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PRIMEDIC™
Saves Life. Everywhere.

HeartSave AS

Operating instructions

MGA22614 / EN / E02

Masthead

Publisher

METRAX GmbH

Rheinwaldstr. 22

D-78628 Rottweil

Germany

Telephone: +49 (0) 741/257-0

Email: info@primedic.com

Web: www.primedic.com

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1 Glossary

Term/Abbreviation	Description
AED	Automated external defibrillator
AHA	American Heart Association
Biphasic impulse	The current flow of the defibrillator changes its direction during shock appliance
BLS	Basic resuscitation measures/ cardio pulmonary resuscitation (Basic Life Support)
CPR	Cardio pulmonary resuscitation
EAR	Used Electronic Appliances Register
ECG	Electrocardiogram
ElektroG	German Electrical Equipment Act
ERC Guidelines	European Resuscitation Council on Cardiopulmonary Resuscitation (CPR)
EU	European Union
HLW	Cardio pulmonary resuscitation
MDD	Medical Device Directive
Medical devices log	Documentation of all data for a medical devices log according to § 7 of the Ordinance on the Operation and Use of Medical Devices (MPBetreibV)- to be maintained by operator, incl. serial number, test data, instructions, technical safety checks.
Metronome	Metronome for chest compressions
MIT	Massachusetts Institute of Technology
MPBetreibV	Medical Device Operator Ordinance
MPG	Medical Devices Act
ÖRE	Public law
Patient impedance	Patience resistance between the SavePads
PTB	Physikalisch-Technische Bundesanstalt (Physical-Technical Federal Institute)
SaveCard	Memory card for data transfer
SavePads	Defibrillation electrode
WEEEE	Engl. Waste of Electrical and Electronical Equipment (in German: Elektro- und Elektronikgeräte-Abfall)

2 Introduction

2.1 Foreword

Dear User,

Your task is to apply the PRIMEDIC™ HeartSave AS to human beings in a medical emergency!

To ensure that you can react quickly and correctly in this special situation and can optimally use the options given with the device, it is necessary for you to read through these operating instructions in your own time beforehand to familiarise yourself with the device, its functions and the areas of application.

Keep these operating instructions near to the device so that you consult any queries which may arise.

If you have any questions regarding this device or other PRIMEDIC™ products, we would be glad to be at your disposal.

You will find our contact address on the masthead at the start of these operating instructions.

2.2 Validity

The descriptions in these operating instructions refer to the PRIMEDIC™ HeartSave AS made by METRAX GmbH. The PRIMEDIC™ HeartSave PAD is referred to as HeartSave in the following operating instructions.

The content of this document can be changed without prior notice.

2.3 Warranty

The warranty period is 24 months and starts on the day of purchase. Please keep the invoice as proof of purchase.

The general guarantee and warranty provisions of METRAX GmbH are applicable.

Any repairs or changes to the device may only be carried out by the manufacturer or by a person or company authorised by the manufacturer.

2.4 Disclaimers

Liability claims in the event of damage to persons or property shall not apply if based on one or more of the following reasons:

- Using the device in a manner for which it was not intended.
- Improper use and maintenance of the device.
- Operating the device with the protective covers removed or when there is obvious damage to cables and/or electrodes.
- Non-compliance with the instructions in these operating instructions with regard to operation, maintenance and repair of the equipment.
- Using accessories and spare parts made by other manufacturers.
- Customer intervention, repairs or constructional changes to the device.
- Customer overrunning of the performance limits.
- Lack of monitoring parts that are subject to wear and tear.
- Treating patients without prior indication.

2.5 Symbols used in these operating instructions

DANGER

Text marked DANGER indicate an extraordinarily serious and present danger which will definitely lead to serious injury or even death if no preventative measures are taken.
You must follow these instructions!

WARNING

Text marked WARNING indicate extraordinarily serious, potential dangers which - if no preventative measures are taken- may lead to serious injury or even death.
You must follow these instructions!

CAUTION

Text marked with CAUTION indicates a potentially dangerous situation which could lead to minor injuries or damage to property.
You must follow these instructions!

ATTENTION

Text marked with ATTENTION indicate possible property damage.
You must follow these instructions!

Note This symbol indicates text which contains important advice/comments or tips.

The instructions are described in the following manner. Follow the instructions in the order in which they are described in the instructions.

▶ First instruction

▶ Second instruction

▶ etc.

• This line marks lists

(3) Numbers in brackets refer to items in diagrams.

< ... > The text in pointed brackets are acoustic instructions/voice prompts from HeartSave.

2.6 Symbols on the HeartSave

CE 0123

Certification authority

IP 55

Protection against contact and dust deposits on the inside and against water spray (jet) from any angle. Details on the unit only valid with energy module fitted.

IP 53

Protect against contact and dust deposition inside and against falling spray water up to 60° from a vertical direction. Details on the energy module are for this one alone.

Follow the operating instructions

Safety symbol "General warning symbols"
The individual meanings are explained in the operating instructions

Do not dispose of device in domestic refuse.

Dangerous electric voltage (high voltage)

Degree of protection BF

GL

Type certification GERMANISCHER LLOYD
in accordance with Certificate No. 75 449-09 HH

Durability of the internal battery MM/YYYY

2.7 Symbols on SavePads

Certification authority


Do not use any more


Observe the operating instructions

Not sterile

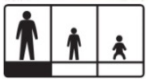
Keeps for 1 day after opening

Storage temperature in Celsius and Fahrenheit

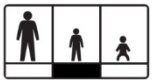

Protect from sunlight


Store in a dry place

Latex-free


Only for adults
min. 8 years, 25 kg

min 8 years, 25 kg


Only for children
1 – 8 years, max. 25 kg

1-8a, max. 25 kg


Remove protective film from adhesive electrodes


Usable until…

Batch code


Follow the operating instructions


Manufacturer

Order number

2.8 Pictogram on the battery

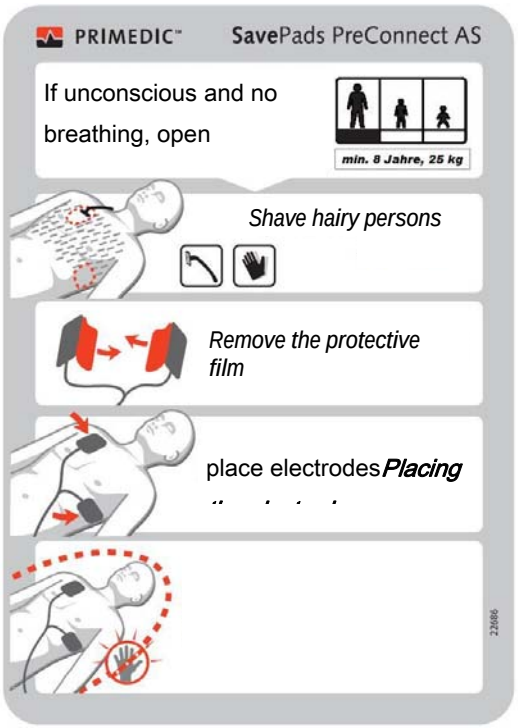
IP 53	Protect against contact and dust deposition inside and against falling spray water up to 60° from a vertical direction. Details on the energy module are for this one alone.
CE 0123	Certification authority
	Protect battery from fire
	Do not charge battery
	At the end of its life, send the power module for recycling. Device contains Lithium metal cells.
	Do not dispose of device in domestic refuse.
	Follow the operating instructions
	Safety symbol "General warning symbols" The individual meanings are explained in the operating instructions
	Can be used until YYYY/MM

2.9 Image mark on the enclosing packaging

Sticker on the encompassing packaging for the PRIMEDIC™ Battery for airfreight despatch

2.10 Brief instructions

The brief instructions can be found on the utensils carrier and helps you with the use of the HeartSave.



Notes on performing cardio pulmonary resuscitation. Wear medical gloves for self-protection!

3 Intended use

The PRIMEDIC™ HeartSave PAD is intended to be used in the private sector by users (also relatives), who are trained to operate the device and carry out lifesaving measures, whose state of knowledge is unknown at the time of the incident.

In public, these are users who want to provide first aid in the event of sudden cardiac death or cardiovascular arrest whose state of knowledge is also unknown.

The target group of this device are also medical professionals who work according to a doctor's (doctors') instructions who only rarely need an AED for foreseeable emergencies in connection with their work.

The PRIMEDIC™ HeartSave PAD is suitable for domestic use and on medical premises.

The device is intended for use on patients with symptoms of a sudden heart death who are unconscious (do not respond to speech) who are not breathing.

The user is guided by the HeartSave with acoustic notices (voice messages) and optical indications as well as by the device identification, so that the defibrillation electrodes are fixed on the body of the victim and the BLS measures, chest compressions, and artificial respiration according to the current recommendations of the ERC can be carried out. The first aider is requested to step back from the patient in order to perform the rhythm analysis and apply a shock. The device monitors and analysis the cardiac rhythm of the patient, loads the capacitor according to patient impedance and delivers the energy automatically with a current-constant biphasic shock. The first 3 shocks are based on the shock strategy with the shock steps 20 A (281 J at 50 Ohm), 25 A (350J at 50 Ohm) and 30A (360J at 50 Ohm) From the third shock on, all further shocks are delivered with the 30 A shock step (360 J at 50 Ohm). In Child defibrillation mode, the energy is reduced to 50 J (1st shock), 70J (2nd shock) and 90 J (3rd and subsequent shocks) at 50 Ohm. For safety reasons, no shock is given with asystolia, as no therapeutic effect is to be expected. Controlled ventricular electrical activity caused by supraventricular tachycardia such as atrial fibrillation, atrial flutter, ventricular extra-systoles and idioventricular rhythms do not lead to a shock being applied.

