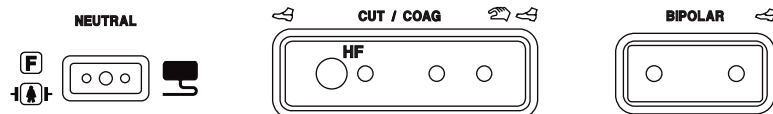
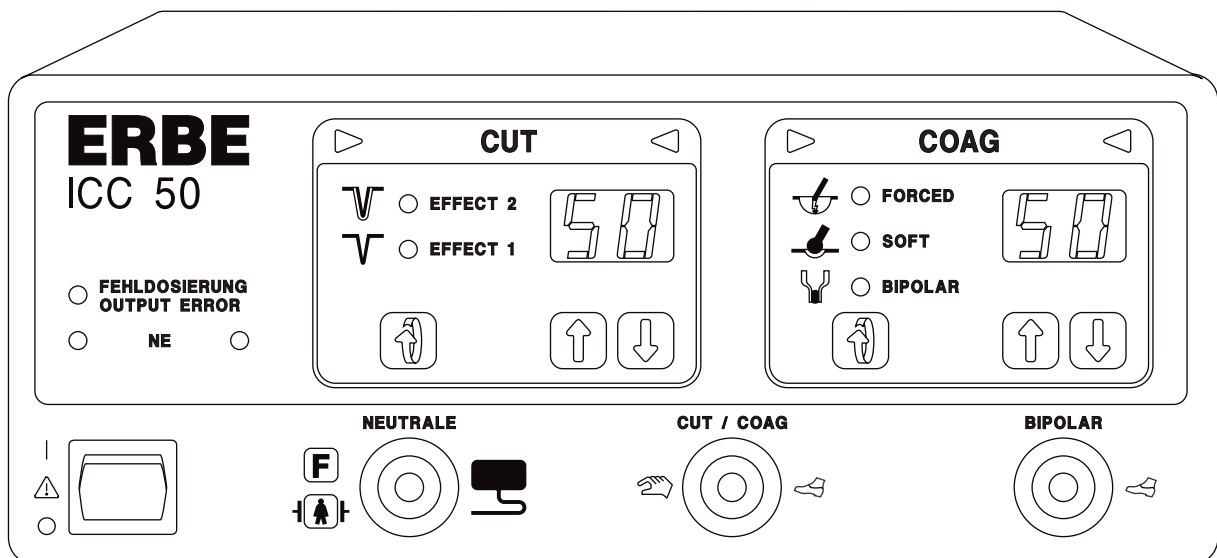
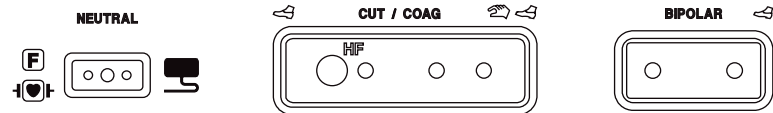
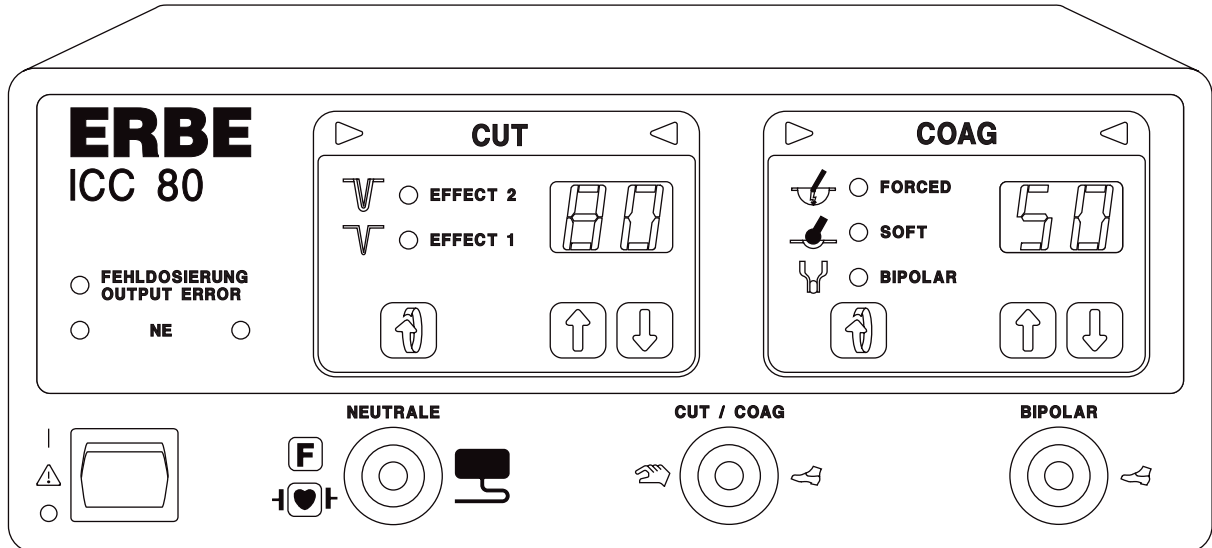


ERBE



ERBOTOM ICC 80 / 50

Instruction manual

08.00

ERBOTOM ICC 80 / 50 v 1.x

10122-103, 10122-101
10122-003, 10122-041

Instruction manual

08.00



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1 INTRODUCTION

1.1 Intended purpose of the ICC 80 / 50

The ICC is a high-frequency surgical unit for cutting and coagulation.

1.2 Explanation of the safety instructions

The WARNING  safety instruction indicates a danger which can result in personal injury.

The CAUTION  safety instruction indicates a danger which can result in property damage.

The IMPORTANT safety instruction indicates a danger which can cause functional failure of the unit.

2 INITIAL OPERATION

Read carefully before initial operation of the unit.

In the development and production of this high-frequency surgical unit, the relevant, generally recognized rules of technology, as well as the valid occupational safety and accident prevention regulations have been taken into consideration. This ensures that patients, employees and third parties are protected from dangers to life and health during intended application of the high-frequency surgical unit, to the extent permitted by the type of application intended.

Initial operation

Before delivery, every high-frequency surgical unit is tested by the manufacturer in regard to its function and safety. To ensure that the unit also functions safely after shipping and installation at the operator's site, the following points should be observed:

The operator should only operate the high-frequency surgical unit if the manufacturer or supplier

1. has subjected the unit to a performance test on site
2. has instructed the parties responsible for operation of the unit in handling of the unit by means of the instruction manual.

3 RISKS AND SAFETY OF HIGH-FREQUENCY SURGERY

3.1 Unintentional thermal tissue damage

High-frequency surgery is associated in principle with various risks for the patient, the personnel and surroundings. In order to avoid these risks in practice, the surgeon and his/her assistants must recognize these risks and observe the appropriate rules for prevention of damage. In the following, these risks and rules for prevention of damage are explained.

3.1.1 Unintentional thermal tissue damage due to HF leakage currents

During high-frequency surgery, the patient unavoidably conducts high-frequency electrical current to ground potential. If the patient makes contact with electrically conductive objects during high-frequency surgery, a high-frequency electrical current can result at the contact point between the patient and this object, which can in turn cause thermal necroses. Not just objects made of metal are electrically conductive objects, but also wet cloths.

WARNING

The patient must be insulated against electrically conductive objects during high-frequency surgery. The black elastic table covers on operating tables demonstrate a certain electrical conductivity for diverting electrical charges. Therefore they are never suitable for ensuring the required insulation of the patient against metal parts of the operating table. For this reason, an electrically insulating intermediate layer, for example dry cover cloths, must be laid between the patient and this black operating table cover during the application of high-frequency surgery.

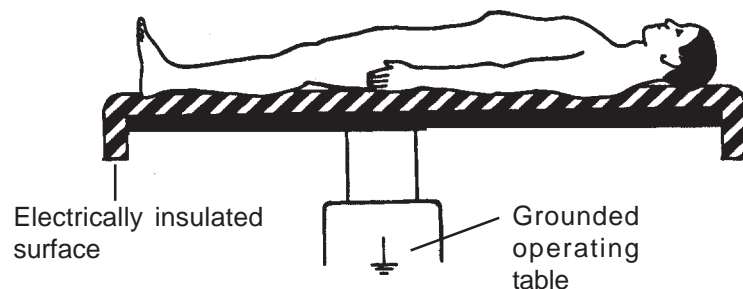


Fig.: Insulated positioning of the patient on the operating table

If it is possible for this intermediate layer to become wet during the operation, for example due to perspiration, irrigation liquid, urine etc., wetting of these intermediate layers must be prevented by a watertight sheet of plastic. Urine should be carried away via catheter.

- Extremities lying against the trunk or skin-to-skin contact points should be insulated from one another by laying dry cover cloths between them.
- Do not apply ECG electrodes closer than 15 cm next to the operating field.
- Needle electrodes or injection cannulae should not be used as ECG electrodes during high-frequency surgery.

3.1.2 Unintentional activation of an HF generator

Unintentional activation of an HF generator can lead to burns on the patient if the active electrode hereby touches the patient directly or indirectly through electrically conductive objects or wet cloths.

Unintentional activation of an HF generator can, for example, be caused by:

- Unintentionally pressing a footswitch pedal
- Unintentionally pressing a fingerswitch
- Defective fingerswitches, footswitches or cables
- Penetration of electrically conductive liquids (blood, amniotic fluid, urine, physiological saline solution, irrigation fluids etc.) into fingerswitches or footswitches.
- Errors within the high-frequency surgical unit

WARNING

To prevent burns on the patient due to unintentional activation of a high-frequency generator, the following application rules should be heeded:

- Never lay active electrodes onto or beside a patient in such a way that they can touch the patient directly or indirectly through electrically conductive objects or wet cloths.
 - The lines to the active electrodes should be positioned in such a way that they touch neither the patient nor other lines.
 - Always set the acoustic signal, which indicates the active status of the high-frequency generator, so that it can be easily heard.
 - For operations in which the cutting or coagulation electrode unavoidably remains in contact with the patient even in a nonactive condition, e.g. for endoscopic operations, particular care is required. If such an electrode is unintentionally activated due to an error, this activated electrode should then not be removed from the body without special supervision. When removing the activated electrode from the patient's body, burns can result on all areas within the body which come into contact with the activated electrode. For this reason, in case such errors occur, the power switch for the high-frequency surgical unit should be switched off immediately before an attempt is made to remove the activated electrode from the body.
-

3.1.3 Unintentional thermal tissue damage due to inappropriate application

Generally speaking, the bipolar coagulation technique should be applied in preference to the monopolar coagulation technique. This particularly applies to coagulations on straight organs, on which the high-frequency current flows over longer areas through diameters which are approximately equal or become even smaller.

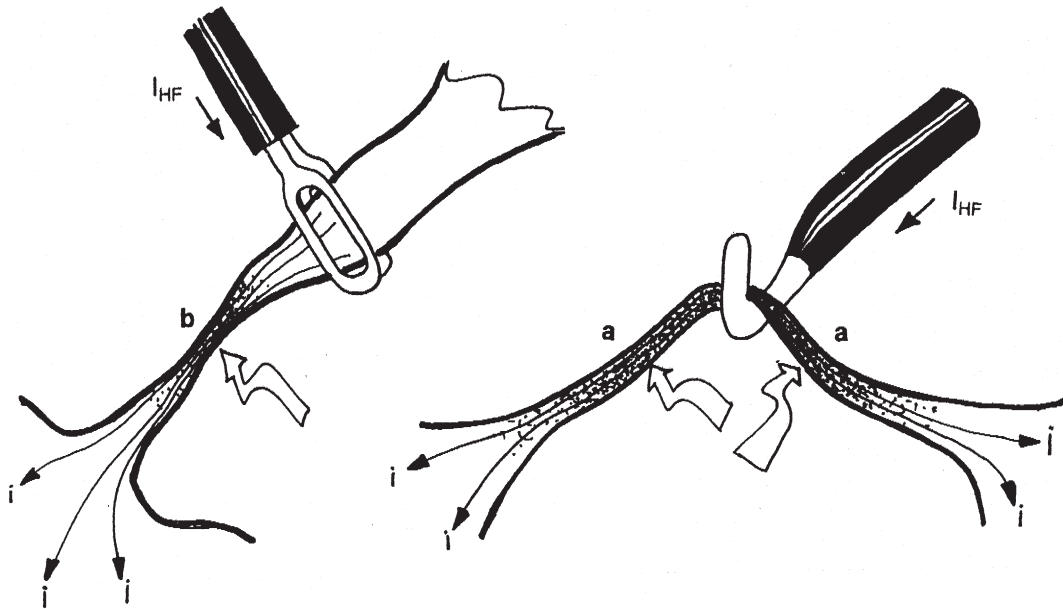


Fig.: Thermal damage of lateral tissue

The tissue is always first heated at places on the tissue where the diameter is smallest. If the HF current flows through the same diameter (a) over longer distances, the tissue coagulates over this entire distance. If the diameter of the tissue next to the application point of the coagulation electrode is smaller than at the point of application, coagulation will also occur next to the application point (b).

WARNING 

Always make certain that the HF current does not flow through thin tissue structures or vessels with a small diameter.

3.1.4 Unintentional thermal tissue damage due to inappropriate or nonapplication of the neutral electrode

With inappropriate or even nonapplication of the neutral electrode, there is a large risk of unintentional thermal tissue damage both at the application point of the neutral electrode as well as to other areas on the patient's body.

The neutral electrode must be applied with its entire surface as closely and reliably as possible to the operating field on the patient's body.

