DEFISIGN *Life*

Automated external defibrillator (AED)

User Guide

Medisol
Saving Lives

Art. no.: 0-48-0411 Rev. a

Sales and service information

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1 Safety Notes

1.1 User profiles

The following people may use the **DEFISIGN *Life***:

- 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 **DEFISIGN *Life*** and which training is required, are country-specific. In any case, legal regulations have to be observed.
- Before using the device, a Medisol 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 **DEFISIGN *Life*** 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 electrodes is pre-connected or a set of children electrodes is placed in the device cover and a spare set of electrodes can be stored in the device.

1.3 Intended Use

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

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1.4 Contraindication for use

- The defibrillator must **not** be used when the person:
  - is responsive
  - is breathing normally
  - has a 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 **DEFISIGN *Life*** is not intended to be used in ambulances and emergency vehicles in movement.

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 Medisol 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.

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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.
- **DEFISIGN *Life*** 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 Medisol 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 Medisol.

1.9 Internet connection

For devices equipped with GSM, the connection to the LifeDataNet G2 server is done over a secured SSL connection and encrypted in AES 128 bits.

1.10 General Notes Regarding the Unit

- A defibrillation can fail with certain disease patterns.
- Some effects may interrupt analysis process e.g.:
  - Agonal respiration phenomenon (GASP) of a patient in cardiac arrest
  - Some non-shockable rhythms of patients in cardiac arrest.

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1.11 Additional Terms

1.11.1 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.

1.11.2 Terms of Warranty

Your Medisol **DEFISIGN *Life*** 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 Medisol, and,
- the Medisol **DEFISIGN *Life*** 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. Medisol makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

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1.12 Symbols/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.
The terms Danger, Warning, and Caution are used in this User Guide to point out potential dangers and to indicate risk levels. Familiarise yourself with their definitions and significance.

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

For general safety notes as listed in this section.

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

Important or helpful user information.

1.12.2 Symbols used on the device

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

Dangerous voltage. Used for electrical dangers during defibrillation.

CE 0459

Notified body of the CE certification (G-MED).

- Symbol for the recognition of electrical and electronic equipment.
- The device must be disposed of in a municipally approved collection point or recycling center 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.

Manufacturer information

Manufacturing date

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Observe the user guide

IP55

Device is protected against dust and spraying water from all directions.

Devices with GSM

Attention: Non-ionic electromagnetic environment. The device contains an HF transmitter.

The **DEFISIGN *Life*** 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 **DEFISIGN *Life*** 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 **DEFISIGN *Life***. A minimum distance of 20 cm must be kept between the device and a pacemaker.
- Turn the device to change the antenna's angle of radiation.

For more details, see section 6.5.3 Measures to prevent electromagnetic interferences.

MD

Indicates that this device is a medical device

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1.12.3 Symbols used on the battery


The battery is recyclable

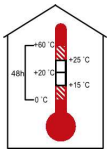

Do not recharge


Do not short-circuit


Do not incinerate


Do not cut


Do not crush



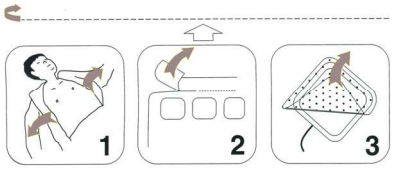
Normal storage temperature duration and allowed out-of-range temperature duration (see chapter 7 Technical Data)


Batteries must not be disposed of with domestic refuse.


Observe the user guide


Battery expiry date

1.12.4 Symbols used on the electrode packaging



- 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

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An open package cannot be conserved more than one day.

Do not expose to sunlight

Do not expose to rain/humidity

Manufacturer information

CE-0408 marking notified body

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

Read the instruction for use.

The packaging is made in low density polyethylene and can be recycled

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2 Components and Operation

2.1 General Information

DEFISIGN *Life* 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 **DEFISIGN *Life*** 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 **DEFISIGN *Life***. 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 Medisol.

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2.2 Design

Defibrillator

DEFISIGN *Life* 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.
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. (DS)-0-21-0040, allows checking the shelf life of the electrodes, when connected to the device.

Languages

The device can be provided with different languages. Optional configuration with 3 languages, selectable after switching the device on.

Metronome

The **DEFISIGN *Life*** sets a configurable pace for the cardiopulmonary resuscitation (CPR).

FreeCPR (option)

Information on the chest compression frequency using impedance variation acquired with defibrillation pads.

Data memory

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.

Data transmission

The **DEFISIGN *Life*** has a SD card slot in order to retrieve the data via SD card.

Power supply (standard)

The device is operated with a non rechargeable, disposable lithium battery. The battery capacity is sufficient for:

- more than 140 shocks at maximum energy, if the device is stored/used in optimal temperature conditions between 15 ... 25 °C.

Available versions

Semi- or fully automatic defibrillator

GSM (option)

The **DEFISIGN *Life*** equipped with GSM is connected to the LifeDataNet G2 Server for device pool management and intervention data transmission.

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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.

Medisol'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)
• [a]Activation of 16,7Hz Filter
• Activation of visual notification in case of elapsed maintenance interval

a.The 16.7 Hz filter must be enabled when the **DEFISIGN *Life*** is installed in trains or railway stations.

