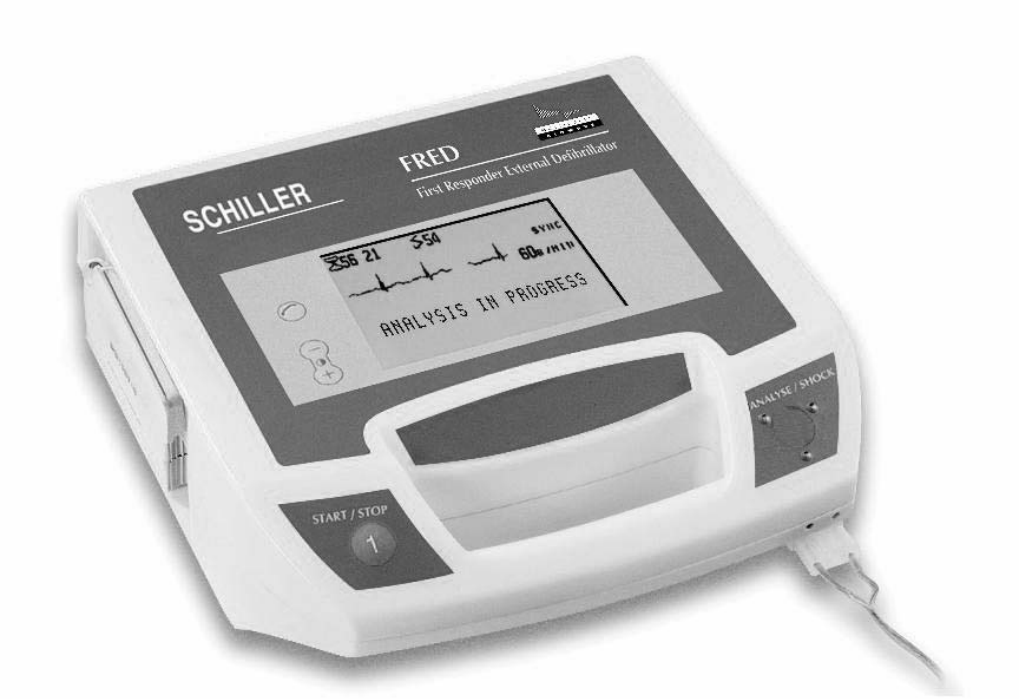
FRED®

Semiautomatic Defibrillator

Version 4

User Guide



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Part No. W1405387

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Revision History

Version	Date	Comment
W1405387	29 January 2001	1st edition
W1405387	20 May 2003	2nd edition
W1405387	07 October 2003	3rd edition

General Information

- The product **FRED®** bears the CE mark
  CE-0459
  indicating its compliance with the provisions of the Council Directive 93/42/EEC about medical devices and fulfills the essential requirements of Annex 1 of this directive.
- The product complies with the electromagnetic immunity requirements of standard IEC 60601-1-2/EN 60601-1-2 "Electromagnetic Compatibility - Medical Electrical Equipment".
- The radio interference emitted by this device is within the limits specified in the standards CISPR11/EN 55011, class B.
- The information given in this manual reflects software version 4. The manual is an integral part of the device and should always be kept near the device. Close observance of the information given in the manual is a prerequisite for proper device performance and correct operation and ensures patient and operator safety. **Therefore, be sure to read the complete manual.**
- To ensure patient safety, the specified measuring accuracy, and interference-free operation, we recommend using only original SCHILLER accessories. The user is responsible if accessories from other manufacturers are used with the device. The warranty does not cover damage resulting from the use of unsuitable accessories and consumables from other manufacturers.
- SCHILLER is responsible for the effects on safety, reliability, and performance of the device, only if
  - assembly operations, extensions, readjustments, modifications, or repairs are carried out by SCHILLER or by persons authorized by SCHILLER
  - the device is used in accordance with the instructions given in this operator's manual.
- The customer is responsible, if the device is employed in a manner different from that described in this manual.
- On request SCHILLER will provide a detailed field service manual.
- This manual is in conformity with the device specifications and safety standards valid at the time of printing. All rights are reserved for devices, circuits, techniques, software programs, and names appearing in this manual.
- The SCHILLER quality management system complies with the international standards EN ISO 9001 and EN 9001.
- No part of this manual may be reproduced without written permission from SCHILLER.
- The safety information given in this manual is classified as follows:

Danger
indicates an imminent hazard. If not avoided, the hazard will result in death or serious injury.

Warning
indicates a hazard. If not avoided, the hazard can result in death or serious injury.

Caution
indicates a potential hazard. If not avoided, this hazard may result in minor personal injury and/or product/property damage.

Manufacturer

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1 Intended Use, Functional Description

1.1 Intended Use

The basic version of **FRED®** is a semiautomatic defibrillator for early defibrillation by EMTs.

The defibrillator comes in two versions: one delivers monophasic shocks, while the other delivers biphasic shocks.

Depending on the defibrillator model, the energy for semiautomatic defibrillation is set to the following values:

shock	**defibrillator model**			
	biphasic	biphasic BUFREN	mono-phasic	mono-phasic BUFREN
1st shock	130 J	90 J	200 J	200 J
2nd shock	130 J	130 J	200 J	300 J
3rd and all subsequent shocks	180 J	180 J	360 J	360 J

EMTs are permitted to use the device in the semiautomatic mode only if the local regulations approve of this practice. The staff must be trained how to use the device and the defibrillation must be carried out under the supervision of a physician.

A special version of FRED® is available for manual defibrillation.

As a general rule, the device must be integrated in the chain of survival developed by the AHA (American Heart Association) and the ERC (European Resuscitation Council):
This chain of survival comprises a series of actions performed by different persons. Each of the actions is significant to ensure continued assistance for patients with cardiac arrest. Time is the decisive factor in the creation of this chain. The chain includes a number of supplementing and integrated phases:

1. Identification of respiratory and cardiac arrest
2. Notification of emergency medical facility
3. Immediate institution of CPR
4. Early defibrillation if indicated
5. Advanced treatment by emergency physician without delay
6. Transfer to an ICU

The following persons are involved in the chain:

- witnesses
- first responders and bystanders
- emergency medical staff / emergency physician
- hospital staff

A break anywhere in the chain can compromise the efficiency of the entire chain.

Biocompatibility

The parts of the product described in this manual, including all accessories that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards. If you have questions in this matter, please contact SCHILLER.

1.2 Functional Description

FRED® is a compact, battery-powered semiautomatic defibrillator (basic model).

The patient is defibrillated via disposable adhesive pads which also acquire the ECG signal for analysis and for determination of the heart rate.

The device prompts the user by text and audio messages (display/speaker).

For documentation purposes, the ECG (5 hours max.) and the intervention (500 events max.) are saved to a PCMCIA card.

The device can be powered from a slot-in, rechargeable NiCd battery or from a slot-in lithium battery. A NiCd battery powers the device for 2.5 hours of monitoring or 90 shocks at 180 Joules (or 60 shocks at 360 Joules). The lithium battery powers the device for five hours of monitoring or 450 shocks at 180 Joules each (or 300 shocks at 360 Joules) (see also section 3.2 "Power Supply").

The following options can be ordered to expand the device functions:

Note

This manual describes a device with all options implemented. The explanations given in this manual may therefore refer to controls or functions which are not available in the device you purchased.

Furthermore, we assume that the factory defaults are active. If the settings differ from the factory defaults (see chapter 7 "Defibrillator Setup"), your device may behave differently.

BUFRDI	ECG Display: for display of the ECG waveform acquired via pads or ECG electrodes
BUFRS	SpO_2 measurement: internal SpO_2 measurement option (includes finger probe and extension cable)
BUFREC3	ECG signal acquisition via separate 3-lead patient cable (requires BUFRDI option for display of the ECG) (includes 3-lead patient cable, electrodes).
BUFREC12	Acquisition of a 12-lead ECG for transmission via GSM to specific software (requires modem (MODEMGSM) and software (SEMA200), as well as the BUFRDI option for ECG display) (includes 10-lead patient cable).
BUFRMAN	Manual defibrillation: permits selection of defibrillation energy, manual shock release (includes ECG display BUFRDI).
BUFRERC	ERC protocol instead of AHA protocol
BUFREN	Energy levels for biphasic shocks in semiautomatic mode. 1st shock 90 J, 2nd shock 130 J, 3rd and all subsequent shocks 180 J.
FREDVO	Recording of – ambient noise (voices - 0.5 h), – ECG (0.5 h) – events (500) on 10-MB PCMCIA card (includes 10-MB card)
FREDWARE	Multimedia system to read and analyze the data stored on the PCMCIA card (includes multimedia PC, 17" monitor, modem, PCMCIA card reader and SAED Reader Pro software)
MODEM1	Modem for transmission of data stored on the PCMCIA card (READER2 software required to receive the data).

MODEMGSM	GSM kit enables FRED® equipped with BUFREC12 to transmit 12-lead ECGs (SEMA200 software required to read the data).
SEMA 200	Software for display and interpretation of the 12-lead ECG transmitted by FRED® equipped with MODEMGSM and BUFREC12 (minimum PC requirements: Pentium II 300 MHz, Windows 95, 98 or NT)
READER0	SAED Reader Light: free software for transmission of the data stored on a PCMCIA card to a PC (serial and PCMCIA) and for viewing of the ECG, Windows 95, 98 and NT compatible.
READER1	Memory card reader software: includes PCMCIA drive, SAED Reader Pro software and hardware key, to read and analyze the data stored on the PCMCIA card (for PC which meets the following minimum requirements: Pentium II, 300 MHz, Windows 95, 98, or NT).
READER2	SAED Reader Pro for laptop equipped with PCMCIA drive: includes SAED Reader Pro software and hardware key, to read and analyze the data stored on the PCMCIA card (for laptop which meets the following minimum requirements: Pentium II, 300 MHz, Windows 95, 98, or NT)

Figure 1-1. ***FRED®*** *equipped with option for manual defibrillation*

2 Controls and Indicators

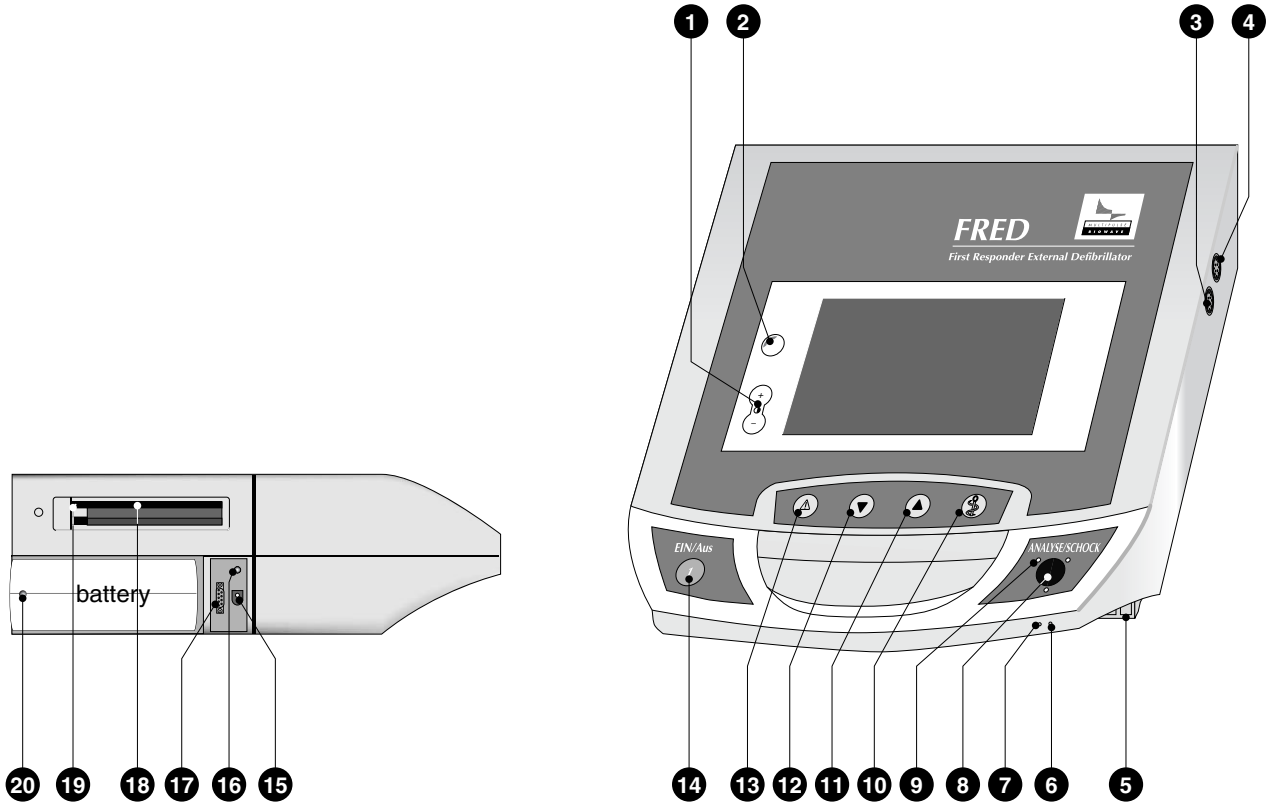


Figure 2-1. Controls and indicators

1 *Contrast adjustment buttons*

2 *Button to start data transmission via modem*

3 *SpO_2 probe connection*

4 *ECG patient cable connection*

5 *Connection for defibrillation pads*

6 *Indicator, blinks when the defibrillation pads are not properly connected or are missing (connector defect, cable break)*

