Fully Automated External Defibrillator

Operation Manual

Reliable technology for life saving

V1.1

Responsibility Information

Manufacturer's Responsible:

Manufacturer shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.
Information in this document is subject to change without notice.

User's Responsible:

The Automated External Defibrillator (AED) is intended for use by personnel who are authorized by a physician/medical director, or who should be trained for basic life support, advanced cardiac life support or other emergency medical response, and who have received training in the use of the AED.
The user should be completely knowledgeable of the information in the *Automated External Defibrillator Operation Manua*l, as all other electronic patient care monitors, good clinical judgment should be used when operating the AED. To ensure patient safety and proper operation, please use manufacturer's authorized parts and accessories only.
Users must keep all shipping containers and packaging materials. When shipping the AED and accessories for calibration, service, or upgrades, the original shipping containers and packaging materials must be used.

Important Note

It is important to know that the AED can increase survival rate of sudden cardiac arrest! But defibrillation cannot guarantee survival no matter how fast the treatment is. For some patients, the underlying problems causing the cardiac arrest is simply not survivable despite any available care.

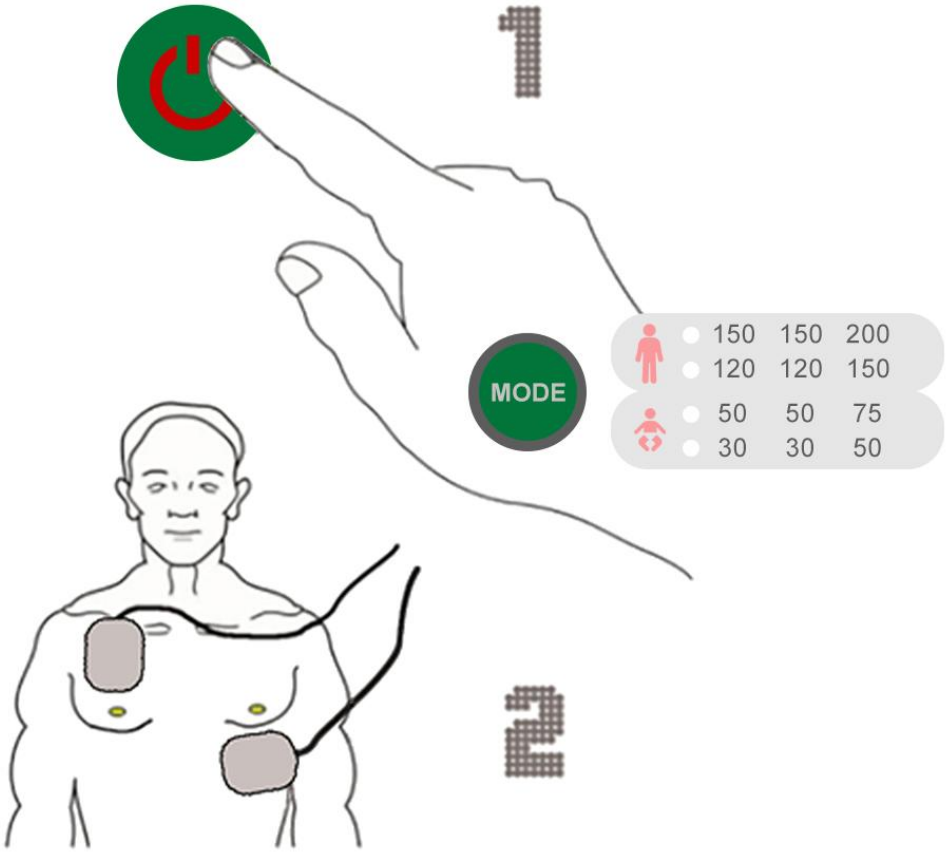
Revision History

Rev	Date	Modification
1.0	2024-05	First release
1.1	2024-07	Modify the pictures of LCD display

Revision History

This operation manual describes the AED with software version 1.0 or later.

Fully Automated External Defibrillator
QUICK REFERENCE



CONTENTS

1. Introduction to the AED

This Operation Manual provides information to guide trained operators in the use and maintenance of the Automated External Defibrillator (AED) and its accessories.
The first chapter includes intended use, an overview of the AED, when and how to use AED properly.