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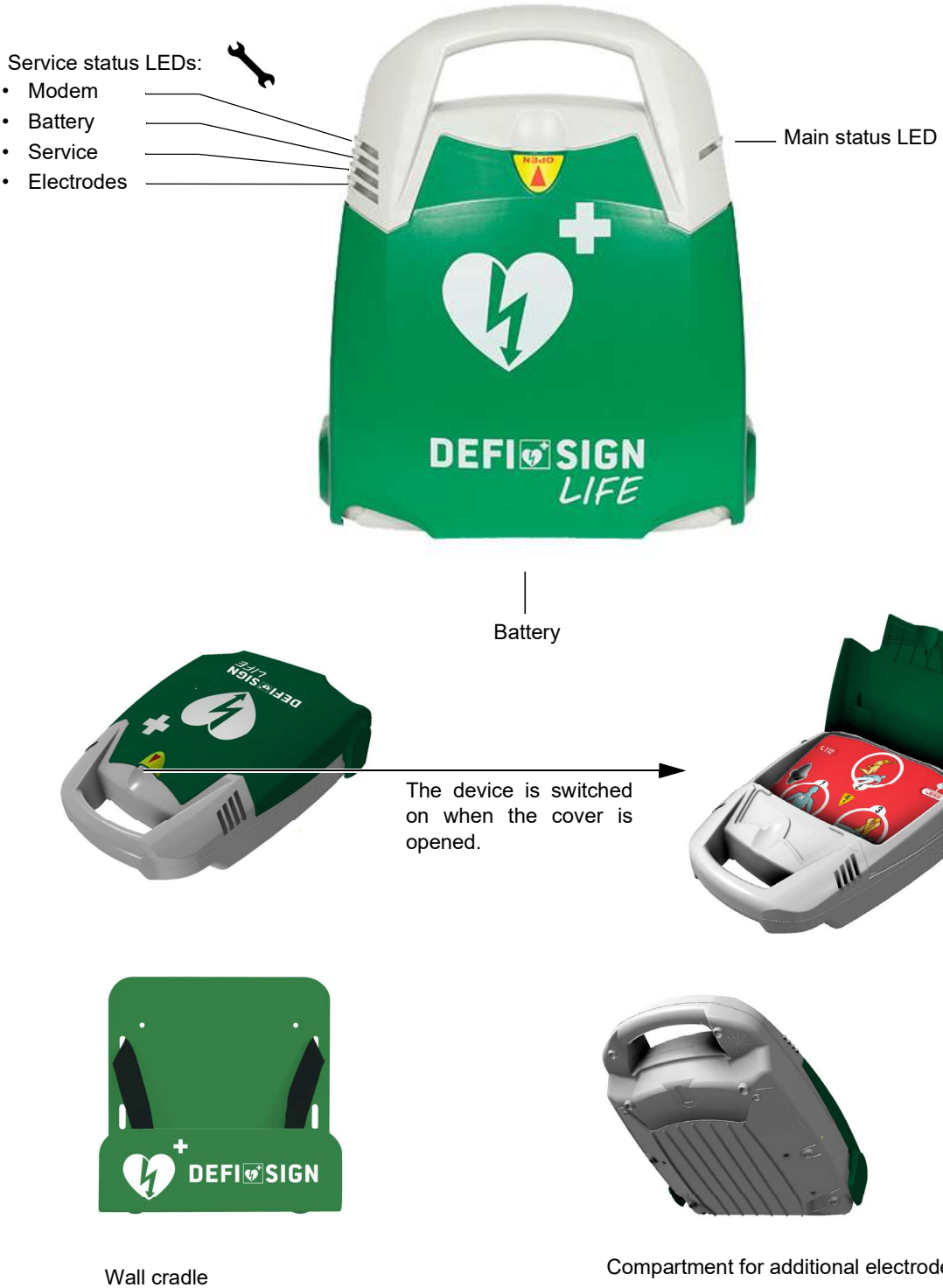
2.3 Operating and Display Elements

2.3.1 Overview DEFISIGN *Life*



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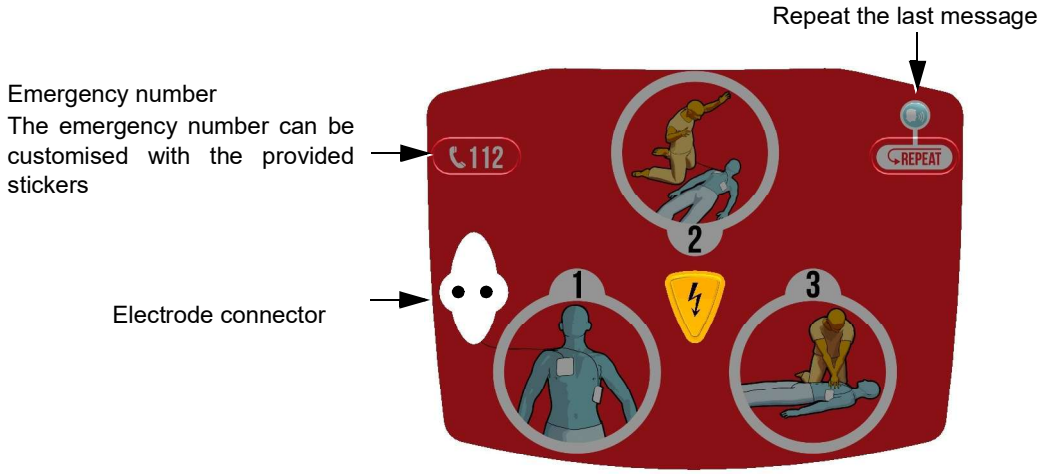
2.3.2 Display and Operating Elements

