PRIMEDIC
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Automated External Defibrillator
Instructions for use

HeartSave **Y | YA**

English

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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	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
MDR	Medical Device Regulation (EU) 2017/745
MIT	Massachusetts Institute of Technology
MPBetreibV	Medical Device Operator Ordinance
MPG	Medical Devices Act
Patient impedance	Patient resistance between the electrodes

2 Introduction

2.1 Foreword

Dear User,
You might need to use 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 might 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 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 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 automated external defibrillator device made by Metrax GmbH. The HeartSave Y|YA series automated external defibrillator is referred to as HeartSave Y|YA 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 regarding operation, maintenance and repair of the device.

Using accessories and spare parts made by other manufacturers.

Autonomous intervention, repairs or constructional changes to the device.

Lack of monitoring of parts or accessories 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

2.5.1 Device Pictogrammes

	Dangerous voltage.
	Defibrillation-proof type BF applied part.
	General warning sign
IP 55	IP55 water and dust resistance
	No dispose of product in domestic refuse
	Refer to instruction manual/booklet
CE 0123	The product bears CE mark indicating that it complies with the requirements of the Medical Device Regulation (EU) 2017/745.
	Manufacturer
EC REP	Authorised representative in the European community
	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

2.5.2 Battery pictogrammes


Protect battery from fire.


Do not charge battery


Recyclable


General warning sign


Refer to instruction manual/booklet.


No dispose of product in domestic refuse


The product bears CE mark indicating that it complies with the requirements of the Medical Device Regulation (EU) 2017/745.


Manufacturer


Manufacturing Date


Expire date

Serial number

2.5.3 Electrodes pictogrammes

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

Refer to instruction manual/booklet.

Type CF applied part

Maximum number of defibrillation shocks up to 50 times

Sales by prescription only

The product bears CE mark indicating that it complies with the requirements of the Medical Device Regulation (EU) 2017/745.

Manufacturer

Authorised representative in the European community

2.5.4 Package pictogrammes

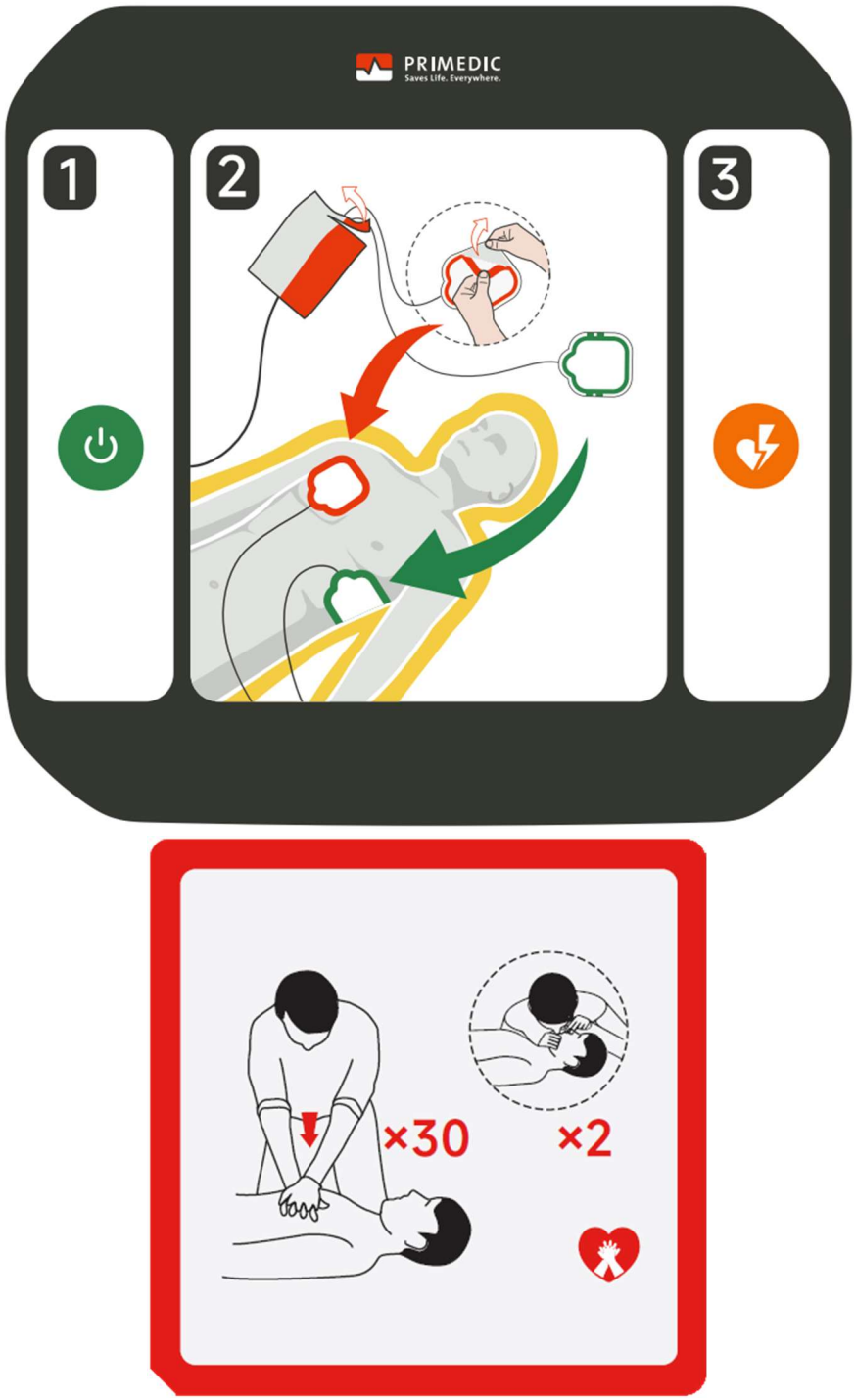
Permissible temperature range in °C

Permissible air humidity range in %

Permissible air pressure specification in hPa

Class 9 Miscellaneous dangerous substances and articles

2.6 Summarized operating instructions



The brief instructions could be found on the device and help you with the use of the HeartSave Y|YA device.

