FRED® easyport®

Automated External Defibrillator (AED)
FRED® easyport®

Art. no.: 2.510544 Rev.: d

User Guide

SCHILLER

The Art of Diagnostics

Sales and Service Information

The SCHILLER sales and service centre network is world-wide. For the address of your local distributor, contact your nearest SCHILLER subsidiary.

In case of difficulty a complete list of all distributors and subsidiaries is provided on our internet site:

http://www.schiller.ch

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1 Safety Notes

1.1 Responsibility of the User

- The device must only be used by qualified physicians or other persons trained in early defibrillation.
- The numerical and graphical results as well as any interpretation suggested by the device must be examined with respect to the patient's overall clinical condition and the quality of the recorded data.
- Make sure that the user has read and understood the user guide, and especially these safety notes.
- Damaged or missing components must be replaced immediately.
- It is the owner's responsibility that the valid regulations for safety and prevention of accidents are observed.
- The device must be stored inaccessible to children.

1.2 Intended Use

- The FRED easyport is an automated external defibrillator (AED) used for the treatment of ventricular fibrillation (VF) and ventricular tachycardia (VT).
- The device may be used with the appropriate electrodes on either adults or children.
- The device must only be used if the following symptoms are found:
  - non-responsive
  - no respiration
  - no pulse
- The device must **not** be used if the patient:
  - is responsive
  - is breathing
  - has pulse
- The FRED easyport 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 sufficiently charged battery, and keep a spare battery on hand.
- Only operate the device in accordance with the specified technical data.
- The device is **not** designed for sterile use.
- Do **not** use this unit in areas where there is any danger of explosion or in the presence of flammable gases such as anaesthetic agents.
-  This unit is BF classified.
- This product is not designed for direct cardiac application.

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1.3 Organisational Measures

- ▲ Before using the unit, ensure that an introduction regarding the unit functions and the safety precautions has been provided and understood.
- ▲ Keep these operating instructions in an accessible place for reference when required. Make sure that they are always complete and legible.
- ▲ These operating instructions do not override any statutory or local regulations, or procedures for the prevention of accidents and environmental protection.

1.4 Safety-Conscious Operation

- ▲ This user guide, and especially these safety notes, must be read and observed.
- ▲ Danger of electric shock!
  The energy applied to the patient can be conducted through the patient to other persons, who may suffer a lethal electric shock. Therefore:
  - – Do not touch the patient, the electrodes or other conducting objects during defibrillation
  - – Do not defibrillate the patient in a puddle of water or on other conducting surfaces.
  - – Switch the device off when it is no longer used.
- ▲ Immediately report any changes that impair safety (including operating behaviour) to the person responsible.
- ▲ Only connect the original SCHILLER pads to the unit.
- ▲ Before switching on, check if the unit's casing and electrode connection are undamaged.

1.5 Operation with other Devices

- ▲ Only use accessories and other parts recommended or supplied by SCHILLER AG. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the unit.
- ▲ Magnetic and electrical fields from X-ray or tomographic devices, portable radio equipment, HF radios and devices labelled with the  symbol can affect the operation of this device. (See section 6.3.1.) Avoid using such devices or maintain a sufficient distance from them.
- ▲ The charging of energy and the release of the defibrillation impulse can disturb other devices. Check these devices after a defibrillation.
- ▲ Sensors and devices that are not defibrillation proof must be disconnected from the patient before a shock is triggered.
- ▲ If the patient has an implanted pacemaker, be sure not to position the electrode directly on top of it.
- ▲ Precautions must be observed when using high-frequency electrosurgical devices. A distance of at least 15 cm must be kept between the defibrillation electrodes and the HF surgical electrodes. If in doubt, disconnect the electrodes and sensors from the unit during use of a HF surgical device.

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1.6 Maintenance

- ▲ Danger of electric shock! Do not open the device. No serviceable parts inside. Refer servicing to qualified personnel only.
- ▲ Before cleaning, switch the unit off and remove the battery.
- ▲ Do not use high temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- ▲ Do not use solvent or abrasive cleaners on either the unit or cable assemblies.
- ▲ Do not, under any circumstances, immerse the unit or cable assemblies in liquid.

1.7 General Safety Notes

- ▲ Operating the device with a defective casing or damaged cables constitutes a danger to life. Therefore:
  - – Immediately replace a damaged unit, or damaged cables and connections.

1.8 General Notes Regarding the Unit

A defibrillation can fail with certain clinical pictures.

1.9 Terms of warranty

Your SCHILLER FRED easyport is warranted against defects in material and manufacture for the duration of one year (as from date of purchase). Excluded from this guarantee is damage caused by an accident or as a result of improper handling. The warranty entitles free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorised or unqualified persons attempt to make repairs.

In case of a defect, send the apparatus to your dealer or directly to the manufacturer. The manufacturer can only be held responsible for the safety, reliability, and performance of the apparatus if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorised by him, and
- the FRED easyport and approved attached equipment is used in accordance with the manufacturer's instructions.

There are no express or implied warranties which extend beyond the warranties hereinabove set forth. SCHILLER makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

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1.10 Display Symbols/Indicators

1.10.1 Symbols Used in this User Guide

The safety level is classified according ANSI Z535.4. The following overview shows the safety symbols and pictograms used in this user guide.

For a possibly dangerous situation, which could lead to serious bodily injury or to death.

For a possibly dangerous situation which could lead to personal injury. This symbol is also used to indicate possible damage to property.

For a direct danger which could lead to severe personal injury or to death.

For general safety notes as listed in this section.

For electrical hazards, warnings or precautionary measures when dealing with electricity.

NOTE for possibly dangerous situations which could lead to damages to property or system failure or **IMPORTANT** for helpful user information.

Reference to other user guides.

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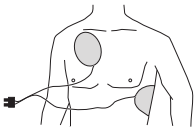
1.10.2 Symbols Used on the Device

BF symbol. The device's signal input is defibrillation protected.

CE 0459

Notified body of the CE certification (G-MED).

Note accompanying documents!



Defibrillation electrode connector.

Symbol for the recognition of electrical and electronic equipment.

This unit must be disposed of in a municipally approved collection point or recycling centre.

Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.

This function must only be used by physicians or other authorised persons (see page 23).

1.10.3 Symbols Used on the Battery

The unit/component can be recycled.

Battery may not be disposed of with domestic refuse.

Do not burn, saw up or crash the battery.

Do not recharge the battery.

Do not short the battery.

Storage temperature for the battery:
unlimited: +15...+25 °C.

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1.10.4 Symbols Used on the Electrode Package

Open the electrode package

Peel off the protective foil

Disposable item; do not reuse

Do not bend packing

Storage temperature for the electrodes

Expiration date

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2 Components and Operation

Its small size and light weight make the **FRED easyport** the ideal companion of physicians, paramedics, public service staff and other persons trained in early defibrillation. Risk patients carry their own rescue device after they and their families have been instructed by their doctor. This dramatically reduces the response time to treat ventricular fibrillation and ventricular tachycardia, granting the victims a much better chance of survival.