Overview

AED is a safe, lightweight, and battery-powered device. It is designed for simple, reliable and portable operation of trained users. The AED is intended to be used in public places, hospitals and homes. It can be used in situations where there could be several minutes before the arrival of advanced life support (ALS) personnel.

The AED recognizes ventricular fibrillation (VF) and pulseless ventricular tachycardia (VT) and guides operators through the defibrillation process. When properly connected to a patient who has an apparent lack of circulation, including unconsciousness, absence of normal breathing and absence of a pulse or signs of circulation, the AED analyzes the patient's heart rhythm, provides visual and voice prompts, determines if a shockable situation exists and then give shock automatically.

The AED delivers the defibrillation shock through two self-adhesive, pre-gelled, low-impedance electrode defibrillator pads. The pads, cable, and connector are sold as disposable kits.

The AED is designed for INFREQUENT USE, and the term is used to describe a DEFIBRILLATOR designed to endure less than 2500 discharges.

The recovery time of defibrillation is less than 5 seconds.

The Automated External Defibrillator is intended to be portable. The Automated External Defibrillator is not intended to be used in ambulance.

Features

- Two-step defibrillation process
- extensive voice and visual prompts for the operator
- continuous event recording for reporting each use and play back from computer software
- daily, weekly and monthly self-test to ensure readiness
- biphasic energy output
- Lock-out protection to prevent inadvertent defibrillation.
- two modes: adult mode and pediatric mode

  Energy Sequence: Adult mode(1): 150J, 150J, 200J
  Adult mode(2): 120J, 120J, 150J
  Pediatric mode(1): 50J, 50J, 75J
  Pediatric mode(2): 30J, 30J, 50J

Why AED

The AED is used to the Sudden Cardiac Arrest (SCA) which is mostly caused by ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT). SCA is the cessation of normal circulation of the blood when the heart unexpectedly stops pumping. The causes of SCA are varied, but the signs or symptoms of SCA are hardly revealed in daily life.

SCA can happen to anyone at any time. According to AHA (American Heart Association) CPR facts and statistics, there are about 300,000 victims of out-of-hospital cardiac arrest each year in the U.S. alone, and less than 8% of people who suffer from cardiac arrest outside the hospital survive.

Early defibrillation is critical to the survival from SCA for several reasons: the most frequent initial rhythm in out-of-hospital witnessed SCA is ventricular fibrillation (VF), the treatment for VF is defibrillation, the probability of successful defibrillation diminishes rapidly over time, and VF tends to deteriorate to asystole over time. To treat VF SCA, rescuers must be able to rapidly combine Cardiopulmonary Resuscitation (CPR) with AED.

Safety Information

The following safety and effectiveness issues are to be considered prior to the usage of AED.

Safety Terms

You may encounter the following terms in this manual and while using your AED:

DANGER Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

NOTE Provides application tips or other useful information to assure that you get the most from your equipment.

General Warnings and cautions

DANGER

- The defibrillator delivers up to 200 joules of electrical energy. Use the AED unit only as described in this manual. Improper use of the device can cause death or injury.
- Hazardous electrical output. The AED is for use by qualified personnel.
- DO NOT TOUCH the AED pads surfaces, the patient, or any conductive material touching the patient during ECG analysis or defibrillation.
- Always stand clear of the patient when delivering a shock.
- DO NOT attempt to perfom any maintenance service on AED during its operation.
- Possible explosion and fire hazard may occur if used in the presence of flammable agents or in an oxygen enriched atmosphere.
- During the charging process, the AED will not analyze the patient's ECG, the operator should constantly pay attention to the patient's response, and be ready to press ON/OFF button in case of any improper conditions for shock. The AED cannot automatically abort the charging process.

WARNING

- There are two modes, adult mode and pediatric mode. According to the patient's age and weight, choose the right mode.
- Defibrillation may cause myocardial injury and skin burn.
- Avoid contact between parts of the Patient's body such as exposed skin of head or limbs, conductive fluids such as gel, blood or saline and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillation current.
- Move the patient away from electrically conductive surfaces prior to the use of AED.
- Do not touch the equipment connected to or metal objects in contact with the patient during defibrillation.
- Disconnect other electrical equipment that have no DEFIBRILLATION-PROOF applied parts from the patient before defibrillation.
- The AED battery packs are not rechargeable. Any attempt to recharge the battery pack may result in fire or explosion.
- Do not immerse AED in water or other liquids. Immersion in fluids may result in fire or explosion.