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

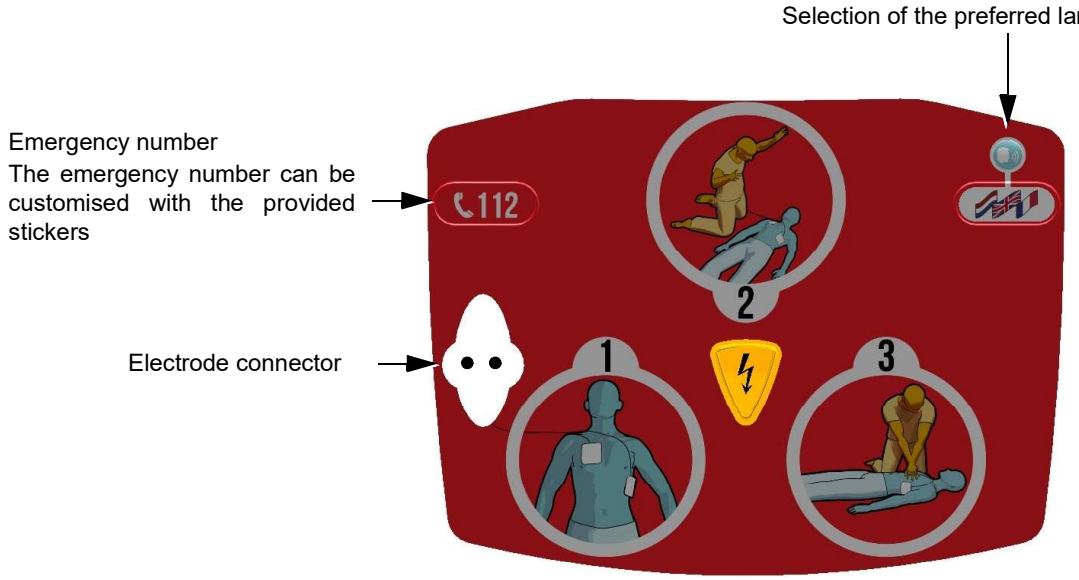
Basic device with one language

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.



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2.4 Function

Immediately after a battery has been inserted, the **DEFISIGN *Life*** 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.

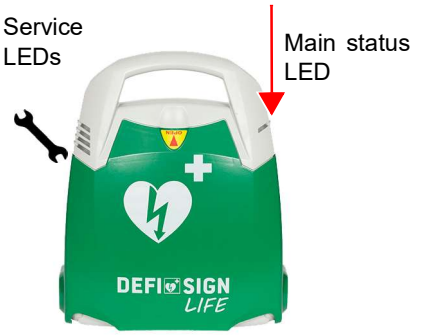

Abb. 2.1 LED indicator

If a problem is detected during this test:

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

- 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 Medisol)
- 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.

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3 Initial operation

⚠ DANGER

Danger of explosion — The **DEFISIGN *Life*** 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

⚠WARNING

Li/MnO2

- **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/MnO2 battery) a battery.

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.

⚠ CAUTION

Patient hazard — **Ensuring operational readiness!**

- Make sure that the device is always equipped with a sufficiently charged battery.
- The expiration date of a new battery, stored in its original packaging at a temperature of 25°C, is indicated on its packaging. It must not be used beyond this date.
- The protective 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 **DEFISIGN *Life*** to direct sunlight or to extreme hot or cold. An ambient temperature higher than 25°C has an adverse effect on the battery life.

i

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

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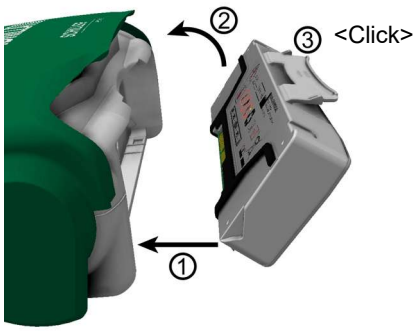


Abb. 3.1 Inserting the battery

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

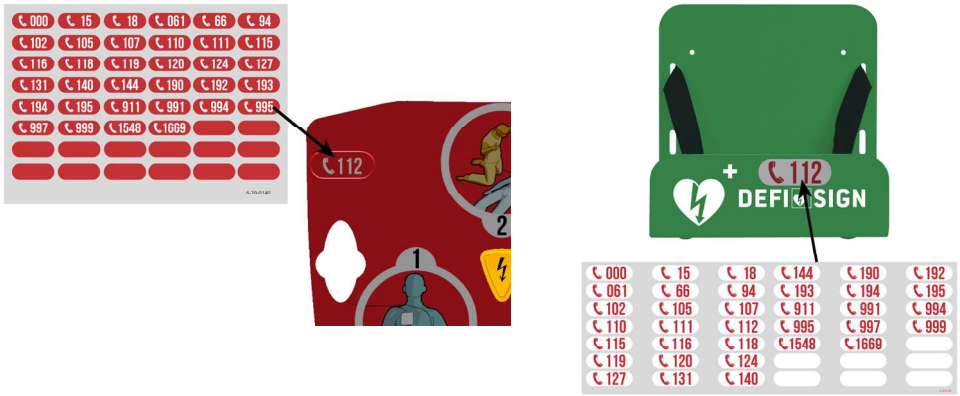
1. Insert the two stop blocks located at the bottom of the battery in the device slots.
2. Perform a rotational movement until the battery locks in place.
3. As soon as the battery is inserted, the **DEFISIGN *Life*** runs a self-test to check the condition of the device and the battery.

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.

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.

⚠ CAUTION

▲ 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.

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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 **DEFISIGN *Life*** 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.

