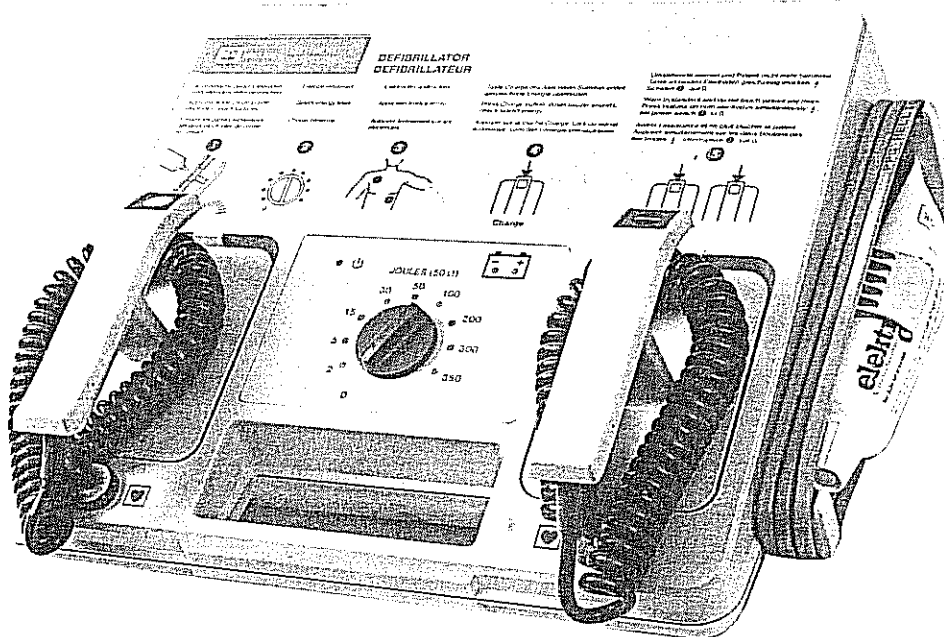


DEFIPOINT SCP 912



DEFIPOINT SCP 912

- * This manual is an integral part of the instrument and describes its normal use. It should always be kept close to the equipment. Observance of the manual is a prerequisite for proper instrument performance and correct operation and ensures patient and operator safety.
- * The symbol  denotes: **Observe the operating instructions!** It serves as an indicator for important facts to be noted when operating the instrument.
- * Information which refers only to certain versions of the instrument is accompanied by the catalog number(s) of the instrument(s) concerned. The catalog number is given on the instrument nameplate.
- * The instrument is not designed for operation in oxygen-enriched atmospheres and/or in zones of risk where explosion hazards may exist.
- * If the device is stored in a cool place and moisture appears on or inside the device after transport to a warmer environment in which it will be applied, the user is obliged to wait until all moisture has evaporated completely, before turning on the device.
- * The protective measures of class I are only effective, if such instruments are connected to power outlet sockets with protective earth contactors.
- * Cables and plugs which are damaged must be replaced immediately. Extension cords, in particular those with multiple connectors, should not be used.
- * Instruments into which liquids have penetrated must be immediately cleaned and checked by a qualified service technician.
- * Patient safety, specified measuring accuracy, and interference-free operation can be guaranteed only if original PPG HELLIGE devices are interconnected (e.g. basic units and plug-in modules) and if accessories are used which are listed in this operation manual or the use of which is expressly permitted by PPG HELLIGE (e.g. patient cables, electrodes, transducers, sensors).
- * Chemicals required for the application or maintenance of the instrument must under all circumstances be stored, prepared, and kept at hand in the containers provided by the manufacturer. Failure to observe this instruction may result in severe consequences for the patient.
- * PPG HELLIGE considers itself responsible for the effects on safety, reliability, and performance of the equipment, only
 - if assembly operations, extensions, readjustments, modifications, or repairs are carried out by PPG HELLIGE or by persons authorized by PPG HELLIGE.
 - if the instrument is used in accordance with the instructions for use.

The address of the nearest PPG HELLIGE sales-service office can be taken from the attached address list.

- * For detailed information on safety, please refer to the enclosed Safety sheet.
- * All publications are in conformity with the instrument specifications and IEC publications on safety of electromedical equipment valid at printing date. All rights are reserved for instruments, circuits, techniques, and names appearing in the manual.

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Displays and Operating Controls

