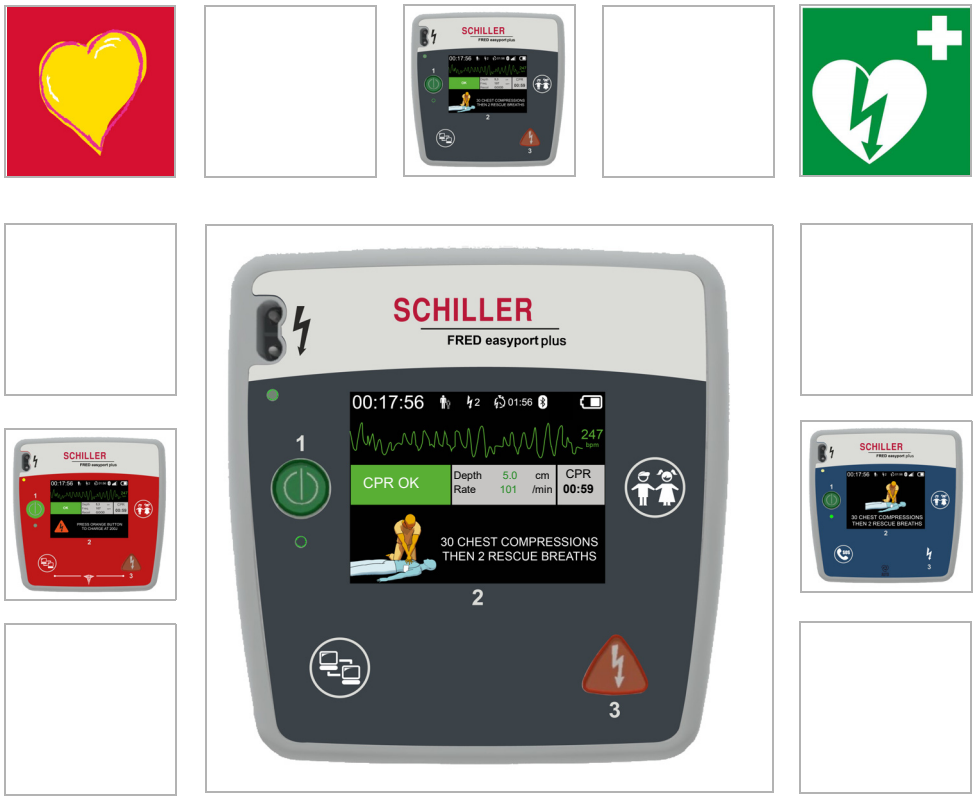
FRED® easyport® plus

Automated external defibrillator (AED)



User Guide

SCHILLER
The Art of Saving Lives

Art. no.: 2.511279 Rev. d

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
Sales information can also be obtained from:
sales@schiller.ch

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EC REP

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CE 0123

FRED® easyport® plus 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. Date of first declaration of conformity CE marking 12.2019

Article no.: 2.511279 Rev. d
Issue date: 15.03.22
Corresponds to: original
Software: ≥ 1.2.2

SCHILLER
The Art of Saving Lives

Table of Contents

Art. no.: 2.511279 Rev. d

Art. no.: 2.511279 Rev. d

Art. no.: 2.511279 Rev. d

Art. no.: 2.511279 Rev. d

1 Safety Notes

1.1 User profiles

The following persons may use the **FRED® easyport® plus**:

- Layperson trained in Basic Life Support and/or on the device
- Healthcare provider trained in Basic Life Support and/or on the device
- Physicians or other healthcare provider trained in Advanced Life Support may use the **FRED easyport plus** with manual override or in monitoring mode.

1.2 Intended Use

▲ The **FRED easyport plus** is a defibrillator with the possibility to deliver a shock either in semi-automatic, fully-automatic or manual mode.

▲ FRED easyport plus® is intended to be used to terminate cardiac arrhythmia such as Ventricular Fibrillation or Ventricular Tachycardia with a defibrillation shock.

▲ The intended patient population are adults >25 kg and children weighing less than 25 kg (younger than 8 years of age).

▲ The portable device is intended to be used in following environmental:

– Primarily in pre-hospital care and transport applications (including ambulances, fixed and rotary wing aircraft) patient's homes or work places.

1.3 Indication for use

▲ **FRED easyport plus** is intended to be used to terminate cardiac arrhythmia such as Ventricular Fibrillation or Ventricular Tachycardia with a defibrillation shock.

Art. no.: 2.511279 Rev. d

1.4 Contraindication for use

AED mode

▲ The defibrillator must **not** be used when the person:
- is responsive
- is breathing normally
- has pulse

Manual defibrillation mode

- Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA), such as idioventricular or ventricular escape rhythms, and in the treatment of asystole.

CPR feedback

▲ The CPR feedback option is contraindicated for use on neonatal and pediatric patients under 8 years and ≤ 25 kg.

▲ CPR feedback option is contraindicated when manual CPR is contraindicated.

Other contraindications

▲ Do not use the device in or near magnetic resonance imaging equipment (MRI).

▲ **Danger of explosion! —** The device must not be used in areas where there is any danger of explosion. There might be a danger of explosion in areas where flammable products (petrol), flammable anaesthetic agents or products for skin cleaning/disinfection are in use, or where the ambient air's oxygen concentration is higher than 25 %.

▲ The device is not designed for sterile use.

▲ The device is not for use in or near magnetic resonance imaging equipment.

1.5 Responsibility of the User

▲ Regulations on who is allowed to use devices like the **FRED easyport plus** and which training is required, are country-specific. In any case, legal regulations have to be observed.

▲ Before using the device, a SCHILLER representative must perform a presentation on the device's operation and safety measures, if it is required by the local regulations.

▲ Interpretation suggested by the device must be examined with respect to the patient's overall clinical condition and the quality of the recorded data.

▲ Damaged or missing components must be replaced immediately.

▲ The device must be stored in a place inaccessible to children.

▲ Properly dispose of the packaging material and make sure it is out of children's reach.

▲ The **FRED easyport plus** 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
- you always keep a new spare battery on hand
- an empty battery must not be reused and must be disposed of immediately
- a set of adult electrodes is pre-connected and a spare set of electrodes must be stored with the device
- the maintenance intervals are observed see 7 Maintenance.

▲ If any serious incident has occurred in relation to the device it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Art. no.: 2.511279 Rev. d

1.6 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.

1.7 Safety-Conscious Operation

- ▲ **Danger of electric shock!** - Danger for user, rescuer and patient.
  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.
- ▲ **Danger of explosion! —** The device must not be used in areas where there is any danger of explosion. There might be a danger of explosion in areas where flammable products (petrol), flammable anaesthetic agents or products for skin cleaning/disinfection are in use, or where the ambient air's oxygen concentration is higher than 25 %.
- ▲ Immediately report any changes that impair safety (including operating behaviour) to the responsible person.
- ▲ Only use original SCHILLER electrodes and accessories.
- ▲ Check that the unit's casing and electrode connections are not damaged.
- ▲ Check expired date of the defibrillation electrodes.
- ▲ After use, refer to the chapter 7 Maintenance.
- ▲ Immediately replace a damaged unit, or damaged cables and connections.
- ▲ Operating the device with a defective casing or damaged cables constitutes a danger to life.
- ▲ Only operate the device in accordance with the specified technical data 8 Technical Data.

1.8 Operation with other Devices

- ▲ 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 8.7). Avoid using such devices or keep a sufficient distance from them.
- ▲ **FRED easyport plus** is not intended to be operated while using high-frequency surgical devices.
- ▲ Interference with other devices - The charging of energy and the release of the defibrillation impulse can disturb other devices. Check these devices before their further use.
- ▲ Other medical equipment applied to patient which has no defibrillation proof applied part must be disconnected from the patient.
- ▲ The patient can be endangered by too high leakage currents (summation of leakage currents) if several devices are connected to the patient. For this reason, devices that are not required should be disconnected from the patient, and only equipment approved by SCHILLER may be connected to the device.

Art. no.: 2.511279 Rev. d

1.9 Maintenance and Cleaning

- ▲ **Danger of electric shock!** Do not open the device. No serviceable parts inside. Refer servicing to qualified personnel only.
- ▲ Do not service, maintain or clean the device while in use with a patient.
- ▲ 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.
- ▲ To ensure patient safety, only use original SCHILLER accessories. The user is responsible for the use of third-party accessories. The warranty does not cover damage resulting from the use of accessories or consumables other than those marketed by SCHILLER.

1.10 Side Effects

- ▲ Defibrillating a patient can cause:
  - skin irritations or burns
  - malfunction or damage of implanted pacemaker

1.11 General Notes Regarding the Unit

A defibrillation can fail with certain disease patterns.

1.12 Networks and Internet

- ▲ When the unit is part of a network, (LAN, WLAN, HIS, etc.), or any other transmission/reception medium, or if exposed to the Internet or other insecure networks, appropriate security measures must be taken to protect the stored patient data.
- ▲ Patient data security and security of the network is the sole responsibility of the user.
- ▲ In order to guarantee the security of the network, Schiller recommends the following:
  - isolating the **FRED easyport plus** network from other networks
  - defining access authorisation for the configuration of the host system, incl. **FRED easyport plus**, so that no unauthorised alterations of the system are possible.

Art. no.: 2.511279 Rev. d

1.13 Additional Terms

1.13.1 Implied authorisation

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would alone, or in combination with this device, fall within the scope of one or more patents relating to this device.

1.13.2 Terms of Warranty

Your SCHILLER **FRED easyport plus** is warranted against defects in material and manufacture according the general terms of condition. 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 of a defect, send the device to your dealer or directly to the manufacturer. The manufacturer can only be held responsible for the safety, reliability, and performance of the apparatus, and assume the warranty, if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorised by him,
- spare parts used for assembly operations, extensions, readjustments, modifications or repairs are recommended or supplied by SCHILLER, and,
- the SCHILLER **FRED easyport plus** 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.

Art. no.: 2.511279 Rev. d

1.14 Symbols/Indicators

1.14.1 Symbols used in this user guide

The safety levels are classified according to ANSI Z535.6. The following overview shows the safety symbols and pictograms used in this user guide.
The terms Danger, Warning, and Caution are used in this User Guide to point out potential dangers and to indicate risk levels. Familiarise yourself with their definitions and significance.

⚠ DANGER	For a direct danger which could lead to severe personal injury or death.
⚠ WARNING	For a possibly dangerous situation which could lead to severe personal injury or to death.
⚠ CAUTION	For a possibly dangerous situation which could lead to personal injury. This symbol is also used to indicate possible damage to property.

For general safety notes as listed in this section.

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

Important or helpful user information.

Do not use the device in or near magnetic resonance imaging equipment (MRI).

Art. no.: 2.511279 Rev. d

1.14.2 Symbols used on the device

General used symbols see 10 Appendix - Symbols.

Reading the instruction for use is mandatory before using the device!

Caution: Consult the warning and safety information in the instructions for use!

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

Dangerous voltage! Used for electrical dangers during defibrillation.

IP44

The device rated IP44 meaning protection against solid objects over 1 mm diameter, e.g. persons fingers, and splash water protected (no harmful effect from vertically splashing water from all direction.

Battery replacement instruction

Bluetooth inside

Attention: non ionising electromagnetic radiation. Some of the devices contain an HF transmitter (Bluetooth).

The **FRED easyport plus** radiates high-frequency electromagnetic energy and can disturb other devices if not installed and operated in accordance with the user guide. However, there is no guarantee that no interference can occur in certain installations. If the **FRED easyport plus** causes interferences, these can be determined by switching the device off/on or by transmitting/not transmitting ECG data. The user can take the following measures to prevent electromagnetic interferences:

- Increase the distance between the disturbed device and the **FRED easyport plus**. A minimum distance of 20 cm must be kept between the device and a pacemaker.
- Turn the device to change the angle of radiation.

For more details, see page 63.

Art. no.: 2.511279 Rev. d

1.14.3 Symbols used on the batteries

For general used symbols see 10 Appendix - Symbols.

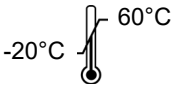
Caution: Consult the warning and safety information in the instructions for use!

Do not incinerate

Do not crush

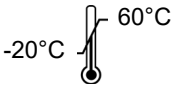
Do not saw

Rechargeable Li-Ion battery



min/max discharging temperature for **rechargeable Li-Ion** battery.
Note: Fully charged batteries may only be stored up to one month at max. discharging temperature.

Primary Lithium Manganese dioxide battery (non-rechargeable)



min/max discharging temperature for **primary Lithium/MnO_2** battery.
Note: Storage at max. discharging temperature will increase the self discharge of the battery.

Expiry date of the primary Lithium/MnO_2 battery.

1.14.4 Symbols used on the CS-2 charger

For general used symbols see 10 Appendix - Symbols.

Indoor use only

CS-2 charger is protection class III

DC voltage

Art. no.: 2.511279 Rev. d

1.14.5 Symbols used on the electrode packaging

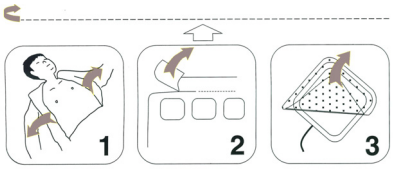
General used symbols see 10 Appendix - Symbols.

Reading the instruction for use is mandatory before using the electrodes!

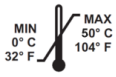
Do not bend packing

Don’t use if the packaging is damaged

Disposable item; do not reuse



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



Storage temperature for the electrodes

Expiry date of the electrodes

An open package cannot be conserved more than one day.

The product is intended to be used on patients weighing 25 kg or more.

The product is intended to be used on patients weighing less than 25 kg.

Art. no.: 2.511279 Rev. d

2 Components and Operation

2.1 General Information

FRED easyport plus is an automated external defibrillator (AED).
The **FRED easyport plus** is available as an automatic, semi-automatic or manual defibrillator.

Local laws and regulations regarding the use of an AED vary from country to country. While some countries allow laypersons to use AEDs without any special training, other countries restrict the use of AEDs to an Emergency Medical Technician or First Responders after they have undergone special training.

Professional use

For the professional use, the **FRED easyport plus** offers an AED with ECG display, an optional data transfer and a manual override.

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 any questions on this matter, please contact SCHILLER.

Art. no.: 2.511279 Rev. d

2.2 Design

Defibrillator

The **FRED easyport plus** is a defibrillator featuring biphasic pulsed defibrillation impulse – ***Multipulse Biowave®***. The defibrillation is done using disposable adhesive electrodes (pads), which also acquires the ECG signal for the analysis. Adhesive electrodes for children and adults are available. The device recognises the connected electrodes and selects the defibrillation energy levels accordingly. Adult electrode can be used also for children. In this case, the child mode has to be selected with the button Adult/Child on the front panel. In the AED mode, the user will be given visual and audible instructions (display/loudspeaker).

Languages

The device can be provided with different languages.

Metronome

The **FRED easyport plus** emits a sound pace for the cardiopulmonary resuscitation (CPR) - rate is configurable.

CPR Feedback (option)

Real time information on the chest compression frequency using the ARGUS LifePoint feedback sensor.

Data memory

The device is equipped with an internal 8 Gbit memory to store 8 hours intervention. During the intervention, data can therefore be saved, including the analysed ECG data. In addition, technical data (logs) will be stored.

Data transmission

- The **FRED easyport plus** has a USB host connection in order to
  - retrieve data via USB memory stick
  - perform software and configuration updates
  - connect the Argus LifePoint feedback sensor
- USB device connection for service
  - Bluetooth connection to host

Power supply

- The device is operated with a rechargeable or non rechargeable lithium battery. The battery capacity is sufficient for (if the device is stored/used in optimal temperature conditions between 15...25 °C:
- with Lithium/MnO_2
  - approx. 70 shocks at max. energy with 2 minutes monitoring between shocks with a total running time of approx. 4 h 50 minutes
  - Standby with weekly selftest: approx. 1 year 6 months
  - Standby with monthly selftest: approx. 2 years 6 months
- with Li-Ion (rechargeable)
  - approx. 70 shocks at max. energy with 2 minutes monitoring between shocks with a total running time of approx. 3 h
  - Standby with weekly selftest approx. 1 year 1 months
  - Standby with monthly selftest approx. 1 year 11 months

Note

When depletion notification is issued (battery below 10%), approx. 5 shocks can be delivered until the battery is completely empty.

Self test RTU (Ready to use)

- To ensure its readiness for use, the device performs a daily, weekly or monthly self-test. Self-test includes the test of the charging circuit and the battery capacity.
- If this test is completed successfully, the green **RTU** (**R**eady-**T**o-**U**se) LED is blinking (two second interval), showing that the device has not detected an error.

Art. no.: 2.511279 Rev. d

2.2.1 Available versions

Model	Description
AED FIRST	AED semi-automatic with or without ECG display (configurable)
AED Fully automated	AED fully automatic with or without ECG display (configurable)
AED MANUAL	AED semi-automatic and manual with ECG display

2.2.2 Overview of the configurable settings

⚠ CAUTION

- ▲ Settings are only modified if requested by the customer, or due to legal requirements.
- ▲ These modifications need to be registered in the device documentation as well as communicated to all users.
- ▲ Modification in the password-protected menus is only allowed by authorised users.
- ▲ Any unauthorized modification may endanger the patient.

