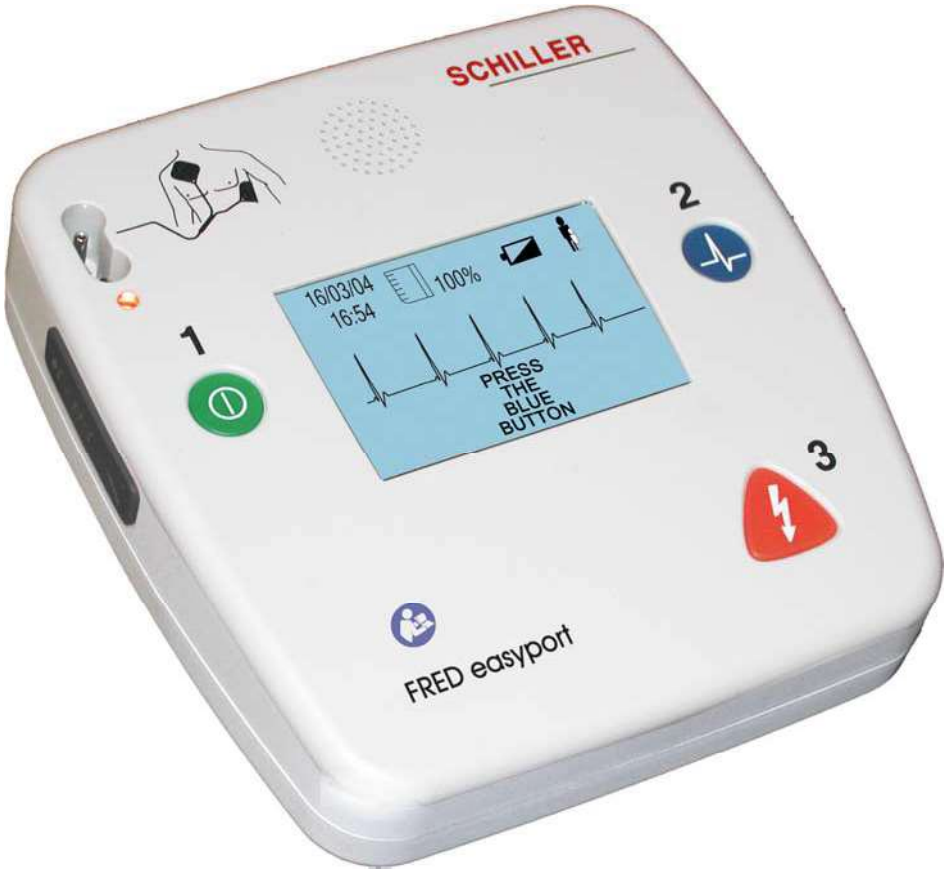
FRED® easyport®

Automated external defibrillator (AED)
FRED® easyport®



User Guide

SCHILLER
The Art of Diagnostics

Art. no.: 2.510544 Rev.: L

Printed on: 28 Apr 2020, 04:14:06 pm; Printed by: PRAKT3.

Sales and Service Information

The SCHILLER sales and service centre network is world-wide. For the address of your local distributer, 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
Sales information can also be obtained from:
sales@schiller.ch

Manufacturer

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CE 0123

The FRED easyport bears the CE-0123 mark (Notified Body TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), indicating its compliance with the essential requirements of the Annex I of the Medical Device Directive 93/42/EE regarding safety, functionality and labelling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use. First declaration 01.01.2004.

Article-No.: 2.510544 Rev.: L
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SCHILLER
The Art of Diagnostics

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1 Safety Notes

1.1 User profiles

The following people may use the FRED easyport:

- Physicians or other trained medical personnel
- other people (non-professionals) trained in early defibrillation
- other people not trained in early defibrillation, as long as they can understand and follow the spoken and displayed instructions.

Even though untrained people may use the device, training and instructions are recommended to guarantee an optimal resuscitation procedure.

1.2 Responsibility of the User

▲ The regulations governing the use and training requirements for devices such as the FRED easyport vary from country to country. In any case, legal regulations have to be observed.

▲ 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.

1.3 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:

– not responsive
– no respiration
– no pulse

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1.4 Contra-indication

- ▲ The device must **not** be used if the patient:
  - – is responsive
  - – is breathing
  - – has a pulse
- ▲ The device is **not** designed for sterile use.
- ▲ Do not use this device in areas where there is any danger of explosion or in the presence of flammable liquids, flammable anaesthetic agents or in places where the ambient air's oxygen concentration is higher than 25 %.
- ▲ The device is not designed for direct cardiac application.
- ▲ The device must be used according to the technical data.

1.5 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, procedures for the prevention of accidents or environmental protection.
- ▲ FRED easyport is an emergency device and must be ready for operation at any time and in all situations. Make sure that
  - – the device is always equipped with a sufficiently charged battery and that a spare battery is at hand
  - – the maintenance steps, in particular the 4-monthly maintenance step indicated by the symbol  , are performed.

1.6 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
  - – Wear rubber gloves
  - – 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 for servicing the monitor.
- ▲ Only connect the original SCHILLER pads to the unit.
- ▲ Before switching on, check if the unit's casing and electrode connection are undamaged.

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1.7 Maintenance

- ▲ Danger of electric shock! Do not open the device. There are 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 aggressive or abrasive cleaners.
- ▲ Do not, under any circumstances, immerse the device or cable assemblies in liquid.

1.8 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.

1.9 General Notes Regarding the Unit

A defibrillation can fail with certain clinical pictures.

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1.10 Terms of Warranty

Your SCHILLER FRED easyport is warranted against defects in material and manufacture, as stated in the Terms and Conditions. Excluded from this warranty is damage caused by an accident or as a result of improper handling. The warranty entitles to 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 the device is defective, send it to your local SCHILLER representative 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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1.11 Symbols

1.11.1 Symbols used in this user guide

The safety level is classified according to ISO 3864-2. The following overview contains the safety symbols and pictograms used in this user guide.

