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PRIMEDIC™
by SPACELABS HEALTHCARE

HeartSave AED-M

Operating instructions

MGA23702 / GB / A

Masthead

Publisher

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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 its direction
BLS	Basic measures of resuscitation / 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 guidelines on Cardio Pulmonary Resuscitation (CPR)
EU	European Union
CPR	Cardio pulmonary resuscitation
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, including serial number, test data, instructions, safety checks.
Metronome	Metronome for chest compressions
MDD	Medical Device Directive
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 (Federal German Physical Technical Institute)
SaveCard	Memory card for data transfer
SavePads	Defibrillation electrode
WEEE	engl. Waste of Electrical and Electronical Equipment (in German: Elektro- und Elektronikgeräte-Abfall)

2 Introduction

2.1 Foreword

Dear User,

You are preparing to face the task of using the PRIMEDIC™ HeartSave AED/AED-M in a medical emergency on human beings!

So that you react quickly and properly in these special circumstances and make optimal use of the opportunity the device provides you with , it is necessary for you to take your time carefully to read through these operating instructions beforehand, thus familiarising yourself with the device, its functions and applications.

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

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

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

The instructions given on the device are no substitute for reading these operating instructions.

2.2 Validity

The descriptions in these operating instructions refer to the PRIMEDIC HeartSave AED-M made by METRAX GmbH. Both units are referred to as HeartSave in the following operating instructions.

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

2.3 Guarantee

The warranty period is 24 months and starts on the day of delivery. The guarantee conditions and additional information can be found at www.primedic.com

2.4 Disclaimers

Liability claims in the event of damages to people or property are excluded if they are 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 if 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.
- Autonomous intervention, repairs or constructional changes to the device.
- Autonomous exceeding of the performance limits.
- Lack of monitoring of parts that are subject to wear and tear.
- Treating patients without prior indication.

2.5 Symbols used in these operating instructions

DANGER

Texts marked DANGER indicate an extraordinarily serious, current danger which will definitely lead to serious injury or even death if no preventative measures are adopted.
You must follow these instructions!

WARNING

Texts marked WARNING indicate extraordinarily serious possible dangers which, should no preventative measures be taken, may lead to serious injury or even death.
You must follow these instructions!

CAUTION

Texts marked with CAUTION indicate a possible dangerous situation which could lead to minor injuries.
You must follow these instructions!

ATTENTION

Texts 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 point marks lists

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

< ... > Texts set in angle brackets denote acoustic information / instructions for the device which are shown simultaneously on the monitor, depending on the device model.

2.6 Pictogrammes

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 is 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

Durability of the internal battery MM/YYYY


Protect battery from fire


Do not charge the battery


Do not reuse

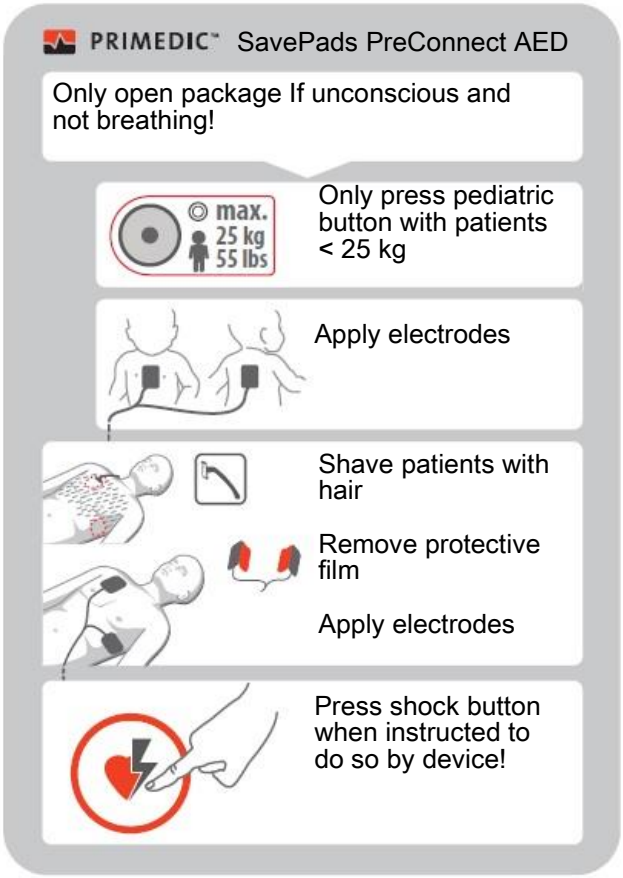

Observe the operating instructions

not sterile

Good for 1 day after opening

	Storage temperature in Celsius and Fahrenheit
	Protect from sunlight
	Store in a dry place
	Latex-free
	Remove protective film from adhesive electrodes
	Batch code
	Manufacturer
REF	Order number
	Can be used until YYYY/MM
	At the end of its life, send the power module for recycling. Device contains Lithium-Ion cells.

2.7 Summarized operating instructions



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

3 Intended use

The PRIMEDIC™ HeartSave AED-M is intended for use by expert medical practitioners working under the instructions issued by a doctor, and for doctors who frequently need an AED for emergency situations that they encounter in the course of their activities.

The integrated voice messages make it possible for the PRIMEDIC™ HeartSave AED-M to be used by laymen. They must be instructed on the unit and be trained in the execution of life-saving measures (BLS), but whose level of knowledge is unknown at the time of the event.

The PRIMEDIC™ HeartSave AED-M is suitable for domestic use and in 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 device with acoustic notices (voice message) and optical indications as well as by the device identification, so that the defibrillation electrodes are fixed on the body of the patient and the BLS measures, chest compressions and rescue breathing according to the current recommendations of the ERC or AHA can be carried out. The first aider is requested to step back from the patient in order to perform the analysing rhythm and apply a shock. The unit monitors and analyses the cardiac rhythm of the patient, loads the capacitor according to patient impedance and delivers the energy with a constant-current biphasic shock when the user presses the trigger button. The first 3 shocks are based on the shock strategy with the shock steps 20A (281J at 50 Ohm), 25A (350J at 50 Ohm) and 30A (360J at 50 Ohm) From the third shock on, all further shocks are delivered with the 30A shock step (360J at 50 Ohm). In pediatric defibrillation mode, the defibrillation 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 delivered with asystole, 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 delivered.

In combination with the ECG monitoring cable, it is possible to carry out restricted rhythmological monitoring of the patient for a short period (a few hours) in the presence of medically-trained personnel.

The PRIMEDIC™ HeartSave AED-M is designed for treating adult patients in combination with the PRIMEDIC™ SavePads PreConnect, PRIMEDIC™ SavePads C or PRIMEDIC™ SavePads Connect disposable electrodes. Children aged 8 years and above and/or with a weight over 25 kg are treated as adults.

Using the coded defibrillation electrodes PRIMEDIC™ SavePads mini, the PRIMEDIC™ HeartSave AED-M can also be used on children aged 1-8 weighing less than 25 kg. By coding the defibrillation electrodes, the maximum defibrillation energy is reduced to a maximum of 90 J according to the current escalation levels. If in an actual emergency these electrodes are not available, the user can switch the defibrillator into the Child defibrillations mode manually. Here too, the maximum defibrillation energy is limited to 90 J even if the defibrillation electrodes for adults are connected.

Note HeartSave defibrillators may only be used as described and under the conditions detailed in these operating instructions!

DANGER

Warning: physical harm

Risk of heart arrhythmia which may lead to death

- ▶ Only use HeartSave as intended

3.1 Indication/Contraindication for Defibrillation

3.1.1 Indications

Only use the HeartSave when the patient:

- is unconscious **and**
- not breathing
- and is older than 1 year

3.1.2 Contraindications

The HeartSave must not be used if the patient:

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

4 Safety information

4.1 General safety advice

Read the operating instructions carefully before using HeartSave for the first time. Only use 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 standing water or rain.

Do not use HeartSave in the presence of flammable materials.

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

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 away from children!