7 *Microphone*

8 *Analyse (orange) / Shock (red) button*

9 *Indicators*
Analyse: green, Shock: red
green = push button to initiate analysis
red = push button to release the shock

10 *"Physician" button: converts the device from semiautomatic to manual operation*

11 *Button to increase the defibrillation energy (manual operation)*

12 *Button to decrease the defibrillation energy (manual operation)*

13 *Button to initiate defibrillator charging (manual operation)*

14 *Button to turn the device on and off (hold button down for approx. 2 s to turn device off)*

15 *Connection for charging unit*

16 *Charging indicator (is illuminated when voltage to charge the NiCd battery is applied at connector **15**)*

17 *Serial interface (modem connection)*

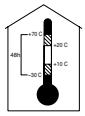
18 *Slot for PCMCIA card (top), the slot below is reserved for future use – do NOT use for PCMCIA card*

19 *Eject button for PCMCIA card (fold out and push)*

20 *Rechargeable NiCd battery or lithium battery*

Explanation of Symbols

Symbols used on the Device and on the Battery

	Type CF signal input, suitable for intracardiac application, defibrillation-proof
	Type BF signal input, defibrillation-proof
	Caution! High Voltage!
	ECG signal input
	Refer to user manual, initiation of defibrillator charging (manual operation)
	Contrast adjustment
	"Physician" button enabling the manual operating mode
▲	increasing energy level
▼	decreasing energy level
	data transmission via modem
	product is recyclable
	do not dispose of with household waste
	do not recharge
	do not short-circuit
	do not incinerate
	do not destroy with a saw
	do not destroy
	unlimited storage between +10 °C and +20 °C, storage for 48 hours max. between +20 °C and +70 °C and between +10 °C and -30 °C
	replace battery after 1 year of operation (dramatically reduced capacity, see page 44)

Symbols used on the Display

	Time elapsed since device was turned on (minutes, seconds)
	Number of shocks delivered since device was turned on
	Battery low
	Data storage on PCMCIA card
	Data storage problem
	QRS blip
	ECG transmission via cellular telephone

3 Putting the Device into Operation and Performance Test

3.1 Safety Information

Danger

Explosion Hazard — FRED® is not designed for use in areas of medical locations where an explosion hazard may occur.
Also, it is not permitted to operate the defibrillator in an oxygen-enriched environment or in the presence of flammable substances (gas) or anesthetics.
Oxygenation in the vicinity of the defibrillation electrodes must be strictly avoided. Temporarily interrupt the oxygen supply.

Warning

Shock Hazard — Observe the following warnings. Failure to do so endangers the lives of the patient, the user and other persons present.

- FRED® is a high-voltage electrotherapy device and must be handled by qualified and specially trained personnel. Improper use of the device can endanger life. Always follow the instructions given in this manual.
- Before using the device, the operator must ascertain that it is in correct working order and operating condition (performance test).
- In particular, the cables, connectors, electrodes as well as sensors and probes must be checked for signs of damage.
- Damaged parts must be replaced immediately, before use.
- Ensure that there are no conductive connections between the patient and bystanders during defibrillation.
- Devices may be connected to other devices or to parts of systems only when it has been made certain that there is no danger to the patient, the operators, or the environment as a result.
  In those instances where there is any element of doubt concerning the safety of connected devices, the user must contact the manufacturers concerned or other informed experts as to whether there is any possible danger to the patient, the operator, or the environment as a result of the proposed combination of devices. Standards IEC 60601-1-1/EN60601-1-1 must be complied with in all cases.

- The device is suitable for application in a humid environment provided the regulations concerning drip-proof equipment of IEC 60601/EN 60601 are strictly observed. However, do not defibrillate patients in a very moist or wet environment, unless absolutely necessary.
- While connected to the charging unit, FRED® must not be used outdoors.

Warning

- Equipment Failure — Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the defibrillator comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems, and cellular telephones are possible sources of interference as they may emit higher levels of electromagnetic radiation.
  Keep the system away from these devices and verify its performance before use.
- Equipment Failure — Similarly, the defibrillator may disturb equipment operating in its vicinity when charging or delivering the shock. Verify the performance of these devices before use.
- Operational readiness — FRED® is an emergency device and must be ready for operation at any time and in all situations. Ensure that the (rechargeable) battery is always fully charged.
- Suffocation Hazard — Dispose of the packaging material, observing the applicable waste-control regulations. Keep the packaging material out of children's reach.

Caution

- Equipment Damage — Exercise great care when using HF surgery equipment on the patient at the same as the defibrillator. As a general rule, a minimum distance between the ECG and defibrillation electrodes and the HF surgery electrodes of 15 cm must be ensured. If this is not possible, disconnect the electrodes and transducer leads while using the HF surgery device.
- Equipment Damage — Avoid triggering shocks repeatedly when electrodes are not applied, because the device temperature may increase to an inadmissible level due to the internal safety discharges.

3.2 Power Supply

The device can be powered from a rechargeable NiCd battery with 2.4 Ah or from a disposable lithium battery.

A NiCd battery powers the device for 2.5 hours of monitoring or 110 shocks at 180 Joules (biphasic) or 60 shocks at 360 Joules (monophasic). A lithium battery provides power for 5 hours of monitoring or 450 shocks at 180 Joules (or 300 shocks at 360 Joules).

For recharging, the NiCd battery may remain in the FRED® defibrillator or it can be inserted in the external charging unit (see section "Charging Unit DG 2002 C2" below).

Charge the battery immediately after each use and leave the charging unit connected to the defibrillator. The battery cannot be overcharged. After 20 hours of charging, the battery has reached 80% of its capacity, after 27 hours, 100%.

- Connect the charger cable to connector **15** (Figure 3-1) and to the power line. Caution: Indicator **16** will light up, even when no battery is inserted for charging.

Note

– It is not possible to operate FRED® without a charged battery.
– Do not recharge NiCd batteries in direct sunlight, on sources of heat or at extremely low ambient temperatures (minimum temperature 5 °C/41 °F). The ambient temperature should not exceed 40 °C/104 °F, as this would have adverse effects on the battery's service life.
– FRED® automatically monitors the battery capacity. As soon as the capacity drops below a given minimum (30 minutes of operation or 7 shocks at 180 Joules each or 5 shocks at 360 Joules each), the  symbol appears.
– Indicator **16** will light up, even when no battery is inserted for charging.

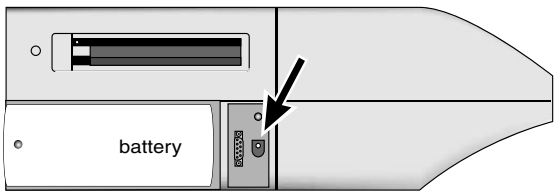


Figure 3-1. Charger cable connection

Charging Unit DG 2002 C2

The charging unit is suitable for fast charging of one or two NiCd batteries. It is specially designed for these batteries and ensures

– optimal performance and
– a long service life of the batteries.

- Connect the charger to the power line.
- Turn the charger on (switch below power input).
- Immediately after inserting a battery, the charge cycle begins (indicator is illuminated). It takes 1 hour to quick-charge a fully depleted battery. Afterwards the charger switches to trickle-charging (indicator blinks).

Lithium Battery

Handle lithium batteries acoording to the following guidelines:

– Store lithium batteries in a well-ventilated room at a constant temperature between 15°C and 20°C. Do not store batteries longer than 10 years (residual capacity of 80%).
– Protect lithium batteries from
  – strong vibrations
  – hard shocks
  – flammable materials
  – pointed objects

- The ambient temperature has a major influence on the life and capacity of lithium batteries. At a constant temperature of 20°C, the following ratings can be expected
  - new battery: 450 shocks at 180 Joules or 5 hours of monitoring
  - battery inside device for 1 year: 150 shocks at 180 Joules or 2 hours of monitoring
  - battery inside device for 2 years: 70 shocks at 180 Joules or 1 hour of monitoring
  - battery inside device for 2.5 years: 50 shocks at 180 Joules or 45 minutes of monitoring
- Avoid releasing the stored energy in a rapid or uncontrolled manner (e.g. by shorting terminals together). Do not incinerate lithium batteries or expose them to high temperatures, do not crush, open or dismantle them.
- Do not use deformed or punctured lithium batteries.

Warranty Information

SCHILLER warrants lithium batteries for a period of 6 months to be free from manufacturing faults. The warranty period begins on the shipping date annotated on the battery. A seal guarantees that the battery is new and unused. Remove or break this seal immediately prior to inserting the battery. SCHILLER assumes no liability for improper handling or reduced capacity as a result of battery usage.

3.3 Turning the Device On and Testing Its Performance

Some Basic Facts

FRED® is turned on and off with the On/Off (1) button. To turn the defibrillator off, the On/Off (1) button must be held down for approx. 2 seconds.

For a functional checkout, the device offers two different tests:

- an automatic test which takes place at power up,
- a manual test.

Warning

Shock Hazard – In addition to the successful self-test, the performance test includes a visual inspection of the cables, connectors, electrodes, sensors and probes before each use. If you identify problems which may impair the patient's or operator's safety, the device must be repaired before it can be used again.

Automatic Power-Up Test

The test display appears immediately after the device is turned on (Figure 3-2). If the device does not identify a problem, it will enable the semiautomatic mode of operation and prompt you to connect the electrodes.

If a problem is identified, an alarm sounds and an error message will be displayed. In this case, turn off the device or interrupt the power supply by removing the battery. Have the device repaired before using it again.

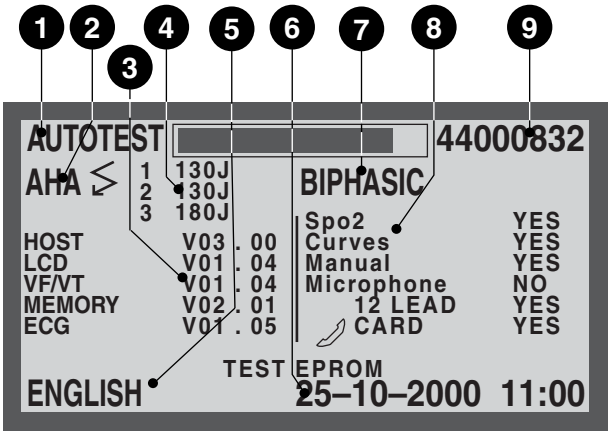


Figure 3-2. Automatic power-up test

1 *Type of test*
2 *Protocol used (AHA / ERC)*
3 *Software version tested*
4 *Energy for shocks 1, 2, and 3*
5 *Selected language*
6 *Date and time*
7 *Pulse shape*
8 *Device options*
9 *Serial number of the device*

Note

- A data storage problem (PCMCIA card) does not affect the other functions of the device. After the test, the device switches to the semiautomatic mode. The symbol blinks to alert to this problem.
- The energy storage system (test discharge) can only be checked with a suitable simulator.

