backup succeeded	The scheduled automatic backup was completed successfully.	No action required.
216	General printer error	A printer problem has occurred, e.g. the paper is jammed	1. Check printer paper. Clear any jam. 2. Power down and Restart the analyzer. 3. Contact us.

No.	Message	Interpretation	Action
217	Replacement:	The message is used in the Activity Log to indicate a performed replacement.	No action required.
290	Warning: SHb detected	FSHb detected in the range of 1-10%.	No action required. For information only.
291	SHb too high	Detected FSHb is greater than 10%. Measurement accuracy is affected.	Repeat the measurement.
292	Turbidity too high	Turbidity is greater than 5%: too high for reliable measurements.	1. Hyperlipemic sample; decrease the lipemic content by e.g. centrifuge or extraction. 2. Perform the measurement on a blood sample from a healthy donor. 3. Contact us.
293	Oxi compensated for HbF	OXI parameters have been HbF compensated. Parameter FHbF may be shown or not shown.	No action required. For information only.
329	QC expiration date exceeded	The quality control measurement was performed on an expired control solution.	Discontinue the use of the lot and set up a valid lot for the control solution.
331	No sample detected during sample aspiration	No sample detected in sensor. Measurement is aborted.	1. Ensure that adequate sample volume is used. 2. Check the sample for clots.
357	Temp. error: Barometer	Temperature in the barometer on the Analyzer Control is outside 37 +/- 1.0 °C.	1. Ensure that the ambient temperature is between 15 and 32 °C. 2. If the system has just performed a cold start, wait for the error to disappear. 3. Shield the analyzer from direct sunlight and other heat sources. 4. Contact us.
375	Calibration status out of limits	The status value is outside the range for the given parameter.	1. Check for and remedy any system messages. 2. Repeat the calibration. 3. Check solution pack status and replace, if necessary. 4. Check sensor cassette status and replace, if necessary.
376	Calibration Drift 1 out of range	The Drift 1 value exceeds the tolerance.	1. Check for and remedy any system messages. 2. Repeat the calibration. 3. Check solution pack status and replace, if necessary. 4. Check sensor cassette status and replace, if necessary.

No.	Message	Interpretation	Action
377	Calibration Drift 2 out of range	The Drift 2 value exceeds the tolerance.	1. Check for and remedy any system messages. 2. Repeat the calibration. 3. Check solution pack status and replace, if necessary. 4. Check sensor cassette status and replace, if necessary.
378	Calibration sensitivity out of range	The sensitivity value is out of range for the given parameter.	1. Check for and remedy any system messages. 2. Repeat the calibration. 3. Check solution pack status and replace, if necessary. 4. Check sensor cassette status and replace, if necessary.
379	Calibration unstable (response fault)	An electrode response fault occurred during calibration.	1. Check for and remedy any system messages. 2. Repeat the calibration. 3. Check solution pack status and replace, if necessary. 4. Check sensor cassette status and replace, if necessary.
443	Ca(7.4) not usable	cCa ²⁺ at a pH of 7.4 is not usable as the actual pH is outside the 7.2-7.6 range.	No action required.
452	Interference during measurement	Interference was detected during measurement.	Check the sample record for possible interfering substances.
484	Today is last day in stat. month - remember to print QC statistics	After the current day, quality control statistics obtained over the month will be deleted and new statistics started.	Print the QC statistics if a copy is required.
487	A new statistical month has begun - remember to export WDC data	A new statistical month has begun.	Make a WDC report disk.
494	Bilirubin too high	Detected bilirubin concentration, ctBil(blood), is greater than 2000 µmol/L. The corresponding plasma bilirubin concentration can be calculated as follows: $ctBil(blood) = (1-Hct) \times ctBil(plasma)$.	No action required.
508	Liquid transport error during rinse	Liquid transport of Rinse failed	Check solution pack or sensor cassette status and replace, if necessary.

No.	Message	Interpretation	Action
512	Temperature error	The temperature was outside the required range during measurement or calibration. All results are marked with "?".	1. Ensure that the ambient temperature is between 15 and 32 °C. 2. If the analyzer has recently performed a cold start, wait for the temperature error to disappear. 3. If the solution pack or sensor cassette has recently been replaced, wait for the temperature error to disappear. 4. Shield analyzer from direct sunlight or heat sources. 5. Contact us.
521	Inhomogeneous sample	Air bubbles were detected in the sample. Results may have "?".	Repeat the measurement.
522	Calibration error	One or more calibration values are erroneous.	1. Check for and remedy any system messages. 2. Repeat the calibration. 3. Check solution pack status and replace, if necessary. 4. Check sensor cassette status and replace, if necessary.
523	Calibration drift out of range	Calibration drift exceeds defined limits.	1. Check for and remedy any System Messages. 2. Perform any pending replacements including electrodes. 3. Check that electrodes are properly installed. 4. Verify that proper solutions and gases are used. 5. Perform the Electrode Troubleshooting procedure.
529	Inlet LS failed to calibrate	Inlet liquid sensor failed to calibrate.	1. Repeat the liquid sensor calibration. 2. Contact us.
531	Sensors LS failed to calibrate	Liquid sensor near the sensor cassette failed to calibrate.	1. Repeat the liquid sensor calibration. 2. Check solution pack status and replace if necessary. 3. Contact us.
537	OXI LS failed to calibrate	OXI module liquid sensor failed to calibrate.	1. Repeat the liquid sensor calibration. 2. Check solution pack status and replace, if necessary. 3. Contact us.
581	OXI spectrum mismatch	Spectrum deviates from the expected blood or QC spectrum. Measurement may be unreliable.	1. Check the sample record for possible interfering substances. 2. Start a calibration. 3. Contact us.

No.	Message	Interpretation	Action
582	tHb calibration cuvette factor outside limits	tHb calibration failed.	1. Perform a calibration. 2. Repeat the tHb calibration. 3. Contact us.
584	tHb calibration wavelength outside limits	tHb calibration failed.	1. Perform a calibration. 2. Repeat the tHb calibration. 3. Contact us.
588	Measured QC value lower than statistical range	The parameter value is below the lower limit of the operator-defined statistical range. Measurement is not included in statistics.	Verify the procedure and repeat the measurement.
589	Measured QC value higher than statistical range	The parameter value is above the upper limit of the operator-defined statistical range. Measurement not included into statistics.	Verify the procedure and repeat the measurement.
593	Insufficient sample	Sample volume is too small for the selected measuring mode. Affected parameters will be marked with "?".	1. Repeat the measurement, ensuring sufficient sample volume. 2. Contact us.
595	Liquid sensor calibration error	One or more of the liquid sensors failed calibration.	1. Repeat the liquid sensor calibration. 2. Check solution pack status and replace, if necessary. 3. Contact us.
606	Cal expired (pH)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	Perform a calibration.
608	Cal expired (pCO2)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	Perform a calibration.
609	Cal expired (pO2)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	Perform a calibration.
610	Cal expired (K)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	Perform a calibration.
611	Cal expired (Na)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	Perform a calibration.
612	Cal expired (Ca)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	Perform a calibration.

No.	Message	Interpretation	Action
613	Cal expired (Cl)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	Perform a calibration.
614	Cal expired (Glu)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	Perform a calibration.
615	Cal expired (Lac)	Too long time passed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	Perform a calibration.
616	Cal expired (OXI)	Too long time elapsed since the last successful calibration of the parameter. Parameter measurement values are reported as ".....".	Perform a calibration.
641	Vi-CELL MetaFLEX/DMS PC restarted	The analyzer was restarted from power off.	No action required. For information only.
642	Vi-CELL MetaFLEX/DMS PC connected to wet section	Added by DMS PC when connection to the wet section is obtained.	No action required.
643	Vi-CELL MetaFLEX/DMS PC disconnected from wet section	The connection from the DMS PC to the wet section is lost.	1. Shut down and Restart the analyzer. 2. Contact us.
648	Calibration failed or not accepted	The last calibration was aborted or not accepted.	1. Check solution pack status and replace, if necessary. 2. Check sensor cassette status and replace, if necessary. 3. Check for and remedy system messages. 4. Repeat the calibration.
662	Barometer out of range	Measured barometer value is outside the measuring range: 60-106.7 kPa.	Contact us.
669	QC value outside control range	Measured parameter value is outside control range.	1. Verify the procedure and repeat measurement. 2. Refer to Quality Control Systems Reference Manual.
679	Barometer error	The measured parameter may be unreliable due to barometer error.	Contact us.
682	OXI module not active	The OXI module is not responding due to an internal communication problem, or the software configuration does not match the analyzer type.	1. Shut down the analyzer, using the Temporary Shutdown function; then restart it. 2. Contact us.

No.	Message	Interpretation	Action
688	ctHb/ceHb too low for OXI calculation	ctHb < 1 mmol/L, or ceHb < 0.75 mmol/L. If ctHb is too low, FHHb, FO2Hb, FCOHb and FMetHb are not calculated. If ceHb = cHHb + cO2Hb is too low, sO2 is not calculated.	If Oxi derivatives are wanted, elevate tHb and/or sO2.
699	Built-in QC measurement started due to calibration error	The analyzer was set up to perform built-in QC measurements in case of calibration errors.	Check Calibration Status and remedy any reported calibration errors.
700	Scheduled built-in QC not run due to errors in last calibration	Last calibration contained an error, and the analyzer was set up to suspend built-in QC measurements in case of calibration errors.	Check Calibration Status and remedy calibration errors.
703	QC expired	QC measurement is overdue (corrective action "Lock analyzer" has been selected in the Setup program: Corrective Actions).	Perform a quality control measurement.
704	Built-in QC measurement is repeated	The scheduled QC measurement was not accepted; the measurement was repeated as requested in the Setup program: Corrective Actions.	No action required.
705	Built-in QC measurement is repeated twice	The scheduled QC measurement was not accepted; the measurement was repeated twice as requested in the Setup program: Corrective Actions.	No action required.
707	Replacement(s) overdue by 10%. Analyzer locked.	Replacement is overdue by 10% (corrective action "Lock analyzer" was selected in the Setup program: Corrective Actions). When the analyzer is locked, scheduled calibrations are performed, but no samples or QC measurements are allowed.	1. Check Replacement Status and replace as required. 2. Unlock analyzer in the Miscellaneous Setup program.
708	Corrective action not possible due to empty solution pack	Scheduled built-in QC measurement was requested, but the solution pack was empty.	Insert a new solution pack.
712	FHbF measurement not possible	Composition of the blood sample makes FHbF measurement too inaccurate, but OXI parameters are compensated for HbF.	If FHbF is wanted change sample composition. For example, elevate sO2 and tHb.
713	ctBil measurement not possible	Blood sample ctHb is so high that hardly any plasma is left to measure plasma bilirubin on. ctHb > 14.56mmol/L.	If ctBil is wanted, lower the ctHb value.
734	General WSM exception	The data management system establishes connection to the analyzing unit, or the connection is lost.	1. Wait a few minutes for the connection to establish. 2. Restart the analyzer. 3. If the error persists, Contact us.

No.	Message	Interpretation	Action
745	Low disk space	Free disk space is low.	Move archive files to another storage device.
770	Failed to restore Custom Setup	The setup could not be restored.	1. Download the setup data from another floppy disk, hard disk or network drive. 2. Contact us if the error persists.
771	Succeeded to restore Custom Setup	Restoring of setup is completed.	No action required.
772	Operator Activity:	Operator activity logged by operator.	No action required.
773	Remote operator logged on with operator:	A remote operator has logged on the analyzer via NetOp.	No action required.
774	Remote operator logged off with operator:	An operator, remotely logged on via NetOp, has logged off, or has been logged off by a local operator.	No action required.
775	Failed to restore Default Setup	Restoring analyzer setup to default values has failed.	Contact us .
776	Succeeded to restore Default Setup	Restoring setup to default values is completed.	No action required.
783	Automatic backup started	Automatic backup (selected in Disk Functions Setup) has started.	No action required. For information only.
785	Automatic archiving started	Automatic archiving (selected in Disk Functions Setup) has started.	No action required. For information only.
786	Automatic archiving completed	Automatic archiving (selected in Disk Functions Setup) completed successfully.	No action required. For information only.
787	Export of data logs started	Export of data logs was started by the operator.	No action required. For information only.
798	Operator logged on	Operator logged on successfully.	No action required. For information only.
799	Operator logged off	Operator logged off.	No action required. For information only.
800	Logon attempt failed	Operator tried to log on but did not provide a valid password.	Provide a valid password to log on.
810	pH locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
811	pCO2 locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.

No.	Message	Interpretation	Action
812	pO2 locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
813	K locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
814	Na locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
815	Cl locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
816	Ca locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
818	Glu locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
819	Lac locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
820	tHb locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
821	MetHb locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.

No.	Message	Interpretation	Action
822	COHb locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
823	HHb locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
824	O2Hb locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
825	sO2 locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
826	HbF locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
827	tBil locked	The parameter has been locked by an Administrator, as reflected in the Activity Log. When a parameter is locked, presumably due to problems with QC, the parameter is repressed in patient results.	Await corrective actions initiated by the Administrator.
831	pH unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
832	pCO2 unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
833	pO2 unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
834	K unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
835	Na unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.

No.	Message	Interpretation	Action
836	Cl unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
837	Ca unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
839	Glu unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
840	Lac unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
841	tHb unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
842	MetHb unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
843	COHb unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
844	HHb unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
845	O2Hb unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
846	sO2 unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
847	HbF unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
848	tBil unlocked	The message is used in the Activity Log to indicate that a previously locked parameter has been unlocked.	No action required. For information only.
855	Base Excess out of range	Base Excess exceeds the +/- 30 mmol/L range.	For information only. No analyzer error was detected.
875	Sample aged	The specified limit for sample age has been exceeded.	Draw and analyze new sample.
886	LIS/HIS: No valid POCT1A DML Device ID file	A file with a valid Device ID does not exist. A valid Device ID is needed in order to use the POCT1A DML protocol.	Contact us to obtain a Device ID file.

No.	Message	Interpretation	Action
963	Leak current in analyzer detected	Leak currents were detected during system calibration and may distort measuring results.	1. Replace inlet connector gasket, sensor cassette or solution pack. 2. Contact us.
964	Leak current in relation to solution pack detected	Leak currents were detected during system calibration and may distort measuring results.	1. Replace solution pack. 2. Contact us.
970	Replace solution pack	This message is shown when the solution pack needs to be replaced. The analyzer will enter "Operator-intervention required".	Replace solution pack.
971	Replace sensor cassette	This message is shown when the sensor cassette needs to be replaced. The analyzer will enter "Operator-intervention required".	Replace sensor cassette.
973	Printer paper must be replaced	No more paper in printer.	Insert new printer paper.
978	Flow selector calibration error	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
979	Inhomogeneous rinse solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
983	Inhomogeneous cal 3 solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
984	The analyzer could not aspirate homogeneous calibration solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1000	Number of pO2 hardware data fail	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1001	Timeout while waiting for pO2 hardware data	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1002	pO2 dark data is out of range	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1004	Unable to calculate oxygen parameter	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1005	Unable to calculate oxygen parameter	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.

No.	Message	Interpretation	Action
1006	Unable to calculate oxygen parameter	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1007	Missing oxygen calibration	No calibration data exists for oxygen.	Perform a calibration.
1008	Unable to calculate oxygen parameter	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1009	Unable to calculate oxygen parameter	Can be shown on a result if unable to calculate oxygen due to an unexpected system error.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1010	Oxi data collection error	Oxi hardware problem	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1011	Oxi has no Blank Cal	Missing Blank Cal. Not necessarily a hardware error.	1. Perform a calibration. 2. Restart the analyzer. 3. Contact us.
1012	Oxi has no sample spectrum	The system has not made a sample measurement yet, or there is a hardware problem.	1. Repeat the measurement. 2. Restart the analyzer. 3. Contact us.
1013	Oxi data collection error	Oxi hardware error	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1014	Oxi Blank Cal. intensity too high	The spectrometer received too high light intensity during Blank Cal.	Check solution pack. During Oxi Blank calibration, the cuvette must be filled with liquid. Perform a calibration. Restart the analyzer. Contact us.
1015	Oxi sample intensity too high	The spectrometer received too high light intensity during sample measurement.	1. Check solution pack. During Oxi Blank calibration, the cuvette must be filled with liquid. 2. Perform a calibration. 3. Repeat the sample measurement.
1016	Oxi Blank Cal. intensity too low	The spectrometer received too low light intensity during Blank Cal.	1. Perform a calibration. 2. Restart the analyzer. 3. Contact us.
1017	Oxi sample intensity too low	The spectrometer received too low light intensity during sample measurement.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.

No.	Message	Interpretation	Action
1018	Oxi electronic adjustment error	Oxi hardware problem.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1019	Oxi Blank Cal. outside limits	Peak value of Blank Cal. spectrum intensity is outside acceptance limits.	1. Check solution pack. The cuvette must be filled with liquid during Blank calibration. 2. Perform a calibration. 3. Restart the analyzer. 4. Contact us.
1020	Oxi neon intensity outside limits	Oxi hardware problem.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1021	Oxi neon correction outside limits	Oxi hardware problem.	1. Restart the analyzer. 2. Contact us.
1022	Oxi background correction outside limits	Oxi hardware problem.	1. Restart the analyzer. 2. Contact us.
1023	Oxi spectrometer memory read problem	Oxi hardware problem.	1. Restart the analyzer. 2. Contact us.
1024	Oxi spectrometer memory write problem	Oxi hardware problem.	1. Restart the analyzer. 2. Contact us.
1025	Oxi hemolyzer tuning problem	Oxi hardware problem.	1. Restart the analyzer. 2. Contact us.
1026	Oxi hemolyzer frequency problem	Oxi hardware problem.	1. Restart the analyzer. 2. Contact us.
1027	Oxi hemolyzer temperature deviation too high	Oxi hardware problem.	1. Restart the analyzer. 2. Contact us.
1028	Oxi neon voltage outside limits	Oxi hardware problem.	1. Restart the analyzer. 2. Contact us.
1029	Oxi light source voltage outside limits	Oxi hardware problem.	1. Restart the analyzer. 2. Contact us.
1030	Oxi hemolyzer voltage outside limits	Oxi hardware problem.	1. Restart the analyzer. 2. Contact us.
1031	Oxi initialization in progress	Oxi initialization in progress.	1. Please wait up to 50 minutes before restarting the analyzer. 2. Restart the analyzer. 3. Contact us.
1032	Oxi data collection problem	Oxi hardware problem.	1. Restart the analyzer. 2. Contact us.

No.	Message	Interpretation	Action
1033	Oxi task was not finished	Internal software problem.	1. Restart the analyzer. 2. Contact us.
1034	Oxi hardware problem	An Oxi hardware problem has occurred.	1. Restart the analyzer. 2. Perform a calibration. 3. Contact us.
1045	Unable to read consumable information	Unable to read information stored on either sensor cassette or solution pack.	1. Reinstall the solution pack and sensor cassette. 2. Restart the analyzer. 3. Contact us.
1061	Pressure test flow error	The sample transport through the analyzer is hindered.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1062	Pressure test pressure error	A leak has been found in the solution transport.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1063	Pressure test vacuum error	A leak has been found in the solution transport.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1064	Temperature in sensor cassette top out of range	Hardware temperature error.	1. Ensure that the ambient temperature is between 15 and 32 °C. 2. If the system has just performed a cold start, wait for the error to disappear. 3. Shield the analyzer from direct sunlight and other heat sources. 4. Contact us.
1065	Temperature in sensor cassette bottom out of range	Hardware temperature error.	1. Ensure that the ambient temperature is between 15 and 32 °C. 2. If the system has just performed a cold start, wait for the error to disappear. 3. Shield the analyzer from direct sunlight and other heat sources. 4. Contact us.
1066	Temperature in sensor cassette substrate out of range	Hardware temperature error.	1. Ensure that the ambient temperature is between 15 and 32 °C. 2. If the system has just performed a cold start, wait for the error to disappear. 3. Shield the analyzer from direct sunlight and other heat sources. 4. Contact us.

No.	Message	Interpretation	Action
1069	Temperature in Oxi cuvette out of range	Hardware temperature error.	1. Ensure that the ambient temperature is between 15 and 32 °C. 2. If the system has just performed a cold start, wait for the error to disappear. 3. Shield the analyzer from direct sunlight and other heat sources. 4. Contact us.
1070	Sensor response error	Unstable signal from sensor.	Repeat measurement
1071	Temperature in Oxi spectrometer out of range	Hardware temperature error.	1. Ensure that the ambient temperature is between 15 and 32 °C. 2. If the system has just performed a cold start, wait for the error to disappear. 3. Shield the analyzer from direct sunlight and other heat sources. 4. Contact us.
1079	Sensor impedance error	Sensor impedance error	1. Perform a calibration. 2. Replace sensor cassette
1081	Inhomogeneous rinse solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1083	Inhomogeneous cal 2 solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1084	Inhomogeneous cal 3 solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1085	Inhomogeneous QC1 solution	Bubbles were detected in the QC1 solution.	1. Perform a refill from the auxiliary program. 2. Replace the solution pack.
1086	Inhomogeneous QC2 solution	Bubbles were detected in the QC2 solution.	1. Perform a refill from the auxiliary program. 2. Replace the solution pack.
1087	Inhomogeneous QC3 solution	Bubbles were detected in the QC3 solution.	1. Perform a refill from the auxiliary program. 2. Replace the solution pack.
1089	Inhomogeneous gas	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1090	No rinse solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.

No.	Message	Interpretation	Action
1092	No cal 2 solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1093	No cal 3 solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1094	No QC1 solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1095	No QC2 solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1096	No QC3 solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1098	No gas	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1099	Pump calibration error	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1100	Outlet LS not empty during pump calibration	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1101	Outlet LS not full during pump calibration	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1111	Inhomogeneous air	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1112	LS inlet not empty	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1113	LS sensors not empty	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1114	LS outlet not empty	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1115	Ws communication error: wrong message format	Internal communication error.	1. Restart the analyzer. 2. Contact us.
1116	Ws communication error: keep alive timeout	Internal communication error.	1. Restart the analyzer. 2. Contact us.