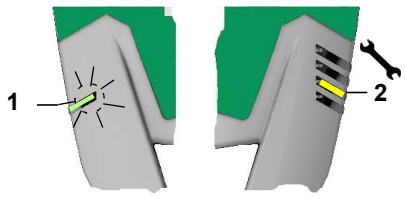

Abb. 3.2 Low battery indication

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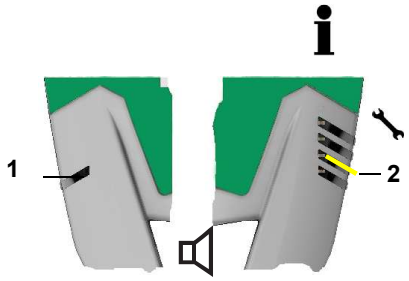
3.2.3 Battery depleted during use, limited mode (CPR)

WARNING

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

If a depleted battery is detected while the device is in use, the device will 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.



Battery LED

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 **DEFISIGN *Life*** 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.

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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.

Electrode connector

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 main status LED is blinking and the service LEDs are off.

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

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4 Defibrillation

4.1 Instructions and Safety Notes

4.1.1 Instructions

- The **DEFISIGN** ***Life*** 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 **DEFISIGN** ***Life*** 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.
- Some effects may interrupt analysis process e.g.:
  - Agonal respiration phenomenon (GASP) of a patient in cardiac arrest
  - Some non-shockable rhythms of patients in cardiac arrest.
- **Patients with implanted pacemakers** — **DEFISIGN** ***Life*** 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

WARNING

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

Shock hazard — for patients

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

- not responsive,
- no respiration,
- no pulse.

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⚠WARNING

Shock hazard — for user and assistants

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

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

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

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

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

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

- During ECG analysis:
  - 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.

▲ Delivering defibrillation shock with bad contact or delivering repeated shock might lead to tissue redness or burns.

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,
- the pacemaker must be checked immediately after finishing the therapy

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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 **DEFISIGN *Life***.

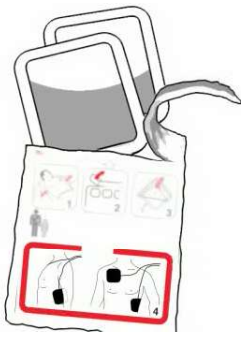
4.2.2 Unpacking and applying electrodes

⚠ CAUTION

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

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.



(1) Defibrillation pad to be placed at the right sternal edge at the level of the 2nd intercostal space.

(2) Defibrillation pad to be placed at the left axillary line at the level of the 5th intercostal space.

(3) If not connected, insert the electrode connector into the electrode port.

Abb. 4.1 Opening the electrode packaging

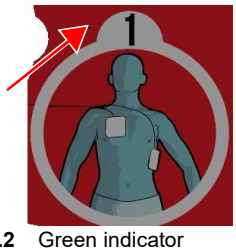


Abb. 4.2 Green indicator

- 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.

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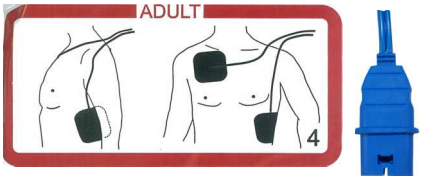
4.2.3 Applying the electrodes to the patient's chest

WARNING

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

Adults and children weighing 25 kg or more

Adult electrodes 80 cm²



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

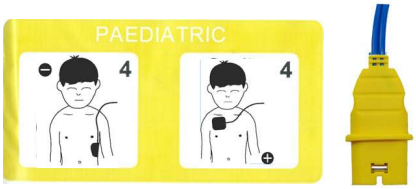
Electrode placement is the same for adults and for children weighing 25 kg or more. Before applying the adhesive electrodes, verify that the application sites on the patient's chest are clean and dry.

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

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

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

Paediatric electrodes 42 cm²



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

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

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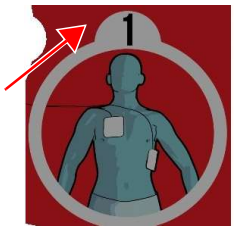
4.2.4 Checking the electrodes



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.

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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.

Semi-Automatic Defibrillation

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

Step 1

Switching on and preparing the device

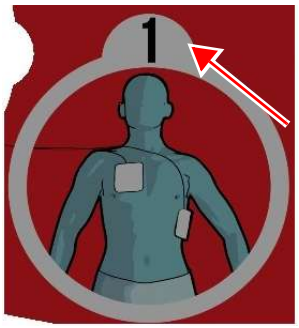

Abb. 4.3 Apply the electrodes

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

Analysing the ECG signal

Abb. 4.4 Analysing, do not touch the patient

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.

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Step 3

Shock delivery

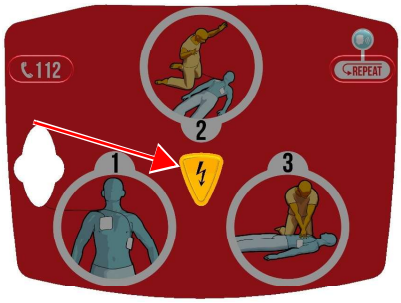


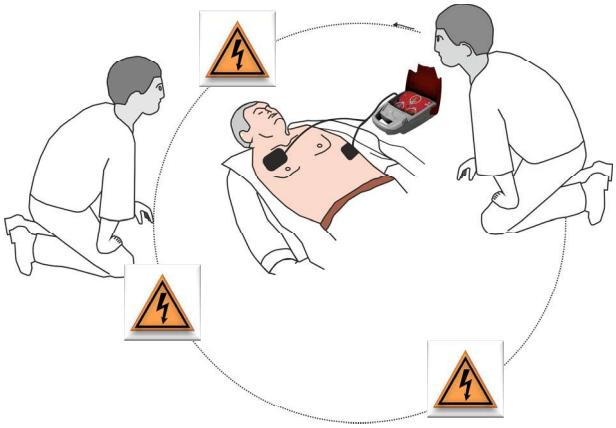
Abb. 4.5 Button to deliver the shock

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

⚠ DANGER

Shock hazard!

