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PRIMEDIC™
Saves Life. Everywhere.

HeartSave AED / AED-M

Operating Instructions

21212 / GB / E02

Masthead

Publisher / contact data

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Proprietary note

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1 Introduction

1.1 Foreword

Dear User,

You are preparing to face the task of using the **PRIMEDIC™ HeartSave** 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 and 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 any queries which may arise.

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

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

1.2 Validity

The descriptions in these operating instructions refer to the

PRIMEDIC™ HeartSave AED und
PRIMEDIC™ HeartSave AED-M

made by METRAX GmbH.

1.3 Warranty

The warranty period is 24 months and starts on the day of purchase. Please keep the invoice as proof of purchase. The general guarantee and warranty provisions of METRAX GmbH are applicable. Any repairs or changes to the device may only be carried out by the manufacturer or by a person or company authorised by the manufacturer.

1.4 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 when there is obvious damage to cables and/or electrodes.
- Non-compliance with the instructions in these operating instructions with regard to operation, maintenance and repair of the equipment.
- Using accessories and spare parts made by other manufacturers.
- Autonomous intervention, repairs or constructional changes to the device.
- Autonomous overrunning of the performance limits.
- Lack of monitoring parts that are subject to wear and tear.
- Treatment of patients without prior indication.

1.5 Symbols used in these operating instructions

DANGER

Texts marked DANGER indicate an extraordinarily serious, actual danger which will definitely lead to serious injury or even death if no preventative measures are adopted.

It is imperative that you follow these instructions!

WARNING

Texts that are marked with WARNING are there to warn you of an extremely dangerous potential hazard which - if no measures are taken to prevent this hazard, could lead to serious injury or even death!

It is imperative that you follow these instructions!

CAUTION

Texts marked with CAUTION indicate a possible dangerous situation which could lead to minor injuries or damage to property.

It is imperative that you pay attention to these texts.

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

tips.

1. This point identifies the first step of a sequence of actions you should take.
2. Second step of an action you should take.
   etc.

- This line marks lists

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

< ... > The text in pointed brackeys are acoustic instructions / arrangements of the equipment which are simultaneously shown on the monitor, depending on the equipment variant.

1.6 Pictograms on the device

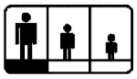
IP55	Protection against contact and dust deposits on the inside and against water spray (jet) from any angle (only in combination with battery)
IP53	in connection with PRIMEDIC™ BatteryPack
IP33	in connection with PRIMEDIC™ PowerLine
	Please observe the operating instructions.
	Do not dispose of device in domestic refuse.
	Dangerous electric voltage (high voltage)
	Degree of protection BF defi-resistant in connection with ECG patient cable
	Type certification GERMANISCHER LLOYD in accordance with Certificate No. 75 449-09 HH

1.7 Pictograms on PRIMEDIC™ SavePads

Not to be reused

Expiry date

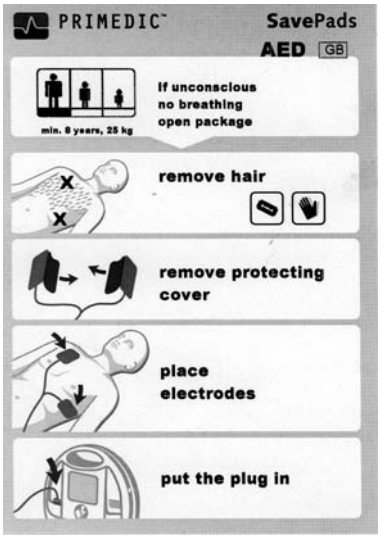
Batch ID



Only for adults

Order number

Storage temperature information in Celsius and Fahrenheit



2 Intended use

PRIMEDIC™ HeartSave AED

This device is intended to be used by non-experts and trained first-aiders. It may only be used on patients who are unconscious and who are not breathing.

The main application is to carry out transthoracic defibrillation in asynchronous mode. The decision on the necessity of applying a shock is carried out automatically by the device.

The operator is guided by spoken instructions and clear written and pictorial information. After switching on the device, the patient is connected to it using the enclosed adhesive electrodes. After this, automatic rhythm analysis is carried out by the device. Only if a rhythm is detected by the device as being ventricular fibrillation (=shockable), does it suggest treatment with a high energy shock. All other rhythms are classified as not requiring a shock. The time from the start of analysis until the shock is applied is less than 30 s.

The energy levels of the first, second and third shock are predefined by the maximum set points for the electric current 20A, 25A and 30A, as well as by the capacitor voltage which depends on the patient impedance.

For safety reasons, no shock is given with asystolia, as no therapeutic effect is to be expected. Controlled ventricular electrical activity caused by supraventricular tachycardia such as atrial fibrillation, atrial flutter, ventricular extra-systoles and idioventricular rhythms does not lead to a shock being applied. After administering a shock, the rhythm is analysed by the device again. If other rhythms that can be treated with a high energy shock are found (ventricular fibrillation), then a recommendation for additional shocks is given. After the second shock, all additional shocks are applied

with the maximum available energy so that with a patient resistance of 70 Ohm up to 100 Ohm, around 360J can be applied. The device supports the user in the reanimation process depending on the factory-setting in accordance with the current guidelines from the European Resuscitation Council (ERC) from 2005 or the American Heart Association (AHA) from 2005 for immediate lifesaving measures to be taken when using an automatic defibrillator.

PRIMEDIC™ HeartSave AED-M

The PRIMEDIC™ HeartSave AED-M is intended for use by suitably qualified first-aiders, trained paramedics and doctors in daily routine, both in clinics and in the preclinical area of emergency medicine. The device can be powered either by a rechargeable removable power source (battery) or from the mains. The compact and light construction allows you to take the PRIMEDIC™ HeartSave with you when transporting a patient. The display shows the paramedic or the doctor the 1-Channel ECG (corresponds to the Einthoven Derivation II) from the adhesive defibrillation electrodes. This allows monitoring via the defibrillation electrodes.

Notes for PRIMEDIC™ HeartSave AED and AED-M:

WARNING

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

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

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

The operator of the PRIMEDIC™ HeartSave has to make sure that the PRIMEDIC™ HeartSave is only used by authorised specialist personnel.

Note

The guidelines governing the application of emergency treatment in the event of cardiac arrest may change. The device currently at issue works in accordance with the International Guidelines 2005 Resuscitation (2005) of the European Resuscitation Council or according to the American Heart Association (AHA) guidelines for cardiopulmonary resuscitation (CPR) 2005.

2.1 Indications

The PRIMEDIC™ HeartSave AED-(M) may only be used for defibrillation if the patient

- is unconscious and
- no normal breathing can be ascertained; and
- after talking to the patient, no other signs of life can be perceived.

2.2 Contraindications

The PRIMEDIC™ HeartSave AED-(M) may not be used for defibrillation if the patient

- is conscious; or
- breathing; or
- shows other signs of life
- is a child under the age of 8 or weighs less than 25 kg respectively.

  Treatment should not be delayed to ascertain the precise age or weight of the patient.

3 Safety information

3.1 General information

Both in conjunction with its accessories and the optional accessories, and also individually, the **PRIMEDIC™ HeartSave** defibrillator fulfils the currently applicable safety standards and complies with the provisions of medical products regulations. The device 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 device and its accessories can be dangerous to you, the patient or third parties!

DANGER

For this reason, we emphatically advise that before using for the first time, all those who are supposed to use this device or want to use it

- must be instructed in a training session about the medical background of defibrillation and the indications or contraindications and thus need to be authorised.
- need to read and take note of these operating instructions and in particular, the safety tips and warnings detailed in them.

Note	The PRIMEDIC™ HeartSave AED / AED-M may only be used by trained and authorised personnel. Reading the operating instructions does not replace training. The PRIMEDIC™ HeartSave AED / AED-M is not licensed for use in explosive areas.

DANGER

Not using the device as intended or using it improperly, exposes you (the user), the patient or third parties to danger

- of an electric shock from the high voltage generated by the device,
- of influencing active implants,
- of burns from incorrectly applied electrodes.

Apart from that, the device can be damaged or destroyed through improper use.

DANGER

Observe the information and rules in the appendix on using the PRIMEDIC™ HeartSave!

Applicable for Europe:

The device complies with the Medical Device Directive (MDD).
The respective national guidelines for operating medical products are applicable.

