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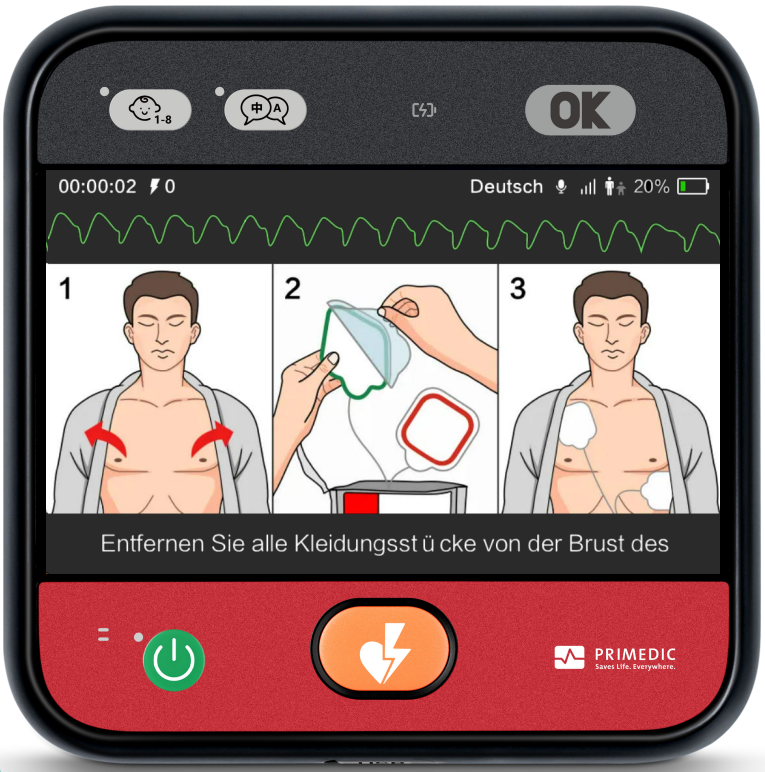

Automated External Defibrillator
Instructions for use

HeartSave **myPAD**

English

24548 EN
Revision: F
Date of issue: 07/2025

Masthead

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These instructions for use may be changed by the manufacturer without prior notice.

Contents

1 Glossary

Term / abbreviation	Description
AED	Automated external defibrillator
AHA	American Heart Association
Biphasic impulse	Current flow direction of defibrillator changes during shock delivery
BLS	Basic resuscitation measures
BPM	Beats per minutes
CPR	Cardiopulmonary Resuscitation
ECG	Electrocardiogram
EMC	Electromagnetic Compatibility
ERC Guidelines	European Resuscitation Council on Cardiopulmonary Resuscitation (CPR)
EU	European Union
LCD	Liquid Crystal Display
MDR	Medical Device Regulation (EU) 2017/745
MPDG	Medical Devices Implementation Act
MIT	Massachusetts Institute of Technology
MPBetreibV	Medical Device Operator Ordinance
Patient impedance	Patient resistance between the electrodes
USB	Universal Serial Bus

2 Introduction

2.1 Foreword

Dear User,
You might need to use the HeartSave myPAD on human beings in a medical emergency.
So that you react quickly and properly in these special circumstances and make optimal use of the opportunity the device provides you with, we recommend that you take your time carefully to read through these instructions for use beforehand, thus familiarising yourself with the device, its functions and applications.
Keep these instructions for use near the device so that you consult them for any queries which might arise.
If you have any questions regarding the start-up, use or maintenance of the HeartSave myPAD, please do not hesitate to contact us.

In case of unexpected device behaviour or events, please contact us.

Serious incidents related to the defibrillator must be reported. If the defibrillator has not performed as expected, contact the manufacturer and the appropriate local authority.
A "serious incident" means an event that has had, could have had, or may have had, directly or indirectly, any of the following consequences such as
• the death of a patient, user or other person
• the temporary or permanent serious deterioration of the health status of a patient, user or other person
• a serious risk to public health.

You will find our contact address on the masthead.

The instructions given on the device are no substitute for reading this instruction for use.

2.2 Validity

The descriptions in these operating instructions refer to the HeartSave myPAD series automated external defibrillator device made by Metrax GmbH. The HeartSave myPAD series automated external defibrillator is referred to as HeartSave in the following operating instructions.

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

2.3 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:

- Use of the device outside its intended purpose or indications for use.
- Failure to comply with operating instructions, safety guidelines, or maintenance procedures.
- Operation of the device with protective covers removed, or when cables/electrodes are visibly damaged.
- Unauthorized repairs, modifications, or third-party components that are not approved by the manufacturer.
- Use of non-certified accessories or consumables.
- Failure to conduct regular inspections on components subject to wear and tear.

2.4 Symbols used in these instructions

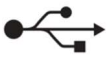
DANGER	Texts marked DANGER indicate an extraordinarily serious, current danger which will definitely lead to serious injury or even death if no preventative measures are adopted.
WARNING	Texts marked WARNING indicate extraordinarily serious, possible dangers which, should no preventative measures be taken, may lead to serious injury or even death.
CAUTION	Texts marked with CAUTION indicate a possible dangerous situation which could lead to minor injuries.
ATTENTION	Texts marked with ATTENTION indicate possible property damage.

NOTE	This symbol indicates text which contains important advice, comments or tips.

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

▶	First instruction
▶	Second instruction
▶	etc.
•	This line marks lists
(3)	Numbers in brackets refer to items in diagrams.
< ... >	Texts set in angle brackets denote acoustic information / instructions for the device

2.5 Pictograms

		Device Pictograms	Battery pictograms	Electrodes pictograms	Package pictograms
	Dangerous voltage	●			
	Defibrillation-proof type BF applied part	●			
	General warning sign	●	●		
IP66	IP66 water and dust resistance	●			
	No dispose of product in domestic refuse	●	●		
	Consult instructions for use	●			
CE 0123	The product bears CE mark indicating that it complies with the requirements of the Medical Device Regulation (EU) 2017/745.	●			●
	Manufacturer	●	●	●	●
	Manufacturing Date	●	●		●
SN	Serial number	●	●		●
	Non-ionizing electromagnetic radiation	●			
UDI	Unique device identifier	●	●	●	●
MD	Medical device	●			●
	Universal Serial Bus (USB) port	●			
LOT	Batch code	●			
REF	Article number	●			
	Battery charging status (re-chargeable battery only)	●			

	WLAN network	●			
	LTE network	●			
	Bluetooth connection	●			
	Protect battery from fire.		●		
	Do not disassemble.		●		
	Do not charge the battery		●		
	Recyclable		●		
	The product bears CE mark indicating that it complies with the requirements of the Medical Device Regulation (EU) 2017/745.		●	●	
	Expire date		●	●	
	Refer to instruction manual/booklet.		●	●	
	Latex free			●	
	Can be used a maximum for 24 hours after opening			●	
	Do not use if package is damaged			●	
	Do not re-use			●	
	Do not bend or fold the electrodes			●	
	Keep away from sunlight			●	
	Keep dry			●	
	Non-sterile product			●	
	Defibrillation-proof type BF applied part			●	
	Maximum number of defibrillation shocks up to 50 times			●	

EC REP	Authorised representative in the European community			●	
	Permissible temperature range in °C				●
	Permissible air humidity range in %				●
	Permissible air pressure specification in hPa				●
	Class 9 Miscellaneous dangerous substances and articles				●
 UN 3481	UN3481 lithium ion battery warning label				●

3 Intended purpose

Devices are designed to be used in case of suspected sudden cardiac arrest, to guide the operator to start resuscitation, to analyse victim's ECG, to deliver defibrillation therapy through self-adhesive electrodes in case of a shockable rhythm and to guide the operator to perform cardiopulmonary resuscitation.

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

DANGER	**Warning: physical harm** Risk of heart arrhythmia which may lead to death ➢ Only use the device as intended **Don't use the device on children aged under 1 year**
CAUTION	In an emergency case the device can operate for at least 20 minutes under -20 °C if device is stored before in terms of storage condition.

3.1 Medical indication

Devices are intended for treatment of victims of cardiac arrest. Victims of cardiac arrest exhibit the following symptoms:

- Unconsciousness
- Absence of normal breathing

3.2 Medical contraindication

Devices should not be used if the patient shows signs of life. Signs of life are:

- Consciousness
- Breathing

3.3 Intended patient group

Devices can be used to treat patients with an age of more than one year.

3.4 Applicable body part

Electrodes are attached to the adult patient's chest in anterior-lateral position. Electrodes are attached to the paediatric patient's chest in anterior-posterior position.

CPR feedback sensor is applied to the patient's chest, between nipples.

3.5 Intended use environment

Devices will be used to provide life support at the scene of an emergency to a PATIENT in a pre-hospital setting. For intended use environment see Appendix D.

Devices are classified as "transportable" according to IEC 60601-1 and can be transported by road ambulances.

3.6 Intended user profile

- Layperson trained in first aid with AED
- Layperson trained in basic or advanced life support
- Qualified medical personnel trained in resuscitation

NOTE	This device can and may be used in an emergency by untrained laypersons if necessary to save a human life.

3.7 Clinical benefit

Helps early defibrillation and improves survival for individual with sudden cardiac arrest.

4 Safety information

4.1 General safety advice

HeartSave myPAD fulfil the currently applicable safety standards and complies with the provisions of the medical products regulations.

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

If HeartSave myPAD used incorrectly, the device and its accessories can be dangerous to the user, the patient or third parties.

DANGER	The device should 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. Always check the environment condition during usage of the device.

NOTE	Take care of the ambient conditions in the technical specifications when storing and operating the device. Always follow the prompts issued by the device.
NOTE	The device will take approximately 1 hour to ready for intended purpose when device is stored under minimum storage temperature (-30°C) or maximum storage temperature (70°C).

WARNING	Keep the device away from children.

