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PRIMEDIC™
Saves Life. Everywhere.

HeartSave PAD

Operating instructions

MGA 22289/ GB / C

Masthead

Publisher

METRAX GmbH
Rheinwaldstr. 22
D-78628 Rottweil
Germany

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1 Introduction

1.1 Foreword

Dear User,

You are faced with the task of using the PRIMEDIC™ HeartSave PAD in a medical emergency on human beings.

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

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

If you should have any questions regarding the device or other PRIMEDIC™ products, we are at your entire 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 PAD made by METRAX GmbH.

1.3 Warranty

The warranty period is 24 months and starts on the day of purchase. It is important to keep the receipt 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-observance of the advice given in these operating instructions with regard to operation, maintenance and repair of the device.
- 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 pay attention to these texts.

	**WARNING** Texts marked WARNING indicate extraordinarily serious, possible dangers which, should no preventative measures be taken, may lead to serious injury or even death. It is imperative that you pay attention to these texts.

	**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.

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

1.6 Pictograms on the device

IP55	Protection against contact and dust deposits on the inside and against jets of water (nozzle) from any angle.
	Please observe the operating instructions.
	Do not dispose of device in domestic refuse.
	Dangerous electric voltage (high voltage)
	Degree of protection CF in connection with ECG patient cable: 10µA patient leakage current (NC – normal condition) 50µA patient leakage current (SFC – single fault condition) 100µA patient leakage current (SFC – defibrillation outputs) according to IEC60601-1 and IEC60601-2-4
GL	GERMANISCHER LLOYD type approval certificate no. 75 449-09 HH

1.7 Pictograms on SavePads

	Not to be reused
	Expiry date
LOT	Batch ID
	Only for adults
REF	Order number
MIN 5° C 41° F MAX 30° C 86° F	Storage temperature information in Celsius and Fahrenheit

2 Intended use

The PRIMEDIC™ HeartSave PAD 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 about 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 30s.

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.

The device supports the user in the reanimation process depending on the factory-setting in accordance with the current guidelines from the European Resuscitation Councils (ERC) from 2005 or the American Heart Association (AHA) from 2005 for immediate lifesaving measures to be taken when using an automatic defibrillator. This includes acoustic instructions for carrying out artificial respiration and heart massage as well as the cyclical process of rhythm analyses and, where necessary, the application of further shock therapy according to the recommendation by the device.

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

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

	**WARNING**
	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.

2.1 Indication/Contraindication for Defibrillation

2.1.1 Indications

The PRIMEDIC™ HeartSave PAD may only be used if the patient:

- is unconscious and
- not breathing

2.1.2 Contraindications

The PRIMEDIC™ HeartSave PAD may not be used if the patient:

- is conscious or
- breathing normally or
- a normal pulse can be felt or
- is a child under the age of 8 or weighing less than 25 kg respectively.

3 Safety information

3.1 General information

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

The device and its accessories are safe when used as intended and taking into account the descriptions and information detailed in these operating instructions.

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

DANGER

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.

WARNING

The PRIMEDIC™ HeartSave PAD may only be used by trained and authorised personnel. Reading the operating instructions does not replace training.

The PRIMEDIC™ HeartSave PAD is not licensed for use in explosive areas.

DANGER

Not using the device as intended or using it improperly, exposes the user, the patient or third parties to the 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.

Note

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

Applicable for Europe:

- The device complies with the Medical Device Directive (MDD).

Also applicable for Germany and Austria:

- The device 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 is to 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 device are to be documented in it.

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

3.2 General safety instructions

	**DANGER** The device may not be used in the vicinity of flammable materials (e.g. cleaning solvents or similar) or in an atmosphere enriched with oxygen or flammable gases/vapours.

3.3 Safety notes for you, the user

	**WARNING** 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 you use it and that it is in good condition. • the state of the patient requires or allows an application. Before using it, check whether the device is in the operating temperature range. This applies for example, if the defibrillator is stored in a rescue vehicle. Do not apply the device if it has been damaged or is defective (e.g. if the defibrillator cable is damaged or the housing has been damaged) Do not touch the patient during defibrillation. Avoid any contact between parts of the patient's body (such as bare skin on head or legs), as well as conductible liquids (such as gels, blood or salt solutions) and metallic objects around the patient (such as bed frame or traction devices) which present unintended paths for the defibrillation current.

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 it, check whether the device is in the operating temperature range. This applies for example, if the defibrillator is stored in a rescue vehicle in the winter.

Do not use the device if it is defective (e.g. if the housing or the defibrillation cable are 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 and unexpired defibrillation electrodes for every patient to avoid any possible burns to the skin!

Only connect the adhesive electrodes to the PRIMEDIC™ HeartSave PAD. Using the electrodes with other devices can cause the patient to be given dangerous leakage currents.

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 PAD 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 PAD and disrupt the way it operates. For this reason, disconnect the patient from the connections of the interfering devices.

DANGER

During defibrillation, disconnect the patient from all other medically used devices which do not have a defibrillation resistance application part.

Keep the defibrillation electrodes away from other electrodes and from metallic parts which are in contact with the patient.

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 a correct analysis.

Stop any reanimation while the PRIMEDIC™ HeartSave PAD is analysing the ECG.

Do not touch the patient during defibrillation. Avoid any contact between

- parts of the patient's body (such as bare skin on head or legs), as well as
- conductible liquids (such as gels, blood or salt solutions) and
- metallic objects around the patient (such as bed frame or traction devices) which present unintended 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 the protection of the device

CAUTION Damage to property

- Repairs, changes, extensions and installations of the PRIMEDIC™ HeartSave PAD may only be carried out by personnel authorised and trained by METRAX
- The PRIMEDIC™ HeartSave PAD 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 PAD** (PAD = Public Access Defibrillator) 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 PRIMEDIC™ HeartSave product family has been designed to be safe and quick to use in an emergency. All functional units are operating elements subject to the following principles:

- Clear organisation of functional units
- Reduction of functions to what is 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.