For Germany, the following is also applicable:

The device is subject to the German Medical Products Act (MPG).
Thus the German Medical Products User Regulations (MPBetreibV) also apply.
The German Medical Products User Regulations is not applicable for medical products which serve neither commercial nor business purposes and where no employees are working in the hazardous area around them.

3.2 General safety instructions:

DANGER

Do not use the device in the vicinity of flammable materials (e.g. cleaning solvent or similar) or in an atmosphere enriched with oxygen or with flammable gases / vapours!

3.3 Safety notes for the user

DANGER

Only use the device on a patient if:

- You have been authorised to do so as a result of training!
- You have ensured its operational safety before using it and that it is in good condition.
- The state of the patient requires or allows an application.

Before using the device, check that it is within the operating temperature range. This applies for example, if the defibrillator is stored in a rescue vehicle.

Do not use the device if it is defective (e. g. if the defibrillation cable is damaged).

3.4 Safety notes for protection of the patient

DANGER

Only use the device on a patient if:

- You have been authorised to do so as a result of training!
- You have ensured its operational safety before using it and that it is in good condition.
- Before using the device, ensure that the device is within the operating temperature range. This is important, for example, when the device is stored in an emergency services vehicle in winter. Do not use the device if it is defective (e. g. if the defibrillation cable is damaged).
- Only use the device with accessories, wearing parts and disposable items which have proven to be completely safe to use by being tested by a testing authority licensed to test the device when equipped ready for use. These conditions are fulfilled by all original PRIMEDIC™ accessories and wearing parts.
- Use new, undamaged defibrillation electrodes before their expiry date for every patient to avoid any possible burns to the skin!
- Only connect the adhesive electrodes to the PRIMEDIC™ HeartSave. Use of the electrode system with other devices can lead to dangerous impedance currents for the patient!
- Do not use the device in the immediate vicinity of other sensitive equipment (e.g. measuring equipment that is sensitive to magnetic fields) or strong sources of interference which could affect the way the PRIMEDIC™ HeartSave works. Keep a sufficient distance away from

	other therapeutic and diagnostic energy sources (e.g. diathermy, high frequency surgery, magnetic resonance tomography). These devices can affect the PRIMEDIC™ HeartSave and disrupt the way it operates. For this reason, disconnect the patient from any interfering devices. • During defibrillation, disconnect the patient from all other medically used devices which do not have a defibrillation resistant application part. • Keep the defibrillation electrodes away from other electrodes and from metallic parts which are in contact with the patient.

	**DANGER** • Do not use the device on children under the age of 8 or on children with an estimated body weight of less than 25 kg. • Position the electrodes precisely according to the description. • Dry the chest and carefully remove any large amount of hair on the patient before applying the defibrillation electrodes. • Do not place the defibrillation electrodes directly over an implanted pacemaker to avoid a possible misinterpretation by the device and to avoid any damage to the pacemaker from the defibrillation impulse. • Do not touch the patient during the ECG analysis and avoid any vibrations. • If the ECG analysis is being carried out in a vehicle, the vehicle has to stop and switch off the engine to guarantee correct analysis. • Stop any reanimation while the PRIMEDIC™ HeartSave is analysing the ECG. • Do not touch the patient during defibrillation. Avoid any contact between o parts of the patient's body (such as bare skin on head or legs), as well as o conductible liquids (such as gels, blood or salt solutions) and o metallic objects in the vicinity of the patient (such as bed frame or stretching device), which represent unintentional paths for the defibrillation current!

3.5 Safety notes for the protection of third parties

	**DANGER** Warn people in the vicinity loudly and clearly before the defibrillation so that they step back from the patient and are no longer in contact with him.

3.6 Safety notes for protecting the device

	**DANGER** Repairs, changes, extensions and installations of the PRIMEDIC™ HeartSave may only be carried out by personnel authorised and trained by METRAX! The PRIMEDIC™ HeartSave does not have any parts that can be repaired by the user! The device may only be equipped and operated with original accessories from PRIMEDIC™. Only clean the device when it is switched off and the electrodes have been removed and only clean it in the prescribed manner.

4 Description of device

4.1 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. The algorithm implemented recognises potentially fatal heart arrhythmia. The defibrillator generates the electric shock necessary to reanimate a patient with a shockable ECG rhythm. This method is the generally recognised therapy. The family of devices is set up on a modular basis. These operating instructions cover the models:

PRIMEDIC™ HeartSave AED	Basic Model without Monitor
PRIMEDIC™ HeartSave AED-M	Basic Model with Monitor

The PRIMEDIC™ HeartSave generation has been designed for rapid and safe use in emergency situations. 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 PRIMEDIC™ AED-M has a high resolution graphics display which offers high image contrast, even in difficult lighting conditions. The ECG monitor can be seen clearly in all positions, e.g. lying down when used outdoors and standing upright in low mounting positions in the ambulance.

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. The power supply PRIMEDIC™ HeartSave is provided either from disposable lithium batteries or rechargeable removable batteries with nickel cadmium cells or from a mains supply. The charging electronics incorporate state-of-the-art technology, ensuring maximum service life of the batteries used. The PRIMEDIC™ HeartSave can be stored on a wall bracket which can be affixed to a wall or in the ambulance. It is easy and quick to remove the PRIMEDIC™ HeartSave when you need it, using the one-hand quick release. The PRIMEDIC(TM) Basic / Comfort charger serves as a power supply for charging the batteries.

A wide range of accessories are available. The wall bracket and accessories are described in separate operating instructions.

4.2 Description of device details

Fig. 1: Front view with cover

1 Carry handle
2 Strap for pulling the lid off the device, replacement date adhesive electrodes
3 Cover of device
4 Status display

Fig. 2: Rear View

1 Receptacle opening for hook of the wall bracket
2 Specification plate

Fig. 3: View from below

1 Release button
2 Power module

Fig. 4: PRIMEDIC™ HeartSave AED front view

1 On / Off button
2 Electrode symbol with LEDs
3 Membrane keyboard
4 "Do not touch patient" symbol (lights up during analysis)
5 Jack for electrode connectors
6 Loudspeaker
7 Trigger button for defibrillation, shock button
8 Language selection button
9 Status display

Fig. 5: PRIMEDIC™ HeartSave AED-M front view

1 On / Off button
2 Membrane keyboard with monitor
3 Menu button to navigate upwards or to increase parameters
4 Select/ confirm button
5 Menu button to navigate down or to decrease parameters
6 Loudspeaker
7 Jack for electrode connectors
8 Trigger button for defibrillation, shock button
9 Status display

Fig. 6: Monitor representation (onlyPRIMEDIC™ HeartSave AED-M)

1 Display of switch-on duration / time sequence HLW cycle
2 Number of detected VFs
3 Number of defibrillations
4 Heart frequency
5 Status line to show CF card capacity, patient impedance, time of day, microphone, battery capacity

6 ECG display
7 Instructions

Fig. 7: PRIMEDIC™ SavePads AED

1 Cover of device
2 Utensils carrier with brief instructions
3 SavePads (defibrillation electrodes)
4 Disposable gloves (not sterile)
5 Disposable razor and respiration cloth

4.3 Symbols in the status display

Display	Meaning	Action to be taken
[redacted] [redacted] OK	Passed device self-test	Device ready to use
	Battery/battery pack capacity is sufficient	
[redacted] [redacted] OK	Battery/battery pack is discharged	Equipment can be used, it may be necessary to charge or replace the battery / AkuPak.
	Passed device self-test	
	Symbol also appears if no power module has been inserted!	Insert battery / AkuPak.
	Symbol also appears if the use by date of the power module has been exceeded.	Check use by date, if necessary replace with new ones.
[redacted]	Device may be defective	Carry out large self-test by replacing the battery / AkuPak or by switching the equipment on again.
	Device defective	Have device repaired by authorised dealer.

	Battery/battery pack is discharged	Equipment can be used, it may be necessary to charge or replace the battery / AkuPak. Carry out large self-test by replacing the battery / AkuPak or by switching the equipment on again.
	Device may be defective	Carry out large self-test by replacing the battery / AkuPak or by switching the equipment on again.
	Device defective	Have device repaired by authorised dealer.