For a possibly dangerous situation which could lead to severe personal 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 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 instructions.

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1.11.2 Symbols used in different locations

Manufacturer symbol

Notified body of the CE certification
- CE 0123TÜV-SÜD Produkte Service GmbH
- CE 408 TÜV AUSTRIA Service

Note accompanying documents!

Consult user guide!

Symbol for the recognition of batteries as well as 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.

Expiry date

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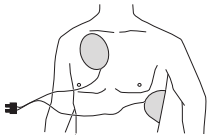
1.11.3 Symbols used on the device

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

IPX4

The device is protected against splashing water.



Defibrillation electrode connector.

This function must only be used by physicians or other authorised persons (see page 30).

1.11.4 Symbols used on the battery

The unit/component can be recycled.

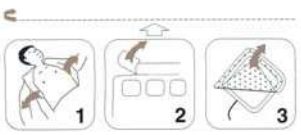
Do not burn, saw up or crash the battery.

Do not recharge the battery.

Do not short-circuit the battery.

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

1.11.5 Symbols used on the electrode package



- Remove the patient's clothes
- Open the electrode packaging
- Peel off the protective foil

Disposable item; do not reuse

Do not bend packing

Storage temperature for the electrodes

Latex-free

Use within one day after opening.

Do not use if the packaging is damaged

Store in a dry location

Protect from direct sunlight

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2 Components and Operation

2.1 General Information

FRED easyport® is an automated external defibrillator (AED).
The **FRED easyport®** is available as a semi-automatic or manual defibrillator.
The regulations governing the use and training requirements for AEDs such as **FRED easyport®** differ from country to country. The laws and regulations for the use of AEDs need to be strictly observed.

Local laws and regulations regarding the use of an AED differs 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 special training.
For training purposes, SCHILLER offers the **FRED easyport® TRAINER**.

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 product parts and accessories described in this user guide that come into contact with the patient when the device is used as intended fulfil the biocompatibility requirements of the applicable standards. If you have any questions in this matter, please contact SCHILLER.

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2.2 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 battery capacity is sufficient for:

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

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

2.2.1 Available options

- SCHILLER ECG memory card
- Manual operation mode (see page 30)

2.2.2 Overview of the configurable settings

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

- Voice volume
- Energy level for 1st, 2nd and 3rd shock (separate settings for adults and children)
- Start of the ECG analysis by pressing a button or automatic
- Enable/disable the 16.7 Hz filter
- Silent operational mode (spoken text with reduced repetition rate)
- Trace deactivation

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2.3 Operating Elements

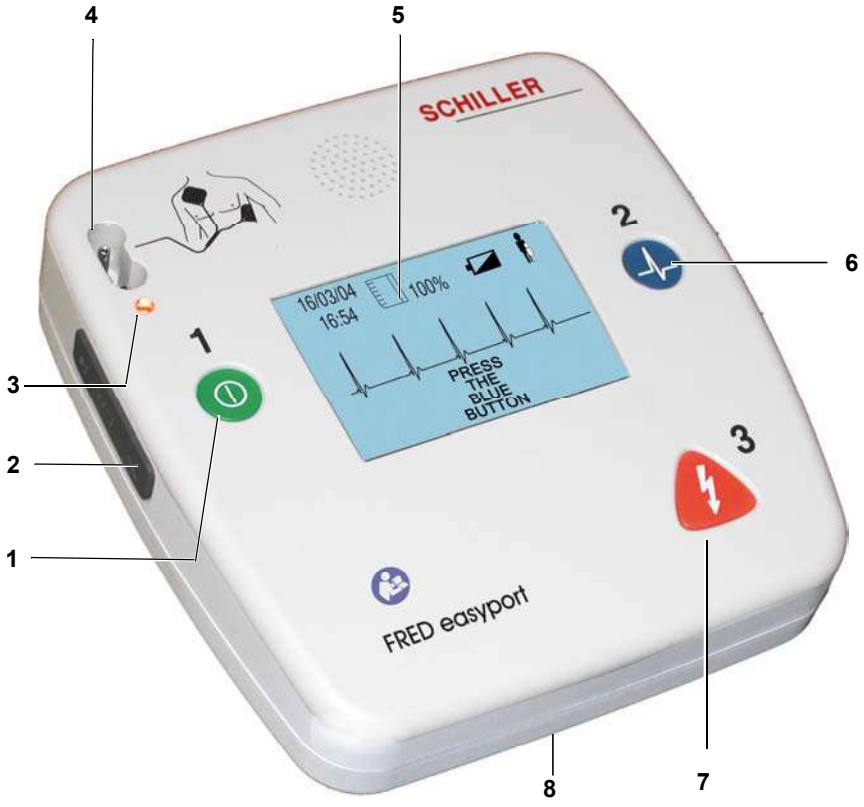

Fig. 2.1 Operating Elements

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

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2.4 Display

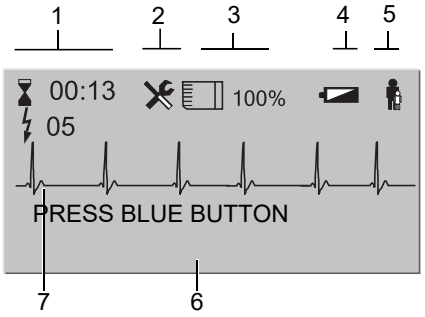

Fig. 2.2 LCD screen

The following information is displayed on the LCD:

(1) Time passed and shocks delivered since the device has been switched on
(2) Perform the function test at the next opportunity (see page 36 section 6.1.3)
(3) Memory card inserted and occupied memory in %
– Flashing = memory card almost full (from 98%)
– Flashing = error (see page 40, section 6.3)
– No indication = memory card not detected or not inserted (see page 40, section 6.3)
(4) Battery low (only 3 more shocks can be released)
(5) Defibrillation electrode type
= adults
= children
(6) Display of defibrillation steps / error messages
(7) ECG signal

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2.5 Function

2.5.1 Self-test

Automatic self-test at switch-on

To ensure its readiness for use, the device runs a self-test to check the unit and the battery.