The power supply of the **PRIMEDIC™ HeartSave PAD** comes from a disposable lithium battery.

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

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

4.2 Description of device details

Fig. 1: HeartSave PAD front view

(1) Carry handle
(2) Cover of device
(3) Strap to pull the cover off the device (with expiry date SavePads)
(4) Status display

Fig. 2: HeartSave PAD rear view

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

Fig. 3: HeartSave PAD View from underneath

(1) Release button for SaveCard
(2) Slot for SaveCard
(3) Release button
(4) Contacts for power module

Fig. 4: HeartSave PAD operating controls

(1) On/Off button
(2) Electrode symbol with LED
(3) Membrane keyboard with patient symbol
(4) "Do not touch patient" symbol (lights up during ECG analysis)
(5) Jack for electrode connector plug
(6) Loudspeaker
(7) Trigger button for defibrillation
(8) Status display

Fig. 5: Primedic utensils carrier with SavePads

(1) Primedic SavePads (defibrillation electrodes)
(2) Artificial respiration cloth and razor
(3) Quick instructions, several languages
(4) Rubber gloves, not sterilised
(5) Primedic utensils carrier with expiry date SavePads

4.3 Status display

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

Display.	Meaning.	Measures to be taken.
	Sufficient battery capacity.	Device ready to use.
	Low battery capacity. No power module inserted.	Device can be used. Nearly time to exchange battery. Insert power module.
	Sufficient battery capacity. Device defective.	Carry out major self-test by reinserting the battery or switching the device on again. Have the device repaired by a dealer.
	Device defective.	Carry out major self-test by reinserting the battery or switching the device on again. Have the device repaired by a dealer.

The battery is monitored using an electronic charge balance process.

Once the battery is exhausted, a warning tone will sound in connection with an audible warning.

	Audible warning.
Battery.	< Battery low, please replace battery >

Note If the device is being used, the corresponding audible warning will be repeated regularly in the selected language. The battery symbol in the status display is activated.

4.4 Data management

Note

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

The data saved can be displayed with the aid of 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. In the software there is a deployment protocol into which further patient data can be entered.

The data saved on the SaveCard should be filed externally after every deployment if possible. If the memory capacity of the SaveCard is full, then no further data will be saved. The device is ready for use both with an exhausted memory and also without a SaveCard.

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 format them with the FAT16 file system. Therefore, when you are formatting, ensure that you do not accidentally transfer the FAT32 file system onto a Windows XP system.

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

Windows 2000, Windows XP, Windows Vista

1. Start a command line window using "Start->Run" and in the entry field, enter "cmd.exe". The command line window will then open.

2. There you enter the following: format f: /U /FS:FAT /X /V: (where f: stands for the drive letter of the of the CF card reading device which you may have to adjust).

4.5 Description of the accessories

The accessories need to be secured appropriately before being transported.

4.5.1 Primedic SavePads

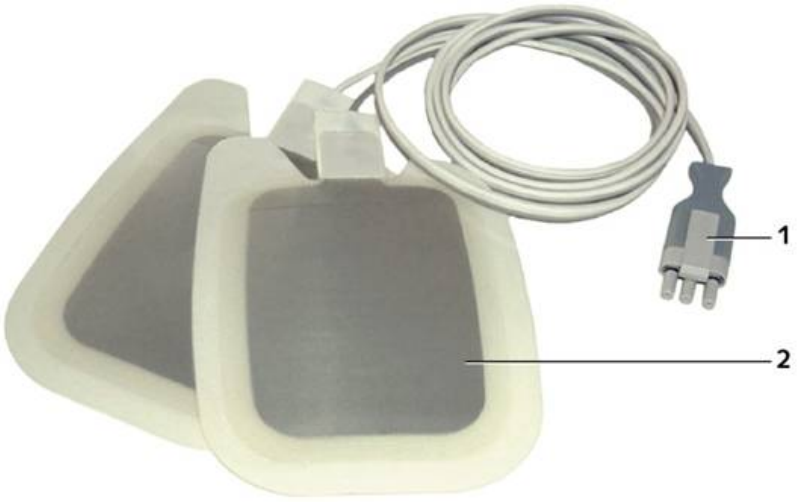


Fig. 6: Primedic SavePads

(1) Plug of the defibrillation electrodes (Primedic SavePads)

(2) Defibrillation electrodes with protective film

4.5.2 Optional accessories

- **PRIMEDIC™ ECG Viewer** (read out and documentation software) Order No.: 96468
- **PRIMEDIC™ HeartSave Bag** Order No.: 96379
- **PRIMEDIC™ SaveBox Basic** Order No.: 96740
- **PRIMEDIC™ SaveBox Advanced** Order No.: 96776
- **Information signs "Defibrillator"** Order No.: 96595

Subject to change without notice.

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 device number and describing the damage to the device.

	**DANGER** Definitely do not use the device if you know of any damage. Endangering health can not be ruled out.

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

Dispose of the packaging material in an environmentally-friendly manner.

5.2 Inserting / Changing the SaveCard

Fig. 7: Inserting / Changing the SaveCard

To remove the SaveCard or to change it, you first of all have to remove the power module.

Procedure:

1. Press the button (1) in fully – this pushes the SaveCard (2) slightly out of its holder.
2. Completely remove the SaveCard from the device and transfer the data (if applicable) onto a PC and insert this card or a new one into the device with the pin end 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. After this, the device will carry out a self-test and is ready to use.