3 Intended Purpose

HeartSave Y|YA 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 Y|YA series defibrillators may only be used as described and under the conditions detailed in these operating instructions.
NOTE	The ECG is intended to identify electrode application, and it is not for diagnosis purposes.

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 Y|YA 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 is 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

HeartSave Y|YA should not be used if the patient shows signs of life. Signs of life are:

- Consciousness
- Breathing

HeartSave Y|YA should not be used on patients younger than one year.

3.3 Intended patient populations

HeartSave Y|YA can be used to treat patients with an age of more than one year.

3.4 Intended users

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

3.5 Scope of usage of device

HeartSave Y|YA should be only used for home healthy environment and EMS medical environment (except airborne).

3.6 Clinical benefit

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

4 Safety information

4.1 General safety advice

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

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

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

NOTE	Take care of 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 away from children.

NOTE	The device will take approximately 2 hours to ready for intended use when device is stored under minimum storage temperature (-30°C) or maximum storage temperature (70°C).

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.

The device should not be used 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 of defibrillator.

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 HeartSave Y|YA)

4.3 Safety notes for the protection of patient

DANGER

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

- Do not use the device on a patient unless you ensure the operational safety.
- Check the device before use to guarantee it is in good condition.
- If the device is defective (e.g. damage of electrodes cable), do not use the device.
- Use new, undamaged, and unexpired electrodes for every patient to avoid any possible burns to the skin.
- Only connect PRIMEDIC electrodes to the HeartSave Y|YA defibrillators.
- 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.).
- The user should stop all physical movement, such as vehicular operation, during the ECG analysis phase to avoid data analysais inaccuracies.

These devices may cause HeartSave Y|YA devices not working properly or doesn't work. Please make sure to disconnect all other devices from the patient before defibrillation.

- Prior to defibrillation, disconnect all other electrically operated medical devices that are not defibrillation-proof and are used on the patient.
- Keep the electrodes away from other electrodes, metal objects and earthed objects.
- Do not use the device on infants under 12-month-old.
- Place the electrodes precisely according to the image guidance.
- Dry the chest and carefully remove hair of large amount on the chest before applying the electrodes.
- Do not place the electrodes over any implanted pacemaker to avoid a possible damage to the pacemaker from the defibrillation energy.
- Do not touch the patient during ECG analysis.
- Stop CPR while HeartSave Y|YA defibrillator is under ECG analysing.
- No touch of other medical devices which may present a danger to the patient as a result of the cumulation of currents.

WARNING

Be aware of the electrodes cable

Strangulation may occur by electrodes cables to the patient. Avoid cable twisting or wrapping into a loop during device usage.

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 (less than 360J). This electrical energy can potentially lead to myocardial damage.

Possibly undesirable side effects on the patient due to muscle contractions as a result of defibrillation.

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

Overvoltage Protection: The HeartSave Y|YA series device includes built-in overvoltage protection to ensure safe operation during unexpected electrical anomalies. This feature is critical to prevent internal damage to the device. Use only manufacturer-recommended batteries, and if any unusual behavior or error messages are displayed, contact authorized service personnel immediately.

WARNING

Repair and installation of HeartSave Y|YA devices should be carried out by professional authorized persons only.

Use original accessories from the manufacturer only.

Clean the device as guided in this instruction of use.

WARNING

If any serious incident occurred in relation to the device, please report to us and the competent authority of the Member State in which you are established.

5 Description of device

5.1 General description

The HeartSave Y|YA series 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 HeartSave Y|YA 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	CPR Sensor	WLAN	LTE
Semi-automated external defibrillator	HeartSave Y0	YES	NO	NO	NO
	HeartSave Y1		NO	YES	NO
	HeartSave Y2		NO	NO	YES
	HeartSave Y3		NO	YES	YES
	HeartSave Y5		YES	NO	NO
	HeartSave Y6		YES	YES	NO
	HeartSave Y7		YES	NO	YES
	HeartSave Y8		YES	YES	YES
Fully-automated external defibrillator	HeartSave YA0	NO	NO	NO	NO
	HeartSave YA1		NO	YES	NO
	HeartSave YA2		NO	NO	YES
	HeartSave YA3		NO	YES	YES
	HeartSave YA5		YES	NO	NO

Defibrillation Mode	Model	Shock Button	CPR Sensor	WLAN	LTE
	HeartSave YA6		YES	YES	NO
	HeartSave YA7		YES	NO	YES
	HeartSave YA8		YES	YES	YES

HeartSave Y|YA series is equipped with device, electrodes and battery, LCD colour display (optional). You could also check chapter 5.2 for detailed information.

HeartSave Y|YA series is designed to be safe and quick to use for emergency. The power supply of HeartSave Y|YA series comes from a non-rechargeable lithium battery.