After successful reanimation after which the patient now breaths independently, the device is left on the patient until professional help arrives.

WARNING

The PRIMEDIC™ HeartSave PAD devices may only be used as described and under the conditions detailed in these operating instructions!

Any use above or beyond this is not considered as intended use and can lead to personal injury or damage to property.

Improper use of the defibrillator can lead to ventricular fibrillation, asystolia or other dangerous dysrhythmia.

3.1 Indication/Contraindication for Defibrillation

3.1.1 Indications

The HeartSave may only be used when the patient shows symptoms of a sudden heart death, in particular when he is:

- Unconscious and
- Not breathing

3.1.2 Contraindications

The HeartSave must not be used if the patient:

- is conscious **or**
- is breathing normally **or**
- is a child is under one year old

4 General safety advice

Read the operating instructions carefully before using the HeartSave for the first time. Only use the HeartSave as described in the operating instructions.

Note the ambient conditions in the technical specifications when storing and operating the device.

Always follow the commands issued by HeartSave!

Use HeartSave on a non-conductive base. Do not use HeartSave in still waters or rain.

Do not use the HeartSave in the presence of flammable materials.

Both in conjunction with its accessories and the optional accessories, and also individually, the HeartSave fulfils the currently applicable safety standards and complies with the provisions of the medical products regulations.

The HeartSave and its accessories are safe when used as intended and when following the descriptions and information detailed in these operating instructions.

Despite this, if used incorrectly, the HeartSave and its accessories can be dangerous to the user, the patient or third parties.

Keep the device out of reach of children!

Applicable for Europe:

- The HeartSave satisfies Medical Device Directive - MDD 2007/47/EU.

For Germany and Austria, the following is also applicable:

- The HeartSave complies with the Medical Devices Law (MPG) and is subject to the Ordinance on the Operation and Use of Medical Devices (MPBetreibV).
- According to the Ordinance on the Operation and Use of Medical Devices (MPBetreibV), the device must be subjected to the regular checks explained in the appendix.
- According to the Ordinance on the Operation and Use of Medical Devices (MPBetreibV), a medical devices log needs to be kept for the device. Regular checks of the equipment are to be documented there.

For the other states in the European Community, national regulations for operating medical devices apply.

5 Description of device

5.1 General description

The PRIMEDIC™ HeartSave PAD is an automatic external defibrillator (AED) with an integrated Single Channel ECG. If needed, the shock appliance is carried out automatically.

The ECG is recorded via PRIMEDIC™ SavePads PreConnect or PRIMEDIC™ SavePads C. The algorithm implemented recognises potentially fatal heart arrhythmia. The defibrillator generates the electroshock which is needed to recover the normal cardiac rhythm. This method is the generally recognised therapy.

The PRIMEDIC™ HeartSave product family has been designed to be safe and quick to use in an emergency. All functional units and operating elements are subject to the following principles:

- Clear organisation of functional units
- Reduction of functions to those necessary
- Intuitive and logical operator guidance
- Clear, self-explanatory operating elements
- Ergonomic layout

The defibrillator unit has been optimised to be safe and ready to use very quickly. The power supply of the PRIMEDIC™ HeartSave PAD comes from a disposable lithium battery.

The PRIMEDIC™ HeartSave PAD can be stored on a PRIMEDIC™ wall bracket which can be affixed to a wall or in the ambulance. It is easy and quick to remove the PRIMEDIC™ HeartSave PAD when you need it, using the one-handed quick release.

Note The wall bracket and accessories are described in separate operating instructions.

5.2 Description of device details

Fig. 1: PRIMEDIC™ HeartSave PAD front view

(1) Status display

(2) Strap to pull the cover off the device (with expiry date of SavePads)

(3) Carry handle

(4) Device cover

Fig. 2: PRIMEDIC™ HeartSave PAD rear view

(1) Identification plate

(2) Receptacle opening for hook of the wall bracket

Fig. 3: PRIMEDIC™ HeartSave AS view from underneath

(1) Contacts for power module

(2) Slot for SaveCard

(3) Release button, SaveCard

(4) Release button, power module

Fig. 4: PRIMEDIC™ HeartSave PAD controls

(1) Child button

(2) Jack for electrode connectors

(3) Connector symbol with LED

(4) Electrode symbol with LED

(5) On/Off switch

(6) "Do not touch the patient" symbol (lights up during ECG analysis)

(7) Loudspeaker

(8) Language selection button

Note

By pressing the Language selection button (8) several times, it is possible to select the desired language from the 4 available languages, using which after each time the button is pressed, the corresponding foreign language will be briefly called.

When switched on, the device will start with the language that was active when it was switched off previously.

Fig. 5: PRIMEDIC™ utensils carrier with SavePads

(1) PRIMEDIC™ SavePads PreConnect (defibrillation electrodes)

(2) Artificial respiration cloth and razor

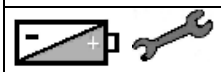
(3) Primedic utensils carrier with expiry date SavePads

(4) Brief instructions

(5) Disposable gloves

(6) Scissors

5.3 Status display

Display.	Meaning	Action to be taken
	Sufficient battery capacity.	Device ready to use
	Low battery capacity. No battery inserted! Symbol also appears if the durability of the battery has been exceeded.	Device can be used. Nearly time to exchange battery. Insert battery Check use by date, if necessary replace with new ones.
 Battery symbol flashes during operation	Internal buffer battery empty (The device is still operational!)	Send the device to the dealer for the replacement of the internal buffer battery
	Sufficient battery capacity. Device defective.	Carry out major self-test by reinserting the battery or switching the device on again. Have the device repaired by a dealer
	Device defective	Carry out major self-test by reinserting the battery or switching the device on again. Have device repaired by authorised dealer.

The battery is monitored using an electronic charge balance process.

The voice command is issued if the battery is exhausted

< Battery low, please replace battery >

Note Voice commands will be issued at regular intervals while the HeartSave is in operation. The battery symbol in the status display is displayed.

5.4 Data management

Note The device automatically records all the data on a removable SaveCard and also records all noise in the surroundings via a microphone.

The saved data can be displayed with the aid of a PC/Laptop and the ECG Viewer software. However, this data may not be used for diagnostic purposes or for therapy for the patient. They only may be used for administrative purposes. The software has a deployment log into which additional patient data can be entered.

The data saved on the SaveCard should be archived externally after every deployment if possible. The SaveCard should then be reformatted if possible (instead of the usual deletion process).

Once the storage capacity of the SaveCard is exhausted, no additional data will be saved. The device remains ready for operation even if the memory is exhausted and even without a SaveCard.

The SaveCard supplied with the device is already formatted and can be used straight away. If you have any problems with the available SaveCard or new CF cards, you have to reformat them with the FAT16 file system. Therefore, when you are formatting, ensure that you do not accidentally transfer the FAT32 file system onto a Windows XP system.

To attain the greatest possible degree of safety, please proceed as follows:

For Windows 2000, Windows XP, Windows Vista, Windows 7

- Open a command window by entering the following sequence of instructions: Start/All Programs/Accessories/Prompt.
- Now enter the following: format f: /U /FS:FAT /X /V: (where f: stands for the drive letter of the of the CF card reading device which may need to be adjusted).

The first time the device is started after formatting a CF card will take much longer because the device still performs various operations. The device then resumes normal operation again.

5.5 Description of the accessories

The accessories need to be secured appropriately before being transported.

5.5.1 PRIMEDIC™ SavePads PreConnect

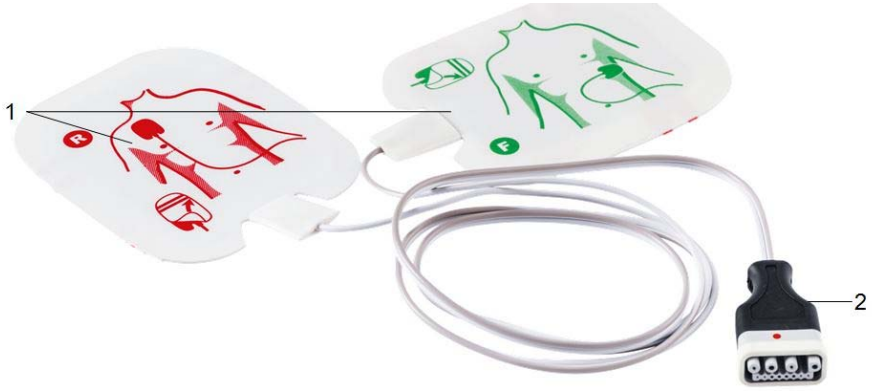


Fig. 6: PRIMEDIC™ SavePads PreConnect (unpacked)

(1) Defibrillation electrodes with protective film

(2) Electrode plug

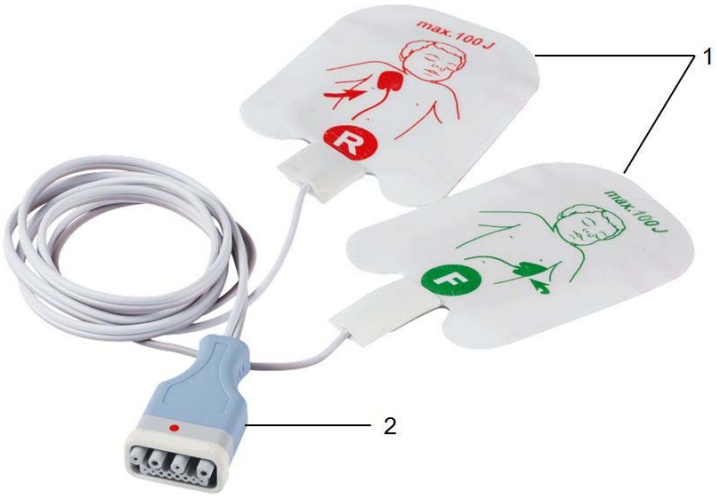


Fig. 7: PRIMEDIC™ SavePads Mini (unpacked)

(1) Defibrillation electrodes with protective film

(2) Electrode plug

5.5.2 Accessories

- PRIMEDIC™ SavePads PreConnect Order no.: 97205
- PRIMEDIC™ SavePads mini Order no.: 97534
- PRIMEDIC™ ECG Viewer Order no.: 96468
- PRIMEDIC™ HeartSave Bag Order no.: 96379
- PRIMEDIC™ Wall bracket SaveBox Basic Order no.: 96740
- PRIMEDIC™ Wall bracket SaveBox Advanced Order no.: 96776
- Information signs Defibrillator Order no.: 96595

Subject to change without notice.

