

# FRED PA-1<sup>®</sup>

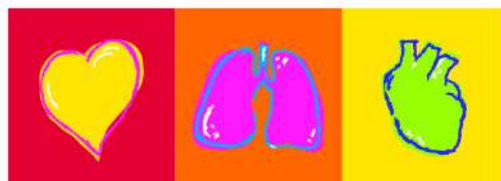
## Automated external defibrillator (AED)

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### User Guide



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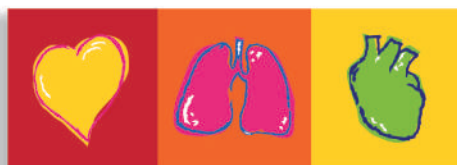
SCHILLER Medical S.A.S.  
4, rue Louis Pasteur  
F- 67162 Wissembourg  
Web:

Tel.: +33 (0) 388 63 36 00  
Fax: +33 (0) 388 94 12 82  
E-mail: [quality@schiller.fr](mailto:quality@schiller.fr)  
[www.schiller-medical.com](http://www.schiller-medical.com)

### Address Headquarters

SCHILLER AG  
Altgasse 68  
CH-6341 Baar, Switzerland  
Web:

Phone: +41 (0) 41 766 42 42  
Fax: +41 (0) 41 761 08 80  
E-mail: [sales@schiller.ch](mailto:sales@schiller.ch)  
[www.schiller.ch](http://www.schiller.ch)



# Table of Contents

- 1 Safety Notes ..... 5**
  - 1.1 User profiles..... 5
  - 1.2 Responsibility of the User ..... 5
  - 1.3 Intended Use ..... 5
  - 1.4 Contraindication for use ..... 6
  - 1.5 Organisational Measures ..... 6
  - 1.6 Safety-Conscious Operation ..... 6
  - 1.7 Operation with other Devices ..... 7
  - 1.8 Maintenance and Cleaning ..... 7
  - 1.9 General Notes Regarding the Unit ..... 7
  - 1.10 Additional Terms ..... 8
    - 1.10.1 Implied authorisation ..... 8
    - 1.10.2 Terms of Warranty ..... 8
  - 1.11 Symbols/Indicators ..... 9
    - 1.11.1 Symbols used in this user guide ..... 9
    - 1.11.2 Symbols used on the device ..... 9
    - 1.11.3 Symbols used on the battery..... 10
    - 1.11.4 Symbols used on the electrode packaging ..... 11
  
- 2 Components and Operation ..... 12**
  - 2.1 General Information ..... 12
  - 2.2 Design..... 13
    - 2.2.1 Overview of the configurable settings ..... 14
  - 2.3 Operating and Display Elements ..... 15
    - 2.3.1 Overview FRED PA-1 ..... 15
    - 2.3.2 Display and Operating Elements..... 16
  - 2.4 Function ..... 17
  
- 3 Initial operation ..... 18**
  - 3.1 Inserting the battery ..... 18
    - 3.1.1 Adding Emergency numbers stickers..... 19
    - 3.1.2 Switching device On and Off..... 20
  - 3.2 Battery monitoring ..... 21
    - 3.2.1 Sufficient battery capacity ..... 21
    - 3.2.2 Low battery capacity indication ..... 21
    - 3.2.3 Battery depleted during use, limited mode (CPR)..... 22
  - 3.3 Replacing the “pre-connected” pads ..... 23
    - 3.3.1 Connect the electrodes ..... 23

<b>4</b>	<b>Defibrillation .....</b>	<b>24</b>
<b>4.1</b>	<b>Instructions and Safety Notes .....</b>	<b>24</b>
4.1.1	Instructions .....	24
4.1.2	Safety notes for AED use.....	24
<b>4.2</b>	<b>Applying the adhesive electrodes.....</b>	<b>26</b>
4.2.1	General information .....	26
4.2.2	Unpacking and applying electrodes.....	26
4.2.3	Applying the electrodes to the patient's chest.....	27
4.2.4	Checking the electrodes .....	29
<b>4.3</b>	<b>Semi-automatic defibrillation .....</b>	<b>30</b>
<b>4.4</b>	<b>Automatic defibrillation.....</b>	<b>32</b>
4.4.1	Functional description of automatic AEDs .....	32
4.4.2	Safety notes for automatic defibrillation .....	32
<b>4.5</b>	<b>Internal safety discharge .....</b>	<b>35</b>
<b>4.6</b>	<b>Finishing the therapy .....</b>	<b>35</b>
<b>4.7</b>	<b>Removing the battery .....</b>	<b>35</b>
<b>5</b>	<b>Communication .....</b>	<b>36</b>
5.1	Retrieving intervention data .....	36
<b>6</b>	<b>Maintenance .....</b>	<b>37</b>
<b>6.1</b>	<b>Maintenance Intervals .....</b>	<b>37</b>
6.1.1	Exemption from the technical safety inspection.....	38
6.1.2	Service/Shelf life .....	38
6.1.3	Visual inspection of the device and accessories.....	39
6.1.4	Mains status LED.....	40
6.1.5	Functional check .....	40
6.1.6	Internal backup battery .....	40
<b>6.2</b>	<b>Cleaning and disinfection .....</b>	<b>41</b>
<b>6.3</b>	<b>Accessories and disposables .....</b>	<b>42</b>
6.3.1	Order Information.....	42
6.3.2	Required accessories .....	42
<b>6.4</b>	<b>Disposal information .....</b>	<b>43</b>
6.4.1	Battery Disposal.....	43
6.4.2	Disposal of accessories that come into contact with the patient.....	43
6.4.3	Disposal at the end of its useful life .....	43
<b>6.5</b>	<b>Troubleshooting .....</b>	<b>44</b>
6.5.1	Error messages.....	44
6.5.2	Troubleshooting .....	45
6.5.3	Measures to prevent electromagnetic interferences.....	46

<b>7</b>	<b>Technical Data .....</b>	<b>47</b>
7.1	System Specifications .....	47
7.2	Classification and safety standards .....	48
7.3	Defibrillation pulse .....	49
7.3.1	Shock Advisory System .....	51
7.4	Electromagnetic interferences .....	52
7.4.1	Electromagnetic emissions .....	52
7.4.2	Electromagnetic immunity .....	52
7.4.3	Recommended minimum distances .....	54
7.5	Literature .....	55
7.6	Glossary .....	55
7.7	Inspection report .....	56
<b>8</b>	<b>Index .....</b>	<b>58</b>



# 1 Safety Notes

## 1.1 User profiles

The following people may use the **FRED PA-1**<sup>®</sup>:

- people trained in early defibrillation
- other people not trained in early defibrillation, as long as they can understand and follow the spoken and displayed instructions.



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

## 1.2 Responsibility of the User



- ▲ Regulations on who is allowed to use devices like the **FRED PA-1**<sup>®</sup> and which training is required, are country-specific. In any case, legal regulations have to be observed.
- ▲ Before using the device, a SCHILLER representative must perform a presentation on the device's operation and safety measures, if it is required by the local regulations.
- ▲ Interpretation suggested by the device must be examined with respect to the patient's overall clinical condition and the quality of the recorded data.
- ▲ Damaged or missing components must be replaced immediately.
- ▲ The device must be stored in a place inaccessible to children.
- ▲ Properly dispose of the packaging material and make sure it is out of children's reach.
- ▲ The **FRED PA-1**<sup>®</sup> is an emergency device and must be ready for operation at any time and in all situations. Make sure that:
  - the device is always equipped with a sufficiently charged battery
  - An empty battery must not be reused and must be disposed of immediately
  - A set of adult or children electrodes is pre-connected and a spare set of electrodes can be stored in the device.

## 1.3 Intended Use



- ▲ The **FRED PA-1**<sup>®</sup> is an automated external defibrillator (AED) used for the treatment of ventricular fibrillation (VF) and ventricular tachycardia (VT).
- ▲ The device may be used with the appropriate electrodes on either adults or children.
- ▲ The device must only be used if the following symptoms are found:
  - not responsive
  - no respiration
  - no pulse

## 1.4 Contraindication for use



- ▲ The defibrillator must **not** be used when the person:
  - is responsive
  - is breathing normally
  - has pulse
- ▲ Do not use the device in or near magnetic resonance imaging equipment (MRI).
- ▲ **Danger of explosion!** — The device must not be used in areas where there is any danger of explosion. There might be a danger of explosion in areas where flammable products (petrol), flammable anaesthetic agents or products for skin cleaning/disinfection are in use, or where the ambient air's oxygen concentration is higher than 25 %.
- ▲ The FRED PA-1 must not be used in ambulances and emergency vehicles.

## 1.5 Organisational Measures



- ▲ Before using the unit, ensure that an introduction regarding the unit functions and the safety precautions has been provided and understood.
- ▲ Keep these operating instructions in an accessible place for reference when required. Make sure that they are always complete and legible.