5.2 Device description

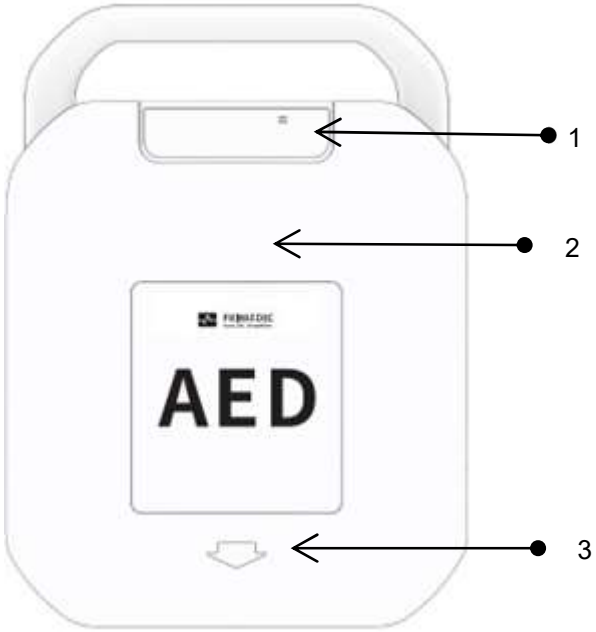


Fig. 1 Front view with lid

(1) Status display
(2) Device lid
(3) Open the lid as directed by the arrow

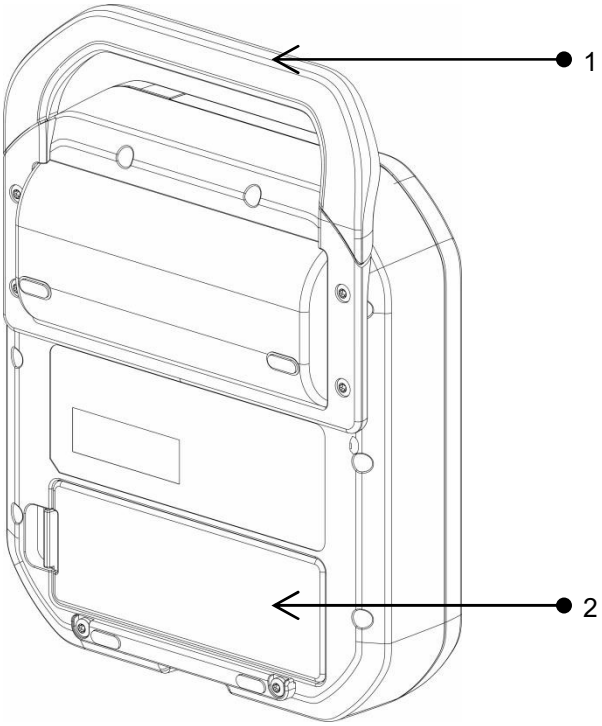


Fig. 2 Back View

(1) Carrying handle

(2) Battery

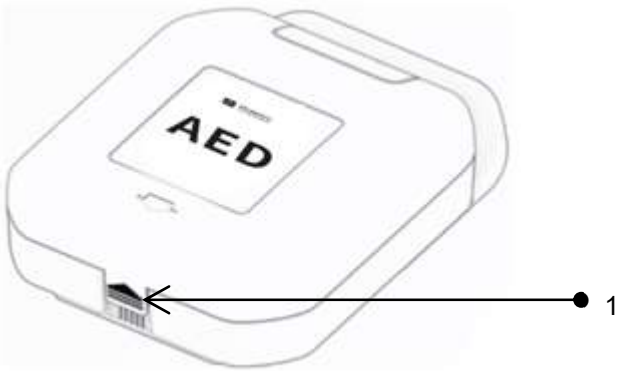


Fig. 3 Bottom View

(1) Device lid latch

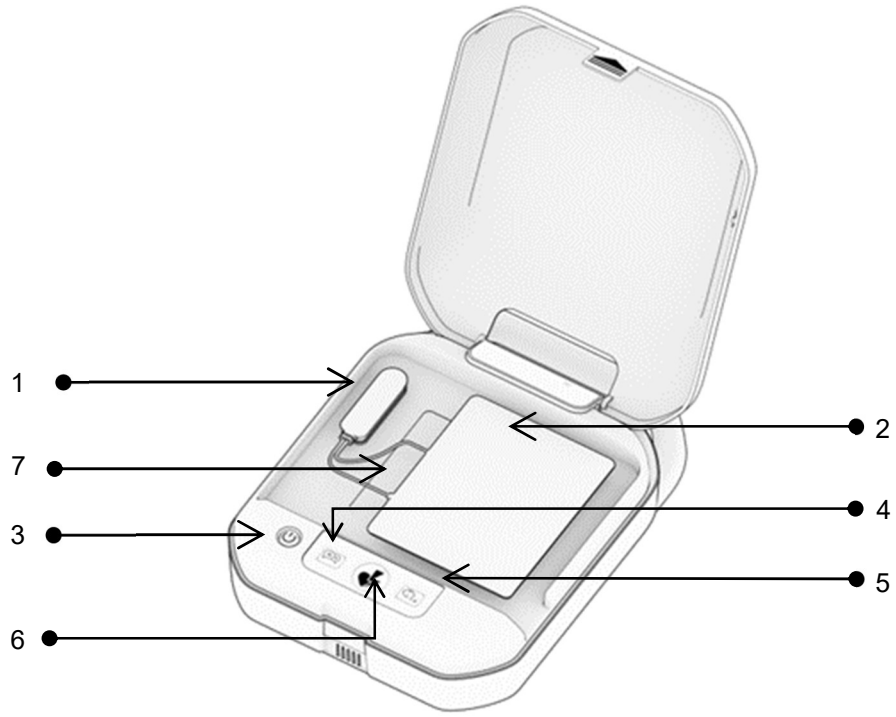


Fig. 4 HeartSave Y|YA series front view

(1) Socket for electrodes and USB
(2) Electrodes
(3) On/Off switch with green back-light
When back-light is green: device switched on as ready for operation
(4) Language button
(5) Child button with back-light
When back-light is green: child mode activated
When back-light not illuminated: adult mode
(6) Shock button with orange back-light (only for HeartSave Y series), flashing when ready to shock
orange back-light (only for HeartSave YA series)
(7) Colour display (optional for HeartSave Y|YA series)
Display content: device operation guidance, ECG wave (1-channel)