4.2 Safety notes for the user

WARNING	Before using the device, ensure the environment temperature is in the range of operating temperature specification. Do not apply the device if it is defect or visible damaged (e.g. damage of cables or housing of the device)

4.3 Safety notes for the protection of patient

DANGER	**To use the device on a patient, you must:** ➢ Use new, undamaged, and unexpired electrodes for every patient to avoid any possible burns to the skin. ➢ Only connect SavePads electrodes to the device. ➢ Do not use the device close or near to other sensitive equipment (e.g. some measuring equipment are always sensitive to magnetic fields) or strong sources of interference. Keep a sufficient distance away from other energy sources (e.g. microwave oven, induction stove, etc.). **These equipments may cause the device not working properly or doesn't work. Please make sure to disconnect all other devices from the patient before defibrillation**. ➢ Place electrodes precisely according to graphic guidance. ➢ In patients with an implantable device, place the pad > 8 cm away from the device, or use an alternative pad position. ➢ Do not touch the patient during ECG analysis. ➢ Stop CPR during ECG analysis.

WARNING	**Be aware of the electrodes cable:** Do not place cables around patient neck to avoid asphyxiation.

Potential side effect: Be aware of shock energy - AED defibrillation works by depolarizing the cardiac muscle with electric current. To achieve the intended purpose, AEDs need to release a large amount of electrical energy. This electrical energy can potentially lead to myocardial damage.

4.4 Safety notes for the protection of third parties

DANGER	Warning surrounding people loudly and clearly before defibrillation to make sure they have no contact with the patient.

4.5 Safety notes for the protection of device

WARNING	Repair and installation of the device should be carried out by professional authorized persons only. Use original accessories from the manufacturer only.

5 Description of device

5.1 General description

The device is an automated external defibrillator (AED) with an integrated single channel ECG.

The ECG is recorded via the electrodes. When a rhythm requiring defibrillation is detected, the device provides a shock to restore the heart rhythm.

There are two type of product models provided: semi-automated and fully-automated.

Characteristics of models are detailed in the following table.

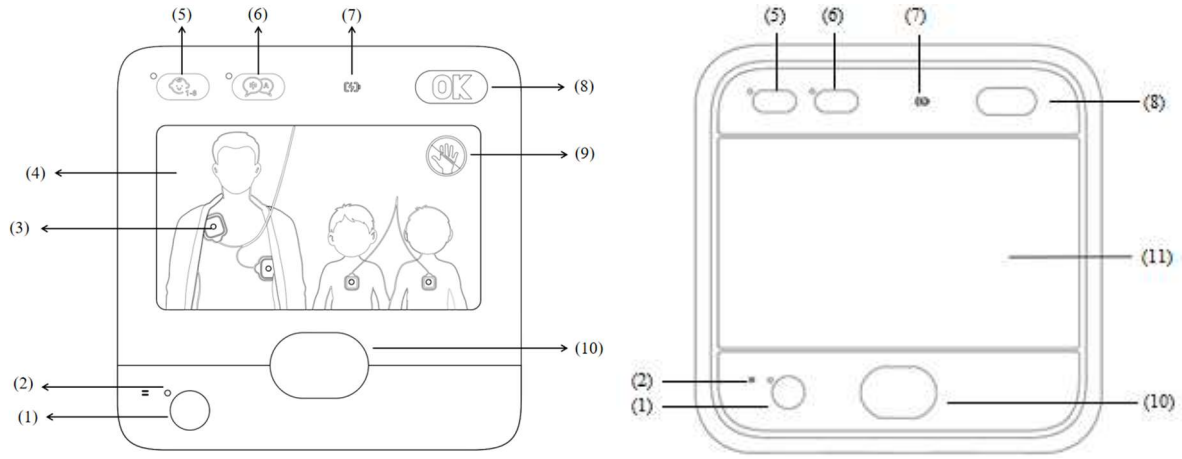
Defibrillation Mode	Model	Shock Button	LCD screen	Touch Screen
HeartSave myPAD Semi-automated external defibrillator	670	YES	NO	NO
	671		NO	NO
	675		YES	NO
	678		YES	YES

Defibrillation Mode	Model	Shock Button	LCD screen	Touch Screen
HeartSave myPAD Fully-automated external defibrillator	670A	NO	NO	NO
	671A		NO	NO
	675A		YES	NO
	678A		YES	YES

HeartSave myPAD is operated using a battery and electrodes. Check chapter 5.2 for detailed information.

HeartSave myPAD is designed to be safe and quick to use for emergency. The power supply of device comes from a non-rechargeable (BATTERY 3C) or rechargeable (BATTERY 3G, optional) lithium battery.

5.2 Device description



myPAD with Graphic LED

myPAD with LCD-Display

Fig. 1 Front view

(1) On/Off switch

(2) Device operation indicator

When indicator is green: device switched on as ready for operation

(3) Electrodes placing indicator

(4) Electrodes placing guidance

(5) Child button

(6) Language button

(7) Charging indicator (only for re-chargeable battery)

When battery is low, charging indicator blinks red.

When battery is charging, indicator blinks yellowish green.

When battery capacity is ready for operation or fully charged, indicator displays yellowish green without blinking.

(8) Status display

(9) No touching patient indicator

(10) Shock button (only for semi-automated device)

(11) LCD display / Touch display (if available)

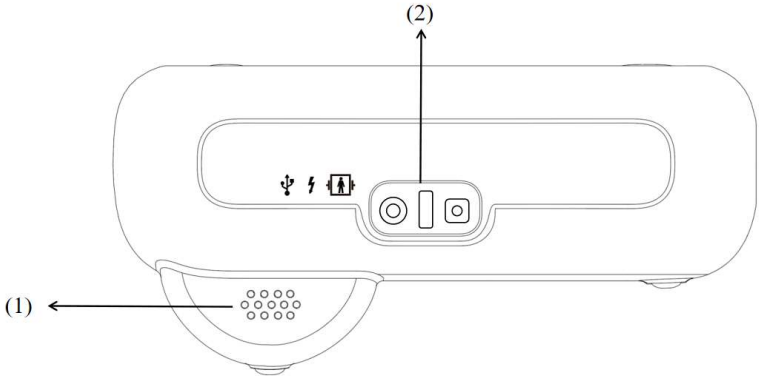


Fig. 2 Left Side View

(1) Loudspeaker
(2) Electrodes socket (with USB type C for data transmission and firmware update)

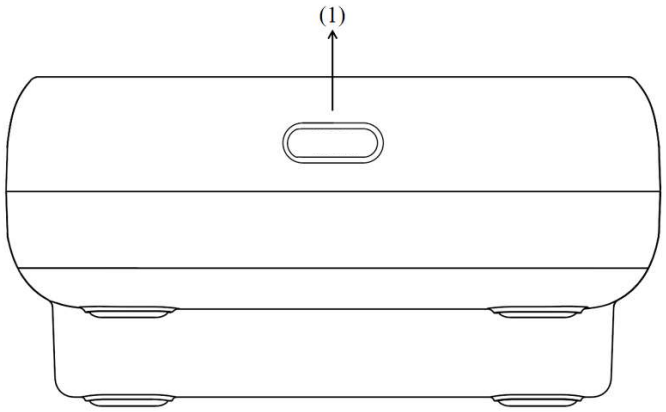


Fig. 3 Front Side View

(1) Charging socket

5.3 Status display

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

Display	Meaning	Action to be taken
	Normal status	Device ready to use.
	Indication of a possible error or during self-test	- Device may be ready for use in an emergency. - Nearly time to replace battery. - Insert the battery. - Plugin electrodes. - Renew electrodes. - In case of an internal error, contact the service department.

The following indications of a possible error may be responsible for the "X" in the status display.

Reason	Possible to use?	Steps
Electrodes not connected	Yes, device is ready for use.	Connect the electrodes for use of the device.
Battery almost empty	Yes, device possible to release at least 6 shocks of 200J.	Indication of battery low by voice prompt. The device could be used until battery empty.
Battery empty	No, device is not ready for use.	Indication of the empty battery by voice prompt. The device will automatically shut down.
Internal error	No, device is not ready for use.	Indication of an internal error by voice prompt. The device will automatically shut down.

NOTE In case of low battery and status display shows

a warning prompt when the device is switched on and the following voice prompt is issued:

< Battery low. Please replace if possible. Continue to use the device if no replacement available >

5.4 Display content

This chapter describes display content for models with LCD display or touch display.

5.4.1 Defibrillation indication

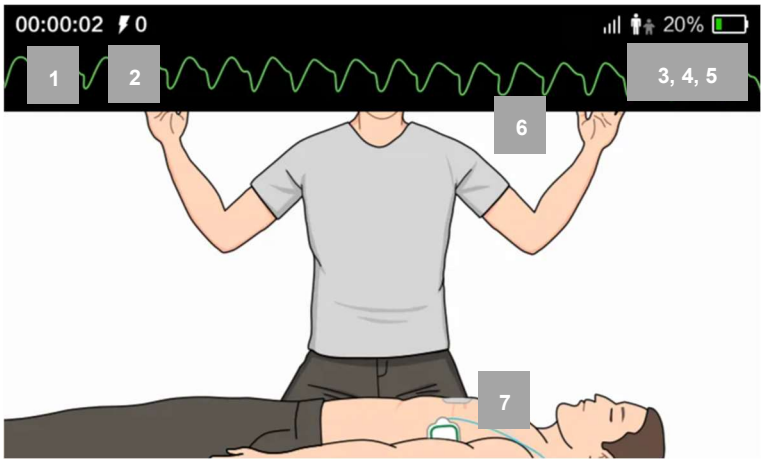


Fig. 4 LCD display during defibrillation

(1) System operation duration
(2) Shock quantity
(3) Network status
- WLAN connected (only for WLAN equipped device)
- LTE connected (only for LTE equipped device)
- Bluetooth connected (only for Bluetooth equipped device)

(4) Adult/child mode
(5) Battery capacity indicator (see chapter 5.4.5 for details)
(6) ECG waveform animation
(7) Operation guidance

