SERVOCARD

DC Defibrillator SC 820
SC 821

Operation Manual

HELLIGE

Contents

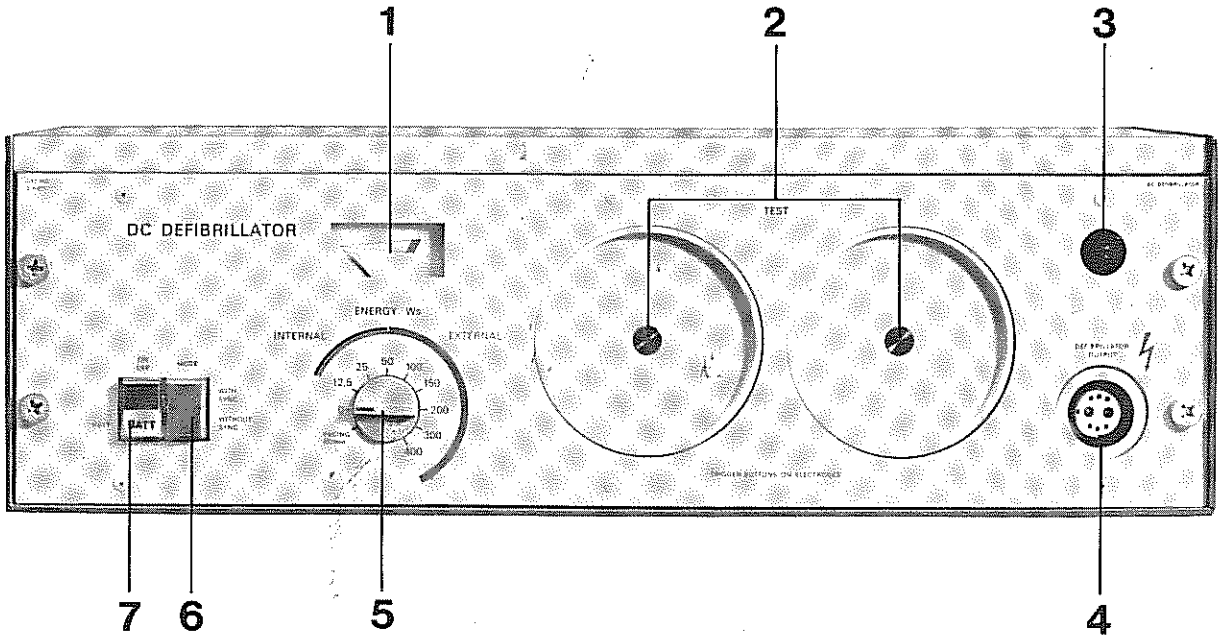

Fig. 1 Front panel

(1) Meter to indicate charge level of the storage capacitor

(2) TEST contact surfaces where electrodes are applied for performance check

(3) Flash lamp for performance check

(4) DEFIBRILLATOR OUTPUT socket for connection of the defibrillator electrodes

(5) ENERGY Ws switch to set the defibrillation energy and for mode selection EXTERNAL, INTERNAL, or PACING 60/min

(6) Illuminated MODE pushbutton to select the mode WITH SYNC or WITHOUT SYNC

(7) Illuminated ON OFF pushbutton to switch the instrument on and off (when the instrument is switched on, the WITHOUT SYNC mode is selected automatically)

In case of power failure, instrument version SC 821 is switched automatically to battery-power operation. This is indicated by illumination of pushbutton (7).

(8) SYNC INPUT socket to connect an ECG instrument for defibrillator synchronization

(9) Instrument fuses

(10) Receptacle for power cord (power-line connection)