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, fulfil the biocompatibility requirements of the applicable standards. If you have questions in this matter, please contact SCHILLER.

2.1 Design

The **FRED easyport** is a battery-powered **automated external defibrillator** (AED) that delivers biphasic defibrillation pulses. The patient is defibrillated via disposable adhesive electrodes (pads), which also acquire the ECG signal for analysis. Adhesive electrodes for children and adults are available. The device recognises the connected electrodes and selects the defibrillation energy levels accordingly. The user will be given visual and audible instructions (display/loudspeaker). The device is powered by a disposable, replaceable lithium battery. The capacity is sufficient for:

- 45 shocks at maximum energy, or
- 2 hours of monitoring or
- 5 years of storage

Our customer service can configure various device functions via a special PC connection (see "Function" section).

2.1.1 Available Options

- SCHILLER ECG memory card
- Manual operational mode (see page 23)

2.1.2 Overview of the Configurable Settings

The following settings can be configured by the SCHILLER after-sales service:

- Voice volume
- Energy levels of the first, second and third shocks, individually for adults and children
- Initiation of ECG analysis with button or automatic
- Activation/deactivation of a 16.7 Hz filter
- Silent operational mode (spoken text with reduced repetition rate)
- Trace deactivation

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2.2 Operating Elements

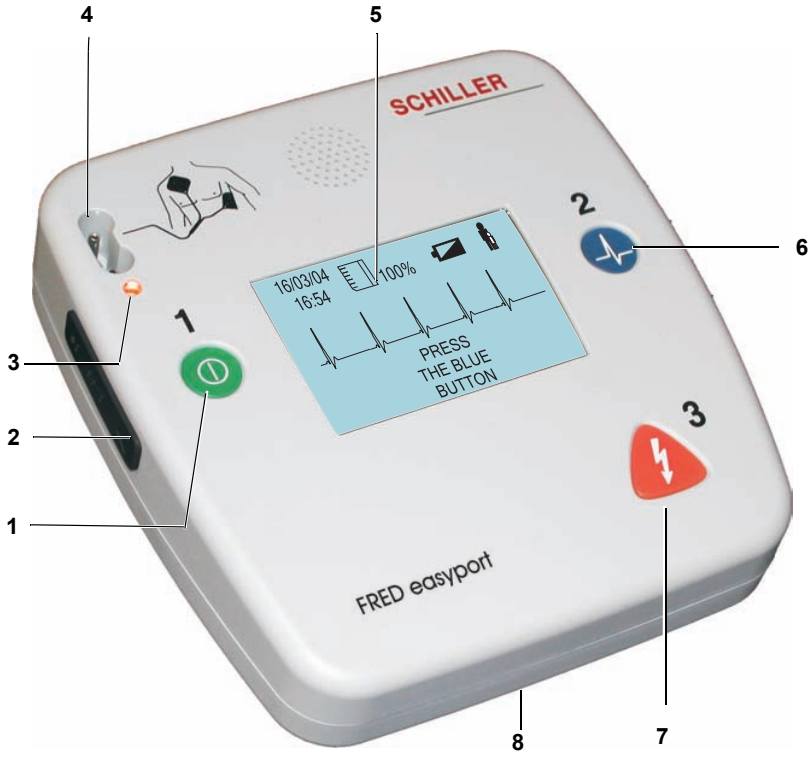

Fig. 2.1 Operating elements

(1) Green button to switch the device on/off
(2) Rubber seal for DS minicard
(3) Yellow indicator lamp; lit as long as no electrodes are connected
(4) Electrode connector
(5) LCD
(6) Blue button to start the analysis
(7) Key to trigger a defibrillation impulse
(8) Battery at back

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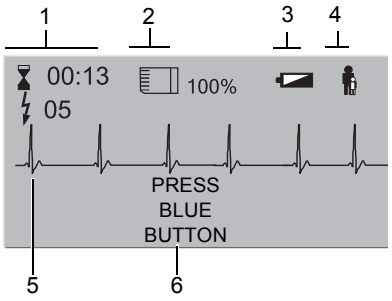
2.3 Display

The following information is displayed on the LCD:



(1) Time and triggered shocks since switch-on
(2) Memory card inserted and memory allocation in %
– Flashing = memory card almost full (from 98%)
– Flashing = error (see page 30, section 6.3)
– No indication = memory card not detected or not inserted (see page 30, section 6.3)
(3) Battery low (only 3 more shocks can be released)
(4) Defibrillation electrode type
= adults
= paediatric
(5) ECG signal
(6) Operational status

Fig. 2.2 LCD

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2.4 Function

2.4.1 Self-Test

To ensure its readiness for use, the device runs a self-test to check the unit and the battery. The self-test is carried out automatically every time the unit is switched on. If the device detects an error during the self-test, an error message is displayed.

2.4.2 Defibrillation Procedure

The user is guided through all operation steps by spoken and displayed instructions.

The FRED easyport runs in semi-automatic mode. This means that the shock must be released by the user.

When the device is switched on, the user is prompted to apply the electrodes to the patient. Next, he or she is prompted to start the ECG recording and to stay clear of the patient. The analysis takes approximately 10 seconds. Depending on the configuration, the unit automatically starts analysing the ECG.

2.4.3 Device Identifies a Shockable Rhythm

If the analysis program detects a shockable rhythm, the defibrillation energy is charged and the user is prompted to deliver the shock. Shockable rhythms are:

- Ventricular fibrillation
- Ventricular tachycardia with a rate exceeding 180 beats per minute

Even if the device detects a shockable rhythm, a shock must only be delivered if lack of breathing and lack of circulatory signs have been established.

If the shock is not successful, the device automatically charges the defibrillation energy for another shock after every further analysis.

The following standard energy levels are preset:

Shock	Adults	Neonates
1	120 joules	15 joules
2	120 joules	30 joules
3	120 joules	50 joules

The SCHILLER service centre can define other settings if required (see section 7, page 32).

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First shock After the shock, the user is prompted to:

1. alternately carry out 30 [1]chest compressions and give 2 breaths for 2 minutes.
2. after 2 minutes, the unit prompts the user again to start a new ECG analysis. Depending on the configuration, this new analysis may start automatically.

Shock unsuccessful: **Second shock release** and prompt to restart with step 1.

[2]Shock successful: Information that no shock is required and

- prompt to carry out cardiac compressions and respiration alternately for 2 minutes until the patient breathes or new instructions follow.
- after 2 minutes, prompt to start a new ECG analysis

For Qualified Physicians only

The analysis can at any time be repeated during CPR by pressing the blue analysis button (2).