Manual Test

The manual test can be initiated at power up by simultaneously pushing buttons On/Off (1) and –. To ensure functional readiness, the device will automatically perform this manual test every day at 12:00 hrs even when switched off (for these tests, however, the display remains dark). If the device identifies a problem in the course of the test, it emits an alarm at 2-minute intervals and briefly displays an error message. Initiate the manual test to clear the alarm.
With a full battery, the device can run these tests for a minimum of 4 weeks.

When you start the manual test at power up, you can check the keyboard for proper functioning after the RAM and EPROM tests. For this test, push the button you are prompted to activate on the display, beginning with the red “Analyse/Shock” button **8**.

Note

- You can interrupt the manual test at any time with On/Off (1).
- We recommend to run a manual test each time the battery is replaced to check the battery capacity.

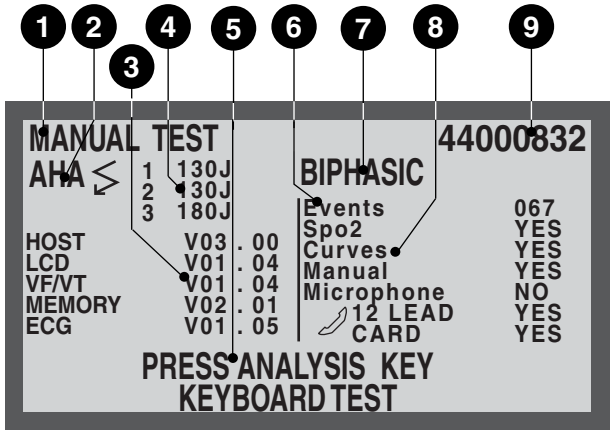


Figure 3-3. Manual test at power up

1 *Type of test*
2 *Protocol used (AHA / ERC)*
3 *Software version tested*
4 *Energy for shocks 1, 2, and 3*
5 *Keyboard test*
6 *Number of stored events (PCMCIA card)*
7 *Pulse shape*
8 *Device options*
9 *Serial number of the device*

Contrast Adjustment

The contrast can be adjusted with the buttons.

Selecting the Language, Setting Date and Time

Refer to chapter 7 "Defibrillator Setup" for details on selecting the language and setting date and time.

Normally, date and time are set at the factory. If you correct the setting and the device still displays the wrong date and/or time, the internal battery is depleted and must be replaced by a service technician.

4 Semiautomatic Defibrillation

4.1 Defibrillator Application Guidelines

Observe the following guidelines to ensure successful and safe defibrillation. Otherwise the lives of the patient, the user and bystanders are in danger.

Warning

- Delivering a defibrillation shock to a patient with normal heart rhythm may induce ventricular fibrillation.
- Position patients flat on a hard surface where they are electrically insulated. The patient must not be allowed to come into contact with metal parts, e.g., bed or litter, to prevent unwanted pathways for the defibrillation current which may endanger the assistants. For the same reason, do not position the patient on wet ground (rain, accident in swimming pool).
  Do not allow the defibrillation electrodes to come into contact with other electrodes or metal parts which are in contact with the patient.
  The patient's chest must be dry, because moisture can cause unwanted pathways for the defibrillation current.
  When using flammable skin cleansing agents, wait until they have completely dried.
- The operator and all assistants must be briefed regarding the preparations for and execution of defibrillation.
  All tasks must be clearly assigned.
  Immediately prior to the shock
  - cardiac massage and ventilation must be interrupted and
  - bystanders must be warned.
- Ensure that there are no conductive connections between the patient and other persons during defibrillation.

Warning

- Pacemaker Patients — Defibrillating a patient with an implanted pacemaker is likely to impair the pacemaker function or cause damage to the pacemaker.
  For this reason
  - do not apply the defibrillation electrodes in the vicinity of the pacemaker,
  - have an external pacemaker at hand,
  - verify the pacemaker for proper functioning as soon as possible after the defibrillation.
- Damage to Myocardium — Please note that children require less energy for successful ventricular defibrillation than adults. For the first biphasic defibrillation shock delivered to babies and small children, select an energy of approx. 1 J/kg body weight. For subsequent shocks, the energy may be increased to 2 or 3 J/kg body weight. When using the monophasic device, the energy for the first shock should be approx. 2 J/kg body weight and it can be increased to 4 J/kg body weight for subsequent shocks.
- Risk of Skin Burns — Owing to the high currents, there is a risk of skin burns.

Note

Depending on the clinical picture, defibrillation may not be successful.

4.2 Safety Information for the Use of a Semiautomatic Defibrillator

In addition to the guidelines set forth in section 4.1, the following rules must be observed when using a semiautomatic defibrillator. Failure to do so may compromise the success of the defibrillation or endanger the patient's life.

Warning

- Semiautomatic defibrillation is only permitted for patients with a body weight greater than 25 kg, who are unconscious, have ceased to breathe and are pulseless.
- During ECG analysis
  – suspend CPR
  – ensure that the patient does not move
  – do not touch the patient.
  Otherwise, artifacts may lead to incorrect analysis results.
- In unfavorable situations the analysis of the ECG may occasionally be incorrect. Therefore the user is obliged to make certain that the conditions for use of a semiautomatic defibrillator are met:
  - unconsciousness,
  - no respiration,
  - no pulse.
  For the same reason, the user is entirely responsible for delivery of the defibrillation shock.
- Do not use the anterior-posterior electrode placement for semiautomatic defibrillation.
- Only specially trained staff authorized by the supervising person responsible for the intervention may use the device in the semiautomatic mode.
- In the semiautomatic mode, the defibrillator cannot deliver synchronized shocks (cardioversion).
- During HF surgical interventions, ECG analysis is not permitted in the semiautomatic mode.

Caution

For semiautomatic defibrillation the energy is fixed at the following levels:

defibrillator delivering biphasic shocks

1st shock	130 J (or 90 J)
2nd shock	130 J
3rd and all subsequent shocks	180 J

defibrillator delivering monophasic shocks

1st shock	200 J
2nd shock	200 J (or 300 J)
3rd and all subsequent shocks	360 J

Note

When testing FRED® with an ECG simulator, be aware that most simulators generate artificial ECG waveforms. These signals are only suitable for a functional test of the device, but not for an evaluation of the analysis program.
With signals from the AHA (American Heart Association) and MIT (Massachusetts Institute of Technology) databases, our analysis program achieved a detection accuracy of 98.8 % (sensitivity) and 99.97 % (specificity).

4.3 Guidelines, Conditions, Limitations and Restrictions in Use

Some Basic Facts

EMTs are permitted to use a semiautomatic defibrillator only if the local regulations approve of this practice.

In addition, it is of utmost importance to observe the safety information given in sections 4.1 and 4.2.

> **Warning**
> Patient Hazard — If, in the course of treatment, the patient spontaneously regains consciousness, a defibrillation shock that may have been advised just before must not be delivered. In this situation, check the patient's pulse again and restart the analysis.

The responsible physician is required to determine the algorithms for the first responders in accordance with AHA or ERC or with local regulations.

Equipment Models and User Groups

Basic Model

The basic version of FRED® is a semiautomatic defibrillator as required by the laws in most countries where semiautomatic defibrillation by EMTs is permitted. The device also meets the AHA and ERC requirements.

Expanded Basic Model

The use of a device expanded with options such as
- additional ECG signal input for patient cable and separate ECG electrodes
- SpO_2 measuring system

is permitted only if
- the local laws authorize its application,
- the supervising physician expressly approves its application,
- the staff is trained accordingly.

Model convertible to manual defibrillation

EMTs are not permitted to use this model if local laws authorize EMTs to employ only semiautomatic defibrillators (without further explanations).

In some countries, however, EMTs and the supervising physicians demand that defibrillators be pushbutton-convertible from semiautomatic to manual operation. In these cases, individual protocols must be determined in cooperation with the EMTs. These will be based on the AHA or ERC protocols or on the respective local regulations. Furthermore, the emergency service is required to ensure that

- the agreed algorithms are observed,
- the staff is trained accordingly,
- the correct use of the device is verified after each intervention.

4.4 Defibrillating a Patient in the Semiautomatic Mode

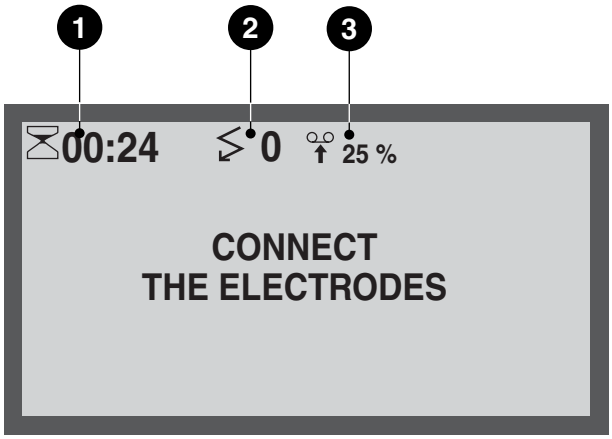


Figure 4-1. Standard display
- ***1*** *Time since device was turned on (minutes, seconds)*
- ***2*** *Number of shocks delivered since device was turned on (not reset to zero when battery replacement is completed within 5 minutes)*
- ***3*** *Data storage on PCMCIA card enabled, percentage value = amount of memory used (recorded ECG)*

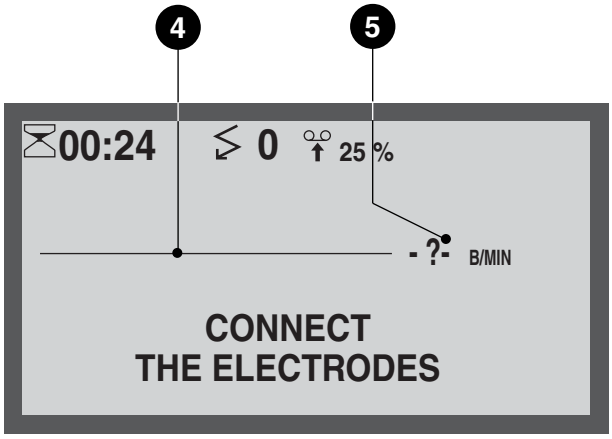


Figure 4-2. Standard display with presentation of the ECG (option)
- ***4*** *Baseline (ECG)*
- ***5*** *Heart rate*

- Switch on the defibrillator with the On/Off 1 button

After the test, the standard display (Figure 4-1 or 4-2 (if device is equipped with the "ECG Display" option)) appears and you will be prompted to connect the electrodes. In addition, the defibrillation pad indicator (**6**, Figure 2-1) blinks and the device emits an alarm tone.

- Apply the pads as shown in Figure 4-3 (STERNUM: right sternal edge at the level of the 2nd intercostal space,
  APEX: left axillary line at the level of the 5th intercostal space).

  Observe the following application guidelines:

  – Use pads before their expiration date.
  – Do **not** reuse the pads.
  – Shave the application points; this improves conductivity and makes removal of the pads easier.
  – Place the pads on the patient such that the connectors point to either side of the patient and that the cables are not hindering CPR measures.
  – The electrodes are pregelled; therefore, do not use additional contact cream or gel.
  – Do not use pads, if the gel is dry.
  – Peel off the backing from each pad and press the pad carefully onto the appropriate site.

Warning
Risk of Skin Burns / Equipment Damage — Do not attach the pads over
– sternum or clavicle
– nipples
– implanted pacemaker or defibrillator devices.

- Connect the lead of the defibrillation pads to the device (**5**, Figure 2-1).