- Do not open unit, remove covers or attempt to repair the AED. All servicing must be performed by qualified personnel.
- Do not place AED pads near the generator of an internal pacemaker. Always apply AED pads to flat skin areas. Avoid application over skin folds such as those under the breasts or on obese patients. Excessive hair, poor adhesion, or air under electrode may cause burns.
- Improperly placed pads may lead to incorrect analysis and inappropriate shock or no shock decision.
- Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis. Follow all instructions in the Operation Manual.
- The patient's pacemakers may reduce the sensitivity of the AED analysis or produce errors in detecting shockable rhythms.
- Do not operate the AED in conjunction with electrocautery or diathermy equipment. Any equipment that emits strong radio frequency (RF) signals can cause electrical interference, distort the ECG signal, and cause inaccurate interpretation of rhythm.
- ECG electrodes and cables contain ferromagnetic materials. They must not be used in the presence of large magnetic fields created by magnetic resonance imaging (MRI) equipment. The large magnetic fields generated by an MRI device could move ferromagnetic equipment with an extremely violent force that could cause serious personal injury or death to persons between the equipment and the MRI device.
- Do not attempt to warm the AED pads with a heat source greater than 35°C (95°F). Do not immerse or clean AED pads with alcohol or solvents. Do not use AED pads, batteries, and other accessories not approved by the Manufacturer. The use of unauthorized accessories may lead to improper equipment operation and provide false analysis results. Follow all label instructions on the AED pads and the battery.
- The AED should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the AED should be observed to verify normal operation in the configuration in which it will be used.
- Do not allow AED pads to touch each other, or to touch other ECG electrodes, lead wires, dressings, and transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillation energy away from the heart.
- Improper use of AED pads may cause the AED to function

improperly or may cause skin burns. Do not use expired, or dry AED pads. Check the expiration date in the electrode package periodically. Do not reuse disposable AED pads. Only use pads approved by the manufacturer. The AED pads replacement please refer to the maintenance section.

- The AED pads are intended for one time use only and must be discarded after use. Reuse can lead to potential cross infection, improper performance of the device, inadequate delivery of energy and/or injury to the patient or the operator.
- During defibrillation, air pockets between the skin and AED pads can cause patient skin burns. To help prevent air pockets, make sure self-adhesive AED pads completely adhere to the skin. Do not use dried out or expired AED pads.
- Use unauthorized accessories may result in increased emissions or decreased immunity of the AED.
- Please remove the battery if you are sure that the AED will not be used for a period of time.
- The high risks may occur if the battery is replaced by untrained personnel.
- Do not use AED pads if it has been removed from the package for more than 24 hours. The adhesive pads should be applied to patient within 30 minutes after removing the protective cover. The AED pads is disposable, if the pads lack of efficacy, please do not use again.
- AED pads should be kept clear of other electrodes or metal parts in contact with patient.
- Technical description indicates that the manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist service personnel in parts repair.

CAUTION

- If the device has been dropped or damaged in any way, refer the device to qualified service personnel for servicing.
- Place the AED in a position that will not harm the patient should it fall. The AED should not be used adjacent to or stacked with other equipment. Keep all cables and connectors away from the patient's neck.
- Observe all CAUTION and WARNING labels on the equipment and accessories.
- The AED may not meet performance specifications if stored, transported or used beyond the specified storage or operating environmental limits.
- Please don’t use mobile phone near AED, radiation field

produced by mobile phone will interfere AED's function.