4.4 Capacity display on the monitor

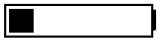
With the HeartSave AED-M, the battery charge of the battery / AkuPak appears on the display. The different images that may be displayed have the following meaning:

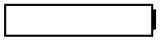
 100 % charged

 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 battery and the optional AkuPak 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	< Charging status battery low. Please recharge >	Charge 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 activated.

4.5 Data management

The HeartSave AED automatically records all ECG data and all spoken communication/environmental sounds using a microphone. In the as-delivered condition, the microphone on the HeartSave AED / AED-M is always switched on. The saved data can be displayed with the aid of a PC / Laptop and the software ECG Viewer. The dat is evaluated purely for administrative or legal purposes and can not be used for diagnosis or treatment of the patient. In the Software there is a deployment protocol in which additional patient data can be entered.

Note

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

The SaveCard should then be re-formatted if possible (instead of the usual deletion process).

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

The SaveCard supplied with the device is already formatted and can be used straight away. If you have problems with the existing SaveCard or with a new CF card, you must format these using the FAT16 file system for use in HeartSave. When formatting, please ensure that you do not accidentally format on a Windows XP system according to FAT32.

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

Windows 2000, Windows XP, Windows Vista

Start a command line window using "Start->Run" 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 which you may have to change).

For Windows 98/ME and older

You can call up the details of the command "format" by entering "format /?".

4.6 Description of the accessories

4.6.1 PRIMEDIC™ SavePads AED

Fig. 8: PRIMEDIC™ SavePads defibrillation electrodes (in the unpacked condition)

1 Plug

2 Defibrillation electrodes with protective film

4.6.2 PRIMEDIC™ battery

Lithium battery, 15V / 2.8 Ah
6 years standby time

4.6.3 PRIMEDIC™ ECG-patient cable, 2-core (Optional accessory for PRIMEDIC™ AED-M)

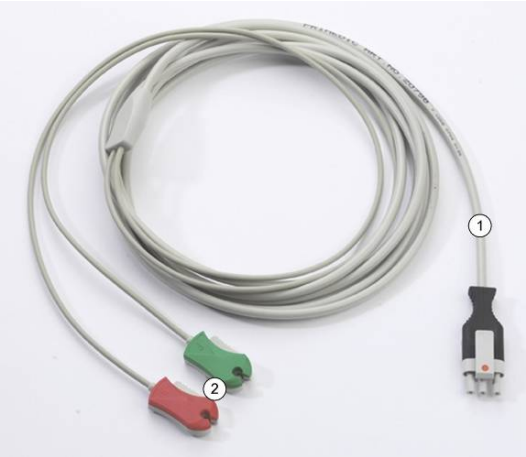


Fig. 9: ECG patient cable

1	2-pin ECG electrode cable with connector
2	Electrode clips, red/green

This cable is only used for ECG monitoring of a patient. This cable can not be used for defibrillation. If the automatic background analysis carried out by the HeartSave AED / AED-M 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.

Additional accessories can be found on our home page "www.primedic.com" under "Online-Shop“

5 Preparatory measures before (initial) start-up

5.1 Unpacking

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.

DANGER

Definitely do not use the device if you know of any damage. A health hazard can not be ruled out.

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

5.2 Inserting / Changing the PRIMEDIC™ SaveCard

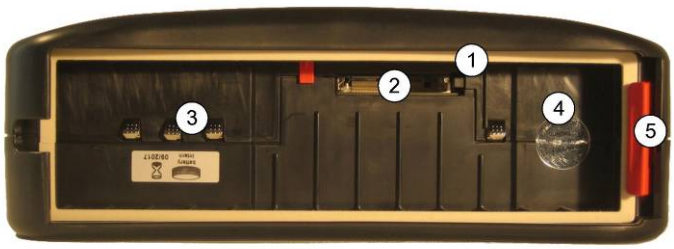


Fig. 10: PRIMEDIC™ HeartSave AED without power module

1	SaveCard removal knob
2	SaveCard slot
3	Contacts for power module
4	Guarantee seal
5	Release button

5.2.1 Inserting the PRIMEDIC™ SaveCard

Before switching the device on for the first time, insert the SaveCard into the specially designed slot (2). Gently press the SaveCard in until the button (1) projects slightly out of the device. Now insert the power module into the device.

Note	The device will now start automatically and will perform a self-test. 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.

5.2.2 Changing the PRIMEDIC™ SaveCard

Before you can remove or replace the SaveCard, you must first remove the power module.

Procedure:

1. Press the button (1) in fully - this pushes the SaveCard (2) slightly out of its holder.
2. Remove the SaveCard and insert a new one into the equipment with the plug end going in first.
3. Gently press the card in until the button (1) projects slightly out of the device.
4. Finally insert the power module into the device again.
5. The HeartSave AED will be ready for operation again after it carries out a subsequent self-test

5.3 Inserting / replacing the energy module

The PRIMEDIC™ HeartSave AED can be operated using 3 different power modules:

- A disposable $LiMnO_2$ battery,
- A rechargeable AkuPak (optional)
- PowerLine (optional)

Before using the PRIMEDIC™ HeartSave for the first time, the power module has to be inserted in the appropriate slot.

CAUTION

Whenever the device has been used, check the power level. If necessary, replace the battery or recharge the battery pack. If this is not possible make sure you always have a second, fully charged battery to hand to ensure that the device is always ready for use!

5.3.1 Inserting the power module

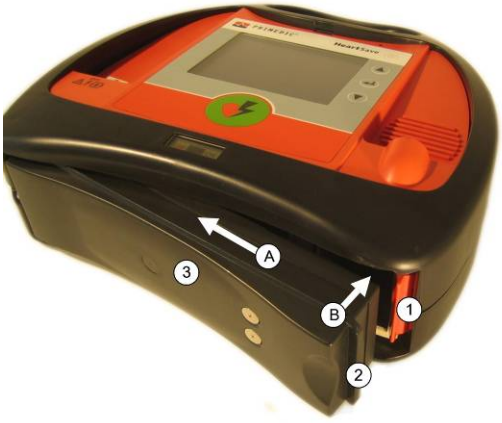


Fig. 11: Inserting the power module

1	Release button
2	Power module tongue
3	Power module

The HeartSave is always supplied with a power module. All three different types of power module are inserted the same way.

Procedure:

1. Lay the device on its back.
2. Push the power module (3) into the device in the direction shown by the arrow (A) until it reaches the back as shown in the diagram.
3. Then press the front of the power module into the slot in the direction shown by the arrow (B) until you hear a "click" as the release button (1) engages securely with the tongue on the power module (2).

The power module should now be flush with the front housing of the device.

If the power module has been inserted correctly, then the device will start automatically and will carry out a self-test. If applicable, follow the acoustic/visual instructions from the device and then switch it off. The HeartSave AED is now ready for use.

	**CAUTION** Monitor the Status Display. If the display is showing "OK", the device is ready to use. (If applicable), switch it off using the on / off button or put the device cover back on. If the display does not read "OK" or if a fault message appears on the monitor, remedy the cause or contact your nearest service station.

5.3.2 Removing the power module from the device

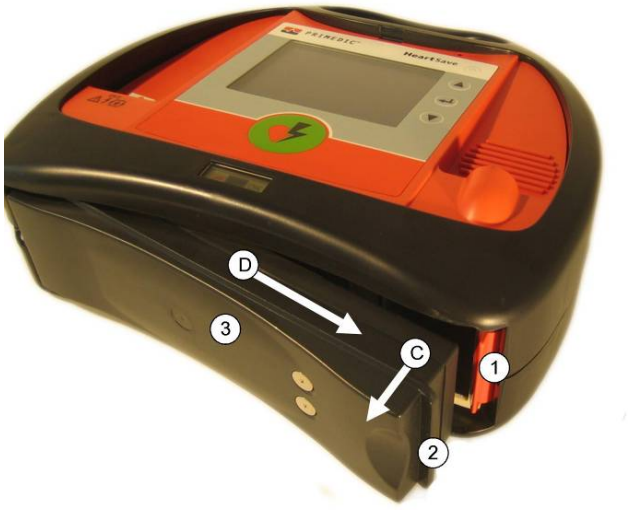


Fig. 12: Removing the power module

1	Release button
2	Power module tongue
3	Power module

	**CAUTION** Only change the power module when the device is switched off and electrode plug is disconnected.

Procedure:

1. Lay the device on its back and press the release button (1) in the direction shown by the arrow (D) until the tongue on the power module (2) is released and the power module (3) protrudes from the slot.
2. Twist the power module slightly in the direction of the arrow (C) and then pull it in the direction of the arrow (D) out of the device.