Manual self-test

A manual self-test can be performed at any time. During manual self-tests, the capacitor is charged with a reduced energy of 15 joule and the safety discharge is tested (see page 35).

2.5.2 Function test

The device reminds the user every 4 months to perform a function test; during function tests, the capacitor is charged to the max. energy value.

2.5.3 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 analysis and to stay clear of the patient. The analysis takes approximately 10 seconds. Depending on the configuration, the unit automatically starts analysing the ECG.

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2.5.4 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	150 Joules	50 joules
2	150 Joules	50 joules
3	150 Joules	50 joules

The SCHILLER service centre can define other settings if required (see section 7, page 42).

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 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 be repeated at any time during CPR by pressing the blue analysis button (2). CPR needs to be interrupted while the analysis is performed.

1. When children electrodes are used, the 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.

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2.5.5 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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2.6 Voice support

Once the device is switched on, it runs a self-test and shows the software and hardware version. The following instructions will be spoken by the device:

Voice	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 4.3.1.
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 4.3.2.
[b] Press the blue button.	PRESS BLUE BUTTON	Heart rhythm analysis is started.
Do not touch the patient; analysing.	DO NOT TOUCH THE PATIENT ANALYSING	(See page 28, Step 2, Analysis)
Movement detected; stand clear.	MOVEMENT DETECTED STAND CLEAR	Technical alarm: Patient was moved during analysis and device could not run analysis.
Device recommends a shock		See section 2.5.4 and page 29.
	DO NOT TOUCH THE PATIENT CHARGING	When this message is displayed, the required energy is charged.
Stand clear of patient. Press orange button.	PRESS ORANGE BUTTON TO SHOCK	
Shock not recommended		See section 2.5.5.
No shock advised.	NO SHOCK ADVISED	See section 2.7.
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 2.7

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 children electrodes are used, the 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.
If the device detects a serious error that makes shock delivery impossible, you are prompted to continue cardiopulmonary resuscitation.

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2.7 Procedure in case of a cardiac arrest

This procedure applies to adults and children.

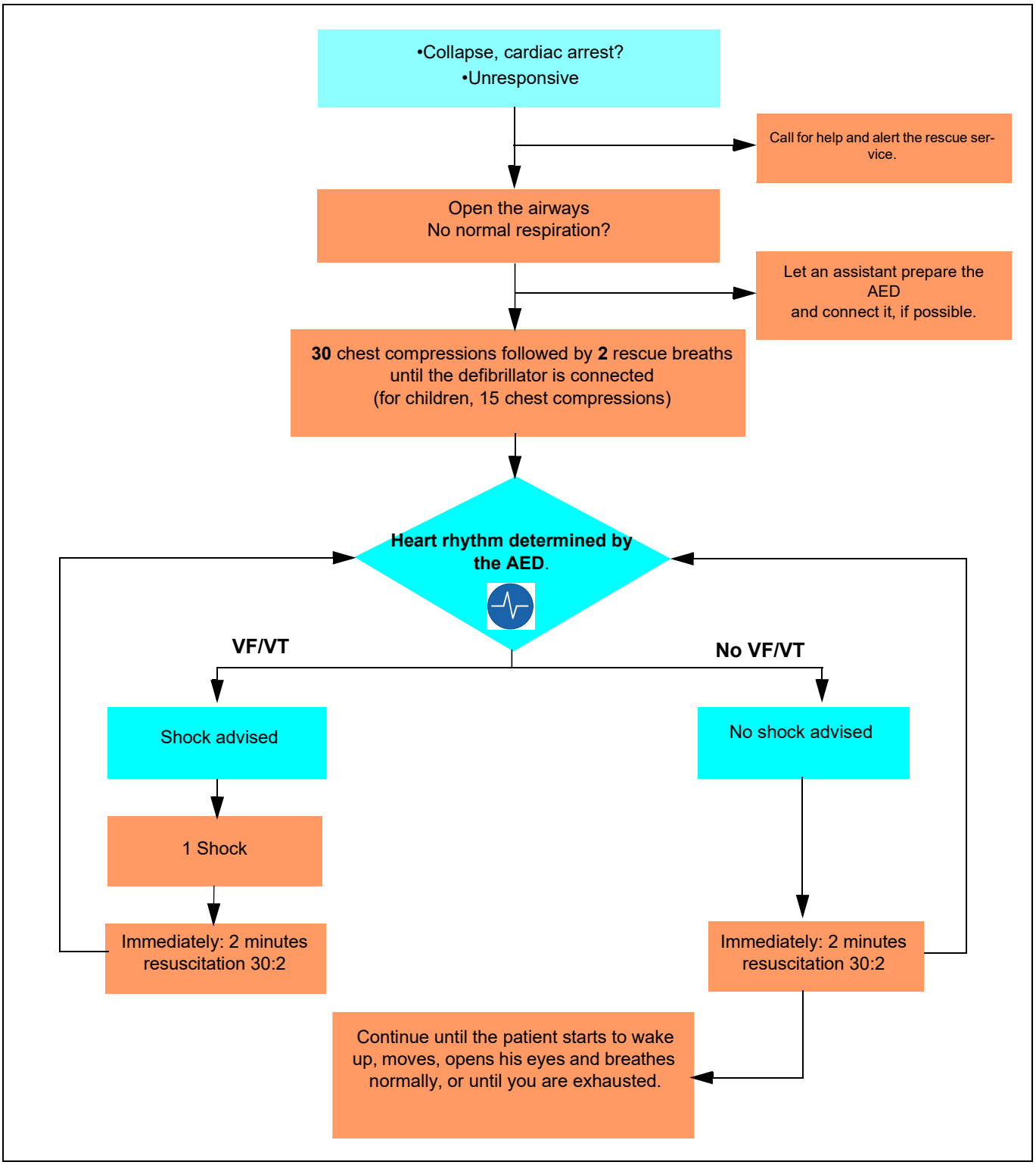

Fig. 2.3 AED algorithm (ERC 2010) or cardiopulmonary resuscitation (CPR) with defibrillation