SCHILLER's service centre can configure the following password-protected parameters:

Configurable device parameters	Detail see	Password required
• Selftest	2.5.2 Performing manual self-test	No
• Bluetooth pairing	see service manual	No
• Device information	8.10 Overview menus	No
• **Device Settings** >>> – Shock settings >>> Energy level for 1st, 2nd and 3rd shock – CPR settings >>> – CPR feedback >>> – Communication >>> – Transmission mode >>>	8.11 Device Settings	Yes
– System settings >>> - Local settings >>> Language, country, Date, Time, Timezone - Base settings >>> - Maintenance >>>(Year month) Lenght Unit (metric/inches); Monitor enable; Device name - Selftest Setting >>> (daily, weekly or monthly) - Volume settings - ECG and HR display - Show pacer markers - Auto Switch off time	8.12 System Settings	Yes
– Restore Factory Defaults – Import/Export settings	8.11.6 Parameter in the Device Settings menu	Yes
• Device update	see service manual	Yes
• Pads expired	3.2.4 Pads expired	No
• Production – Metronome CPR Time and number of breats	see service manual	Yes
• Log Files	see service manual	Yes

Art. no.: 2.511279 Rev. d

2.3 Operating and Display Elements

2.3.1 Overview FRED easyport plus

The picture below shows the user interface for an AED with ECG and CPR feedback display.

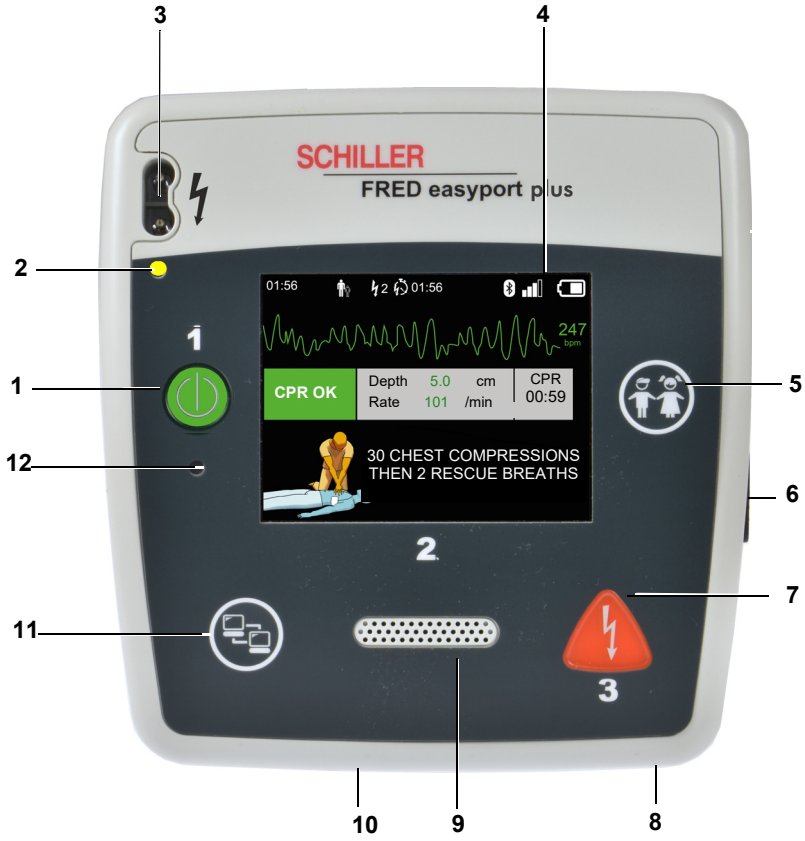


Fig. 2.1 Operating Elements

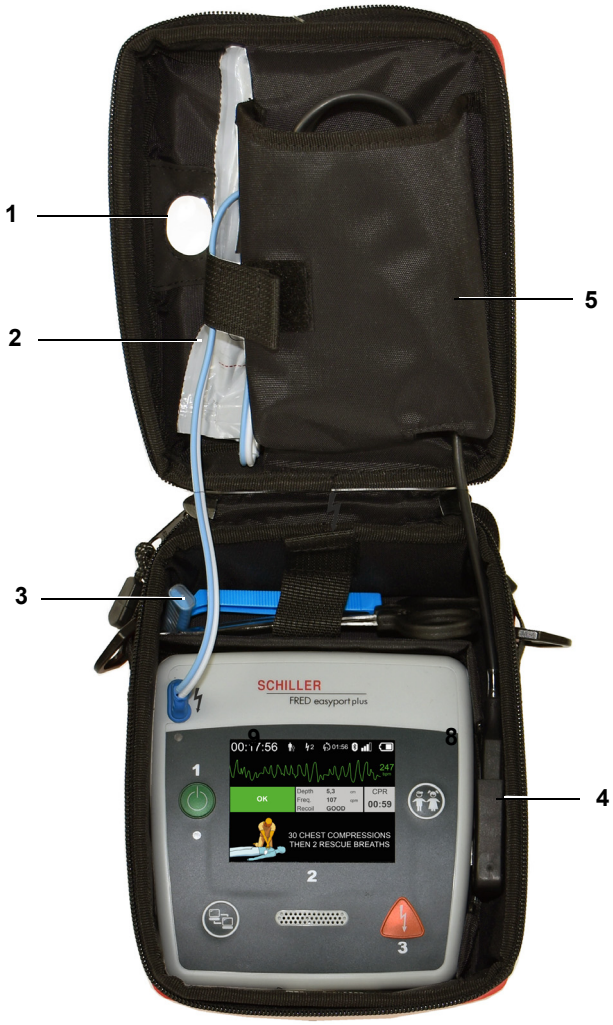
(1) Green button to switch the device on/off and RTU LED (Ready -to-use LED)
(2) Orange indicator lamp; lit as long as no electrodes are connected
(3) Electrode connector
(4) LCD screen
(5) Switching to child mode when using adult electrodes (PATIENT button)
(6) USB connector for Argus LifePoint sensor or USB memory stick
(7) Orange button: key to trigger a defibrillation impulse (SHOCK button)
(8) Battery at back
(9) Loudspeaker
(10) Microphone
(11) Data transfer (COM) button
(12) Ambient light sensor

⚠ CAUTION

▲ To ensure patient safety
– only use original SCHILLER electrodes (3)
– connect only the LifePoint sensor to the USB port (6)
– connect only USB memory stick to USB port (6), when device is not in use.

Art. no.: 2.511279 Rev. d

2.3.2 FRED easyport plus with bag

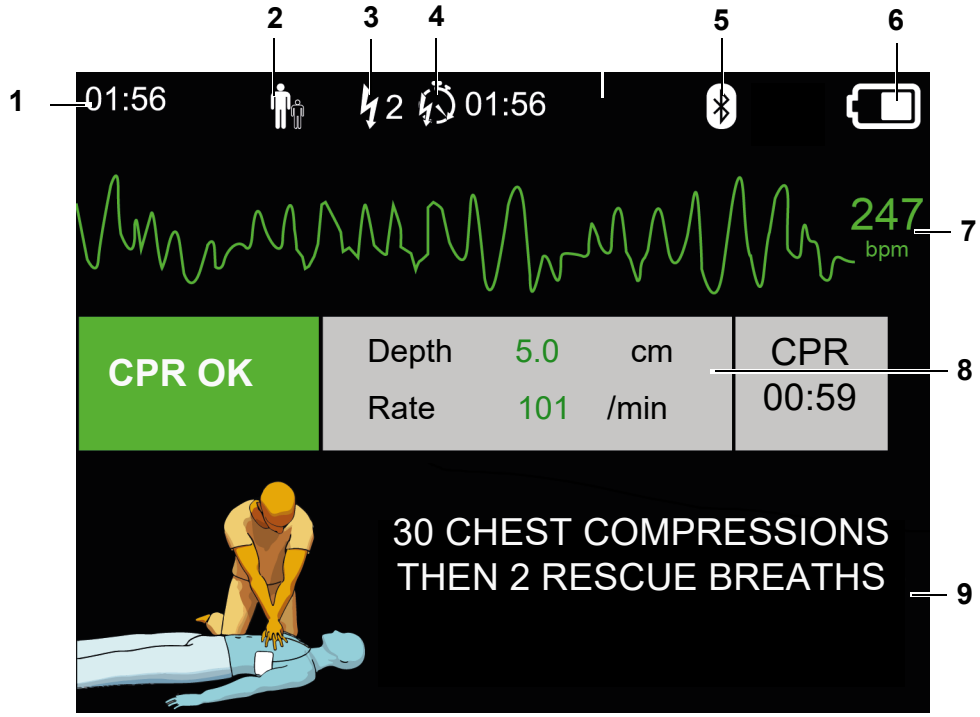


(1) RTU LED (Ready -to-use LED) transparent window
(2) Defibrillation electrode compartment
(3) Scissor and razor compartment
(4) Connection ARGUS LifePoint CPR feedback sensor (USB Port)
(5) ARGUS LifePoint compartment

Art. no.: 2.511279 Rev. d

2.4 Display

The following information is displayed on the LCD:

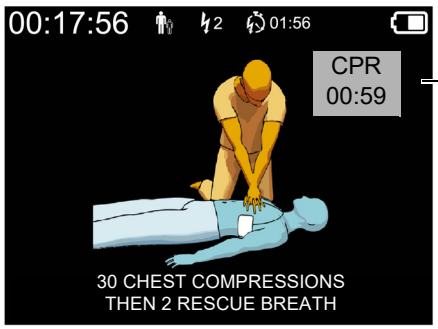


(1) Time passed since the device has been switched on
(2) Selected patient type:

= Adult

= Child 

(3) Number of shocks delivered
(4) Time passed since the last shock has been delivered
(5) Bluetooth activated
(6) Battery status
(7) ECG signal with heart rate
(8) CPR feedback display when LifePoint feedback sensor is connected.
(9) Display of defibrillation steps, user advices



Display CPR timer configurable

Display without CPR feedback and ECG/HR information

Art. no.: 2.511279 Rev. d

2.5 Functions

2.5.1 Automatic Self-test

⚠WARNING

▲ The automatic self-test does not replace the regular visual inspection of the device between the test intervals see 7.1.2 Visual inspection of the device and accessories.

Automatic self-test intervals (RTU)

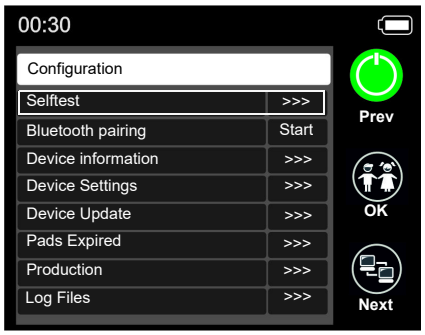
- To ensure its readiness for use, the device performs a daily, weekly or monthly self-test at 2.00 AM. This setting must only be configured by service personnel authorised by Schiller (see 8.12.3 Self-test Settings).
- Self-test includes the test of the charging circuit and the battery capacity. With a passed RTU test it is possible to deliver at least 5 shocks at maximum energy.
- If this test is completed successfully, the green RTU (ready to use) LED **(1)** is blinking (two second interval), showing that the device has not detected an error.
- If a notification is in progress (visual and/or acoustic), the battery autonomy is reduced or an error was detected during the last self-test.
- For the notification details, refer to chapter 7.6.2 General errors & troubleshooting and 7.6.3 Technical notification, page 62

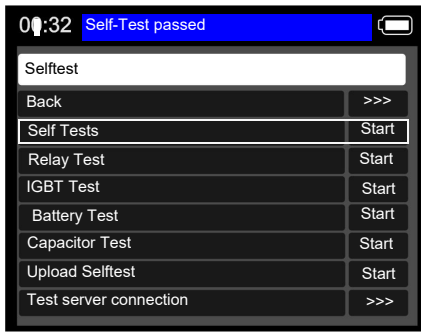
Fig. 2.2 RTU LED indicator

If a problem is detected during this test:
- an acoustic notification is issued (continuously beep-beep)
- the “RTU” LED (1) is not blinking

➜ Switch on the device to display the error message on the LCD.

2.5.2 Performing manual self-test





A manual self-test is indicated when a new battery has been inserted or after use of the device. This test does not affect the automatic self-test intervals.

1. Press and hold the button  while switching the device on  .
   The Configuration menu appears with the selected “Selftest” menu.
2. Press the “OK” button  and select with the “Next” button  “Do Self Tests” and start it with the “OK” button  . These tests takes about 30 seconds.
3. Test in progress is displayed on the top of the display.
4. If a connection via network to the Schiller data Management server (SDM) exist, select "Upload Selftest" to upload result of the test to the SDM server.
5. After successfully “Self-Test Passed”, switch off the device immediately to prevent discharging the battery.

➜ If a failure is displayed, see chapter 7.6.3 Technical notification, page 62.

Art. no.: 2.511279 Rev. d

2.5.3 Defibrillation procedure

The user is guided through all operation steps by spoken and displayed instructions. When the device is ready for shock delivery, the user is advised not to touch the patient and a warning tone with the illuminated high voltage symbol is activated.

The FRED easyport plus 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 not to touch the patient during the analysis phase. The analysis takes approximately 16 seconds. *Depending on the result, the user is prompted to deliver a shock or to start with CPR.*

The FRED easyport plus runs in *automatic mode:*

This device delivers defibrillation shocks automatically, i.e. there is no need to trigger the shock. When the device is switched on, the user is prompted to apply the electrodes to the patient. Next, he or she is prompted not to touch the patient during the analysis phase. The analysis takes approximately 16 seconds. *If a shock is advised, a countdown accompanies the last 3 seconds before the shock is automatically delivered.*

The FRED easyport plus runs in *manual mode:*

The basic functions are the same as for the ***semi-automatic mode.*** In addition, the manual mode can be activated. In this mode, the professional rescue staff can deliver a shock to the patient based on their own decision.
In this case, the professional rescue staff must follow the AHA or ERC protocols or other legal requirements.

Art. no.: 2.511279 Rev. d

3 Initial operation

⚠ DANGER

Danger of explosion — The **FRED easyport plus** must not be used in areas where there is any danger of explosion. Areas may be susceptible to explosion if flammable substances (gas), flammable anaesthetics, or products used to clean or disinfect the skin are used. Moreover, the defibrillator must not be used in an environment that is favourable to combustion. This is the case when ambient air contains more than 25% oxygen or nitrous oxide (laughing gas). Oxygenation in the vicinity of the defibrillation pads must be strictly avoided. Less than 25% oxygen in the ambient air is considered safe. Dangerously high oxygen concentrations can only occur in oxygen masks or in enclosed areas, such as hyperbaric chambers.

3.1 Batteries

3.1.1 General information and safety notes

There are two types of batteries:

Rechargeable Li-Ion

Non rechargeable LiMnO2

⚠WARNING

- ▲ **Danger of explosion!** The battery must not be exposed to high temperatures or disposed of with household waste.
- ▲ Do not expose the battery to chemicals that could dissolve ABS, polypropylene, polyvinyl chloride, nickel, mylar or steel.
- ▲ Do not short-circuit, cut, destroy, burn a battery.
- ▲ Use always the protective cover when storing spare batteries.

Patient hazard! — **Incorrect battery capacity indication**

- ▲ After inserting a new battery, always run a manual Self-test to check the condition of the device and the battery (see 2.5.2 Performing manual self-test)
- ▲ Replace the battery if the device indicates a battery problem. A defective battery must not be used.
- ▲ Turn off the device before removing the battery.

⚠ CAUTION

Patient hazard — **Ensuring operational readiness!**

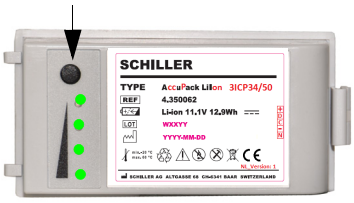
- ▲ Make sure that the device is always equipped with a sufficiently charged battery.
- ▲ The expiration date of a new battery, stored in its original packaging at a temperature of 25°C, is indicated on its packaging. It must not be used beyond this date.
- ▲ The protective cover of the battery must remain on during the entire storage time. The protective cover must only be removed when the battery is used.
- ▲ Do not expose the **FRED easyport plus** to direct sunlight or to extreme hot or cold. An ambient temperature higher than 25°C has an adverse effect on the battery life.

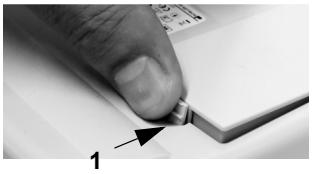
Art. no.: 2.511279 Rev. d

3.1.2 Battery replacement

WARNING

- ▲ Always keep a new spare battery on hand (observe the expiration date).
- ▲ Always check that the rechargeable Li-Ion battery is fully charged before inserting.
- ▲ If only one LED is flashing twice every second (quick flashing) the capacity is below 10%. Immediately replace the battery with a fully charged battery.
- ▲ If replacing battery during use on the Patient disconnect electrode connector.





→ If using the rechargeable Li-Ion battery, press the button to activate the battery capacity test. All 4 LEDs light up when battery capacity is between 75 to 100 %. For details on the charging status, see 6.1.2 LED Status display of the rechargeable Lithium Ion battery, page 50.

1. Remove the battery by pressing the locking mechanism in the direction of the arrow **(1)**.
2. Insert the battery into the device as shown on the picture **(2)**. Make sure it clicks into place.
3. As soon as the battery is inserted, the user has to run a manual Self-test to check the condition of the device and the battery, see 2.5.2 Performing manual self-test.
4. After successfully Test “Self Test Passed”, switch off the device immediately to prevent discharging the battery.

→ If a failure is displayed, see chapter 7.6.1 Error notification, page 61.

3.1.3 Switching device On and Off

Switching ON → Press the “ON/OFF” (1) button

Switching OFF → Press the “ON/OFF” (1) button for 3 seconds.

Forced shutdown procedure

If the device cannot be switched off via the above procedure, remove the battery and insert it again.

Art. no.: 2.511279 Rev. d

3.2 Battery monitoring

- The lithium battery ensures that the device stays fully operative (and performs the self-test) for several years (at a temperature between 15 °C and 25 °C), provided that the device is not being used.
- Battery service life depends on device use and ambient conditions.

▲ The battery must be replaced once the expiration date has been exceeded.

▲ The old battery must be recycled in accordance with local regulations.

