FRED PA-1

Automated External Defibrillator (AED)

User Guide

SCHILLER
The Art of Saving Lives

Art. no: 0-48-0240 Rev. h

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:

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CE 0459

The **FRED PA-1** bears the CE-0459 mark (Notified Body GMED), indicating its compliance with the general safety and performance requirements of Annex I of the Medical Device Regulation (EU) 2017/745 regarding safety, functionality, and labelling. The requirements apply to patients, users, and third persons who come into contact with this device within the scope of its intended use. First declaration xxxxx.

The summary of safety and clinical performance is available on the EUDAMED website.

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1 Safety Notes

1.1 User Profiles

The following persons may use the **FRED PA-1**:

- **BLS** Qualified medical personnel trained for Basic Life Support (BLS), semi-automatic defibrillation, and Cardiopulmonary Resuscitation (CPR) on the **FRED PA-1** may use the Automated External Defibrillator (AED) operating mode of the **FRED PA-1** in semi-automatic or fully automatic mode.
- **Laypersons** trained in BLS and the **FRED PA-1**, may use the AED operating modes of the **FRED PA-1** in semi-automatic or fully automatic mode.
- **Laypersons**, even though training and instructions are recommended to guarantee an optimal resuscitation procedure.

Laypersons must contact healthcare professionals (such as emergency services) immediately when they start to use the **FRED PA-1**.

1.2 Intended Use

1.2.1 General intended purpose

The **FRED PA-1** is intended for cardiac arrest management:

- Defibrillation (automatic, semi-automatic, or manual) of patients presenting shockable Electrocardiography (ECG) rhythms.
- Provide CPR guidance.

Target population

The **FRED PA-1** can be used for:

- Adult and paediatric older than 8 years old or weighing more than 25 kg.
- Paediatric from 1 year old to less than 8 years old or less than 25 kg
- Paediatric younger than 1 year old.

The portable **FRED PA-1** is intended to be used in the following environments:

- Pre-hospital care
- Patient’s homes
- Public
- Workplaces

1.2.2 General warnings and precautions for use

Responsibility of the user

- Regulations on who is allowed to use devices like the **FRED PA-1** and which training is required are country-specific. In any case, legal regulations have to be observed.
- Before using the device, a SCHILLER representative must perform a presentation on the device's operation and safety measures if the local regulations require it.
- The numerical and graphical results and any interpretation given must be examined with respect to the overall clinical condition of the patient and the general recorded data quality.
- Damaged or missing components must be replaced immediately.

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- The **FRED PA-1** must be stored in a place inaccessible to children.
- Properly dispose of the packaging material and make sure it is out of reach for children.
- The **FRED PA-1** is an emergency device and must be ready for operation at any time and in all situations.

Check that:

- The **FRED PA-1** is always equipped with a sufficiently charged battery
- Always keep a new spare battery on hand
- An empty battery must not be reused and must be disposed of immediately
- A set of adult electrodes is pre-connected, and a spare set of electrodes can be stored with the device.
- If any serious incident has occurred in relation to the **FRED PA-1**, it should be reported to the manufacturer and the competent authority of the Member State in which the user or patient is established.

Organisational measures

- Before using the **FRED PA-1**, ensure that an introduction regarding the **FRED PA-1** functions and the safety precautions have been provided and understood.
- Keep these operating instructions in an accessible place for reference when required. Check that they are always complete and legible.

Safety conscious operation

- **Danger of electric shock.** Danger for the user, rescuer, and patient. The energy applied to the patient can be conducted through the patient to other persons, who may suffer a lethal electric shock. Therefore:
  - Do not touch the patient, the electrodes, or other conducting objects during defibrillation.
  - Do not defibrillate the patient in a puddle of water or on other conducting surfaces.
  - Switch the **FRED PA-1** off when it is no longer used.
- **Danger of explosion.** The **FRED PA-1** must not be used in areas where there is a danger of explosion. There might be a danger of explosion in areas where flammable products (petrol), flammable anaesthetic agents, or products for skin cleaning/disinfection are in use or where the ambient air's oxygen concentration is higher than 25%.
- Immediately report any changes that impair safety (including operating behaviour) to the responsible person.
- Only use original SCHILLER electrodes and accessories.
- Check that the **FRED PA-1**'s casing and electrode connections are not damaged.
- Check the expiration date of the defibrillation electrodes on the packaging.
- After use; refer to Chapter 6 Maintenance
- Immediately replace a damaged **FRED PA-1** or damaged cables and connections.
- Operating the **FRED PA-1** with a defective casing or damaged cables constitutes a danger to life.
- Only operate the **FRED PA-1** in accordance with the specified technical data. Refer to Chapter 7 Technical Data
- Do not operate the **FRED PA-1** in ambulances and emergency vehicles in movement.

1.2.3 Defibrillation function

Intended purpose

The **FRED PA-1** is intended to be used to terminate cardiac arrhythmias classified as shockable with a high voltage defibrillation shock (automatic or semi-automatic external defibrillation).
In AED mode, **FRED PA-1** provides a prompted cardiopulmonary reanimation protocol combined with ECG analysis periods. The Shock Advisory System (SAS) delivers information on whether a shock needs to be delivered or not.

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The **FRED PA-1** provides advice for cardiopulmonary reanimation through several means depending on the device configuration:

- **Metronome.** The **FRED PA-1** prompted a regular sound to guide the rescuer to perform a chest compression at the rate recommended by the international guidelines.
- **FreeCPR.** This option is used as a guide in the practice of CPR for patients with suspected cardiac arrest, where CPR can be performed with the heel of the hand. It provides real-time feedback on the performed CPR compression rate based on impedance measurement by the defibrillation electrodes and the recommendations of the international guidelines.

In semi-automatic mode, the user interaction is required to deliver the shock. Whereas, in fully automatic mode, the user interaction is not required to deliver the shock. With the online version, **FRED PA-1** can transmit post-intervention information using a 4G network.

1.3 Medical Indications

▲ The **FRED PA-1** is intended to be used to terminate cardiac arrhythmias classified as shockable with a defibrillation shock.

▲ In the standard chain of survival, which concerns both non-shockable and shockable ECG rhythms patients, **FRED PA-1** is designed to provide the user with guidance to perform CPR.

▲ Notes:

– Shockable ECG rhythms: Ventricular Fibrillation (VF) and pulseless Ventricular Tachycardia (VT).

– Non-shockable ECG rhythms: asystole, Pulseless Electrical Activity (PEA), or any other type of rhythm.

1.4 Clinical Benefits

Expected patient benefits: Cardiac Arrest

Defibrillation

▲ Defibrillation needs to be delivered in case of VF and pulseless VT. Overall survival to cardiac arrest is dismal (usually lower than 10%). It is consistent to focus on a shorter-term outcome for defibrillation, namely the removal of fibrillation right after an electric shock. Learned societies do not define the expected success of electric defibrillation. SCHILLER Medical defines it according to the bibliographic state-of-the-art. It is aimed to be > 80% at 5 seconds post-shock (150 or 200 joules).

SAS

▲ The performance (sensitivity) and safety (specificity) of the SAS are driven by IEC Standard 60601-2-4 (International Electrotechnical Commission and IEC 2018) and learned societies (AHA) consensus (Kerber et al. 1997). In summary, sensitivity for shockable rhythms VF should be higher than 90%, and specificity for non-shockable rhythms should be higher than 95%.

CPR

▲ The **FRED PA-1** provides information for the rescuer to know when to perform CPR. CPR is monitored so that the rescuer is guided to follow the guidelines (ERC, AHA). The global performance related to CPR fully depends on the rescuer's skills.

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1.5 Contraindication for Use

▲ The **FRED PA-1** is not intended for patients who are not in cardiac arrest:

AED mode

▲ The defibrillator must not be used when the person:
- Is responsive
- Is breathing normally
- Has a pulse

CPR feedback

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

Other contraindications

▲ Do not use the **FRED PA-1** in or near Magnetic Resonance Imaging (MRI) equipment.

▲ **Danger of explosion.** The **FRED PA-1** must not be used in areas where there is any danger of explosion. There might be a danger of explosion in areas where flammable products (petrol), flammable anaesthetic agents, or products for skin cleaning/disinfection are in use or where the ambient air's oxygen concentration is higher than 25%.

▲ The **FRED PA-1** is not intended to be used in ambulances and emergency vehicles in movement.

▲ The **FRED PA-1** is not designed for sterile use.

1.6 Operation with other Devices

▲ Magnetic and electrical fields from x-ray or tomographic devices, portable radio equipment, HF radios, and devices labelled with the  symbol can affect the operation of this device (refer to section 7.6 Electromagnetic Interferences). Avoid using such devices or keep a sufficient distance from them.

▲ **FRED PA-1** is not intended to be operated while using high-frequency surgical devices.

▲ **Interference with other devices.** The charging of energy and the release of the defibrillation impulse can disturb other devices. Check these devices before their further use.

▲ Other medical equipment applied to a patient that has no defibrillation proof applied part must be disconnected from the patient.

▲ The patient can be endangered by too high leakage currents (summation of leakage currents) if several devices are connected to the patient. For this reason, devices that are not required should be disconnected from the patient, and only equipment approved by SCHILLER may be connected to the **FRED PA-1**.

▲ If the patient has a pacemaker implanted, do not position the electrode directly onto the pacemaker. Check the pacemaker after the defibrillation.

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1.7 Maintenance and Cleaning

- ▲ **Danger of electric shock.** Do not open the **FRED PA-1**. There are no serviceable parts inside. Refer servicing to qualified personnel only.
- ▲ Do not service, maintain, or clean the **FRED PA-1** while in use with a patient.
- ▲ Before cleaning, switch the **FRED PA-1** off and remove the battery.
- ▲ Do not use high-temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- ▲ Do not use aggressive or abrasive cleaners (refer to section 6.2 Cleaning and Disinfecting).
- ▲ Do not, under any circumstances, immerse the **FRED PA-1** or cable assemblies in liquid.
- ▲ To ensure patient safety, only use original SCHILLER accessories. The user is responsible for the use of third-party accessories. The warranty does not cover damage resulting from the use of accessories or consumables other than those marketed by SCHILLER.

1.8 Known Side Effects

- Defibrillating a patient can cause:
  - Skin irritations or burns
  - Malfunction or damage of implanted pacemaker

1.9 General Notes for the FRED PA-1

A defibrillation can fail with certain disease patterns.

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1.10 Cybersecurity

1.10.1 Networks and internet

- ▲ The security of the network is the sole responsibility of the user.
- ▲ When the **FRED PA-1** 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 PA-1** network from other networks
  - – Defining access authorisation for the configuration of the host system, including the **FRED PA-1**, so that no unauthorised alterations of the system are possible.
  - – Use Transport Layer Security (TLS) 1.2 or higher for communication with system server and SDM server.
- ▲ If the connection between the **FRED PA-1** and the server is bad or loss, this can result in an impossible analysis of post-intervention data. The user should identify, analyse, evaluate, and control these risks related to the connection to networks.
- ▲ 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 (additional) items
  - – Update/upgrade of the **FRED PA-1**

1.10.2 Patient data (personal data)

- ▲ Patient data security is the sole responsibility of the user. Therefore:
  - – Delete personal data (intervention file) before sending the device for repair or maintenance.
  - – If the device has been sent to SCHILLER with personal data, the data is deleted before starting the repair or maintenance process.

Exception investigation in case of incident reporting

- ▲ If the **FRED PA-1** is sent for investigation in case of incident reporting, the intervention data are very important to detect the cause. Therefore:
  - – The **FRED PA-1** can be sent to SCHILLER by the responsible organisation with personal data
  - – The intervention file with the personal data can be exported if possible (refer to section 5.1.1 For standard FRED PA-1 with an SD card) and sent to SCHILLER by the responsible organisation.
  - – After the investigation, SCHILLER confirms that all personal data has been deleted from services, applications, and the **FRED PA-1**. The **FRED PA-1** is returned to the customer without any personal data.

1.10.3 Setup security guidance

- ▲ For the online version prefer network communication rather than SD card for updates
- ▲ Do not use a self-signed certificate on the server.
- ▲ For networks and the internet; refer to section 1.10.1 Networks and internet

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1.11 Additional Terms

1.11.1 Implied authorisation

Possession or purchase of the **FRED PA-1** does not convey any express or implied license to use the **FRED PA-1** with replacement parts which would alone, or in combination with the **FRED PA-1**, fall within the scope of one or more patents relating to the **FRED PA-1**.

1.11.2 Terms of warranty

Your SCHILLER **FRED PA-1** is warranted against defects in material and manufacture according to 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 **FRED PA-1** 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:

- Persons authorised by him are to carry out assembly operations, extensions, readjustments, modifications, or repairs,
- Spare parts used for assembly operations, extensions, readjustments, modifications, or repairs are recommended or supplied by SCHILLER.
- The SCHILLER **FRED PA-1** and approved attached equipment are used in accordance with the manufacturer's instructions.

There are no express or implied warranties that extend beyond the warranties herein/above 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 10 years from the date the last **FRED PA-1** was placed on the market.