5.4 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.

Figure see chapter 4.6.2

DANGER

On no account try to charge the battery. There would be risk of an explosion!

Note

Use the battery before its use-by date expires. After the equipment has been used, the battery should, if necessary, be replaced by a new one (so that the full period of operation will be available for the next deployment).

In any event, heed the instruction leaflet enclosed with the battery and store it safely with these operating instructions.
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.
When sending the battery, observe the separate shipping regulations.

5.5 PRIMEDIC™ AkuPak (optional)

You can charge the AkuPak in two different ways:

- with the PRIMEDIC™ ClipCharger (optional)
- with the PRIMEDIC™ Charger Basic / Comfort Charger (optional)

The integrated detection of charge endpoint detection protects the bettery from harmful deep discharge. If the battery charge is too low, both a visual and an acoustic signal are issued.

In case an AkuPak is stored outside the equipment, its charge status can be checked by presing button (2).

Fig. 13: PRIMEDIC™ AkuPak Battery charge indicator

1 Battery charge indicator

2 push button to activate battery charge indicator

Battery charge indicator (1) means:

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

Note

When charging using the Charger Basis / Charger Comfort, 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 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, independant of its current charge status. After recharging, the programmed 80%-limit is operative for the next automatic full recharge.

Note

Charging the PRIMEDIC ™ AkuPaks outside the stipulated operating temperature 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 can not be assured. Charging the PRIMEDIC ™ battery pack is interrupted at temperatures of more than 45°C.

5.5.1 Charging the PRIMEDIC™ AkuPak with the PRIMEDIC™ ClipCharger

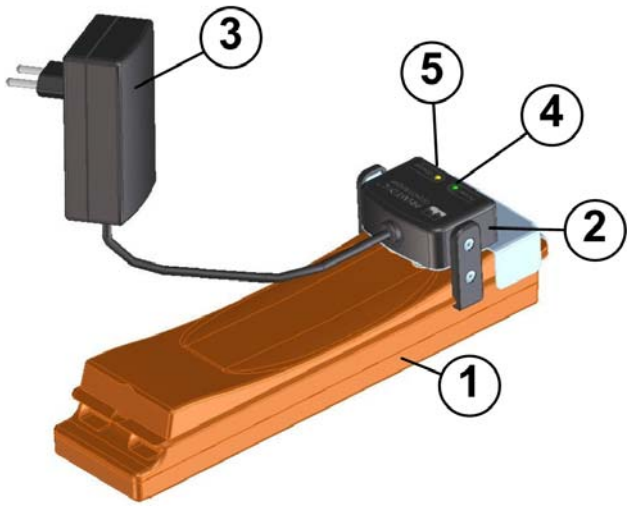


Fig. 14: PRIMEDIC™ AkuPak with PRIMEDIC™ ClipCharger

1	AkuPak
2	ClipCharger
3	Mains plug
4	green LED (Power)
5	yellow LED (Charge)

Procedure:

1. Removing the PRIMEDIC™ AkuPak from the device.
2. Position the ClipCharger on the AkuPak in accordance with Fig. 14.
3. Now plug the mains plug into a plug socket. The green LED (Power) and the yellow LED (Charge) light up and signal "Power Available".

   Charging is started if it becomes necessary because of the remaining residual energy. The yellow Charge LED on the ClipCharger indicates charging. Charging time is approx. 2 1/2 hours. The yellow LED goes out when charging is complete.
4. Pull the mains plug out of the plug socket and release the ClipCharger from the AkuPak.

Note	Nickel Cadmium batteries are subject to natural wear and should be exchanged at the latest after 2.5 years depending on the frequency of use.

5.5.2 Loading the PRIMEDIC ™ battery pack in the optional charger Basic / Comfort.

Please refer to the separate operating instructions for the charger Basic / Comfort.

5.5.3 Connecting up the PRIMEDIC ™ PowerLine (optional accessory)

Fig. 15: PRIMEDIC ™ PowerLine

Procedure:

1. Insert the PRIMEDIC ™ PowerLine following the instructions in chapter 5.3.
2. Then plug the mains plug of the mains cable into a socket in the vicinity of the patient.
3. The 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.

5.6 Periodic device self-test

5.6.1 Self-test after switching on the PRIMEDIC™ HeartSave devices

The device self-test is run automatically by switching the HeartSave on, or by inserting the power module in the device to check all important functions and signal setups.

If the power module is replaced and the unit has first registered a fault, the large self-test (FULL) is carried out automatically. Please proceed to follow the device instructions.

5.6.2 Periodic self-tests

The HeartSave carries out a periodic self-test as detailed below.

	Frequency	Effect of test
SHORT	Daily	Software, operating membrane, ECG calibration, clock, internal voltage supply and HV part at 0 V
MEDIUM	First day of the month	Software, operating membrane, ECG calibration, clock, internal voltage supply and HV part at 300 V
LONG	On the 1st. July and on the 1st. January every year	Software, operating membrane, ECG calibration, clock, internal voltage supply and HV part at 1600 V
FULL	After identifying an internal error	Software, operating membrane, ECG calibration, clock, internal voltage supply and HV part at 1600 V, microphone test, key query

5.7 Configuration of the PRIMEDIC™ HeartSave

5.7.1 Configuration of the PRIMEDIC™ HeartSave AED (without monitor)

The PRIMEDIC™ HeartSave AED has been configured in the factory. It is not possible to change these settings.

5.7.2 Configuration of the PRIMEDIC™ HeartSave AED-M (with monitor)

The PRIMEDIC™ HeartSave AED-M 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 5.10.
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:

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

Parameters	Selection options
Page 1	
Basic	List of available profiles.
Profile 1	The profile that is currently active is marked as "active" by the entry
Profile 2	identified by the entry "active".
Profile 3	By selecting it, the respective profile can be activated.
Page 2	
Microphone:	[On/Off]
BLS information:	[On / Off]
CPR sounds	[0% / 25% / 50% / 75% / 100%]
CPR cycles	1-5
Contrast:	from 40 to 120
Systole sound:	[0% / 25% / 50% / 75% / 100%]
Volume:	[0% / 25% / 50% / 75% / 100%]
Page 3	
Guideline	ERC/AHA
Language	depending on language packages installed
Date	in format DD/MM/YYYY
Time	00:00 in 24 h format
Network filter	[50Hz/60Hz/Off]
Display	[0 degrees / 180 degrees]
Page 4	
New PIN	0000-9999
PIN Repeat	0000-9999
Change PIN	Confirmation for “Change PIN“
Save to profile	This is used the save the parameters in the selected profile
PIN	Input field for current PIN
Profile selection	Basic, Profile 1, Profile 2, Profile 3
Page 5	
ARM SW	x.xx(Version number) xxxxxxxx (check sum 8 digits), Date
DSP SW	x.xx(Version number) xxxx (Check sum 4-digits), Date
MSP SW	x.xx(Version number) xxxx (Check sum 4-digits), Date
ULF	Check sum 8-digit
Serial No.	XXXX
Page 6	
BQ SW Version:	x.x
BQ serial number:	x

5.8 Simple change of configuration – example: Time

To change the time, proceed as follows:

1. Navigate the cursor by pressing the key ▼ down several times to the menu item < To page 2 >
2. Press this several times to get to page 3.
3. 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.
4. Change the hour by pressing the ▲ or ▼ key.

   Confirm the correct value with the ↵ key. The minute is now highlighted. Then change this as described under 3 and then press the key ↵
5. To exit the setup menu, move the marking with the key ▼ to the menu item **End Setup** and confirm this with the key ↵.

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

5.9 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:

1. Use the key ↵to change into the setup menu
2. Change to page 4 of the menu
3. Navigate with the key ▲ to the entry < PIN > and confirm your selection with the key ↵
4. 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
5. Navigate to the entry < New PIN > and enter your new PIN as described above.
6. Navigate to the entry < Repeat PIN > and enter your PIN again.
7. Select the menu parameter < Change PIN > and confirm your new PIN with the key ↵
8. 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.