3.2.1 Sufficient battery capacity indication while the device is switched off

⚠ CAUTION

▲ This indication is based on the last Self-test (RTU) test. Depending on the set testing interval (daily, weekly or monthly) the remaining battery capacity may be closed to the low battery indication. Therefore we recommend:

– use self-test interval daily or weekly and
– always keep a new spare full battery on hand

The RTU LED on the **FRED easyport plus** is blinking green when the battery capacity is sufficient to perform the resuscitation protocol with approx. 5 shocks at max energy.

3.2.2 Low battery capacity indication while the device is switched off

- Low battery capacity indication is the same during self-test and the manual self test as after inserting the battery or during use.
- If the battery capacity falls below 10%, the RTU LED is off and a acoustical notification is issued. These indications are issued until the battery is replaced. The battery must be replaced as soon as possible.
- Despite the low battery indication, the device is still able to perform about 5 defibrillations.
- Always switch off the device and disconnect electrode connector before removing the battery.
- The remaining battery capacity depends on the use and ambient conditions.

Fig. 3.1 Battery low indication

Art. no.: 2.511279 Rev. d

3.2.3 Battery depleted during use, limited mode (CPR)

⚠WARNING

▲ Patient hazard — Defibrillation is no longer possible if a depleted battery is detected. The battery needs to be replaced immediately.

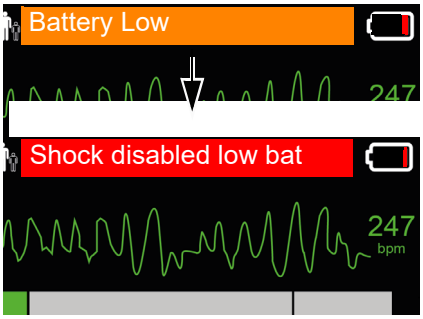


Fig. 3.2 Depleted battery indication

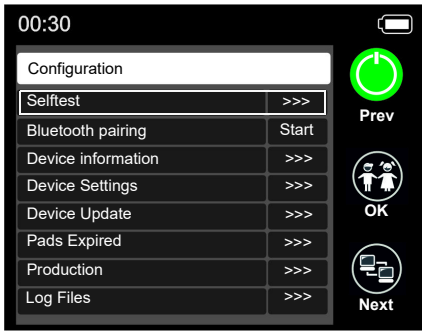
If a depleted battery is detected while the device is in use, the device will show after the “Low battery” notification the “Shock disabled low bat” notification. An audible signal is emitted and the battery symbol on the display is blinking red.

➜ Immediately shut down the device, disconnect electrode connector and replace the battery.

3.2.4 Pads expired

To monitor the expiry date of the defibrillation pads, always enter the expiry date printed on the packaging. A notification “Pads expired” appears when the selftest detects that the entered data has expired. Replace the electrodes as soon as possible.

Procedure



1. Press and hold the button  while switching the device on  .
2. Go to menu “Pads expired” select Year and month and enter the expiry date from the defibrillation pads packaging.
   – Verify the entered date in the menu **Configuration > Device information > Pads Expired**.

Art. no.: 2.511279 Rev. d

3.2.5 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 -5°C to 50 °C. Lower or higher ambient temperatures will have a negative impact on the battery's life or on the electrodes.

To ensure its readiness for use, the device runs a self-test to check the unit and the battery. A self-test can be performed any time. An enhanced periodic test can be performed in a defined interval (daily, weekly or monthly).

- Status OK: green blinking LED
- Device failure status: LED OFF

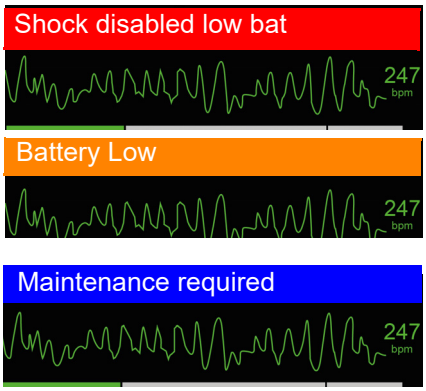
If the device detects an error during the self-test, an acoustical notification is activated.

➜ A self-test can be executed anytime see paragraph 2.5.2 Performing manual self-test.

3.2.6 Display of technical notifications

- Only technical notifications are issued, no physiological alarms.
- High and low priority technical notifications are issued according to 60601-1-8.
- Notification and information are issued according the description below.
- High Priority Volume Low=> 74dB(A)@1m, High => 80dB(A)@1m
- Low Priority Volume Low=> 49 dB(A)@1m, High => 60dB(A)@1m

The technical notifications and information are displayed as follows:



- High priority technical notifications
  - Text with red background
  - four beeps every 15 seconds
- Low priority notification
  - Text with orange background
  - two beeps every 30 seconds
- Information
  - Text with blue background
  - one beep every 60 seconds

All notifications disappear automatically when the cause has been remedied.
The list of the notification can be found in chapter 7.6.3 Technical notification

Operator position
The operator is closer than 1 m from the device.

⚠ CAUTION

▲ Ensure that the environmental noise is below the set sound volume for audio prompts and notifications. (Volume Low/Mid/High 50/55/60dB) see 8.12 System Settings.

▲ Do not set Volume below the environmental noise.

Art. no.: 2.511279 Rev. d

4 Defibrillation

4.1 Instructions and Safety Notes

4.1.1 Instructions

- The **FRED easyport plus** is a high-voltage electrotherapy device. Only personnel authorised by local law are permitted to use these devices. Improper use can endanger life.
- Non medical personnel is only permitted to use an AED such as the **FRED easyport plus** if local law approves of this practice.
- The success of the defibrillation depends on the correct application of the defibrillator but also on the heart's condition. It is the physician's responsibility to take any additional measures (e.g. adrenaline).
- According to AHA/ERC guidelines, even children under 8 years may be defibrillated.
- The electrodes should be applied in the anterior-anterior position. With children, anterior-posterior placement is advised to prevent a short-circuit between the two defibrillation electrodes, if the chest is to small for anterior-anterior position.
- A defibrillation can fail with certain disease patterns.
- **Patients with implanted pacemakers** — **FRED easyport plus** features an electronic pacer pulse suppression algorithm and therefore, pacemaker pulses are not taken into account during the analysis. Depending on the pacemaker model and on the position of the electrodes, the compensation pulse following every pacer pulse may be considered as a QRS complex. In this case, the analysis can be distorted and inaccurate. It depends on the pacer pulse parameters whether or not the compensation pulse is counted as a QRS complex.

4.1.2 Safety notes for defibrillation use

WARNING

▲ Changes, including the operational behaviour, affecting safety must be immediately reported to the responsible.

Shock hazard — for patients

▲ In unfavorable situations, the possibility of ECG analysis errors should not be dismissed. The device must therefore only be used if the following symptoms are found:

– not responsive,
– no respiration,
– no pulse.

Art. no.: 2.511279 Rev. d

⚠WARNING

Shock hazard — for user and assistants

▲ Position the patient flat on a firm, electrically insulated surface.

▲ Make sure that there are no conductive connections between the patient and other persons during ECG analysis and defibrillation.

▲ The patient must not come into contact with metal parts, e.g. a bed or stretcher, in order to prevent secondary contacts or paths for the defibrillation current that could endanger the assistants. For the same reason, do not position the patient on a wet surface (rain, swimming pool accidents).

▲ Do not allow the defibrillation electrodes to come into contact with other electrodes or metal parts which are in contact with the patient.

▲ The patient's chest must be dry because moisture can cause unwanted pathways for the defibrillation current. For safety, wipe off flammable skin cleansing agents.

▲ The assistants' tasks must be clearly defined as follows:

- During ECG analysis and shock:
  - suspend CPR,
  - ensure that the patient lies as motionless as possible,
  - do not touch the patient, otherwise, artefacts may lead to incorrect analysis results and recommended shock will be cancelled.

Risk of skin burns — for the patient

▲ Due to the high currents, there is a risk of skin burns at the electrode application site. This is why the electrodes must not be placed on or above:
  - the sternum,
  - the clavicle or,
  - the nipples.

▲ Do not use expired electrodes

Risk of malfunction of implanted pacemaker!

▲ Defibrillating a patient with an implanted pacemaker is likely to impair the pacemaker function or cause damage to the pacemaker.
For this reason:
  - defibrillation pads must not be positioned near the pacemaker.

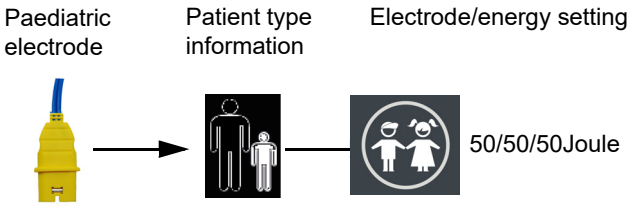
Art. no.: 2.511279 Rev. d

4.1.3 Defibrillating children

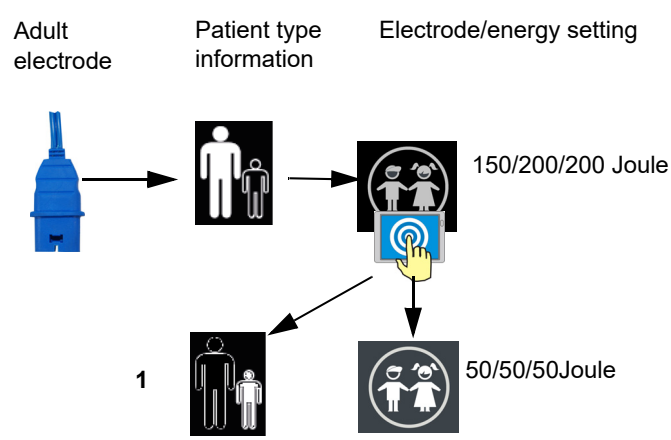
⚠WARNING

- ▲ For the defibrillation of children, the paediatric pads should be used.
- ▲ If no paediatric pads are available adult electrodes can be used when patient type “Child” has been selected. Warning! Double check that the patient type setting and type of electrodes is “Child”. (see illustration **1** below).

When paediatric pads are used, the patient type setting **Adult** or **Child** on the screen **does not** overrule the energy setting: when paediatric pads are connected to the device, the energy setting is always paediatric.



If no children electrodes are available, adult electrodes can be used. When adult pads are used, the patient type setting “**Child”** on the screen **does** overrule the energy setting Adult to “**Child”**.



→ In that case, anterior-posterior placement is advised to prevent a short-circuit between the two defibrillation electrodes when using adult electrodes.

Art. no.: 2.511279 Rev. d

4.2 Applying the adhesive electrodes

⚠WARNING

▲ Do **not** reuse the pads ⊘. If reused, the electrical properties may be insufficient, which could lead to patient injury.

⚠ CAUTION

▲ Only use the pads up to their 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.
▲ Placement of pads may be different whether the patient is an adult or a children

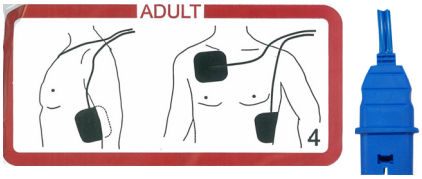
4.2.1 General information

Adult and Paediatric

i

If no children electrodes are available, adult electrodes can be used. When adult pads are used, the patient type setting "**Child"** on the screen **does** overrule the energy setting Adult to "**Child".** The pads positioning **anterior-posterior** shall be observed.

Adult electrodes 80 cm²



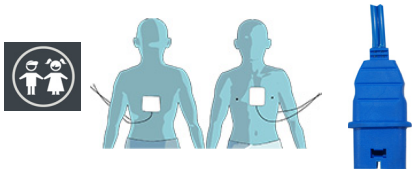
The adult electrodes (80 cm²) with the blue connector are used for adults and children weighing 25 kg or more.

The adult electrodes can be used also for paediatric by pressing the  button.

In this case, observe the application site for "**Paediatric electrodes 80 cm²",** see picture below**.**

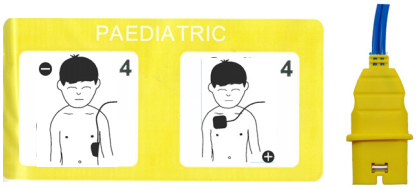
Adult electrodes 80 cm²" for children

Paediatric electrodes 80 cm²



If adult electrodes are used for children weighing less than 25 kg (younger than 8 years of age) use the  button to reduced the energy. It is recommended to apply the electrodes with the surface of 80 cm² anterior- posterior.

Paediatric electrodes 42 cm²



The paediatric electrodes with the yellow connector are used for children weighing less than 25 kg (younger than 8 years of age). The device automatically distinguishes between adult electrodes and paediatric electrodes. The energy setting is automatically reduced when paediatric electrodes are connected.

It is recommended to apply the electrodes with the surface of 42 cm² **anterior-anterior.**

Art. no.: 2.511279 Rev. d

4.2.2 Unpacking and applying electrodes

⚠ CAUTION

▲ Risks for the user and the patient — The packaging of pre-connected electrodes is welded to the electrode cable. Do not remove the packaging from the electrode cable (risk of damaging the cable).

▲ Check expiring date of the electrodes.

After having removed the clothes from the patient's upper body, perform the following steps:

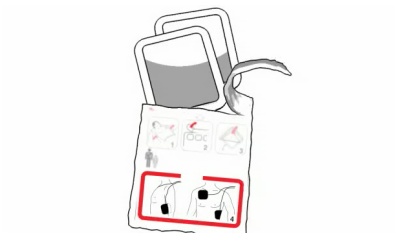


Fig. 4.1 Opening the electrode packaging

➜ Open the electrode packaging and apply the electrodes to the patient's chest according to chapter 4.2.3 Applying the electrodes to the patient's chest

➜ If not connected, insert the electrode connector into the electrode port.

Fig. 4.2 Orange electrode indicator

- The orange indicator is on and the device repeats the instructions until the electrodes are applied, or until the electrode connector is connected to the device, respectively, and the electrode-skin resistance (impedance) has reached an acceptable level.
- After several repetitions to apply and connect the electrodes, the device recommends performing a cardiopulmonary resuscitation cycle. The device will then switch off if it has not detected an acceptable impedance between the two electrodes after 15, **30** minutes or never. (see configuration 8.12 System Settings)

Art. no.: 2.511279 Rev. d

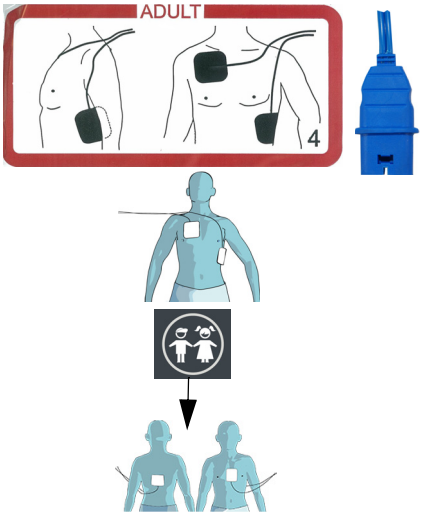
4.2.3 Applying the electrodes to the patient's chest

⚠WARNING

▲ Skin covered with sea water, sand, sunscreen, or skin or body care products may impair electrode contact or cause the electrodes to become disconnected.

Adult and paediatric electrodes

Adult electrodes 80 cm²



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

The adult electrodes can be used also for paediatric by pressing the  button.

In this case, observe the application site for "**Paediatric electrodes 80 cm²**", see picture below**.** You are prompted to confirm selection with the same button. The paediatric setting is then indicated by the illuminated paediatric button.

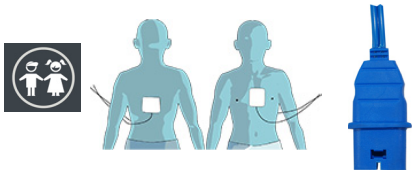
Electrode placement is the same for adults and for children weighing 25 kg or more. Before applying the adhesive electrodes, verify that the application sites on the patient's chest are clean and dry.

1. Carefully shave the application sites if the patient's chest is hairy.
2. Apply the electrode as shown at the right sternal edge at the level of the 2nd intercostal space. Do **not** apply the electrode on top of the clavicle (uneven surface).
3. Apply the electrode as shown in the picture on the left axillary line at the level of the 5th intercostal space.

The electrodes must have good contact with the patient's skin. Air bubbles under the electrodes must be avoided. To avoid air bubbles, place one edge of the adhesive electrode on the patient's chest, then gradually smooth it out toward the other edge to remove any air.
Place the electrodes on the patient's chest so that the connections point to either side of the patient in order not to hinder CPR.

Adult electrodes 80 cm² for paediatric

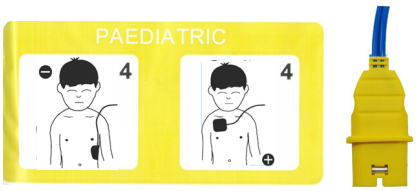
Electrodes 80 cm² for Paediatric



If adult electrodes are used for children weighing less than 25 kg (younger than 8 years of age) use the  button to reduced the energy.

It is recommended to apply the electrodes with the surface of **80 cm² anterior-posterior.**

Paediatric electrodes 42 cm²

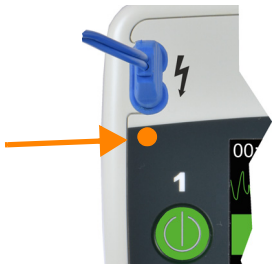


The paediatric electrodes with the yellow connector are used for children weighing less than 25 kg (younger than 8 years of age). Before applying the adhesive electrodes, verify that the application sites on the patient's chest are clean and dry.The device automatically distinguishes between adult electrodes and paediatric electrodes. The energy setting is automatically reduced when paediatric electrodes are connected.

When defibrillating children with the electrode surface of 42 cm², it is recommended to choose the **anterior-anterior** position.

Art. no.: 2.511279 Rev. d

4.2.4 Checking the electrodes



If the resistance (impedance) reaches an unacceptable value, the device interrupts and prompts the user to check the electrode application; in addition, the orange indicator is on.