6 Preparatory measures before (initial) start-up

6.1 Unpacking

DANGER

Danger caused by damaged device

Risk of burns and heart arrhythmia as the result of electric shock

- ▶ Do not use damaged devices

After delivery, first of all check the packaging and the device for transport damage.

If you notice any damage to the device, immediately contact your transport company, dealer or directly contact technical services at METRAX GmbH, stating the serial number and describing the damage to the device.

Satisfy yourself that the scope of delivery is complete in accordance with the enclosed delivery note.

Scope of delivery:

- HeartSave PAD
- Battery 6
- SaveCard
- Operating instructions
- SavePads PreConnect
- Kit holder with: Disposable razors, Nitrile gloves, scissors, respiration cloth
- ECG viewer

6.2 Inserting/replacing the SaveCard

Fig. 8: Inserting/replacing the SaveCard

To remove the SaveCard or to change it, firstly remove the power module.

Procedure:

- Press the button (2) in fully – this pushes the SaveCard (1) slightly out of its holder.
- Completely remove the SaveCard from the device and transfer the data (if applicable) onto a PC and insert this card, or a new one, in the device with the pin end first.
- Gently press the card in until the button (2) projects slightly out of the device.
- Finally insert the power module into the device again.

Note

Where possible, the data saved on the SaveCard should be archived externally after each deployment. Once the storage capacity of the SaveCard is exhausted, no further data will be saved. The device remains ready for operation even if the memory is exhausted and even without a SaveCard.

To read out the saved data, you can use the software PRIMEDIC™ ECG Viewer which is available as an optional accessory.

6.3 Inserting/replacing the energy module

Before using the HeartSave for the first time, the battery has to be inserted in the appropriate slot.

Note

The PRIMEDIC™ HeartSave PAD is always supplied with a battery.

Check the battery level after each use. If necessary, the battery should be replaced with a new one.

6.3.1 Inserting the power module

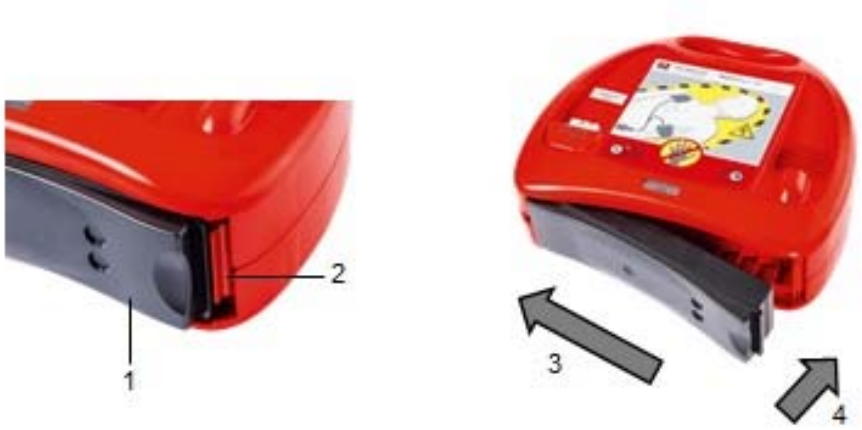


Fig. 9: Inserting the power module

Procedure:

- Lay the device on its back.
- Push the (new) battery (1) in the direction of the arrow (3) into the device until it reaches its end position as shown in the diagram.
- Then press the battery in the direction of the arrow (4) into the power module slot until the release button (2) locks the power module tongue securely into position.
- Press the battery completely into the device until you hear the "Click" when it slots into place and the battery is flush with the outside edge of the device.
- After this, the device will carry out a self-test and is ready to use.

Note

If the battery has been installed correctly, the device will start independently once the cover of the housing has been removed and it will run a self-test. Now follow the acoustic instructions from the device and then switch it off. Now the device is ready to use.

ATTENTION

Danger: Faulty device

Device is not operational

- Only use the device when the status display indicates an "OK"

6.3.2 Removing the power module from the device

Note Only change the power module when the device is switched off and the defibrillation electrodes plug is disconnected.

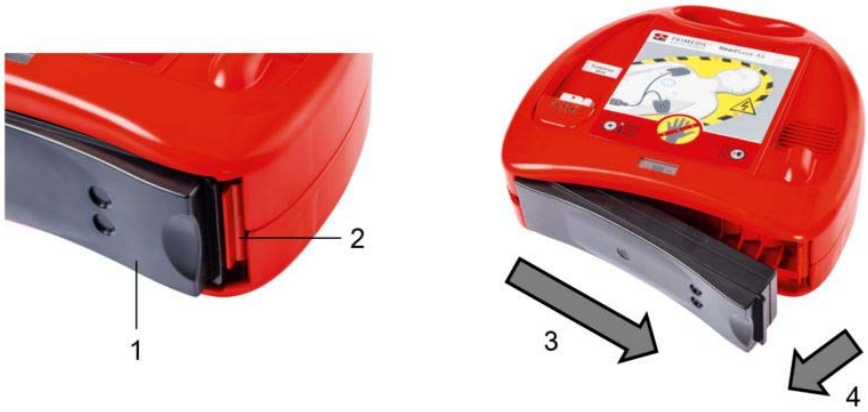


Fig. 10: Removing the battery

Procedure:

- Lay the device on its back.
- Press the unlocking button (2) to the right until the tongue on the power module is released and the power module (1) snaps out of the slot slightly.
- Twist the power module slightly in the direction of the arrow (4) and then pull it in the direction of the arrow (3) out of the device.

6.4 PRIMEDIC™ Battery

The battery is a disposable lithium battery. It is fully charged when delivered. This type of battery is state-of-the-art and was selected due to its extremely long service life and energy storage.

WARNING

Do not charge the battery

Risk of explosion

- ▶ Replace the empty battery

ATTENTION

Note the battery expiry date

Device is not operational

- ▶ Replace batteries after passing their expiry date

Heed the documentation enclosed with the battery and keep it safe with these operating instructions.

Note	If the device has to be sent away to technical services, remove the battery before sending it and put some adhesive insulation tape over its contacts. Observe the separate shipping regulations when sending the battery.

7 HeartSave self-tests

7.1 Self-test after switching the HeartSave on

The HeartSave is switched on either by opening the device cover, pressing the On/Off switch or by inserting the battery when the device cover is removed Afterwards, the HeartSave runs a device self-test to check all the important functions and signal mechanisms.

If the power module has been replaced and if the has device ascertained an error beforehand, the extensive self-test (LONG) is automatically carried out.

7.2 Automatic, periodic self-tests

The HeartSave carries out automatic self-tests to ensure that it is always ready for operation.

	Frequency	Test coverage
SHORT	Daily	Software, operating membrane, ECG calibration, clock, internal voltage supply and HV part at 0 V, impedance measurement, loudspeaker
MEDIUM	First day of the month	Software, operating membrane, ECG calibration, clock, internal voltage supply and HV part at 300 V, impedance measurement, loudspeaker
LONG	On the 1st. July and on the 1st. January each year	Software, operating membrane, ECG calibration, clock, internal voltage supply and HV part at 1600 V, impedance measurement, loudspeaker

7.3 Tests during equipment operation

The HeartSave monitors the most important equipment and safety functions permanently during operation. If a fault is detected during one of the many internal self-tests and this fault no longer ensures safe operation of the unit, the unit will switch off, the spoken message "Internal Error" will be issued, and the service symbol appears in the status display.

Note

Under certain circumstances this error will only be present temporarily, or it may be reversible, and for this reason you should always switch the unit on again after this message appears and after a waiting period of approx. 30 seconds, and then wait for the result of the internal switching on self-test. If this is successful, you can continue to use the unit without any problems. If the error remains, please send the unit to our service department for a more accurate analysis.

8 Operating the HeartSave and sequence of reanimation

Note The sequence of the reanimation is realised in the device according to the recommended guidelines of the European Resuscitation Council (ERC 2010). We recommend the user has carried out before using the HeartSave.

8.1 Switching the HeartSave

The HeartSave is switched on either by opening the device cover, pressing the On/Off switch or by inserting the battery when the device cover is removed Afterwards, the HeartSave runs a device self-test to check all the important functions and signal mechanisms.

If the power module has been replaced and if the has device ascertained an error beforehand, the extensive self-test (LONG) is automatically carried out.

It is important to ensure that the loudspeaker is working.

8.2 Checking and preparing the patient

Check to see whether the patient is unconscious and is not breathing normally. Proceed as follows:

- Please talk to patient and touch him/her to see whether he or she is still conscious.
- Make sure the emergency services have been notified.
- If there is no response, hyperextend the patient's head and check that he/she is breathing.
- If the patient is breathing normally, bring him/her into a stable position on his/her side and continue to treat him/her.
- If the patient is not breathing normally, expose his/her breast area to attach the defibrillations electrodes. Make sure the patient is lying on a hard surface in order to ensure the chest compressions are effective. If the HeartSave is not already available, make sure someone collects it in order to carry out further treatment.
- Using the supplied razor, remove breast hair from the area where the defibrillation electrodes are to be attached.
- If the surface of the skin is damp, dry the skin at the spots where the defibrillation electrodes are to be attached to improve the adhesion.