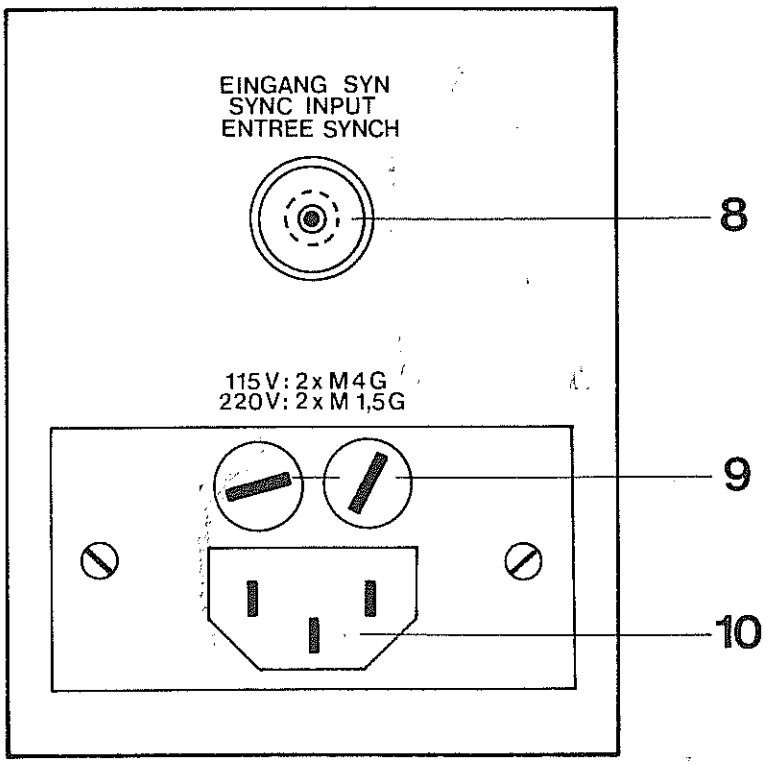

Fig. 2 Side connection panel

1 General Description

The DC Defibrillator SC 820/SC 821 is designed as an insertion module for basic units and models of the SERVOCARD system. The instrument version SC 821 is also equipped with a built-in rechargeable battery which supplies power immediately in case of a line-power failure. A charging circuit provides for the recharging of the battery when the instrument is connected to a line-power source.

Unsynchronized as well as synchronized defibrillation (cardioversion) is possible with the DC Defibrillator SC 820/821.

During DC defibrillation, the whole myocardium is briefly depolarized by a strong single-phase impulse of suitable amplitude. This eliminates any ectopic centers which cause atrial or ventricular fibrillation, for example. If the SA node is still intact, it can resume its pacemaker function. In the SERVOCARD system, the current impulse is generated by the discharge of a storage capacitor charged immediately before. The doctor himself releases the impulse using the trigger button on the one electrode.

The discharge circuit of the defibrillator contains an induction coil which gives the impulse a physiologically favourable shape. The discharge resistance which the patient represents for the defibrillation impulse is approximately 50 to 100 Ω. The current/time diagram for the defibrillation impulse remains unchanged as far as the above resistance range and the shape of the curve are concerned; only the amplitude is dependent on the resistance.

The energy level on the DC Defibrillator SC 820/SC 821 can be adjusted in 8 steps from 10 to 350 J. The energy values refer to the energy to be released into an external resistance of 50 Ω. The energy stored in the capacitor must be approx. 25 % higher due to the ohmic losses of the induction in the discharge circuit.

The discharge curve corresponds approximately to a sinusoidal halfwave with aperiodic decay. The impulse duration is approximately 5 ms, measured on the baseline from the start of the impulse to the intersection of the tangent to the trailing edge and the zero line with an external resistance of 50 Ω (Fig. 3).