WARNING 

The effective contact surface, i.e. the electrical conductive value between the neutral electrode and the patient must correspond to the HF capacity used, meaning the intensity of the HF current. Here the effective contact surface means the surface of the neutral electrode which has electrically conductive contact to the skin of the patient during high-frequency surgery.

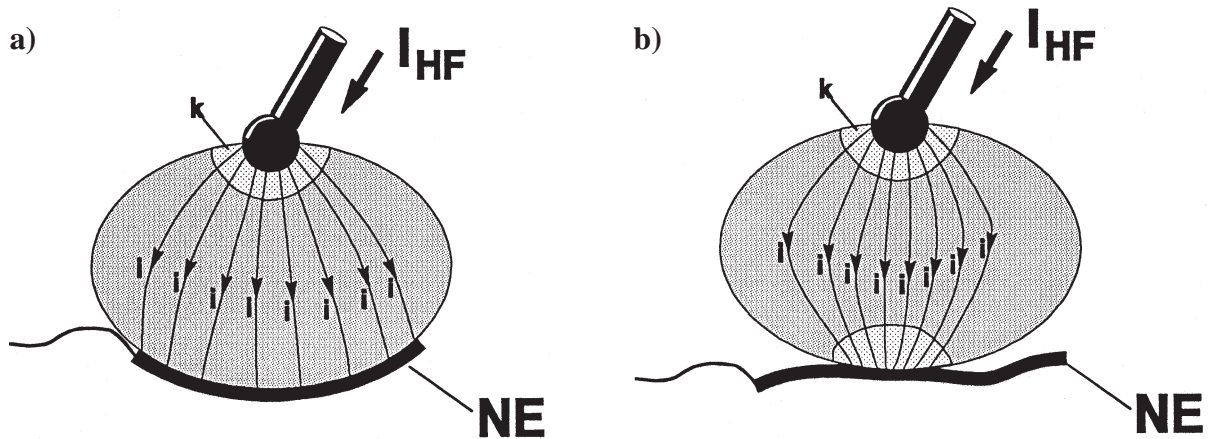


Fig.: The neutral electrode must be applied at an appropriate location on the patient's skin using the entire contact surface available (a). If the neutral electrode has only partial contact to the patient's skin (b), there is a risk that burning will occur at this location

3.1.5 Unintentional thermal tissue damage due to unsuitable and/or faulty accessories

It must be ensured that only accessories in perfect condition are used for high-frequency surgery. Only accessories that are compatible or tested by the unit manufacturer must be used. This applies both to the active electrodes including cable and plugs, as well as to the neutral electrodes including cables and plugs.

When using an instrument with electric insulation, it is necessary to be certain that these insulations are not overloaded and destroyed by overly high electric voltages. The electric output voltages for the high-frequency surgical unit are indicated for the various cutting and coagulation modes relative to the possible settings in this instruction manual. The electric strength of the instrument insulation can be found in the technical data for the instruments or, in case of doubt, can be requested from the manufacturer of the respective instrument.

WARNING 

All insulation on electrodes, electrode holders, cables, plugs etc. must be in perfect condition.

3.1.6 Unintentional thermal tissue damage due to inattentiveness

Like a scalpel, high-frequency surgery is always a potential source of danger if handled without care.



The cutting or coagulation electrodes should always be handled with care and laid aside in the intervals between use so that neither the patient nor other persons can come in contact with the electrodes.

Laying unused electrode handles or coagulation forceps on the patient, next to the patient or within folds on the cover cloths is dangerous. Cases of burns on patients are known which were caused by laying the coagulation forceps within folds on the cover cloths which penetrated through the cloths into the patient's skin and resulted in burns without being noticed.

3.1.7 Unintentional thermal tissue damage due to output error

The risk of unintentional thermal tissue damage is proportionate to the intensity and time limit set on the unit for cutting or coagulation.



The intensity for cutting or coagulation should only be set and only activated for as long as necessary for the intended purpose.

An insufficient effect at a standard setting can, for example, be caused by poor attachment of the neutral electrode, poor contact in the connectors, defective cables or electrically insulating tissue remnants on the active electrode. This must be checked before setting at a higher power.

3.1.8 Unintentional thermal tissue damage due to the ignition of flammable liquids, gases and/or vapors

During high-frequency surgery, electric sparks or arcs that can ignite flammable liquids, gases or vapors occur at the active electrode.

WARNING 

Make certain during high-frequency surgical operations that anesthetics, skin cleaning agents and disinfectants are nonflammable. If their use is unavoidable, they must have completely evaporated and the vapor must be removed from the area of spark formation before switching on the high-frequency surgical unit.



Before application of high-frequency surgery in the gastro-intestinal tract, it must be ensured that no flammable (endogenous) gases are present here. There is danger of explosion if flammable gases are present. For this reason, these gases must be extracted and/or eliminated by flushing out the affected lumen with CO₂ before using high-frequency surgery.

During transurethral resection (TUR), H₂O molecules may dissociate into H₂ and O₂ in the arc between the resection loop and the irrigation liquid. These gases may collect on the roof of the urinary bladder as a highly explosive gas mixture. If resection is performed in this gas mixture, dangerous explosions may occur.

3.1.9 Unintentional burns due to hot electrodes

Cutting and/or coagulation electrodes become hot during cutting and/or coagulation procedures indirectly through the heated tissue and through the electric arc.

WARNING 

Tissue can be unintentionally burnt immediately after cutting and/or coagulation procedures if electrodes that are still hot touch the tissue. Attention must be especially paid to this during endoscopic operations, such as during pelviscopic fallopian tube coagulation or during endoscopic polypectomy.

3.2 Electric shock

An electric shock may occur if the high-frequency surgical unit delivers a too heavy low-frequency current or if a too heavy low-frequency current flows through the patient into the high-frequency surgical unit from another voltage source.

3.3 Stimulation of nerves and muscles

A known risk of high-frequency surgery is the unintentional electric stimulation of the patient's nerves and muscles. This stimulation can result from low-frequency electrical currents that are caused either by low-frequency current sources or due to electrical arcs between an active electrode and the patient's tissue.

Electric alternating current with a frequency above 300 kHz is unable to stimulate nerves and muscles.

During cutting procedures, forced coagulation and spray coagulation, the unavoidable electric arcs between an active electrode and the tissue nevertheless have the effect that a portion of the high-frequency alternating current is rectified, from which more or less strongly modulated, low-frequency current components result which stimulate electrically stimuable structures such as nerves and muscles.

This can result in more or less strong spasms or muscle contractions.

WARNING 

When using high-frequency surgery on electrically stimuable structures, contractions of the affected muscles must be taken into account. This can occur, for example, during endoscopic operations in the urinary bladder in the vicinity of the obturator nerve and during operations in the area of the facial nerve.

3.4 Cardiac pacemaker

For patients with implanted cardiac pacemakers or pacemaker electrodes, irreparable damage to the pacemaker and disturbance of the pacemaker function, which can lead to ventricular fibrillation, must be reckoned with.

3.5 Danger of explosion

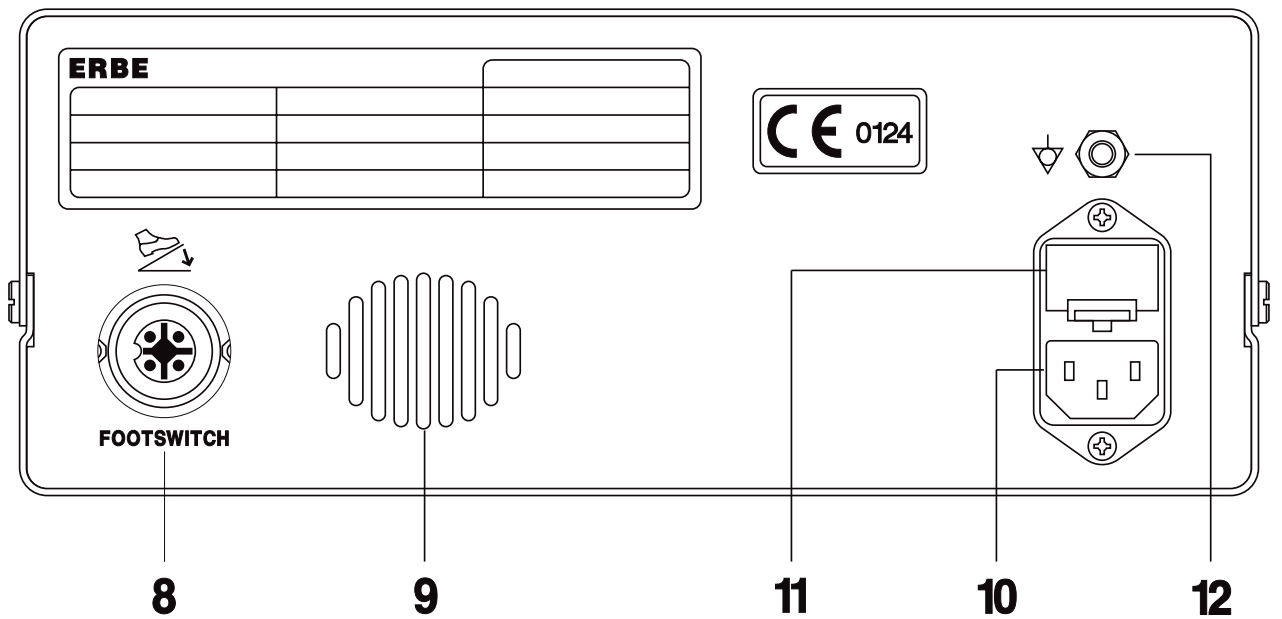
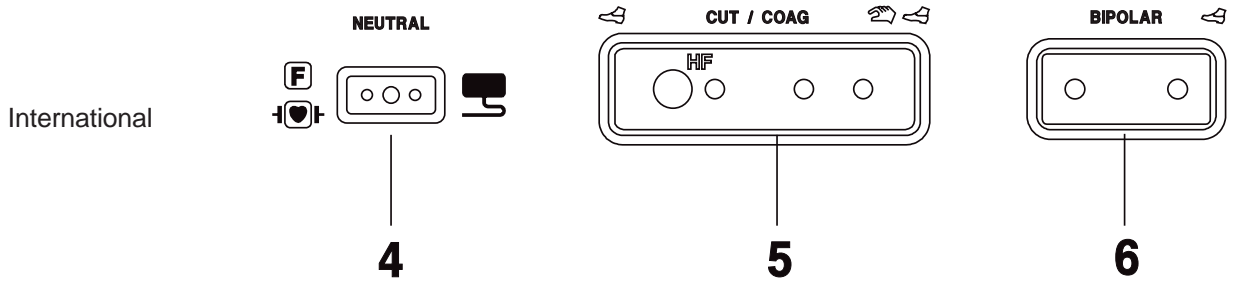
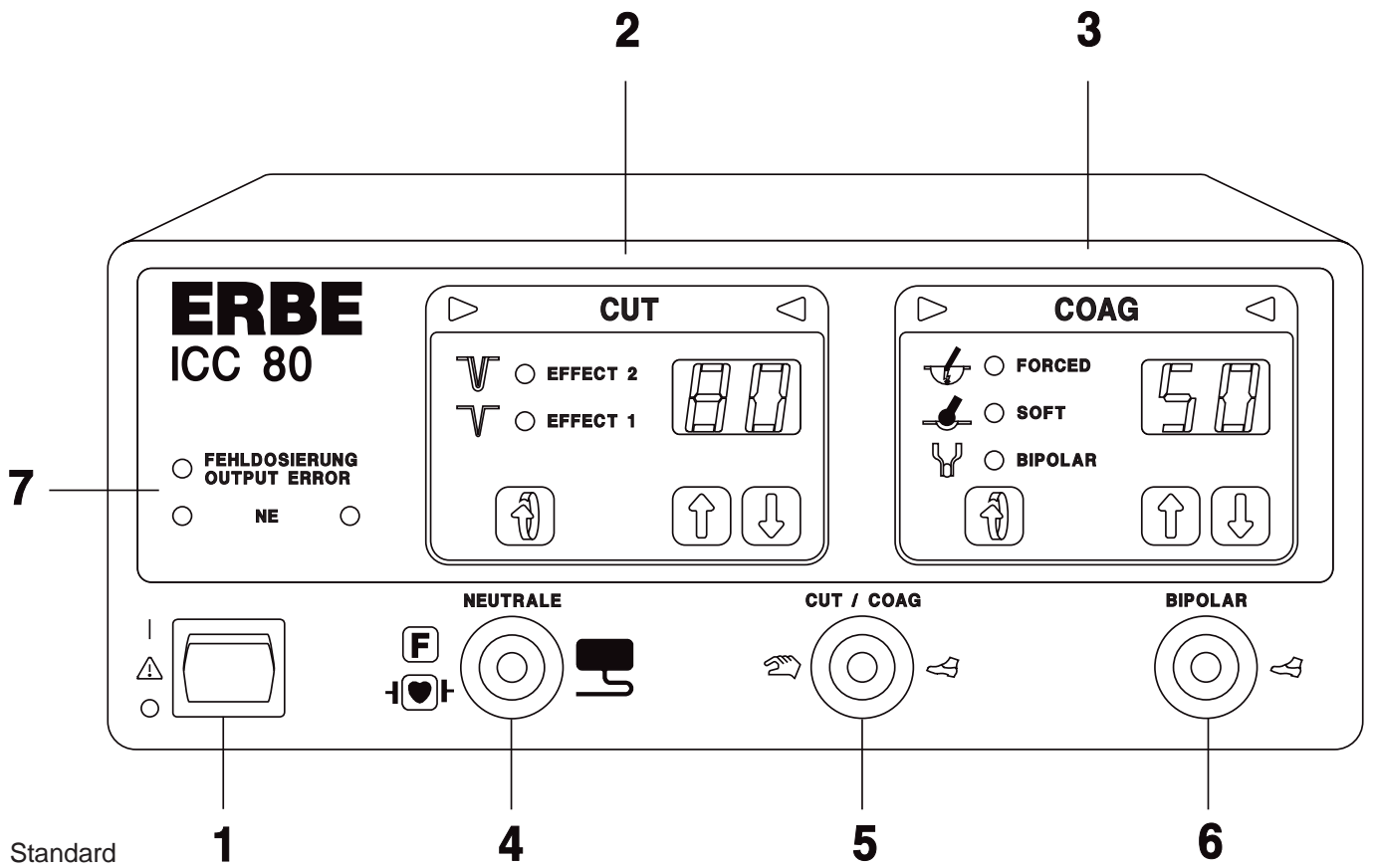
High-frequency surgical units always generate sparks during operation on the active electrode. For this reason, it is necessary to make certain during interventions that anesthetics, degreasers and disinfectants are neither flammable nor explosive. They should at least have evaporated completely before switching on the high-frequency surgical unit and be removed from the area of spark formation.