- Follow all battery pack labeling instructions. Do not install expired battery packs.
- Recycle or dispose of AED pads and battery packs in accordance with your local laws. To avoid fire and explosion hazard, do not burn, incinerate or crush the battery pack.
- Use and store the AED only within the range of environmental conditions specified in the technical specifications, see **Appendix A**.
- Do not repeatedly charge and discharge defibrillator in rapid succession. If repetitive testing is needed, wait at least 1 minute for every three discharge to avoid damaging equipment.
- Always verify remaining capacity of a non-rechargeable battery after use. Change the battery if it is low.
- Battery replacement is recommended after 2 years in standby mode due to degradation of the battery chemistry. Periodic maintenance and testing is highly recommended to ensure proper battery performance.
- Do not clean the AED with ketone or any flammable agent. Do not attempt to sterilize the AED or any of its accessories.
- Store AED pads in a cool, dry location (between 41°F to 95°F (5°C to 35°C)). Do not sterilize, immerse, or clean the AED pads with alcohol or solvents.
- Recycle the defibrillator and its accessories at the end of their service lives. Items should be recycled according to national and local regulations.
- Each pair of disposable AED pads is packaged in sealed envelopes of opaque material suitable to protect the gel from light and moisture. Please do not open AED pads package before use.
- Do not apply AED pads on skin that shows signs of irritation or injury.
- After using disposable AED pads, follow your local clinical procedures for recycling.
- The battery is disposable and non-rechargeable. Please refer to the maintenance section for battery replacement.

NOTE

- If the device has been dropped or damaged in any way, refer the device to qualified service personnel (the local distributor) or contact the manufacturer for servicing.
- Observe all CAUTION and WARNING labels on the equipment and its accessories.

- If the battery pack is removed for any reason, the user must label the AED as "Out of service due to battery operation".

Indications for Use

The AED should be used to treat someone you think may be a patient of SCA. A patient in SCA:

- Unconsciousness; and
- Absence of normal breathing; and
- Absence of a pulse or signs of circulation.

According to the patient's age and weight, choose the right mode and select the proper energy. According to 2015 ERC Guidelines, The AED should be connected with AED pads (Pediatric) and set to a pediatric mode for children aged 1-7years. This manual recommend that children 1-7 years of age and weight 15Kg to 25Kg choose **Pediatric mode (1)**, weight less than 15Kg choose **Pediatric mode (2)**.The patients who are adults in cardiac arrest should be used energy level of 150J to 200J, **Adult mode (1)** is a default set. For more than 8 years age and weight range from 25kg to 45kg, **Adult mode (2)** is a good choice. It should be shifted Adult mode (1) if Adult mode (2) energy defibrillation fails.

Contraindications

Do NOT use the AED when the patient:

- Is conscious; or
- Is breathing; or
- Has detectable pulse or other signs of circulation.

Not for use on infant patients.

Device Tracking

Many countries' law requires the tracking of AED. If you have the responsibility of the corresponding law, please notify the manufacturer, in case this product has been received, lost, stolen or destroyed or has been donated, resold or otherwise distributed to different organization.

Unpacking

- Carefully inspect each packing container for damage.
- Examine the unit for any signs of damage that may have occurred during shipping.
- If the contents are incomplete or damaged or if the unit fails to pass its self-test after battery installation, contact the manufacturer's Technical Service Department.

Review the shipping list to ensure that all items ordered were received.

Qualified Operators

The AED permits trained users to operate a brief electrical shock to patients experiencing fibrillation or SCA. Qualified operators are those who are authorized by a physician/medical director, or who should be trained in basic life support, advanced cardiac life support or other emergency medical response, and who have received training in the use of the AED.

2. Setting up the AED

Package Contents

Check the contents of the AED box to be sure it contains:

- 1 Fully Automated External Defibrillator (with battery)
- 1 package of AED pads (Adult) (AED pads (Pediatric) for purchase)
- 1 Operation Manual
- 1 Qualified Certificate
- 1 AED Carrying Bag

Setting up the AED

It is very simple and quick to set up AED.

Step 1: Install the battery
If the AED has a battery installed, you can skip **Step 1**.
For detailed steps to install the battery, see the **Check the battery** of 4**. Maintenance of AED**.

Step 2: Running a self-test. After installing the battery, press Power ON/OFF button to perform a self-test. At power-up, the following tests are performed: battery, main processor, memory and program, ECG acquisition system, and defibrillator.

Step 3: Place the Quick Reference Guide for using the AED to treat a patient of sudden cardiac arrest in the defibrillator carry bag, check the AED pads expired date.