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
1x Towel

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 replace battery. - Insert the battery. - Plugin electrodes. - Renew electrodes. - In case of an internal error, contact the service department.
	Battery capacity 20%-100%	Battery ready to use (Only for HeartSave Y|YA with LCD display)
	Battery capacity 10%-19%	Battery ready to use (Only for HeartSave Y|YA with LCD display)
	Battery capacity 0%-9%	Change battery if possible (Only for HeartSave Y|YA with LCD display)

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

Reason	Possible to use?	Procedure
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 360J.	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

If the battery is empty and the display shows

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

< Low Battery! Please replace battery as soon as possible. Continue to use the device if no replacement available > or **< Battery error >**

6 Device preparation

6.1 Unpacking

DANGER

Danger may occur by damaged device

➢ Do not use damaged devices

When receive the delivery, check the transport damage of packaging and device. Check whether the delivered package is complete as listed according to enclosed delivery note.

If you notice any damage, immediately contact your logistic supplier, dealer or directly contact authorized service. Provide them serial number and describe the damage of the device.

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 first use. However, if electrodes were replaced or unplugged, they must be reconnected to the device with the following steps.

Fig. 6 Inserting electrodes

Installation procedure:

- ▶ Pull the latch to allow the lid to be opened.
- ▶ Insert the electrodes plug into the socket.
- ▶ Place the electrodes into the device.

NOTE The excess cable of the electrode is packed in the pouch.

ATTENTION

Status display may show “X” after replacing electrodes

➢ In this case, please open the lid or press the on/off button to switch on the device. Wait until self-test finish and device status display will show “OK”.

WARNING

- Keep the electrodes always plugged in.
- Do not open the electrodes pouch except immediately prior to use.
- Do not bend the electrodes with extra force.
- Check the seals of electrodes pouch/cable and 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 first use of HeartSave Y|YA, the battery transport seal must be removed and insert the battery 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 place the battery close to fire or heat.
- Please avoid storage under direct sunlight.
- Do not use other batteries on HeartSave Y|YA to prevent unsafe device operation.

ATTENTION

- Always take care of the battery expiry date.
- Replace the battery if it is expired.

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

NOTE	If the device must be sent to customer services, remove the battery, and use tapes to cover the battery contacts. Check if any battery special shipping regulations in case of battery shipment or send the battery to customer service.

6.3.2 Battery insertion

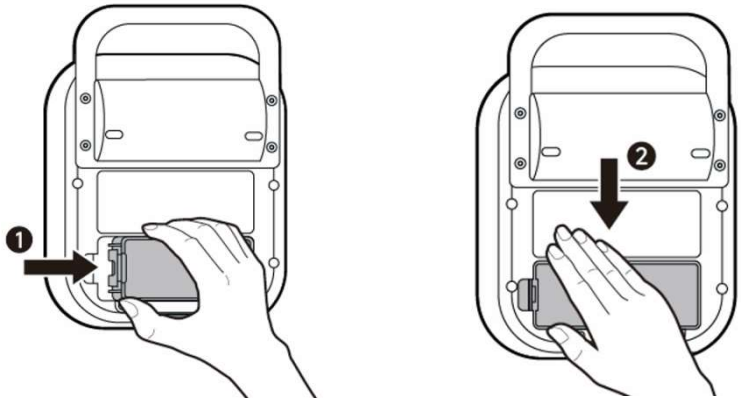


Fig. 7 Insert the battery

Procedure:

- ▶ Put the device top down on a flat surface.
- ▶ 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 battery slot until the battery flap securely in the slot.
- ▶ Press the battery completely into the device until you hear a "click" when it slide into slot.
- ▶ When battery inserted, the device will carry out a self-test. Follow the voice messages.
- ▶ After self-test has been done successfully, the 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:
Switch on the device again and wait for a complete self-test finish.

6.3.3 Battery removal

NOTE Only remove battery when device is switched off.

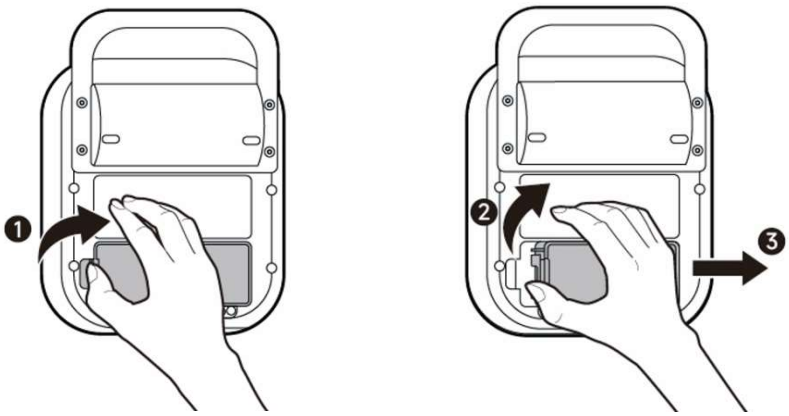


Fig. 8 Removing the battery

Procedure:

- ▶ Put the device top down on a flat surface.
- ▶ Press the unlocking flap (1) to the right until the flap on the battery is released and the battery out of the slot slightly.
- ▶ Push 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 when switch on the device

When HeartSave Y|YA is switched on by opening the lid or pressing on/off button, the device performs a quick self-test to check all key functions and signal mechanisms.