This can occur if:

– the cable is disconnected from the device and/or,
– if the electrodes are not properly applied to the patient's chest
– if expired electrodes are used

In this case the device:

- Asks to check that the electrodes are connected and applied to the patient's chest and then recommends performing a CPR cycle.
- resumes the intervention where it has been interrupted when it detects that the resistance between both electrodes is acceptable again.
- switches off if it still does not detect acceptable impedance between both electrodes after 15, **30** minutes or never. (see configuration 8.12 System Settings).

Follow these steps to check the electrodes:

1. Insert the connector as specified in 4.2.2 Unpacking and applying electrodes on page 33.
2. Press the defibrillation pads onto the patient's chest one after the other to find out which one makes the orange indicator switch off.
3. Carefully press this electrode onto the patient's skin.
4. If the above steps do not solve the problem, apply new electrodes.

If the electrode error remains:

➜ Perform CPR even if the device switches off

To remove the electrodes from the patient's chest, see 4.7 Finishing the therapy.

Art. no.: 2.511279 Rev. d

4.3 Semi-automatic defibrillation

WARNING

- ▲ Patient hazard — The guidelines given in 4.1 Instructions and Safety Notes must be observed.
- ▲ Always follow the written instructions and the picture on the monitor, as the spoken instructions may not be understood in a noisy environment.

Semi-Automatic Defibrillation

Depending on the configuration of the device, the instruction provided by the device in step 4 can follow directly after step 1 if the "Start with Analysis" parameter is set to "No". (see 8.11.2 CPR setting).

Step 1

Switching on and preparing the device

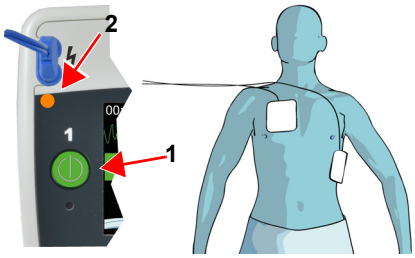
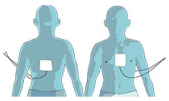


Fig. 4.3 Apply the adult electrodes

1. Switch the device on (**1**).
2. Assess the patient's condition: not responsive, no respiration, no pulse.
3. Apply the defibrillation electrodes to the patient's chest (see 4.2 Applying the adhesive electrodes).
4. Insert the electrode connector into the electrode port.

"Electrode LED" is on **(2)** as long as the electrodes are not properly applied to the patient's chest and/or the electrode connector is not properly connected to the device.

Adult electrodes for paediatric



If using adult electrodes for paediatric press the button  and confirm selection with the same button. The button lights up white and the patient type icon on the LCD indicates that the paediatric protocol is active. When defibrillating children with the electrode **surface of 42 cm²**, it is recommended to choose the **anterior-anterior** position.

Step 2

Analysing the ECG signal

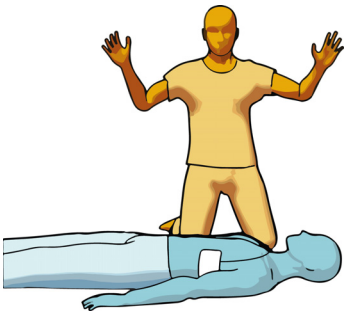


Fig. 4.4 Analysing, do not touch the patient

5. The analysis is automatically triggered, without user intervention. A message prompts the user not to touch the patient and the pictogram is displayed.

- If the device detects ventricular fibrillation or ventricular tachycardia with a heart rate exceeding 150 bpm, Step 3 Shock delivery follows; otherwise, continue with Step 4, Performing cardiopulmonary resuscitation.

Art. no.: 2.511279 Rev. d

Step 3

Fig. 4.5 Button to deliver the shock

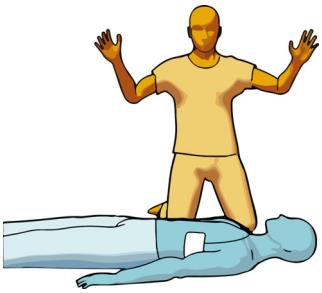
Shock delivery

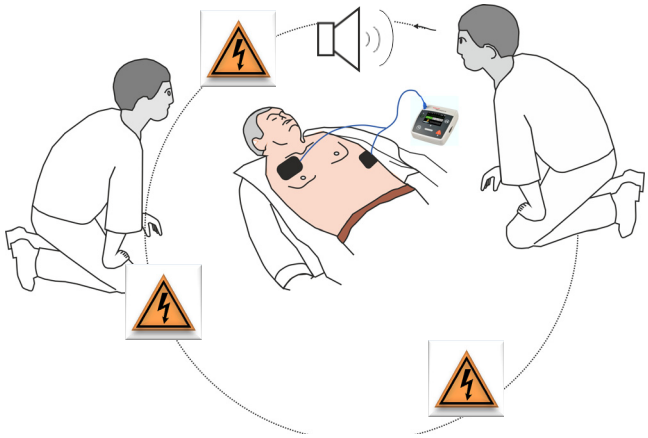
When the energy is charged, the user is prompted to trigger the shock by pressing the illuminated  orange button.

⚠ DANGER

Shock hazard!

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

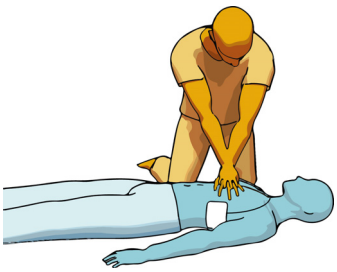




6. Deliver the shock by pressing the button  .

   After the shock delivery, proceed with Step 4 Performing cardiopulmonary resuscitation.

Step 4



Performing cardiopulmonary resuscitation

7. Perform a CPR cycle. According to the configuration of the device, a CPR cycle consists of:
   - – performing chest compressions for the set period of time, or
   - – alternately performing 30 chest compressions and 2 breathes for the set period of time.

After the CPR cycle, the device continues automatically with Step 2 Analysing the ECG signal.

Finishing the therapy

See 4.7 Finishing the therapy.

Art. no.: 2.511279 Rev. d

4.4 Automatic defibrillation

The laws and regulations for the use of automatic defibrillators differ from country to country. While some countries allow laypersons to use automatic defibrillators without any special training, other countries restrict the use of AEDs to EMTs or First Responders who have undergone special training.

4.4.1 Functional description of automatic AEDs

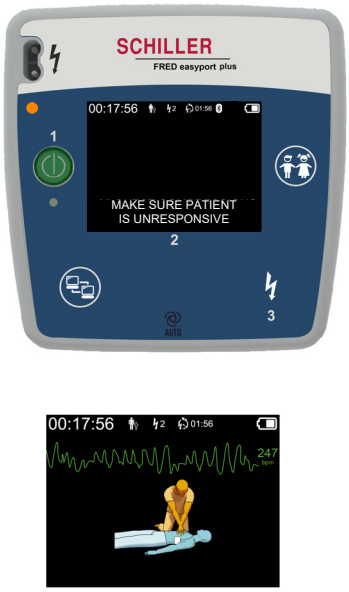


Fig. 4.6 **FRED easyport plus** Automatic

This device delivers defibrillation shocks automatically, i.e. there is no need to start the analysis or trigger the shock.

Voice and text prompts displayed on the screen keep the user informed regarding the therapy.

Text displayed:
- Make sure patient is unresponsive
- Plug and apply the electrodes
- Do not touch the patient
- Shock advised
- Warning! Shock!
- Shock delivered
- 30 Chest compression then 2 rescue breath

Optional display
- ECG curve (when configured)
- CPR feedback when using LifePoint sensor

If a shock is advised, the energy is automatically charged. A countdown accompanies the last 3 seconds before the shock is delivered.

4.4.2 Safety notes for automatic defibrillation

⚠ DANGER

Risks for patient, users and assistants!

Once the device has been switched on and the electrodes have been applied, the ECG analysis is started automatically and a shock is delivered automatically if a shockable rhythm is present. The user is informed of an ongoing analysis or shock release via written and acoustic messages.

- ▲ Touching or transporting the patient during analysis may lead to an incorrect analysis. Analysis results are only valid if the patient remained unconscious during the entire analysis and was not touched.
- ▲ For this reason, chest compressions and artificial respiration must be suspended during the analysis.
- ▲ The patient must not be touched or transported (e.g. stretcher) during analysis and shock delivery.
- ▲ The notes in section 4.1 Instructions and Safety Notes page 29 must be observed.

Art. no.: 2.511279 Rev. d

4.4.3 Automatic defibrillation procedure

Depending on the configuration of the device, the instruction provided by the device in step 4 can follow directly after step 1 if the "Start with Analysis" parameter is set to “No”. (see 8.11.2 CPR setting).

Step 1

Switching on and preparing the device

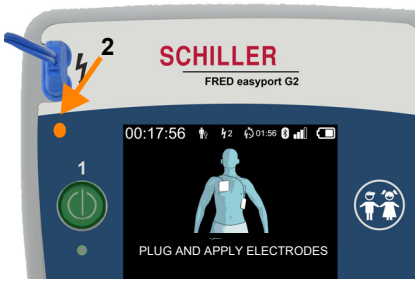
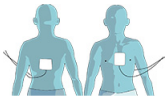


Fig. 4.7 Apply the adult electrodes

1. Switch the device on (**1**).
2. Assess the patient's condition: not responsive, no respiration, no pulse.
3. Apply the defibrillation electrodes to the patient's chest (see 4.2 Applying the adhesive electrodes).
4. Insert the electrode connector into the electrode port.

“Electrode LED" is on **(2)** as long as the electrodes are not properly applied to the patient's chest and/or the electrode connector is not properly connected to the device.

Adult electrodes for paediatric



If using adult electrodes for paediatric press the button  . The button lights up white and the patient type icon on the LCD indicates that the paediatric protocol is active. When defibrillating children with the electrode surface of 42 cm^2, it is recommended to choose the **anterior-anterior** position.

Step 2

Analysing the ECG signal

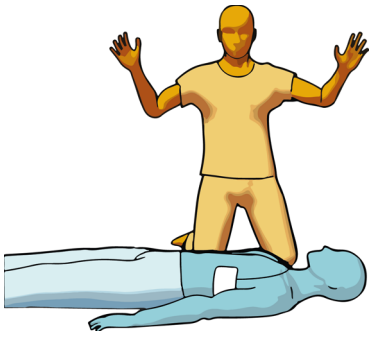


Fig. 4.8 Analysing, do not touch the patient

5. The analysis is automatically triggered, without user intervention. A message prompts the user not to touch the patient and the pictogram is displayed.

- If the device detects ventricular fibrillation or ventricular tachycardia with a heart rate exceeding 150 bpm, Step 3 Shock delivery follows; otherwise, continue with Step 4, Performing cardiopulmonary resuscitation.

Art. no.: 2.511279 Rev. d

Step 3

Automatic shock delivery

As soon as the energy charge is completed, the device automatically delivers the shock, without user intervention. SHOCK ADVISED!" and "WARNING! SHOCK!" is displayed on the screen, the flash symbol 

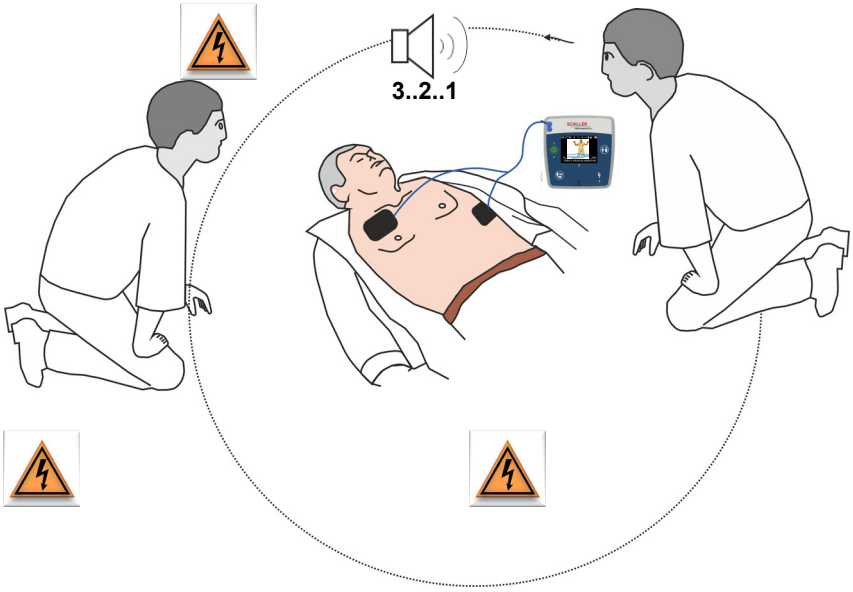
lights up and a voice countdown

3..2..1 is issued before the shock is delivered.

⚠ DANGER

Shock hazard!

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



After the shock delivery, proceed with Step 4 Performing cardiopulmonary resuscitation.

Step 4

Performing cardiopulmonary resuscitation

6. Perform a CPR cycle. According to the configuration of the device, a CPR cycle consists of:
   - performing chest compressions for the set period of time, or
   - alternately performing 30 chest compressions and 2 breathes for the set period of time.

After the CPR cycle, the device continues automatically with Step 2 Analysing the ECG signal.

Finishing the therapy

See 4.7 Finishing the therapy.

Art. no.: 2.511279 Rev. d

4.5 Defibrillation in manual mode

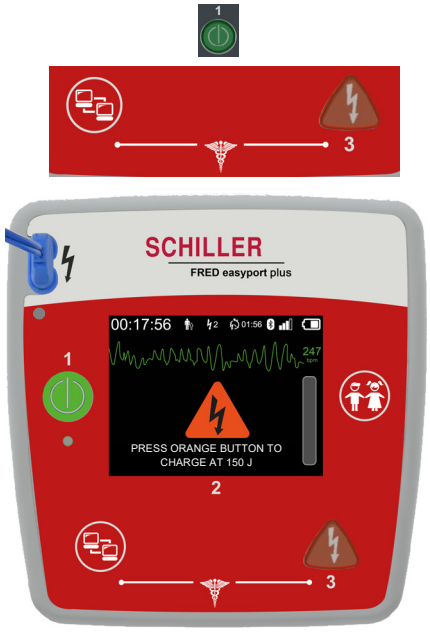
The **FRED easyport plus** version including the manual option is clearly labelled with a red foil. If the user does not activate the manual mode, the unit will run in the semi-automatic mode. The defibrillation will then be carried out as described in section 4.3.

⚠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 are 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

4.5.1 Switching over to manual mode

- The device cannot be switched over to the manual mode during the defibrillation process (analysis, charging, shock release).
- To operate the **FRED easyport plus** in semi-automatic mode again, it must be shut off and on again.



1. Switch the device on by pressing the green button 1 .
2. Simultaneously press the Data transfer (COM) button and the shock button.
3. Release the buttons as soon voice prompt starts.
   The message "Press COM and SHOCK again to start manual mode" is displayed.
4. Within 5 seconds, press again the Data transfer button and the shock button.
5. Connect the electrode cable to the device and apply the electrodes to the patient.

The following is displayed:
- ECG curve
- The advice to charge the energy (according to the factory settings – see page 68) with the orange shock button.

Defibrillator charging

6. Press shock button 3 .
   - Energy charging progress is displayed and beep is issued to indicate the charging process.

   - As soon as the set energy is reached, the orange button 3 lights up and steady warning tone is issued.
   - You are prompted to release the shock (see next page)

Art. no.: 2.511279 Rev. d

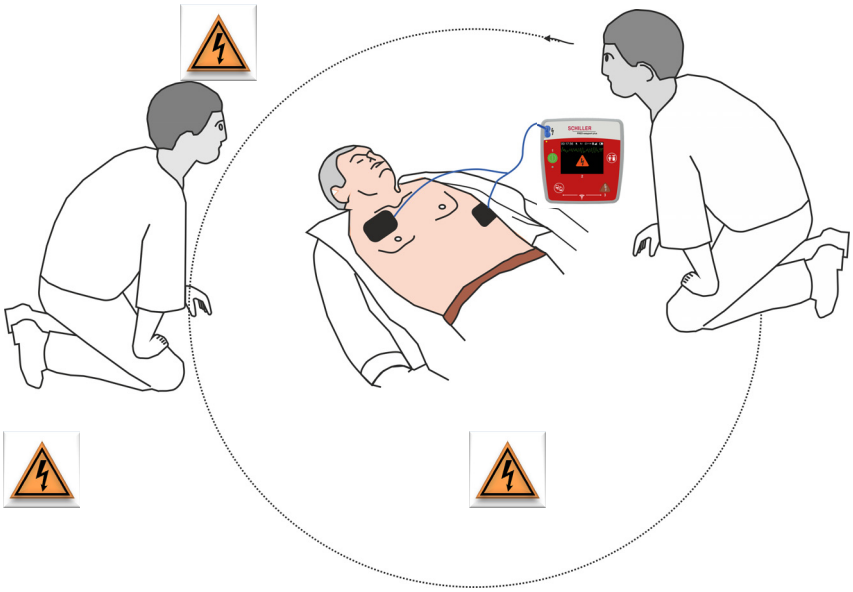
4.5.2 Shock delivery in manual mode

⚠ 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.



7. Deliver the shock by pressing the button  .

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

Art. no.: 2.511279 Rev. d

4.6 Monitoring mode

4.6.1 With Defi-Pads

The monitoring mode with the defibrillation pads is used when the AED algorithm detects a normal rhythm and no shock is advised, but the patient's cardiac rhythm needs to be monitored. The same applies after a successful defibrillation when rhythm and other vital data of the patient are stable.
In addition to monitoring by the device, the patient also needs to be permanently monitored by the medical staff. If the cardiac rhythm changes to a VF / VT during monitoring, the device switches to AED mode and the defibrillation protocol is activated.