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3 Operation

3.1 Initial operation

⚠ DANGER

- ▲ Explosion hazard! This device is not intended for use in potentially explosive areas. 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.
- ▲ 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 battery inserted into the device has a life time of approx. 2.5 years, if the device is switched on only for the regular maintenance intervals. Additional switch-ons, and storage conditions outside the temperature range of 15-25 °C will reduce the life time of 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.
3. Check the battery status on the display. If the battery is low, the battery symbol (1) is displayed.

- If the Function test symbol is displayed, proceed as detailed in section 6.1.3 Function test.

Fig. 3.1 Inserting the battery

⚠ 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 42). 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 (observe the expiration date).
  – Always note the number of switch-ons and the battery's running time in the Inspection Report on page 48, 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.

▲ SCHILLER recommends always keeping a spare battery at hand.

Function test

The function test is performed by the user (see Function test page 36).

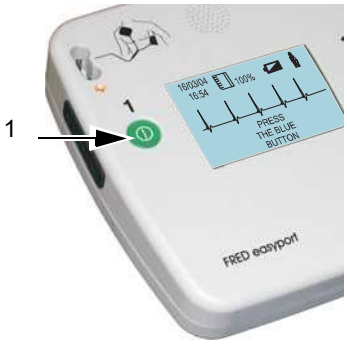
Stipulated interval:

- when the device is put into operation or delivered to the end user.
- After that, every 4 months

When the device is in mobile use and therefore exposed to changing ambient conditions, we recommend to regularly perform a self-test (see Performing a manual self-test page 35).

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.



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.

Important!

If it is not possible to switch the device off, remove and reinsert the battery.

Fig. 3.2 Switching the device on/off

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 Defibrillation

4.1 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.
  - must **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.
- Due 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 AED 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 defibrillation electrodes

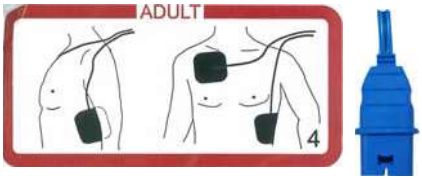
⚠ CAUTION

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

Adult and paediatric electrodes

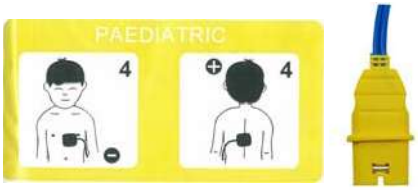
Adult electrodes

The adult electrodes with the blue connector are used for adults and children from 25 kg.



Paediatric electrodes

The paediatric electrodes with the yellow connector are used for children weighing less than 25 kg.The energy setting is automatically reduced with the Paediatric electrodes.



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4.3.1 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.

Adults and children from 25 kg

Electrode placement is the same for adults and for and children weighing 25 kg or more (see Fig. 4.1 Adult electrode application sites and Fig. 4.2 Electrode application sites for children weighing 25 kg or more).

▲ The safety distance between the two electrodes should be approx. 3 cm.

Fig. 4.1 Adult electrode application sites

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 that the cables do not hinder cardiopulmonary resuscitation (CPR).

Fig. 4.2 Electrode application sites for children weighing 25 kg or more

Children weighing less than 25 kg

The energy setting is automatically reduced with the Paediatric electrodes.

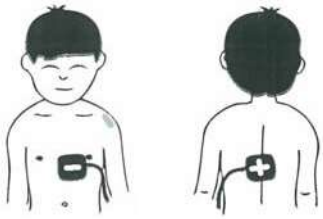

Fig. 4.3 Application sites for children less than 25 kg

1. Clean and dry the application points for the electrodes (see Fig. 4.3). Only clean the skin by vigorously rubbing it with a dry cloth.
2. Apply one electrode on the left of the right nibble as illustrated in Fig. 4.3
3. Apply the second electrode on the back on the same level as the chest electrode as illustrated in Fig. 4.3.

Make sure that the connections are positioned on the outside so that the cables do not hinder cardiopulmonary resuscitation (CPR).

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4.3.2 Checking the electrodes

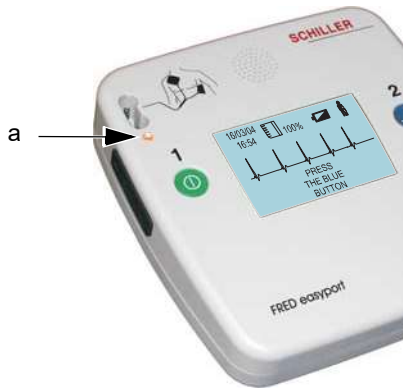

Fig. 4.4 Electrode LED

If the resistance between the skin and an electrode is 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
5. apply new defibrillation pads to these points.

4.3.3 Device is not working, error message

If the device detects a serious error that makes shock delivery impossible, you are prompted to continue cardiopulmonary resuscitation until the rescue service arrives. In the meantime, you can switch the device off and on again to try to get it back into operating condition.