2.4.4 Device Detects no Shockable Rhythm

If the analysis program does not identify a shockable rhythm, the **FRED easyport** informs the user:

- that no shock is required
- that he or she should alternately carry out 30 chest compressions and 2 breaths for 2 minutes
- after 2 minutes, prompt to start a new ECG analysis

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1. When paediatric electrodes are used, CPR is carried out in the rhythm 15:2 if 2 rescuers are on the spot, otherwise in the 30:2 rhythm.
2. CPR should be continued even after a successful shock to reduce the risk of momentary electrical myocardial stunning after the defibrillation.

2.5 Voice Support

When the device is switched on, it carries out a self-test and indicates the software and hardware version. The following instructions will be spoken by the device:

Language	Display	Note
[a]Place electrodes on chest and plug into machine.	PLACE ON ELECTRODES PLUG INTO MACHINE	Technical alarm: Electrodes not connected. The yellow light goes out as soon as the electrodes are properly placed. See section 4.3.2.
Poor connection; press the electrodes	CHECK THE ELECTRODES	Technical alarm: The contact between the electrodes and the skin is not sufficient. The patient resistance exceeds 200 Ohm. See section 4.3.3.
[b]Press blue button.	PRESS BLUE BUTTON	Heart rhythm analysis is started.
Do not touch the patient. Analysis in progress.	DO NOT TOUCH THE PATIENT ANALYSING	See page 21, Step 2, Analysis
Stop movement.	MOVEMENT DETECTED STAND CLEAR	Technical alarm: Patient was moved during analysis and device could not run analysis.
Device recommends a shock		See section 2.4.3 and page 22.
Do not touch the patient. Charging.	DO NOT TOUCH THE PATIENT CHARGING	
Stand clear of patient. Press orange button.	PRESS ORANGE BUTTON TO SHOCK	
Shock not recommended		See section 2.4.4
No shock advised.	NO SHOCK ADVISED	See section 2.6
Immediately resume CPR – 30[c] chest compressions, then 2 rescue breaths – continue until patient is breathing normally.	30 CHEST COMPRESSIONS THEN 2 RESCUE BREATHS	See section 2.6

a. In the "silent" mode, this text is only spoken once.
b. In the "silent" mode, this text is only repeated every 2 minutes.
c. When paediatric electrodes are used, CPR is carried out in the rhythm 15:2 if 2 rescuers are on the spot, otherwise in the 30:2 rhythm.

If the device is switched off and back on again (e.g. to change the battery), the language support will resume from the step at which the device was shut off.

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2.6 Procedure in Case of Cardiac Arrest

This procedure applies to adults and children.

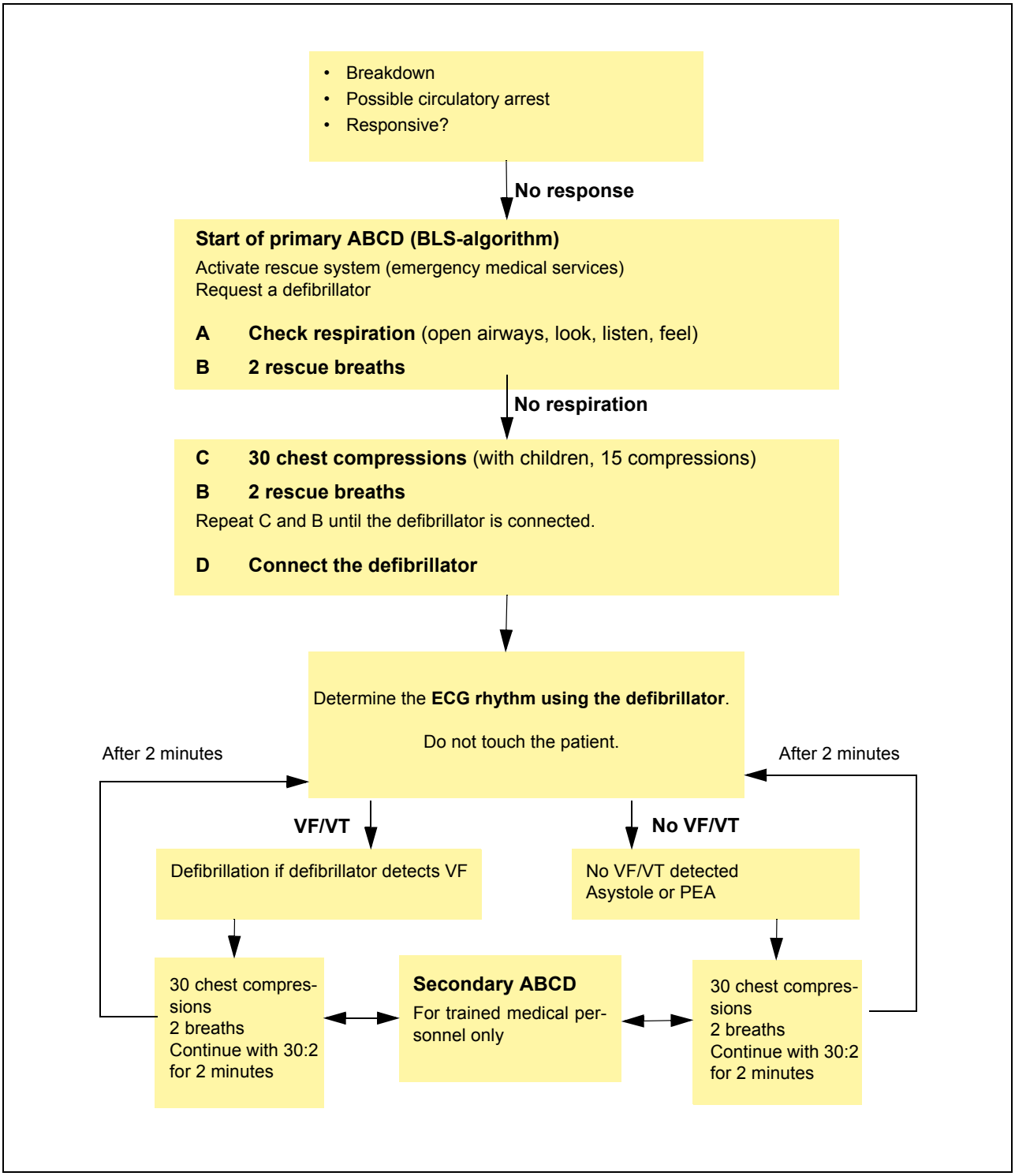

Fig. 2.3 BLS AED algorithm or cardiopulmonary resuscitation (CPR) with defibrillation

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3 Operation

3.1 Start-up and Preparation

DANGER

- ▲ Danger of explosion! The device is not designed for use in areas where an explosion hazard may occur. In addition, use of the defibrillator is not permitted in an oxygen-enriched environment or in the vicinity of flammable substances (gasoline) or anaesthetics. Oxygenation in the vicinity of the defibrillation electrodes must be strictly avoided.
- ▲ Danger of electric shock! The FRED easyport is a high-voltage electric therapy device. Improper use of the device can endanger life. Always follow the instructions given in this user guide.
- ▲ Before using the device, the user 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.
- ▲ The user must make sure that there are no conductive connections between the patient and other persons during ECG analysis and defibrillation.
- ▲ Avoid defibrillation in very moist or wet surroundings.
- ▲ To ensure the defibrillator's readiness for use, always keep a spare battery on hand.