## 1.6 Safety-Conscious Operation




- ▲ **Danger of electric shock!** - Danger for user, rescuer and patient.  
The energy applied to the patient can be conducted through the patient to other persons, who may suffer a lethal electric shock. Therefore:
  - do not touch the patient, the electrodes or other conducting objects during defibrillation.
  - do not defibrillate the patient in a puddle of water or on other conducting surfaces,
  - switch the device off when it is no longer used.
- ▲ **Danger of explosion!** — The device must not be used in areas where there is any danger of explosion. There might be a danger of explosion in areas where flammable products (petrol), flammable anaesthetic agents or products for skin cleaning/disinfection are in use, or where the ambient air's oxygen concentration is higher than 25 %.
- ▲ Immediately report any changes that impair safety (including operating behaviour) to the responsible person.
- ▲ Only use original SCHILLER electrodes.
- ▲ Check that the unit's casing and electrode connections are not damaged.
- ▲ After use, refer to the chapter [6 Maintenance](#).
- ▲ Immediately replace a damaged unit, or damaged cables and connections.
- ▲ Operating the device with a defective casing or damaged cables constitutes a danger to life.
- ▲ Only operate the device in accordance with the specified technical data.



## 1.7 Operation with other Devices



- ▲ Magnetic and electrical fields from X-ray or tomographic devices, portable radio equipment, HF radios and devices labelled with the  symbol can affect the operation of this device (see section 7.4). Avoid using such devices or keep a sufficient distance from them.
- ▲ **FRED PA-1<sup>®</sup>** 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.

## 1.8 Maintenance and Cleaning



- ▲ **Danger of electric shock!** Do not open the device. No serviceable parts inside. Refer servicing to qualified personnel only.
- ▲ Before cleaning, switch the unit off and remove the battery.
- ▲ Do not use high-temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- ▲ Do not use aggressive or abrasive cleaners.
- ▲ Do not, under any circumstances, immerse the device or cable assemblies in liquid.
- ▲ To ensure patient safety, only use original SCHILLER accessories. The user is responsible for the use of third-party accessories. The warranty does not cover damage resulting from the use of accessories or consumables other than those marketed by SCHILLER.

## 1.9 General Notes Regarding the Unit



A defibrillation can fail with certain disease patterns.

## 1.10 Additional Terms

### 1.10.1 Implied authorisation

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

### 1.10.2 Terms of Warranty

Your SCHILLER **FRED PA-1**<sup>®</sup> is warranted against defects in material and manufacture according the general terms of condition. Excluded from this warranty is damage caused by an accident or as a result of improper handling. The warranty entitles to free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorised or unqualified persons attempt to make repairs.

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

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorised by him,
- spare parts used for assembly operations, extensions, readjustments, modifications or repairs are recommended or supplied by SCHILLER, and,
- the SCHILLER **FRED PA-1**<sup>®</sup> and approved attached equipment is used in accordance with the manufacturer's instructions.



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

## 1.11 Symbols/Indicators

### 1.11.1 Symbols used in this user guide

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



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



For a possibly dangerous situation which could lead to severe personal injury or to death.



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



For general safety notes as listed in this section.



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



Important or helpful user information.

### 1.11.2 Symbols used on the device



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



Caution! High voltage!



CE-0459 marking (notified body LNE/G-MED).



Do not dispose of the **FRED PA-1**<sup>®</sup> and its accessories in the household waste.



Manufacturer symbol, manufacturing date.



Observe the user guide

### 1.11.3 Symbols used on the battery



The battery is recyclable



Do not recharge



Do not short-circuit



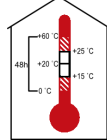
Do not incinerate



Do not cut



Do not crush



Normal storage temperature duration and allowed out-of-range temperature duration (see chapter 7 [Technical Data](#))



Battery must not be disposed of in the household waste

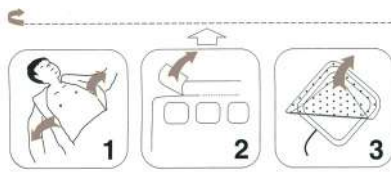


Observe the user guide



Battery expiry date

**1.11.4 Symbols used on the electrode packaging**



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



Disposable item; do not reuse



Do not bend packing



Storage temperature for the electrodes



Expiry date of the electrodes



An open package cannot be conserved more than one day.



Do not expose to sunlight



Does not contain latex



Do not expose to rain



Consult the user guide



Manufacturer symbol, manufacturing date



CE-0408 marking notified body



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

## 2 Components and Operation

### 2.1 General Information

**FRED PA-1®** is an automated external defibrillator (AED).

AEDs are semi-automatic or fully automatic defibrillators

The regulations governing the use and training requirements for AEDs such as the **FRED PA-1®** differ from country to country. The laws and regulations for the use of automatic defibrillators need to be strictly observed.



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

Highly frequented areas are typical places for the operation of a **FRED PA-1®**. Some examples below:

- airports
- train stations
- shopping centres
- public swimming pools
- sport centres
- public institutions



#### **Biocompatibility**

The parts of the product described in this user guide, including all accessories, that come in contact with the patient during the intended use, fulfil the biocompatibility requirements of the applicable standards. If you have any questions in this matter, please contact SCHILLER.

## 2.2 Design

<b>Defibrillator</b>	<p><b>FRED PA-1</b><sup>®</sup> is a defibrillator featuring the BTE (biphasic truncated exponential) waveform. The patient receives a defibrillation shock using disposable electrodes. The ECG signal is analysed using the same electrodes.</p> <p>Moreover, the user is guided by voice prompts and pictograms (loudspeaker/LEDs next to pictograms). The device 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 device.</p>
<b>Languages</b>	<p>The device can be provided with different languages. Optional configuration with 3 languages, selectable after switching the device on.</p>
<b>Metronome</b>	<p>The <b>FRED PA-1</b><sup>®</sup> sets a configurable pace for the cardiopulmonary resuscitation (CPR).</p>
<b>FreeCPR (option)</b>	<p>Information on the chest compression frequency using impedance variation acquired with defibrillation pads.</p>
<b>Data memory</b>	<p>The device is equipped with an internal memory. During the intervention, data can therefore be saved, including the analysed ECG data. In addition, technical data (logs) will be stored.</p>
<b>Data transmission</b>	<p>The <b>FRED PA-1</b><sup>®</sup> has a SD card slot in order to retrieve the data via SD card.</p>
<b>Power supply (standard)</b>	<p>The device is operated with a non rechargeable, disposable lithium battery. The battery capacity is sufficient for:</p> <ul style="list-style-type: none"><li>• more than 140 shocks at maximum energy, if the device is stored/used in optimal temperature conditions between 15 ... 25 °C.</li></ul>
<b>Available versions</b>	<p>Semi- or fully automatic defibrillator</p>

### 2.2.1 Overview of the configurable settings



#### Important!

- ▲ Modifications that can be made via software program are only performed if requested by the customer, or if required by legal requirements.
- ▲ These modifications need to be registered in the device documentation as well as communicated to all users.

SCHILLER's service centre can configure the following parameters:.