No.	Message	Interpretation	Action
1117	Oxi spectrometer temperature drift	A large deviation in temperature has been observed. This is probably due to a change in the ambient environment.	Perform a calibration.
1120	Sensor replacement successful	This message is shown in the Activity Log following a successful replacement of the sensor cassette.	No action required. For information only.
1121	The port did not open during sensor replacement	This message is shown in the Activity Log after a failed sensor cassette replacement.	1. Reinstall the sensor cassette. 2. Restart the analyzer. 3. Contact us.
1123	The sensor chip data could not be read or written during replacement	This message is shown in the Activity Log after a failed sensor cassette replacement.	1. Reinstall the sensor cassette. 2. Restart the analyzer. 3. Contact us.
1124	An unregistered sensor was installed during replacement	This message is shown in the Activity Log after a sensor cassette replacement, that did not identify a previously conditioned cassette.	No action required. For information only.
1125	An unregistered and used sensor was installed during replacement	This message is shown in the Activity Log after a sensor cassette replacement. It informs that the sensor cassette installed is already used and no information exists about the conditioning hereof.	No action required. For information only.
1126	A registered sensor had been used before installation	This message is shown in the Activity Log after a sensor cassette replacement. It informs that the sensor cassette installed has been used before.	No action required. For information only.
1134	The chip information for the solution pack cannot be read or written	This message is shown in the Activity Log after a failed solution pack replacement.	1. Reinstall the solution pack. 2. Restart the analyzer. 3. Contact us.
1135	The solution pack has been used before	This message is shown in the Activity Log after a failed solution pack replacement.	Reinstall the solution pack.
1140	The solution pack has used the maximum number of measurements at installation	This message is shown in the Activity Log after a failed solution pack replacement.	Reinstall the solution pack.
1142	The printer door is open. Printing not possible	Printer door open.	1. Ensure that the printer paper is properly installed. 2. Close the printer door.
1143	Internal printer is offline. Printing not possible	Printer hardware error.	1. Ensure that the printer paper is properly installed. 2. Close the printer door.
1144	Check that printer door is closed and that paper is present	Printer hardware error.	1. Ensure that the printer paper is properly installed. 2. Close the printer door.

No.	Message	Interpretation	Action
1145	A printer error has occurred. Call service technician	Printer hardware error.	1. Ensure that the printer paper is properly installed. 2. Close the printer door.
1146	Printer paper replaced	This message is shown in the Activity Log after replacement of printer paper.	No action required. For information only.
1147	Inlet opened during rinse	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1148	Inlet open during calibration	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1149	Inlet open during wet section activity	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1150	Inlet closed without aspirating sample	This message is shown in the Activity Log when a measurement has been cancelled due to inlet being closed before aspiration could be completed.	No action required. For information only.
1151	Inlet not closed: no sample aspirated	This message is shown in the Activity Log when a measurement has been cancelled due to inlet being closed too late.	No action required. For information only.
1152	The solution pack chip data could not be read or written during replacement	This message is shown in the Activity Log when a replacement of the sensor cassette or solution pack has failed. The reason was that it was impossible to communicate with the chip on the consumable.	Repeat replacement operation.
1157	No valid FTC programs detected	System error.	Contact us.
1160	The top thermistor is not connected	The top thermistor is not connected	1. Restart the analyzer. 2. If still present replace top thermistor
1161	The top thermistor short circuited	The top thermistor short circuited	1. Restart the analyzer. 2. If still present replace top thermistor
1163	The sensor cassette thermistor is not connected	The sensor cassette thermistor is not connected	1. Restart the analyzer. 2. If still present replace sensor cassette
1164	The sensor cassette thermistor is short circuited	Sensor cassette thermistor is short circuited	1. Restart the analyzer. 2. If still present replace sensor cassette
1165	Solution pack not properly installed	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1166	Solution pack expired	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.

No.	Message	Interpretation	Action
1167	Sensor cassette not properly installed	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1168	Sensor cassette expired	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1169	Unable to pump solutions	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1170	Inlet has been open for too long	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1171	Inlet is missing or in unknown state	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1172	Sensor cassette damaged	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1173	Solution pack damaged	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1174	Inlet opened while the analyzer was busy	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1175	Sensor temperature error	Hardware temperature error (Thermistor).	1. Ensure that the ambient temperature is between 15 and 32 °C. 2. If the system has just performed a cold start, wait for the error to disappear. 3. Shield the analyzer from direct sunlight and other heat sources. 4. Contact us.
1176	A liquid sensor error was detected	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1177	A flow selector error was detected	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1178	A pump calibration error was detected	Shown on screen when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1180	An error occurred when trying to communicate with wet section	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.

No.	Message	Interpretation	Action
1181	A software or hardware error exists in wet section	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1183	Valve malfunctioning	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1184	Leak detected	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1185	Warning: Free memory is low	The internal memory is low.	Restart the analyzer.
1186	Free system memory is critically low	The internal memory is critically low.	Restart the analyzer.
1187	Disk shows signs of wear	The permanent memory is showing exhaustion signs and should probably be replaced soon.	Contact us.
1188	Disk shows serious signs of wear	The permanent memory is showing exhaustion signs and should be replaced soon.	Contact us.
1189	FTC aborted, LS state change error	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1190	Inlet open	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1191	QA Portal communication enabled	Shown in the Activity Log after enabling QA Portal communication	No action required. For information only.
1192	QA Portal communication disabled	Shown in the Activity Log after disabling QA Portal communication	No action required. For information only.
1193	QA Portal output queue cleared	Shown in the Activity Log when the QA Portal has been reset.	No action required. For information only.
1194	Vi-CELL MetaFLEX not connected to QA Portal	The analyzer is not connected to the QA Portal.	1. Contact your IT engineer. 2. Check QA Portal Communication Setup, including TCP/IP address, port no. and password. 3. Check that QA Portal is responding. 4. Check network connections.
1195	Vi-CELL MetaFLEX not connected to QA Portal - incorrect password	The analyzer was refused connection to the QA Portal due to incorrect password.	Enter the correct password in the analyzer's QA Portal Communication Setup.
1196	Vi-CELL MetaFLEX connected to QA Portal	The analyzer is connected to the QA Portal.	No action required. For information only.
1197	Vi-CELL MetaFLEX disconnected from QA Portal	The analyzer is disconnected from the QA Portal.	No action required. For information only.

No.	Message	Interpretation	Action
1198	Vi-CELL MetaFLEX<>QA Portal communication error - XML packet could not be parsed	Communication error between the analyzer and the QA Portal.	Contact IT engineer or contact us .
1199	FTC program has been retried	This message is found in the Activity Log when a measurement or calibration activity has been retried due to error.	No action required. For information only.
1200	Solution pack empty	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1201	Solution pack lifetime expired	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1202	Expiration date reached	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1203	Lifetime in analyzer exceeded	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1204	No more activities left	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1216	Lifetime in analyzer exceeded	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1217	No more tests left	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1218	Expiration date reached	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1219	RiLiBÄK Violation: Value above upper limit	The measured value lies above the upper RiLiBÄK range.	No action required.
1220	RiLiBÄK Violation: Value below lower limit	The measured value lies below the lower RiLiBÄK range.	No action required.
1221	System temperature out of range	Hardware temperature error (all).	1. Ensure that the ambient temperature is between 15 and 32 °C. 2. If the system has just performed a cold start, wait for the error to disappear. 3. Shield the analyzer from direct sunlight and other heat sources. 4. Contact us.

No.	Message	Interpretation	Action
1222	Temperature system error	Hardware temperature error (Top/bottom thermistor).	1. Ensure that the ambient temperature is between 15 and 32 °C. 2. If the system has just performed a cold start, wait for the error to disappear. 3. Shield the analyzer from direct sunlight and other heat sources. 4. Contact us.
1223	Analyzer did not connect at start-up	The analyzer DMS has not been able to establish contact to the WS(M) at start-up.	1. Restart the analyzer. 2. Contact us.
1224	Analyzer is temporarily shut down	Shown in the Activity Log after temporary shutdown of the analyzer.	No action required.
1225	The sample is older than a day	The time between sampler draw time and aspiration is larger than 1 day.	Either sampler draw time has been entered incorrectly or time of the analyzer is incorrect. Change either to correct the error.
1226	The sample age is negative	The time between sampler draw time and aspiration is less than zero.	Either sampler draw time has been entered incorrectly or time of the analyzer is incorrect. Change either to correct the error.
1227	Correction for bicarbonate contains errors from pH, pCO ₂	Chloride is corrected for bicarbonate, calculated from pH and pCO ₂ . Errors from pH, pCO ₂ results in this error on chloride.	No action required.
1228	Correction for lactate contains errors from K ⁺ , Na ⁺ , Ca ²⁺	Lactate is corrected for ion strength, calculated from K ⁺ , Na ⁺ , Ca ²⁺ . Errors from K ⁺ , Na ⁺ , Ca ²⁺ results in this error on lactate.	No action required.
1230	Inlet Gasket Holder replaced	Shown in the activity log at the time of a replacement.	No action required.
1231	Inlet probe replaced	Shown in the activity log at the time of a replacement.	No action required.
1232	Inlet Connector Gasket replaced	Shown in the activity log at the time of a replacement.	No action required.
1233	Inlet cleaned	Shown in the activity log at the time when an inlet cleaning was performed.	No action required.
1234	Demonstration software - not for clinical purposes	Demonstration software - not for clinical purposes	No action required.
1235	Failed to aspirate sample	Aspiration failed	Remove sampler. Retry aspiration
1236	Failed to aspirate sample	Aspiration failed, due to blocked inlet	Remove sampler. Retry aspiration
1240	Liquid transport failed	Unstable aspiration from solution pack	No action required
1242	Liquid transport failed	Unstable aspiration from solution pack	No action required
1243	Liquid transport failed	Unstable aspiration from solution pack	No action required
1244	Liquid transport failed	Unstable aspiration from solution pack	No action required

No.	Message	Interpretation	Action
1245	Liquid transport failed	Unstable aspiration from solution pack	No action required
1246	Liquid transport failed	Unstable aspiration from solution pack	No action required
1247	Liquid transport failed	Unstable aspiration from solution pack	No action required
1248	Liquid transport failed	Unstable aspiration from solution pack	No action required
1249	Liquid transport failed	Unstable aspiration from solution pack	No action required
1250	Liquid transport failed	Unstable aspiration from solution pack	No action required
1253	Failed to aspirate sample	Aspiration failed sample not detected	Retry aspiration
1254	Failed to aspirate sample	Aspiration failed sample not detected	Retry aspiration
1257	Liquid transport failed	Unstable aspiration from solution pack	No action required
1258	Liquid transport failed	Unstable aspiration from solution pack	No action required
1259	Liquid transport failed	Unstable aspiration from solution pack	No action required
1260	Liquid transport failed	Unstable aspiration from solution pack	No action required
1261	Liquid transport failed	Unstable aspiration from solution pack	No action required
1262	Liquid transport failed	Unstable aspiration from solution pack	No action required
1263	Liquid transport failed	Unstable aspiration from solution pack	No action required
1264	Liquid transport failed	Unstable aspiration from solution pack	No action required
1265	Liquid transport failed	Unstable aspiration from solution pack	No action required
1266	Liquid transport failed	Unstable aspiration from solution pack	No action required
1267	Liquid transport failed	Unstable aspiration from solution pack	No action required
1268	Liquid transport failed	Unstable aspiration from solution pack	No action required
1271	Failed to aspirate sample	Aspiration failed sample not detected	Retry aspiration
1272	Failed to aspirate sample	Aspiration failed sample not detected	Retry aspiration
1275	Liquid transport failed	Unstable aspiration from solution pack	No action required
1276	Liquid transport failed	Unstable aspiration from solution pack	No action required
1279	Liquid transport failed	Unstable aspiration from solution pack	No action required
1280	Liquid transport failed	Unstable aspiration from solution pack	No action required
1281	Liquid transport failed	Unstable aspiration from solution pack	No action required
1282	Liquid transport failed	Unstable aspiration from solution pack	No action required
1283	Liquid transport failed	Unstable aspiration from solution pack	No action required
1284	Liquid transport failed	Unstable aspiration from solution pack	No action required
1285	Liquid transport failed	Unstable aspiration from solution pack	No action required
1286	Liquid transport failed	Unstable aspiration from solution pack	No action required
1290	Liquid transport failed	Unstable aspiration from solution pack	No action required
1292	Liquid transport failed	Unstable aspiration from solution pack	No action required
1294	Liquid transport failed	Unstable aspiration from solution pack	No action required

No.	Message	Interpretation	Action
1295	Activity has been repeated due to the following reason:	This message is shown in the activity log when an activity is repeated automatically. It lists the error and parameter id that was the cause of the repeat.	No action required.
1296	Printer out of paper	The printer is out of paper. A new paper roll must be inserted	Insert a new paper roll
1297	Printer is offline	The printer is offline due to either a bad or missing power / USB connection	1. Check the power connection 2. Check the USB connection 3. Contact us.
1298	Printer lid open	The printer lid is open	Close the printer lid
1299	Rinse activity repeated:	A rinse activity has been repeated. The following entries in the log explains the reason for the repeat.	No action required.
1300	Calibration activity repeated:	A calibration activity has been repeated. The following entries in the log explains the reason for the repeat.	No action required.
1301	QC activity repeated:	A QC activity has been repeated. The following entries in the log explains the reason for the repeat.	No action required.
1302	Startup activity repeated:	A startup activity has been repeated. The following entries in the log explains the reason for the repeat.	No action required.
1303	Activity repeated:	An activity has been repeated. The following entries in the log explains the reason for the repeat.	No action required.
1304	Calibration activity repeated	A calibration activity has been repeated. The following entries in the log explains the reason for the repeat.	No action required.
1305	End of repeat reason list	This message indicates the end of repeat reasons. See errors 1299-1304.	No action required.
1306	Solution pack manually removed	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1307	Disk space less than fifteen percent	The disk space on the analyzer is low.	Delete some archives to free up space on the drive.
1308	Disk space less than one percent	The disk space on the analyzer is less than 1%	Contact us.
1309	Unable to start FTC activity - FTC activity in progress	Unable to start FTC activity	Contact us.
1310	Response error	Sensor (Metabolit) does not work properly	Replace sensor

No.	Message	Interpretation	Action
1311	The analyzer chip data could not be read or written	It's not possible to read or write data to the analyzer chip	Contact us.
1312	Export data logs failed	The export data log operation has failed.	1. Make sure the selected export path exists. 2. Make sure enough space is available.
1313	Export data logs done	The export data log operation has completed successfully.	No action required.
1314	Sensor temperature error during rinse	Sensor temperature error (substrate) during rinse	Check sensor status and replace, if necessary.
1315	Cal backlog error (pH)	Cal backlog error (pH), leaping signals on rinse	Perform rinse
1316	Cal backlog error (pCO2)	Backlog unstable, leaping signals on rinse	Perform rinse
1317	Cal backlog error (pO2)	Backlog unstable, leaping signals on rinse	Perform rinse
1318	Cal backlog error (K)	Backlog unstable, leaping signals on rinse	Perform rinse
1319	Cal backlog error (Na)	Backlog unstable, leaping signals on rinse	Perform rinse
1320	Cal backlog error (Ca)	Backlog unstable, leaping signals on rinse	Perform rinse
1321	Cal backlog error (Cl)	Backlog unstable, leaping signals on rinse	Perform rinse
1322	Cal backlog error (Glu)	Backlog unstable, leaping signals on rinse	Perform rinse
1323	Cal backlog error (Lac)	Backlog unstable, leaping signals on rinse	Perform rinse
1324	Inhomogeneous rinse solution (LS sensors)	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1325	Sensor thermistor recalibrated	Show in activity log when a recalibration of the sensor thermistor has been performed	Information only
1326	Sensor thermistor recalibration failed - thermistor mal-functioning	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1327	Analyzer locked by operator	Operator has locked the analyzer	No action required.
1328	Analyzer locked on request from LIS	The analyzer was locked on request from LIS	No action required.
1330	pO2 substrate thickness	The thickness of the pO2 substrate is outside the ranges	1. Perform calibration 2. Replace sensor cassette
1331	Intervention required entered	The analyzer enters UIR	No action required.
1332	Intervention required exited	The analyzer exits UIR	No action required.
1335	Solution pack replaced	This message is used in the Activity log to indicate replacement of solution pack	No action required

No.	Message	Interpretation	Action
1336	Sensor cassette replaced	This message is used in the Activity log to indicate replacement of sensor cassette	No action required
1337	Printer paper replaced	This message is used in the Activity log to indicate replacement of printer paper	No action required
1338	Demo mode enabled	This message is used in the Activity log to indicate that Vi-CELL MetaFLEX demo mode has been enabled	No action required
1339	Demo mode disabled	This message is used in the Activity log to indicate that Vi-CELL MetaFLEX demo mode has been disabled	No action required
1340	Sensor cassette maintenance by Analyzer has been interrupted	This message is used in the Activity log to indicate startup using a sensor cassette which has been left without an FTC activity for more than 2 hour.	No action required
1341	Leak detected	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1342	Leak detected	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1343	Unable to pump solutions	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1344	Solution pack removed	This message is used in the Activity log to indicate replacement of solution pack	No action required
1345	Solution pack inserted	This message is used in the Activity log to indicate replacement of solution pack	No action required
1346	Sensor cassette removed	This message is used in the Activity log to indicate replacement of sensor cassette	No action required
1347	Sensor cassette inserted	This message is used in the Activity log to indicate replacement of sensor cassette	No action required
1348	Warning - Battery low	This message is used in the Activity log to indicate low battery level	Plug analyzer into mains
1349	Analyzer shutdown due to low battery	Analyzer shutdown due to low battery	No action required
1350	Clot suspected in Inlet	Clot suspected in Inlet	No action required
1351	Clot suspected in sensor cassette	Clot suspected in sensor cassette	No action required
1352	Clot suspected in OXI module	Clot suspected in OXI module	No action required
1353	Operator Action Needed entered	The analyzer has entered Operator Action Needed	Operator should perform action shown on screen
1354	Operator Action Needed exited	The analyzer has exited Operator Action Needed	No action required

No.	Message	Interpretation	Action
1355	Conditioned Sensor Startup	Conditions for performing a conditioned sensor startup was fulfilled. The analyzer does not initially perform calibration with every measurement.	No action required
1356	Non-Conditioned Sensor Startup	Conditions for performing a conditioned sensor startup was fulfilled. The analyzer does not initially perform calibration with every measurement.	No action required
1357	Software upgrade initiated	This message is shown in the activity log when a software upgrade has been initiated	No action required
1358	Upgraded from	This message is shown in the activity log when a software upgrade has been performed	No action required
1359	Upgrade option:	This message is shown in the activity log when a software upgrade has been performed	No action required
1360	No clots detected in Analyzer	This message is shown in the activity log when the clot detection program did not detect any clots	No actions
1361	Internal reference electrode error in sensor cassette	The reference electrode is malfunctioning.	Replace sensor cassette
1362	Inlet gasket cleaning has been started	Guided troubleshooting step has been started by operator	No action required
1363	Inlet gasket cleaning has been skipped	Guided troubleshooting step has been skipped by operator	No action required
1364	Inlet gasket cleaning test ok	Test after action by operator is ok	No action required
1365	Inlet gasket cleaning test failed	Test after action by operator has failed	No action required
1366	Inlet gasket holder replacement has been started	Guided troubleshooting step has been started by operator	No action required
1367	Inlet gasket holder replacement has been skipped	Guided troubleshooting step has been skipped by operator	No action required
1369	Inlet gasket holder replacement test failed	Test after action by operator has failed	No action required
1371	Solution pack replacement skipped	Guided troubleshooting step has been skipped by operator	No action required
1372	Solution pack replacement test ok	Test after action by operator is ok	No action required
1373	Solution pack replacement test failed	Test after action by operator has failed	No action required

No.	Message	Interpretation	Action
1374	Inlet connector gasket replacement started	Guided troubleshooting step has been started by operator	No action required
1375	Inlet connector gasket replacement skipped	Guided troubleshooting step has been skipped by operator	No action required
1376	Inlet connector gasket replacement test ok	Test after action by operator is ok	No action required
1377	Inlet connector gasket replacement test failed	Test after action by operator has failed	No action required
1378	Inlet gasket holder replacement test ok	Test after action by operator is ok	No action required
1379	Solution pack replacement started	Guided troubleshooting step has been started by operator	No action required
1380	Manual flush started	Guided troubleshooting step has been started by operator	No action required
1381	Manual flush skipped	Guided troubleshooting step has been skipped by operator	No action required
1382	Manual flush test ok	Test after manual flush is ok	No action required
1383	Manual flush test failed	Test after manual flush has failed	No action required
1384	Replace inlet gasket holder	The inlet gasket holder needs to be replaced.	Replace inlet gasket holder
1386	System time adjusted more than 2 hours	No action	No action
1387	Glu not usable	pO2 too low for reliable cGlucose measurement	N/A
1388	Low Wi-Fi signal quality	Low Wi-Fi signal quality detected	No action required.
1389	Unsupported Wi-Fi configuration	Wi-Fi USB adapter and/or configuration not supported	No action required.
1390	Inlet cannot be closed	The inlet cannot be closed	1. Remove any blocking items 2. Contact us.
1391	Inlet is not in the correct position	The inlet is not in the correct position	Contact us.
1392	Remove sampling device	The inlet cannot be closed before the sampling device is removed	1. Remove sampling device 2. Contact us.
1393	Inlet is not mounted	The analyzer has no inlet module installed	1. Install the inlet module 2. Contact us.
1394	Calibration of the inlet failed	The analyzer could not calibrate the inlet	Contact us.
1395	Dialysis fluid result - not for clinical purposes	Dialysis fluid result. Do not use the result for clinical purposes.	No action required.
1396	Sensor cassette replacement is recommended	Sensor cassette replacement is recommended	Replace sensor cassette

No.	Message	Interpretation	Action
1397	Solution pack replacement recommended	Solution pack replacement recommended	Replace solution pack
1398	Recommended action removed	Recommended action removed. Just info	No action needed
1399	Inlet Cover is attached	Inlet Cover attached	No action just info
1400	Inlet Cover is removed	Inlet Cover removed	No action just info
1401	Inlet Gasket Holder error	Inlet Gasket Holder did not return to expected position after aspiration	Remove/replace the Inlet Gasket Holder.
1402	pO2 too low. cGlucose Linearity out of range.	At pO2 levels <25 mmHg, glucose linearity is out of range at high glucose concentrations	When a sample has low pO2 levels and cGlu is required, repeat the measurement with an arterial sample.
1403	Run ampoule-based QC measurements	Ampoule-based QC measurements must be done after Solution Pack replacements	Do ampoule-based QC measurements.
1404	Run ampoule-based QC measurements	Ampoule-based QC measurements must be done after Sensor Cassette replacements	Do ampoule-based QC measurements.
1405	Inconsistent database	QC lot numbers in the database do not match those read from the smart chip in the Solution Pack	Do the Solution Pack replacement procedure again with the same Solution Pack. Restart the analyzer.
1406	The analyzer is not horizontal	The analyzer is not on a horizontal surface	Put the analyzer on a horizontal surface.
1528	Clot suspected in sensor cassette	Clot suspected in sensor cassette	No action required
1529	Clot suspected in sensor cassette	Clot suspected in sensor cassette	No action required
1530	Clot suspected in sensor cassette	Clot suspected in sensor cassette	No action required
1531	Clot suspected in sensor cassette	Clot suspected in sensor cassette	No action required
1532	Clot suspected in sensor cassette	Clot suspected in sensor cassette	No action required
1533	Clot suspected in sensor cassette	Clot suspected in sensor cassette	No action required
1534	Clot suspected in sensor cassette	Clot suspected in sensor cassette	No action required
1535	Clot suspected in sensor cassette	Clot suspected in sensor cassette	No action required
1536	Clot suspected in sensor cassette	Clot suspected in sensor cassette	No action required
1537	Clot suspected in sensor cassette	Clot suspected in sensor cassette	No action required

No.	Message	Interpretation	Action
1538	Inhomogeneous cal 2 solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1539	Inhomogeneous cal 3 solution	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1540	Inhomogeneous QC1 solution	Bubbles were detected in the QC1 solution.	1. Perform a refill from the auxiliary program. 2. Replace the Solution Pack.
1541	Inhomogeneous QC2 solution	Bubbles were detected in the QC2 solution.	1. Perform a refill from the auxiliary program. 2. Replace the Solution Pack.
1542	Inhomogeneous QC3 solution	Bubbles were detected in the QC3 solution.	1. Perform a refill from the auxiliary program. 2. Replace the Solution Pack.
1543	Inhomogeneous gas	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.
1544	Inhomogeneous air	Shown in the Activity Log when "Operator-intervention required" has been entered due to this reason.	The analyzer will automatically enter "Operator-intervention required". Follow the instructions shown on the screen.