8.3 Defibrillation

DANGER

Danger of damage to health of user or a third party

Triggering heart arrhythmia and burns through electrocution

- Do not touch the patient during defibrillation
- Warn third parties about the dangers of defibrillation
- Do not touch any conductive materials (metal, blood, water, other liquids, etc.) during defibrillation

DANGER

Warning of explosion

Risk of burns

- Do not use the device in potentially explosive areas
- Do not use the device in oxygen-enriched atmospheres
- Do not use the device in the presence of flammable materials

DANGER

Warning: Potential malfunctions

Active implants may lead to a false diagnosis

- Do not stick the defibrillation electrodes directly over a pacemaker or similar.

WARNING

Warning: Physical harm

Risk of skin burns

- Remove heavy build-up of hair at the electrode positions
- Where necessary, dry the skin before attaching the electrodes

ATTENTION

Material damage to other devices

- Remove all devices at risk from the defibrillation from patients before defibrillation.
- Do not attach the defibrillation electrodes directly over a pacemaker or similar.

Defibrillation with HeartSave can be performed on children or adults. Use the Child mode for patients who are younger than 8 years or weigh less than 25 kg. Use the Adult mode for patients who are older than 8 years or weigh more than 25 kg.

The therapy should not be delayed in order to determine the precise age or weight of the patient.

Note	The defibrillator starts automatically in Adult mode.

8.3.1 Defibrillation in Adult mode

Note	Follow the voice commands issued by HeartSave!

Note	For this, you will need to take the disposable gloves out of the cover of the device and put them on.

After the self-test has been completed successfully by the device, the following BLS voice instructions (BLS= the basic measures of cardio pulmonary resuscitation) are given.

< Adult Mode >

< Call emergency services >

< Apply electrodes one after the other to patient's bare chest >

< Plug in electrode cable >

The last two spoken instructions are repeated for one minute. If the device cannot recognise a patient impedance at that time, the device will give instructions for one cycle of cardio pulmonary resuscitation:

< Give 30 chest compressions >

< Give 2 rescue breaths >

Afterwards the device will give instructions to attach the electrodes for maximum one minute. This procedure will go on until the device recognises a valid patient impedance and begins with the rhythm analysis.

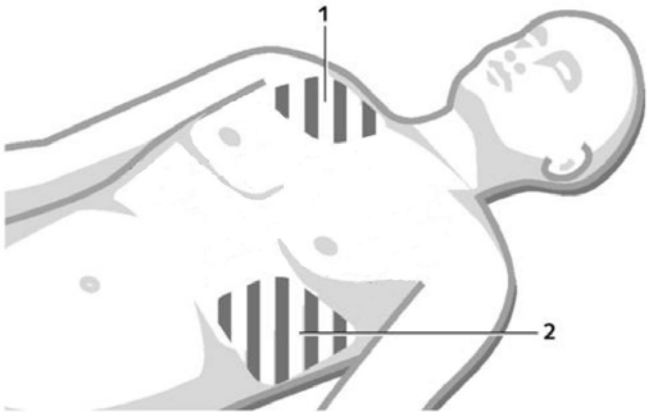


Fig. 11: Position of electrodes on adults

The positions of the electrodes are:

- On the right chest area, below the collar bone (1) and
- On the left side of the chest, above the top of the heart on the axillary line (2).

8.3.2 Defibrillation in Child mode

If the patient is younger than 8 years old or weighs less than 25 kg, please use the SavePads mini. When these electrodes are inserted, HeartSave will automatically switch to Child mode. If you do not have any SavePads mini available, you can switch to Child mode manually by pressing the Child button with the SavePads PreConnect. If HeartSave is in Child mode, the LED indicator next to the Child button will illuminate.
Child mode has been especially developed for the needs of children. In Child mode, HeartSave supplies less electricity than in Adult mode.

< Child Mode >

< Call emergency services >

< Apply electrodes one after the other to patient's bare chest >

The last two spoken instructions are repeated for a period of one minute. If the device cannot recognise a patient impedance at that time, the device will give instructions for one cycle of cardio pulmonary resuscitation:

< Give 30 chest compressions >

< Give 2 rescue breaths >

Afterwards the device will give instructions to attach the electrodes for maximum one minute. This procedure will go on until the device recognises a valid patient impedance and begins with the rhythm analysis.

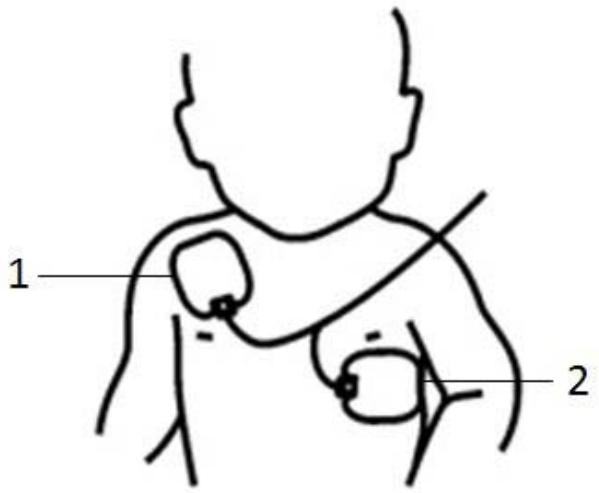


Fig. 12: Electrode positions on a child

The positions of the electrodes are:

- On the right chest area, below the collar bone (1) and
- On the left side of the chest, above the top of the heart on the axillary line (2).

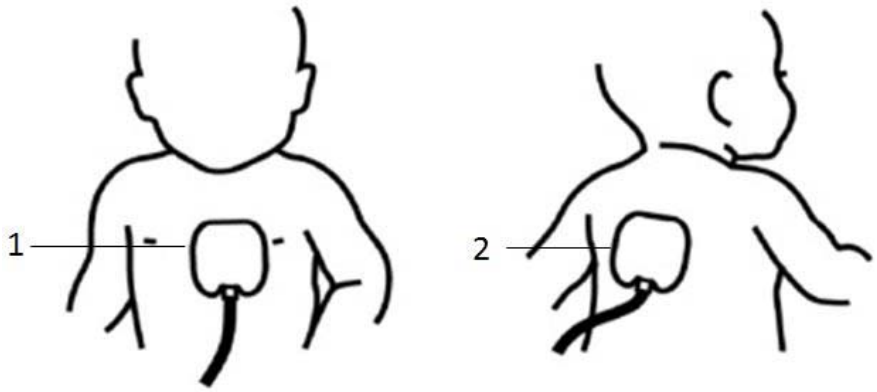


Fig. 13: Alternative electrode positions on a child

The positions of the electrodes are:

- (1) in the middle of the chest
- (2) on the back at the same height as the heart
- **Attach both electrodes so that the patient's heart lies in between them.**

8.4 Opening SavePads and placing electrodes

WARNING

Damage to gel layer on defibrillation electrodes

Skin burns

- Be careful not to touch the gel layer before attaching the electrodes

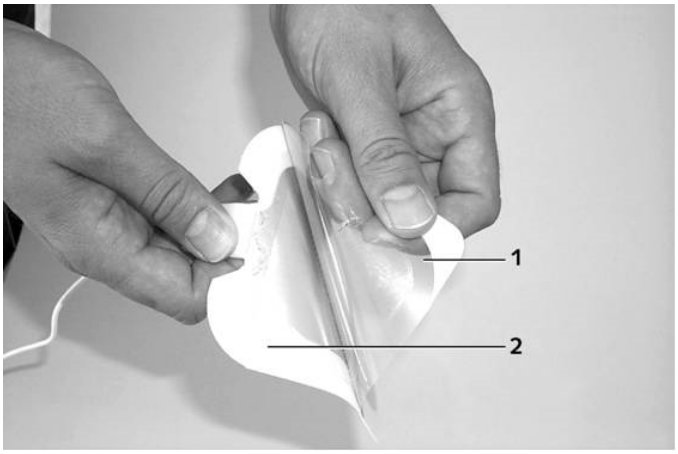


Fig. 14: Removing the film from the electrodes

(1) Protective film on electrodes

(2) SavePads defibrillations electrodes

The HeartSave will give a voice prompt for you to apply the defibrillation electrodes to the patient.

< Apply electrodes one after the other to patient's bare chest >

Procedure:

- Open the defibrillation electrodes bag by tearing open the protective cover along the tear strip.
- Remove the protective film (1) from one of the electrodes (2) and then immediately place the electrode on the position you had ascertained previously.
  Proceed to remove the protective film from the second electrode and place it in its position.
- Smooth the electrodes onto the patient ensuring there are no air bubbles under the electrodes!

8.5 Plug in electrode cable

Note If you have already inserted the SavePads, HeartSave will skip this step and begin analysing the patient's cardiac rhythm

Fig. 15: Plug in electrode cable

(1) Socket

(2) Connector symbol

(3) Electrode plug

Procedure:

- After hearing the voice prompt
  < Plug in electrode cable >
  insert the connector (3) of the electrode cable into the socket (1) on the HeartSave as shown above.
- Make sure the red point points forwards.

The red "Plug symbol LED" (2) on the device should go out.

Note Once the electrodes are connected to the patient and the electrode plug is plugged in, the BLS instructions are automatically interrupted.

8.6 Checking the electrodes

If the device signalises **< Check electrodes >**, there may be many reasons for this:

- Electrode plug connector not plugged in. This will be signalled by blinking LEDs in the electrode plug connector symbol and on the electrodes positions on the front foil.
- Too little resistance between electrodes (e.g. electrodes fixed too closely). The LEDs blink on the electrodes positions on the front foil.
- Too high resistance between the electrodes (e.g. not removed chest hair of the patient). The LEDs blink on the electrodes positions on the front foil.
- Air pockets between skin and defibrillation electrodes cause a bad contact. The LEDs blink on the electrodes positions on the front foil.
- Dried out electrodes. The LEDs flash on the electrodes positions on the front foil.

