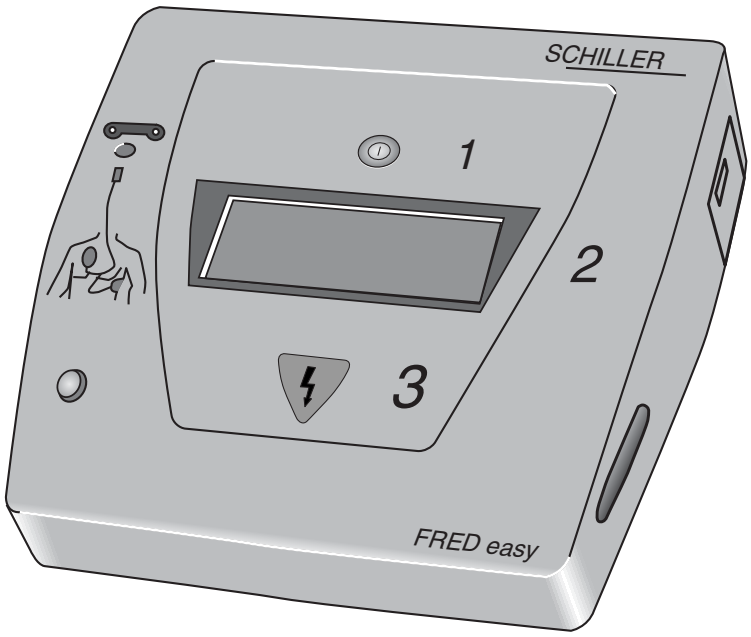
FRED easy®

Automated External Defibrillator (AED)

User Guide



CE - 0459

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THE ART OF DIAGNOSTICS

Part No. 0-48-0013

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General Information

- **FRED easy®** 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 I of this directive. **FRED easy®** is a class IIb device.
- 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 CISPR 11 standard.
- The user guide is an integral part of the device and should always be kept near the device. Close observance of the information given in the user guide is a prerequisite for using the device as intended for and correct operation and ensures patient and operator safety. **Therefore, be sure to read the complete user guide.**
- To ensure patient safety, the specified measuring accuracy, and interference-free operation, we recommend to use only original SCHILLER accessories. The user is responsible if accessories from other manufacturers are used. 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 manual.
- The customer is responsible, if the device is employed in a manner different from the method described in this manual.
- On request SCHILLER will provide a detailed field service manual.
- The manufacturer is only liable for SCHILLER-supplied accessories.
- The user guide informs the device operator about the intended use, exact function, operation and required preventive maintenance. It is not a substitute for product training.
- 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 or product/property damage.

- This manual conforms 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 ISO 9001 and ISO 13458.
- No part of this manual may be reproduced without written permission from SCHILLER.

Manufacturer

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1 Intended Use

FRED easy® is an automated external defibrillator (AED).

AEDs are devices for semiautomatic defibrillation by non-medical staff. They are particularly easy to operate and their use is relatively harmless for both the patient and the operator.

FRED easy® is also available as an automatic external defibrillator.

Note

This document describes the semiautomatic version of **FRED easy®**. Refer to section 6.4 for information on operating the device in the automatic mode.

The regulations governing the use and training requirements for AEDs such as **FRED easy®** differ from country to country. The local laws and regulations must be observed in each case.

Note

The laws and regulations for the use of AEDs differ from country to country. While some countries allow laypersons to use AEDs without any special training, other countries restrict the use of AEDs to EMTs or First Responders after they have undergone a special training. For teaching purposes, we offer the **FRED easy® TRAINER** version.

Typical sites for the installation of **FRED easy®** units would be much-frequented buildings such as

- airports
- railway stations
- shopping malls
- public swimming pools
- sports centers
- municipal/public offices

Biocompatibility

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

2 Product Description and Function

Product Description

FRED easy® is a battery-powered, automated, external defibrillator that delivers biphasic defibrillation pulses.

The patient is defibrillated via disposable adhesive electrodes (pads) which also acquire the ECG signal for analysis. The operator can choose between adhesive electrodes for children and for adults. The device identifies the connected electrode type and automatically preselects the corresponding energy levels for defibrillation.

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

The intervention is documented on a memory card that records the ECG, speech and events (see section "Intervention Summary" on page 21).

The device is powered by a plug-in, disposable lithium battery. The battery capacity is sufficient for

- 180 shocks at maximum energy or
- 6.5 hours of monitoring (alternately 30 minutes ON and 30 minutes OFF) or
- 5 years standby operation.

As an alternative, we can supply a rechargeable NiCd battery. When new or fully charged, its capacity is sufficient for

- 45 shocks at maximum energy or
- 80 minutes of monitoring

Our customer service can configure various device functions via a special PC connection (see section “Functional Description”).

Variants and Options

Semiautomatic Defibrillator

Equipment Models

- standard version
- Ethernet version (data transmission via Ethernet, see section "6.4)
- Online version (Online communication via SNMP protocol, see section 6.5)
- automatic version (automatic defibrillator, see section 6.6)

Options

- ECG display (see section "ECG Display", page 22)
- conversion to manual defibrillation (see section "Manual Defibrillation", page 22)
- Metronome (see section 6.3)

Functional Description

Ensure Operational Readiness

As soon as a battery is inserted, **FRED easy®** runs a self-test of the device and the battery. If this test does not reveal any problems, the green indicator starts blinking to indicate that the device is ready for operation, and the displayed information disappears. The device also runs a self-test each time it is turned on.

If the device identifies a problem during these self-tests
- it emits an alarm tone
- the green indicator does not blink.

The alarm tone continues until the battery is depleted. With the ⏻ button (arrow, Figure 2-1) the self-test can be repeated and the corresponding error message will appear.

In addition, the device runs a self-test every 7 days; this self-test is announced by a beep. If the device identifies a problem during this self-test
- it emits an alarm tone
- the green indicator does not blink.

When equipped with the optional NiCd battery, the device runs a daily self-test.

By pressing the ⏻ key (arrow, Figure 2-1) you can view the corresponding error message.

In this situation a new self-test must be initiated by insertion of a battery. Depending on the result of the self-test, the error message will disappear or a new one appears.

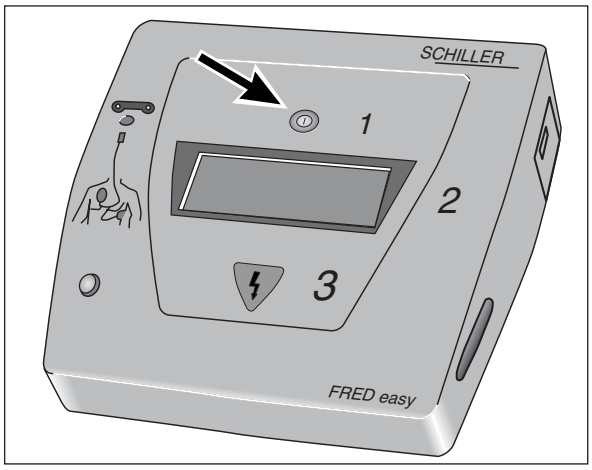


Figure 2-1. FRED easy®, button to turn the device on and off and to initiate the analysis

Defibrillation (semiautomatic defibrillator)

The operator is informed of each operating step by voice and text which is displayed on the screen.

After activation of the ⏻ button, an introductory text tells the operator what to do, if the patient is unconscious or does not breathe.

FRED easy® will continue repeating this introductory text until defibrillation pads are attached to the patient. The device can also be configured to skip the introductory text and to prompt the operator immediately to attach the pads.

After that **FRED easy®** will ask the operator to start ECG analysis and warns not to touch the patient any more. The analysis takes approx. 10 seconds. Depending on its configuration, the device may automatically start the ECG analysis.

Note

- With signals from the AHA (American Heart Association) database, **FRED easy®** achieved a detection accuracy of 98.43 % (sensitivity) and 99.80 % (specificity).
- The device may be configured to automatically start the ECG analysis.

Device identifies a shockable rhythm

If the analysis algorithm identifies a shockable rhythm, the device will automatically charge the required defibrillation energy and, when charged, prompts the user to deliver the shock.

Shockable conditions are

- ventricular fibrillation or
- ventricular tachycardia with a rate greater than 180 B/min.

If the algorithm detects a shockable rhythm, the shock may still only be released if the patient does not show any signs of circulation.

After an unsuccessful shock **FRED easy®** prompts the user to perform CPR for two minutes (in Norway: three minutes): 30 chest compressions to every two breaths.

Warning

Patient Hazard — In the treatment of children only 15 chest compressions must be performed to every two breaths.

After these two (three) minutes, the device again prompts the user to start ECG analysis. The device may be configured to automatically restart analysis.

If the device again detects a shockable rhythm, it will automatically charge the defibrillation energy necessary for the second or third shock. For all subsequent shocks the energy remains fixed at the level of the third shock.

Note

The energy levels can be set to the default values or the SCHILLER customer service can adjust customer-specific energy settings (see 9 „Technical Specifications“).

After a successful shock **FRED easy®** prompts the user to perform CPR (30 chest compressions to every two breaths) until the patient starts breathing or until new instructions are given.

Device identifies no shockable rhythm

If the algorithm does not identify a shockable rhythm, **FRED easy®** informs the user that a shock is not necessary and prompts to perform CPR (30 chest compressions to every two breaths) until the patient starts breathing or until new instructions are given.