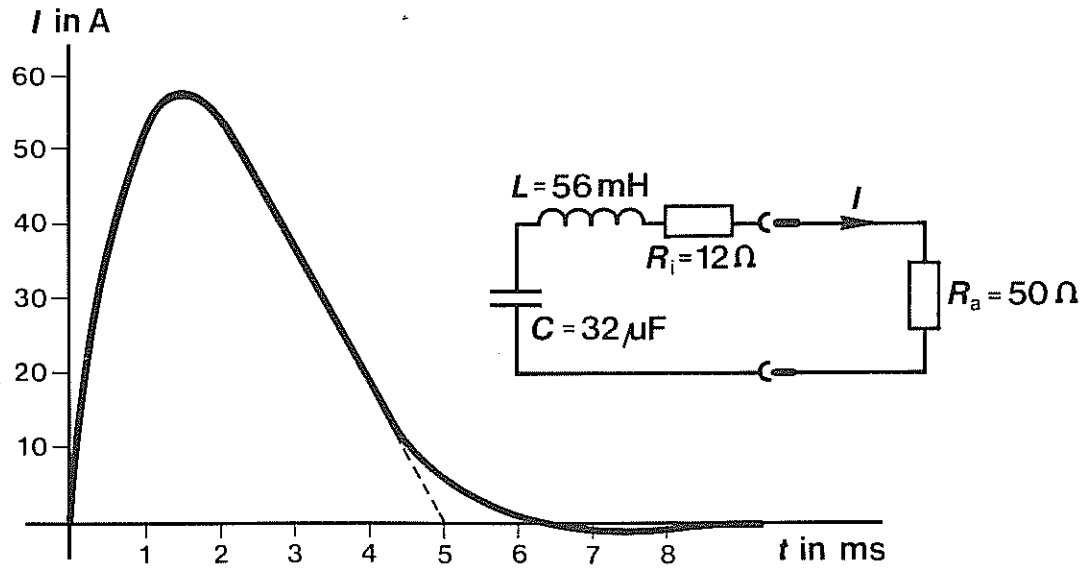

Fig. 3. Discharge curve at an external resistance of 50 Ω

There are two methods of defibrillation:

With *unsynchronized* defibrillation, the impulse can be delivered any time. This method is used to eliminate ventricular fibrillation and flutter.

With *synchronized* defibrillation, also known as cardioversion, the impulse delivery is synchronized with the patient's ECG. A trigger impulse is derived from the R-wave of the ECG (usually a suitable EINTHOVEN limb lead) which initiates the discharge of the storage capacitor approximately 20 ms after the R-peak. Thus, the capacitor discharge is prevented from coinciding with the vulnerable phase of the cardiac cycle which could cause ventricular fibrillation.

In case of disordered action of the heart, the vulnerable phase is not always present. During ventricular fibrillation or flutter it is not present. Therefore, a synchronized discharge is not required and the impulse can be released any time.

No one is allowed to touch the patient during impulse delivery. According to the regulations on handling high voltages, the operator must inform all others in the room that the impulse is about to be released.

2 Operation

The numbers in parentheses refer to the operating controls and individual elements shown in Fig. 1 and 2 (fold-out page, left).

2.1 Installation

Do not fail to observe the instructions and important information on patient and operator safety given on the *Installation* sheet in the Appendix before using the instrument. Always ensure that the front panel of the Defibrillator is in the operator's field of vision.

Special note for SC 821:

This instrument can be operated with power from the built-in rechargeable batteries, as well as with line power. In case of line-power failure, the instrument switches automatically from line to battery power.

2.2 Performance Check

A performance check should be carried out approx. once a month.

- Insert the electrode for external defibrillation with anterior-anterior electrodes into DEFIBRILLATOR OUTPUT socket (4) and lock
- Set ENERGY switch (5) to an energy stage between 10 and 350 J

  It is advisable not to select too high an energy stage, in order to prevent burning of the contact surfaces should the pressure on the electrodes be too low.
- Switch instrument on using pushbutton (7): green half of pushbutton (6) lights up (WITHOUT SYNC)

  If the red half of the button lights up, indicating the WITH SYNC mode, switch to the WITHOUT SYNC mode by pressing pushbutton (6).
- Press electrodes firmly onto the TEST contact surfaces (2)
- Depress the white start button on the one electrode: charging begins (the pointer in meter (1) deflects)
- After the red trigger button on the other electrode lights up, it must be depressed within 10 s: the discharge is indicated by a flash of pilot lamp (3)

  The instrument should be checked regularly by our sales-service technicians to ensure that its reliability is not impaired, especially in regard to the insulation of voltage-conducting components. Use the separate test lamp instead of the incorporated testing device when applying anterior-posterior or paddle electrodes.