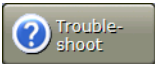
Activity Log

The **Activity log** is where activities done on or by the analyzer are saved.

Troubleshooting Messages in the Activity Log

1 Select **Menu > Data logs > Activity log**.

2 Select the message.

3 Select .

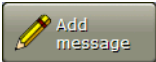
4 Follow the instructions on the screen.

Viewing Activities in the Activity Log

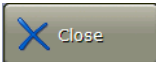
Select **Menu > Data logs > Activity log**.

Adding a Message to the Activity Log

1 Select **Menu > Data logs > Activity log**.

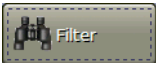
2 Select  .

3 Enter the message.

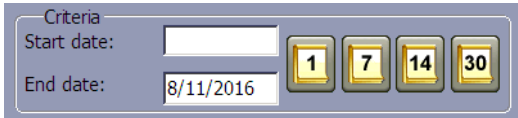
4 Select  .

Filtering Activities from the Activity Log

1 Select **Menu > Data logs > Activity log**.

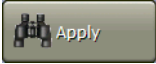
2 Select  .

3 In the **Criteria** frame, choose an option and follow the steps for it.

Option	Steps
To select a time period prior to today's date	Select the number button for the number of days you want. 
To select a start and end date	Enter data in the Start date: and End date: fields

4 Select the next criterion. If necessary, enter or select a value for it.

5 If necessary, do step 4 again.

-
- 6 Select  **Apply**.
-

Analyzer Service

For service, [contact us](#). You may have to supply the installation number (serial number) of the analyzer and the version number of the installed software.

Finding the Installation Number (Serial Number) of the Analyzer

- 1 Select **Menu > Utilities > Setup > General setup > Analyzer settings > Analyzer ID**.
- 2 Read the installation number (serial number) on the screen.

NOTE The installation number (serial number) can also be found on the rear panel of the instrument, printouts of QC, Calibration and Patient results and on printouts from data logs.

Finding the Version of Software Installed

- 1 Select **Menu > Analyzer status**.
 - 2 Read the software version in the lower left corner of the screen.
-

Overview

A calibration ensures that measurement results are accurate and reliable.

This chapter contains information on:

- [Calibrations - Automatic and Manual](#)
- [Identification of Calibrations in Screens](#)
- [Manual Calibration of the Oximetry Parameters](#)
- [Frequency of Automatic Calibrations](#)
- [Finding the Status of Calibrations](#)
- [Calibration Status Symbols](#)
- [Automatic Calibrations](#)
- [Manual tHb Calibrations](#)
- [Calibration Results](#)
- [Reviewing Calibration Results](#)
- [Calibration Verification](#)

Calibrations - Automatic and Manual

The analyzer calibrates most parameters automatically. Only, the sensitivity calibration of the oximetry parameters must be done manually. On the analyzer, this calibration is known as a **tHb calibration**.

If necessary, an extra calibration can be requested. The calibration materials in the Solution Pack are used for this calibration as well as for the calibrations done automatically.

Identification of Calibrations in Screens

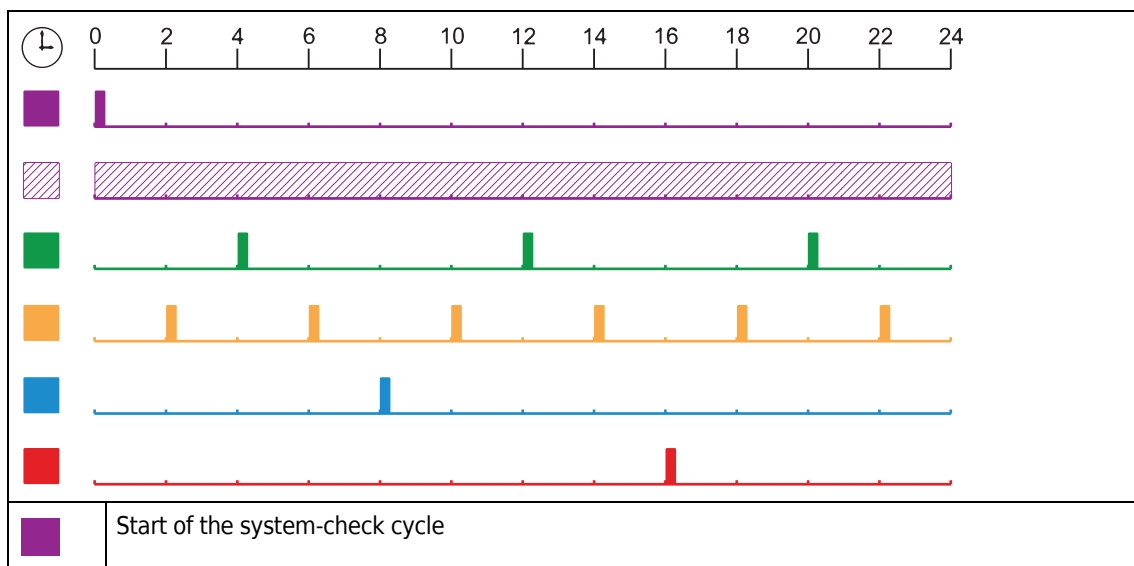
Calibration type	Location	Calibration identifiers	
Automatic calibrations	The Analyzer status screen	Calibration	
	The Calibration log screen	BG	pO_2
		BG, Met	pCO_2 , cGlu, cLac
		Elec, pH	pH, cK ⁺ , cNa ⁺ , cCa ²⁺ , cCl ⁻
		Oxi	Oximetry parameters
Manual calibration of the oximetry parameters	The Analyzer status screen	tHb Cal	
	The Calibration log screen	tHb calibration	Sensitivity calibration of the oximetry parameters

Manual Calibration of the Oximetry Parameters

On the analyzer a manual calibration of the oximetry parameters is known as a tHb calibration. The calibration adjusts the optical system of the analyzer to make sure that the results of the oximetry parameters are accurate and reliable.

Frequency of Automatic Calibrations

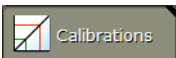
Automatic calibrations are scheduled by default to be done at regular intervals. Automatic calibrations are also done in connection with replacements, troubleshooting, and startup.



	System checks
	Built-in QC measurements
	Sensitivity calibration of $p\text{CO}_2$, $c\text{Glu}$, $c\text{Lac}$ and status calibration of the oximetry parameters
	Sensitivity calibration of pH and the electrolytes ($c\text{K}^+$, $c\text{Na}^+$, $c\text{Ca}^{2+}$, $c\text{Cl}^-$)
	Sensitivity calibration of $p\text{O}_2$

Finding the Status of Calibrations

- 1 Select **Menu > Analyzer status**.

- 2 Select .

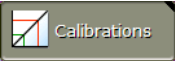
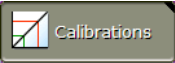
NOTE A symbol in the **Calibration Type** column shows the status of a calibration. Refer to [Calibration Status Symbols](#).

Calibration Status Symbols

Symbol	Indication
	The calibration was completed successfully.
	An error was found on one or more calibration result.
	A scheduled calibration is pending. The last calibration was completed successfully.
	A scheduled calibration is pending. The last calibration was not completed successfully.

Automatic Calibrations

Requesting an Unscheduled Calibration from the Analyzer Status Screen

- 1 Select **Menu** > **Analyzer status**.
- 2 Select .
- 3 Select **Calibration** as the **Calibration Type**.
- 4 Select .

Requesting an Unscheduled Calibration from the Menu

Prerequisite — Verify that the analyzer displays **Ready** in the top left corner of the screen.

- 1 Select **Menu** > **Start programs** > **Calibration programs** > **Calibration**.

Manual tHb Calibrations

Performing a tHb Calibration

Prerequisites:



A S7770 ctHb calibration ampoule



An Ampoule Opener



A QUALICHECK Adapter

- The box that contains the S7770 ctHb calibration ampoule has been stored at a constant temperature (18-32 °C) for 5 hours.
- The analyzer displays **Ready** in the top left corner of the screen.
- There are no calibration errors on the tHb parameter.

**WARNING**

Risk of infection. Make sure you do not prick or scratch yourself on the Inlet Probe.
Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

-
- 1 Remove an ampoule from its box.

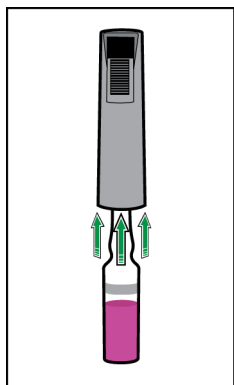
IMPORTANT The ampoules are sensitive to light.

- 2 Put the lid back on the box.

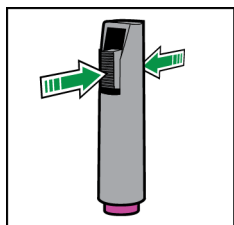
-
- 3 Hold the ampoule between your thumb and first finger and shake it vigorously for a minimum of 15 seconds.

-
- 4 Hold the ampoule neck-side up between your fingers and tap the top until all solution collects in the lower part of the ampoule.

-
- 5 Put the ampoule in the Ampoule Opener.

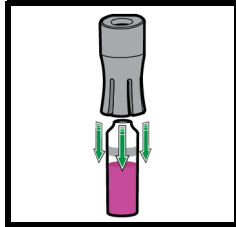


-
- 6 Use your fingers to apply pressure in the directions shown to break off the neck of the ampoule.



7 Remove the ampoule from the Ampoule Opener.

8 Put the QUALICHECK Adapter over the open end of the ampoule.



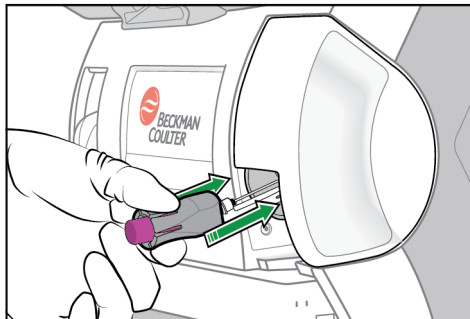
9 Select **Menu > Start programs > Calibration programs > tHb calibration**.

10 Scan the barcode on the insert for the S7770 ctHb Calibration Solution.
The analyzer opens the inlet.

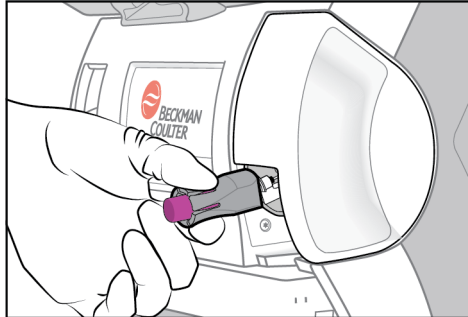
11 Turn the QUALICHECK Adapter with the ampoule so the logo faces upwards.

12 Put the QUALICHECK Adapter with the ampoule over the Inlet Gasket.

13 Push the adapter with the ampoule into the analyzer as far as it will go and hold it there.



- 14 Hold the adapter with the ampoule in the pushed-in position until the analyzer prompts you to remove it.



- 15 When the analyzer prompts you, remove the adapter with the ampoule. The analyzer closes the inlet.

NOTE Sensitivity results between 80% and 120% without errors are acceptable.

Calibration Results

Finding a Calibration Result

- 1 Select **Menu > Data logs > Calibration log**.

- 2 Select the calibration.

NOTE **BG** = pO_2 calibrations; **BG, Met** = pCO_2 , cGlu, cLac calibrations; **Elec, pH** = pH, cK^+ , cNa^+ , cCa^{2+} , cCl^- calibrations and **Oxi** = oximetry parameter calibrations.

- 3 Select  **Result**.

Identification of Calibrations in the Calibration Log Screen

Calibration identifiers	Parameters
BG	pO_2
BG, Met	pCO_2 , cGlu, cLac
Elec, pH	pH, cK^+ , cNa^+ , cCa^{2+} , cCl^-
Oxi	Oximetry parameters

Understanding Calibration Results

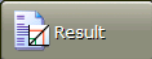
Font style	Description
Bold black	A result from the current calibration
Dark grey	A result from a previous calibration. The result is still valid.
Red and Bold red	An error occurred. A message attached to the result describes the error.

Symbol	Description
?	An error occurred or the result is outside a recommended range: • Drift value is outside the drift tolerance range • Status value is outside the default range • Sensitivity value is outside the default range
.....	The analyzer could not calculate the value

Viewing Calibration Result Messages

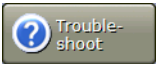
1 Select **Menu** > **Data logs** > **Calibration log**.

2 Select the calibration.

3 Select  **Result**.

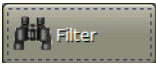
4 Select  **Messages**.

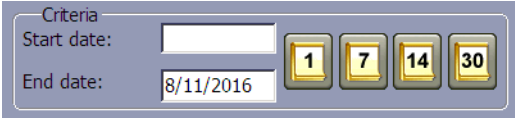
Troubleshooting Results Messages

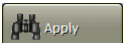
- 1 Select the message.
- 2 Select .
- 3 Follow the instructions on the screen.

Reviewing Calibration Results

Filtering Data from the Calibration Log

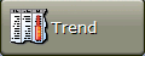
- 1 Select **Menu > Data logs > Calibration log**.
- 2 Select .
- 3 In the **Criteria** frame, choose an option and follow the steps for it:

Option	Steps
To select a time period prior to today	Select the number button for the number of days you want. 
To select a start and end date	Enter data in the Start date: and End date: fields

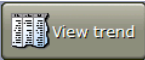
- 4 Select the next criterion. If necessary, enter or select a value for it.
- 5 Repeat Step 4 for each criterion.
- 6 Select .

Viewing Trends in Calibration Results

Prerequisite — You have filtered the calibration results from the **Calibration log**. Refer to [Filtering Data from the Calibration Log](#).

1 Select .

2 Select the parameter.

3 Select .

Status in the Calibration Log Screen

The symbols in the **Status** column of the **Calibration log** screen shows the overall status of each calibration.

Symbol	Description
✓	The calibration was successful
?	An error was found on one or more parameters

Calibration Verification

Calibration verification is a process that lets you verify the calibration and reportable range of the parameters measured by the analyzer.

Calibration verification is a 3-stage process:

- **Stage 1:** Analyze a minimum of three different levels of QC solution.

NOTE On the analyzer, these measurements are referred to as calibration verification measurements.

- **Stage 2:** Use the calibration-verification measurement results to verify the calibration and reportable range of the measured parameters. Follow your laboratory guidelines.
- **Stage 3:** If necessary, change the reportable range of parameters.

Frequency of Calibration Verification

Follow your laboratory requirements.

Stage 1 - Analyzing Different Levels of Control Solution

Preparing a Beckman Coulter Calibration-Verification Ampoule for Use

Prerequisites:



A calibration-verification ampoule



An Ampoule Opener

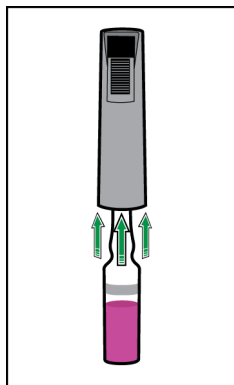


A QUALICHECK Adapter

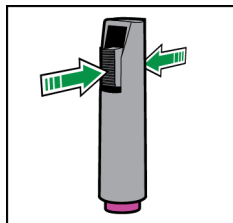
NOTE The Beckman Coulter box that contains the QC ampoules for calibration verification has been stored at a constant temperature (18-32 °C) for 5 hours.

NOTE If there are errors on calibration results, they will be shown on the calibration-verification results.

- 1 Remove a calibration-verification ampoule from its box.
- 2 Put the lid back on the box.
The ampoules are sensitive to light.
- 3 Hold the ampoule between your thumb and first finger and shake it for a minimum of 15 seconds.
- 4 Hold the ampoule neck-side up and tap the top until all the solution collects in the lower part of the ampoule.
- 5 Put the ampoule in the Ampoule Opener.

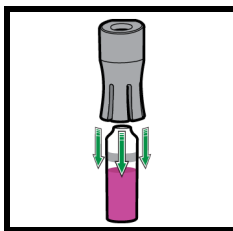


-
- 6 Use your fingers to apply pressure in the directions shown, to break off the neck of the ampoule.



-
- 7 Gently pull the ampoule out of the Ampoule Opener.

-
- 8 Put the QUALICHEK Adapter over the open end of the ampoule.



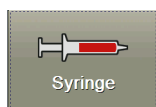
-
- 9 Do a calibration-verification measurement immediately.
-

Performing a Calibration-Verification Measurement

Prerequisites:

- A calibration-verification mode has been set up. Refer to [Setting Up a Calibration-Verification Mode](#) in [CHAPTER 8, Setup](#).
- The calibration-verification control solution is prepared for use. Refer to [Preparing a Beckman Coulter Calibration-Verification Ampoule for Use](#).
- Make sure that the analyzer displays **Ready** in the top left corner of the screen.

NOTE Beckman Coulter calibration-verification ampoules are for single use only.



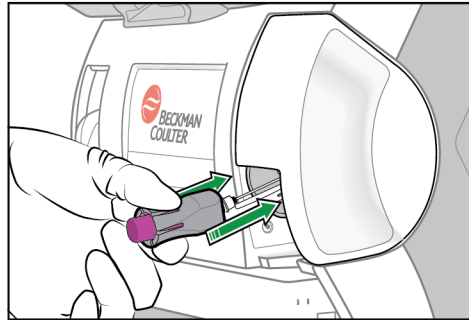
- 1 Select **Syringe**.
- The analyzer opens the inlet.

-
- 2 Select **Cal Verification**.

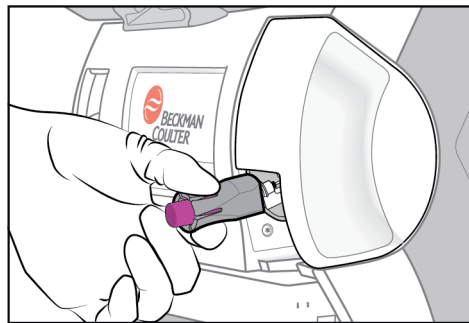
3 Turn the QUALICHECK Adapter with the ampoule so the logo faces upwards.

4 Put the QUALICHECK Adapter with the ampoule over the inlet gasket.

5 Push the adapter with the ampoule into the analyzer as far as it will go and hold it there.



6 Hold the adapter with the ampoule in the pushed-in position until the analyzer tells you to remove it.



7 When the analyzer tells you to, remove the adapter with the ampoule.
The analyzer closes the inlet.

8 Enter enough information to identify the calibration-verification control solution in the **Patient ID** field.

NOTE Enter a maximum of 20 characters. If more are entered they will not be sent to LIS/HIS systems.

9 If necessary, enter a note.

10 Select  .

NOTE Results are not temperature-corrected. If the ampoule temperature was not 25 °C, you must temperature-correct the results manually. Results are saved in the **Patient Results log**.

 WARNING

Risk of biohazardous contamination if you have skin contact with the ampoule and its contents. The ampoule could contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the ampoule in accordance with your local regulations and acceptable laboratory procedures.

11 Remove the ampoule from the adapter and dispose of it as biohazardous waste.

Post-Requisite — Perform calibration-verification measurements with a minimum of 3 levels of calibration-verification control solution.

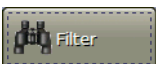
Stage 2 - Using Results to Verify Reportable Ranges

Finding a Calibration-Verification Measurement Result

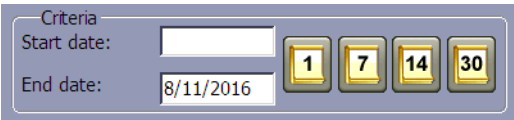
Calibration-verification results are saved in the **Patient Result log**. The results are identified as *Cal Verification* in the **Sample type** column.

NOTE Results for pH, $p\text{CO}_2$ and $p\text{O}_2$ must be corrected if the temperature of the ampoule during the measurement was above or below 25 °C.

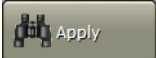
1 Select **Menu > Data logs > Patient Results log**.

2 Select  .

- 3 In the **Criteria** frame, choose an option and follow the steps for it.

Option	Steps
To select a time period prior to today's date	Select the number button for the number of days you want. 
To select a start and end date	Enter data in the Start date: and End date: fields

- 4 For **Sample type**, select *Cal. Verification*.

- 5 Select .

- 6 Select the measurement.

- 7 Select .

NOTE The result must be temperature corrected.

Calibration-Verification Measurement Results Symbols

Problems on calibration-verification results are marked with one or more of the symbols shown in the table below.

Symbol	Description
?	An error occurred. A message attached to the result describes the error
↑↑	The result is above the upper limit of the reportable range
↓↓	The result is below the lower limit of the reportable range
.....	No result could be calculated or the result is outside the range of indication of the analyzer
*	Operator-defined correction factors were used to calculate the result

Temperature Correcting Calibration-Verification Results Based on Range+ QUALICHECK Measurements

NOTE Results for pH, $p\text{CO}_2$ and $p\text{O}_2$ must be corrected if the temperature of the ampoule during measurements was above or below 25 °C.

- Find the temperature constant (A) in the table.