Configurable device parameters

The SCHILLER customer service can configure the following device parameters:

- upon power up: introductory text or immediate prompt to apply the defib pads
- volume of the voice prompts
- energy levels for the 1st, 2nd and 3rd shock, separate adjustments for adults and children
- initiation of ECG analysis with button or automatic
- activation/deactivation of a 16.7-Hz filter

3 Controls and Indicators

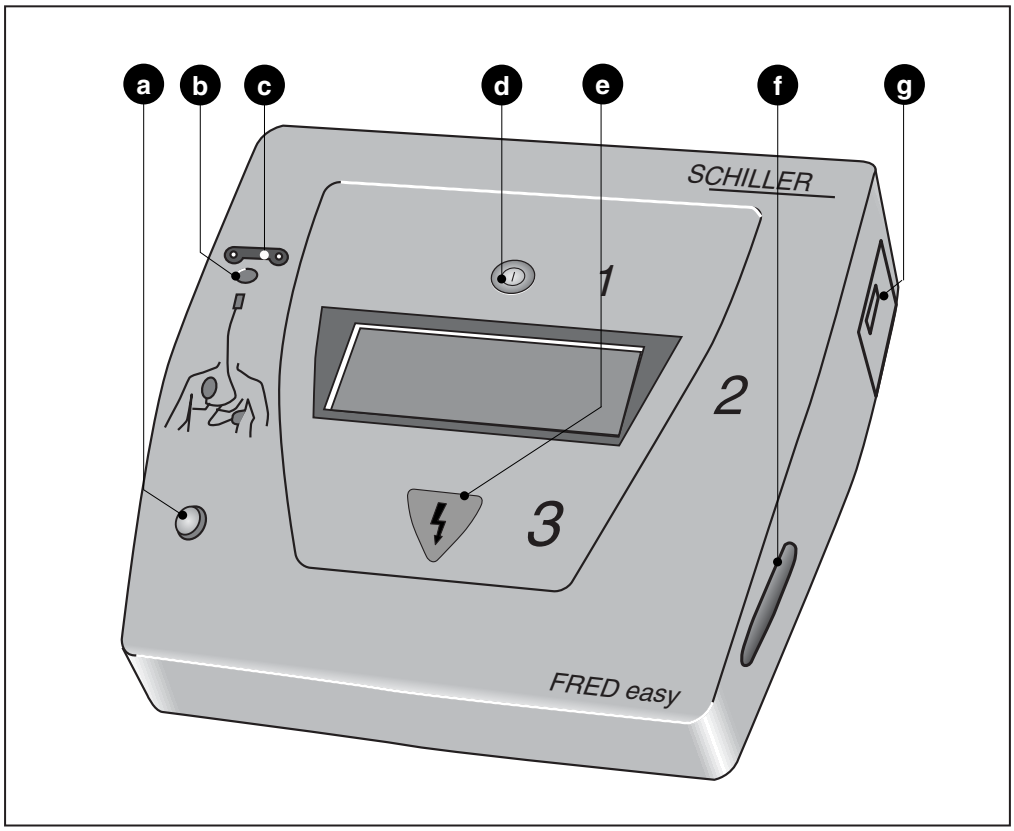


Figure 3-1. Controls and indicators

- *a Green indicator blinks when device is ready for operation*
- *b Yellow indicator is illuminated while no pads are connected*
- *c Connection for defib pads*
- *d Green ⏻ button to turn the device on and off and to initiate the analysis (press the button only briefly, if you wish to initiate an analysis; otherwise you would turn the device off)*
- *e Button to trigger the defibrillation shock*
- *f Memory card*
- *g Battery*

*Figure 3-2. **FRED easy®** for semiautomatic and manual defibrillation*

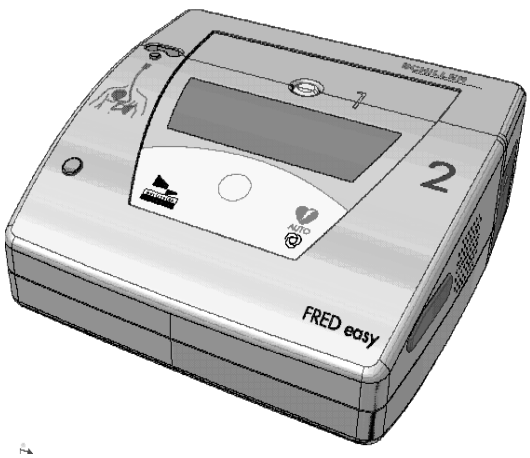
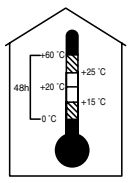


*Figure 3-3. **FRED easy®** for automatic defibrillation*

Explanation of Symbols

Symbols on the device and accessories

	Type BF signal input, defibrillation-proof
	Caution! High Voltage!
	Defibrillation pad expiration date
	Consult accompanying documents
	Open defib pad package
	Peel off protective foil
	Disposable item, do not reuse
	Do not bend packing
	Storage temperature range for the electrodes
	Product is recyclable
	Do not dispose of with household waste, separate disposal required
	Do not recharge
	Do not short-circuit
	Do not incinerate
	Do not destroy with a saw
	Do not destroy
	Unlimited storage between +15 °C and +25 °C, storage for 48 hours max. between +25 °C and +60 °C and between +15 °C and 0 °C

Symbols used on the display

	Number of shocks delivered since device was turned on
	Battery capacity
	Memory card
	Memory card not identified
A	Adult pad identified
C	Pediatric pad identified
	Time elapsed since device was turned on (minutes, seconds)

4 Putting the Device into Operation and Functional Test

4.1 Safety Information

Danger

Explosion Hazard — **FRED easy®** is not designed for use in areas 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 flammable anesthetics.
Oxygenation in the vicinity of the defibrillation electrodes must be strictly avoided.

Oxygen concentrations below 25% of the ambient air are not considered dangerous. Dangerous, high oxygen concentrations can only occur in oxygen masks or in enclosed areas, such as hyperbaric chambers.

Warning

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

- **FRED easy®** is a high-voltage electrotherapy device. Only authorized personnel is permitted to use these devices. Improper use of the device can endanger life. Always follow the instructions given in this user guide.
- Before using the device, the operator is required to ascertain that it is functioning correctly and in good operating condition. In particular, the cables, connectors and electrodes must be inspected. Damaged parts must be replaced immediately, before use.
- The operator is required to ensure that during ECG analysis and defibrillation there is no conductive connection between the patient and other persons.
- 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 manufacturers concerned or other informed experts must be contacted 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. Standard IEC 60601-1-1 must be complied with in all cases.
- The device is suitable for application in a humid environment provided the regulations concerning splash-proof equipment of IEC 60601-2-4 are strictly observed.

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 equipment away from these devices and verify its performance before use.
- If the devices are used in the vicinity of power networks operating at a frequency of 16.7 Hz (railway systems in some countries), the 16.7-Hz filter should be activated via the configuration menu. The filter should be turned off, when the device is not used in the vicinity of these networks.

Warning

- Equipment Failure — 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 easy®** is an emergency device and must be ready for operation at any time and in all situations. Ensure that the device is always equipped with a charged battery and always have a spare battery at hand.
- Suffocation Hazard — Dispose of the packaging material, observing the applicable waste-control regulations. Keep the packing 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, the distance between the defib pads and the HF surgery electrodes should not be less than 15 cm. If this is not ensured, disconnect the electrodes and transducer leads while using the HF surgery device.
- Disconnect all transducers and devices that are not defibrillation-proof from the patient before defibrillation.

4.2 Inserting the Battery

Figure 4-1. Inserting the battery

Warning

Shock Hazard — When the green indicator blinks, the device is ready for operation. In addition, the cables, connectors and electrodes must be visually inspected on a regular basis. If problems are identified which may impair the patient's or operator's safety, the device must be repaired before it can be used again.

Warning

Erroneous capacity indication —

- Replace the battery when the device indicates a battery problem. In some cases the device may continue to operate with the old battery but the indicated capacity may be incorrect.
- **Turn off the device** before removing an intact battery. Otherwise the device is unable to determine the exact capacity when the battery is reinserted and will report "ERROR BATTERY", which makes the battery useless.

Caution

Equipment Damage — Use the connector in the battery compartment for service purposes only.

The device is normally powered by a disposable lithium battery. As an alternative, a rechargeable NiCd battery can be used (see section 4.3 "NiCd Batteries").

With the lithium battery, the device is ready for operation for a minimum of 5 years (including the weekly functional test), provided it is not used on a patient.

Each time the device is turned on it checks the battery and indicates the remaining capacity on the display.

After five years – if the device has not been used on a patient – the battery must be replaced with a new one.

Insert the battery as shown in Figure 4-1. Verify that

- the battery label faces up
- the battery clicks audibly into place.

As soon as a battery is inserted, **FRED easy®** runs a self-test of the device and the battery.

If there are no problems with the device and the battery, the green indicator starts blinking to indicate that the device is ready for operation, and the displayed information disappears.

Note

- Do not expose **FRED easy®** to direct sunlight or temperature extremes. The ambient temperature should be between 0 and 50 °C. Higher or lower temperatures adversely affect the life of the battery.
- **FRED easy®** automatically monitors the battery capacity. When the capacity drops below the minimum level
  - an alarm tone sounds
  - the green indicator stops blinking.

Warning

Erroneous capacity indication — Do NOT use the Lithium battery to power the **FRED easy® TRAINER** device, because this device does not monitor the battery capacity.

Note

If the device is turned off for less than 5 minutes (e.g. to replace the battery), all data remains stored and, after the self-test, the device continues to operate as if it had never been turned off.