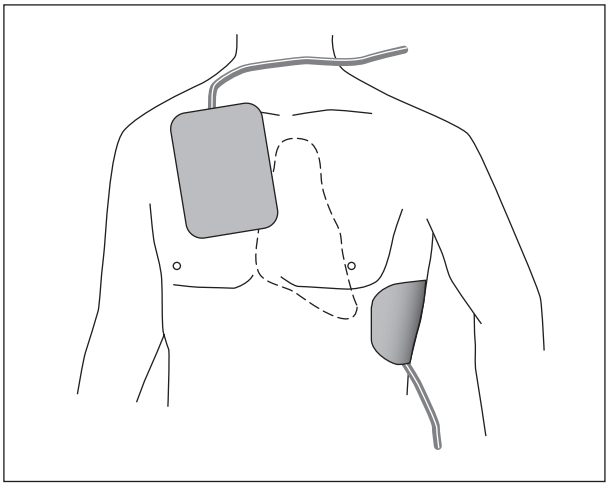


Figure 4-3. Defibrillation pad application points (patient in supine position)

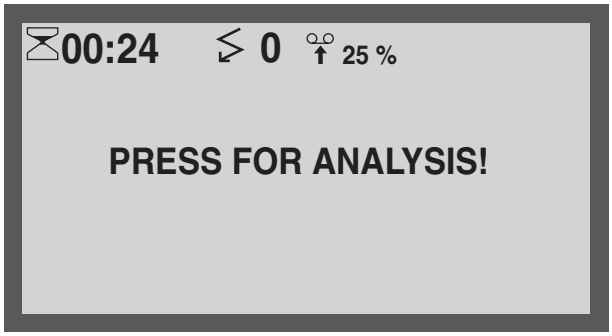


Figure 4-4. "Press for analysis" prompt

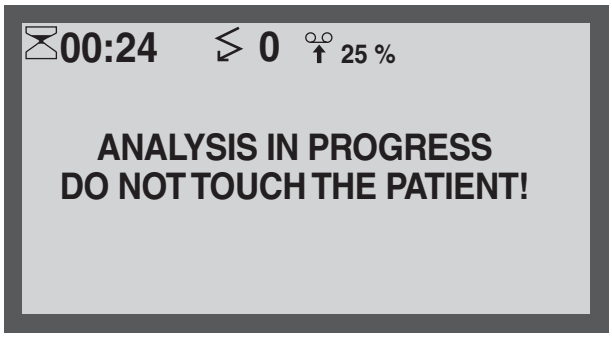


Figure 4-5. "Analysis in progress, do not touch the patient" message

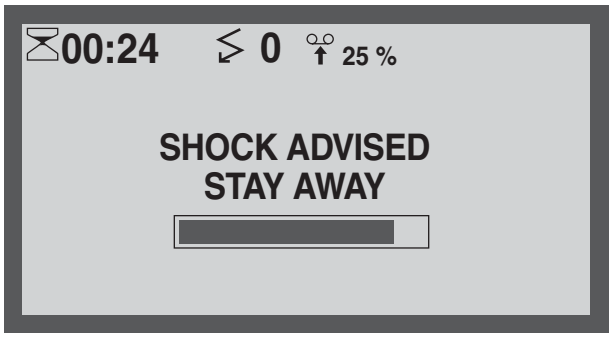


Figure 4-6. Message when device identifies shockable rhythm

- After connection of the electrodes, the message "Press for analysis" appears and the indicators of the red “Analyse/Shock” button start blinking green.
- Do not touch the patient any more and warn all those present.
- Now press the red “Analyse/Shock” button to initiate ECG analysis.

The message "Analysis in progress, do not touch the patient" appears (Figure 4-5). The analysis takes approx. 9 seconds.

The following operating steps depend on whether or not the device identifies a shockable rhythm.

Device identifies a shockable rhythm

When the analysis program detects

– ventricular fibrillation or
– ventricular tachycardia with a rate greater than 180 B/min,

you will see the message "Shock advised, stay away" and defibrillator charging begins (Figure 4-6).

You can watch the energy charging process by looking at the bar diagram. The device will charge to the factory-set energy levels:

defibrillator delivering biphasic shocks
1st shock: 130 J (or 90 J)
2nd shock 130 J
3rd and all subsequent shocks 180 J

defibrillator delivering monophasic shocks
1st shock: 200 J
2nd shock 200 J (or 300 J)
3rd and all subsequent shocks 360 J

When the selected energy is charged,

– the device emits an audio signal
– the message "Stay away, shock" appears
– the indicators in the red “Analyse/Shock” button start blinking red.

Note

- If the heart rhythm changes to a non-shockable rhythm after the "Shock advised" message, the device will discharge the energy internally when it has identified the new rhythm.
- If an electrode becomes disconnected during ECG analysis, the message "Connect the electrodes" will be displayed and the device stops analyzing. The analysis must be restarted after application of the electrode.
- If, during analysis, the impedance at one of the electrodes reaches an inadmissible value, the message "Check the electrodes" will appear and the device suspends the analysis. The analysis continues as soon as the high impedance is eliminated.

- Do not touch the patient any more and warn all those present.
- Press the red “Analyse/Shock” button within the next 20 seconds to trigger the shock (if you do not trigger the shock within this period, the energy will be discharged internally and you will have to restart the analysis).

Danger

Shock Hazard — High voltage is present at the electrodes until the capacitor is completely discharged. During this period, do not touch the electrodes or the patient.

After delivery of the shock, the message "Press for analysis" returns.

After the 3rd shock, the device prompts you to check the pulse and, if no pulse is present, to perform cardiopulmonary resuscitation for 1 minute.

Afterwards, the device again prompts you to initiate ECG analysis and to deliver up to 3 shocks (if ventricular fibrillation or tachycardia (HR > 180 B/min) persists).

Device identifies no shockable rhythm

Device with AHA protocol

If the analysis program does not detect a shockable rhythm, the message "No shock advised, check the pulse! If no pulse – 1 minute CPR" (Figure 4-7) appears.

After that minute, you will see the message "Check the pulse! If no pulse, press for analysis".

The audible prompt for this action will be repeated every 2 minutes.

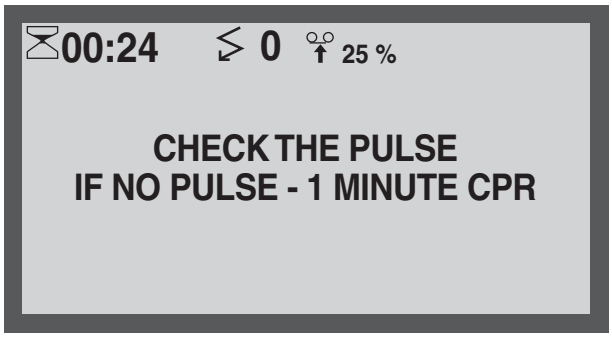


Figure 4-7. Message when device identifies no shockable rhythm

Note

The message "Check the pulse! If no pulse – 1 minute CPR" will also appear when the ECG signal quality is insufficient for a correct analysis.

Device with ERC protocol

If the analysis program does not detect a shockable rhythm, the message "No shock advised, check the pulse! If no pulse - 3 minutes CPR" (Figure 4-7) appears.

If the analysis was performed after a shock, the message will read "... – 1 minute CPR" instead of "... – 3 minutes CPR".

After these 3 minutes, you will see the message "Check the pulse! If no pulse, press for analysis".

Note

- If the device is turned on and the analysis program detects asystole, the message "Check the pulse! If no pulse – 3 minutes CPR" appears.
- If the analysis program detects asystole after a shock, the message "Check the pulse! If no pulse -1 minute CPR" appears. If asystole persists after that minute, the message "Check the pulse! If no pulse – 3 minutes CPR" is displayed.
- The message "Check the pulse! If no pulse – 1 minute CPR" will also appear when the ECG signal quality is insufficient for a correct analysis.

Internal Safety Discharge

A safety circuit ensures that the stored defibrillation energy is discharged internally if the shock is not correctly delivered. This situation exists when

- the shock is not delivered within 20 seconds of defibrillator charging (audio signal),
- there is an electrode problem,
- the battery voltage is insufficient,
- the device is defective,
- you select a lower energy value in manual mode after charging,
- you turn the device off.

Warning
Patient Hazard — If the device behavior differs from the description given in this manual, the defibrillator is defective and must be repaired.

Ending Therapy

- Turn off the device after therapy (push On/Off (1) button for approx. 2 seconds).
- Disconnect the electrode lead.
- Carefully remove the pads from the patient's skin (Figure 4-8) and discard them immediately (hospital waste) to prevent that they are reused.

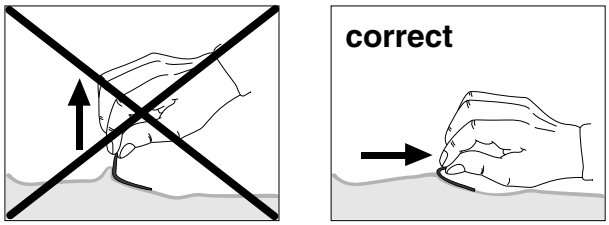


Figure 4-8. Removing the pads

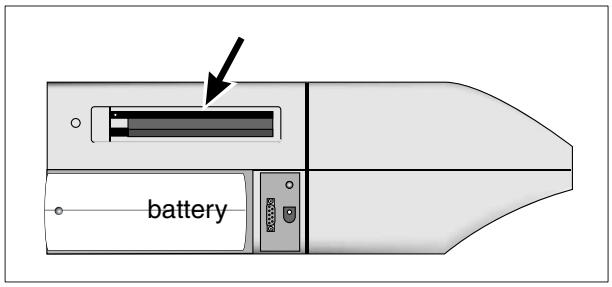


Figure 4-9. Slot for PCMCIA card

Overview of events documented with date and time:

- power on
- start of analysis
- analysis result
- defibrillator charging
- shock release
- internal discharge
- switchover to manual operation
- electrode alarm
- "battery low" alarm
- putting the SpO_2 module into operation
- end of SpO_2 measurement
- asystole alarm (manual mode)
- fibrillation / flutter alarm (manual mode)

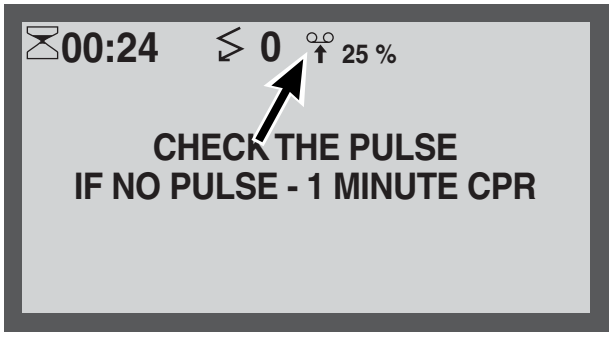


Figure 4-10. Data storage function enabled

Intervention Documentation

To document the code, the ECG (1 lead, 5 hours max.) and the intervention (500 events max., see overview at left) are saved to a 2-MB PCMCIA card.

Always insert the card in the upper slot (Figure 4-9)! Inserting the card will automatically activate the memory function and the symbol appears on the display (Figure 4-10). The number next to the symbol indicates the percentage of the storage capacity used.

When the storage capacity is exhausted, the symbol blinks, when the memory function is disturbed, the symbol blinks.

Note

- Insert the PCMCIA card in the upper slot only!
- When the option FREDVO is installed, voices within a radius of 3 m around the scene of the emergency can be recorded (0.5 h max.).
- The multimedia system FREDWARE or the SAED Reader Pro software is required to read and clear the PCMCIA card (in the transmission mode, the card can also be cleared while inserted in FRED®, section 6.5).

Alarms

FRED® distinguishes between technical and medical alarms. If a medical alarm is present, the device emits a continuous tone, in case of technical alarms, the device sounds an intermittent tone. In most alarm situations, the alarm tone is accompanied by a voice prompt.

5 Cleaning and Maintenance

5.1 Cleaning and Disinfection

Device and Cables

Danger

– Shock Hazard — Remove the (rechargeable) battery, before cleaning the device. This ensures that the device will not be turned on inadvertently while you are cleaning it. Danger to life! Before cleaning the paddles, disconnect them from the device.

– Shock Hazard, Equipment Damage — Liquids must not be allowed to enter the device. Devices into which liquids have penetrated must be immediately cleaned and checked by a service technician, before they can be reused.

- Discard disposable electrodes immediately after use to prevent that they are reused (hospital waste).
- Before cleaning the electrode or sensor leads, disconnect them from the device. Clean and disinfect cables by wiping them down with a gaze pad moistened with cleaning agent or disinfectant. Do not immerse the cable connectors in liquid. The device can be cleaned with all cleaning agents and disinfectants commonly used in hospitals.
- The device surface too can be wiped down with a cloth moistened with a cleaning solution or disinfectant. Liquids must not be allowed to enter the device.