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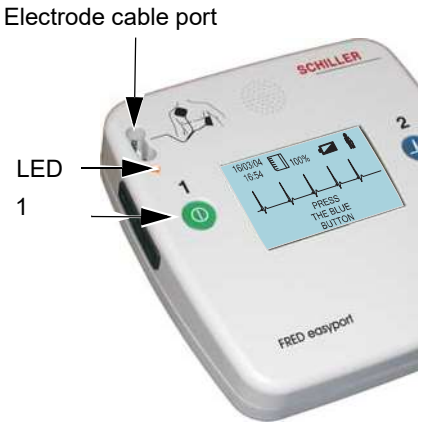
4.4 Defibrillation procedure

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

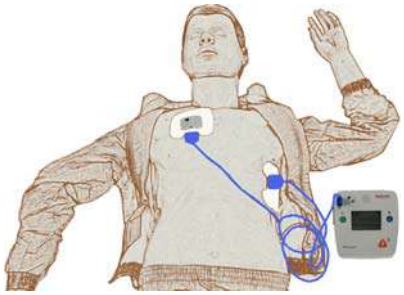


1. Switch the device on by pressing the green button (1).
2. Check the state of the patient. See ABCD, section 2.7.
3. You are prompted to continue the resuscitation and to place on the electrodes.
4. Connect the electrode cable to the device (see Fig. 4.5).
5. Place on the defibrillation electrodes as shown in Fig. 4.1. 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 4.3.2.

Fig. 4.5 Switch unit on

Step 2

Analysis



6. You are prompted to start the analysis.
7. Press blue button (2). A message prompts the user 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.

Fig. 4.6 Analysis

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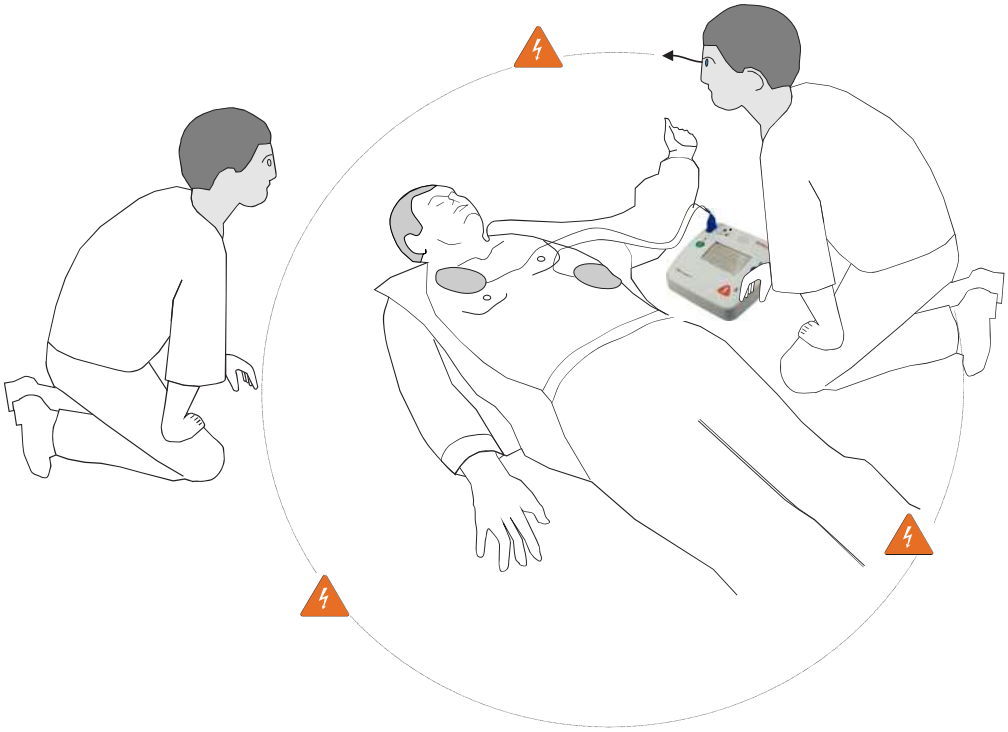
Step 3

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 on an individual procedure with the rescue staff. This procedure must follow the AHA or ERC protocols or the local legal requirements. Furthermore, 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. Connect the electrode cable to the device (see Fig. 4.5).
2. Switch the device on by pressing the green button (1).
3. Simultaneously press the blue (2) and the orange (3) buttons.
   The message "CONFIRM MANUAL MODE" is displayed.
4. Within 5 seconds, again press the blue (2) and the orange buttons (3).

The following is displayed:
- – ECG curve
- – The selected energy (according to the factory settings – see page 18)
- – Prompt to press the blue button to charge the energy

Defibrillator charging

] 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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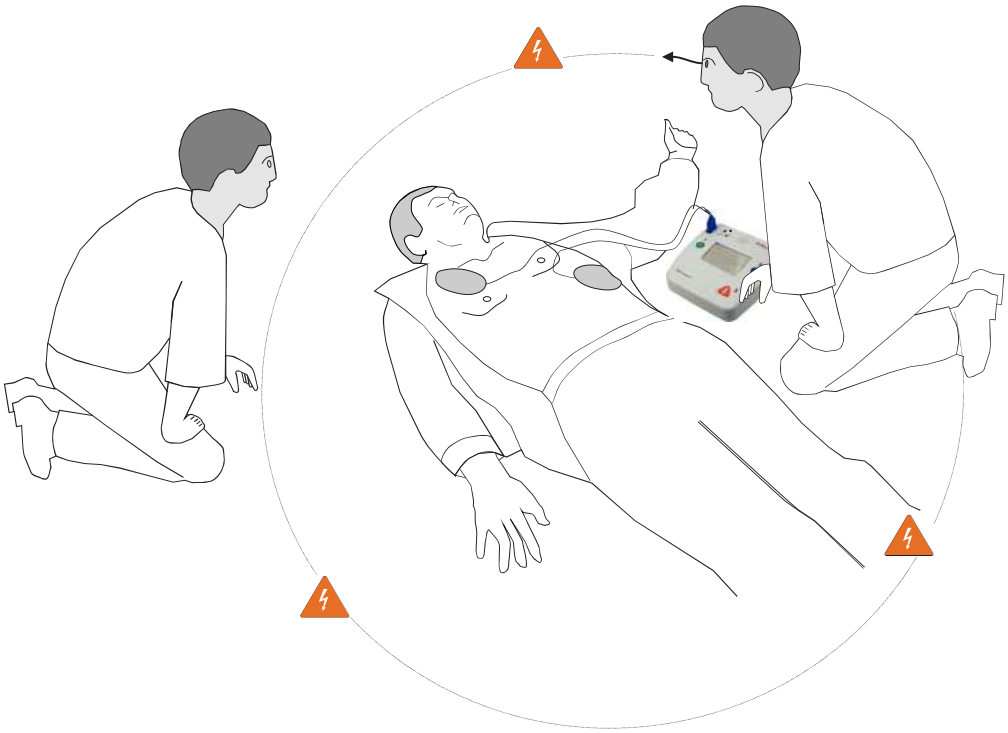
Shock delivery in manual mode