1.11.3 Reporting security incidents and vulnerability disclosure policy

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

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1.12 Symbols and Indicators

1.12.1 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. Danger, Warning, and Caution are used in this user guide to point out potential dangers and indicate risk levels. Familiarise yourself with their definitions and significance.

⚠ DANGER	This symbol warns of possible direct danger, which could lead to severe personal injury or death.
⚠ WARNING	This symbol warns of a possible dangerous situation that could lead to severe personal injury or death.
⚠ CAUTION	This symbol warns of a dangerous situation that could lead to personal injury and/or indicate possible property damage.

For general safety notes as listed in this section.

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

This symbol warns of dangerous situations that could damage property or system failure and provides other important user information.

1.12.2 Symbols used on the FRED PA-1

For generally used symbols; refer to Chapter 9 Appendix - Symbols

BF symbol. The **FRED PA-1** signal input is defibrillation-protected.

Dangerous voltage. Used for electrical dangers during defibrillation.

Notified body of the CE certification (GMED).

Symbol for the recognition of electrical and electronic equipment.

- The **FRED PA-1** must be disposed of in a municipally approved collection point or recycling centre when it is no longer required.
- Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.

Identification of the manufacturer

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Manufacturing date

Observe the user guide

IP55

The **FRED PA-1** is protected against dust and spraying water from all directions.

Devices with a cellular connection

Attention. Non-ionising electromagnetic radiation. The **FRED PA-1** contains an HF transmitter.

The **FRED PA-1** radiates high-frequency electromagnetic energy during telemetric ECG data transfer and can disturb other devices if not installed and operated in accordance with the user guide.

However, even in the case of correct installation/operation, there is no guarantee that no interferences can occur.

If the **FRED PA-1** causes interferences, these can be prevented by switching it off.

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

- Increase the distance between the disturbed device and the **FRED PA-1**. A minimum distance of 20 cm must be kept between the **FRED PA-1** and a pacemaker.
- Turn the **FRED PA-1** to change the antenna's angle of radiation.

For more details; refer to section 6.6 Electromagnetic Interference.

Indicates that the **FRED PA-1** is a medical device

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1.12.3 Symbols used on the batteries


The battery is recyclable

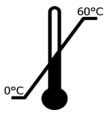

MM/YY Primary Lithium Manganese dioxide (Li-MnO_2) battery, non-rechargeable.


Do not short-circuit


Do not dispose of it in a fire


Do not open or dismantle


Do not deform or damage



Minimum/maximum discharging temperature for Lithium/MnO_2 battery

Note: Storage at maximal discharging temperature increases the self-discharge of the battery.


Batteries must not be disposed of with domestic refuse.


Observe the user guide


YYYY-MM Expiry date of the primary Li-MnO_2 battery.

Reference number


Identification of the manufacturer


Notified body of the CE certification (GMED)

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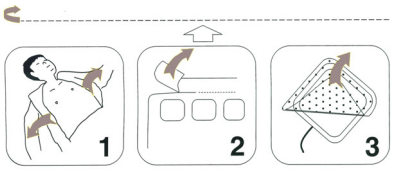
1.12.4 Symbols used on the electrode packaging

For generally used symbols; refer to Chapter 9 Appendix - Symbols

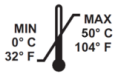


- Remove the patient's clothes.
- Open the electrode packaging.
- Peel off the protective foil.

Do not reuse

Do not bend packaging

Do not use if packaging is damaged



Storage temperature for the electrodes

Expiry date of the electrodes

An open package cannot be conserved for more than one day.

Do not expose to sunlight

Do not expose to rain/humidity

Identification of the manufacturer

CE-0408 marking notified body

For use by or on the order of a physician or person licensed by state law.

Reading this user guide is mandatory before using the electrodes.

The packaging is made of low-density polyethene and can be recycled.

2 Components and Operation

2.1 General Information

FRED PA-1 is an Automated External Defibrillator (AED).

The **FRED PA-1** is available as an automatic and semi-automatic 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 Emergency Medical Technicians or First Responders after they have undergone special training.

Highly frequented areas are typical places for the operation of a **FRED PA-1**. For example:

- Airports
- Train stations
- Shopping centres
- Public swimming pools
- Sport centres
- Public institutions

Biocompatibility

The parts of the **FRED PA-1** 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 in this matter, contact SCHILLER.

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2.2 Design

2.2.1 General design

Defibrillator

FRED PA-1 is a defibrillator featuring the Biphasic Truncated Exponential (BTE) waveform. The patient receives a defibrillation shock using disposable electrodes. The ECG signal is analysed using the same electrodes; in addition, the user is guided by voice prompts and pictograms (loudspeakers/LEDs next to pictograms). The **FRED PA-1** recognises the connected electrodes (adult or children electrodes) and selects the defibrillation energy accordingly. An RFID tag in the connector (for electrodes with article no. 0-21-0040) allows checking the shelf life of the electrodes when connected to the **FRED PA-1**.

Languages

The **FRED PA-1** can be provided with different languages. Optional configuration with 3 languages, selectable after switching the **FRED PA-1** on.

Metronome

The **FRED PA-1** emits a sound pace for CPR. The CPR rate is configurable.

FreeCPR (option)

A CPR Guide with FreeCPR based on the impedance measurement by the defibrillation electrodes.

Data memory

The **FRED PA-1** is equipped with an internal memory. During the intervention, data can, therefore, be saved, including the analysed ECG data. In addition, technical data (logs) are stored.

Data transmission

The **FRED PA-1** has an SD card slot in order to:

- Retrieve data via an SD card
- Perform software and configuration updates

The **FRED PA-1** online version has a cellular network connection to the LifeDataNet G2 Server for device pool management and intervention data transmission.

Power supply (standard)

The **FRED PA-1** is operated with a non-rechargeable, disposable lithium battery. The battery capacity is sufficient for (if the **FRED PA-1** is stored/used in optimal temperature conditions between 15 to 25°C):

- More than 140 shocks at maximum energy
- 4 hours and 30 minutes of continuous operation with intermittent charging.

For devices with an SD card

- Several years in standby Standby duration corresponding to laboratory tests at 25°C, 6 years with weekly self-tests.

For devices with cellular network

- Several years in standby. Standby duration corresponding to laboratory tests at 25°C, with a constant, good GSM connection and without antenna roaming, 3 years with weekly self-tests.

Self-test

To ensure its readiness for use, the **FRED PA-1** performs a daily, weekly, or monthly self-test (refer to section 6.1 Maintenance Intervals). Self-test includes a test of the charging circuit and battery capacity. If this test is completed successfully, the green Ready-To-Use (RTU) LED blinks (at two-second intervals), showing that the **FRED PA-1** has not detected an error.

Cellular network (option)

The **FRED PA-1** equipped with a cellular network is connected to the LifeDataNet G2 Server for device pool management and intervention data transmission.

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2.2.2 Available versions

Model	Description
FRED PA-1 Semi-automatic	AED Semi-automatic
FRED PA-1 Automatic	AED Fully automatic
FRED PA-1 Semi-automatic Online	AED Semi-automatic with 4G connection
FRED PA-1 Automatic Online	AED Fully automatic with 4G connection

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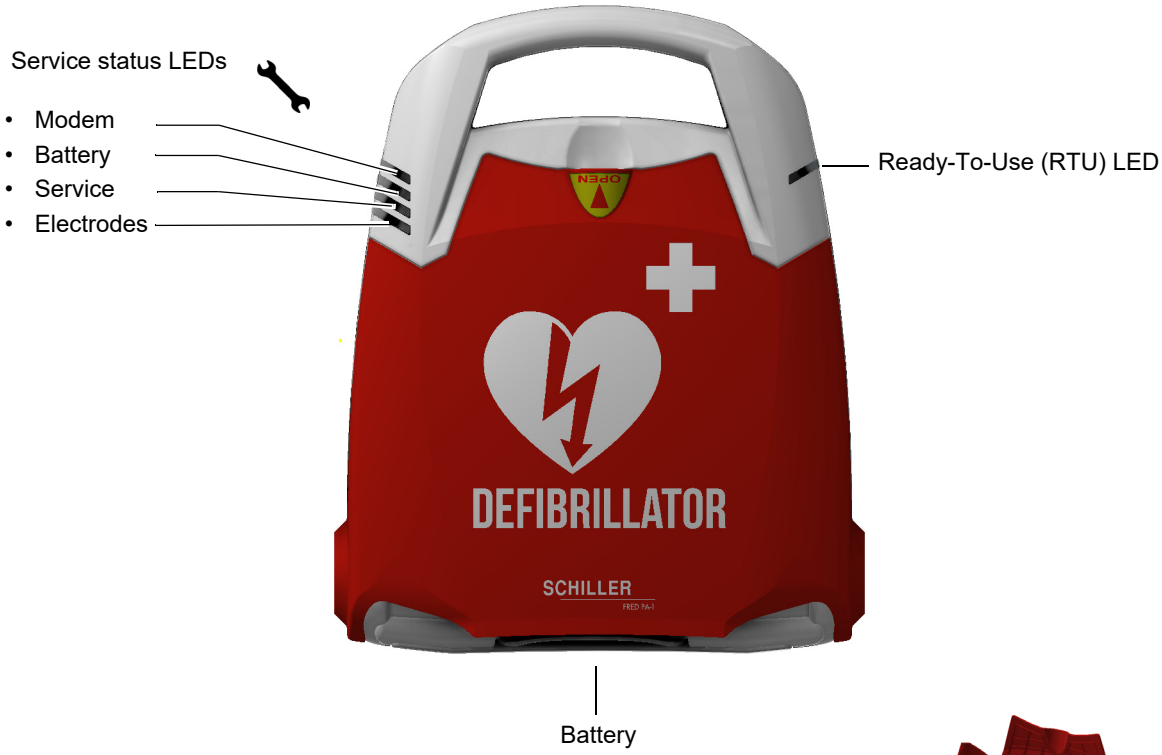
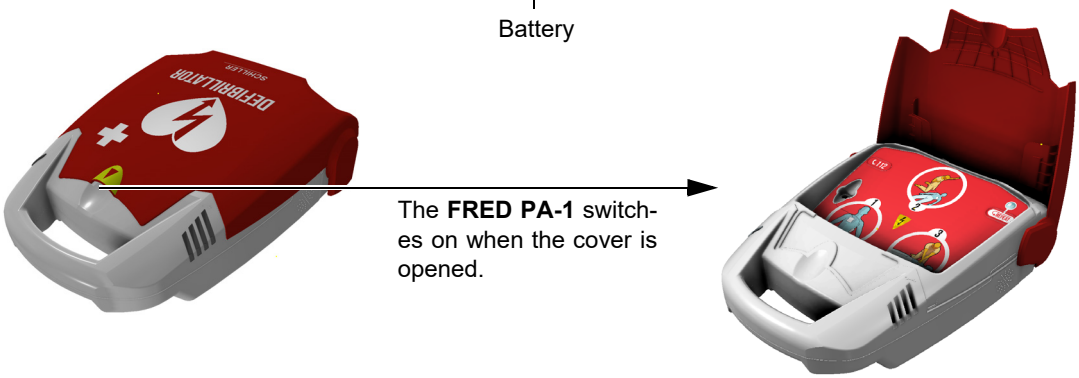
2.3 Operating and Display Elements

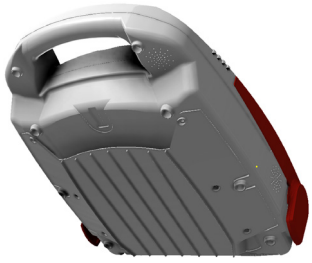
2.3.1 FRED PA-1 overview





The **FRED PA-1** switches on when the cover is opened.

Wall cradle



Compartment for additional electrode

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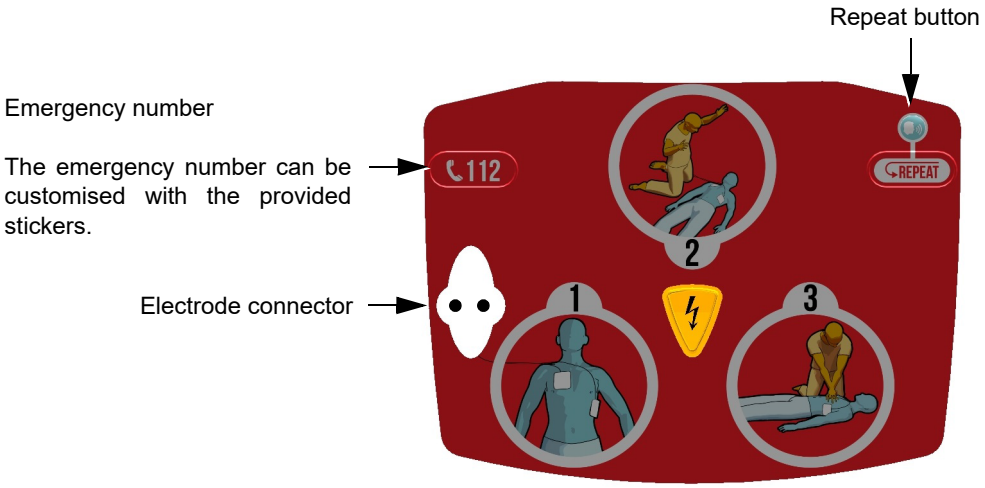
2.3.2 Operating elements

In addition to the voice prompts, the resuscitation steps are indicated by pictograms, and the current step is highlighted with a flashing LED.