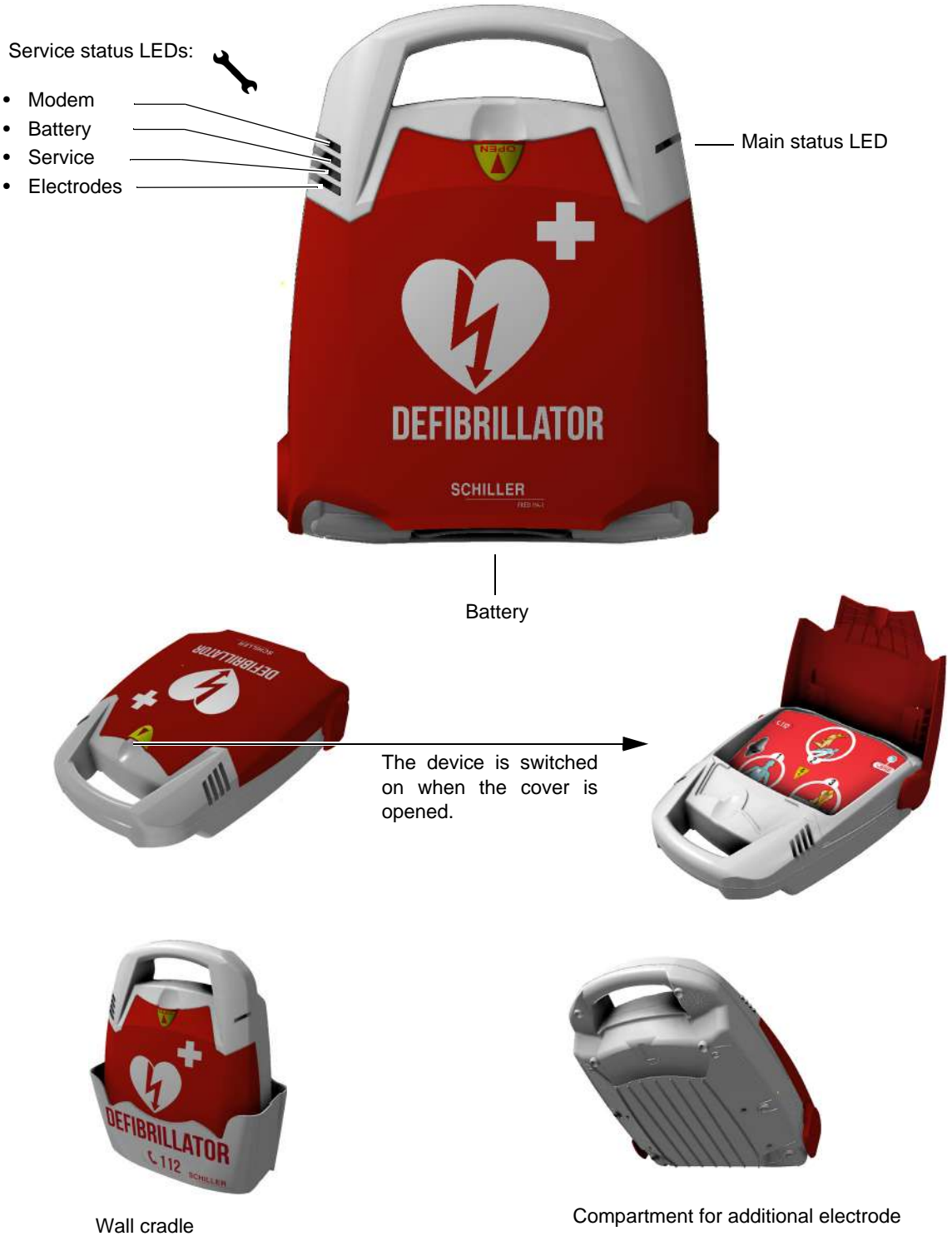
#### Configurable parameters

- Selection of the default language at device start
- Energy level for 1st, 2nd and 3rd shock (separate settings for adults and children)
- Number of chest compressions for children (15 or 30)
- Self-test frequency (daily or weekly)
- Choice between "continuous chest compressions" or "alternating chest compressions/breaths" during CPR cycles
- Date and time
- Update of the software/change of the device language
- Selection of the AED protocol (short or long instructions)
- Activation of notification if no RFID defibrillation pads are detected
- Activation of notch filter (50/60Hz)
- Activation of 16,7Hz Filter
- Activation of sound notification in case of elapsed maintenance interval
- Temperature warning



## 2.3 Operating and Display Elements

### 2.3.1 Overview FRED PA-1

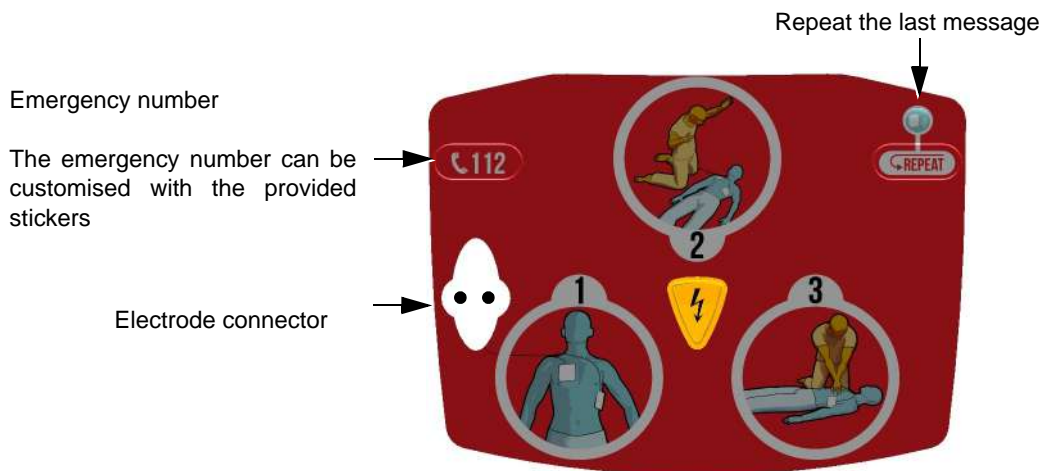


### 2.3.2 Display and Operating Elements

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

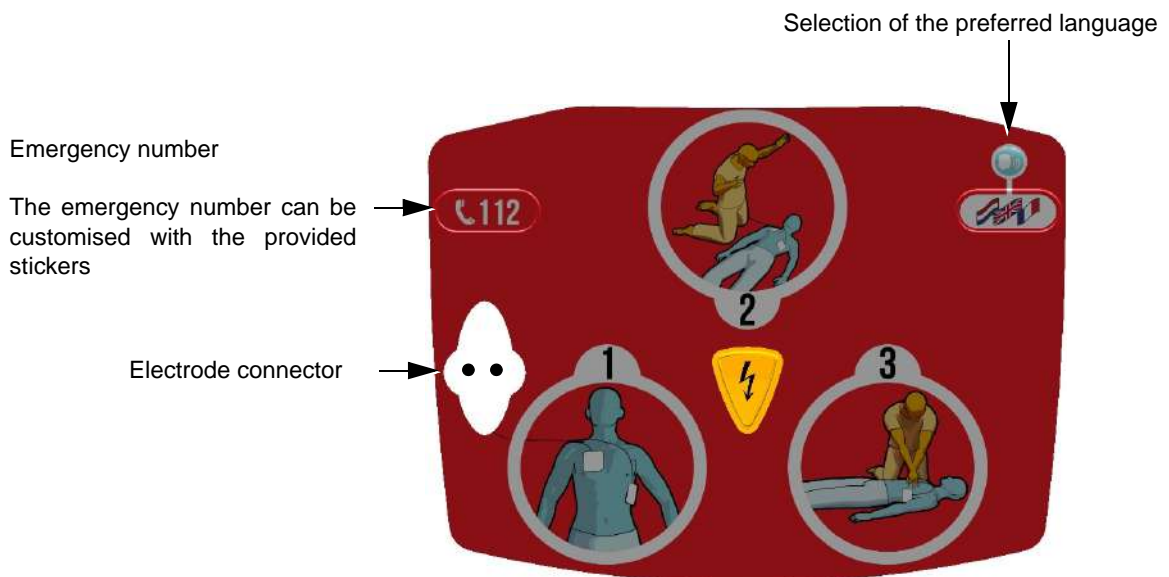
#### Basic device with one language

As soon the cover of the device is opened, the device starts issuing acoustic advices. With the "Repeat Key", the last message is repeated.



#### Multiple language device

As soon as the cover of the device is opened, the device starts issuing acoustic advices 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.



## 2.4 Function

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

If a problem is detected during this test:

- an acoustic alarm is issued,
- the status LED stops blinking
- additional information are given by the service LEDs

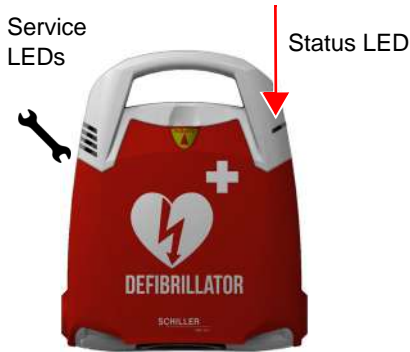


Fig. 2.1 LED indicator

**i**

- If an alarm is in progress (visual and/or 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/or acoustic) can only be reset by removing and reinserting the battery.
- For the alarm details, refer to chapter [6.5.1 Error messages](#).

## 3 Initial operation



**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 in enclosed areas, such as hyperbaric chambers.

### 3.1 Inserting the battery



- ▲ **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<sub>2</sub> battery) a battery.

Li/MnO<sub>2</sub> Patient hazard! — **Incorrect battery capacity indication**

- ▲ A new battery is initialised at first insertion
- ▲ Replace the battery if the device indicates a battery problem. A defective battery must not be used.
- ▲ Turn off the device before removing the battery.



Patient hazard — **Ensuring operational readiness!**

- ▲ Make sure that the device is always equipped with a sufficiently charged battery.
- ▲ The expiration date of a new battery, stored in its original packaging at a temperature of 25°C, is indicated on its packaging. It must not be used beyond this date.
- ▲ The protective 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.

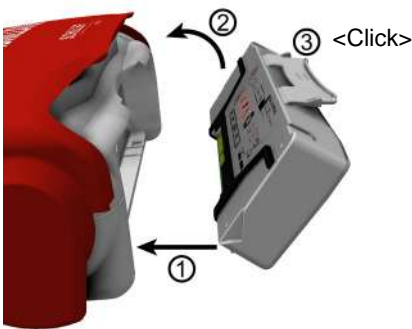


- Each time the device is turned on, it verifies that the battery is functioning properly



→ Remove the protective cap from the battery contacts before inserting the battery in the device.

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 device 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 device and the battery.

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

If this test does not reveal any problems, the green indicator is blinking and all service status LEDs are off, showing that the device has not detected an error.

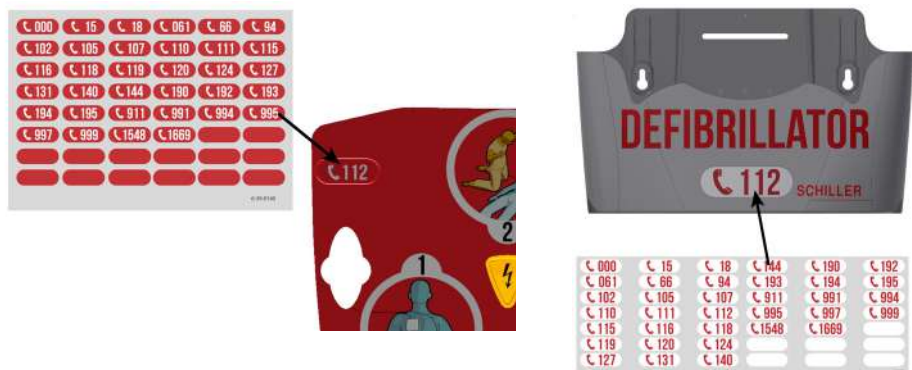
Fig. 3.1 Inserting the battery



If the device is used on a patient, this test can be cancelled by opening the cover.