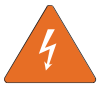
⚠ DANGER

▲ 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.



5. 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 data
- 500 events with date and time of intervention with the following data:
  - Power on
  - Start of analysis
  - Analysis result
  - Defibrillator charging
  - Defibrillation shock
  - Internal discharge
  - Electrode alarm
  - "Battery low" alarm

The memory card is evaluated on a PC.

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 penetrating the device.
- ▲ The functioning of the device can only be guaranteed with an SD card from SCHILLER.

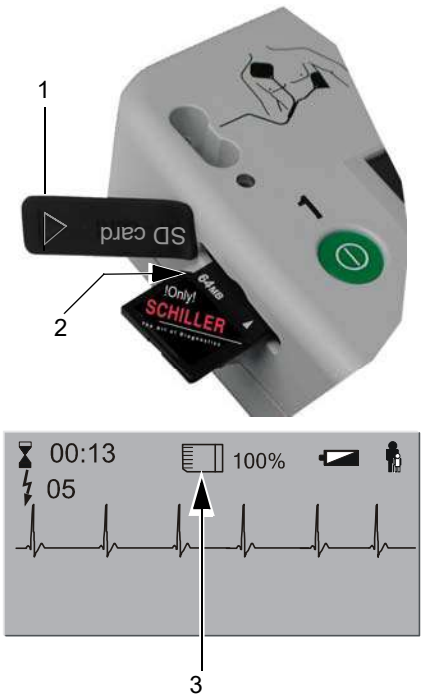

Fig. 5.1 SD card inserted

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 device's operation!
(See section Error detection 6.3)

6 Maintenance

6.1 Maintenance intervals

Note

The device must be serviced on a regular basis. The test results must be recorded and compared with 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
As required	• Self-test (6.1.2 Performing a manual self-test)	→ User
Monthly	• Visual inspection of the device and electrodes • Check the expiration date on the electrodes and battery (incl. spare battery)	→ User
Every 4 months	• Function test according to the instructions (see page 34 to 36 and page 48, 8.4 Inspection Report)	→ User
Every 4 years	• Safety and measurement checks according to the instructions given in the service manual	→ Service staff authorised by SCHILLER

6.1.1 Visual inspection of the device

Inspect the device and electrodes for the following:

- Device casing not broken or cracked
- Electrode connection undamaged?
- Schiller memory card inserted?
- Expiration date on electrode packaging
- Expiration date of the battery and spare battery

Defective units or damaged cables must be replaced immediately.

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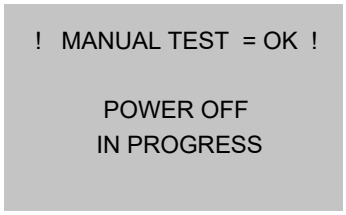
6.1.2 Performing a manual self-test

- When the device is in mobile use and therefore exposed to changing ambient conditions, we recommend to regularly perform a self-test.
- The battery discharge due to the self-test is reduced to a minimum.



Performing a self-test

1. **Press and hold** the green button until the message **“Manual TEST = OK”** is displayed. The device shuts down automatically.

When the interval for the four-monthly function test has expired, the message **“Maintenance Confirm”** is displayed.

1. Simultaneously press the **On/Off** and the **shock key**. The function test is performed (see page 36).
2. Press the On/OFF key if the function test is to be performed at a later stage.

If an error message is displayed, continue as described in section Error detection on page 39.

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6.1.3 Function test

- The device features a maintenance interval surveillance; after 4 months, the symbol reminds the user to perform the function test.
- You can use the manual self-test to check whether the function test needs to be performed (see page 35)
- The function test can also be performed before the 4-month interval has elapsed.
- In the case of new devices, the symbol is displayed as a reminder to perform the complete function test when putting the device into operation.
- If the symbol is **not** displayed on your new device, it means that the function test has been performed by the distributor or medical product representative before the device was delivered to you.

⚠ CAUTION

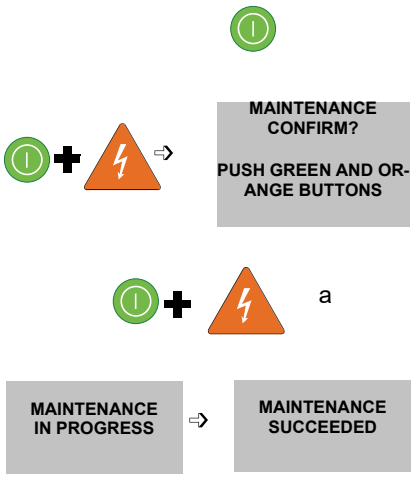
▲ The function test takes between 30 and 180 seconds. Switch off the device immediately after having performed the function test! Battery discharge!

▲ With a function test duration of 30 seconds, the loss in battery capacity is 2%.

▲ Protocol test results and operation duration in Inspection Report on page 48.