Beckman Coulter calibration-verification control solutions (Range+ QUALICHECK products)		
Parameter	Temperature constants (A)	
	Level 1	Level 2
pH	0.0013	0.0026
$p\text{CO}_2$	-0.0056	-0.0071
$p\text{O}_2$	-0.0098	-0.0107

NOTE It is not necessary to temperature correct the results for Range+ QUALICHECK solution level 3.

- Use the equations in the table to correct results for parameters that were measured at temperatures above or below 25 °C.

Parameter	Equation for temperature correction
pH	$\text{pH}_{\text{corrected to 25 °C}} = \text{pH}_{\text{measured}} - A (t - 25)$
$p\text{CO}_2$	$(p\text{CO}_2)_{\text{corrected to 25 °C}} = (p\text{CO}_2)_{\text{measured}} \times [1 - A (t - 25)]$
$p\text{O}_2$	$(p\text{O}_2)_{\text{corrected to 25 °C}} = (p\text{O}_2)_{\text{measured}} \times [1 - A (t - 25)]$

Example:

The pH calibration-verification measurement result was 7.100 for a level 1 solution. The temperature of the ampoule during the measurement was 32 °C not 25 °C. The result must therefore be corrected.

The temperature constant for a level 1 solution for pH is 0.0013.

The equation for temperature correction of pH values is:

$$\text{pH}_{\text{corrected to 25 °C}} = \text{pH}_{\text{measured}} - A (t - 25) = 7.100 - 0.0013 (32 - 25) = 7.091$$

Using Temperature-Corrected Calibration-Verification Results

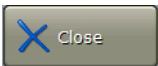
Prerequisites — Temperature corrected calibration-verification results. Refer to [Temperature Correcting Calibration-Verification Results Based on Range+ QUALICHECK Measurements](#).

Use the results to verify the reportable range of all measured parameters. Follow your laboratory guidelines.

Stage 3 - Changing Reportable Ranges

Change the Reportable Range of Parameters

Prerequisite — New reportable ranges established during calibration verification. Refer to [Performing a Calibration-Verification Measurement](#).

- 1 Select **Menu > Utilities > Setup > Analysis setup > Reportable ranges**.
- 2 Select the parameter in the **Parameters** field.
- 3 Enter new values for the upper and lower limits of the reportable range.
- 4 If necessary, do steps 2 and 3 again for each parameter.
- 5 Select .

CHAPTER 11

Cleaning Procedures

Overview

Proper cleaning can help extend the service life of the instrument and ensure experimental accuracy. When conducting any cleaning, take all necessary biosafety precautions and use proper personal protective equipment.

This chapter contains information on:

- [Cleaning](#)
 - [Cleaning the Inlet Gasket](#)
 - [Cleaning the Touch Screen](#)
 - [Cleaning the Analyzer Exterior](#)
 - [Flushing the fluid transport system](#)
- [Disinfecting](#)
 - [Disinfecting the Touch Screen](#)
 - [Disinfecting the Analyzer Exterior](#)
 - [Disinfecting the Fluid Transport System](#)

Cleaning

The analyzer must always be kept clean. Exterior surfaces, the Inlet Gasket, and other parts of the analyzer must be cleaned when they are contaminated with blood and/or other liquids.

Cleaning the Inlet Gasket

Clean and check the Inlet Gasket weekly and replace if damaged. Refer to [Replacing the Inlet Connector Gasket](#) in [CHAPTER 12, Replacement/Adjustment Procedures](#).

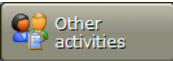
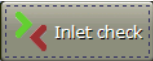
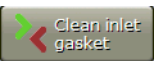
Prerequisite — A lint-free cloth

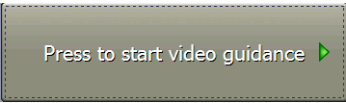
WARNING

Risk of infection. Make sure you do not prick or scratch yourself on the Inlet Probe.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

1 Select **Menu > Analyzer status**.

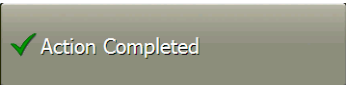
2 Select  >  > .

3 Select .

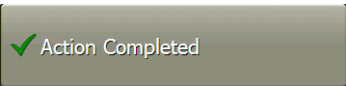
The analyzer opens the inlet.

4 Ensure the Inlet Probe is not bent. If it is bent, replace it. Refer to [Replacing the Inlet Probe](#) in [CHAPTER 12, Replacement/Adjustment Procedures](#).

5 Dampen a lint-free cloth with water.

6 Select .

7 Gently wipe the inlet gasket and the area around it until it is clean.

8 Select .

The analyzer closes the inlet.

Cleaning the Touch Screen

Prerequisite — A lint-free cloth

- 1 Lightly dampen a lint-free cloth with tap water.
- 2 Put your finger on a part of the screen that is not active and hold it there.
- 3 Gently wipe the screen.

Cleaning the Analyzer Exterior

Prerequisites:

- A lint-free cloth
- A mild soap or detergent

NOTE Beckman Coulter has not tested whether cleaning wet wipes can be used for this purpose.

NOTE The Sensor Cassette compartment and the top surface of the Solution Pack compartment must be cleaned by a Beckman Coulter Representative. [Contact us.](#)

- 1 Lightly dampen a lint-free cloth with soapy water or a mild detergent.
- 2 Wipe the analyzer exterior.

Flushing the fluid transport system

Prerequisites:



A MetaFLEX Flush Device



A paper tissue or a cloth

⚠ WARNING

Risk of infection. Make sure that you wear gloves during replacement and maintenance procedures.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

NOTE The analyzer will automatically start the workflow for the flush of the fluid transport system when necessary.

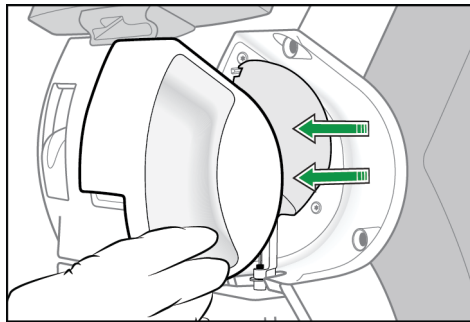
1 Draw tap water into the Flush Device up to the 2.5 mL mark.

2 Pull the plunger of the Flush Device up to the 5 mL mark to draw air into it.

3 Select

Press to start video guidance ▶

4 Pull off the inlet cover.



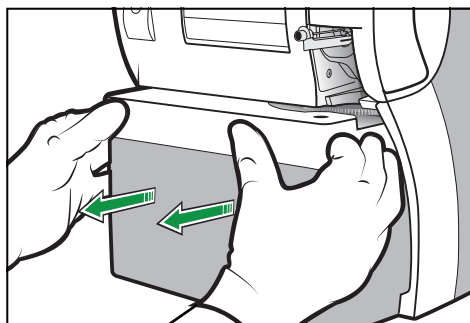
5 Select

✓ Action Completed

The analyzer opens the inlet.

6 Wait until the Solution Pack is ejected.

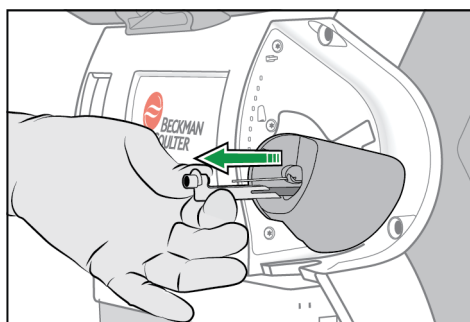
- Remove the Solution Pack.



- Select

✓ Action Completed

- Pull out the Inlet Gasket Holder.



- Select

✓ Action Completed

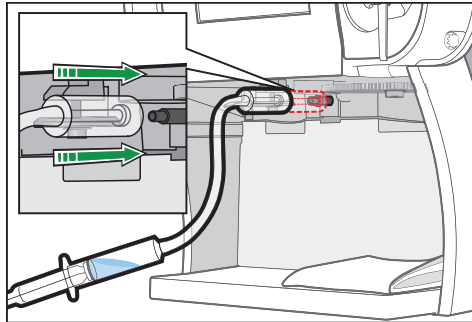
The analyzer closes the inlet.

- Put a tissue or a cloth under the inlet.

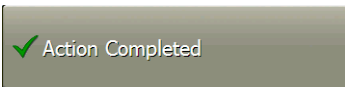
- Select

✓ Action Completed

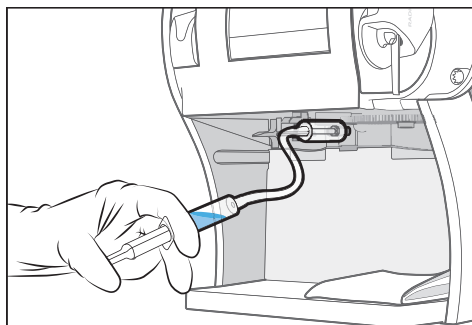
- 13** Connect the tip of the Flush Device to the waste connector in the Solution Pack compartment.



- 14** Select

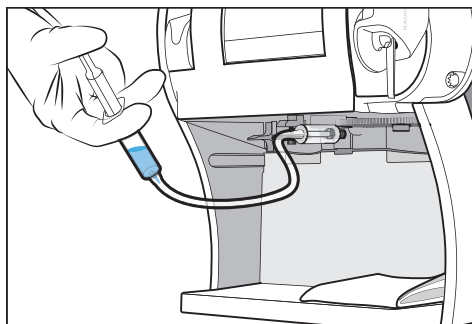


- 15** Hold the Flush Device as shown.



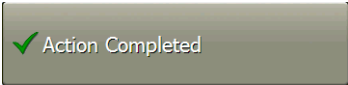
- 16** Inject a very small quantity of air to fill approximately 1 cm of the tube.

- 17** Hold the Flush Device as shown.



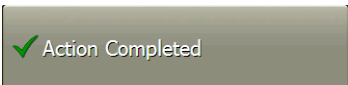
- 18** Inject a very small quantity of water to fill approximately 1 cm of the tube.

19 Do steps 15 to 18 again repeatedly to clean the fluid transport system.

20 Select .

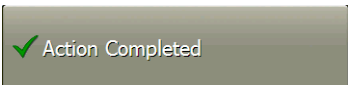
21 Inject water until an unbroken stream of water comes out of the Inlet Probe.

NOTE The fluid path is flushed, when this is possible. If it is not possible, repeat Steps 15 to 18 and Step 2.

22 Select .

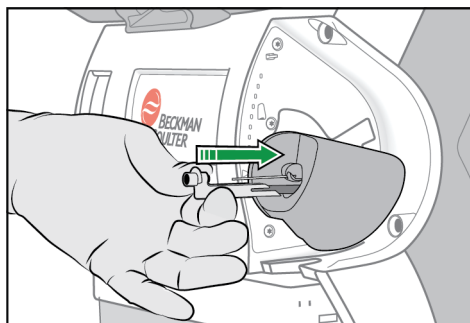
23 Disconnect the Flush Device.

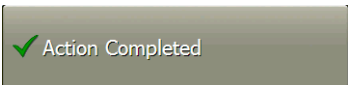
24 Remove the tissue or the cloth.

25 Select .

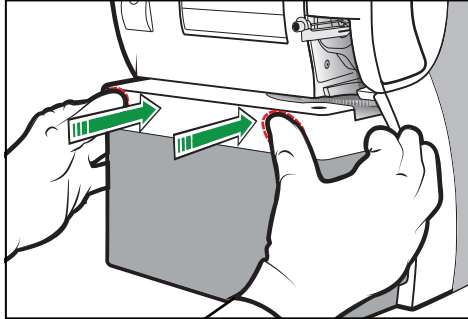
The analyzer opens the inlet.

26 Put the new Inlet Gasket holder over the slide and insert it. Make sure that the Inlet Probe is in the center of the gasket and that the Inlet Gasket Holder clicks in place.



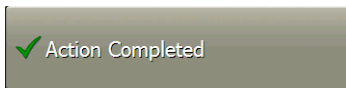
27 Select .

- 28** Put your thumbs on the white part of the Solution Pack and push the Solution Pack into its compartment until it clicks in place. The analyzer closes the inlet.



- 29** Put on the inlet cover.

- 30** Select



Disinfecting

To determine how often to disinfect the analyzer, follow your local, state and federal guidelines.

Disinfecting the Touch Screen

Disinfect the touch screen as needed.

Prerequisites:

- The analyzer is clean
- A lint-free cloth
- A solution of 70% isopropyl alcohol (2-propanol) or 70% ethanol

- 1** Lightly dampen a lint-free cloth with a recommended disinfection solution.
- 2** Put your finger on a part of the screen that is not active and hold it there.
- 3** Gently wipe the screen.

Disinfecting the Analyzer Exterior

Disinfect the exterior as needed.

Prerequisites:

- The analyzer is clean
- A lint-free cloth
- A solution of 70% isopropyl alcohol (2-propanol), 70% ethanol or 5% sodium hypochlorite

NOTE Beckman Coulter has tested that these solutions can be used for disinfecting the analyzer exterior. Beckman Coulter has not tested whether disinfection wet wipes can be used for this purpose. The Sensor Cassette compartment and the top surface of the Solution Pack compartment must be disinfected by a Beckman Coulter Representative.

1 Lightly dampen a lint-free cloth with a recommended disinfection solution.

2 Wipe the analyzer exterior.

Disinfecting the Fluid Transport System

To disinfect the fluid transport system, perform the long-term shutdown procedure. Refer to [Long-Term Shutdown of the Analyzer](#) in [CHAPTER 7, Shutdown](#).

Replacement/Adjustment Procedures

Overview

Proper maintenance can help extend the service life of the instrument and ensure experimental accuracy. When conducting any maintenance work, take all necessary biosafety precautions.

IMPORTANT In addition to parts specifically discussed, for all replacement parts, use only parts provided by Beckman Coulter to ensure proper functioning of the instrument. Never disassemble any part of the instrument without prior authorization. Beckman Coulter assumes no responsibility for any instrument problems resulting from the use of any part not authorized by Beckman Coulter for use with the instrument.

This chapter contains information on:

- [General Warnings and Cautions](#)
- [Replacement Intervals for Consumables and Inlet Connector Gasket](#)
- [Replacements](#)
- [Maintenance](#)
- [Connecting Peripherals](#)

General Warnings and Cautions

WARNING

Risk of infection. Only let authorized personnel collect and work with biologic samples. Make sure to wear gloves.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

WARNING

Risk of infection. Dispose and handle all used sampling devices, quality control (QC) ampoules, Solution Packs, Sensor Cassettes, Inlet Probes, Inlet Gasket Holders, Inlet Connector Gaskets and Inlet Modules as biohazardous waste.¹ Follow your local regulations.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

WARNING

Risk of infection. Make sure you do not prick or scratch yourself on the Inlet Probe.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

WARNING

Risk of infection. Make sure that you wear gloves during replacement and maintenance procedures.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

Replacement Intervals for Consumables and Inlet Connector Gasket

The recommended replacement intervals shown in the table are only a guideline. They are based on a default of 10 sample analyses per day. For analyzers with a higher sample throughput, the number of **Expected measurements per day** can be changed in the setup, so the analyzer can calculate the most probable replacement date and send a message about it.

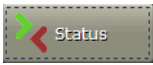
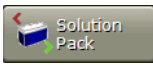
Consumables	Default tests or activities per day	Recommended replacement interval after installation
Solution Pack	10	Maximum 30 days or when the number of activities is zero
Sensor Cassette	10	Maximum 30 days or when the number of tests is zero
Inlet Gasket Holder	10	12 months
Inlet Connector Gasket	10	12 months

Replacements

Solution Pack

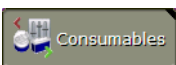
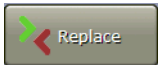
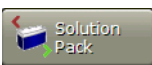
Viewing the Solution Pack Status

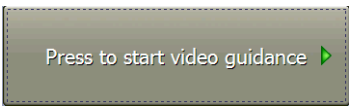
- 1 Select **Menu > Analyzer status > Consumables**.

- 2 For more information, select  **Status** >  **Solution Pack**.

Replacing the Solution Pack

- 1 Select **Menu > Analyzer status**.

- 2 Select  **Consumables** >  **Replace** >  **Solution Pack**.

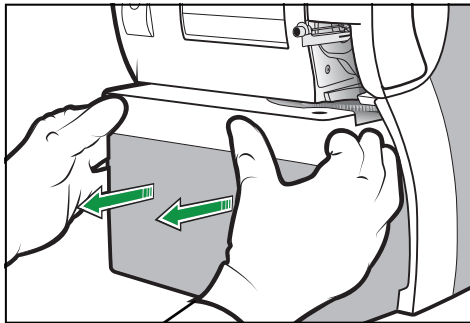
- 3 Select  **Press to start video guidance**.
- The analyzer opens the inlet.

- 4 Wait until the Solution Pack is released.

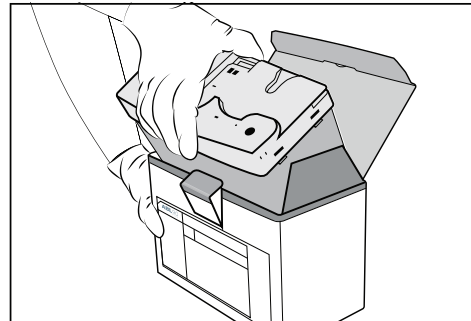
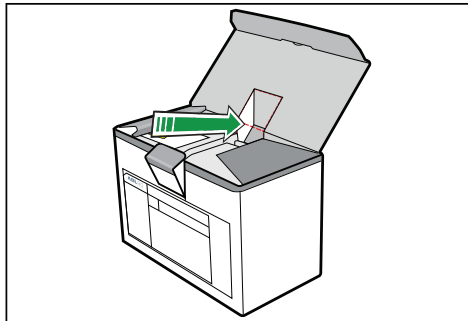
⚠ WARNING

Risk of biohazardous contamination if you have skin contact with the Solution Pack and its contents. The Solution Pack could contain residual biological material and must be handled with care. Clean up spills immediately. Dispose of the Solution Pack in accordance with your local regulations and acceptable laboratory procedures.

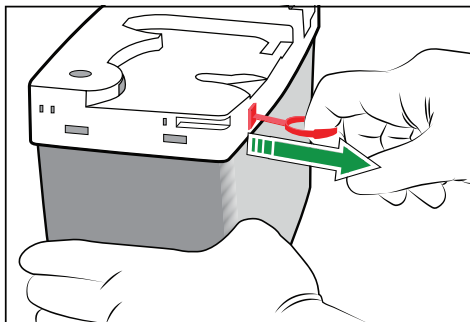
- 5** Remove the Solution Pack and dispose of it as biohazardous waste.



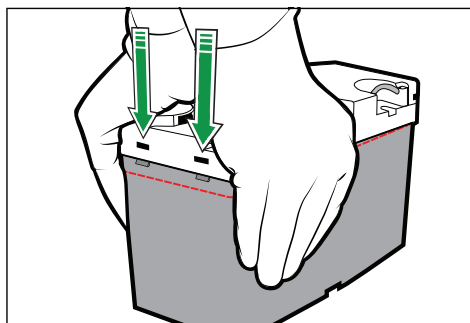
- 6** Lift the new Solution Pack out of its box as shown.



- 7** Pull the red pin out of the new Solution Pack.



- 8 Put the palms of your hands over the edges of the lid as shown.

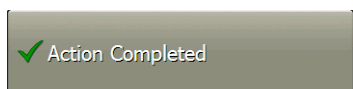


- 9 Press down firmly and evenly with both hands until the tabs click into the 2 holes.

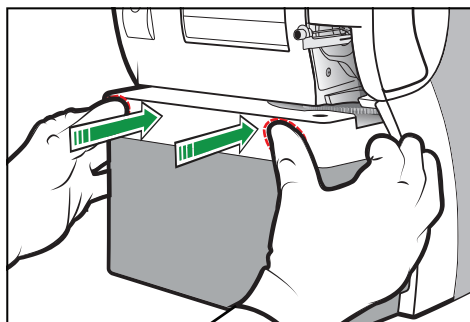
NOTE For the Solution Pack to be activated correctly, both tabs must click in place.



- 10 Select

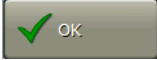


- 11 Put your thumbs on the white part of the Solution Pack and push the Solution Pack into its compartment until it clicks in place.



The analyzer closes the inlet.

12 Enter necessary data.

13 Select .

Can a Solution Pack be Used Again?

A Solution Pack removed from one analyzer can be used on another if these 3 conditions are met:

- the Solution Pack is installed before its **Scheduled to replace:** date
- the Solution Pack is installed before its **Expiration date:**
- the Solution Pack has some remaining activities

This data can be seen in the **Solution Pack Status** screen.

Status Logs

Status logs include all the data that tells something about the performance of a consumable that has been removed from the analyzer. The data can be printed or exported to a USB flash drive.

Printing Solution Pack Status Logs

1 Select **Menu > Data logs > Replacement log**.

2 Select the **Solution pack removed** activity.

3 Select .

Exporting Solution Pack Status Logs

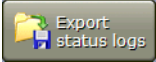
Prerequisites:

- A USB flash drive

1 Plug in the USB flash drive.

2 Select **Menu > Data logs > Replacement log**.

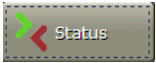
-
- 3 Select the **Solution pack removed** activity.
-

- 4 Select .
-

Sensor Cassette

Viewing the Sensor Cassette Status

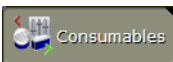
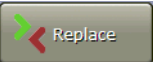
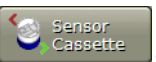
-
- 1 Select **Menu > Analyzer status > Consumables**.
-

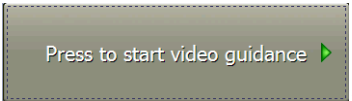
- 2 For more information, select  > .
-

Replacing the Sensor Cassette

NOTE The analyzer has to condition a new Sensor Cassette after it is installed. This process can take up to 4 hours.

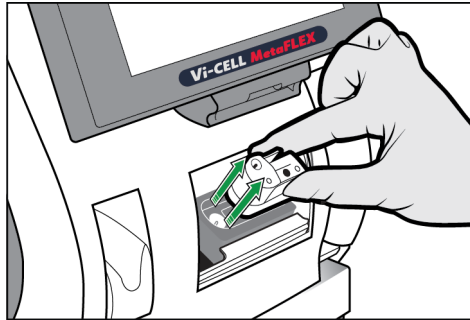
-
- 1 Select **Menu > Analyzer status**.
-

- 2 Select  >  > .
-

- 3 Select .
-

- 4 Wait until the Sensor Cassette compartment opens.
-

-
- 5 Remove the Sensor Cassette and dispose of it as biohazardous waste.



