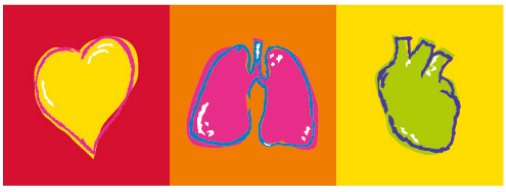
FRED easyport plus®

Automated external defibrillator (AED)

Service handbook



SCHILLER
The Art of Saving Lives

Art. no.: 2.540108 Rev. e02

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

Manufacturer

SCHILLER AG
Altgasse 68
CH-6341 Baar, Switzerland

Phone: +41 (0) 41 766 42 42
E-mail: sales@schiller.ch
Web: www.schiller.ch

The FRED easyport plus Service manual is valid for the following devices:

- FRED easyport plus
- DEFISIGN POCKET PLUS
- FRED easyport trainer (without defiboard fitted)

EU REP

Schiller Medizintechnik GmbH
Otto-Lilienthal-Ring 4
85622 Feldkirchen
Germany

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/EEC 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

Change of notified body

Until latest 2027-12-31, the responsibility for surveillance of the device is transferred to the CE0459 mark (Notified Body: GMED).

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Software: ≥1.3.1

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1 Safety Notes

⚠ WARNING

▲ Read and follow these safety notes including the intended use and the information given in this instruction for use to prevent any injuries or damages.

1.1 Intended Use

1.1.1 General intended purpose of the medical device

- The **FRED easyport plus** is a defibrillator with the possibility to deliver a shock 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.

1.1.2 User profiles

The following persons may use the **FRED easyport plus®** service manual:
This Service Handbook is for qualified service personnel only, trained by Schiller AG. Refer to the operating instruction manual 2.511279 version f01 or newer for operation the device.

1.2 Limitation

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

▲ The **FRED easyport plus** is not designed for sterile use.

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

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1.3 General Warnings & Precautions for use

1.3.1 Responsibility of the User

- Specify the competencies of the personnel for operation and repair.
- Ensure that service personnel have read and understood these service instructions. In particular this section “safety notes" must be read and understood.
- Damaged or missing components must be replaced immediately.
- The service personnel is responsible for compliance with all applicable accident prevention regulations and safety regulations.

1.3.2 Organisational Measures

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

1.3.3 Safety-Conscious Operation

- **Danger of electric shock!** Do not open the device without disconnecting the device from the mains.
- Before cleaning, switch the unit off.
- Do not place any liquids on the unit. If liquid should be spilled over the device, immediately disconnect the device from the mains and wipe it. The device must be serviced before reusing.
- Do not, under any circumstances, immerse the unit or cable assemblies in liquid
- Do not use solvent or abrasive cleaners on either the unit or cable assemblies.
- Do not use high temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- As soon as the GSM module is switched on, all persons must keep a distance of at least 20 cm from the sending antenna of the **FRED easyport plus**.
- The transmission of ECG recordings from the **FRED easyport plus** is not permitted in areas in which mobile phones are not allowed.

1.3.4 Operation with other Devices

- Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult the technical service department or your local representative.
- Portable communication devices, HF radios and devices labelled with the  symbol (non-ionic electromagnetic radiation) can affect the operation of this device.

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1.3.5 Cybersecurity

Networks and Internet

- ▲ The security of the network is the sole responsibility of the user.
- ▲ When the **FRED easyport plus** is part of a network (LAN, WLAN, HIS) 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.
- ▲ To guarantee the cybersecurity 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, including the **FRED easyport plus**, so that no unauthorised system alterations are possible.
  - – Use an SMTP server with authentication with TLS support.
  - – Use Transport Layer Security (TLS) 1.2 or higher for communication with the system server and SEMA server.
- ▲ If the connection between the **FRED easyport plus** and the server is bad/intermittent, this can result in an impossible analysis of post-intervention data. The user should identify, analyse, evaluate, and control these risks related to the network connection.
- ▲ Any changes to the networks could introduce new risks that require additional analysis by the user. These changes include:
  - – Changes in network configuration.
  - – Connection/disconnection of (other) items.
- ▲ Update/upgrade of the **FRED easyport plus**.

Patient data (personal data)

- ▲ Patient data security is the sole responsibility of the user.
  - – The intervention file does not contain any patient data that allows conclusions to be drawn about the patient's identity.

Exception investigation in case of incident reporting

- ▲ The intervention file can be exported and sent to SCHILLER by the responsible organisation. Avoid to add personal data to the intervention file when transmitting it in any form.

Setup security guidance

- ▲ For updates, network communication is preferred rather than USB memory stick
- ▲ For networks and the internet security see "Network and Internet" in this chapter. Recommendations for protecting access to Wi-Fi technology:
  - – To avoid unauthorised access, ensure that the **FRED easyport plus** is not accessible for unauthorized persons.
  - – Do not divulge login credentials to third parties.
  - – Use a safe password with minimum 8 digits and it should include a combination of letters (capital, small), numbers, and characters.
  - – Use always encryption WPA2 or higher.

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1.4 Additional Terms

1.4.1 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.

1.4.2 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.

Support period

Software updates are available for 8 years from when the last **FRED easyport plus** was placed on the market.

1.4.3 Reporting security incidents and vulnerability disclosure policy

If you have found a vulnerability in one of our products or services, send us the details. SCHILLER will acknowledge your message within 3 days and validate the vulnerability within 10 days. Allow 90 days before disclosing this vulnerability publicly.

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1.5 Symbols/Indicators

1.5.1 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 Service handbook 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.
	Observe precautions for handling electrostatic sensitive devices
	Especially important or helpful information
	Used tool for the following procedure.
	Do not use the device in or near magnetic resonance imaging equipment (MRI).
	Cross-reference

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1.5.2 Symbols used on the device

- Symbols used for operating and display elements.
  See:
  2.3 Operating and Display Elements, page 19
  2.4 Display, page 21
- General used symbols
  Instruction for use 2.511279

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.

Automatic defibrillation. This device automatically delivers the defibrillation shock.

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 (Wi-Fi).

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.

11 Technical Data, page 74

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1.5.3 Symbols used on the batteries

General used symbols

Instruction for use 2.511279

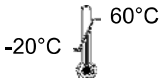
Caution: Consult the warning and safety information in the instructions for use!

Do not dispose in fire

Do not deform or damage

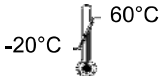
Do not open or dismantle

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.

DC voltage

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1.5.4 Symbols used on the CS-2 charger

General used symbols

Instruction for use 2.511279

Indoor use only

CS-2 charger is protection class III

DC voltage

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1.5.5 Symbols used on the electrode packaging

General used symbols

Instruction for use 2.511279

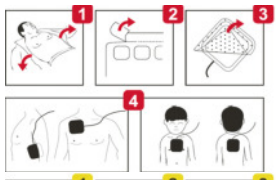
Reading the instruction for use is mandatory before using the electrodes!

Do not bend packing

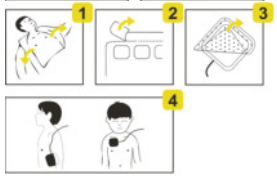
Don't use if the packaging is damaged

Disposable item; do not reuse

Adults
Children



Paediatric



1. Open the clothes
2. Open the electrode package
3. Peel off the protective foil
4. Place, attach the electrodes.

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.

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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.

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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)

Audible and visual real-time information on the chest compressions speed, depth, and recoil, 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
  - WLAN 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. 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

Self test RTU (Ready to use)

- To ensure its readiness for use, the device performs a daily, weekly or monthly selftest. Selftest 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.

Note

- When depletion notification is issued (battery below 10%[1]) approx. 5 shocks can be delivered until the battery is completely empty.

1. This threshold can be changed for parameter “RTU Battery Threshold” to 20% or 50%. 8.4.3 Selftest Settings, page 57

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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

⚠ WARNING

- ▲ 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.
- ▲ To avoid unauthorised access to the configuration, ensure that the **FRED easyport plus** and this service guide is not accessible for unauthorized persons.
- ▲ 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 Selftest, page 22	No
• Bluetooth pairing	With SW 1.3.0 disabled	No
• Device information	8.1 Overview menus, page 49	No
• **Device Settings** >>> – Shock settings >>> Energy level for 1st, 2nd and 3rd shock – CPR settings >>> – CPR feedback >>> – Communication >>> – Transmission mode >>>	8.2 Device information, page 51	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	8.4 System Settings, page 56	Yes
– Restore Factory Defaults – Import/Export settings	8.3.6 Parameter in the Device Settings menu, page 55	Yes
• Device update	see service manual	Yes
• Pads expired	3.2.4 Pads expired, page 27	No
• Production – Metronome CPR Time and number of breats	see service manual	Yes
• Log Files	see service manual	Yes

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2.3 Operating and Display Elements

2.3.1 Overview FRED easyport plus

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

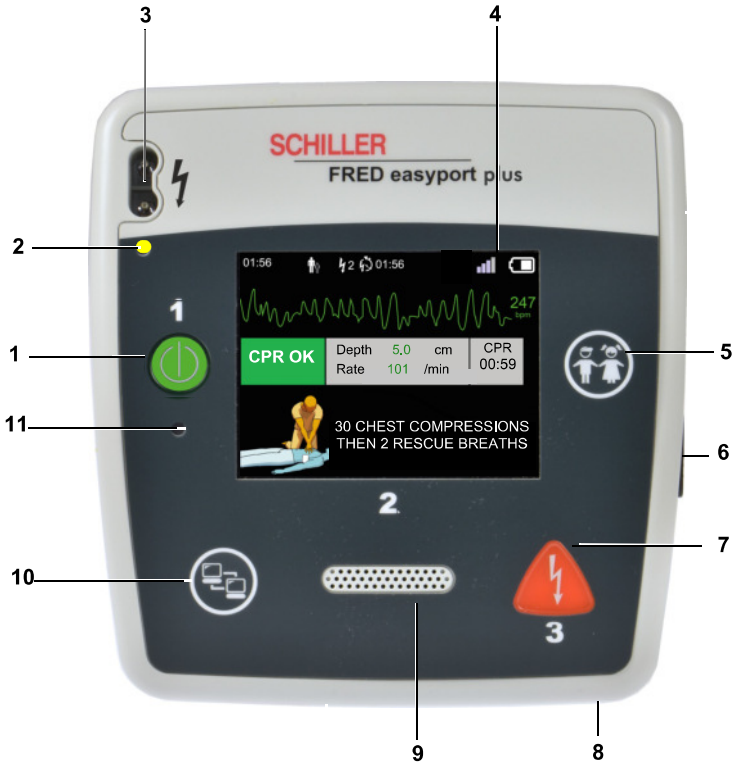

Fig. 2.1 Operating Elements

(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) Data transfer (COM)
(11) 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.