⚠WARNING

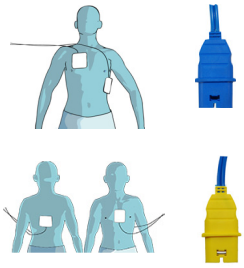
▲ The monitoring mode must never be used by non-medical staff if the local law exclusively allows semi-automatic defibrillators for this user group.
However, there are countries where rescue teams and medical supervision staff request the option to monitor the heart rhythm when a defibrillation is not required. 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 to this operation mode is only possible when:
– "ECG curve display" is set to "Yes" see 8.12 System Settings
– "Monitoring enable" is set to "Yes", see 8.12.2 Base Settings
– a normal ECG rhythm has been detected during analysis (No shock advised) followed by the first advice for CPR (after approx. 25 seconds) and the following CPR phase. If parameter "Start with analysis" is set to "No" you can switch just when the CPR advise starts.

During analysing phase, it is not possible to select this mode.
Note: Programming "Auto switch" off is disabled in this mode.

Procedure



The procedure is valid for all FRED easyport plus versions; therefore, buttons can have different colours.

1. Normal procedure for applying Defibrillation pads as described in this manual.
2. When a normal rhythm is detected and the voice advice "2 rescue breaths" has been given:

→ press simultaneously the COM and the PATIENT buttons.

The message "Press COM and PATIENT again to start monitor mode" is displayed.

3. Within 5 seconds, press again the COM and PATIENT buttons.
The display shows the ECG curve and heart rate. The "Monitor" mode is displayed on the bottom of the LCD display.

→ When the device detects a VF/VT during monitoring, it will switch to AED protocol (after approx 10s) and starts analysing. Follow the instruction issued by the device as described in this user guide.

→ To leave the monitoring mode, you can also disconnect the defibrillation pads cable for about 5 seconds. The instruction issued by the device starts again with "Plug and apply the electrodes".

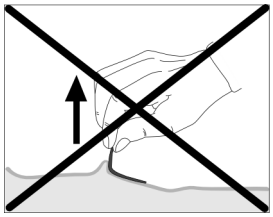
Art. no.: 2.511279 Rev. d

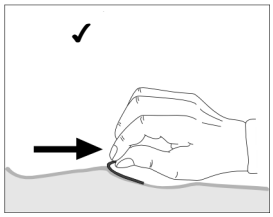
4.7 Finishing the therapy

1. Switch the device off as soon as the therapy is finished by pressing the button  for 3 seconds.
2. Disconnect the electrode cable.

Adhesive electrodes and adhesive pad

– Carefully remove the electrodes or adhesive pad (LifePoint) from the patient's skin.





– Discard the disposable pads immediately after use to prevent their reuse (hospital waste).

– Clean the device, cables and sensors as described in section 7.2 page 56

3. Add new defibrillation electrodes and enter expiring date as described in chapter 3.2.4 Pads expired.

Art. no.: 2.511279 Rev. d

4.8 ARGUS LifePoint

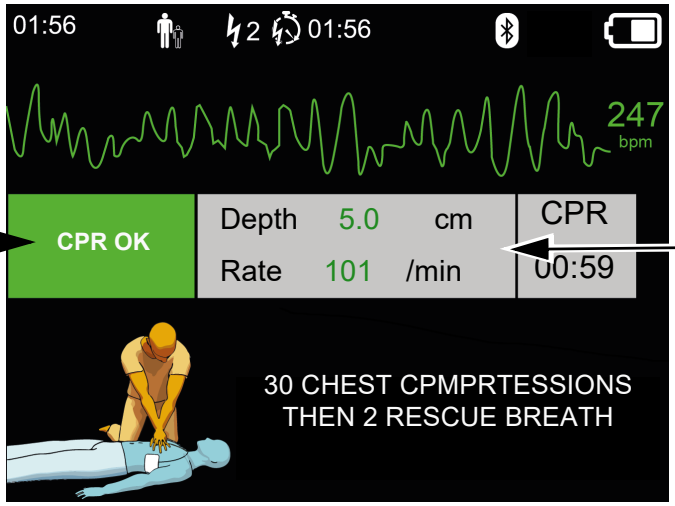
4.8.1 ARGUS LifePoint

The ARGUS LifePoint measures the compression depth and rate and recoil* after each compression (*except in France, Germany, UK and USA.)

⚠ CAUTION

▲ The LifePoint is not suitable for use on children younger than 8 years or less than 25 kg.

- The range for the depth of compressions is 4.5 to 6.2 cm which is the range for adult patients. There is no recommended target depth for paediatric patients < 8 years or < 25 kg.
- We recommend using an adhesive pad so that the sensor remains in position and does not lift off when relieved, which can lead to inaccurate measured values.
- The red side of the sensor must be attached to the adhesive pad.



Text and voice advice to improve the CPR quality

Measured value from ARGUS LifePoint sensor

Metronome speed [/min]	Press Faster	CPR OK	Press Slower
100	≤ 90	CPR OK	≥120
110	≤ 100	CPR OK	≥130
120	≤ 110	CPR OK	≥140

Depth [mm]	Press Deeper	CPR OK	Press Shallower
1-127	≤ 45	CPR OK	≥ 62

Art. no.: 2.511279 Rev. d

4.8.2 Setup of the sensor

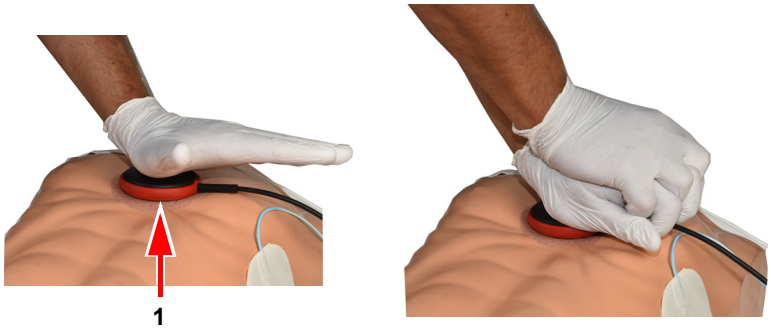
⚠ CAUTION

▲ Only use the securing pads up to their expiration date.
▲ Do **not** reuse the pads.

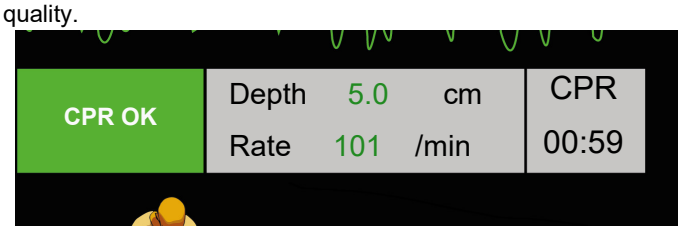
1. Connect the LifePoint USB cable to the USB connector.
2. Switch on the device.

3. Attach the adhesive securing pad on the patient's chest and peel off the foil.
4. Place the LifePoint on the patient chest and start CPR.

5. Place your hand on the sensor so that the heel of your hand **(1)** is in the middle of the sensor.



6. Start with CPR and monitor the compression quality on the device and follow the instructions given by the device (see page before).
7. The displayed measurements in the middle of the screen informs you about your CPR quality.



8. After finishing the intervention, see 4.7 Finishing the therapy.

Art. no.: 2.511279 Rev. d

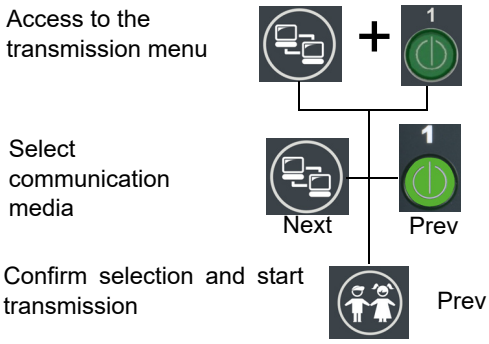
5 Communication

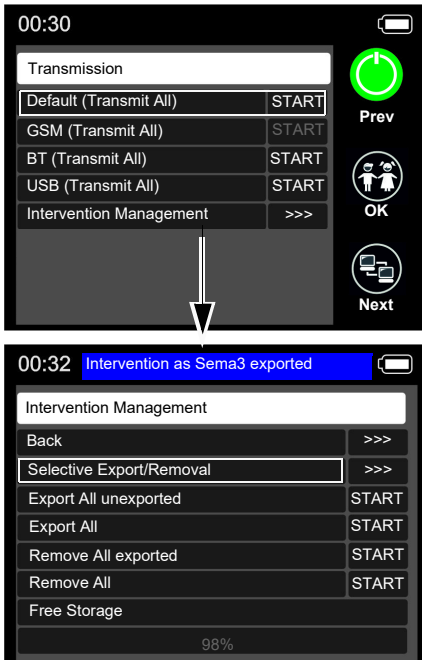
- To read the intervention data, use the appropriate SCHILLER software. Contact your SCHILLER representative.
- The following transmission possibilities are available to retrieve the intervention data:
  – directly to USB memory stick
  – via Bluetooth bridge to a **secured** network/server by manual transmission or automatically after intervention. The transmission to the server can be tested in the menu Selftest/Test server connection

5.1 Transmission menu

- The default transmission mode is Bluetooth.
- To transmit the data to the USB memory stick choose the “Intervention Management” menu.

➜ To access the Transmission menu Press and hold the “Data transfer” button while switching the device on.





Transmission menu

As shown in the “Transmission” menu, the parameters “Default (Transmit All)” and BT (Transmit All) are active. With both parameters, the data will be transmitted via Bluetooth.

➜ To transmit the data to a USB stick, open the intervention management menu.

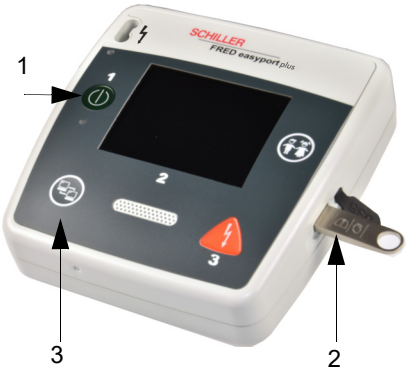
Sub-menu Intervention management

- Select Export/Removal menu:
  – Select For Export
  Export Selected (0)
  – Select for Removal
  Remove Selected (0)
- Export All Unexported
- Export All
- Remove All Exported
- Remove All
- Free Storage XX%

Art. no.: 2.511279 Rev. d

5.1.1 Retrieving intervention data via USB

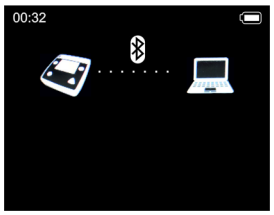
- If setup “Auto Start” in the transmision menu is set to “Yes”, the device starts the transmission automatically, when point 2 has been executed. The Point 3 till 4 are then not needed. See Setting 8.11.5 Transmission mode.



1. Insert the USB memory stick (2)
2. Press and hold the “Data transfer” button (3) while switching the device on (1). (If “Auto Start is set to “ Yes” the transmission starts automatically after 5 seconds)
3. Select the Intervention menu.
4. Choose one of the following export functions:
   – Selective Export/Removal function (The selected exported files will be removed!)
   – Export all unexported
   – Export all
5. Press the Child button to start the transfer. The data transfer progress is displayed on the LCD (blue bar on top of the display). A transmission of about 2 % storage takes approx. 40 seconds.
6. After transmission remove the USB stick and close the connector with the protective cap to seal it against water and dust ingress.

5.1.2 Retrieving intervention data via Bluetooth bridge

- Make sure that the device is paired with the Bluetooth bridge and the bridge is connected to a **secured** network.
- After transmission, the data will be marked as exported [EXP].
- If setup “Auto Start” in the transmision menu is set to “Yes” the device starts the transmission automatically, when point 1 has been executed. The Point 2 is then not needed. See Setting 8.11.5 Transmission mode.



7. Press and hold the data transfer button (3) while switching the device on. (If “Auto Start is set to “ Yes” the transmission starts automatically after 5 seconds)
1. Select the Intervention menu.Select “Default (Transmit all)” and confirm selection with the “Child” button.
2. The data transmission is displayed.
3. After final transmission the device will be switched off automatically.

5.1.3 Automatic transmission of intervention data via Bluetooth bridge

If the transmission mode is set to “Auto Power on” to “10 min” the device behaves as follows:

- The device switches on in Transmission mode and automatically starts transmission of the latest intervention data for a max. duration of 10 minutes. The device then switches off.See Setting 8.11.5 Transmission mode.
- This only applies if the device has previously been switched on in normal mode and if the intervention data is valid.
- If the server is not reachable or not all data has been transmitted within the 10 minutes, the device will shutdown and retry the transmission again after 10 minutes.

Art. no.: 2.511279 Rev. d

6 Charging Unit CS-2

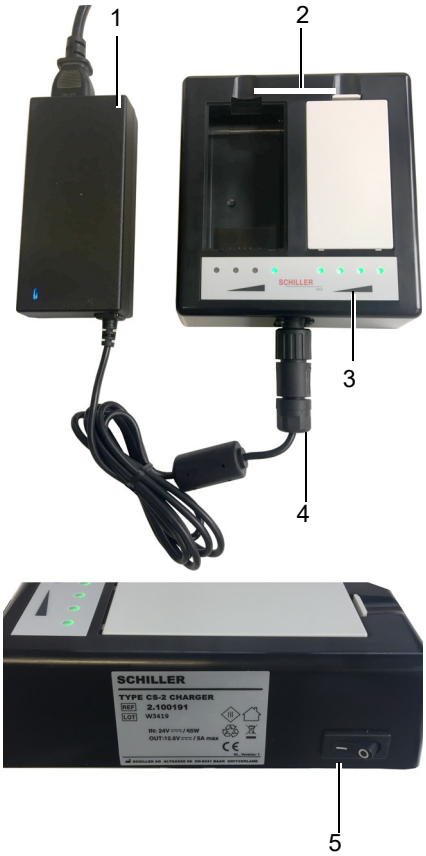
DANGER

- ▲ Electrical shock hazard. Do not operate the device if the earth connection is suspect or if the power cord is damaged or suspected of being damaged.
- ▲ Mains operation with the external power supply unit is only possible in protected areas (IP20) and a public low-voltage power supply network with a protective earth connection and **not** suitable for use in vehicles or aircrafts.

CAUTION

- ▲ The external power supply unit must be connected in a way that makes easy disconnection from the mains possible.
- ▲ This battery charger is not intended for domestic private use and has to be stored in a place inaccessible to children.
- ▲ The batteries supplied are rechargeable Lithium-Ion 11.1 V, 12.9 Wh. Only use rechargeable batteries supplied by SCHILLER.
- ▲ We recommend that the batteries are replaced every 500 charge / discharge cycles.
- ▲ Inserting the non rechargeable Battery Lithium MnO2 is indicated by not flashing LED's on the charger (see 6.1.1 LED Status display of the charger)

6.1 Overview battery charger



(1) External power supply for the battery charger CS-2.
(2) Battery slot 1 and 2.
(3) Battery charging status LED 1 to 4
(4) DC connection
(5) On/Off switch

- Insert the battery in the charger unit and push home until the battery clicks in place with the catch.
- Switch on the CS-2 charger
- To remove a battery, press the catch to release it.

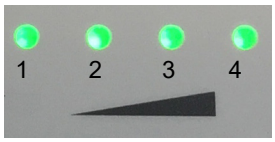
CAUTION

- ▲ Always use the protective cover when storing the spare battery.

Charging time to 100 %: 2 h

Art. no.: 2.511279 Rev. d

6.1.1 LED Status display of the charger



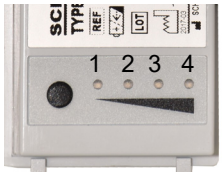
Status	LED 1	LED 2	LED 3	LED 4	Charging Status
Normal	OFF	OFF	OFF	ON	Start up, charger supplied and switch on without battery
	Quick flash	OFF	OFF	OFF	0-25%
	ON	Quick flash	OFF	OFF	25-50%
	ON	ON	Quick flash	OFF	50-75%
	ON	ON	ON	Quick flash	75-100%
	ON	ON	ON	ON	100%
Low voltage	Slow flash	OFF	OFF	OFF	Pre-charge mode for low battery voltage
Failure	Quick flash	OFF	OFF	Quick flash	Pre-charge mode for low battery voltage >90 min. Battery deep discharged. Battery defective
	OFF	quick flash	quick flash	OFF	Fast charging time over 3 hours

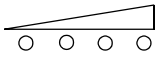
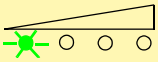
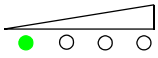
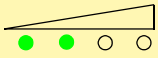
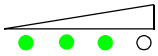
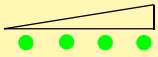
Status when non rechargeable Lithium MnO2 is inserted

Status	LED 1	LED 2	LED 3	LED 4	Status
Wrong battery inserted or defective	OFF	OFF	OFF	ON	LED 4 is on. None of the LEDs are flashing.

6.1.2 LED Status display of the rechargeable Lithium Ion battery

Battery capacity status after pushing the button.



	LED 1	LED 2	LED 3	LED 4	Capacity [%]
	OFF	OFF	OFF	OFF	0
	**Quick flash**	**OFF**	**OFF**	**OFF**	**below 10 !**
	ON	OFF	OFF	OFF	10 - 25
	ON	ON	OFF	OFF	25 - 50
	ON	ON	ON	OFF	50 - 75
	ON	ON	ON	ON	75 - 100

Art. no.: 2.511279 Rev. d

7 Maintenance

⚠WARNING

▲ To ensure readiness for use of the device, always observe the maintenance intervals as described in this chapter.

▲ The automatic self-test does not replace the regular visual inspection of the device between the test intervals.

7.1 Maintenance Intervals

- Because **FRED easyport plus** is an emergency device, some verifications have to be done as written in the following table in order to maintain the device operational, including the accessories. The test results must be recorded and compared to the values accompanying the documents (see 8.9 Inspection report)
- If used in optimal conditions the **FRED easyport plus** does not need any particular maintenance tests since the device is able to test itself automatically on a regular basis, and it issues a notification if any action either from the user or from a technician is required.
- Local regulations in your country may stipulate additional or different inspection intervals and tests.
- The following table indicates the intervals and competence of the maintenance work required.