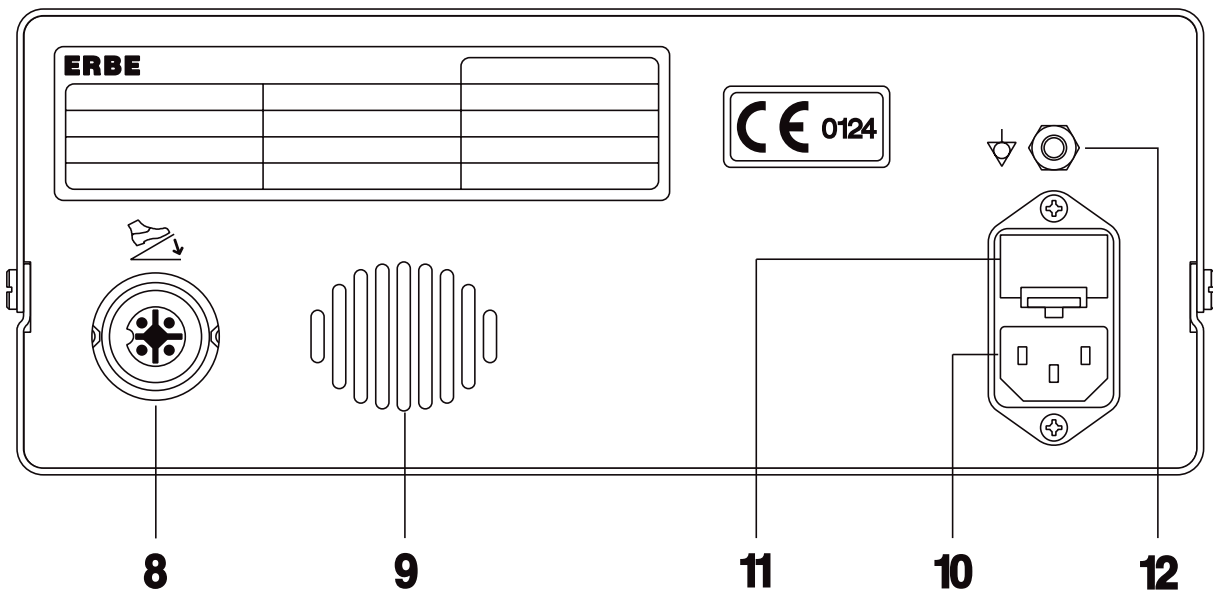
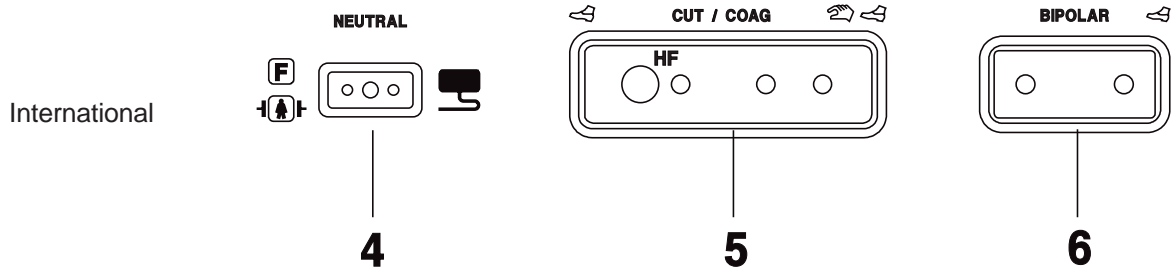
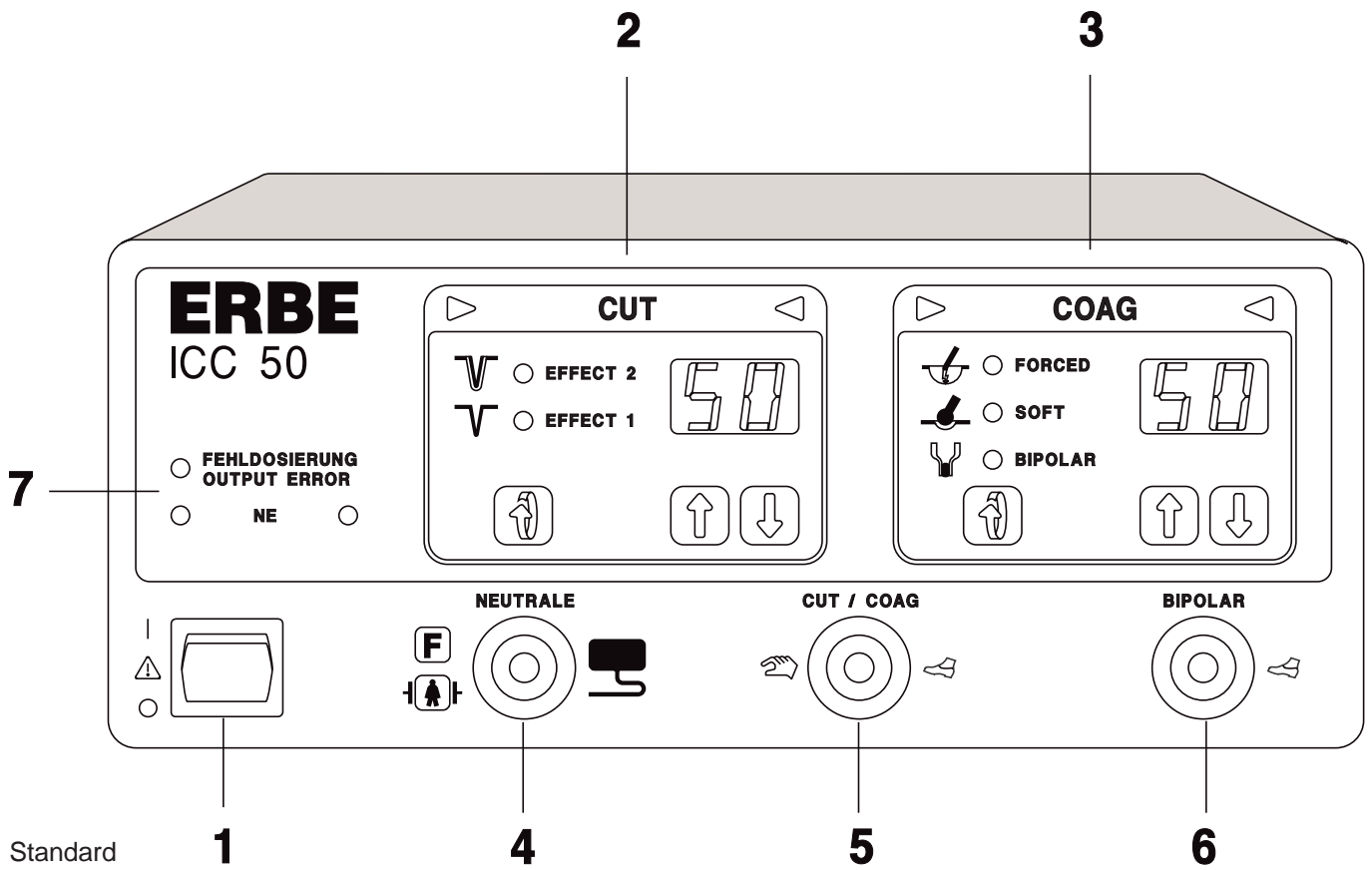
3.6 Interference with other electronic equipment

High-frequency surgical units normally generate high-frequency electrical voltages and currents which can interfere with other electronic equipment.

When installing or arranging sensitive electronic equipment in the operating room, this problem should be taken into consideration. In principle, sensitive electronic equipment should be set up as far as possible from the high-frequency surgical unit and particularly from the cables providing HF current. In addition, the cables providing HF current, which act like broadcast antennas, should not be unnecessarily long and should never be positioned parallel or too close to cables from sensitive electronic equipment.

The unit has been fitted with a special generator in consideration of the disturbance of sensitive electronic equipment, which generates a relatively low interference level as compared to conventional high-frequency surgical units.





4 DESCRIPTION OF THE HIGH-FREQUENCY SURGICAL UNIT

4.1 General description

Cutting with automatic control of the HF voltage (Cut)

The ERBOTOM ICC is equipped with automatic open and closed loop control systems which control and regulate the parameters relevant to the cutting quality so that each respectively selected cutting quality is guaranteed to be reproducible and constant.

Adjustable power limitation in the cutting mode

Since the ICC units are equipped with automatic control of the HF voltage in the cutting mode, a power setting in regard to cutting quality is not required. The adjustable power limitation is primarily intended to guarantee the safety of the patient from unintentional thermal tissue damage, and to protect fine cutting instruments, such as fine needle electrodes, from destruction due to overly high HF currents if these come in contact in activated condition with other metallic instruments.

Soft coagulation

Soft coagulation can be activated by key or pedal.

Forced coagulation

Forced coagulation is advantageous if an efficient hemostasis is to be achieved with relatively small-surface electrodes.

Forced coagulation can be activated by key or pedal.

Bipolar coagulation

In bipolar coagulation mode, the ICC provides an unmodulated HF voltage with such a low amplitude that electric arcs between the coagulation electrode and tissue can hardly occur. In this way, both carbonization as well as adhesion of the coagulum to the coagulation electrode is extensively prevented.

The adjustable power limitation serves the purpose of protecting fine bipolar coagulation instruments, such as pointed bipolar coagulation forceps, from being thermally destroyed in case of a short between the two forcep tips.

The footswitch is used for activation.

4.2 Description of the controls



This symbol, in accordance with EN 60 601-1, is intended to indicate to the user that this unit must only be used on the patient if the user is acquainted with the operation and features of this unit.

1 Power switch

Using this power switch, the unit is switched on and off.

Each time after being switched on, the unit automatically proceeds with various performance checks. If an error in the unit or in the accessories is recognized here, a warning signal sounds and the determined error is indicated by a corresponding error number. (See Chapter 8.1, Automatic performance checks after switching on the unit). If no error is determined, the unit is ready to operate.

After the automatic performance check, the basic setting appears on the front panel, whereby all relevant optical displays blink and the unit cannot be activated until any key on the front panel is briefly depressed as confirmation that the basic setting should be used. Then the relevant displays light continuously and the unit can be activated using the setting available. These settings can be changed or adapted to the respective requirements at any time.

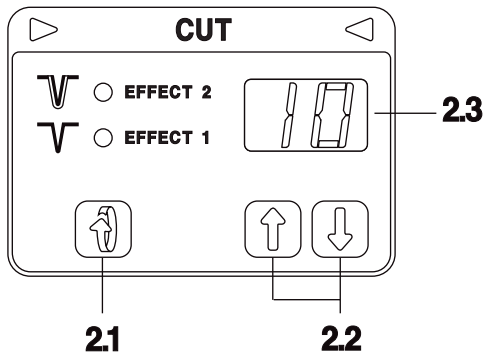
2-3 Function fields

The CUT and COAG function fields can be adjusted separately from one another, although not activated simultaneously for reasons of safety.

WARNING 

Function fields that are not used may be switched off completely to prevent unintentional activation. To do this, the power limitation must be set down so far in the corresponding function field until a beep is heard and “—“ appears on the digital display. The corresponding function field cannot be activated in this condition.

2 CUT function field



2.1 Setting of the coagulation EFFECT when cutting

Here the required cutting quality in regard to the coagulation effect on the cutting edges can be adjusted.

Level 1 corresponds to a low coagulation effect.

Level 2 corresponds to a high coagulation effect.

2.2 Setting of the power limitation

ICC 50

The HF power output can be limited in 1 watt steps from 50 watts to 1 watt. If the display shows “—”, the Cut mode is switched off.

ICC 80

The HF power output can be limited in 1 watt steps from 80 watts to 1 watt. If the display shows “—”, the Cut mode is switched off.

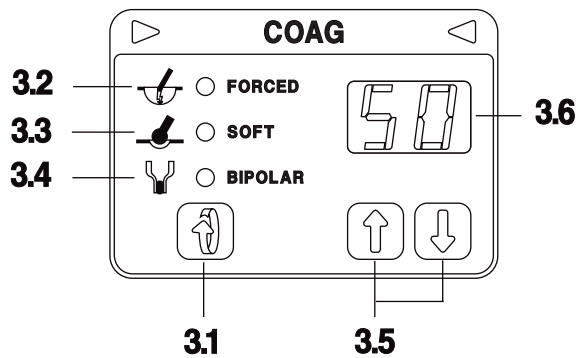
2.3 Display of the set power limitation in watts

This display shows the respectively set power limitation

Activation

This can be done using either the yellow key on the electrode handle or the yellow pedal on the footswitch. Activation is visually signaled by continuous illumination of the triangle symbol in the upper part of the CUT function field and also acoustically signaled. Cutting instruments are connected to the CUT/COAG socket.