5.4.2 CPR guidance display

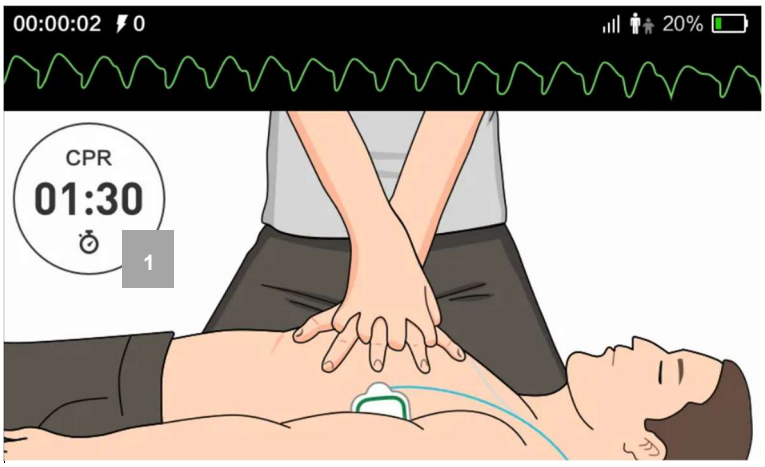


Fig. 5 LCD display during CPR

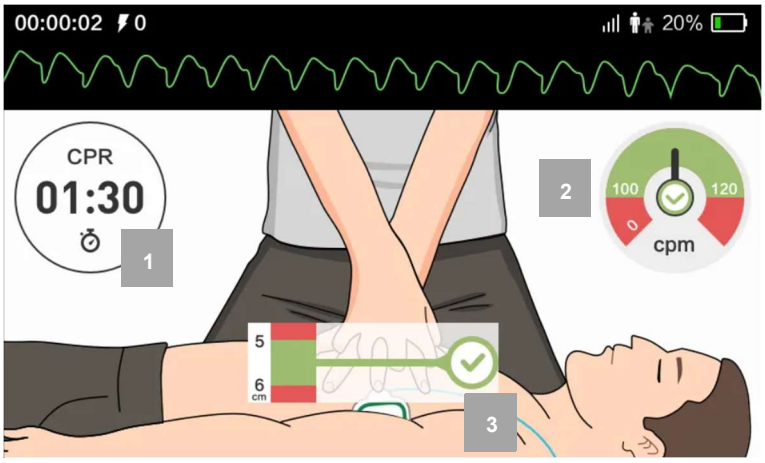


Fig. 6 LCD display during CPR with CPR feedback sensor

(1) CPR remain time
(2) CPR frequency indication (only for electrodes with CPR sensor. Recommended as 100 to 120cpm, cpm: compression per minute)
(3) CPR depth indication (only for electrodes with CPR sensor. Recommended as 5 to 6cm)

For more detailed CPR feedback sensor information, please refer to Chapter 7.7.5

Indication	Meaning	Action to be taken
	Battery capacity full	Battery ready to use
	Battery capacity 20%-100%	Battery ready to use
	Battery capacity 10%-19%	Change/charge battery if possible
	Battery capacity 0%-9%	Change/charge battery immediately

6 Device preparation

6.1 Unpacking

When you receive the delivery of the package, check if no damage of the packaging, and all components are included.

In case of any damage of products, please contact your logistic supplier, dealer or authorized distributor. Provide serial number and description of damage in case of necessary.

6.2 Prepare electrodes when replacing

When replace new electrodes, they must be reconnected to the device with the following steps.

Fig. 7 Connect electrodes to the device

Installation steps:

- ▶ Check the expire date of the electrodes. Do not use expired electrodes.
- ▶ Insert the electrodes plug into the socket. (If not connected)

6.3 Prepare the battery when replacing

The power supply of the device comes from a non-rechargeable or rechargeable lithium battery.

6.3.1 Battery safety information

WARNING	➢ Do not use broken or over discharged batteries on device.

ATTENTION	➢ Check battery expire date regularly. ➢ Always make sure the battery is ready for next usage, replace if battery low (BATTERY 3C) or charge the battery (BATTERY 3G).

Keep documents enclosed with the battery and follow the operating instruction for safety and further potential checks.

6.3.2 Battery removal

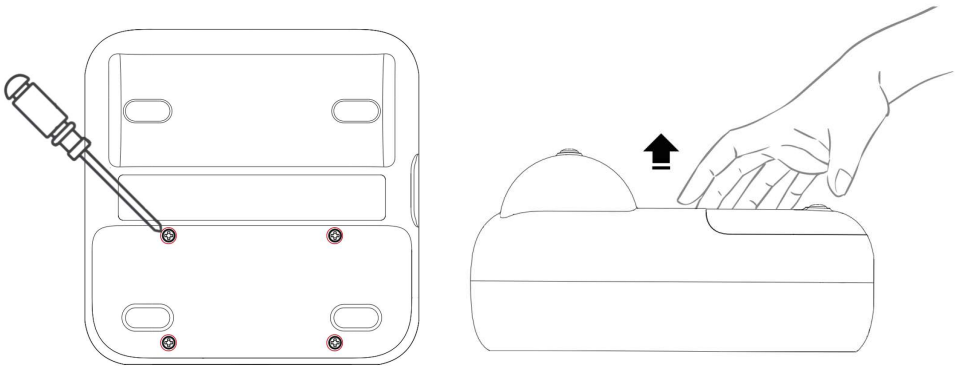


Fig. 8 Removing the battery

When maintenance of battery or SIM card is required, battery must be removed with following steps.

Steps:

- Put the device top down on a flat surface.
- Use Phillips (PH1) screwdriver to remove 4 screws from the battery.
- Pull the battery with the direction of the arrow out of the slot slightly.

6.3.3 Remove battery seal

The new battery is attached with battery seal for transportation. Remove the yellow seal from battery before use.

6.3.4 Battery insertion

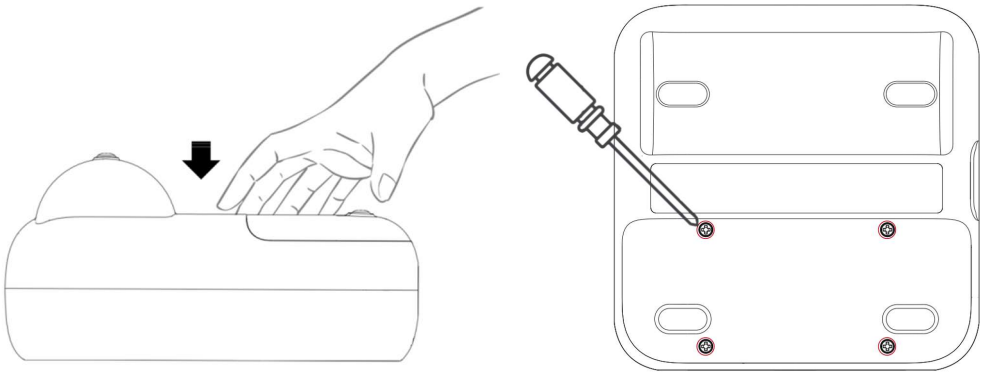


Fig. 9 Insert the battery

Steps:

- Put the device top down on a soft flat surface.
- Place the (new) battery in the direction of the arrow into the device until it reaches its end position as shown in the diagram.
- Tight 4 screws with Phillips (PH1) screwdriver until fully fixed.
- When battery inserted, device will start a self-test after 1 minute. Follow the voice prompts to finish the self-test of device.
- When self-test finished without “X” from status display, device is ready for use.

ATTENTION	**Status display may show “X” after battery insertion** ➢ If status display does not show 'OK', follow the steps below: (1) Remove and assemble the battery OR switch on the device again (2) Repeat a device self-test.

6.3.5 Battery capacity alert

⚠ **WARNING**	When you hear **< Battery low. Please replace if possible >** at least 6 shocks (max. energy) could be delivered. But please replace the battery or charge the rechargeable battery (BATTERY 3G only). If battery not charged or replaced, this voice prompt is also repeated by end of every CPR cycle.

6.3.6 Battery storage

We suggest to store the device with battery inserted in and keep device standby.

HINWEIS	We recommend the storage of device and battery with temperature between 15°C and 35°C for expected lifetime.

6.3.7 BATTERY 3G maintenance and exchange

When battery disassembled from a device and not use for a long time, we recommend you charging the battery at least once a month to keep better battery health.

6.3.8 BATTERY 3G charging

We recommend charging the battery in following cases:

- ► After each use
- ► When the charging indicator blinks red
- ► When you hear the voice prompt **< Battery low. Please replace if possible >**

Please use only the supplied charging adapter.

Connect the adapter to charging socket in Fig. 3. The indicator on the front upper side of the device will show green light. Recap the charging socket when device charging finished.

6.4 Self-test

The device status is indicated via status display with following conditions.

Device status		Status display
Device normal	Device is ready for use	
Device abnormal	Electrodes expired	
	Electrodes error	
	Electrodes plug not inserted	
	Battery not installed	
	Battery low	
	Battery error	
	Device error	

6.4.1 Self-test when device switched on

When you press power button to switch on device, it performs a quick self-test to check all main functions and modules.

Self-test category	Self-test content
Self-test when device switched on	main control module, internal power module, electrodes, therapy module

6.4.2 Battery insertion self-test

When battery installed, the device will perform a manual self-test after 1 minute of installation.

Self-test category	Self-test content
Battery insertion self-test	main control module, battery, internal power module, electrodes, therapy module, max. energy charge and discharge, speaker, buttons, network module, Bluetooth module

6.4.3 Periodic automatic self-tests

The device carries out periodic self-tests to ensure the device always ready for use.

Self-test category	Self-test content
Daily/Weekly*	main control module, battery, internal power module, electrodes, therapy module, network module

Monthly** (First day of each month)	main control module, battery, internal power module, electrodes, therapy module, network module, 50J charge and discharge, speaker, Bluetooth module, temperature
Half year** (First day of January and July)	main control module, battery, internal power module, electrodes, therapy module, network module, max. energy charge and discharge, speaker, Bluetooth module, temperature

* The daily/weekly self-test is set to “05:00 a.m.” of the time zone on the test day. The self-test time could be configured to other time of the day. To change daily or weekly self-test, contact your distributor or Metrax.

** The monthly and half year self-test date could be modified. To change the date, contact your distributor or Metrax.

NOTE	The device is not able to perform automatic time zone update. To change time zone setting, please contact your distributor or Metrax.

NOTE	Periodical maintenance and safety test is not required, and the device is equipped with periodic self-tests function. Users are advised to follow the local regulation.

6.4.4 Device status internal monitoring

The device continuously perform internal monitoring of functions and safety. In case of any fatal error or malfunction of the device, the status display will show "X" and prompts a signal tone regularly. Please check the device status display from time to time.

NOTE	Under some circumstances this “X” might present temporarily or could be reversible. In these cases, you could use battery insertion to perform self-test to fix. If it is helpful, you can continue to use the devices. If it is not helpful, please contact our customer service department for help.

6.5 Language button

To select the language of voice prompts, press the language button during operation. The device optionally supports up to 6 languages. When press language button, the current language is briefly announced via voice. For LCD/touch display devices, a language indication also displayed on the screen.