3.1.1 Inserting the Battery

The device is powered by a non-rechargeable lithium battery. The battery has a guaranteed standby operation of at least 5 years if the device is not used.

After five years – if the device has not been used – the battery must be replaced.

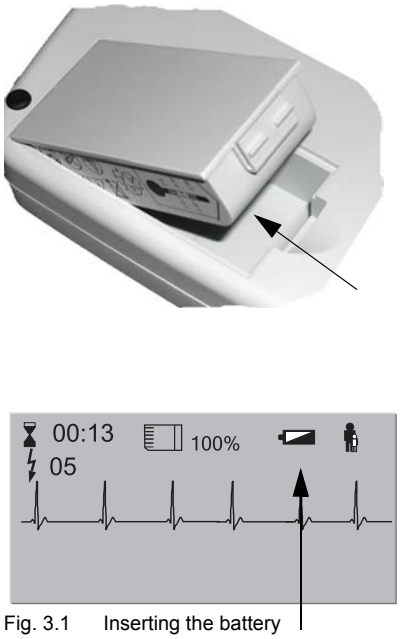

Fig. 3.1 Inserting the battery

1. Insert the battery into the device as shown in Fig. 3.1. Make sure it clicks into place.
2. Switch the unit on. A self-test will run. (See section 2.4.1.)
3. Check the battery status on the display. If the battery is low, the battery symbol (1) is displayed.

WARNING

- ▲ To enable a quick reaction in the case of any emergency, the high-potential capacitor is charged on switch-on, reducing the battery's capacity (see page 32). The battery capacity is also reduced by the capacitor's trickle charge while the unit is on.
  For these reasons:
  - – Always keep a new spare battery on hand
  - – Always note the number of switch-ons and the battery's running time in the Inspection Report on page 36, even when you only demonstrate the device to other users.

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3.1.2 Ensuring Operational Readiness

- Do not expose the device to direct sunlight, or extremely high or low temperatures. The ambient temperature should be in the range of 0...40 °C. Lower or higher ambient temperatures will have a negative impact on the battery's life.

To ensure its readiness for use, the device runs a self-test to check the unit and the battery. The self-test is carried out when the unit is switched on. If the device detects an error during the self-test, an error message is displayed.

⚠ CAUTION

- ▲ The duration of the self-test and the display check is max. 30 seconds. Immediately switch the device off afterwards! Battery discharge!
- ▲ Note the test results and the duration of the operation in the Inspection Report on page 36.
- ▲ If you only carry out the self-tests, the battery will last for approx. 30 switch-ons.
- ▲ SCHILLER recommends always to keep a spare battery on hand.

3.1.3 Switching on and off

- When the device is switched off for less than 5 min. (e.g. for battery replacement or by mistake), the data remains stored and the operation is continued after the self-test as if the device had not been switched off.

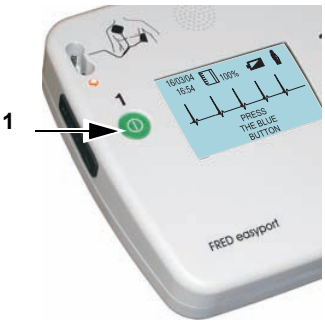

Fig. 3.2 Switching the unit on/off

Switching on

➜ Switch the device on by pressing the green button (1). It can at any time be switched off using the same button.

Switching off

➜ To switch off the device, keep the green button (1) pressed for at least 3 seconds. A safety discharge ensures that the stored defibrillation energy is discharged internally.

The device is switched off automatically 5 minutes after an electrode error is indicated.

3.1.4 Internal Safety Discharge

A safety discharge ensures that the stored defibrillation energy is discharged internally. It is carried out if:

- the battery voltage is insufficient
- the device is defective
- the device is turned off

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4 Defibrillating

4.1 General 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.

- The patient must:
  - **not** come into contact with other persons during defibrillation.
  - **not** come into contact with metal parts, e.g. bed or litter, or be positioned on wet ground (rain, accident in swimming pool), to prevent unwanted pathways for the defibrillation current, which may endanger the assistants.
- 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, as moisture causes unwanted pathways for the defibrillation current. For safety, wipe off flammable skin cleansing agents.
- Owing to the high currents, there is a risk of skin burns at the site of the electrodes. This is why the electrodes must not be placed on or above:
  - the sternum, clavicle or mamillas
- Immediately prior to the shock, the heart massage (CPR) and artificial respiration must be stopped and bystanders must be warned.
- 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, and check the implanted pacemaker for proper functioning as soon as possible after the shock.

4.2 Additional Safety Notes

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

⚠WARNING

- To ensure correct analysis of the heart rhythm, the patient must lie as still as possible and must not be touched, as this can lead to incorrect analysis results due to artefacts.
- The user must apply the ABCD procedure (BLS algorithm) to determine if the AED may be used.
- If, in the course of treatment, a patient spontaneously regains consciousness, a defibrillation shock that may have been advised just before must not be delivered.
- If the ECG signal changes such that the shock is not recommended, the shock delivery is automatically blocked in the AED mode.

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4.3 Applying the Pads

CAUTION

- ▲ Use the defibrillation electrode pads only up to the indicated expiration date. Please note that the indicated expiration date only applies if the vacuum pack is intact.
- ▲ The pads are pre-gelled, so there is no need to use extra contact agent.
- ▲ Do **not** reuse the pads.

4.3.1 Adult and Paediatric Electrodes

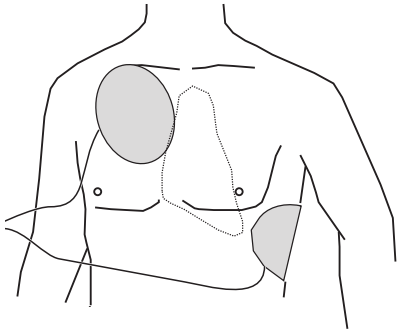
Large electrodes The large electrodes are to be used for adults and children from 25 kg body weight.

Small electrodes The small electrodes are intended for children with a body weight under 25 kg.

4.3.2 Applying the Electrodes

WARNING

- ▲ Good contact between the skin and the adhesive electrodes must be ensured. Suntan oil, sand or salt reduce the adhesive quality.
- ▲ The applied pads must have good contact with the patient's skin, and air bubbles under the pads must be avoided. To do so, stick on one end of the pad, then smooth it out to the other end.