2.3 Electrode Application

Various electrodes are available for internal and external defibrillation. For application of these electrodes in various cases, refer to our application note on *Cardiac Electrotherapy.*

The application of the anterior-anterior electrodes is described below, since this information is very important for emergency therapy.

- Cover the contact surfaces of the electrodes with an ample amount of electrode cream

  The nozzle of the tube can be removed to enable the electrode cream to be squeezed out more rapidly (Fig. 4).

  If there is the possibility that manual cardiac massage must be carried out after defibrillation, it is not advisable to use electrode cream, since the operator's hands would slip from the patient's chest. In these cases, it has proved to be advantageous to place linen cloths soaked in a saline solution between the skin and the electrodes (Fig. 5).

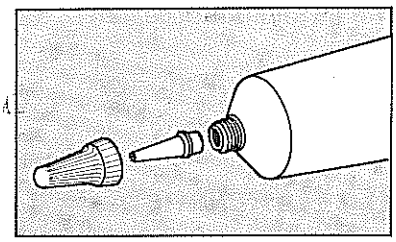

Fig. 4

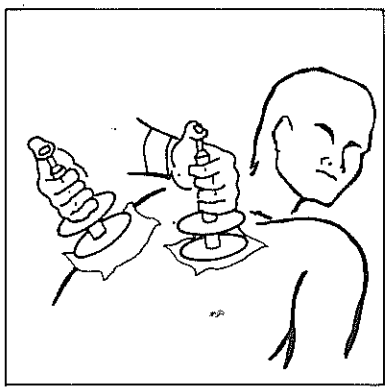

Fig. 5

- Apply the electrodes (Fig. 5) in such a way that as much of the impulse current as possible flows through the myocardium (the imaginary connecting line between the midpoints of the two electrodes should lie over the center of the heart)

- During impulse delivery press the electrodes firmly onto the thorax

  The electrode handles must always be clean and dry, otherwise the operator may be exposed to electrical hazard.

  Defibrillator electrodes must not come into contact with other electrodes or with metal parts which in turn are in contact with the patient. If a pressure transducer has been applied which is not defibrillation-proof, it must be electrically separated from the pressure measuring instrument (pull out the plug).

2.4 Nonsynchronized Defibrillation

- Lay the patient on a surface which is not too soft so that he is an a supine position and electrically isolated

  The patient should not come into contact with metal parts, e.g. the bed frame or litter, to avoid undesired paths for the defibrillation current.

- Prepare the patient and the electrodes as described in the previous section or in the application note·
- Switch ENERGY switch (5) to 0
- Switch the instrument on using pushbutton (7); the green half of pushbutton (6) lights up

  When the instrument it turned on, it automatically switches to the WITHOUT SYNC (non-synchronized) mode, regardless of which mode it was switched to before.
- Connect the electrode lead for internal or external defibrillation to DEFIBRILLATOR OUTPUT socket (4) (must lock)
- Using ENERGY switch (5), set the necessary energy level

  The energy level for defibrillation depends on the mode of application, age, and constitution of the patient. The thickness of the tissue is also a factor which influences the amount of energy required for external application. According to IEC recommendations, the energy adjusted on this defibrillator is not the stored energy, but the energy to be released into an external resistance of 50 Ω (patient resistance + electrode-to-skin contact restistance). The ENERGY selector switch (5) is labelled accordingly.

  The relation between the energy to be released into 50 Ω and the energy stored in the capacitor is shown in the following table:

Energy in J 1 J (Joule) = 1 Ws (Watt-second)

released into 50 Ω	10	20	40	80	120	160	240	350
stored	12.5	25	50	100	150	200	300	435

The storage capacitor is automatically discharged, if the ENERGY selector switch (5) is set to 80 J or more while the electrode lead for internal defibrillation is connected. Thus, internal defibrillation can never be carried out with more than 40 J.