Starting the function test

- Make sure that no electrodes are connected.
- The device can be switched off at any time during the function test. To do so, press and hold the green button for at least 3 seconds.



1. Switch on the device on by pressing the green button.
2. When the message “CONNECT ELECTRODES” is displayed, simultaneously press the **On/Off** and **Shock** buttons. As soon as the message shown on the left is displayed, release both buttons. If you press and hold the buttons for too long, the device is switched off!
3. Start the function test by once again simultaneously pressing the **On/Off** and **Shock** buttons.
4. The function test takes between 30 and 180 seconds.
5. The message “Regeneration SUCCEEDED” or “Regeneration FAILED” is displayed.
6. Press the green button (press and hold for 3 seconds) to switch off the device.

Function test results

Function test successful	The message “Regeneration SUCCEEDED” is displayed.
Function test not successful	The message “Regeneration FAILED” is displayed. If this message is displayed, please contact your SCHILLER distributor. The device must not be used before it has been checked and repaired.

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6.1.4 Maintenance interval for the battery

Important

- The battery is maintenance-free during its normal life.
- The spare battery has a life time of 5 years at room temperature storage condition.
- Storage conditions outside the temperature range 15-25 °C will reduce the life time of the battery!
- 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 42). To ensure the device's readiness for use, the battery must be replaced by a new, non-expired battery.

6.1.5 Battery disposal

WARNING

▲ Explosion hazard! The battery must not be burned or disposed of in domestic waste.

▲ Acid burn hazard! Do not open or heat up the battery.

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

6.1.6 Disposal at the end of its 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 device 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

▲ Before cleaning, switch the unit off and remove the battery. Do not, under any circumstances, immerse the device in cleaning liquid and do not sterilise it 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/or invalidate the warranty.

Your local representative stocks all the disposables and accessories available for the FRED easyport. A comprehensive 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 information on all SCHILLER products.

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6.3 Error detection

▲ If it is not possible to get the device back into operating condition within a reasonable period of time, continue cardiopulmonary resuscitation until the rescue service arrives.

Forcing a shut-down

▲ If the device cannot be shut off by means of the normal procedure (press and hold the green button for 3 seconds), remove and then reinsert the battery.

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 the 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 (expiry date) – incorrect application of electrodes	→ Replace electrodes
	• Device defective	→ Apply electrodes according to the instructions in section 4.3.1
		→ Replace the device
Message: Check the electrodes	• Short-circuit between the electrodes	→ Apply electrodes according to the instructions in section 4.3.1
	• Device defective	→ Replace the device
Device cannot be switched off	• Green button pressed for less than 3 seconds	→ Press and hold the green button until the device switches off
	• Software hang-up	→ Remove and then reinsert the battery
	• Device defective	→ Replace the device
No analysis	• ECG signal too weak	→ Perform cardiac massage again
	• ECG signal disturbed by 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 the device
Unable to deliver shock	• Battery too low	→ Replace battery
	• Electrode error due to resuscitation efforts	→ Reapply electrodes
	• Rhythm has changed	→ Run new analysis
	• Device defective	→ Replace the device

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Error	Cause	Remedy
"Error xxx-xxx"	• Device is not ready for operation or defective.	➜ Switch the unit off and then on again to confirm. If the error message is still displayed, continue cardiopulmonary resuscitation until the rescue service arrives. ➜ Replace the device
"Error 100-900"	• Short circuit of the electrode plug/cable/device	➜ Replace electrodes ➜ Device defective
"Error 100-001"	• It was not possible to fully charge the charging condenser.	➜ Unplug the electrodes, switch the device off/on and perform the function test, page 36.
Battery capacity indicator is flashing	• Battery almost empty	➜ Replace battery
Symbol  is not displayed	• SCHILLER memory card not/not correctly inserted • The card is defective	➜ Switch off device and properly insert memory card ➜ Replace card by a new SCHILLER card
Symbol  is flashing	• Memory card not detected because inserted with device switched on • No SCHILLER SD card used	➜ Switch off and restart device ➜ Use SCHILLER card
Memory card does not save any data	• Memory card defective • Device defective	➜ Replace memory card ➜ Replace the device
Date and time wrong on memory card	• Internal watch misadjusted • Device defective	➜ Have updated the internal watch by an authorised person via data transfer ➜ Replace the device

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6.3.1 Preventing electromagnetic interferences

"Non-ionising electromagnetic radiation"

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the FRED easyport. The distance depends on the output performance of the communication device, as indicated below.

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
Bluetooth devices Class I/II/III	2400	0.01/0.025/0.1	0.23 0.73
Mobile phone - GSM900 - GSM850, NMT900, DCS 1800	 900 850, 900, 1800	 2 1	 3.3 2.3
Walkie-talkie (rescue service, police, fire brigade, servicing)	81-470	5	2.6
Mobile telephone system (rescue service, police, fire brigade)	81-470	100	12

It can be deducted from the table that **portable** HF telecommunication devices must not be used within a radius of 3 m from the FRED easyport and its cables.
For transmitters not included in the above table, the recommended distance (d in meters) can be calculated using the following formulas:

Frequency range 80 - 800 MHz

$$d = \frac{12}{10\,V/m} \times \sqrt{P}$$

Frequency range 800 MHz – 2.5 GHz

$$d = \frac{23}{10\,V/m} \times \sqrt{P}$$

d = recommended minimum distance in meters
P = transmitting power in watts

⚠ CAUTION

▲ There is no guarantee that interferences will not occur in a particular installation. If the FRED easyport causes interferences, these can be identified by switching the device on/off.

The user can take the following measures to solve this problem:

- Increase the distance to the source of interference
- Turn the device to change the angle of radiation.
- Only use original accessories.

For detailed information of the IEC/EN 60601-1-2 Tables 201, 202 und 206 see service handbook.

