



PRIMEDIC
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Automated External Defibrillator Instructions for use

HeartSave Y | YA

English

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Masthead

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Non-compliance with this gives rise to a right to claim damages and can have consequences under criminal law (refer to DIN 34).

Revision: D

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

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1 Glossary

Term / abbreviation	Description
AED	Automated external defibrillator
AHA	American Heart Association
Biphasic impulse	The current flow of the defibrillator changes direction during shock appliance
BLS	Basic resuscitation measures
CPR	Cardiopulmonary Resuscitation
ECG	Electrocardiogram
ERC Guidelines	European Resuscitation Council on Cardiopulmonary Resuscitation (CPR)
EU	European Union
MDD	Medical Device Directive
MIT	Massachusetts Institute of Technology
MPBetreibV	Medical Device Operator Ordinance
MPG	Medical Devices Act
Patient impedance	Patient resistance between the Electrode Pads

2 Introduction

2.1 Foreword

Dear User,

You are faced with the task of using the HeartSave Y | YA 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 may arise.

If you have any questions regarding the start-up, use or maintenance of the HeartSave Y | YA 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

- 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 at the start of these instructions for use.

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

2.2 Validity

The descriptions in these operating instructions refer to the HeartSave Y | YA series automatic external defibrillator device made by Jiangsu Yuyue. The HeartSave Y | YA series automatic 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:

Using the device in a manner for which it was not intended.

Improper use and maintenance of the device.

Operating the device with the protective covers removed or when there is obvious damage to cables and/or electrodes.

Non-compliance with operating instructions with regard to operation, maintenance and repair of the equipment.

Using accessories and spare parts made by other manufacturers.

Autonomous intervention, repairs or constructional changes to the device.

Lack of monitoring that are 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.

It is imperative that you follow these instructions!



WARNING

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

It is imperative that you follow these instructions!



CAUTION

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

It is imperative that you follow these instructions!

ATTENTION

Texts marked with ATTENTION indicate possible property damage.

It is imperative that you follow these instructions!

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

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

- ▶ First instruction
 - ▶ Second instruction
 - ▶ etc.
 - This line marks lists
- (3) Numbers in brackets refer to items in diagrams.

< ... > Texts set in angle brackets denote acoustic information / instructions for the device

2.5 Pictogrammes



The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfil the essential requirements of Annex I of this directive.

IP 55

Dust-protected
Protected against water jets.



Refer to instruction manual/booklet.



Environmentally friendly use



Do not dispose of device in domestic refuse.



Dangerous voltage.



Defibrillation-proof type BF applied part.



Manufacturer



Authorised representative in the European community



Use-by date



Protect battery from fire.



Do not charge battery



Recyclable


















Do not re-use



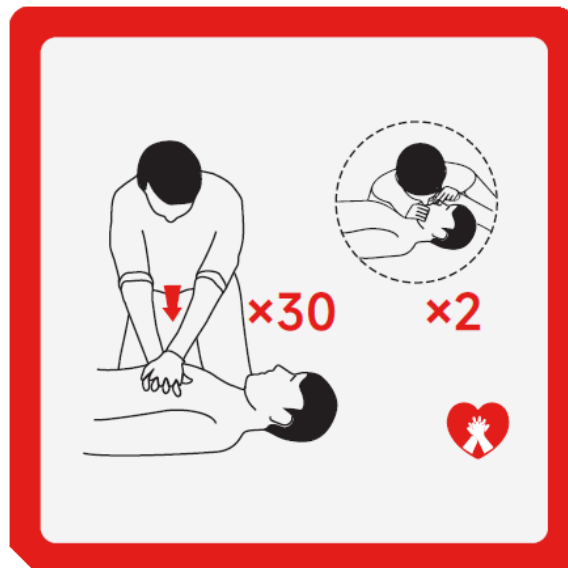
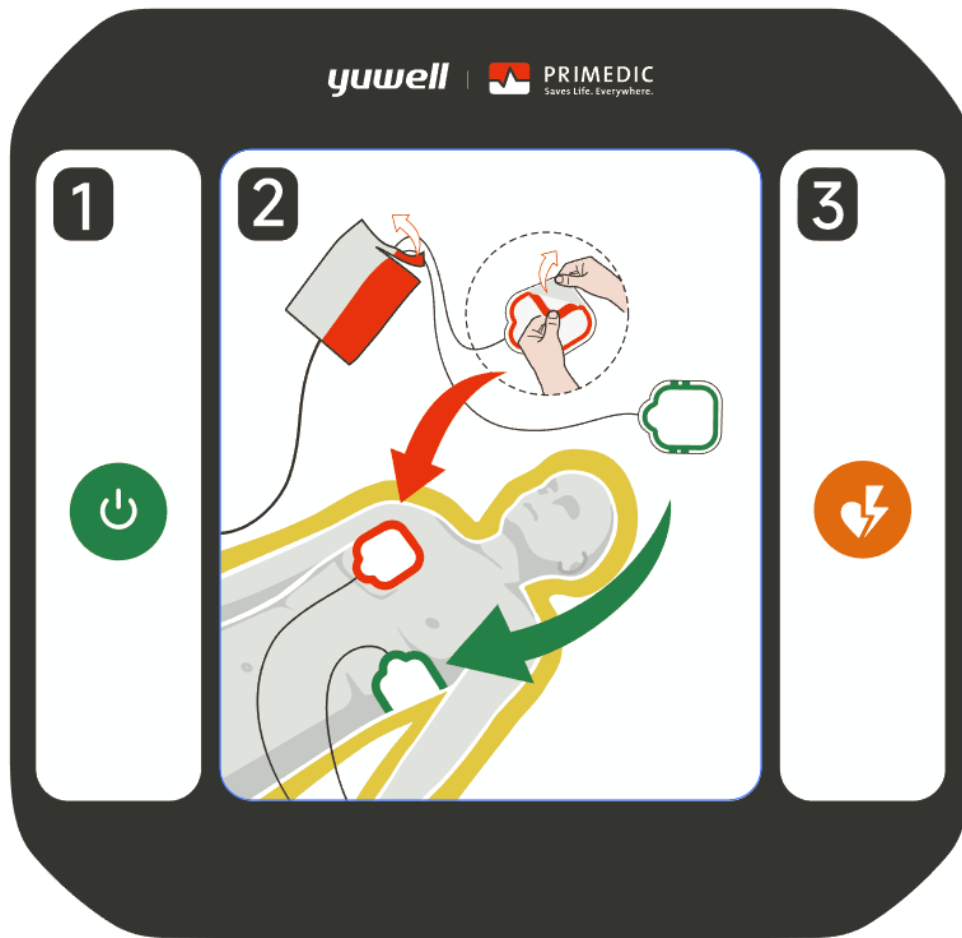
not sterile



Can be used a maximum for 24 hours after opening

	Permissible temperature range in C
	Permissible air humidity range in %
	Permissible air pressure specification in hPa
	Keep away from sunlight
	Keep dry
 max.50 x	Maximum number of defibrillation shocks up to 50 times
	Latex free
	Do not bend or fold the electrodes
	Do no use if package is damaged
	Batch code
	Article number
	Caution
	Date of manufacture
	Serial number
	Non-ionizing electromagnetic radiation

2.6 Summarized operating instructions



The brief instructions can be found on the device and helps you with the use of the HeartSave Y | YA series.