- Apply the electrodes (see previous section and our application note on *Cardiac Electrotherapy*), press anterior electrodes down firmly
- Do not touch the patient any more; warn all those present
- When using anterior-anterior electrodes, depress the white start button on the one electrode: capacitor charging begins, the pointer in the meter (1) indicates the rising energy
- The red trigger button on the other electrode lights up — depress within 10 seconds: the defibrillation impulse is released immediately and a buzzer sounds

  If the red trigger button is not activated within 10 seconds of its lighting up, the storage capacitor is discharged internally (safety discharge). The white start button must then be depressed again to recharge the capacitor. If there is a break in the impulse circuit (electrodes not applied, connector not locked, defective lead, or electrodes, etc.), the storage capacitor is discharged (safety discharge) 200 ms after depression of the red trigger button. With the other sets of electrodes, a trigger button is provided on only one of the electrodes. Once this button has been depressed, storage-capacitor charging begins. If the button is held depressed, the impulse is delivered as soon as charging is completed. The button can also be depressed briefly and then depressed again for impulse delivery within 10 seconds of the red lamp lighting up.
- Once therapy is ended, turn the energy selector switch (5) to 0 and switch the instrument off using pushbutton (7), *clean* the electrodes and *sterilize* the internal electrodes (see relevant section)

2.5 Synchronized Defibrillation (Cardioversion)

- Lay the patient on a surface which is not too soft so that he is in a supine position and electrically isolated

  The patient should not come into contact with metal parts, e.g. the bed frame or litter, to avoid undesired paths for the defibrillation current.

- Prepare the patient and the electrodes as described in the previous section or in the application note

- Apply the ECG electrodes (EINTHOVEN limb lead), connect the patient cable to the ECG ELECTRODES connector (8) of the Therapy or Heart-rate Monitor, and adjust the instrument as described in the corresponding operation manual

  For detection of cardiac-action potentials, refer to our application note on *Electrocardiography* and relevant literature on the subject. Silver-silver-chloride electrodes must be used without fail, otherwise an excessive polarization potential after defibrillation could, in certain cases, simulate cardiac arrest on a cardioscope or recorder.

- Switch ENERGY switch (5) to 0

- Switch the instruments on using pushbutton (7): the green half of pushbutton (6) lights up

  When the instrument is turned on, it automatically switches to the WITHOUT SYNC (non-synchronized) mode, regardless of which mode it was switched to before.

- Switch to the WITH SYNC mode using pushbutton (6): the red upper half of the button lights dimly, and with each incoming synchronizing impulse it briefly gives a brighter light

- Connect the electrode lead to DEFIBRILLATOR OUTPUT socket (4) (must lock)

- Using ENERGY switch (5) set the necessary energy level (see section 2.4)

- Apply the electrodes (see section 2.3 and our application note on *Cardiac Electrotherapy*), press anterior electrodes down firmly

- Do not touch the patient any more; warn all those present

- When using anterior-anterior electrodes, depress the white start button on the one electrode: capacitor charging begins, the pointer in meter (1) indicates the rising energy

- The red trigger button on the other electrode lights up — depress within 10 seconds: the defibrillation impulse is released by the next R-wave from the patient; the buzzer sounds

  A negative spike in the ECG waveform on the screen of a connected Memoscope indicated the point at which triggering takes place.

  If the red trigger button is not activated within 10 seconds of its lighting up, the storage capacitor is discharged internally (safety discharge). The white start button must then be depressed again to recharge the capacitor. If there is a break in the impulse circuit (electrodes not applied, connector not locked, defective lead, or electrodes, etc.), the storage capacitor is discharged (safety discharge) 200 ms after depression of the red trigger button.

  With the other sets of electrodes, a trigger button is provided on only one of the electrodes. When this button is depressed, the storage capacitor begins charging. If the button is held depressed, the impulse is released by the first R-wave from the patient after charging is terminated. The button can also be depressed briefly and then depressed again within 10 seconds of its lighting up. The impulse is then released by the next R-wave from the patient. With cardioversion the normal sinus rhythm is ideally resumed immediately after defibrillation (immediate reduction). In some cases it does not appear until a few minutes later (interval reduction). If the arrhythmia persists, a second impulse will generally restore the full sinus rhythm. In the majority of cases, the optimum result is expected two to three weeks after defibrillation.

- Once therapy is ended, turn the energy selector switch (5) to 0 and switch the instrument off using pushbutton (7), *clean* the electrodes and *sterilize* the internal electrodes.