Note	The data saved on the SaveCard should be filed externally after every deployment if possible. If the memory capacity of the SaveCard is full, then no further data will be saved. The device is ready for use both with an exhausted memory and also without a SaveCard. To read out the saved data, you can use the software **PRIMEDIC™ ECG Viewer** which is available as an optional accessory.

5.3 Inserting / Changing the power supply unit (Battery)

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

Note

The HeartSave PAD is always supplied with a battery.

Check the status display every time after you have used the device. If necessary, the battery should be exchanged for a new one.

5.3.1 Inserting the battery

Fig. 8: Inserting the battery

Procedure:

1. Lay the device on its back.
2. Push the (new) battery (3) in the direction of the arrow (1st) into the device until it reaches its end position as shown in the diagram.
3. Then press the battery at the front in the direction of the arrow (2nd) into the power module slot until the release button (4) locks the power module tongue securely into position.
4. Press the power module completely into the device until you hear the "click" when it slots into place and the power module is flush with the outside edge of the device.

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.

	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 show "OK", remedy the cause or contact your nearest service station. The device will switch itself off.

5.3.2 Removing the battery from the device

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

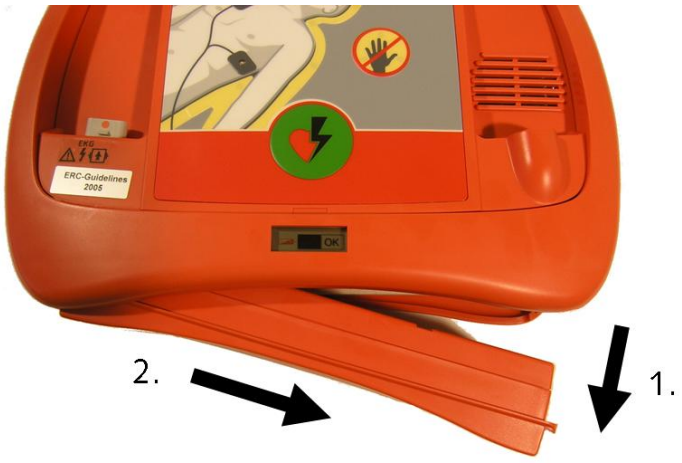


Fig. 9: Removing the battery

Procedure:

1. Lay the device on its back and press the release button (as described in5.3.1) to the right until the tongue of the power module is released and the power module snaps out of the slot.
2. Twist the power module slightly in the direction of the arrow (1st) and then pull it in the direction of the arrow (2nd) 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 power storage.

WARNING

On no account try to charge the battery.

There would be risk of an explosion!

CAUTION

Use the battery before its use-by date expires.

After using the device, the battery should be (if necessary) exchanged for a new one (to guarantee a full period of operation when next deployed).

In any event, heed the instruction leaflet 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.

When sending the battery, observe the separate shipping regulations.

6 Device self-test

6.1 Self-test after switching on the HeartSave PAD

The self-test is triggered by switching on the **PRIMEDIC™ HeartSave PAD** or by inserting the battery in the device. The HeartSave PAD runs a device self-test to check all the important parameters and signal mechanisms.

If the power module has been changed and if the device had previously found a fault, then the full self-test (FULL) is automatically triggered. Please proceed to follow the device instructions.

6.2 Automatic, periodic self-tests

The Primedic HeartSave PAD automatically carries out self-tests to ensure that it is ready to use.

	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 July 1st and January 1st every year	Software, operating membrane, ECG calibration, clock, internal voltage supply and HV part at 1600 V
FULL	After changing the power module or detection of an internal fault	Software, operating membrane, ECG calibration, clock, internal voltage supply and HV part at 1600 V, microphone test

7 Operating the device and sequence of reanimation

Note	The sequence of reanimation has been devised in accordance with the recommended guidelines of the European Resuscitation Council (Resuscitation (2005) 67S1, p7—p23) in the device. Ensure that you have completed appropriate training before using the device.

7.1 Switching the PRIMEDIC™ HeartSave PAD on / off

7.1.1 Switching the PRIMEDIC™ HeartSave PAD on

The device is automatically activated by removing its cover. If the device is not switched on automatically, switch it on by pressing the on / standby button. After this, all buttons are activated, 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.

7.1.2 Switching the PRIMEDIC™ HeartSave PAD off

The PRIMEDIC™ HeartSave PAD can be switched off in different 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 switches off automatically.

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

7.2 Voice output by the device / Preliminary examination of the patient

Note	During the course of the voice output, you will be asked to examine the patient. For this, you will need to take the rubber gloves out of the cover of the device and put them on.

After the self-test has been successfully performed by the device, the following BLS instructions are given:

< Talk to patient >

< Call emergency services >

< Open up airways, carefully overstretch head >

< Check breathing >

< If there is not breathing, Give 30 chest compressions >

< Give 2 x rescue breaths >

< Apply electrodes to patients bare chest >

< Plug in electrode cable >

7.3 Undressing the patient

Note	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.

7.4 Determining the position of the electrodes

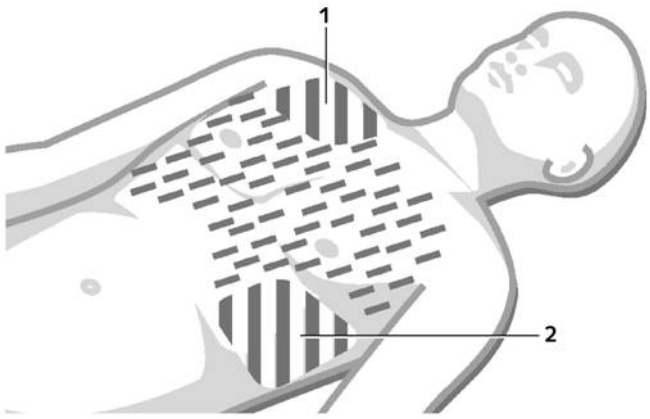


Fig. 10: Positions of electrodes on the patient

The positions of the electrodes are:

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

7.5 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.