1. Clean and dry the application points for the electrodes (see Fig. 4.1). Only clean the skin by vigorously rubbing it with a dry cloth.
2. Apply one electrode above the right nipple. Do not apply it on the clavicle (uneven).
3. Apply the other electrode slantwise below the left breast as illustrated in Fig. 4.1.
4. Make sure that the connections are positioned on the outside so they do not hinder heart massage (CPR).

Fig. 4.1 Electrode application points

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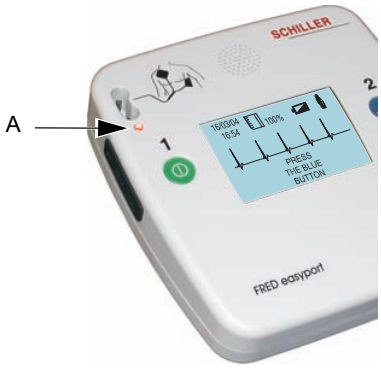
4.3.3 Checking the Electrodes



If the resistance between the skin and an electrode should be too high, a message is displayed and the yellow electrode LED (A) (fig. 4.2) remains lit. Proceed as follows:

1. Alternately press down firmly on the defibrillation pads and check when the message disappears. Carefully press that pad onto the patient's skin once again.
   If the message does not disappear,
2. remove both defibrillation electrodes
3. wipe rests of contact agent off with a cloth
4. Shave both application areas to remove the uppermost layer of skin.
5. apply new defibrillation pads to these points

Fig. 4.2 Electrode LED

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4.4 Defibrillation Procedure

When the device is switched on, it gives spoken and displayed instructions up to the defibrillation. Exactly follow the instructions.

Step 1

Switching on and preparing the device

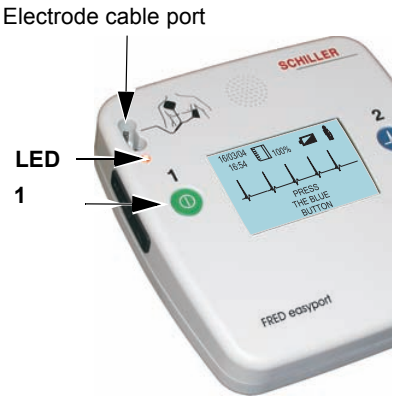

Fig. 4.3 Switch unit on

1. Switch the device on by pressing the green button (1).
2. Check the state of the patient. See ABCD, section 2.6.
3. You are prompted to continue the resuscitation and to stick on the electrodes.
4. Stick on the defibrillation electrodes as shown in Fig. 4.1.
5. Connect the electrode cable to the unit. (See Fig. 4.3.) The yellow electrode indicator LED will go out as soon as the device is able to identify an acceptable electrode resistance. If the LED is not switched off, see section 4.3.3.

Step 2

Analysis

Fig. 4.4 Analysis

6. You are prompted to start the analysis.
7. Press blue button (2). You are prompted to stay clear of the patient.

If the device detects ventricular fibrillation or ventricular tachycardia with a heart rate exceeding 180 beats/min., Step 3 follows; otherwise continue with Step 4, Cardiopulmonary resuscitation.

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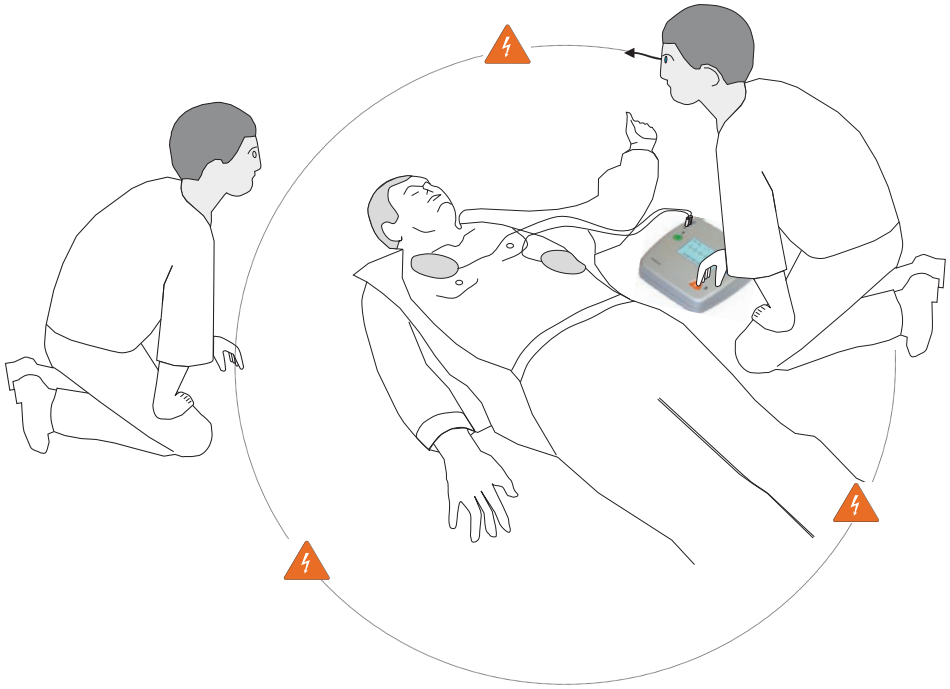
Step 3

Shock delivery

As soon as the energy for a shock is charged, the device prompts the user to deliver the shock by pressing button 3.

▲ Danger of electric shock!

- Do not, under any circumstances, touch the patient during shock delivery.
- Make sure that the patient does not touch any conducting objects.



8. Deliver the shock by pressing the button  .

   After the shock, the device immediately instructs you to continue with **step 4** – CPR.

Step 4

Cardiopulmonary resuscitation

9. Carry out cardiopulmonary resuscitation. Alternate between 30 chest compressions and 2 breaths for 2 minutes. After 2 minutes, the device restarts with Step 2, Analysis.

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4.5 Defibrillation in Manual Mode

The FRED easyport version including the manual option is clearly labelled with a red foil. If the user does not activate the manual mode during switch on, the unit will run in the semi-automatic mode. The defibrillation will then be carried out as described in section 4.4.

⚠WARNING

- ▲ Danger to the patient! The device must only be switched over to the manual mode by the physician.
- ▲ It is very important that the guidelines and safety notes in sections 4.1 and 4.2 be observed.
- ▲ The manual operational mode must never be used by non-medical staff if the local law exclusively allows semi-automatic defibrillators for this user group. However, there are countries where rescue teams and medical supervision staff request the switch-over option from the semi-automatic to the manual mode on the push of a button. In this case, it is necessary to agree an individual procedure with the rescue staff. This procedure must follow the AHA or ERC protocols or the local legal requirements. Further more, the rescue organisation must ensure that
  - – the specified algorithms are kept
  - – the staff is trained in the procedure

Switching over to Manual/Semi-Automatic Mode

- The device cannot be switched over to the manual mode during the defibrillation process (analysis, charging, shock release).
- To operate the FRED easyport in semi-automatic mode again, it must be shut off and remain off for at least 5 minutes.