Interval	Maintenance - replacement	Responsible
After each use	• Replace the electrodes. • After battery insertion the user has to run a manual Self-test to check the condition of the device and the battery. See 2.5.2 Performing manual self-test. • Visual inspection of the device see 7.1.2 Visual inspection of the device and accessories. • Clean and disinfect device see 7.2 Cleaning • Enter expiry date of the new electrode pads 3.2.4 Pads expired.	➜ User
Regularly between the set RTU test interval (daily, weekly or monthly)	• Check that the “RTU” LED is blinking green (see 7.6.1 Error notification) • Visual inspection of the device and accessories. If device is not used several weeks clean and disinfect device, see 7.1.2 Visual inspection of the device and accessories.	➜ User
Every 3 years	• Technical safety inspection and software updates (if needed) are advised according to SCHILLER documentation (available for technical departments authorised by SCHILLER), see 7.1.3 Functional check. • Enter new maintenance reminder date, see 8.12.2 Base Settings.	➜ Service staff authorised by SCHILLER
Every 6 years	• Replacement of internal backup battery. A technical safety inspection and a software update (if needed) are advised after opening the device, see 7.1.3 Functional check. **Note:** The replacement of the internal backup battery is advised. Should this internal backup battery not be replaced every 6 years, SCHILLER cannot ensure the proper time stamping of the intervention.	➜ Service staff authorised by SCHILLER

Art. no.: 2.511279 Rev. d

7.1.1 Service/Shelf life

Device The device has defined Service Life of 8 years if maintenance intervals have been observed according to section 7.1 Maintenance Intervals and the directive IEC/EN 62353.

Battery Rechargeable Lithium Ion battery (approx.4 years), Li-MnO2 6 years, see manufacturing date on the battery and internal battery cell (approx. 6 years)

Electrodes see expiring date on the electrodes pouch (approx.2 years)

Securing pads for Lifepoint see expiring date on the pouch (approx.2 years)

Art. no.: 2.511279 Rev. d

7.1.2 Visual inspection of the device and accessories

Regularly (in between the set RTU test interval) and after each use, inspect visually the device and the cables in order to detect possible mechanical damages.
If you observe damages or dysfunctions which can endanger the safety of the patient or user, only use the device once it has been serviced.

Points to inspect:

- Check that the RTU LED is blinking, see 7.6.1 Error notification
- Device and LifePoint sensor casing undamaged?
- No excessive soiling or damage?
- Legible nameplate at the rear of the device?
- Legible inscriptions on the front face of the device?
- Expiration date of the electrode not elapsed?
- Check that the electrode packaging is not damaged?
- Expiration date of the Li-MnO2 battery not elapsed?
- Expiration date of the Li- Ion battery not elapsed? (4 years from manufacturing date or the maximum number of charging cycles 500 has been reached, see 7.1.4 Maintenance of the rechargeable Li-Ion battery)
- Expiration date of the securing pads not elapsed?
- Clean and disinfect the device if it was not used several week (see 7.2 Cleaning)

Important

▲ Electrodes past their expiration date must be replaced immediately
▲ Batteries past their expiration date must be replaced immediately. (see manufacturing date on the batteries)
▲ Defective units or damaged cables must be replaced immediately.
▲ Replace or repair immediately the device, if the “RTU” LED is not blinking (see details in chapter 7.6.1 Error notification).

If the device is defective or if problems have been detected by the device during the self-test, the device must be repaired before use.

If a problem is detected during this self-test:

- the “RTU” LED is OFF and an audible signal is emitted if a critical error is detected as:
  - battery empty
  - any other critical error

➜ see detail in chapter 7.6.1 Error notification.

Art. no.: 2.511279 Rev. d

7.1.3 Functional check

WARNING

Patient hazard — If the device's behaviour differs from the description given in this user guide or the “RTU” LED is OFF with an acoustic signal, the battery is depleted or the device is defective and must be repaired.

CAUTION

▲ In case of intensive use of the device, SCHILLER recommends that these inspections be performed at shorter interval.

▲ The regulations in force in each country regarding inspection frequency must be observed (if shorter intervals than those recommended by SCHILLER are imposed).

Points to inspect:

- Visually inspect the device and the accessories (see 7.1.2 Visual inspection of the device and accessories).
- Check for proper functioning.
- Measure the energy delivered at 50 Ohms.

7.1.4 Maintenance of the rechargeable Li-Ion battery

Important

- The battery's performance and life largely depend on how and under which ambient conditions the battery is used.
- The rechargeable battery is maintenance-free during its normal life.

Replacing Power Battery Li-Ion

- The battery must be replaced after 4 years from the manufacturing date on the battery, regardless of whether or not the unit has been used, or whether the maximum number of charging cycles (500) has been reached.
  - Numbers of recharging cycle (Cycle counts) can be found in the menu **Configuration > Device information > More information > Battery info**.
  - The power battery needs to be replaced when the battery capacity indication in the menu **Battery info**, parameter **“Full Charge Capacity”** is below 960.
- Only store fully charged batteries. If a battery is not used, recharge it every 6 months.
- Recommendation: Store not used battery with a state of charge between 50-70% at an ambient temperature of 20°C, ± 5°C
- Check battery contact for corrosion.

Access the menu Battery info

➜ Press and hold the button  while switching the device on 

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Art. no.: 2.511279 Rev. d

7.1.5 Maintenance of the non rechargeable Lithium/MnO2 battery

Important

- The battery's performance and life largely depend on how and under which ambient conditions the battery is used.
- The non-rechargeable battery is maintenance-free during its life.
- The self discharge of the battery is approx. 1% per year at 25°C. A storage at higher temperature increases the self discharge (e.g approx. 16% per year at 60°C).

Replacing Li-MnO2 battery

- The battery needs to be replaced when the battery depletion is displayed.
- The battery must be replaced after 6 years from the manufacturing date on the battery.
- Recommendation: Store not used battery at a ambient condition of 20°C, ± 5°C.
- Check battery contact for corrosion.

Art. no.: 2.511279 Rev. d

7.2 Cleaning

Cleaning removes dust, dirt and stains; however, this does not constitute a disinfection. Use commercially available detergents intended for clinics, hospitals and practices.

7.2.1 Detergents

Please refer to the manufacturer's information regarding the detergents.

Admissible detergents

- 50 % isopropyl alcohol
- Neutral detergents
- Soap water
- All products that are suitable for ABS0 plastic (housing device), Polycarbonate PC (LCD window) and Polyester PES (keyboard)

Non-admissible detergents

Never use products containing the following:

- Ethyl alcohol
- Acetone
- Hexane
- Abrasive cleaning powder
- Plastic-dissolving products

Art. no.: 2.511279 Rev. d

7.3 Disinfection

Use commercially available disinfectants intended for clinics, hospitals and practices to disinfect the device.
Wipe disinfection removes certain bacteria and viruses. Please refer to the manufacturer's information.

7.3.1 Disinfectant

Admissible disinfectants

- Isopropyl alcohol (50 %)
- Propanol (50 %)
- Ethyl hexanal
- Aldehyde (2-4 %)
- Ethanol (50 %)
- all products that are suitable for ABS plastic

Non-admissible disinfectants

Never use products containing the following:

- Organic solvents
- Ammonia-based detergent
- Abrasive cleaning agents
- 100% alcohol, Virex, Sani-Master
- Sani-Cloth®, Ascepti® or Clorox® wipes
- HB Quat®
- Conventional cleaner (e.g. Fantastic®, Tilex® etc.)
- Conductive solution
- Solutions or products containing the following ingredients:
  - Ketone (Acetone)
  - Ammonium chloride
  - Betadine
  - Chlorine, wax or wax compound
  - Sodium salt

Art. no.: 2.511279 Rev. d

7.3.2 Cleaning and disinfecting the device, cable and sensor

DANGER

Shock hazard — Remove the battery before cleaning the device. This ensures that the device will not be turned on inadvertently while you are cleaning it.
Risk of death! Disconnect the defibrillation pads before cleaning the device.
Risk of shock, equipment damage — Liquids must not enter the device. If a liquid has penetrated the device, it must not be used until it has been checked by a service technician.

WARNING

- ▲ Do not immerse the unit nor the cable or sensor in liquid and do not sterilise them!
- ▲ Do not apply tension to the sensor cable.
- ▲ Do not use aggressive cleaners.
- ▲ Do not use any phenol-based agents or peroxide compounds for cleaning.
- ▲ Reusable sensor must be treated as biologically dangerous material after usage and desinfected according to the manufacturer's instructions.
- ▲ Observe the manufacturer's notes when cleaning the sensors and cables.

1. Remove the battery and the LifePoint sensor.
2. Make sure that the USB port is covered with the protective cap.
3. Wipe the equipment housing and sensor with a dampened cloth and a mild cleaning solution. The manufacturer recommends using 50 % alcohol.
4. Dispose of single-use applied parts and protective coverings according to the relevant regulations.

Notes on the cleaning and disinfection

Device casing → Wipe the device with dampened cloth; make sure no liquid enters the device especially not into the electrodes pads connector. All cleaning or disinfection products commonly used in hospitals and containing alcohol (maximum 50 %) are appropriate. If liquids enter the device, it can only be re-operated after it has been checked by the technical support department.

Argus Lifepoint sensor → Using cleaning agents with alcohol content that are adequate for sensitive materials such as TPU or PU, at room temperature (approx. 20 °C) as listed in the sensors instruction for use. Wipe the sensor surface with dampened cloth.

Electrodes → Discard the disposable electrodes immediately after use to prevent their reuse (hospital waste).

Art. no.: 2.511279 Rev. d

7.4 Accessories and disposables

⚠WARNING

Risk to Persons, Equipment Damage — 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 consumables and accessories for the **FRED easyport plus**. A full list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch). In case of difficulty, contact SCHILLER. Our staff will be pleased to help process your order or to provide details for all SCHILLER products.

7.4.1 Order Information

Accessories/Disposable

Part No.	Description
	Applied parts
2.230377 (0-21-0040)	1 pair of disposable adhesive defibrillation pads for adults, 80 cm²; pre-connected and RFID
2.155061	1 pair of disposable adhesive defibrillation pads for adults, 80 cm²;
2.155067	1 pair of disposable adhesive defibrillation pads for children, 42 cm²
2.100860	Argus LifePoint feedback sensor
2.100519	Securing pads LifePoint feedback sensor (set of 5 pcs)
	Consumables
4.350063	LiMnO2 Battery pack FRED easyport plus
4.350062	Li-Ion Battery pack, rechargeable, FRED easyport plus
	Other parts
2.200191	Li-Ion CS-2 Battery charger two bay Hy-Line
2.200146	Power supply for CS-2 Battery charger 100-240 VAC/24 V 2.7 A
2.300000	Power cord CH straight
2.300002	Power cord SCHUKO straight
2.300011	Power cord UK straight
2.310420	USB AM/AF adapter 90/90°
2.156095	Bag (Red)
2.511279	User Guide, English

7.4.2 Required accessories

- User Guide
- One pair of adhesive pads
- 2 Batteries

Art. no.: 2.511279 Rev. d

7.5 Disposal information

7.5.1 Battery Disposal

WARNING

- ▲ Danger of explosion! The battery must not be incinerated, exposed to high temperatures or disposed of with household waste.
- ▲ Do not expose the battery to chemicals that could dissolve ABS, polypropylene, polyvinyl chloride, nickel, mylar or steel.
- ▲ Do not cut, destroy, or incinerate the battery.
- ▲ 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.

7.5.2 Disposal of accessories that come into contact with the patient

Disposable articles (e.g. pads, razor etc.) must be disposed of as hospital waste.

7.5.3 Disposal at the end of its useful life

At the end of their service life, the device and its accessories must be recycled in compliance with local regulations. Apart from the internal and plug-in batteries, the device does not contain hazardous material and can be recycled like any other piece of electronic equipment. In accordance with national law, the battery must be disposed of at an appropriate waste disposal station or returned to SCHILLER.

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

Art. no.: 2.511279 Rev. d

7.6 Troubleshooting

- 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.

Forced shutdown procedure

- If the device cannot be switched off via normal OFF, remove the battery, wait 15 seconds and insert it again.

7.6.1 Error notification

If a problem is detected during this test:

- an acoustic notification is issued (continuously beep-beep)
- the “RTU” LED (1) is not blinking

➜ Switch on the device to display the error message on the LCD and refer to the tables in section 7.6.3 Technical notification to identify the source of error.

7.6.2 General errors & troubleshooting

Problem	Possible causes	Remedy
The “RTU” LED is OFF and the device cannot be turned on.	• Battery depleted/defect	➜ Replace the battery.
	• No battery inserted, or battery not correctly inserted.	➜ Insert the battery correctly.
	• Device defective.	➜ Have the device repaired.
The **“RTU” LED is OFF** and an acoustical notification is issued.	**Display after a self test:**	➜ Switch the device on and check error message.
	• Relay test failed	➜ If “Battery test failed” is displayed, replace the battery and run again a manual self-test.
	• IGBT test failed	
	• Battery test failed	➜ If other error message is displayed, have the device repaired.
	• Capacitor test failed	
The device prompts the user to check that the electrodes are properly applied and connected.	• Short-circuit between the pads.	➜ Apply the pads exactly as described.
	• Poor pad contact.	➜ Firmly press down on the pads.
	• Electrodes connector not connected to the device	➜ Connect the electrodes connector to the device
	• Dry contact agent by using degraded defibrillation pads (see expired date on the packaging)	➜ Use new electrodes.
	• Device defective.	➜ Have the device repaired.
The device cannot be turned off.	• Software hangs	➜ Remove battery and insert it again.
	• Device defective.	➜ Have the device repaired.
Incorrect analysis result (e.g. the device does not detect a shockable rhythm, even though the patient exhibits ventricular fibrillation).	• Insufficient ECG signal quality.	➜ Repeat chest compressions.
	• Electromagnetic waves disturb the ECG signal.	➜ Turn off the source of interference (e.g. radio transmitter, cellular telephone). Position the patient outside the range of interference.
	• Patient moved during analysis.	➜ Do not move patient during the analysis.
	• Device defective.	➜ Have the device repaired.
Defibrillation shock cannot be delivered.	• Insufficient battery charge level.	➜ Replace the battery.
	• CPR caused pads error.	➜ Re-apply the pads.
	• Device defective	➜ Have the device repaired.
	• Using degraded defibrillation pads (see expired date on the packaging)	➜ Use new electrodes.

Art. no.: 2.511279 Rev. d

Problem	Possible causes	Remedy
The notification tone does not stop.	• Selftest failed	➜ Switch the device on, read error message, remedy the cause and run a new selftest.
	• Battery defect.	➜ Replace the battery.
	• Device defective.	➜ Have the device repaired.
Pads expired	• Entered electrode expiry date expired	➜ Check expiry date on the electrode packaging. Proceed as in chapter 3.2.4 described.
Maintenance required notification	• Entered maintenance interval reminder date expired (8.12.2 Base Settings)	➜ Technical safety inspection and software updates required (see 7.1 Maintenance Intervals, 3 years)

7.6.3 Technical notification

Low priority notification displayed on orange background

Notification/error	Possible causes	Remedy
Reset patient data storage	• Failure to write intervention data to the internal memory	➜ After unsuccessfully retrying writing to memory the failure “Not recording patient data” appears see below.
Not recording patient data	• Failure to write intervention data to the internal memory	➜ Get the device repaired after intervention
Test Not Executed, Pads Connected	• Connected pads during relay selftest detected	➜ Ignored notification “Disconnect Defib Pads For Test” during the selftest. Start again selftest.
Battery Low	• Battery capacity falls below 10%	➜ If during intervention is issued make sure having a spare battery and replace it when possible
Charging Not Possible	• Battery capacity to low to charge to capacitor	➜ Replace battery immediately
Selftest failed:	• one of the test below failed	➜ see single tests below
– Relay test failed	• Device defective.	➜ Switch the device on and check error message. ➜ If other error message is displayed, have the device repaired.
– IGBT test failed	• Insulated Gate Bipolar Transistors defective	➜ Have the device repaired.
– Battery test failed	• Battery not enough capacity or defective	➜ Replace the battery and run again a manual self-test.
– Capacitor test failed	• Charging the capacitor takes to long or is not possible	➜ Have the device repaired.

High priority technical notification displayed on red background

Notification/error	Possible causes	Remedy
Battery empty. Shutdown In	• Battery empty	➜ Replace battery immediately
Battery is very cold/hot	• Battery performance limited because temperature below/above the allowed limits (-20/60°C)	➜ Replace battery with a stored battery within the temperature limits. Note this message is only disaplyed when using the rechargeable battery
Shock disabled, low battery	• Battery capacity to low to charge the capacitor	➜ Replace battery immediately.
Key stuck detected	• Key stuck detected	➜ Shock key was pressed during start-up of the device or the key stucks. Cycle power off-on again and make sure that shock key is not pressed
Defibrillation failure	• Device failure	Have the device repaired.
ECG VF/VT Detected	• You are in monitoring mode and device detects VF/VT	➜ Device switches automatically to defibrillation. AED protocol starts (see 4.6 Monitoring mode)

Art. no.: 2.511279 Rev. d

7.7 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 plus**. The minimum distance of 0.3 m has been tested according to IEC 60601-1-2 for a wide range of telecommunication equipment, as shown in the following table:

HF source Wireless communications devices	Transmitter frequency [MHz]	Testing frequency [MHz]	Max. power P [W]	Distance d [m]
Various radio services (TETRA 400)	380-390	385	1.8	0.3
- Walkie-talkies (FRS) - Rescue service, police, fire brigade, servicing (GMRS)	430-470	450	2	0.3
LTE band 13/17	704-787	710/745/780	0.2	0.3
- GSM800/900 - LTE band 5 - Radio telephone (microcellular) CT1+, CT2, CT3	800-960	810/870/930	2	0.3
- GSM1800/1900 - DECT (radio telephone) - LTE Band 1/3/4/25 - UMTS	1700-1990	1720/1845/1970	2	0.3
- Bluetooth, WLAN 802.11b/g/n - LTE Band 7 - RFID 2450 (active and passive transponders and reading devices)	2400-2570	2450	2	0.3
WLAN 802.11a/n	5100-5800	5240/5500/5785	0.2	0.3

⚠ CAUTION

- ▲ **Portable** HF telecommunication devices must not be used within a radius of 0.3 m from the **FRED easyport plus** and its cables.
- ▲ Do not place the **FRED easyport plus** on top of other electric/electronic devices - i.e. maintain a sufficient distance to other devices (this includes the patient cables).