When battery inserted to HeartSave Y|YA, the device will perform a manual self-test.

Manual self-test

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

With a ticking metronome sound, the devices 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 devices 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 Periodic automatic self-tests

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

Type of test	Test coverage
Daily*	Check main control module, battery, speaker, internal power module, electrodes, treatment module.
Monthly (First day of each month)	Check main control module, battery, speaker, internal power module, electrodes, treatment module, 1J charge and discharge and 200J charge and discharge, speaker.
Half-year (01.01 and 01.07 of every year)	Check main control module, battery, speaker, internal power module, electrodes, treatment module, 1J charge and discharge and 360J charge and discharge, speaker.

* The daily self-test is set to “05:00 a.m.” of the time zone. The self-test time depends on time zone setting.

NOTE	The device is not able to perform automatic time zone update. Time zone setting should be done by HeartSave Y|YA configuration tool.

6.4.3 Device status internal monitoring

The HeartSave Y|YA 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.

DANGER

Risk of delay therapy

➢ Please continue to use the device in emergency, even when device display "X" in status display.

6.5 Language button

You can press the language selection button during operation until the desired language is selected. The HeartSave Y|YA optionally supports up to 4 languages. With pressing the language button, the selected language is briefly announced.

7 Using HeartSave Y|YA

NOTE	The rescue procedure which applied for HeartSave Y|YA is according to the recommended guidelines of European Resuscitation Council or American Heart Association.

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.

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 as usual. Do following steps:

- ▶ Close up to patient and attempt to call patient and tap the body to check the conscious.
- ▶ If the patient does not respond, place your head in the patient's neck and check whether you can detect any sign of breathing. If necessary, check the airway for foreign bodies.
- ▶ If the patient is not breathing as usual, expose the breast area and attach electrodes. If the defibrillator is not available yet, ask other people to collect immediately.
- ▶ Using the supplied razor, remove breast hair from the position where the electrodes will be attached.
- ▶ If the skin is wet, dry the skin at the position where the electrodes will be attached to ensure adhesion.
- ▶ If the skin has any lint, dust or dirt on, please clean before attach electrodes.
- ▶ Make sure to call emergency services.

7.2 Switching on HeartSave Y|YA

HeartSave Y|YA is automatically activated by opening the lid of the device. If the device is not switched on automatically, switch it on by pressing the on/off switch button. When device is switched on, all option buttons are selectable, except shock button (HeartSave Y only) because defibrillation function is not possible to be triggered unless the device has detected a defibrillation required rhythm.

Immediately after the device is switched on, a quick self-test is carried out to check key functions of the deivce.

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

< Power on >

< Call emergency services >

< Analysing rhythm, don't touch the patient>

If the electrodes are plugged into the socket and not connected to the patient, following prompts are issued:

< Power on >

< Call emergency services >

< Plug in electrodes>

7.3 Check the patient category

HeartSave Y|YA defibrillator could be used for adults or children. The child mode is only used for patients who are younger than 8 years and/or weigh less than 25 kg. Otherwise use the adult mode for patients.

You can press child button to switch to child mode. If HeartSave Y|YA is in child mode, the indicator LED of the child button will illuminate (green).

Child mode is especially developed for the defibrillation of child. The child mode of HeartSave Y|YA supplies less energy than adult mode.

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

7.4 Plug in electrode cable

NOTE	If the electrodes plug is already inserted, then skip this step.

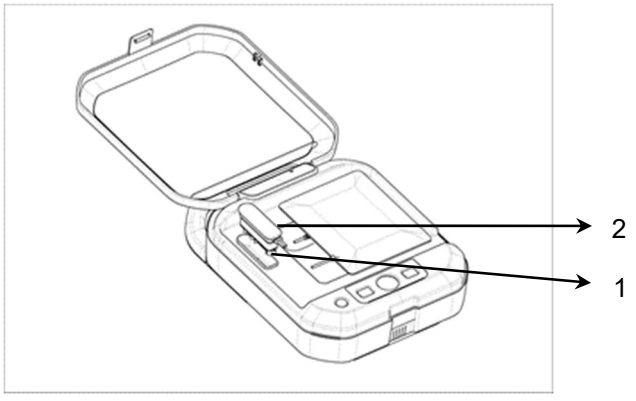


Fig. 9 Plug in electrodes cable

(1) Socket

(2) Electrodes plug

Procedure:

- ▶ When hearing the voice prompt **< Plug in electrodes >**,
- ▶ Insert the plug (2) of electrodes into the socket (1) on HeartSave Y|YA as shown above.

NOTE	If electrodes are not plugged in after several voice prompts, the device will switch to cardiopulmonary resuscitation automatically. When electrodes are plugged in, CPR instructions will be interrupted immediately.

7.5 Prepare the patient

NOTE	Please wear the disposable gloves from accessory kit.

7.5.1 Removing clothes from patient

Use supplied razor to remove breast hair from the position where electrodes will be attached.

7.5.2 Placing electrodes

WARNING

Avoid damage to gel layer of electrodes

Skin burning risk

- Be careful not to touch gel layer before attaching electrodes to patient
- Be careful, gel layer damage may cause skin burning.

CAUTION

- Do not use expired electrodes, damaged electrodes. Also do not use electrodes from damaged pouch.
- Check electrodes pouch to ensure integrity of seals and validity from expiry date.

If such electrodes are used for defibrillation, worse patient therapy or skin burning may occur.