3 Intended use

The HeartSave Y | YA series automatic external defibrillator, is intended to be used on adults and children in a ventricular fibrillation.

HeartSave Y | YA series also guide operator throughout cardiopulmonary resuscitation (CPR) with voice guidance.

When a patient develops ventricular fibrillation or ventricular tachycardia, the device gives a shock to the heart to restore the disordered rhythm to normal.

The HeartSave Y | YA series is kept on the patient until professional assistance arrives even if the patient starts to breathe again.

The equipment is designed for treating adult patients and children patients in combination with the Electrode Pads OBS-DE/P(303A1204)/REF 97847. Patients aged 8 years and above and / or with a weight over 25 kg are treated as adults. Patients aged 1-8 weighing less than 25 kg are treated as children.

NOTE HeartSave Y | YA series defibrillators may only be used as described and under the conditions detailed in these operating instructions!



DANGER

Warning: physical harm

Risk of heart arrhythmia which may lead to death

- Only use HeartSave Y | YA series as intended
- Don't use the HeartSave on children aged under 1 year



CAUTION

In an emergency case the HeartSave Y | YA series can operate for at least 20 minutes from temperature to -20 °C.

3.1 Medical indication

HeartSave Y | YA should be used when the patient has all of the following symptoms:

- Unconsciousness
- Absence of normal breathing
- Absence of signs of circulation

3.2 Medical contraindication

HeartSave should not be used if the patient shows one of the following symptoms:

- Consciousness
- Breathing
- Signs of circulation

4 Safety information

4.1 General safety advice

HeartSave Y | YA series fulfill the currently applicable safety standards and complies with the provisions of the medical products regulations.

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

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

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

Always follow the commands issued by HeartSave Y | YA series!
Do not use the HeartSave Y | YA series in the presence of flammable materials.
Keep the device out of reach of children!



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. Monitor the use of the device at all times.

The device may not use in places where there is a risk of explosion

4.2 Safety notes for the user



WARNING

Only use the device on a patient if:

- You have ensured its operational safety before using it and that it is in good condition.
- the state of the patient requires or allows an application.

Before using the device, ensure that the temperature is within the operating temperature range.

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)

4.3 Safety notes to protect the patient



DANGER

To use HeartSave Y | YA series on a patient, you must:

- Do not use the device on a patient unless you have ensured its operational safety.
- Check the device before using it and guarantee that it is in good condition!
- If the equipment is defective (e.g. if the defibrillation cable is damaged), do not use the equipment.
- 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 HeartSave Y series and HeartSave YA series external defibrillators.
- 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 Y series and HeartSave YA series automatic external defibrillators. Keep a sufficient distance away from other energy sources (e.g. microwave oven, induction cooker etc.).

These devices can affect the PRIMEDIC automatic external defibrillators and disrupt the way it operates. For this reason, disconnect all other devices from the patient before carrying out defibrillation.

- Prior to defibrillation, disconnect all other electrically operated medical devices that are not defibrillation-proof and are used on the patient.
- Keep the defibrillation electrodes away from other electrodes, metal objects and earthed objects!
- Do not use the device on children under the age of 1!
- 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 damage to the pacemaker from the defibrillation impulse.
- Do not touch the patient during the ECG analysis.
- Stop any reanimation while the PRIMEDIC HeartSave Y series and HeartSave YA series automatic external defibrillators is analysing the ECG.
- The use of several medical devices simultaneously may present a danger to the patient as a result of the cumulation of patient currents.

4.4 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.

4.5 Safety notes for protection of the device



WARNING

Repairs and installations of the PRIMEDIC HeartSave Y series and HeartSave YA series automatic external defibrillators may only be carried out by personnel authorized persons.

Use only original accessories from the manufacturer.

Clean the device in the prescribed manner, i.e., only in its power-off state and with the electrodes disconnected.

5 Description of device

5.1 General description

The HeartSave Y | YA series is an automatic external defibrillator (AED) with an integrated Single Channel ECG.

The ECG is recorded using the Electrode Pads. When a rhythm requiring defibrillation is detected, the HeartSave provides a shock to restore the heart rhythm.

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

Characteristics of models are detailed in the following table.

Defibrillation mode	Model	Shock button
Semi-automatic external defibrillator	HeartSave Y	YES
Fully-automatic external defibrillator	HeartSave YA	NO

The HeartSave Y | YA series have been designed to be safe and quick to use in an emergency. The power supply of the HeartSave Y | YA series comes from a non-rechargeable lithium battery.

The HeartSave Y | YA series is composed of a host, Electrode Pads and battery. For further information see chapter 5.2.

5.2 Device description

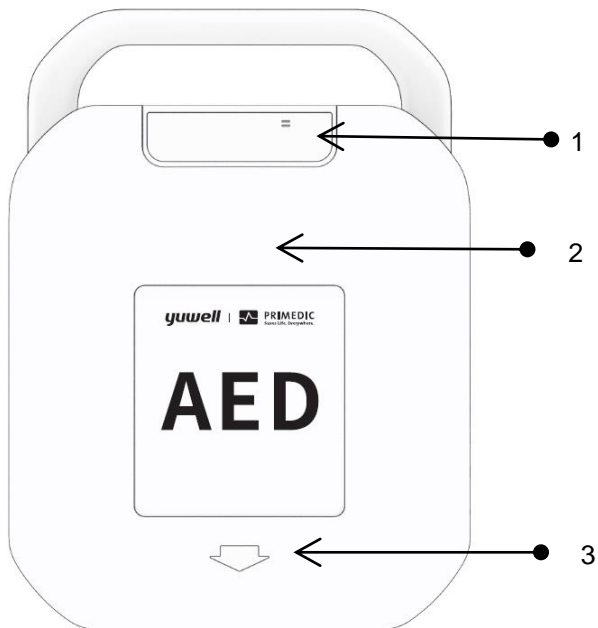


Fig. 1 Front view with cover

- (1) Status display
- (2) Device cover
- (3) Open the cover as directed by the icon