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2.3 Important Information

2.4 Defibrillation

2.5 Battery Charging

2.6 Cleaning and Maintenance

3. Technical Data

4. Equipment

5. Appendix

Safety

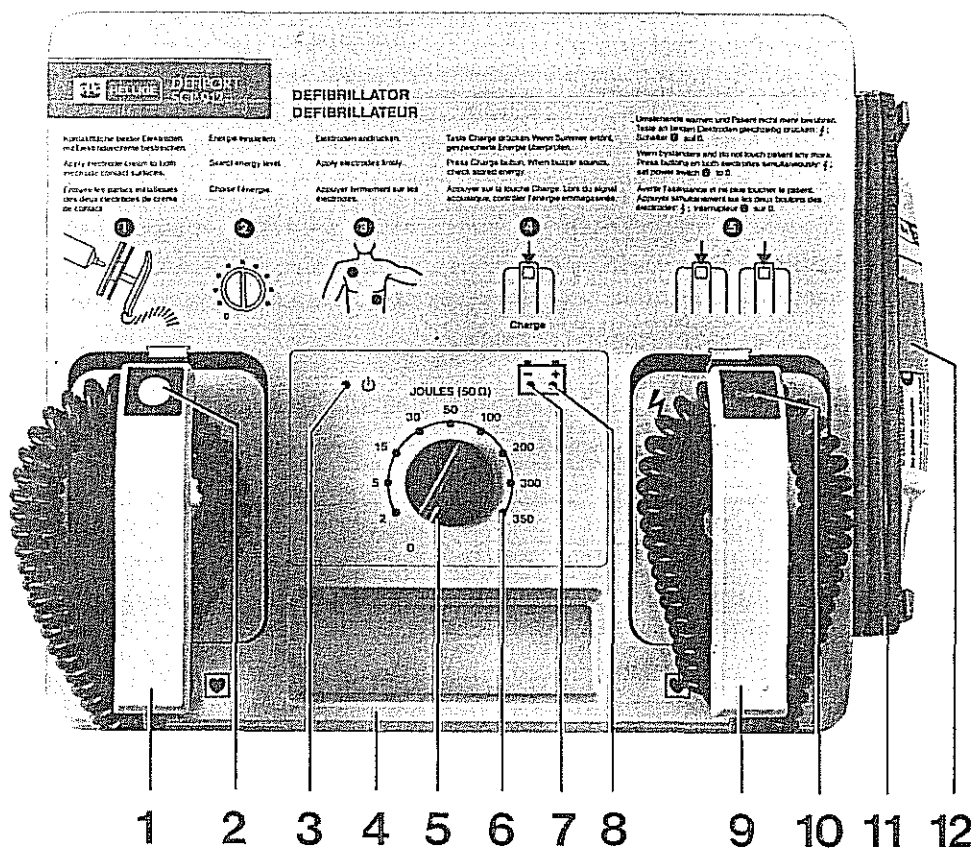


Figure 1 Displays and Operating Controls

- (1) Defibrillator electrode
- (2) Defibrillation pulse trigger button (button (9) must be pressed simultaneously)
- (3) Pilot lamp (green) lights up when the instrument is connected up to the mains power supply
- (4) Carrying handle
- (5) Energy selector switch
- (6) Pilot lamp (red) lights up when the required energy has been stored
- (7) Battery pilot lamp (red) lights up when the battery needs charging (only in instruments with built-in battery)
- (8) Pilot lamp (yellow) lights up as soon as the instrument is connected up to the mains power supply and the battery is being charged (only in instruments with built-in battery)
- (9) Defibrillation electrode
- (10) Energy storage initiation button
- (11) Power cord
- (12) Cream tube holder

Symbols used



Battery



Isolated patient connection type CF in accordance with IEC



Protective insulation, instrument of Protection Class II



Stand-by operation

For your notes

1. General Description

The defibrillator DEFIPORT SCP 912 is a portable cardiac therapy instrument for use in emergencies. Two versions of the instrument are available: one for line power only and one also fitted with a built-in rechargeable battery for use independent of line power.

As it is primarily for emergency application, it can only be used for nonsynchronized external defibrillation.

The energy to be delivered into a 50- Ω external resistance (patient resistance + skin-electrode resistance) can be adjusted in steps from 0 to 350 Joules (Ws). The energy storage process is indicated by the red pilot lamp lighting up. As soon as the set amount of energy has been stored, a beep indicates that the instrument is ready to deliver the defibrillation pulse. As a safety measure, both electrode handles have a pushbutton, which must be pressed simultaneously for the pulse to be triggered.

The current-discharge curve corresponds approximately to a sinusoidal halfwave with aperiodic decay. Figure 2 shows the discharge curves for several external resistances.

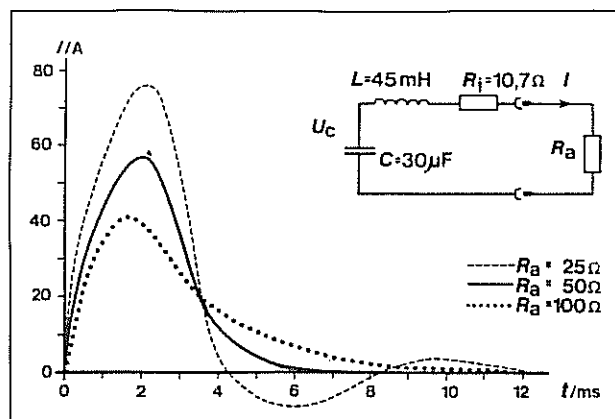


Figure 2

For instruments with a built-in battery a pilot lamp indicates that the battery requires recharging. Battery charging begins as soon as the instrument is connected up to a power line and the yellow pilot lamp lights up.

To ensure that the defibrillator is always in an operable condition we recommend you leave the instrument permanently connected to a power line or to recharge the battery at least once a month. With power line supply the instrument can be used even if the battery is totally depleted.

For your notes

2. Operation

Where the operating controls are marked with an ID number in parentheses, this ID number always refers to Figure 1 in Section 1.

2.1 Installation

- * Before using the instrument for the first time it is essential to refer to the information on safety and operation on the enclosed sheet entitled **Safety**.
- * Instruments which are intended for emergency application should not be exposed to low temperatures during storage and transport to avoid misting at the installation site. Otherwise the operator must wait until moisture has vaporized.
- * The instrument is in Protection Class II.
- * Defibrillator SCP 912 is an instrument equipped with an internal electrical current power source (only in versions of the instrument with built-in battery).
- * Before operating the instrument in zones of risk where explosion hazards may exist and/or oxygen-enriched atmospheres refer to the relevant information on the enclosed sheet entitled **Safety**.
- * Always set up the instrument so that the operator has a clear view of the front panel.
- * Plug power cord (11) into wall outlet. The yellow pilot lamp (8) lights up and the battery is charged (only in instruments with built-in battery). When not in operation, always leave the instrument connected to the power line to ensure the battery always remains charged.
- * When connected to the power line, instruments with a built-in battery are ready for operation even when the battery is totally depleted.
- * Carry out performance check (see Section 2.2.) at regular intervals (approx. once a month).