5.10 Calling up/activating a profile

Certain parameter settings for the menu can be summarised into profiles. Saved profiles can be called up as follows:

1. Use the key ↵to change into the setup menu
2. Select your required profile using the keys ▲ ▼ and confirm it with the key ↵
3. 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“

5.11 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:

1. Use the key ↵to change into the setup menu
2. Change the required parameters from the various pages of the menu to suit your needs.
3. Change to page 4 of the menu.
4. Use the key ▲ to navigate to the entry < Profile selection > and confirm your selection with the key ↵
5. 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 ↵
6. Navigate with the key ▲ to the entry < PIN > and confirm your selection with the key ↵
7. 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
8. Change to the menu entry < Save to profile > and confirm your selection with the key ↵
9. On the right next to the cursor the entry < OK > should appear. This means the profile is saved.
10. Now leave the menu by using the key ▼ to navigate to the menu item < End Setup > and confirm this with the key ↵

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 profile "Basic".

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.

6 Operating the device and sequence of reanimation

The sequence of the reanimation is realised in the device according to the recommended guidelines of the European Resuscitation Council (ERC): Resuscitation 2005, 67S1, S7—S23, or the American Heart Association (AHA), 2005: American Heart Association (Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (CPR) 2005). Make sure that before using the device you have completed suitable training.

Note	On the HeartSave AED, the guideline for the sequence of operation is preconfigured in the factory. A software update is necessary for changing the guidelines. If necessary, contact Metrax Service or your local dealer. After the software update, the identification on the device must match the software programmed.
Note	On the HeartSave AED-M you can select the guideline used in the setup menu.

6.1 Switching the PRIMEDIC™ HeartSave on / off

6.1.1 Switching the PRIMEDIC™ HeartSave on

The device is automatically activated by removing its cover. If the device does not switch on automatically, switch it on by pressing the on / off button. After this, all buttons are unlocked, apart from the trigger button. Triggering defibrillation is only activated once ventricular fibrillation (VF) has been ascertained.

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.

6.1.2 Switching off the PRIMEDIC™ HeartSave

The PRIMEDIC™ HeartSave can be switched off in different ways:

- By pressing the on/off button for approx. 3 seconds. A warning beep will sound simultaneously.
- 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 switches off automatically.

Note	If the device detects a fault, it will automatically switch off to avoid possible injuries.

6.2 Voice prompts from device / Preliminary examination of patient according to standards

During the course of the voice output, you will be asked to examine the patient.

Note	For your own protection, please take the rubber gloves out or the lid of the device first and put them on.

After the device has successfully carried out the self-test, the following Basic Life Support (BLS) instructions (the basic measures of cardio pulmonary resuscitation) are issued. Here on the basis of ERC 2005

< Talk to patient >

< Call emergency services >

< Open up airways, carefully hyperextend head >

< Check breathing >

< If not breathing, 30 times cardiac massage >

< 2x artificial respiration >

< Position electrodes >

< Plug in electrode plugs >

6.3 Undressing the patient

If during your preliminary examination, you have ascertained that the patient may need defibrillation, undress the upper body to be able to position the electrodes.

6.4 Determining the position of the electrodes

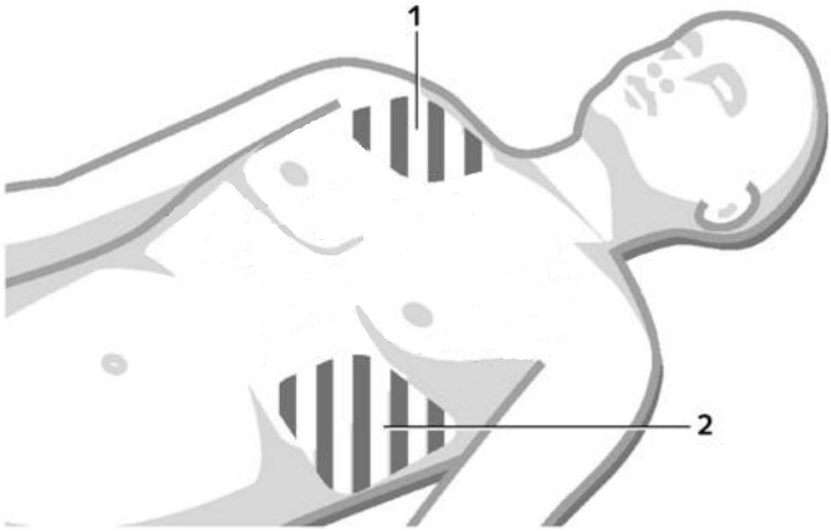


Fig. 16: Position the electrodes on the patient

The positions of the electrodes are:

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

6.5 Opening PRIMEDIC™ SavePads

On the utensils carrier you will find 1 pair of electrodes, 1 razor, 1 artificial respiration cloth and 1 pair of disposable gloves. Open the defibrillation electrodes bag by tearing open the protective cover along the tear strip.

6.6 Removing hair growth from chest

If the patient has hair growing where the electrodes need to be positioned, you must remove it. Use the enclosed razor to remove the hair from the electrode positions.

6.7 Removing protective film from PRIMEDIC™ SavePads.

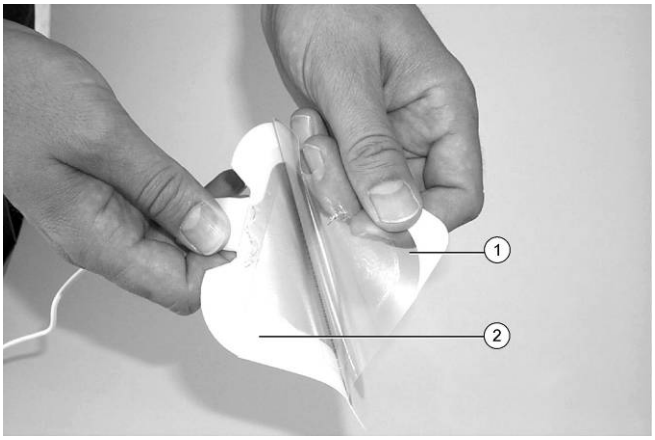


Figure 17: Removing protective film from PRIMEDIC™ SavePads.

1 Protective film
2 Electrode

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

When the device asks you to:

< Position electrodes >

proceed as follows:

1. First, remove the protective film (1) from one electrode (2) and them immediately place the electrode on the position you had ascertained previously. Refer to label stuck on the back of the electrodes.
2. Proceed to remove the protective film from the second electrode and place it in its position.
3. Smooth the electrodes onto the patient ensuring there are no air bubbles under the electrodes!

	DANGER
	Do not touch the floor, objects, clothing or other body parts with the electrodes (once the protective film has been removed). The conductive layer of gel on the electrodes might be removed by this. A thinner layer of gel could reduce the success of defibrillation or lead to burns of the skin under the electrodes during defibrillation!

Make sure that with the device variant without a monitor, the red electrode symbol LEDs on the membrane keyboard go out. With the device variant with a monitor, the sign on the display must disappear.

Note	Refer to the summarised operating instructions on the packaging of the adhesive electrodes.

6.8 Plug in electrode plug

Fig. 18: Plug in electrode cable

1 Electrode plug with interlocking jack

2 Jack

Action prompt:

< Plug in electrode plugs >

1. Before positioning the electrodes on the patient, carry out the BLS steps as instructed!
2. Once the electrodes are connected to the patient and the electrode plug is plugged in, the BLS instructions are automatically interrupted.
3. Insert the plug connector (1) of the electrode cable in the HeartSave socket (2). Make sure that the locking pin (2) locks into place.

Note	To be able to unplug the electrode plug, you have to push firmly on the top part of the locking pin while at the same time pulling the plug up.

6.9 Checking the electrodes

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

- Electrode plug not plugged in
- There is contact between the defibrillation electrodes or a conductive gel connection.
- Hair growth on patient not removed.
- Air pockets between skin and defibrillation electrodes cause a bad contact.
- Dried out electrodes.

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

6.10 Carrying out the ECG analysis

If the defibrillation electrodes have been applied, the device will automatically start the analysis. Now the patient has to be put in an immobile position and may no longer be touched.

The device prompts:

< Do not touch patient, rhythm analysis >

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

DANGER

Take care that during the analysis phase, the Auto switch is not continuously pressed as otherwise safety shutdown of the equipment is effected.