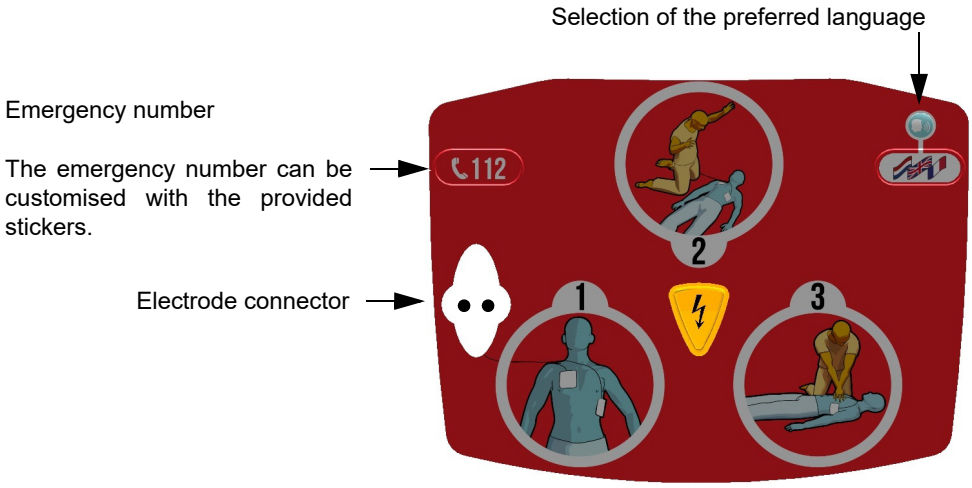
FRED PA-1 with one language

As soon the cover of the **FRED PA-1** is opened, the **FRED PA-1** starts issuing audio prompts. The last message is repeated when the **Repeat** button is pressed.



Multiple language FRED PA-1

As soon as the cover of the **FRED PA-1** is opened, the **FRED PA-1** starts issuing audio prompts in the default language. The two other languages can be selected at any time during the resuscitation procedure by pressing the button above the flag label.



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2.4 Function

2.4.1 Automatic self-test

Self-test includes the test of the charging circuit and the battery capacity.

Battery insertion

Immediately after a battery has been inserted, the **FRED PA-1** performs a test of the components and battery. If this test is completed successfully, the RTU LED is blinking, and all service status LEDs are off, showing that the **FRED PA-1** has not detected an error.

RTU Test

To ensure its readiness for use, the **FRED PA-1** performs a daily or weekly self-test at 12:00 AM. This setting must only be configured by service personnel authorised by SCHILLER (refer to section 6.1 Maintenance Intervals).

If a problem is detected during this test:

- An acoustic alarm is issued,
- The RTU LED stops blinking
- The service LEDs give additional information.

Fig. 2.1 LED indicator

Additional information

- If an alarm is in progress (visual and acoustic), the battery autonomy is reduced.
- In addition, the device performs a daily or weekly self-test (this setting must only be configured by service personnel authorised by SCHILLER)
- An alarm (visual and acoustic) can only be reset by removing and reinserting the battery.
- For the alarm details; refer to section 6.5.1 Error messages.

2.4.2 Defibrillation procedure

The user is guided through all operation steps by verbal instructions and the pictogram on the **FRED PA-1**. When the **FRED PA-1** is ready for shock delivery, the user is advised not to touch the patient, and a warning tone with the illuminated high voltage symbol is activated.

The FRED PA-1 runs in semi-automatic mode

This means that the user must release the shock. When the **FRED PA-1** is switched on, the user is prompted to apply the electrodes to the patient. Next, they are prompted not to touch the patient during the analysis phase. For the duration of the analysis; refer to section 7.3.1 Shock Advisory System (SAS). Depending on the result, the user is prompted to deliver a shock or to start with CPR.

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The FRED PA-1 runs in automatic mode

The **FRED PA-1** delivers defibrillation shocks automatically; that is, there is no need to trigger the shock. When the **FRED PA-1** is switched on, the user is prompted to apply the electrodes to the patient. Next, they are prompted not to touch the patient during the analysis phase. For the duration of the analysis; refer to section 7.3.1 Shock Advisory System (SAS). If a shock is advised, a countdown accompanies the last 3 seconds before the shock is automatically delivered.

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3 Initial Operation

3.1 General Information and Safety Notes

DANGER

Danger of explosion

- The **FRED PA-1** 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 enclosed areas, such as hyperbaric chambers.

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, or charge (Li/MnO_2 battery) a battery.
- Always use the protective cover when storing spare batteries.

Patient hazard incorrect battery capacity indication

- A new battery is initialised when first inserted
- Replace the battery if the **FRED PA-1** indicates a battery problem. A defective battery must not be used.
- Turn off the **FRED PA-1** before removing the battery.

CAUTION

Patient hazard ensuring operational readiness

- Check that the **FRED PA-1** 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 cap of the battery must remain on during the entire storage time. The protective cap must only be removed when the battery is used.
- Do not expose the **FRED PA-1** to direct sunlight or to extreme hot or cold. An ambient temperature higher than 25°C has an adverse effect on the battery life.

Each time the **FRED PA-1** is turned on, it checks that the battery is functioning properly.

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3.2 Inserting the Battery

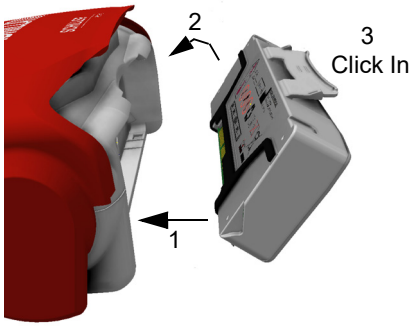


Fig. 3.1 Inserting the battery

Insert the battery as indicated in the illustration on the left.

1. Insert the two stop blocks located at the bottom of the battery in the **FRED PA-1** slots.
2. Perform a rotational movement until the battery locks in place.
3. As soon as the battery is inserted, the **FRED PA-1** runs a self-test to check the condition of the **FRED PA-1** and the battery.

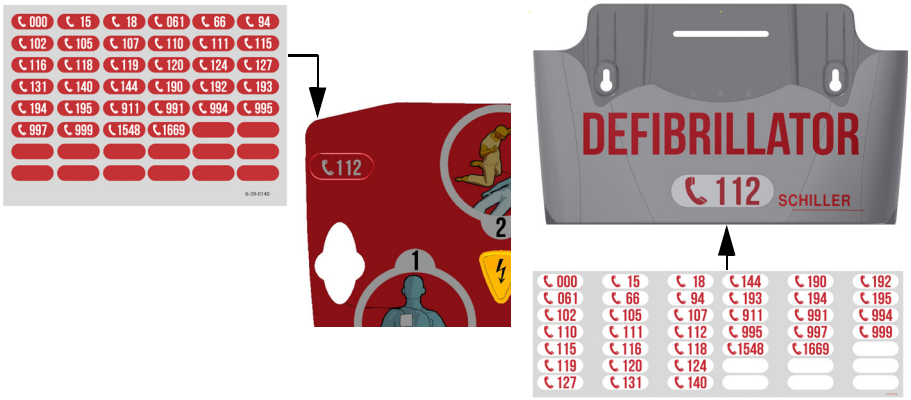
During the test, the modem LED is on, and the electrode LED is blinking. This test can last for more than 1 minute.

If this test does not reveal any problems, the RTU is blinking, and all service status LEDs are off, showing that the **FRED PA-1** has not detected an error.

If the **FRED PA-1** is used on a patient, this test can be cancelled by opening the cover.

3.3 Adding Emergency Number Stickers

If your country's emergency number differs, apply the sticker with the correct one.



3.4 Switching the FRED PA-1 On and Off

Switching ON → Open the cover. The 3 LEDs for the resuscitation steps are briefly lit.

Switching OFF → Close the cover.

Forced shutdown procedure
If the **FRED PA-1** cannot be switched off via the above procedure, remove the battery and reinsert it after 10 seconds.

⚠ CAUTION

▲ If a patient is detected while closing the cover, the **FRED PA-1** remains on, and the resuscitation process goes on.

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If the cover is re-opened within 30 seconds after closing, the device resumes the intervention.

3.5 Battery Monitoring

- The lithium battery ensures that the **FRED PA-1** stays fully operative (and performs the self-test) for several years (at a temperature of between 15 to 25°C), provided that the **FRED PA-1** is not being used.
- Battery service life depends on **FRED PA-1** 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.

3.5.1 Sufficient battery capacity

The RTU LED (green) on the **FRED PA-1** is blinking when the battery capacity is sufficient to perform the resuscitation protocol.

3.5.2 Low battery capacity indication

- Low battery capacity indication is the same during self-test, after the battery has been inserted, and during use.
- Despite the low battery indication, the **FRED PA-1** can still be used as normal and is still able to defibrillate.
- Always switch off the **FRED PA-1** before removing the battery.
- The remaining battery capacity depends on the use and ambient conditions.

If the battery capacity falls below 10%, the RTU LED (1) and the orange battery LED (2) blink. These indications are issued until the battery is replaced. The battery must be replaced as soon as possible.

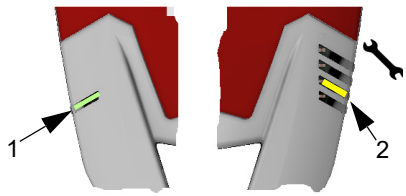

Fig. 3.2 Low battery indication

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3.5.3 Battery depleted during use, limited mode CPR

WARNING

Patient hazard

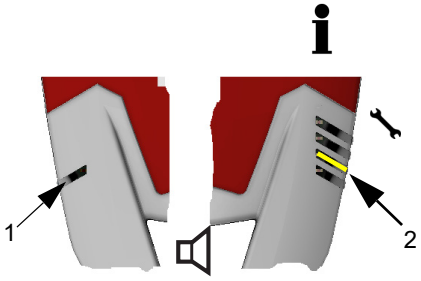
▲ Defibrillation is no longer possible if a depleted battery is detected. The battery needs to be replaced immediately.

Depleted battery while in use

The **FRED PA-1** prompts the user to replace the battery and perform CPR. An audible signal is emitted. The RTU LED is off, and the orange battery LED blinks until the battery is replaced.

Depleted battery during self-test

An audible signal is emitted, the main status LED (1) is off, and the battery LED (2) blinks until the battery is replaced.



Battery LED

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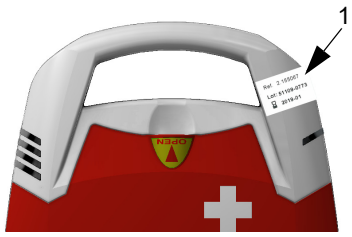
3.6 Replacing the pre-connected Pads

3.6.1 Expired pads

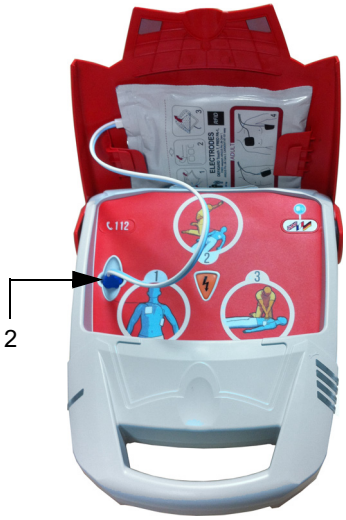
The **FRED PA-1** is delivered with pre-connected pads. To replace the pads after use or if the shelf life has expired, proceed according to the following instructions:

- Only use the pads up to their expiration date.
- Note that the expiration date of the pads only applies if the vacuum pack is intact.
- Do not reuse the pads.

3.6.2 Connect the electrodes



1. Remove the battery
2. Remove the sticker with the LOT/Expiration date from the electrode pouch and stick it above the RTU LED (1).



3. Open the cover.
4. Connect the electrode cable to the **FRED PA-1** (2)
5. Place the electrode pack in the cover and close the cover.
6. Check that the cover does not squeeze/compress the electrode cable or the electrode packaging when closed.
7. Insert the battery after closing the cover.
8. The **FRED PA-1** is ready for use when the RTU LED is blinking, and the service LEDs are off.