2.2 Performance Check

The performance check can only be carried out using the test lamp 301 495 00, available as an accessory.

- * Set energy selector switch (5) at 350 Joules.

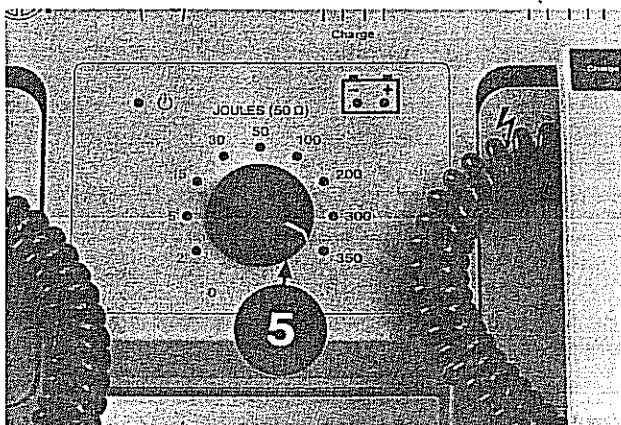


Figure 1

- * If the red pilot lamp lights up, the battery needs charging. (Depending on the state of charge of the battery, it may still be possible to perform the instrument test. If the battery is totally depleted (the instrument no longer indicates any functions), the instrument must be operated using the power line.)

Note:

The battery pilot lamp (7) only lights up during the energy storage process!

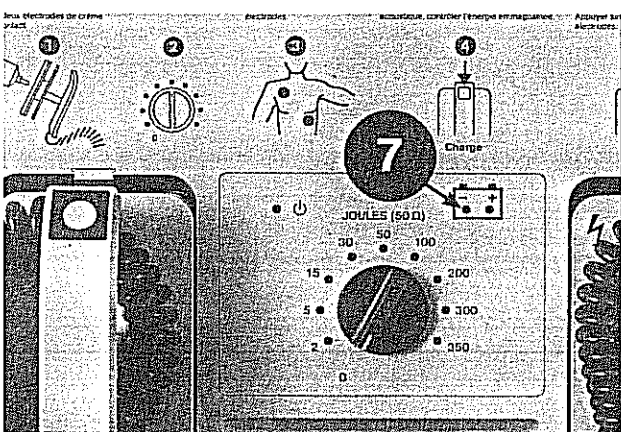


Figure 2

- * Remove the two electrodes from the holder (always tilt the electrodes towards you when taking them out or putting them back in (as shown in Figure 3) as there is an elastic latch only on the top end of the holder). Insert the test lamp T (Figure 4) between the contact surfaces C and press the electrodes against one another firmly.



Figure 3

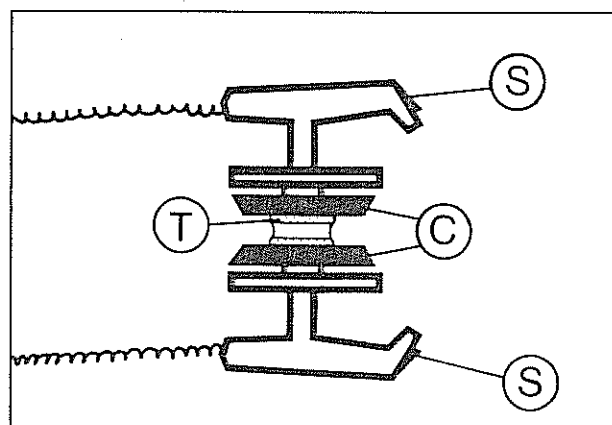


Figure 4

- * Start the energy storage process by pressing the **Charge** button (in the handle of the right-hand electrode). The red pilot lamps (6) light up one after the other as soon as the set amount of energy has been stored (Figure 5).

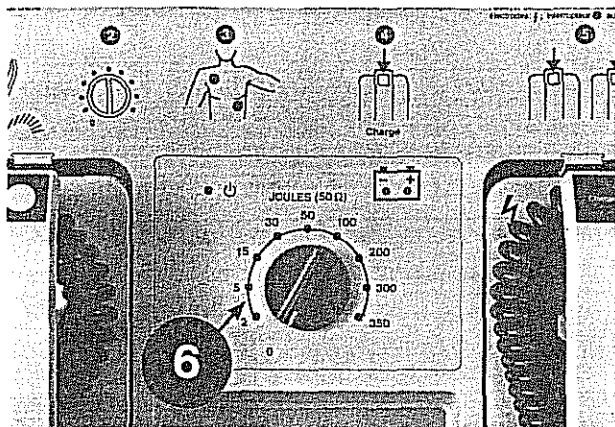


Figure 5

- * A buzzer sounds when the storage process is complete. Simultaneously, the pilot lamp (6) lights up at 350 Ws indicating that the set amount of energy has been stored. Trigger the defibrillation pulse within the next 16 s by pressing the two pressbuttons (2) and (10) in the electrode handles simultaneously: test lamp flashes (provided a defibrillation pulse has been delivered), buzzer stops, and red pilot lamp (6) is switched off.
- * For instruments with a built-in battery, if the battery capacity is no longer sufficient to store the adjusted amount of energy, the storage capacitor is discharged internally for safety reasons. In this case neither of the pilot lamps light up and the buzzer does not sound.