3 COAG function field



3.1 Selection of the coagulation mode

By pressing this key, one of the following coagulation modes can be selected:

3.2 Forced coagulation

3.3 Soft coagulation

3.4 Bipolar coagulation

3.5 Power limitation

The HF power output can be limited in FORCED, SOFT and BIPOLAR-COAG mode in 1 watt steps from 50 watts to 1 watt. If the display shows “—”, the Coag mode is switched off.

3.6 Display of the adjusted power limitation in watts

This display shows the respectively adjusted power limitation

Activation

Forced and Soft coagulation can be activated using the blue key on the electrode handle or the blue pedal. Bipolar coagulation can be activated via the blue pedal.

Activation is signaled by illumination of the triangle symbols in the COAG function field as well as acoustically.

Monopolar instruments are connected to the CUT / COAG socket, bipolar instruments to the BIPOLAR socket.

4 Connecting socket for neutral electrodes

For monopolar cutting and/or coagulation, a suitable neutral electrode must be used that must both be connected to the unit as well as carefully applied to the patient.

The ICC is equipped with a Neutral Electrode Monitoring System (NE) which automatically monitors the electrical connection between the neutral electrode and the unit as well as application of the neutral electrode on the patient. The latter only then however if neutral electrodes with two contact surfaces are used.

WARNING

If single-surface neutral electrodes are used, the NE only monitors the electrical connection between the neutral electrode and the unit, but not the application of the neutral electrode on the patient.



The pictograms beside the connecting socket for neutral electrodes have the following explanation:

Neutral electrode in general



The unit conforms to the requirements in EN 60 601-2-2, Sec. 19.101b, according to which the applied part of the unit is insulated to ground potential compatible to HF technology.



The ICC conforms to the requirements of Type CF in accordance with EN 60 601-1. In addition, this pictogram indicates, in accordance with EN 60 601-2-2, that the neutral electrode can remain applied to the patient during defibrillation.

5 Connecting socket for monopolar cutting or coagulation instruments

Electrode handles with or without fingerswitches can be operated at this connecting socket. This connecting socket can be activated via fingerswitch or the pedals of a footswitch.

6 Connecting socket for bipolar coagulation instruments

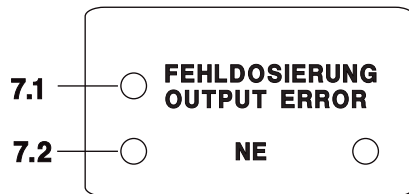
Bipolar instruments can be connected to this connecting socket. The bipolar coagulation mode is activated via pedal.

CAUTION

When using pointed bipolar coagulation forceps, the tips can be thermally damaged due to electric currents that are too high. To prevent this, it is recommended that the power limitation be set as low as possible and/or make certain that the tips of the bipolar coagulation forceps do not touch one another.

7 Safety field

High-frequency surgical units of the ERBOTOM ICC series are equipped with various safety devices to protect the patients and users.



7.1 Unit-related output error

The ICC is equipped with automatic monitoring of the HF output parameters, which monitors deviations in the actual value from the set value of each adjusted HF output parameter. This produces warning signals and/or switches off the HF generator if the deviation is so large that the required quality of the effect (cutting or coagulation) is no longer ensured. For the operator, the display of unit-related output error serves the purpose that he/she is immediately able to check whether deviations due to the presence or absence of this required effect are caused by the unit or not.

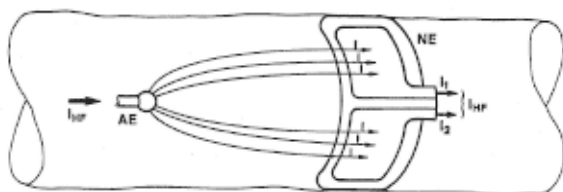
Deviations in the HF output parameters from the set HF output parameters on the ICC can only result from loads where impedance is too low, e.g. coagulation electrodes that are too large, short circuit between an active and neutral electrode, or due to an error in the unit.

7.2 NE monitor

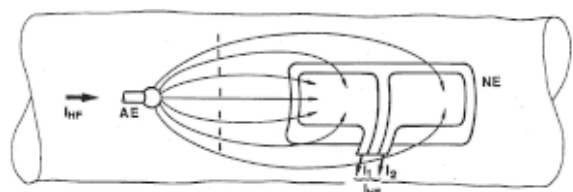
The green signal lamp lights if a neutral electrode is connected to the unit. When using neutral electrodes with two contact surfaces, this green signal lamp only then lights if the neutral electrode is applied sufficiently well to the patient. Monopolar instruments can only then be activated if the green signal lamp is lit. If a monopolar instrument is activated while the green signal lamp is not lit, this error is indicated by illumination of a red signal lamp. At the same time, the corresponding error number is displayed and an acoustic warning signal is given.

The red signal lamp lights if a monopolar operating mode is activated while no neutral electrode is connected to the unit and/or while a neutral electrode with two contact surfaces is not sufficiently well applied to the patient.

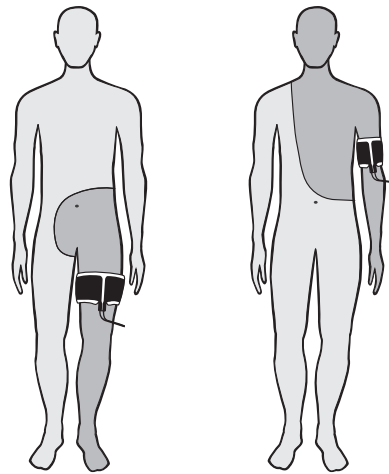
Application of the neutral electrode



Suitable neutral electrode - applied correctly



Suitable neutral electrode - applied incorrectly



Correct application of the neutral electrode

Maximum activation time

The high-frequency generator of a high-frequency surgical unit must only be activated for a brief time to cut or coagulate. To prevent the high-frequency generator from remaining activated for too long unintentionally due to an error, for example from a defective footswitch, the maximum activation time is automatically limited to 30 s. This limit on the activation time can, if this seems practical for a specific reason, be changed via Test program 3 from 1 to a maximum of 99 seconds.

If the cutting or coagulation mode is activated for longer than the set maximum activation time, the high-frequency generator is automatically deactivated and error number 1 is displayed. After releasing the fingerswitch or footswitch that has been pressed for too long, the high-frequency generator can immediately be reactivated.

8 Connecting socket for a dual-pedal footswitch

A dual-pedal footswitch can be connected to this connecting socket. When using a dual-pedal footswitch, the CUT function field can be activated with the yellow pedal and the COAG function field can be activated with the blue pedal.

9 Loudspeaker for acoustic signals

Always set up the unit in such a way that acoustic signals are easily heard from this speaker. The volume of the acoustic signals is set at the factory.



The volume of the acoustic signals can be changed by a technician authorized to this. In consideration of protection of the patient and the user against unintentional burns due to contact with an active electrode, the acoustic signals should be set in such a way that the user can clearly perceive them. This especially applies for unintentional activation of the high-frequency generator.

10 Power connection

This high-frequency surgical unit must only be connected via the power cord supplied by the unit manufacturer or one of these of equal quality, which bears the national test symbol, to correctly installed hospital grade power sockets. Here, for reasons of safety, no multiple sockets or extension cords must be used if possible. If their use is unavoidable, they must be equipped with a correctly functioning grounded connector.

Changeover of the line operation voltage and power fuses

The unit can be operated at the following power voltages: 100, 120, 230, 240 V. To changeover the power operating voltage, pull out fuse drawer 11, remove the gray changeover switch from the fuse drawer and replace so that the correct line operation voltage is visible in the small window. Slide fuse drawer 11 back in.

The power fuses do not need to be replaced when switching over the line operation voltage.

11 Power fuses

The unit is secured with two fuses. If these fuses fail, an authorized technician should inspect the unit for possible errors before putting back into operation. When replacing a power fuse, be aware of the fuse value indicated on the unit's rating plate.

12 Terminal for power equalization

For this, see Chapter 6 INSTALLATION.

5 TECHNICAL DATA, SIGNALS, DIAGRAMS

5.1 Technical data

Cut	
HF voltage waveform for Effect 1	unmodulated sinusoidal alternating voltage
HF voltage waveform for Effect 2	pulse-modulated sinusoidal alternating voltage
Rated frequency	350 kHz
Peak voltage for Effect 1	500 V _p
Peak voltage for Effect 2	800 V _p
Crest factor for Effect 1	2 (ICC 80) 3 (ICC 50)
Crest factor for Effect 2	4
Cutting quality	2 coagulation effects selectable
HF rated power for Effect 1 and Effect 2	80 watts at R _L = 500 ohms (ICC 80) 50 watts at R _L = 500 ohms (ICC 50)
HF power limitation	1 to 80 watts in 1 watt steps (ICC 80) 1 to 50 watts in 1 watt steps (ICC 50)
Setting the HF power limitation	via up/down keys
Precision of the HF power limitation	+/- 5%
Display of the HF power limitation	7-segment display, 2 decimal places
Activation of the cutting mode	via key or pedal
HF output sockets	1

Soft coagulation	
HF voltage waveform	unmodulated sinusoidal alternating voltage
Rated frequency of the HF voltage	350 kHz
Peak value of the HF voltage	max. 190 V _p with no load
HF rated power	50 watts at 200 ohms
HF power limitation (P _{HFmax.})	from 1 watt to 50 watts in 1 watt steps
Setting of the HF power limitation	via up/down keys
Display of the HF power limitation	7-segment display, 2 decimal places
Precision of the HF power limitation	+/- 5%
Activation of Soft coagulation	via key or pedal
HF output sockets	1

Bipolar coagulation	
HF voltage waveform	unmodulated sinusoidal alternating voltage
Rated frequency of the HF voltage	350 kHz
Peak value of the HF voltage	max. 190 V _p with no load
HF rated power	50 watts at 200 ohms
HF power limitation (P _{HFmax.})	from 1 watt to 50 watts in 1 watt steps
Setting of the HF power limitation	via up/down keys
Display of the HF power limitation	7-segment display, 2 decimal places
Precision of the HF power limitation	+/- 5%
Activation of the bipolar coagulation	via pedal
HF output sockets	1

Forced coagulation	
HF voltage waveform	pulse-modulated sinusoidal alternating voltage
Rated frequency of the HF voltage	350 kHz
Peak value of the HF voltage	max. 900V _p
HF rated power	50 watts at 500 ohms
HF power limitation	from 1 watt to 50 watts in 1 watt steps
Precision of the power limitation	+/- 5%
Setting of the HF power limitation	via up/down keys
Display of the HF power limitation	7-segment display, 2 decimal places
Activation of the forced coagulation	via key or pedal
HF output sockets	1

Safety features	
Protection class according to EN 60 601-1	I
Type according to IEC 601-1	CF
Switching of the neutral electrode	Floating output
Monitoring of single-surface neutral electrodes	Auto. monitoring of the electric connection between the neutral electrode and high-frequency surgical unit
Monitoring of dual-surface neutral electrodes	Automatic monitoring a) of the electric connection between the neutral electrode and high-frequency surgical unit. b) of the electric compact resistance R _ü between the two partial surfaces of the neutral electrode and patient.
Max. permissible contact resistance R _ü between the two partial surfaces of divided neutral electrodes	260 ohm
Warning signals for activation and R _ü > 260 ohms	Red signal lamp and acoustic signal lamp
Monitoring of output error	yes
Auto. limitation of max. HF power	Adjustable in 1 watt steps
Auto. limitation of the max. activation time	Yes, adjustable via test program no. 3
Auto. performance check	Self check after unit is switched on
Automatic error recognition	Yes
Automatic error message	Yes

Classification according to EU directive 93/42/EEC	
Class	IIb

Automatic documentation	
Automatic storage of operating errors	yes
Automatic storage of performance errors	yes
Automatic storage of safety errors	yes

Power connection	
Power voltage	100V/ 120V/ 230V/ 240V ±10%
Rated power frequency	50 / 60 Hz
Power consumption in Standby mode	4 watts
Power consumption at maximum HF power	200 watts (ICC 80) 100 watts (ICC 50)
Current consumption in Standby mode	approx. 20 mA
Max. current consumption at maximum HF power	approx. 2.0 A (ICC 80) approx. 1.0 A (ICC 50)
Potential equalization terminal	yes
Power fuses	T 2.0 A