4.3 NiCd Batteries (Option)

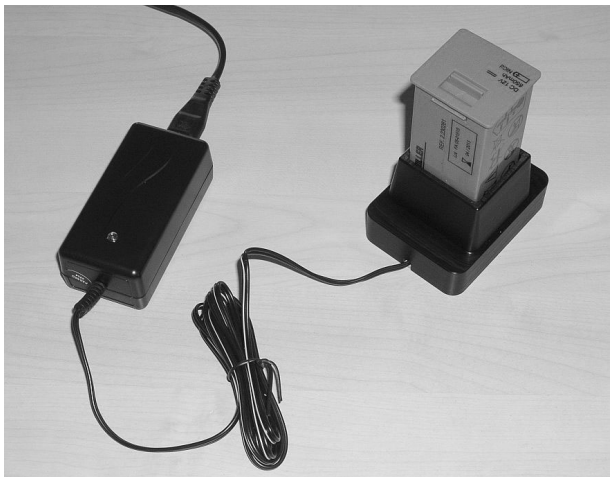


Figure 4-2. Charging unit

As an alternative a rechargeable NiCd battery (12 V, 650 mAh) is available for the defibrillator. The capacity of a new, fully charged battery is sufficient for

- 45 shocks at maximum energy or
- 80 minutes of monitoring

With this type of battery, however, the remaining capacity is not indicated. The symbol appears when a battery is inserted; it starts blinking when the capacity reaches a given minimum value. Replace the battery in this case and recharge.

Note

The battery symbol appears only when the device is equipped with a new version of the CPU board (these boards have a 12-digit serial number).

To recharge these batteries, use the charging unit with part no. 3-55-0030. The charging time is 1 hour maximum.

When equipped with the NiCd battery, the device runs a daily self-test.

5 Defibrillation

5.1 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.

Non-medical staff is permitted to use an AED such as **FRED easy®** only if local jurisdiction approves of this practice. Make sure that **FRED easy®** is only accessible to persons who are legally authorized to use an AED.

Warning

Risk for patients, users and assistants —

- Position the patient flat on a surface which is not too soft and where he is 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.
  For safety, wipe off flammable skin cleansing agents.
- 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
  - heart massage and artificial respiration 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 defib pads near the pacemaker,
  - have an external pacemaker at hand,
  - check the implanted pacemaker for proper functioning as soon as possible after the shock.
- Risk of Skin Burns — Owing to the high currents, there is a risk of skin burns.

Note

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

5.2 Safety Information for the Use of an AED

In addition to the guidelines set forth in section 5.1, the following rules must be observed when using an AED. Failure to do so may compromise the success of the defibrillation or endanger the patient's life.

Warning

- Patient Hazard — Only patients without response, respiration and signs of circulation may be defibrillated with an AED.
- During ECG analysis
  – suspend CPR
  – ensure that the patient lies as motionless as possible
  – 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 an AED are met:
  - no response,
  - no respiration,
  - no signs of circulation.

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.

Special notes for devices with automatic ECG analysis

Caution

Risk for patients, users and assistants —

With these devices it is not necessary to initiate the ECG analysis with the green button. The "analysing" status is indicated in written and audible form. To achieve a correct analysis, do not touch or move the patient during the analysis.

Danger

Patient Hazard —

- Touching or transporting the patient during analysis may impair the analysis. A valid analysis result can only be obtained when the patient does not move and is not touched while the analysis is in progress.
- An ECG signal disturbed by CPR measures may cause an incorrect analysis. For this reason, heart massage and artificial respiration must be suspended during the analysis. The patient must not be touched during analysis and shock delivery.

5.3 Defibrillating the Patient

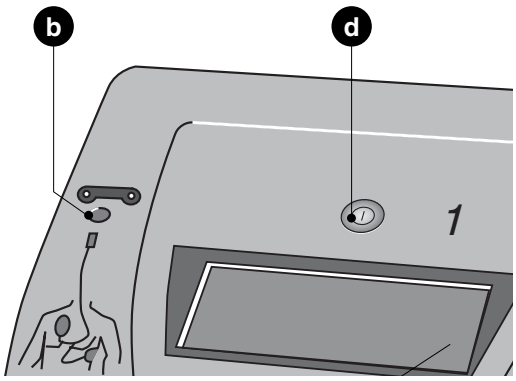


Figure 5-1. Operating controls

d Button to turn the device on

b Indicator is illuminated when the defibrillation pads are not connected and/or not attached to the patient

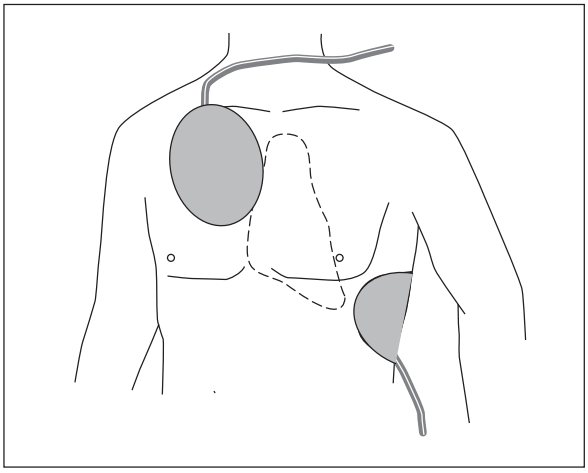


Figure 5-2. Pad application points
(+): right sternal edge at the level of the 2nd intercostal space,
(-): left axillary line at the level of the 5th intercostal space)

Warning

Risk of Skin Burns / Equipment Damage — Do not apply the defibrillation pads over

- sternum or clavicle
- nipples
- implanted pacemaker or defibrillator devices.

Poor Electrode Contact — Sea water, sand and sunscreen products may impair electrode contact or the electrodes may become disconnected.

Turn on the device by briefly (1 second maximum) pressing the ⏻ button (**d**, Figure 5-1). The device emits a beep upon power on. Then the defibrillator addresses the operator with an introductory text and prompts the operator to determine the patient status. When no signs of circulation can be identified, the device prompts the operator to apply the defib pads.

The introductory text will be repeated until the device detects the applied defib pads.
The device may also be configured to skip the introductory text. In that case, the operator will be asked to apply the defib pads immediately after turning the device on.
Furthermore, the electrode indicator (**b**, Figure 5-1) is illuminated to signal that defib pads must be attached to the patient and connected to the device.

Applying the Defib Pads

For use with an AED, the defibrillation electrodes (pads) should be applied on the apex and sternum as usual. However, you may choose the anterior-posterior positions to avoid shorting the pads together, e.g., when defibrillating small children.

- Before applying the pads, check the application points on the patient's chest (Figure 5-2); they must be clean and dry. Then clean the skin by rubbing the application points vigorously with a dry cloth. Do not use alcohol or alcohol wipes. This could increase the contact impedance. Shave, if the patient's chest is hairy.
- Apply the STERNUM pad (+) above the right nipple. Do not apply the pad on the clavicle (uneven surface).
- The applied pads must have good contact with the patient's skin. Air bubbles under the pad must be avoided. To do so, stick on one end of the pad, then smooth it out to the other end.

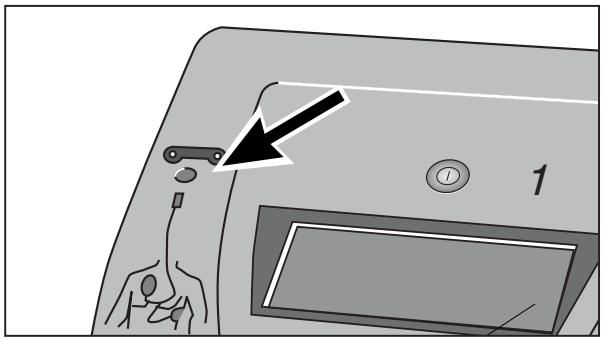


Figure 5-3. Yellow defib pad indicator

- Adhesive electrodes for adults / children (AHA "Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care", page I-64)
  - The large adult electrodes with a surface area of 78 cm^2 should be used on adults and on children weighing 25 kg or more.
  - The small pediatric electrodes with a surface area of 28 cm^2 should be used on children weighing less than 25 kg (younger than 8 years of age).
- Use the pads before their expiration date. Please note that the indicated expiration date only applies when the vacuum pack is intact. The pads are pregelled. Do **not** use extra contact agent (gel). Do **not** reuse the pads.
- 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.

If the contact impedance is high, the message "Check the electrodes" will appear and the yellow indicator (Figure 5-3) remains illuminated.

Follow these steps to check the pads:

- Alternately press down firmly on the defibrillation pads and check when the message "Check the electrodes" disappears.
- Press that pad for which the message disappeared again onto the skin.

If the message "Check the electrodes" does not disappear,

- Remove the two defib pads.
- Wipe rests of contact agent off with a cloth.
- Shave the two application points to remove the epidermal skin layer.
- Apply new defib pads to these points.

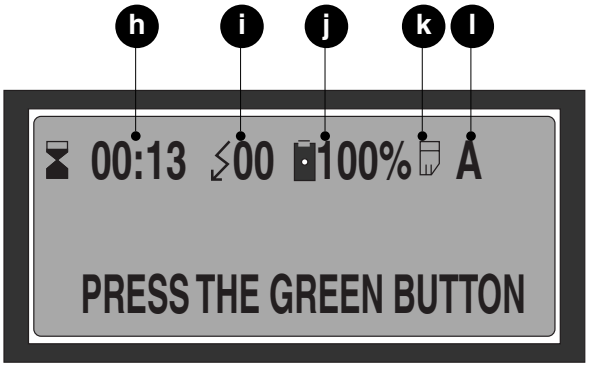


Figure 5-4. On-screen display

h Time since device was turned on

i Number of delivered shocks

j Residual battery capacity

k Memory card inserted

l Adult pads (A) or pediatric pads (C) connected

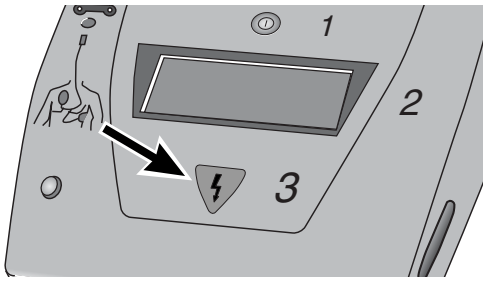


Figure 5-5. Button to trigger the defibrillation shock

Note

- If the patient's rhythm changes to a non-shockable rhythm after the message "Shock advised", the defibrillation energy will be discharged internally.
- If an electrode becomes disconnected during ECG analysis, the message "Connect the electrodes" will be displayed and the device suspends the analysis.
- If, during ECG analysis, the impedance at one of the defib pads 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.