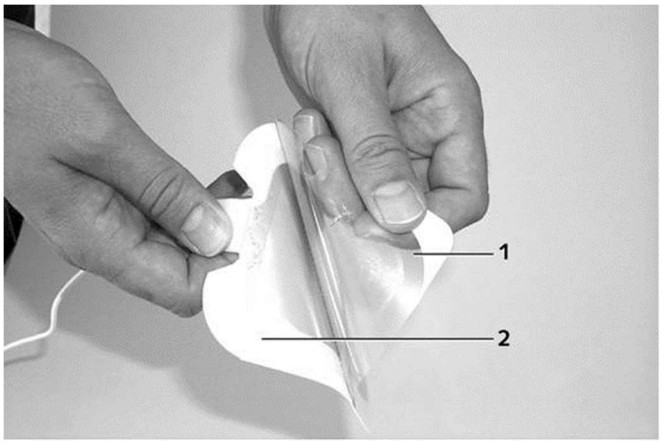


Fig. 10 Removing the foil from electrodes

(1) Protection foil of electrodes

(2) Electrodes

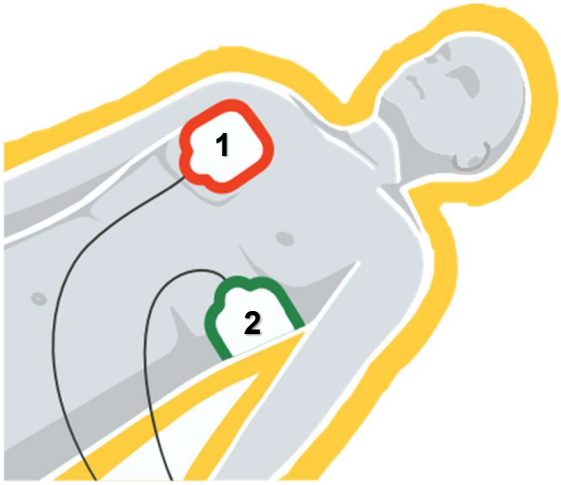


Fig. 11 Position of electrodes on adults

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.

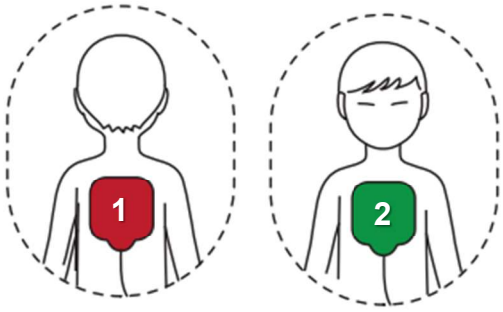


Fig. 12 Position of electrodes on children

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 Y|YA 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 >

Procedure:

- ▶ 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. 11 for adults and Fig. 12 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!

NOTE	If electrodes are not attached to the patient after several voice prompts, the device will switch to cardiopulmonary resuscitation automatically. When electrodes are well applied to patient, CPR instructions will be interrupted immediately.
NOTE	It is recommended to use following models of electrodes, which with CE marking for

defibrillation.

Manufacturer	Model	Remark
Baisheng Medical Co., Ltd.	OBS-DE/P	See Appendix A for details

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 >

7.6 Carrying out the ECG analysis

If electrodes applied, the device would 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.

7.7 Defibrillation

DANGER

Danger to user, patient or third parties

Triggering heart arrhythmia

- ➢ Do not touch patient during defibrillation
- ➢ Warning third parties of defibrillation danger and step away
- ➢ If patient wakes up during therapy, stop the resuscitation

NOTE	Pressing the shock key during capacitor charging (before it turns red) will not result in release of shock.
NOTE	Defibrillation may cause muscle contractions of the patient.
NOTE	When device is charging or ready for shock: • if device still detects a shockable rhythm, the device won't abort defibrillation process unless manual abortion. • 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:

HeartSave Y series	HeartSave YA series
semi-automated external defibrillator	**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 administer a shock without requiring further action**

After shock delivered, no ECG analysis again, the device will proceed with cardio-pulmonary resuscitation (CPR).

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

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

< No shock advised >

< Safe touching patient >

< Begin CPR >

7.8 Cardio-pulmonary resuscitation (CPR)

As a configuration of HeartSave Y|YA for CPR, we follow 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.

< No shock advised > or shock released

< Safe touching patient >

< Begin CPR >

Adult mode	Child mode
< Give 30 chest compressions >	**< Give 15 chest compressions >**
< Give 2 rescue breaths >	**< Give 2 rescue breaths >**

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 paediatric basic resuscitation, ERC-2021 recommends 30 chest compressions with 2 ventilations or continuous chest compressions in children during CPR.

< No shock advised > or shock released

< Safe touching patient >

< Begin CPR >

Adult mode	Child mode
Continuous chest compression	**< Give 15 chest compressions >** **< Give 2 rescue breaths >** or Continuous chest compression

7.8.3 CPR configuration of the HeartSave Y|YA

The HeartSave Y|YA offers the possibility to configure cardiopulmonary resuscitation measures as customer requirement. For instance, 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 are also valid for child mode.
The default CPR configuration is defined for CPR for trained rescuer. To change the configuration, please contact your dealer or customer service.

7.8.4 CPR metronome function

During chest compressions, HeartSave Y|YA also equipped with metronome function which guide you with correct frequency for chest compression. Please follow the rhythm. The last five CPR metronome tones sound a little different to hint a break after the compression cycle. The artificial respiration is also guided by two acoustic outputs. From the second to fifth CPR cycle, only these acoustic signals are provided by device.

NOTE	When CPR period finishes (2 min.), device returns to ECG analysis.

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

7.8.5 CPR feedback sensor

This chapter only applies to the electrodes with CPR feedback sensor (303A1205)

The device provides voice prompts about real-time compression feedback if it is connected with a CPR feedback sensor.

During chest compressions, when you use electrodes (303A1205) with CPR feedback sensor, the device will provide compression quality feedback.