7 Use device

NOTE	The therapy procedure of the device is applied according to the recommended guidelines of European Resuscitation Council

DANGER	**Warning: explosion** Risk of burns ➢ Do not use the device in potentially explosive areas. ➢ Do not use the device in oxygen-enriched atmospheres. ➢ Do not use the device close to flammable materials.

WARNING	**Warning: physical harm** Risk of skin burns ➢ Remove hair at the electrodes placing area. ➢ Where necessary, dry the skin before attaching the electrodes.

7.1 Examining and preparing the patient

Check to see whether the patient is unconscious and is not breathing as usual. Do following steps:

- ▶ Close up and call patient with tapping shoulder to check the consciousness
- ▶ If patient does not respond, check any sign of breathing. If necessary, check the airway for respiration.
- ▶ Call emergency services
- ▶ Start chest compressions and get a defibrillator. If a defibrillator is available, turn it on and follow the instructions.

Remove clothes from chest area and attach electrodes. In case of chest hair covered, use provided razor to remove hair for electrodes attached position.

- ▶ In case of skin is wet, dry skin with provided towel from accessory kit.
- ▶ If the chest has any lint, dust or dirt on, clean with provided towel before attach electrodes

7.2 Check the patient category

The device is intended to be used for adults or children. For patient younger than 8 years old or weight less than 25 kg, please use child mode of the device.

NOTE	Patient therapy should not be delayed in case of determine the precise age or weight of the patient.

7.3 Switching on device

To switch on the device, press the power button. The device can deliver a defibrillation shock only when detects a shockable cardiac rhythm.

When device is switched on, the following prompts are issued:

< Power on >

< Call emergency services >

< Apply electrodes as shown >

When electrodes connected to the device and pads are attached to patient, following prompts are issued:

< Power on >

< Call emergency services >

< Analysing rhythm, don't touch the patient >

When device is switched on, graphic on display as below together with voice prompts (only for device with display):

< Call emergency service >

Fig. 10 LCD display when device switched on (if available)

If patient is younger than 8 years or weight less than 25 kg, press child button to use child mode for therapy. When device is operating in child mode, the child button will illuminate.

Child mode is intended for defibrillation of child. This mode provides less shock energy than adult mode.

7.4 Prepare the patient

7.4.1 Removing clothes from patient

Remove clothing from the patient. If chest hair covers the skin, use the provided razor to remove the hair at the locations where the electrodes are to be placed.

7.4.2 Placing electrodes

Steps:

- ▶ Open the electrodes pouch.
- ▶ Remove the protection foil from one of the electrodes and then immediately place the electrodes onto specified position. (Refer to Fig. 13 for adults and Fig. 14 for children)
- ▶ Then remove the protection foil from the second electrodes and place onto specified position.

Press electrodes carefully to ensure good contact and no air bubbles under electrodes!

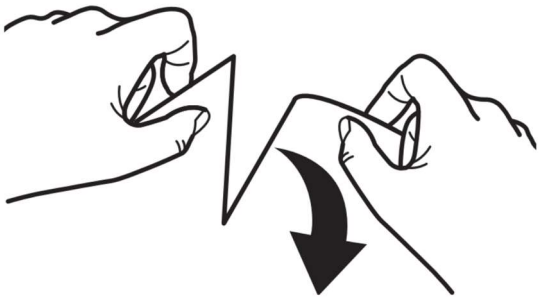


Fig. 11 Open electrodes pouch

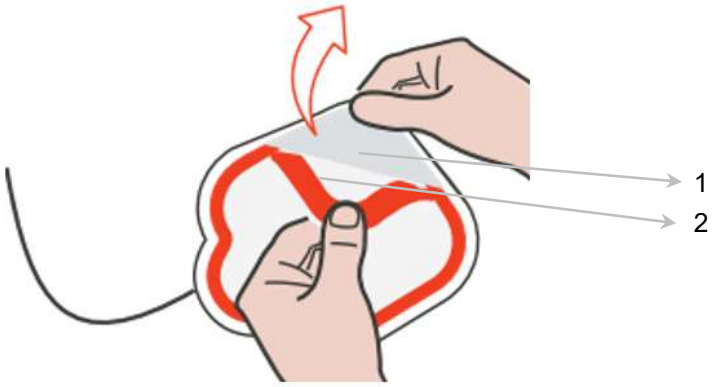


Fig. 12 Removing the foil from electrodes

(1) Protection foil of electrodes
(2) Electrodes

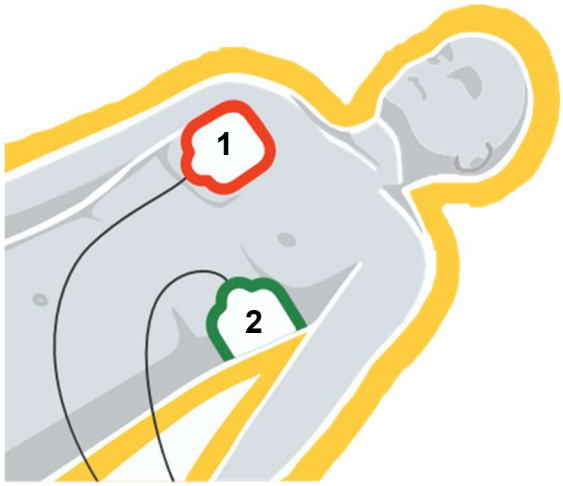


Fig. 13 Position of electrodes on adults

Red **1**: On the right chest area, below the collarbone and

Green **2**: On the left side of the chest, above the apex of the heart on the axillary line.

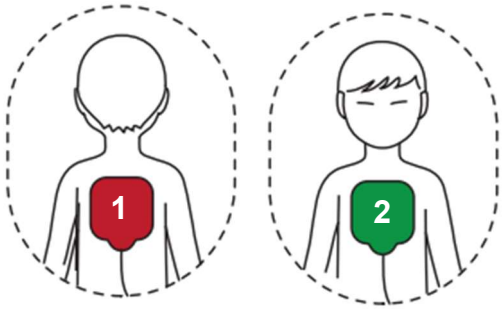


Fig. 14 Position of electrodes on children

Red **1**: on the back at the same height as the heart

Green **2**: in the middle of the chest

The device will give a voice prompt to guide you applying electrodes to the patient.

< Apply electrodes as shown >

< Remove all clothing from patient's chest, unpack electrodes and apply them to patient's bare chest as shown >

NOTE

If electrodes are not attached to the patient after several voice prompts, the device will switch to cardiopulmonary resuscitation automatically. See chapter 8 and Appendix for details.

When electrodes are well applied to patient, CPR instructions will be interrupted immediately and switch to rhythm analysis.

NOTE

The device shall use following models of electrodes for defibrillation.

Manufacture	Trade name	Model	Remark
Baisheng Medical Co., Ltd.	SavePads PLUS C	OBS-DE/P 303A1206	See Appendix A for details
	SavePads PLUS CS	OBS-DE/P 303A1207	

WARNING	**If electrodes are not well applied, ECG signal may not possible to be analysed** In this case, device will provide voice prompt: **< Apply electrodes as shown >** **Avoid damage to gel layer of electrodes** Skin burning risk ➢ Be careful not to touch gel layer before attaching electrodes to patientBe careful, gel layer damage may cause skin burning.

CAUTION	➢ Do not use expired or damaged electrodes, including damaged pouch. ➢ Check validity from expire date.

7.5 Carrying out the ECG analysis

If electrodes applied, the device will start rhythm analysis automatically.

The patient should be placed in a stable place and not be touched. The device will provide voice prompts:

< Analysing rhythm, don't touch the patient >

The device algorithm will evaluate ECG signal of patient whether defibrillation is required.

If the device detects external interference (e.g., shaking the patient, etc.) that affects ECG signal, the device voice prompts:

< Patient movement detected. Don't touch the patient. >

During the process of heart rhythm analysis, the system will first filter the original collected ECG signal to filter out the low-frequency baseline drift and high-frequency noise interference, then the system will further eliminate the possible interference in the signal including patient shaking, respiration, muscle contraction, etc.

NOTE	The ECG shown on the display is intended to identify electrode application and not for diagnosis purposes.

7.6 Defibrillation

NOTE	Shock will be delivered only when shock button lit and pressed. (for semi-automated model) Defibrillation may cause muscle contractions of the patient. When device is charged and ready for shock: • if device detects a shockable rhythm, the device won't abort defibrillation. • if device detects a non-shockable rhythm, the device will abort defibrillation process automatically.

If the device clearly identifies VF, it will recommend defibrillation. The device issues voice prompts:

myPAD semi-automated external defibrillator	myPAD fully-automated external defibrillator
< Don't touch the patient, press flashing shock button, deliver shock now >	**< Don't touch the patient, shock will be delivered in: “Three”, “Two”, “One” >**
A continuous tone and the shock button flash **"orange"**	
Press the shock button in time according to the voice instruction	**Automatically deliver a shock without requiring further action**

After shock delivered, the device will proceed with cardio-pulmonary resuscitation (CPR) guidance until next ECG analysis.

Defibrillation and CPR are repeated according to the directives of the ERC-Guidelines.

If the device can not find a shockable rhythm, then you hear:

< No shock advised >

< Safe touching patient >

< Begin CPR >

DANGER	**Danger to user or third parties** Triggering heart arrhythmia ➢ Before and during defibrillation, all resuscitation participants must stand back and avoid contact with the patient or other possible electrical conductors (e.g., stretchers).

7.7 Cardio-pulmonary resuscitation (CPR)

The device follows recommendations of 2021 ERC guidelines, which differentiate the approach to resuscitation for trained and lay rescuers. Perform chest compressions on a firm surface whenever feasible.

7.7.1 CPR for trained rescuers

The 2021 ERC guidelines recommend that trained first responders perform 2 ventilations after chest compressions. For trained first responders, different procedures are recommended for adults and children. For adults, ERC2021 recommends 30 chest compressions alternating with 2 ventilations. For children, ERC2021 recommends 15 chest compressions alternating with 2 ventilations.

In child mode, we offer different configurations of 15 to 30 chest compressions followed by 2 ventilations.. To change the configuration, please contact your dealer or our service.