9. If requested, add a spare set of electrodes in the compartment on the **FRED PA-1** underside.

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4 Defibrillation

4.1 Instructions and Safety Notes

4.1.1 Instructions

- The **FRED PA-1** is a high-voltage electrotherapy device. Only personnel authorised by local law are permitted to use these devices. Improper use can endanger life.
- Non-medical personnel are only permitted to use an AED such as the **FRED PA-1** if local law approves of this practice.
- The success of the defibrillation depends not only on the correct application of the defibrillator but also on the heart's condition. It is the physician's responsibility to take any additional measures (for example, adrenaline).
- According to the AHA/ERC guidelines, even children under 8 years old may be defibrillated.
- The adult electrodes should be applied in the antero-lateral position when used on adult and paediatric patients older than 8 years old or weighing more than 25 kg. On paediatric patients weighing less than 25 kg or younger than 8 years old, it is recommended to apply the adult electrodes (surface area 80m²) antero-posterior. When defibrillating paediatric patients with paediatric electrodes (surface area 42 cm²), it is recommended to choose the antero-lateral position.
- A defibrillation can fail with certain disease patterns.

Patients with implanted pacemakers

- **FRED PA-1** features an electronic pacer pulse suppression algorithm, and therefore, pacemaker pulses are not considered during the analysis. Depending on the pacemaker model and the position of the electrodes, the compensation pulse following every pacer pulse may be considered a QRS complex. In this case, the analysis can be distorted and inaccurate. It depends on the pacer pulse parameters whether or not the compensation pulse is counted as a QRS complex.
- The required energy for a successful defibrillation depends on several parameters (body constitution). For emergency medical treatment, AHA/ERC recommends a biphasic impulse. Depending on configuration settings, the energy of the 3 first shocks can be increased.

4.1.2 Safety notes for defibrillation use

⚠ WARNING

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

Shock hazard for patients

▲ In unfavourable situations, the possibility of ECG analysis errors should not be dismissed. The **FRED PA-1** must, therefore, only be used if the following symptoms are found:

– Not responsive
– No respiration
– No pulse

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⚠ WARNING

Shock hazard for users and assistants

- ▲ Position the patient flat on a firm, electrically insulated surface.
- ▲ Check that there are no conductive connections between the patient and other persons during ECG analysis and defibrillation.
- ▲ The patient must not come into contact with metal parts, a bed, or a stretcher in order to prevent secondary contacts or paths for the defibrillation current that could endanger the assistants. For the same reason, do not position the patient on a wet surface (rain, swimming pool accidents).
- ▲ The operator must avoid contact between parts of the patient's body, such as exposed skin of the head or limbs, conductive fluids such as gel, blood, or saline, and metal objects such as a bed frame or a stretcher, which may provide unwanted pathways for the defibrillating current.
- ▲ Do not allow the defibrillation electrodes to come into contact with other electrodes or metal parts that are in contact with the patient.
- ▲ The patient's chest must be dry because moisture can cause unwanted pathways for the defibrillation current. For safety, wipe off flammable skin cleansing agents.
- ▲ The assistants' tasks must be clearly defined as follows:

During ECG analysis and shock:
- – Suspend CPR
- – Check that the patient lies as motionless as possible
- – Do not touch the patient; otherwise, artefacts may lead to incorrect analysis results, and the recommended shock is cancelled.

Immediately prior to the shock:
- – Stop chest compressions and CPR

Risk of skin burns for the patient

- ▲ Due to the high currents, there is a risk of skin burns at the electrode application site. Therefore, the electrodes must not be placed on or above:
  - – The sternum
  - – The clavicle
  - – The nipples
- ▲ Delivering defibrillation shock with bad contact or delivering repeated shock might lead to tissue redness or burns.
- ▲ Do not use expired electrodes.

Risk of malfunction of implanted pacemaker

- ▲ Defibrillating a patient with an implanted pacemaker is likely to impair the pacemaker’s function or cause damage to the pacemaker.
  For this reason:
  - – Defibrillation pads must not be positioned near the pacemaker
  - – The pacemaker must be checked immediately after finishing the therapy.

Risk of malfunction

- ▲ Using a defibrillator in AED mode in a moving vehicle can interfere with SAS and lead to false decisions related to patient treatment advice.
- ▲ The agonal respiration phenomenon (GASP) of a patient in cardiac arrest may interrupt the analysis process.

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4.1.3 Defibrillating paediatric patients

⚠ WARNING

- ▲ For the defibrillation of paediatric patients, paediatric pads (yellow connector) should be used.
- ▲ If no paediatric pads are available, adult electrodes can be used.

Fig. 4.1 Paediatric electrode

- Always use paediatric pads to defibrillate paediatric patients weighing less than 25 kg or younger than 8 years old while using the **FRED PA-1**. Paediatric pads can be recognised thanks to the packaging of the electrodes and their yellow connector.
- The paediatric electrodes (surface area 42 cm²) should be applied in the antero-lateral position.
- When paediatric pads are connected to the **FRED PA-1**, the energy setting is automatically adapted:
  - 1st shock: 50 joules
  - 2nd shock: 50 joules
  - 3rd shock: 50 joules

4.2 Application of the Adhesive Electrodes

⚠ WARNING

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

⚠ CAUTION

- ▲ Only use pads up to there expiration date. Note that the indicated expiration date only applies if the vacuum pack is intact.
- ▲ The pads are pre-gelled, so there is no need to use an extra contact agent.
- ▲ The placement of pads may be different depending on if the patient is an adult or a child.

4.2.1 General information

- The pre-connected electrodes are stored in the defibrillator cover and can be accessed when the cover is opened.
- A spare set of adult or paediatric electrodes can be found in the compartment at the bottom of the **FRED PA-1**.

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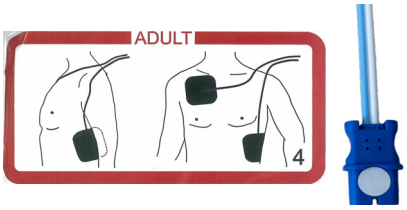
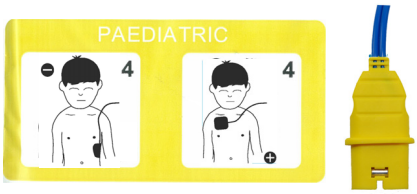


Adult electrodes 80 cm²

The adult electrodes (surface area 80 cm²) with the blue connector are used for adult and paediatric patients aged 8 years old or weighing 25 kg or more.



Paediatric electrodes 42 cm²

The paediatric electrodes with the yellow connector are used for paediatric patients younger than 8 years old or weighing less than 25 kg. The **FRED PA-1** automatically distinguishes between adult electrodes and paediatric electrodes. The energy setting is automatically reduced when paediatric electrodes are connected.

4.2.2 Unpacking the electrodes

⚠ CAUTION

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

▲ Check the expiration date of the electrodes.

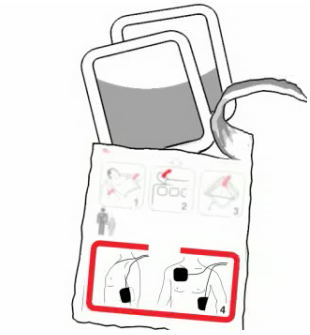


Fig. 4.2 Opening the electrode packaging

During a cardiac arrest, use the **FRED PA-1** on the patient as follows:

- If no emergency services have been alerted, call the local emergency number.
- Switch On the **FRED PA-1** by opening the cover.
- Remove the clothes from the patient's upper body.
- Shave the patient's upper body if necessary.
- Open the electrode packaging carefully.
- If not pre-connected, insert the electrode connector into the electrode port of the **FRED PA-1**.
- Apply the electrodes to the patient's chest. Refer to section 4.2.3 Applying the electrodes for the proper placement.

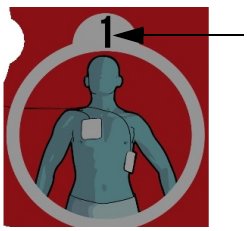


Fig. 4.3 Green indicator

Notes:

- The green indicator is blinking, and the **FRED PA-1** repeats the instructions until the electrodes are applied, or until the electrode connector is connected, respectively, and the electrode-skin resistance (impedance) has reached an acceptable level.
- After several repetitions to apply and connect the electrodes, the **FRED PA-1** recommends performing a CPR cycle. The **FRED PA-1** will then switch off if it has not detected an acceptable impedance between the two electrodes after 5 minutes.

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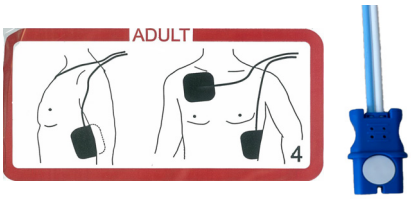
4.2.3 Applying the electrodes

⚠ WARNING

- ▲ Skin covered in seawater, sand, sunscreen, or skin or body care products may impair electrode contact or cause the electrodes to become disconnected.
- ▲ The skin must be intact.

General indications

Adult electrodes 80 cm²

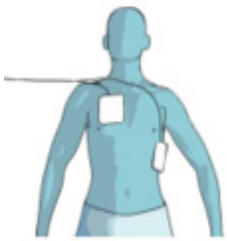


Before applying the adhesive electrodes, check that the application sites on the patient's chest is clean and dry.

1. Carefully shave the application area if the patient's chest is hairy.
2. Apply the electrode as shown on the electrode packaging except when using adult electrodes on a paediatric weighing less than 25 kg or younger than 8 years old; then refer to the section below. Do not apply the electrode on top of the clavicle (uneven surface).

The electrodes must have good contact with the patient's skin. Air bubbles under the electrodes must be avoided. To avoid air bubbles, place one edge of the adhesive electrode on the patient's chest, then gradually smooth it out toward the other edge to remove any air.

Place the electrodes on the patient's chest so that the connections point to either side of the patient in order not to hinder CPR.



Shown left is the placement of adult electrodes (80 cm²) on adult or paediatric patients weighing 25 kg or more or older than 8 years old.

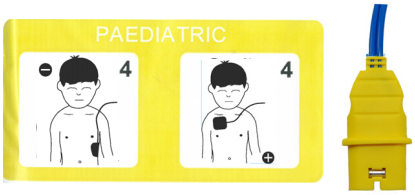
The adult electrodes (surface area 80 cm²) with the blue connector are used for adult and paediatric patients weighing 25 kg or more or older than 8 years old.

The electrodes should be in an antero-lateral position.

1. Apply the first electrode, as shown at the right sternal edge at the level of the 2nd intercostal space. Do not apply the electrode on top of the clavicle (uneven surface).
2. Apply the second electrode, as shown in the picture, on the left axillary line at the level of the 5th intercostal space.

Refer to the picture on the left or to the pictures on the electrodes for the correct positioning.

Paediatric electrodes 42 cm²



Placement of paediatric electrodes (surface area 42 cm²) on paediatric patients weighing less than 25 kg or younger than 8 years old.

The paediatric electrodes (surface area 42 cm²) with the yellow connector are used for paediatric patients weighing less than 25 kg or younger than 8 years old.

The **FRED PA-1** automatically distinguishes between adult electrodes and paediatric electrodes. The energy setting is automatically reduced when paediatric pads are connected. The electrodes should be in an antero-lateral position.

1. Apply the first electrode, as shown at the right sternal edge at the level of the 2nd intercostal space. Do not apply the electrode on top of the clavicle (uneven surface).
2. Apply the second electrode, as shown in the picture, on the left axillary line at the level of the 5th intercostal space.

Refer to the picture on the left or to the pictures on the electrodes for the correct positioning.

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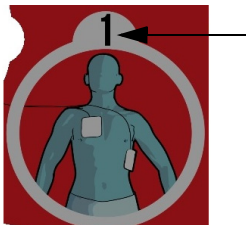
4.2.4 Checking the electrodes



If the resistance (impedance) reaches an unacceptable value, the **FRED PA-1** interrupts and prompts the user to check the electrode application; in addition, the green indicator is blinking.

This can occur:

– The cable is disconnected from the **FRED PA-1**
– If the electrodes are not correctly applied to the patient's chest.

In this case, the **FRED PA-1**:

- Prompts to check that the electrodes are connected and applied to the patient's chest and then recommends performing a CPR cycle if no corrective action has been taken.
- Resumes the intervention where it has been interrupted when it detects that the resistance between both electrodes is acceptable again.
- Switches off if it still does not detect acceptable impedance between both electrodes after 5 minutes.

Follow these steps to check the electrodes:

1. Insert the connector as specified in 3.6.2 Connect the electrodes.
2. Press the defibrillation pads onto the patient's chest one after the other to find out which one makes the green indicator switch Off,
3. Carefully press this electrode onto the patient's skin.
4. If the above steps do not solve the problem, apply new electrodes
5. If the electrode error remains, perform CPR even if the **FRED PA-1** switches off.

To remove the electrodes from the patient's chest (refer to section 4.6 Finishing the Therapy)

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4.3 Semi-automatic Defibrillation

⚠ WARNING

Patient hazard

▲ The guidelines given in 4.1 Instructions and Safety Notes must be observed.

Depending on the configuration, the instructions provided by the **FRED PA-1** may be shortened.