Applicable for Europe:

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

For Germany and Austria, the following is also applicable:

- 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 is an automatic external defibrillator (AED) with an integrated Single Channel ECG.

The ECG is recorded using the PRIMEDIC™ SavePads. HeartSave can detect potentially fatal heart arrhythmia. HeartSave generates the electric shock needed to bring the patient back to consciousness (defibrillation). This method is the generally recognized 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 very quickly ready to use. The loading time for a defibrillation is approx. 12 seconds with a battery capacity of approx. 90 % of the rated value.

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

5.2 Description of device details

Fig. 1: Front view with cover

(1) Status display

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

(3) Carry handle

(4) Cover of the device

Fig. 2: Rear View

(1) Identification plate

(2) Fixings for wall mounting

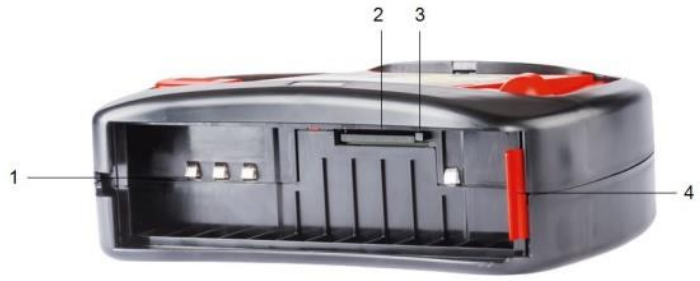


Fig. 3: View from below (without energy module)

(1) Contacts for energy module

(2) Slot for SaveCard

(3) Release button, SaveCard

(4) Release button, energy module

Fig. 4: PRIMEDIC™ HeartSave AED-M front view

(1) Pediatric button

(2) Jack for electrode plugs

(3) Connector symbol with LED

(4) Monitor

(5) On/Off switch

(6) Button to navigate upwards or to increase parameters

(7) Select/ confirm button

(8) Button to navigate downwards or to reduce parameters

(9) Loudspeaker

(10) Shock button (shock button for defibrillation)

Note

You can change the language in the Setup Menu on Page 3. You can choose from 4 languages. The individual language is quoted briefly after activation.

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

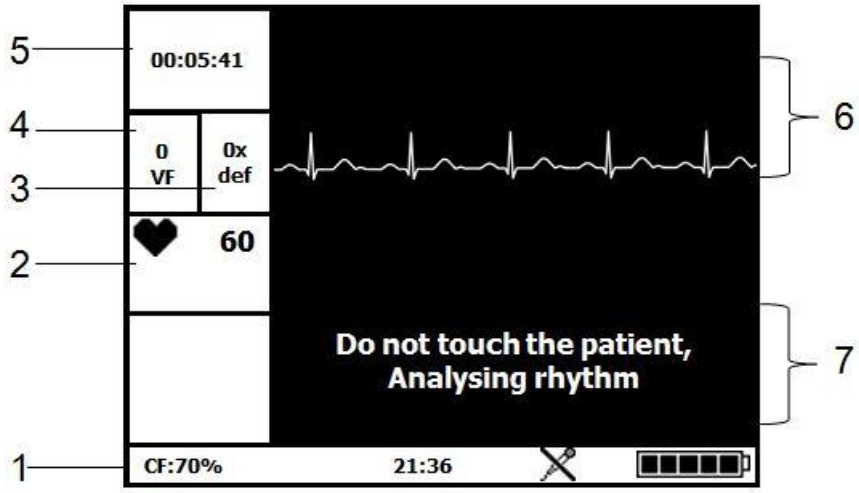


Illustration similar

Fig. 5: Monitor illustration

(1) Status line to show CF card capacity, patient impedance, time of day, microphone, battery capacity

(2) Heart rate

(3) Number of defibrillations

(4) Number of detected VFs

(5) Display of switch-on duration / time sequence CPR cycle

(6) ECG display

(7) Instructions

Fig. 6: PRIMEDIC™ SavePads AED

(1) PRIMEDIC™ SavePads PreConnect (defibrillation electrodes)

(2) Artificial respiration cloth and razor

(3) Rescue kit with expiry date SavePads

(4) Brief instructions

(5) Disposable gloves

(6) Scissors

5.3 Status display

In the table below is a list of the possible things displayed in the status display and their meanings.

Display.	Meaning	Action to be taken
	Sufficient battery capacity.	Device ready to use
	Low battery capacity. No energy module inserted! Symbol also appears if the use by date of the energy module has been exceeded.	Device can be used. Promptly exchange battery. Insert power module. 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. Low battery capacity. No energy module inserted!	Carry out major self-test by reinserting the battery or switching the device on again. Have device repaired by authorized dealer.

The battery is monitored using an electronic charge balance process.

Note

Once the energy module is exhausted, a warning tone will sound in connection with a spoken warning.

< Battery low, please replace battery > or.
< Charging status battery low, please recharge >

Note

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

5.4 Capacity display on the monitor

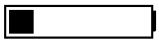
With the HeartSave AED-M, the battery charge of the battery / AkuPak appears on the display. The different images that may be displayed have the following meaning:

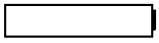

100 % charged


80 % charged


60 % charged


40 % charged


20 % charged


0% (device runs on until charge is exhausted)


Fault in the device or service life of the power module has expired

The optional AkuPak LITE and the battery are monitored by means of electronic charge measurement to ensure the most accurate capacity display possible. In addition to this display, all HeartSave units issue a warning if the battery is about to be exhausted.

	Audible warning.	Display on monitor
AkuPak LITE	< Charging status battery low, please recharge >	Charging status battery low, please recharge
Battery	< Battery low, please replace battery >	Battery low, please replace battery

If the device is being used, the corresponding voice prompt will be repeated regularly in the selected language.

The battery symbol in the status display is displayed.

5.5 Data management

Note HeartSave automatically records all deployment data (ECG, environmental noise etc.) onto a removable SaveCard.

The stored data can be viewed using a PC / laptop and the software PRIMEDIC ™ ECG Viewer (optional accessory). However, this data may not be used for diagnostic purposes or for therapy for the patient. It should only be used for administrative or legal purposes. The software has a deployment log into which additional patient data can be entered.

Once the storage capacity or the maximum number of files of the SaveCard is exhausted, no further data will be saved.

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.

Note The data saved on the SaveCard should be archived after every deployment if possible. Delete the data from the SaveCard after archiving.

Operating the software is described separately.

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 formatting the SaveCard, ensure that you do not accidentally transfer the FAT32 file system.

Proceed as follows:

For Windows Vista, Windows 7, Windows 8, Windows 8.1

- Start a command line window using "Start->Execute" and in the entry field, enter "**cmd.exe**". The command line window will then open.
- There you enter the following: **format f: /U /FS:FAT /X /V:** (where f: stands for the drive letter of the CF card reading device which you may have to adjust).

5.6 Accessories

The accessories need to be secured appropriately before being transported.

5.6.1 Standard accessories

Batterie 6, Order No. 97641 / AkuPak LITE, Order No. 97196 (depending on version)

SavePads PreConnect, Order No. 97085

Fig. 7: PRIMEDIC™ SavePads PreConnect (unpacked)

(1) Defibrillation electrodes with protective film

(2) Electrode plug

5.6.2 Optional accessories

PRIMEDIC™ SavePads mini, Order No.: 97534

PRIMEDIC™ SavePads Connect Cable 12, Order No.: 97384

PRIMEDIC™ SavePads Connect (1 Pair), Order No. 96516

PRIMEDIC™ SavePads Connect (5 Pairs), Order No. 96710

ECG electrodes, Order No. 96592

Carrying case with storage compartments, Order No.: 96379

Wall-mounting box SaveBox, Order No.: 96740

Wall-mounting box with Alarm SaveBox Advanced, Order No.: 96776

Wall-mounting bracket with unlocking facility, Order No.: 96378

Defibrillator Signs Set 1 Order No.: 97016

Monitoring cable, 2-core 12, Order No. 97385

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.