Caution

Equipment Damage — Do not disinfect the device surface with phenol-based disinfectants or peroxide compounds.

5.2 Maintenance

Checks before each use

- Before each use, visually inspect the device, the leads and electrodes.

If you detect damages or impaired functions which may result in a hazard to the patient or the operator, the device must be repaired before it can be used again.

Regular Checks

FRED® is an emergency device and must always be ready for use. The following checks should be performed at regular intervals:

Once a week

- visual inspection of the device and the accessories

Once a year

These inspections can be carried out by SCHILLER service technicians within the framework of a maintenance agreement. If other persons perform these inspections, please ensure that they have received adequate training and are experienced in carrying out preventive maintenance checks.

- Visually inspect the device and the accessories for signs of mechanical damage that may impair the device functions. Replace damaged parts immediately.
- Check that the device labeling relevant for safety is legible. Labeling which is missing or illegible must be renewed.
- Perform functional test using the "manual test" feature.
- Measure the equivalent leakage current.
- Measure the energy delivered in 50 Ohms.
- Carefully check the electrode cables for mechanical damage, short-circuits and lead breaks.

The device does not require additional maintenance interventions.

Disposal at the End of Its Service Life

At the end of its service life, the device and the accessories must be disposed of in compliance with the local regulations. Apart from the internal and slot-in (rechargeable) battery, the device does not contain hazardous material and may be disposed of like any other electronic equipment.

6 Optional Device Features

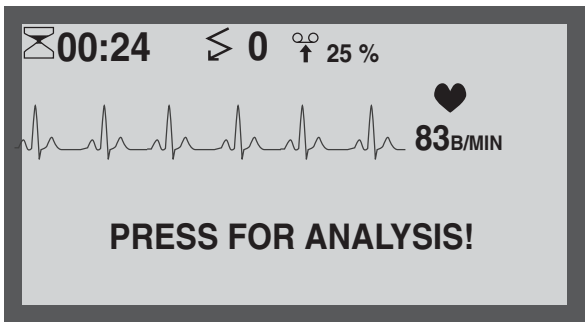


Figure 6-1. Screen with ECG waveform, heart rate and QRS blip

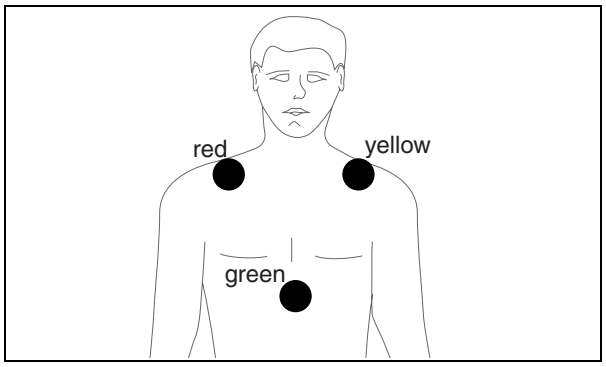


Figure 6-2. Electrode application points (3-lead patient cable)

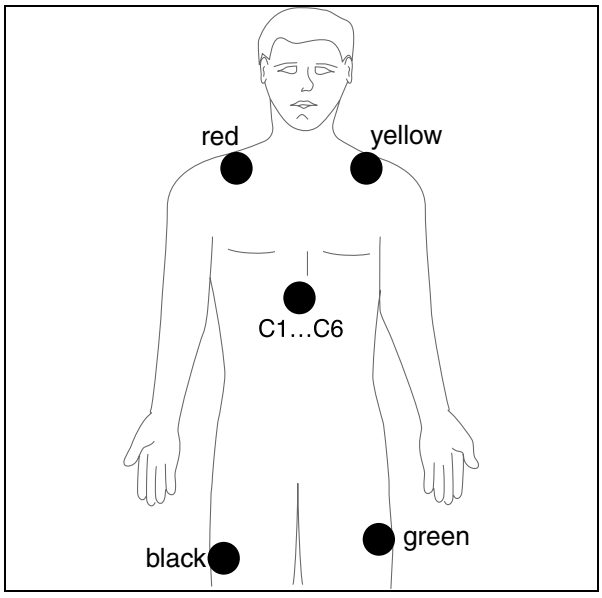


Figure 6-3. Electrode application points (10-lead patient cable)

6.1 ECG Display

This option allows you to view

- the ECG waveform
- the heart rate (numeric value) and
- the QRS blip (heart symbol)

on the display (Figure 6-1).

If an ECG signal is not available because neither pads nor ECG electrodes are applied, but an SpO_2 sensor is connected, the pulse rate will be displayed instead of the heart rate and the letter S replaces the QRS blip.

6.2 Patient Cable and ECG Electrode Connection

This option allows you to acquire the ECG signal via pads or separate ECG electrodes. Depending on the option you choose you can connect a 3-lead, 4-lead, or 10-lead patient cable to connector **4** (green). If the device receives two ECG signals (both from the pads and from the ECG electrodes), the signal acquired with the pads always has priority. Only when this ECG signal is not available or disturbed will the device use the ECG signal acquired with the ECG electrodes. Also, the device will always choose the ECG lead that provides the best signal quality.

Warning

False Alarms — Use only silver-silver chloride electrodes. These electrodes prevent polarization voltages which may simulate cardiac arrest.

Note

The ECG signal input is a high-insulation port and it is defibrillation-proof (type CF).

6.3 SpO_2 Measuring System

Some Basic Facts

The SpO_2 measuring system measures and monitors the oxygen saturation of hemoglobin in the arterial blood and supplies the plethysmogram signal (channel 2).

The system measures arterial oxygen saturation by a method called pulse oximetry. This method is based on the measurement of the different absorption spectra of reduced hemoglobin and oxyhemoglobin. Therefore, the probes consist of an IR light source on one side (2 LEDs) and a photodetector on the other side which collects the incident light. After penetrating through the tissue and blood, the radiation from the LEDs causes an electrical signal in the photodetector. Since oxyhemoglobin absorbs less red light than reduced hemoglobin, this method allows the system to determine the oxygen saturation.

The SpO_2 measuring system is activated and deactivated by connection and removal of the sensor lead.

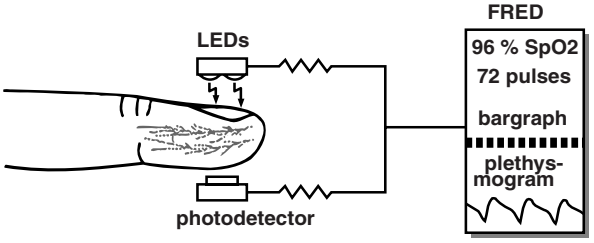


Figure 6-4. Principle of operation

Note

The SpO_2 signal input is a high-insulation port and it is defibrillation-proof (type CF).

Warning

Patient Safety — Use only the sensors and probes listed in chapter 9 "Order Information". These probes ensure patient safety during defibrillation.

Application Tips

- Use only the probes listed in the "Order Information" chapter. Apply the probes as described in their instructions for use.
- Do not exert too much pressure when applying the probe to avoid erroneous readings and blistering. Inadequate oxygen supply to the skin, not heat, causes blisters.
- Be careful to ensure continued circulation at the probe site.
- Change the probe site at least every 24 hours to allow the skin to breathe.
- Incident light may cause inaccurate readings. Cover the measuring site with a cloth, if necessary.
- It may not be possible to measure SpO_2 values, if cardiac output is determined at the same time by means of the dye dilution technique.
- It may not be possible to measure SpO_2 values or the pulse rate, if the circulation is impaired (e.g. by a blood-pressure cuff or by an extremely high vascular resistance).
- Remove nail varnish and artificial finger nails before applying the probe. Both may lead to inaccurate readings.
- Do not apply the finger probe to the same arm as the blood-pressure cuff.

Probe Application

Finger Probe

- Insert the patient's forefinger into the probe as far as it will go. Make sure that the finger tip (pad) covers the entire probe window. This is to prevent that extraneous light reaches the photodetector. Use the Y-Universal Probe on patients with very long finger nails.

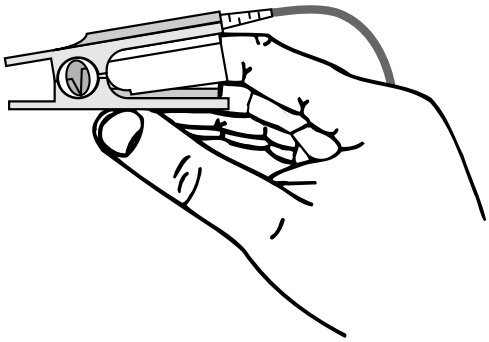


Figure 6-5. Finger probe

Y-Universal Probe for Adults - Finger

- Apply the light source of the probe on top of the finger nail. Align the photodetector such that it is directly opposite the light source. Carefully secure the probe and the lead with adhesive tape. Do not wrap the tape too tight.

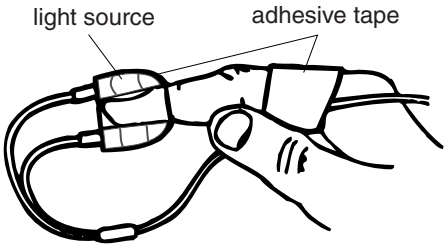


Figure 6-6. Y-universal probe

Y-Universal Probe for Infants - Foot

- Apply the sensor to a well perfused part of the foot with the light source in a top position to prevent that extraneous light reaches the photodetector. Position the photodetector directly opposite the light source. Carefully secure the probe with adhesive tape. Do not wrap the tape too tight.

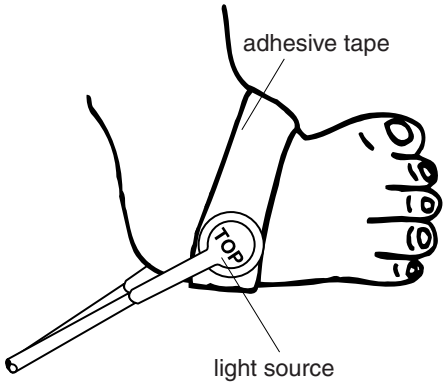


Figure 6-7. Y-universal probe applied to the foot

Y-Universal Probe for Infants - Hand

- Apply the sensor to a well perfused part of the hand with the light source in a top position to prevent that extraneous light reaches the photodetector. Position the photodetector directly opposite the light source. Carefully secure the probe with adhesive tape. Do not wrap the tape too tight.

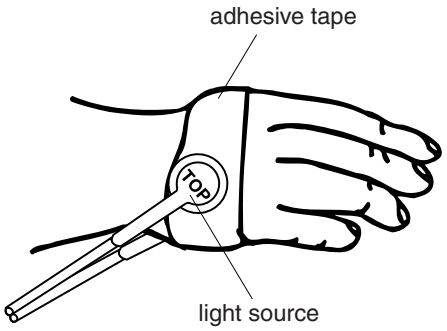


Figure 6-8. Y-universal probe applied to the hand

Wrap-Around Sensor for Children - Toes

- Apply the sensor to the child's toe with the light source on the toe nail to prevent extraneous light from reaching the photodetector. Again, position the photodetector directly opposite the light source. Carefully secure the probe and the lead with adhesive tape. Be careful not to exert too much pressure with the tape.

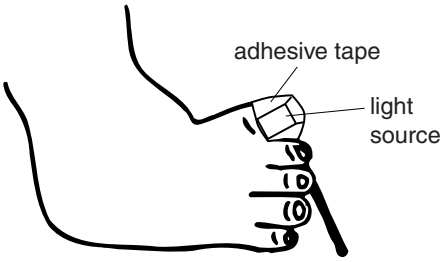


Figure 6-9. Wrap-around sensor for children, applied to the toe

Wrap-Around Sensor for Neonates - Foot

- Apply the wrap-around sensor for neonates to a well perfused part of the foot with the light source in a top position to prevent that extraneous light reaches the photodetector. Position the photodetector directly opposite the light source. Carefully secure the probe with adhesive tape. Do not wrap the tape too tight.