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



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.

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

Abb. 4.6 **DEFISIGN *Life*** Automatic

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.

4.4.2 Safety notes for automatic defibrillation

DANGER

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.

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Automatic defibrillation

Step 1

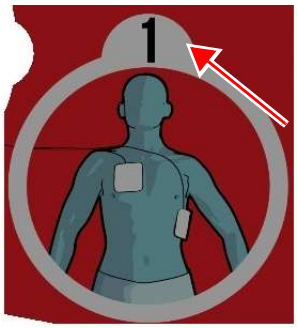

Abb. 4.7 Apply the electrodes

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" 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.

Step 2

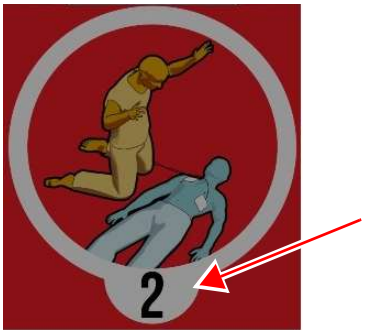

Abb. 4.8 Analysing, do not touch the patient

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.

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Step 3

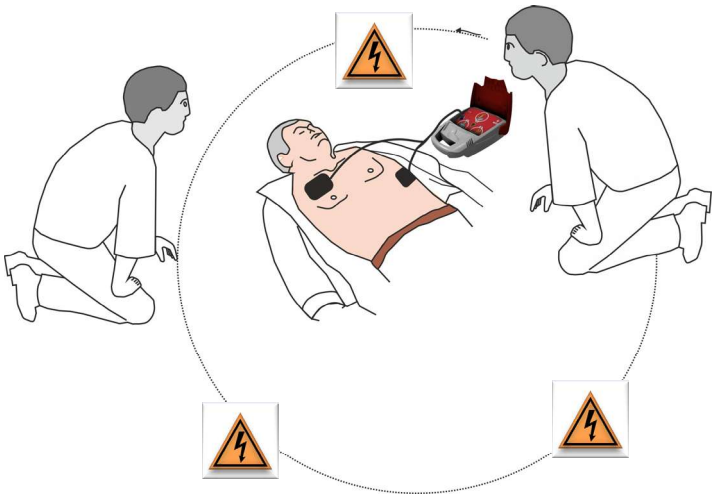
Automatic shock delivery

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.

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4.5 Internal safety discharge

WARNING

▲ 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 Abb. 4.9 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
- Patient with implanted pacemaker must check the functioning of the pacemaker immediately.

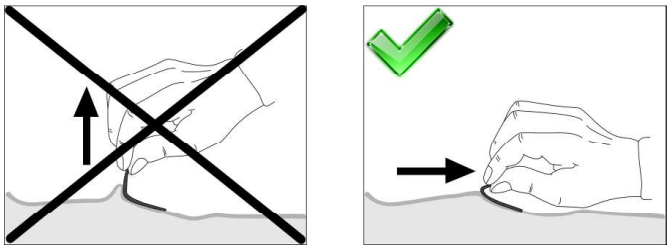
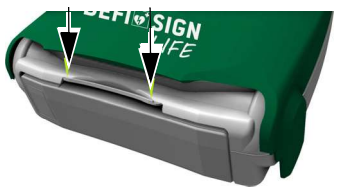


Abb. 4.9 Removing the adhesive pads

- 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 21)

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5 Communication

5.1 Retrieving intervention data

5.1.1 For standard device with SD card

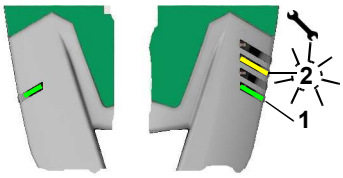
▲ Only use standard SD cards (do not use mini or micro SD cards).

- To read the intervention data, use the appropriate Medisol software. Contact your Medisol 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.

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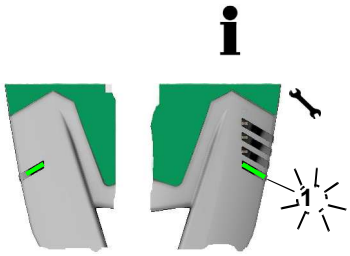
5.1.2 For device equipped with GSM



- **DEFISIGN *Life*** with GSM option is delivered with an embedded SIM card that shall not be removed.
- After use on a patient, intervention data will be automatically sent to the Medisol Server after next self-test (10 minutes after shut down).
- The GSM communication is active while transmitting to the LifeDataNet G2 service is running. This is indicated by the blinking Modem LED (1) see picture above.

Device management

The devices equipped with GSM module are managed by the SCHILLER Server LifeDataNet G2.
The **DEFISIGN *Life*** sends information automatically to the server to ensure that it is operational if needed.
The **DEFISIGN *Life*** sends after each self-test the:

- self-test result
- battery status
- pads expiry date
- "Alive" status

Authorised users have also the possibility to schedule remote software and configuration update through the LifeDataNet G2 server. These updates will be downloaded and applied by the device at next connection, typically at next self-test.