< No shock advised > or **< shock released >**

< Safe touching patient >

< Begin CPR >

Adult mode	Child mode
< Give 30 chest compressions >	**< Give 15 chest compressions >**

7.7.2 CPR for lay rescuers

According to the ERC 2021 guidelines, untrained adult first responders are advised to perform continuous chest compressions only, without ventilation, during resuscitation. If the first responder has not received specific training in pediatric basic life support, the ERC 2021 guidelines recommend

either chest compressions with 2 ventilations or continuous chest compressions for children during CPR.

< No shock advised > or **< shock released >**

< Safe touching patient >
< Begin CPR >

Adult mode	Child mode
Continuous chest compression	Continuous chest compression
< Perform chest compressions for 2 minutes >	**< Perform chest compressions for 2 minutes >**
…	**…**
< 10 seconds chest compressions remaining >	**< 10 seconds chest compressions remaining >**
…	**…**
< Stop chest compression >	**< Stop chest compression >**

7.7.3 CPR configuration of the device

The default config of CPR according to chapter 7.7.1. To change the config of device as chest compressions only, as chapter 7.7.2, please contact dealer or our service.

7.7.4 CPR metronome function

During chest compressions, the device provides metronome function to guide you perform correct frequency of chest compression. Please follow the rhythm. For device config as chapter 7.7.1, the artificial respiration is also guided by two acoustic outputs.

NOTE	When a CPR cycle finished, device start another cardiac rhythm analysis.

Cardiopulmonary resuscitation (CPR) should be always performed until emergency service arrive.

7.7.5 CPR feedback sensor

This chapter only applies to the electrodes with CPR feedback sensor.

The device provides voice prompts about real-time compression feedback when connected to a CPR feedback sensor.

During chest compressions, when you use electrodes with CPR feedback sensor, the device will provide compression quality feedback in voice prompts.

NOTE	Corrective prompts about depth of chest compression are produced only for adult patients. In child mode, CPR quality feedback is disabled.

To attach the CPR feedback sensor

- ▶ Position the CPR feedback sensor so that the compression area is in the middle of the chest, between nipples.

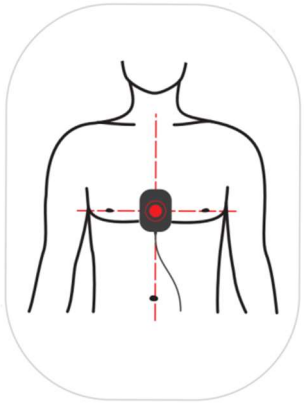


Fig. 15 CPR feedback sensor positioning

NOTE	Recommended compression frequency: 100-120 / min When compression less than 100 / min, voice prompts **< Press faster >** When compression greater than 120 / min, voice prompts **< Press slower >** Recommended compression depth for adult: 5 - 6 cm When compression depth less than 5 cm, voice prompts **< Press harder >** When compression depth greater than 6 cm, voice prompts **< Press lighter >**

7.8 After use

To switch off the device, you may

- Pressing on/off button for approx. 3 seconds. You will hear a beep accordingly.
- When device is not connected to patient for 30 minutes, it will switch off automatically

NOTE	When the device detects that electrodes are correctly applied, it will not switch off automatically.

To keep the device always ready for use, after therapy and use, please

- ▶ Check if device is damaged after each use.
- ▶ Clean the device and accessories after each use. Disinfect the device and accessories in case of infection risk, see section 13.1.
- ▶ Replace electrodes, check and replace battery if necessary.
- ▶ If any malfunctions or noticeable issues happened, please contact customer service.

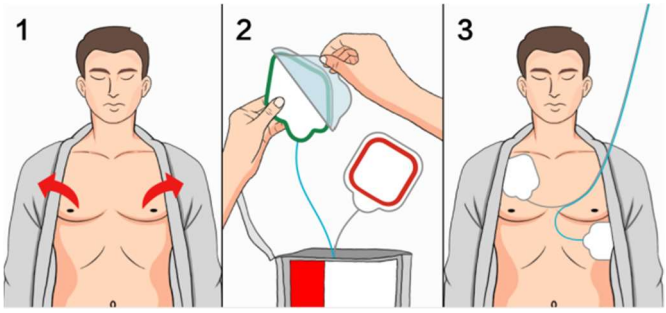
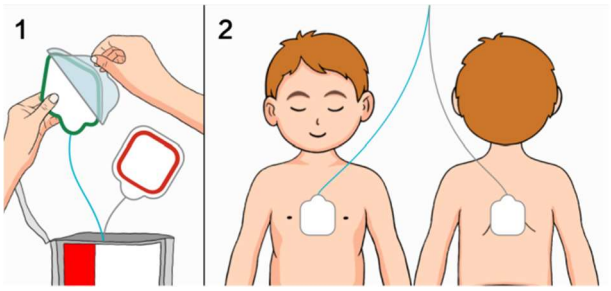
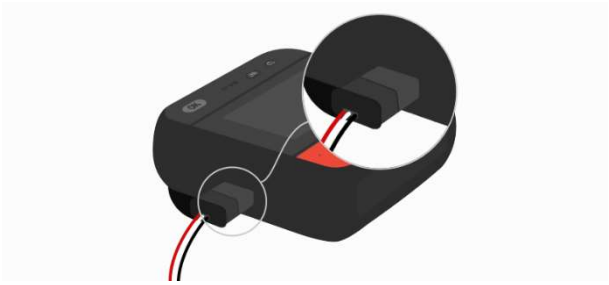
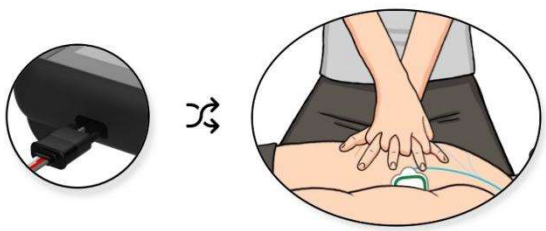
8 Additional Function

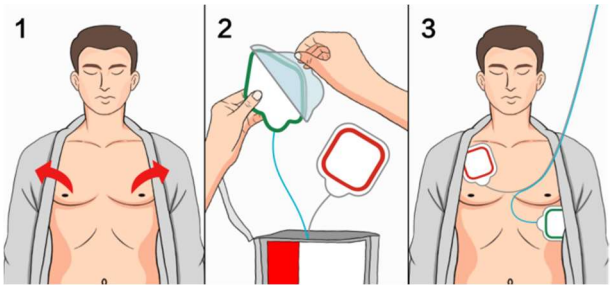
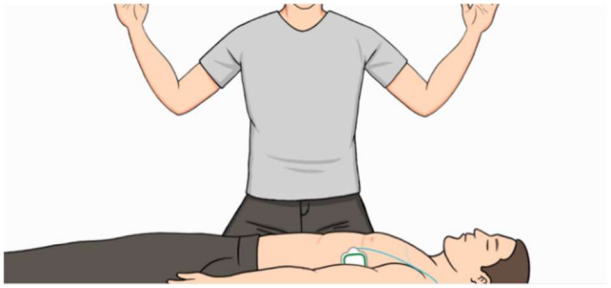
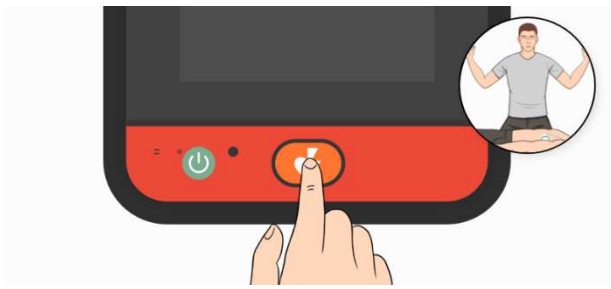
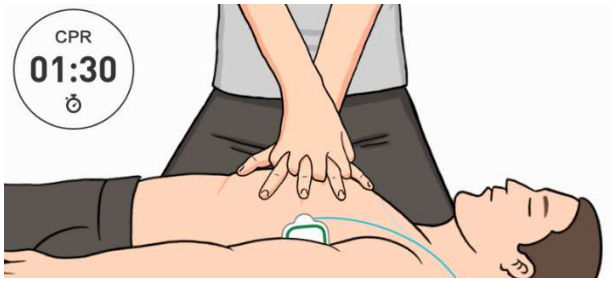
Refer to the Primedic myAED Config guidance.

NOTE	To connect your device with myAED Config APP, Bluetooth paring code is mandatory during the connection. The paring code is last 6-digit of your device serial number.

9 Voice prompts and graphic guidance

The device provides voice prompts, graphics or animation guidance (if available) during therapy for user.

Operation/Therapy	Voice prompts	Graphic guidance
Switch on device	**< Power on >** **< Call emergency services >**	
Device preparation	**< Adult mode >**	
	< Child mode >	
	< Plug in electrodes >	
	< Apply electrodes as shown >	

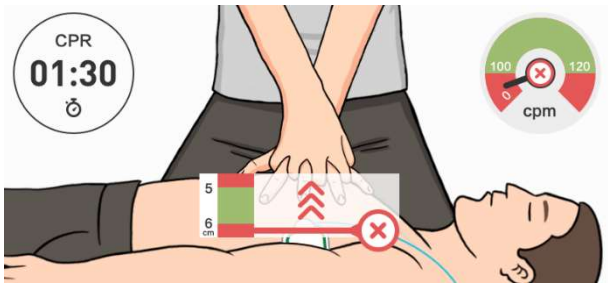
Patient preparation	**< Apply electrodes as shown >**	
Shock delivery	**< Don't touch the patient >**	
	< Analysing rhythm >	
	< Deliver shock now >	
	OR **< No Shock advised >**	
CPR	**< Begin CPR >**	
	< Give 30 chest compressions > OR **< Give 15 chest compressions >**	

< Press faster >

OR

< Press slower >

(only when compression not good when use CPR sensor)

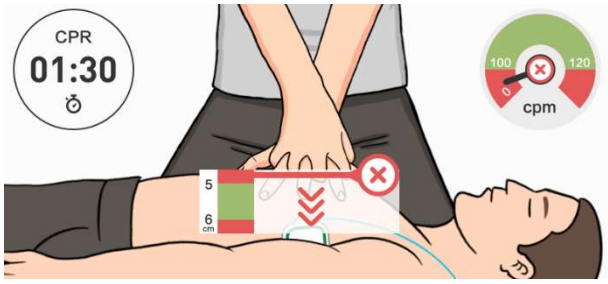


< Press lighter >

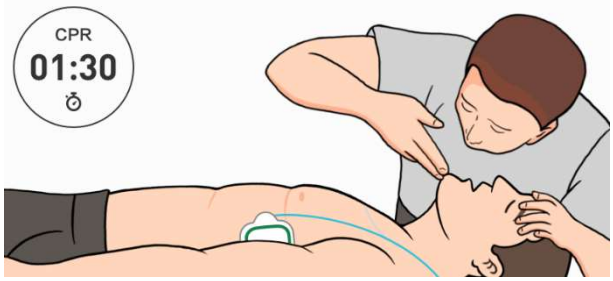
OR

< Press harder >

(only when compression not good when use CPR sensor)



< Give two rescue breaths >



10 Data management

10.1 Data storage

Device support storage following data:

Data type	Data description
System log	Serial number, software release version, total duration of operation, battery information, electrodes information, accumulated self-test quantity, last self-test result, error code if last self-test failed
Therapy log	Record ECG
	Recorded impedance
	Delivered shock data (quantity, shock energy)
	Emergency time, CPR duration
	CPR feedback sensor data (only for devices with CPR sensor)
Event log	Error event, warning event, configuration event, device status information, device analysis, CPR feedback information (only for devices with CPR sensor)
Audio log	Voice messages of the device

NOTE When the storage of device is full or the maximum number of files is reached, the oldest data will be overwritten.