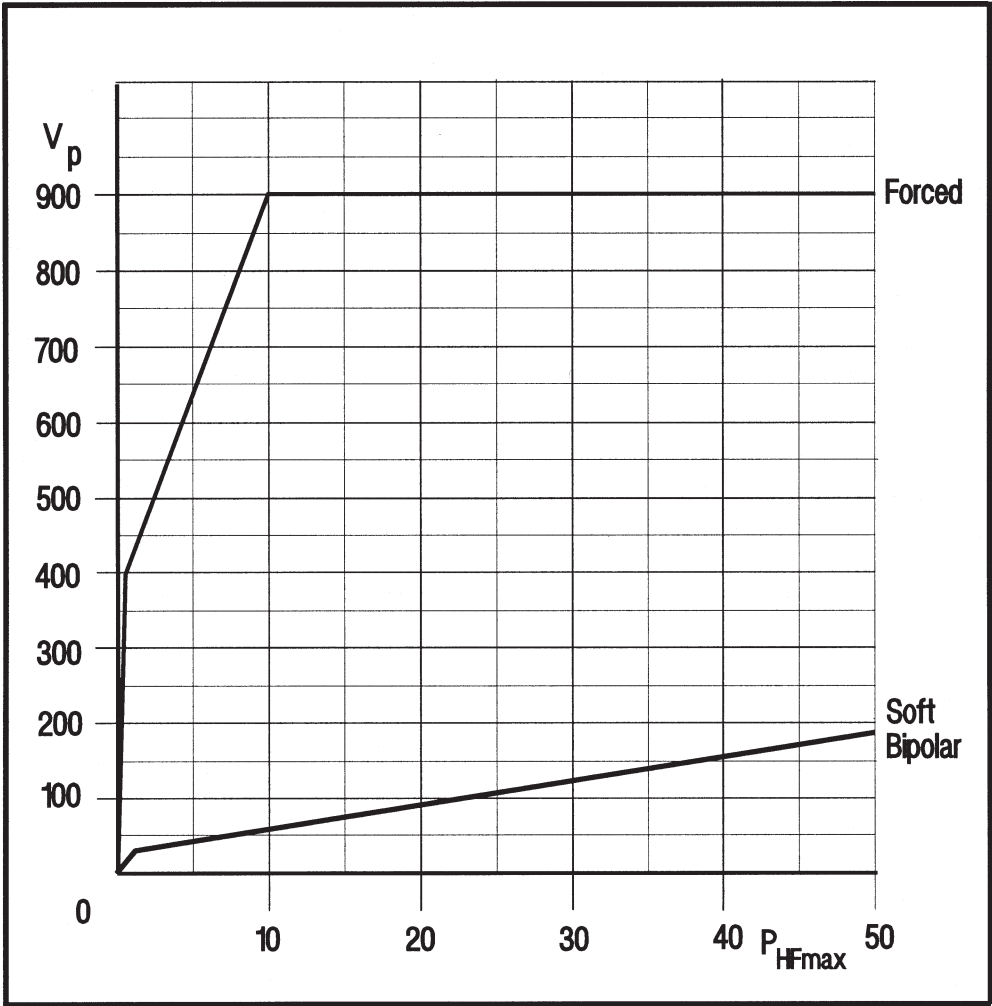
DIMENSIONS	
W x H x D	275 x 105 x 255 mm
Weight	2.8 kg

Environmental conditions for shipping and storage of the unit	
Temperature	-40°C to + 70°C
Air humidity, relative	30% to 95%

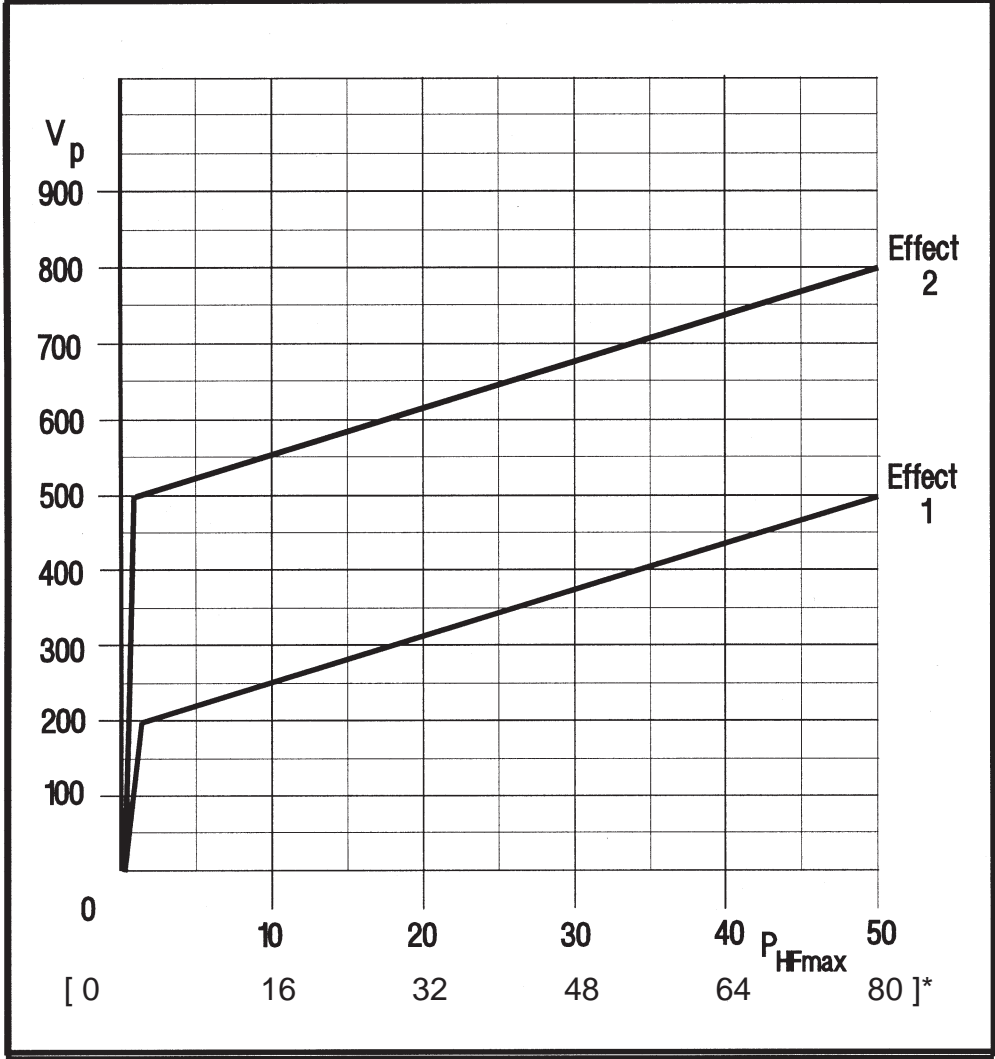
Environmental conditions for operation of the unit	
Temperature	+10°C to + 40°C
Air humidity, relative	30% to 75%, noncondensing

5.2 Diagrams

Peak value V_p of the HF output voltage in Soft and Forced coagulation mode as a function of the setting of the power limitation P_{max} with no load.

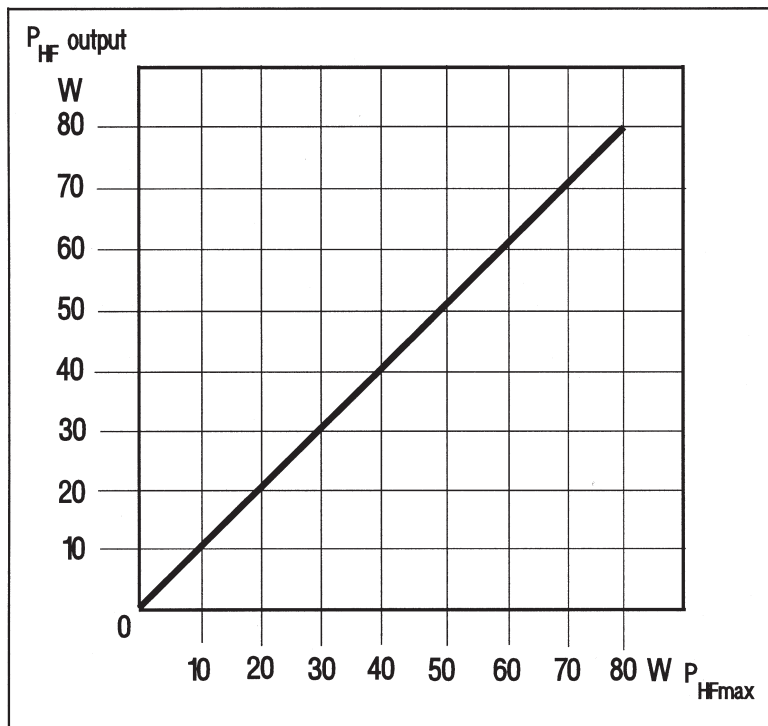


Peak value V_p of the HF output voltage in Cutting mode for Effect 1 and Effect 2 as a function of the setting of the power limitation P_{max} with no load.

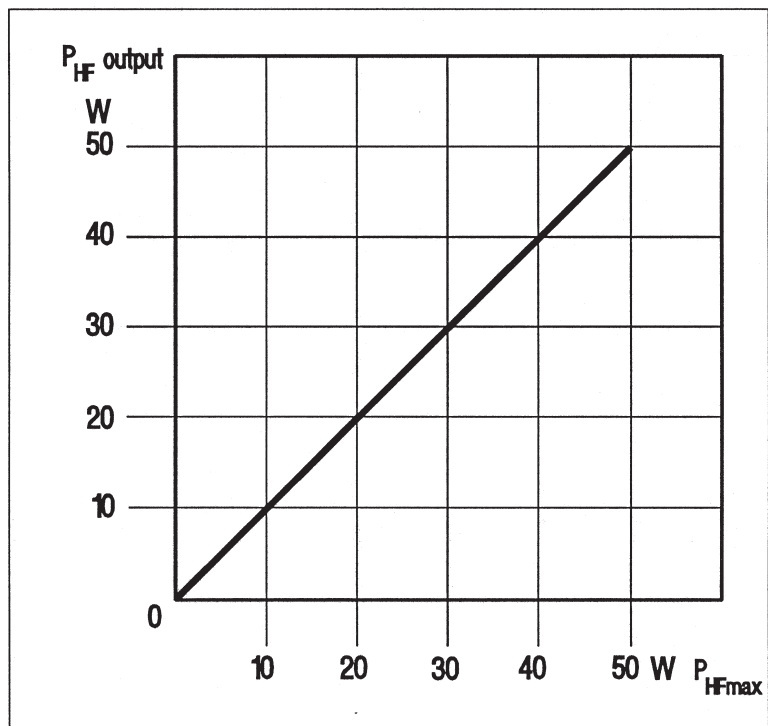


* for ICC 80

The HF power output $P_{HF\ output}$ for all operating modes as a function of the setting of the power limiton P_{max} .



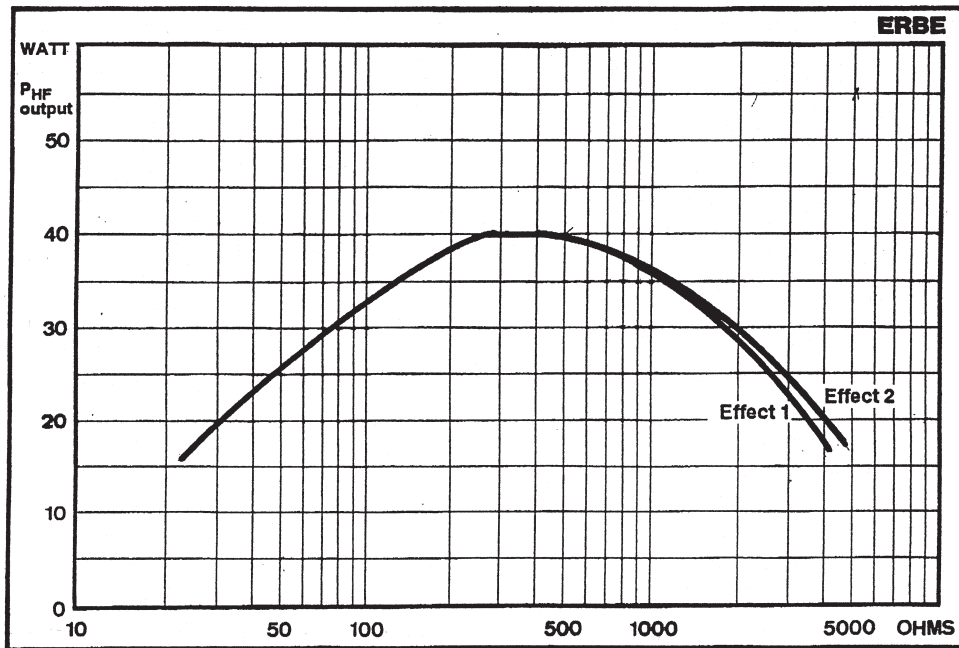
ICC 80



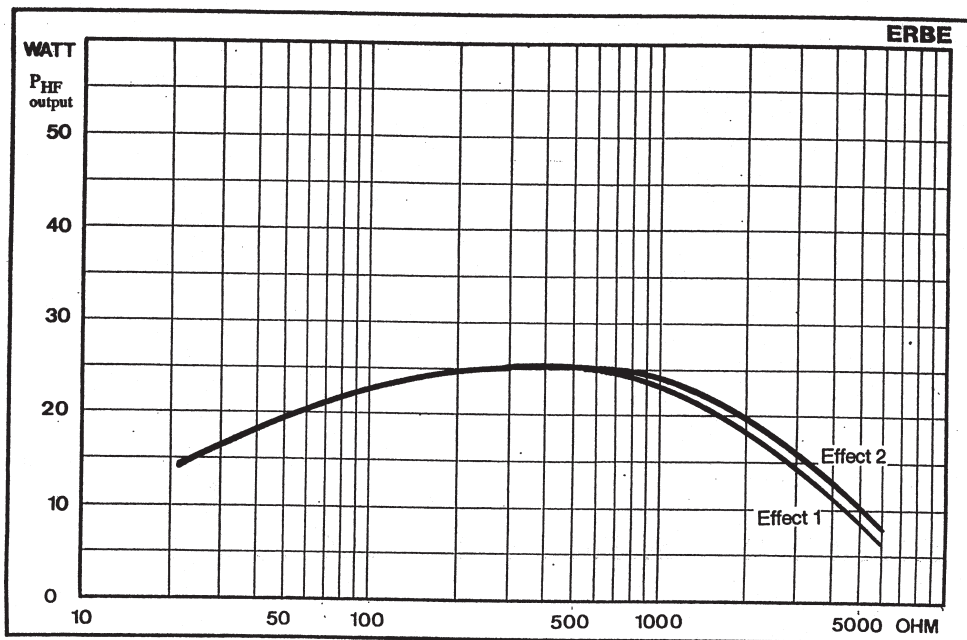
ICC 50

- | | |
|---------------|--------------------------------------|
| Cut Effect 1 | At a load resistance of 500 Ω |
| Cut Effect 2 | At a load resistance of 500 Ω |
| Forced Coag. | At a load resistance of 500 Ω |
| Soft Coag. | At a load resistance of 200 Ω |
| Bipolar Coag. | At a load resistance of 200 Ω |