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6 Maintenance

6.1 Maintenance Intervals

- Because **DEFISIGN *Life*** 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 7.8 Inspection report)
- If used in optimal conditions (see Chapter 6.1.1 Exemption from the technical safety inspection), the **DEFISIGN *Life*** 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.

WARNING

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.

CAUTION

- In case of intensive use of the device, Medisol 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 Medisol are imposed).

Interval	Maintenance - replacement	Responsible
After each use	• Replace the electrodes. • After battery insertion, check that the main status LED is blinking and that the other LEDs are off (see 6.1.4 Main status LED) • Visual inspection of the device see 6.1.3 Visual inspection of the device and accessories. • Retrieve the intervention data and clear the intervention memory (. Refer to 5.1 Retrieving intervention data, 5.1.1 For standard device with SD card.	➜ User
Once a Week/Month	• Check that the green main status LED is blinking and all other LEDs are off (see 6.1.4 Main status LED) • Visual inspection of the device and accessories, see 6.1.3 Visual inspection of the device and accessories. • **DEFISIGN *Life*** equipped with GSM module can be exempted from this maintenance intervals as long as the device is remotely under supervision through the LifeDataNet G2 server.	➜ User

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Interval	Maintenance - replacement	Responsible
Every 3 years	• Perform a software update (if new version available) • Visual inspection of the device and accessories, see 6.1.3 Visual inspection of the device and accessories • Check for proper functioning. • Measure the energy delivered at 50 Ohms with appropriate material **Note:** For an exemption from the 3-year technical service inspection, see section 6.1.1 Exemption from the technical safety inspection	➜ Service staff authorised by Medisol
Every 6 years	• Replacement of internal backup battery. • Perform a software update (if new version available) • Visual inspection of the device and accessories, see 6.1.3 Visual inspection of the device and accessories • Check for proper 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, Medisol cannot ensure the proper time stamping of the intervention.	➜ Service staff authorised by Medisol

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.

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6.1.1 Exemption from the technical safety inspection

Exemption from the 3-year technical safety inspection is possible if the **DEFISIGN *Life*** is exclusively used within the optimal conditions as stated below:

Optimal factors	**Fulfilled**	**Not fulfilled**
• Environmental conditions before use:		
– Temperature between +15...25 °C	☐	☐
– No daily temperature variation over 10°C	☐	☐
– Protection against direct sunlight	☐	☐
– Humidity 30 to 65 % (no condensation)	☐	☐
– Protection against dust	☐	☐
• Operation sites		
– no mobile operation sites (e.g train, car, bus, airplane, …)	☐	☐
– not placed on walls with risk of vibrations (e.g. near doors, windows, ...)	☐	☐
Exemption from the technical safety inspection of the DEFISIGN *Life* if all factors are fulfilled	Yes ☐	No ☐
Location: **Date:**		
Carried out by:		

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.

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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 (main status LED is off and Electrodes LED is blinking, only by using the electrodes reference (DS)-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)

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6.1.4 Main 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 (DS)-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.

6.2 Cleaning and disinfection

DANGER

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

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).

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6.3 Accessories and disposables

WARNING

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

Your local representative stocks all the consumables and accessories for the **DEFISIGN *Life***. A full list of all Medisol representatives can be found on the Medisol website https://www.medisolinternational.com. In case of difficulty, contact Medisol. Our staff will be pleased to help process your order or to provide details for all Medisol products.

6.3.1 Order Information

Devices

Part No.	Description
1-127-9902	**FRED PA-1®** (**DEFISIGN *Life***) semi-automatic
1-127-9901	**FRED PA-1®** (**DEFISIGN *Life***) fully automatic
1-127-9904	**FRED PA-1®** (**DEFISIGN *Life***) semi-automatic with GSM communication module
1-127-9903	**FRED PA-1®** (**DEFISIGN *Life***) fully automatic with GSM communication module
1-127-3780	Multiple-language option
1-127-5180	Wall bracket
1-127-3580	FreeCPR (CPR feedback option)

Accessories/Disposable

Part No.	Description
(DS)-0-21-0040	1 pair of disposable adhesive defibrillation pads for adults, 80cm²; pre-connected with RFID
2.155067	1 pair of disposable adhesive defibrillation pads for children, 42cm²;
4-07-0025	Battery pack **FRED PA-1®** (**DEFISIGN *Life***)
5-35-0043	SD Card
9-75-0010	1 year LifeDataNet G2 access (incl. GSM Data and access to LifeDataNet G2 Server). 3 years commitment minimum per unit.
6-39-0172	Set of emergency number and flag stickers for device
6-39-0148	Set of emergency number stickers for wall bracket
0-48-0411	User Guide, English

6.3.2 Required accessories

- User Guide
- One pair of adhesive pads
- 1 lithium battery

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6.4 Disposal information

6.4.1 Battery Disposal

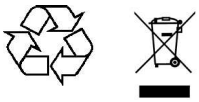
- Danger of explosion! The battery must not be incinerated, exposed to high temperatures or disposed of with household waste.
- Do not expose the battery to chemicals that could dissolve ABS, polypropylene, polyvinyl chloride, nickel, mylar or steel.
- Do not cut, destroy, or incinerate the battery.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

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 Medisol.

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

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

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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.

Description	Device State	Main 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	✓	○	OFF	○	●	○	➜ Replace the electrodes and then remove the battery and insert it again
Device needs service	✓	●	OFF	○	○	●	➜ Contact your sales representative
Service delay expired	✓	○	OFF	○	○	●	➜ Contact your sales representative
Device out of order	⚠	○	ON	○	○	●	➜ Replace the device

✓ 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.