Step 1

Switching on and preparing the FRED PA-1

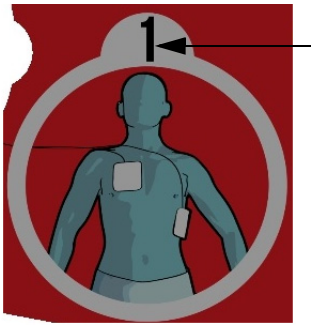

Fig. 4.4 Apply the electrodes

1. Open the cover to switch the **FRED PA-1** On.
   – If the cover is missing, remove the battery and reinsert it to switch the **FRED PA-1** On.
2. Assess the patient's condition: not responsive, no respiration, no pulse.
3. Apply the defibrillation electrodes to the patient's chest (refer to section 4.2 Application of the Adhesive Electrodes).
4. Insert the electrode connector into the electrode port if necessary.

The **Apply the electrodes** LED blinks for as long as the electrodes are not correctly applied to the patient's chest or the electrode connector is not correctly connected to the **FRED PA-1**.

Step 2

Analysing the ECG signal

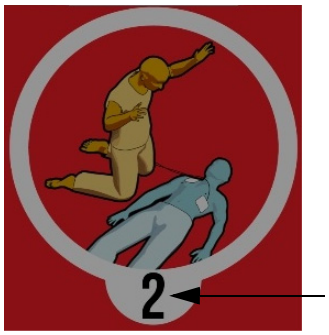

Fig. 4.5 Analysing, do not touch the patient.

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

If the **FRED PA-1** detects VF or VT with a Heart Rate (HR) exceeding 150 bpm, Step 3 Shock delivery follows; otherwise, continue with Step 4, Performing CPR.

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Step 3

Shock delivery

DANGER

Shock hazard

- ▲ Do not, under any circumstances, touch the patient during shock delivery.
- ▲ Check that the patient does not or cannot touch any conducting objects.

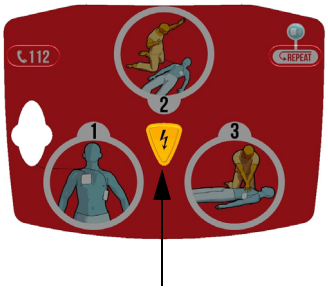
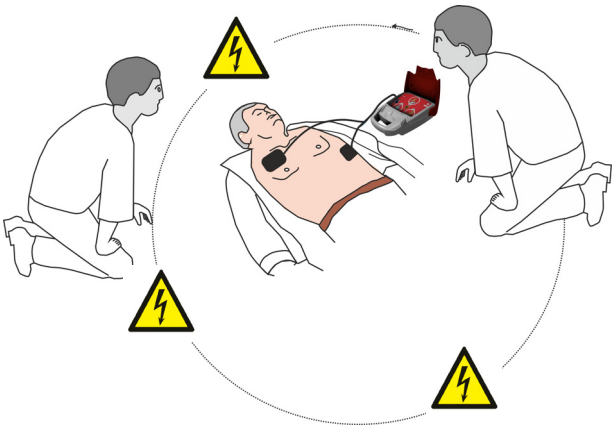


Fig. 4.6 Button to deliver the shock

Once the analysis has been performed, the **FRED PA-1** charges automatically if a shock is recommended. When the energy is charged, the **Shock** button blinks, and the user is prompted to trigger the shock by pressing the **Shock** button. After the shock, the **FRED PA-1** prompts the user to perform CPR immediately.



6. Deliver the shock by pressing the **Shock** button 

   After the shock delivery, proceed with Step 4 Performing CPR.

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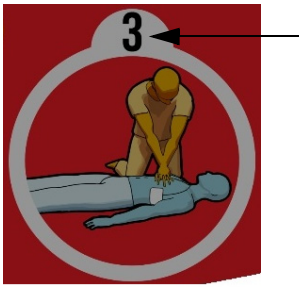
Step 4

Performing CPR

- If the **FreeCPR** option is activated, the **FRED PA-1** instructs the rescuer to adjust the chest compression frequency.
- **FreeCPR** measures the compression rate based on the impedance measurement by the defibrillation electrodes.



7. Perform a CPR cycle. According to the configuration of the **FRED PA-1**, a CPR cycle consists of:
   – Performing chest compressions for the set period of time
   – Alternately performing 30 chest compressions and 2 breathes for the set period of time.
   – Alternately performing 15 chest compressions and 2 breathes for the set period of time.

After the CPR cycle, the **FRED PA-1** continues automatically with Step 2 Analysing the ECG signal.

Finishing the therapy

Refer to section 4.6 Finishing the Therapy

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4.4 Automatic Defibrillation

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

4.4.1 Functional description of automatic AEDs

Depending on the configuration, the instructions provided by the **FRED PA-1** may be shortened.

Fig. 4.7 **FRED PA-1** Automatic

The **FRED PA-1** delivers defibrillation shocks automatically; that is, there is no need to trigger the shock.

Voice prompts and LEDs next to the pictogram keep the user informed regarding the therapy steps.

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

4.4.2 Safety notes for automatic defibrillation

DANGER

Risks for patients, users, and assistants

- Once the **FRED PA-1** has been switched on by opening the cover and the electrodes have been applied, the ECG analysis is started automatically, and a shock is delivered automatically if a shockable rhythm is present. The user is informed of an ongoing analysis or shock release via acoustic messages.
- Touching or transporting the patient during analysis may lead to an incorrect analysis. Analysis results are only valid if the patient remained unconscious during the entire analysis and was not touched.
- For this reason, chest compressions and artificial respiration must be suspended during the analysis.
- The patient must not be touched or transported (for example, on a stretcher) during analysis and shock delivery.
- The notes in section 4.1 Instructions and Safety Notes page 30, must be observed.

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4.4.3 Automatic defibrillation procedure

Depending on the configuration, the instructions provided by the **FRED PA-1** may be shortened.

Step 1

Switching on and preparing the FRED PA-1

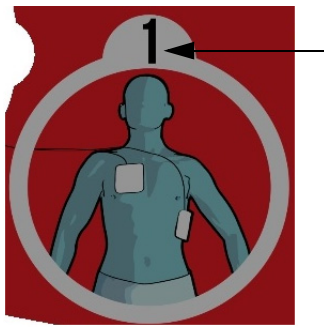

Fig. 4.8 Apply the electrodes

1. Open the cover to switch the **FRED PA-1** On.
   – If the cover is missing, remove the battery and reinsert it to switch the **FRED PA-1** On.
2. Assess the patient's condition: not responsive, no respiration, no pulse.
3. Apply the defibrillation electrodes to the patient's chest (refer to 4.2 Application of the Adhesive Electrodes).
4. Insert the electrode connector into the electrode port if necessary.

The **Apply the electrodes** LED blinks for as long as the electrodes are not correctly applied to the patient's chest or the electrode connector is not correctly connected to the **FRED PA-1**.

Step 2

Analysing the ECG signal

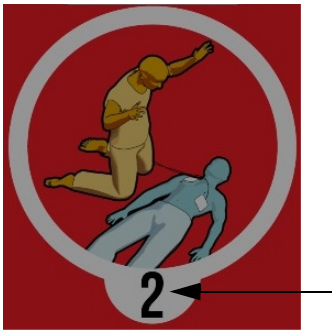

Fig. 4.9 Analysing, do not touch the patient.

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

If the **FRED PA-1** detects VF or VT with a HR exceeding 150 bpm, Step 3 Automatic shock delivery follows; otherwise, continue with Step 4 Performing CPR.

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Step 3 Automatic shock delivery

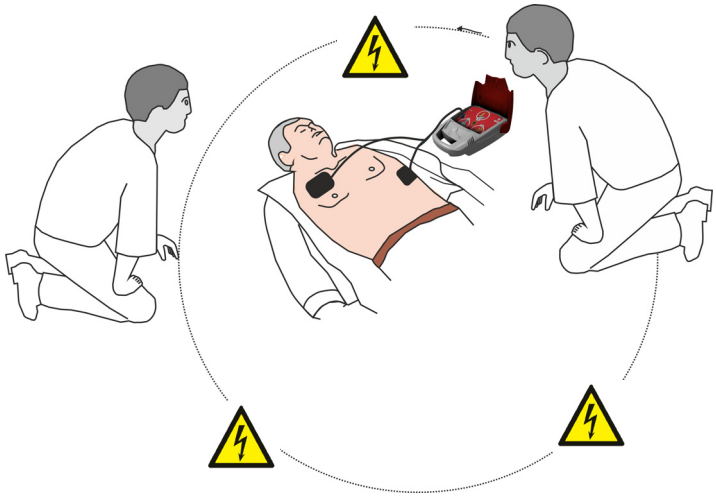
DANGER

Shock hazard

▲ Do not, under any circumstances, touch the patient during shock delivery.

▲ Check that the patient does not or cannot touch any conducting objects.

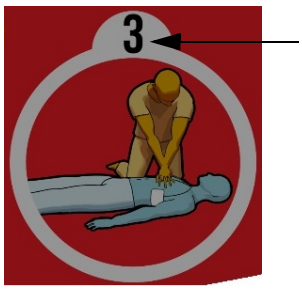
Once the analysis has been performed, the **FRED PA-1** charges automatically if a shock is recommended. As soon as the energy charge is completed, the **FRED PA-1** automatically delivers the shock without user intervention. A verbal countdown starts, and the orange LED blinks until the shock is delivered. After the shock, the **FRED PA-1** prompts the user to perform CPR immediately.



After the shock delivery, proceed with Step 4 Performing CPR.

Step 4 Performing CPR

- If the **FreeCPR** option is activated, the **FRED PA-1** instructs the rescuer to adjust the chest compression frequency.
- **FreeCPR** measures the compression rate based on the impedance measurement by the defibrillation electrodes.



6. Perform a CPR cycle. According to the configuration of the **FRED PA-1**, a CPR cycle consists of:
   – Performing chest compressions for the set period of time
   – Alternately performing 30 chest compressions and 2 breathes for the set period of time.
   – Alternately performing 15 chest compressions and 2 breathes for the set period of time.

After the CPR cycle, the **FRED PA-1** continues automatically with Step 2 Analysing the ECG signal.

Finishing the therapy

Refer to section 4.6 Finishing the Therapy.

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4.5 Internal Safety Discharge

⚠ WARNING

▲ If the **FRED PA-1** behaviour differs from the description given in this user guide, the **FRED PA-1** is defective and must be repaired.

An internal safety discharge ensures that the stored energy is discharged within the **FRED PA-1** every time a defibrillation shock is not delivered correctly. An internal discharge is performed if:

- The shock has not been delivered within the 20 seconds following the end of the defibrillation energy charging
- An electrode error is detected
- The battery voltage is insufficient
- The **FRED PA-1** is defective
- The **FRED PA-1** is switched off before the shock is delivered.

4.6 Finishing the Therapy

- Disconnect the electrode cable.
- Switch off the **FRED PA-1** once the therapy has been completed (close the cover).
- Carefully remove the pads from the patient's skin (refer to Fig. 4.10 Removing the adhesive pads)
- Discard the disposable pads immediately after use to prevent their reuse (hospital waste).
- Clean the **FRED PA-1**, cables, and sensors as described in section 6.2 Cleaning and Disinfecting.
- Connect new electrodes (refer to 3.6.2 Connect the electrodes)
- Retrieve the intervention data (refer to 5.1 Retrieving Intervention Data)
- Patients with implanted pacemakers must check the functioning of the pacemaker immediately.

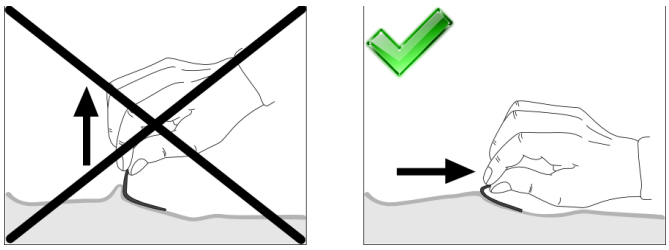

Fig. 4.10 Removing the adhesive pads

i If the **FRED PA-1** is turned off for less than 5 minutes, all data is stored (even if the battery is removed). The **FRED PA-1** continues to count the number of shocks delivered, to measure the time elapsed since the **FRED PA-1** was turned on, and to store intervention events from the point at which the **FRED PA-1** was turned off.

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4.7 Replacing the Battery

1. Close the cover of the **FRED PA-1**.
2. Press the two ends of the battery lock down (1) as indicated to remove the battery.
3. Insert a new battery (refer to 3.2 Inserting the Battery).

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5 Communication

⚠ CAUTION

- ▲ Always follow the Cybersecurity rules in section 1.10 Cybersecurity
- ▲ In case of a bad connection, improve transmission by moving closer to an efficient communication point.

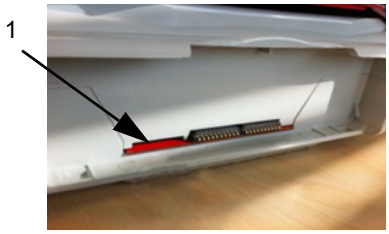
5.1 Retrieving Intervention Data

5.1.1 For standard FRED PA-1 with an SD card

- Only use standard SD cards (do not use mini or micro SD cards).
- To read the intervention data, use the appropriate SCHILLER software. Contact your SCHILLER representative.