-
- 6 Select

✓ Action Completed

-
- 7 Pull the foil off the new Sensor Cassette Pack, unscrew the lid and lift out the Sensor Cassette.

-
- 8 Select

✓ Action Completed

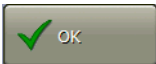
-
- 9 Press the new Sensor Cassette in place.



-
- 10 Select

✓ Action Completed

-
- 11 Enter necessary data.

12 Select .

NOTE If you select the **Exit conditioning** button, the more frequent calibrations that normally follow in the 24 hours after a Sensor Cassette replacement will not be done. This may have an effect on the accuracy and precision of patient results in this period of time.

Calibration Frequency After a Sensor Cassette Replacement

Calibrations are done more frequently in the 24-hour period that follows a Sensor Cassette replacement. This has an effect on the number of analyses that can be done per hour during this time period.

NOTE A calibration takes up to 2½ minutes.

Time period after a replacement	Calibration frequency
0-4 hours	In connection with every measurement
4-6 hours	Every 15 minutes
6-8 hours	Every 30 minutes
8-12 hours	Every hour
12-24 hours	Every 2 hours

Can a Sensor Cassette be Used Again?

A Sensor Cassette removed from one analyzer can be used on the same or on another Vi-CELL MetaFLEX analyzer if these 6 conditions are met.

- The Sensor Cassette is kept right side up after its removal. This prevents damage to the sensors.
- The Sensor Cassette is installed within 2 hours of its removal.
- The Sensor Cassette is installed before its **Scheduled to replace** date.
- The Sensor Cassette is installed before its **Expiration date**.
- The Sensor Cassette has some remaining activities.
- The Sensor Cassette was not removed from an analyzer during a long-term shutdown procedure.

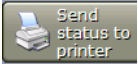
This data can be seen in the **Sensor Cassette Status** screen.

Status Logs

Status logs include all the data that tells something about the performance of a consumable that has been removed from the analyzer. The data can be printed or exported to a USB flash drive.

Printing Sensor Cassette Status Logs

- 1 Select **Menu > Data logs > Replacement log**.
- 2 Select the **Sensor Cassette removed** activity.

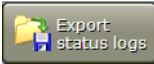
- 3 Select .

Exporting Sensor Cassette Status Logs

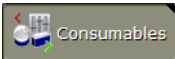
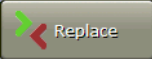
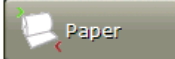
Prerequisites:

- A USB flash drive

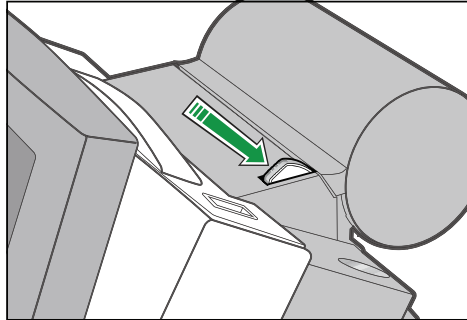
- 1 Plug in the USB flash drive.
- 2 Select **Menu > Data logs > Replacement log**.
- 3 Select the "Sensor cassette removed" activity.

- 4 Select .

Replacing the Thermal Printer Paper

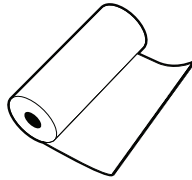
- 1 Select **Menu > Analyzer status**.
- 2 Select  **Consumables** >  **Replace** >  **Paper**.

- 3 Press the release button.



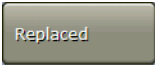
- 4 Open the cover and remove the used paper roll.

- 5 Put in the new paper roll. Make sure the paper unwinds from below.

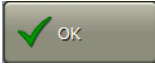


- 6 Make sure some paper extends out of the printer.

- 7 Close the cover. The cover must click in place.

- 8 Select .

- 9 Enter necessary data.

- 10 Select .

Protection of Printed Data

NOTE Do not expose data printed on the thermal printer paper of the analyzer to high temperatures, high humidity, direct sunlight, water, alcoholic or organic solvents, freshly-developed diazo copy sheets or materials that contain polyvinylchloride (PVC), and do not scratch them. Keep the printed data in polyethylene, polypropylene or polyester folders or boxes.

These precautions will help you to protect your printed data.

Replacing the Inlet Gasket Holder

Replace the Inlet Gasket Holder every 12 months.

WARNING

Risk of infection. Make sure you do not prick or scratch yourself on the Inlet Probe.

Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

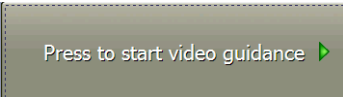
WARNING

Risk of infection. The used Inlet Gasket Holder could have been in contact with biologic samples and must be handled as potentially infectious.

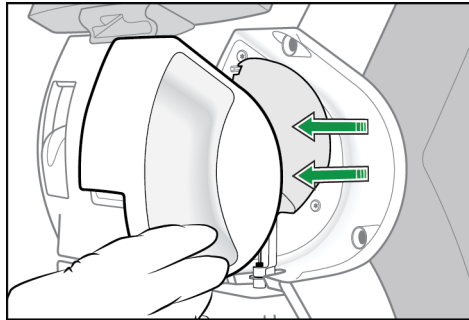
Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

1 Select **Menu > Analyzer status.**

2 Select  **Other activities** >  **Inlet check** >  **Repl. Inlet Gasket Holder** .

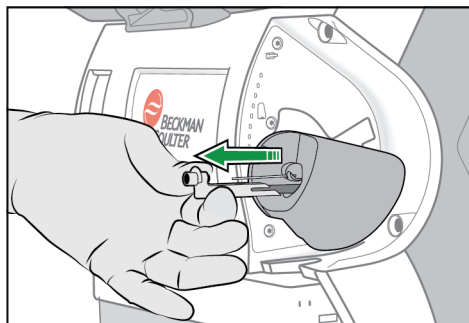
3 Select  **Press to start video guidance** .

- 4 Pull off the inlet cover.



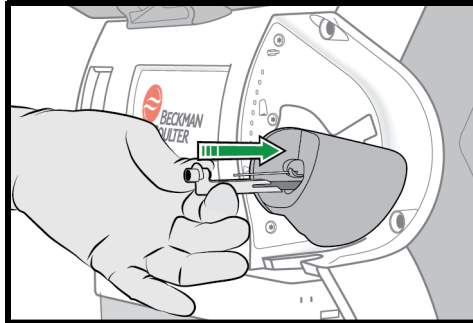
- 5 Select ✓ Action Completed.
The analyzer opens the inlet.

- 6 Pull out the Inlet Gasket Holder.



- 7 Select ✓ Action Completed.

-
- 8 Put the new Inlet Gasket holder over the slide and insert it. Make sure that the Inlet Probe is in the center of the gasket.



NOTE Make sure the Inlet Gasket Holder clicks in place.

-
- 9 Select  Action Completed .
The analyzer closes the inlet.

-
- 10 Put on the inlet cover.

-
- 11 Select  Action Completed .
-

Replacing the Inlet Probe



WARNING

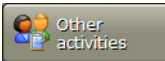
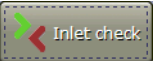
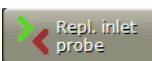
Risk of infection. Make sure you do not prick or scratch yourself on the Inlet Probe.
Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

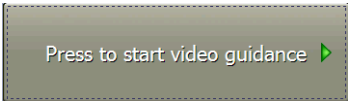


WARNING

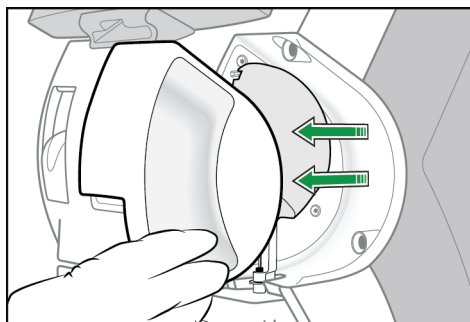
Risk of infection. The used Inlet Probe could have come in contact with biologic samples and must be handled as potentially infectious.
Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

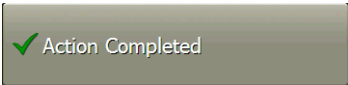
- 1 Select **Menu > Analyzer status.**

- 2 Select  >  > .

- 3 Select .

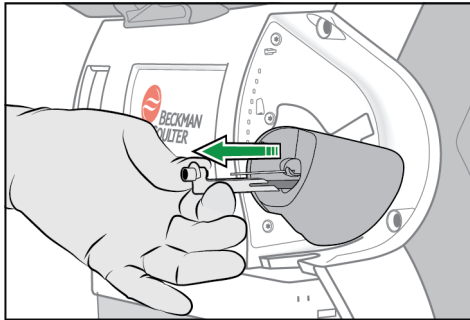
- 4 Pull off the inlet cover.



- 5 Select .

The analyzer opens the inlet.

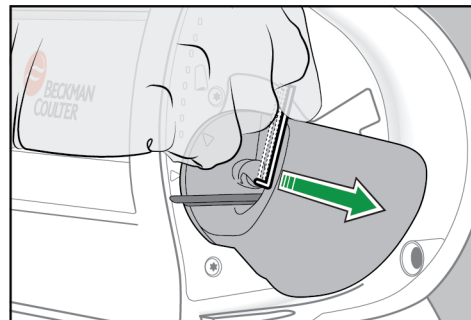
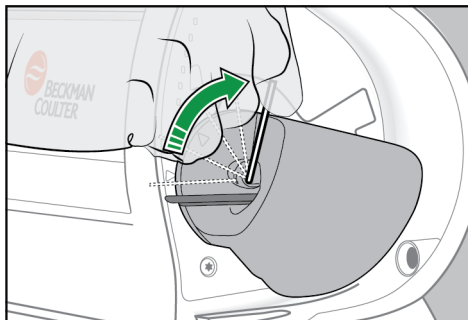
- 6 Pull out the Inlet Gasket Holder.



- 7 Select

✓ Action Completed

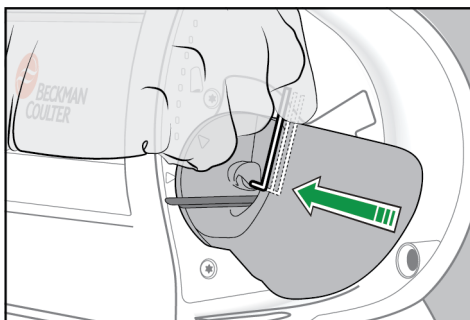
- 8 Lift up the Inlet Probe as far as it will go and pull it to the right to remove it.



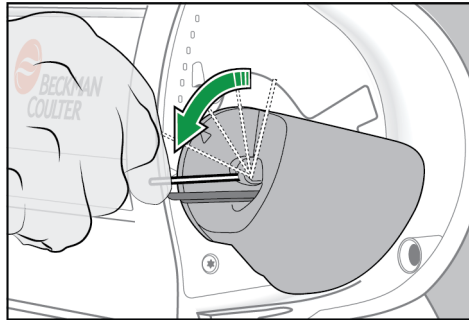
- 9 Select

✓ Action Completed

- 10 Hold the new Inlet Probe in a vertical position and put it in place.



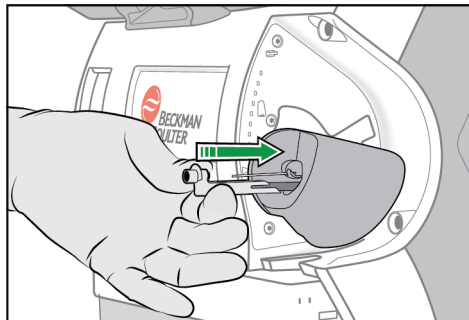
- 11** Lower the Inlet Probe.



- 12** Select

✓ Action Completed

- 13** Put the new Inlet Gasket holder over the slide and insert it. Make sure that the Inlet Probe is in the center of the gasket.



NOTE Make sure the Inlet Gasket Holder clicks in place.

- 14** Select

✓ Action Completed

The analyzer closes the inlet.

- 15** Put on the inlet cover.

- 16** Select

✓ Action Completed

Replacing the Inlet Connector Gasket

Replace the Inlet Connector Gasket every 12 months.

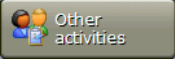
Prerequisite — A pair of tweezers

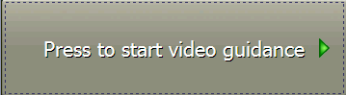
WARNING

Risk of infection. The used Inlet Connector Gasket has been in contact with biologic samples and must be handled as potentially infectious.

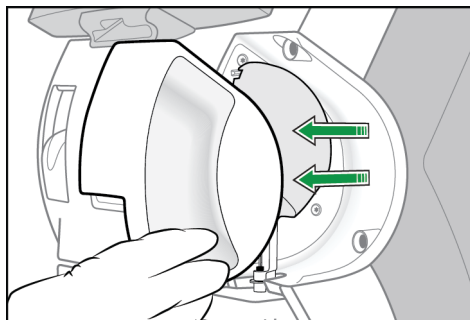
Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

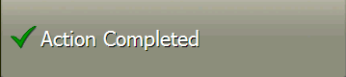
-
- 1 Select **Menu > Analyzer status.**

-
- 2 Select  >  > .

-
- 3 Select .

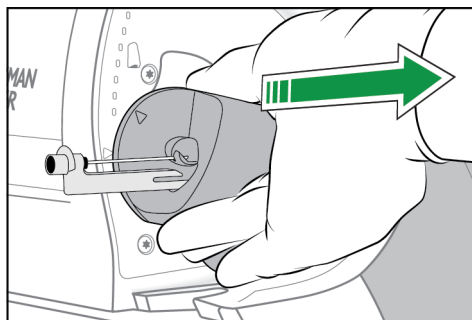
-
- 4 Pull off the inlet cover.



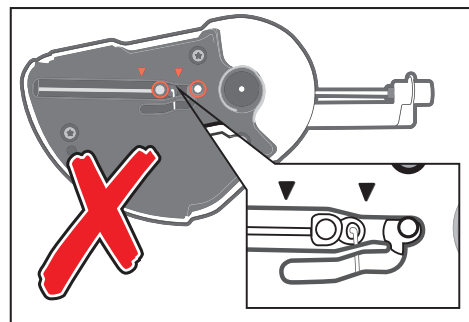
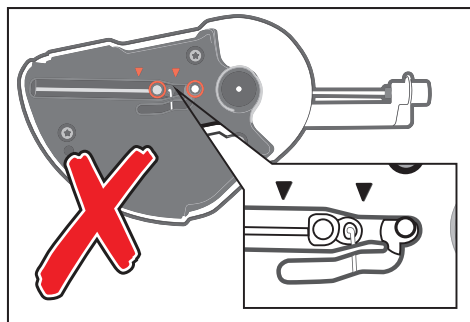
-
- 5 Select .

The analyzer opens the inlet.

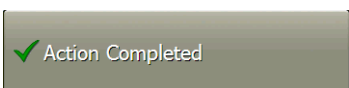
- 6 Hold the Inlet Module as shown and pull to the right.



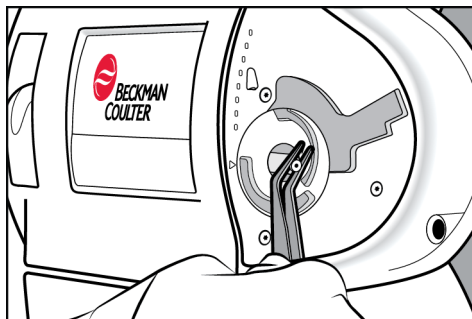
- 7 Make sure that the tabs on the inner side of the Inlet Module are in the correct position.



- 8 Select



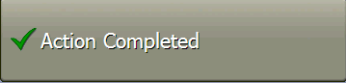
- 9 Pull out the Inlet Connector Gasket with a pair of tweezers.



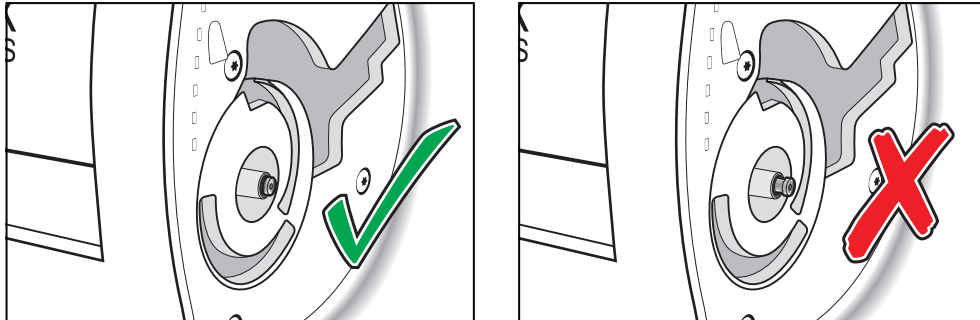
- 10 Select

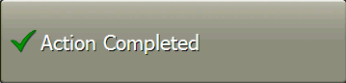


-
- 11** Put tap water on the new Inlet Connector Gasket.
-

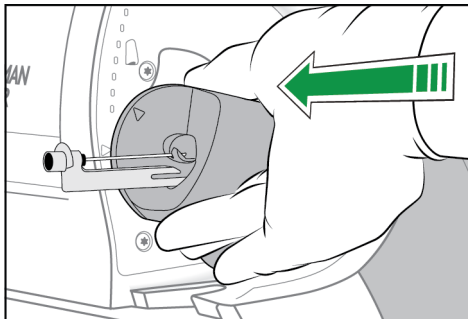
- 12** Select .
-

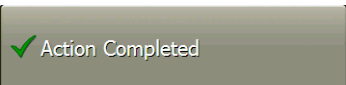
- 13** Push the new Inlet Connector Gasket in place as shown.



- 14** Select .
-

- 15** When the analyzer tells you to, hold the Inlet Module as shown and push the end into the inlet connector until it clicks in place.



- 16** Select .
-

The analyzer closes the inlet.

- 17** Put on the inlet cover.

18 Select



Replacing the Inlet Module



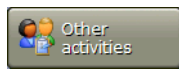
WARNING

Risk of infection. The used Inlet Module has been in contact with biologic samples and must be handled as potentially infectious.

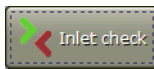
Use universal precautions when working with pathogenic materials. Means must be available to decontaminate the instrument and to dispose of biohazardous waste.

1 Select **Menu > Analyzer status.**

2 Select



>

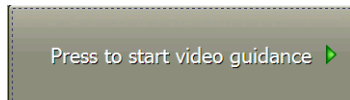


>

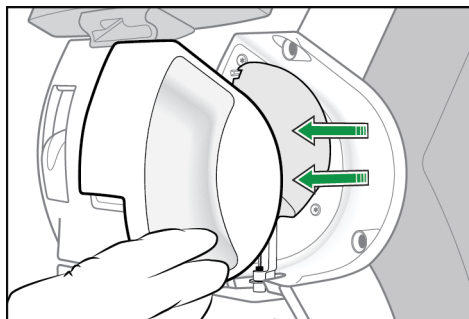


NOTE Only a new Inlet Module is necessary.

3 Select



4 Pull off the inlet cover.

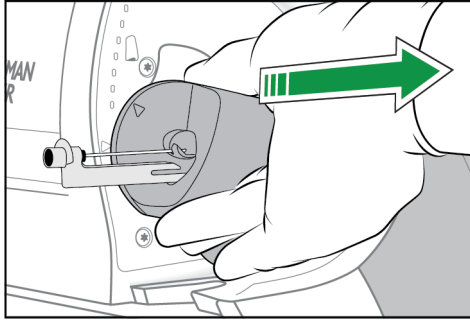


5 Select

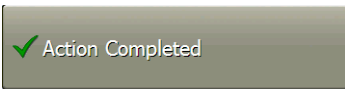


The analyzer opens the inlet.

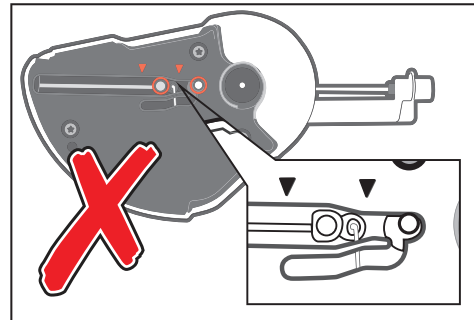
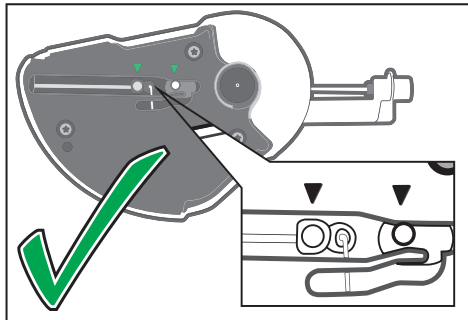
- 6 Hold the Inlet Module as shown and pull to the right.



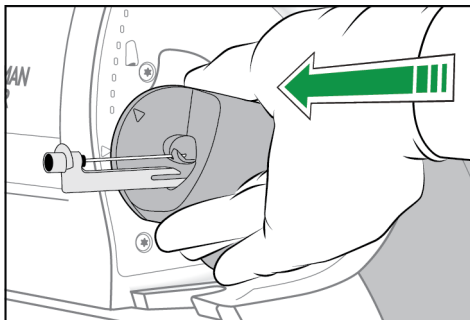
- 7 Select



- 8 Make sure that the tabs on the inner side of the new Inlet Module are in the correct position.



- 9 When the analyzer tells you to, hold the new Inlet Module as shown and push the end into the inlet connector until it clicks in place.



10 Select

✓ Action Completed

The analyzer closes the inlet.

11 Put on the inlet cover.

12 Select

✓ Action Completed

Replacing the Fuse

Use two F2.5A, 250 V fuses.

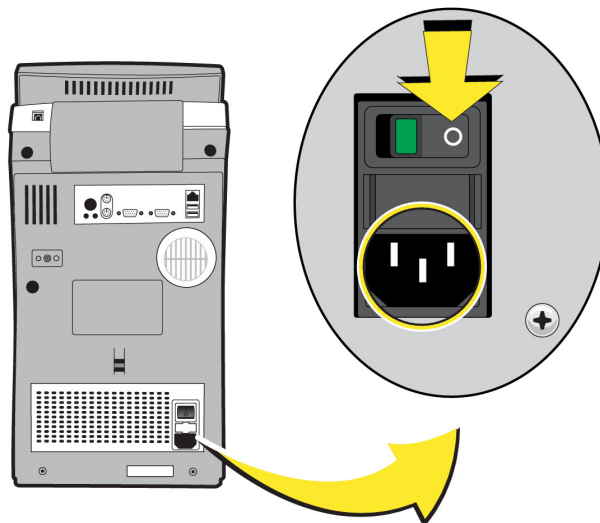
IMPORTANT [Contact us](#) if the fuses continue to blow after being replaced.