If after charging, the pilot lamp does not show the selected energy value, the instrument is impaired and must be checked.

The actual amount of energy delivered can only be determined by means of a special defibrillator testing instrument.

- * After completing the test, reset the energy selector switch to zero and return the electrodes - as shown in Figure 6 - to the holders provided.

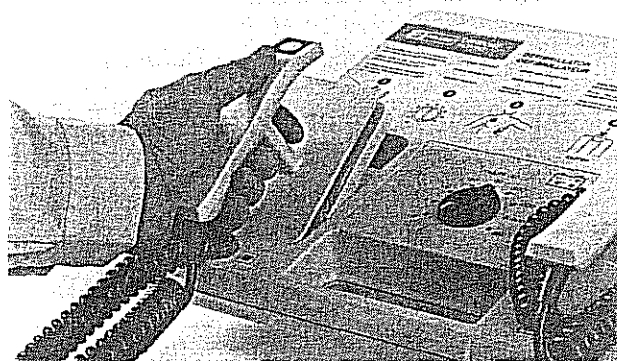


Figure 6

2.3 Important Information

The following points must be observed to ensure safe and successful application of the instrument.

- * Technical medical instruments such as the Defibrillator SCP 912 may only be used by persons who have sufficient knowledge and experience to ensure correct application.
- * Before applying the instrument the operator must check if it is in correct working order and operating condition.
- * The defibrillation electrodes must be clean and dry.
- * The person carrying out the defibrillation should have at least one assistant.
- * All assistants must be briefed regarding the preparations for and the execution of defibrillation.
- * All tasks must be assigned unambiguously.
- * Position the patient flat on a surface which is not too soft and make sure he is **electrically insulated**. The patient should not be allowed to come into contact with metal parts, e.g., bed or litter, in order to prevent shunts and current paths which endanger the assistants. For the same reasons the patient must not be placed on wet surfaces (rain, bathing accidents)
- * If possible have a pacemaker at hand.
- * Should cardiac arrest occur or be imminent during the preparations for defibrillation, administer heart massage and artificial respiration.
- * Do not allow the defibrillator electrodes to come into contact with other electrodes or metal parts which are in contact with the patient.
- * Disconnect any transducers or instruments from the patient which are not defibrillation-proof.
- * Immediately before pulse release interrupt heart massage and artificial respiration, disconnect tubes, and have assistants step back.
- * The patient's chest must be dry. Moisture causes shunts. Combustible skin cleaning agents must be completely dry for safety reasons.
- * Oxygenation in the vicinity of the defibrillation electrodes must be strictly avoided; if necessary, interrupt the oxygen supply.
- * In patients with an implanted pacemaker, defibrillation is likely to lead to the pacemaker becoming damaged or its function impaired. Therefore, the following should be observed:
 - Select the lowest possible defibrillation energy level for the intended application.
 - If possible, the defibrillation electrodes should not be applied in the vicinity of the pacemaker electrodes.
 - For this application, it is of the utmost importance to have an external pacemaker at hand.
 - After the defibrillation the working order of the implanted pacemaker should be checked.

2.4 Defibrillation

To ensure safe and successful application of the instrument it is essential to observe the information given in Section 2.3.

- * Take the electrodes out of their holders (only as indicated in Figure 7) and cover the contact surfaces with a thick layer of electrode cream.

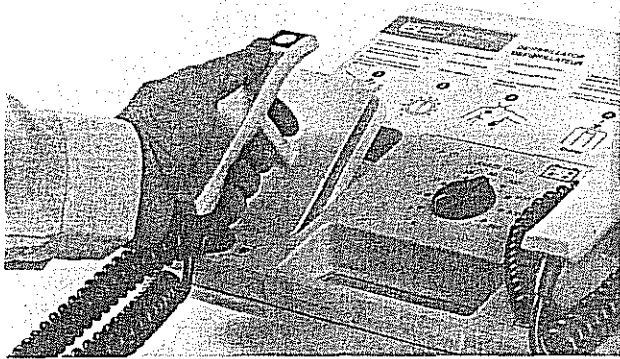


Figure 7

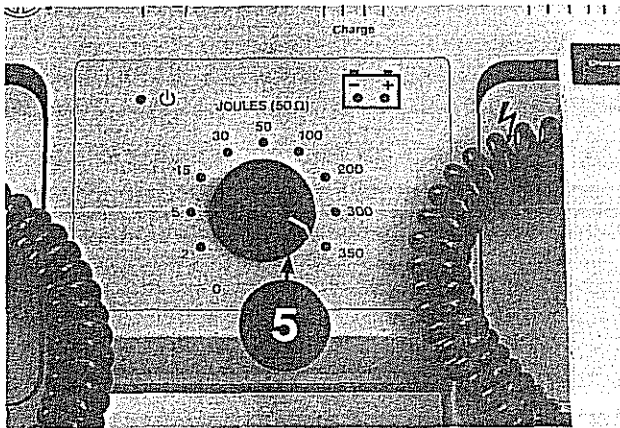


Figure 8

- * Set energy selector switch (5) to the required energy level.