An SD card is required to retrieve the intervention data. The SD card must be configured according to the following instructions.

1. With a computer, create a directory called, *from_device* on the SD card.
2. Remove the battery from the **FRED PA-1**.



3. Insert the SD card (1).
4. Insert the battery; the **FRED PA-1** is switched on automatically.

5. The modem LED (2) is on, and the service LED (3) is blinking throughout the data transfer process, which can last more than 5 minutes.
6. The data transfer is finalised when the modem LED (1) and the service LED (2) are off.
7. Remove the battery and then remove the SD card from the **FRED PA-1**.
8. Insert the battery.

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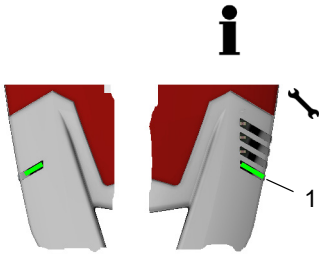
5.1.2 For FRED PA-1 equipped with a cellular network



- **FRED PA-1** with the cellular network option is delivered with an embedded SIM card that must not be removed.
- After use on a patient, intervention data is automatically sent to the SCHILLER Server after the next self-test (10 minutes after shutdown).
- Network communication is active while the LifeDataNet G2 service is running, as indicated by the Modem LED (1) blinking shown in the left image.

FRED PA-1 Management

FRED PA-1 is equipped with a cellular network module managed by the SCHILLER Server LifeDataNet G2.

FRED PA-1 sends information automatically to the server to check, if required that it is operational.

After each self-test, **FRED PA-1** sends:

- Self-test results
- Battery status
- Pads expiry date
- Alive status

Authorised users can also schedule remote software and configuration updates as well as download log files through the LifeDataNet G2 server. Log files are only used by SCHILLER personnel for investigation.

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6 Maintenance

6.1 Maintenance Intervals

- Because **FRED PA-1** is an emergency device, some verifications must be completed as written in the following table in order to maintain the **FRED PA-1** operational, including the accessories. The test results must be recorded and compared to the values accompanying the documents (refer to 7.9 Inspection Report)
- 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.

⚠ WARNING

▲ **Patient hazard.** If the **FRED PA-1** behaviour differs from the description given in this user guide or the RTU LED is not blinking, the **FRED PA-1** is defective and must be repaired.

⚠ CAUTION

▲ When the **FRED PA-1** is used intensively, SCHILLER recommends shorter intervals between inspections.

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

Interval	Maintenance replacement	Responsible
After each use	• Replace the electrodes. • After battery insertion, check that the RTU LED is blinking and that the other LEDs are off (refer to section 6.1.4 RTU LED) • Visual inspection of the **FRED PA-1** (refer to section 6.1.3 Visual inspection of the FRED PA-1 and accessories) • Retrieve the intervention data and clear the intervention memory (refer to section 5.1 Retrieving Intervention Data) • Clean and disinfect the **FRED PA-1** (refer to section 6.2 Cleaning and Disinfecting)	→ User
Once a Week	• Check that the RTU LED is blinking, and all other LEDs are off (refer to section 6.1.4 RTU LED) • Visual inspection of the **FRED PA-1** and accessories. If the **FRED PA-1** has not been used for several weeks, clean and disinfect the **FRED PA-1** (refer to section 6.1.3 Visual inspection of the FRED PA-1 and accessories)	→ User

FRED PA-1 equipped with a cellular network module can be exempt from this maintenance interval as long as the **FRED PA-1** is remotely under supervision through the LifeDataNet G2 server.

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Interval	Maintenance replacement	Responsible
Every 3 years	• Perform a software update (if a new version is available). • Visual inspection of the **FRED PA-1** and accessories (refer to section 6.1.3 Visual inspection of the FRED PA-1 and accessories) • Check for correct functioning. • Measure the energy delivered at 50 Ohms with the appropriate material.	➜ Service staff authorised by SCHILLER
Every 6 years	• Replacement of internal backup battery. • Perform a software update (if a new version is available) • Visual inspection of the **FRED PA-1** and accessories (refer to section 6.1.3 Visual inspection of the FRED PA-1 and accessories) • Check for correct functioning. • Measure the energy delivered at 50 Ohms with appropriate material • Perform a leakage current test **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 correct time stamping of the intervention.	➜ Service staff authorised by SCHILLER

Points to inspect

- Visually inspect the **FRED PA-1** and the accessories (refer to section 6.1.3 Visual inspection of the FRED PA-1 and accessories).
- Check for correct functioning.

Measure the energy delivered at 50 Ohms.

6.1.1 Device status file

FRED PA-1 can create a file about its current status automatically to help with the maintenance.

The device status file is created every time the **FRED PA-1** is switched on and during each self-test if an SD card is inserted.

The name of the file is written to help identify which **FRED PA-1** it comes from and when it was created. For example:

SerialNumber_CurrentDate_CurrentTime_device_status.txt

The device status file contains several pieces of information, including:

- The current date, that is, when the device status file was created.
- **FRED PA-1** serial number
- Next maintenance date
- Package version (of the installed software)
- Status of the electrodes
- Regular battery level as a percentage
- Current alarm list

6.1.2 Service and shelf life

FRED PA-1

The **FRED PA-1** has a defined service life of 10 years if maintenance intervals have been observed according to section 6.1 Maintenance Intervals and the directive IEC/EN 62353.

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Battery Main battery (approximately 6 years); see the expiry date on the battery and internal battery cell (approximately 6 years)

Electrodes Electrode packaging (2 years); see the expiry date on the electrode pouch.

6.1.3 Visual inspection of the FRED PA-1 and accessories

Regularly and after each use, visually inspect the **FRED PA-1** and the cables to detect possible mechanical damages.

If there are any damages or dysfunctions which could endanger the safety of the patient or user, only use the **FRED PA-1** once it has been serviced.

Points to inspect

- Check that the RTU LED is blinking and all the other LEDs are off (refer to section 6.5.1 Error messages)
- **FRED PA-1** casing is undamaged
- No excessive soiling or damage
- A legible nameplate at the rear of the **FRED PA-1**
- Legible inscriptions on the front face of the **FRED PA-1**
- The expiration date of the electrodes has not elapsed (refer to section 3.6.2 Connect the electrodes)
- The expiration date of the battery has not elapsed
- Clean and disinfect the **FRED PA-1** if it has not been used for several weeks (refer to section 6.2 Cleaning and Disinfecting).

▲ Electrodes past their expiration date must be replaced immediately (RTU LED is off and the electrodes LED is blinking, only by using the electrodes reference 0-21-0040)

▲ Batteries past their expiration date must be replaced immediately. (refer to section expiry date on the batteries.)

▲ A defective **FRED PA-1** or damaged cables must be replaced immediately.

▲ Replace or repair immediately the **FRED PA-1** if the RTU LED is not blinking. (refer to section 6.5.1 Error messages).

6.1.4 RTU LED

If the **FRED PA-1** is defective or if the **FRED PA-1** has detected problems during the self-test, the **FRED PA-1** must be repaired before use.

If a problem is detected during this self-test:

- An acoustic alarm is issued
- The RTU LED is blinking if a non-critical error is detected as:
  - Battery almost empty
  - Electrode nearly expired (only with electrodes reference 0-21-0040)
- The RTU LED is no longer blinking if the **FRED PA-1** is no longer operational.
- The corresponding service LED is blinking.

For more details; refer to section 6.5.1 Error messages.

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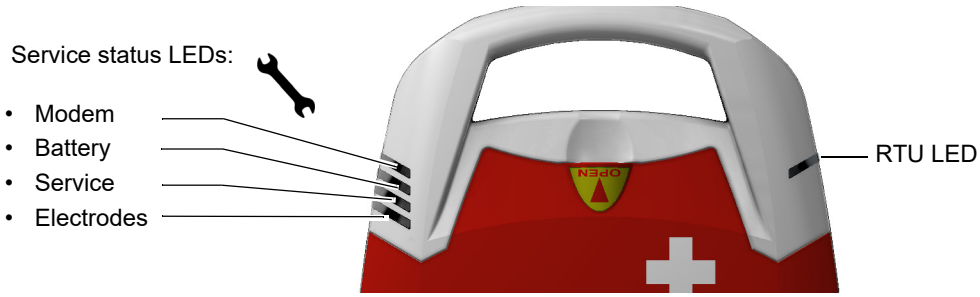

6.1.5 Maintenance of the non-rechargeable Li/MnO_2 battery

Important

- The battery's performance and life depend on how and under what ambient conditions the battery is used.
- The non-rechargeable battery is maintenance-free during its life.
- The self-discharge of the battery is approximately 1% per year at 25°C. Storage at higher temperatures increase the self-discharge (for example, by approximately 16% per year at 60°C).

Replacing Li-MnO_2 battery

- The battery must be replaced when the battery depletion is displayed.
- The battery must be replaced after 6 years from the manufacturing date on the battery.

Recommendations

- Store unused batteries at an ambient condition of 20°C ± 5°C.
- Check the battery contacts for corrosion.

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6.2 Cleaning and Disinfecting

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

6.2.1 Cleaning detergents

Refer to the manufacturer's information regarding the detergents.

Admissible detergents

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

Non-admissible detergents

Never use products containing the following:

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

6.2.2 Disinfection

Use commercially available disinfectants intended for clinics, hospitals, and practices to disinfect the **FRED PA-1**. Wipe disinfection removes certain bacteria and viruses. Refer to the manufacturer's information.

Admissible disinfectants

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

Non-admissible disinfectants

Never use products containing the following:

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

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6.2.3 Cleaning and disinfecting the FRED PA-1, cable, and sensor

DANGER

- ▲ **Shock hazard.** Remove the battery before cleaning the **FRED PA-1**. This ensures that the **FRED PA-1** is not turned on inadvertently while you are cleaning it.
- ▲ **Risk of death.** Disconnect the defibrillation pads before cleaning the **FRED PA-1**.
- ▲ **Risk of shock and equipment damage.** Liquids must not enter the **FRED PA-1**. If a liquid has penetrated the **FRED PA-1**, it must not be used until a service technician has checked it.

WARNING

- ▲ Do not immerse the **FRED PA-1**, the cable, or the sensor in liquid, and do not sterilise them.
- ▲ Do not apply tension to the sensor cable.
- ▲ Do not use aggressive cleaners.
- ▲ Do not use any phenol-based agents or peroxide compounds for cleaning.
- ▲ Reusable sensors must be treated as biologically dangerous material after usage and disinfected according to the manufacturer's instructions.
- ▲ Observe the manufacturer's notes when cleaning the sensors and cables.

Protocols

1. Remove the battery
2. Wipe the equipment housing and sensor with a dampened cloth and a mild cleaning solution. The manufacturer recommends using 50% alcohol.
3. Dispose of single-use applied parts and protective coverings according to the relevant regulations.

Equipment damage

Do not clean the surface of the **FRED PA-1** with phenol-based disinfectants or peroxide compounds.

FRED PA-1 casing

→ Wipe the **FRED PA-1** with a dampened cloth; check that no liquid enters the **FRED PA-1**, especially not into the electrode's pads connector. All cleaning or disinfection products commonly used in hospitals and containing alcohol (maximum 50%) are appropriate. If liquids enter the **FRED PA-1**, it can only be operated again after the technical support department has checked it.

Electrodes

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

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6.3 Order Information

⚠ WARNING

- ▲ **Risk to persons, and equipment damage.** Always use SCHILLER replacement parts and disposables or products approved by SCHILLER. Failure to do so may endanger life and invalidate the warranty.
- ▲ Using accessories, transducers, and cables other than those specified or provided by the equipment manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in incorrect operation.

Your local representative stocks all the consumables and accessories for the **FRED PA-1**. A full list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch). In case of difficulty, contact SCHILLER to process your order or to receive details for all SCHILLER products.

6.3.1 Order information

Devices

Part No.	Description
1-127-9902	**FRED PA-1** semi-automatic
1-127-9901	**FRED PA-1** fully automatic
1-127-9904	**FRED PA-1** semi-automatic with cellular network communication module
1-127-9903	**FRED PA-1** fully automatic with cellular network communication module

Accessories

Part No.	Description
0-21-0040	1 pair of disposable adhesive defibrillation pads for adults, 80 cm²; pre-connected with RFID
2.155067	1 pair of disposable adhesive defibrillation pads for children, 42 cm²

6.3.2 Consumables and other parts order information

Consumables

Part No.	Description
4-07-0025	Battery pack **FRED PA-1**
5-35-0043	SD Card

Other parts

Part No.	Description
1-127-5180	Wall bracket
6-39-0172	Set of emergency number and flag stickers for **FRED PA-1**
6-39-0148	Set of emergency number stickers for wall bracket
0-48-0240	User Guide, English

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6.3.3 Basic package content

- **FRED PA-1**
- User guide
- Sticker sheets
- Pair of adhesive pads
- Li/MnO_2 non-rechargeable battery

6.4 Disposal Information

6.4.1 Battery disposal

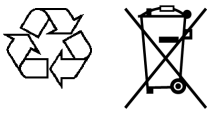
- ▲ Danger of explosion. The battery must not be incinerated, exposed to high temperatures, or disposed of with household waste.
- ▲ Do not expose the battery to chemicals that could dissolve ABS, polypropylene, polyvinyl chloride, nickel, mylar, or steel.
- ▲ Do not cut, destroy, or incinerate the battery.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

The battery must be disposed of in municipally approved areas or returned to SCHILLER.