### 3.1.1 Adding Emergency numbers stickers

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



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



▲ If a patient is detected while closing the cover, the device will remain ON and the resuscitation process will go on.



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

## 3.2 Battery monitoring



- The lithium battery ensures that the device stays fully operative (and performs the self-test) for several years (at a temperature between 15 °C and 25 °C), provided that the device is not being used.
- Battery service life depends on device use and ambient conditions.
- ▲ The battery must be replaced once the expiration date has been exceeded.
- ▲ The old battery must be recycled in accordance with local regulations.

### 3.2.1 Sufficient battery capacity

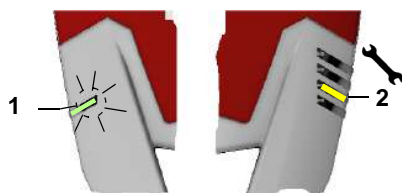


The main status LED (green) on the **FRED PA-1**<sup>®</sup> is blinking when the battery capacity is sufficient to perform the resuscitation protocol.

### 3.2.2 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 device can still be used as normal and is still able to perform defibrillations.
- Always switch off the device before removing the battery.
- The remaining battery capacity depends on the use and ambient conditions.



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

Fig. 3.2 Low battery indication

### 3.2.3 Battery depleted during use, limited mode (CPR)

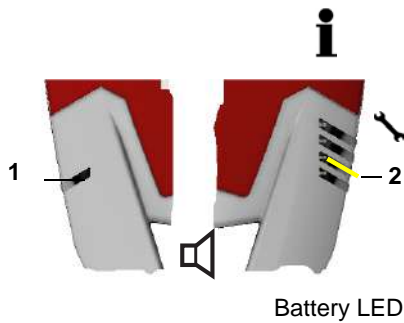


Patient hazard — Defibrillation is no longer possible if a depleted battery is detected. The battery needs to be replaced immediately.

If a depleted battery is detected while the device is in use, the device will prompt the user to replace the battery and perform CPR. An audible signal is emitted. The main status LED is off and the orange battery LED is blinking 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) is blinking until the battery is replaced.





### 3.3 Replacing the "pre-connected" pads


The FRED PA-1® is delivered with "pre-connected" pads. To replaced 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.
- ▲ Please note that the expiration date of the pads only applies if the vacuum pack is intact.
- ▲ Do not reuse the pads.

#### 3.3.1 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 main status LED.



3. Open the cover.
4. Connect the electrode cable to the device.
5. Put the electrode pack in the cover and close the cover.
6. Make sure that neither the electrode cable nor the electrode packaging are squeezed by the cover.
7. Insert the battery after closing the cover.
8. The device is ready for use when the status LED is blinking and the service LEDs are off.

Electrode connector

9. If requested, add a spare set of electrodes in the compartment on the device's underside.



# 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 is 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 on the correct application of the defibrillator but also on the heart's condition. It is the physician's responsibility to take any additional measures (e.g. adrenaline).
- According to AHA/ERC guidelines, even children under 8 years may be defibrillated.
- The electrodes should be applied in the anterior-anterior position. With children, anterior-posterior placement is advised to prevent a short-circuit between the two defibrillation electrodes.
- 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 taken into account during the analysis. Depending on the pacemaker model and on the position of the electrodes, the compensation pulse following every pacer pulse may be considered as a QRS complex. In this case, the analysis can be distorted and inaccurate. It depends on the pacer pulse parameters whether or not the compensation pulse is counted as a QRS complex.

### 4.1.2 Safety notes for AED use



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

#### Shock hazard — for patients

- ▲ In unfavorable situations, the possibility of ECG analysis errors should not be dismissed. The device must therefore only be used if the following symptoms are found:
  - not responsive,
  - no respiration,
  - no pulse.

**Shock hazard — for user and assistants**

- ▲ Position the patient flat on a firm, electrically insulated surface.
- ▲ Make sure that there are no conductive connections between the patient and other persons during ECG analysis and defibrillation.
- ▲ The patient must not come into contact with metal parts, e.g. a bed or stretcher, in order to prevent secondary contacts or paths for the defibrillation current that could endanger the assistants. For the same reason, do not position the patient on a wet surface (rain, swimming pool accidents).
- ▲ Do not allow the defibrillation electrodes to come into contact with other electrodes or metal parts which are in contact with the patient.
- ▲ The patient's chest must be dry because moisture can cause unwanted pathways for the defibrillation current. For safety, wipe off flammable skin cleansing agents.
- ▲ The assistants' tasks must be clearly defined as follows:
  - During ECG analysis:
    - suspend CPR,
    - ensure that the patient lies as motionless as possible,
    - do not touch the patient, otherwise, artefacts may lead to incorrect analysis results.
  - Immediately prior to the shock:
    - stop chest compressions and artificial respiration (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. This is why the electrodes must not be placed on or above:
  - the sternum,
  - the clavicle or,
  - the nipples.

**Risk of malfunction of implanted pacemaker!**

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

## 4.2 Applying the adhesive electrodes

### 4.2.1 General information



- ▲ The pads are sufficiently pre-gelled. Do not use extra contact agent.
- ▲ Do not reuse the pads.
- ▲ 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 children electrodes can be found in the compartment on the bottom of the FRED PA-1.

### 4.2.2 Unpacking and applying electrodes



- ▲ 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).

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

→ Open the electrode packaging and apply the electrodes to the patient's chest.

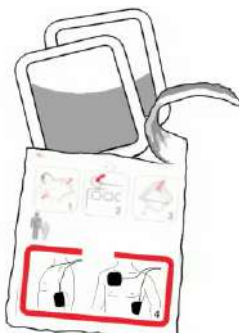


Fig. 4.1 Opening the electrode packaging

- (1) Defibrillation pad to be placed at the right sternal edge at the level of the 2<sup>nd</sup> intercostal space.
- (2) Defibrillation pad to be placed at the left axillary line at the level of the 5<sup>th</sup> intercostal space.
- (3) If not connected, insert the electrode connector into the electrode port.



Fig. 4.2 Green indicator

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

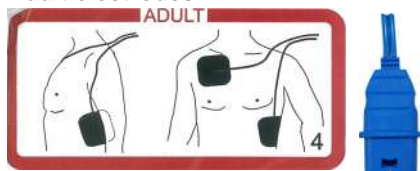
### 4.2.3 Applying the electrodes to the patient's chest



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

#### Adult and paediatric electrodes

##### Adult electrodes



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

##### Paediatric electrodes



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

#### Adults and children weighing 25 kg or more

Electrode placement is the same for adults and for children weighing 25 kg or more (see Fig. 4.4 Electrode application sites for children weighing 25 kg or more). Before applying the adhesive electrodes, verify that the application sites on the patient's chest are clean and dry.

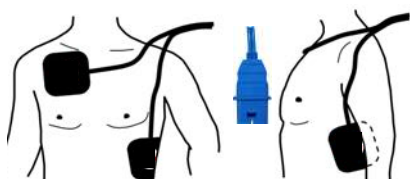


Fig. 4.3 Adult electrode application sites

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

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

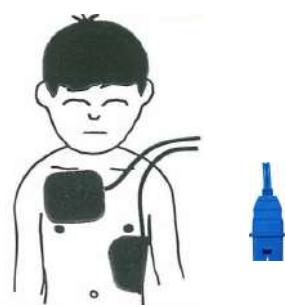


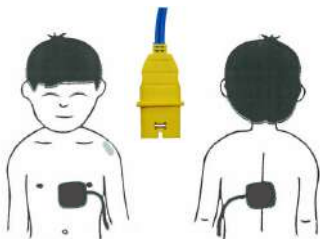
Fig. 4.4 Electrode application sites for children weighing 25 kg or more

7. 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.

**Children weighing less than 25 kg** (younger than 8 years of age)

Electrode placement on children weighing less than 25 kg (see [Fig. 4.5 Application sites for children weighing less than 25 kg](#)). Before applying the adhesive electrodes, verify that the application sites on the patient's chest are clean and dry.

When defibrillating children, it is recommended to choose the anterior-posterior position to avoid short-circuiting the electrodes.



**Fig. 4.5** Application sites for children weighing less than 25 kg

**4.2.4 Checking the electrodes**



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

This can occur if:

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



In this case the device:

- Asks to check that the electrodes are connected and applied to the patient's chest and then recommends performing a CPR cycle.
- resumes the intervention where it has been interrupted when it detects that the resistance between both electrodes is acceptable again.
- switches off if it still does not detect acceptable impedance between both electrodes after 5 minutes.

Follow these steps to check the electrodes:

1. Insert the connector as specified in [3.3.1 Connect the electrodes](#) on page 25.
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.

If the electrode error remains:

→Perform CPR even if the device switches off



To remove the electrodes from the patient's chest, see [4.6 Finishing the therapy](#).

## 4.3 Semi-automatic defibrillation



Patient hazard — The guidelines given in [4.1 Instructions and Safety Notes](#) must be observed.

### Semi-Automatic Defibrillation



Depending on the configuration of the device, the instructions provided by the device may be shortened.