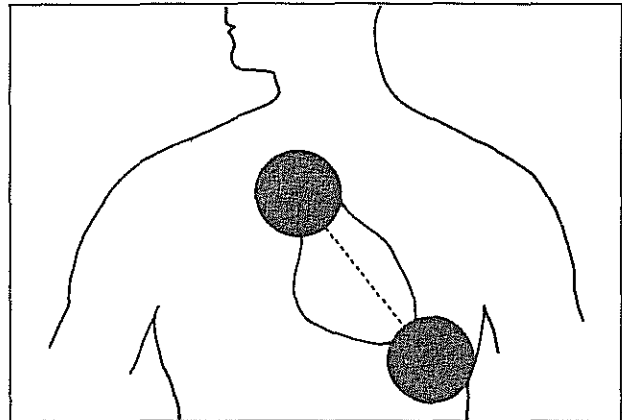


Figure 9

The energy level for defibrillation depends on the defibrillation method, the patient's age, and his constitution. The thickness of the tissue is also a factor which influences the amount of energy required for external application.

The amount of energy required for successful ventricular defibrillation without damaging the myocardium has been a matter of scientific controversy for many years. The manufacturer is, therefore, not able to make any recommendations.

According to IEC recommendations, the energy adjusted on this defibrillator is not the stored energy, but the energy released into an external resistance of 50 Ω (patient resistance + electrode-to-skin contact resistance). The energy selector switch is labelled accordingly.

- * Apply the electrodes so that the greater part of the pulse current passes through the myocardium (optimal connecting line between the centers of the two electrodes is over the cardiac median line; Figure 9)

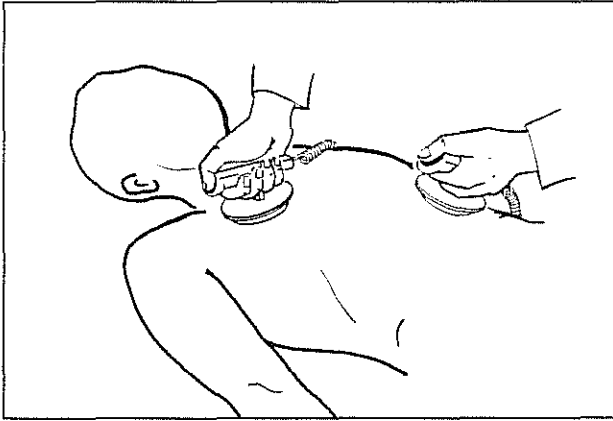


Figure 10

- * When triggering pulse press down the electrodes firmly onto the thorax (Figure 10).
- * Do not touch the patient any more and warn all those present.
- * Press **Charge** button (10) to initiate the energy storage process and ensure the red pilot lamps (6) light up one after the other until the adjusted amount of energy has been achieved (Figure 1). As soon as the buzzer sounds trigger the defibrillation pulse by pressing the two buttons in the electrode handles (trying to ensure this is performed at the end of an expiration).

If the pulse is not triggered within 16 s of the buzzer sounding, the storage capacitor is discharged internally for safety reasons. In this case the charging process must be repeated by pressing the **Charge** button (10) to be able to deliver a defibrillation pulse. If there is a break in the pulse circuit (electrodes not applied, lead or electrodes defective), the storage capacitor is discharged internally 125 ms after the defibrillation pulse has been triggered.

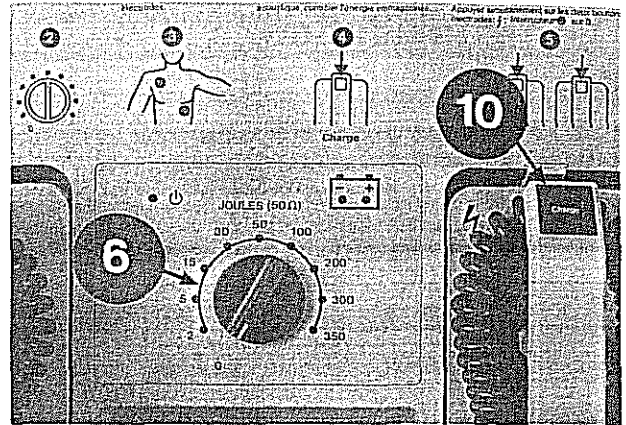


Figure 11

- * For instruments with a built-in battery, if the battery capacity is no longer sufficient to store the adjusted amount of energy, the storage capacitor is discharged for safety reasons. In this case neither of the pilot lamps light up and the buzzer does not sound. Continue to operate the instrument with a power line if at hand. It is sufficient to connect the power cord to a wall outlet.

If after charging, the pilot lamp does **not** show the selected energy value, the instrument is defective and must be checked.

- * Once therapy is ended, set energy selector switch to zero and clean electrodes and instrument as described in Section 2.6.

2.5 Battery Charging

(applies to instruments with built-in battery only)

Once a month the battery should be checked as described below:

When performing this test ensure the instrument is not connected to the power line!

- * Turn the energy selector switch (5) to 350 J and initiate storage process by pressing the **Charge** button (10). The red pilot lamp (7) must **not** be lit.

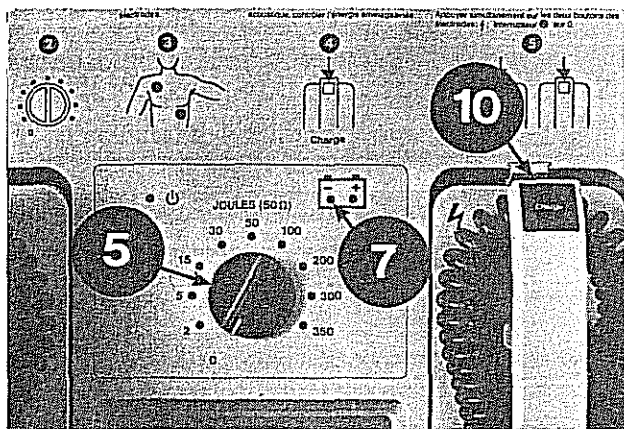


Figure 12

- * If the red battery pilot lamp lights up, the battery must be charged by plugging power cord into wall outlet. As soon as the yellow battery pilot lamp lights up, the battery is charged. After a charging period of approx. 8 to 9 hours, the battery is fully charged. Longer charging periods do not damage the battery.