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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

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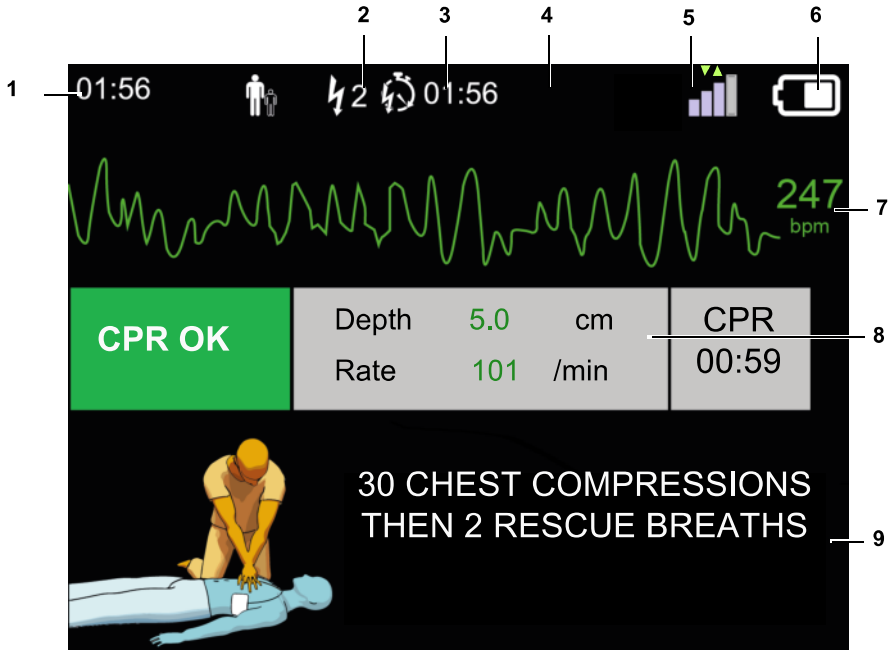
2.4 Display

The following information is displayed on the LCD:

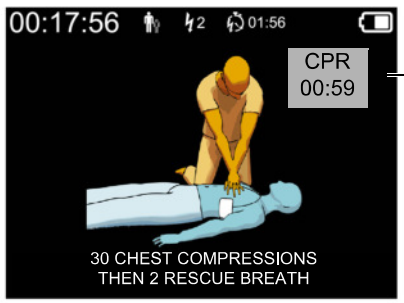


(1) Time passed since the device has been switched on
(2) Selected patient type:

= Adult

= Child

(3) Number of shocks delivered
(4) Time passed since the last shock has been delivered
(5) WLAN status and signal quality display
– purple bars connected/grey bars not connected (disabled)
– green arrow up = upload, green arrow down = download
(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

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2.5 Functions

⚠ WARNING

▲ The automatic selftest does not replace the regular visual inspection of the device between the test intervals.
6.2.3 Visual inspection of the device and accessories, page 37

2.5.1 Performing automatic Selftest

Automatic selftest intervals (RTU)

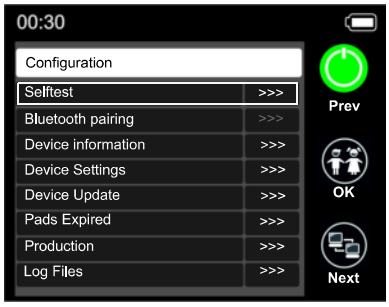
- To ensure its readiness for use, the device performs a daily, weekly or monthly selftest at 2.00 AM. This setting must only be configured by service personnel authorised by Schiller.
  8.4.3 Selftest Settings, page 57
- Selftest includes the test of the charging circuit and the battery capacity. With a passed RTU test it is possible to deliver at least 6 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 selftest.
- Notification details
  7.1 Error notification, page 46

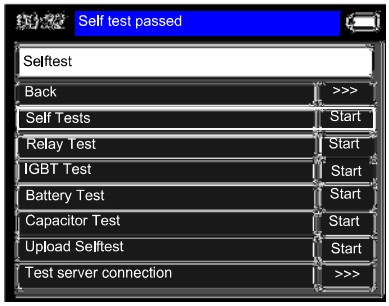
Fig. 2.2 RTU LED indicator

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

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

2.5.2 Performing manual Selftest





A manual selftest is indicated when a new battery has been inserted or after use of the device. This test does not affect the automatic Selftest 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” but17:05ton . 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.
7.1 Error notification, page 46

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3 Initial operation

3.1 Batteries

⚠ 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.

⚠ WARNING

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

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 new battery, always run a manual Selftest to check the condition of the device and the battery.

2.5.2 Performing manual Selftest, page 22

▲ 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.

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⚠ 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.

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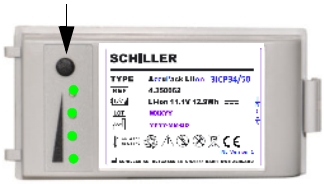
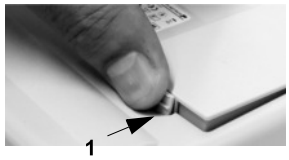
3.1.2 Battery replacement

⚠ 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%. Replace immediately 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 LED lights up when battery capacity is between 75 to 100%.
5.1.2 LED Status display of the rechargeable Lithium Ion battery, page 35



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 Selftest to check the condition of the device and the battery.
2.5.2 Performing manual Selftest, page 22
4. After successfully Test “Self Test Passed”, switch off the device immediately to preventing discharging the battery.

→ If an failure is displayed.
7.1 Error notification, page 46

3.1.3 Switching device On and Off

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

Switching OFF → Press the “ON” (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.

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3.2 Battery monitoring

- The lithium battery ensures that the device stays fully operative (and performs the selftest) 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 Selftest (RTU) test. Depending on the set testing interval (daily, weekly or monthly) the remaining battery capacity may be close to the low battery indication. Therefore we recommend:
- use selftest 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. 6 shocks at max energy.

3.2.2 Low battery capacity indication while the device is switched off

Fig. 3.1 Battery low indication

- Low battery capacity indication is the same during selftest and the manual self test as after inserting the battery or during use.
- If the battery capacity falls below 10%[a], 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 6 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.

a. This default threshold of 10% can be changed to a “RTU Battery Threshold” of 20 or 50%.
8.4.3 Selftest Settings, page 57

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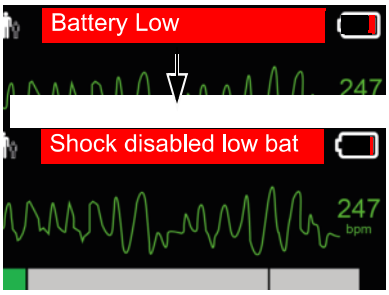
3.2.3 Battery depleted during use, limited mode (CPR)

⚠ WARNING

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



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.

Fig. 3.2 Depleted battery indication

3.2.4 Pads expired

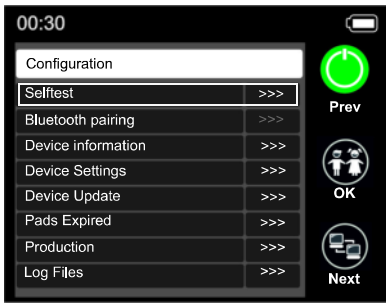
⚠ WARNING

▲ The set expired date does not replace the regular visual inspection of the pads expired date between the selftest test intervals.

6.2.3 Visual inspection of the device and accessories, page 37

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.
3. Verify the entered date in the menu Device information.

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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 selftest to check the unit and the battery. A selftest 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 selftest, an acoustical notification is activated.

➜ A selftest can be executed anytime.

2.5.2 Performing manual Selftest, page 22

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4 Communication

- To read the intervention data, use the appropriate SCHILLER software. Contact your SCHILLER representative.
- The intervention file does not contain any patient data that allows conclusions to be drawn about the patient's identity.
- The following transmission possibilities are available to retrieve the intervention data:
  - directly to USB memory stick
  - via WLAN is 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.

⚠ WARNING

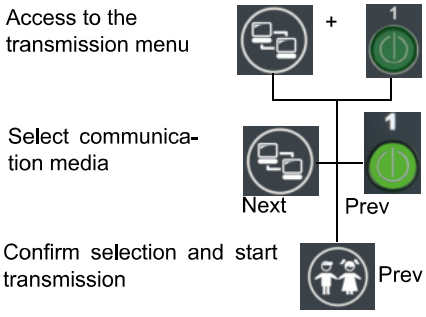
- ▲ The security of the network is the sole responsibility of the user.
- ▲ When the unit is part of a network (LAN, WLAN, HIS) or any other transmission/reception medium, or if exposed to the Internet or other insecure networks, appropriate security measures must be taken to protect the configuration of the device.
- ▲ To guarantee the cybersecurity of the network, SCHILLER recommends the following:
  - Defining access authorization for the host system's configuration, including the physical access to the **FRED easyport plus** so that no unauthorized system alterations are possible.
  - Use an SMTP server with authentication with TLS support
  - Use Transport Layer Security (TLS) 1.2 or higher to communicate with the system and SEMA servers or SCHILLER Device Manager
  - Do not divulge login credentials to third parties.
  - Use a safe password with minimum 8 digits and it should include a combination of letters (capital, small), numbers, and characters.
  - Use always WPA2 encryption

8.3.4 Communication, page 53 (WLAN)

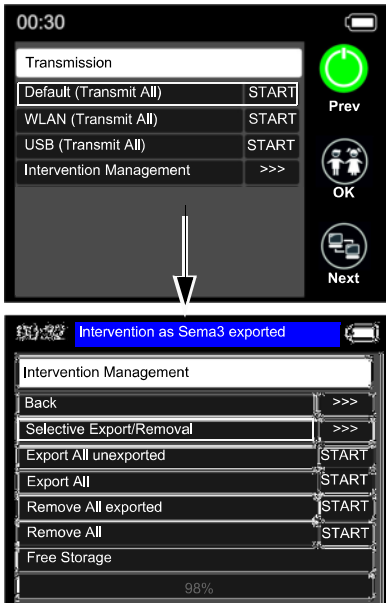
4.1 Transmission menu

- The default transmission mode is WLAN (Bluethoot is deactivated in SW version 1.3.0)
- 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.



Art. no.: 2.540108 Rev. e02



Transmission menu

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

➜ 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%

4.2 Retrieving intervention data via USB

- If setup “Auto Start” in the transmission 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.

8.3.5 Transmission mode, page 55

1. Insert the USB memory stick (2)
2. Press and hold the “Data transfer” button (2) while switching the device on (1).
3. Select the Intervention menu.
4. Choose on of the following export functions:
   - Selective Export/Removal function (The selected 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). At 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.

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4.3 Retrieving intervention data via WLAN

4.3.1 Communication Settings on the device

⚠ CAUTION

▲ To avoid unauthorised access, ensure that the FRED easyport plus is not accessible for unauthorized persons.

▲ Setup communication setting for the SEMA server for a secure data access and transmission.

– Set SSL encryption to **Yes**
– Use a strong password
– Switch off service when not used

8.3.4 Communication, page 53

4.3.2 Retrieving intervention data

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

8.3.5 Transmission mode, page 55

1. 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)
2. Select the Intervention menu.Select “Default (Transmit all)” and confirm selection with the “Child” button.
3. The data transmission is displayed.
4. After final transmission the device will be switched off automatically.

4.3.3 Automatic transmission of intervention data

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.

8.3.5 Transmission mode, page 55

- 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.

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4.4 Export/Import configuration via USB

⚠ WARNING

▲ Check the USB before update/upgrade process for traces of malware, download update/upgrade hashed file, check hash of downloaded file to exclude malware injection, perform update/upgrade by educated service technician, run checks upon update/upgrade to check all device functionalities. Restore configuration from file or SDM. If update/upgrade is suspicious or malfunctioning initiate factory restore mode.

4.4.1 Export configuration to a USB mass storage device

- **Note**: Ensure that the USB mass storage device is FAT32 formatted and has sufficient storage capacity available.

1. Connect the USB mass storage device to the USB port of the FRED easyport plus.
2. On the FRED easyport plus, press and hold the **Children** button while turning on
3. Use the **Communication** button to scroll down to the **Device Settings** option.
4. Press the **Children** button.
5. For the password, press **Communication, Children, Communication, Children.**
6. Use the **Communication** button to scroll down to the **Export Settings** option.
7. Press the **Children** button to start the export.
   – The menu header displays ***User Defaults Exported***.
8. Remove the USB mass storage device from the FRED easyport plus.
9. To leave the configuration menu, restart the FRED easyport plus.

4.4.2 Import configuration from a USB mass storage device

- Export the log files to verify that the default settings have been imported correctly.
- **Note**: Ensure that the USB mass storage device is FAT32 formatted and has sufficient storage capacity available.

1. On the root level of the USB mass storage device, create the directory path: **D:\FEP200**
2. Copy the **Settings** folder from the export into the D:\FEP200\ directory.
3. Connect the USB mass storage device to the USB port of the FRED easyport plus.
4. On the FRED easyport plus, press and hold the **Children** button while turning on
5. Use the **Communication** button to scroll down to the **Device Settings** option.
6. Press the **Children** button.
7. For the password, press **Communication, Children, Communication, Children.**
8. Use the **Communication** button to scroll down to the **Import Settings** option.
9. Press the **Children** button to start the import.
   – The menu header displays ***User Defaults Imported***.
10. Remove the USB mass storage device from the FRED easyport plus.
11. To leave the configuration menu, restart the FRED easyport plus.

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4.5 Import configuration via SDM

⚠ WARNING

▲ To avoid unauthorised access, ensure that the FRED easyport plus is not accessible for unauthorized persons.

▲ Setup communication setting for the **SDM** (Schiller Device Manager) for a secure data access and transmission.

– Set SSL encryption to **Yes.**
– Check integrity of transferred information
– Set the “Auto update settings” to Off
– Switch off service when not used

8.3.4 Communication, page 53

▲ If configuration is suspicious or malfunctioning initiate factory restore mode.

4.5.1 Setup communication to SDM

1. Enter the Communication settings for SDM transmission.
   8.3.4 Communication, page 53
2. Make sure the ApplicationID is set in the SDM.
3. Make sure that WLAN access point is accessible.
4. Go to Selftest and select menu Selftest/Test SDM server connection.
   – This will established the communication channel between the Device and the SDM server with generation of the authentication token in the device.