### Step 1



Fig. 4.6 Apply the electrodes

### Switching on and preparing the device

1. Open the cover to switch the device on.
  - If the cover is missing, remove the battery and insert it again to switch the device on.
2. Assess the patient's condition: not responsive, no respiration, no pulse.
3. Apply the defibrillation electrodes to the patient's chest (see [4.2 Applying the adhesive electrodes](#)).



"Apply the electrodes" is blinking as long as the electrodes are not properly applied to the patient's chest and/or the electrode connector is not properly connected to the device.

### Step 2



Fig. 4.7 Analysing, do not touch the patient

### Analysing the ECG signal

4. 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 device detects ventricular fibrillation or ventricular tachycardia with a heart rate exceeding 150 bpm, [Step 3 Shock delivery](#) follows; otherwise, continue with [Step 4, Performing cardiopulmonary resuscitation](#).



### Step 3

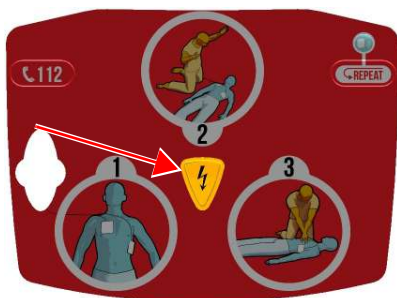


Fig. 4.8 Button to deliver the shock

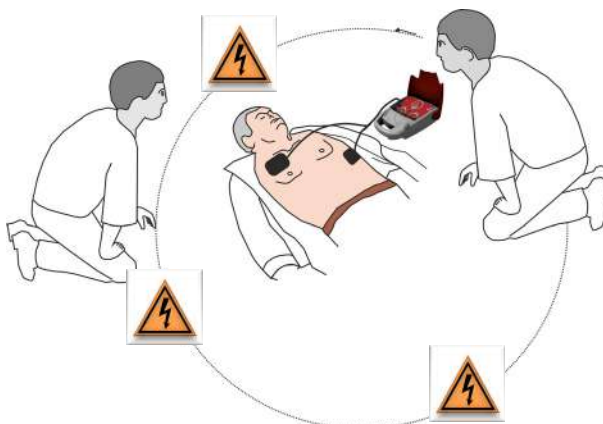
### Shock delivery

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



**Shock hazard!**

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



5. Deliver the shock by pressing the button ⚡.

After the shock delivery, proceed with [Step 4 Performing cardiopulmonary resuscitation](#).

### Step 4

### Performing cardiopulmonary resuscitation



If the **FreeCPR** option is activated, the device 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 device, a CPR cycle consists of:
  - performing chest compressions for the set period of time, or
  - alternately performing 30 chest compressions and 2 breathes for the set period of time.

After the CPR cycle, the device continues automatically with [Step 2 Analysing the ECG signal](#).



### Finishing the therapy

See [4.6 Finishing the therapy](#).

## 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 of the device, the instructions provided by the device may be shortened.

This device delivers defibrillation shocks automatically, i.e. 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, a countdown accompanies the last 3 seconds before the shock is delivered.



Fig. 4.9 FRED PA-1<sup>®</sup> Automatic

### 4.4.2 Safety notes for automatic defibrillation



#### Risks for patient, users and assistants!

Once the device 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 (e.g. stretcher) during analysis and shock delivery.
- ▲ The notes in section [4.1 Instructions and Safety Notes page 26](#) must be observed.

## Step 1



Fig. 4.10 Apply the electrodes

## Step 2



Fig. 4.11 Analysing, do not touch the patient

### Automatic defibrillation

## Switching on and preparing the device

1. Open the cover to switch the device on.
  - If the cover is missing, remove the battery and insert it again to switch the device on.
2. Assess the patient's condition: not responsive, no respiration, no pulse.
3. Apply the defibrillation electrodes to the patient's chest (see [4.2 Applying the adhesive electrodes](#)).



"Apply the electrodes" LED is blinking as long as the electrodes are not properly applied to the patient's chest and/or the electrodes connector is not properly connected to the device.

## Automatic ECG analysis


4. 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 device detects ventricular fibrillation or ventricular tachycardia with a heart rate exceeding 150 bpm, [Step 3 Automatic shock delivery](#) follows; otherwise, continue with [Step 4, Performing cardiopulmonary resuscitation](#).

## Step 3

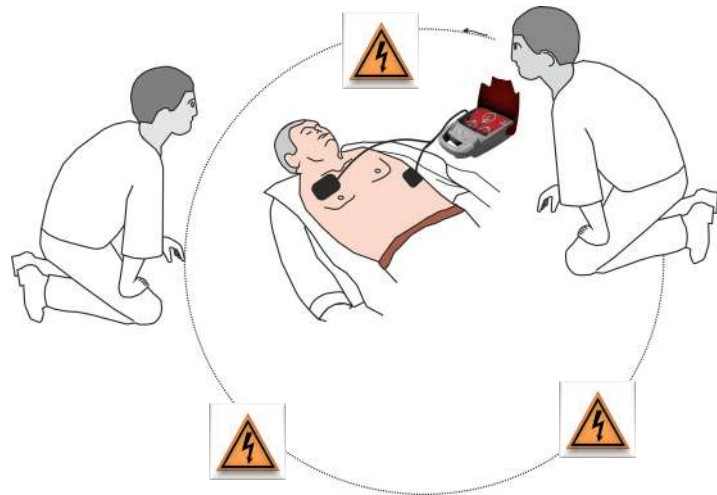
### Automatic shock delivery

As soon as the energy charging is completed, the device automatically delivers the shock, without user intervention. An acoustic countdown starts and the orange button  blinks until the shock is delivered.

**⚠ DANGER**

Shock hazard!

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



After the shock delivery, proceed with [Step 4 Performing cardiopulmonary resuscitation](#).

## Step 4

### Performing cardiopulmonary resuscitation



If the **FreeCPR** option is activated, the device instructs the rescuer to adjust the chest compression frequency.

**FreeCPR** measures the compression rate based on the impedance measurement by the defibrillation electrodes.

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

After the CPR cycle, the device continues automatically with [Step 2 Analysing the ECG signal](#).



## Finishing the therapy

See [4.6 Finishing the therapy](#).

## 4.5 Internal safety discharge



- ▲ If the device's behaviour differs from the description given in this user guide, the device is defective and must be repaired.

An internal safety discharge ensures that the stored energy is discharged within the device every time a defibrillation shock was not delivered correctly. An internal discharge is performed if:

- the shock has not been delivered within the 20 seconds following the end of defibrillation energy charging
- an electrode error is detected
- the battery voltage is insufficient
- the device is defective
- the device is switched off before the shock is delivered.

## 4.6 Finishing the therapy

- Disconnect the electrode cable.
- Switch off the device once the therapy has been completed (close the cover).
- Carefully peel the pads off the patient's skin (see Fig. 4.12 Removing the adhesive pads)
- Recycle the disposable pads immediately after use to keep them from being reused by mistake (hospital waste).
- Connect a new "pre-connected" pad see 3.3.1 Connect the electrodes.
- Retrieve the intervention data see 5.1 Retrieving intervention data

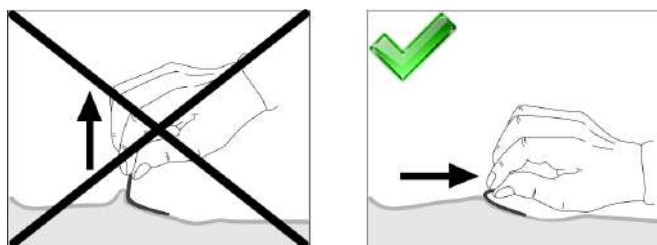


Fig. 4.12 Removing the adhesive pads



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

## 4.7 Replacing the battery



1. Close the cover of the device.
2. Press the two ends of the battery lock down as indicated to remove the battery.
3. Insert a new battery (see 3.1 Inserting the battery page 20)

# 5 Communication

## 5.1 Retrieving intervention data



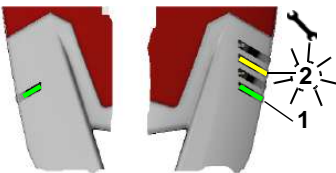
- ▲ Only use standard SD cards (do not use mini or micro SD cards).
- To read the intervention data, use the appropriate SCHILLER software. Contact your SCHILLER representative.

To retrieve the intervention data, an SD card is required. 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 device.



3. Insert the SD card in the slot.
4. Insert the battery. The device is switched on automatically.



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

# 6 Maintenance

## 6.1 Maintenance Intervals



- Because **FRED® PA-1** is an emergency device, some verification has to be done as written in the following table in order to maintain the device operational, including the accessories. The test results must be recorded and compared to the values accompanying the documents (see [7.7 Inspection report](#))
- If used in optimal conditions (see Chapter [6.1.1 Exemption from the technical safety inspection](#)), the **FRED® PA-1** does not need any particular maintenance tests since the device is able to test itself automatically on a regular basis, and it issues a warning if any action either from the user or from a technician is required.
- Local regulations in your country may stipulate additional or different inspection intervals and tests.
- The following table indicates the intervals and competence of the maintenance work required.