6.4.2 Disposal of patient-related accessories

Disposable articles (for example, pads and razors) must be disposed of as hospital waste.

6.4.3 Disposal at the end of its useful life



At the end of their service life, the **FRED PA-1** and its accessories must be recycled in compliance with local regulations. Apart from the internal and plug-in batteries, the **FRED PA-1** 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.

European legislation has defined that the **FRED PA-1** is considered electronic waste equipment. It can be returned to the distributor or manufacturer, where the **FRED PA-1** is disposed of in compliance with legal requirements. The customer must bear the shipping costs. The **FRED PA-1** 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 **FRED PA-1** to your distributor or the manufacturer for proper disposal. In this way, you contribute to the recycling and other forms of utilisation of old electrical and electronic equipment. Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.

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6.5 Errors and Troubleshooting

- If it is not possible to get the **FRED PA-1** back into operating condition within a reasonable time, continue CPR until the rescue service arrives.

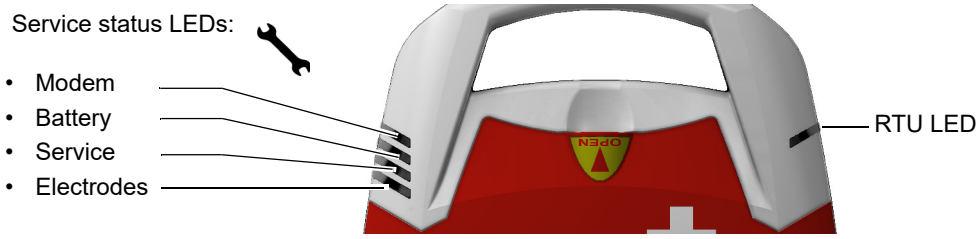
Forced shutdown procedure

- If the **FRED PA-1** cannot be switched off normally (closing the cover), remove the battery and reinsert it after 10 seconds.

6.5.1 Error messages

If a problem is detected during the self-test:

→ Refer to the table to identify the source of error with the different LEDs.



Description	FRED PA-1 state	RTU LED	Alarm sound	Battery LED	Electrode LED	Service LED	Remedy
Power supply problem or corrupted firmware	⛔	○	ON	○	○	○	→ Contact your sales representative.
Battery pack defect	⚠	○	ON	●	○	○	→ Replace the battery
The main battery is almost empty (lower than 10%), or the battery's shelf life has expired.	✓	●	OFF	●	○	○	→ Replace the battery
First case: the electrodes expire within 2 months. Second case: no RFID defibrillation pads are detected (configuration).	✓	●	OFF	○	●	○ **or** ●	→ First case: Replace the electrodes → Second case: During the last test, no electrodes were detected. Check the connection of the pre-connected electrodes and start a new test or wait for the next periodic test.
Electrodes expiration date exceeded	✓	○	OFF	○	●	○	→ Replace the electrodes, remove the battery and reinsert it.
FRED PA-1 needs a service	✓	●	OFF	○	○	●	→ Contact your sales representative.
Service delay expired	✓	○	OFF	○	○	●	→ Contact your sales representative.
FRED PA-1 is out of order	⚠	○	ON	○	○	●	→ Replace the **FRED PA-1**

✓ Normal **FRED PA-1** state. The **FRED PA-1** is fully operational. A defibrillation shock can be given.

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Restricted **FRED PA-1** state. The **FRED PA-1** is not able to charge the HV capacitor and deliver a defibrillation shock. It only indicates to perform CPR.

Critical **FRED PA-1** state. The **FRED PA-1** is out of order.

6.5.2 General errors and troubleshooting

Forced shutdown procedure
If the **FRED PA-1** cannot be switched off normally (closing the cover), remove the battery and reinsert it after 10 seconds.

Problem	Possible causes	Remedy
The Status indicator is not blinking and the **FRED PA-1** cannot be turned on.	• Battery defect. • No battery inserted, or battery not correctly inserted. • **FRED PA-1** is defective.	→ Replace the battery. → Insert the battery correctly. → Have the **FRED PA-1** repaired.
The status indicator is blinking, and the **FRED PA-1** cannot be turned on.	• **FRED PA-1** cover is missing	→ Remove the battery and reinsert it to start the **FRED PA-1** into the resuscitation process.
The **FRED PA-1** prompts the user to check that the electrodes are properly applied and connected.	• Short-circuit between the pads. • Poor pad contact. • Electrodes connector, not connected to the **FRED PA-1** • Dry contact agent. • **FRED PA-1** is defective.	→ Apply the pads exactly as described. → Firmly press down on the pads. → Connect the electrodes to the **FRED PA-1** → Use new electrodes. → Have the **FRED PA-1** repaired.
The **FRED PA-1** cannot be turned off.	• Close the cover • Software hangs • **FRED PA-1** defective.	→ Hold down the cover so that the magnetic sensor is activated → Remove the battery and reinsert it. → Have the **FRED PA-1** repaired.
Incorrect analysis result (for example, the **FRED PA-1** does not detect a shockable rhythm, even though the patient exhibits VF).	• Insufficient ECG signal quality. • Electromagnetic waves disturb the ECG signal. • Patient moved during analysis. • **FRED PA-1** is defective.	→ Repeat chest compressions. → Turn Off the source of interference (for example, radio transmitter or cellular telephone). Position the patient outside the range of interference. → Do not move the patient during the analysis. → Have the **FRED PA-1** repaired.
Defibrillation shock cannot be delivered.	• Insufficient battery charge level. • CPR caused pads error. • **FRED PA-1** is defective.	→ Replace the battery. → Re-apply the pads. → Have the **FRED PA-1** repaired.
The alarm tone does not stop.	• Battery defect. • **FRED PA-1** is defective.	→ Replace the battery. → Have the **FRED PA-1** repaired.
Battery LED is On.	• Battery almost depleted.	→ Replace the battery.
No data was recorded on the SD card.	• Card defect. • **FRED PA-1** is defective.	→ Replace the card. → Have the **FRED PA-1** repaired.
The electrodes LED continue to blink even after replacing the electrodes	• Alarms are not reset	→ Remove the battery and reinsert it to force a test
Difficulty to insert the battery	• Protective cap not removed	→ Remove the contacts protective cap
The **FRED PA-1** does not start the automatic test by inserting a battery	• The battery contacts are dirty • The battery is empty	→ Clean the battery contacts with an alcohol-dampened cloth → Use a new battery

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6.6 Electromagnetic Interference

6.6.1 Measures to prevent electromagnetic interferences

Non-ionising electromagnetic radiation

Precautions must be taken to prevent adverse events to the Patient and the Operator due to electromagnetic disturbance.

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the **FRED PA-1**. The minimum distance of 0.3 meter has been tested according to IEC 60601-1-2 for a wide range of telecommunication equipment, as shown in the following table:

HF Source	Transmitter frequency [MHz]	Power P [W]	Distance d [m]
Radiotelephone (microcellular) CT1+, CT2, CT3	885-887	0.010	0.23
Cordless DECT telephone, WLAN, UMTS phone	1880-2500	0.25	1.17
Mobile phone USA	850/1900	0.6	1.8
Mobile phone - GSM900, - GSM850, NMT900, DCS 1800	900 850,900,1800	2 1	3.3 2.3
Walkie-talkie (rescue service, police, fire brigade, service)	81-470	5	2.6
Mobile telephone system (rescue service, police, fire brigade)	81-470	100	11.7
RFID (active and passive transponders and reading devices)	433 865-868	0.5	0.85 1.62

⚠ CAUTION

- ▲ Portable HF telecommunication devices must not be used within a radius of 0,3 meter from the **FRED PA-1** and its cables.
- ▲ Do not place the **FRED PA-1** on top of other electric/electronic devices; that is, maintain a sufficient distance from other devices (this includes the patient cables).

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

d = Recommended minimum distance in Meters
P = Transmitting power in Watts

For more information on operation in an electromagnetic environment according to IEC/EN 60601-1-2; refer to the Service manual.

6.6.2 Additional measures

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

- Increase distance to the source of interference.
- Turn the device **FRED PA-1** to change the angle of radiation.

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- Only use original accessories (especially defibrillation electrodes)
- The device **FRED PA-1** should not be used adjacent to or stacked with other equipment.
- Observe the maintenance intervals as stated in 6.1 Maintenance Intervals.

⚠ CAUTION

▲ Use of the **FRED PA-1** adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the **FRED PA-1** and the other equipment should be observed to verify that they are operating normally.

▲ Using accessories, transducers, and cables other than those specified or provided by the equipment manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in incorrect operation.

▲ However, there is no guarantee that no interference can occur in certain installations. If the **FRED PA-1** causes interferences, these can be prevented by switching off the **FRED PA-1**.

i For more detailed information; refer to section 7.5 Telecommunication (options)

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7 Technical Data

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

7.1 System Specifications

Manufactured by	SCHILLER MEDICAL
Device name	**FRED PA-1**
Dimensions	310 x 255 x 100 mm (h x l x w)
Weight	Approximately 2.5 kg with battery and standard accessories
Protection class of the device housing	IP55 (protection against dust and water jets)
Recorded data	ECG signal recording (2 hours) Technical events (500 events)
Power supply	
Battery type	Lithium/MnO_2 15V, 2.8 Ah
Battery life	The power supply is suitable for continuous operation for 4 hours and 30 minutes with intermittent loading or more than 140 shocks at maximum energy if the **FRED PA-1** is stored/used in optimal temperature conditions between 15 to 25°C. For a standard **FRED PA-1** with an SD card.
Standby duration	• Several years in standby: Standby duration corresponding to laboratory tests at 25°C: 6 years with weekly self-tests. For the **FRED PA-1** with cellular network • Several years in standby: Standby duration corresponding to laboratory tests at 25°C, with a constant, good cellular network connection and without antenna roaming: 3 years with weekly self-tests.
Environmental conditions	
Device	
Operation	• -5 to 40°C at a relative humidity of 30 to 95% (non-condensing)
Storage before use	• -5 to 40°C with the battery inserted and including electrodes at a relative humidity of 30 to 95% (non-condensing); however, this may result in a reduced battery life. Optimal conditions are 15 to 25°C to ensure maximum battery life. • Atmospheric pressure 700 to 1060 hPa
Storage and transport	• -20 to 50°C at a relative humidity of 30 to 95% (non-condensing) • Atmospheric pressure 500 to 1060 hPa
Battery and Electrodes	
Operating temperature battery $LiMnO_2$	• 0 to 60°C
Storage and transport temperature electrode pads	• 0 to 50°C (maximum of 10 days between -40 to 0°C and 50 to 75°C)

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7.2 Classification and Safety Standards

Standards	**FRED PA-1** complies with IEC standard 60601-2-4. In compliance with the requirements of IEC standard 60601-2-4, the **FRED PA-1** is a device for infrequent use.
EMC	Refer to Chapter 7 Technical Data
Compliance	• **FRED PA-1** bears the (Notified Body GMED) mark indicating its compliance with the provisions of Directive 93/42/EEC (modified by Directive 2007/47/EEC) regarding medical devices and fulfils the essential requirements of Annex I of this directive. • **FRED PA-1** is a class IIb device.
Patient Protection	BF type, resistant to defibrillation shocks.
Explosions protection	**FRED PA-1** is not designed to be used in the presence of flammable mixtures of anaesthetic agents with air or oxygen.

The SCHILLER quality management system complies in full with the international standard ISO 13485.

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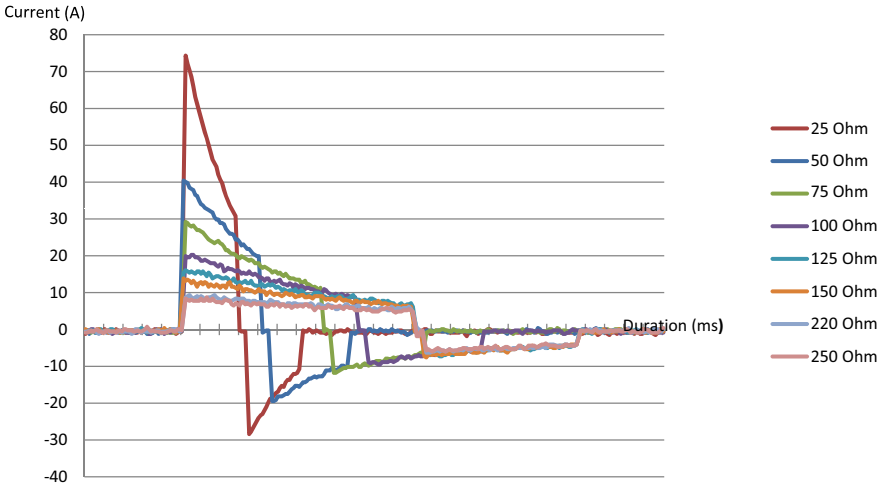
7.3 Defibrillation Pulse

Form

- Biphasic truncated exponential waveform
- Maintains the energy delivered to the patient at an approximately constant level with regard to patient resistance.