Remove the insulation film between the energy module and the unit. Proceed as described in Chapter 0.

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

Scope of delivery:

- HeartSave AED / AED-M
- Battery 6 / AkuPak LITE (depending on version)
- SaveCard
- Operating instructions
- SavePads PreConnect
- Accessories 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 plug 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

The data saved on the SaveCard should be archived externally after every deployment if possible. 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 Power module

Before using the HeartSave for the first time, you must insert the power module in the specially designed slot.

Note

For the first message "Battery low, please replace battery / Charging status battery low, please recharge" there are still at least 3 energy discharges at max. energy available. The energy module should be replaced if this message appears.

Note

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

6.3.1 Insert energy module.

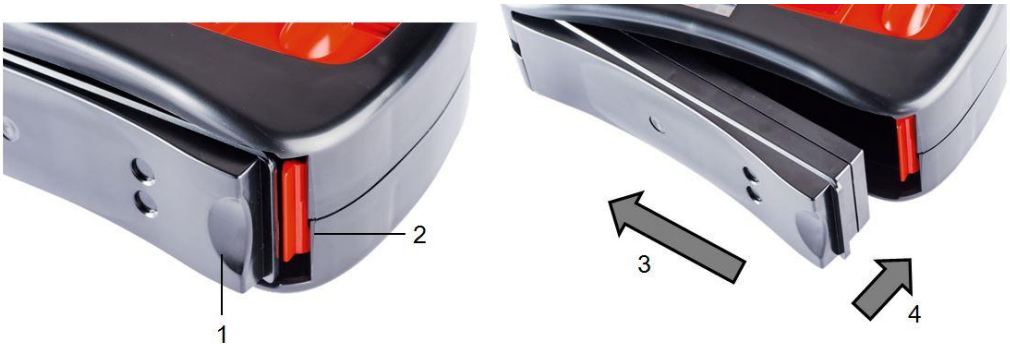


Fig. 9: Insert energy module

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'

If the status display does not indicate an 'OK', proceed as follows:

- Switch on the device and wait for the result of the self-test.

6.3.2 Remove the power module

Note Only replace the energy module when the device is switched off and the defibrillation electrodes plug is disconnected.

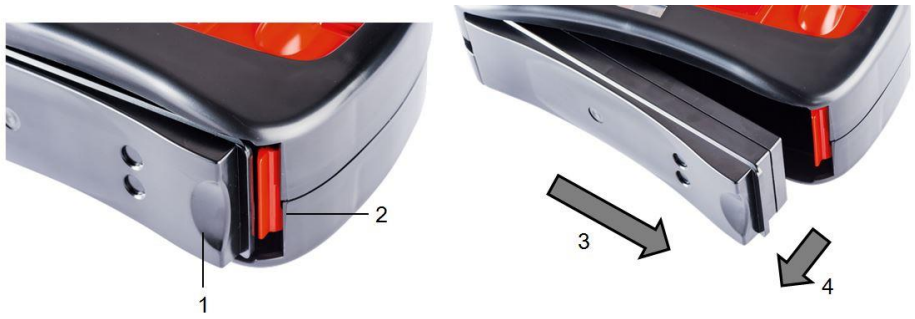


Fig. 10: Removing the energy module

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 flat battery

ATTENTION

Note the battery expiration date

Device is not operational

- ▶ Replace batteries after passing their expiration 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.

6.5 PRIMEDIC™ AkuPak LITE

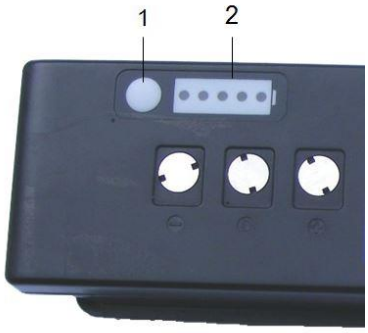


Fig. 11: PRIMEDIC™ AkuPak LITE battery charge indicator

(1) Push-button to activate battery charge indicator

(2) Battery charge indicator

Battery charge indicator (1) means:

● ● ● ● ●	81% - 100 % charged
● ● ●	41% - 60% charged
●	1% - 20% charged

Note

When charging using the Charger Basic, the PRIMEDIC™ AkuPak is automatically charged up again fully if the level falls below 80% of the charge capacity.

This 80%-limit can temporarily be made inoperative by pressing 3 seconds on push button (2), i.e., the PRIMEDIC™ AkuPak can be recharged even before reaching this limit. This, for example, is practical if you wish to fully recharge PRIMEDIC™ AkuPak prior to next use, independent of its current charge status. After recharging, the programmed 80%-limit is operative for the next automatic full recharge.

Note Charging the PRIMEDIC™ AkuPak LITEs outside the operating temperatures quoted in the appendix can cause damage to the rechargeable battery.

A completely discharged battery must be charged for at least 2 hours. If the charging time is too short, incorrect interpretation of the rechargeable battery charge status may occur. Trouble-free functioning of the equipment cannot be assured. Charging the PRIMEDIC™ AkuPak is interrupted at temperatures above 45°C.

6.6 Connecting the PRIMEDIC™ PowerLine (mains unit) (optional accessory)

Fig. 12: PRIMEDIC™ PowerLine

Procedure:

- Insert the PRIMEDIC™ PowerLine following the instructions in chapter 6.3.1.
- Then plug the mains plug of the mains cable into a socket in the vicinity of the patient.
- The PRIMEDIC™ HeartSave carries out a self-test and is then ready for use.

Note METRAX GmbH recommends that you keep the HeartSave unit, with the PRIMEDIC™ PowerLine inserted, continuously connected to the mains, so that the equipment self-tests are carried out automatically.

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 a fault is detected, the large self-test (LONG) is carried out automatically.

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 power supply and HV part at 0 V, impedance measurement
MEDIUM	First day of the month	Software, operating membrane, ECG calibration, clock, internal power supply and HV part at 300 V, impedance measurement
LONG	On the 1st. July and on the 1st. January every year	Software, operating membrane, ECG calibration, clock, internal power supply and HV part at 1600 V, impedance measurement

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 waiting for approx. 30 seconds, and then wait for the result of the internal switch-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 Configuration

The PRIMEDIC™ HeartSave has been configured in the factory. In the setup menu (displayed on the monitor) you can change certain parameters. You can save different configurations in a total of four profiles for different user groups. To activate a profile see Chapter 8.3. The device always starts in the profile „Basic“, independently of which changes have been made to the configuration before switching off or removing the power module.

General navigation:

- Press the selection / confirmation key during operation to open the setup menu ↵.
- Press the button ▲ (up) or the button ▼ (down) to navigate in the menu and to increase or respectively decrease a selected parameter
- Press the button ↵ to select a parameter and to confirm the changed value.

Parameters	**Selection options**
Basic	[Active/]
Profile1	[Active/]
Profile 2	[Active/]
Profile 3	[Active/]
Page 2:	
Microphone:	[On/Off]
BLS information:	[On / Off]
HLW sound	[0 % / 25% / 50% / 75% / 100%]
CPR cycles adult	1-15
CPR cycles child	1-15
CPR Pediatric Mode	[15:2 / 30:2]
Systole sound:	[0 % / 25% / 50% / 75% / 100%]
Volume:	[25% / 50% / 75% / 100%]
Page 3:	
Language:	(depends on installed language packages)
Date:	in format DD/MM/YYYY
Time:	00:00 in 24 h format
Mains filter	[50Hz/60Hz/Off]
Display:	[0 degrees / 180 degrees]

Parameters	Selection options
Contrast:	from 60 to 180
Page 4:	
New PIN	0000-9999
Repeat PIN	0000-9999
Change PIN	[OK, fault]
Save to profile	[OK, fault]
PIN entry	0000-9999
Profile selection	Basic/Profile 1/Profile 2/Profile 3
Page 5:	
ARM SW:	x.xx(Version number) xxxx (Check sum 8-digits)
	Date (e.g. Jul 11 2005)
DSP SW:	x.xx(Version number) xxxx (Check sum 4-digits)
	Date (e.g. Jul 11 2005)

8.1 Simple change of configuration – example: Time

To change the time, proceed as follows:

- Use the key ↵ to change into the setup menu
- Navigate the cursor with the ▲ button to the menu point "to Page 2"
- Actuate the ↵ button to go to Page 2 of the menu.
- Switch to Page 3 with the ↵ button
- Navigate to "Time of day" with the ▲ button and confirm the input with the ↵ button
- Set the hours and minutes using the buttons ▲ and ▼.
- Confirm the input with the ↵ button
- Move the cursor by pressing the key ▲ to the menu item Time. Select the highlighted menu item Time by pressing the ↵ key. The hour is then highlighted.