1. Switch the device on by pressing the green button (1).
2. Simultaneously press the blue (2) and the orange (3) buttons.
   The message "CONFIRM MANUAL MODE" is displayed.
3. Within 5 seconds, again press the blue (2) and the orange buttons (3).

The following is displayed:

- – The ECG curve
- – The selected energy (according to the factory settings – see page 12)
- – Prompt to press the green button to charge the energy

Charging the Energy

➜ Press blue button (2).

The following is displayed:

- – Energy charging progress
- – As soon as the set energy is reached, the orange button (3) is lit
- – Prompt to release the shock

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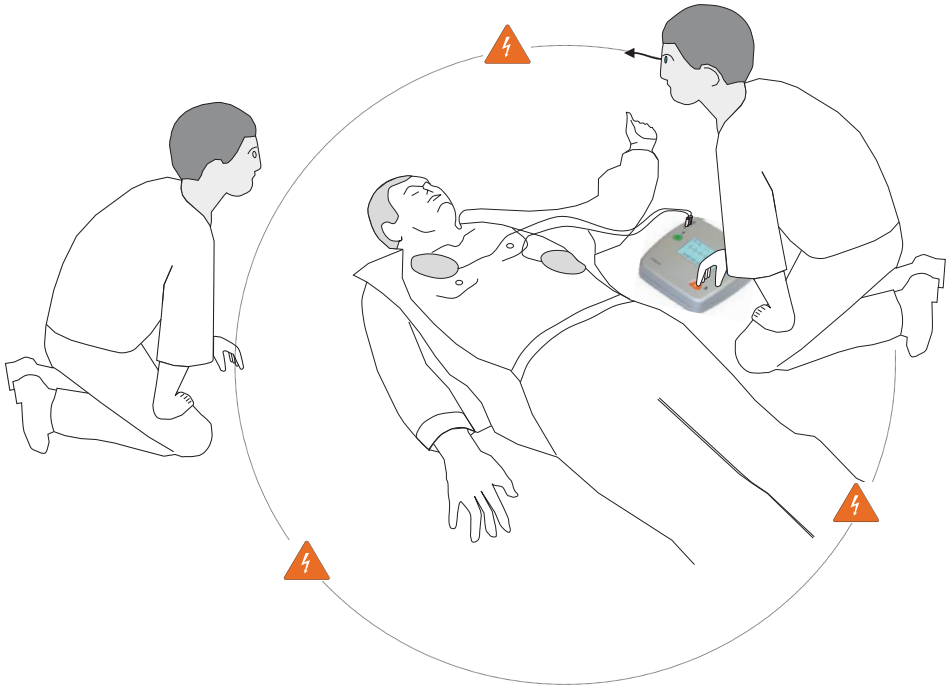
Shock Delivery in Manual Mode

⚠ DANGER

- ▲ Danger to the patient! Before you release the shock, check the displayed ECG curve to make sure that a shockable rhythm is present.
- ▲ Danger of electric shock!
  - – Do not, under any circumstances, touch the patient during shock delivery.
  - – Make sure that the patient does not touch any conducting objects.



4. Deliver the shock by pressing the button  .

If the shock is not released within 20 seconds, an internal safety discharge is initiated.

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4.5.1 Finishing the Therapy

1. Switch the device off as soon as the therapy is finished (keep the button pressed for approx. 3 seconds).
2. Disconnect the plug of the electrode line.
3. Carefully pull the electrodes off the patient's skin.
4. Discard the disposable pads immediately after use to prevent their reuse (hospital waste).

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5 Documentation of an Intervention

To document an intervention using the unit, the following data can be recorded using the memory card:

- ½ hour of ECG
- 500 events with date and time of intervention with the following data:
  - Power on
  - Start of analysis
  - Analysis result
  - Charging of the defibrillator
  - Defibrillation shock
  - Internal discharge
  - Electrode alarm
  - "Battery low" alarm

The memory card is evaluated on a PC using the SAED READER software.

5.1 Inserting the Memory Card

WARNING

- ▲ Equipment damage! The memory card slot must always be covered with the plastic cover. This is to prevent moisture in the device.
- ▲ The functioning of the device can only be guaranteed with an SD card from SCHILLER.

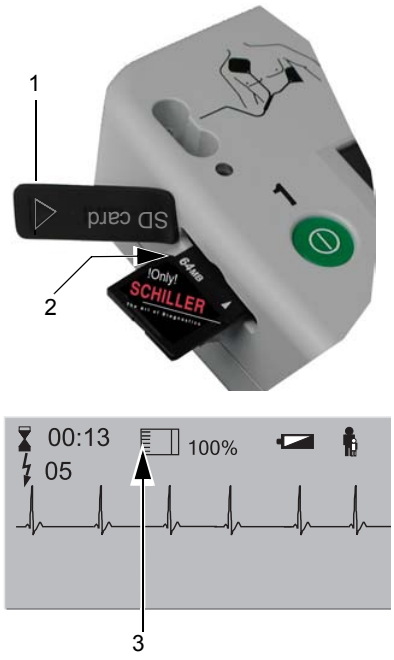

Fig. 5.1 Memory card inserted

1. Open the plastic cover (1).
2. Insert the memory card (2) with the shaped indent facing upward.
3. Carefully close the plastic cover.

When the memory card is full, the symbol (3) flashes.

Make sure that you only insert the card with the device turned off and in the way shown in Fig. 5.1 (shaped intend (2) facing upward). Otherwise, the card will not be detected by the device and the symbol is not displayed.

After inserting the card, close the plastic cover again.

WARNING

If the flashing symbol is displayed even though the card is inserted, check if the card is intended by SCHILLER for this device.
Incorrect or defective cards can impair the unit's operation!
(See section Error Detection 6.3.)

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6 Maintenance

6.1 Maintenance Intervals

Note

The unit must be serviced on a regular basis. The test results must be recorded and compared to the values in the accompanying documents.

The following table indicates the intervals and responsibilities of the maintenance work required.

Interval	Maintenance	Responsible
Before each use	• Visual inspection of the device and electrodes	➜ User
Monthly	• Visual inspection of the device and electrodes • Check of the electrodes' expiration date	➜ User
Every 4 months	• Functional tests according to the instructions (see page 36, 8.4 Inspection Report)	➜ User
Every 4 years	• All measurement inspections and calibration according to the instructions in the service handbook	➜ Service staff authorised by SCHILLER
Every 5 years	• Replacement of the battery in the device and check of the spare battery's expiration date	➜ User

6.1.1 Visual Unit Check

Inspect the device and electrodes for the following:

➜ Device casing not deformed?
➜ Electrode connection undamaged?
➜ Expiration date indicated on the electrode package
➜ Expiration dates of the battery and spare battery

Defective units or damaged cables must be replaced immediately.