Interval	Maintenance - replacement	Responsible
After each use	<ul style="list-style-type: none"> <li>• Replace the electrodes.</li> <li>• After battery insertion, check that the status LED is blinking and that the other LEDs are off (see <a href="#">6.1.4 Mains status LED</a>)</li> <li>• Visual inspection of the device see <a href="#">6.1.3 Visual inspection of the device and accessories</a>.</li> </ul>	→ User
Once a Week/Month	<ul style="list-style-type: none"> <li>• Check that the green main status LED is blinking and all other LEDs are off (see <a href="#">6.1.4 Mains status LED</a>)</li> <li>• Visual inspection of the device and accessories, see <a href="#">6.1.3 Visual inspection of the device and accessories</a>.</li> </ul>	→ User
Every 3 years	<ul style="list-style-type: none"> <li>• Technical safety inspection is advised according to SCHILLER documentation (available for technical departments authorised by SCHILLER), see <a href="#">6.1.5 Functional check</a>.</li> </ul> <p><b>Note:</b> For an exemption from the 3-year technical service inspection, see section <a href="#">6.1.1 Exemption from the technical safety inspection</a></p>	→ Service staff authorised by SCHILLER
Every 6 years	<ul style="list-style-type: none"> <li>• Replacement of internal backup battery. A technical safety inspection and a software update (if needed) are advised after opening the device, see <a href="#">6.1.5 Functional check</a></li> </ul> <p><b>Note:</b> The replacement of the internal backup battery is advised. Should this internal backup battery not be replaced every 6 years, SCHILLER cannot ensure the proper time stamping of the intervention.</p>	→ Service staff authorised by SCHILLER

### 6.1.1 Exemption from the technical safety inspection

Exemption from the 3-year technical safety inspection is possible if the **FRED PA-1®** is exclusively used within the optimal conditions as stated below:

Optimal factors	Fulfilled	Not fulfilled
<ul style="list-style-type: none"> <li>• Environmental conditions before use:               <ul style="list-style-type: none"> <li>– Temperature between +15...25 °C</li> <li>– No daily temperature variation over 10°C</li> <li>– Protection against direct sunlight</li> <li>– Humidity 30 to 65 % (no condensation)</li> <li>– Protection against dust</li> </ul> </li> </ul>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<ul style="list-style-type: none"> <li>• Operation sites               <ul style="list-style-type: none"> <li>– no mobile operation sites (e.g train, car, bus, airplane, ...)</li> <li>– not placed on walls with risk of vibrations (e.g. near doors, windows, ...)</li> </ul> </li> </ul>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<b>Exemption from the technical safety inspection of the FRED PA-1 if all factors are fulfilled</b>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

<b>Location:</b>	<b>Date:</b>
<b>Carried out by:</b>	

### 6.1.2 Service/Shelf life

**Device** The device has 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](#).

**Battery** Main battery (approx.6 years), see expiring date on the battery and internal battery cell (approx. 6 years)

**Electrodes** Electrode packaging (2 years), see expiring date on the electrodes pouch.



### 6.1.3 Visual inspection of the device and accessories

Regularly and after each use, inspect visually the device and the cables in order to detect possible mechanical damages.

If you observe damages or dysfunctions which can endanger the safety of the patient or user, only use the device once it has been serviced.

**Points to inspect:**

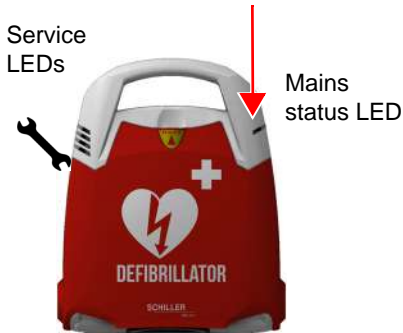
- Check that the main status LED is blinking and all the other LEDs are off, see [6.5.1 Error messages](#)
  - Device casing undamaged?
  - No excessive clogging or damage?
  - Legible nameplate at the rear of the device?
  - Legible inscriptions on the front face of the device?
  - Expiration date of the electrode elapsed? (see section [3.3.1 Connect the electrodes page 25](#).)
  - Expiration date of the battery elapsed?
- 
- ▲ Electrodes past their expiration date must be replaced immediately (Electrode and Service LEDs are on, only by using the electrodes reference 0-21-0040)
  - ▲ Batteries past their expiration date must be replaced immediately. (see expiring date on the batteries)
  - ▲ Defective units or damaged cables must be replaced immediately.
  - ▲ Replace or repair immediately the device, if the main status LED is not blinking. (see details in chapter [6.5.1 Error messages](#))

### 6.1.4 Mains status LED

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

If a problem is detected during this self-test:

- an acoustic alarm is issued,
  - the main status 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 main status LED is no more blinking if the device is no more operational
  - the corresponding service LED is blinking
- see detail in chapter [6.5.1 Error messages](#).



### 6.1.5 Functional check



Patient hazard — If the device's behaviour differs from the description given in this user guide or the main status LED is not blinking, the device is defective and must be repaired.



- ▲ In case of intensive use of the device, SCHILLER recommends that these inspections be performed at shorter interval.
- ▲ The regulations in force in each country regarding inspection frequency must be observed (if shorter intervals than those recommended by SCHILLER are imposed).

#### Points to inspect:

- Visually inspect the device and the accessories (see [6.1.3 Visual inspection of the device and accessories](#)).
- Check for proper functioning.
- Measure the energy delivered at 50 Ohms.

## 6.2 Cleaning and disinfection



Shock hazard — Remove the battery before cleaning the device. This ensures that the device will not be turned on inadvertently while you are cleaning it.  
 Risk of death! Disconnect the defibrillation pads before cleaning the device.

Risk of shock, equipment damage — Liquids must not enter the device. If a liquid has penetrated the device, it must not be used until it has been checked by a service technician.



**Equipment damage!** Do not clean the surface of the device with phenol-based disinfectants or peroxide compounds.

**Device casing**

→ Wipe the device with dampened cloth; make sure no liquid enters the device. All cleaning or disinfection products commonly used in hospitals and containing alcohol (maximum 70 %) are appropriate. If liquids enter the device, it can only be re-operated after it has been checked by the technical support department.

**Cables, electrodes**

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

## 6.3 Accessories and disposables



Risk to Persons, Equipment Damage — Always use SCHILLER replacement parts and disposables, or products approved by SCHILLER. Failure to do so may endanger life and/or invalidate the warranty.

Your local representative stocks all the consumables and accessories for the **FRED PA-1®**. A full list of all SCHILLER representatives can be found on the SCHILLER website ([www.schiller.ch](http://www.schiller.ch)). In case of difficulty, contact SCHILLER. Our staff will be pleased to help process your order or to provide details for all SCHILLER products.

### 6.3.1 Order Information

#### Devices

Part No.	Description
1-127-9902	<b>FRED PA-1®</b> semi-automatic
1-127-9901	<b>FRED PA-1®</b> fully automatic
1-127-3780	Multiple-language option
1-127-5180	Wall bracket
1-127-3580	FreeCPR (CPR feedback option)

#### Accessories/Disposable

Part No.	Description
0-21-0040	1 pair of disposable adhesive defibrillation pads for adults, 80cm <sup>2</sup> ; pre-connected with RFID
2.155067	1 pair of disposable adhesive defibrillation pads for children, 80cm <sup>2</sup> ;
4-07-0025	Battery pack FRED PA-1
5-35-0043	SD Card
6-39-0140	Set of emergency number stickers for device
6-39-0141	Set of flag stickers for device (for multi language option)
6-39-0148	Set of emergency number stickers for wall bracket
0-48-0240	User Guide, English

### 6.3.2 Required accessories

- User Guide
- One pair of adhesive pads
- 1 lithium 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 up the battery.



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

### 6.4.2 Disposal of accessories that come into contact with the patient



Disposable articles (e.g. pads, etc.) 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 device and its accessories must be recycled in compliance with local regulations. Apart from the internal and plug-in batteries, the device does not contain hazardous material and can be recycled like any other piece of electronic equipment. In accordance with national law, the battery must be disposed of at an appropriate waste disposal station or returned to SCHILLER.

According to European legislation, this device is considered as electronic waste equipment. It can be returned to the distributor or manufacturer where the device will be disposed of in compliance with legal requirements. The customer must bear the shipping costs. This unit must be disposed of in a municipally approved collection point or recycling centre when no longer used.

If no such collection point or recycling centre is available, you can return the unit to your distributor or the manufacturer for proper disposal. In this way, you contribute to the recycling and other forms of utilisation of old electrical and electronic equipment. Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.

## 6.5 Troubleshooting



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

### Forced shutdown procedure

- If the device cannot be switched off via normal OFF procedure (closing the cover) remove the battery and insert it again.

### 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.



Normal device state. The device is fully operational. A defibrillation shock can be given.



Restricted device state. The device is not able to charge the HV capacitor and to deliver a defibrillation shock. It only indicates to perform CPR.



Critical device state. The device is out of order.

Description	Device State	Status 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
Main battery almost empty (lower than 10%) or main battery shelf life expired			OFF				→ Replace the battery
Electrodes will expire within 2 months or no RFID defibrillation pads are detected (configuration)			OFF				→ Replace the electrodes
Electrodes expiration date exceeded			ON				→ Replace the electrodes and then remove the battery and insert it again
<sup>a</sup> Temperature out of the limits			configurable				→ Contact your sales representative
Device needs service			OFF				→ Contact your sales representative
Service delay expired			ON				→ Contact your sales representative
Device out of order			ON				→ Replace the device

- a. If 2/3 of the single measurements over a duration of 48 hours are out of the limits, the device will give a warning (Electrode and Service LEDs will light + sound alarm if configured); the status LED continues to blink.  
The frequency of the temperature verification during the 48 hours can be configured from 1h to 24h

**Alarm limits:**

+50 °C for the high limit and -5°C for the low limit.