Note Excessive hair can greatly increase the resistance between the adhesive electrodes and the surface of the skin thus reducing the effectiveness of the electric shock.

7.6 Drying the skin

In certain situations (e.g. after an acute myocardial infarction), it may be necessary to dry the skin in the respective positions. A dry surface is essential for the adhesive electrodes to stick on.

7.7 Opening SavePads and positioning electrodes

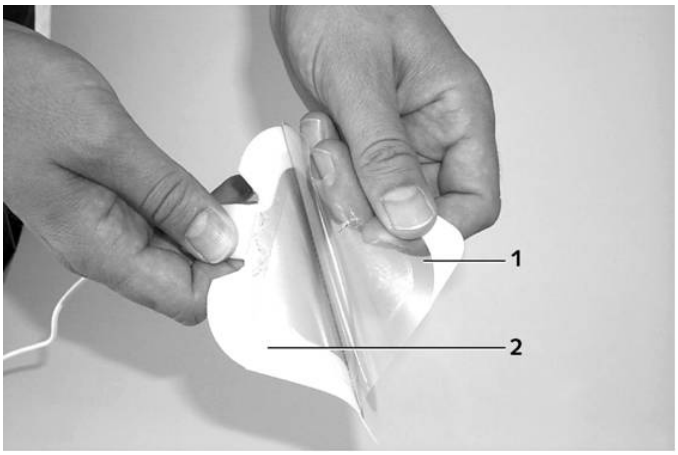


Fig. 11: Removing the film from the electrodes

(1) Protective film on electrodes

(2) SavePads adhesive electrodes

The PRIMEDIC™ HeartSave PAD will give spoken instructions for you to apply the defibrillation electrodes to the patient. **< Apply electrodes to patients bare chest >**

Procedure:

1. Open the defibrillation electrodes bag by tearing open the protective cover along the tear strip.
2. Remove the protective film (1) from one of the electrodes (2) and then immediately place the electrode on the position you had ascertained previously. Refer to label stuck on the back of the electrodes.
3. Proceed to remove the protective film from the second electrode and place it in its position.
4. Smooth the electrodes onto the patient ensuring there are no air bubbles under the electrodes! Display **< Apply electrodes to patients bare chest >** must go out.

	DANGER
	Do not touch the floor, other objects, clothing or other parts of the body with the electrodes (after removing the protective film) as it may remove the conducting layer of gel on the electrodes. **A reduced layer of gel could cause burns on the skin under the electrodes during defibrillation.** Please make sure that the red electrodes symbol LEDs on the membrane keyboard go out.

7.8 Plugging in the electrode plugs

Fig. 12: Plugging in the electrode plugs

Procedure:

1. Before positioning the electrodes on the patient, carry out the BLS actions as instructed.
2. After the voice message asks you to **< Plug in electrode cable >**, insert the plug of the electrode cable into the jack on the HeartSave PAD as shown in the diagram above.
3. Make sure that the locking pin locks into place.

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

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.

7.9 Checking the electrodes

If the device notifies a fault, this could be for several reasons:

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

Remedy the cause of the fault.

7.10 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 announces: **< Do not touch the patient, Analysing rhythm >**

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

Please note that the trigger button must not be pressed permanently during the analysis phase since this will cause the device to initiate an internal safety cut-off.

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.

7.11 Defibrillation required

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

The device announces:

< Shock advised >

< Device is charging >

< Do not touch the patient >

< Device is charging >

< Do not touch the patient >

Once the capacitor has been loaded internally, the energy for the defibrillation impulse is available for 15 seconds and is signalled by a continuous beep and the trigger button lighting up "green". If you do not defibrillate within this period, an internal safety discharge will follow and the ECG will be analysed again.

< Stand clear of patient, Press lit shock button now >

Note	If the trigger button is pushed while the capacitor is charging (before the button turns green) no shock will be released and an internal safety discharge will be initiated instead.

DANGER

Before pressing the trigger button, ensure that all devices connected to the patient are removed if they are not defibrillation protected.

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.

This process is repeated in accordance with the ERC Guidelines 2005. After that, there will be a pause, depending on the set-up setting for cardiopulmonary resuscitation (CPR).

The charge time of the capacitor for defibrillation depends on the available battery capacity. If the power module is slightly discharged, the charge time can be slightly longer.

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

Note	If, when the device is switched on, no ECG is done for 10 minutes or no button is pressed, the device automatically switches off. An intermittent warning beep is signalled for approx. 30 seconds before switching off. Pressing any button or any other activity will interrupt the switching off process.

7.12 Defibrillation not required

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

< No shock advised >

< Cardiopulmonary resuscitation >

< Give 30 chest compressions >

< Give 2 rescue breaths >

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

7.13 Keep the defibrillator ready for use

- At the end of a reanimation, clean the device, replace the SavePads and check or if necessary exchange the power supply unit so that the **PRIMEDIC™ HeartSave PAD** is ready to use again for the next time as soon as possible.
- If any malfunctions or noticeable problems occur, please contact your nearest service station.

8 Cleaning, maintenance and dispatch

8.1 Cleaning

	**WARNING** Only clean the device when it is switched off and with the electrodes unplugged. Beforehand, remove the power module from the device Do not use any dripping wet cloths to clean it. Do not spill any liquids over the device and do not immerse it in any liquids.

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

Use a slightly damp, clean cloth.

Use normal disinfectant to disinfect it

(e.g. Gigasept FF, Bacillol or Spitacid).

8.2 Servicing

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

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

8.2.1 Servicing check list

1. Check the expiry date

- of the SavePads
- of the battery pack (optional) and
- if necessary replace the parts.