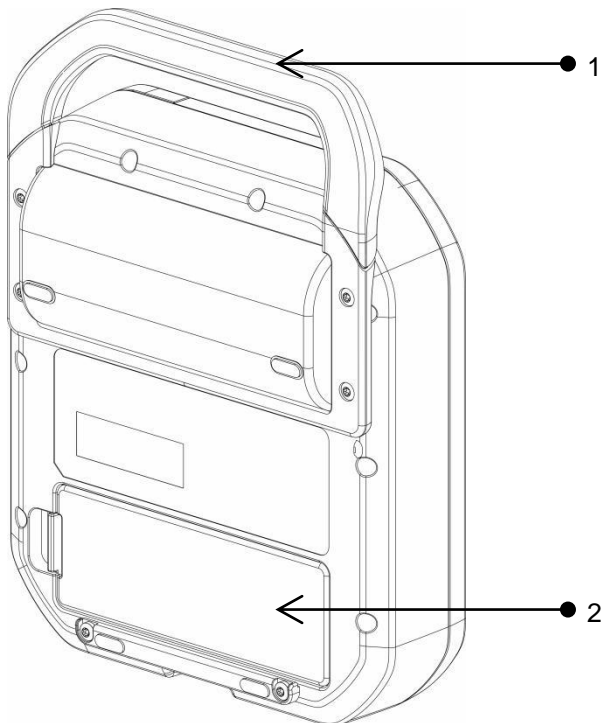


Fig. 2 Rear View

- (1) Carrying handle
- (2) Battery



Fig. 3 View from below

(1) Device cover opening lock

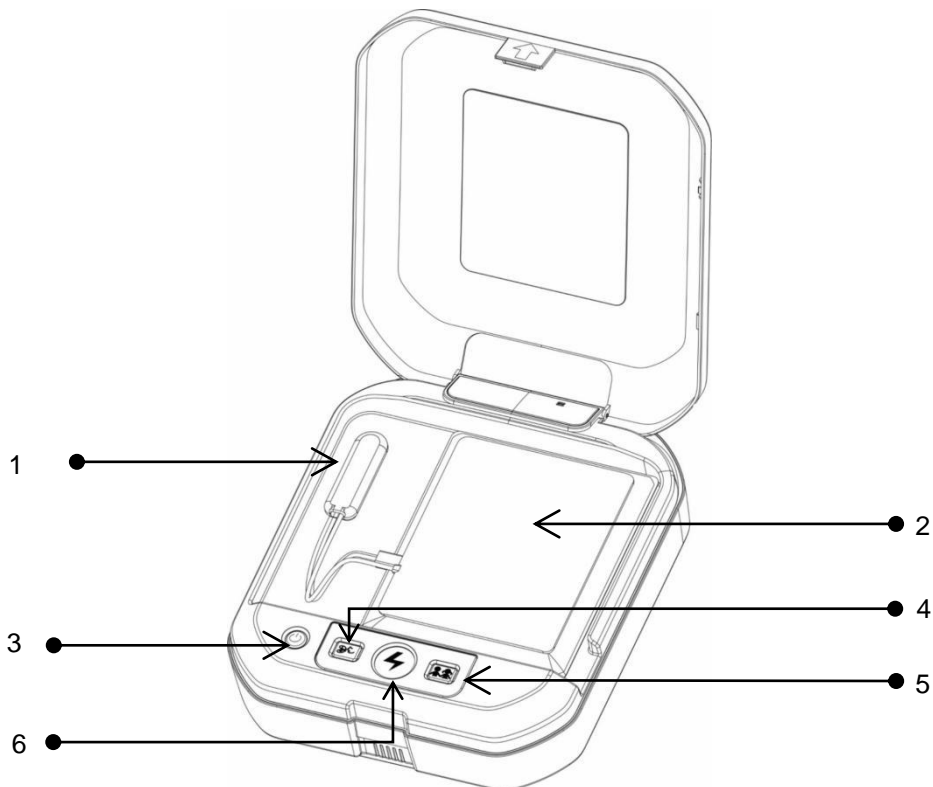


Fig. 4 HeartSave Y | YA series front view

- (1) Jack for electrode connectors and USB port
- (2) Electrode Pads
- (3) On/Off switch with green back-light
Lights green: the equipment is turned on, and can work correctly
- (4) Language change button
- (5) Child button with back-light
Lights green: child mode
Does not light: adult mode
- (6) Shock button with red back-light only for HeartSave Y series (release button for defibrillation)
Flashing red: ready to be shocked

5.3 Accessory kit of the HeartSave Y | YA

The emergency kit is attached to the back of the HeartSave Y | YA and contains the following accessories:





- 1x Scissor
- 1x Disposable razor
- 1x Pair of disposable gloves
- 1x Resuscitation mask

Fig. 5 Accessory kit of the HeartSave Y | YA

5.4 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 exchange battery. Insert power module. Connect SavePads Renew SavePads 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	Usable: Yes/No	Procedure
Electrodes not connected	Yes, device is ready for use.	Can be used after connecting the electrodes.
Battery almost empty	Yes, device is operational with at least 6 shocks at 360 J.	Indication of the almost empty battery by a voice announcement. The device can continue to be used until the battery is empty.
Battery empty	No, device is not ready for use.	Indication of the empty battery by a voice announcement. The device will automatically shut down.
Internal error	No, device is not ready for use.	Indication of an internal error by a voice announcement. The device will shut down automatically.

NOTE



If the battery is empty and the display shows a warning tone sounds when the device is switched on and the following voice command is issued:

< Low Battery! Please replace battery as soon as possible > or < Battery depleted, device will automatically shut down >

6 Preparatory measures before (initial) start-up

6.1 Unpacking



DANGER

Danger caused by damaged device

- Do not use damaged devices

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

If you notice any damage to the device, immediately contact your transport company, dealer or directly contact authorized service personnel only, stating the serial number and describing the damage to the device.

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

6.2 Inserting electrode

The electrodes on the HeartSave Y | YA are pre-connected at the factory and do not need to be additionally plugged in before initial use. However, if these have been replaced or unplugged, they must be reconnected to the device using the following procedure.



Fig. 6 Inserting electrode

Installation procedure:

- ▶ Press the lid to open the device cover.
- ▶ Insert the electrode plug into the electrode interface.
- ▶ Place the electrode pads in the device.

ATTENTION

Device not ready for use after changing the electrodes

After changing the electrodes of the HeartSave Y/YA – the device still states “X” not ready for use.

- ▶ Switch on the device by open the lid or pressing the on/off button. Wait until the self-test is performed and the device status changes to “OK”.



WARNING

- Keep the electrodes connected to the equipment at all times.
- Do not open the electrode packaging until immediately prior to use.
- Do not bend the electrode pads forcefully.
- Make sure the pads package and cable of integrity of seals and validity of expiry date before use.

6.3 Install the battery

The power supply of the HeartSave Y | YA series comes from a non-rechargeable lithium battery. Before using the HeartSave Y | YA for the first time, the transport seal must be removed and the battery inserted into the device.

6.3.1 Battery safe information



WARNING

- Do not charge the battery! Risk of explosion!
- Do not disassemble, puncture or incinerate batteries. Do not short the battery terminals. They may ignite, explode, or leak, causing personal injury.
- Do not put the battery close to fire or heat, please avoid storing it under direct sunlight.
- Do not use other batteries on HeartSave to ensure safe operation.

ATTENTION

- Note the battery expiry date
- Replace batteries after passing their expiry date

Keep the documentation that enclosed with the battery and follow the operating instruction for safekeeping.