The device repeats the following voice messages:
< Check electrodes >

< Apply electrodes one after the other to patient's bare chest >

If the plug on the PRIMEDIC™ SavePads has not been inserted in the unit, the following additional instruction appears

< Plug in electrode cable >

These spoken instructions are repeated for a period of one minute. If the device cannot recognise a patient impedance at that time, the device will give instructions for five cycles of cardio pulmonary resuscitation:

< Give 30 chest compressions >

< Give 2 rescue breaths >

Afterwards, the device will once again give instructions to attach the electrodes for a maximum period of one minute. This procedure will go on until the device recognises a valid patient impedance and begin with the rhythm analysis.

- ▶ **Remedy the cause of the fault.**

8.7 Carrying out the ECG analysis

DANGER

Danger of damage to health of user, patient or a third party

Triggering heart arrhythmia

- Do not touch the patient during defibrillation
- Warn third parties about the dangers of defibrillation
- Do not touch any conductive materials (metal, blood, water, other liquids, etc.) during defibrillation
- If the patient wakes up during reanimation, stop defibrillation

If the defibrillation electrodes have been applied, the device will automatically start the analysis.

Now the patient has to be put in an immobile position and may no longer be touched. The device prompts:
< Do not touch the patient, Analysing rhythm >
and the "Do not touch the patient" zone on the keyboard membrane flashes.

Note If the ECG analysis is conducted in a vehicle, the engine will need to be switched off for analysis in order not to distort the results.

The algorithm of the device program will now check the ECG for ventricular fibrillation. This process takes approx. 7 - 12 seconds. If the device identifies a ventricular fibrillation, it will recommend defibrillation and will trigger it automatically.

8.8 Defibrillation required

Note Pressing the shock key during power charging (before it turns green) does not result in release of shock. Instead, it leads to internal safety discharge.

Note Defibrillation may cause muscle contractions in the patient.

If the device clearly identifies VF, then it will recommend defibrillation which is automatically prepared inside the device.

The device prompts:

< Shock required >

< Chest compressions >

< Metronome >

< Shock will be delivered in 3, 2, 1 >

< It is now safe to touch the patient >

To reduce the time without chest compressions, the metronome is activated during the charging phase. This time may vary depending on the charge level of the battery. Carry out the chest compressions until the metronome tone stops.

Once the capacitor is charged internally, power for the defibrillation pulse is available for 15 seconds. This is signalled by the voice message
< Stand clear of patient >

Warn those around you loudly before applying the defibrillation!

Defibrillation and cardio pulmonary resuscitation (CPR) are repeated according to the directives of the ERC Guidelines 2010.

The charge time of the capacitor for defibrillation depends on the available battery capacity. Charging may take longer if the power module is partly discharged.

If an error occurs during charging, an intermittent warning beep will sound.

8.9 Defibrillation not required

If the device cannot find a shockable rhythm, it will recommend cardio pulmonary resuscitation (CPR).

< No shock advised >

< Cardio pulmonary resuscitation >

< Give 30 chest compressions >

< Give 2 rescue breaths >

Furthermore, during the chest compressions, you will be supported by the installed metronome function which will give you the correct frequency for the chest compressions (100 compressions/min). Be sure that you keep the given rhythm. The artificial respiration will also be supported by two acoustic outputs. From the second to fifth CPR cycle, only these sound signals are emitted. For your support, the correct measures for cardio pulmonary resuscitation are illustrated in pictograms on the utensils carrier.

Note Once the CPR time has expired (2 mins.), the device returns to ECG analysis.

Carry out cardio pulmonary resuscitation until the emergency services arrive. Once the patient is conscious again, lay him or her down and take care of him/her until the emergency services arrive.

8.10 Switching off HeartSaves

HeartSave can be switched off in various ways:

- By pressing the on/off button for approx. 3 seconds. A warning beep will sound simultaneously. This time has been chosen to avoid it being switched off accidentally.
- By closing the cover of the device.
- If the device does not recognise a signal for 10 minutes and if no button is pressed, it will switch off automatically.

If HeartSave detects a fault, it will switch off automatically to prevent any injuries.

Note If, when the device is switched on, no ECG is done for 10 minutes or no button is pressed, the device automatically switches off. Approx. 30 seconds before the switch-off this is signalised by an interrupted warning tone. Pressing any button or any other activity will interrupt the switching off process.

8.11 Keeping the defibrillator ready for use

- Check the HeartSave for damage after each use.
- Clean HeartSave and accessories after each use. Disinfect HeartSave and accessories if there is a risk of infection, see section 9.1.
- Replace the SavePads and check/replace the battery as required so that the HeartSave is ready for operation again as quickly as possible.
- If any malfunctions or noticeable problems occur, please contact an authorised service partner.

9 Cleaning, inspection and dispatch

9.1 Cleaning

WARNING

Warning: physical harm to user

Risk of electrocution

- Only clean the device when switched off
- Do not immerse the device in liquids
- Use damp cloths to clean

Clean HeartSave and all its accessories, such as the wall bracket, with commercially available household cleaners.

Use a slightly damp, clean cloth. Use ordinary wiping disinfectants to disinfect (e.g. Gigasept FF, Bacillol or Spitacid).

9.2 Servicing

ATTENTION

Warning: Property damage

The device does not have any parts which are allowed to be modified by the user

- Do not carry out any repairs to the device
- Do not carry out any modifications to the device
- Do not dismantle the HeartSave
- Only use original accessories!

Regardless of how often the HeartSave is used, we recommend you carry out a regular visual check on the HeartSave and accessories at least once per year.

Make sure that the housing, cable, SavePads and all the other accessories are undamaged.

9.2.1 Servicing check list

- ▶ Check the expiry date
  - Of the SavePads and
  - The battery
- ▶ If necessary replace the parts.

- ▶ Check whether
  - The status display "OK" is shown!
  - You can switch on the device.
  - The device automatically carries out the self-test after being switched on.
  - The slot for the power supply is clean.
  - The device is fully equipped.

Contact service if the device has a fault.

Note For more detailed information on the regular safety and metrological checks in accordance with the Ordinance on the Operation and Use of Medical Devices (MPBetreibV), refer to the Appendix.

9.3 Sending HeartSave

DANGER

Risk of fire due to short circuit

- ▶ Before sending, protect the contacts of the power module with insulating adhesive tape.

Use the original box where possible. Remove the battery and pack and send separately.

If the original box is no longer available, use suitable packaging materials to protect the HeartSave from impact and damage.

Pay attention to national and international shipping regulations concerning the transport of Lithium-metal batteries.

10 Using the equipment on ships

Using the following PRIMEDIC™ HeartSave (M250) devices on merchant navy ships:

PRIMEDIC™ HeartSave PAD / AED / AED-M / HS6 / HS6-S

with the energy supply module

PRIMEDIC™ battery 3, 15 V DC, 2Ah $LiMnO_2$

fulfils the EMC requirements of "Zone for the bridge and the open deck" as per the "Guidelines for the Performance of Type Approvals" or "Test Requirements for Electrical/Electronic Equipment and Systems" of the "Rules for Classification and Construction", Book VI "Additional Rules and Guidelines" of "Germanischer Lloyd," 2003.

11 Disposal

CAUTION

Warning: Physical harm

Risk of acid burns

- Dispose of the device and single parts according to local regulations

Fig. 16: Disposal

In accordance with the founding principles of the company Metrax GmbH, your product has been developed and made using high quality materials and components which are recyclable.

At the end of its service life, recycle the device through disposal companies registered under public law (council recycling facilities). Proper disposal of this product helps with environmental protection.

Through the registration of Metrax GmbH with the responsible authorities, we ensure that the disposal and utilisation of electronics devices brought to the market by us is secure in accordance with the EU directive on the disposal of electronic and electrical equipment (WEEE-directive).

In Germany, in accordance with the law on bringing electrical and electronic equipment onto the market, taking it back and disposing of in an environmentally friendly manner

(Electrical and Electronic Equipment Act– ElektroG) Metrax is registered with EAR (register of old electronic equipment) under the number: 73450404.

For business customers in the European Union

Please contact your dealer or supplier if you want to dispose of electrical and electronic equipment. He will have further information on this for you.

Information for disposal in countries outside the European Union

This symbol is only applicable within the European Union.