2. Check whether

- the status display "OK" is showing.
- you can switch on the device.
- the device automatically carries out the self-test after being switched on.
- the slot for the power supply is clean.
- the device is fully equipped.

When doing so, pay attention to the following:

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.

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

8.3 Dispatching the PRIMEDIC™ HeartSave PAD

Note	If you want to return the device for additional equipping or for a service, it is important that you remove the power module from the device first and include it with the device, but packaged separately. Where possible, use the original box.

9 Disposal

Fig. 13: 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 registration of Metrax GmbH with the responsible authorities, we ensure that the disposal and utilisation of electronics devices introduced onto the market by us is secure in accordance with the EU directive on the disposal of electronic and electrical equipment (WEEE-directive).

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: 25658828 . [f8]

CAUTION

Improper 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. 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.

10 Technical Data

Defibrillation

Operating modes: Asynchronous, external

Patient impedance: 23 – 200 Ohm

Impulse shape: Biphasic, current regulated (CCD)

Output power in AUTO mode 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: 50 discharges, at 20 °C, with a new battery

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

ECG

Lead: 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 – 44 Hz (- 3 dB) SR = 101 samples/s

Impedance measurement

Defibrillation: 23 ... 200 Ohm (accuracy +/-20 %)

Measurement frequency: 30 kHz

Alarms

System:	ECG, defibrillator, power supply, data storage
Physiological:	Ventricular fibrillation (VF)
Analysis duration:	Approx. 7 s until VF is recognised at 90 % rated capacity

Power supply

Battery	$LiMnO_2$ 15V, 2.0Ah (0° to 20°) service life in device is 3 years at 20 °C

Data storage

Memory type:	CompactFlashCard 32 – 256 MB possible

Safety

Classification:	Medical product in class IIb, Protection category I, Type BF, Defi-resistant,
Identification:	CE 0123 The device is a medical product and complies with the EC Directive 93 / 42 / EEC

Other

operating conditions:	0 ... 50 °C, 30 ... 95 % rel. humidity, however without condensation 700 hPa ... 1060 hPa continuous operation
Storage conditions:	20 ... 70 °C, 20 ... 95 % rel. humidity, however without condensation, 500 hPa ... 1060 hPa continuous operation
Dimensions:	28 x 25 x 9 cm (W x H x D)
Weight:	approx. 2 kg (without power supply)

Standards applied

Standards (for licensing in the EU the corresponding harmonised European standards EN were used instead of the IEC standards):

IEC 60601-1:1988 + A1:1991 + A2:1995
IEC 60601-1-2:2001
IEC 60601-2-4:2002
EN1789:2003

Subject to change without notice.

11 Warranty conditions

The warranty period is 24 months and starts on the day of purchase. It is important to keep the receipt 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 battery pack) or damage caused after transfer of risk as a result of incorrect or negligent handling, excessive wear or are caused by special external influences which are not provided for according to the contract. The same applies if inappropriate changes or incorrect repair work is carried out by the buyer or by a third party.

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

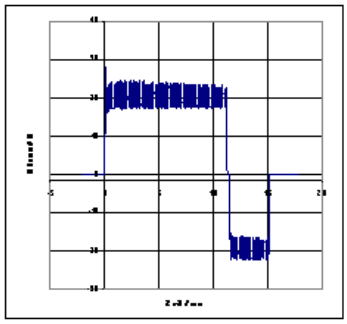
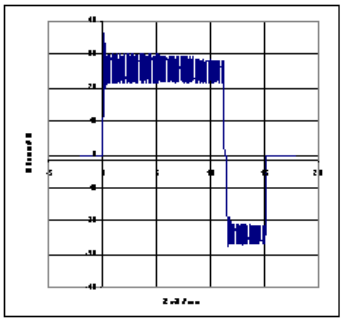
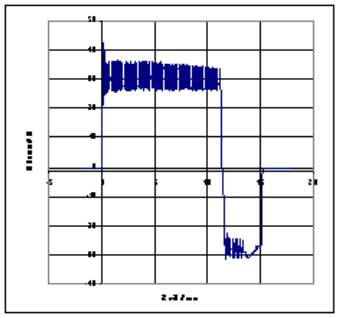
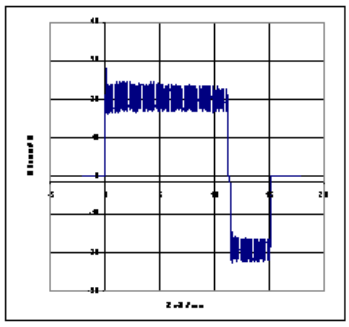
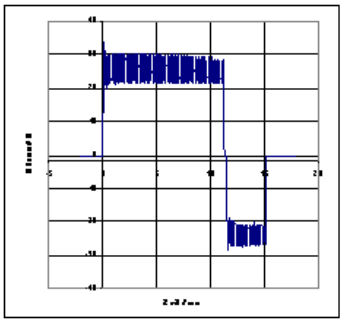
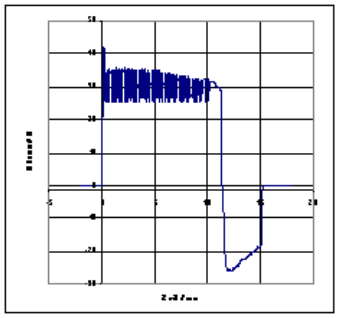
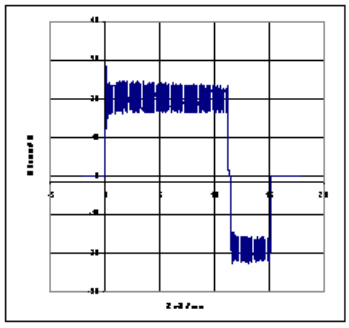
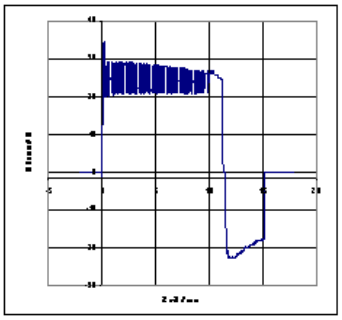
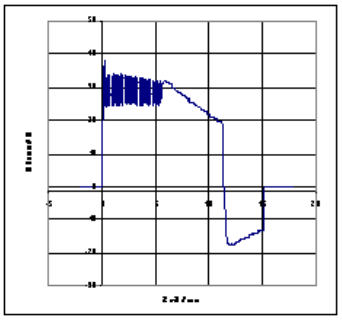
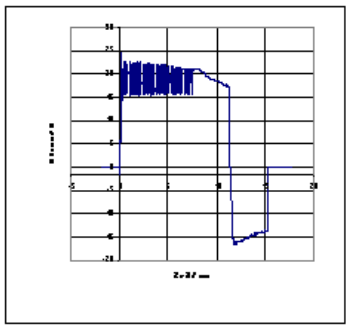
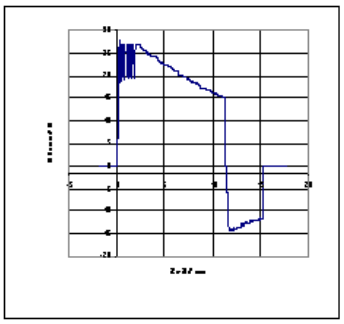
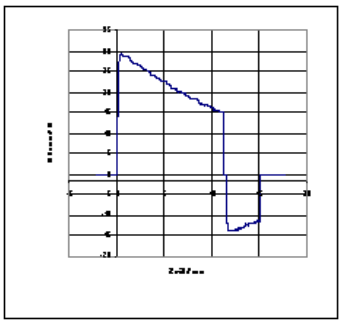
Warranty claims made by the buyer against the seller (dealer) are not affected by this guarantee.