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

6.3.2 Insert battery.

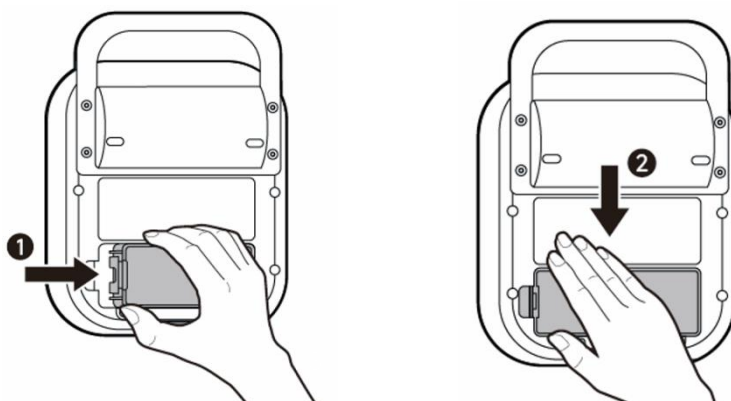


Fig. 7 Insert battery

Procedure:

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

ATTENTION

Indication of possible error

- If the status display does not show 'OK', proceed as follows:
Switch on the device and wait for the result of the self-test.

6.3.3 Remove battery

NOTE Only replace battery when the device is switched off.

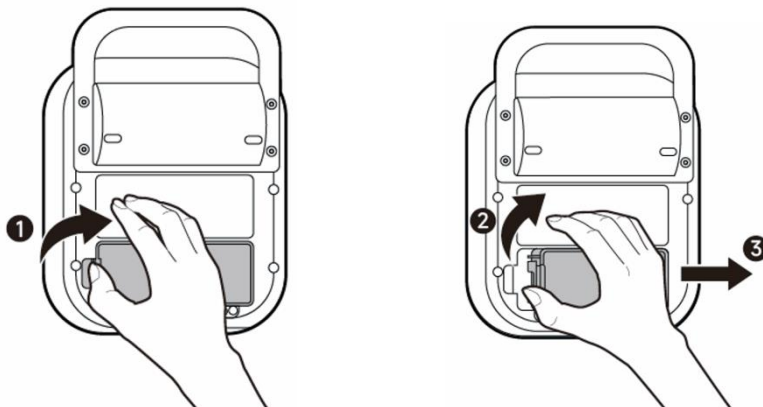


Fig. 8 Removing the battery

Procedure:

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

6.4 Self-test

6.4.1 Self-test after switching the HeartSave Y | YA series on

After starting the Heart Save Y&YA series the devices runs a self-test to check all the important functions and signal mechanisms.

If the battery is not in the device and the display status shows "X", the device will perform a manual self-test when the battery is inserted.

Manual self-test

Please follow the instructions of the device after inserting the battery:

With a ticking metronome sound, the device signals that the self-test is in process.

1. The lid must be closed for the manual self-test.
If the lid is open after inserting the battery, the device will give the voice prompt **< Close the lid >**. After three repetitions without closing the lid the test will be continued.
2. The device will give the voice prompt **< Device testing, if defibrillation is needed, please open the lid and press the power button to interrupt the test >**.
3. The device will make a short audio test.
4. **< Self testing please wait >**
5. The device will give the voice prompt **< Manual self-check, please open the lid and follow the instructions >**
Open the lid of the device.
6. The device will give the voice prompt **< Unplug electrodes >**
Unplug electrodes.
7. The device will give the voice prompt **< Plug in electrodes >**
Plug in electrodes.
8. The device will give the voice prompt **< Please press the blinking buttons >**
Press language button
Press Shock button
Press child button
9. The device will give the voice prompt **< Test completed >**
Voice prompt **< Device okay >** if the device's functionality is guaranteed.
Voice prompt **< Device not ready for use >** – Please execute the test again. If it is not successful, please contact our service team.

6.4.2 Automatic, periodic self-tests

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

	Frequency	Test coverage
SHORT	Daily*	Check main control module, battery, power module, electrode pads, treatment module.
MEDIUM	First day of the month	Check main control module, battery, power module, electrode pads, treatment module, 1J charge and discharge and 200J charge and discharge, speaker.
LONG	On the 1st. July and on the 1st. January every year	Check main control module, battery, power module, electrode pads, treatment module, 1J charge and discharge and 360J charge and discharge, speaker.

* The daily self-test is set to "05:00 a.m." UTC (universal time coordinated). Please be informed that the device does not recognize time changes for specific regions. The self-test time depends on the region and time zone.

6.4.3 Automatic monitoring of the device

The HeartSave monitors the most important equipment and safety functions permanently during operation. If one of the many internal self-tests detects an error that no longer ensures the safe operation of the device, the symbol "X" appears in the status display and the device emits a signal tone at regular time intervals. Please check the device to determine the cause of the error.

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

6.5 Language switch

You can press the language selection key during operation until the desired language is selected. The HeartSave Y | YA optionally supports up to 4 languages. After each new press, the selected language is briefly announced.

7 Using the HeartSave

NOTE The sequence of the reanimation is realized in the device according to the recommended guidelines of the European Resuscitation Council or American Heart Association.



DANGER

Warning of explosion

Risk of burns

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



WARNING

Warning: physical harm

Risk of skin burns

- Remove hair at the electrode positions
- Where necessary, dry the skin before attaching the electrodes

ATTENTION

Material damage to other devices

- Remove all devices which are at risk from the defibrillation from patients before defibrillation.

7.1 Examining and preparing the patient

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

- ▶ Please lean down and talk to patient and touch him/her to see whether he or she is still conscious.
- ▶ If the patient does not respond, place his head in the neck and check whether you can detect any breathing. If necessary, check the airway for foreign bodies.
- ▶ If the patient is not breathing normally, expose his/her breast area to attach the defibrillation electrodes. If the HeartSave is not already available, make sure someone collects it in order to carry out further treatment.
- ▶ Using the supplied razor, remove breast hair from the spots where the defibrillation electrodes are to be attached.
- ▶ If the surface of the skin is damp, dry the skin at the spots where the defibrillation electrodes are to be attached to improve the adhesion.
- ▶ If the surface of the skin has lint, dust or some dirt, please clean it.
- ▶ Make sure the emergency services have been alerted.

7.2 Switching the HeartSave on

HeartSave is automatically activated by removing its cover on the device. If the device is not switched on automatically, switch it on by pressing the On/Off button. After this, all buttons are unlocked, apart from the shock button (only suitable for HeartSave Y series). Defibrillation cannot be triggered until the device has detected a rhythm requiring defibrillation.

Directly after switching it on, an internal self-test is carried out to check important functions and signal devices.

If no contact of the electrodes with the patient is detected when the device is switched on, the following prompt is issued:

< Power on >

< Call emergency services >

7.3 Check the patient category

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

You can switch to child mode by pressing the child button. If HeartSave is in child mode, the indicator LED next to the Child button will illuminate (green).