The HF power output $P_{HF\ output}$ in Cutting mode as a function of the load for Effect 1 and Effect 2 each at a set power limitation P_{max} of 40 watts (ICC 80), 25 watts (ICC 50)

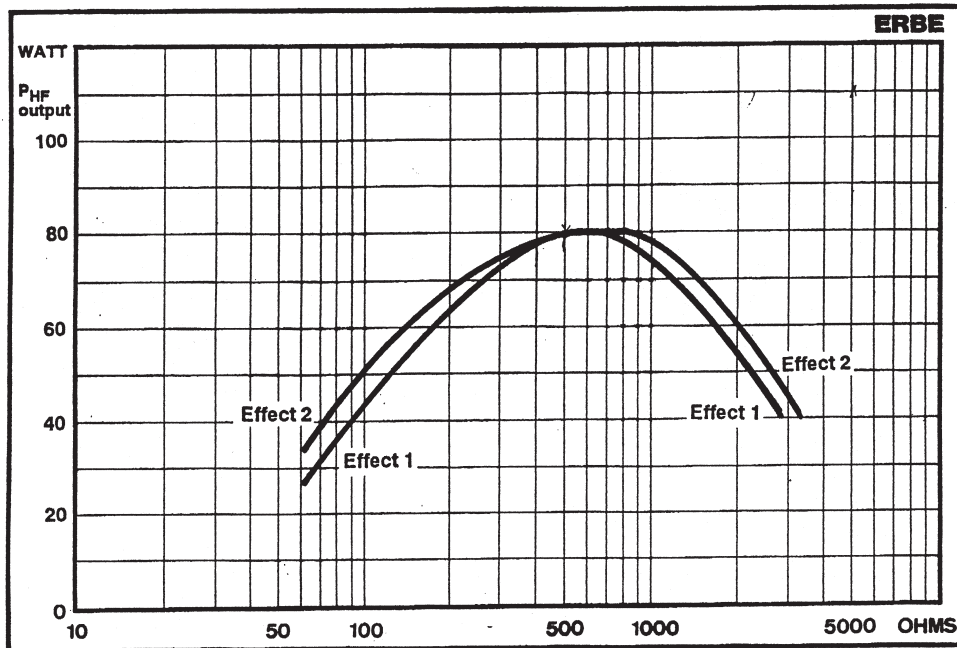


ICC 80

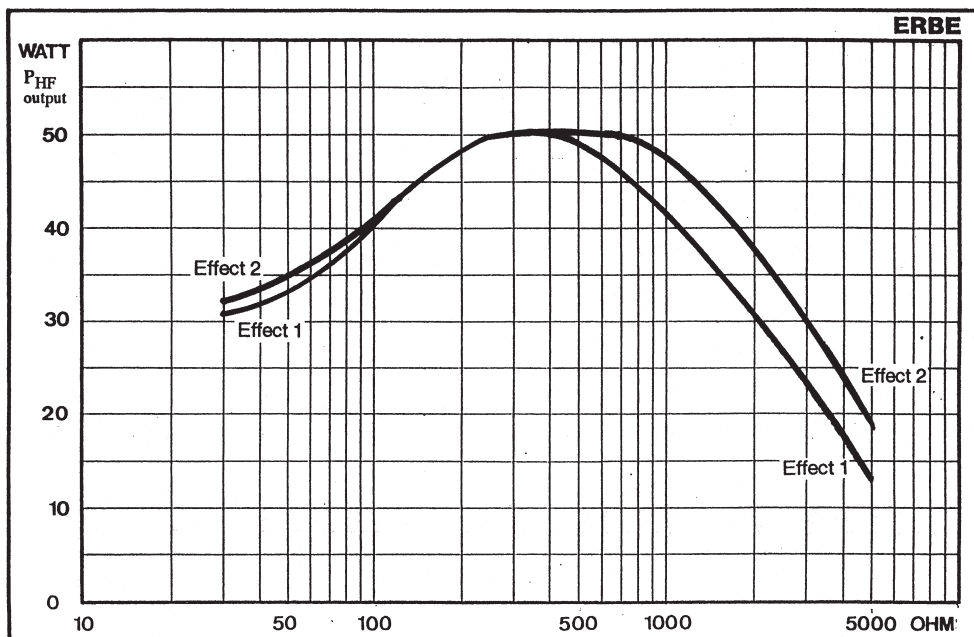


ICC 50

The HF power output $P_{HF\text{ output}}$ in Cutting mode as a function of the load for Effect 1 and Effect 2 each at a set power limitation P_{max} of 80 watts (ICC 80), 50 watts (ICC 50).

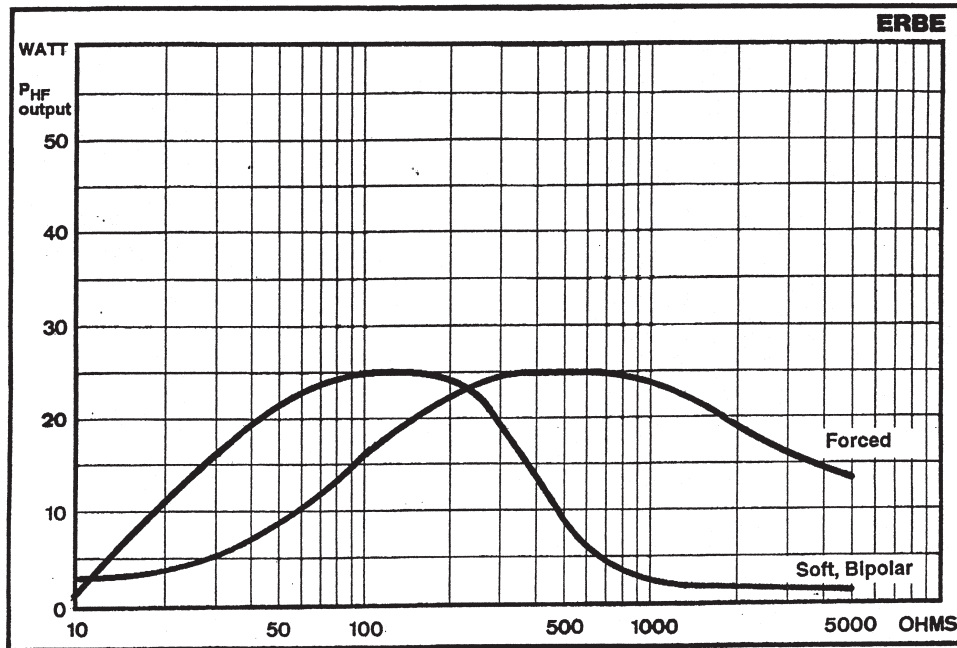


ICC 80

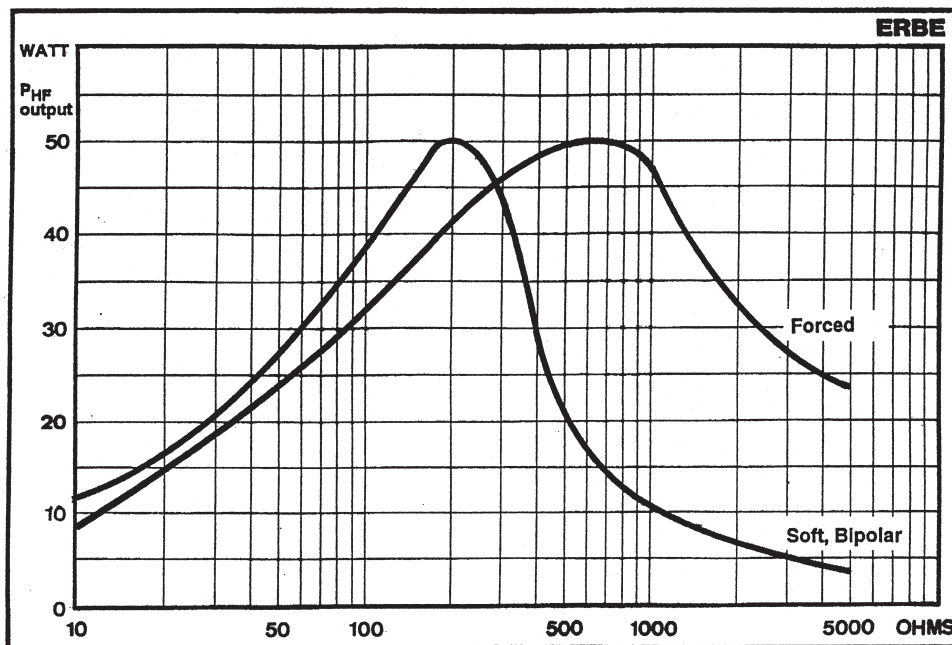


ICC 50

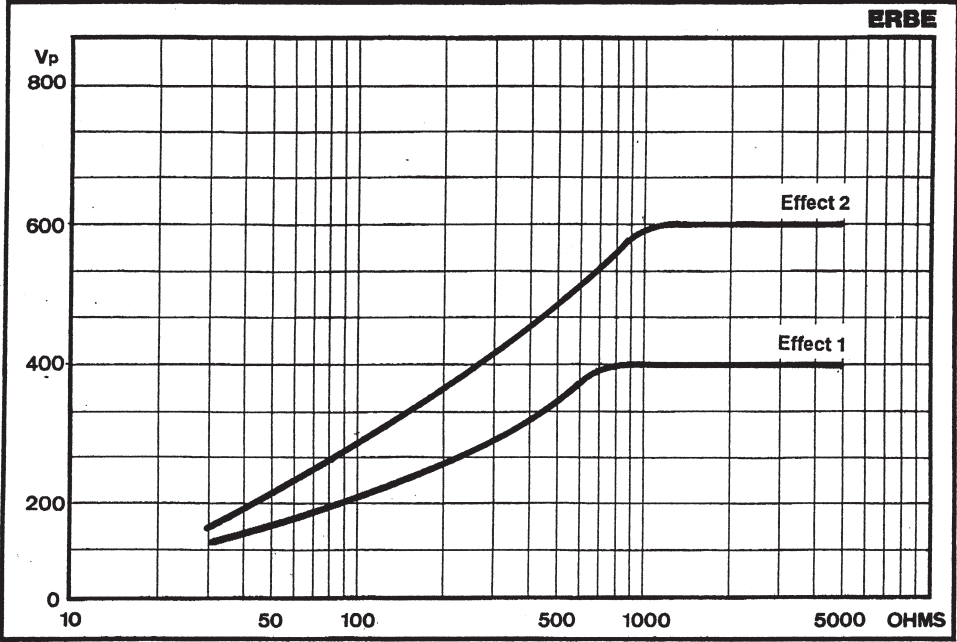
The HF power output $P_{HF\ output}$ in Forced, Soft and Bipolar mode as a function of the load, each at a set power limitation P_{max} of 25 watts.



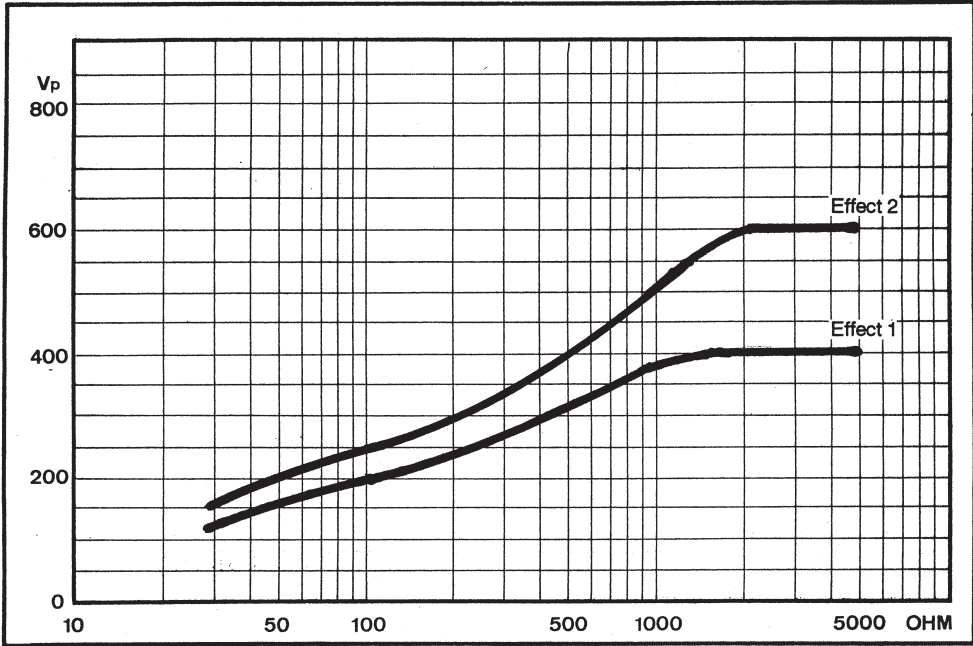
The HF power output $P_{HF\ output}$ in Forced, Soft and Bipolar mode as a function of the load, each at a set power limitation P_{max} of 50 watts.