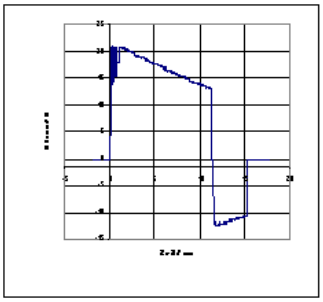
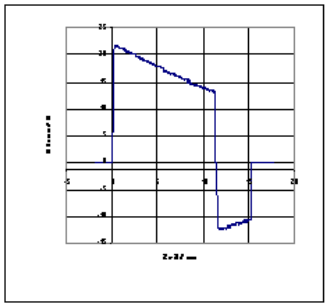
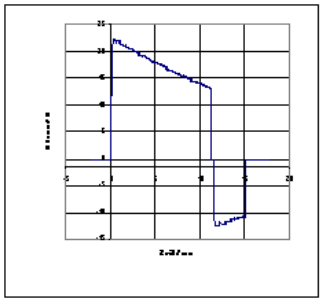
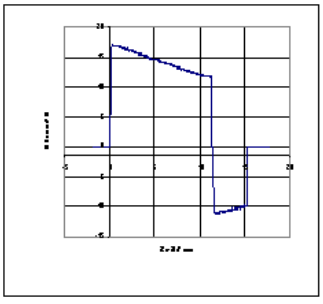
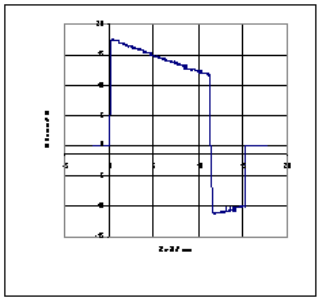
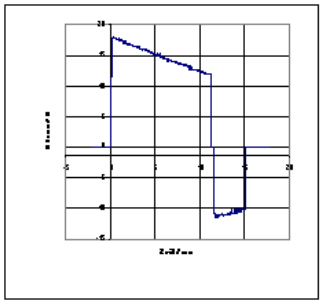
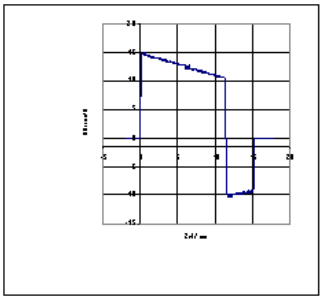
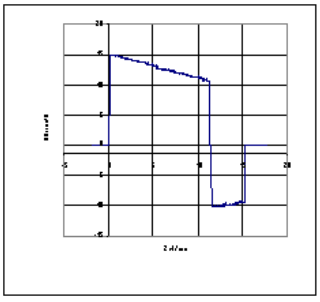
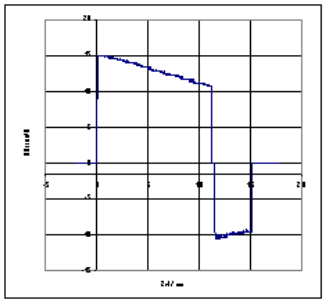
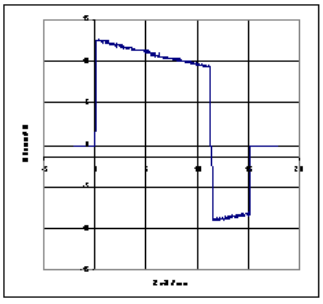
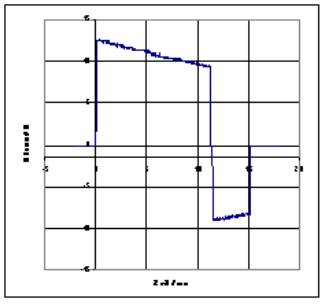
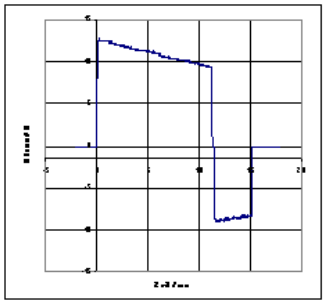
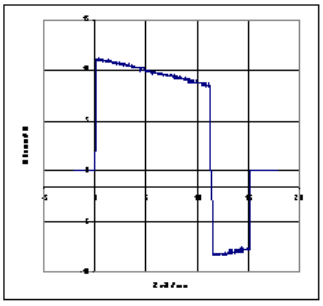
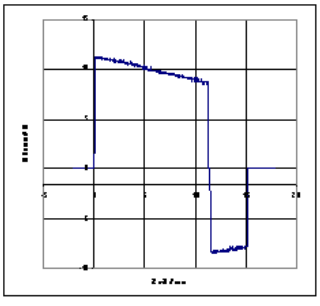
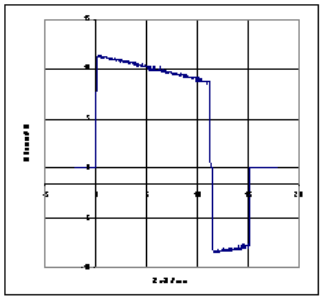
In the case of a warranty claim, please return the device with proof of purchase (e.g. invoice) stating your name and address to your dealer or to METRAX.