The rest of the workflow is described in steps:

step 1: The device requests initiation of the ECG analysis with the ⏻ button or automatically initiates ECG analysis (as configured).

Note

Press the ⏻ button only briefly (1 second max.) to initiate an analysis. Otherwise you would turn the device off.

During the analysis, the message „Do not touch the patient – analysing" is displayed. The analysis takes approx. 10 seconds.

From now on contact with the patient must be avoided and the bystanders must be warned.

The following operation depends on whether the device identifies a shockable rhythm (continue with steps 2 and 3 in that case) or whether no shockable rhythm is identified (continue with step 4).

step 2: The device detects ventricular fibrillation or ventricular tachycardia with a rate above 180 B/min and automatically starts charging the defib for the first shock.

step 3: As soon as the defib is charged, it prompts the user to trigger the shock with the ⚡ button.

After delivery of shock the device checks the outcome of the defibrillation by running an automatic analysis.

If the shock was **not** successful, the device prompts the user to perform CPR (30 chest compressions to every two breaths) for two minutes (in Norway: for three minutes). After these two (three) minutes, the device again prompts the user to start ECG analysis.

Steps 2 and 3 will be repeated until a delivered shock is successful. For the second and third shock, the device will charge to the configured energy levels. For all subsequent shocks it will charge to the energy level of the third shock.

After a successful shock, step **4** will follow.

step 4: The device prompts the user to perform CPR (30 chest compressions to every two breaths) until the patient starts breathing or until new instructions are given.

Warning
Patient Hazard — In the treatment of children only 15 chest compressions must be performed to every two breaths.

Internal Safety Discharge

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

- a non-shockable rhythm is identified
- the shock is not delivered within 20 seconds of defibrillator charging
- an electrode problem is identified
- the battery voltage is insufficient
- the device is defective
- the device is turned off.

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

Ending Therapy

- Turn off the device after therapy (push ⏽ button for approx. 3 seconds).
- Disconnect the electrode lead.
- Carefully peel the pads off the patient's skin (Figure 5-6).
- Discard the disposable pads immediately after use to prevent that they are reused (hospital waste).

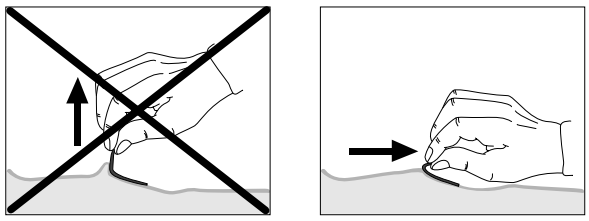


Figure 5-6. Removing the defibrillation pads

Overview of events documented with date and time:

- power on
- start of analysis
- analysis result
- defibrillator charging
- defibrillation shock
- internal discharge
- electrode alarm
- "battery low" alarm

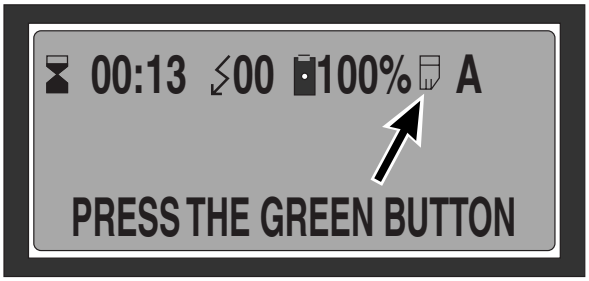


Figure 5-7. Memory card inserted

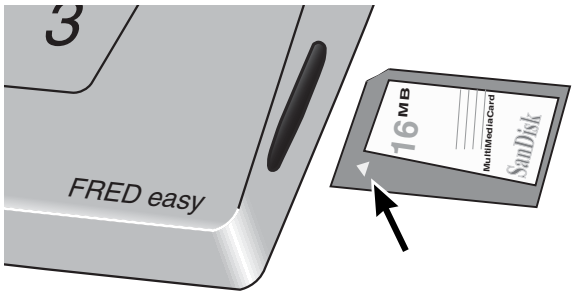


Figure 5-8. Inserting the memory card (text facing up, insert in direction indicated by arrow)

Intervention Summary

The following can be saved to the memory card as a documentation of the intervention

- 45 minutes of ECG data
- 45 minutes of sound
- 500 events concerning the intervention (see list at left).

Inserting the memory card automatically activates the memory function and the symbol appears on the display (Figure 5-7).

The memory card is analyzed on a PC with the SAED READER software program.

The symbol starts blinking when the memory card is full.

Be sure to turn off the device before inserting the memory card and insert the card as shown in Figure 5-8 (text facing up, observe direction indicated by arrow). Otherwise the device will not identify the card and the symbol appears.

Having inserted the card, close the card slot with the plastic cover.

If the symbol does not appear although you have inserted the card, check whether this is a special SCHILLER card intended for use with this device.

Caution

Equipment Damage —

- Always close the card slot with the plastic cover. Otherwise, moisture may penetrate into the device.
- Always turn off the device before inserting or removing the memory card.
- Do not plug the Ethernet adapter into the slot.

6 Options and Equipment Versions

6.1 ECG Display (Option)

With the ECG display option installed, the ECG will be displayed on the screen (Figure 6-1).

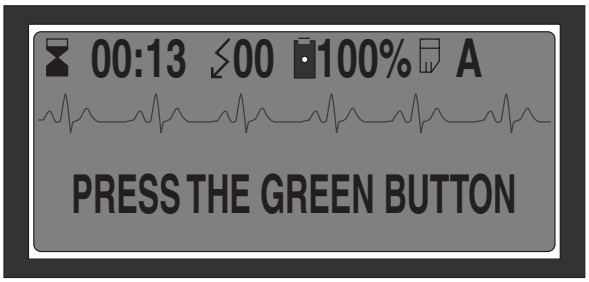


Figure 6-1. Screen display with ECG waveform

6.2 Manual Defibrillation (Option)

*Figure 6-2. **FRED easy®** for semiautomatic and manual defibrillation*

Switching to the manual mode

> **Warning**
> Patient Hazard — Only a physician is allowed to enable the manual mode. Observe the information given in sections 5.1 and 5.2.

Non-medical staff is not permitted to use the manual mode, if local laws authorize non-medical staff to employ semiautomatic defibrillators only.

In some countries, however, EMT's 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 EMT's. 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

You select the manual mode by simultaneously pushing the green and the orange buttons (**1** + **3**,

Figure 6-2). You will be prompted to push the buttons a second time. This must be done within 5 seconds.

Note

It is not possible to set the device to the manual mode while turning it on. Therefore, do not press the orange button at the same time you switch the defibrillator on. The device must be switched on first, before it can be set to the manual mode.

Note

It is not possible to switch the defibrillator to the manual mode while a defibrillation procedure is in progress (analysis, charging, shock delivery).

Manual operation

The screen displays

- the ECG waveform
- the selected energy and
- a prompt to push the green energy charging button.

After depression of the green button, the defibrillator begins charging. The charging procedure can be watched on the screen.

When the selected energy has been reached, the orange button lights up and both a voice prompt and a message ask the user to deliver the shock (orange button).

Note

If the shock is not delivered within 20 seconds, an internal safety discharge will occur.

The energy values of the first three shocks are those defined for the semiautomatic mode. For all subsequent shocks the energy level of the third shock is maintained.

Switching to the semiautomatic mode

To return to the semiautomatic mode, switch off **FRED easy®** and leave it turned off for at least 5 minutes.

6.3 Metronome (Option)

Devices with the "Metronome" option generate a steady beat during CPR to mark the frequency for chest compressions. The frequency can be selected between 85 and 150 beats/s (requires the FredCo software).

6.4 Ethernet Version

Figure 6-3. Ethernet version

Figure 6-4. Ethernet adapter connected

Some Basic Facts

With this version, the stored intervention data can be transmitted via the Ethernet / IP network.

The memory card is installed in the device and cannot be removed.

A blank memory card has a storage capacity for 500 events and 45 minutes of ECG data including ambient noise (voices).

When the memory card is full, the symbol  blinks and no more data can be stored. The stored data will be cleared after the transmission.

For the transmission of data an Ethernet adapter is plugged into the Ethernet connector of the device. In order to protect other electric devices from interference during data transmission, a ferrite core must be attached to the Ethernet cable in close proximity to the Ethernet adapter (see "Installing the ferrite core" at the end of this section).

Connecting the Ethernet Adapter

- Insert the Ethernet adapter into the connector from below (Figure 6-4).

Configuration

- Start the FredCo software program and select the "Network" tab (**1**).

> **Note**
>
> A password provided by SCHILLER must be entered for access to the network parameters.

The IP data (internet protocol) depend on the infrastructure of your network:

– in "Static mode", your network administrator will provide this information
– in "Dynamic mode", the configuration takes place automatically and some of the entry fields are not visible.

- Check that the MAC Address (**2**) displayed on the screen is identical with the address indicated on the underside of the device.
- The password (**3**) must be identical with the password for access to the server where the data transmission software (Life Data Net) is installed.
- You can choose any login (**3**). However, it must be identical with the login for access to the server where the Life Data Net software is installed.

> **Note**
>
> Please note that in the "Dynamic mode" **FRED easy®** does **not** switch off automatically, if it cannot connect to the server. The device continually tries to connect to the server, thus depleting the battery. If the data transfer does not start within 5 minutes (progress indicator), remove the battery to terminate the process.
> If **FRED easy®** is able to connect to the server, it will automatically disconnect 5 minutes after the data transfer or when the Ethernet communication ends.