The peak value V_p of HF output voltage in Cutting mode each for Effect 1 and Effect 2 and at a setting of the power limitation to 40 watts (ICC 80) and 25 watts (ICC 50) as a function of the load.

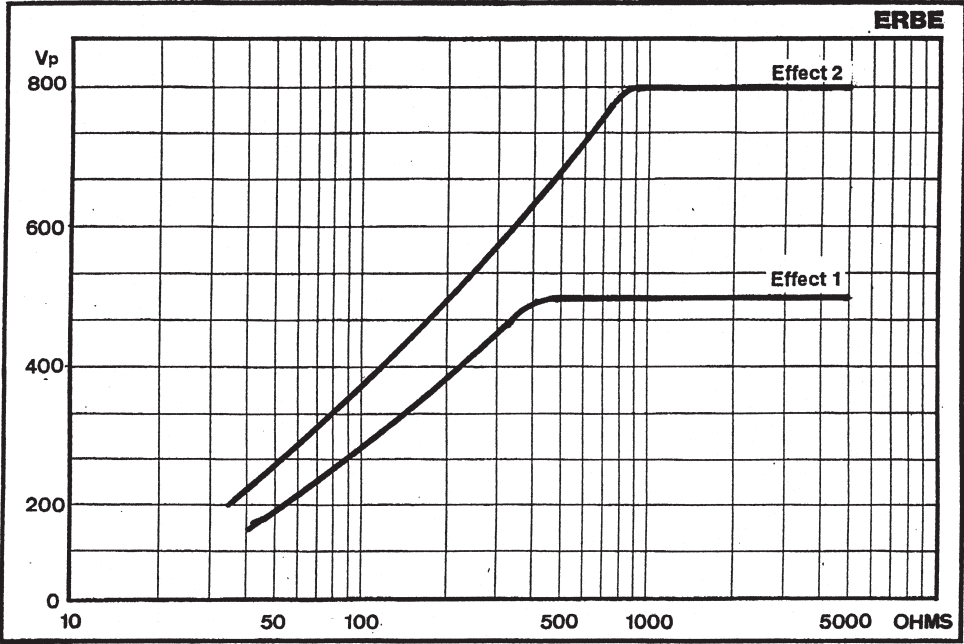


ICC 80

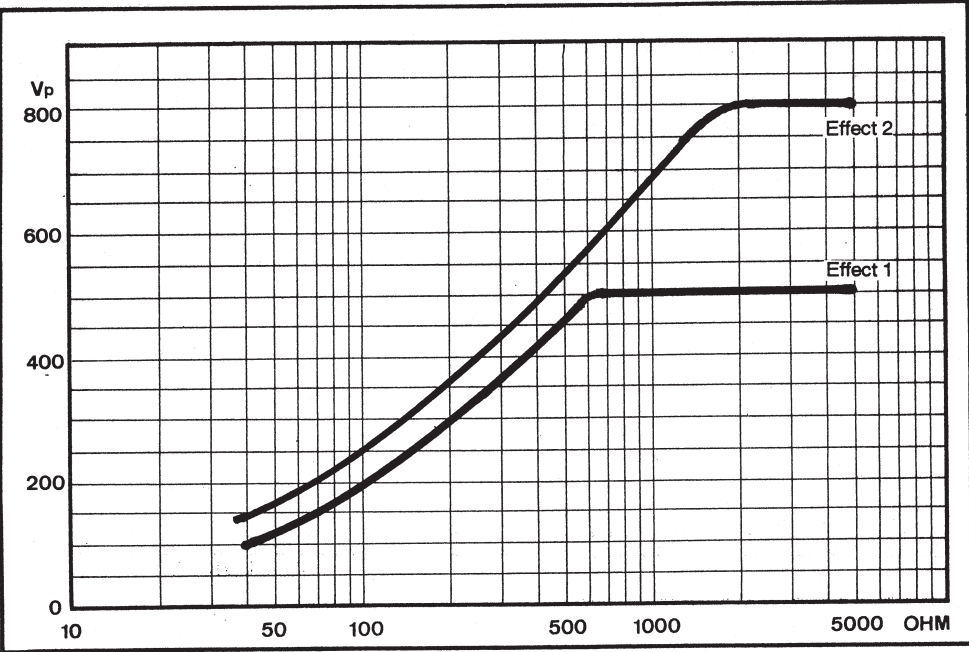


ICC 50

The peak value V_p of the HF output voltage in Cutting mode each for Effect 1 and Effect 2 and at a setting of the power limitation to 80 watts (ICC 80 and 50 watts (ICC 50) as a function of the load.

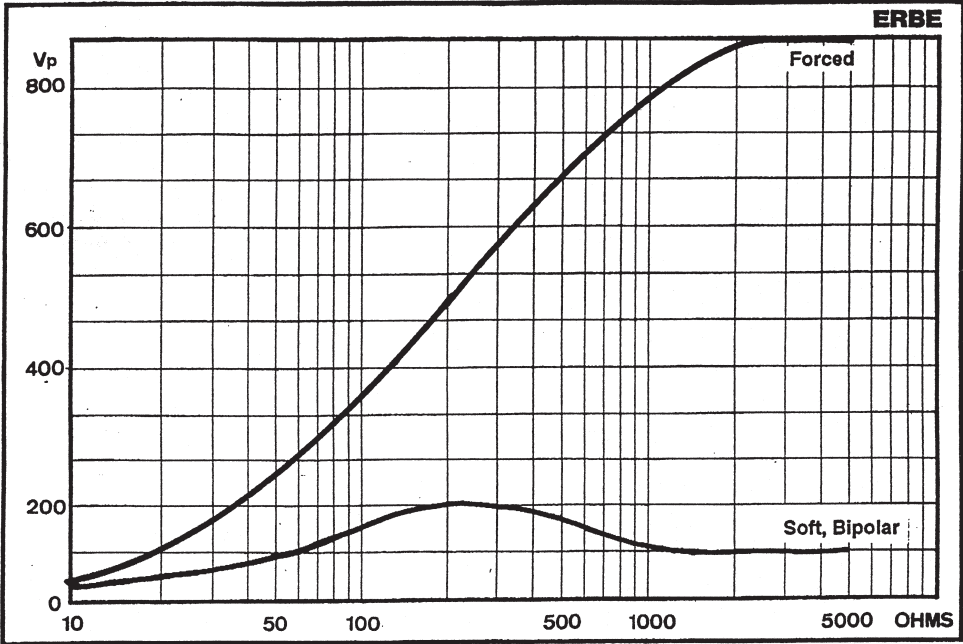


ICC 80

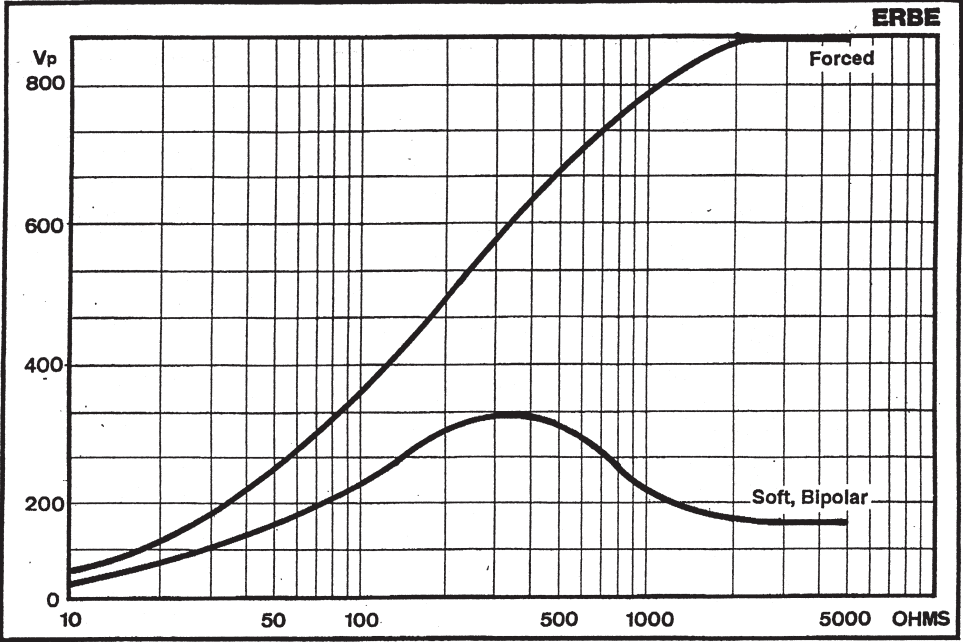


ICC 50

The peak value V_p of the HF output voltage in Soft, Bipolar and Forced coagulation mode, each at a setting of the power limitation to 25 watts as a function of the load.



The peak value V_p of the HF output voltage in Soft, Bipolar and Forced coagulation mode, each at a setting of the power limitation to 50 watts as a function of the load.



6 INSTALLATION

6.1 Spatial requirements

High-frequency surgery units must only be operated in medically used rooms. The spatial requirements, in regard to electric installation, affect e.g. the grounded conductor system, the ground fault interrupt system, as well as measures for preventing electrostatic charges.

The unit is used in rooms in which personnel can pick up electrostatic charges, for example in rooms with electrically nonconductive floors, thus touching the front panel of the units can lead to a brief illumination of light diodes or seven-segment displays due to discharge of an electrostatic charge. However, this occurrence does not change the settings on the front panel.

6.2 Set-up possibilities in the operating room

ICC model series units can be set up in principle on tables, consoles on ceiling suspensions or wall-mounted arms, as well as on special equipment carts.

6.3 Power connection

High-frequency surgical units must only be connected via the power cord provided by the unit manufacturer or one of equal quality equipped with the national test symbol to a correctly installed hospital grade power socket. Here, no outlet power socket or extension cord should be used if possible for reasons of safety. If their use is unavoidable, these must be equipped with a protective ground in perfect working order. The power outlet must be secured with a fuse with at least 10 A rated current.

6.4 Potential equalization

If necessary, the unit can be connected to the potential equalization of the room. This should prevent low-frequency electrode currents, e.g. low-frequency leakage currents in a defective protective ground system, from endangering the patient.

ICC model series units are equipped with a potential equalization connector on the unit back panel according to DIN 42 801. In this way, the units can be connected via a potential equalization line to a potential equalization terminal at the set-up location.

6.5 Explosion protection

High-frequency surgical units intentionally generate electric sparks between an active electrode and tissue. Electric sparks may also result within the unit. For this reason, high-frequency surgical units must not be used in areas where there is a danger of explosion. Considered as explosive is the area up to 20 cm above the floor and the area around and below the operating table, if flammable or explosive cleaning agents, disinfectants, anesthetics, etc. are used. High-frequency surgical units are normally installed outside the zone designated as potentially explosive.

WARNING 

Footswitches are used within the potentially explosive area nevertheless and must therefore be designed as explosion-protected.

6.6 Protection against moisture

ICC model series high-frequency surgical units are protected against the penetration of moisture in accordance with EN 60 601-2-2 . In spite of this, these units should not be set up in the vicinity of hoses or containers which contain liquids. Liquids should not be placed above or even on the unit. Only those footswitches may be used which are watertight in accordance with EN 60 601-2-2 Sec. 44.6 aa. Only those electrode handles with key switches must be used which conform to EN 60 601-2-2, Sec. 44.6 bb.

6.7 Cooling

ICC model series units must be set up in such a way that free air circulation around their housing is ensured. For that reason, set-up in confined corners, shelves etc. is not permissible.

6.8 HF interferences

High-frequency surgical units intentionally generate high-frequency voltages and currents. It must therefore be taken into consideration during set-up and operation that other electromedical equipment may be subjected to functional interference.

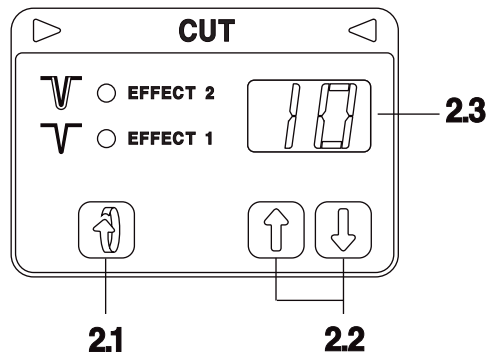
6.9 Receiving inspection

The unit should be checked immediately upon receipt for shipping damage and be subjected to a performance test. In case of damage due to shipping, this must be immediately reported to the shipping agent and a damage report must be filled out to secure the claim for damage compensation. This must include, in addition to the name and address of the recipient, the date of receipt, type and serial number of the unit supplied, as well as a description of the damages.

The unit's original packaging should be retained during the guarantee period so that the unit can be returned in the original packaging if this becomes necessary.

6.10 Programming the basic setting

The basic setting on the unit can be changed and programmed if necessary as follows:



1. Switch off the unit.
2. Press key 2.1 and switch on the power switch.
“Pr.” “1” appears on the displays = Test program 1.
3. Press key 2.1. This activates Test program 1. The most recently stored basic setting appears. If however no basic setting has yet been programmed by the user, “—” appears on the displays.
4. Set the required new basic settings.
5. By continuously pressing the key 2.1, the new basic setting can be stored in the unit. However, it is only then stored if, after approx. 2 seconds, a brief beep can be heard. This signals that the newly set basic setting has been stored in the unit. It appears automatically each time the unit is switched on.
6. After releasing key 2.1, “Pr.” “1” appears on the display.
7. To return to the normal operating mode, switch off the unit.