4.5.2 Import user settings from SDM

The SDM settings **“Auto Update Setting” On** or **Off** leads to the following behaviour:

OFF:
SDM send settings to the device, the notification (orange) ***“New SDM Default Settings”*** appears. This setting must be imported manually by the user.

➜ Go to menu **Device Setting > Import Setting from SDM** and select **START.** If no settings are available the START button is grey (deactivated)

– After successfully import the notification “***Imported SDM Settings***” appears.
– 8.3.6 Parameter in the Device Settings menu, page 55

ON:
SDM send settings to the device and the settings are automatically updated. Notification “***Imported SDM Settings***” appears.

➜ For both transmission, check integrity of transferred information.

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5 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.

5.1.1 LED Status display of the charger, page 35

5.1 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 till 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.

ℹ

Charging time to 100%: 2 h

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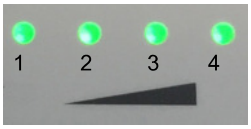
5.1.1 LED Status display of the charger



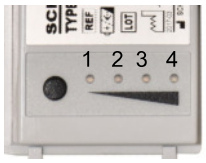
Status	LED 1	LED 2	LED 3	LED 4	Charging Status
Normal	OFF	OFF	OFF	ON	Start up, charger supplied and switch on without battery
	Quick flash	OFF	OFF	OFF	0-25%
	ON	Quick flash	OFF	OFF	25-50%
	ON	ON	Quick flash	OFF	50-75%
	ON	ON	ON	Quick flash	75-100%
	ON	ON	ON	ON	100%
Low voltage	Slow flash	OFF	OFF	OFF	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. Non of the LEDs are flashing.

5.1.2 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

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6 Tests and inspections

⚠ WARNING

- ▲ To ensure readiness for use of the device, always observe the maintenance intervals as described in this chapter.
- ▲ The automatic selftest does not replace the regular visual inspection of the device between the test intervals.
- ▲ The user/responsible organisation is responsible to maintain the device (update software/hardware) according to the maintenance interval described below. In addition, the user/responsible organisation must update the device according to the manufacturer Field Safety Notices.

6.1 Maintenance Intervals

- 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.
- Immediate maintenance is required when device is malfunctioning or does not behave as expected.

Interval	Maintenance - replacement	Responsible
Every 3 years	• Technical safety inspection and software updates (if needed) are advised according to SCHILLER documentation (available for technical departments authorised by SCHILLER). 6.3.4 Defibrillator button key and LED test, page 39 • Enter new maintenance reminder date. 8.4.2 Base Settings, page 57	→ 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. 6.3.4 Defibrillator button key and LED test, page 39 **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

6.1.1 Service/Shelf life

Device The device has defined Service Life of 8 years if maintenance intervals have been observed accordingly.
6.1 Maintenance Intervals, page 36 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)

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6.2 Recurrent Test

6.2.1 General requirements

The test procedure is according the directive IEC/EN 62353. The test must be carried out:

- tests before putting into service
  (This will be done from the manufacturer and the test protocol will be delivered with the device)
- at the recommended service intervals (Recurrent testing)
- after repairing (or as soon the device was opened or modified)

6.2.2 Overview Tests

(1) Inspection by visual check
(2) Recurrent tests of:
  – Leakage current of the device
  – Isolation resistance
(3) Function test of safety relevant functions
(4) Testprotocol

Specify the measuring setup in the test protocol according IEC 62353 and 60601-1.

6.2.3 Visual inspection of the device and accessories

Regularly 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.
  7.1 Error notification, page 46
- Device and LifePoint sensor casing undamaged?
- No excessive clogging 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?
- 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.
  6.3.4 Defibrillator button key and LED test, page 39
- Expiration date of the securing pads not elapsed?
- Check 2- wire ECG cable undamaged?

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6.3 Functional test

⚠ 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
  6.2.3 Visual inspection of the device and accessories, page 37
- Check for proper functioning.
- Measure the energy delivered at 50 Ohms.
- ARGUS Lifepoint sensor (function can be checked by using a CPR manikins)

6.3.1 Rechargeable Li-Ion battery check

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  .

Test criteria: (record in the maintenance report)

- When battery is fully charged the actual charged capacity should not be lower than 960.
- Cycle count not greater than 500.

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6.3.2 Non rechargeable Lithium/MnO2 battery check

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.

6.3.3 Selftest

The device has an integrated selftest. During this test the relay, battery and defibrillation capacitor are tested.
This test can be executed in the menu **Configuration/Selftest/Do Selftests.**
See:

2.5.1 Performing automatic Selftest, page 22
2.5.2 Performing manual Selftest, page 22

The results are displayed in the message area. Following test are executed:

Relay test/IGBT test/battery test/capacitor test

Test criteria: (record in the maintenance report)

- Shock key lights up and an audible notification is given.
- Self test passed notification appears.

6.3.4 Defibrillator button key and LED test

- Simulator by means of a Defi test device (e.g. IMPULSE 7000 DP Defi test device (Fluke or others)
- Setup Defi test device
- 6.4.1 Defi Test AED mode, page 41
- Yellow paediatric test plug

1. Switch on the device while pressing the shock key.The message “key stuck detected” appears and electrode lights up.
2. Connect the simulator to the electrode connector. The electrode LED goes off.
3. Press the paediatric button twice. Button LED lights up and adult indication changes to paediatric.

Test criteria: (record in the maintenance report)

- Buttons working
- Button LED paediatric lights up.

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6.3.5 Children/paediatric electrode detection

Use the children/paediatric electrodes with the yellow connector

1. Switch the device on.
2. Plug in the yellow children electrodes plug.

Test criteria: (record in the maintenance report)

- The device is switching to child/paediatric.

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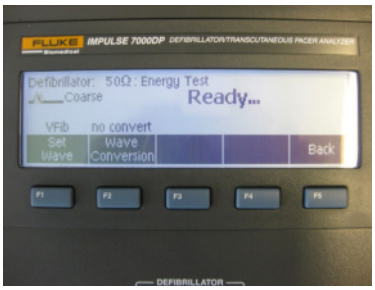
6.4 Measurement test

- Defi test device, e.g. IMPULSE 7000 DP Defi test device (Fluke or others) using the scope output Defibrillation cable.
- The Test procedure follows the AED algorithm with first shock adults 150 J, second shock 200 J. After switching to Child third shock with 50 J.

6.4.1 Defi Test AED mode

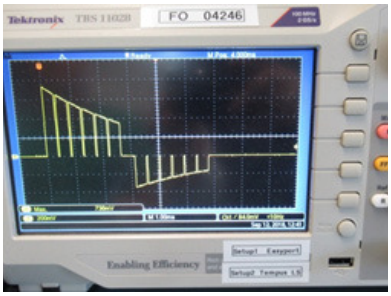


1. Connect electrode cable on the Defi test device. Check polarity.
2. Select Defibrillator 50 Ohm Energy test.
3. Select Set wave then set Wave Form to VFib then select Done.
4. Switch the **FRED easyport plus** on the defibrillator recommends shock delivery. The shock button lights up.

⚠ CAUTION

Danger of electric shock!

▲ Make sure that the connection cable between the Defi test device and the Defi pads connector of the **FRED easyport plus®** is fitted correctly. Do not touch cables or device.



Note: Amplitude varies depending on the delivered energy.

5. Press the shock button to release the first shock (150 Joule)
6. Check signal on the scope.
7. Read the delivered energy on the Defi test device.
8. Release the second shock after 2 minutes CPR phase (200 Joule)
9. Check signal on the scope.
10. Read the delivered energy on the Defi test device.
11. Select the child button and release shock after 2 minutes CPR phase (50 Joule)
12. Check signal on the scope.
13. Read the delivered energy on the Defi test device
14. Select on the Defi tester “Set wave”, select “Wave Form normal rhythm”. Wait till next analyse of the ECG signal. It should detect a non shockable rhythm.

Test criteria: (record in the maintenance report)

- AED detects shockable rhythm, shock delivered with 150 Joules ± 10%
- AED detects shockable rhythm, shock delivered with 200 Joules ± 12.5%
- AED detects shockable rhythm, shock delivered with 50 Joules ± 10%
- AED detects non shockable rhythm

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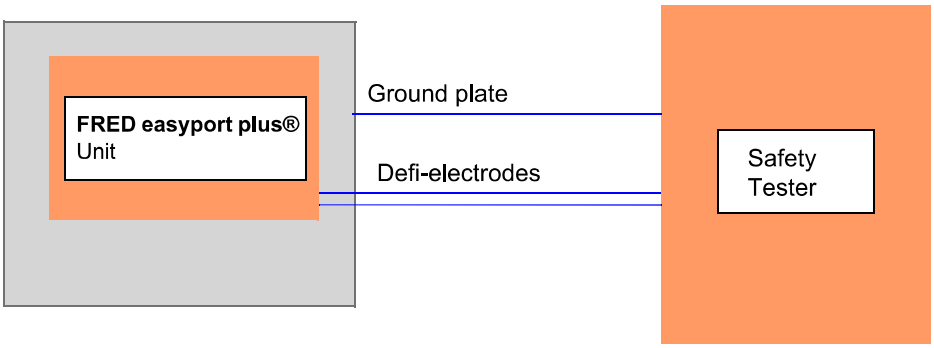
6.5 Leakage current test (Safety test)

Tooling required /test equipment

- A calibrated multi-channel leakage current tester (Safety Tester according IEC/EN 60601-1 or IEC/EN 62353) such as those from Metron, Seaward, Rigel, Fluke, Bender etc.
- Defibrillator cable
- Power supply with main cable

IMPORTANT!

- The test devices listed above are subject to the instructions according to ISO 9000 in regards to Test Equipment Control
- **FRED easyport plus** is a class II device
- Isolation type BF for defibrillation output



6.5.1 Leakage current test procedure

1. Follow Following the tester's instructions, attach the tester to the following parts:
   – Defibrillator cable (modified for test)
   – USB cable (modified for test)
2. Ensure the **FRED easyport plus** is equipped with a sufficient charged battery
3. Perform the tests defined in the test criteria and ensure the **FRED easyport plus** meets the thresholds defined in the table.

Test criteria: (record in the maintenance report)

Defibrillator input/output

- Equipment leakage current < 0.01
- Patient leakage current type BF SFC U -AP < 5 mA
- Patient leakage current type BF NC DC< 0.01 mA
- Patient leakage current type BF NC AC < 0.1 mA

  – NC = Normal condition
  – SFC =Single Fault Condition
  – DC = direct current
  – AC = alternated current

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Safety test protocol

Test Organisation: Name of the tester:	❑ Check before first use (Reference value) ❑ Recurrent test ❑ Test after repair
Requesting Organisation:	
Device: FRED easyport plus	ID. No.:
Type:	Serial no.:
Manufacturer: SCHILLER AG	Safety class: II Internal powered
Type of applied part: BF	
Accessories:	

Test: Test equipment: Serial number:		Pass	Fail
Visual inspection 6.2.3 Visual inspection of the device and accessories, page 37		q	❑
Isolation and Leakage 6.5.1 Leakage current test procedure, page 42 **Measurement:**	Measured value		
Equipment leakage current	.....mA	q	q
Patient leakage current	..... mA	❑	❑
Isolation resistance:	..... MΩ ❑ Not tested	❑	❑
Functional Test (7.3 Functional test page 53)		q	q

Remarks:

Overall comments:

❑ No safety or functional problem detected.

❑ No direct risk, the problems can be solved in a short time.

❑ The device must be placed out of order to solve the problems.

❑ The device does not fulfil the needs (repairing or placing out of order recommended).

Validated by: .....Date / Sign: .....

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6.6 Inspection report

The user guide must be read before the inspection.