DANGER

Observe the patient during the entire reanimation. It is possible at any time that the patient may regain consciousness and does not need to be defibrillated. If that is the case, do not carry out the defibrillation under any circumstances.

The rhythm identification detector continuously analyses the ECG, even after a rhythm in need of defibrillation has been identified.

6.11 Defibrillation required

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 >
< Do not touch the patient >
< Device is charging >
< Do not touch the patient >

If the condenser is charged internally, then the power for the defibrillation impulse is available for 15 seconds. This is signalled with the trigger button being lit up green.

The device prompts:

< Stand clear of patient. Deliver shock now >

1. Turn on green lit trigger key to give shock.

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

DANGER

Before pressing the trigger button, disconnect all equipment which is not defibrillation-proof from the patient!

Before and during the energy discharge, all those participating in the reanimation have to step back and all contact with the patient or conductive parts (e.g. a stretcher) must be avoided.

Once the defibrillation pulse has been given, a two minute phase follows for cardio pulmonary resuscitation (CPR). On the HeartSave AED-M you can freely select the cycles for the HLW between 1-5. The default is preset to 4.

Capacitor charging time 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.

WARNING

When the first message "Charge Battery" is issued, there are still at least 3 power discharges with max. energy available. The power module should be replaced when this message appears.

Note

If the device is switched on and for 10 minute no ECG is recorded or no key is pressed, then the device will automatically switch off. Approx. 30 seconds before the switch-off this is signalised by an interrupted warning tone. Pressing any button or any other activity will interrupt the switching off process.

Note

In basic state of the device variant with a monitor, a dotted line appears on the display with the message "Check electrodes" if the electrodes are not connected up. As soon as a derivation via the electrodes occurs, the ECG signal appears on the monitor.

If you have not noticed the possibility of administering a shock, the device internally destroys the power charged and the heart rhythm is analysed again. If there is still a shockable rhythm present, the device will prompt:

< Do not touch the patient >
< Analysing rhythm >
< Shock advised >
< Device is charging >
< Do not touch the patient > ...
< Stand clear of patient. Deliver shock now >

Please make sure that you definitely use this chance of administering a shock!

If you do not deliver a shock again, then this process will be repeated several times.

6.12 Defibrillation not required

If the device can not find a shockable rhythm, then it recommends cardiopulmonary resuscitation (CPR).

< No shock advised >
< Cardiopulmonary resuscitation >
< 30 x cardiac massage>
< 2x artificial respiration >

Once the CPR time has expired, the device returns to ECG analysis.

6.13 Keeping the defibrillator ready for use

At the end of a reanimation, clean the device, replace the PRIMEDIC™ SavePads and check or, if necessary, replace the power supply unit so that the PRIMEDIC™ HeartSave device is ready to use again as soon as possible. Charge the PRIMEDIC™ battery pack to ensure that sufficient energy is available for the device to be used again.

Note	If any malfunctions or noticeable problems occur, please contact your nearest service station.

6.14 Monitoring the patient with the PRIMEDIC™ AED-M

After successful defibrillation with the AED-M, the patient can be monitored by the monitoring function using the SavePads electrodes already used whilst they are being transferred to hospital. On the HeartSave AED-M you only have the lead II (Einthoven) 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.

7 Cleaning, maintenance and dispatch

7.1 Cleaning

WARNING

Only clean the device when it is switched off and with the electrodes unplugged. Before cleaning, remove the power module from the device or if there is an optional mains power supply, unplug it from the mains! Do not use any dripping wet cloths to clean it. Never pour liquids over the device and do not immerse it in any liquids!

- Clean the PRIMEDIC™ HeartSave and all its accessories, such as the wall bracket, with commercially available household cleaners.
- Use a slightly damp, clean cloth.
- Use ordinary wiping disinfectants to disinfect (e.g. Gigasept FF).

7.2 Servicing

Independently of the use of the device, we recommend regular visual inspection / servicing of the PRIMEDIC™ HeartSave and its accessories by the user / service technician on a regular basis, at least once a year.

Make sure that the housing, cable, PRIMEDIC™ SavePads and all the other accessories are undamaged!

Servicing checklist:

- Check the expiry date of the PRIMEDIC™ SavePads.
- Check the expiry date of the power module and if necessary, replace the parts with original parts!
- Check that the status display is showing "OK".
- Check whether you can switch on the device.
- Check whether the device carries out a self-test automatically after being switched on!
- Check whether the slot for the power supply is clean!
- Check that the device is fully equipped!
- Check that the device is labelled and that the label is legible.

	DANGER
	• If parts of the housing or insulation are damaged, they must be repaired or exchanged immediately. • If parts of the housing or insulation are damaged, do not use the device or switch it off immediately. • Have the device repaired as soon as possible by the manufacturer.

7.3 Dispatching the PRIMEDIC™ HeartSave

If the HeartSave has to be returned for servicing or to be upgraded, then the power module must always be removed from the device and must be sent in with the device, but packaged separately. Protect the contacts of the power module with insulating adhesive tape.
Where possible, use the original box.

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

Through the registration of Metrax GmbH with the responsible authorities we ensure that disposal and recycling of electrical devices introduced by us onto the market in accordance with the EU Directive on the disposal of waste electrical and electronic equipment (WEEE directive) is guaranteed.

For Germany, in accordance with the law on bringing electrical and electronic equipment onto the market, taking 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.

	CAUTION
	Incorrect disposal of the device or its individual parts can lead to injury.

For business customers in the European Union:

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

9 Technical Data

Defibrillation

Operating modes: Asynchronous, external

Patient impedance: 23 – 200 Ohm

Impulse shape: Biphasic, current regulated (CCD)

Output power at:

Patient impedance	1st. stage	2nd. stage	3rd. stage
25 Ohm	143 J	201 J	277 J
50 Ohm	281 J	350 J	360 J
75 Ohm	348 J	360 J	360 J
100 Ohm	344 J	343 J	343 J
125 Ohm	314 J	316 J	317 J
150 Ohm	290 J	293 J	293 J
175 Ohm	269 J	272 J	272 J

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

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

Discharges: 200 discharges at 20 °C with a new PRIMEDIC™ battery 6 at any energy of 360 J.
70 discharges at 20 °C with a new fully charged PRIMEDIC™ AkuPakat any energy of 200 J.
50 discharges at 20 °C with a new fully charged PRIMEDIC™ AkuPakat any energy of 360 J.

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

ECG

Derivation: 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 d.c. 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 recognised

Monitor (at AED-M)

Type:	High resolution LCD monitor, 95x72mm (Diagonal 120mm, 4.7 inches)
Resolution:	320x240 Pixels (Pixel size: 0.36 x 0.36mm)
Displays:	Heat frequency, number of defibrillations, number of VFs identified, resuscitation time, date, time, power capacity, ECG graph
Presentation:	X 25mm/sec, Y 10mm/mV

Power supply

Battery:	$LiMnO_2$ 15V, 2.8Ah (0° to 20°) service life in device is max. 6 years at 20°C
Removable battery (battery	NiCd 12V / 1.4Ah, service life max. 2.5 years, depending on use
PowerLine:	100…240 Volt, 50/60 Hz

Data storage

Memory type:	CompactFlashCard 32 MB – 2 GB possible

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 operation
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 kg (without power 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

10 Warranty conditions

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

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

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

Warranty and also legally entitled warranty claims are not applicable if the usefulness of the device is only negligibly affected, or in the case of normal wear and tear (e.g. consumables such as 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 against METRAX are excluded out unless such claims are based on intent or gross negligence or compulsory legal liability standards.