Note If no key is pressed for one minute, the device automatically leaves the Setup Menu and goes back to standby.

8.2 Changing the PIN

The PIN is used to save profiles. Entering a PIN is absolutely necessary. If you want to change the PIN you will always need to know the old PIN.

proceed as follows:

- Use the key ↵ to change into the setup menu
- Switch to Page 5 of the menu.
- Navigate with the key ▲ to the entry < PIN > and confirm your selection with the key ↵
- Enter the current PIN as follows: Using the keys ▲ ▼ you can increase or decrease a digit. With the key ↵ you can change to the next digit. After the fourth digit, it jumps back to the menu item
- Navigate to the entry < New PIN > and enter your new PIN as described above.
- Navigate to the entry < Repeat PIN > and enter your PIN again.
- Select the menu parameter < Change PIN > and confirm your new PIN with the key ↵ .
- On the right next to the cursor the entry < OK > should appear. This means your new PIN is active.

Note When the device is first delivered, the PIN is always set in the factory to 0000.

8.3 Calling up/activating a profile

Certain parameter settings for the menu can be summarised into profiles.

Saved profiles can be called up as follows:

- Use the key ↵ to change into the setup menu
- Select your required profile using the keys ▲ ▼ and confirm it with the key ↵
- The selected profile is active

Note Please note that your profile selection is only active until the device is switched off. The devices always starts with the profile „Basic“

8.4 Saving menu parameters in a profile

Certain parameter settings for the menu can be saved as profiles. The profiles Basic, Profile 1, Profile 2, and Profile 3 are available.

If you want to save parameters in a profile or want to change a profile, proceed as follows:

- Use the key ↵ to change into the setup menu
- Change the required parameters from the various pages of the menu to suit your needs.
- Change to page 4 of the menu.

- Use the key ▲ to navigate to the entry < Profile selection > and confirm your selection with the key ↵
- Use the keys ▲ ▼ to select the required profile which is to be used to save the menu parameters previously selected. Confirm this with the key ↵
- Navigate with the key ▲ to the entry < PIN > and confirm your selection with the key ↵
- Enter the current PIN as follows: Using the keys ▲ ▼ you can increase or decrease a digit. With the key ↵ you can change to the next digit. After the fourth digit, it jumps back to the menu
- Change to the menu entry < Save to profile > and confirm your selection with the key ↵
- On the right next to the cursor the entry < OK > should appear. This means the profile is saved.
- Now leave the menu by using the button ▼ to navigate to the menu item < End > and confirm this with the button ↵

If you want to change the configuration that your device starts up with when it is switched on, you have to save your changed menu parameters in the "Basic" profile.

Note The parameter „Network filter“ can only be changed temporarily while operating the device. After starting the device, the network filter is always switched off initially.

8.5 Ratio chest compression:ventilation in Pediatric Mode

The ratio between chest compressions and rescue breathing can be changed in the **Pediatric mode** as follows.

- **(1) Give 30 chest compressions : Give 2 rescue breaths**
- **(2) Give 15 chest compressions : Give 2 rescue breaths**

In order to set the desired ratio between the chest compressions:ventilation, you need to adjust the following parameters as shown in the table:

Setting	CPR cycles child	CPR pediatric mode
(1)	5 cycles	30:2
(2)	7 cycles	15:2

Note In the standard delivered condition, the ratio between chest compression and rescue breathing is 30:2.

9 Operating the HeartSave and sequence of resuscitation

Note The sequence of the reanimation is realised in the device according to the recommended guidelines of the European Resuscitation Council (ERC Guidelines 2015). We recommend the user has carried out before using HeartSave.

9.1 Switching the HeartSave on

HeartSave is automatically activated by removing its cover on the device. If the device is not switched on automatically, switch it on by pressing the On/Off button. After this, all buttons are unlocked, except the shock button. Triggering the defibrillation is only released after detecting the ventricular fibrillation.

Directly after switching it on, an internal self-test is carried out to check important functions and signal devices. Standby is confirmed by a beep. It is important to ensure that the loudspeaker is working.

9.2 Examining 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 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.

9.3 Defibrillation

DANGER

Danger of damage to health of user or a third party

Triggering heart arrhythmia and burns caused by 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 Pediatric 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 automatically starts in Adult Mode.

9.3.1 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 successfully finished 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 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 analysing rhythm.

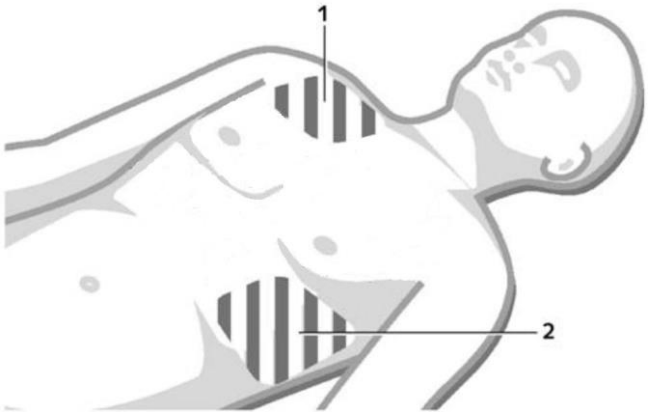


Fig. 13: Position of electrodes on adults

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 apex of the heart on the axillary line (2).

9.3.2 Defibrillation in Pediatric Mode

Note

In order to use adult electrodes (SavePads PreConnect or SavePads C) in Pediatric Mode, proceed as follows:

- ▶ Open the cover on the unit / switch HeartSave on
- ▶ Insert the electrode plug into the socket on HeartSave
- ▶ **Push the pediatric button**
- ▶ Stick the electrodes onto the naked upper torso
- ▶ Follow the voice prompts issued by HeartSave

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 Pediatric Mode. If you do not have any SavePads mini available, you can switch to pediatric mode by pressing the pediatric button with the SavePads PreConnect.If HeartSave is in Pediatric Mode, the indicator LED next to the pediatric button will illuminate.
The Pediatric Mode has been especially developed for the needs of children. In Pediatric Mode, the HeartSave supplies less energy than in Adult Mode.

<Pediatric 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 analysing rhythm.

Fig. 14: Position of electrodes 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 apex of the heart on the axillary line (2).

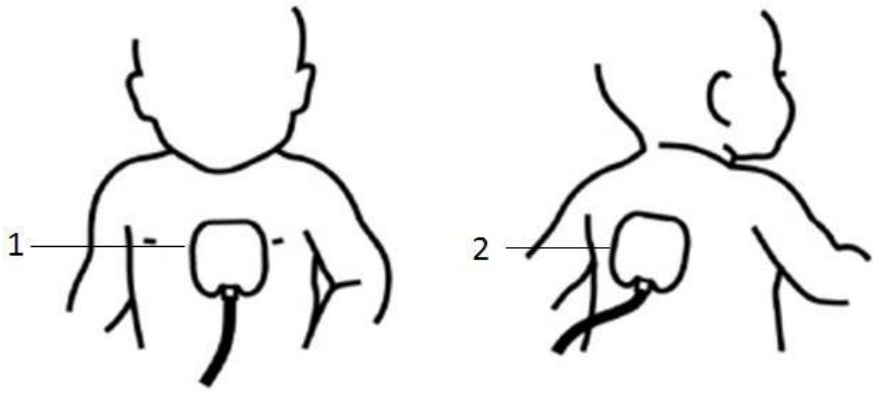


Fig. 15: alternative position of electrodes on a child

The positions of the electrodes are:

- (1) in the middle of the chest
- (2) on the back at heart level

Attach both electrodes so that the patient's heart lies in between them.