In order to have the defibrillator always ready for use in an emergency, we recommend leaving the instrument connected to the power line or to charge the battery once a month.

Power supply for instrument version without battery

from the power line, instrument in Protection Class II according to IEC specification 601

Model for rated voltage 240 V

- * operating range 216 to 264 V, 49 to 65 Hz
- * rated current 0.46 A

Model for rated voltage 220 V

- * operating range 198 to 242 V, 49 to 65 Hz
- * rated current 0.5 A

Model for rated voltage 115 V

- * operating range 104 to 126 V, 49 to 65 Hz
- * rated current 0.97 A

Power supply for instrument version with built-in battery

from the power line as described above; from built-in nickel-cadmium accumulator:

- * rated voltage 18 V
- * rated capacity 500 mAh
- * service life 3 to 4 years or 800 to 1000 partial discharges or 150 complete discharges
- * charging time after complete discharge approx. 8 to 9 h, overcharge protection
- * battery charging via built-in power-supply unit also during operation with line power
- * number of possible defibrillation pulses with 350 J (into 50 Ω) approx. 25

Ready for operation

immediately

Operating position

any

Environment

Operation

under the following conditions regarded as normal:

- * temperature between 0 and 40 °C
- * relative humidity between 30 and 95 % (no condensation)
- * barometric pressure between 700 and 1060 mbar

Storage and transport

- * temperature between -30 and +60 °C
- * relative humidity between 20 and 95 %
- * barometric pressure between 500 and 1060 mbar

Dimensions

- * width 332 mm
- * height 130 mm
- * depth 300 mm

Weight

- * instrument version for line-power operation approx. 5.4 kg
- * instrument version for line- and battery-power operation incl. battery approx. 5.8 kg

4. Equipment

Subject to modification; please refer to latest list of accessories

101 088 01 DEFIPORT SCP 912
 for line-power operation

101 088 02 DEFIPORT SCP 912
 for line- and battery-power
 operation

Accessories

227 307 02 Operation Manual

217 083 01 Electrode cream (100 ml tube)

217 083 05 Electrode cream (package with
 10 tubes)

301 495 00 Test lamp

For your notes

General Information on the Safe Application of Electromedical Equipment

For the application of technical equipment the observance of various safety precautions is mandatory. The recommendations given in sections 1, 2 and 3 are based on IEC publications on the safety of electromedical equipment valid at date of printing.

A further prerequisite for the safe use of electromedical equipment is a staff of adequately trained personnel. It is the responsibility of the hospital administration to provide adequate instruction.

1. Electrical Safety

Protection Classes

To guarantee patient and operator safety, national and international committees have issued standards for the safety of medically used rooms and electromedical equipment. According to these standards, mains-operated equipment must be provided with an additional safety precaution for protection against electric shock mediated by contact with accessible metal parts in normal use besides a basic safety insulation of the live parts. For this purpose, IEC has defined so-called protection classes.

The protection classes for electromedical equipment are mainly Class I, for equipment on which a safety precaution with protective earth (ground) connector has been applied, and Class II, for equipment on which a safety precaution without protective earth (ground) connector has been applied.

In class I equipment, the metal enclosure is connected to the protective earth conductor in the fixed wiring of the installation via the earthing contact. Thus the accessible metal parts cannot become live in the event of a failure of the basic insulation.

Class II equipment has a double or reinforced insulation, since there are no provisions for protective earthing or particular requirements on installation conditions. A total breakdown of a double or reinforced insulation is not regarded as a single fault condition, and is assumed to be unlikely.

PPG HELIGE equipment belongs to one of these protection classes. The protection class is always indicated on the device's nameplate:

Please note: Battery-powered equipment and Class II equipment are not protectively earthed.

no symbol protection class I



protection class II

Isolated Patient

Modern concepts of electrical safety demand that the patient is in a floating, non-earthed (grounded) state during the application of electromedical equipment. The purpose of an isolation from earth (ground) is to prevent that the patient becomes part of a second, unintentional circuit via earth (ground) in case of a single-fault condition while connected to the equipment. For some groups of equipment, e.g. devices for evaluation of vital functions as well as devices which conduct an electrical current through the body, this type of insulation must be provided as a standard feature.

When the patient is connected to more than one device, remember that the leakage currents from all of these devices add up.

PPG HELIGE equipment for the evaluation of vital parameters (such as blood pressure, heart sound, temperature) as well as some equipment for evaluation of physiological action potentials (such as ECG or EEG signals) either has an isolated patient input (floating input) or it operates with an isolating transducer. If the equipment has a floating patient input, the entire input circuitry to which the patient is connected is isolated which means that it has no electrically conductive connections to other parts of the circuitry or to the enclosure. The signals are transmitted via isolating couplers, e.g. transformers or opto-couplers.

When using equipment with floating patient inputs, care must be taken that neither the patient nor any of the conductive parts connected to the patient (connectors, electrodes, transducers) come into contact with other grounded conductive parts, as this could bridge the patient's isolation and cancel the intended protective effect.