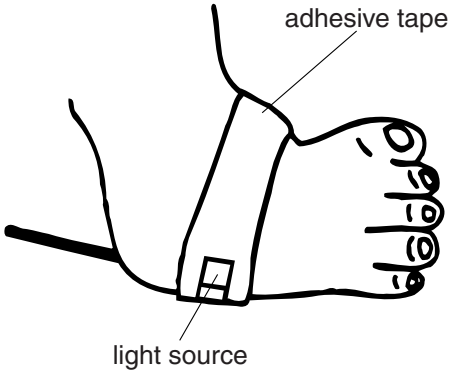


Figure 6-10. Wrap-around sensor for neonates, applied to the foot

Ear Probe for Adults

- To increase the perfusion in the ear lobe, rub it for 1 to 2 minutes (to increase the effect you may apply a 70% percent concentration of isopropyl alcohol). As an alternative you can use a vasodilating cream. Attach the probe to the ear lobe with the light source on the outer side, hooking the bow onto the ear, if desired.

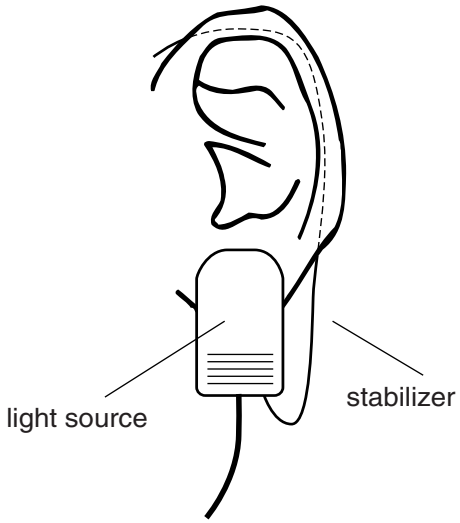


Figure 6-11. Ear probe

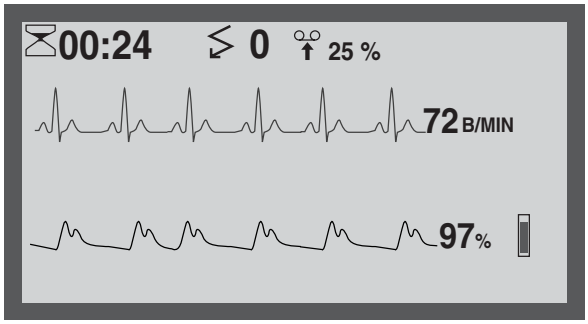


Figure 6-12. SpO_2 window on the display (semi-automatic mode, "ECG Display" option installed)

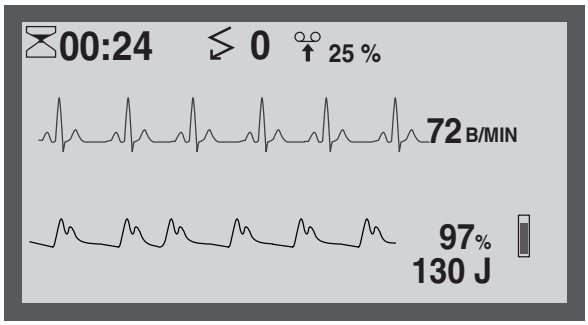


Figure 6-13. SpO_2 window on the display (manual mode)

Displaying the Plethysmogram, SpO_2 Value and Bar Graph

- Apply the probe as described above and connect the lead to connector **3** (blue).
- After approx. 8 seconds you will see

– the plethysmogram,

– the SpO_2 value and

– the bar graph indicating the signal strength

on the display (Figure 6-12).

This window will also show any SpO_2-related system messages.

Messages referring to the operation of the defibrillator (e.g. "Press for analysis") have a higher priority and will therefore briefly hide the SpO_2 window.

In the manual mode the display also indicates the selected defibrillation energy below the SpO_2 value (Figure 6-13).

Note

– The plethysmogram amplitude is not an indicator of signal quality, because the system automatically amplifies small amplitudes. Watch the bar graph and check that the plethysmogram is physiological in shape.

– If an ECG signal is not available, the pulse rate will be indicated instead of the heart rate. The heart symbol blinking with each QRS complex will be replaced by the letter S.

Caution

False Parameter Reading, Patient Safety — To ensure correct SpO_2 readings, the bar graph must never indicate less than 2/3 of the display range.

6.4 Manual Operation

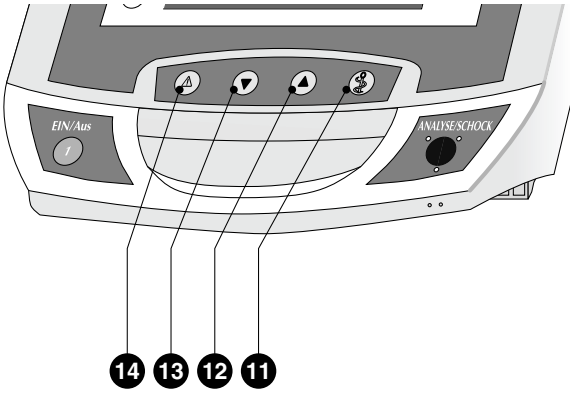


Figure 6-14. Buttons for manual operation of the device

11 *Physician button to enable the manual mode*
12 *Button to increase the defibrillation energy*
13 *Button to decrease the defibrillation energy*
14 *Button to initiate defibrillator charging*

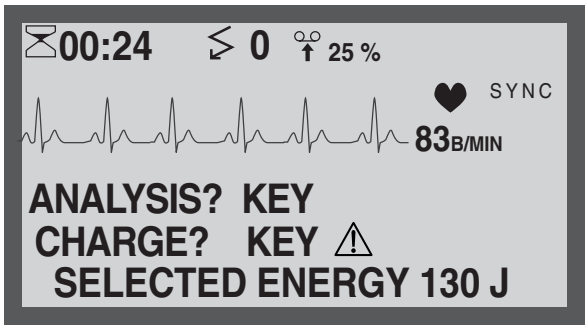


Figure 6-15. Manual mode display

Enabling the Manual Mode

Figure 6-14 shows the additional buttons on devices for manual defibrillation.

Warning
Patient Hazard — Only a physician is allowed to enable the manual mode. Observe the information given in sections 4.1, 4.2 and 4.3.

- To enable the manual mode, press the button and confirm the displayed message by pressing the button again.

Figure 6-15 shows the display of a device operating in the manual mode.

Note
- It is not possible to enable the manual mode while the defibrillator is charged or while the device is analyzing the ECG.
- Enabling the manual mode does not reset the counter for the delivered shocks to "0".
- To return to the semiautomatic mode, turn the device briefly off and on again.

Manual Defibrillation

In the manual mode

- you can still initiate ECG analysis with the red “Analyse/Shock" button,
- you must initiate defibrillator charging with the ⚠ button,
- the device selects the following energy levels:
  defibrillator delivering biphasic shocks
  1st shock: 130 J (or 90 J),
  2nd shock 130 J
  3rd and all subsequent shocks 180 J
  defibrillator delivering monophasic shocks
  1st shock: 200 J,
  2nd shock 200 J (or 300 J),
  3rd and all subsequent shocks 360 J
- the device automatically selects synchronized defibrillation if an ECG signal is available (message SYNC next to the QRS blip, Figure 6-15). The ECG signal can be acquired either via the pads or via ECG electrodes. If an ECG signal is not available, the device will select non-synchronized defibrillation after 3 seconds (message SYNC disappears).

Remember: For synchronized defibrillation (cardioversion) the defibrillation shock is delivered in synchronization with the heart action, because the heart is still working. As a prerequisite, the patient's ECG signal must be supplied to the defibrillator. After the physician has given the "defibrillation command" by pressing the appropriate button, the device will wait for the next QRS complex to derive the trigger signal for actual delivery of the shock.

Caution
No Shock — In the synchronized mode the shock button must be held depressed until the shock has been delivered.

- Apply the pads as shown in Figure 6-16 (STERNUM: right sternal edge at the level of the 2nd intercostal space,
  APEX: left axillary line at the level of the 5th intercostal space; also observe the information given in section 4.4 "Defibrillating a Patient in the Semiautomatic Mode").

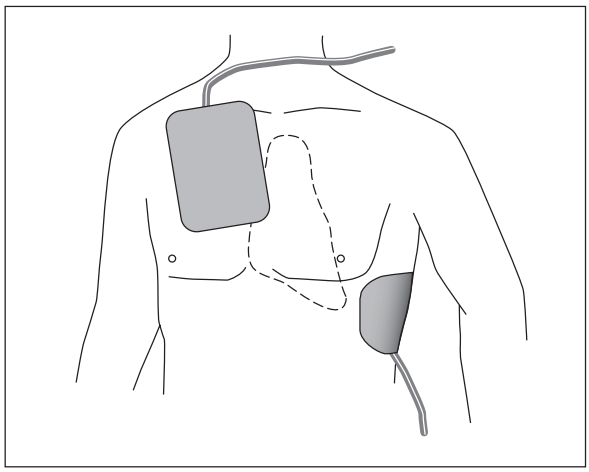


Figure 6-16. Pad application points

- Do not touch the patient any more and press the red “Analyse/Shock” button to initiate ECG analysis.
- When the analysis program detects

– ventricular fibrillation or
– ventricular tachycardia with a rate greater than 180 B/min,

you will see the message "Shock advised, stay away".

- Now select the required defibrillation energy with the buttons ▲ and ▼.

The energy required for successful ventricular defibrillation depends on your patient’s

– age,
– thickness of the tissue, and
– constitution

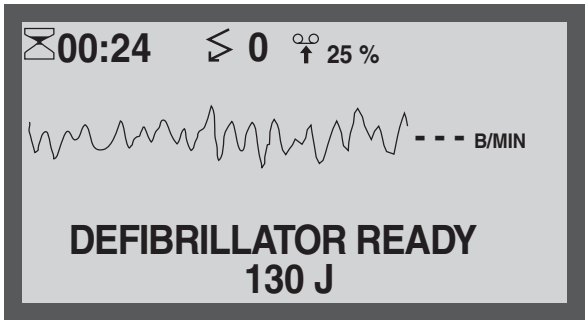


Figure 6-17. Defibrillator ready

Warning
Even if the analysis program does not recommend a shock although you suspect that a shockable arrhythmia exists, the physician can manually charge the defibrillator and trigger a shock.

Please note that children require less energy for successful ventricular defibrillation than adults.

With defibrillators delivering monophasic shocks:

For the first defibrillation shock delivered to babies and small children, select an energy of approx. 2 J/kg body weight. For subsequent shocks, the energy may be increased to 4 J/kg body weight (AHA “Guidelines 2000 for Cardio-pulmonary Resuscitation and Emergency Cardiovascular Care”, page I-64).

With defibrillators delivering biphasic shocks:

For the first defibrillation shock delivered to babies and small children we recommend an energy of approx. 1 J/kg body weight. For subsequent shocks, the energy may be increased to 2 J/kg body weight.

You can choose from the following energy levels:

defibrillator delivering biphasic shocks

1 J, 2 J, 4 J, 6 J, 8 J, 15 J, 30 J, 50 J, 70 J, 90 J, 110 J, 130 J, 150 J, 180 J

defibrillator delivering monophasic shocks

5 J, 10 J, 15 J, 20 J, 25 J, 30 J, 40 J, 45 J, 50 J, 100 J, 200 J, 300 J, 360 J

- Do not touch the patient any more and warn all those present.
- Initiate defibrillator charging with the ⚠ button.

The charging process can be watched on the defibrillator display. When the charge level has been reached,

– the message "Defibrillator ready" and the stored energy will be displayed (Figure 6-17),
– the device emits an audio signal,
– the indicators of the red “Analyse/Shock” button start blinking red.

- Now trigger the shock within the next 20 seconds by pushing the red “Analyse/Shock” button.
- Check the patient's ECG.
- End the therapy as described in chapter 4.