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

12 Depiction of the current time function

Below you can see the graph shapes of the defibrillation impulse in manual mode depending on the load resistance.

	Stage 1	Stage 2	Stage 3
25 Ohm			
30 Ohm			
50 Ohm			
75 Ohm			

	Stage 1	Stage 2	Stage 3
100 Ohm			
125 Ohm			
150 Ohm			
175 Ohm			
200 Ohm			

13 Rhythm detection system

The rhythm detection system of the PRIMEDIC™ HeartSave PAD analyses the patient's ECG and supports you if the device identifies a shockable or a non-shockable rhythm.

The device's rhythm detection system includes:

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 that the maximum critical value, then the device ascertains 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 device's rhythm detection system has been designed so that a defibrillation shock is recommended if the system has been connected up to a patient who is unconscious, not breathing and has no pulse and the system ascertains 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 advised >**
- Measures symmetry and energy content of the signal
- Filters and measures artefacts and interference
- Detects pacemakers
- Measures the QRS rate

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

To validate the databases used: AHA and MIT

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

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

The databases used have a total length of 10,004 minutes. The calculation was made in accordance with IEC60601-2-4-2003.

Sensitivity

= Number of "correct shockable" algorithm decisions

Total number of ECGs in which dispensing an impulse is clinically recommended

Specificity

= Number of "correct not shockable" algorithm decisions

Total number of ECGs in which dispensing an impulse is clinically not recommended

False positive rate

= Number of "incorrect shockable" algorithm decisions

Total number of ECGs in which dispensing an impulse by the device is not recommended

Positive predictive value

= Number of "correct shockable" algorithm decisions

Total number of ECGs in which dispensing an impulse is recommended by the device VF

14 Guidelines and manufacturer's declaration – Electromagnetic emissions

The PRIMEDIC™ HeartSave family is designed for operation 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.		
Emitted interference measurements	**Confor-mance**	**Electromagnetic environment - code of practice**
HF emission according to CISPR 11	Group 1	The PRIMEDIC™ HeartSave family uses HF energy exclusively for its internal functioning. This means that its HF emission is very low and it is unlikely that equipment in the vicinity will be disrupted.
HF emissions according to CISPR 11	Class B	The PRIMEDIC™ HeartSave family is suitable for use in all facilities, including residential areas and those which are directly connected to a public supply network which also supplies buildings that are used for residential purposes.
Emission of harmonics according to IEC 61000-3-2	Class B	
Emission of voltage fluctuations / flickering according to IEC 61000-3-3	Compliant	

The PRIMEDIC™ HeartSave family is designed for operation in the electromagnetic environment as described below. The customer or user of the PRIMEDIC™ HeartSave should ensure that it is used in an environment of this kind.			
Interference resistance tests	**IEC 60601 impulse test level**	**Confor-mance level**	**Electromagnetic environment code of practice**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Corridor floors should be made of wood or concrete or be covered with ceramic tiles. If the floor is covered with a synthetic material, the relative air humidity should be at least 30%.
Quick transient electrical interference/bursts according to IEC 61000-4-4	± 2 kV for AC power lines ± 1 kV for input and output lines	± 2 kV for AC power lines	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	± 1 kV normal mode voltage ± 2 kV common mode voltage	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 of U_T) for ½ period 40 % U_T (60 % dip of U_T) for 5 periods 70 % U_T (30 % dip of U_T) for 25 periods < 5 % U_T (>95 % dip of U_T) for 5 seconds	< 5 % U_T (>95 % dip of U_T) for ½ period 40 % U_T (60 % dip of U_T) for 5 periods 70 % U_T (30 % dip of U_T) for 25 periods < 5 % U_T (>95 % dip of U_T) for 5 seconds	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.
COMMENT U_T is the a.c. supply voltage before applying the impulse test levels.			