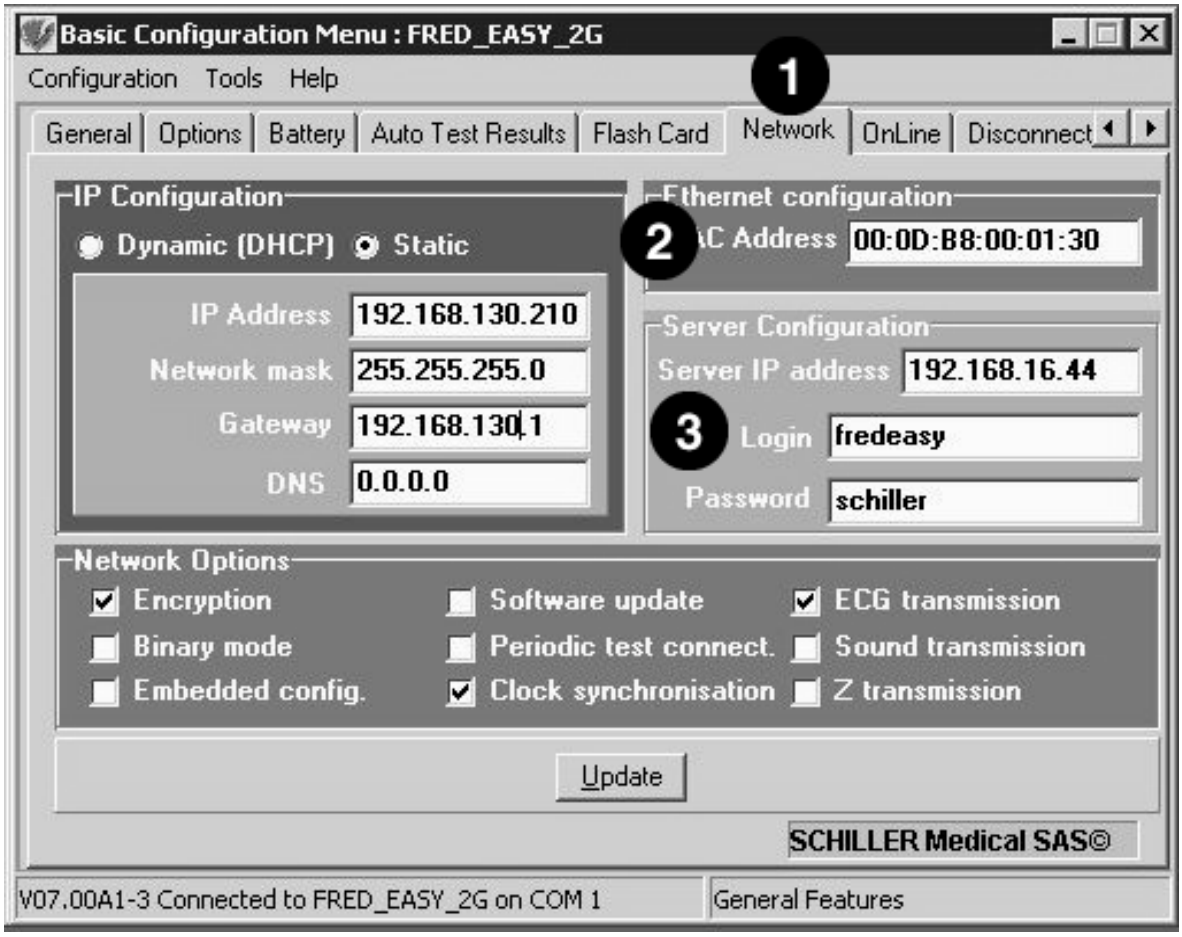


Figure 6-5. Configuration

Transmitting Data

- Turn the defibrillator off.
- Plug the Ethernet adapter into the connector.

The defibrillator will automatically be turned on and enters the data transmission mode:

TRANSMISSION MODE

When the device does not operate in the dynamic mode (see above), the following message displays:

NETWORK PARAMETERS CONFIGURATION

The device configures the necessary parameters, logs on and sends its authentification information to the server where Life Data Net is installed.

CONNECTION AND AUTHENTIFICATION

After a successful authentification, the internal Ethernet clock of **FRED easy®** is synchronized with the server clock.

After an unsuccessful authentification, the following message appears:

TRANSMISSION FAILURE

ERROR CODE: 008 OPENING SESSION

If there are no data on the memory card, you will receive this message:

MEMORY CARD EMPTY NO DATA TO TRANSFER

You can turn off the device and remove the Ethernet adapter.

Note

After 1 minute, the device will automatically switch off.

If information is stored on the memory card, the transmission will start and the percentage of transmitted data is displayed.

DATA TRANSFER 22 %

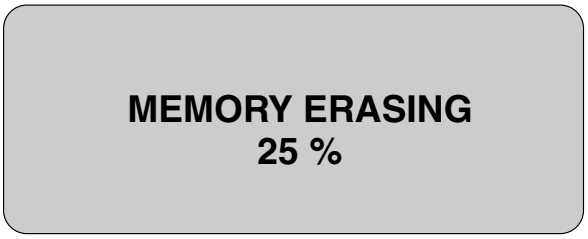
Note

Should the Ethernet adapter be removed during the transmission, it will resume after the next authentification.

At the end of the transmission procedure, the display shows:

CLOSE SESSION

After the transmission the data are removed from the memory card. The percentage of removed data is indicated.



At the end you will hear an audio signal and see the message:

You can turn off the device and remove the Ethernet adapter.

Error Messages

Code	Message	Problem	Remedy
001	SD CARD READING	Error reading memory card	Turn device off and on again; if message recurs, the device must be repaired.
002	NOT ENOUGH MEMORY	Technical problem	Turn device off and on again; if message recurs, the device must be repaired.
003	NETWORK CONFIGURATION	Erroneous network configuration	Check network configuration; if message recurs, the device must be repaired.
004	ADAPTER DISCONNECTED	Ethernet adapter not connected	Turn device off and connect Ethernet adapter; if message recurs, use another Ethernet adapter; if message recurs, the device must be repaired.
005	PATIENT DETECTED	The device has detected a connected patient.	Disconnect electrodes from device.
006	BATTERY LEVEL	Battery depleted	Insert a new battery.
007	TIME OUT INACTIVITY	Device not used for more than 3 minutes	Turn device off and on again; if message recurs, the device must be repaired.
008 009 010	SESSION OPENING	No communication with server.	Check communication with server and network configuration, restart data transmission; if message recurs, the device must be repaired.
011 012	SESSION CLOSING	No communication with server.	
013 014 015	DATA TRANSMISSION	Erroneous data transmission	
016 017	DATA ERASING	Internal error deleting data	Turn device off and on again; if message recurs, the device must be repaired.

Installing the Ferrite Core

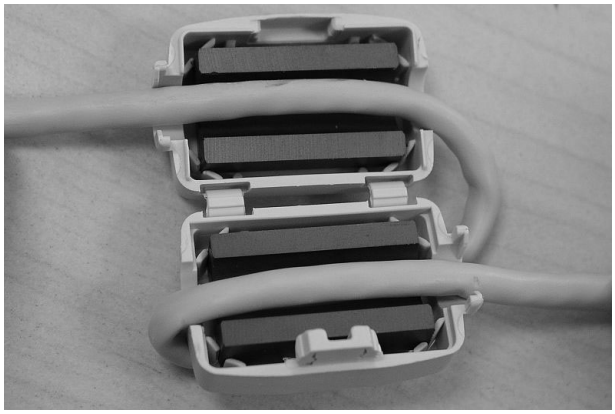


Figure 6-6. Placing the cable into the ferrite core

Figure 6-7. Reducing the size of the loop

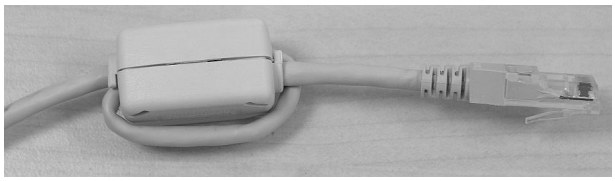


Figure 6-8. Correctly installed ferrite core

- Form a loop and route the cable through the open ferrite core (Figure 6-6).
- Clap down the ferrite core - without closing it completely - and check the cable position.
- Reduce the loop size as far as possible. To do so, pull on the long end of the cable (Figure 6-7).
- Close the ferrite core completely (Figure 6-8).

Accessories

Part No.	Description
1-58-5300	Ethernet adapter
5-30-0003	Ethernet cable (3 m, category 5)
4-33-0002	Ferrite core
0-05-0026	Ethernet cable (3 m, with ferrite core)

6.5 Online Version

Figure 6-9. Online version in wall mount bracket

Figure 6-10. Accessory bag

Some Basic Facts

This version supports the communication between the deployment center and the device, using the SNMP protocol (**S**imple **N**etwork **M**anagement **P**rotocol).

The SNMP Manager allows the following functions and tasks to be executed at all connected devices from the deployment center:

- monitoring the battery capacity and the device temperature
- installing software
- modifying the device configuration
- triggering an audible alarm or a visual indication at the devices
- triggering an alarm in the deployment center when set alarm limits are violated

The device is inserted in a special wall mount bracket. An accessory bag can be attached to the front panel of the device.

There are two communication options:

- via cable
- via WiFi (WLAN).

With the WiFi version, the WiFi module and the antenna are integrated in the wall mount bracket.

The system is powered from a separate power supply unit or via the data network, if the device is equipped with "POE" (Power On Ethernet).

The device starts sending data as soon as it is placed in the wall mount bracket after an emergency intervention.