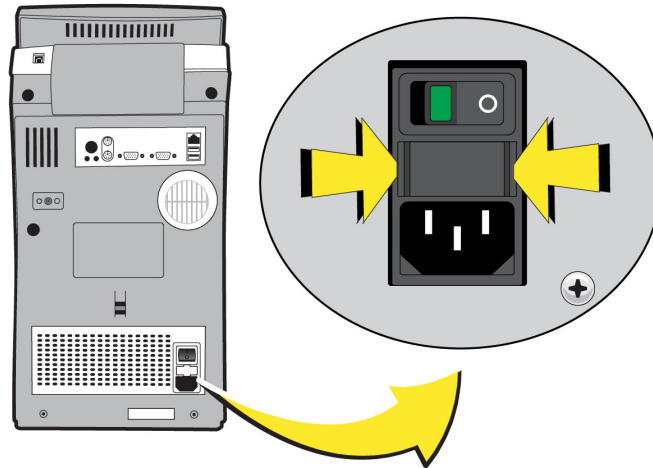
WARNING

Risk of personal injury. A shock hazard exists if the power cable is connected. Turn off the Analyzer and disconnect the primary power cable before performing these procedures.

1 Turn off the instrument and disconnect the power cable.



- 2 Press both sides of the fuse holder of the instrument inwards using a flat head screwdriver, and pull out the fuse holder.



CAUTION

Risk of instrument damage. Ensure that you use the correct fuse type and rating (2 x F2.5A, 250 V) to prevent the risk of fire and/or improper instrument operation.

- 3 Check whether the fuse installed is blown, and replace the blown fuse with a new one.
The specifications of the fuse required are: F2.5A, 250 V.



- 4 Insert the fuse holder.
- 5 Reconnect the power cable.

Maintenance

Battery

Recharging the Analyzer Battery

To recharge the analyzer battery, connect the analyzer to the mains power supply.

Installing and Servicing the Battery

To install or service the battery, [contact us](#).

Analyzer Preventative Maintenance Service

[Contact us](#) to schedule preventative maintenance service for your analyzer every 12 months.

Connecting Peripherals

Connecting a USB External Keyboard / Mouse

Connect the external keyboard/mouse cable to the external keyboard/mouse port of the analyzer. Refer to [Figure 1.2](#).

NOTE The analyzer will find the connection to the external keyboard/mouse immediately.

Connecting a Non-USB (PS/2) External Keyboard or Mouse

- 1 Perform a temporary shutdown. Refer to [Temporary Shutdown of the Analyzer](#) in [CHAPTER 7, Shutdown](#).
 - 2 Connect the external keyboard/mouse cable to the external keyboard/mouse port of the analyzer.
 - 3 [Restart the analyzer](#).
-

Connecting an External Barcode Reader

To connect an external barcode reader, [contact us](#).

Connecting the Analyzer to a Network

Prerequisite — RJ45 connector.

To connect the analyzer to a network, connect the network cable to the network connector and the network cable port of the analyzer.

Overview

Your instrument may have been shipped directly to your laboratory, in which case you will need to set up and connect the instrument. Refer to this chapter for the instrument installation procedure.

NOTE The Vi-CELL MetaFLEX Bioanalyzer is self-contained with the software preloaded on the internal computer.

This chapter contains information on:

- [Instrument Transportation and Storage](#)
- [Installation Environment Validation](#)
- [Unpacking the Instrument and Inspecting the Materials for Defects or Omissions](#)

Instrument Transportation and Storage

Refer to [Disinfecting](#) in [CHAPTER 11, Cleaning Procedures](#), prior to transportation or storage.

Attention to the following items is required when transporting or storing the instrument:

- Take caution to protect the instrument from exposure to rain or sunlight.
- Always place the instrument on a flat, stable surface, and take note of the symbol for *this side up*.
- Temperature range: see [Temperature and Humidity](#).
- Analyzer weight <12 kg; transport the instrument using only appropriate equipment so as to guard against personal injury.

Installation Environment Validation

IMPORTANT This instrument is intended for indoor use only.

Verify whether the installation environment satisfies the following requirements:

Worktable



Risk of instrument damage. Place the instrument on a level surface. Failing to do so places the system in danger of toppling and can result in damage. Take all necessary precautions throughout the process of storing or transporting the instrument.

- The tabletop must be smooth and level.
- Minimum tabletop load bearing capacity: 25 kg (55 lbs).
- The tabletop must not vibrate or shake.
- Minimum tabletop dimensions: 50 cm x 50 cm (19.7 in. x 19.7 in.); minimum vertical space above tabletop: 20 cm (7.9 in.)
- Position the instrument in such a manner that it will facilitate disconnection of the power cable at the instrument end.

Ventilation and Cleaning

IMPORTANT If necessary, use ventilation equipment, but airflow must not be allowed to blow directly on the system, as it can affect the reliability of the data.

- Ensure that the working environment is well ventilated for proper heat dissipation.
- Maintain a clearance of at least 30 cm (11.8 in.) from the back of the instrument for heat dissipation.
- Keep the environment as dust free as possible.
- Avoid direct exposure to sunlight.
- Avoid placing near heat sources or exposing to drafts.
- Avoid corrosives or flammable gases.

Power Source

IMPORTANT Do not use this device in close proximity to sources of strong electromagnetic radiation (unshielded intentional RF sources), as these may interfere with the proper operation.



CAUTION

Risk of instrument damage. Use an outlet with power fail protection to prevent damage to the Sensor Cassette during extended power outages.



CAUTION

Risk of instrument damage. Ensure that the power source is properly grounded. Improper grounding can cause electric shock and damage the system.

Temperature and Humidity



CAUTION

Risk of instrument damage and/or erroneous results. To ensure reliability, the system must be operated in the specified environment, within the required temperature and humidity ranges. If the ambient temperature or humidity level falls outside the ranges mentioned above, use appropriate air conditioning.

- Operating temperature: 15-32°C (59-89.6°F).
- Relative humidity: 20-80%.

Unpacking the Instrument and Inspecting the Materials for Defects or Omissions

Take care to store the instrument in a suitable environment where it can remain in the proper position.

Check that the following components on the packing list are present:

- Vi-CELL MetaFLEX Analyzer
- Vi-CELL MetaFLEX Safety Notices and Basic Troubleshooting Package Insert
- Startup Kit that contains:
 - Backflush device
 - (1) Thermal paper roll
 - U.S. power cord (125 V)

Installing the Instrument and Connecting the Equipment

- 1** Remove the analyzer and any optional peripherals from the each respective box placing them flat on the instrument worktable.
Reach under the base of the instrument to lift the Bioanalyzer out of the package.
NOTE Take care not to lift the instrument by the screen or inlet cover.
- 2** Ensure all minimum clearance are met. Refer to [Worktable](#) and [Ventilation and Cleaning](#).
- 3** Turn the power switch on. Refer to [Figure 1.2](#).
- 4** Follow the instructions on screen.
The instrument automatically goes into startup mode.
NOTE Startup mode may take up to 4 hours to complete. It is not necessary to be present during this process.
- 5** If applicable, install the thermal printer paper. Refer to [Replacing the Thermal Printer Paper](#) in [CHAPTER 12, Replacement/Adjustment Procedures](#).
- 6** Install a new Solution Pack. Refer to [Replacing the Solution Pack](#) in [CHAPTER 12, Replacement/Adjustment Procedures](#).
- 7** Install a new Sensor Cassette. Refer to [Replacing the Sensor Cassette](#) in [CHAPTER 12, Replacement/Adjustment Procedures](#).
- 8** If applicable, install the mouse. Refer to [Connecting a USB External Keyboard / Mouse](#) or [Connecting a Non-USB \(PS/2\) External Keyboard or Mouse](#) in [CHAPTER 12, Replacement/Adjustment Procedures](#).
- 9** If applicable, install the external printer. Refer to [Installing an External Printer for the Analyzer](#) in [CHAPTER 8, Setup](#).

Derived and Input Parameters

Overview

This section describes the different types of parameters available on the Vi-CELL MetaFLEX instrument. Some parameters are measured by the analyzer, others are calculated from equations that use measured / keyed-in / default values of other parameters.

Parameter Types

The table below describes the three parameter types available on the Vi-CELL MetaFLEX instrument.

Parameter type	Description
Measured parameters	Parameters that are measured by the analyzer
Input parameters	Parameters that are keyed-in (entered) by an operator
Derived parameters	Parameters that are calculated from measured, input and default values

Parameter Symbols

The symbols for the parameters are based on the principles described by Wandrup.⁴ Each symbol has three parts:

1. A character in italics that is an abbreviation of the property (quantity).

Examples:

- *p* for pressure
- *c* for concentration
- *F* for fraction
- *V* for volume

2. An abbreviation of the parameter.

Examples:

- O₂ for oxygen
- CO₂ for carbon dioxide
- COHb for carboxyhemoglobin

3. A character that is an abbreviation of the system.

Examples:

- B for blood
- P for plasma
- a for arterial blood
- $\bar{v}$ for mixed venous blood
- A for alveolar air
- T for temperature

Example:

$pO_2(a)$, where p = pressure, O_2 = oxygen, (a) = arterial blood.

Input Parameters – Definitions and Acceptable Values

Input parameters are parameter values that can be entered by operators, or transferred to the analyzer from an interfaced database. Only values that fall within a given range are accepted.

Parameter symbol	Definition	Unit	Input range
T	Temperature	°C	15.0-45.0
		°F	59.0-113.0
N/A	Temperature NOTE This is a data field in the Quality control identification screen. To get the correct QC results, it is necessary that the ampoule temperature is entered in this field.	°C	18.0-32.0
		°F	64.4-89.6
FO ₂ (I)	Fraction of oxygen in dry inspired air	%	0-100
		Fraction	0.000-1.000
ctHb	Concentration of total hemoglobin in blood. NOTE Is used if the analyzer version does not include the oximetry measuring system.	g/dL	0.0-33.0
		g/L	0-330
		mmol/L	0.0-20.5
RQ	Respiratory quotient, ratio between the CO ₂ production and the O ₂ consumption	Fraction	0.00-2.00
pO ₂ ($\bar{v}$)	Oxygen tension of mixed venous blood	mmHg; Torr	0.0-750.0
		kPa	0.00-100
sO ₂ ($\bar{v}$)	Oxygen saturation of mixed venous blood	%	0.0-100.0
		Fraction	0.000-1.000

Parameter symbol	Definition	Unit	Input range
Q_t	Cardiac output; volume of blood delivered from the left ventricle into the aorta per unit of time. NOTE Also termed CO or C.O.	L/min	0.0-100.0
VO_2	Oxygen consumption; total amount of oxygen used by the whole organism per unit of time	mL/min	0-21000
		mmol/min	0.0-937.1
VCO	Volume of carbon monoxide added to the sample for measurement and calculation of $V(B)^5$	mL	0.0-1000.0
FCOHb(1)	The fraction of COHb measured before a CO injection	%	0.0-100.0
		Fraction	0.000-1.000
FCOHb(2)	The fraction of COHb measured after a CO injection	%	0.0-100.0
		Fraction	0.000-1.000

Derived Parameters

Derived parameters are calculated from equations that can include the measured and/or input (keyed-in) values of other parameters. The accuracy of derived parameters depends on the accuracy and availability of these values.

There are two types of derived parameter:

Derived parameter type	Explanation	Symbols on derived parameter results
Calculated	Necessary measured and keyed-in values are available	Subscript c. For example: x.xxx _c mmol/L
Estimated	Necessary keyed-in and/or measured values are not available. Default values are used. NOTE Default values are only used for missing measured values, when they are clinically appropriate. NOTE Estimated oxygen status parameter values may deviate significantly from the <i>true</i> values.	Subscript e. For example: x.xxx _e mmol/L

NOTE When a necessary measured value is outside the range of indication, no default value is used. No result is given for the derived parameter.

Default Values of Parameters

Parameter values that are necessary in order to calculate derived parameters are given a default value when no other value is available.

Parameter symbol /name	Parameter type	Description	Default value	When is the default used?
T	Input	Temperature	37.0 °C (98.6 °F)	When no value is entered
Temperature	Input	Ambient temperature NOTE This is a data field in the Quality control identification screen. To get the correct QC results, it is necessary that the room temperature is entered in this field.	25.0 °C (77 °F)	When no value is entered
$FO_2(I)$	Input	Fraction/(%) of oxygen in dry inspired air	0.21 (21.0%)	When no value is entered
RQ	Input	Respiratory quotient, ratio between the CO_2 production and the O_2 consumption	0.86	When no value is entered
ctHb	Measured	Concentration of total hemoglobin in blood	9.3087 mmol/L, (15.00 g/dL or 150 g/L)	When the parameter cannot be measured
FCOHb	Measured	Fraction/(%) of carboxyhemoglobin in total hemoglobin in blood	0.004/ (0.4 %)	When the parameter cannot be measured
FMetHb	Measured	Fraction/(%) of methemoglobin in total hemoglobin in blood	0.004/ (0.4%)	When the parameter cannot be measured
$p50(st)$	Derived	Partial pressure (or tension) of oxygen at half saturation (50%) in blood under standard conditions: $T = 37\text{ °C}$ $pH = 7.40$ $pCO_2 = 5.33\text{ kPa}$ $FCOHb, FMetHb, FHbF$ are set to zero	3.578 kPa (26.84 mmHg)	When the parameter cannot be derived

Definitions of Derived Parameters

Acid-Base Derived Parameters – Definitions

Symbol	Definition
pH(T)	pH of blood at temperature
$cH^+(T)$	Concentration of hydrogen ions in blood at temperature
$pCO_2(T)$	Partial pressure (or tension) of carbon dioxide at temperature
$cHCO_3^-(P)$	Concentration of hydrogen carbonate in plasma (also termed actual bicarbonate)
cBase(B) or ABE	Actual Base Excess, the concentration of titrable base when the blood is titrated with a strong base or acid to a plasma pH of 7.40, at pCO_2 of 5.33 kPa (40 mmHg) and 37 °C, at the actual oxygen saturation [2,3,4]. Positive values (base excess) indicate a relative deficit of non-carbonic acids; negative values (base deficit) indicate a relative excess of non-carbonic acids.
cBase(B,ox)	cBase(B) of fully oxygenated blood
cBase(Ecf) or SBE	Standard Base Excess, an <i>in vivo</i> expression of base excess. ^{5,6,7} It refers to a model of the extracellular fluid (one part of blood is diluted by two parts of its own plasma) and is calculated using a standard value for the hemoglobin concentration of the total extracellular fluid.
cBase(Ecf,ox)	cBase(Ecf) of fully oxygenated blood
$cHCO_3^-(P,st)$	Standard Bicarbonate, the concentration of hydrogen carbonate in the plasma from blood that is equilibrated with a gas mixture with $pCO_2 = 5.33$ kPa (40 mmHg) and $pO_2 \geq 13.33$ kPa (100 mmHg) at 37 °C ^{6,8}
ctCO ₂ (P)	Concentration of total carbon dioxide, (free CO ₂ + bound CO ₂) in plasma
ctCO ₂ (B)	Concentration of total carbon dioxide in blood (also termed CO ₂ content). Calculated based on the total CO ₂ concentrations in the two phases: plasma and erythrocyte fluid. ⁶
pH(st)	Standard pH (or eucapnic pH), defined as the pH of plasma of blood equilibrated to $pCO_2 = 5.33$ kPa (40 mmHg). By ensuring the normal value of pCO_2 , the respiratory influence from pH is removed, and pH(P,st) therefore reflects the metabolic status of the blood plasma.
VCO ₂ /V(dry air)	The volume fraction of carbon dioxide in dry air

Oximetry Derived Parameters – Definitions

The oximetry parameters are only derived if the analyzer cannot measure them.

Parameter	Definition
FHHb	Fraction of deoxyhemoglobin in total hemoglobin in blood. Deoxyhemoglobin is the part of total hemoglobin which can bind oxygen, and thus forms oxyhemoglobin. It is also termed reduced hemoglobin, RHb.
FO ₂ Hb	Fraction of oxyhemoglobin in total hemoglobin in blood
sO ₂	Oxygen saturation, the ratio between the concentrations of oxyhemoglobin and the hemoglobin minus the dyshemoglobins
Hct	Hematocrit, the ratio between the volume of erythrocytes and the volume of blood

Oxygen Derived Parameters - Definitions

Symbol	Definition
$pO_2(T)$	Partial pressure (or tension) of oxygen at temperature
$pO_2(A)$	Partial pressure (or tension) of oxygen in alveolar air
$pO_2(A,T)$	Partial pressure (or tension) of oxygen in alveolar air at temperature
$pO_2(a)/FO_2(I)$	Oxygen tension ratio of arterial blood and the fraction of oxygen in dry inspired air
$pO_2(a,T)/FO_2(I)$	Oxygen tension ratio of arterial blood at temperature and the fraction of oxygen in dry inspired air
$p50$	Partial pressure (or tension) of oxygen at half saturation (50%) in blood. High and low values indicate decreased and increased affinity of oxygen to hemoglobin, respectively.
$p50(T)$	Partial pressure (or tension) of oxygen at half saturation (50%) in blood at temperature
$p50(st)$	Partial pressure (or tension) of oxygen at half saturation (50%) in blood at standard conditions: $T = 37\text{ }^{\circ}\text{C}$ $pH = 7.40$ $pCO_2 = 5.33\text{ kPa}$ $FCOHb, FMetHb, FHbF$ are set to zero. $p50(st)$ may, however, vary due to variations in 2,3-DPG concentration or to the presence of abnormal hemoglobins.
$pO_2(A-a)$	Difference in the partial pressure (or tension) of oxygen in alveolar air and arterial blood. Indicates the efficacy of the oxygenation process in the lungs.
$pO_2(A-a,T)$	Difference in the partial pressure (or tension) of oxygen in alveolar air and arterial blood at temperature
$pO_2(a/A)$	Ratio of the partial pressure (or tension) of oxygen in arterial blood and alveolar air. Indicates the efficacy of the oxygenation process in the lungs.
$pO_2(a/A,T)$	Ratio of the partial pressure (or tension) of oxygen in arterial blood and alveolar air at temperature

Symbol	Definition
$pO_2(x)$ or p_x	Oxygen extraction tension of arterial blood. Reflects the integrated effects of changes in the arterial $pO_2(a)$, ctO_2 and $p50$ on the ability of arterial blood to release O_2 to the tissues. ⁹
$pO_2(x,T)$ or $p_x(T)$	Oxygen extraction tension of arterial blood at temperature
$ctO_2(B)$	Total oxygen concentration of blood. Also termed O_2 content.
$ctO_2(a-\bar{v})$	Oxygen concentration difference between arterial and mixed venous blood
BO_2	Hemoglobin oxygen capacity; the maximum concentration of oxygen bound to hemoglobin in blood saturated, so that all deoxyhemoglobin is converted to oxyhemoglobin.
$ctO_2(x)$	Extractable oxygen concentration of arterial blood. Defined as the amount of O_2 that can be extracted per liter of arterial blood at an oxygen tension of 5.0 kPa (38 mmHg), which maintains a constant pH and pCO_2 . ⁹
DO_2	Oxygen delivery; the total amount of oxygen delivered to the whole organism per unit of time
Q_t	Cardiac output; volume of blood delivered from the left ventricle into the aorta per unit of time. Also termed CO or C.O.
VO_2	Oxygen consumption; total amount of oxygen utilized by the whole organism per unit of time
$FO_2(I)$	Fraction of oxygen in dry inspired air
$FShunt$	Relative physiological shunt or concentration-based shunt. ^{6,9,10} - Calculated from the pulmonary shunt equation: $\frac{\dot{Q}_s}{\dot{Q}_t} = \frac{1}{1 + \frac{ctO_2(a - \bar{v})}{ctO_2(A) - ctO_2(a)}}$ if both arterial and mixed venous blood samples are used. - May be estimated from one arterial sample by assuming a constant difference in the concentrations of total oxygen in arterial and mixed venous blood: $ctO_2(a-\bar{v}) = 2.3$ mmol/L (5.15 mL/dL)
$FShunt(T)$	$FShunt$ at temperature
RI	Respiratory Index; ratio between the oxygen tension difference of alveolar air and arterial blood and the oxygen tension of arterial blood.
$RI(T)$	Respiratory Index; ratio between the oxygen tension difference of alveolar air and arterial blood and the oxygen tension of arterial blood at temperature.
$VO_2/V(\text{dry air})$	Volume fraction of oxygen in dry air

Symbol	Definition
Q_x	Cardiac oxygen compensation factor of arterial blood defined as the factor by which the cardiac output should increase to allow release of 2.3 mmol/L (5.1 mL/dL) oxygen at a mixed venous pO_2 of 5.0 kPa (38 mmHg) ^{6,9}
$V(B)$	Volume of blood, calculated when $FCOHb$ and $V(CO)$ values are keyed in ⁶

Electrolyte Derived Parameters – Definitions

Parameter	Definition
Anion Gap, K^+	Difference between the concentration of the cations (sodium and potassium), and the measured anions (chloride and bicarbonate)
Anion Gap	Difference between the concentration of the cation (sodium), and the measured anions (chloride and bicarbonate)
$cCa^{2+}(7.4)$	Concentration of calcium cations at pH = 7.40
$mOsm$	$[1/1000] \times$ Number of moles of ions that contribute to the osmotic pressure of a solution

Data Necessary to Derive Electrolyte Parameters

The table shows the measured parameters that are necessary to calculate the derived electrolyte parameters.

Parameter	Unit	Necessary measured parameters
Anion Gap, K^+	mmol/L, meq/L	cK^+ , cNa^+ , cCl^-
Anion Gap	mmol/L, meq/L	cNa^+ , cCl^-
$cCa^{2+}(7.4)$	mmol/L, meq/L, mg/dL	pH, cCa^{2+} NOTE pH must be between 7.2-7.6 to calculate this parameter.
$mOsm$	mmol/kg	cNa^+ , $cGlu$

Calculation of Derived Parameters

Sample Type

Unless otherwise stated, a derived parameter will be calculated or estimated irrespective of the sample type selected on the **Patient identification** screen: Some parameters, however, are defined for arterial or capillary samples only; they will be calculated only for sample types entered as "Arterial" or "Capillary".

- Arterial
- Capillary
- Venous
- Mixed venous
- Cord blood arterial
- Cord blood venous
- Fetal scalp
- Not specified

The symbol for system (blood (B) or plasma (P)) is not stated in the equations unless it is important for the calculation.

Units and Symbols Used in Equations

All definitions and equations are based on SI units. If "T" for temperature is not stated, the calculation is based on a temperature of 37.0 °C.