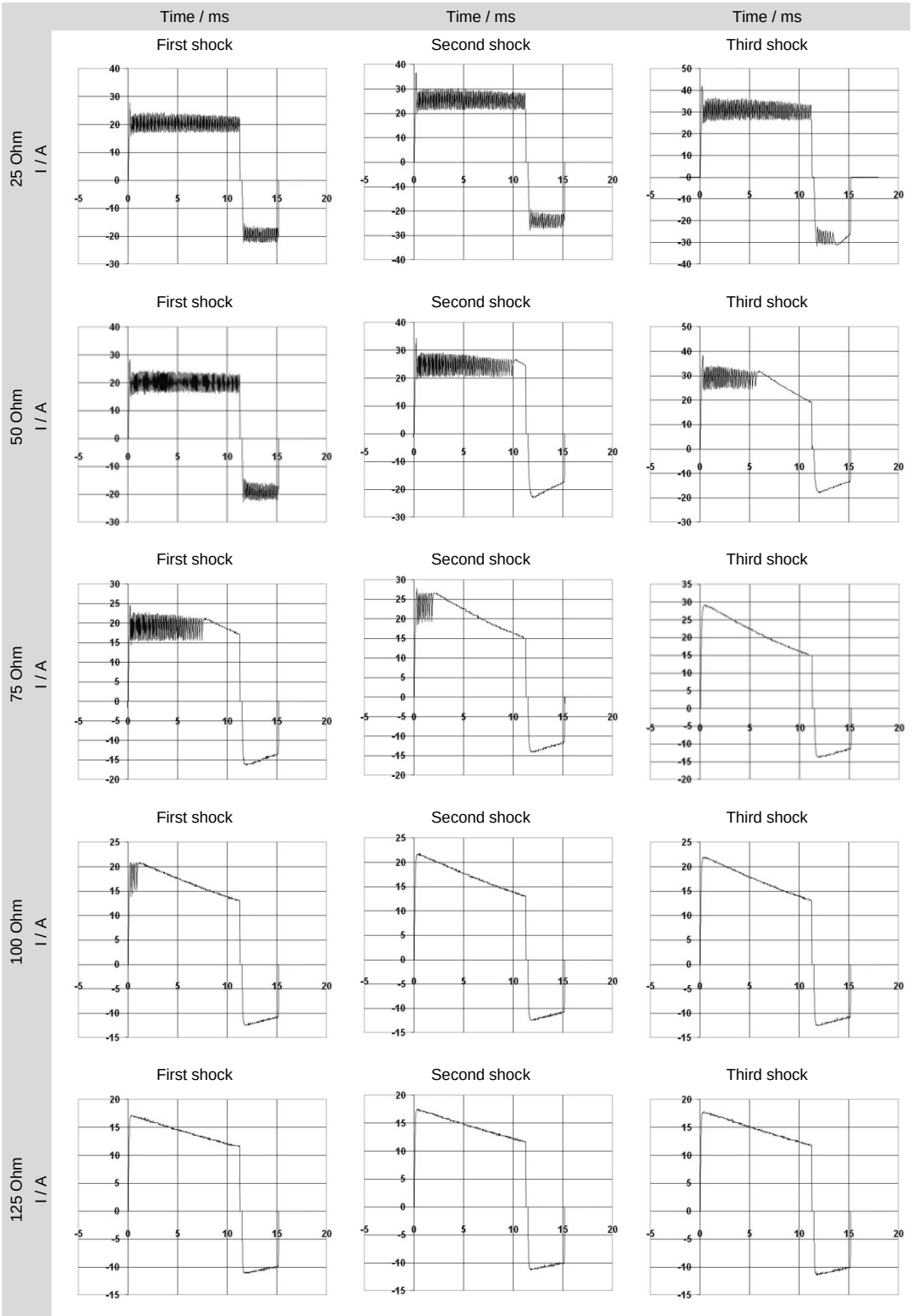
Warranty claims made by the buyer against the seller (dealer) are not affected by this guarantee.

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.

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

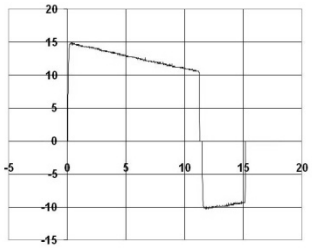
11 Depiction of the current time functions

Depiction of the current controlled defibrillation impulse depending on the patient resistance and the current set.

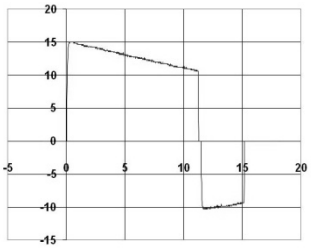


150 Ohm
I / A

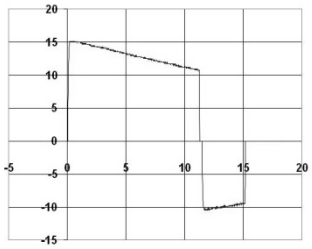
First shock



Second shock

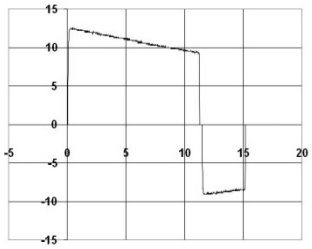


Third shock

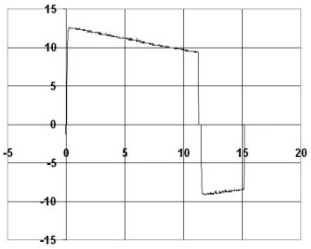


175 Ohm

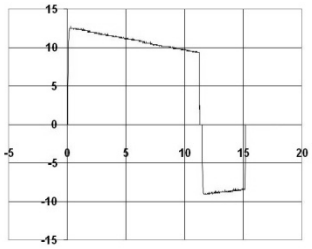
First shock



Second shock



Third shock



12 Rhythm detection system

The rhythm detection system on the PRIMEDIC™ 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

Ascertaining the electrode contact

The transthoracic impedance of the patient is measured by the defibrillation electrodes. If the baseline impedance is greater that 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 defibrillation when the system detects a shockable rhythm.

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

Operator control of the output of defibrillation shocks

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

The Algorithm:

- Observes the ECG rhythm across a continuous recording of 10 seconds, of which 7 seconds have been used for an initial diagnosis or to display the message "Shock recommended."
- Measures the symmetry of the ECG signal by several wave form factors and area abive and below the moving average of the signal. Shockable ryhthms show greater symmetry than non-shockable rhythms.
- Measures the ratio of the signal energy content in a frequency band typical for shockable rhythms and the total of the signal energy content. For shockable rhythms the signal energy concentrates in a specific frequency band and its fraction with respect to the total signal energy is higher.
- Derives from these two signal processing steps two parameters and compares them to a threshold. If both parameters drop below their respective threshold for a specific amount of time, the device will rate the heart rhythm shockable. However, if one of the parameters exceeds its higher threshold value, this shocking recommendation is retracted.
- Filters and measures artefacts and interference. If a specific artefact level is exceeded no reliable signal analysis is possible and the heart rhythm is rated non-shockable.

- Detects pacemaker pulses and removes them from the ECG signal before rhythm evaluation.
- Measures the heart rate. If it drops below a threshold, the heart rhythm is rated non-shockable.

Cardiac rhythms used to test the rhythm detection system in the device

For validation the following databases have been used:

- AHA Database for Evaluation of Ventricular Arrhythmia Detectors (80 records with 35 min length each)
- MIT-BIH Arrhythmia Database (48 records with 30 min length each)
- European ST-T Database (48 records with 120 min length each)

These databases contain ECG rhythms with ventricular fibrillation (VF) of varying amplitudes, ventricular tachycardia and sinus rhythms with – amongst others – supreventricular tacjycardias, atrial fibrillation/flutter, sinus rhythm with premature ventricular contractions (PVC), asystole and pacemaker pulses. All records are valid for evaluation of the VT-/VF-rhythm detector with respect to used electrode systems and ECG signal processing characteristics. For validation the ECG was converted to an analog signal and put out to the device under test. The detection result was than read back by the validation system and compared to the reference annotation.

For calculation of performance values those segments in the ECG data records marked with the PhysioBank annotation codes ventricular flutter/fibrillation ("[" start, "]" end; see also www.physionet.org) are selected as shockable, all others as not shockable. These segments also include ventricular tachycardias, but these are not annotated seperately. Hence, they could not be considered in calculation of performance values.

For evaluation, the test and reference annotations of segments with a length of 12 seconds were compared to each other. Segments containing a shift between shockable and non-shockable rhythms were not taken into account

Performance results (weighted average):

Sensitivity	97,68% (Requirement of IEC 60601-2-4:2003: >90%)
Specificity	99,99% (Requirement of IEC 60601-2-4:2003: >95%)
False positive rate	0,01 %
Real predictive value	98,59 %

The databases used have a total length of about 10,000 minutes. The calculation was made in accordance with IEC60601-2-4-2003.