12 Technical Data

Defibrillation

Operating modes: Asynchronous, external

Patient impedance: 23 – 200 Ohm

Impulse shape: Biphasic, current regulated (CCD)

Output power at:

Patient impedance	1st stage	2nd stage	3rd stage
25 Ohm	165 J	254 J	310 J
50 Ohm	298 J	348 J	360 J
75 Ohm	336 J	346 J	346 J
100 Ohm	320 J	320 J	320 J
125 Ohm	296 J	296 J	296 J
150 Ohm	274 J	274 J	274 J
175 Ohm	236 J	236 J	237 J

Output energy in Child mode:

Patient impedance	1st stage	2nd stage	3rd stage
25 Ohm	37 J	53 J	70 J
50 Ohm	48 J	68 J	87 J
75 Ohm	48 J	66 J	84 J
100 Ohm	45 J	62 J	79 J
125 Ohm	41 J	57 J	73 J
150 Ohm	38 J	53 J	68 J
175 Ohm	35 J	49 J	63 J

Accuracy: All data is subject to a tolerance of +/- 15%

Impulse length: Positive phase 11.25 ms, negative phase 3.75 ms

Discharges: 180 discharges at 50 Ohm, at 20°C, with a new battery

Charge time: 12 +/-3 seconds with a battery at 90% of the rated capacity

ECG	
Derivation:	II
Heart frequency:	30 – 300 min-1 (Accuracy +/- 1/min, 1%)
Input:	Class BF, for 2-pin patient cable, defibrillation protected
Input resistance:	> 5 MOhm @ 10 Hz
Recovery time after shock appliance:	10 s until a new shock obligatory rhythm is detected
Input d.c. voltage:	± 0.5 V
Bandwidth:	0.5 – 44 Hz (- 3 dB) SR = 101 samples/s
Impedance measurement	
Defibrillation:	23 ... 200 Ohm (accuracy +/- 20%)
Measurement frequency:	30 kHz
Analysis	
Analysis recognition:	Ventricular fibrillation (VF), ventricular tachycardia (VT)
Analysis duration:	Approx. 7 s until VF is recognised
Period from analysis begin until the end of high voltage load (by full battery/after six shocks/after 15 shocks)	19 s / 20 s / 20 s
Period from switching on until the end of high voltage load (by full battery/after six shocks/after 15 shocks)	32 s / 32 s / 33 s
Power supply	
Battery	$LiMnO_2$ 15V, 2.8Ah (0° to 20°C) service life in device is max. 6 years at 20°C
Data storage	
Memory type:	SaveCard (CompactFlash Card) 2GB

Safety

Classification:	According to IEC 60601-1: Medical electrical device of the type BF, defibrillation protected in accordance with EC Directive 93 / 42 / EEC: Class IIb (device, battery, electrode)
Identification:	CE 0123 (Notified body: TÜV SÜD Product Service GmbH) The device is a medical product and complies with the EC Directive 93 / 42 / EEC

Other

Operating conditions (device including battery and defibrillation electrodes):	0 ... 50°C, 30 ... 95% rel. humidity, but without condensation 700 hPa ... 1060 hPa
Conditions for storage/transport (incl. battery):	- 20 ... 70°C, 20 ... 95% rel. humidity, but without condensation 500 hPa ... 1060 hPa
Conditions for storage/transport defibrillation electrodes	0 ... 50°C, 20 ... 95% rel. humidity, but without condensation, 500 hPa ... 1060 hPa -40°C ... 70°C for maximum 10 days
Dimensions:	28 x 25 x 9 cm (W x H x D)
Weight:	approx. 2 kg (without battery)
Standards applied	Standards (for licensing in the EU, the corresponding harmonised European standards EN were used instead of the IEC standards): IEC 60601-1:1988 + A1:1991 + A2:1995 IEC 60601-1-2:2001 IEC 60601-2-4:2002 EN1789:2007

Subject to change without notice.

13 Warranty conditions

The warranty period is 24 months and starts on the day of purchase. Please keep the invoice as proof of purchase.

Within this time period, METRAX will remedy any defects in the device free of charge provided they are based on material or manufacturing faults. The device can be reinstated to its original condition either by means of repair or replacement as chosen by METRAX.

A claim made under warranty does not extend the original warranty period.

Warranty and also legally entitled warranty claims are not applicable if the usefulness of the device is only negligibly affected, or in the case of normal wear and tear (e.g. consumables such as battery pack) or damage caused after transfer of risk as a result of incorrect or negligent handling, excessive wear or are caused by special external influences which are not provided for according to the contract. The same applies if inappropriate changes or incorrect repair work is carried out by the buyer or by a third party.

All other claims against METRAX GmbH are excluded, unless such claims are based on intent or gross negligence or compulsory legal liability standards.

Warranty claims made by the buyer against the seller (dealer) are not affected by this guarantee.

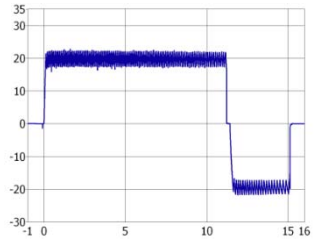
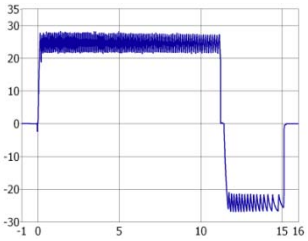
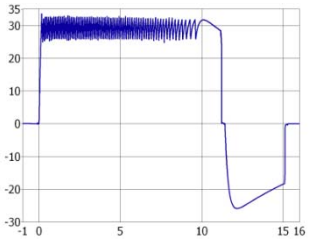
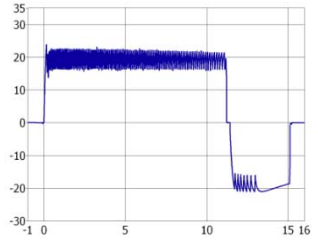
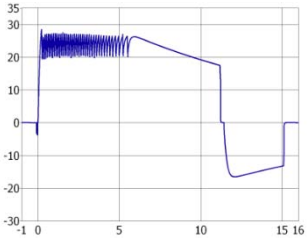
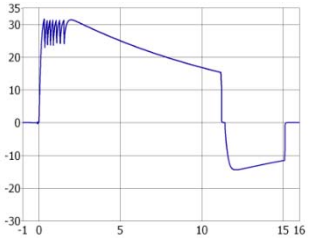
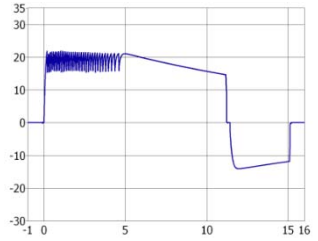
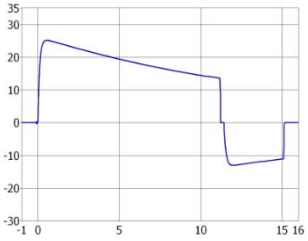
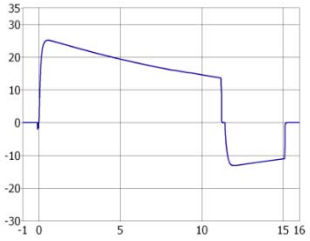
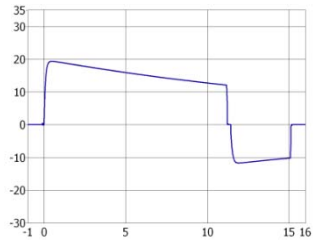
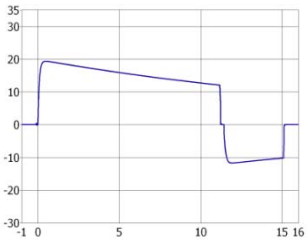
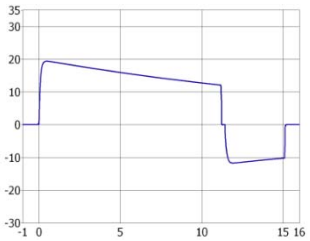
In the case of a warranty claim, please return the device, with proof of purchase (e.g. invoice) stating your name and address, to your dealer or to METRAX GmbH.

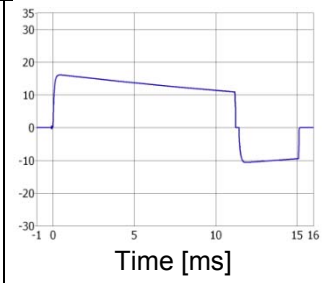
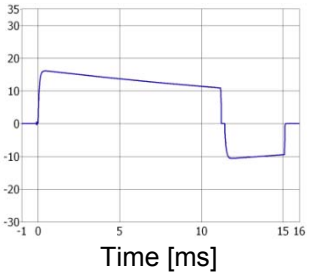
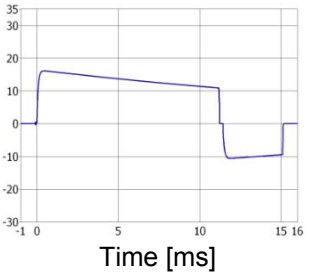
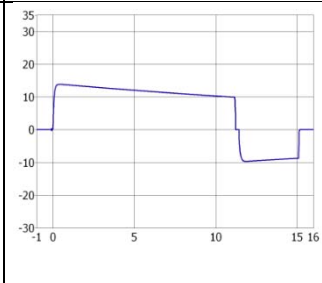
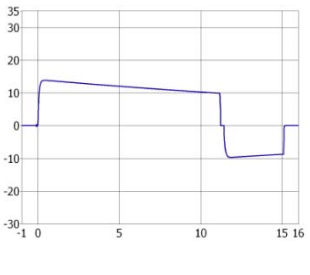
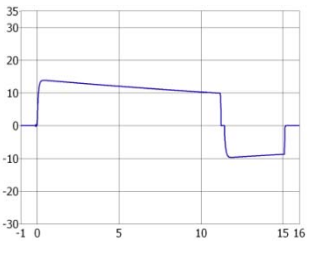
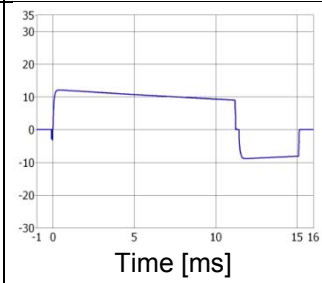
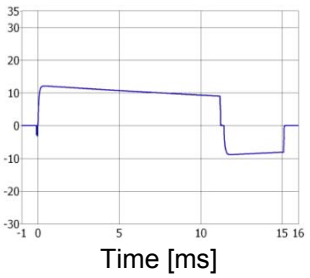
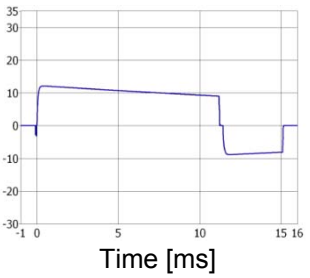
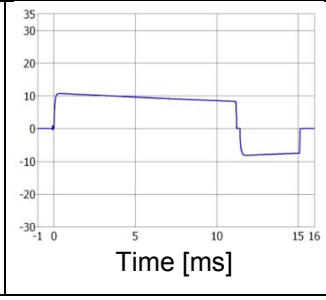
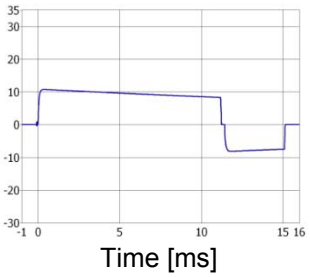
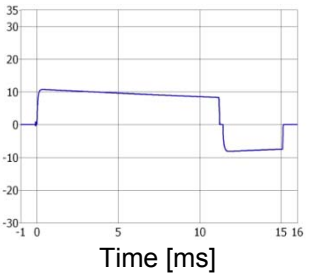
METRAX After-Sales Service is glad to be at your disposal, even after the warranty period has expired.