Electrically conductive contact with parts which have conductive connections to the heart (e.g. pressure transducers, tube connections and cocks made of metal, guide wires, electrode catheters and the metal parts of syringes) must be avoided in any event.

For this reason, the following guidelines should be observed:

- touch only with insulating rubber gloves

- keep parts with conductive connections to the heart isolated from ground
- attach pressure transducers which are not fully isolated isolated from ground
- do not use metal tube fittings or cocks.

The safe isolation of the patient and the specified accuracy can only be guaranteed if patient cables, electrodes, transducers, and probes mentioned in the user manuals are used.

Identification of Patient Connections

In accordance with IEC 601 (2) the patient connections on the equipment are labelled with graphic symbols which mark their classification.



Type CF equipment: equipment with highly isolated patient connections, for intracardiac application, connections not defibrillation-proof.



Type CF equipment as above, connections defibrillation-proof.



Type BF equipment: equipment with isolated patient connections, connections not defibrillation-proof.



Type BF equipment as above, connections defibrillation-proof.



Type B equipment: equipment with non-isolated patient connections, connections not defibrillator-proof.

Equipment and Operation Site

Class II equipment can be used in any room irrespective of the safety precautions taken in this room, unless applied in or near the heart. The same applies to battery-powered equipment.

The application of equipment in or near the heart, however, requires further safety precautions since leakage currents from electrical equipment can flow through the heart. During direct cardiac application, currents prove to be dangerous which otherwise do not present a hazard at all. Such currents cannot be avoided merely by the use of faultless equipment of type CF, an appropriate electrical installation is also required. Safety precautions in the environment of the patient must be equal to the isolation provided by an isolated F-type patient input, for instance.

Potential Equalization

As an additional measure for measurements in or near the heart equipment of Class I, which is per se connected to the room's potential equalization system via the protective-earth conductor of the power connector, must be connected to the potential-equalization system via a separate potential-equalization cable.

If the protective earth (ground) connector is interrupted this potential-equalization cable assumes the function of the protective earth (ground) conductor. Without potential equalization and with the protective earth (ground) connector interrupted, the earth leakage current which is permitted to amount to 500 μ A may flow through the electrically sensitive patient via the operator. All equipment of Class I has a connector for connection to the room's potential-equalization system via the potential-equalization cable.

In accordance with the types of connectors presently used, the following potential-equalization cables are available for delivery:

- 919 199 75 potential-equalization cable, plug-socket
- 919 199 37 potential-equalization cable, socket-socket

When, in examinations in or near the heart, the device is applied alone or in conjunction with other devices, an additional conductive connection must be established between the device and any one point of the potential equalization, e.g., the examination table.

Interconnection of Equipment

Interconnection of equipment is permitted only when the safety of the patient, the operator, and the environment will not be impaired. If the specifications do not contain any information as to the possibility of interconnecting equipment, the user is obliged to consult the manufacturer or an expert about the effects on the patient, the operator, and the environment, when two devices are coupled.

For the transmission of alarm signals to the hospital's nurse-call system, for instance, this requirement entails the insertion of an isolation relay (refer to section Equipment in the user manual).

When interconnecting two devices, also observe the information given in the IEC standard 601-1-1.

Operation during HF Surgery

Special care is to be taken when the cardiac action potential is picked up during HF surgery. Equipment for peroperative use is therefore supplied with patient cables with built-in protective resistors. These are an effective means for limiting HF currents flowing off via the ECG electrodes. In addition, the active surgical electrode should under all circumstances be applied at least 15 cm away from the nearest ECG electrode.

Utmost caution is advised when HF surgery is performed on pacemaker patients as the pacemaker may be damaged or its function be impaired. Furthermore fibrillation may be induced by interference caused by demodulation of the electrocautery current. The patient should be continuously monitored and a defibrillator be kept nearby.

Operation during Defibrillation

The patient cable mentioned above is also useful when defibrillation is required while ECG electrodes are applied to the patient. The protective resistors reduce the amount of current flowing off via the ECG electrodes.

Some equipment has devices protecting their input stages against over-voltages occurring during defibrillation. The patient-cable connections of such equipment are marked as defibrillation-proof by the relevant graphic symbol (see page 1).

If in doubt, it is best to disconnect the patient cable from the equipment during defibrillation in order to protect the patient and the equipment.

Particular care is to be taken when defibrillating pacemaker patients because defibrillation voltages are likely to damage the pacemaker or impair its function. Therefore, the following measures are recommended:

- The amount of energy selected for a specific application should be as small as possible.
- The defibrillation electrodes should not be applied near the pacemaker electrodes.
- An external pacemaker should be kept nearby.
- The pacemaker performance should be checked as soon as possible after defibrillation.

2. Environment

The equipment is designed for operation in an environment where no flammable anesthetics and/or flammable cleaning agents are present.

Furthermore, the equipment is of **limited applicability in oxygen-enriched atmospheres**. This atmosphere is considered to exist when the oxygen or nitrous-oxide content of the room air is above 24 %.

Limited applicability of equipment means that only those parts may be operated in an oxygen-enriched atmosphere which have no sparking components and which do not reach temperatures above 120 °C in normal condition (e.g. electrodes and electrode leads).

Another point in selecting the environment is the fact that electric or magnetic interference fields impede the measurement and recording of action potentials or, in extreme cases, prevent it completely. Therefore, the equipment should not be positioned near X-ray or diathermy equipment, near high-power motors or transformers. The vicinity of electrical cables carrying large currents (>100 A) should also be avoided.