Sensitivity

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

Specificity

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

False positive rate

= Number of "incorrect shockable" algorithm decisions / Total number of ECGs in which a shock is not clinically recommended

Positive predictive value

= Number of "correct shockable" algorithm decisions / Total number of ECGs where the device recommends VF shock therapy

13 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 has to emit electromagnetic energy to warrant its intended function. Neighbouring electromagnetic devices could be influenced.
HF emissions according to CISPR 11	Class B	The PRIMEDIC™ HeartSave is suitable for use in all locations including those in residential areas and those which are in the immediate vicinity of a public supply network which also supplies buildings that are used for residential purposes.
Emission of harmonics according to IEC 61000-3-2	n/a for battery / PRIMEDIC™ battery pack	
Transmission of voltage fluctuations / Flicker according to IEC 61000-3-3	n/a for battery / PRIMEDIC™ battery pack	

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.			
Immunity to interference testing	**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™ battery pack	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™ battery pack	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% U_t (> 95% dip in Ut) for ½ period 40% U_t (60% dip in U_t) for 5 periods 70% U_t (30% dip in U_t) for 25 periods < 5% U_t (> 95% dip in Ut) for 5s	n/a for battery / PRIMEDIC™ battery pack	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: U_t is the a.c. supply voltage before applying the 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**
			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. 
Conducted HF interference according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz outside the ISM bands [a] 3 V_{eff} 150 kHz to 80 MHz outside the ISM bands [a]	Not applicable for battery n.a.	
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 40.66MHz 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 measured at the location at which the PRIMEDIC™ HeartSave is being used exceeds the conformance levels for HF listed above, then the PRIMEDIC™ HeartSave should be observed to prove that it is functioning as intended. If unusual performance characteristics are observed, then it may be necessary to take additional measures, such as change the orientation or the location where the PRIMEDIC™ HeartSave 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 40.66MHz 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.		

14 General information and rules for use of the optional PRIMEDIC™ battery pack

A Nickel-Cadmium battery pack (NiCd battery) has been selected to operate the PRIMEDIC™ HeartSave, as this type of battery in practise has several advantages over other types of batteries.

The NiCd battery has a high power density, i.e. with the same physical size, the PRIMEDIC™ battery can provide much more defibrillation or has longer standby time than, for example, a comparable lead battery.

Handling the NiCd battery is unproblematic. With a modern, microprocessor controlled charge switch as used in the PRIMEDIC™ battery pack, it is possible to attain very short charging times while at the same time, conserving the battery pack.

If the NiCd battery is only slightly discharged and then recharged over a longer period of time, the typical "Memory" effect occurs. The practical consequence of this "Memory" effect is that the battery, although it has a large nominal charging capacity, behaves like a small battery with low capacity.

An example to illustrate this

A battery has a capacity of e.g. 60 defibrillations. The power for 5 defibrillations is used and the battery is then recharged. If this is repeated over a long period of time, the "Memory" effect may occur, i. e. the capacity of the battery is reduced to 5 to 6 defibrillations, as the battery has been "trained" to perform 5 defibrillations.

It takes a great amount of effort to reverse the "Memory" effect, meaning that the battery can no longer be sensibly used once its "Residual capacity" falls below a practicable value.

Avoiding the "Memory" effect

To avoid the memory effect, the battery must be fully discharged from time to time so that it is possible to intermittently carry out a complete charge cycle. In practice this can be done in several ways:

If the battery has only been slightly discharged, do not recharge it immediately. There is usually still enough energy available that you can continue to work with the remaining energy at a later point in time. The PRIMEDIC™ ClipCharger does not always charge a rechargeable battery immediately. Only once it falls below a certain threshold, is the battery charged.

The optimum way to achieve this is with a fully automatic discharger / charger, which performs defined discharging before every charging process. For safety reasons, this charging technique is not used for batteries that are charged in the defibrillator directly. Otherwise the unfortunate case could occur that the defibrillator is needed just at the moment in time at which the battery is fully discharged.

The fully automatic discharge / charge device has been realised as a care function in the PRIMEDIC™ Charger Comfort available as an option. This optional accessory (it can also be retrofitted) allows you to charge a second PRIMEDIC™ battery pack and the Care Function prevents the occurrence of the "Memory" effect.

Other effects of batteries

Batteries have two additional properties in daily practice:

- Self-discharge
- Ageing after being used for a long time.

Self-discharge of a battery means that in practical use, that a battery that is still full, slowly but surely loses its charge. After around 4 weeks only around 90% of the capacity is still available. This effect normally only need to be taken into consideration if several batteries have been charged in "reserve".

Even with optimal care of a battery, after a time period of approx. 2 – 3 years (depending on the frequency of use) an **ageing effect** occurs. After around 500 – 1000 charge cycles (depending on the type) a battery is no longer able to transfer the electrical energy charged into the chemical reservoir. The battery is thus rendered useless and must be replaced with a new one.

15 Safety checks

(it is possible that other national regulations may be applicable)

In accordance with the German Medical Products User Regulations (MPBetreibV) § 6 (safety checks) the operator in the event of commercial and economic use undertakes to carry out regular checks or have them carried out. METRAX recommends carrying out safety checks in accordance with the MPBetreibV §6 every 24 months. The safety checks may only be carried out by or be assigned to the persons described in the MPBetreibV §6 (4).

The safety checks carried out are to be documented in accordance with MPBetreibV §7.

In accordance with the German Medical Products User Regulations (MPBetreibV) § 6 (Safety checks) the operator is obliged to have regular checks carried out. In accordance with the German Medical Products User Regulations (MPBetreibV) § 6, METRAX stipulate these checks be carried out in a 24-month cycle.

The safety checks may only be assigned to people who, because of their training, their knowledge and their experience gained through practical activity, can carry the checks out properly and do not need instruction to do so.

If during the safety check, faulty are found which could be hazardous to patients, employees or third parties, then the operator must immediately inform the responsible authorities in accordance with German Medical Products User Regulations (MPBetreibV) § 3.

In the medical products log to be kept in accordance with the German Medical Products User Regulations (MPBetreibV) § 7, the following data is to entered:

- Time of carrying out the work
- Name of person or company carrying out the work and
- Measures taken.

The responsibility of METRAX GmbH only covers the information provided in the operating instructions. This applies in particular for readjustments, repairs and changes to the device.

16 Using the equipment on ships

16.1 Use of PRIMEDIC™ HeartSave units together **with a PRIMEDIC™ battery** on ships in the merchant navy:

The use of the following **PRIMEDIC™ HeartSave (M250)-**units:

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

with the energy supply module

PRIMEDIC™ Battery 15VDC 2.8Ah LiMnO4

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

16.2 Use of PRIMEDIC™ HeartSave units together **with a PRIMEDIC™ AkuPak** on ships in the merchant navy:

PRIMEDIC™ HeartSave units with a PRIMEDIC™ battery, have been EMC checked for compliance with "Test Requirements for Electrical / Electronic Equipment and Systems" of "Germanischer Lloyd," 2003.

Because the "**PRIMEDIC™ AkuPak 12VDC 1.2Ah NiCd**", whilst supplying the PRIMEDIC™ HeartSave (M250) units behave as the "PRIMEDIC™ battery", we can transpose the experience gained from all EMC test results to the combinations of the PRIMEDIC™ AkuPak with all PRIMEDIC™ HeartSave (M250) units.

These combinations fulfil, during supply mode, the requirements of "Zone for the bridge and the open deck".

Recharging the PRIMEDIC™ AkuPak requires a PRIMEDIC™ ClipCharger as the charger unit.

Recharging must **be carried out in a dry room which is isolated by metallic screening from** "Zone for the bridge and the open deck".

The equipment combination always fulfils, during charging, or in parallel charging mode, the EMC requirements of the "General Power Supply Zone".

About Us.

METRAX GmbH is specialised in developing state-of-the-art devices for emergency medicine. Established in 1973 in Rottweil, today Metrax is considered to be an outstanding example of the strengths in German development technology: Innovative vision, top quality and complete dedication in research and development have been the company's distinguishing features for the last 30 years. The result of this is high precision and extremely reliable high-tech devices which are so user friendly that they set new standards. With the brand PRIMEDIC™, Metrax offers a reliable programme for emergency medicine: Professional defibrillators and mobile ultrasound scanners. Emergency rescue services around the world are familiar with PRIMEDIC™ as a guarantor for the highest quality and innovative medical technology.

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