9.4 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

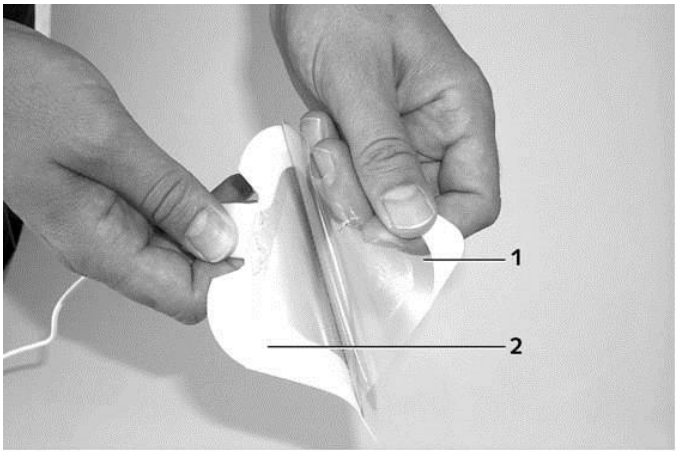


Fig. 16: Removing the film from the electrodes

(1) Protective film on electrodes

(2) SavePads defibrillation electrodes

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!

9.5 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. 17: 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 HeartSave as shown above.
- Make sure the red dot points to the front.

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.

9.6 Check electrodes

If the device reports the fault **< Check electrodes >**, this can be for several reasons:

- Electrode plug connector not plugged in. This will be signalled by flashing LEDs in the electrode plug connector symbol and on the electrodes positions on the front film.
- Too little resistance between electrodes (e.g. electrodes fixed too close to each other). The LEDs blink on the electrodes positions on the front foil.
- Too high resistance between the electrodes (e.g. chest hair not removed from the patient). The LEDs blink on the electrodes positions on the front foil.
- Air pockets between skin and defibrillation electrodes create a bad contact. The LEDs blink on the electrodes positions on the front foil.
- Dried out electrodes. The LEDs blink 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 analysing rhythm.

▶ It is very important to remedy the cause of the fault!

9.7 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.

The patient must now be put in an immobile position and must no longer be touched. The device prompts:
< Do not touch the patient, analysing rhythm >
and the "do not touch patient" zone flashes on the membrane keyboard.

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 programme 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.

9.8 Defibrillation required

Note Pressing the shock key during power charging (before it turns green) does not result in release of shock, it rather 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 advised >

< Device is charging >

< Chest compressions >

< Metronome >

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 a continuous acoustic warning, the voice message

< Stand clear of patient >

< Press lit shock button now >,

a continuous tone and the shock button lighting up in "green".

Warn those around you loudly before applying the defibrillation!

- ▶ Actuate the green illuminated shock button to apply the shock.

If you do not defibrillate within 15 secs, an internal safety discharge will follow and the ECG will be analysed again.

Defibrillation and cardio-pulmonary resuscitation (CPR) are repeated according to the directives of the ERC Guidelines 2015.

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 should occur during charging, an intermittent warning beep will sound.

9.9 Defibrillation not required

If the device cannot find a shockable rhythm, then it recommends 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 to 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 monitor him/her until the emergency services arrive.

9.10 Switching HeartSave off

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 recorded for 10 minutes or no button is pressed, the device automatically switches off. Approx. 30 seconds before the switch-off this is signalized by an interrupted warning tone. Pressing any button or any other activity will interrupt the switching off process.

9.11 Keeping the defibrillator ready for use

- ▶ Check 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 10.1.
- ▶ Renew the SavePads and replace or charge the energy module, if necessary, so that the HeartSave is ready for use as quickly as possible.
- ▶ If any malfunctions or noticeable problems occur, please contact your nearest service station.

9.12 Monitoring the patient

After successful defibrillation, the patient can be monitored by the monitoring function using the SavePads electrodes already used whilst they are being transferred to hospital. The Lead II (Einthoven) is available. If in this situation, ventricular fibrillation is detected again, renewed resuscitation can be carried out very quickly. For this purpose, the vehicle must be stopped and the engine switched off to ensure the analysis is correct.

If you need to monitor the ECG of a patient in other situations, please use the 2-core ECG patient cable.

This cable is only used for ECG monitoring of a patient. This cable cannot be used for defibrillation. If the automatic background analysis carried out by the HeartSave detects a heart rhythm that is in need of defibrillation, the following verbal message is issued:

< Analysis Recommended. Use SavePads >

In order to be able to carry out defibrillation, the ECG cable must be removed and replaced by the SavePads.

10 Cleaning, maintenance and despatch

10.1 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 surface disinfectants to disinfect (e.g. Gigasept FF, Bacillol or Spitacid).

10.2 Servicing

ATTENTION

Warning: property damage

The device does not have any parts which can 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 HeartSave
- Only use genuine accessories!

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

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

10.2.1 Servicing check list

- ▶ Check the expiration date
  - of the SavePads and
  - the battery / AkuPak LITE
- ▶ if necessary replace the parts.

- ▶ Check whether
  - the status display "OK" is shown!
  - the device is fully equipped.

Contact service if there is a fault on the device.

10.3 Sending the HeartSave

DANGER

Risk of fire due to short circuit

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

Use the original box where possible.

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

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

11 Disposal

⚠ CAUTION

Warning: physical harm

Risk of acid burns

- ▶ Dispose of the device and its individual parts according to local regulations

Fig. 18: 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 via 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 List of error codes

The following table lists all messages that the unit emits when it switches off because of a severe error. This switch-off is carried out with the spoken message "Internal Error"; the cause of the error is displayed with the error code number from the first column and the text from the second column. The other columns list the possible causes of the error and the remedial measures that can be carried out by the user themselves.

Error code	Error text	Cause(s)	User action
50	HV, Internal FSM error	Error during the shock appliance	- return the device for servicing
51	HV, CPLD error	Error during the shock appliance	- return the device for servicing
52	HV, +5V voltage failed	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
53	HV, +5VSW voltage failed	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
54	HV, +24V voltage failed	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
55	HV, VREF voltage failed	Error in voltage reference	- return the device for servicing
56	HV, HVPWR voltage failed	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
57	HV, RLPWR voltage failed	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
58	HV, Current setup DAC failed	Error when setting the current specifications - defect in the high voltage section	- return the device for servicing
59	HV, RTCCLK error was detected	Error in generation of system clock	- restart the device - if the error persists: Return the device for servicing
60	HV, MCLK error was detected	Error in system clock generation	- restart the device - if the error persists: Return the device for servicing
61	HV, HVHALT event was detected	Emergency shutdown during the shock application	- return the device for servicing
62	HV, HVHALT net error was detected	Error during the test of the emergency shutdown	- return the device for servicing