2.6 Pacing via the Defibrillator Electrodes

It is sometimes necessary to stimulate the cardiac action after defibrillation by external and periodic application of current impulses. This is the case, for example, when defibrillation does not lead to the spontaneous resumption of the sinus rhythm, but causes complete cardiac arrest. In such situations it is possible to provide external stimulation with a fixed frequency and amplitude via the defibrillator electrodes of DC Defibrillator SC 820/SC 821.

The success of such a measure depends on the condition of the patient's heart and his constitution and is not always guaranteed.

- Switch the instrument on using pushbutton (7) and turn switch (5) to PACING
- Prepare the patient as described in section 2.3
- Connect the anterior-anterior-electrode lead for external defibrillation to socket (4) and lock
- Press the electrodes firmly onto the thorax (Fig. 4, section 2.3)
- Do not touch the patient any more; warn all those present
- Depress the buttons on both of the electrodes and keep them depressed: stimulation proceeds with a constant voltage and at a rate of 60 impulses/min; a buzzer sounds with every impulse
- Once therapy is ended, turn energy selector switch (5) to 0 and switch the instrument off using pushbutton (7) and clean the electrodes (see section 2.7)

2.7 Cleaning and Sterilizing the Electrodes

As a safety measure, disconnect the plug of the electrode lead from the instrument before handling the contact surfaces of the electrodes.

After use, the electrodes (not the leads!) can be cleaned with soap and warm water. Cleaning solutions such as TERGICIDE are permissible. *The pushbuttons should not be allowed to get wet!*

The internal defibrillator electrodes and leads can be sterilized using the ethylene oxide method. Sterilization with steam is not admissible since electrical creepage distances can be caused by residual moisture. The contact inserts can be removed and sterilized using any method. Make sure that the electrodes are absolutely dry before being used again. Damp electrodes are hazardous for the operator. The leads of the external electrodes should not be sterilized with the electrodes, as this would cause the insulating material to crack.

3 Specifications

Modes

defibrillation without synchronization:

moment of impulse delivery is independent of patient's cardiac action potential

defibrillation with synchronization:

moment of impulse delivery is dependent on patient's cardiac action potential

pacing via defibrillator electrodes:

free-running pacing impulses at constant rate and amplitude

Defibrillation

capacitor discharge via inductivity (damped serial oscillating circuit), impulse shape corresponds approx. to a sinusoidal halwave with aperiodic decay

energy selectable:

Stored energy	Energy released into an external resistance of 50 Ω
12.5 J	10 J
25 J	20 J
50 J	40 J
100 J	80 J
150 J	120 J
200 J	160 J
300 J	240 J
435 J	350 J

possible deviation from rated energy values within + 2.5 % and −15 %;
impulse duration with 50-Ω load resistance approx. 5 ms, measured from impulse start to the intersection of the zero line and the inflectional tangent to the trailing edge of the impulse;
charging time of storage capacitor 1 to 6 s (3 to 11 s for SC 821 in battery operation), dependent on selected energy level;
internal safety discharge approx. 10 s after charging in case of *non-release* and approx. 0.2 s *after impulse release* in case of interrupted discharge circuit;
charge level indicated on meter marked at 0 to 100 %

Pacing

periodic discharge of storage capacitor via defibrillator electrodes:

impulse shape as for defibrillation;
charge energy approx. 6 J;
impulse amplitude approx. 400 V;
impulse rate approx. 60/min

Discharge circuit

serial oscillating circuit: capacitance 32 μF ± 10 % inductive 56 mH ± 10 % and loss resistance 12 Ω ± 10 % in series with external termination (patient)

Impulse output

isolated (no connection with other circuit elements or case, test voltage DC 11 kV), short-circuit-proof

Sync input

for ECG signal or derived squarewave impulses:

ECG signal with R-wave amplitude of 0.3 to 2 V
or
squarewave impulse with amplitude of 0.5 to 24 V and duration of 20 to 150 ms;
trigger impulses indicated by pilot lamp