6.1.2 Functional Test

➜ Switch the device on and carry out a self-test.

⚠ CAUTION

▲ The duration of the self-test and the display check is max. 30 seconds. Immediately switch the device off afterwards! Battery discharge!
▲ Note the test results and the duration of the operation in the Inspection Report on page 36.

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6.1.3 Maintenance Interval for the Battery

Important

- The battery is maintenance free during its normal life.
- The battery must be replaced after 5 years, regardless of whether or not the unit has been used.
- When you demonstrate the device to other users, the battery's life is reduced by the number of switch-ons and the duration of the operation (see battery capacity on page 32). To ensure the device's readiness for use, the battery must be replaced by a new, non-expired battery.

6.1.4 Battery Disposal

WARNING

▲ Danger of explosion! Battery may not be burned or disposed of with domestic refuse.

▲ Danger of acid burns! Do not open or heat up the battery.

The battery is to be disposed of in municipally approved areas or sent back to SCHILLER.

6.1.5 Disposal at the End of the Device's Useful Life

This unit must be disposed of in a municipally approved collection point or recycling centre when no longer used.

If no such collection point or recycling centre is available, you can return the unit to your distributor or the manufacturer for proper disposal. In this way, you contribute to the recycling and other forms of utilisation of old electrical and electronic equipment.

Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.

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6.2 Cleaning

6.2.1 Cleaning the Casing

WARNING

- ▲ Switch the unit off before cleaning and remove the battery. Do not, under any circumstances, immerse the apparatus into a cleaning liquid or sterilise with hot water, steam, or air.
- ▲ Do not use any phenol-based agents or peroxide compounds for cleaning.

→ Wipe the unit's casing with a tissue dampened in a cleaning or disinfection solution (70% alcohol). Make sure that no liquid enters the unit.

6.2.2 Accessories and Disposables

WARNING

- ▲ Always use SCHILLER replacement parts and disposables, or products approved by SCHILLER. Failure to do so may endanger life and invalidate the guarantee.

Your local representative stocks all the disposables and accessories available for the FRED easyport. A full list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch). In case of difficulty, contact our head office in Switzerland. Our staff will be pleased to help process your order or to provide any details for all SCHILLER products.

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6.3 Error Detection

Error	Cause	Remedy
Display is not lit when the unit is switched on	• Battery not inserted correctly or defective	➜ Insert battery correctly or replace it
	• Device defective	➜ Replace device
Yellow electrode LED is lit	• Electrode cable not plugged in	➜ Plug in electrode cable
	• Electrode-to-skin contact impedance too high because of:	
	– old electrodes (expiration date)	➜ Replace electrodes
	– incorrect application of electrodes	➜ Apply electrodes according to the instructions in section 4.3.2
	• Device defective	➜ Replace device
Message: Check the electrodes	• Short-circuit between the electrodes	➜ Apply electrodes according to the instructions in section 4.3.2
	• Device defective	➜ Replace device
Device cannot be switched off	• Green button pressed for less than 3 seconds	➜ Keep the green button pressed for at least 3 seconds
	• Device defective	➜ Replace device
No analysis	• ECG signal too weak	➜ Perform cardiac massage again
	• ECG signal interference through electromagnetic waves	➜ Turn off source of signal interference, e.g. radio equipment or cell phone, or move patient outside field of interference
	• Patient moved or touched during analysis	➜ Do not move or touch patient during analysis
	• Device defective	➜ Replace device
Unable to deliver shock	• Battery too low	➜ Change battery
	• Electrode error caused by resuscitation measures	➜ Reapply electrodes
	• Heart rhythm has changed	➜ Run new analysis
	• Device defective	➜ Replace device
Message “Error xxx”	• Device defective	➜ Replace device
Battery capacity indicator is flashing	• Battery almost empty	➜ Replace battery
Symbol  is not displayed	• SCHILLER memory card not/not correctly inserted	➜ Switch off device and properly insert memory card
	• The card is defective	➜ Replace card by a new SCHILLER card
Symbol  is flashing	• Memory card not detected because inserted with device switched on	➜ Switch off and restart device
	• No SCHILLER SD card used	➜ Use SCHILLER card
Memory card does not save any data	• Memory card defective	➜ Replace memory card
	• Device defective	➜ Replace device
Date and time wrong on memory card	• Internal watch misadjusted	➜ Have updated the internal watch by an authorised person via data transfer
	• Device defective	➜ Replace device

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6.3.1 Measures to Prevent Electromagnetic Interferences

"Non-ionic electromagnetic radiation"

The device is designed for use in an electromagnetic environment in accordance with IEC/EN 60601-1-2, tables 201, 202 and 204. If the device should nevertheless be disturbed, especially in the vicinity of equipment labelled with the symbol "Non-ionic electromagnetic radiation", check the recommended minimum distance according to IEC/EN 60101-1-2, table 206. For further details, please refer to the service handbook.

The following table lists devices and their typical frequency ranges and transmitting power and the resulting minimum distances.

HF source	Transmitter frequency [MHz]	Power P [W]	Distance d [m]
Radio telephone (microcellular) CT1+, CT2, CT3	885-887	0.010	0.23
Cordless DECT telephone, WLAN, UMTS phone	1880-2500	0.25	1.17
Mobile phone USA	850/1900	0.6	1.8
Mobile phone - GSM900 - GSM850, NMT900, DCS 1800	 900 850, 900, 1800	 2 1	 3.3 2.3
Walkie-talkie (rescue service, police, fire brigade, service)	81-470	5	2.6
Mobile telephone system (rescue service, police, fire brigade)	81-470	100	11.7

For transmitters not included in the above table, the recommended distance (d in meters) can be calculated using the following formulas:

Frequency range 0.15–80 MHz

$$d = \frac{3.5}{3V} \times \sqrt{P}$$

Frequency range 80–800 MHz

$$d = \frac{3.5}{3V/m} \times \sqrt{P}$$

Frequency range 800 MHz–2.5 GHz

$$d = \frac{7}{3V/m} \times \sqrt{P}$$

d = recommended minimum distance in meters

P = transmitting power in Watts

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7 Technical Data

Where nothing else is indicated, the data refers to a temperature of 25 °C.