10.2 Data output

The device support to export data from device to a storage device. This data may not be used for diagnostic purposes or therapy for the patient.

Follow these steps to export data from device:

- ▶ Remove the electrode plug from the electrode socket
- ▶ Plug in USB drive which includes Metrax authorized license file
- ▶ Switch on device
- ▶ The data will be exported to the USB stick automatically
- ▶ When child button backlight continuously illuminated, data successfully exported.

For more details, please contact your local distributor or manufacturer.

10.3 Device configuration

The device is configured at manufacturer or your distributor. You may also use myPrimedic Config APP to change the basic settings of the device.

NOTE	To change the configurations, please contact your local distributor or the manufacturer.

10.4 WLAN configuration

WLAN module of device is optional. The WLAN module supports device remote management and monitoring. To get support of WLAN configuration and updates, please contact customer service.

NOTE	The data transmission from device to server via WLAN is encrypted.

10.5 LTE configuration

LTE module of device is optional. The LTE module supports device remote management and monitoring. To get support of LTE configuration and updates, please contact customer service.

NOTE	The data transmission from device to server via LTE is encrypted.

11 Accessories

The accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.

⚠ **WARNING**	Use accessories specified in this chapter. The use of other accessories may cause damage to the device or not meet the claimed specifications. Single-use accessories are not designed to be reused. Reuse may cause a complication and affect the measurement accuracy.

⚠ **CAUTION**	The accessories may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If accessory performance is degraded due to aging or environmental conditions, contact authorized service personnel only.

11.1 Therapy accessories

Name	Trade name	Model	Remark
Electrodes	SavePads PLUS C	OBS-DE/P 303A1206	Defibrillation-proof applied part. Disposable electrodes for adult and child
	SavePads PLUS CS	OBS-DE/P 303A1207	

NOTE	**Lifetime of electrodes**
	All models of electrodes are valid for use for up to 48 months, plus an additional 12 months shelf life, please replace the electrodes before they expire. Electrodes are for single use and cannot be reused. Please replace the electrodes immediately after therapy.

Replacement of electrodes

NOTE	Do not open electrodes pouch during replacement!

Unplug the connector to remove used or expired electrodes, plug-in new electrodes to the device. See electrodes pouch for details of the installation.

11.2 Battery

Name	Model	Remark
BATTERY 3C	NRL03C	12V, 2.8Ah, Non-rechargeable lithium battery
BATTERY 3G	NRL03G	14.4V, 2.95Ah, Rechargeable Li-ion battery

Battery replacement

BATTERY 3C is non-rechargeable battery with standby lifetime of 48 months and 12 months shelf life, for non-rechargeable batteries, replace the battery before expire date.

BATTERY 3G is rechargeable battery with lifetime of 12 years, charge the battery at low capacity, replace the battery before expire date.

The method of battery replacement is detailed in chapter 6.

11.3 Charging adapter (only for rechargeable battery)

Applicable for rechargeable batteries (BATTERY 3G). The device should be placed at a stable position when connected to AC. To disconnect the device from the power supply, disconnect the adapter from the AC power outlet, and disconnect the adapter from the device. Be sure to plug the silicon cover back.

Name	Parameter
Adapter for rechargeable battery	Input 100-240V, 50/60Hz, Max. 0.5A Output 5.0V ⎓ 2.0A

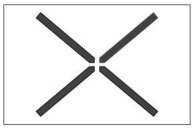
⚠ WARNING	Only use PRIMEDIC adapter for BATTERY 3G charging.

12 Troubleshooting

This section explains problems you may encounter while using the device, for information about keeping your defibrillator in a state of readiness.

Troubleshooting:

Problem	Possible cause	What to do
Unable to power on	The battery may not be inserted in the device.	Insert battery.
	The battery may be depleted	According to the 6.3 to replace a new battery

Status display 	Internal error	Remove battery and install again to restart device and execute self-test.
	The electrodes are not plugged in the AED	According to 6.2 insert the electrodes
	The electrodes are expired	Changing the electrodes
	The battery is low!	According to the 6.3 to replace a new battery
Voice instructions < **Battery low. Please replace if possible** >	Low Battery	According to the 6.3 to replace a new battery

If you encounter problems and faults that are difficult to solve or cannot be solved by yourself, please contact authorized service personnel.

12.1 Self-test by user

In case if you notice any issue or malfunction with the device, you may check by steps below:

- Remove the battery wait for at least 1 minute, then install again;
  OR
  Switch on device, then press power button **3 times** within 8 seconds from device switched on.
- Follow the voice and graphic guidance to finish the self-test
- When self-test complete, device will prompt the testing result. Please keep electrodes connected. When test passed, status display shows "OK". When test failed, status display shows "X";
- In case of “X” exists, please contact customer service.

13 Cleaning, service and disposal

13.1 Cleaning

The device should be cleaned after each use or at least annually. The cleaning frequency should be increased in areas where the environment is heavily polluted or sandy.

Validated cleaning agents are:

- Water (Drinking water quality)
- Ethanol (75%)

We recommend cleaning your device every time after each use. To clean your device, follow these rules:

1. Shut down the device.

2. Clean the Status-Display using a soft, clean cloth.

3. Clean the exterior surface of the device using a soft, clean cloth dampened with the recommended cleaning agents.

4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.

5. Dry your device in a ventilated place.

6. Visual inspection of device surface. Clean immediately if stained. The device shall keep no rusting, fading, staining after cleaning.

NOTE	If you use the device in hospital or institute, please check your agency regulations regarding device cleaning.

13.2 Servicing

We recommend performing a visual inspection of the device at least once a year to check device, electrodes, battery and all other accessories are not physically damaged.

For service questions please contact us directly under:

service@primedic.com
+49 741 257 275

13.3 Shipment of the device

Where possible, use the original box. If the original box is no longer available, use suitable packaging materials make the device fixed and well wrapped to protect the HeartSave from impact and damage.

Please hold carrying handles when transport device to an emergency place.

Pay attention to the national and international shipping regulations concerning the transport of Lithium batteries. Contact your dealer or the manufacturer for more information.

13.4 Disposal

⚠ **CAUTION**	**Warning: physical harm** Risk of acid burns ➢ Dispose the device, battery and single parts according to local regulations

Fig. 16 Disposal

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

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

Through 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 business customers in the European Union

Please contact your dealer or supplier if you want to dispose of electrical and electronic equipment.

Appendix A: Technical Data

DEFIBRILLATION

Operating modes	HeartSave myPAD Semi-automated external defibrillator HeartSave myPAD Fully-automated external defibrillator
Waveform type	Biphasic truncated exponential, auto-compensation according to patient impedance
Optional output energy	For adults: 150 J, 170 J, 200 J For children: 50 J
Default shock series	Default adult energy sequence: Level 1: 150 J Level 2: 170 J Level 3: 200 J

Default children energy sequence:

Level 1: 50 J

Level 2: 50 J

Level 3: 50 J

The energy configuration of the latter level must be greater than or equal to the energy of the previous level.

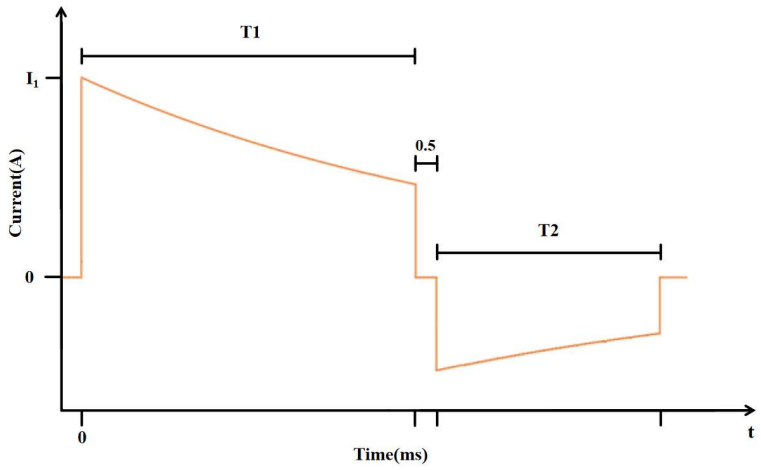
Meeting ERC guidelines 2021 and AHA guidelines 2020 by default

Delivered Energy Accuracy

Mode	Impedance / Energy	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω
Child mode	50J	43	50	52	52	52	50	48
Adult mode	150J	128	150	155	157	159	160	158
	170J	147	170	178	184	188	189	184
	200J	173	200	209	216	222	223	217

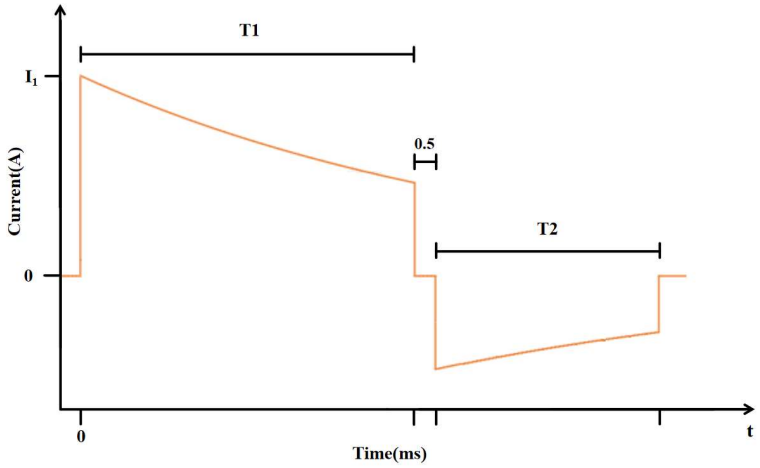
Data in J with tolerance of ±15%.