7 CLEANING AND DISINFECTION OF THE UNIT

7.1 Cleaning and disinfection of the unit

The unit housing should only be cleaned and disinfected with nonflammable and nonexplosive agents. Make certain here that no moisture penetrates into the unit.

We recommend a spray or wipe-down disinfection. However, the information from the disinfectant manufacturer absolutely must be observed here.

WARNING

If cleaning or disinfection of the unit with flammable or explosive agents unavoidable, this must be completely evaporated from the unit before switching on the unit.

Use no alcohol or disinfectant products with an alcohol base. The surface coating on the front plate may become detached.

8 PERFORMANCE CHECKS

Before every application, the user should check the functional efficiency of the unit and the accessories. The ICC is equipped for this with various automatic performance checks that, each time the power switch is switched on, are performed briefly and then signal and display recognized errors. However, not all possible errors are automatically detected and displayed.

8.1 Automatic performance test after switching on the unit

Each time the unit is switched on, it goes through an automatic performance check. If performance errors are detected here, these errors are signaled acoustically and an error number assigned to the respective error is displayed. The following performance errors of the unit and of accessories connected to the unit can be automatically recognized:

1. If a key on the front panel is depressed or shorted out due to an error once the power switch is switched on, this error is signaled acoustically after switching on the power switch and indicated by an error number.
2. If a key on the electrode handle is shorted out or bypassed at low resistance (e.g. due to moisture in the electrode handle) due to an error or depressed while the power switch is switched on, this error is signaled acoustically after the power switch is switched on and indicated by an error number.
3. If the contact of a footswitch is shorted out due to an error or if a pedal is stuck or a pedal is depressed while the power switch is switched on, this error is signaled acoustically and indicated by an error number.

8.2 Acoustic signal check

When activating a function field, the appropriate relevant acoustic signal must be heard. These signals can be checked as follows:

- Switch off the unit.
- Press key 2.1 and switch on the power switch. "Pr." "1" appears on the displays.
- Using key 3.5, Test program 5 can be selected.
- Press key 2.1 to activate Test program 5. "t.-" appears in the CUT display.
- The 4 various activation tones can be selected via the keys 2.2.
- By pressing key 3.1, the sound is set to maximum volume.
- Test program 5 can be interrupted by pressing key 2.1.
- Switch off the unit to return to normal operating mode.

8.3 Visual signal check

When activating a function field, the relevant visual signals must be illuminated. These signals can be checked as follows:

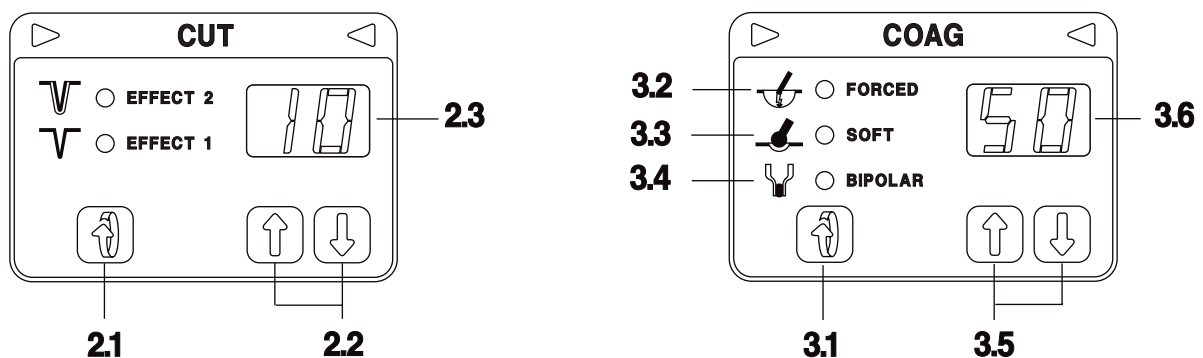
- Switch on the unit.
- Press key 2.1 and switch on the power switch. "Pr." "1" appears on the displays.
- By pressing key 3.5, Test program 4 is set.
- Press key 2.1. This activates Test program 4. All visual signals are illuminated.
- Test program 4 can be interrupted by pressing key 2.1.
- Switch off the unit to return to the normal operating mode.

8.4 Automatic error documentation

The various errors recognized by the error recognition system are assigned error numbers. If an error occurs, it is not only immediately signaled visually and acoustically, but also the corresponding error number is additionally stored in the unit where it then remains once the unit has been switched off. In this way, errors are automatically documented so that the causes of errors or malfunctions can be determined immediately after they occur or even later. 20 memory locations are available, so that up to 20 error numbers can be stored. The number of the most recent error is always stored in memory location 1 and all previously stored error numbers are shifted to the next higher memory location number. Once all memory locations are assigned, the oldest stored error number is automatically deleted from memory location 20 when a new error occurs. The number of the most recent error is stored in memory location 1. The error numbers in memory locations 1 to 20 can always be called up via Test program no. 2 as follows:

Calling up Test program 2:

Automatic error documentation



- Press key 2.1 when the unit is switched off and simultaneously switch on the power switch.
- “Pr.” = Program appears in CUT display 2.3.
- “1” = Test program 1 appears in COAG display 3.6.
- Select Test program 2 by pressing the ↑ key 3.5.
- Start the selected Test program 2 by pressing key 2.1.
- “1.” = Memory location number 1 appears in the CUT display 2.3.

The error number stored at memory location 1 appears in the COAG display 3.6.

Calling up the stored error numbers

- The memory locations 1 to 20 can be called up by pressing keys 2.2.

The error number stored at the respective number locations appears on the COAG display 3.6. If “—” appears in the COAG display, no error number is stored at the corresponding memory location.

- The cause of the error corresponding to each error number is given in the error list.
- Test program 2 can be concluded by briefly pressing key 2.1.

CAUTION Do not press key 2.1 too long, because this will delete all stored error numbers automatically.

Deleting stored error numbers

After evaluating the stored error numbers, it is practical to delete these error numbers. This prevents error numbers from being evaluated several times.

- Press key 2.1 long enough uninterruptedly until a beep is heard. At the same time, the previously displayed error numbers disappear on display 3.6.

Error list Erbotom ICC 80 / 50

ERROR no.	Error	How to proceed
1	Maximum time limit exceeded	Deactivate and restart the unit. CAUTION Monitoring of the activation time should prevent the unit from being activated too long in case of an error in the unit or in the accessories.
2	Neutral electrode not connected to unit, or when using dual-surface neutral electrode, the contact resistance between the two contact surfaces is too high	Check the connection of the neutral electrode to the unit and/or the application of the neutral electrode on the patient. If no error can be found, also check the cable to the neutral electrode for possible defects.
3	The unit was activated without acknowledging the front panel setting.	The unit can only be activated when the front panel has been completely set.
4	Cut mode was activated while the power limitation was set to "--".	The Cut mode can only then be activated if the power limitation is not set to "--".
5	Coag. mode was activated while the power limitation was set to "--".	The Coag mode can only then be activated if the power limitation is not set to "--".
6	The Coag. mode was activated by fingerswitch while the Coag. mode was set to Bipolar.	The Bipolar mode can only be activated by footswitch.
7	Several activation signals were present simultaneously.	This error can result for electrode handles with two keys if one diode within the electrode handle is defective.
8	Not used	
9	Not used	
10	Power supply voltage during self-check too high	This error can occur if the change from Coag. mode to Cut mode is made too quickly. If this error repeatedly appears, even after longer pauses between Coag. mode and Cut mode, notify the Technical Service.
11	Output error. Power supply current already too high before activating the HF generator.	Notify the Technical Service
12	Output error. Power supply voltage too low during activation.	Notify the Technical Service
13	Output error. Power supply voltage too high during activation.	Notify the Technical Service
14	Output error. Voltage in Cut mode more than 20% too high.	Notify the Technical Service
15	Output error. Voltage in Coag. mode more than 20% too high.	Notify the Technical Service
16	Output error. Voltage in Soft or Bipolar mode more than 20% too high.	Notify the Technical Service
17	Output error. Pulse duration of the HF voltage in Cut mode Effect 2 or in Forced mode beyond the permitted tolerance.	Notify the Technical Service
18	Output error. Modulation frequency in the Cut mode Effect 2 or in Forced mode beyond the permitted tolerance.	Notify the Technical Service
19	Not used	
20	As the power switch was switched on, the pedal for the Cut mode was already depressed.	Check whether there was an operator error or the pedal is defective.

21	As the power switch was switched on, the pedal for the Coag. mode was already depressed.	Check whether there was an operator error or the pedal is defective.
22	As the power switch was switched on, the fingerswitch for the Cut mode was already depressed.	Check whether there was an operator error or the fingerswitch is defective.
23	As the power switch was switched on, the fingerswitch for the Coag mode was already depressed.	Check whether there was an operator error or the fingerswitch is defective.
24	As the power switch was switched on, the ↑ key for the power limitation in Cut mode was already depressed.	Check whether there was an operator error or the key is defective.
25	As the power switch was switched on, the ↓ key for the power limitation in Cut mode was already depressed.	Check whether there was an operator error or the key is defective.
26	As the power switch was switched on, the Mode key setting the Coag. modes was already depressed.	Check whether there was an operator error or the key is defective.
27	As the powerswitch was switched on, the ↑ key for the power limitation in Coag. mode was already depressed.	Check whether there was an operator error or the key is defective.
28	As the power switch was switched on, the ↓ key for the power limitation in Coag. mode was already depressed.	Check whether there was an operator error or the key is defective.

CAUTION

This error list only contains error descriptions relevant to the operator.
An extended error list, which particularly describes technical errors, can be found in the technical service documentation.

9 SAFETY CHECKS

To prevent a reduction in safety for the unit due to age, wear etc., § 6 of the regulation concerning the installation, operation and use of active medical products (BetreibVaMP) prescribes regular safety checks. The operator must have the safety checks which have been established for this unit properly performed to the prescribed extent. The safety checks must only be done by the manufacturer or by persons expressly authorized by him.

The following safety checks have been established for the ICC :

- Inspection of inscriptions and instruction manual
- Visual inspection of the unit and accessories for damage
- Inspection for electrical safety according to EN 60 601-1.
 - a) Grounded conductor inspection
 - b) Leakage current inspection
- Performance test of all switches and control lamps on the unit
- Inspection of the monitoring devices
- Inspection of the automatic start mode
- Measurement of power output in the CUT operating mode.
- Measurement of power output in the COAGULATE operating mode.
- Measurement of the high-frequency capacities in the various operating modes
- The high-frequency surgical unit must undergo a safety check at least once a year.

The results of these safety checks must be entered in the medical product logbook.

If deficiencies are found during the safety checks, by which patients, employees or third parties could be endangered, the unit must not be operated until these deficiencies have been rectified by a professional technical service.

10 MAINTENANCE, CARE AND DISPOSAL OF THE UNIT

10.1 Maintenance of the unit including reusable accessories

Maintenance of the unit including the reusable accessories includes preventive and corrective measures for servicing. Therefore established, regularly performed safety checks (see Chapter 9) represent preventive measures, while changes and repairs can be summarized under the category of corrective maintenance. Through regular maintenance, the unit including the reusable accessories should be kept within the required status specified in the technical data, and operational readiness and safety are guaranteed for this until the next maintenance date.

10.1.1 Changes and repairs

Changes and repairs must not reduce the safety of the unit and its accessories for the patient, the user and the surroundings. This is considered fulfilled if structural and functional features have not been changed at the expense of safety (DIN 57 751-1/VDE 0751-1). Changes and repairs to the unit, in consideration of the special safety requirements for high-frequency surgical units, must only be performed by the manufacturer or by persons expressly authorized to do this by him. If unauthorized persons perform improper changes or repairs to the unit or accessories, the manufacturer assumes no liability. Additionally in this case, the guarantee claim becomes void.

10.2 Care of the unit

Effective protection of the unit from damage also includes, in addition to proper operation and maintenance, the safe set-up of the unit. This also includes, in addition to safe fixation of the unit to its base, its protection from moisture, contamination and contact with flammable or explosive substances. To ensure good radiation of unit heat resulting from operation, air circulation around the cooling fans and the heat sink must not be impeded.

10.3 Disposal of the unit

The unit can be disposed of at the end of its useful life as standard electronic scrap.

11 CONDITIONS OF GUARANTEE

11.1 Customer service

If you are interested in a service contract, please contact ERBE Elektromedizin or an authorized retailer. Do you have questions regarding high-frequency surgery, the ICC or on this instruction manual? Wish you like the latest scientific publications on high-frequency surgery? Please contact an ERBE employee or your local branch office. We would be glad to help you.

11.2 Conditions of guarantee

The unit and accessories must be immediately examined upon receipt for defects and shipping damage. Claims for damage compensation in this regard are only considered valid if the Seller or Shipping agent is immediately notified. A damage report must be filled out.

The term of guarantee for the ICC is 1 year, for accessory parts 6 months, calculated from the date of delivery. A claim of guarantee can only be made when the properly completed guarantee certificate is presented.

The scope of the guarantee encompasses no-cost repair of the unit, provided the damage was caused by a material or manufacturing error. Other claims, particularly claims of damage compensation, are excluded.

Repair must only be performed by ERBE, one of our representatives, or by an authorized retailer. The claim of guarantee becomes void if improper changes or repairs were made.

Through guarantee performances, the guarantee is neither extended nor renewed.