Child mode has been especially developed for the needs of children. In Child Mode, the HeartSave supplies less energy than in Adult Mode.

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

7.4 Plug in electrode cable

NOTE If you have already inserted the Electrode Pads, the HeartSave will skip.

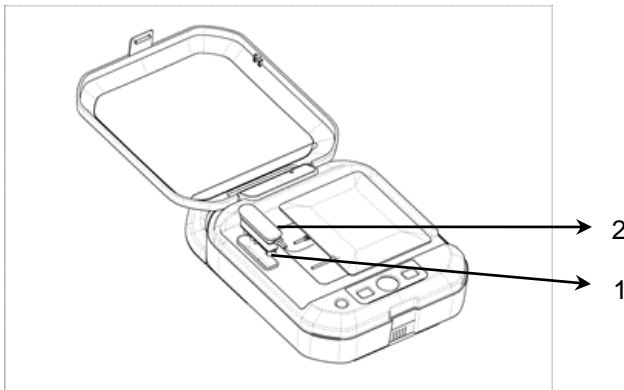


Fig. 9 Plug in electrode cable

- (1) Socket
- (2) Electrode plug

Procedure:

- ▶ After hearing the voice prompt < **Plug in electrodes** > ,
- ▶ Insert the connector (2) of the electrode cable into the jack (1) on HeartSave as shown above.

NOTE If the electrodes are not inserted in the device after repeated requests, the device automatically switches to cardiopulmonary resuscitation.
As soon as the electrode plug is inserted, the CPR instructions are automatically interrupted.

7.5 Prepare the patient

NOTE For this, you will need to take the disposable gloves out of the Accessory kit and put them on.

7.5.1 Removing clothes from patient

Using the supplied razor, remove breast hair from the spots where the defibrillation electrodes have to be placed.

7.5.2 Placing electrodes



WARNING

Damage to gel layer on defibrillation electrodes

Skin burns

- Be careful not to touch the gel layer before attaching the electrodes
- Be careful, damage to the gel layer can cause skin burns.



CAUTION

- Do not use the electrode if it is expired, damaged or the package is damaged.
- Check electrodes packaging to ensure integrity of seals and validity of expiry date.

If above electrodes are used, it may cause delays in patient treatment and skin burns.

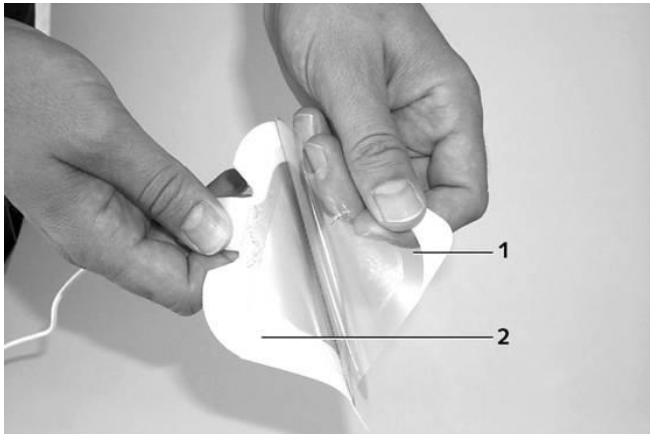


Fig. 10 Removing the film from the electrodes

- (1) Protective film on electrodes
- (2) Defibrillation electrodes pads

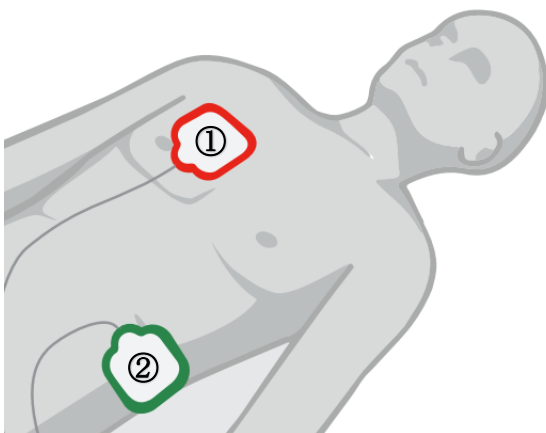


Fig. 11 Position of electrodes on adults

The positions of the electrodes are:

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.

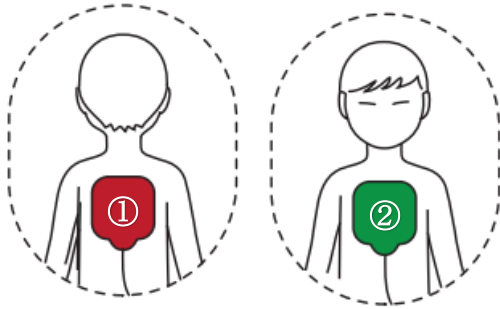


Fig. 12 Position of electrodes on children

The positions of the electrodes are:

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

Green ②: in the middle of the chest

HeartSave will give a voice prompt for you to apply the defibrillation 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 >

Procedure:

- ▶ Open the defibrillation electrodes package.
- ▶ Remove the protective film from one of the electrodes and then immediately place the electrode on the position you had ascertained previously. (Refer to Figure 11 for adults and Figure 12 for children)
- ▶ Proceed to remove the protective film from the second electrode and place it in its position.
- ▶ Smooth the electrodes onto the patient ensuring there are no air bubbles under the electrodes!

NOTE If the electrodes are not attached to the patient after several requests, the device automatically switches to cardiopulmonary resuscitation.
Once the electrodes are correctly placed on the patient, the CPR instructions are automatically interrupted.



WARNING

If the electrodes are not attached well, the ECG signal is not presently analyzed

The device will voice prompt: < Apply electrodes as shown >

7.6 Carrying out the ECG analysis



DANGER

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

Triggering heart arrhythmia

- Do not touch the patient during defibrillation
- Warn third parties about the dangers of defibrillation
- If the patient wakes up during reanimation, stop the resuscitation

If the defibrillation electrodes have been applied, the device will automatically start the analysis. The patient must now be put in an immobile position and must no longer be touched. The device prompts:

< Don't touch the patient, analysing rhythm >

The algorithm of the device program now checks the ECG for a rhythm requiring defibrillation.

7.7 Defibrillation required


NOTE Pressing the shock key during power charging (before it turns red) does not result in release of shock.

NOTE Defibrillation may cause muscle contractions in the patient.

NOTE When the device is charging or ready for shock condition:

- if the device still detect a shockable rhythm, the device can not automatically abort defibrillation.
- if the device detected a non-shockable rhythm, the device can automatically abort defibrillation.

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

	HeartSave Y series semi-automatic external defibrillator	HeartSave YA series fully-automatic external defibrillator
	<p>< Don't touch the patient, press flashing shock button, deliver shock now ></p> <p>A continuous tone and the shock button flashes "red"</p> <p>Press the shock button in time according to the voice instruction</p>	<p>< Don't touch the patient, shock will be delivered in: "Three", "Two", "One" ></p> <p>Automatically administer a shock without requiring further action</p>

NOTE Do not touch the patient while a shock is delivered.