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

Interference resistance tests	IEC 60601 impulse test level	Conformance level	Electromagnetic environment code of practice
Conducted HF interference according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz outside the ISM bands	3 V	Portable and mobile radio transceivers should not be used closer to the PRIMEDIC™ HeartSave, including its cables, than the recommended protective distance which is calculated according to the equation applicable to transmission frequencies. Recommended protective distance $d = 1{,}2\sqrt{P}$ $d = 4\sqrt{P}$ $d = 0{,}6\sqrt{P}$ 80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$ 800 MHz to 2.5 GHz With *P* as the maximum power rating of the transmitter in Watts (W) in accordance with information provided by the manufacturer of the transmitter and *d* as the recommended protective distance in metres (m).[b] The field strength of stationary radio transmitters should be less that the conformance level for all frequencies in accordance with an inspection on location.[d] Interference is possible in the vicinity of devices which have the following pictogram. 
	10 V_{eff} 150 kHz to 80 MHz in the ISM bands	3 V	
Radiated HF interference according to IEC 61000-4-3	10 V_{eff} 80 MHz to 2.5 GHz	20 V/m	

COMMENT 1 At 80 MHz and 800 MHz the higher frequency range is applicable.

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

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

[b] The 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 protective distances in these frequency ranges.

[c] The field strength of stationary transmitters, such as base stations of wireless telephones and mobile field radio transmitters, amateur radio stations, AM and FM radio and television transmitters can theoretically not be precisely determined in advance. To determine the electromagnetic environment with regards to the stationary transmitters, a study of the location should be considered. If the field strength 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.

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

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

The PRIMEDIC™ HeartSave family 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 in W	**Protective distance depends on the transmission frequency m**			
	150 kHz to 80 MHz outside the ISM bands $d = 1{,}2\sqrt{P}$	150 kHz to 80 MHz in the ISM bands $d = 4\sqrt{P}$	80 MHz to 800 MHz $d = 0{,}6\sqrt{P}$	800 MHz to 2.5 GHz $d = 1{,}2\sqrt{P}$
0.01	0.12	0.4	0.06	0.12
0.1	0.37	1.26	0.19	0.36
1	1.17	4.00	0.60	1.15
10	3.69	12.65	1.90	3.64
100	11.67	40.00	6.00	11.50

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.

COMMENT 1 At 80 MHz and 800 MHz the higher frequency range is applicable.

COMMENT 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.

COMMENT 3 The conformance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency band of 80 MHz and 2.5 GHz are defined to reduce the probability that mobile/portable communication devices can cause interference, if they are unintentionally brought into the vicinity of the patient. For this reason, the additional factor of 10/3 is applied when calculating the recommended protective distances in these frequency ranges.

COMMENT 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.

15 Safety checks

In accordance with the Ordinance on the Operation and Use of Medical Devices (MPBetreibV) § 6 (Safety checks) the user is obliged to have regular checks carried out. In accordance with the Ordinance on the Operation and Use of Medical Devices (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 defects are found during a safety check which could endanger

patients, device users or third parties, in accordance with the Ordinance on the Operation and Use of Medical Devices (MPBetreibV) § 3, the operator must immediately inform the responsible authority.

In the medical products log to be kept in accordance with the Ordinance on the Operation and Use of Medical Devices (MPBetreibV) § 7, the following data is to entered:

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

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

To always be able to keep the records up to date, you will find our STK test reports on the Internet at

www.primedic.de

in the area "Service."

16 Index of diagrams

17 Use of devices on ships

17.1 Use of PRIMEDIC™ HeartSave devices **with PRIMEDIC™ Battery** on merchant navy ships:

The use of **PRIMEDIC™ HeartSave** devices like

PRIMEDIC ™ HeartSave PAD (M250),
PRIMEDIC ™ HeartSave AED (M250),
PRIMEDIC ™ HeartSave AED-M (M250),
PRIMEDIC ™ HeartSave 6 (M250),
PRIMEDIC ™ HeartSave 6S (M250)

with the power supply module

PRIMEDIC™ Battery 15VDC 2,8Ah LiMnO4

meet the EMC requirements of “Bridge and open deck zone” according to “Guidelines for the Performance of Type Approvals” respectively “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.

17.2 Use of PRIMEDIC™ HeartSave devices **with PRIMEDIC™ AkuPak** on merchant navy ships:

PRIMEDIC™ HeartSave devices have been EMC tested together with a PRIMEDIC™ Battery to fulfill the “Test Requirements for Electrical / Electronic Equipment and Systems” of ”Germanischer Lloyd,” 2003.

As the “**PRIMEDIC™ AkuPak 12VDC 1,2Ah NiCd**” behaves as the “PRIMEDIC™ Battery” during supply of PRIMEDIC™ HeartSave (M250) devices, the experience of the all EMC tests results can be transferred to the combinations PRIMEDIC™ AkuPak / PRIMEDIC™ HeartSave (M250) devices.

These combinations meet the EMC requirements of “Bridge and open deck zone” during supply operation.

The recharging of PRIMEDIC™ AkuPak requires PRIMEDIC™ PowerPak as a charging device.

Recharging must be executed in a dry room which is separated from the “Bridge and open deck zone” by metal shielding.

The device combination will meet the EMC levels of “General Power distribution zone” during charging and charging parallel operation in any case.

Contact details

METRAX GmbH
Rheinwaldstr. 22
D-78628 Rottweil

Phone: +49 (0) 741/257-0
Email: sales@primedic.de
Web: www.primedic.de

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 program 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.

Your dealers

Headquarter/Manufacturing:

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

METRAX GmbH
Shanghai Rep. Office
Unit B, 11/F First Trade Tower
No.985 Dongfang Road,
Pudong New Area
Shanghai 200122
China
Tel.: +86 21 632846-66
Fax: +86 21 633656-90
sro@metraxchina.com

METRAX GmbH
India Rep. Office
B-1, Lower Grownd Floor,
Growne Palza Surya
New Friends Colony
New Delhi - 110065
Indien
Tel.: +91 11 26841741
Fax: +91 11 26841742
sales@metraxindia.com

METRAX GmbH
Moskau Rep. Office
Ul. Vavilowa 5, corpus 3
119334 Moskau
Russland
Tel.: +7 95 23170-61
Fax: +7 95 23170-62
info@metrax.ru