If the accompanying documents do not read otherwise, the equipment is constructed according to IEC 601-1, section 5.3. This means that **the equipment must be specially protected against humidity, e.g. when it is applied outside the hospital**. Air vents must be left unobstructed to ensure free circulation of air for cooling the equipment. Furthermore the equipment is designed for operation under the following environmental conditions which, according to IEC 601-1, are regarded as normal, if the corresponding specifications do not read otherwise:

- temperature between +10 and 40 °C
- relative humidity between 30 and 75 %
- atmospheric pressure between 700 and 1060 hPa.

For storage of the equipment, the data given in the user manuals under specifications must be observed. In most cases an ambient storage temperature between -30 and +50 °C is admissible. However, note that equipment for emergency application should be stored in such a way as to enable immediate operation under the normal conditions as stated in the user manual.

3. Connecting Equipment to the Power Line

Before the equipment is connected to the power line, the user must ascertain that the voltage and the frequency indicated on the nameplate correspond to the voltage and frequency of the local power line.

The protective measures of class I are effective only if such equipment is connected to wall outlets with earthing (ground) contacts.

Do not use extension cords, especially not those with multiple connectors (stumbling hazard, interruption of protective ground conductor or power supply, loose contact).

Before use, check cables for signs of deterioration. Replace damaged cables and connectors immediately.

When disconnecting equipment from the power line, pull the plug out of the wall outlet first, then remove the power cord from the equipment.

If you do not observe this rule, you may come into contact with the line power when metal parts, such as the contact pins of electrodes, are introduced into the socket of the power cord.

4. Exchanging Plug-in and Insertion Modules

Plug-in and insertion modules are equipment components which can be exchanged without the use of tools. The user of electromedical equipment is permitted to exchange them.

Before exchanging modules, basic units of the SERVOMED series must be switched off to prevent functional disturbances. The basic unit may be switched on again after the knurled screws of the inserted plug-in have been tightened, i.e. all rear connectors have full contact.

Modules of the VICOM-sm system can be exchanged at any time, even while the SMU basic unit is turned on.

Modules which have been removed from their basic units should be stored in such a way that their electronic components will not be damaged and foreign bodies as well as humidity are prevented from ingress.

5. Cleaning and Disinfection

Before cleaning line-power operated equipment, remove the power cord from the power line. Furthermore the relevant information in the user manuals regarding appropriate cleaning and disinfection methods must be observed to prevent damage. If the cleaning and disinfection instructions do not read otherwise, electromedical equipment and its accessories are not suitable for autoclaving or hot-air sterilization.

Equipment into which liquids or foreign bodies have penetrated must be cleaned and checked by a specialist before they are used again.

6. Markings and Caution Labels

Markings and caution labels on the equipment are important for its safe and reliable use. They must not be removed.

7. Handling of Chemicals

Chemicals required for the application or maintenance of the equipment must under all circumstances be stored, prepared, and kept at hand in the containers provided by the manufacturer. Failure to observe this instruction may result in severe consequences for the patient.

8. The Alarm System

The alarm system of monitoring equipment must be checked for proper functioning at regular intervals. Nurse-call systems connected with the monitoring installation must be included in these performance checks. The test procedures are described in the user manuals of the monitors concerned.

9. Maintenance

In case of interference please observe the relevant section in the user manual. Furthermore, the engineers in the PPG HELLIGE sales-service offices will be pleased to advise the customer and help eliminate any problems.

Safe and reliable operation can be guaranteed only if the equipment is serviced at regular intervals. Equipment can be serviced by the sales-service personnel, possibly within the framework of a maintenance contract. Information on servicing can be obtained from the sales-service offices.

On request PPG HELLIGE will provide a detailed service manual.

10. Literature

- (1) IEC Publication 601-1: Safety of Medical Electrical Equipment (1988)
- (2) IEC Publication 513: Basic Aspects of the Safety Philosophy of Electrical Equipment Used in Medical Practice (1976)
- (3) WEINBERG, D.J.; ARTLEY, J.L.; WHALEN, R.E.; McINTOSH, H.D. and STARMER, C.F.: Electric Shock Hazards in Cardiology. I R E Trans. Bio-Medical Electronics B M E 9: 244 (1962).
BRUNER, J.M.R.: Hazards of Electrical Apparatus. Anesthesiology 28: 396 to 425 (1967).
ROY, O.Z. SCOTT, J.R. and PARK, G.C.: 60-Hz Ventricular Fibrillation and Pump Failure Thresholds Versus Electrode Area. IEE Transactions on Biomedical Engng. 1: 45 to 48 (1976).
ROY, O.Z.: Summary of cardiac fibrillation thresholds for 60 Hz currents and voltages applied directly to the heart. Med. and Biol. Eng. & Comput. 18: 657...659 (1980)

This publication is part of the user manual. It is based on the relevant safety standards valid at date of printing (April 1992).

What is your opinion?

Dear Customer,

The information in this user manual is meant to give you the best possible help in becoming familiar with this PPG HELLIGE product and to enable you to benefit from its full use.

Only you, however, know whether the manual serves its purpose in your everyday routine. Therefore, we would like to ask you to answer our questions on the postcard below. By knowing your opinion, we will be able to improve the user instructions in future.

We appreciate your assistance!

Ulrich Bichelkamp

PPG HELLIGE
Design Center



	true	in part	false
The manual structure is practice-oriented	☐	☐	☐
All required information is given	☐	☐	☐
All information is correct	☐	☐	☐
The number of illustrations is sufficient	☐	☐	☐
The illustrations are a great help	☐	☐	☐
The index is a great help	☐	☐	☐

Corrections/suggestions for improvement: _____

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