The ECG will not be analyzed again, the device will continue with the CPR.

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

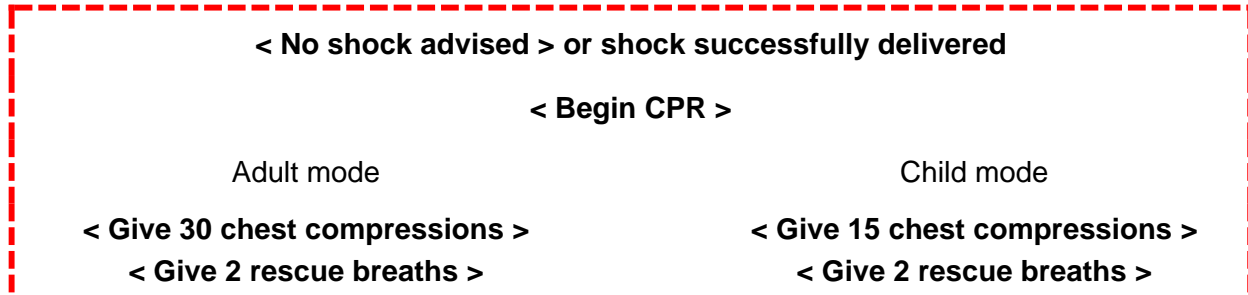
If the device cannot find a shockable rhythm, then it recommends cardio-pulmonary resuscitation (CPR).

7.8 Cardio-pulmonary resuscitation (CPR)

As a configuration of the HeartSave Y | YA for CPR we follow the recommendations of the 2021 ERC guidelines. The 2021 ERC guidelines differentiate the approach to resuscitation for trained and lay rescuers.

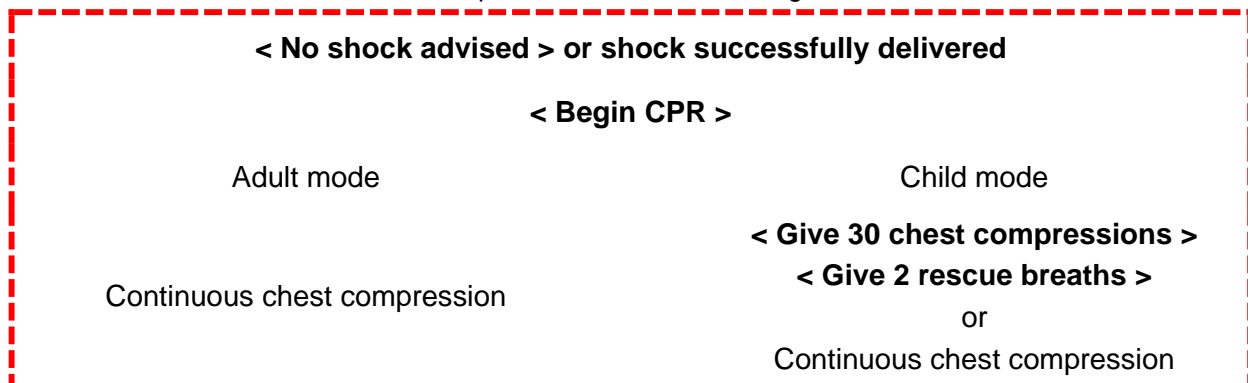
7.8.1 CPR for trained rescuers

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.



7.8.2 CPR for lay rescuers

The 2021 ERC guidelines do not recommend that untrained adult first responders perform ventilations, but only continuous chest compressions during resuscitation. If the first responder has not completed separate training in pediatric basic resuscitation, ERC-2021 recommends 30 chest compressions with 2 ventilations or continuous chest compressions in children during CPR.



7.8.3 CPR configuration of the HeartSave Y | YA

The HeartSave offers the possibility to design the cardiopulmonary resuscitation measures individually and customer-specific. For example, it is possible to dispense with ventilation in adult mode and only perform chest compressions.

In child mode, we offer to increase configuration from 15 to 30 chest compressions + 2 ventilations. Continuous chest compressions can also be set for the child mode.

The default CPR configuration is CPR for trained first responders. For a change, please contact your specialist dealer or the service team.

7.8.4 CPR metronome function

Furthermore, during the chest compressions, you will be supported the metronome function which will give you the correct frequency for the chest compression. Be sure that you keep to the given rhythm. The last five CPR metronome tones before a break in chest compressions will be different. The artificial respiration will also be supported by two acoustic outputs. From the second to fifth CPR cycle, only these sound signals are emitted.

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

Carry out cardio pulmonary resuscitation until the emergency services arrive.

7.9 Keeping the defibrillator ready for use

- ▶ Check the HeartSave for damage after each use.
- ▶ Clean HeartSave and accessories after each use. Disinfect HeartSave and accessories if there is a risk of infection, see section 11.1.
- ▶ Replace the Electrode Pads and check and replace the battery as required so that HeartSave is ready for operation again as quickly as possible.
- ▶ If any malfunctions or noticeable problems occur, please contact service personnel only.

HeartSave can be switched off in various ways:

- By pressing the on/off button for approx. 3 seconds. A warning beep will sound simultaneously. This time has been chosen to avoid it being switched off accidentally.
- By closing the cover of the device.
- If the device does not recognize a signal for 30 minutes and if no button is pressed, it will switch off automatically.
- Wait at least 30 seconds after switching off before removing the energy module.

8 Data management

8.1 Data storage

Device support storage following data:

Data type	Data description
System log	Serial number, software release version, total time of operation, battery information, electrode information
Therapy log	Record ECG Recorded impedence Delivered shock data
Event log	Error event, warning event, configuration event, information event
Audio log	Voice messages of the device

NOTE Once the storage capacity of the device is exhausted or the maximum number of files is reached there will be cyclic storage.

8.2 Data output

The HeartSave support export data to USB disk. This data may not be used for diagnostic purposes or for therapy for the patient.

Check software version methods:

- ▶ Plug in USB disk with corresponding M600-license file
- ▶ Switch the device on
- ▶ When the child button backlight is on, it indicates that the data was successfully exported.

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

NOTE The USB disk used for data export, only supports USB 2.0 FAT32 format, and does not support other format and protocol.

8.3 Configuration item

The device is configured at factory.

NOTE To change the configurations, please contact your local distributor or the manufacturer. If the configuration is changed independently, the device is no longer ready for operation and reports "Internal Error".

9 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 equipment 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.

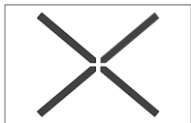
9.1 Standard accessories

Name	Module	REF	Remarks
Electrode	OBS-DE/P(303A1204)	97847	Disposable defibrillation electrodes for adult and child
Battery	NRL01C	97846	12V, 4.2Ah, not rechargeable

10 Troubleshooting

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


Troubleshooting During Use:

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
State displays 	Internal error	Reboot device and execute self-test.
	The electrodes are not plugged in the AED	According to 6.2 insert the Electrode Pads
	The electrodes are expired	Changing the Electrode Pads
	The battery is low!	According to the 6.3 to replace a new battery
Voice instructions < Low Battery! Please replace battery as soon as possible >	Low Battery	According to the 6.3 to replace a new battery
Voice instructions < Battery depleted, device will automatically shut down >	Battery Depleted	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.