Attach the CPR feedback sensor:

- ▶ Prepare the patient skin, shave hair from skin if necessary. If the patient's chest with sweat or blood, clean it completely.
- ▶ Position the CPR feedback sensor so that the compression area is in the middle of the chest, on the lower half of the sternum.

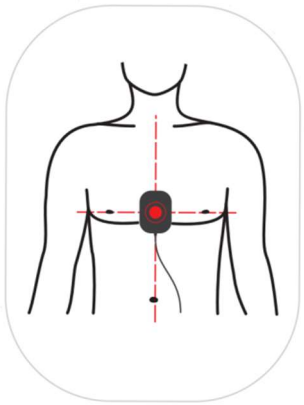


Fig. 13 CPR feedback sensor positioning

7.9 Keeping the defibrillator ready for use

- ▶ Check if HeartSave Y|YA is damaged after each use.
- ▶ Clean HeartSave Y|YA and accessories after each use. Cleaning HeartSave Y|YA and accessories in case of infection risk, see section 11.1.
- ▶ Replace electrodes, check and replace battery if necessary.
- ▶ If any malfunctions or noticeable issues happened, please contact customer service.

HeartSave Y|YA has 3 options to switch off:

- Pressing on/off button for approx. 3 seconds. You will hear a beep accordingly.
- Closing device lid.
- If the device does not recognize an operation for 30 minutes, it will switch off automatically.
- Wait at least 30 seconds after switching off before removing battery.

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, electrodes information
Therapy log	Record ECG
	Recorded impedance
	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 Y|YA 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:

- ▶ Plug in USB stick which includes M600-license file
- ▶ Switch on device
- ▶ When child button backlight continuously illuminated, data successfully exported.

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

NOTE	The USB storage for data export must be FAT32 formatted. The HeartSave Y|YA supports no other format or 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".

8.4 WLAN configuration

HeartSave Y|YA series adapted WLAN module as optional accessory. The WLAN module supports device remote management and monitoring.

NOTE	When the device adapts WLAN module: • The data transmission via WLAN is encrypted. • Use decryption key provided by manufacture to configure network connection. • Ensure the hyper security before connect to network.

To get support of WLAN configuration and updates, please contact PRIMEDIC customer service.

WARNING

Potential connect to unsecured network

This device may be connected to a public network. Please ensure that you are using a secure, protected network connection to prevent unauthorized access and data leakage.

The cyber security of device will be configured by our authorized maintenance service of Metrax.

8.5 LTE configuration

HeartSave Y|YA series adapted LTE module as optional accessory. The WLAN module supports device remote management and monitoring.

NOTE	When the device adapts LTE module: • The data transmission via LTE is encrypted. • Use decryption key provided by manufacture to configure network connection. • Ensure the hyper security before connecting to network.

To get support of LTE configuration and updates, please contact Metrax customer service.

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 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.

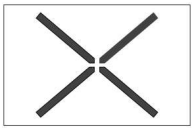
9.1 Standard accessories

Name	Model	Remark
Electrodes	OBS-DE/P(303A1204)	Disposable electrodes for adult and child
	OBS-DE/P(303A1205)	Disposable electrodes for adult and child with CPR feedback sensor
Battery 1A	NRL01A	24V, 2.4Ah, non-rechargeable
Battery 1C	NRL01C	12V, 4.2Ah, non-rechargeable

10 Troubleshooting

This section explains problems you may encounter while using the HeartSave Y|YA 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
Status display 	Internal error	Reboot 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 < Low Battery! Please replace battery as soon as 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.

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%)

We recommend cleaning your device every time after each use. To clean your device, follow the steps below:

1. Shut down the device, disconnect cables, and remove the battery.
2. Clean the exterior surface of the device using a soft, clean cloth dampened with the recommended cleaning agents.
3. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
4. Dry your device in a ventilated, cool place.

NOTE	To keep the status display clear for visual inspection, we recommend you also clean the status display with a soft, clean cloth dampened supported by glass cleaner (e.g. S.C.Johnson&Son Windex).

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 Y|YA.
- ➢ Only use genuine accessories!
- ➢ Maintenance and service are not allowed during the use of the device.
- ➢ The device may only be opened by persons authorized by Metrax.

We recommend performing a regular visual inspection of the device every one year.

Make sure that the electrodes, 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 Y|YA

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 Y|YA 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

- Device Disposal: Dispose of the device through certified recycling centers in accordance with local regulations. Do not discard in household waste.
- Battery Disposal: Batteries contain hazardous substances. Protect battery terminals with insulating tape to prevent short circuits before recycling. Dispose of batteries at designated collection points as required by local regulations.
- Environmental Protection: Recycling helps conserve resources and reduce environmental pollution. Contact your local authority or dealer for more guidance on proper disposal.

Fig. 14 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

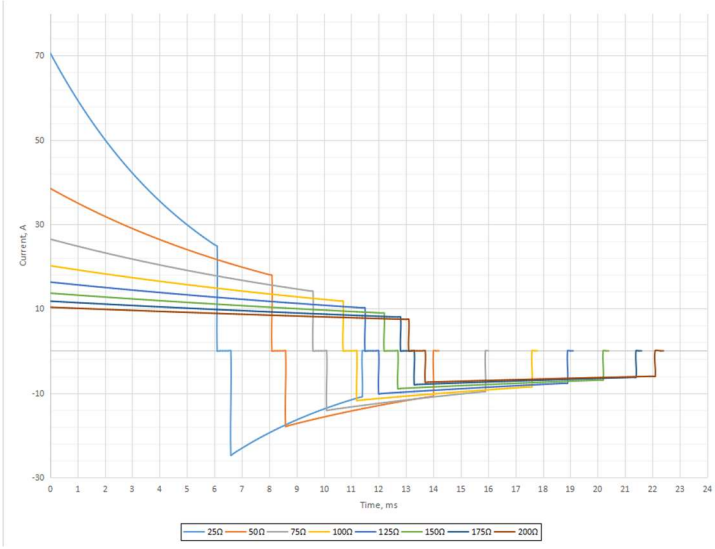
Operating modes	HeartSave Y series: semi-automated external defibrillator HeartSave YA series: fully-automated external defibrillator
Impulse shape	Biphasic truncated exponential, auto-compensation according to patient impedance.
Optional output energy	For adults:100 J, 150 J, 170 J, 200 J, 300 J, 360 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 with tolerance of ±2J or ±10%, the higher of the two.