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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.	• Battery defect. • No battery inserted, or battery not correctly inserted. • Device defective.	→ Replace the battery. → Insert the battery correctly. → Have the device repaired.
The Status indicator is blinking and the device cannot be turned on.	• Device cover is missing	→ Remove the battery and insert it again to start the device into the resuscitation process.
The device 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 device • Dry contact agent. • Device defective.	→ Apply the pads exactly as described. → Firmly press down on the pads. → Connect the electrodes connector to the device → Use new electrodes. → Have the device repaired.
The device cannot be turned off.	• Close the cover • Software hangs • Device defective.	→ Hold down the cover so that the magnetic sensor is activated → Remove battery and insert it again. → Have the device repaired.
Incorrect analysis result (e.g. the device does not detect a shockable rhythm, even though the patient exhibits ventricular fibrillation).	• Insufficient ECG signal quality. • Electromagnetic waves disturb the ECG signal. • Patient moved during analysis. • Device defective.	→ Repeat chest compressions. → Turn off the source of interference (e.g. radio transmitter, cellular telephone). Position the patient outside the range of interference. → Do not move patient during the analysis. → Have the device repaired.
Defibrillation shock cannot be delivered.	• Insufficient battery charge level. • CPR caused pads error. • Device defective.	→ Replace the battery. → Re-apply the pads. → Have the device repaired.
The alarm tone does not stop.	• Battery defect. • Device defective.	→ Replace the battery. → Have the device repaired.
Battery LED is ON.	• Battery almost depleted.	→ Replace the battery.
No data recorded on the SD card.	• Card defect. • Device defective.	→ Replace the card. → Have the device repaired.
The electrodes LED continue to blink even after replacing the electrodes	• Alarms are not reset	→ Remove the battery and insert it again to force a test
Difficulty to insert the battery	• Protective cap not removed	→ Remove the contacts protective cap

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Problem	Possible causes	Remedy
The device does not start the automatic test by inserting a battery	• The battery contacts are dirty • The battery is empty	➜ Clean the battery contacts with alcohol dampened cloth ➜ Use a new battery

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 **DEFISIGN *Life***. 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, - 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

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.

⚠ CAUTION

▲ However, there is no guarantee that no interference can occur in certain installations. If the **DEFISIGN *Life*** 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.

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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®** (**DEFISIGN *Life***)
Distributed by	Medisol BV under the Name **DEFISIGN *Life***
Dimensions	310 x 255 x 100 mm (h x l x w)
Weight	Approx. 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	Power supply, suitable for continuous operation for 4 hours and 30 minutes with intermittent loading Lithium/MnO_2 15 V, 2.8 Ah
Battery type Battery life	• more than 140 shocks at maximum energy, if device is stored/used in optimal temperature conditions between 15 ... 25 °C. **For device with SD card** • Several years in standby (standby duration corresponding to laboratory tests at 25°C: 6 years with weekly self-tests) **For device with GSM** • 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)
Environmental conditions	
Device	
Operation	• -5...40 °C at a relative humidity of 30 to 95% (no condensation)
Storage before use	• -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.
Storage and transport	• Atmospheric pressure 700 to 1060 hPa • -20 ... 50 °C at a relative humidity of 30 to 95% (no condensation) • Atmospheric pressure 500 to 1060 hPa
Battery and Electrodes	
Storage and Transport temperature battery $LiMnO_2$	• 5 ... 35 °C (48h max. between -20...5°C and 35...60°C)
Storage and transport temperature electrode pads	• 0 ... 50 °C (max.10 days between -40...0°C and 50...75°C)

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7.2 Classification and safety standards

Standards	**FRED PA-1®** (**DEFISIGN *Life***) complies with IEC standard 60601-2-4. According to IEC standard 60601-2-4, **FRED PA-1®** (**DEFISIGN *Life***) is a device for infrequent use.
EMC	See 7 Technical Data.
Compliance	• **FRED PA-1®** (**DEFISIGN *Life***) bears the CE 0459 (Notified Body GMED) 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®** (**DEFISIGN *Life***) is a class IIb device.
Patient Protection	BF type, resistant to defibrillation shocks.
Explosions protection	**FRED PA-1®** (**DEFISIGN *Life***) is **not** designed to be used in the presence of flammable mixtures of anaesthetic agents with air or oxygen.

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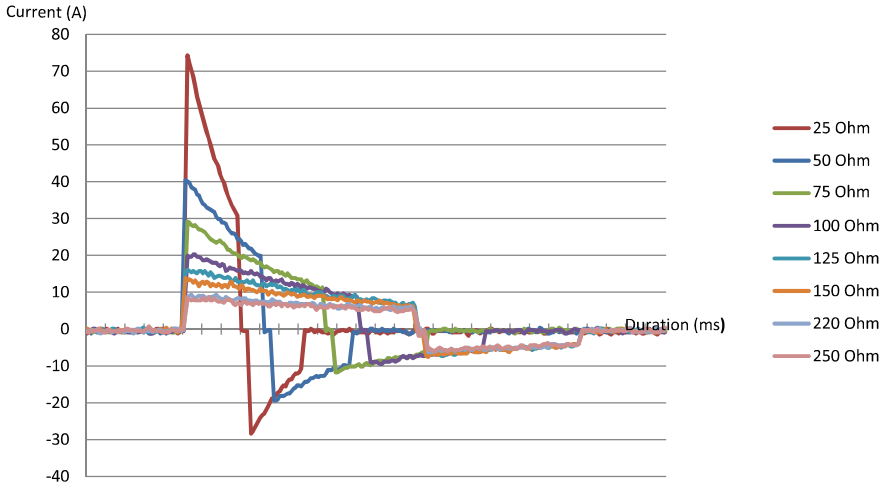
7.3 Defibrillation pulse