Waveform parameters (200J)



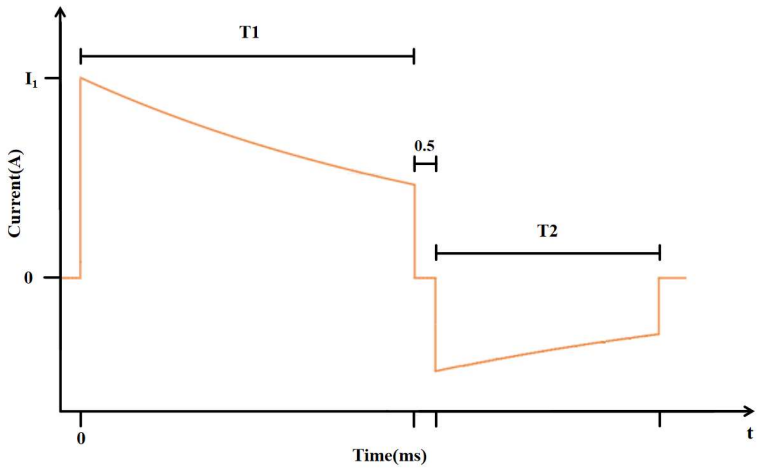
Impedance	I1/A	T1/ms	T2/ms	Energy/J
25Ω	64	2.8	2.8	173
50Ω	38	4.1	4.1	200
75Ω	27	6.3	4.3	209
100Ω	21	8.4	5.6	216
125Ω	17	10.4	7	222
150Ω	14	12	8	223
175Ω	13	12	8	217

Waveform parameters (170J)



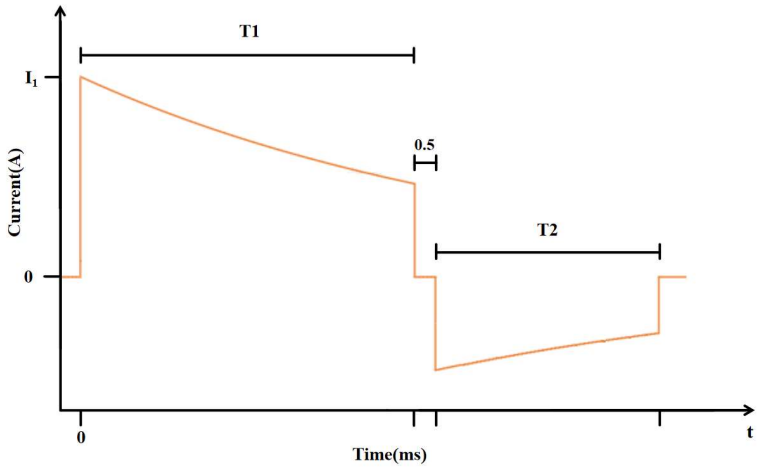
Impedance	I1/A	T1/ms	T2/ms	Energy/J
25Ω	59	2.8	2.8	147
50Ω	35	4.1	4.1	170
75Ω	25	6.3	4.3	178
100Ω	19	8.4	5.6	184
125Ω	16	10.4	7	188
150Ω	13	12	8	189
175Ω	11	12	8	184

Waveform parameters (150J)



Impedance	I1/A	T1/ms	T2/ms	Energy/J
25Ω	55	2.8	2.8	128
50Ω	32	4.5	4.5	150
75Ω	23	6.3	5.0	155
100Ω	18	8.0	5.3	157
125Ω	14	9.7	6.4	159
150Ω	12	11.5	7.7	160
175Ω	11	12.0	8.0	158

Waveform parameters (50J)



Impedance	I1/A	T1/ms	T2/ms	Energy/J
25Ω	32	2.8	2.8	43
50Ω	19	4.5	4.5	50
75Ω	13	6.3	5.0	52
100Ω	10	8.0	5.3	52
125Ω	8	9.0	6.0	52
150Ω	7	9.0	6.0	50
175Ω	6	9.0	6.0	48

Charge duration

Parameter of HeartSave for charging to first shock:
1) new BATTERY 3C
From switch on to charge 150/200 J done: no more than 17/22 s
From AED analysis to charge 150/200 J done: no more than 8/12 s
2) new BATTERY 3G
From switch on to charge 150/200 J done: no more than 13/16 s
From AED analysis to charge 150/200 J done: no more than 5/8 s
3) BATTERY 3C after 15 times of max energy discharges
From switch on to charge 150/200 J done: no more than 17/22 s
From AED analysis to charge 150/200 J done: no more than 8/12 s
4) BATTERY 3G after 15 times of max energy discharges
From switch on to charge 150/200 J done: no more than 13/16 s
From AED analysis to charge 150/200 J done: no more than 5/8 s

Applicable impedance range

25 - 200Ω

ELECTRODES

Manufacture	Baisheng Medical Co., Ltd.
Trade name and model	SavePads PLUS C OBS-DE/P 303A1206 (Adult and child without CPR feedback sensor) SavePads PLUS CS OBS-DE/P 303A1207 (Adult and child with CPR feedback sensor)
Standby life	Up to 48 months + 12 months shelf life (Standby life duration verified under environment condition of 25°C, higher ambient temperature may reduce lifetime)
Total area	117 ± 10 cm²
Effective area	86 ± 10 cm²
Cable length	1.40 ± 0.2 m
Maximum number of defibrillation shocks	50 shocks
Positioning of electrodes	Electrode placement depends on the patient's age. Refer to Section 7.5.2 for details
CPR feedback sensor	1 cable connected (for electrodes with CPR feedback sensor only)

SSCP (Summary of safety and clinical performance)	EUDAMED link preparation ongoing.

BATTERY

Model	BATTERY 3C (NRL03C) BATTERY 3G (NRL03G)
Battery type	$LiMnO_2$, 12V, 2.8Ah, non-rechargeable (NRL03C) Li-ion, 14.4V, 2.95Ah, rechargeable (NRL03G)
Standby life	BATTERY 3C: Up to 48 months + 12 months shelf life Condition: The device is powered by a new battery at 20 °C± 5 °C of ambient temperature, weekly self-test, no switch on of device, no network connection. BATTERY 3G: Up to 12 years Condition: The device is powered by a new battery at 20 °C± 5 °C of ambient temperature, weekly self-test, no switch on of device, no network connection, with charging cycle of no more than 500 times.
Operating time	BATTERY 3C Operate 9 hours by a new battery at 20°C ± 5°C of ambient temperature, not performing defibrillation charges or discharges, voice volume set to low, display brightness set to indoor. BATTERY 3G Operate 14 hours by a new battery at 20°C ± 5°C of ambient temperature, not performing defibrillation charges or discharges, voice volume set to low, display brightness set to indoor.
Discharge times	BATTERY 3C

	130 times 200 J discharge by a new battery at 20°C ± 5°C of ambient temperature, voice volume set to low, display brightness set to indoor. BATTERY 3G 230 times 200 J discharge by a new battery at 20°C ± 5°C of ambient temperature, voice volume set to low, display brightness set to indoor.
Discharge times after shelf-life time	After shelf-life time of standby under storage condition, BATTERY 3C is expected to support approximately 6 times of shocks. BATTERY 3G is expected to support more than 6 times of shocks if fully charged.
Remaining charge after **< Battery low>** is prompted	When the remaining battery capacity is low, the device will announce **< Battery low >** when device switched on. Device can keep standby mode for more than 1 month. The device can perform at least 10 times 150J or 6 times 200 J discharge, then operate 40 minutes. (The device is powered by a battery at 20 °C± 5 °C of ambient temperature). If charging is no longer possible, the device automatically switches to cardiopulmonary resuscitation mode.
CPR FEEDBACK SPECIFICATION	Range of compression frequency: 100-120cpm. Accuracy of compression frequency: ±3cpm. Range of compression depth:50-60mm. Accuracy of compression depth: ±5 mm or ±10%, whichever is larger.
USB SPECIFICATION	
USB port	1 x USB Electrodes socket: serial communication port
WLAN SPECIFICATION	(if available)
WLAN standard	IEEE 802.11 b/g/n
Frequency	2.4 GHz
Maximum radiated output power	20.5 dBm EIRP (RF power including maximum antenna gain (3.37 dBi)
Wireless transmission rate	Max. 150 Mbps
LTE SPECIFICATION	(if available)
Channel	LTE-FDD: B1/B3/B7/B8/B20/B28A LTE-TDD: B38/B40/B41
Transmission power	LTE-FDD: 23±2 dBm LTE-TDD: 23±2 dBm
Standard	3GPP E-UTRA Release 11

COLOUR DISPLAY	(if available)
Type	Colour LCD display (only for 675, 675A) Touch LCD display (only for 678, 678A)
Working mode	Auto, in-door, outdoor (Self-adjust display brightness based on environment brightness)
Size	4.3 inch (10,9 cm)
Resolution	800 x 480
ECG waveform animation	1-Channel

DATA STORAGE

Internal storage	8G
ECG wave	160 hours
Event	10 000 events
Audio log	32 hours
CPR data	160 hours
Self-test report	Minimum of 3,650 reports
Log data	100 000 events

MYPRIMEDIC CONFIG APP

Minimum requirement of device	**iOS**	**Android**
CPU	2.5 GHz	2.0 GHz
RAM	3 GB	6 +1 GB
Storage	64 GB	64 GB
Display	1792 x 828	2408 x 1080
Bluetooth	5.0	5.1
OS	iOS14	Android 11