11 Cleaning, maintenance, despatch and disposal

11.1 Cleaning

 WARNING

Warning: physical harm to user
 Risk of electrocution

- Only clean the device when switched off
- Do not immerse the device in liquids

Recommended cleaning agents are:

- Water
- Ethanol (75%)
- Isopropyl alcohol (70%)

To clean your equipment, follow these rules:

1. Shut down the equipment, disconnect cables, and remove the battery.
2. Clean the Status-Display using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment 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 equipment in a ventilated, cool place.

11.2 Servicing

ATTENTION

Warning: property damage

- Do not carry out any repairs to the device.
- Do not carry out any modifications to the device.
- Do not dismantle HeartSave.
- Only use genuine accessories!
- Maintenance and service are not allowed during the use of the device.

We recommend performing a regular visual inspection of the device.

Make sure that the Electrode Pads, battery and all the other accessories are undamaged.

Check the device and accessories regularly. Select the intervals so that the operational readiness and operational safety of the device are permanently guaranteed.

For service questions please contact us directly under:

service@primedic.com

+49 741 257 275

11.3 Sending the HeartSave



DANGER

Risk of fire due to short circuit

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

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 info.

11.4 Disposal



CAUTION

Warning: physical harm

Risk of acid burns

- Dispose the device, battery and single parts according to local regulations



Fig. 13 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 Y series: semi-automatic external defibrillator
 HeartSave YA series: fully-automatic external defibrillator

Impulse shape: Biphasic truncated exponential, auto-compensation according to patient impedance.

Optional output energy For adults: 100 J, 150 J, 170 J, 200 J, 300 J, 360 J
 For children: 10 J, 15 J, 20 J, 30 J, 50 J, 70 J, 100 J
 Refer to Chapter 8.3 for the configuration methods

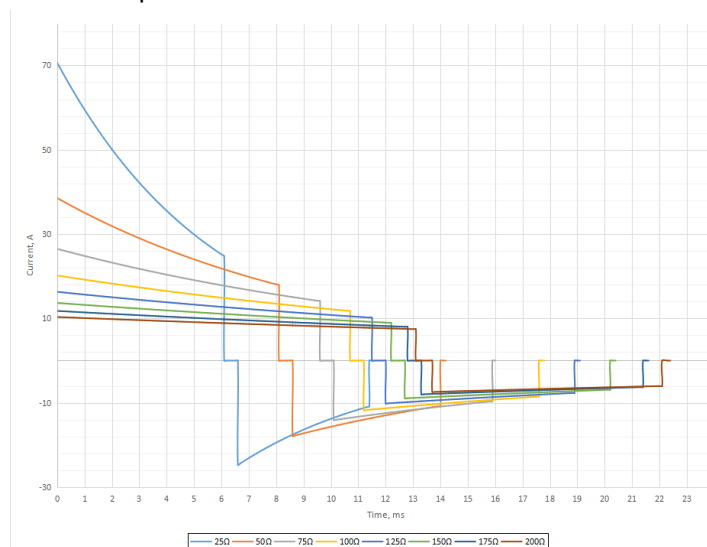
Default Shock series Default adult energy sequence:
 Level 1: 200 J
 Level 2: 300 J
 Level 3: 360 J
 Default children energy sequence:
 Level 1: 50 J
 Level 2: 70 J
 Level 3: 100 J
 Shocks: Level 1, level 2, and level 3 can be configured,
 The energy configuration of the latter level must be greater than or equal to the energy of the previous level.
 Meeting ERC guidelines 2021 and AHA guidelines 2020 by default

360J defibrillation waveform into impedance into of 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 175Ω

R (Ω)	25	50	75	100	125	150	175
10	9.7	10	9.7	9.3	8.9	8.5	8.1
15	15	15	15	14	13	13	12
20	20	20	20	19	18	17	16
30	29	30	29	28	27	25	24
50	49	50	49	47	45	43	41
70	68	70	68	65	62	60	57
100	97	100	97	93	89	85	81
150	146	150	146	140	134	128	122
170	166	170	166	159	151	145	138
200	195	200	195	187	178	170	163
300	292	300	292	280	267	255	244
360	351	360	350	336	321	306	293

Data in J ±10%

Waveform parameters



Charge time: Parameter for the HeartSave Y | YA for charging the first shock:
 1) new battery
 From open device cover to charge 200 J done: no more than 7 s
 From open device cover to charge 360 J done: no more than 14 s
 From AED analysis to charge 200 J done: no more than 5 s
 From AED analysis to charge 360 J done: no more than 12 s
 2) new battery after 15 time of 360 J discharges
 From open device cover to charge 200 J done: no more than 7 s
 From open device cover to charge 360 J done: no more than 14 s
 From AED analysis to charge 200 J done: no more than 5 s
 From AED analysis to charge 360 J done: no more than 12 s

Impedance measurement 25~300Ω

Defibrillation electrode REF 97847
 OBS-DE/P(303A1204): Disposable defibrillation electrodes

Shelf life with sealed package Up to 36 months


Total area 105±10 cm²

Maximum number of defibrillation shocks Up to 50 shocks

Battery REF 97846
 NRL01C

Battery type LiMnO₂ ,12V, 4.2Ah, non-rechargeable

Standby life Up to 5 years

Operating time	150 times 360 J discharge or operate 12 hours. (The equipment is powered by a new battery at 20 °C± 5 °C of ambient temperature, not performing defibrillation charges or discharges, voice volume set to low.)
Remaining charge after < Battery low > is prompted	When the remaining battery capacity is 12 %, the device will announce < Battery low >. 6 times 360 J discharge or operate 30 minutes. (The equipment is powered by a new battery at 20 °C± 5 °C of ambient temperature, not performing defibrillation charges or discharges.). If charging is no longer possible, the device automatically switches to cardiopulmonary resuscitation.
USB specification	
USB port	1 port: USB 2.0
Data storage	
ECG wave event	10 hours 2000 events
Audio log	2 hours
self-test report	3650 reports
Safety	
Classification	Medical product in class IIB, Device with internal power supply, Defibrillation-proof type BF
Identification	 <p>The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfill the essential requirements of Annex I of this directive.</p>
Classification	IP55
Environment specification	
Operating conditions <i>Recommended condition to save lifetime of the battery.</i>	-5°C to 55 °C(23 °F~131 °F), 5 to 95 % rel. humidity, but without condensation 570 hPa to 1062 hPa
Transportation and storage conditions <i>Recommended condition to save lifetime of the battery.</i>	Short term : -30 °C~+70 °C (-22 °F~158 °F), 5 to 95 % rel. humidity, but without condensation 570 hPa to 1062 hPa Long term : +15 °C~+35 °C (59 °F~95 °F), 5 to 95 % rel. humidity, but without condensation 570 hPa to 1062 hPa
Dimensions (L x W x H)	29.6 cm x22.0 cm x9.7 cm (±0.1 cm)
Weight	approx. 2.5 kg (with energy module, battery and pads) (±0.3 kg)