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 till 200 J) at 25 till 175 Rpat [Ω] is ± 3 J or ±15 % (the higher value is assumed) see table below:

	Energy delivered [J] in load resistance Rpat [Ω]							**Deviation in Joule** 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

Medisol's customer service department can change the default energy levels to the following values:
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)

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

With full battery:

- approx. 10 seconds

After 15 discharges with max. energy:

- approx. 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) • 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 pads	• 80 cm² active surface
Paediatric pads	• 42 cm² active surface

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7.3.1 Shock Advisory System

WARNING

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

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 **DEFISIGN *Life***. However, when the analogue signals of the database are run on the **DEFISIGN *Life*** via electrode connector, the **DEFISIGN *Life***'s rhythm detector signal-processing characteristics are applied. Moreover these signals are of appropriate length to allow decisions to be made by the detector system.

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

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

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

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

Table 1: DEFISIGN ***Life*** 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.

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The DEFISIGN ***Life*** 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.

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7.4 Telecommunication GSM (option)

Frequency range	Quad band GSM/GPRS/EDGE 850/900/1800/1900 MHz UMTS/HSPA+ 850/900/AWS1700/1900/2100 MHz
Supported SIM cards	3 and 1.8 V
Data transmission	GPRS class B
Max. transmitting power	• UMTS/HSPA – Class 3 (0.25 watt) • GSM 850/900 MHz – Class 4 (2 watt) • GSM 1800/1900 MHz – Class 1 (1 watt) • EDGE 850/900 MHz – Class E2 (0.5 watt) • EDGE 1800/1900 MHz – Class E2 (0.4 watt)
FCC identification **IC**	R17HE910 5131A-HE910
Standards	• FCC, IC • PTCRB • R&TTE • GCF • RoHS/WEEE • CE • ANATEL • KCC • CCC • JATE

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7.5 Electromagnetic interferences

The **FRED PA-1®** (**DEFISIGN *Life***) is intended for use in the electromagnetic environment specified below. The customer or the user of the **FRED PA-1®** (**DEFISIGN *Life***) should assure that it is used in such an environment.

7.5.1 Electromagnetic emissions

Emission measurement	Compliance with the regulations	Electromagnetic environment - explanations
RF emissions CISPR 11	Group 1	**FRED PA-1®** (**DEFISIGN *Life***) 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®** (**DEFISIGN *Life***) 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	

7.5.2 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.			

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Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
			Recommended minimum distances Portable and mobile HF telecommunication devices must keep the recommended minimum distance from the **FRED PA-1®** (**DEFISIGN *Life***). and all its components, incl. cables; the recommended minimum distance is calculated based on the transmitter's frequency.
Conducted HF IEC 61000-4-6	3 Veff between 150 kHz and 80 MHz outside of the ISM frequency bands[a] 10 Veff between 150 kHz and 80 MHz in ISM frequency bands [a]	Not applicable 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 MHz 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 Watt (W) according to manufacturer data, and d the recommended minimum distance in metres (m)[b]. The field strength of stationary HF transmitters (according to an on-location measurement [c]) must not exceed the conformity level for each frequency range [d]. When operating the device near devices bearing the symbol “ionising radiation”, interferences can occur. 
Note 1	For 80 MHz to 800 MHz, the higher frequency range applies.		
Note 2	These guidelines might not always be applicable. Electromagnetic radiation is influenced by absorption and reflection on structures, objects and people.		

a. The ISM frequency bands (ISM = industrial, scientific, medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

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®** (**DEFISIGN *Life***) 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®** (**DEFISIGN *Life***).

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

7.5.3 Recommended minimum distances

The **DEFISIGN *Life*** is intended to be used in electromagnetic environments in which it is possible to control radiated HF interferences. The user of the **DEFISIGN *Life*** can prevent electromagnetic interferences by always keeping a minimum distance between portable/mobile HF communication devices (transmitters) and the **DEFISIGN *Life***. 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 **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 MHz 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 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.

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7.6 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

7.7 Glossary

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

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

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

CPR Cardiopulmonary resuscitation

VT Ventricular tachycardia

VF Ventricular fibrillation

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7.8 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 Main status LED	☐	☐	☐	☐	☐
➜ Visual inspection of the device and accessories					
➜ Device casing undamaged?					
➜ No excessive clogging or damage?	☐	☐	☐	☐	☐
➜ Legible nameplate at the rear of the device?	☐	☐	☐	☐	☐
➜ Legible inscriptions on the front face of the device?	☐	☐	☐	☐	☐
➜ Expiration date of the accessories elapsed?	☐	☐	☐	☐	☐
Date:					
Performed by:					
Checks - once a Week/once a Month					
Visual inspection of the device and accessories (see previous table)	☐	☐	☐	☐	☐
The main status indicator  **is lit green an no others LEDs are blinking** see 6.1.4 Main status LED	☐	☐	☐	☐	☐
Date:					
Performed by:					
Checks - every 3 years					
Visual inspection of the device and accessories (see previous table)	☐	☐	☐	☐	☐
Functional test					
➜ Check for proper functioning (see 6.1.4 Main status 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, please notify your Biomedical Department ❒, your local Medisol distributor ❒, or the authorized Customer Service for your area ❒:

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

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