### 6.5.2 Troubleshooting



#### Forced shutdown procedure

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

Problem	Possible causes	Remedy
The Status indicator is not blinking and the device cannot be turned on.	<ul style="list-style-type: none"> <li>Battery defect.</li> <li>No battery inserted, or battery not correctly inserted.</li> <li>Device defective.</li> </ul>	<ul style="list-style-type: none"> <li>→ Replace the battery.</li> <li>→ Insert the battery correctly.</li> <li>→ Have the device repaired.</li> </ul>
The Status indicator is blinking and the device cannot be turned on.	<ul style="list-style-type: none"> <li>Device cover is missing</li> </ul>	<ul style="list-style-type: none"> <li>→ Remove the battery and insert it again to start the device into the resuscitation process.</li> </ul>
The device prompts the user to check that the electrodes are properly applied and connected.	<ul style="list-style-type: none"> <li>Short-circuit between the pads.</li> <li>Poor pad contact.</li> <li>Electrodes connector not connected to the device</li> <li>Dry contact agent.</li> <li>Device defective.</li> </ul>	<ul style="list-style-type: none"> <li>→ Apply the pads exactly as described.</li> <li>→ Firmly press down on the pads.</li> <li>→ Connect the electrodes connector to the device</li> <li>→ Use new electrodes.</li> <li>→ Have the device repaired.</li> </ul>
The device cannot be turned off.	<ul style="list-style-type: none"> <li>Close the cover</li> <li>Software hangs</li> <li>Device defective.</li> </ul>	<ul style="list-style-type: none"> <li>→ Hold down the cover so that the magnetic sensor is activated</li> <li>→ Remove battery and insert it again.</li> <li>→ Have the device repaired.</li> </ul>
Incorrect analysis result (e.g. the device does not detect a shockable rhythm, even though the patient exhibits ventricular fibrillation).	<ul style="list-style-type: none"> <li>Insufficient ECG signal quality.</li> <li>Electromagnetic waves disturb the ECG signal.</li> <li>Patient moved during analysis.</li> <li>Device defective.</li> </ul>	<ul style="list-style-type: none"> <li>→ Repeat chest compressions.</li> <li>→ Turn off the source of interference (e.g. radio transmitter, cellular telephone). Position the patient outside the range of interference.</li> <li>→ Do not move patient during the analysis.</li> <li>→ Have the device repaired.</li> </ul>
Defibrillation shock cannot be delivered.	<ul style="list-style-type: none"> <li>Insufficient battery charge level.</li> <li>CPR caused pads error.</li> <li>Device defective.</li> </ul>	<ul style="list-style-type: none"> <li>→ Replace the battery.</li> <li>→ Re-apply the pads.</li> <li>→ Have the device repaired.</li> </ul>
The alarm tone does not stop.	<ul style="list-style-type: none"> <li>Battery defect.</li> <li>Device defective.</li> </ul>	<ul style="list-style-type: none"> <li>→ Replace the battery.</li> <li>→ Have the device repaired.</li> </ul>
Battery LED is ON.	<ul style="list-style-type: none"> <li>Battery almost depleted.</li> </ul>	<ul style="list-style-type: none"> <li>→ Replace the battery.</li> </ul>
No data recorded on the SD card.	<ul style="list-style-type: none"> <li>Card defect.</li> <li>Device defective.</li> </ul>	<ul style="list-style-type: none"> <li>→ Replace the card.</li> <li>→ Have the device repaired.</li> </ul>
The electrodes LED continue to blink even after replacing the electrodes	<ul style="list-style-type: none"> <li>Alarms are not reset</li> </ul>	<ul style="list-style-type: none"> <li>→ Remove the battery and insert it again to force a test</li> </ul>
Difficulty to insert the battery	<ul style="list-style-type: none"> <li>Protective cap not removed</li> </ul>	<ul style="list-style-type: none"> <li>→ Remove the contacts protective cap</li> </ul>
The device does not start the automatic test by inserting a battery	<ul style="list-style-type: none"> <li>The battery contacts are dirty</li> <li>The battery is empty</li> </ul>	<ul style="list-style-type: none"> <li>→ Clean the battery contacts with alcohol dampened cloth</li> <li>→ Use a new battery</li> </ul>



### 6.5.3 Measures to prevent electromagnetic interferences



"Non-ionic electromagnetic radiation"

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the **FRED PA-1**<sup>®</sup>. The distance depends on the output performance of the communication device as indicated below.

HF source	Transmitter frequency [MHz]	Power P [W]	Distance d [m]
Radio telephone (microcellular) CT1+, CT2, CT3	885-887	0.010	0.23
Cordless DECT telephone, WLAN, UMTS phone	1880-2500	0.25	1.17
Mobile phone USA	850/1900	0.6	1.8
Mobile phone			
- GSM900,	900	2	3.3
- GSM850, NMT900, DCS 1800	850,900,1800	1	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



It can be deducted from the table that **portable** RF telecommunication devices must not be used within a radius of 3 m from the device and its cables.



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

Further measures to prevent electromagnetic interferences:

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

- Increase distance to the source of interference.
- Turn the device to change the angle of radiation.
- Only use original accessories (especially defibrillation electrodes)
- The device should not be used adjacent to or stacked with other equipment.



For more detailed information, please refer to page 55.

# 7 Technical Data



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

## 7.1 System Specifications

<b>Manufactured by</b>	SCHILLER MEDICAL
<b>Device name</b>	<b>FRED PA-1®</b>
<b>Dimensions</b>	310 x 255 x 100 mm (h x l x w)
<b>Weight</b>	Approx. 2.5 kg with battery and standard accessories
<b>Protection class of the device housing</b>	IP55 (protection against dust and water jets)
<b>Recorded data</b>	ECG signal recording (2 hours) Technical events (500 events)
<b>Power supply</b>	Power supply, suitable for continuous operation with intermittent loading
<b>Battery type</b>	Lithium/MnO <sub>2</sub> 15 V, 2.8 Ah
<b>Battery life</b>	<ul style="list-style-type: none"><li>• more than 140 shocks at maximum energy, if device is stored/used in optimal temperature conditions between 15 ... 25 °C.</li><li>• Several years in standby (standby duration corresponding to laboratory tests at 25°C: 6 years with weekly self-tests)</li></ul>
<b>Environmental conditions</b>	
<b>Device</b>	
Operation	<ul style="list-style-type: none"><li>• -5...40 °C at a relative humidity of 30 to 95% (no condensation)</li></ul>
Storage before use	<ul style="list-style-type: none"><li>• -5...40 °C with the battery inserted and incl. electrodes at a relative humidity of 30 to 95 % (no condensation) but resulting in a reduced battery life; optimal conditions: 15...25 °C to ensure maximum battery life.</li></ul>
Storage and transport	<ul style="list-style-type: none"><li>• Atmospheric pressure 700 to 1060 hPa</li><li>• -20 ... 50 °C at a relative humidity of 0 to 95% (no condensation)</li><li>• Atmospheric pressure 500 to 1060 hPa</li></ul>
<b>Battery and Electrodes</b>	
Storage and Transport temperature battery LiMnO <sub>2</sub>	<ul style="list-style-type: none"><li>• 5 ... 35 °C (48h max. between -20...5°C and 35...60°C)</li></ul>
Storage and transport temperature electrode pads	<ul style="list-style-type: none"><li>• 0 ... 50 °C (max.10 days between -40...0°C and 50...75°C)</li></ul>

## 7.2 Classification and safety standards


### Standards

**FRED PA-1**<sup>®</sup> complies with IEC standard 60601-2-4.  
 According to IEC standard 60601-2-4, **FRED PA-1**<sup>®</sup> is a device for infrequent use.

### EMC

See [7 Technical Data](#).

### Compliance

- **FRED PA-1**<sup>®</sup> bears the  0459 (Notified Body LNE/G-MED) mark indicating its compliance with the provisions of the Directive 93/42/EEC (modified by the Directive 2007/47/EEC) regarding medical devices and fulfils the essential requirements of Annex I of this directive.
- **FRED PA-1**<sup>®</sup> is a class IIb device.

### Patient Protection

BF type, resistant to defibrillation shocks.

### Explosions protection

**FRED PA-1**<sup>®</sup> is **not** designed to be used in the presence of flammable mixtures of anaesthetic agents with air or oxygen.