14 Depiction of the current-time function

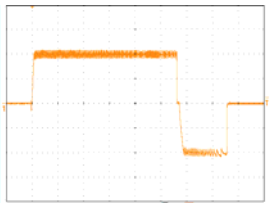
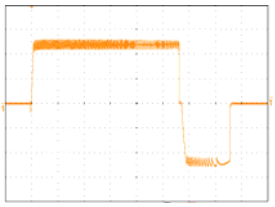
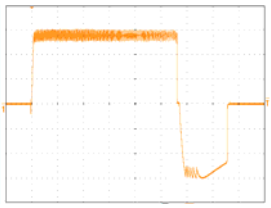
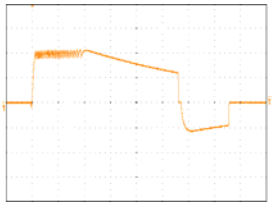
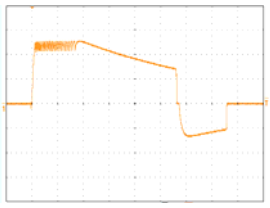
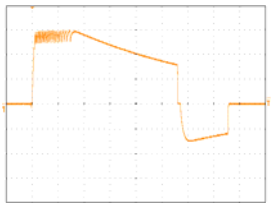
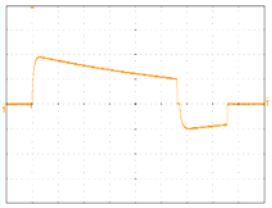
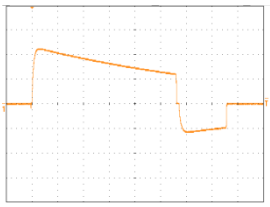
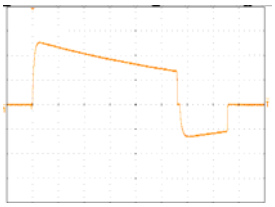
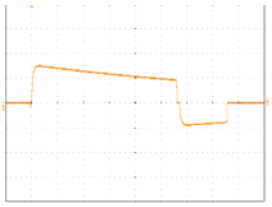
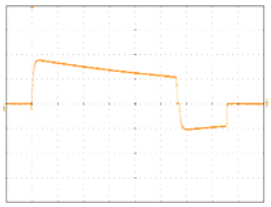
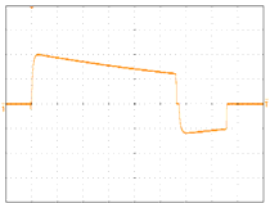
The following diagrams show the graphs for the defibrillation pulse displayed depending on the load resistance.

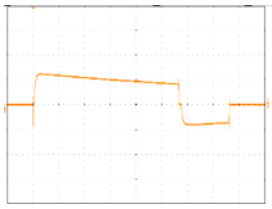
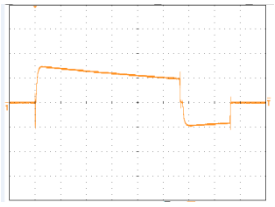
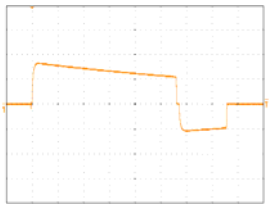
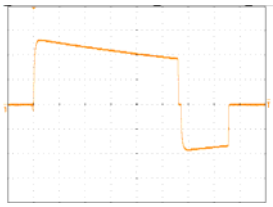
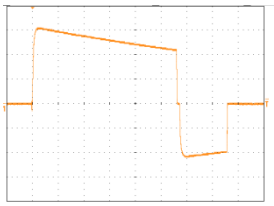
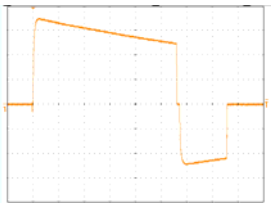
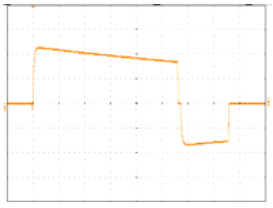
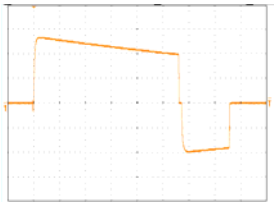
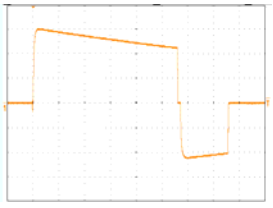
14.1 Adult mode

	First shock	Second shock	Third shock	
25 Ohm	 Time [ms]	 Time [ms]	 Time [ms]	Current [A]
50 Ohm	 Time [ms]	 Time [ms]	 Time [ms]	Current [A]
75 Ohm	 Time [ms]	 Time [ms]	 Time [ms]	Current [A]
100 Ohm	 Time [ms]	 Time [ms]	 Time [ms]	Current [A]

	First shock	Second shock	Third shock
125 Ohm			 Current [A]
150 Ohm			 Current [A]
175 Ohm			 Current [A]
195 Ohm			 Current [A]

14.2 Child mode

	First shock	Second shock	Third shock
25 Ohm	Y=2A/Div; X=2ms/Div 	Y=5A/Div; X=2ms/Div 	Y=5A/Div; X=2ms/Div 
50 Ohm	Y=5A/Div; X=2ms/Div 	Y=5A/Div; X=2ms/Div 	Y=5A/Div; X=2ms/Div 
75 Ohm	Y=5A/Div; X=2ms/Div 	Y=5A/Div; X=2ms/Div 	Y=5A/Div; X=2ms/Div 
100 Ohm	Y=5A/Div; X=2ms/Div 	Y=5A/Div; X=2ms/Div 	Y=5A/Div; X=2ms/Div 

	First shock	Second shock	Third shock
125 Ohm	Y=5A/Div; X=2ms/Div 	Y=5A/Div; X=2ms/Div 	Y=5A/Div; X=2ms/Div 
150 Ohm	Y=2A/Div; X=2ms/Div 	Y=2A/Div; X=2ms/Div 	Y=2A/Div; X=2ms/Div 
175 Ohm	Y=2A/Div; X=2ms/Div 	Y=2A/Div; X=2ms/Div 	Y=2A/Div; X=2ms/Div 

15 Rhythm detection system

The rhythm detection system on the HeartSave analyses the patient's ECG and supports it if the unit detects a shockable or non-shockable rhythm.

The rhythm detection system on the device comprises:

- Ascertaining the electrode contact
- Automatic evaluation of the ECG
- Operator control of the defibrillation shock therapy

The transthoracic impedance of the patient is measured by the defibrillation electrodes. If the baseline impedance is greater than the maximum critical value, then the device determines whether the electrodes are not in good enough contact with the patient or if they are not connected properly to the device. ECG analysis and dispensation of defibrillation shocks are therefore prevented. The voice output says "Check electrodes" if the contact of the electrodes is insufficient.

Automatic Interpretation of the ECG

The rhythm detection system of the device is designed to recommend a defibrillation shock when the system is has been connected up to a patient and the system detects a rhythm which requires defibrillation

With all other ECG rhythms, including asystolia and normal sinus rhythms, the HeartSave rhythm detection system does not recommend defibrillation.

Operator control of the output of defibrillation shocks

The device's rhythm detection system triggers an automatic power charge if the device detects a cardiac rhythm which requires defibrillation. Optical and acoustic messages are emitted to show you that the device recommends giving a defibrillation shock. If a defibrillation shock is recommended, you decide whether and when the shock is to be given.

The Algorithm:

- Observes the ECG rhythm across a continuous recording of 10 seconds, of which 7 seconds have been used for an initial diagnosis or to display the message "Shock advised."
- Measures symmetry and energy content of the signal
- Filters and measures artefacts and interference
- Detects pacemakers
- Measures the QRS rate

15.1 Adult mode

For validation the following databases have been used: AHA and MIT

Performance results (weighted average, rhythms identified in the databases as VF are evaluated as requiring defibrillation):

- Sensitivity 99.30%
- Specificity 99.88%
- False positive rate 0.04 %
- Real predictive value 97.93 %

The databases in use have a total length of 10,004 minutes. The calculation was made in accordance with IEC 60601-2-4:2010.

As cardiac rhythms requiring defibrillation, in the calculation we look at the characteristic values of the sections in the ECG datasets above databases, which are marked with the PysioBank Annotations code for ventricular flutter ("[" Begin, "]" End; also refer *www.physionet.org*) using the PhysioBank Annotations code.

These sections also contain ventricular tachycardia that however are not separately annotated and therefore cannot form part of the statistic.

The rhythm detection system using these data thus meets the requirements of IEC 60601-2-4:2010 (sensitivity> 90%, specificity> 95%).

15.2 Child mode

For validation the following database has been used: Development and validation dataset of the Physical-Technical Federal Institute (PTB) Berlin. These data were collected by the PTB as part of research project MNPQ 07/09 of the German Federal Ministry of Economics and Technology.