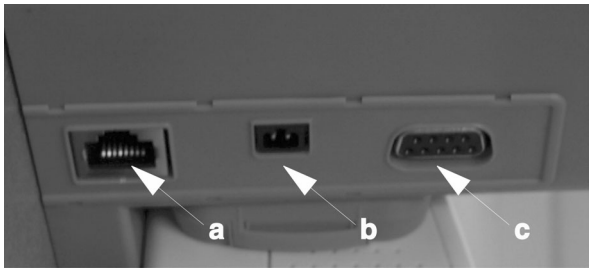


Figure 6-11. Connectors
a Ethernet
b Power supply
c RS232

Figure 6-12. Indicator

Note

Operate the online version only with the Lithium battery. Do NOT install rechargeable NiCd batteries.

Do not remove the battery from the device, while the device is inserted in the wall mount bracket.

Turn off the device, before inserting it in the wall mount bracket. Otherwise no data will be transmitted.

Setup

- Connect the power supply unit to the socket in the middle **b** and plug it into a grounded wall outlet (not required for devices with "POE").
- Connect the data network cable (Ethernet) to the connector on the left **a**.
- Turn the device OFF and insert it in the wall mount bracket:
  - The device switches on and starts transmitting the data from its memory card (same as with the Ethernet version, see section 6.4).
  - The indicator (Figure 6 12) blinks while the device communicates with the data network.
  - The same screens are displayed as during the Ethernet transmission (see section 6.4).

When all data have been transmitted, the display illumination switches off and the message "FRED easy Online ready" appears. You will see this message whenever the device can communicate with the data network. In addition, the indicator light (Figure 6 12) blinks in this case.

When the communication is interrupted, the message "no server" appears and the indicator is permanently on.

With the "SCHILLER Life Data Net" software, you can read and process the transmitted data.

For configuration of the online version of FRED easy® you can connect a PC to the serial RS232 interface (**c**, Figure 6-11) (requires FredCo software).

Maintenance Mode

While inserted in the wall mount bracket, the device can be set to the maintenance mode. This is achieved by simultaneously pressing the ⏽ and  buttons. A message to this effect appears on the display.

While in Maintenance Mode, the device can be removed from the wall mount bracket for service interventions. The server will notice in this case, that the device was not removed for an emergency intervention.

After the device has been returned to the wall mount bracket, the Maintenance Mode must be switched off again with both buttons.

Configuration (Online Version)

- Start the FredCo software and select the "Online" tab (1).

You need to enter the following data:

– ˜Server IP adress (**2**):
IP address of the SNMP Manager who is the addressee for online **FRED easy®** error messages

– ˜RO Community password (**2**):
Password to be entered at the PC where the **FRED easy®** setup information can be read online

– RW Community password (**2**):
Password to be entered at the PC where the **FRED easy®** setup can be modified online

– Delay (**3**):
Interval at which **FRED easy®** sends the same error message (e.g. Battery low) online to the SNMP Manager.

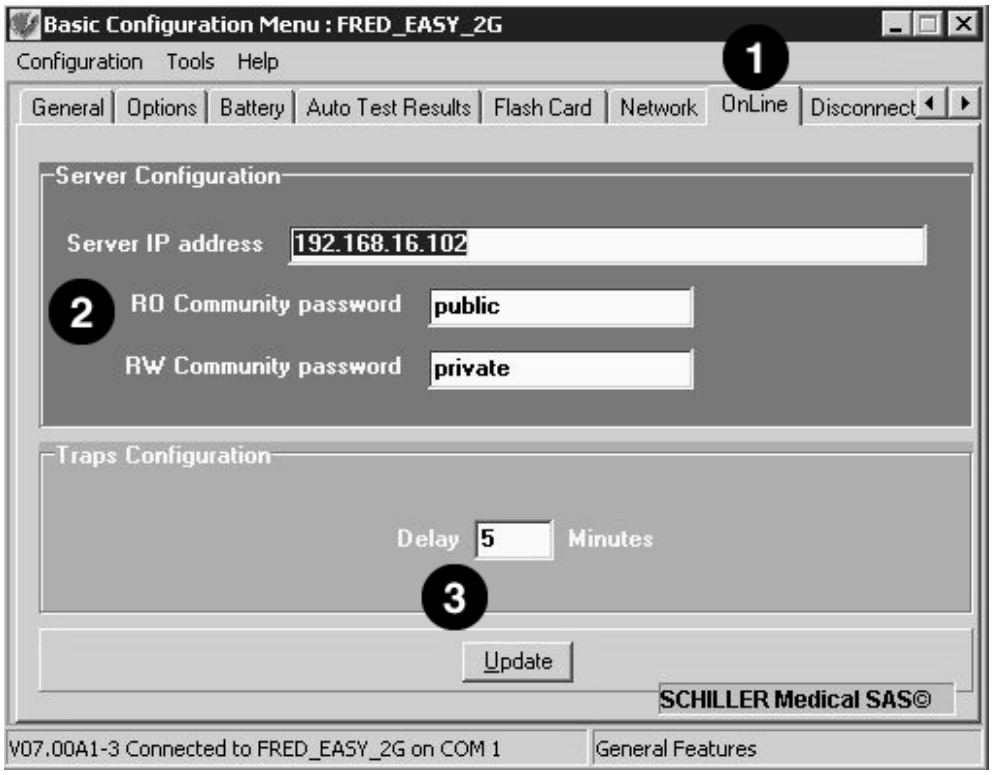


Figure 6-13. Configuration

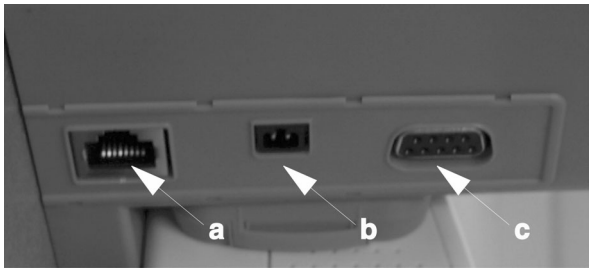


Figure 6-14. Connectors,
a Ethernet
b Power supply
c RS232

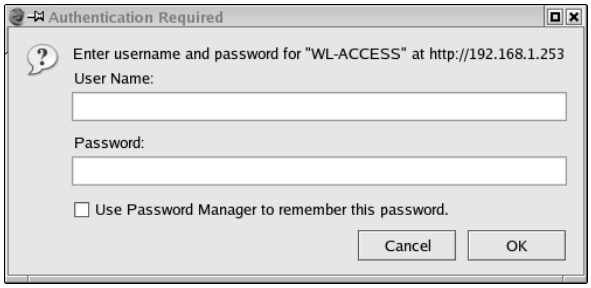


Figure 6-15. Windows dialogue for entry of the User Name and the Password

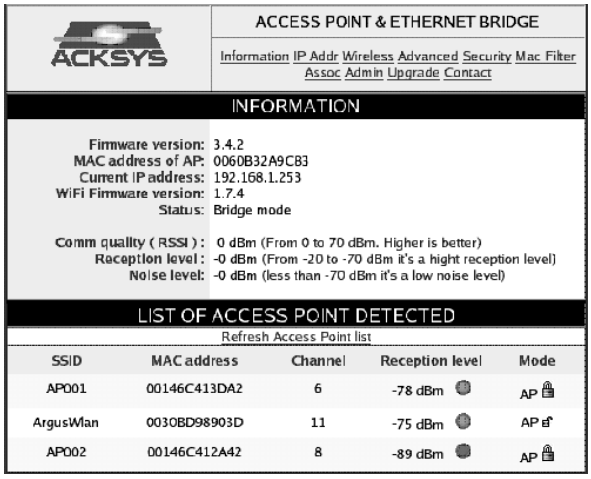


Figure 6-16. Administrator Module

Configuration of the WiFi Module

Preparation

- Remove the device from the wall mount bracket.
- Connect a PC to the Ethernet port **a** of the wall mount bracket (RJ45 line).
- Modify the PC's network configuration to allow it to communicate with the module. IP address to be entered at the PC: 192.168.1.1; net mask: 255.255.255.0.
- Connect the power supply to socket **b**.

Module Configuration

For modification of the module parameters (IP address, SSID, security, etc.), access the Administrator website: enter http://192.168.1.253 (192.168.1.253 is the module's default IP address).

The Windows dialogue displays (Figure 6-15).

- To be able to use the Administrator module, enter "root" both as the "User Name" and "Password" and confirm the entry with "OK".

The Administrator module screen shown at left displays:

- From the displayed list, select one of the access points detected by the module (one line).
- Note down the SSID, Channel and Mode information of the selected access point.

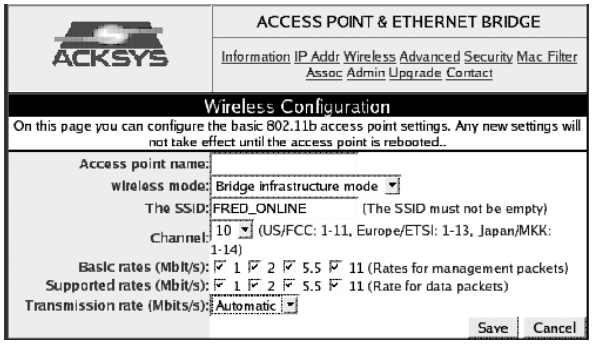


Figure 6-17. Administrator module

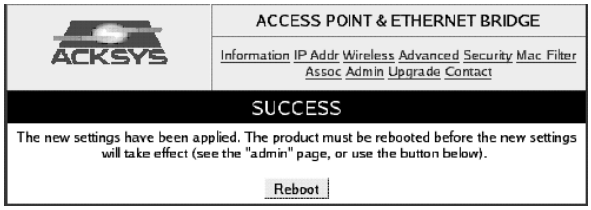


Figure 6-18. Administrator Module

Figure 6-19. Confirmation window

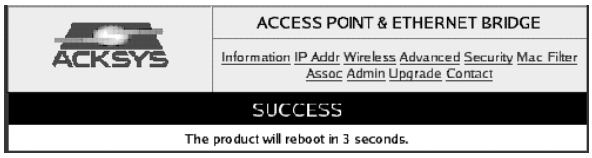


Figure 6-20. Administrator Module

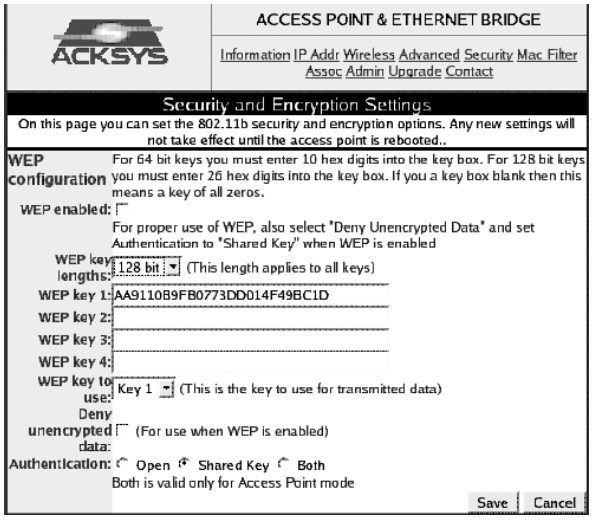


Figure 6-21. Administrator Module

- Click "Wireless" at the top of the dialogue.