Error code	Error text	Cause(s)	User action
63	HV, Disarm cannot be performed	Error during the internal discharge, not possible to discharge the condenser	- return the device for servicing
64	HV, HV capacitor overvoltage was detected	Error during the high voltage load, voltage at the condenser too high	- return the device for servicing
65	HV, HV charger error was detected	Error during the high voltage load, impossible to load the high voltage	- return the device for servicing
66	HV, Error of HV measurement circuit	Error during measurements in high voltage section	- return the device for servicing
67	HV, HV charge time is too big	Error during the high voltage load, impossible to load the high voltage	- return the device for servicing
68	HV, Too big current was detected	Current too high during shock delivery	- return the device for servicing
69	HV, Too low current at shock was detected	Current too low during shock delivery, possibly due to fault in final stage	- return the device for servicing
70	HV, Current sensor error	Error in the current regulation	- return the device for servicing
71	HV, SHKEN net error	Error during the safety test before the shock delivery	- return the device for servicing
72	HV, START net error	Error during shock release	- restart the device - if the error persists: Return the device for servicing
75	HV, HV hardware protection error	Error during shock release	- restart the device - if the error persists: Return the device for servicing
76	HV, Residual voltage after disarm error	Residual current too high at the condensor after the discharge	- restart the device - if the error persists: Return the device for servicing
79	HV, Operator warning error	Error during the shock preparation, defective output for the user	- return the device for servicing
80	HV, Shock mode error	Defective switching between synchronous and asynchronous shock modality	- restart the device - if the error persists: Return the device for servicing
84	PRWIN fail > 100 ms	Error in the voltage supply, possibly due to a flat accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
87	Program update error	Error during program update, the update will be interrupted	- return the device for servicing

90	Tasks start/run error	Error during internal processing	- restart the device - if the error persists: Return the device for servicing
91	Menu init error	Defective display in the Setup menu	- return the device for servicing
92	Shock key error	Error during the check of critical input elements (e.g. shock button)	- restart the device - if the error persists: Return the device for servicing
93	Charge time-out error	The high voltage charge lasts too long, possibly due to a fault in the final stage	- return the device for servicing
94	Disarm time-out error	Impossible to discharge the residual energy in the condensor, possibly due to a fault in the final stage	- return the device for servicing
96	AVDD exceed	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
97	AVDD drop	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
98	CVDD exceed	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
99	CVDD drop	Error in the voltage supply, possibly due to a flat accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
100	DVDD exceed	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
101	DVDD low	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
102	5V exceed	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing

103	5V drop	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
104	24V exceed	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
105	24V drop	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
106	PWRIN exceed	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
107	PWRIN drop	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
108	Battery exceed	Internal battery voltage too high	- restart the device - if the error persists: Return the device for servicing
110	Temperature exceed	Operating temperature too high	- operate the device in a cooler environment
111	Temperature drop	Operating temperature too low	- operate the device in a warmer environment
116	HDQ interface fail	Error communicating with energy module	- restart the device - if the error persists: Return the device for servicing
117	CYCLE time error	Error during the shock delivery	- return the device for servicing
118	VREF exceed	Error in the voltage supply, possibly due to a flat accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
119	VREF drop	Error in the voltage supply, possibly due to an empty accumulator/battery	- charge and/or replace the energy module - if the error persists: Return the device for servicing
120	Battery/accumulator fail	Energy module voltage too low	- charge and/or replace the energy module
121	DSP timeout error	Internal communication error	- restart the device - if the error persists: Return the device for servicing
122	Previous error detected - need full test	General description of error detected during self test	- restart the device - if the error persists: Return the device for servicing

123	Programme code area corrupt	Error in the programme memory	- return the device for servicing
124	Keyboard error	Error in the membrane keyboard	- restart the device - if the error persists: Send the unit in to the Service Department - do not push any key during equipment test!
125	ECG calibration error	Error during the ECG calibration	- restart the device - if the error persists: Return the device for servicing
127	Clocks (32 kHz or 3.6864MHz) error	Error in system clock generation	- restart the device - if the error persists: Return the device for servicing
129	Wrong hardware platform	Error during the hardware detection	- return the device for servicing
138	Protected variable error	Defective storage of important variables	- return the device for servicing
140	Impedance measurement error	Error during the impedance measurement	- return the device for servicing
150	Aura LED Test error	Error during the test of the LED aura	- return the device for servicing
151	Electrode coding error	Defective electrode type	- use different electrodes and/or different electrode cables - check the electrode plug housing

13 Technical Data

Defibrillation

Operating modes: Asynchronous, external

Patient impedance: 23 – 200 Ohm

Impulse shape: Biphasic, current regulated (CCD)

Output energy in Adult mode:

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 pediatric 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

ECG

Line: Einthoven 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

CMRR: > 85 dB

Input DC voltage: ± 0.5 V

Bandwidth:	0.5 – 40 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)
Analysis duration:	Approx. 7 s until VF is recognized
Period from start of the analysis until the end of high voltage charge (with fully charged battery / after six shocks / after 15 shocks)	27 s / 27 s / 27 s
Period from switching on until the end of high voltage load (with fully charged battery / after six shocks / after 15 shocks)	40 s / 40 s / 40 s

Monitor

Type:	High-resolution LCD monitor, 95 x 72 mm (diagonals 120 mm, 4.7 inch)
Resolution:	320 x 240 pixels (pixel size: 0.36 x 0.36 mm)
Displays:	Heat frequency, number of defibrillations, number of VFs identified, resuscitation time, date, time, power capacity, ECG graph
Presentation:	X 25 mm/sec, Y 10 mm/mV

Data storage

Memory type:	CompactFlashCard 2 GB

Safety

Classification:	Medical product in class IIb, Device with internal power supply, Type BF, Defi-resistant,
Identification:	CE 0123
	The device is a medical product and complies with EC Directive 93 / 42 / EEC

Other

Operating conditions:	0 ... 55 °C, 30 ... 95 % rel. humidity, but without condensation 700 hPa ... 1060 hPa continuous mode
Storage conditions:	- 20 ... 70 °C, 20 ... 95 % rel. humidity, but without condensation 500 hPa ... 1060 hPa
Dimensions:	28 x 25 x 9 cm (W x H x D)
Weight:	approx. 2.0 Kg (without energy module) approx. 2.5 kg (with energy module)
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 60601-1-4:1996 IEC 60601-1-2:2001 IEC 60601-2-4:2002 EN1789:2003 IEC 60601-1-6:2004

Subject to change without notice

14 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 GmbH will remedy any defects in the device free of charge if they are based on material or manufacturing faults. The device can be reinstated to its original condition as selected by METRAX GmbH either by repair or replacement.

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

Guarantee 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 AkuPak) 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 on 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.

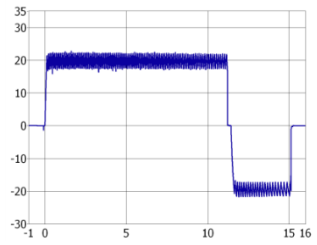
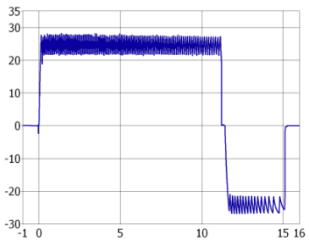
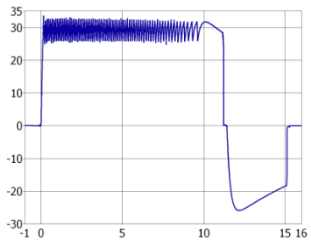
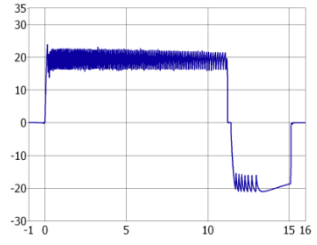
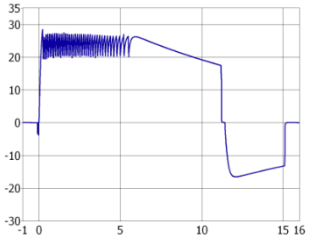
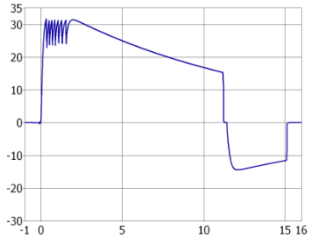
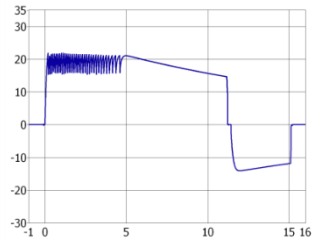
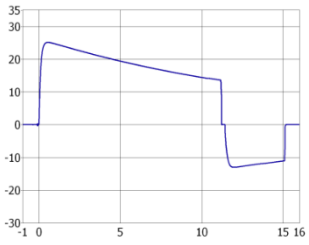
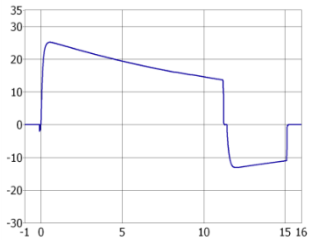
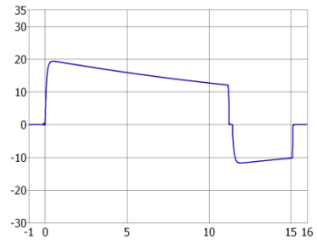
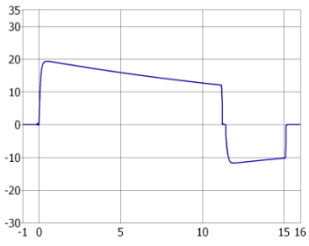
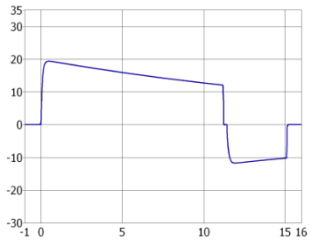
In the case of a warranty claim, please return the device, with proof of purchase (e.g. invoice) stating your name and address, to your dealer or to METRAX GmbH.