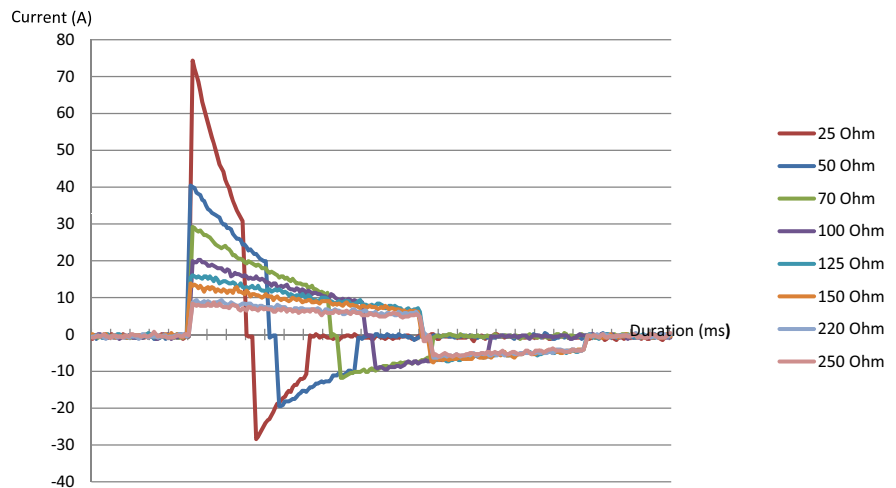


The SCHILLER quality management system complies in full with the international standards ISO 9001 and ISO 13485.

## 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



### Default energy settings

Accuracy at 50Ω:  $\pm 3$  J or  $\pm 15$  % (the higher value is assumed)

SCHILLER's customer service department can change the default energy levels to the following values:  
70 – 90 – 120 – 150 – 200 J (adults)  
30 – 50 – 70 J (children)  
(automatic adaptation when paediatric pads are connected)

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

(Maximum time between start of the analysis and shock availability, in semi-automatic mode)

With full battery:

< 20 seconds


After 15 discharges with max. energy:

< 20 seconds


### 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)
- Via disposable pads applied to the patient in an anterior-lateral or anterior-posterior position

**Safety discharge when:**

- A non shockable rhythm has been detected
- The shock is not delivered within the 20 seconds after charging
- An electrode problem is detected
- Battery voltage is insufficient
- The device is defective
- The device is turned off.

**Defibrillation pad connection**

BF type

**Defibrillation electrodes**

Electrode cable, 2 m in length

Adult and Paediatric pads

- 80 cm<sup>2</sup> active surface

### 7.3.1 Shock Advisory System

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

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

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

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

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

Table 1: FRED 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 (FredEasy, Schiller Medical SAS, France) used by the fire brigade of Paris.

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

## 7.4 Electromagnetic interferences

The **FRED PA-1**<sup>®</sup> is intended for use in the electromagnetic environment specified below. The customer or the user of the **FRED PA-1**<sup>®</sup> should assure that it is used in such an environment.


### 7.4.1 Electromagnetic emissions

Emission measurement	Compliance with the regulations	Electromagnetic environment - explanations
RF emissions CISPR 11	Group 1	<b>FRED PA-1</b> <sup>®</sup> 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	<b>FRED PA-1</b> <sup>®</sup> 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	

### 7.4.2 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 s	Not applicable	No mains power is used
Power frequency (50/60 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 and/or hospital environment.

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

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
Conducted HF IEC 61000-4-6	3 Veff between 150 kHz and 80 MHz outside of the ISM frequency bands <sup>a</sup>  10 Veff between 150 kHz and 80 MHz in ISM frequency bands <sup>a</sup>	Not applicable  Not applicable	<p><b>Recommended minimum distances</b> Portable and mobile HF telecommunication devices must keep the recommended minimum distance from the <b>FRED PA-1</b><sup>®</sup> and all its components, incl. cables; the recommended minimum distance is calculated based on the transmitter's frequency.</p> <p>No mains power is used</p>
Radiated HF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	<div style="border: 1px solid black; padding: 2px; width: fit-content;"> <math display="block">d = \frac{12}{10} \times \sqrt{P}</math> </div> between 80 MHz and 800 MHz  <div style="border: 1px solid black; padding: 2px; width: fit-content;"> <math display="block">d = \frac{23}{10} \times \sqrt{P}</math> </div> between 800 MHz and 2.5 GHz  where P is the maximum transmitting power of the transmitter in Watt (W) according to manufacturer data, and d the recommended minimum distance in metres (m) <sup>b</sup> .  The field strength of stationary HF transmitters (according to an on-location measurement <sup>c</sup> ) must not exceed the conformity level for each frequency range <sup>d</sup> .  When operating the device near devices bearing the symbol "ionising radiation", interferences can occur.  
Note 1 Note 2	For 80 MHz to 800 MHz, the higher frequency range applies. These guidelines might not always be applicable. Electromagnetic radiation is influenced by absorption and reflection on structures, objects and people.		

- a. The ISM frequency bands (ISM = industrial, scientific, medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- b. The conformity levels within the ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz serve to minimise the probability of interferences caused by mobile/portable communication equipment that accidentally happens to be in the patient environment. The formula for the calculation of the recommended distance has been adapted by the factor 10/3 for transmitters in this frequency range.
- c. The field strength of stationary transmitters, e.g. base stations for radio telephones (mobile or cordless) and portable radio equipment, amateur radios, AM and FM radios and TV signals cannot be predicted accurately in a theoretical way. In order to analyse electromagnetic environments caused by stationary HF transmitters, an electromagnetic analysis on site should be considered. If the measured field strength exceeds the HF conformity level, it needs to be checked whether the **FRED PA-1**<sup>®</sup> can be used in this environment. If an abnormal behaviour is detected, additional measures need to be taken, e.g. reorientation or change of location of the **FRED PA-1**<sup>®</sup>.
- d. For the frequency range between 150 kHz and 80 MHz, the field strength must be lower than 3 V/m.



**7.4.3 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 transmitters' max. transmitting power.

Max. 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 <b>outside of</b> the ISM frequency band	$d = \frac{12}{10} \times \sqrt{P}$ between 150 kHz and 80 MHz <b>within</b> the ISM frequency band	$d = \frac{12}{10} \times \sqrt{P}$ between 80 MHz and 800 MHz	$d = \frac{23}{10} \times \sqrt{P}$ between 800 MHz and 2.5 GHz
0,01			0,12	0,23
0,1			0,38	0,73
1	Not applicable	Not applicable	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 MHz 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 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
- 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.

## 7.5 Literature

**European Resuscitation Council (2015)**

Guidelines 2015 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

**American Heart Association (2015)**

Guidelines 2015 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care

## 7.6 Glossary

- ABCD** The primary ABCD
- A = Airways (check if airways are free)
  - B = Breathing (artificial respiration)
  - C = Circulation (circulatory signs or cardiac massage)
  - D = Defibrillation
- AED** Automated external defibrillator. This term is also used for semi-automatic defibrillators
- BLS** Basic Life Support (artificial respiration and cardiac massage)  
CPR is frequently used synonymously
- CPR** Cardiopulmonary resuscitation
- VT** Ventricular tachycardia
- VF** Ventricular fibrillation


## 7.7 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, see 6.1.4 Mains status LED	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
→ Visual inspection of the device and accessories					
→ Device casing undamaged?					
→ No excessive clogging or damage?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
→ Legible nameplate at the rear of the device?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
→ Legible inscriptions on the front face of the device?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
→ Expiration date of the accessories elapsed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Date:</b>					
<b>Performed by:</b>					

Checks - once a Week/once a Month					
<b>Visual inspection of the device and accessories</b> (see previous table)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>The main status indicator  is lit green and no other LEDs are blinking see 6.1.4 Mains status LED</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Date:</b>					
<b>Performed by:</b>					

Checks - every 3 years					
<b>Visual inspection of the device and accessories</b> (see previous table)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Functional test</b>					
→ Check for proper functioning (see 6.1.4 Mains status LED)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
→ Measure the energy delivered at 50 ohms.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Date:</b>					
<b>Performed by:</b>					

Replacement - every 6 years					
Internal backup battery replacement.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Date:</b>					
<b>Performed by:</b>					

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

Name: .....

Tel.: .....

# 8 Index

## A

Accessories .....	44
Appendix	
Glossary .....	57
Inspection Report .....	58
Literature .....	57
Order information .....	56
Required accessories.....	44

## B

Battery	
Battery Disposal .....	45
Battery is empty .....	24
Inserting the battery .....	20
Low battery.....	23
Sufficient battery capacity .....	23
Biocompatibility .....	14

## C

Cleaning .....	43
Configurable parameters	
Energy levels.....	16
Controls and indicators	
-Display .....	18

## D

Danger of electric shock!.....	8
Danger of explosion .....	8, 20
Defibrillation	
Automatic defibrillation .....	34
Defibrillator application guidelines.....	26
Finishing the therapy.....	37
Internal safety discharge .....	37
Semi-automatic Defibrillation .....	32
Design .....	15
Disinfection.....	43
Display Symbols/Indicators	
in this User Guide.....	11
on the display .....	12
on the electrode packaging .....	13
used on the battery .....	12
used on the device .....	11
Disposal information	
Accessories into contact with patients ..	45
At the end of useful life.....	45
Battery.....	45

## E

Electrodes	
Adult and paediatric electrodes.....	29
Checking the electrodes.....	31
Open the electrode packaging .....	28

## F

Function .....	17
----------------	----

## M

Maintenance	
Internal backup battery .....	42
Maintenance Intervals.....	39
Test.....	42
Visual inspection.....	41

## S

Safety Notes .....	7
Self-test.....	19

## T

Technical Data	
Defibrillation impulse.....	51
Dimensions .....	49
Energy levels .....	51
Environmental conditions.....	49
Patient impedance .....	51
Patient Protection .....	50
Power supply .....	49
Protection class .....	49
Standards .....	50
Weight.....	49
Terms of Warranty .....	10
Trouble Shooting.....	46