Power supply

line operation (SC 820 and SC 821)

from the power line, instrument construction in protection class I:

model for rated AC voltage 220 V

operating range 200 to 240 V, 49 to 65 Hz;
rated current 0.9 A

model for rated AC voltage 115 V

operating range 100 to 120 V, 49 to 65 Hz;
rated current 1.8 A

battery operation (SC 821)

from two incorporated, series-connected, gas-proof lead accumulators:

rated voltage 12 V;
rated capacity 1.8 Ah;
service life approx. 3 to 4 years or approx. 180 complete discharges or approx. 1000 partial discharges

battery charged via built-in charger with overcharge protection:

charging time, dependent on remaining charge level, 12 to 24 h for full charge and 6 to 12 h for 80 to 90 % of rated capacity

Running time per battery charge (SC 821 only)

approx. 20 defibrillations at 435 J of stored energy

Ready for operation

immediately

Operating position

vertical to horizontal

Environment

operation
the instrument is designed for operation under the following conditions which are regarded as normal:

temperature + 10 and + 40 °C;
relative humidity between 30 and 75 %;
atmospheric pressure between 700 and 1060 mbar (at 40 °C storage temperature, battery capacity drops to approx. 50 % after 5 month, at higher temperatures marked increase in self-discharge)

Dimensions	frame:		
	width	491 mm	(19.32 in)
	height	152.5 mm	(6.00 in)
	depth	310.5 mm	(12.25 in)
Weight	SC 820 approx. 17 kg (38 lb)		
	SC 821 with batteries approx. 19 kg (42 lb)		

4 Equipment

111 389 02	DC Defibrillator SC 820 for line operation or
111 389 05	DC Defibrillator SC 821 for line and battery operation

Accessories

227 070 02	Operation manual
227 017 09	Application note on *Electrocardiography*
227 017 18	Application note on *Cardiac Electrotherapy*
217 190 01	Set of defibrillator electrodes for external defibrillation consisting of 2 anterior electrodes
217 191 01	Set of defibrillator electrodes for external defibrillation consisting of 1 anterior electrode and 1 posterior electrode
301 285 00	Contact insert for children to fit anterior electrodes of electrode sets 217 190 01 and 217 191 01
301 286 00	Contact insert for infants to fit anterior electrodes of electrode sets 217 190 01 and 217 191 01
217 192 01	Set of defibrillator electrodes for internal defibrillation consisting of 2 paddle electrodes
301 280 00	Contact paddle for adults to fit electrode set 217 192 01
301 281 00	Contact paddle for children to fit electrode set 217 192 01
301 282 00	Contact paddle for infants to fit electrode set 217 192 01
217 083 05	Electrode cream (package of 10 tubes)
303 422 41	Electrode support to hold electrodes
301 495 00	Test lamp

HELLIGE

HELLIGE GMBH
Heinrich-von-Stephan-Str. 4
D-7800 Freiburg im Breisgau
Telefon (0761) 4011-1
Telex 772705 heli d

227 070 02 BA(e)–8003

Installation

1 Protection against electric shock hazards

To guarantee patient and operator safety, national and international committees have issued standards on safety for medically used rooms and electromedical equipment. According to these standards mains operated equipment must be provided with an additional safety precaution besides a basic safety insulation of the live parts for protection against electric shocks in normal use. For this purpose the IEC [1] has defined so-called protection classes.

The protection classes for electromedical instruments are mainly Class I, a safety precaution with protective earth (ground) connector, and Class II, a safety precaution without protective earth (ground) connector:

Instruments of Class I have their accessible conductive parts connected to the protective earth (ground) conductor in the fixed wiring of the installation via the protective earth (ground) terminal. If insulating defects occur, the pre-connected overcurrent protective device respond and the accessible conductive parts cannot become live.

Instruments of Class II have a double or reinforced insulation. The simultaneous failure of two insulations is in this case assumed to be most unlikely.

Our instruments belong to the one or to the other protection class. Some of the instruments can be operated in both protection classes. Therefore, they are provided with a device for changing over from Class I to Class II.