The following SI units are used:

Description	Unit
Concentration	mmol/L
Temperature	°C
Pressure	kPa
Fractions	- (not %)

The following symbols are used in the equations:

$$\log(x) = \log_{10}(x)$$

$$\ln(x) = \log_e(x)$$

Equations

Equations for Acid-Base Parameters

pH(T) - Equation 1¹¹

$$\text{pH}(T) = \text{pH}(37) - [0.0147 + 0.0065 \times (\text{pH}(37) - 7.40)][T - 37]$$

NOTE The equation is different from that of previous Beckman Coulter analyzers. The constant 0.0146 is now changed to 0.0147, to be in accordance with CLSI-approved guidelines.¹²

The change corresponds to -0.1 mpH/°C.

cH⁺(T) - Equation 2

$$cH^+(T) = 10^{(9 - \text{pH}(T))}$$

pCO₂(T) - Equation 3⁷

$$pCO_2(T) = pCO_2(37) \times 10^{[0.019 \times (T - 37)]}$$

NOTE The equation is different from that of previous Beckman Coulter analyzers. The constant 0.021 is now changed to 0.019, to be in accordance with CLSI-approved guidelines.⁸

The change corresponds to 2%/5 °C.

cHCO₃⁻(P) - Equation 4

$$cHCO_3^-(P) = 0.23 \times pCO_2 \times 10^{[\text{pH} - \text{pK}_p]}$$

where pK_p = 6.095

cHCO₃⁻(P) includes ions of hydrogen carbonate, carbonate and carbamate in the plasma.

NOTE The equation is different from that of previous Beckman Coulter analyzers. The pK_p is now constant, to be in accordance with CLSI-approved guidelines.⁷

The change corresponds to 5% in the pH range 7-7.8.

cBase(B) - Equation 5⁷

$$cBase(B) = (1 - 0.014ctHb)(cHCO_3^-(P) - 24.8 + (1.43 \text{ } ctHb + 7.7)(\text{pH} - 7.4))$$

NOTE The equation is different from that of previous Beckman Coulter analyzers. The calculation is done in accordance with CLSI-approved guidelines [5].

However, the previous method [9] is considered a better method. The change corresponds to less than 0.6 mmol/L in the reference ranges for pH, $p\text{CO}_2$ and ctHb. The previous range checks are retained. Outside the ± 50 mmol/L range, no values are displayed. Outside the range ± 30 mmol/L, values are tagged with “?”.

cBase(B,ox) - Equation 6⁸

$$c\text{Base}(\text{B,ox}) = c\text{Base}(\text{B}) - 0.3062 \times \text{ctHb} \times (1 - s\text{O}_2)$$

If ctHb is not measured or keyed in, the default value will be used.

If $s\text{O}_2$ is not measured, it will be calculated from equation 39.

cBase(Ecf) - Equation 7⁵

$$c\text{Base}(\text{Ecf}) = c\text{HCO}_3^-(\text{P}) - 24.8 + 16.2 (\text{pH} - 7.4)$$

See the note in [cBase\(B\) - Equation 5⁷](#).

cBase(Ecf,ox) - Equation 8

$$c\text{Base}(\text{Ecf,ox}) = c\text{Base}(\text{Ecf}) - 0.3062 \times 3 \times (1 - s\text{O}_2)$$

$c\text{HCO}_3^-(\text{P,st})$ - Equation 9^{8,13}

$$c\text{HCO}_3^-(\text{P,st}) = 24.47 + 0.919 \times Z + Z \times a' \times (Z - 8)$$

Where

Equation	Description
9.1	$a' = 4.04 \times 10^{-3} + 4.25 \times 10^{-4} \times \text{ctHb}$
9.2	$Z = c\text{Base}(\text{B}) - 0.3062 \times \text{ctHb} \times (1 - s\text{O}_2)$

ctCO₂(P) - Equation 10^{7,5}

$$\text{ctCO}_2(\text{P}) = 0.23 \times p\text{CO}_2 + c\text{HCO}_3^-(\text{P})$$

ctCO₂(B) - Equation 11⁶

$$\text{ctCO}_2(\text{B}) = 9.286 \times 10^{-3} \times p\text{CO}_2 \times \text{ctHb} \times \left[1 + 10^{(\text{pH}_{\text{Ery}} - \text{pK}_{\text{Ery}})} \right] + \text{ctCO}_2(\text{P}) \times \left(1 - \frac{\text{ctHb}}{21.0} \right)$$

where

Equation	Description
11.1	$pH_{Ery} = 7.19 + 0.77 \times (pH - 7.40) + 0.035 \times (1 - sO_2)$
11.2	$pK_{Ery} = 6.095 - \log[1 + 10^{(pH_{Ery} - 7.84 - 0.06 \times sO_2)}]$

pH(st) - Equation 12¹³

pH (st): see equations 5.3-5.5 in the table below.

Equation	Description
5.3	$pH(st) = pH + \log\left(\frac{5.33}{pCO_2}\right) \times \left(\frac{pH(Hb) - pH}{\log pCO_2(Hb) - \log(7.5006 pCO_2)}\right)$
5.4	$pH(Hb) = 4.06 \times 10^{-2}ctHb + 5.98 - 1.92 \times 10^{(-0.16169ctHb)}$
5.5	$\log pCO_2(Hb) = -1.7674 \times 10^{-2}ctHb + 3.4046 + 2.12 \times 10^{(-0.15158ctHb)}$

Equations for Electrolyte Parameters

Anion Gap, K⁺ Equation 43

$$\text{Anion Gap, K}^+ = cNa^+ + cK^+ - cCl^- - cHCO_3^-$$

Anion Gap - Equation 44

$$\text{Anion Gap} = cNa^+ - cCl^- - cHCO_3^-$$

cCa²⁺(7.4) - Equation 45¹⁴

$$cCa^{2+}(7.4) = cCa^{2+} \times 10^{-0.24(7.4-pH)}$$

Due to biological variations, this equation can only be used for a pH value in the range 7.2-7.6.

NOTE The equation is different from that of previous Beckman Coulter analyzers. The previous equation was an approximation of the current equation.

The change corresponds to 1% in the pH range 7.2-7.6.

Equations 46 and 47

Refer to [Oxyhemoglobin Dissociation Curve \(ODC\)](#).

mOsm - Equation 48¹⁵

$$mOsm = 2cNa^+ + cGlu$$

Equations for Oxygen Parameters

$pO_2(T)$ - Equation 14^{11,16}

The standard Oxygen Dissociation Curve (ODC) is used (i.e. $p50(st) = 3.578$ kPa) at actual values of pH, pCO_2 , FCO_{Hb} , $FMetHb$, $FHbF$ (refer to [Equations 46 and 47](#)).

$pO_2(T)$ is calculated by a numerical method using:

$$t_i(T) = ctHb \times (1 - FCO_{Hb} - FMetHb) \times sO_{2,i}(T) + \alpha O_2(T) \times pO_{2,i}(T)$$

Where changes in the equations for pH(T) and ctO_2 correspond to less than 0.5% of $pO_2(T)$ in the reference range for pH, pCO_2 , pO_2 and $ctHb$ and T in the interval 32-42 °C, using $FHbF = 0.5\%$.

Equation	Description	See...
14.1	$S = ODC(P,A,T)$	Eq. 47
14.2	$sO_{2,i}(T) = \frac{S \times (1 - FMetHb) - FCO_{Hb}}{1 - FCO_{Hb} - FMetHb}$	Eq. 46.12
14.3	$pO_{2,i}(T) = \frac{P}{\frac{FCO_{Hb}}{sO_{2,i}(T) \times (1 - FCO_{Hb} - FMetHb)}}$	Eq. 46.10
14.4	$\alpha O_2 = 0.015e^{[-1.15 \times 10^{-2}(T-37.0) + 2.1 \times 10^{-4} \times (T-37.0)^2]}$	-
14.5	P is the variable during iteration.	-
14.6	$A = ac - 1.04 \times \frac{\partial pH}{\partial T} \times (T - 37.0)$	-
14.7	T = temperature in °C (keyed-in).	-
14.8	$\frac{\partial pH}{\partial T} = -1.47 \times 10^{-2} - 6.5 \times 10^{-3} \times (pH(37) - 7.40)$ When $t_i(T) = t_i(37.0)$, then $pO_{2,i}(T) = pO_2(T)$	-

NOTE A dash (-) indicates the entry does not apply.

$pO_2(A)$ - Equation 15⁶

$$pO_2(A) = FO_2(I) \times (p(amb) - 6.275) - pCO_2 \times [RQ^{-1} - FO_2(I) \times (RQ^{-1} - 1)]$$

If $FO_2(I)$ and RQ are not keyed in, they are set to the default values.

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

$pO_2(A,T)$ - Equation 16^{8,6,17}

$$pO_2(A,T) = FO_2(I) \times [p(amb) - p_{H_2O}(T)] - pCO_2(T) \times [RQ^{-1} - FO_2(I) \times (RQ^{-1} - 1)]$$

$$p_{H_2O}(T) = 6.275 \times 10^{[2.36 \times 10^{-2} \times (T - 37.0) - 9.6 \times 10^{-5} \times (T - 37.0)^2]}$$

If $FO_2(I)$ and RQ are not keyed in, they are set to the default values.

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

$pO_2(a)/FO_2(I)$ - Equation 17

$$pO_2(a) / FO_2(I) = \frac{pO_2(a)}{FO_2(I)}$$

The calculation cannot be performed on the basis of the default $FO_2(I)$ value, and the calculation requires that the sample type is entered as "Arterial" or "Capillary".

$pO_2(a,T) / FO_2(I)$ - Equation 18

$$pO_2(a,T) / FO_2(I) = \frac{pO_2(a,T)}{FO_2(I)}$$

The calculation cannot be performed on the basis of the default $FO_2(I)$ value, and the calculation requires that the sample type is entered as "Arterial" or "Capillary".

$p50$ - Equation 19

Refer to equation 46.10.

The ODC is determined as described in *Equations 46 and 47*.

$$p50 = \frac{P}{1 + \frac{FCOHb}{0.5 \times (1 - FCOHb - FMetHb)}}$$

Where

Description	See...
$P = ODC(S,A,T)$	Eq. 47
$S = \frac{0.5 \times (1 - FCOHb - FMetHb) + FCOHb}{1 - FMetHb}$	Eq. 46.11
$A = a$	-
$T = 37.0 \text{ } ^\circ\text{C}$	Eq. 46.13

NOTE A dash (-) indicates the entry does not apply.

p50(T) - Equation 20

The ODC is determined as described in *Equations 46 and 47*.

$$p50(T) = \frac{P}{1 + \frac{FCO_{Hb}}{0.5 \times (1 - FCO_{Hb} - F_{MetHb})}}$$

where

Description	See...
$P = ODC(S, A, T)$	Eq. 47
$S = \frac{0.5 \times (1 - FCO_{Hb} - F_{MetHb}) + FCO_{Hb}}{1 - F_{MetHb}}$	Eq. 46.11
$A = a - 1.04 \times \frac{\partial pH}{\partial T} \times (T - 37.0)$	-
$\frac{\partial pH}{\partial T} = -1.47 \times 10^{-2} - 6.5 \times 10^{-3} \times (pH(37) - 7.40)$	-
$T =$ temperature in °C (keyed-in)	-

NOTE A dash (-) indicates the entry does not apply.

p50(st) - Equation 21

p50 is calculated for pH = 7.40, $pCO_2 = 5.33$ kPa, $FCO_{Hb} = 0$, $F_{MetHb} = 0$, $F_{HbF} = 0$.

The ODC is determined as described in *Equations 46 and 47*.

$$p50(st) = ODC(S, A, T)$$

Where

Description	See...
$S = 0.5$	Eq. 46.11
$A = a_6$ corresponds to pH = 7.40, $pCO_2 = 5.33$ kPa, $FCO_{Hb} = 0$, $F_{MetHb} = 0$, $F_{HbF} = 0$	Eq. 46.13
$T = 37.0$ °C	-

NOTE A dash (-) indicates the entry does not apply.

pO₂(A-a) - Equation 22

$$pO_2(A-a) = pO_2(A) - pO_2(a)$$

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

$pO_2(A-a,T)$ - Equation 23

$$pO_2(A-a,T) = pO_2(A,T) - pO_2(a,T)$$

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

$pO_2(a/A)$ - Equation 24

$$pO_2(a/A) = \frac{pO_2(a)}{pO_2(A)}$$

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

$pO_2(a/A,T)$ - Equation 25

$$pO_2(a/A,T) = \frac{pO_2(a,T)}{pO_2(A,T)}$$

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

$pO_2(x)$ or p_x - Equation 26⁹

The ODC is determined as described in *Equations 46 and 47*.

$pO_2(x)$ is calculated by a numerical method, with the use of these equations:

Equation	Description	See...
26.1	$S = ODC(P,A,T)$	Eq. 47
26.2	$sO_{2,i} = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$	Eq. 46.12
26.3	$pO_{2,i} = \frac{P}{1 + \frac{FCOHb}{sO_{2,i} \times (1 - FCOHb - FMetHb)}}$	Eq. 46.10
26.4	$t_i = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i} + 0.0105 \times pO_{2,i}$	-
26.5	$A = a$	-
26.6	$T = 37^\circ C$	-

NOTE A dash (-) indicates the entry does not apply.

When $t_i = ctO_2 - 2.3$ mmol/L, then $pO_{2,i} = pO_2(x)$, where ctO_2 is determined as described in equation 27.

$pO_2(x)$ cannot be calculated on the basis of a default $ctHb$ value.

$pO_2(x)$ can only be calculated if the measured $sO_2(a) \leq 0.97$.

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

$pO_2(x, T)$ - Equation 50^{9,17}

The ODC is determined as described in *Equations 46 and 47*.

$pO_2(x)$ is calculated by a numerical method, with the use of these equations:

Equation	Description	See...
50.1	$S = ODC(P, A, T)$	Eq. 47
50.2	$sO_{2,i}(T) = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$	Eq. 46.12
50.3	$pO_{2,i}(T) = \frac{P}{1 + \frac{FCOHb}{sO_{2,i}(T) \times (1 - FCOHb - FMetHb)}}$	Eq. 46.10
50.4	$t_i(T) = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i}(T) + \alpha O_2(T) \times pO_{2,i}(T)$	-
50.5	$A = a - 1.04 \times \frac{\partial pH}{\partial T} \times (T - 37.0)$	Eq. 20
50.6	$T =$ temperature	-
50.7	$\alpha O_2(T) = 0.0105e^{[-0.115 \times (T - 37) + 21 \times 10^{-5} \times (T - 37)^2]}$	-
50.8	$pO_{2,i} = pO_2(x, T)$ when $t_i(T) = ctO_2(37^\circ C) - 2.3 \text{ mmol/L}$	-

NOTE A dash (-) indicates the entry does not apply.

$pO_2(x, T)$ is calculated in accordance with OSA V3.0.

$pO_2(x, T)$ can only be calculated if the measured $sO_2(a) \leq 0.97$.

$pO_2(x, T)$ is tagged with ? if any of the following parameters: sO_2 , $FMetHb$, $FCOHb$, pO_2 , pCO_2 , pH or $ctHb$ is tagged with ?.

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

ctO_2 - Equation 27⁶

$$ctO_2 = \alpha O_2 \times pO_2 + sO_2 \times (1 - FCOHb - FMetHb) \times ctHb$$

αO_2 is the concentrational solubility coefficient for O_2 in blood (here set to 0.0105 mmol/L/kPa at 37 °C.⁵

ctO₂ cannot be calculated on the basis of a default ctHb value.

NOTE The equation is different from that of previous Beckman Coulter analyzers. The oxygen solubility coefficient is now changed from 0.00983 to 0.0105 to be in accordance with CLSI-approved guidelines.⁵

The change corresponds to 0.00067 mmol/L/kPa.

ctO₂(a- $\bar{v}$) - Equation 28

$$ctO_2(a-\bar{v}) = ctO_2(a) - ctO_2(\bar{v})$$

where ctO₂(a) and ctO₂($\bar{v}$) are calculated from equation 27 for arterial and mixed venous blood, respectively. The calculation requires two measurements and input of both pO₂($\bar{v}$) and sO₂($\bar{v}$).

BO₂ - Equation 29¹⁸

$$BO_2 = ctHb \times (1 - FCOHb - FMetHb)$$

BO₂ cannot be calculated on the basis of a default ctHb value.

ctO₂(x) or c_x - Equation 30⁹

The ODC is determined, as described in *Equations 46 and 47*.

$$ctO_2(x) = ctO_2(a) - t_i$$

where

Equation	Description	See...
30.1	$t_i = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i} + 0.0105 \times pO_2(5)$	-
30.2	$pO_2(5) = 5.00 \text{ kPa}$	-
30.3	$S = ODC(P, A, T)$	Eq. 47
30.4	$P = pO_2(5) \times \left[1 + \frac{FCOHb}{sO_{2,i} \times (1 - FCOHb - FMetHb)} \right]$	Eq. 46.9
30.5	$sO_{2,i} = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$	Eq. 46.12
30.6	$A = a$	-
30.7	$T = 37.0 \text{ }^\circ\text{C}$	-

NOTE A dash (-) indicates the entry does not apply.

ctO₂(a) is determined as described in equation 27.

ctO₂(x) cannot be calculated on the basis of a default ctHb value.

$ctO_2(x)$ can only be calculated if the measured $sO_2(a) \leq 0.97$.

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

DO₂ - Equation 31

$$\dot{DO}_2 = ctO_2 \times Q_t$$

Q_t is the cardiac output and is an input parameter for the calculation of $\dot{DO}_2$.

If Q_t is not keyed in, $\dot{DO}_2$ will not be calculated.

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

Q_t - Equation 32

$$\dot{Q}_t = \frac{\dot{VO}_2}{ctO_2(a - \bar{v})}$$

If $\dot{VO}_2$ is not keyed in, Q_t will not be calculated.

VO₂ - Equation 33

$$\dot{VO}_2 = Q_t \times ctO_2(a - \bar{v})$$

If Q_t is not keyed in, $\dot{VO}_2$ will not be calculated.

FShunt - Equation 34⁶

$$FShunt = \frac{ctO_2(c) - ctO_2(a)}{ctO_2(c) - ctO_2(\bar{v})}$$

Equation	Description
34.1	$FShunt \cong \frac{ctO_2(A) - ctO_2(a)}{ctO_2(A) - ctO_2(\bar{v})}$
34.2	$FShunt = \left[1 + \frac{ctO_2(a) - ctO_2(\bar{v})}{ctO_2(A) - ctO_2(a)} \right]^{-1}$ where: $ctO_2(c)$: total oxygen in pulmonary capillary blood $ctO_2(a)$: total oxygen in arterial blood $ctO_2(A)$: total oxygen in alveolar air. Oxygen tension = $pO_2(A)$. $ctO_2(\bar{v})$: total oxygen in mixed venous blood

Equation	Description
34.3	$ctO_2(a) = 0.0105pO_2(a) + ctHb \times (1 - FCOHb - FMetHb) \times sO_2(a)$
34.4	$ctO_2(A) = 0.0105pO_2(A) + ctHb \times (1 - FCOHb - FMetHb) \times sO_2(A)$
34.5	$ctO_2(\bar{v}) = 0.0105pO_2(\bar{v}) + ctHb \times (1 - FCOHb - FMetHb) \times sO_2(\bar{v})$ where: $pO_2(a)$: oxygen tension in arterial blood; measured $pO_2(A)$: oxygen tension in alveolar blood. See equation 15. $pO_2(\bar{v})$: oxygen tension in mixed venous blood; measured and then entered $sO_2(a)$: oxygen saturation in arterial blood; can be measured $sO_2(A)$: oxygen saturation in (alveolar) blood calculated from equation 39 where $P = pO_2(A)$ $sO_2(\bar{v})$: oxygen saturation in mixed venous blood; measured and then entered The calculation requires that the sample type is entered as "Arterial" or "Capillary" If $sO_2(a) > 0.97$, the default value (3.578 kPa) will be used to estimate the ODC. If no venous sample is measured, $FShunt$ is estimated assuming: $ctO_2(a) - ctO_2(\bar{v}) = 2.3 \text{ mmol/L}$ in equation 34.2

FShunt(T) - Equation 35^{6,16}

$$FShunt(T) = \left[1 + \frac{ctO_2(a,T) - ctO_2(\bar{v},T)}{ctO_2(A,T) - ctO_2(a,T)} \right]^{-1}$$

where:

$ctO_2(a,T)$: total oxygen in arterial blood at temperature

$ctO_2(A,T)$: total oxygen in alveolar blood at temperature

$ctO_2(\bar{v},T)$: total oxygen in mixed venous blood at temperature

Equation	Description
35.1	$ctO_2(a,T) = ctO_2$ calculated from equation 25 for arterial pO_2 and sO_2 values at 37 °C
35.2	$ctO_2(A,T) = \alpha O_2(T) \times pO_2(A,T) + ctHb \times (1 - FCOHb - FMetHb) \times sO_2(A,T)$
35.3	$\alpha O_2(T) = 0.0105e^{[-1.15 \times 10^{-2} \times (T - 37.0) + 2.1 \times 10^{-4} \times (T - 37.0)^2]}$
35.4	$pO_2(A,T)$ is calculated from equation 16
35.5	$sO_2(A,T) = S$
35.6	$S = ODC(P,A,T)$ See equation 47
35.7	$P = pO_2(A,T)$

Equation	Description
35.8	$A = a - 1.04 \times \frac{\partial pH}{\partial T} \times (T - 37.0)$
35.9	$T =$ temperature (keyed-in)
35.10	$\frac{\partial pH}{\partial T} = -1.47 \times 10^{-2} - 6.5 \times 10^{-3} \times (pH(37) - 7.40)$ If $sO_2(a) > 0.97$, the default $p50(st)$ (3.578 kPa) will be used to determine the ODC.
35.11	$ctO_2(\bar{v}, T) = ctO_2(\bar{v})$ at 37 °C is calculated from equation 27 for mixed venous blood values of pO_2 and sO_2 . If no mixed venous sample is measured, the $FShunt(T)$ is estimated assuming $ctO_2(a, T) - ctO_2(\bar{v}, T) = 2.3$ mmol/L in equation 35.

RI - Equation 36

$$RI = \frac{pO_2(A) - pO_2(a)}{pO_2(a)}$$

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

RI(T) - Equation 37

$$RI(T) = \frac{pO_2(A, T) - pO_2(a, T)}{pO_2(a, T)}$$

The calculation requires that the sample type is entered as "Arterial" or "Capillary".