The window shown at left will appear (Figure 6-17).

- Fill out the following fields:
  - **wireless mode**: Bridge infrastructure mode
  - **The SSID**: enter the SSID number noted down earlier
  - **Channel**: enter the channel number noted down earlier
- Click "Save" to save the entries.

The window shown at left will appear (Figure 6-18).

- Click "Reboot".

The confirmation window will appear (Figure 6-19).

- Click "OK".

Now you will see Figure 6-20.

Reinitialization of the module will start within the next 3 seconds.

If the access point mode is encrypted (locked padlock), click "Security". Now you will see Figure 6-21.

- Enter the length of the key code at "WEP key lengths". Contact your network administrator to obtain this value.
- Enter the key code "WEP key 1". Contact your network administrator to obtain this code.
- Click "Save" to save the entries.
- As before, click "Reboot" and then "OK".
- Disconnect the line from port a (Figure 6-14).
- Place the device into the wall mount bracket.

Note

With the WiFi version, port **a** is only required for configuration of the module. Do not connect any other cable to this port.

Accessories

1-58-5302	Wall mount bracket (standard)
1-58-5301	Wall mount bracket (WiFi)
9-48-0003	Power supply unit
6-90-0045	Support for power supply unit
35066	Power cord for power supply unit
0-80-0013	Accessory bag for online version

6.6 Automatic Version

Note

The laws and regulations for the use of automatic defibrillators differ from country to country. While some countries allow laypersons to use automatic defibrillators without any special training, other countries restrict the use of AEDs to EMTs or First Responders after they have undergone a special training. For teaching purposes, we offer the **FRED easy® TRAINER**.

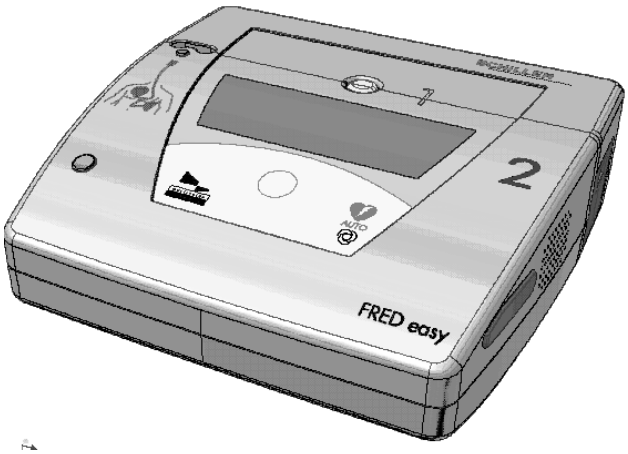


*Figure 6-22. **FRED easy®** for automatic defibrillation*

Functional Description

This device delivers the defibrillation shocks automatically, i.e., there is no need to initiate the analysis and trigger the shock. The analysis will start as soon as the electrodes are applied and the device is turned on. The user is informed of the ongoing analysis by speech and text.

During the analysis the patient must not be touched or moved.

Speech and text messages on the screen keep the user informed about the intervention.

If a shock is recommended, the energy is automatically charged. When the device is ready to deliver the shock, the orange indicator blinks. A countdown accompanies the last four seconds before the shock is delivered.

Defibrillation

Warning

Patient Hazard — Observe the information given in sections 5.1 and 5.2. Use of the defibrillator is permitted only when the patient is unconscious, does not breathe and shows no signs of circulation.

After power up, the user is prompted to apply the electrodes and to connect them to the device (unless this was already done).

When the electrodes are properly applied, the user will be warned not to touch the patient any more and the device informs about the ongoing analysis.

If a shock is recommended, the user receives a warning about the imminent shock. The orange indicator blinks, and after a 4-second countdown the shock is delivered.

If no shock is recommended and after a shock, the device prompts the user to administer CPR (30 chest compressions to every two breaths) until the patient starts breathing or until new instructions are given.

All other device functions are identical with those of the semiautomatic defibrillator variant.

7 Cleaning, Maintenance, Disposal

7.1 Cleaning and Disinfection

– Shock Hazard — Remove the battery, before cleaning the device. This ensures that the device will not be turned on inadvertently while you are cleaning it. Danger to life! Disconnect the pads before cleaning the device.

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

- Wipe the device surface 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.

7.2 Maintenance

Checks before each use

Before each use, the device and pads must be visually inspected for signs of damage.

If the equipment is damaged or its function is impaired, representing a risk for the victim and the operator, it must be repaired before use.

Regular Checks

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

Once a week / once a month

- Visually inspect the device and the accessories.
- Check that the green indicator (**a,** Figure 3-1) blinks.
- Check the pads' expiration date.

> **Note**
>
> In the Appendix of this manual, we have provided an Inspection Checklist that you should copy to keep track of the regular preventive maintenance performed.

When the device is defective or does not function properly (green indicator not blinking), it must be repaired before use. Pads past their expiration date must be immediately replaced.

Technical Safety Inspections (every 5 years)

These technical safety 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.
- Run a functional test.
- Measure the leakage current.
- Measure the energy delivered in 50 Ohms.
- Replace the plug-in Lithium battery.
- Replace the internal backup battery.

The old batteries must be disposed of to local regulations.

The device does not require additional maintenance interventions.

7.3 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 plug-in batteries, the device does not contain hazardous material and can be disposed of like any other electronic equipment.

According to European legislation, this device is considered as waste electronic equipment. It can be returned to the dealer or manufacturer where the device will be disposed of in compliance with legal requirements. The customer will bear the shipping costs.

8 Error Messages, Troubleshooting

8.1 Error Messages

Message	Problem	Remedy
DEFIBRILLATOR: ERROR …	– Technical problem	– Turn device off and on again; if message recurs, repair the device
DEFIBRILLATOR: COMMUNICATION ERROR	– Technical problem	– Turn device off and on again; if message recurs, repair the device
ERROR DEFIBRILLATOR XX (2)	– Technical problem	– Turn device off and on again; if message recurs, repair the device
SYSTEM ERROR	– Technical problem	– Turn device off and on again; if message recurs, repair the device
ERROR ADC	– Technical problem	– Turn device off and on again; if message recurs, repair the device
ERROR LCD	– Technical problem	– Turn device off and on again; if message recurs, repair the device
ERROR OKI	– Technical problem	– Turn device off and on again; if message recurs, repair the device
ERROR DSP	– Technical problem	– Turn device off and on again; if message recurs, repair the device
ERROR EEPROM	– Device configuration problem	– Turn device off and reconfigure.
TIME AND DATE RESET TO 01/01/98 >REINSERT BATTERY	– Wrong date	– Turn device off and reconfigure.
ERROR BATTERY INSERT NEW BATTERY	– Battery problem	– Turn device off and insert new batteries.
ERROR BATTERY	– Battery problem	– Turn device off and insert new batteries.
CONFIGURATION DATA RESET TO DEFAULT > REINSERT BATTERY	– Battery problem	– Turn device off and insert new batteries.
BATTERY LEVEL INFO > REINSERT BATTERY	– Battery depleted	– Turn device off and insert new batteries.

8.2 Troubleshooting

Problem	Possible Cause	Remedy
Green indicator does not blink and/or device cannot be turned on.	– Battery defect.	– Insert new battery.
	– No battery inserted, or battery not correctly inserted.	– Insert battery correctly.
	– Device defect.	– Have device repaired.
Yellow indicator at electrode connector does not go out.	– Electrodes past expiration date.	– Use new electrodes.
	– Dry electrode gel.	– Use new electrodes.
	– High electrode contact impedance.	– Apply electrodes exactly as described; shave application sites.
	– Device defect.	– Have device repaired.
Message “Check the electrodes”.	– Short-circuit between the electrodes.	– Apply electrodes exactly as described.
	– Poor electrode contact.	– Firmly press down on electrodes.
	– Electrodes past expiration date.	– Use new electrodes.
	– Dry electrode gel.	– Use new electrodes.
	– Device defect.	– Have device repaired.
Device cannot be turned off.	– Power button was pressed less than 3 seconds.	– Press power button at least 3 seconds.
	– Device defect.	– Have device repaired.
Incorrect analysis result (e.g. device does not detect shockable rhythm, even though the patient exhibits ventricular fibrillation).	– Insufficient ECG signal quality.	– Repeat heart massage.
	– Electromagnetic waves disturb the ECG signal.	– Turn off source of interference (e.g. radio equipment, cellular telephone). – Position patient outside range of interference.
	– Patient moved during analysis.	– Do not move patient during analysis.
	– Device defect.	– Have device repaired.
Shock cannot be delivered.	– Insufficient battery charge level.	– Insert new battery.
	– CPR measures caused an electrode problem.	– Reapply electrodes.
	– Cardiac rhythm has changed.	– Repeat analysis.
	– Device defect.	– Have device repaired.
Alarm tone does not stop.	– Battery defect.	– Insert new battery.
	– Device defect.	– Have device repaired.
Message “Error xxx”	– Device defect.	– Have device repaired.
Battery capacity indicator blinks.	– Battery almost depleted.	– Insert new battery.