Serial number: _____

6.3 Functional test, page 38					
6.2.3 Visual inspection of the device and accessories, page 37					
→ Visual inspection of the device and accessories	☐	☐	☐	☐	☐
→ Device casing undamaged?	☐	☐	☐	☐	☐
→ No excessive clogging or damage?	☐	☐	☐	☐	☐
→ Legible nameplate at the rear of the device?	☐	☐	☐	☐	☐
→ Legible inscriptions on the front face of the device?	☐	☐	☐	☐	☐
→ Expiration date of the accessories elapsed?	☐	☐	☐	☐	☐
→ Check 2- wire ECG cable undamaged?	☐	☐	☐	☐	☐
6.3.3 Selftest, page 39					
→ Check that the “RTU” LED is blinking	☐	☐	☐	☐	☐
6.3.4 Defibrillator button key and LED test, page 39					
• When battery is fully charged the actual charged capacity should not be lower than 960., page 38	☐	☐	☐	☐	☐
• Cycle count not greater than 500., page 38	☐	☐	☐	☐	☐
6.3.4 Defibrillator button key and LED test, page 39					
• Buttons working, page 39	☐	☐	☐	☐	☐
• Button LED paediatric lights up., page 39	☐	☐	☐	☐	☐
6.3.5 Children/paediatric electrode detection, page 40					
• The device is switching to child/paediatric., page 40	☐	☐	☐	☐	☐
6.4.1 Defi Test AED mode, page 41					
• AED detects shockable rhythm, shock delivered with 150 Joules ± 10%, page 41	☐	☐	☐	☐	☐
• AED detects shockable rhythm, shock delivered with 200 Joules ± 12.5%, page 41	☐	☐	☐	☐	☐
• AED detects shockable rhythm, shock delivered with 50 Joules ± 10%, page 41					
• AED detects non shockable rhythm, page 41	☐	☐	☐	☐	☐
6.5.1 Leakage current test procedure, page 42					
• Equipment leakage current < 0.01, page 42	☐	☐	☐	☐	☐
• Patient leakage current type BF SFC U -AP < 5 mA, page 42	☐	☐	☐	☐	☐
• Patient leakage current type BF NC DC< 0.01 mA, page 42	☐	☐	☐	☐	☐
• Patient leakage current type BF NC AC < 0.1 mA, page 42	☐	☐	☐	☐	☐
Life item replacements					
Internal backup battery replacement.	☐	☐	☐	☐	☐
Date:					
Performed by:					

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

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

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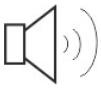
7 Troubleshooting

- 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.

7.1 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 to identify the source of error.

7.1.2 Technical error messages, page 48

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7.1.1 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 • IGBT test failed • Battery test failed • Capacitor test failed	→ If "Battery test failed" is displayed, replace the battery and run again a manual selftest. → If other error message is displayed, have the device repaired.
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.
CPR feedback shows wrong or no measuring	• Wrong application	→ Continue CPR without to rely on the CPR feedback.
	• Software failure	→ Check after intervention function of the CPR feedback system.
	• Sensor defective	
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.
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 described. 3.2.4 Pads expired, page 27
Maintenance required notification	• Entered maintenance interval reminder date expired 8.4.2 Base Settings, page 57	→ Technical safety inspection and software updates required. 6.1 Maintenance Intervals, page 36 (3 years)

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7.1.2 Technical error messages

Medium priority error messages displayed on orange background

Error message	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	→ Remove pads
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

High priority error messages displayed on red background

Error messages	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 displayed when using the rechargeable battery
Shock disabled, low battery	• Battery capacity to low to charge the 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 selftest.
– Capacitor test failed	• Charging the capacitor takes to long or is not possible	→ Have the device repaired.
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.

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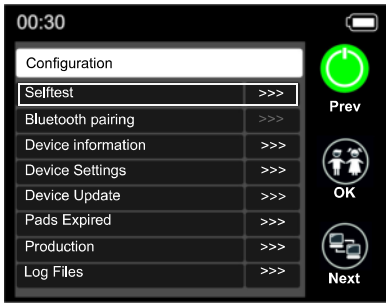
8 Configuration



To get access to the settings:

→ Press and hold the button while switching the device on.
The Configuration menu appears.

→ Enter the password ; ; for the Device setting menu.

8.1 Overview menus

Menu/parameters	Sub menu/Parameter	Sub menu/Parameter	Sub menu/Parameter/details
Selftest >>>	all tests 2.5.2 Performing manual Selftest, page 22	-	-
Bluetooth pairing	>>>	-	With SW 1.3.0 disabled
Device information >>>	(S/N; RefNr; Device Name; SW and HW versions; Pads Expired date; Maintenance date; Guidelines; Battery >>>; Bluetooth >>>; SDM Settings Name		
Device Settings >>> 8.2 Device information, page 51	**Shock settings >>>** 8.3.1 Shock setting, page 52	Energy adult/children 1/2/3	
	CPR settings >>> 8.3.2 CPR setting, page 52	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 >>> 8.3.3 CPR Feedback, page 53	Limits >>> Feedback delay CPR Voice prompts Average Rate Max CPR Enable Recoil	Rate limits >>> Depth limits adult >>> Depth limits paediatric >>>
	Communication >>> 8.3.4 Communication, page 53	SDM >>> SEMA >>>	-
	Transmission mode >>> 8.3.5 Transmission mode, page 55	Media Auto power on Auto start	-

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Menu/parameters	Sub menu/Parameter	Sub menu/Parameter	Sub menu/Parameter/details
Device Settings >>> 8.2 Device information, page 51	System settings >>> 8.4 System Settings, page 56	Local settings >>> 8.4.1 Local Settings, page 56	Language, Country, Date, Time, Time-zone, Time Sync etc.
		Base settings >>> 8.4.2 Base Settings, page 57	Maintenance >>> (Year month) Length Unit (metric/inches); Monitor enable; Device name
		Selftest settings >>> 8.4.3 Selftest Settings, page 57	RTU Wakeup Interval for test Auto RTU send
		Volume	Low/Mid/High
		Shock Pacer markers	Off/On
		Auto Switch off time	
	8.3.6 Parameter in the Device Settings menu, page 55		-
	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, page 27
Production >>>	Metronome CPR Time and breath time (number of breath)		see service manual
Log Files >>>	Start		see service manual

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8.2 Device information

8.2.1 Following information are given in the Device information menu.

S/N	Serial number of the device
RefNr	Reference number of the device
SW Version	Software version
HW Version	Hardware version
SW Version Defi	Software version Defi
HW Version Defi	Hardware version
	More information >>>
Guideline	ERC/AHA
Address	MAC address
	Battery info >>>
Battery version	Battery Version
Full charge capacity	Normal value approx. 1129 (replace when value is below 960 when fully charged)
Actual charge battery	Voltage 11.187
Current now	Cycle count (reaching approx. 500 cycles replace battery)
Temperature	Actual battery temperature (only for rechargeable)

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8.3 Device Settings

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

8.3.1 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

8.3.2 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.

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8.3.3 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.

8.3.4 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: • Hostname (IP address of the SDM server – (semadev.schiller.ch) • Port host – (8080) • SSL (Certificate validation) – **No**/Yes Note: authentication token is generated from the application-id and serial number of the device
	Auto Update Settings	Allows to update Settings via SDM server – On/**Off** When set to Off and a Default setting from the SDM have been down-loaded a notification is displayed (New SDM Default Setting). The setting must be manually imported. Go to menu Device Setting > Import Setting from SDM and select START. 4.5.2 Import user settings from SDM, page 33
	Upload interventions	Allows to upload intervention data to SDM server – On/**Off**

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Parameter	Parameter	Description/Selection
SEMA >>> **CAUTION-** - Use always encryption - Use a safe password with minimum 8 digits and it should include a combination of letters (capital, small), numbers, and characters.	• Hostname • Port host • User name • Password • SSL • Upload intervention	Setup of the following SEMA server parameters: • Hostname of the SDM server – (semadev.schiller.ch) • Port host – (8080) • User Name – Default • Password – System • SSL (Certificate validation) – **No**/Yes – START Import Certificate if Yes • Upload intervention data to SEMA server – On/**Off**
WLAN >>> **CAUTION-** - Use always encryption - Use a safe password with minimum 8 digits and it should include a combination of letters (capital, small), numbers, and characters.	**WLAN >>>**	Status Information WLAN: • Connection Status • BSSID • Channel • RSSI • Local IP • Remote server IP • Remote Client IP • SW Version • S/N (Serial number)
	SSID	SSID = Enter network name.
	Security	Selection of the encryption protocol: **WPA2 Default** / WPE PEAP / WPE EAP-TLS (WPE not available yet)
	Password	Enter password for WPA2 protocol
	Import Passkey (Not available yet)	Import for long password via USB stick.
	User Name	Definition of the user name
	Domain	Enter domain address
	Certificate (Not available yet)	Download the certificate via USB port of the device when **EAP-TLS** is selected Connect USB stick to the device and press START at Import Certificate
	Import Certificate	START import certificate
	Server (Not available yet)	Access from server to the device (PCR protocol disabled)
	Server Port	Port address
	Install firmware	WLAN Firmware update Rename File and safe on the USB stick under following path: E:\FEP200\Firmware\COM\NORA-W36X-SW.bin

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8.3.5 Transmission mode

Parameter	Values	Description
Media	• **BT** • USB • WLAN	Selection of the preferred transmission via USB or WLAN Note: With new software 1.3.0 BT setting is equal WLAN setting.
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. 8.3.5 Transmission mode, page 55 • 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 WLAN or USB.

8.3.6 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

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8.4 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.

8.4.1 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.

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8.4.2 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! 6.1 Maintenance Intervals, page 36 Check entered date in the menu **Configuration > Device information > Maintenance** 8.1 Overview menus, page 49.
Length unit	• **metric** • inches	Set units for display with LifePoint sensor
ECG Signal mode enabled	• **Yes** • NO	If set to Yes the device can be switched to ECG signal 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”. 8.4 System Settings, page 56 Detailed description and warnings see instruction for use chapter ECG signal mode

8.4.3 Selftest 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
RTU Battery Threshold	• **10%** • 20% • 50%	Threshold for the RTU “Battery low” notification. This is only applied during RTU selftest. The “Battery low” notification during use will be still 10%.

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8.5 Production setting

Following setting are only for production setup and information.

Menu>>>/Parameter	Parameter	Value/Description
Metronome Settings >>>	• **CPR Time** • Breath Time • Number of breath	• 1 min/ **2 min**/ 3 min • 1 s/ **2 s** /3 s • 2
ADCS_U_BAT	-	Display of battery voltage normally approx.11.1 V
Temperature	-	Display of the rechargeable battery temperature. If non rechargeable battery is use no Temp value is displayed
Temperature CPU		Display of the CPU temperature
Calib Temp at 20°C		Do not Calibrate Temp. This is only for production. If calibration is started while environmental temperature is not 20°C, capacity display of the non rechargeable battery may be wrong!
Impedance		Display of the measured impedance of the applied part (Electrode - patient or simulator.
Last system event		Display of the last system event recorded in the log file.

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9 Update software

⚠ WARNING

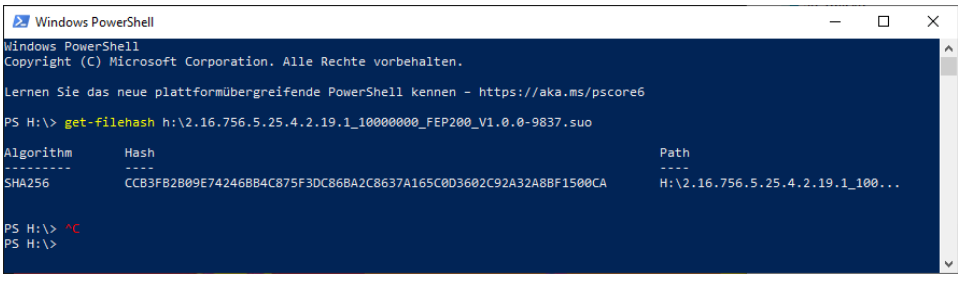
- ▲ For PC, networks and USB memory stick, appropriate security measures must be taken to warranty a secure download of the software.
- ▲ Make sure that qualified service personnel only, trained by Schiller AG may update/upgrade the device.
- ▲ In order to guarantee the cybersecurity of the PC, networks and USB memory stick, Schiller recommends the following:
  - defining access authorisation for the configuration of the host system, incl. **FRED easyport plus** so that no unauthorised alterations of the system are possible
  - installing the latest antivirus/firewall programs on the PC/Host in order to prevent malware from affecting the system
  - taking the appropriate measures to check the system's security and ensure safe operation when changing the network configuration, installing security updates.
  - regularly installing security updates on the PC/Host
  - check the USB before update/upgrade process for traces of malware, download update/upgrade hashed file, check hash of downloaded file to exclude malware injection, perform update/upgrade by educated service technician, run checks upon update/upgrade to check all device functionalities. Restore configuration from file or SDM. If update/upgrade is suspicious or malfunctioning initiate factory restore mode.

9.1 Download and preparing software

Important information

Only use USB memory stick with Status LED to be able to check functionality with the **FRED easyport plus** and having status during copying the files from the stick to the device, because the LCD of the device stays black!

1. Download latest software from the extranet to your PC.
2. Check according release note software/Hardware compatibility.
3. Check the SHA256-hash of your current SUO file and compare it to the SHA256-hash provided in the software release note.



Use “Windows PowerShell” app on your computer see above and use the command:
“get-filehash path:\filename.suo”
Note: You can copy-past the file name.