7.1 System Data

Manufacturer	SCHILLER MEDICAL
Device name	FRED easyport (**F**irst **R**esponder **E**xternal **D**efibrillator)
Dimensions	35 x 133 x 126 mm (h x l x w)
Weight	490 g
Protection case	IPX 4
Power supply	Internal power supply
Battery	
Battery type	Lithium
Battery life	• 45 shocks at maximum energy, or • 2 hours of monitoring (alternately 30 min. on, 30 min. off)

Battery capacity decrease on switch-on: approx.	2%
Battery capacity decrease by 5 min. monitoring: approx.	4.0%
Total battery capacity decrease by switch-on and 5 minutes monitoring: approx.	**6%**

Environmental conditions	
Operating temperature	• 0 ºC...40 ºC relative humidity at 0...95% (noncondensing) • Atmospheric pressure 500...1060 hPa
Storage and transport temperature	• -20 ºC...50 ºC; relative humidity at 0...95% (noncondensing) • Atmospheric pressure 700...1060 hPa
Display	
Type	• High-resolution colour LCD, backlit
Dimensions	• 60 x 40 mm
Safety standard	IEC/EN 60601-2-4 The device is designed for 2500 shocks
EMC	• IEC/EN 60601-2-4 • CISPR 11 class B The device can be exposed to the following interferences without any impairment: • Static discharges up to 8 kV • Energy in the radio frequency range up to 20 V/m (80...2500 MHz, 5 Hz modulated) • Magnetic fields of 100 A/m, 50 Hz
Conformity	CE according to directive 93/42/EEC, class IIb

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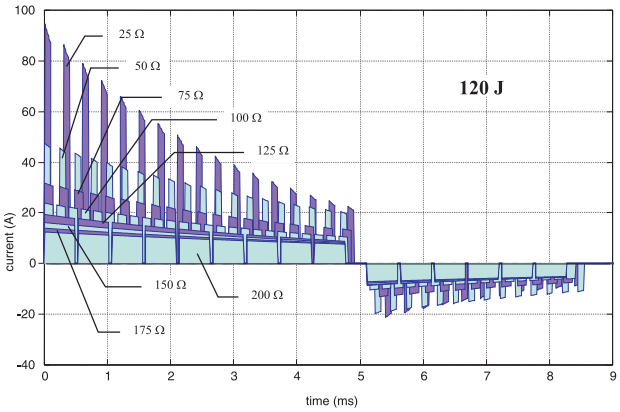
7.2 Defibrillation Impulse

Form

- Biphasic pulsed defibrillation impulse with fixed physiological optimum phase durations
- Near stabilisation of the emitted energy in function with the patient resistance using pulse-pause modulation depending on the measured patient resistance.



Standard energy settings

Adults
Neonates

Deviation at 50 ohms: ±3 J or ±15% (the higher value is assumed)

- 120/120/120 joules
- 15/30/50 joules (automatic switch-over when children electrodes are connected)

Other energy setting

Adults
Neonates

Our customer service can change the default energy settings to the following values:

- 15/30/50/70/90/120 joules
- 15/30/50/70 joules

Time to shock standby

- From the start of the analysis
- For max. energy after switch-on

(With new batteries and after 15 discharges at max. energy output)

- 30 seconds
- 40 seconds

Charge control and monitoring

Automatic shock recommendation of analysis

Display of shock standby

Key  is lit

Shock delivery

Using key 

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Safety discharge when:	• the battery voltage is insufficient • the device is defective • the device is turned off
Shock delivery	Via disposable adhesive electrode pads applied in the anterior-anterior lateral position
Defibrillation electrode connection	BF type
Defibrillation electrodes Electrodes for adults Electrodes for children	Electrode cable 1.2 m long • 50 cm^2 active surface • 28 cm^2 active surface
VF/VT detection	**Conditions for ECG analysis** Minimal amplitude for signals to be analysed >0.15 mV; signals <0.15 mV assessed as asystole **Shock recommendation** In case of VF and TV (TV >180 b/min.) **Sensitivity 96.4 %** Correct detection of shockable rhythms **Specificity 99.8%** Correct detection of **non**-shockable rhythms These values were determined with an AHA database containing VF and VT with or without artefacts.

7.2.1 Storage of an Intervention (Option)

Storage of ECG	30 minutes
Storage of events	500 events

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8 Appendix

8.1 Accessories

Article no.	Article description
2.155056	Single-use defibrillation pads for adults
2.155057	Single-use defibrillation pad for children
3.940002	Battery
2.156038	Carrying pouch
4.150169	Mini SD memory card 16 MB

8.2 Literature

European Resuscitation Council (2005) Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (67 S1:1-146).

American Heart Association (2005) Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (9:1-170 ISBN 0080448704).

Cansell A. (2000) Wirksamkeit und Sicherheit neuer Impulskurvenformen bei transthorakaler Defibrillation – Biphasische Impulskurvenformen – Notfall- & Rettungsmedizin, Springer-Verlag 3: 458 – 474.

8.3 Glossary

ABCD The primary ABCD

A = Airways (check breathing)
B = Breathing (artificial respiration)
C = Circulation (circulatory signs or cardiac massage)
D = Defibrillation

ACLS Advanced Cardiovascular Life Support. (ACLS Manual AHA 2001)

AED Automated external defibrillator. This term is also used for semi-automatic defibrillators (SAED).

SAED Semi-automatic external defibrillator. The shock is released by the user.

BLS Basic Life Support (artificial respiration and cardiac massage)
CPR is frequently used synonymously

CPR Cardiopulmonary resuscitation

CPR Cardiopulmonary resuscitation

PEA Pulseless electrical activity

VT Ventricular tachycardia

VF Ventricular fibrillation

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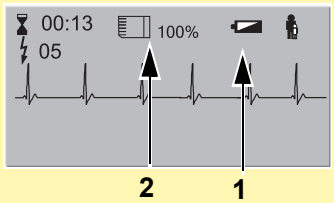
8.4 Inspection Report

▲ The user guide must be read before the inspection.
▲ **Recommended inspection interval:** Every 4 months

Serial no.: _____

Test	Results	Date				
General condition ➜ External condition	• No isolation or mechanical problems	❒	❒	❒	❒	❒
Accessories ➜ Availability and condition **WARNING** Only use a SCHILLER memory card! Incorrect cards can impair the unit's operation!	• Electrodes (expiration date and compatibility) • User guide • SCHILLER memory card 	❒ ❒ ❒	❒ ❒ ❒	❒ ❒ ❒	❒ ❒ ❒	❒ ❒ ❒
Self-test (automatic when the unit is switched on) ➜ Switch unit on Immediately switch the unit off after the self-test (battery discharge)! Note the time used for the self-test.	• The standard screen is displayed.  (1) If the battery symbol is displayed, replace the battery. (2) Check the symbol and memory.	❒ Operation time [min.]: ❒	❒ Operation time [min.]: ❒	❒ Operation time [min.]: ❒	❒ Operation time [min.]: ❒	❒ Operation time [min.]: ❒
Notes						
Inspection carried out by:						

In case of a defect, please contact the service department of your hospital ❒, your SCHILLER representative ❒ or the local after-sales service ❒.

Name: ..... Phone: .....

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