7 Technical Specifications

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

7.1 System Specifications

Manufacturer	SCHILLER AG
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 casing	IP**X4**
Power Supply	Internal power supply
Battery	
Battery type	Li/MnO_2, 12 V 750 mAh
Battery capacity	• 45 shocks at maximum energy, or • 2 hours of monitoring (alternately 30 min. on, 30 min. off)
	Battery capacity decrease on switch-on or for a function test of 30 seconds: approx. 2% Battery capacity decrease for 5 min. of monitoring: approx. 4.0% **Total** battery capacity decrease due to switch-on and 5 minutes of monitoring: approx. **6%**
	• Battery capacity decrease due to the self-test: approx. 0.5%
Ambient conditions device	
Operating temperature	• 0 ... 40 ºC; relative humidity at 0...95% (noncondensing) Atmospheric pressure 700 to 1060 hPa
Transport	• -10 ºC...50 ºC; relative humidity at 10...95% (noncondensing)
Storage	• 5 ºC...50 ºC; relative humidity at 10...95% (noncondensing) Atmospheric pressure 500...1060 hPa
Ambient conditions defibrillation electrodes	
Storage	• 0 ºC...50 ºC
Storage max. 10 days	• -40 ºC...75 ºC
Display	
Type	• High-resolution LCD, backlit
Dimensions	• 60 x 40 mm

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7.2 Safety standard

DEFIBRILLATOR	IEC/EN 60601-2-4 – the device is designed for more than 2500 shocks
EMC	• IEC/EN 60601-2-4 • CISPR 11 class B The device can be exposed to the following interferences without impairment: • Static discharges up to 8 kV • Energy in the radio frequency range of 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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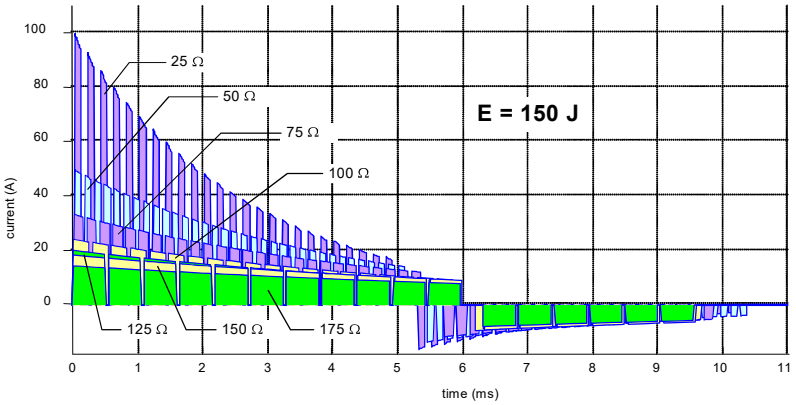
7.3 Defibrillation impulse

Shape

- 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.



Default energy settings

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

Adults
- 150/150/150 joules

Neonates
- 50/50/50 joules (automatic switch-over when children electrodes are connected)

Alternative energy settings

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

Adults
- 90/120/150 joules

Neonates
- 30/50/70 joules

Time to shock standby

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

- From the start of the analysis: 30 seconds
- For max. energy after switch-on: 40 seconds

Charge control/monitoring

25...175

Display of shock standby

Key  is lit

Shock delivery

Using key 

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Safety discharge if:	• 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	Electrode cable: 2 m long
Electrodes for adults	• 80 cm2 active surface, blue connector
Electrodes for children	• 80 cm2 active surface, yellow connector
Shelf life	• see labelling electrode packaging
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 VT (VT> 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.

7.3.1 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
2.155061	Single-use defibrillation pads for adults
2.155067	Single-use defibrillation pad for children
2.155063	Single-use defibrillation pads for adults in box
2.155068	Single-use defibrillation pads for children in box
2.155065	Single-use defibrillation pads for adults (pre-connected)
2.230292	Battery $LiMnO_2$
2.156047	Carrying pouch
3.940010	Mini SD card, programmed

8.2 Literature

European Resuscitation Council (2010) Guidelines 2010 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (13:523–542 DOI 10.1007/s10049-010-1368-x).

American Heart Association (2010) Guidelines 2010 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (ISBN 978-1-61669-043-4, AHA product no. 0-1040)

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

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8.3 Glossary

ACLS	Advanced Cardiovascular Life Support. (ACLS Manual AHA 2010)
ERC	European Resuscitation Council
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
PEA	Pulseless Electrical Activity
VT	Ventricular Tachycardia
VF	Ventricular Fibrillation

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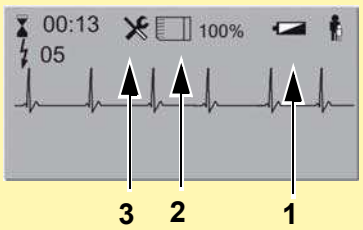
8.4 Inspection Report

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

Serial no.: _____

Test	Result	Date				
General condition						
) External condition	• No isolation or mechanical problems	❒	❒	❒	❒	❒
Accessory						
) Availability and condition	• Electrodes and battery (expiration date and compatibility)	❒	❒	❒	❒	❒
⚠WARNING	• User Guide	❒	❒	❒	❒	❒
Only use a SCHILLER memory card! Incorrect cards can impair the unit's operation!	• SCHILLER memory card 	❒	❒	❒	❒	❒
Performing the function test (see page 36)	• The standard screen is displayed. 	❒	❒	❒	❒	❒
) Switch on the device and check the display.		Operating time [min]:	Operating time [min]:	Operating time [min]:	Operating time [min]:	Operating time [min]:
(3) Perform the function test	(1) If the battery symbol is displayed, the battery must be replaced.					
Switch the device off immediately after the function test (battery discharge)! Protocol the duration of the function test.	(2) Check for the symbol and memory space.	❒	❒	❒	❒	❒
Notes						
Manual self-test		❒	❒	❒	❒	❒
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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Signature Manifest

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