4. Plug your USB memory stick into your computer.
5. Create a new folder called FEP200, inside that folder create another folder called Firmware, inside that folder create a SUO folder (FEP200>Firmware>SUO).
6. Copy the new software file into the SUO folder.

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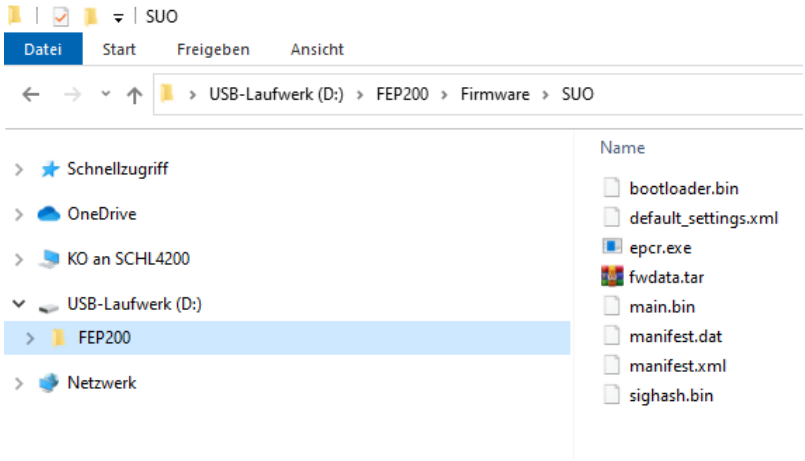
7. Extract the contents of the SUO file, deleting the SUO file afterwards.
8. Once you have the correct file in the root directory of the USB stick you can remove the USB from the computer.



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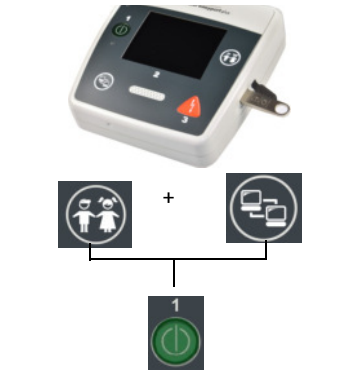
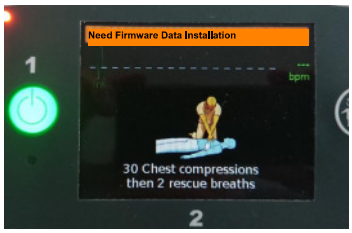
9.2 Firmware installation

9.2.1 Firmware main file





After verifying and extracting the SUO to the UBS memory key you can follow the following steps for install the FW main file to the device:

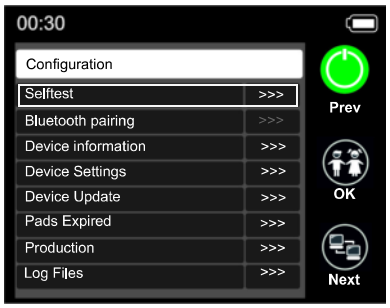
1. Switch off the device
2. Connect the UBS Memory key to the device while the device is switched off
3. Press and hold the PAEDIATRIC MODE and COMMUNICATION key and Switch ON device.
4. Device will start copying files to device and install the FW. After Installation is finished, the device will start automatically.

Note:
Use USB memory stick with LED, because the LCD of the device stays black!

5. Proceed as following:
   - If message “NEED bootloader installed” or “NEED Firmware Data installation” switch off the device and follow procedure.
     9.2.2 Firmware data (audio files) and bootloader update, page 61
   - If no message appears switch off the device and follow procedure.
     9.2.3 Tests to be performed after Firmware installation, page 62

9.2.2 Firmware data (audio files) and bootloader update

If requested after main firmware installation install bootloader and/or Firmware data files.



Ensure that the USB stick is still plug in with the right bootloader and/or Firmware data file and follow the procedure.

1. Press and hold the button while switching the device on. The Configuration menu appears. Check that USB memory LED is blinking.
2. Press the “Next” button and select “Device update” and confirm with the “OK” button. Enter the password ; ; .
3. Press the “Next” button and select the requested installation “Install bootloader“ or “Install Firmware” and confirm with the “OK” button .
4. Device will start copying file to device and install the file. After Installation is finished, switch the device off and restart to execute the test.
   9.2.3 Tests to be performed after Firmware installation, page 62

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9.2.3 Tests to be performed after Firmware installation

Preconditions:

Update device to newest FW and Audio Files.

9.2.2 Firmware data (audio files) and bootloader update, page 61

Procedure test

1. Press and hold the button  while switching the device on  . The Configuration menu appears.
2. Select menu “Device Information” and
   - check S/N and RefNr with the device label
   - check the SW Version with the Version in table 1
3. Select “Device Settings->System Settings->Local Settings” and
   - check Language setting
   - check Country setting
   - check Date
   - check Time
   - check Timezone
4. Select “Device Settings->System Settings->Selftest Settings” and
   - check RTU Wakeup
5. Power down device
6. Power up the device and
   - check the audio prompts are heard in **“requested language”**

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9.3 Setup new LCD with older device

- New LCD display (4.600144) is delivered as complete unit, top housing (4.310675) with built in LCD part number 4.600143 (4.600138 eol).
- With older devices serial number 9000.008999/Trainer 9010.000699 and lower, the HW configuration (in the eeprom) must be update to center the display.

Note

- USB A to mini B cable
- Set HW Config using the epcr.exe
  - Use the epcr.exe of SUO that provides the 1.3.1 (or higher) firmware as older epcr.exe do not support the -yh command:
    epcr.exe -s COMx -ye <pw> -yh 0 2

1. Connect the device via the USB port inside the battery compartment.
   The COM port number can be found in the Device Manager (it will appear as “STMicroelectronics Virtual COM Port (COMx)”).
2. Run the command epcr.exe -s COMx -ye 7664242 -yh 0 2
3. Insert the new battery and check the display

➜ The display should now be centred.

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10 Assembly & Disassembly

10.1 Safety Notes

▲ Before opening the device for work, ensure that the battery is removed and the high voltage defibrillator capacitor has been fully discharged.

▲ Follow the procedures for the prevention of accidents and environmental protection according your national guidelines

- Observe precautions for handling electrostatic sensitive devices when opening the device.
- The FRED easyport plus contains static sensitive CMOS components; observe antistatic precautions:
- When carrying out any maintenance procedures always place the unit on an earthed antistatic mat.
- Personnel must be earthed when handling any boards or components.
- Always use an antistatic bag when transporting boards or components.

Before opening

➔ Switch off the device

➔ Remove the battery in order to ensure that the device does not start up accidentally.

➔ Disconnect the defibrillation electrode cables from the device

10.1.1 Battery Disposal

▲ Danger of explosion! The battery must not be incinerated, exposed to high temperatures or disposed of with household waste.

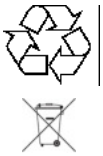
▲ Do not expose the battery to chemicals that could dissolve ABS, polypropylene, polyvinyl chloride, nickel, mylar or steel.

▲ Do not cut, destroy, or incinerate the battery.

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

▲ Danger of electrolyte leakage. Risk of corrosion.

▲ Dispose unreachable from children



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

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10.1.2 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.

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10.2 Opening the Case

- Philips screwdriver 1
- Low abrasion antistatic mat

- The unit is susceptible to abrasion damage. To prevent scratching, always place the unit on a soft, non-abrasive cloth when carrying out maintenance procedures.
- Take care not to place any strain on the connecting ribbon cable when removing the top assembly. Ensure that the cable assembly is not crimped or twisted and that the top assembly is not placed on the cable assembly.
- Care must be taken when removing and replacing connectors. Never use force. Never strain the cable assemblies.

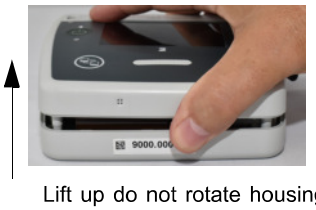
▲ After re-assembly the functional and safety tests must be carried out according to the recurrent test.
6.2 Recurrent Test, page 37

10.2.1 Procedure

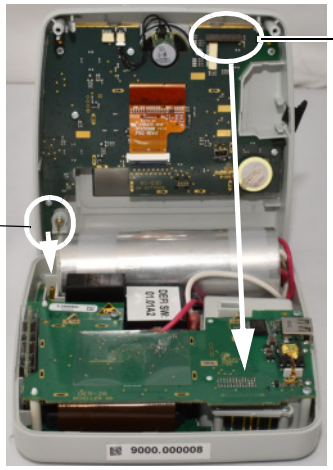
1. Remove the battery
2. Loosen the 4 Philips screws.

Note:
With the battery holder 2 mm longer screws are used (PT K30x12, 4.910253)

3. Carefully lift up the upper housing. Do not rotate the housing until the inner plugs (Defibrillator connector and the board connector) are unplugged. See next picture.



Lift up do not rotate housing until board and defii connector are unplugged!!!!



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GSM board option

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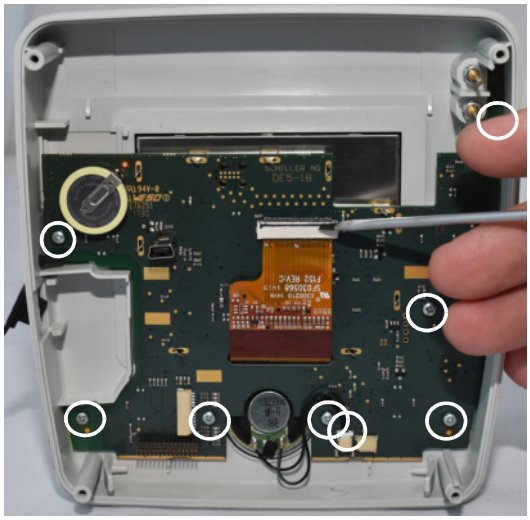
10.2.2 Removing CPU print

1. Unlock flat ribbon connector and pull out the LCD flat ribbon cable.
2. Unscrew 7 screws, to remove the CPU.
3. Disconnect the loudspeaker connector.



Housing with LCD complete 4.600143
see 9.3 Setup new LCD with older device, page 63

10.2.3 Replacing the internal battery

⚠ CAUTION

▲ To avoid mechanical damages, use proper tools to replace the battery.

1. Unlock the button cell spring and replace the battery.

Button Cell

2. Check polarity.
3. Dispose the old battery safely.
10.1.1 Battery Disposal, page 64

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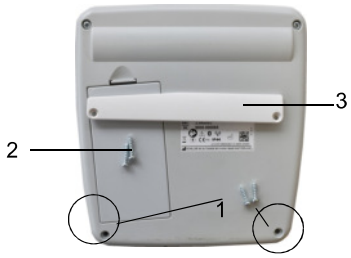
10.2.4 Battery holder assembly

- Philips screwdriver 1
- Battery holder 4.310731 (3)
- 2x Screw 12 mm 4.910253 (2)

1. Remove the 2 screws (1) and replace it with the screws 12 mm (2).
2. Fit the battery holder (3) with the two 12 mm screws.



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10.2.5 Defective foil/keypad replacing

The following table shows the variants of device and foils to be replaced.

Device	Part number device	Part number foil
FEP plus FIRST	3.940060	4.450520
FEP plus AUTO	3.940063	4.450525
FEP plus MANUAL	3.940066	4.450523
FEP plus FIRST Medisol	3.940060	4.450552
FEP plus AUTO Medisol	3.940063	4.450553

4.450520

4.450525

4.450523

4.450552

4.450553

-

1. Remove old foil.
2. Residual adhesive can be removed with adhesive remover.
3. Position the foil first according the ON/OFF key and then position the foil that it fits correctly.