Performance results:

- Sensitivity 90.9%
- Specificity 99.6%
- False positive rate 0.4 %
- Real predictive value 90.9 %

The PTB dataset consisted of 529 records which were almost evenly split into a development and a validation data set (265/264). The development data set can be made accessible to manufacturers. The validation dataset on the other hand must remain confidential in order to prevent the rhythm detection system from being aligned too closely to the data. This methodology meets the recommendations of IEC 60601-2-4:2010.

Cardiac rhythms not requiring defibrillation are found in 509 of the 529 records; cardiac rhythms requiring defibrillation appear in just 20 of the records as these a very rare occurrences in children. The cardiac rhythms not requiring defibrillation cover thigh blockages and supraventricular tachycardia, as well as normal sinusoidal rhythms.

Sensitivity

$$\frac{\text{Number of "}\textit{correct shockable}\text{" algorithm decisions}}{\text{Total number of ECGs in which a shock is clinically recommended}}$$

Specificity

$$\frac{\text{Number of "}\textit{correct not shockable}\text{" algorithm decisions}}{\text{Total number of ECGs in which a shock is not clinically recommended}}$$

False positive rate

$$\frac{\text{Number of "}\textit{incorrect shockable}\text{" algorithm decisions}}{\text{Total number of ECGs in which a shock is not clinically recommended}}$$

Positive predictive value

$$\frac{\text{Number of "}\textit{correct shockable}\text{" algorithm decisions}}{\text{Total number of ECGs where the device recommends VF shock therapy}}$$

16 Guidelines and manufacturer declarations about electromagnetic compatibility

Guidelines and manufacturer declaration – Electromagnetic emissions		
The PRIMEDIC™ HeartSave AS is designed for use in an environment as described below. The customer or user of the PRIMEDIC™ HeartSave PAD should ensure that it is used in an environment of this kind.		
Emitted interference measurements	Conformity	Electromagnetic environment - Guideline
HF emissions as per CISPR 11	Group 1	The PRIMEDIC™ HeartSave PAD only uses HF energy for its internal function. This means that its HF emission is very low and it is unlikely that equipment in the vicinity will be disrupted.
HF emissions as per CISPR 11	Class B	The PRIMEDIC™ HeartSave family is suitable for use in all facilities, including residential areas and those which are directly connected to a public supply network which also supplies buildings that are used for residential purposes.
Emission of harmonics according to IEC 61000-3-2	Class B	
Emission of voltage fluctuations/flickering according to IEC 61000-3-3	Compliant	

Guidelines and manufacturer declaration – Electromagnetic interference immunity			
The PRIMEDIC™ HeartSave PAD is designed for operation in the electromagnetic environment as described below. The customer or user of the PRIMEDIC™ HeartSave PAD should ensure that it is only operated in a suitable environment.			
Interference resistance tests	IEC 60601 impulse test level	Conformity level	Electromagnetic environment code of practice
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floor should be made of wood or concrete or be tiled with ceramic tiles. If the floor is covered with a synthetic material, the relative air humidity should be at least 30%.
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to the typical values found in a commercial or hospital environment.

<table>
<tr><td colspan="4">Guidelines and manufacturer declaration – Electromagnetic interference immunity</td></tr>
<tr><td colspan="4">The PRIMEDIC™ HeartSave PAD is designed for operation in the electromagnetic environment as described below. The customer or user of the PRIMEDIC™ HeartSave PAD should ensure that it is only operated in a suitable environment.</td></tr>
<tr><td>Strength test</td><td>IEC 60601 impulse test level</td><td>Conformity level</td><td>Electromagnetic environment code of practice</td></tr>
<tr><td>Conducted HF interference according to IEC 61000-4-6

Radiated HF interference according to IEC 61000-4-3</td><td>3 Veff
150 kHz to 80 MHz outside the ISM-band

3 Veff
150 kHz to 80 MHz inside the ISM-band

10 V/m
80 MHz to 2.5 GHz</td><td>Not relevant for PRIMEDIC™ HeartSave AS due to the internal current supply of the device

Not relevant for PRIMEDIC™ HeartSave AS due to the internal current supply of the device

10 V/m</td><td>Portable and mobile radio transceivers should not be used closer to the PRIMEDIC™ HeartSave PAD, including its cables, than the recommended protective distance which is calculated according to the equation applicable to transmission frequencies.

Recommended protective distance
N/A

N/A

$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2{,}3\sqrt{P}$ 800 MHz to 2.5 GHz

with P as the maximum power rating of the transmitter in Watts (W) in accordance with information provided by the manufacturer of the transmitter and d as the recommended protective distance in metres (m). [b]
The field strength of stationary radio transmitters in accordance with an inspection on location c should be less than the conformity level for all frequencies. [d]
It is possible in the vicinity of devices which have the following pictogram.</td></tr>
</table>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not be applicable in all cases. The spread of electromagnetic factors is affected by absorption and reflections from buildings, objects and people.

a The ISM frequency ranges (for industrial, scientific and medical applications) 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 in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency band from 80 MHz and 2.5 GHz are defined to reduce the probability that mobile/portable communication devices can cause interference, if they are unintentionally brought into the vicinity of the patient. For this reason the additional factor of 10/3 is applied when calculating the recommended safety distance in these frequency ranges.

c The field strength of stationary transmitters, such as base stations of wireless telephones and mobile field radio transmitters, amateur radio stations, AM and FM radio and television transmitters can theoretically not be precisely determined in advance. To determine the electromagnetic environment with regards to the stationary transmitters, a study of the location should be considered. If the field strength at the location where the PRIMEDIC™ HeartSave AS is being used exceeds the upper conformity level, the PRIMEDIC™ HeartSave AS must be observed to prove that it is functioning properly. If unusual performance characteristics are observed, then it may be necessary to take additional measures, such as change the orientation or the location where the PRIMEDIC™ HeartSave AS is being used.

d Above the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Recommended protective distances between portable and mobile HF telecommunication devices and the PRIMEDIC™ HeartSave PAD product line				
The PRIMEDIC™ HeartSave AS is designed for use in an electromagnetic environment in which the HF interference is controlled. The customer or user of the PRIMEDIC™ HeartSave PAD can help avoid electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the PRIMEDIC™ HeartSave PAD– independently of the output power of the communication device, as shown below.				
Power rating of transmitter in W	Protective distance depends on the transmission frequency m			
	150 kHz to 80 MHz outside the ISM bands	150 kHz to 80 MHz inside the ISM bands	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2{,}3\sqrt{P}$
0.01	N/A	N/A	0.12	0.23
0.1	N/A	N/A	0.38	0.73
1	N/A	N/A	1.2	2.3
10	N/A	N/A	3.8	7.3
100	N/A	N/A	12	23
For transmitters with a maximum power rating that is not given in the table above, the distance can be determined by using the equation for the relevant column, whereby P is the maximum power rating of the transmitter in Watts (W) according to the manufacturer of the transmitter. NOTE 1 At 80 MHz and 800 MHz the higher frequency range is applicable. NOTE 2 The ISM frequency ranges (for industrial, scientific and medical applications) 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 The conformity level in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz and 2.5 GHz are intended to reduce the likelihood of mobile/portable communication devices causing interference if they are unintentionally carried into the treatment area. For this reason, the additional factor of 10/3 is applied when calculating the recommended protective distances in these frequency bands. NOTE 4 These guidelines may not be applicable in all cases. The spread of electromagnetic factors is affected by absorption and reflections from buildings, objects and people.				

17 Safety checks

Additionally to the recommended maintenance activities of the operator, METRAX GmbH also prescribes a technical safety check to be carried out by Metrax or a person authorised by Metrax every two years. The test protocols necessary for the checks can be provided by Metrax GmbH. Only authorised persons can operate the device. Please consider also the national regulations in your country concerning technical safety checks.

18 Appendix

18.1 Index of diagrams

About Us

METRAX GmbH is specialised in developing state-of-the-art devices for emergency medicine. Established in 1973 in Rottweil, today Metrax is considered to be an outstanding example of the strengths in German development technology: The company has stood out over the past 30 years for its innovative vision, top quality and absolute dedication to research and development. The result are ultra-reliable and precise high-tech equipment with a level of user-friendliness which sets new standards.

With its PRIMEDIC™ brand, Metrax offers a reliable programme for emergency medicine: Professional defibrillators and mobile ultrasound scanners. Emergency rescue services around the world are familiar with PRIMEDIC™ as a guarantee of the highest quality and innovative medical technology.

Your dealers

Headquater:

METRAX GmbH
Rheinwaldstr. 22
D-78628 Rottweil
Germany
Tel.: +49 741 257-0
Fax: +49 741 257-235
www.primedic.com
info@primedic.com

CE 0123

Representative Offices:

METRAX GmbH
Shanghai Rep. Office
Room 720, Block B, Urbank 88 Office Park
No.88, North Zhangjiabang Road
Pudong,Shanghai 200122
P. R. China
Tel.: +86 21 583199-80
Fax: +86 21 583177-79
www.primedic.com.cn
info@metrax.cn

METRAX GmbH
Representative office
Ul. Vavilowa 5, corpus 3
Office 406-3
119334 Moscow
Russia
Tel.: +7 495 722 1705
www.primedic.com.ru
info@metrax.ru

METRAX GmbH
德国曼吉世有限公司上海代表处
上海浦东新区北张家浜路 88 号
200122
左岸 88 创意园 B 座 720 室
电话： +86 21 583199-80
传真： +86 21 583177-79
www.primedic.com.cn
info@metrax.cn

METRAX GmbH
Представительство в странах СНГ
119334 Москва Россия
ул.Вавилова, д.5, корп.3, офис 406-3
тел.: +7 495 722 1705
www.primedic.com.ru
info@metrax.ru