Waveform parameters



Charge time	When bring the device from the specified AED wall cabinet, the parameter of HeartSave Y|YA charging for first shock as below: 1) new battery From open device lid to charge 200 J done: no more than 7s From open device lid to charge 360 J done: no more than 14s From AED analysis to charge 200 J done: no more than 5s From AED analysis to charge 360 J done: no more than 12s 2) new battery after 15 time of 360 J discharges From open device lid to charge 200 J done: no more than 7s From open device lid to charge 360 J done: no more than 14s From AED analysis to charge 200 J done: no more than 5s From AED analysis to charge 360 J done: no more than 12s
Applicable impedance range	25 - 300Ω
ELECTRODES	
Manufacture	
Model	Baisheng Medical Co., Ltd. OBS-DE/P(303A1204): Disposable electrodes OBS-DE/P(303A1205): Disposable electrodes with CPR feedback sensor
Lifetime with sealed pouch	at least 5 years
Total area	105 ± 10 cm²
Maximum number of defibrillation shocks	Up to 50 shocks
SSCP (Summary of safety and clinical performance)	EUDAMED link preparation ongoing.

BATTERY	
Model	Battery 1A (NRL01A), Battery 1C (NRL01C) (both model are applicable for all models of Heart Y|YA series)
Battery type	LiMnO2, 24V, 2.4Ah, non-rechargeable (NRL01A) LiMnO2, 12V, 4.2Ah, non-rechargeable (NRL01C)
Standby life	at least 5 years
Operating time	150 times 360 J discharge by a new battery at 20 °C± 5 °C of ambient temperature, not performing defibrillation charges or discharges, voice volume set to low. Operate 12 hours 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 significantly reduced, the device will announce **< Battery low>.** At least 6 times 360 J discharge or operate 30 minutes. (The device is powered by a 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
WLAN SPEFICICATION	(only available on device with WLAN module)
WLAN standard	IEEE802.11 b/g/n
Frequency & channel	Station mode: 2.4 GHz, channel 1-13 Access Point mode: 2.4 GHz, channel 1-11
Maximum conducted output power	15dBm
Maximum radiated output power	18 dBm EIRP (RF power including maximum antenna gain (3 dBi)
Safety	WPA/WPA2/WPA3, EAP-TLS, PEAP
LTE SPECIFICATION	(only available on device with LTE module)
Channel	LTE-FDD: B1/B3/B5/B7/B8/B20/B28 LTE-TDD: B38/B40 GSM: EGSM900/DCS1800
Transmission power	EGSM900: 33±2 dBm DCS1800: 30±2 dBm LTE-FDD: 23±2 dBm LTE-TDD: 23±2 dBm
Standard	3GPP E-UTRA Release 11

COLOUR DISPLAY	(only available on device with colour display)
Type	Colour LCD display
Working mode	Auto, indoor, outdoor (Self-adjust display brightness based on environment brightness)
Size	4.3 inch
Resolution	800 x 480
ECG Wave	1-Channel
DATA STORAGE	
ECG wave	10 hours
event	2000 events
Audio log	2 hours
self-test report	3650 reports
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	IP55
ENVIRONMENT SPECIFICATION	
Operating conditions	-5°C to 55 °C, 5 to 95 % rel. humidity, but without condensation 570 hPa to 1062 hPa
Transportation and storage conditions	Short term (≤ 1 week): -30 °C to 70 °C, 5 to 95 % rel. humidity, but without condensation 570 hPa to 1062 hPa Long term (> 1 week): 15 °C to 35 °C, 5 to 95 % rel. humidity, but without condensation 570 hPa to 1062 hPa
Dimensions (L x W x H)	29.6 cm x 22.0 cm x 9.7 cm (±0.1 cm)
Weight	approx. 2.5 kg (with energy module, battery and electrodes) (±0.3 kg)
Minimum lifetime with combined device, electrodes and battery	At least 2 years with storage condition of temperature 15°C-35°C, humidity ≤ 80%, air pressure 570hPa to 1062hPa.

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
Drop test	1.6m, complies with requirement of EN1789:2007+A2:2014

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

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 Y|YA 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)

■ 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 device configured with HeartSave Y|YA 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	≥90 %	
VT, pulseless	≥75 %	
Nonshockable (specificity)	≥95 %	met
Positive predictive value	Report only	>97 %
False positive rate	Report only	<2 %

Appendix D: EMC

The device 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 device (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 device 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 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, theaters. 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.

Emitted interference measurements	Conformance	Electromagnetic environment - code of practice
RF emissions according to CISPR 11	Group 1	The device 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 device.
RF emissions according to CISPR 11	Class B	The device 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 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.

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 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.

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.

Immunity to interference testing	IEC 60601 test level	Level of conformance	Compliance level
Conducted RF interference according to IEC 61000-4-6	3 Vrms 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 Vrms 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 communications 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		
	5500MHz	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
	5785MHz		

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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