Q_x - Equation 38⁹

The ODC is determined as described in *Equations 46 and 47*.

$$Q_x = \frac{2.3}{ctO_2(a) - t_i}$$

Equation	Description	See...
38.1	$t_i = ctHb \times (1 - FCOHb - FMetHb) \times sO_{2,i} + 0.0105pO_2(5)$	-
38.2	$pO_2(5) = 5.00 \text{ kPa}$	-
38.3	$S = ODC(P, A, T)$	-
38.4	$P = pO_2(5) \times \left[1 + \frac{FCOHb}{sO_{2,i} \times (1 - FCOHb - FMetHb)} \right]$	Eq. 46.9
38.5	$sO_{2,i} = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$	Eq. 46.12
38.6	$A = a$	-
38.7	$T = 37.0 \text{ } ^\circ\text{C}$	-

NOTE A dash (-) indicates the entry does not apply.

$ctO_2(a)$ is determined as described in equation 27

Q_x cannot be calculated on the basis of a default $ctHb$ value

Q_x can only be calculated if the measured $sO_2(a) \leq 0.97$

The calculation requires that the sample type is entered as "Arterial" or "Capillary"

V(B) - Equation 42⁶

$$V(B) = \frac{V(CO)}{24 \times (FCOHb(2) - FCOHb(1)) \times 0.91 \times ctHb}$$

Equation	Description
42.1	$V(B) = \frac{V(CO)}{21.84 \times (FCOHb(2) - FCOHb(1)) \times ctHb}$
42.2	$V(CO)$ = volume (in mL) of carbon monoxide injected according to the procedure and the value keyed in
42.3	$FCOHb(1)$ = fraction of COHb measured before the CO injection
42.4	$FCOHb(2)$ = fraction of COHb measured after the CO injection

$VCO_2/V(\text{dry air})$ - Equation 51

$$VCO_2 / V(\text{dry air}) = \frac{pCO_2}{p(\text{amb}) - 6.275}$$

VO₂/V(dry air) - Equation 52

$$VO_2 / V(\text{dry air}) = \frac{pO_2}{p(\text{amb}) - 6.275}$$

Equations for Oximetry Parameters**FHHb - Equation 41**

$$FHHb = 1 - sO_2 \times (1 - FCOHb - FMetHb) - FCOHb - FMetHb$$

If sO₂ is not measured, it will be calculated from equation 39.

If dyshemoglobins (FCOHb, FMetHb) are not known, they are set to the default values.

FO₂Hb - Equation 40

$$FO_2Hb = sO_2 \times (1 - FCOHb - FMetHb)$$

If sO₂ is not measured, it will be calculated from equation 39.

If dyshemoglobins (FCOHb, FMetHb) are not known, they are set to the default values.

sO₂ - Equation 39

The ODC is determined as described in *Equations 46 and 47* (points I and III).

$$sO_2 = \frac{S \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$$

Where

Description	See...
S = ODC(P,A,T)	-
$P = pO_2 + \frac{pO_2 \times FCOHb}{sO_2 \times (1 - FCOHb - FMetHb)}$	Eq. 46.9
A = a	-
T = 37.0 °C	-

NOTE A dash (-) indicates the entry does not apply.

Hct - Equation 13¹⁸

$$Hct = 0.04939 \times ctHb$$

Hct cannot be calculated on the basis of a default ctHb value.

NOTE The equation is different from that of previous Beckman Coulter analyzers. The previous equation $Hct = 0.0485 \times ctHb + 8.3 \times 10^{-3}$ was changed to ensure that $Hct = 0$ when $ctHb = 0$. The slope was adjusted to make Hct identical for the two equations when $ctHb = 9.3087$ mmol/L.

The change corresponds to 1% in the ctHb range 6.3-12.3.

FHbF - Equation 49

An iterative method is used to calculate FHbF. The input parameters are sO_2 , $ceHb$ (effective hemoglobin concentration) and cO_2HbF (concentration of fetal oxyhemoglobin).

In the calculations the following are assumed: $pH = 7.4$, $pCO_2 = 5.33$ kPa, $FCOHb = 0$, $FMetHb = 0$, $cDPG = 5$ mmol/L, and $temp = 37$ °C.

Equation	Description	See...
49.1	An estimate of FHbF is made: $FHbF_{est} = 0.8$	-
49.2	$pO_{2,est} = ODC(sO_{2,A}, T)$; where the constant A depends on $FHbF = FHbF_{est}$	Eq. 47
49.3	sO_2 (for fetal blood) = $ODC(pO_{2,est}, A, T)$; where $FHbF = 1$	Eq. 47
49.4	$cO_2HbF_{est} = sO_2 \text{ (fetal blood)} \times ceHb \times FHbF_{est}$	-
49.5	$\Delta FHbF_{est} = \frac{cO_2HbF_{meas.} - cO_2HbF_{est}}{ceHb}$	-
49.6	If $ \Delta FHbF_{est} \geq 0.001$, proceed to equation 49.7. If $ \Delta FHbF_{est} < 0.001$, proceed to equation 49.9.	-
49.7	$FHbF_{est,new} = FHbF_{est,old} + \Delta FHbF_{est}$	-
49.8	Return to equation 49.2.	-
49.9	End of iteration. The value for FHbF has converged.	-

NOTE A dash (-) indicates the entry does not apply.

Converting Results to Other Units

You can use the equations in the table to convert results to other units.

Parameter	Unit		Equation to convert
Temperature (T)	T°F	=	$9/5 (T^{\circ}C) + 32$
	T°C	=	$5/9 (T^{\circ}F - 32)$
cK^+ , cNa^+ , cCl^-	cX (meq/L)	=	cX (mmol/L) where X is K^+ , Na^+ or Cl^-

Parameter	Unit		Equation to convert
cCa^{2+}	cCa^{2+} (meq/L)	=	$2 \times cCa^{2+}$ (mmol/L)
	cCa^{2+} (mg/dL)	=	$4.008 \times cCa^{2+}$ (mmol/L)
	cCa^{2+} (mmol/L)	=	$0.5 \times cCa^{2+}$ (meq/L)
	cCa^{2+} (mmol/L)	=	$0.2495 \times cCa^{2+}$ (mg/dL)
Pressure	p (mmHg)	=	$p(\text{Torr}) = 7.500638 \times p(\text{kPa})$
	p (kPa)	=	$0.133322 \times p(\text{mmHg}) = 0.133322 \times p(\text{Torr})$
ctHb*	ctHb (g/dL)	=	$1.61140 \times ctHb$ (mmol/L)
	ctHb (g/L)	=	$16.1140 \times ctHb$ (mmol/L)
	ctHb (mmol/L)	=	$0.62058 \times ctHb$ (g/dL)
	ctHb (mmol/L)	=	$0.062058 \times ctHb$ (g/L)
ctCO ₂ , ctO ₂ , ctO ₂ (a- $\bar{v}$), BO ₂	Vol %	=	$2.241 \times$ (mmol/L)
	Vol %	=	mL/dL
	mmol/L	=	$0.4462 \times$ (mL/dL)
VO ₂	VO ₂ mmol/min	=	VO ₂ /22.41 mL/min
cGlu***	cGlu (mg/dL)	=	$18.016 \times cGlu$ (mmol/L)
	cGlu (mmol/L)	=	$0.055506 \times cGlu$ (mg/dL)
cLac**/**	cLac (mg/dL)	=	$9.008 \times cLac$ (mmol/L)
	cLac (mmol/L)	=	$0.11101 \times cLac$ (mg/dL)
	cLac (meq/L)	=	cLac (mmol/L)
ctBil	ctBil (μmol/L)	=	$17.1 \times ctBil$ (mg/dL)
	ctBil (μmol/L)	=	$1.71 \times ctBil$ (mg/L)
	ctBil (mg/dL)	=	$0.0585 \times ctBil$ (μmol/L)
	ctBil (mg/L)	=	$0.585 \times ctBil$ (μmol/L)

* See 8.

** cLac conversion is based on the molecular weight of lactic acid.

*** See 19.

Oxyhemoglobin Dissociation Curve (ODC)

ODC Equations

These equations account for the effect of FCOHb on the shape of the Oxyhemoglobin Dissociation Curve (ODC) in accordance with the Haldane equation.

Equation 46^{16, 17}

$$y - y^0 = (x - x^0) + h \times \tanh[k^0(x - x^0)]$$

where $k^0 = 0.5343$

Equation	Description
46.1	$x = \ln p$
46.2	$y = \ln \frac{s}{1-s}$
46.3	$y^0 = \ln \frac{s^0}{1-s^0}$ where $s^0 = 0.867$
46.4	$x^0 = x^{00} + a + b = \ln(p^{00}) + a + b$ where $p^{00} = 7$ kPa.

The actual position of the ODC in the coordinate system ($\ln(s/(1-s))$ vs $\ln(p)$) used in the mathematical model, is expressed by equations 46.3 and 46.4.

The symbols a and b reflect the ODC displacement from the reference position to its actual position in this coordinate system:

a describes the displacement at 37 °C.

b the additional displacement due to the temperature difference from 37 °C.

The ODC Reference Position

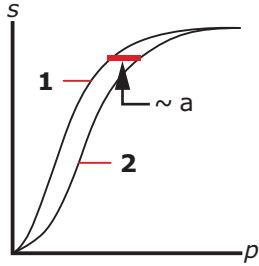
The reference position of the ODC was chosen to be the one that corresponds to the default value for $p_{50(st)} = 3.578$ kPa, which is traditionally considered the most likely value of p_{50} for adult humans under standard conditions, namely:

$pH = 7.40$; $pCO_2 = 5.33$ kPa; $FCOHb, FMetHb, FHbF = 0$; $cDPG = 5$ mmol/L.

The ODC Displacement

The ODC displacement which is described by a and b in the coordinate system ($\ln(s/(1-s))$ vs $\ln(p)$), is given by the change in p_{50} from the default to its actual value in a more common coordinate system (sO_2, pO_2).

Equation	Description
46.5	$x - x^0 = \ln \frac{p}{7} - a - b$
46.6	$h = h^0 + a$, where $h^0 = 3.5$

Equation	Description
46.7	$b = 0.055 \times (T - T^0)$ $T^0 = 37 \text{ }^{\circ}\text{C}$
46.8	$p = pO_2 + M \times pCO$ where $M \times pCO$ is taken from the Haldane equation: ²⁰ $\frac{pO_2}{cO_2Hb} = M \times \frac{pCO}{cCOHb}$ to give equation 46.9
46.9	$p = pO_2 + \frac{pO_2}{sO_2} \times \left[\frac{FCOHb}{1 - FCOHb - FMetHb} \right]$ or equation 46.10
46.10	$pO_2 = \frac{p}{1 + \frac{FCOHb}{sO_2 \times (1 - FCOHb - FMetHb)}}$ The ordinate, s, may loosely be termed the combined oxygen/carbon monoxide saturation of hemoglobin and is described by equation 46.11.  1 = Reference position 2 = Actual position
46.11	$s = \frac{cO_2Hb + cCOHb}{cO_2Hb + cCOHb + cHHb}$ $s = \frac{sO_2 \times (1 - FCOHb - FMetHb) + FCOHb}{1 - FMetHb}$ or
46.12	$sO_2 = \frac{s \times (1 - FMetHb) - FCOHb}{1 - FCOHb - FMetHb}$

The Actual ODC Position

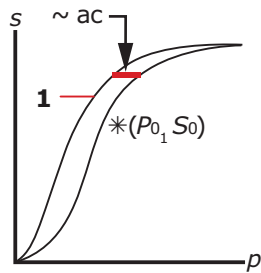
The actual position of the ODC at 37 °C for a given sample is, in principle, determined in two steps:

1. The calculation of the combined effect on the ODC position at 37 °C of all known causes for displacement (= ac in equation 46.13), and based on this position.
2. The computation by a numerical method of the actual position of the ODC curve by shifting it to pass through the known set of coordinates (P_0, S_0).

Equation	Description
46.13	$a = a_c + a_6$
46.14	$a_c = a_1 + a_2 + a_3 + a_4 + a_5$
46.15	$a_1 = -0.88 \times (\text{pH} - 7.40)$
46.16	$a_2 = 0.048 \times \ln \frac{p\text{CO}_2}{5.33}$
46.17	$a_3 = -0.7 \times \text{FMetHb}$
46.18	$a_4 = (0.06 - 0.02\text{FHbF}) \times (\text{cDPG} - 5)$
46.19	$a_5 = -0.25 \times \text{FHbF}$

Determining the Actual Displacement

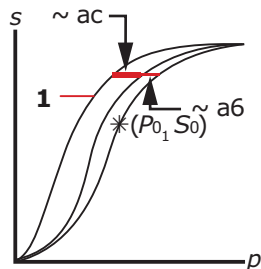
- 1 $p\text{O}_2$, $s\text{O}_2$ can be used. If $s\text{O}_2 > 0.97$, the calculation is based on the calculation in steps 2 or 3.



1 = Reference position

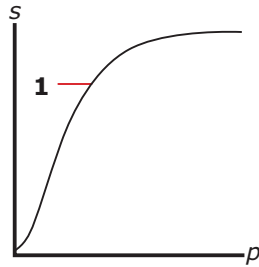
Coordinates (P_0, S_0) are calculated from equations 46.9 and 46.11. If FCOHb and FMetHb are not known, the default values are used.

The ODC is shifted from the reference position to a position that corresponds to the effect of all measured parameters according to step 1. The magnitude of the shift is a_c . The ODC is then further shifted to pass through the point P_0, S_0 . The magnitude of the shift is a_6 .



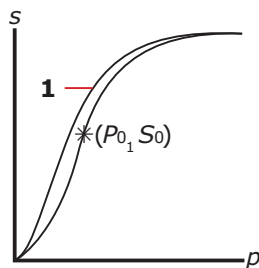
1 = Reference position

- 2 $sO_2 > 0.97$ (or erroneous) and $p50(st)$ is known. Coordinates (P_0, S_0) are calculated from $(p50(st), 0.5)$ with the use of equations 46.9 and 46.11. Reference position of the ODC.



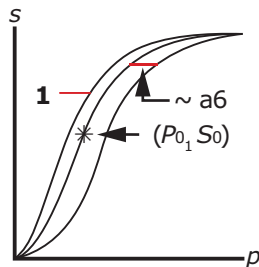
1 = Reference position

The ODC is shifted from the reference position to pass through the point (P_0, S_0) . In this position, the ODC reflects the $p50(st)$ of the sample, i.e., the particular sample, but at standard conditions.



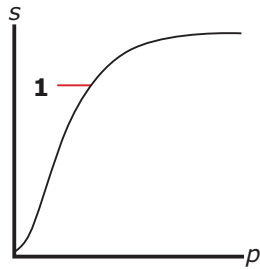
1 = Reference position

The ODC is further shifted, as determined by the effect of the measured parameters (ac), to its actual position. This position reflects the $p50(act)$ of the sample.

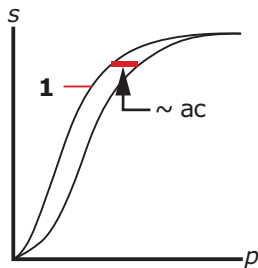


1 = Reference position

3 $sO_2 > 0.97$ (or erroneous). Reference position of the ODC.



The position of the actual ODC can now be approximated from the reference position, using the actual values of pH, pCO_2 , FCOHb, FMetHb and FHbF to determine the shift ac.



1 = Reference position

NOTE The curves are used only to illustrate the principles of the ODC determination.

Coordinates on the ODC

Calculation of a set of coordinates on the ODC is symbolized by:

Equation 47:

$$S = ODC(P, A, T) \text{ or } P = ODC(S, A, T)$$

These equations are symbolic representations of the relationship between saturation (S), tension (P), displacement (A) and temperature (T).

To calculate S or P and to further calculate sO_2 and pO_2 , the other variables should be specified. S and P are calculated using numerical methods.

P is input to equation 46.1.

S is input to equation 46.2.

A is input to equation 46.5.

T is input to equation 46.7.

APPENDIX C

Ordering Information

Overview

This chapter lists the parts available to order and the part numbers available for purchase on the Vi-CELL MetaFLEX instrument (PN B93017).

This chapter contains information on:

- [Sensor Cassette - Part Numbers](#)
- [Solution Packs - Part Numbers](#)
- [Spare Parts and Accessories - Part Numbers](#)
- [Quality Control Products - Part Numbers](#)
- [Cleaning Products - Part Numbers](#)

Sensor Cassette - Part Numbers

Item	Volume	Part number
Vi-CELL MetaFLEX sensor cassette	300 samples	B93030

Solution Packs - Part Numbers

Item	Volume	Part number
Vi-CELL MetaFLEX solution pack	680 activities	B93029

Spare Parts and Accessories - Part Numbers

Product	Part number
Printer paper (1 roll)	B97800
ctHb Calibration Solution S7770	B93035
Inlet Probe	B94697
Inlet Gasket with holder	B94696

Product	Part number
Inlet Connector Gasket	B94699
Inlet Module	B94648
Vi-CELL MetaFLEX Flush Device	B94722
Vi-CELL MetaFLEX Rolling Stand Kit	B93041
Vi-CELL MetaFLEX Rolling Stand tray with Adjustable tray	B93042
Startup Kit	B97759

Quality Control Products - Part Numbers

QUALICHECK5+ Solutions	Code number (REF)
S7730 Level 1 (marked with a red color code)	B93032
S7740 Level 2 (marked with a yellow color code)	B93033
S7750 Level 3 (marked with a blue color code)	B93034
S7760 Level 4 (marked with a green color code)	B98251

NOTE Refer to the product-specific package insert for the concentration values of each solution.

Range+ QUALICHECK Solutions (for calibration verification use)	Code number (REF)
S7930 Level 1	B98046
S7940 Level 2	B98047
S7950 Level 3	B98048

Other QC products	Code number (REF)
QUALICHECK Opener and Adapter for ABL90 (925-214)	C81228

Cleaning Products - Part Numbers

Cleaning products	Code number (REF)
Sodium Hypochlorite Solution	A32319

Abbreviations

The following list is a composite of the symbols, abbreviations, acronyms, and reference designators either used in this manual or related to the information in it. When the same abbreviation (or reference designator) is used for more than one word (or type of component), all meanings relevant to this manual are included, separated by semicolons.

°C — degrees Celsius

°F — degrees fahrenheit

± — plus or minus

Ag — silver

AgCl — silver chloride

AgNO₃ — silver nitrate

BCI — Beckman Coulter Incorporated

CDRH — Center for Devices and Radiological Health

cm — centimeters

CO — carbon monoxide

CSV — comma separated value

CV — coefficient of variation

DANAK — Danish Accreditation

DFM — Danish Institute of Fundamental Metrology

dL — deciliter

DPD — Diphenyldiazonium

DPLEC — Danish primary laboratory for Electrochemistry

FHbCO — fraction of carboxy-hemoglobin in total hemoglobin

g — grams

Hb — hemoglobin

Hct — hematocrit

HiCN — cyanohemoglobin

HIS — hospital information system

HPLC — high performance liquid chromatography

IEC — International Electrotechnical Commission

IUPAC — International Union of Pure and Applied Chemistry

KCl — potassium chloride

KCN — potassium cyanide

kHz — kilohertz

L — liter

LIS — laboratory information system

LED — light-emitting diode

MCH — Mean Corpuscular Hemoglobin Concentration

MethHb — methemoglobin

mL — milliliter

m — meter

mm — millimeter

mmol — millimole

mW — milliwatt

NIST — National Institute of Standard Technology

nm — nanometer

PN — part number

PVC — polyvinyl chloride

QC — quality control

RBC — red blood cell

RCF — relative centrifugal force

RoHS — Restriction of Hazardous Substances Directive

SHb — sulfhemoglobin

SRM — standard reference material

USB — universal serial bus

USPTO — United States Patent and Trademark Office

VAC — voltage alternating current

VA — volt-ampere

V — volts

W — watts

WDC — worldwide datacheck system

μL — microliters

μ — micron

μm — micrometer

μmol — micromole

Glossary

Bar-code symbol — A group of parallel bars and spaces with encoded characters. A bar-code symbol generally contains a leading quiet zone, a start character, data characters, a check character, a stop character, and a trailing quiet zone.

Bar — A strip (or element) that is usually black and has minimum reflectance.

Coefficient of variation (CV%) — A measure of the variability in signal intensity that is generated as particles pass repeatedly through the laser beam. This variability is expressed as a percentage of the average signal intensity.

Control — A substance used to routinely monitor the performance of an analytical process that has the characteristic being measured (for example, IMMUNO-TROL cells or CYTO-TROL control cells)

cCa²⁺ — Concentration of calcium ions in plasma.

cCl⁻ — Concentration of chloride ions in plasma.

cGlu — Concentration of D-glucose in plasma.

cH⁺ — Concentration of hydrogen ions in blood.

cLac — Concentration of L-lactate in plasma.

cK⁺ — Concentration of potassium ions in plasma.

cNa⁺ — Concentration of sodium ions in plasma.

ctBil — Concentration of total bilirubin in plasma.

ctHb — Concentration of total hemoglobin in blood.

Controls and indicators — Instrument controls are the mechanisms you use to communicate with the instrument. Indicators are the mechanisms the instrument uses to communicate with you.

Defaults — Original settings for the instrument. You can change them to customize the settings for your laboratory.

FCO₂Hb — Fraction of carboxyhemoglobin in total hemoglobin in blood.

FHHb — Fraction of deoxyhemoglobin in total hemoglobin in blood.

FHbF — Fraction of fetal hemoglobin in total hemoglobin in blood.

FMetHb — Fraction of methemoglobin in total hemoglobin in blood.

FO₂Hb — Fraction of oxyhemoglobin in total hemoglobin in blood.

Mean — Arithmetic average of a group of data. See also [Standard deviation \(SD\)](#) and [Coefficient of variation \(CV%\)](#).

sO₂ — Oxygen saturation, the ratio between the concentrations of oxyhemoglobin and the hemoglobin minus the dyshemoglobins.

pCO₂ — Partial pressure (or tension) of carbon dioxide in blood.

pO₂ — Partial pressure (or tension) of oxygen in blood.

pH — A measure of the acidity or alkalinity of a sample.

Quality control QC — A comprehensive set of procedures a laboratory sets up to ensure that an instrument is working accurately and precisely.

Select — To position the mouse cursor on an item, and then press and release a mouse button to choose that item.

Specimen ID — ID assigned to a Specimen draw as opposed to a tube.

Standard deviation (SD) — A measure of difference from the mean. A measure of precision.

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- Introduction
- System Overview
- Operation Principles
- Startup
- Quality Control
- Sample Analysis
- Data Review
- Shutdown
- Setup
- Troubleshooting
- Calibration
- Cleaning Procedures
- Replacement/Adjustment Procedures
- Derived and Input Parameters
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