6.5 Transferring Data from a PCMCIA Card

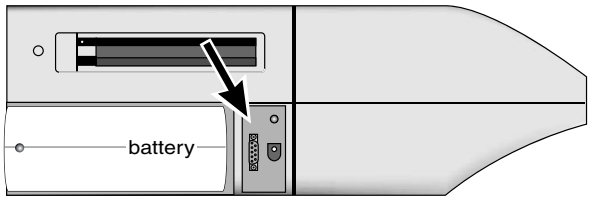


Figure 6-18. Modem port

Figure 6-19. Power-on display

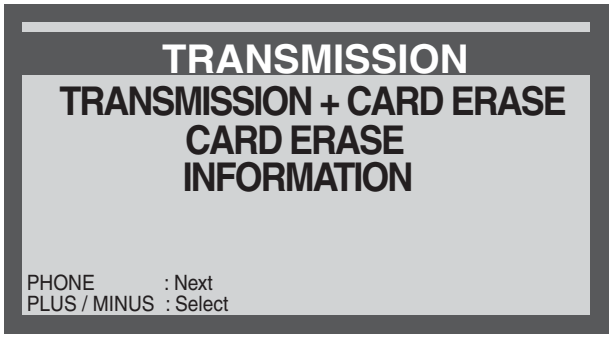


Figure 6-20. Menu

Caution

ECG analysis is not possible while the ECG is being transferred. Therefore, the device should not be connected to the patient any more.

Some Basic Facts

This option allows you to transfer all data stored on the PCMCIA card to a PC either via modem or directly via a data cable (null modem cable).

For the transfer you need either a Hayes-compatible modem, model V90/56 K, or a null modem cable.

The setup menu (chapter 7 "Defibrillator Setup") allows you to enter 3 telephone numbers which the device dials automatically. If the first number is busy, FRED® will try the second number; if this number is also busy, the third number will be used. If the communication link cannot be established, an error message will be displayed (not required if a null modem cable is used).

It takes about 10 to 15 minutes to transfer the data of a full 2-MB card and about 50 minutes for a full 10-MB card.

- Turn off FRED® and connect either the modem or the null modem cable to the modem port (Figure 6-18).
- Either connect the modem to the power line and telephone network or connect the null modem cable to the PC.
- Turn on the modem.
- Simultaneously press ✆ and On/Off 1 to turn on FRED®.

The display shown in Figure 6-19 will appear.

Now you can adjust the contrast. The contrast cannot be adjusted later because the contrast buttons are needed to control the device during data transfer.

- Press the ✆ button.

A menu (Figure 6-20) with the following options appears

– transmission
– transmission + card erase
– card erase
– information (displays information about the last data transfer session)

Figure 6-21. "Call phone number" display

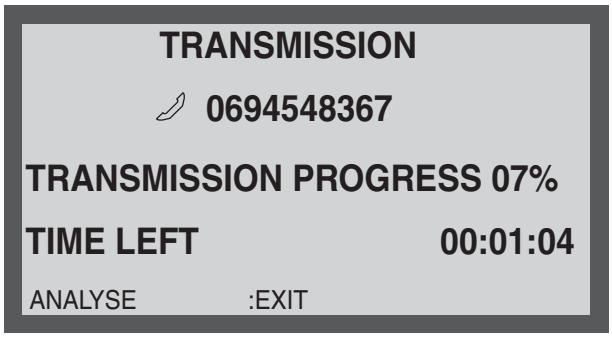


Figure 6-22. Data transmission

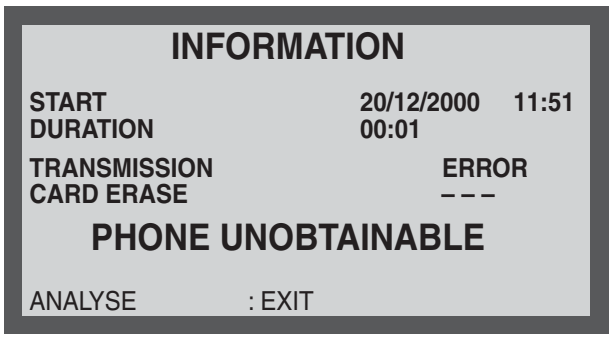


Figure 6-23. Information about the data transmission session

Transmitting Data

- Using the button, select menu item "Transmission" and confirm the selection with .

The modem will be activated and it will dial the first of the three telephone numbers you entered (Figure 6-21).

Once the communication link has been established, the data transmission will begin ("Transmission Progress"). The time required to complete the transmission is always indicated (Figure 6-22).

After the transmission the information about the session will be summarized on the display (Figure 6-23). The transmission time is indicated in hours and minutes.

Erasing the PCMCIA Card

The card erase function is protected with a password. Only persons who know the password are able to erase data. You will be prompted to enter the password after selection of the menu item "Transmission + Card Erase" or "Card Erase".

After you have entered the password (see below) the device either begins transmitting (and then deleting) data or you will see a message informing you that data are being deleted.

✂----------

Enter the password by pressing the following buttons in the order shown:
, +, -, red “Analyse/Shock” button , , +, -, red “Analyse/Shock” button.

6.6 Transmission of the 12-Lead ECG

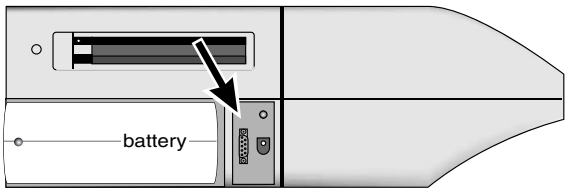


Figure 6-24. Port for cellular telephone

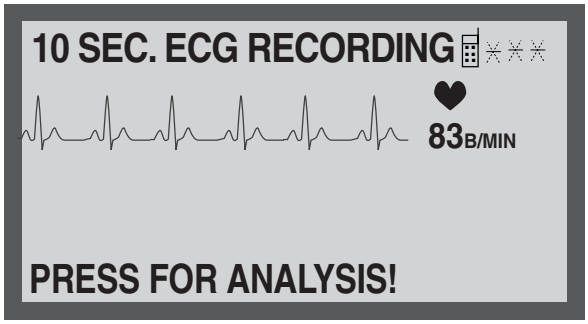


Figure 6-25. Recorded ECG segment

Some Basic Facts

This option allows you to transmit a 10-second segment of the 12 standard ECG leads to a PC via a GSM cellular telephone.

For this type of transmission you need a GSM cellular telephone with integrated Hayes-compatible modem and serial RS232 interface.

In the setup menu (chapter 7 "Defibrillator Setup") you can enter 3 telephone numbers (different from those for data from the PCMCIA card) which the device will dial automatically. If the first number is busy, FRED® will try the second number; if this number is also busy, the third number will be used. An error message will be displayed when the communication link cannot be established.

Transmitting Data

The data transmission takes about 3 minutes.

- Turn off FRED® and connect the cellular telephone to the serial interface (Figure 6-24).
- Turn on the cellular telephone.
- Apply the ECG electrodes as described in section 6.3 and connect them to the device, using a 10-lead patient cable.
- Turn on FRED®.
- When FRED® is in normal mode, press the button.

FRED® will now acquire the ECG for a period of 10 seconds (all 12 standard leads simultaneously) (Figure 6-25). At the same time, FRED® dials the telephone number(s).

Figure 6-26. Number called

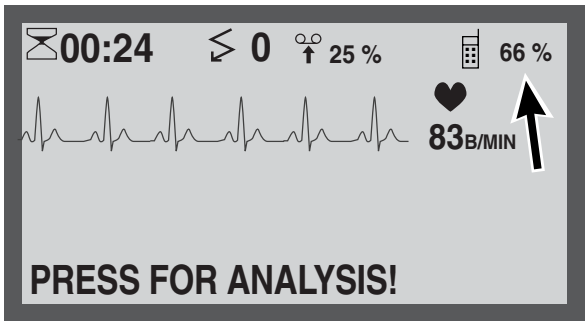


Figure 6-27. ECG transmission status display

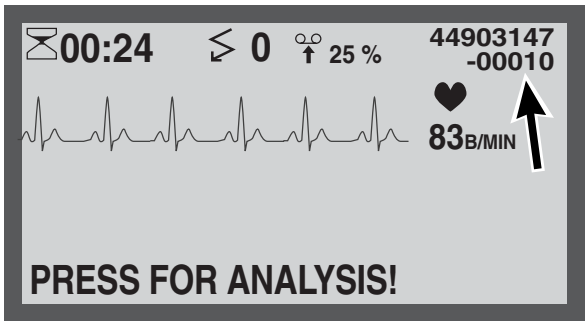


Figure 6-28. Patient ID number

After acquisition of the ECG, the telephone number called appears on the display (Figure 6-26).
Once the communication link has been established, the device starts sending the ECG (Figure 6-27). The transmission status is continually indicated (arrow, Figure 6-27).
After the ECG transmission, the patient ID number is displayed and sent to the PC (Figure 6-28). FRED® generates this patient ID number automatically. The ID is composed of the serial number of the device and a number incremented with each new patient. The number increments only when FRED® was turned off for at least 5 minutes between two patients.

7 Defibrillator Setup

Displaying the Setup Menu

The defibrillator has a setup menu which allows you to permanently adjust many of the device functions to your preferred settings and to save them.

- To access the setup menu, turn on FRED® by simultaneously pressing the buttons and On/Off 1.

The display shown in Figure 7-1 will appear.

Figure 7-1. Power-on display

Now you can adjust the contrast. The contrast cannot be adjusted later because the contrast buttons are needed to control the device during setup.

- Press the button.

A menu with the following options appears (Figure 7-2).

– Configuration (device setup)
– Factory Default (select to restore the factory defaults)
– Identification (for service only)
– Phone (select to enter the telephone numbers for data transfer via modem)

All menu items are password-protected (see bottom of page 34).

Configuration

- Using the button, select menu item "Configuration" and confirm the selection with .
- Enter the password.

The Configuration menu appears for setup of the device (Figure 7-3).

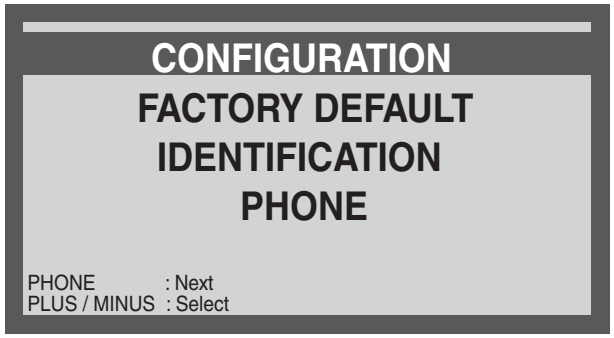


Figure 7-2. Menu

The operating steps for setup of the device are always the same:

- With you position the bar cursor on the item to change and make the adjustment with + and -.

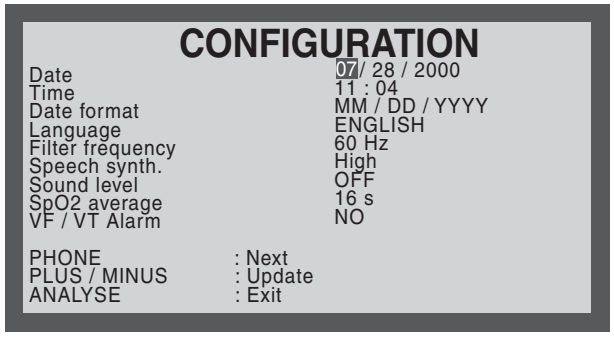


Figure 7-3. Configuration menu

Example:

You would like to choose another language.

- Press repeatedly until the bar cursor highlights the current language.
- Use + or - to select the new language.
- Once you have made all necessary changes, press the red “Analyse/Shock” button to exit the configuration menu.

Device Settings [Factory Defaults]

Date	enter day, month, year (format DD / MM / YY) or month, day, year (format MM / DD / YY)
Time	enter hours, minutes
Date format	choose the date format (DD / MM / YY or MM / DD / YY)
Language	choose the language
Filter frequency	frequency of the AC line filter (50 Hz, 60 Hz)
Speech synthesis	select to enable and disable the voice prompts and to adjust the volume (off, [high], middle, low)
Sound level	select to adjust the volume of alarm tones and of the QRS beep ([off], high, middle, low) "off" means: no QRS beep, but low volume for alarm tones
SpO_2 average	SpO_2 averaging (integration) time ([16], 8 s)
VF/VT	select if you wish to be alerted to ventricular fibrillation and tachycardia (HR greater than 180 B/min) in manual mode

Restore Factory Defaults

The menu item "Factory Default" allows you to restore the factory defaults (in the table at left the factory defaults are shown in angular brackets [ ]). The function does not affect these settings:

– Date
– Time
– Date format
– Language
– Filter frequency

These settings will not be restored.