For permanent HF telecommunication devices (e.g. radio and TV), the recommended distance can be calculated using the following formula : $d = 1.2 \times \sqrt{P}$ for 150 kHz to 800 MHz and $d = 2.3 \times \sqrt{P}$ for 800 MHz to 2.7 GHz

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

i For more information on operation in an electromagnetic environment according to IEC/EN 60601-1-2, please consult the service manual.

Art. no.: 2.511279 Rev. d

7.7.1 Measures to prevent electromagnetic interferences

Further measures to prevent electromagnetic interferences:

The user can take the following measures to prevent electromagnetic interferences:

- Increase distance to the source of interference.
- Turn the device to change the angle of radiation.
- Only use original accessories (especially patient cables)
- The device should not be used adjacent to or stacked with other equipment.
- Observe the maintenance intervals as stated in 7.1 Maintenance Intervals, page 51.

⚠ CAUTION

▲ However, there is no guarantee that no interference can occur in certain installations. If the FRED easyport plus causes interferences, these can be prevented by switching off the device.

Art. no.: 2.511279 Rev. d

8 Technical Data

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

8.1 System Specifications

Manufactured by	SCHILLER
Device name	**FRED easyport plus**
Dimensions	46 x 150 x 143 mm (h x l x w) With bag: 110 x 190 x 170 mm (h x l x w)
Weight	Approx. 0.780 kg with battery (battery = 93g) Approx. 0.870 kg with battery and electrodes Approx. 1.510 kg with bag, electrodes & feedback sensor (feedback sensor = 161g)
Protection class of the device housing	IP44 (The enclosure is protected against foreign solid objects of ≥ 1 mm and splashing water from all directions)
Recorded data	ECG signal and event recording 8 hours
Power supply	Power supply, suitable for continuous operation with intermittent loading
Battery type Battery life (if device is stored/used in optimal temperature conditions between 15 to 25 °C) Battery life (low temperature -5°C)	• Lithium/MnO_2 12 V, 16.8 Wh (non rechargeable) • Li-Ion 11.1 V, 12.9 Wh (rechargeable) • with Lithium/MnO_2 – approx. 80 shocks at max. energy with 2 minutes monitoring between shocks with a total running time of approx. 4 h 50 minutes – Standby with weekly selftest approx. 1 year 6 months – Standby with monthly selftest approx. 2 years 6 months • with Li-Ion (rechargeable) – approx. 70 shocks at max. energy with 2 minutes monitoring between shocks with a total running time of approx. 3 h – Standby with weekly selftest approx. 1 year 1 months – Standby with monthly selftest approx. 1 year 11 months • min. 52 shock at max. energy with 2 minutes monitoring between shocks with a total running time of approx. 4 h 50 minutes
Battery charging station	Two bay battery charger 100...240 VAC Hy line Charging time to 100%: 2 h
Interface	• USB A 2.0 host (max. 500mA) • USB mini B 2.0 device only for service • Bluetooth 4.0
Display	• High resolution color LCD 320x 240, 3.5 “ • ECG curve display 61 x 15 mm (configurable) • CPR feedback • Action picture

Art. no.: 2.511279 Rev. d

Signal sound level ready to shock	• 60 dBA
Environmental conditions	Note: *The environmental conditions for the device depend on the electrode and are determined by it)*
For operation device	• *-5 °C* ... 50 °C relative humidity at 10 - 95 % (non condensing) Atmospheric pressure 540...1060 hPa (5000m to -400m) • If higher or lower temperatures prevail during use, a limited operation time of up to **1 hour** is possible, if device has been stored previously at room temperature. See “environmental conditions for transient operation”
Transport /Storage device	• -10...50°C / +5...50°C, humidity 10...95% (non condensing), pressure 500...1060 hPa.
Environmental conditions For transient operation device	Operation in NORMAL USE for a period not **more than 20 min** under the following environmental operating conditions: • a temperature range of - 20 °C to + 50 °C; • a relative humidity range of 10 to 95%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa. Operation in NORMAL USE for a period of **1 hour** under a temperature range of - 10°C to + 50°C.
Environmental conditions	
For Transport and storage between uses of the device	• - 40 °C to + 5 °C without relative humidity control; • + 5 °C to + 35 °C at a relative humidity 10 to 95%, non-condensing; • > 35 °C to 70 °C at a water vapour pressure up to 50 hPa; after having been removed from its protective packaging and subsequently between uses.
Time for warming up/cooling down	• 30 minutes; Time required for the **FRED easyport plus** to warm or cool from the minimum/ maximum storage temperature between uses until the **FRED easyport plus** is ready for its intended use when the ambient temperature is 20 °C.
Environmental condition device according RTCA DO-160 A1	• Operating low Temperature: -15°C • Short-time low Temperature: -20°C due to battery (-40.0°C according RTCA DO-160 A1) • Ground Survival low Temperature: -20°C due to battery (-50.0°C according RT-CA DO-160 A1) • Operating high Temperature: 50°C • Short-time high Temperature: +60°C • Ground Survival high Temperature: +85°C
Environmental conditions Battery	Note: *The environmental conditions for the battery depend on the device and are determined by it)*
Discharge temperature	• -20°C ...+60°C *(Limited by the device to -5 °C ... 50 °C)*
Storage and Transport temperature battery Li-Ion	• 5 ...35 °C (Transport 48h max. between -20...5°C and 35...60°C) **Note:** The limited storage temperature prevents a too hight self discharging. Storage at temperature between -20...+50°C for less than 1 month!
Environmental conditions Electrodes	
Operating	• 0 °C...+50 °C *(If device is operated below 0°C make sure that the electrodes are stored above 0°C before applied to the patient)*
Storage	• 0 °C...+50 °C
Transportation	• max.10 days between -40...0°C and 50...75°C)

Art. no.: 2.511279 Rev. d

8.2 Classification and safety standards

Standards

FRED easyport plus complies with IEC standard 60601-2-4.
In compliance with the requirements of IEC 60601-2-4, the **FRED easyport plus** is a device for frequent use when used with rechargeable battery and a device for non-frequent use when used with disposable battery.

Other standards

- IEC 60601-1-11: Requirements for medical device used in the home healthcare environment
- IEC 60601-1-12: Environmental condition for emergency medical devices
- EN 1789 Medical vehicles and their equipment
- RTCA DO-160 A1: Environmental condition for airborne devices

EMC

- IEC/EN 60601-1-2
- CISPR 11 class B

The device can be exposed to the following interferences without any impairment:

- Static discharges up to 15 kV
- Field strength up to 10 V/m in the radio frequency range of (80...2700 MHz, 5 Hz modulated)
- Magnetic fields of 100 A/m, 50 Hz

Compliance

- **FRED easyport plus** bears the CE 0123 (Notified Body TÜV Süd) mark indicating its compliance with the provisions of the Directive 93/42/EEC (modified by the Directive 2007/47/EEC) regarding medical devices and fulfils the essential requirements of Annex I of this directive.
- **FRED easyport plus** is a class IIb device.

Patient Protection

BF type, resistant to defibrillation shocks.

Explosions protection

FRED easyport plus is **not** designed to be used in the presence of flammable mixtures of anaesthetic agents with air or oxygen.

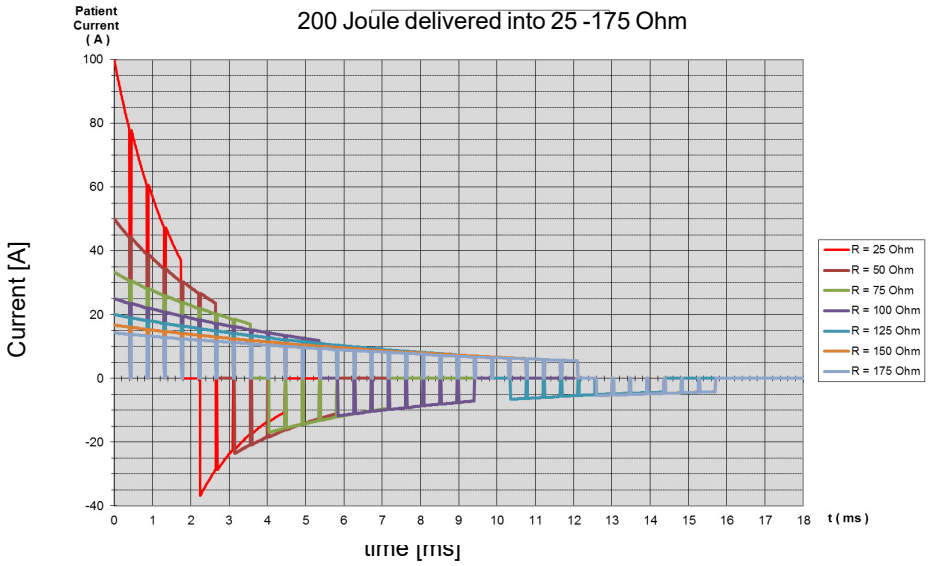
Art. no.: 2.511279 Rev. d

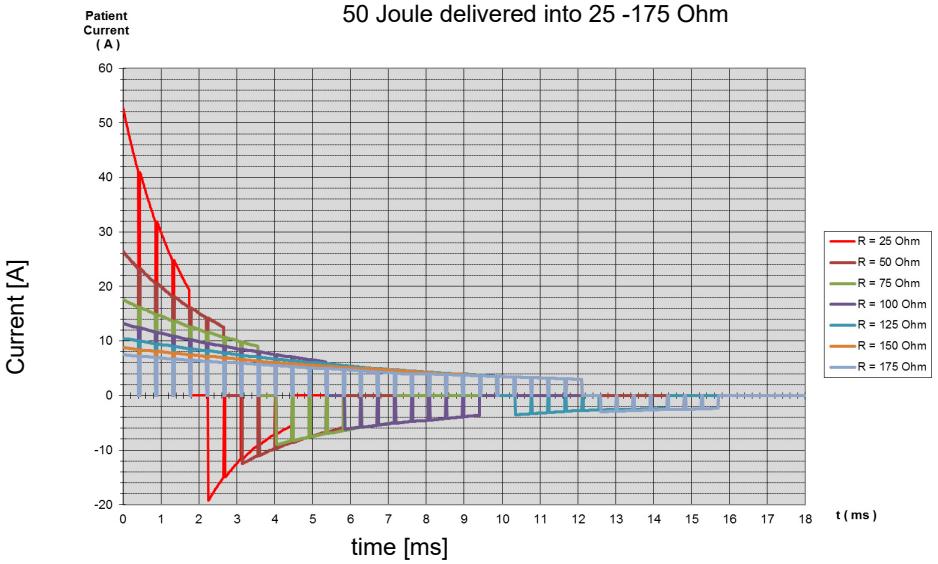
8.3 Defibrillation pulse

Defibrillation Waveform

- Pulsed BTE (Biphasic Truncated Exponsential) ***Multipulse Biowave®*** with fixed physiological optimum phase durations
- Maintains the energy delivered to the patient at an approximately constant level with regard to patient resistance (up to 175 Ohms)

Printout: Current – left y-axis, (--- mean current calculated for each cycle)





Accuracy for AED and manual shock

Deviation from the selected energy (1 till 200 J) at 25 till 175 Rpat [Ω]:
± 3 J or ± 15 % (the higher value is assumed)

Art. no.: 2.511279 Rev. d

Default energy settings AED	Default energy for 1, 2, 3 and following shocks is: for adults: 150/200/200 Joule for children: 50/50/50 Joule SCHILLER's customer service department can change the default energy levels to other values. (automatic adaptation when paediatric pads are connected or when the paediatric manual override is triggered)
Default energy settings manual mode	Following energies can be set by configuration: Adults: 2, 4, 8, 15, 30, 50, 70, 90, 120, **150**, 200 Joule Paediatrics: 2, 4, 8, 15, 30, **50**, 70, 90, Joule SCHILLER's customer service department can change the default energy levels to other values. (automatic adaptation when paediatric pads are connected or when the paediatric manual override is triggered)
Cycle time: rhythm analysis – shock availability (in semi/fully-automatic mode)	Maximum time between start of the analysis and shock availability, in semi-automatic mode at **max. energy of 200 J** with *rechargeable battery for frequent use* / **non rechargeable battery for infrequent use**
• With full battery: • After 15 discharges: • from switch-on of the device to charge at max. energy:	• < *16 seconds* / **< 23 seconds** • < *22 seconds* / **< 23 seconds** • < *22 seconds* / **< 28 seconds**
Charging time for shock – manual mode	Time used to charge the storage capacitor to the **max. energy of 200 J** in manual mode with *rechargeable battery for frequent use* / **non rechargeable battery for infrequent use**
• with fully charged battery • after 15 discharges with max. energy • from switch-on of the device with pads	• < *14 seconds* / **< 24 seconds** • < *14 seconds* / **< 24 seconds** • < *19 seconds* / **< 28 seconds**
Cycle time: rhythm analysis – shock availability (in semi/fully-automatic mode)	Maximum time between start of the analysis and shock availability, in semi-automatic mode **at recommended energy of 150 J** with *rechargeable battery for frequent use* / **non rechargeable battery for infrequent use**
• With full battery: • After 15 discharges:	• < *15 seconds* / **< 17 seconds** • < *15 seconds* / **< 17 seconds**
Charging time for shock – manual mode	Time used to charge the storage capacitor to the **recommended energy of 150 J** in manual mode with *rechargeable battery for frequent use* / **non rechargeable battery for infrequent use**
• with fully charged battery • after 15 discharges with max. energy	• < *12 seconds* / **< 18 seconds** • < *12 seconds* / **< 18 seconds**

Art. no.: 2.511279 Rev. d

Patient impedance at which shock delivery is possible	25 to 250 Ω
Indication when ready to shock	The orange button  is lit and warning tone is issued
Shock delivery	• With the orange button  (in semi-automatic) • Via disposable pads applied to the patient in an anterior-lateral or anterior-posterior position
Safety discharge when:	• A non shockable rhythm has been detected (e.g motion of the patient or CPR by the caregiver before shock release) • The shock is not delivered within the 20 seconds after charging • An electrode problem is detected • Battery voltage is insufficient • The device is defective • The device is turned off.
Defibrillation pad connection	BF type
Defibrillation electrodes	Electrode cable, 2 m in length
Adult and Children pads	• 80 cm² active surface
Paediatric pads	• 42 cm² active surface

Art. no.: 2.511279 Rev. d

8.3.1 Shock Advisory System

The Shock Advisory System (SAS) validation test set consists of 17,803 ECG waveforms coming from the PhysioNet databases [1]. These files (MIT-VFDB) are subsets of the general PhysioNet databases recognised as standard in ECG tests. PhysioNet databases are ECG Holter recordings with full diagnostic bandwidth [0.05 - 125] Hz. The bandwidth of the devices that recorded the signals is larger than that of the **FRED easyport plus**. However, when the analogue signals of the database are run on the **FRED easyport plus** via electrode connector, the **FRED easyport plus**'s rhythm detector signal-processing characteristics are applied. Moreover these signals are of appropriate length to allow decisions to be made by the detector system.

The validation test set database used to establish compliance with the AHA requirements [2] and the IEC Standards [3] is used independently to develop the rhythm recognition detector.

The SAS validation test set contains the following ECG samples (see test sample size in Table 1):

- coarse ventricular fibrillation (VF) (>200 µV peak-to-peak amplitude)
- shockable ventricular tachycardia (VT hi) (HR >150 bpm, rushes that last more than 8s)
- asystole (≤100 µV peak-to-peak amplitude)
- normal sinus rhythm (NSR) (PQRS-T waves visible, HR 40-100 bpm)
- other organized rhythm (N) (includes all rhythms except those in other listed categories)

For each test sample, in function of the expert rhythm annotation and the SAS decision (shock/no shock), an interpretation table is built and shows the true positive (correct classification of a shockable rhythm), true negative (correct classification of a non-shockable rhythm), false positive (non-shockable rhythm incorrectly classified as a shockable rhythm), false negative (shockable rhythm incorrectly classified as non-shockable). Finally, the results of the detector performance are reported in terms of: specificity-Sp (TN/(TN+FP)), true predictive value (TP/(TP + FP)), sensitivity-Se (TP/(FN + TP)), false positive rate (FP/(FP + TN)).

Table 1: FRED easyport plus SAS performance by rhythm category meets AHA recommendations [2] and IEC Standards [3] for adult defibrillation on artefacts-free MIT-VFDB signals:

Rhythms		Test sample size	Performance goal	Observed performance
Shockable	Coarse VF	308	Sensitivity > 90%	Meets [2-3]
	VT hi	202	Specificity > 75%	Meets [2-3]
Non Shockable	NSR	1023	Sensitivity > 99%	Meets [2-3]
	Asystole	4798	Sensitivity > 95%	Meets [2-3]
	Other rhythms	1425	Sensitivity > 95%	Meets [2-3]
	Total NS	7246	Sensitivity > 95%	Meets [3]

The **FRED easyport plus** SAS test has been completed with a validation database consisting of 2,475 couples of ECGs and transthoracic Impedance Cardiogram (ICG) from out-of-hospital cardiac arrest (OHCA) interventions, recorded with Automated External Defibrillators (FredEasy, Schiller Medical SAS, France) used by the fire brigade of Paris.