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10.2.6 Replacement part numbers

Part number	Description
4.260 699	2 x Contacts for Defi cable connection
4.812114	*Shrink hose condensator*
4.450509	Foil condensator cover
4.450522	Foil HV Module
4.910 228	7 x Screws-Zhead K25 x5
4.910219	4 x Screws-ZheadK30x10
4.450352	Cable foil
4.450520	Front foil FEP200J
4.600143	Housing top FEP200J incl. LCD (4.310675 Housing top and 4.600144 LCD Module not as single item available)
3.2867	Com.-Module
3.2865	CPU-Print
4.310676	Housing bottom FEP200J
4.310677	Battery contacts
4.910228	2 x Screws-Zhead K25x5
4.435389	USB cover
4.812114	HV condensator 200J
4.450521	Foil condensator
4.350062	Rechargeable battery (Li-Ion 11.1 V, 13.3 Wh rechargeable)
4.350063	Primary battery (Lithium/MnO_2 12 V, 15.6 Wh non rechargeable)
4.310686	Button ON/OFF
4.310687	Button shock
3.940414	Loudspeaker
4.430 370	Sealing loudspeaker 30mm
4.920 002	2 x Nut M2.5
4.930 034	2 x Washer M2.5
4.310 686	Button ON/OFF
4.310 688	Button SOS
4.435389	USB Cover (not on the explosion view)
4.350046	Button cell 3V CR2032 (not on the explosion view)
4.310677	Battery holder (using the longer screws PT K30x12, 4.910253)

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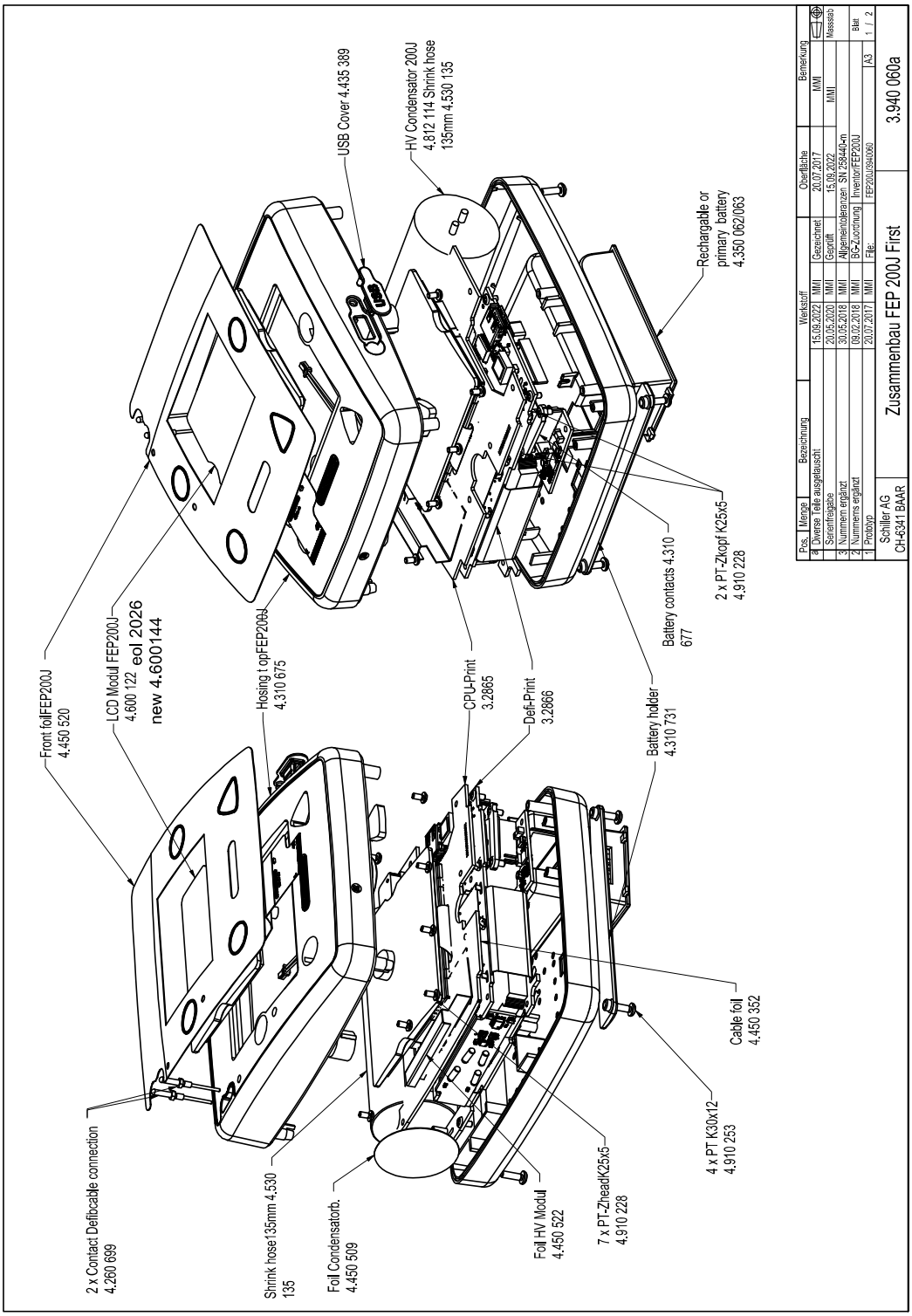
10.2.7 Explosion view



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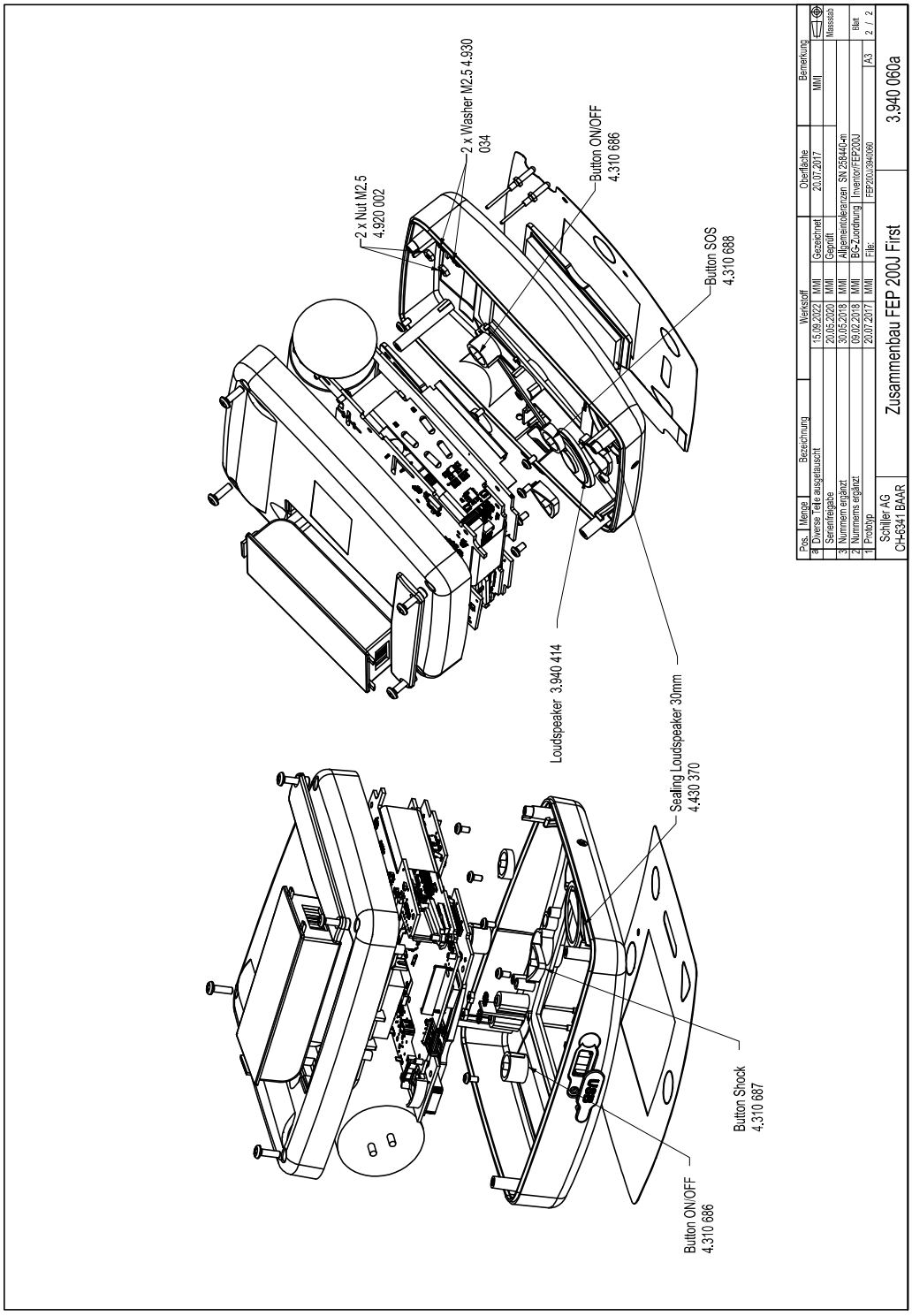
2 x Nut M2.5
4.920 002
2 x Washer M2.5 4.930
034
Button ON/OFF
4.310 686
Button SOS
4.310 688
Loudspeaker 3.940 414
Sealing Loudspeaker 30mm
4.430 370
Button Shock
4.310 687
Button ON/OFF
4.310 686
Zusammenbau FEP 200J First
3.940 060a
Schiller AG
CH-6341 BAAR

11 Technical Data

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

11.1 System Specifications

Manufactured by	SCHILLER
Device name	**FRED easyport plus®**
Dimensions	46 x 150 x 143 mm (h x l x w) With big bag: 110 x 190 x 170 mm (h x l x w) With small bag: 70 x 185 x 150 mm (h x l x w)
Weight	Approx. 0.777 kg with battery (battery = 93g) Approx. 0.866 kg with battery and electrodes Approx. 1.509 kg with bag, electrodes & feedback sensor (feedback sensor = 161 g)
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	• Lithium/MnO_2 12 V, 16.8 Wh (non rechargeable) • Li-Ion 11.1 V, 12.9 Wh (rechargeable)
Battery life	• 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
(if device is stored/used in optimal temperature conditions between 15 to 25°C)	• 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
Battery life (low temperature -5°C)	• 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. 500 mA) • USB mini B 2.0 device only for service • WLAN (Bluetooth LE 5.0 not used)

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Display	• High resolution color LCD 320x 240, 3.5“ • ECG curve display 61 x 15 mm (configurable) • CPR feedback • Action picture
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	• *0°C*...50°C relative humidity at 10 - 95% (non condensing) Atmospheric pressure 540...1060 hPa (5000 m to -400 m) • 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	Operation in NORMAL USE for a period not **more than 20 min** under the following environmental operating conditions:
For transient operation device	• 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 RTCA 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!

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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)

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11.2 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 Basic safety
- IEC 60601-1-11: Requirements for medical device used in the home healthcare environment
- IEC 60601-1-12: Environmental condition for emergency medical devices included test according:
  - RTCA: b) Vibration tests in accordance with Section 8, Table 8-1, of either EUROCAE ED-14G or RTCA DO-160G (Category S for fixed wing or Category U for rotary wing)
  - RTCA: DO-160G: 20102 Section 6, Category A EUROCAE ED-14G or RTCA DO-160G (humidity)
- EN 1789 Medical vehicles and their equipment

EMC

- IEC/EN 60601-1-2
- RTCA: DO-160G (Section 21 Emission of Radio Frequency Energy)
- RTCA: DO-160G (Section 20 Radio Frequency Susceptibility)
- 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 to 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.
- **FRED easyport plus** lifetime is 8 years with respect to the Council Directive EU 93/42.
- Hereby, SCHILLER AG declares that the radio equipment type **FRED easyport plus** is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: https://www.schiller.ch/en/conformity

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.

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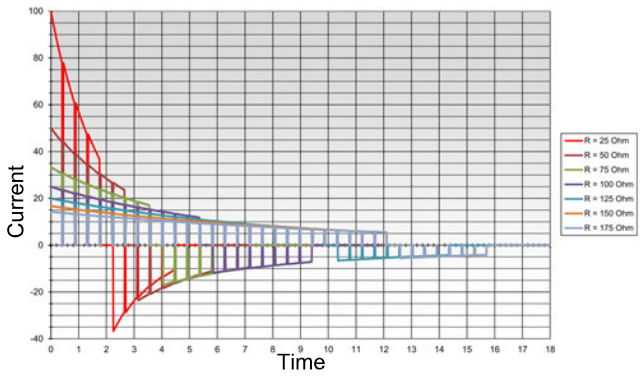
11.3 Defibrillation pulse

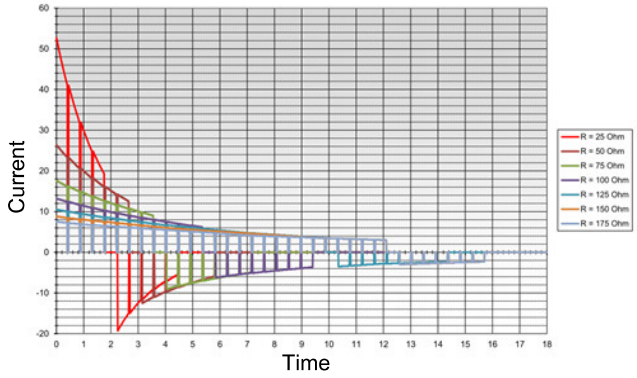
Waveform

Pulsed biphasic truncated exponential waveform ***Multipulse Biowave*** with fixed pulse duration and variable phase duration for impedance compensation.