Entering the Telephone Numbers for Data Transmission

The menu item "Phone" allows you to enter six telephone numbers which the device will dial automatically (three numbers for transmission of the data from the PCMCIA card and three numbers for transmission of the 12 standard ECG leads). In addition, you can enter 2 initialization sequences for the modem: one sequence for the external modem (transmission of the data from the PCMCIA card), one sequence for the modem integrated in the cellular telephone (transmission of the 12 standard ECG leads).

When you have entered the password, the entry screen will appear (Figure 7-4).

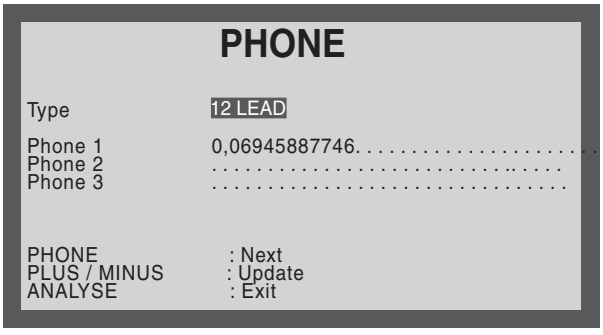


Figure 7-4. Screen for entry of the telephone numbers

At "Type" you can choose among four different entries:

CARD	select to enter three different telephone numbers for transmission of the data from the PCMCIA card
12 LEAD	select to enter three different telephone numbers for transmission of the ECG
CARD Hayes	select to enter the initialization sequence for the PCMCIA modem (required only if the default sequence does not work)
12 LEAD Hayes	select to enter the initialization sequence for the cell phone modem (required only if the default sequence does not work)

Entering the Telephone Number

- Using + or -, select either "CARD" or "12 LEAD".
- Use to move the cursor to the position for entry of the first digit (or to the position whose digit you want to change).
- Using + or -, choose the digit you want to enter. The comma sign "," is used to enter a pause, required to access the outside line.
- The red “Analyse/Shock” button is used to delete the entire telephone number.
- When you have entered the full telephone number, position the cursor on "Type" and press the red “Analyse/Shock” button to quit the function.

Entering an Initialization Sequence

- Using + or -, select either "CARD Hayes" or "12 LEAD Hayes".
- Using move the cursor to the position whose character you want to change.
- Use + or – to choose the character and enter the Hayes sequence (separation by blanks). Do not enter the prefix AT because FRED® adds it automatically (for the Hayes sequence, please refer to the instruction manual that comes with your modem or cellular telephone).
- With the red “Analyse/Shock” button you can delete the entire sequence (for safety reasons, you must press the button twice).
- When you have entered the full sequence, position the cursor on "Type" and press the red “Analyse/Shock” button to quit the function.

8 Technical Specifications

Defibrillator (biphasic)

- Defibrillation energy levels in manual mode (delivered into 50 ohms):
  1 – 2 – 4 – 6 – 8 – 15 – 30 – 50 – 70 – 90 – 110 – 130 – 150 and 180 Joules
- Defibrillation energy levels in semi-automatic mode (delivered into 50 ohms):
  either 130 – 130 – 180 Joules
  or 90 – 130 – 180 Joules
- Error:
  ± 15 % or ± 2 J
- Capacitor charge time with full (rechargeable) battery after 15 shocks of 180 Joules:
  6 s

Defibrillator (monophasic)

- Defibrillation energy levels in manual mode (delivered into 50 ohms):
  5 - 10 – 15 – 20 – 25 - 30 – 35 – 40 -- 46 – 50 – 100 - 200 - 300 and 360 Joules
- Defibrillation energy levels in semi-automatic mode (delivered into 50 ohms):
  200 – 200 – 360 Joules
  or 200 – 300 – 360 Joules
- Error:
  ± 15 % or ± 2 J
- Capacitor charge time with full (rechargeable) battery after 15 shocks at 180 Joules:
  8 s

- Operating modes:
  semiautomatic defibrillation
  synchronized defibrillation
  non-synchronized defibrillation
- Synchronization:
  shock released 20 ms after R-wave
- Energy indication:
  indication of the selected and charged energy on the display, audible and visual "charge done" indication
- Energy selection
  automatic or manual with buttons
  - Safety discharge:
    – 20 s after charging
    – if battery charge level is insufficient
    – if device is defective
    – 160 ms after shock
    – when device is turned off
- Defibrillation electrodes:
  disposable adhesive defibrillation electrodes (pads)
- Connection for defibrillation electrodes:
  type BF

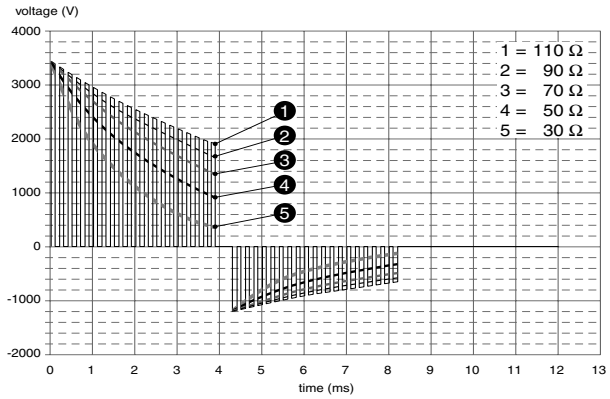


Figure 8-1. Discharge curves at 180 Joules (biphasic)

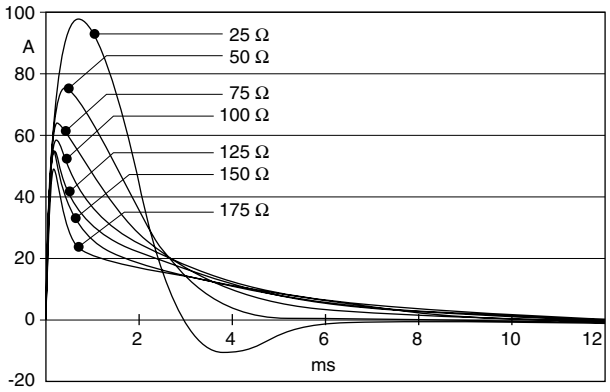


Figure 8-2. Discharge curves at 360 Joules (monophasic)

VT / VF Detection

- Shock advised:
  in the presence of VF and VT (VT > 180 B/min)
- Sensitivity: 98.8 % (AHA and MIT)
  Specificity: 99.97 % (AHA and MIT)
- Conditions for ECG analysis:
  minimum amplitude for signals suitable for analysis > 0,20 mV
  signals < 0.2 mV are considered as asystole
- Definition:
  Sensitivity: correct identification of a shockable rhythm
  Specificity: correct identification of **non**-shockable rhythms.

Display

- LCD, 130 x 70 mm, alphanumeric presentation of measuring values and device settings, display of symbols, of the ECG (option) and of the plethysmogram (option)
- Sweep speed:
  25 mm/s (± 5 %)

ECG Signal Input (optional)

- Input without electrical connection to the applied part (type CF), defibrillation-proof, monitoring of the electrode-to-skin contact impedance
- Input impedance:
  > 2.5 Mohms
- DC input voltage:
  ± 1 V max.
- Patient leakage current:
  < 0.1 µA
- Frequency range:
  0.5 to 40 Hz (- 3 dB) with 3-lead and 4-lead patient cable
  0.05 to 150 Hz (-3 dB) only with 10-lead patient cable
- Common-mode rejection:
  > 100 dB
- Control range:
  ± 5 mV
- Recovery time after defibrillation shock:
  6 s

Heart Rate Indication

- Heart rate indication:
  with digits
- Measuring range:
  10 B/min to 300 B/min
- Error:
  ± 5 B/min
- Minimum amplitude for triggering:
  0.2 mV
- Minimum QRS width:
  5 ms
- Baseline correction after overranging:
  after 200 ms

Memory

- Storage of ECG (5 h max.) and code-related events (500 max.) on 2-MB PCMCIA memory card
  or (option)
  storage of up to 0.5 hours of ECG data, 0.5 hours of ambient noise, 500 events on 10-MB PCMCIA memory card
- The multimedia system FREDWARE or the SAED Reader Pro software is needed to read the PCMCIA memory card.

SpO_2 Measurement

- Type CF signal input, defibrillation-protection by probe
- Probe:
  finger or Y-probe
- Measuring range:
  0...100 %
- Recovery time after defibrillation shock:
  8 s or 16 s (as configured)
- Error:
  70 to 99 % O_2: ± 2 %
  50 to 69 % O_2 ± 3 %
- Integration time
  8 or 16 s
- Signal strength indication:
  with bar graph
- Amplitude adjustment:
  automatic

Power Supply

Internal Power Source (slot-in rechargeable battery)

- NiCd, 12 V, 2.4 Ah
- Sufficient for 2.5 hours of monitor operation or 110 shocks of 180 J each
- Charging with FRED® AC power adapter
- Charge time:
  20 hours to reach 80 % of its capacity,
  27 hours to reach 100 % of its capacity

or

from slot-in lithium battery

- Sufficient for 5 hours of monitor operation or 450 shocks of 180 J each (at 20 °C)

or

- After 1 year of daily functional tests and device not used: sufficient for 2 hours of monitor operation or 150 shocks of 180 J each (at 20 °C)

or

- After 5 years of storage (at 20 °C) in the original case sufficient for 4.5 hours of monitor operation or 400 shocks of 180 J each

Operational Readiness

- Immediately after automatic power-on test

Environment

- Transport/storage:
  temperature –30 to + 50 °C
  relative humidity 30 to 95 %, no condensation
  atmospheric pressure 500 to 1060 hPa
- Operation:
  temperature 0 to + 50 °C
  relative humidity 30 to 95 %, no condensation
  atmospheric pressure 700 to 1060 hPa
  protection category IP 23 (inside instrument bag)
  IP 20 (outside instrument bag, charger connected)

Dimensions and Weight

- width 260 mm
  depth 255 mm
  height 90 mm
  weight 4.2 kg (with battery and accessories)

9 Order Information

Part No.	Description
FREDBI	FRED®, basic device, biphasic
FRED	FRED®, basic device, monophasic

Accessories

Defibrillation

W1410241	Disposable adhesive defibrillation electrodes for adults (1 pair)
W1404262	Disposable adhesive defibrillation electrodes for children (1 pair)

ECG

U50063	ECG patient cable. 4-lead cable (red, yellow, green, black), elbow connector, with clip connection
W1409608	ECG patient cable. 3-lead cable (red, yellow, green), elbow connector, with clip connection
W1402037	ECG patient cable. 10-lead cable, elbow connector, with clip connection
72365	Adhesive ECG electrodes for adults, 34 mm diam., 50/case

SpO_2 Measurement

U50153	Finger probe
U50106	Y-probe
U50105	Oxilink for Y-probe
W1401977	Flexible probe for neonates
W1402254	Flexible probe for children
W1402377	Disposable finger probe for adults, 10/case
W1402378	Disposable probe for body weight between 15 and 45 kg, 10/case
W1402379	Flexible disposable probe, hand/foot, for body weight between 3 and 15 kg, 10/case
W1402380	Flexible disposable probe, hand/foot, for body weight < 3 kg, 10/case
W1401994	Disposable fixation straps for SpO_2 probes, 40/case
U50072	Extension cable, 1.5 m

General Accessories

W1405387	User's Manual
BUFRLI	Lithium battery
BUFRNC	NiCd battery, 12 V, 2.4 Ah
W1405308	Accessory bag
W1405309	Carrying bag
W1411876	PCMCIA card, 2 MB
W1411877	PCMCIA card, 10 MB
W1405307	Wall-mount system (for cars)

Literature

1. American Heart Association: **Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care**. ISBN 0-87493-325-0.
2. European Resuscitation Council (1998): **Guidelines for Resuscitation**. ISBN 0 444 82957 1.
3. Jost D. et al. (1998) **Expérience française de la défibrillation semi-automatique**. JEUR 3: 124-131.

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