Shock test	Complies with requirements of 10.1.3a), IEC 60601-1-12:2014
Vibration test	Complies with requirements of 10.1.3b) IEC 60601-1-12:2014
Other	
Standards applied	Standards (for licensing in the EU, the corresponding harmonised European standards EN were used instead of the IEC standards): IEC 60601-1:2005+AMD1:2012+AMD2:2020 IEC 60601-1-2:2014+AMD1:2020 IEC 60601-2-4:2010+AMD1:2018 IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 IEC 62366-1:2015+A1:2020 IEC 62304: 2006+AMD1:2015 IEC 60601-1-12:2014+A1:2020
Subject to change without notice	

Appendix B: Warranty

Within 6-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 condition 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 measures artefacts
- Calculates several ECG signal parameters including frequency and morphological parameters - rejects implantable pacemaker artefacts
- Measures the QRS rate

Rhythm Categories

■ Shockable rhythms:

Ventricular fibrillation (VF): amplitude $\geq 0.2\text{mV}$

Pulseless Ventricular tachycardia (pVT)

■ Unshockable 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

Test results on the performance of the equipment 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):		met
VF	$\geq 90\%$	
VT, pulseless	$\geq 75\%$	
Nonshockable (specificity)	$\geq 95\%$	met
Positive predictive value	Report only	$>97\%$
False positive rate	Report only	$<2\%$

Appendix D: EMC

The equipment meets the requirements of IEC 60601-1-2: 2014.



DANGER

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.
- Other devices may affect this equipment even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.

NOTE

- ▶ The equipment 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 equipment may affect this equipment.
 - ▶ This equipment 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, theaters. If it is used in special environment, such as magnetic resonance imaging environment, the equipment may be disrupted by the operation of nearby equipment.
-

The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Emitted interference measurements	Conformance	Electromagnetic environment - code of practice
RF emissions according to CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions according to CISPR 11	Class B	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Interference immunity test	IEC 60601 test level	Level of conformance
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV ± 15 kV air
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	30A/m	30A/m

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

The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity to interference testing	IEC 60601 test level	Level of conformance	Compliance level
Conducted RF interference according to IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 V _{rms}	3V _{rms} 0.15MHz~80MHz,80% AM at 1kHz (IEC 61000-4-6) 0.15MHz~80MHz,80% AM at 5Hz (IEC 60601-2-4)
	6 V _{rms} in ISM bands and amateur radio bands between 0.15 MHz and 80MHz	6 V _{rms}	6V _{rms} in ISM and amateur radio bands between 0.15MHz~80MHz,80% AM at 1kHz
Radiated RF disturbances according to IEC 61000-4-3	For EM fields: 3V/m 80MHz~2.7GHz (IEC 61000-4-3) , 1KHz,80%, AM 10V/m,20V/m, 80MHz~2.5GHz (IEC 60601-2-4) 5Hz,80%, AM		
Proximity fields from RF wireless communication s equipment IEC61000-4-3	Freq MHz	Test Level P: max power, d: distance, E: Immunity Level	Compliance level
	385MHz	P=1.8W d=0.3m E=27V/m for TETRA400	P=1.8Wd=0.3m E=27V/m for TETRA400
	450MHz	P=2W d=0.3m E=28V/m for GMRS460; FRS460	P=2W d=0.3m E=28V/m for GMRS460; FRS460
	710MHz	P=0.2W d=0.3m E=9V/m for LTE Band 13, 17	P=0.2W d=0.3m E=9V/m for LTE Band 13, 17
	745MHz		
	780MHz		
	810MHz	P=2W d=0.3m E=28V/m for GSM800/900; TETRA800; iDEN820; CDMA850; LTE-Band 5	P=2W d=0.3m E=28V/m for GSM800/900; TETRA800; iDEN820; CDMA850; LTE-Band 5
	870MHz		
	930MHz		
	1720MHz	P=2W d=0.3m E=28V/m for GSM1800, CDMA1900; GSM1900; DECT; LTE-Band 1,3,4,35; UMTS	P=2W d=0.3m E=28V/m for GSM1800, CDMA1900; GSM1900; DECT; LTE-Band 1,3,4,35; UMTS
1845MHz			
1970MHz			

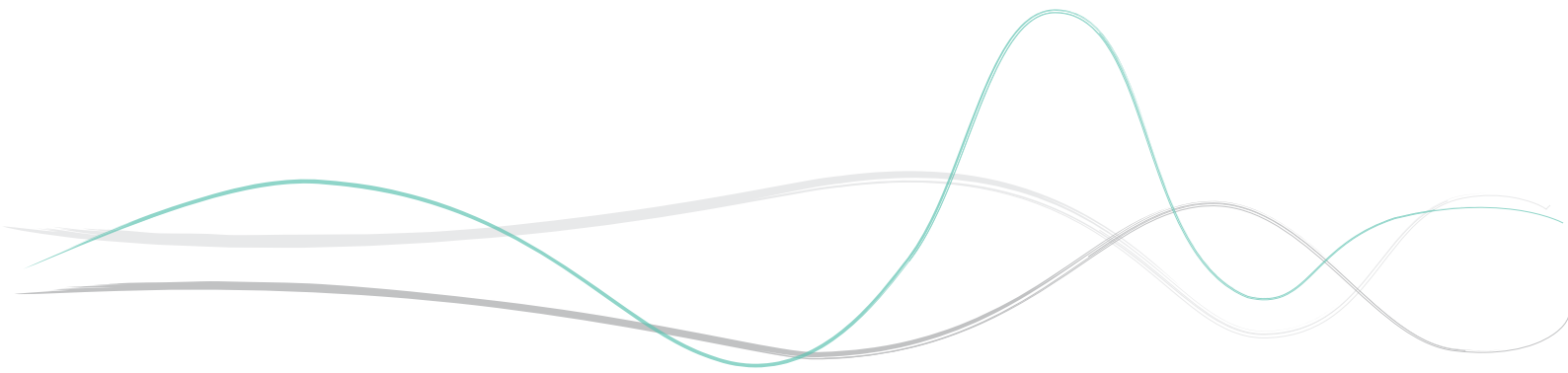
	2450MHz	P=2W d=0.3m E=28V/m for Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	P=2W d=0.3m E=28V/m for Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7
	5240MHz	P=0.2W d=0.3m E=9V/m for WLAN 802.11 a/n	P=0.2W d=0.3m E=9V/m for WLAN 802.11 a/n
	5500MHz		
	5785MHz		

NOTE

- ▶ The equipment is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the equipment 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 equipment 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.

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