SAFETY

Classification	Device with internal power supply, Defibrillation-proof type BF
Identification	CE 0123 The product bears CE mark indicating its conformity with the provisions of the Medical Device Regulation (EU) 2017/745 concerning medical devices and fulfil the essential requirements of Annex I of this directive.
Classification	IP66

ENVIRONMENT SPECIFICATION

Operating conditions	-5 °C to 55 °C, 0 to 95 % rel. humidity, but without condensation 540 hPa to 1062 hPa (The device supports operate at least 20 minutes under -20 °C if device is stored in terms of storage condition before)
Short term transport and storage conditions (<1 week)	-30 °C to 70 °C, 0 to 95 % rel. humidity, but without condensation 510 hPa to 1062 hPa
Long term transport and storage conditions (≥1 week)	-5 °C to 55 °C, 0 to 95 % rel. humidity, but without condensation 510 hPa to 1062 hPa
Dimensions (L x W x H)	670, 671, 670A, 671A: 151 mm x 151 mm x 73 mm (±2 mm) 675, 678, 675A, 678A: 151 mm x 151 mm x 76 mm (±2 mm)
Weight	670, 671, 670A, 671A: approx. 1.0 kg (±0.2 kg) 675, 678, 675A, 678A: approx. 1.1 kg (±0.2 kg)
Minimum lifetime with combined device, electrodes and battery	At least 4 years with storage condition of temperature 15°C-35°C, humidity ≤ 80%, air pressure 540hPa to 1060hPa.
Drop test	Test with height 1.6m.
Shock test	Complies with requirements of 10.1.3a), IEC 60601-1-12:2014+ AMD1:2020 and 10.1.3, IEC 60601-1-11:2015+AMD1:2020 CSV
Vibration test	Complies with requirements of 10.1.3b), IEC 60601-1-12:2014+ AMD1:2020 and 10.1.3, IEC 60601-1-11:2015+AMD1:2020 CSV
SOFTWARE INFORMATION OF THE DEVICE	AED embedded software (version: 01.00.00.00)

Appendix B: Warranty

Within the 8-year warranty period, the manufacturer 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 function as selected by the manufacturer 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 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 the manufacturer are excluded out unless such claims are based on intent or gross negligence or compulsory legal liability standards.

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 the manufacturer.

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

Appendix C: Rhythm detection system

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

The Algorithm

- Filters interference and detects artefacts
- Calculates several ECG signal parameters including frequency and morphological parameters - rejects implantable pacemaker artefacts

Rhythm Categories

■ Shockable rhythms:

Ventricular fibrillation (VF): amplitude ≥0.2mV

Pulseless Ventricular tachycardia (pVT)

■ Non-shockable rhythms: normal sinus rhythm, supraventricular tachycardias, atrial fibrillation/flutter, sinus bradycardia, idioventricular rhythms, PVC (extra ventricular contraction) characteristic sinus rhythm, asystole.

Rhythm Database Source:

The ECG evaluation data in the algorithm evaluation database comes from the international standard database. The ECG data of each database can be downloaded at https://www.physionet.org. To collect ECG data for various rhythms, the following 8 databases were selected, which are described below:

- VFDB：MIT-BIH Malignant Ventricular Ectopy Database
- CUDB：CU Ventricular Tachyarrhythmia Database
- MITDB：MIT-BIH Arrhythmia Database
- EDB：European ST-T Database
- SVDB：MIT-BIH Supraventricular Arrhythmia Database
- AFDB：MIT-BIH Atrial Fibrillation Database
- LTAFDB：Long Time AF Database
- SDDB：Sudden Cardiac Death Holter Database
- SHAOXING: A 12-lead Electrocardiogram Database For Arrhythmia Research
- AHADB: The American Heart Association Database
- NSTDB: The MIT-BIH Noise Stress Test Database
- MDB: Metrax GmbH DataBase

Test results on the performance of the device configured with HeartSave shockable rhythm analysis algorithm. Meet IEC 60601-2-4 requirements.

Test results on IEC 60601-2-4 requirements are shown below.

Rhythm category	Requirement	Test result
Shockable (sensitivity)		
VF	≥90 %	passed
VT, pulseless	≥75 %	passed
Non-shockable (specificity)		
Normal sinus rhythm (NSR)	≥99 %	passed
Asystole (ASYS)	≥95 %	passed

Sinus rhythm, supraventricular tachycardia, sinus bradycardia, atrial fibrillation/atrial flutter, heart block, ventricular autonomic rhythms, pacemaker rhythms with characteristics of ventricular extrasystole (PVC)	≥95 %	passed
Positive predictive value	Report only	98.2%
False positive rate	Report only	0.9%

Appendix D: EMC

The device meets the requirements of IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-2-4:2010+ AMD1:2018.

NOTE

- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Portable and mobile RF communications device may affect this device.
- This device is intended for use in professional healthcare facility environment, or in home healthcare environment such as restaurants, cafes, shops, stores, markets, schools, churches, libraries, outdoors (streets, sidewalks, parks), domiciles (residences, homes, nursing homes), train stations, bus stations, airports, hotels, hostels, pensions, museums, theatres. If it is used in special environment, such as magnetic resonance imaging environment, the device may be disrupted by the operation of nearby equipment.

The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Phenomenon of Emission	Standard and level	Note
Radiated Emissions	CISPR 11 Class B	Its radio frequency emission is very low, and the possibility of interference to nearby electronic equipment is very small.
Conducted Emissions	CISPR 11 Class B	
Harmonic emission	IEC 61000-3-2 Class A	--
Voltage Flicker	IEC 61000-3-3	--

The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Phenomenon of immunity	Standard and level	Compliance level
Electrostatic discharge (ESD)	IEC 61000-4-2 ±8kV contact ±15 kV air	±8kV Contact discharge ±15kV Air discharge
Electrical fast transient/burst	IEC 61000-4-4 ±2 kV 100KHz repetition frequency	±2 kV 100KHz repetition frequency
Surge input AC power port	IEC 61000-4-5 ±1kV Line-to-Line	±1kV Line-to-Line
Voltage dips and Voltage Interruptions	IEC 61000-4-11 0% UT for 0.5 cycle 0% UT for 1 cycle 70% UT for 25 cycles 0% UT for 250 cycles	0% UT for 0.5 cycle 0% UT for 1 cycle 70% UT for 25 cycles 0% UT for 250 cycles
Power frequency Magnetic field	IEC-61000-4-8 30 A/m 50Hz / 60Hz	30 A/m 50Hz / 60Hz
Conducted RF	IEC 61000-4-6 3Vrms 0.15MHz~80MHz 6Vrms in ISM and amateur radio bands 0.15MHz~80MHz	3Vrms 0.15MHz~80MHz 6Vrms in in ISM and amateur radio bands between 0.15MHz~80MHz 80% AM at 1kHz 80 % index, at 5 Hz* according to IEC 60601-2-4:2018 (Clause 202).

NOTE	UT is the mains AC before applying the impulse test level. If the device is operated within the electromagnetic environment listed in Table Guidance and Declaration - Electromagnetic Immunity, the device will remain safe and provide the following essential performance: energy accuracy, CPR function, data stored.

<table>
<tr><td colspan="4">The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><td>Phenomenon</td><td colspan="3">Standard and level</td></tr>
<tr><td rowspan="2">Radiated RF</td><td colspan="3">IEC 61000-4-3
For EM fields:
10V/m 80MHz~2.7GHz, 80% AM at 1kHz,
20V/m*,80 MHz to 2500 MHz, 80% AM at 5Hz*, according to IEC 60601-2-4:2018 (Clause 202).</td></tr>
<tr><td>Freq
MHz</td><td>Test Level
P: max power, d:distance,
E:Immunity Level</td><td>Compliance level</td></tr>
<tr><td rowspan="12">For Proximity fields
from RF wireless communications equipment</td><td>385</td><td>P=1.8W d=0.3m E=27V/m for TETRA400</td><td>P=1.8W d=0.3m E=27V/m for TETRA400</td></tr>
<tr><td>450</td><td>P=2W d=0.3m E=28V/m for GMRS460; FRS460</td><td>P=2W d=0.3m E=28V/m for GMRS460; FRS460</td></tr>
<tr><td>710</td><td rowspan="3">P=0.2W d=0.3m E=9V/m for LTE Band 13, 17</td><td rowspan="3">P=0.2W d=0.3m E=9V/m for LTE Band 13, 17</td></tr>
<tr><td>745</td></tr>
<tr><td>780</td></tr>
<tr><td>810</td><td rowspan="3">P=2W d=0.3m E=28V/m for GSM800/900; TETRA800; iDEN820; CDMA850;LTE Band 5</td><td rowspan="3">P=2W d=0.3m E=28V/m for GSM800/900; TETRA800; iDEN820; CDMA850;LTE Band 5</td></tr>
<tr><td>870</td></tr>
<tr><td>930</td></tr>
<tr><td>1720</td><td rowspan="3">P=2W d=0.3m E=28V/m for GSM1800, CDMA1900; GSM1900; DECT; LTE Band 1,3,4,35;UMTS</td><td rowspan="3">P=2W d=0.3m E=28V/m for GSM1800, CDMA1900; GSM1900; DECT; LTE Band 1,3,4,35;UMTS</td></tr>
<tr><td>1845</td></tr>
<tr><td>1970</td></tr>
<tr><td>2450</td><td>P=2W d=0.3m E=28V/m for Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7</td><td>P=2W d=0.3m E=28V/m for Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7</td></tr>
<tr><td>5240</td><td rowspan="3">P=0.2W d=0.3m E=9V/m for WLAN 802.11 a/n</td><td rowspan="3">P=0.2W d=0.3m E=9V/m for WLAN 802.11 a/n</td></tr>
<tr><td>5500</td></tr>
<tr><td>5785</td></tr>
<tr><td>Proximity magnetic fields (IEC 61000-4-39:2017)</td><td colspan="3">30 kHz, 8A/m, Dwell Time (3 second),
134,2 kHz, 65A/m, Dwell Time (3 second)
13,56 MHz, 7,5A/m, Dwell Time (3 second)</td></tr>
</table>

NOTE

- The device is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended below, according to the maximum output power of the communication equipment.
- If the device is operated within the electromagnetic environment listed in Table **Guidance and Declaration - Electromagnetic Immunity**, the device

will remain safe and provide the following essential performance: energy accuracy, CPR function, data stored.

- 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.

Appendix E: Index Diagram

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