Accuracy of delivered shock

Deviation of the delivered energy from the selected energy, 30 to 200 joules at 25 until 175 Rpat [Ω] is ± 3 joules or ± 15% (the higher value is assumed); see the table below.

	Energy delivered [J] in load resistance Rpat [Ω]							**Deviation in [J]** of the selected energy [J] in load resistance Rpat [Ω]							**Deviation in [%]** of the selected energy [J] in load resistance Rpat [Ω]						
Energy selected [J]	25 [Ω]	50 [Ω]	75 [Ω]	100 [Ω]	125 [Ω]	150 [Ω]	175 [Ω]	25 [Ω]	50 [Ω]	75 [Ω]	100 [Ω]	125 [Ω]	150 [Ω]	175 [Ω]	25 [Ω]	50 [Ω]	75 [Ω]	100 [Ω]	125 [Ω]	150 [Ω]	175 [Ω]
30 [J]	29.2	28.5	28.2	27.8	28	27	25.9	0.8	1.5	1.8	2.2	2.0	3.0	4.1	2.7	5.0	6.0	7.3	6.7	10	13.7
70 [J]	68.3	66.6	66.2	65.3	65.9	63.7	61	1.7	3.4	3.8	4.7	4.1	6.3	9	2.4	4.9	5.4	6.7	5.9	9	12.9
120 [J]	117.4	114.3	113.6	111.9	112.7	108.8	104.8	2.6	5.7	6.4	8.1	7.3	11.2	15.2	2.2	4.8	5.3	6.7	6.1	9.3	12.7
200 [J]	195.7	190.6	189.2	186.2	187.8	181.5	174.6	4.3	9.4	10.8	13.8	12.2	18.5	25.4	2.2	4.7	5.4	6.9	6.1	9.3	12.7

Default energy settings

- SCHILLER's customer service department can change the default energy levels to the following values:
  - 90 –120 – 150 – 200 joules (Adults)
  - 30 – 50 – 70 joules (Paediatric)
    (Automatic adaptation when paediatric pads are connected)

Cycle time: rhythm analysis – shock availability (in semi-automatic mode)

Time between the start of the analysis and shock availability in semi-automatic mode.

With full battery:

- Approximately 10 seconds

After 15 discharges with maximum energy:

- Approximately 10 seconds

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Patient impedance at which shock delivery is possible	25 to 250 Ω (Impedance is compensated up to 200 Ω)
Indication when ready to shock	The orange button is lit
Shock delivery	• With the orange button (in semi-automatic) • Using disposable pads applied to the patient in an antero-lateral or antero-posterior position.
Safety discharge when:	• A non-shockable rhythm has been detected • The shock is not delivered within 20 seconds after charging • An electrode problem is detected • Battery voltage is insufficient • The **FRED PA-1** is defective • The **FRED PA-1** is turned off.
Defibrillation pad connection	BF type
Defibrillation electrodes	Electrode cable, 2 meters in length
Adult pads:	• 80 cm² active surface area
Paediatric pads:	• 42 cm² active surface area

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7.3.1 Shock Advisory System (SAS)

⚠ WARNING

- ▲ Agonal respiration phenomenon (GASP) of a patient in cardiac arrest may interrupt the analysis process
- ▲ Some non-shockable rhythms of patients in cardiac arrest may interrupt the analysis process

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

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

The SAS validation test set contains the following ECG samples (refer to the test sample size in the table below):

- Course VF (> 200 µV peak-to-peak amplitude)
- Shockable VT hi (HR > 150 bpm, rushes that last more than 8 seconds)
- Asystole (≤ 100 µV peak-to-peak amplitude)
- Normal Sinus Rhythm (NSR) (PQRS-T waves visible, HR 40 to 100 bpm)
- Other organised rhythms (N) (includes all rhythms except those in other listed categories)

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

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In the table below, **FRED PA-1** SAS performance by rhythm category meets AHA recommendations [2] and IEC Standards [3] for adult defibrillation on artefacts-free MIT-VFDB signals:

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

[1]: The MIT-BIH Malignant Ventricular Arrhythmia Database http://physionet.org/physiobank/database/vfdb/

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

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

The **FRED PA-1** SAS test has been completed with a validation database consisting of 2,475 couples of ECGs and transthoracic Impedance Cardiogram (ICG) from Out-of-Hospital Cardiac Arrest (OHCA) interventions, recorded with Automated External Defibrillators (FRED easy, SCHILLER Medical SAS, France) used by the fire brigade of Paris.

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

7.4 Configuration Settings

Important

- Modifications that can be made via software programs are only performed if requested by the customer or if required by legal requirements.
- These modifications need to be registered in the **FRED PA-1** documentation as well as communicated to all users.

SCHILLER's service centre can configure the following parameters:

- Selection of the default language at **FRED PA-1** start
- The energy level for the 1st, 2nd, and 3rd shock (separate settings for adults and paediatric)
- Number of chest compressions for paediatric patients (15 or 30)
- Self-test frequency (daily or weekly)
- Choose between **continuous chest compressions** or **alternating chest compressions/breaths** during CPR cycles.
- Date and time
- Update of the software
- Change of the **FRED PA-1** language
- Selection of the AED protocol (short or long instructions)
- Activation of notification if no RFID defibrillation pads are detected
- Activation of notch filter (50 to 60 Hz)

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- Activation of 16,7 Hz Filter
  - The 16.7 Hz filter must be enabled when the **FRED PA-1** is installed in trains or railway stations.
- Activation of visual notification in case of elapsed maintenance interval.

7.5 Telecommunication (options)

Module	LE910C1-WWX
Frequency range	836 MHz (TX) and 882 MHz (RX/IDLE) – 4G Band 5 1950 MHz (TX) and 2140 MHz (RX/IDLE) – 4G Band 1
Supported SIM cards	3 and 1.8V
Data transmission	LTE Cat. 1 • Uplink up to 5 Mbps • Downlink up to 10 Mbps
Maximum transmitting power	• 4G LTE – Class 3 (0.2 Watt)
FCC identification **IC ID**	• RI7LE910C1 • 5131A-LE910C
Standards	• FCC/IC, PTCRB, ISED • RED/GCF

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7.6 Electromagnetic Interferences

The **FRED PA-1** is intended for use in the electromagnetic environment specified below. The customer or the user of the **FRED PA-1** should ensure that it is used in such an environment.

7.6.1 Electromagnetic emissions

Emission measurement	Compliance with the regulations	Electromagnetic environment explanations
RF emissions CISPR 11	Group 1	**FRED PA-1** 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 PA-1** 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	

7.6.2 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	IEC 60601-1 conformity	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	No mains power is used
Surge IEC 61000-4-5	± 1 kV between conductors ± 2 kV conductor-earth	Not applicable	No mains power is used
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 seconds	Not applicable	No mains power is used
Power frequency (50 to 60 Hz) magnetic field IEC 61000-4-8	3 A/m	IEC 60601-1 conformity	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

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

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 PA-1** and all its components, including cables; the recommended minimum distance is calculated based on the transmitter's frequency.
Conducted HF IEC 61000-4-6	3 V_{eff} between 150 kHz and 80 MHz outside of the ISM frequency bands[a]	Not applicable	
	10 V_{eff} between 150 kHz and 80 MHz in ISM frequency bands[a]	Not applicable	No mains power is used
Radiated HF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = \frac{12}{10} \times \sqrt{P}$ Between 80 and 800 MHz $d = \frac{23}{10} \times \sqrt{P}$ Between 800 MHz and 2.5 GHz Where P is the maximum transmitting power of the transmitter in Watts (W) according to manufacturer data, and d is 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.  Non-ionising electromagnetic radiation

Note 1: For 80 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 to 6.795 MHz, 13.553 to 13.567 MHz, 26.957 to 27.283 MHz, and 40.66 to 40.70 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’s 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, for example, 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 PA-1 can be used in this environment. If abnormal behaviour is detected, additional measures need to be taken, for example, reorientation or change of location of the FRED PA-1.

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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7.6.3 Recommended minimum distances

The **FRED PA-1** is intended to be used in electromagnetic environments in which it is possible to control radiated HF interferences. The user of the **FRED PA-1** can prevent electromagnetic interferences by always keeping a minimum distance between portable/mobile HF communication devices (transmitters) and the **FRED PA-1**. The recommended minimum distances are listed in the following table according to the transmitter's maximum transmitting power.

Maximum transmitting power of the transmitter (W)	**Distances according to the transmitter's frequency (m)**			
	$d = \frac{3,5}{3} \times \sqrt{P}$ Between 150 kHz and 80 MHz **outside of** the ISM frequency band	$d = \frac{12}{10} \times \sqrt{P}$ Between 150 kHz and 80 MHz **within** the ISM frequency band	$d = \frac{12}{10} \times \sqrt{P}$ Between 80 and 800 MHz	$d = \frac{23}{10} \times \sqrt{P}$ Between 800 MHz and 2.5 GHz
0,01	Not applicable	Not applicable	0,12	0,23
0,1			0,38	0,73
1			1,2	2,3
10			3,79	7,27
100			12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in Metres (M) can be determined 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: At 80 and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6,765 to 6,795 MHz, 13,553 to 13,567 MHz, 26,957 to 27,283 MHz, and 40,66 to 40,70 MHz.

Note 3: An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: 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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7.7 Literature

European Resuscitation Council Guidelines 2015 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

American Heart Association Guidelines 2015 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

7.8 Glossary

ABCD The primary ABCD

A = Airways (check if the 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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7.9 Inspection Report

The user guide must be read before the inspection.

Serial number: _____

Checks after each use					
➜ Check that the green indicator is blinking and all the other LEDs are Off (refer to section 6.1.4 RTU LED)	☐	☐	☐	☐	☐
➜ Visual inspection of the **FRED PA-1** and accessories					
➜ The **FRED PA-1** casing is undamaged					
➜ No excessive soiling or damage	☐	☐	☐	☐	☐
➜ Legible nameplate at the rear of the **FRED PA-1**	☐	☐	☐	☐	☐
➜ Legible inscriptions on the front face of the **FRED PA-1**	☐	☐	☐	☐	☐
➜ Expiration date of the accessories has not elapsed	☐	☐	☐	☐	☐
Date:					
Performed by:					
Checks once a Week or Month					
Visual inspection of the FRED PA-1 and accessories (see previous table)	☐	☐	☐	☐	☐
The RTU LED (1) is lit green, and no other LEDs are blinking (refer to section 6.1.4 RTU LED) 	☐	☐	☐	☐	☐
Date:					
Performed by:					
Checks every 3 years					
Visual inspection of the FRED PA-1 and accessories (see previous table)	☐	☐	☐	☐	☐
Functional test					
➜ Check for proper functioning (refer to section 6.1.4 RTU LED)	☐	☐	☐	☐	☐
➜ Measure the energy delivered at 50 Ohms.	☐	☐	☐	☐	☐
Date:					
Performed by:					
Replacement every 6 years					
Internal backup battery replacement.	☐	☐	☐	☐	☐
Date:					
Performed by:					

In case of problems, notify your Biomedical Department ❒, your local SCHILLER distributor ❒, or the authorised Customer Service for your area. ❒

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

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12 Appendix - Symbols

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

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

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

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CE XXXX	Notified body (e.g. CE 0123 marking notified body TÜV SÜD)
UK CA	UKCA marking (UK Conformity Assessed)
CE	CE marking, affirms its conformity with European standards
TÜV SÜD C US	NRTL symbol (Nationally Recognised Testing Laboratory) TÜV SÜD as accredited NRTL certification provider
	Regulatory Compliance Mark for the Australian standards
	The device is recyclable
	Symbol for the recognition of electrical and electronic equipment. Device must not be disposed of in the household waste.
	Symbol for the recognition of a battery. Battery must not be disposed of in the household waste.
4 LDPE	The packaging is made in low density polyethylene and can be recycled.
Rx Only	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non ionising electromagnetic radiation. To indicate that the device contains a Radio Frequency (RF) transmitter to transmit data (e.g Bluetooth or WiFi)
	Contains a Bluetooth module
	Do not reuse
LATEX	Latex-free
	Use-by date (expiry date of battery, electrodes or other consumables)
	Temperature range for storage or transport, respectively
	Pressure range for storage or transport, respectively

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	Humidity range for storage or transport, respectively
	Consult instruction for use (indicates the need for the user to consult the instructions for use)
	Use within X days after opening (electrodes or other consumables)
	Keep dry (store in a dry location)
	Keep away from sunlight (protect from direct sunlight)
	Fragile, handle with care
	Transport upwards (this way up)
	Do not use hooks
	EIP = electronic information product (does not contain any toxic and hazardous substances or elements above the maximum concentration values (product can be recycled and re-used)).

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