The protection class can always be seen from the instrument's nameplate: instruments of Class I have no special identification, instruments of Class II bear the symbol indicated below, instruments with protection class change-over device bear both of the symbols indicated below. From the position of this device the operator can conclude which protection class is effective.

 Class I  Class II

Upon delivery the protection-class change-over device is set to Class I. Only qualified service personnel is allowed to change the instrument to Class II after it has been clarified in what location the equipment will be applied.

Modern concepts of electrical safety demand that the patient is in a floating, not earthed (grounded) state during the use of electromedical instruments. The purpose of an insulation from earth (ground) is to prevent that the patient becomes part of a second unintentional circuit via earth (ground) in case of a first fault while he is connected to the instrument.

Our instruments for the evaluation of vital functions and also some instruments for the evaluation of action potentials (ECG amplifiers, electrocardiographs) are either provided with a specially isolated transducer or an isolated patient input (floating input). If the instrument is equipped with an isolated patient input, the input circuit connected to the patient is isolated and has no electrically conductive connections to the enclosure or other parts of the circuitry. The signals are transmitted via isolated couplers, e.g. transformers or light couplers.

Instruments equipped with an isolated patient input which are suitable for intracardiac applications bear the heart symbol which has been agreed upon on an international level in IEC publication 601-1 of the International Electrotechnical Commission.

The Application Determines Equipment and Environment

General cardiologic examinations with instruments for the evaluation of action potentials and vital functions can be performed in any room irrespective of the safety precautions taken in this room if the instrument is equipped with an F-type isolated (F = floating) applied part.

Measurements in or at the heart for the evaluation of potentials and vital functions require further safety precautions since leakage currents of electrical instruments can flow through the heart.

Therefore, during measurements in or at the heart, currents which can safely be applied during general cardiologic examinations now prove to be dangerous. Such currents cannot be avoided merely by the use of faultless instruments, appropriate installation is also required.

Instruments for measurements in or at the heart can be connected to the potential-equalization system of the room via a separate potential-equalization cable as an additional measure. If due to a fault the protective earth (ground) connector is interrupted, this potential-equalization system assumes the securing function of the protective earth (ground) conductor. For the connection of a potential-equalization cable, every instrument of protection class I is equipped with a connector. Potential-equalization cables are available for delivery on request.

[1] IEC = International Electrotechnical Commission

2 Environment

The instruments are not designed for operation in hazardous locations. Regulations concerning hazardous locations are, however, not applicable where no flammable anesthetics are present and no flammable liquids are used as skin-cleansing agents and skin disinfectants.

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 them completely. Therefore, the instruments should not be positioned near X-ray or diathermal equipment, near high-power motors or transformers. The vicinity of electrical cables carrying large currents should also be avoided.

The instruments must be especially protected against humidity, e.g. if they are applied outside the hospital. As for the rest, the instruments are designed for operation under the following climatic conditions which according to IEC 601-1 are regarded as normal:

temperature between + 10 and + 40 °C
relative humidity between 30 and 75 %
atmospheric pressure between 700 and 1000 mbar

if the corresponding specifications do not read otherwise.

3 Connection to the Power Line

Before the instrument or the system 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.

4 Exchanging Plug-in Modules

Plug-ins are modules provided with knurled screws which can be exchanged without using any tools. Plug-ins may be exchanged by the user. In order to prevent functional disturbances in the plug-in, the basic unit must be switched off during the exchange. The basic unit may only be switched on again after the knurled screws of the inserted plug-in have been tightened, i.e. all rear connectors have full contact.

5 Repairs and Maintenance

If interferences occur, please observe the section *Interference Elimination* in the respective application note. Furthermore, our engineers in the sales-service offices will be pleased to advise the customer and help eliminate the interferences. Our sales-service technicians will also change the instruments from one protection class to the other.

It is possible to have the instruments maintained by our sales-service personnel, possibly within the framework of a maintencance contract. Information regarding these possibilities can be obtained from our sales-service offices.

6 Literature

[1] IEC Publication 601-1: Safety of Medical Electrical Equipment (1977).

[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. IRE Trans. Bio-Medical Electronics BME 9: 244 (1962).

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