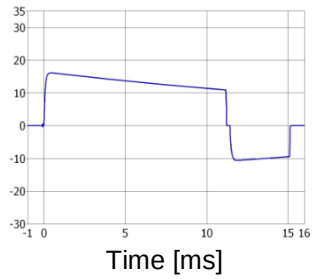
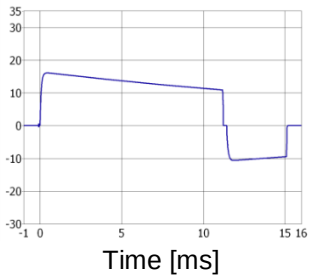
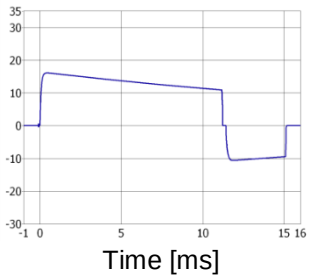
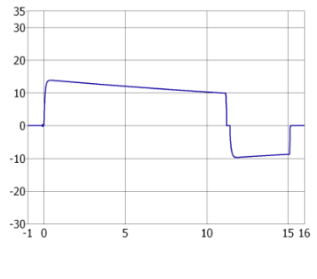
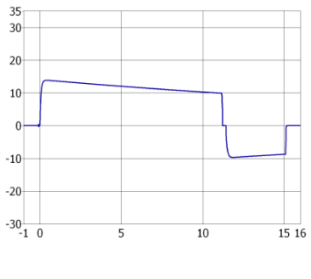
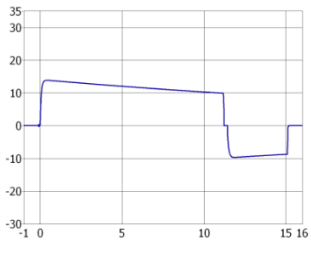
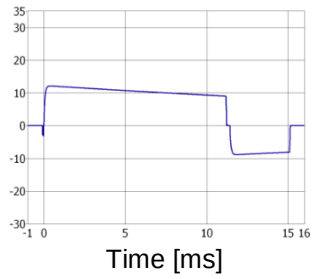
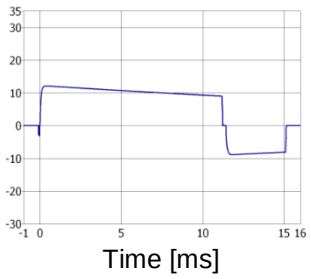
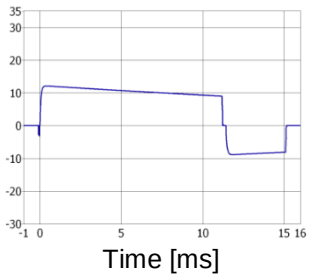
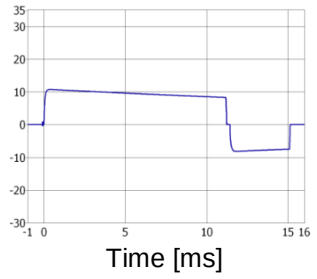
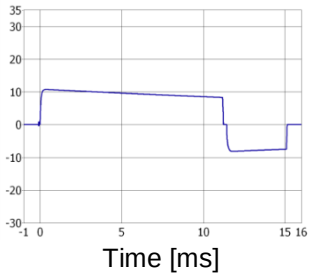
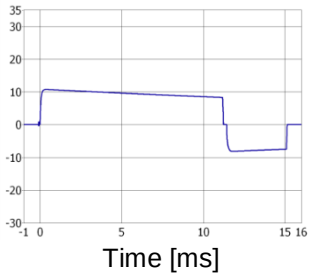
METRAX After-Sales Service is glad to be at your disposal, even after the warranty period has expired.

15 Depiction of the current time functions

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

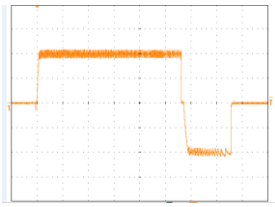
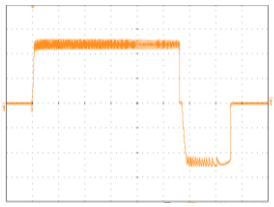
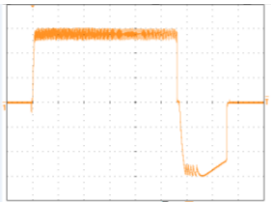
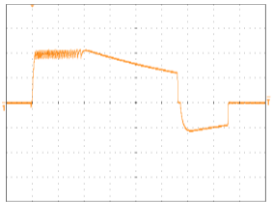
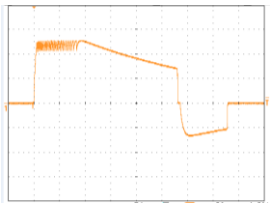
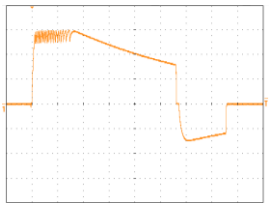
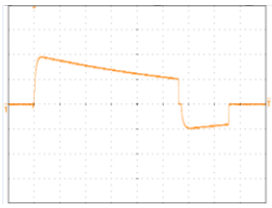
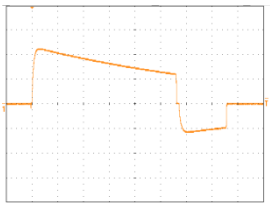
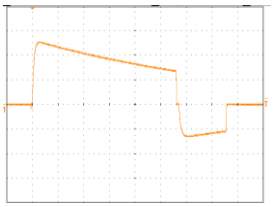
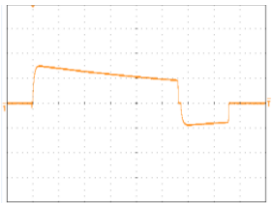
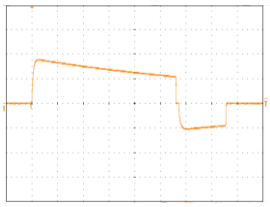
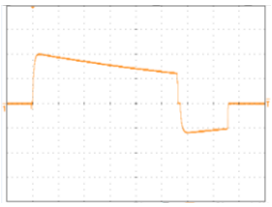
15.1 Adult Mode