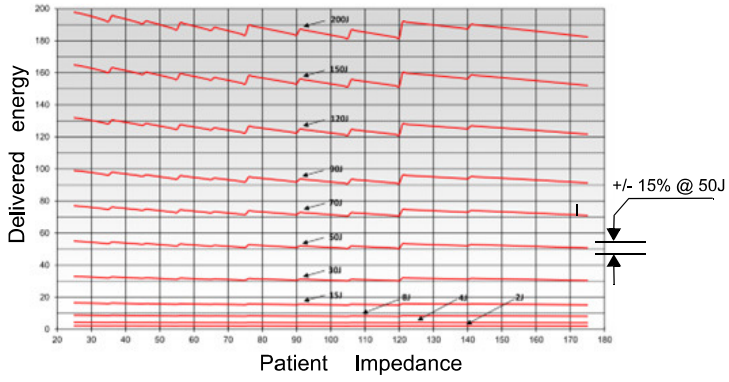
- The impedance range for shock delivery is 25 to 250 Ohms



Waveform shape of delivered current in the function of time in milliseconds for different impedances ranging from 25 to 175 Ω at 200 joules of selected energy.



Waveform shape of delivered current in the function of time in milliseconds for different impedances ranging from 25 to 175 Ω at 50 joules of selected energy.



The delivered energy output curves in the function of patient impedance. Each curve corresponds to a rated energy selection.

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Accuracy of delivered energies

Accuracy of measured delivered energy for each couple of most of the rated delivered energies and impedance value. 25 to 175 Ω is the required range for impedance compensation as required by the IEC 60601-2-4 standard.

Rpat [Ω]	25	50	75	100	125	150	175
Rated delivered energy [J]	Deviation from the rated delivered energy (1 to 200 joules) at 25 to 175 Rpat [Ω] ± 3 J or ± 15% (the higher value is assumed)						
10	± 3 J	± 3 J	± 3 J	± 3 J	± 3 J	± 3 J	± 3 J
15	± 3 J	± 3 J	± 3 J	± 3 J	± 3 J	± 3 J	± 3 J
20	± 3 J	± 3 J	± 3 J	± 3 J	± 3 J	± 3 J	± 3 J
30	± 15%	± 15%	± 15%	± 15%	± 15%	± 15%	± 15%
50	± 15%	± 15%	± 15%	± 15%	± 15%	± 15%	± 15%
100	± 15%	± 15%	± 15%	± 15%	± 15%	± 15%	± 15%
150	± 15%	± 15%	± 15%	± 15%	± 15%	± 15%	± 15%
200	± 15%	± 15%	± 15%	± 15%	± 15%	± 15%	± 15%

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:
- *< 16 seconds* / **< 23 seconds**

After 15 discharges:
- *< 22 seconds* / **< 23 seconds**

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from switch-on of the device to charge at max. energy:	• < *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	• < *14 seconds* / **< 24 seconds**
after 15 discharges with max. energy	• < *14 seconds* / **< 24 seconds**
from switch-on of the device with pads	• < *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:	• < *15 seconds* / **< 17 seconds**
After 15 discharges:	• < *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	• < *12 seconds* / **< 18 seconds**
after 15 discharges with max. energy	• < *12 seconds* / **< 18 seconds**
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

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11.4 Shock Advisory System (SAS)

⚠ WARNING

▲ Performance and Safety of SAS meet the highest recommended guidelines and standards. Nevertheless, in some rare cases, some difficult rhythms might still be misclassified

SAS Validation process

SCHILLER AEDs are highly sophisticated, microprocessor-based devices embedding a Shock Advisory System (SAS) that analyse multiple features of the electrical signal (ECG) received from the patient's heart. The ECG signal is acquired via the defibrillation electrode pads, usually in antero-lateral (or sterno-apical) position (equivalent to a lead II ECG). For paediatric patients under 8 years old, the antero-posterior position of the defibrillation pads is recommended.

SCHILLER AEDs are thought to be operated by rescuers who do not need to recognize or interpret heart rhythms. For this reason, SAS is an essential component of the AED.

The SAS should recommend the following:

- A shock if the analysed rhythms is a lethal ventricular arrhythmia: either a Ventricular Fibrillation (VF) or a rapid Ventricular Tachycardia (VThi);
- No shock for non-shockable ECG rhythms.

Detailed descriptions of the shockable/non-shockable rhythms categories are given in the following section:

A rhythm analysis by the SAS is requested and is run automatically and periodically after each CPR period. The operator must press a button in some AED models to initiate the rhythm analysis. A rhythm analysis requires 5 to 10 seconds, depending on the SAS configuration.

The performance of the SAS embedded in SCHILLER AEDs is evaluated on two criteria: sensitivity (Se) and specificity (Sp). Se refers to the AED's ability to detect life-threatening ventricular arrhythmias. Sp refers to the AED's ability to detect normal sinus rhythms or arrhythmias that should not be shocked.

The American Heart Association (AHA) task force published a consensus document [1] reflecting the views of the AHA scientific members on AEDs SAS validation. This document is intended to supplement existing AED SAS performance requirements from the IEC standard [2].

Validation databases

The process of validation of SAS uses two independent ECG signals databases, one for learning and one for validation.

Each database is composed of recordings from Holter systems and SCHILLER Medical AEDs. Moreover, each database includes both adult and paediatric recordings.

The diagnostic bandwidth of Holter signals (0,05 to 150 Hz) has been limited to (0,5 to 30 Hz) so that the frequency content of the signals is typical of the one found in SCHILLER Medical AED recordings.

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Validation DBs	Recording method	Patient type	Number of patients	Number of 10 seconds ECG segments
PhysioNet MIT-VFDB [6]	Holter	Adult	21	567
IH DB	Holter	Paediatric 7 years IQR [5 to 8] years	47	69
OHCA DB	AED SCHILLER FRED EASY	Adult	733	1132
OHCA DB	AED SCHILLER FRED EASY	Paediatric 8 years IQR [0,5 to 16] years	188	275
All Databases			**989**	**2043**

Table 1: Summary of ECG databases used for SAS validation. MIT-VFDB is a subset of the general PhysioNet database recognised as the standard in ECG tests.

- Database (DB)
- Intra-Hospital (IH)
- Out-Of-Hospital Cardiac Arrest (OHCA)
- MIT-BIH Malignant Ventricular Arrhythmia Database (MIT-VFDB).

ECG Annotations

The rhythm annotation is performed by expert observation on 10 seconds of ECG segments/strips (one ECG channel). At least three expert decisions (for example, emergency physicians, experienced cardiologists, electro-physiologists, and biomedical engineers) are combined for a consensus rhythm annotation. The rhythm annotation follows the AHA classification scheme [1], defining the following rhythm types:

Shockable rhythms

- VF is coarse Ventricular Fibrillation (> 200 µV peak-to-peak amplitude)
- VThi is rapid Ventricular Tachycardia (Heart Rate-HR > 150 bpm, rushes that last more than 8 seconds).

Non-shockable rhythms

- Asystole as asystole (peak to peak amplitude ≤ 100 µV) during more than 4 seconds
- NSR as Normal Sinus Rhythm (P-QRS-T waves visible, HR > 40 bpm and HR < 100 bpm).
- N as another non-shockable rhythm (includes all rhythms except those in other listed categories:
  - For example, Atrial Fibrillation/Flutter (AF), Sinus Bradycardia (SB), Supraventricular Tachycardia (SVT), Premature Ventricular Contractions (PVCs), Heart Blocks (HB), as mentioned in [1].

Intermediate rhythms

- VT lo as other Ventricular Tachycardia (HR > 40 bpm and < 150 bpm, more than 3rushes).
- Fine VF as fine VF (peak-to-peak amplitude > 100 µV and ≤ 200 µV) during more than 4 seconds.

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SAS Performance

The performance of SAS shown in the tables below is above expectations according to AHA recommendations [1] and the IEC standard [2]. Thereby, SCHILLER AEDs embedded SAS are effective and for patients.
The algorithm's performance is evaluated by comparing the SAS decision with the consensus diagnosis of three expert annotators.

An interpretation table is built and shows:

- The True Positive (TP) is a correct classification of a shockable rhythm.
- The True Negative (TN) is a correct classification of a non-shockable rhythm (Asystole or N or NSR).
- The False Positive (FP) is a non-shockable rhythm (Asystole or N or NSR) that has been incorrectly classified as a shockable rhythm.
- The False Negative (FN) is a VF or VThi that has been incorrectly classified as non-shockable.
- The sensitivity (Se) of the device for shockable rhythms is:
  - Se_VF = TP/(TP + FN), applied to VF rhythms
  - Se_VThi = TP/(TP + FN), applied to VThi rhythms.
- The True Predictive Value (TPv) is the probability that a shock is needed when it is recommended by the AED:
  - TPv = (TP)/(TP + FP) applied to both VF and VThi results.
- The Specificity (Sp) of the device for non-shockable rhythms is:
  - Sp_NSh = TN/(FP + TN)
- The False Positive Rate (FPr) is:
  - FPr = FP/(FP + TN), applied to non-shockable rhythms.

The test sample sizes proposed per category reflect a balance between reasonable confidence in performance and realistic limits on data available to demonstrate it. The minimum sample sizes defined to reach significant results may be exceeded. The 90% single-sided lower confidence limit (LCL 90%) is one parameter to measure this significance. For each rhythm category, the LCL 90% should be calculated based on test results. This process will give a 90% probability that the actual performance is greater than the lower confidence limit calculated. In other words, this value indicates if the computed Sensitivity (Se) and Specificity (Sp) have a low enough disparity in accordance with the number of analysed segments.

For each category, the observed test results, Sensitivity (Se), Specificity (Sp) and LCL 90% must equal or exceed the performance goal.

Rhythms	Minimum test sample size	Test sample size	Performance goal		Observed performance	
			Se, SP (%)	LCL 90%	Se, SP (%)	LCL 90%
VF	200	571	Se > 90%	> 87%	Met [1]	Met [1]
VThi	50	213	Se > 75%	> 67%	Met [1]	Met [1]
NSR	100	118	Sp > 99%	> 97%	Met [1]	Met [1]
N	30	452	Sp > 95%	> 88%	Met [1]	Met [1]
Asystole	100	634	Sp > 95%	> 92%	Met [1]	Met [1]
		Intermediate rhythms				
VT Io	25	26	Report only	Report only	> 10% shocked	NA
Fine VF	25	29	Report only	Report only	> 40% shocked	NA

Table 2: Performance for SAS (VFDetectClean V2.031) as required by AHA (Artefact Free ECG samples) [1].

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	VF	VThi	Non-shockable rhythms NSR/N/Asystole
Shock	546	204	9
No Shock	25	9	1195
Performance goal	Sensitivity > 90%	Sensitivity > 75%	Specificity > 95%
Observed performance	Met [2]	Met [2]	Met [2]
Additional performance without a goal			
True predictive value	> 90%		NA
False positive rate	NA		< 5%

Table 3: Performance for SAS (VFDetectClean V2.031) as required by IEC standard (Artefact Free ECG samples) [2].

- Not Applicable (NA)

SAS Configuration

The SAS embedded in the device can be configured as analysis with anteriority. This SAS setting uses a combination of algorithms launched in two stages [3-5] to deliver a shock advisory decision at a minimal delay after the end of chest compressions. The SAS configured as analysis without anteriority starts a chest compression-free VF detection at an analysis request without trying to optimise hands-off time. The SAS does not analyse after a shock-advised decision is reached in both configurations.

References

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[2]: Standard IEC 2010 60601-2-4, ed 3
[3]: Didon, Jean-Philippe, Vessela Krasteva, Sarah Menetre, Todor Stoyanov, et Irena Jekova. 2011.«Shock Advisory System with Minimal Delay Triggering after End of Chest Compressions: Accuracy and Gained Hands-off Time». Resuscitation, Proceedings of the Eleventh Wolf Creek Conference, 82 (décembre): S8-15. https://doi.org/10.1016/S0300-9572(11)70145-9.
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[6]: Greenwald, Scott D. 1992. «The MIT-BIH Malignant Ventricular Arrhythmia Database ». physionet.org. https://doi.org/10.13026/C22P44.

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11.4.1 ECG HR Display

The ECG wave and the heart rate can be optional displayed for the semi-/fully automatic AED. With the manual AED this setting is by default on. This option is only for qualified medical personnel trained for Advanced Cardiac Life Support (ACLS).