This supplementary test completes the validation of the SAS and achieves the results summarised in table 1. A report of the global validation test results is available on request.

[1]: The MIT-BIH Malignant Ventricular Arrhythmia Database

http://physionet.org/physiobank/database/vfdb/

[2]: Automatic External Defibrillators for Public Access Defibrillation : Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms and Enhancing Safety ; Circulation, 1997 ; 95 :1677-1682.

[3]: Standard IEC 2010 60601-2-4, ed 3.

Art. no.: 2.511279 Rev. d

8.4 Bluetooth standard

Modules	PAN1026
FCC ID **IC ID**	T7VPAN10 216Q-PAN10
Transmission standards	Bluetooth BT version 4.0 BR/LE
Frequency range	2.402 ..-2480 MHz
Max. power output	+4 dBm

8.5 Charging unit

Device name	CS-2 Charger
Dimensions	42 x 140 x 130mm (h x l x w)
Weight	0.900 kg
Charger power supply	
Input Output	24 VDC, 65 W 12.6 VDC, 5 A
External Power supply	Medical grade power supply type FSP065M-DAA class I (only for indoor use)
Input Output	100 - 240 VAC, 50-60 Hz, 65 W 24 VDC, 2.7 A
Ambient conditions	
Operation	• 0... 40 ºC, relative humidity of 0...95 % (non condensing)
Transport	• -10... 40 ºC, relative humidity of 10...95 % (non-condensing)
Storage	• -10... 60 ºC, relative humidity of 10...95 % (non-condensing)
Protection class	Class III according to IEC 60335-1
Ingress protection	Only for indoor use
EMC/safety	CE -marking

Art. no.: 2.511279 Rev. d

8.6 ARGUS LifePoint sensor

Sensor name	Argus LifePoint
Dimensions	80 x 25 mm (diameter/ depth)
Weight	152 g
Cable length	2 m
Power supply	5 VDC via USB from the medical device
Environmental conditions	Note: *The environmental conditions for the LifePoint depend on the device and are determined by it)*
Operation Transport / Storage	• -5 ºC ... 50 ºC relative humidity at 10 - 95 % (non condensing) • -10...50°C / +5...50°C, humidity 10...95% (non condensing), pressure 500...1060 hPa.
For Transport and storage between uses	• -40... 75 ºC, relative humidity of 10...95 % (non-condensing) Atmospheric pressure 500...1060 hPa (5000m to -400m) for above
Measured values	
Frequency	1 to 160 compression/min (cpm)
Compression depth	1 to 127 mm
Accuracy	± 3 compressions/min ± 5% at 50 mm (laboratory condition)
Life cycle	500’000 compressions
Dust and water protection	IP66
Protection class	Type BF defibrillation proof

Art. no.: 2.511279 Rev. d

8.7 Literature

European Resuscitation Council Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

8.8 Glossary

ABCD The primary ABCD
A = Airways (check if airways are free)
B = Breathing (artificial respiration)
C = Circulation (circulatory signs or cardiac massage)
D = Defibrillation

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

ALS Advanced Life support (protocol)

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

CPR Cardiopulmonary resuscitation

VT Ventricular tachycardia

VF Ventricular fibrillation

Art. no.: 2.511279 Rev. d

8.9 Inspection report

The user guide must be read before the inspection.

Serial number: _____

Checks - after each use					
➜ Check that the LED “RTU” is blinking, see 2.5.2 Performing manual self-test	☐	☐	☐	☐	☐
➜ Visual inspection of the device and accessories	☐	☐	☐	☐	☐
➜ Device and LifePoint sensor casing undamaged?	☐	☐	☐	☐	☐
➜ No excessive clogging or damage?	☐	☐	☐	☐	☐
➜ Expiration date of the accessories not elapsed?	☐	☐	☐	☐	☐
➜ Check that the electrode packaging is not damaged?	☐	☐	☐	☐	☐
➜ Expiration date of the Li-MnO2 battery not elapsed?	☐	☐	☐	☐	☐
➜ Replaced used defibrillation electrodes?	☐	☐	☐	☐	☐
➜ Batteries fully charged? (inserted in the device and spare battery)	☐	☐	☐	☐	☐
Date:					
Performed by:					
Checks - once a Week/once a Month					
Visual inspection of the device and accessories (see previous table)	☐	☐	☐	☐	☐
The “RTU LED” is blinking green (see 2.5.2 Performing manual self-test)	☐	☐	☐	☐	☐
Date:					
Performed by:					
Checks - every 3 years					
Visual inspection of the device and accessories (see previous table)	☐	☐	☐	☐	☐
Functional test					
➜ Check for proper functioning (see 2.5.2 Performing manual self-test)	☐	☐	☐	☐	☐
➜ Measure the energy delivered at 50 ohms.	☐	☐	☐	☐	☐
Date:					
Performed by:					
Replacement - every 6 years					
Internal backup battery replacement.	☐	☐	☐	☐	☐
Date:					
Performed by:					

In case of problems, please notify your Biomedical Department ❒, your local SCHILLER distributor ❒, or the authorized Customer Service for your area ❒:

Name: ..... Tel.: .....

Art. no.: 2.511279 Rev. d

8.10 Overview menus

Menu/parameters	Sub menu/Parameter	Sub menu/Parmeter	Sub menu/Parmeter/details
Selftest >>>	all tests (2.5.2 Performing manual self-test	-	-
Bluetooth pairing	Start	-	see service manual
Device information >>>	(S/N; RefNr; Device Name; SW and HW versions; Pads Expired date; Maintenance date; Guidelines; Battery >>>; Bluetooth >>>; SDM Settings Name		
Device Settings >>> 8.11 Device Settings	**Shock settings >>>** 8.11.1 Shock setting	Energy adult/children 1/2/3	
	CPR settings >>> 8.11.2 CPR setting	Start with analysis Show CPR timer CPR Timer counting Metronom AED Metronome Ratio Metronome Rate **Manual Setting >>>**	 Following only for Manual AED: Metronome Metronome ratio CPR Voice prompts
	CPR feedback settings >>> 8.11.3 CPR Feedback	Limits >>> Feedback delay CPR Voice prompts Average Rate Max CPR Enable Recoil	Rate limits >>> Depth limits adult >>> Depth limits paediatric >>>
	Communication >>> 8.11.4 Communication	SDM >>> SEMA >>>	-
	Transmission mode >>> 8.11.5 Transmission mode	Media Auto power on Auto start	-
	System settings >>> 8.12 System Settings	Local settings >>> 8.12.1 Local Settings	Language, Country, Date, Time, Time-zone, Time Sync etc
		Base settings >>> 8.12.2 Base Settings	Maintenance >>> (Year month) Length Unit (metric/inches); Monitor enable; Device name
		Selftest settings >>> 8.12.3 Self-test Settings	RTU Wakeup Interval for test Auto RTU send
		Volume	Low/Mid/High
		Shock Pacer markers	Off/On
		Auto Switch off time	
	8.11.6 Parameter in the Device Settings menu		-
	Restore Factory Defaults	Start	-
	Import settings	Start	-
	Import settings from SDM	Start	-
	Export settings	Start	-
	Export settings from SDM	Start	-
Device update >>>	Install Firmware data and bootloader **SW version >>>**		see service manual
Pads expired >>>	Year/Month	-	3.2.4 Pads expired
Production >>>	Metronome CPR Time and breath time (number of breath)		see service manual
Log Files >>>	Start		see service manual

Art. no.: 2.511279 Rev. d

8.11 Device Settings

The following settings can be configured by the SCHILLER after-sales service and are password protected.
The default settings are printed **bold.**

8.11.1 Shock setting

Parameter	Values	Description
Energy adult 1st shock	• 2, 4, 8, 15, 30, 50, 70, 90, 120, **150**, 200 Joule	Sets the energy which will be delivered for the first shock in AED in adult mode
Energy adult 2nd shock	• 2, 4, 8, 15, 30, 50, 70, 90, 120, 150, **200** Joule	Sets the energy which will be delivered for the second shock in AED in adult mode
Energy adult 3rd shock	• 2, 4, 8, 15, 30, 50, 70, 90, 120, 150, **200** Joule	Sets the energy which will be delivered for the third shock in AED in adult mode
Energy child 1st shock	• 2, 4, 8, 15, 30, **50***, 70, 90, Joule	Sets the energy which will be delivered for the first shock in AED in child mode
Energy child 2nd shock	• 2, 4, 8, 15, 30, **50**, 70, 90, Joule	Sets the energy which will be delivered for the second shock in AED in child mode
Energy child 3rd shock	• 2, 4, 8, 15, 30, **50**, 70, 90, Joule	Sets the energy which will be delivered for the third shock in AED in child mode

8.11.2 CPR setting

Parameter	Values	Description
Start with Analysis	• No • **Yes**	If Yes is set, the device starts with the analysis as soon as defibrillation electrodes are applied. If No is set, the device prompts the user to perform CPR before the analysis. Analysis will start once the 2-minute CPR interval has ended.
Show CPR Timer	• **No** • Yes	Display of the CPR timer on the status line.
CPR Timer counting	• **Up** • Down	Timer counting up or down
Metronome AED	• **On** • Off • CPR	Metronome default behaviour only for AED mode
Metronome Ratio	• **30:2** • 15:2 • Cont	Metronome Setting
Metronome rate	• **100 cpm** • 101-120	Sets the frequency of the metronome
	Additional settings for the AED MANUAL	
Manual Settings >>>		
Metronome MAN	• On / **Off** / CPR	Metronome default behaviour in manual mode
Metronome Ratio	• **30:2** / 15:2 / Cont	Metronome Setting in Manual mode
CPR Voice Prompts	• Yes • **No**	Voice prompt in manual mode yes or no.

Art. no.: 2.511279 Rev. d

8.11.3 CPR Feedback

Parameter	Values	Description
Rate Limits >>> – Lower (cpm) – Upper (cpm)	 – **100** – **120**	Rate limit setting for the Argus LifePoint CPR feedback sensor
Depth Limits Adult>>> – Upper (mm) – Lower (mm)	 – **62** – **45**	Adult limit setting for the Argus LifePoint CPR feedback sensor
Depth Limits Paediatrics>>> – Upper (mm) – Lower (mm)	 – **52** – **35**	Paediatric limit setting for the Argus LifePoint CPR feedback sensor
Feedback delay (sec)	• **3** • 1-21	Time to display new average feedback values
CPR Voice prompts	• **Yes** • No	Yes activates the voice prompt during CPR
Average Rate max. CPR	• **3** • 1-11	Numbers of measurement to calculate the average CPR rate.
Enable Recoil	• **No** • Yes	Enable the recoil measuring.

8.11.4 Communication

To check the setup communication exit Communication/Device setting menu, go to “Self Test” menu and select Test server connection/ SDM or SEMA.

Parameter	Parameter	Description/Selection
SDM >>> Schiller Device Manager	SDM	Activation connection to SDM. – On/**Off.**
	SDM server >>>	Setup of the following SDM server parameters: • Hostename of the SDM server – (semadev.schiller.ch) • Port host – (8080) • SLL (Certificate validation) – No/**Yes**
	Auto Update Settings	Allows to update Settings via SDM server – On/**Off**
	Upload interventions	Allows to upload intervention data to SDM server – On/**Off**

Art. no.: 2.511279 Rev. d

Parameter	Parameter	Description/Selection
SEMA >>>	• Hostename • Port host • User name • Password • SLL • Upload intervention	Setup of the following SEMA server parameters: • Hostename of the SDM server – (semadev.schiller.ch) • Port host – (8080) • User Name – Default • Password – System • SLL (Certicate validation) – No/**Yes** • Upload intervention data to SDM server – **On**/Off

8.11.5 Transmission mode

Parameter	Values	Description
Media	• **BT** • USB	Selection of the preferred transmission via Bluetooth bridge or USB.
Auto Power On	• **OFF** • 10 min	OFF/ 10 min If the transmission mode is set to “Auto Power on” to “10 min” the device behaves as follows: • The device switches on in Transmission mode and automatically starts transmission of the latest intervention data for a max. duration of 10 minutes. The device then switches off.See Setting 8.11.5 Transmission mode. • This only applies if the device has previously been switched on in normal mode and if the intervention data is valid. If the server is not reachable or not all data has been transmitted within the 10 minutes, the device will shutdown and retry the transmission again after 10 minutes.
Auto Start	• **No** • Yes	Yes When device is started in Transmission mode  +  the data transmission starts automatically after 5 s via the defined media BT or USB.

8.11.6 Parameter in the Device Settings menu

This parameter are shown after System Settings menu.

Parameter	Values	Description
Restore Factory defaults	• Start	Sets the device setting to factory default
Import Settings	• Start	Imports setting from other device via USB (cloning)
Import Settings from SDM	• Start	Imports setting from other device via SDM server
Export Settings	• Start	Export setting to USB for other devices (cloning)
Export Settings to SDM	• Start	Export setting to SDM server

Art. no.: 2.511279 Rev. d

8.12 System Settings

You will find the following setting at the bottom of the display.

Parameter	Values	Description
Volume	• **Low (>50)** • Mid (>55) • High (>60)	Sets the volume of audio prompts and notifications. **Caution:** ▲ Ensure that the environmental noise is below the set sound volume (Low/Mid/High)
Show pacer markers	• *OFF* • *On*	*Shows pacer makers on the ECG display when set to ON. (only displayed for the AED manual)*
ECG and HR	• **No** • Yes	Display HR and ECG curve *(not displayed for the AED manual because it is standard activated)*
Auto Switch off	• **30 min** • 15 min • never	Sets the auto switch off time. “Device not used. Shutdown In 2.00..1.59” is displayed and acoustical notification is issued before the device switches off.

8.12.1 Local Settings

Parameter	Values	Description
Language	• **English*** German French Spanish Italian etc…	Sets of the language in which the device will always start by default.
Country	• **Other** • France, Germany, UK, USA...	-
Date	• -	Sets the date
Time	• -	Sets the time
DST (Summer Time)	• *OFF* • *On*	Automatically sets Summer/Winter time when activated
Timezone	• **selected Timezone**	Shows the selected timezone
Select Time zone	• **UTC** • Non-regional Timezones >>> • Country specific Time-zones>>>	Sets the time zone to calculate appropriate date & time
Time Sync with GPS	• ***OFF*** • *On*	GPS not available with version 1.2.0
Time Sync with server	• **OFF** • On	Time is automatically synchronised when connected to server during transmission.

Art. no.: 2.511279 Rev. d

8.12.2 Base Settings

Parameter	Values	Description
Maintenance >>>	• Year • Month	Entering date for the next maintenance reminder. If expired notification “Maintenance required” appears. **Warning:** Do not enter date longer than 3 years see 7.1 Maintenance Intervals! ➜ Check entered date in the menu **Configuration > Device information > Maintenance**, see 8.10 Overview menus.
Length unit	• **metric** • inches	Set units for display with LifePoint sensor
Monitoring enable	• **Yes** • NO	If set to Yes the device can be switched to monitoring mode when: • 2-wire ECG cable is applied and detected • Defibrillation pads are applied and a normal rhythm is detected. Note: This is only possible when the ECG curve display is set to “Yes” see 8.12 System Settings. Detailed description see 4.6 Monitoring mode.

8.12.3 Self-test Settings

Parameter	Values	Description
RTU Wakeup	• Off • **On**	Off = the interval for test are not selectable and the interval for the test is deactivated On = Wakeup for test for the defined interval see below.
Interval for test	• daily • **weekly** • monthly	Interval set for Ready to use tests
Auto RTU send	• **No**	Not available

Art. no.: 2.511279 Rev. d

9 Index

Art. no.: 2.511279 Rev. d

10 Appendix - Symbols

This appendix lists all general symbols that may be present on the device, label and accessories. Not all of those symbols are necessarily present on your device.

This appendix has its own article number, which is independent of the user guide's article number.

	Identification of the manufacturer
	Identification of the manufacturing date
	Identification of the distributor
	Identification of the importer
MD	Medical device
SN	Serial number
REF	Reference number
LOT	Batch code
GTIN	Global Trade Item Number
CAT	Catalogue number
QTY	Quantity
UDI	UDI: unique device identification as QR code machine readable and human readable as number (e.g  (01) 0 7613365 00210 2 (21)xxxx.xxxxxx)
	Number of pieces in the packaging
EC REP	Authorised European representative
CE XXXX	Notified body (e.g CE 0123 marking notified body TÜV SÜD)

CE	CE marking, affirms its conformity with European standards
	Regulatory Compliance Mark for the Australian standards
	The device is recyclable
	Symbol for the recognition of electrical and electronic equipment. Device must not be disposed of in the household waste.
	Symbol for the recognition of a battery. Battery must not be disposed of in the household waste.
	The packaging is made in low density polyethylene and can be recycled.
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non ionising electromagnetic radiation. To indicate that the device contains a Radio Frequency (RF) transmitter to transmit data (e.g Bluetooth or WiFi)
	Contains a Bluetooth module
	Do not reuse
	Latex-free
	Use-by date (expiry date of battery, electrodes or other consumables)
	Temperature range for storage or transport, respectively
	Pressure range for storage or transport, respectively
	Humidity range for storage or transport, respectively
	Consult instruction for use (indicates the need for the user to consult the instructions for use)
	Use within X days after opening (electrodes or other consumables)

Art. no.: 2.520164 Rev. a

	Keep dry (store in a dry location)
	Keep away from sunlight (protect from direct sunlight)
	Fragile, handle with care
	Transport upwards (this way up)
	Do not use hooks
	EIP = electronic information product (dos not contain any toxic and hazardous substances or elements above the maximum concentration values (product can be recycled and re-used).

Art. no.: 2.520164 Rev. a

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Art. no.: 2.520164 Rev. a