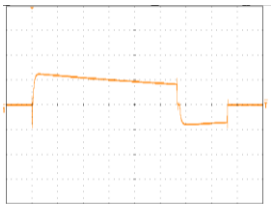
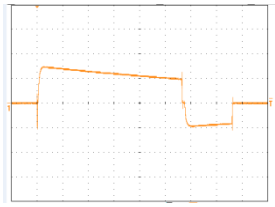
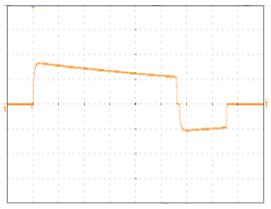
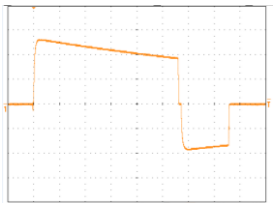
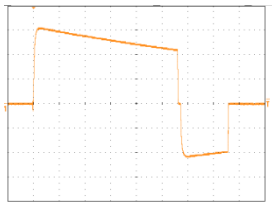
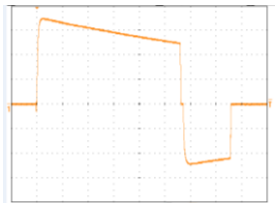
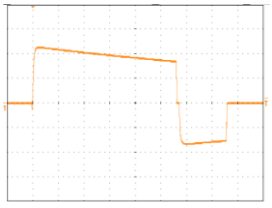
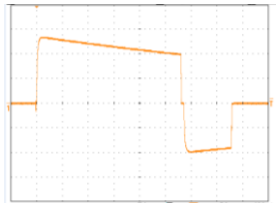
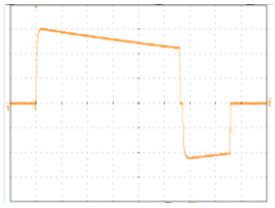
	First shock	Second shock	Third shock
25 Ohm			
50 Ohm			
75 Ohm			
100 Ohm			

	First shock	Second shock	Third shock
125 Ohm			
150 Ohm			
175 Ohm			
195 Ohm			

Current [A]

15.2 Pediatric 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 

16 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.

Operator control of the defibrillation shock therapy:

- 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 over a continuous recording history 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

16.1 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 IEC60601-2-4:2010.

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 Annotationscode for ventricular flutter ("[" Begin, "]" End; also refer *www.physionet.org*) using the PhysioBank Annotationscode.

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%).

16.2 Pediatric 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.

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

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

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

17 Guidelines and manufacturer's declaration – Electromagnetic emissions

for PRIMEDIC™ HeartSave AED/AED-M (in the following referred to as PRIMEDIC™ HeartSave)

The PRIMEDIC™ HeartSave is designed for use in an environment as described below. The customer or user of the PRIMEDIC™ HeartSave should ensure that the device is only used in an environment of this kind.		
Emitted interference measurements	Conformance	Electromagnetic environment - code of practice
HF emissions according to CISPR 11	Group 1	The PRIMEDIC™ HeartSave only uses HF energy for its internal function. This means that its HF emission is very low and it is unlikely that electronic devices in the vicinity are disrupted.
HF emissions according to CISPR 11	Group 2	The PRIMEDIC™ HeartSave must emit electromagnetic energy to carry out its intended function efficiently. Neighbouring electromagnetic devices could be influenced.
HF emissions according to CISPR 11	Class B	The PRIMEDIC™ HeartSave is suitable for use in all facilities, including residential areas and those directly connected to a public supply network which also supplies buildings used for residential purposes.
Emission of harmonics according to IEC 61000-3-2	n/a for battery / PRIMEDIC™ AkuPak	
Transmission of voltage fluctuations / Flicker according to IEC 61000-3-3	n/a for battery / PRIMEDIC™ AkuPak	

The PRIMEDIC™ HeartSave is designed for use in an environment as described below. The customer or user of the PRIMEDIC™ HeartSave should ensure that the device is only used in an environment of this kind.			
Interference immunity test	**IEC 60601 test level**	**Level of conformance**	**Electromagnetic environment - guidelines**
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV ± 6 kV air	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%.
Rapid transient electrical disturbances/ bursts according to IEC 61000-4-5	± 2 kV for AC power lines ± 1 kV for incoming and outgoing lines	n/a for battery / PRIMEDIC™ AkuPak	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	n/a for battery / PRIMEDIC™ AkuPak	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.
Voltage dips, short breaks and fluctuations in the supply voltage according to IEC 61000-4-11	< 5% Ut (> 95% dip in Ut) for ½ period 40% UT (60% dip in UT)for 5 periods 70% UT (30% dip in UT)for 25 periods < 5% Ut (> 95% dip in Ut) for 5s	n/a for battery / PRIMEDIC™ AkuPak	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment. If the user of the PRIMEDIC™ HeartSave requires continued functioning even when disruptions in the power supply occur, it is recommended that the PRIMEDIC™ HeartSave is fed from a power supply free of disruptions or a battery.
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.
Note: UT is the mains AC before applying the impulse test level.			

The PRIMEDIC™ HeartSave is designed for use in an environment as described below. The customer or user of the PRIMEDIC™ HeartSave should ensure that it is used in an environment of this kind.

Immunity to interference testing	**IEC 60601 test level**	**Level of conformance**	**Electromagnetic environment - guidelines**
Conducted HF interference according to IEC 61000-4-6	3 Veff 150 kHz to 80 MHz outside the ISM bands a 3 Veff 150 kHz to 80 MHz outside the ISM bands a	Not applicable for battery n.a.	Portable and mobile radio transceivers should not be used any closer to the PRIMEDIC™ HeartSave, including its cables, than the recommended protective distance which is calculated according to the equation applicable for the transmission frequency. Recommended protective distance: $d = \left[\frac{3,5}{V1}\right]\sqrt{P}$ $d = \left[\frac{12}{V2}\right]\sqrt{P}$ $d = \left[\frac{12}{E1}\right]\sqrt{P}$ for 80 MHz to 800 MHz $d = \left[\frac{23}{E1}\right]\sqrt{P}$ for 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 transmitters in accordance with an investigation on locations should be lower that the level of conformance. Interference is possible in the vicinity of devices which have the following pictogram. 
Radiated HF disturbances according to IEC 61000-4-3	10 V/m 80 MHz to 2 GHz	10 V/m for battery	

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 reflection 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 conformance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency band from 80 MHz to 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 between 150 kHz and 80 MHz 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 conformance level, the PRIMEDIC™ HeartSave 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 changing the orientation or the location where the PRIMEDIC™ HeartSave is being used.

Recommended protective distances between portable and mobile HF telecommunication devices and the PRIMEDIC™ HeartSave

The PRIMEDIC™ HeartSave is designed for use in an electromagnetic environment in which the HF interference is controlled. The customer or user of the PRIMEDIC™ HeartSave can help avoid electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the PRIMEDIC™ HeartSave – independently of the output power of the communication device, as shown below.

Power rating of transmitter W	Protective distance depends on the transmission frequency m	
	80 MHz to 800 MHz $d = \left[\frac{12}{E1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{23}{E1}\right]\sqrt{P}$
0.01	0.12	0.23
0.1	0.32	0.73
1	1.2	2.3
10	3.8	7.3
100	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 that belongs to the respective 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 purpose of the concordance levels in the ISM frequency bands between 150 kHz and 80 MHz and 2.5 GHz is to reduce the probability of mobile/portable communication devices causing interruptions 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.

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.

18 Safety checks

We recommend a regular technical check of our defibrillators in accordance with our stipulations, at intervals of 24 months. The national stipulations must be observed.

19 Appendix

19.1 Index of diagrams

About Us

For 40 years, Metrax GmbH has been at the service of medical technology and produces professional and automated external defibrillators for professionals and laymen of compromise-free high quality. Well-engineered and safe technology, simple operation, high quality and absolute reliability under extreme conditions. These are the distinctive characteristics of PRIMEDIC defibrillators.

OSI Systems took over Metrax GmbH in October 2014. With the PRIMEDIC defibrillators, Spacelabs Healthcare (medical technology division of OSI-Systems) supplements its product palette in the field of patient monitoring and cardiology products.

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