Patient cable	Defibrillation Pads
Heart rate	
Range	• 30 to 250 beats/minute
Sensitivity	Fixed gain 10 mm/mV and sweep speed 12.5 mm/s
Suppression of large T-waves	Maximum amplitude of T-wave according to IEC 60601-2-27 section 201.12.1.101.17: 0.87 mV
ECG amplifier	
Frequency range	1 to 25 Hz

⚠ WARNING

▲ The ECG signal and heart rate display have been tested against the IEC 60601-2-27. The minimum detection range of QRS amplitude is 0.5 mV to 5 mV for durations of the QRS wave between 40 ms and 120 ms for all patients. Due to the design and the application as a defibrillator ECG amplifier, the HR display outside this QRS amplitude detection range or HR higher than 250 bpm might differ. However, these limitations are not relevant for use in determining a shockable or non-shockable rhythm.

▲ Therefore:

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

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11.5 WLAN standard

Module	NORAW36600B
FCC ID **IC ID**	XPYNORAW3 8595A-NORAW3
Transmission standards	Combined 2.4 GHz / 5 GHz Wi-Fi 802.11a/b/g/n (2.4 GHz Bluetooth LE 5) not used
Frequency range	2412 - 2.484 MHz WiFî 5158– 5825 MHz WiFi (2.400 - 2.4835 MHz BT) not used
Max. power output	+21 dBm

11.6 Charging unit

Device name	CS- 2 Charger
Dimensions	42 x 140 x 130 mm (h x l x w)
Weight	0.900 kg
Charger power supply	
Input	24 VDC, 65 W
Output	12.6 VDC, 5 A
External Power supply	
Input	100 - 240 VAC, 50-60 Hz, 65 W
Output	24 VDC, 2.7 A
Ambient conditions	
Operation	• 0... 40°C, relative humidity of 0...95% (non condensing)
Transport	• -10... 40°C, relative humidity of 10...95% (non-condensing)
Storage	• -10... 60°C, 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

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11.7 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	• -5°C... 50°C relative humidity at 10 - 95% (non condensing)
Transport / Storage	• -10...50°C / +5...50°C, humidity 10...95% (non condensing), pressure 500...1060 hPa.
For Transport and storage between uses	• -40... 70°C, relative humidity of 10...95% (non-condensing) Atmospheric pressure 500...1060 hPa (5000 m to -400 m) 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/Lifetime	500,000 compressions/8 years with respect to the Council Regulation EU 2017/ 745 Annex I, Requirement 6.
Dust and water protection	IP66
Protection class	Type BF defibrillation proof

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11.8 Electromagnetic interferences

The **FRED easyport plus** is intended for use in the electromagnetic environment specified below. The customer or the user of the **FRED easyport plus** should assure that it is used in such an environment.

11.8.1 Electromagnetic emissions

Emission measurement	Compliance with the regulations	Electromagnetic environment - explanations
RF emissions CISPR 11	Group 1	**FRED easyport plus** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	**FRED easyport plus** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Not applicable	
Voltage fluctuations IEC 61000-3-3	Not applicable	

11.8.2 Electromagnetic immunity

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV between conductors ± 2 kV conductor-earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180° 225°, 270° and 315° 0% UT; 1 cycle 70% UT; 25/30 cycles h) Single phase: at 0° 0% UT; 250/300 cycle	Not applicable	No mains power is used
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	100 A/m	Power frequency magnetic fields should be that of a typical commercial and/or hospital environment.
Proximity magnetic fields IEC 61000-4-39	30 kHz - 8 A/m 134.2 Khz -65 A/m 13.56 Mhz - 7.5	8 A/m 65 A/m 7.5 A/m	Proximity magnetic fields should be used not closer than 50 mm to any part of this device including cables.

Note: U_T indicates the AC voltage of the mains before the test level.

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Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
			Recommended minimum distances Portable and mobile HF telecommunication devices must keep the recommended minimum distance from the **FRED easyport plus** and all its components, incl. cables; the recommended minimum distance is calculated based on the transmitter's frequency.
Conducted HF IEC 61000-4-6	3 Vrms outside ISM band 6 Vrms in the ISM & amateur radio band 150 kHz to 80 MHz [a]	$[V_1]$ = 3 Vrms $[V_1]$ = 6 Vrms	$d = \frac{3.5}{V_1} \times \sqrt{P}$
Radiated HF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = \frac{12}{10} \times \sqrt{P}$ between 80 MHz and 800 MHz $d = \frac{23}{10} \times \sqrt{P}$ between 800 MHz and 2700 GHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	see section 11.8.3	see section 11.8.3	Minimum recommended distance to wireless communication equipment to this tested frequencies is 0.3 m. where P is the maximum transmitting power of the transmitter in Watt (W) according to manufacturer data, and d the recommended minimum distance in metres (m)[b]. The field strength of stationary HF transmitters (according to an on-location measurement [c]) must not exceed the conformity level for each frequency range [d]. When operating the device near devices bearing the symbol "ionising radiation", interferences can occur. 

Note 1 For 80 MHz to 800 MHz, the higher frequency range applies.
Note 2 These guidelines might not always be applicable. Electromagnetic radiation is influenced by absorption and reflection on structures, objects and people.

a. The ISM frequency bands (ISM = industrial, scientific, medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
The amateur Frequency band are: 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz,28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

b. The conformity levels within the ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz serve to minimise the probability of interferences caused by mobile/portable communication equipment that accidentally happens to be in the patient environment. The formula for the calculation of the recommended distance has been adapted by the factor 10/3 for transmitters in this frequency range.

c. The field strength of stationary transmitters, e.g. base stations for radio telephones (mobile or cordless) and portable radio equipment, amateur radios, AM and FM radios and TV signals cannot be predicted accurately in a theoretical way. In order to analyse electromagnetic environments caused by stationary HF transmitters, an electromagnetic analysis on site should be considered. If the measured field strength exceeds the HF conformity level, it needs to be checked whether the **FRED easyport plus** can be used in this environment. If an abnormal behaviour is detected, additional measures need to be taken, e.g. reorientation or change of location of the **FRED easyport plus**.

d. For the frequency range between 150 kHz and 80 MHz, the field strength must be lower than 3 V/m.

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11.8.3 Immunity to proximity fields from RF wireless communications equipment

Test frequency [MHz]	Band[a] [MHz]	Service	Modulation	max. power P [W]	Distance d [m]	Immunity level [V/m]
385	380-390	Various radio services (TETRA 400)	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430-470	- Walkie-talkies (FRS) - Rescue service, police, fire brigade, servicing (GMRS)	FM [c] ± 5 KHz ± 1 KHz sine	2	0.3	28
710 745 780	704-787	LTE band 13/17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800-960	- GSM800/900 - LTE band 5 - Radio telephone (microcellular) CT1+, CT2, CT3	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	- GSM1800/1900 - DECT (radio telephone) - LTE Band 1/3/4/25 - UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	- Bluetooth, WLAN 802.11b/g/n - LTE Band 7 - RFID 2450 (active and passive transponders and reading devices)	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11a/n	Pulse modulation 217 Hz	0.2	0.3	9

a.For some services, only the uplink frequencies are included.

b.The carrier shall be modulated using a 50% duty cycle square wave signal.

c.As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case

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11.8.4 Recommended separation distances

For fixed installed HF-Transmitters (z.B Radio und TV transmitters) the following minimum distance to the transmitter can be calculated as follows:.

Maximum Power Output [Watts]	Separation distance according frequency of the transmitter [m]	
	150 kHz to 80 MHz $d = \frac{3.5}{V_1} \times \sqrt{P}$	80 MHz to 3000 GHz $d = \frac{6}{E_1} \times \sqrt{P}$
0.01	0.04	0.06
0.1	0.11	0.19
1	0.35	0.6
10	1.1	1.9
100	3.5	6

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

Note 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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11.9 Literature

European Resuscitation Council (2021) Guidelines 2021 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

American Heart Association (2020) Guidelines 2020 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

11.10 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

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

CPR Cardiopulmonary resuscitation

VT Ventricular tachycardia

VF Ventricular fibrillation

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12 Revision history

12.1 Overview revision history

The table below shows the major changes and additions in each revision of this Service handbook.

Rev.:	Date:	Change description
a	21.02.2020	Initial release for software 1.0.0
b	8.07.2021	Update to new software 1.2.0 Detailed 1.10.2/1.10.3/1.10.4 /1.10.5 Update as Instruction for use and referring for other general symbols to IFU. 2.2.1 Update version 2.2.2 Improved table with the configurable settings 2.3.1 Add Key names PATIENT/SHOCK/COM 2.5.1 Add info Time for selftest 2.5.2 Add upload to Server point 4. 2.6.2 Add Warning disconnect electrode connector when replacing battery 2.7.1 Add caution battery test 2.7.2 Add disconnect electrode connector when replacing battery 2.7.4 Add pads expired chapter 2.7.5 Add chapter 2.8 Add chapter 2.8.3 Technical error messages and High prio alarms 3 Add new information automatic transmission 3.2.3 Add information of new automatic transmission 3.2.4 New chapter automatic transmission 4 Update Configuration 4.1 Update configuration overview 4.2.2 Update CPR setting 4.2.3 CPR feedback add pediatric 4.2.4 Add new chapter Communication 4.2.5 Add new chapter Transmission mode 4.2.6 Add new chapter Parameter in the device setting menu 4.3.2 Add maintenance date and monitoring enable parameter 7.1.1 Update Self life 7.3.1 Split information rechargeable/non rechargeable battery 7.3.3 Update information 7.3.4 Update information 7.4 Update Measurement test according production test procedure inc. test 150/200 and 50 for children 7.6 Update table wit new criterias from 7.4 9.1 Add battery life at low temp (-5°C); Add Note: The environmental conditions for the device depend on the electrode and are determined by it)" Add battery environmental condition for battery and Electrodes separately (bottom page 66) 9.3 Add additional graphic plot Add semi/fully for cycle time Add addition info Safety discharge e.g motion detected 9.5 Add for indoor use only 9.6 Add Note: The environmental conditions for the device depend on the electrode and are determined by it)" Add this section 10
c	20.09.2022	Update new condensator and battery holder (FEP+1.2.3) 8.2.3 Battery holder assembly (SAGCM-117 Battery lock improvement) 8.2.4 Updated/add following -4.812110 HV condensator 200J by 4.812 114 -4.450521 Foil condensator by shrink hose 4.530135 -4.310731 Battery holder with screws 12 mm 4.910253 8.2.5 Replaced explosion diagram
d	20.07.2023	Update address manufacturer Update according instruction for use 2.511297 8.1.1/8.1.2 Add disposable information 8.2.3 Add internal battery replacement
e	29.08.2024	Update Service manual under MDD valid for Software 1.2.4 or higher Structure and Look&Feel aligned to IFU 2.511279 New cross-Reference element §11.8.2 Add information Proximity magnetic fields IEC 61000-4-39 and add missing table for immunity on the following page

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Rev.:	Date:	Change description
e01	15.04.2025	Update Service manual under MDD valid for Software 1.3.0 or higher -General updated new WLAN module. Bluetooth not used and menu BT is disabled. -Deleted Chapter 4.2 Retrieving data via Bluetooth bridge (BT) and replaced it with 4.3 Retrieving intervention data via WLAN -Changed Chapter numbering 4.1.1 Retrieving intervention data via USB to Chapter 4.2 -Title page back mentioning "The FRED easyport plus Service manual is valid for the following devices: FRED easyport plus DEFISIGN POCKET PLUS (SAGCM-1165) 2.4 Add WLAN Status display 4 Add Cybersecurity information and safety notes SAGCM-1547 4.1 Update transmission menu without BT 4.2 4.3 Changed Title to WLAN 4.3.1 Add new sub chapter with cybersecurity safety notes SAGCM-1547 4.3 Export configuration to a USB mass storage device SAGCM-1188/SAGCM-1195 4.4 Import configuration from a USB mass storage device SAGCM-1188/SAGCM-1195 4.5 Add new chapter Import Configuration via SDM 8.3 Update Communication with WLAN settings and other helpful infos 10.5.2 Add new chapter Foil/keypad replacement (SAGCM-1165) 11.2 Add RED Statement 11.5 Changed BT to new WLAN module NORAW36600B (BT is not used) Minor changes to reflect 2-wire ECG cable 6.2.3 Visual inspection 6.6 Inspection report 8.4.2 Menu Monitoring to ECG signal mode
e02	1.04.2026	2.2 delete recoil restriction note 8.3.3 Set default recoil to YES 9.3 Add chapter "Setup new LCD with older device" replacement new LCD for older devices 11.7 Lifepoint sensor transport/Storage condition from 75 to 70 °C

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