Problem	Possible Cause	Remedy
The memory card symbol  is not displayed or the  symbol appears.	– No memory card is inserted. – The card is inserted the wrong way round.	– Turn the device off and insert the card with the proper orientation.
	– The card was inserted with the device turned on.	– Turn device off and on again.
	– Memory card write-protected.	– Turn device off and remove card. – Remove write protection and reinsert card. – Turn device on again.
	– Device defect.	– Have device repaired.
No data recorded on memory card.	– Card defect.	– Replace card.
	– Device defect.	– Have device repaired.
Incorrect date and time on card.	– Internal clock error.	– Have system parameters updated by an authorized person (configuration kit for remote charging).
	– Device defect.	– Have device repaired.

9 Technical Specifications

- Shape of the defibrillation pulse:
  - biphasic pulsed defibrillation pulse with approximately constant phases for optimal physiological compatibility
  - maintains approximately constant the delivered energy as a function of the patient resistance, applying pulse-pause modulation that varies with the measured patient resistance
- Energy settings:
  - our customer service can change the default energy settings to the following values:
    1 – 2 – 4 – 6 – 8 – 15 – 30 – 50 – 70 – 90 – 110 – 130 – 150 J (adults)
    1 - 2 – 4 – 6 – 8 – 15 – 30 – 50 – 70 (children)
  - accuracy for 50 ohms: ± 3 J or ± 15 % (whichever is greater)
- Charge time to max. energy after power-up:
  29 seconds
- Charge time to max. energy from initiation of analysis and after delivery of 15 shocks of max. energy: 25 seconds
- Charge control and monitoring:
  automatic when the analysis algorithm recommends a shock
- Patient resistance 30 to 175 ohms
- Charge time from “shock advised” to “ready to shock”:
  < 10 s
- Interval between shocks (in manual mode):
  < 25 s
- Indication when ready to shock:
  button lights up
- Shock delivery:
  with the button (in semiautomatic or manual mode)
- Internal safety discharge in the following situations:
  - a non-shockable rhythm is identified
  - the shock is not delivered within 20 seconds of charging
  - an electrode problem is identified
  - the battery voltage is insufficient
  - the device is defective
  - the device is turned off.
- Number of shocks with maximum energy (to EN 60601-2-4):
  2500

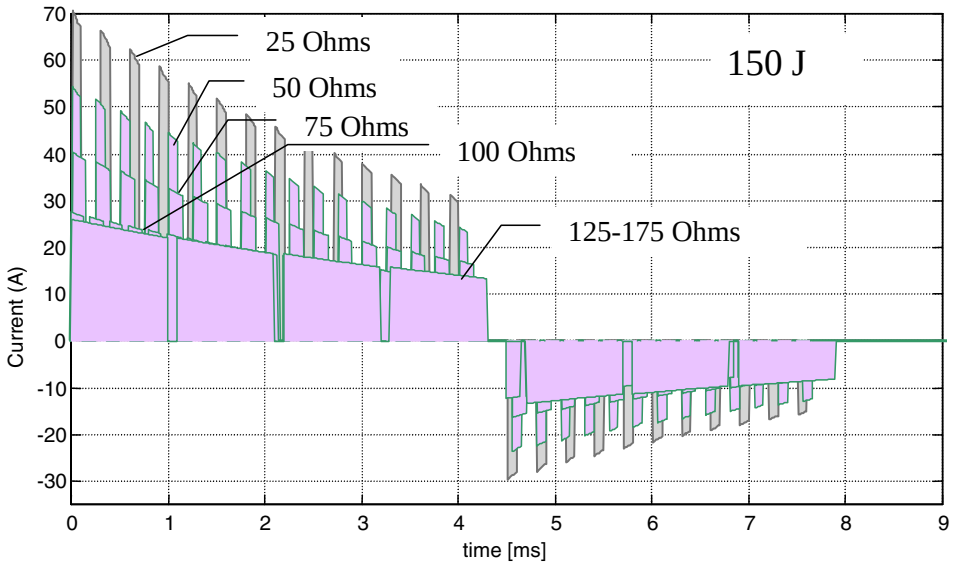


Figure 9-1. Discharge curve

- Shock delivery:
  via disposable adhesive pads applied in the anterior-anterolateral or anterior-posterior position
- Connection for defibrillation pads:
  type BF
- Defibrillation pads:
  - adult pad:
    active surface of 78 cm^2
  - pediatric pad:
    active surface of 28 cm^2
  - length of pad connection cable: 2 m
- VT / VF detection:
  - shock advised:
    for VF and VT (VT > 180 B/min)
  - sensitivity: 98.43 %
    specificity: 99.8 %; these values were determined with an AHA database containing VF and VT with or without artifacts
  - conditions for ECG analysis:
    minimum amplitude for signals suitable for analysis > 0.15 mV
    signals < 0.15 mV are considered as asystole
  - definition:
    sensitivity: correct identification of shockable rhythms
    specificity: correct identification of **non**-shockable rhythms
- Display:
  - high-resolution LCD, 100 mm x 37 mm, electroluminescent backlighting, display of text and symbols
- Intervention summary:
  - storage of 30 minutes of ECG data
  - storage of 30 minutes of ambient noise (voices)
  - storage of up to 500 events
  - with "Ethernet data transmission" option: 500 events, 45 minutes of ECG data incl. voices
- Power supply
  - device with internal electrical power source
  - suitable for continuous operation with intermittent loading
  - lithium battery capacity
    - 180 shocks at maximum energy or
    - 6.5 hours of monitoring (alternately 30 minutes ON and 30 minutes OFF) or
    - 5 years standby operation.
  - capacity of the rechargeable NiCd battery
    - 45 shocks at maximum energy or
    - 80 minutes of monitoring
- Environment:
  - transport/storage:
    temperature – 30 to + 50 °C
    relative humidity 0 to 95 %, no condensation
    atmospheric pressure 500 to 1060 hPa
  - operation:
    temperature 0 to + 50 °C
    relative humidity 0 to 95 %, no condensation
    atmospheric pressure 700 to 1060 hPa
  - IP X4
- Electromagnetic compatibility:
  - **FRED easy®** uses radio frequency signals for internal control purposes only. The radio interference emitted is within the limits of the standard CISPR 11 for class B equipment.
  - **FRED easy®** can be exposed to the following levels of interference without losing its functionality:
    - static discharges up to 8 kV
    - energies at the radio frequency level up to 20 V/m (80 to 2500 MHz, 5 Hz modulated)
    - electromagnetic fields of 100 A/m, 50 Hz
- Dimensions and weight:
  - width 220 mm
  - depth 230 mm
  - height 70 mm
  - weight approx. 1.5 kg (incl. battery)

Note

Unless otherwise stated, all data are valid at a temperature of 25 °C.

10 Order Information

Part No.	Description
1-58-9900	**FRED easy®** standard
1-58-9000	**FRED easy®** Ethernet version
1-58-5303	Ethernet adapter
1-58-9300	**FRED easy®** Online version
1-58-9100	**FRED easy®** automatic defibrillation
EASY T2	**FRED easy®** Trainer

Accessories

0-21-0003	Disposable adhesive defibrillation electrodes for adults (1 pair), 78 cm^2
0-21-0000	Disposable adhesive defibrillation electrodes for children (1 pair), 28 cm^2
0-48-0013	User Guide, English
4-07-0001	Disposable lithium battery
0-02-0003	Rechargeable NiCd battery
3-55-0030	Charger, 100 - 240 V, 50 – 60 Hz
0-80-0012	Instrument bag
0-80-0008	Instrument bag, reinforced
5-35-0006	Memory card

Literature

1. European Resuscitation Council: **Guidelines for Resuscitation 2005**.
2. 2005 American Heart Association: **Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.**

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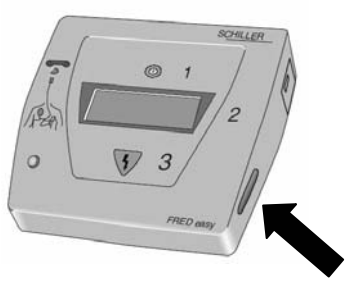
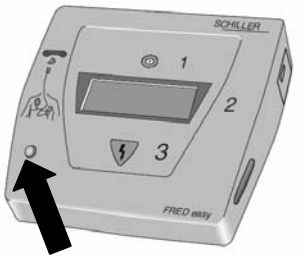
V

W

SCHILLER MEDICAL	INSPECTION CHECKLIST – FRED EASY	Number : **FRHOM0012** Index : A Page : 1 / 1

Periodic Inspections:

Weekly (devices that are frequently used)
Monthly (devices that are infrequently used)

SERIAL NUMBER:		**INSPECTION DATE**				
INSPECTIONS	**RESULTS**					
Visual Inspection	– insulation intact, no mechanical damage	☐	☐	☐	☐	☐
Accessories all accessories available and intact	– electrodes (expiration date) – user guide – memory card  – …… – ……	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐
Self test	– Green indicator blinks  	☐	☐	☐	☐	☐
Comments:						
Inspection performed by:						

Reminder:

Once every 7 days, the device will run a self test. The beginning of the self test is indicated by a beep.

In case of problems, please notify your Biomedical Department ☐, your SCHILLER Sales Representative ☐ or the Customer Service of your area ☐:

Contact: ..... Telephone: .....

Attention:
Use this document only after carefully reading the User Guide.