Step 4: Store the AED in accordance with your site's emergency response protocol. Typically, the defibrillator should be easy to reach in a location free of obstacles. This could include a location near existing emergency equipment, such as fire extinguishers and first-aid kits. When considering location, avoid areas that expose the defibrillator to moisture, dust, or extreme temperatures.

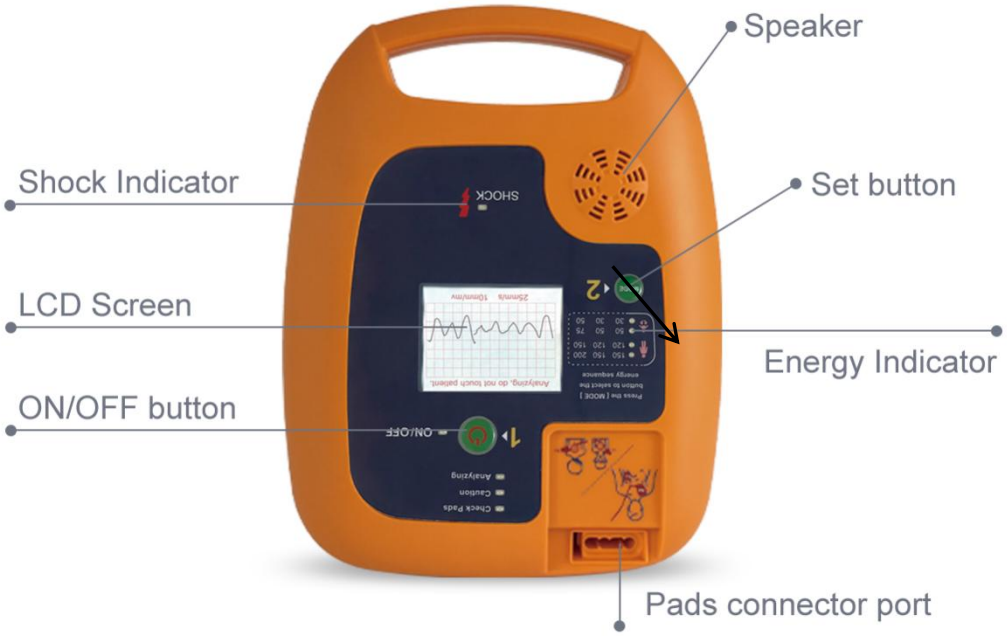
DANGER

Possible explosion and fire hazard if used in the presence of flammable agents or in an oxygen enriched atmosphere.

NOTE

Always store AED with a set of AED pads and a battery installed, so it will be ready to use.

Controls and Indicators



Controls and Indicators

Controls

The AED is designed for ease of operation. After putting the AED pads on the patient and connecting them to the AED unit, the operator performs this simple three-step process:

1. Turn the power ON and select the mode.
2. Follow LCD screen, LED prompts on the panel and voice prompts from the speaker.

ON/OFF button

Green ON/OFF button to power on or off the AED.

SET button

choose the adult mode or pediatric mode and choose the energy.

Battery Indicator

Power button LED indicates the battery status.

Power LED is light
Indicates the charge left in the battery is adequate.

Power LED flashes slowly
Indicates the charge left in the battery is partially depleted.

Power LED flashes fast
Indicates the charge left in the battery is low.

Adult/Pediatric

The green LED light
Indicates the currently selected energy sequence.

Shock Indicator The lamp will light when charging ready, to indicate everyone stay clear and don't touch patient.

ALARM SIGNALS

When preparing-to or about-to-deliver-energy-to-the-PATIENT, the AED provides verbal alarm signal and visual alarm signal.

The ALARM CONDITION is when the RHYTHM RECOGNITION DETECTOR has reached a determination that a shockable rhythm is detected and the discharge control is active.

The ALARM CONDITION is other alarm condition and a high priority alarm condition.

The sound pressure level of verbal alarm signal is 60dB. The verbal alarm signal and visual alarm signal generated by the alarm conditions are shown in the table below.

See below for other information signals.

Verbal alarm signal
Everyone clear, do not touch patient
Shock will be delivered
Verbal information signals
System ok
System failed
Replace new Battery
Check responsiveness
Give two breaths
Plug in cable
Attach pads to patient's bare chest
Check AED pads
Adult mode
Pediatric mode
Analyzing heart rhythm, do not touch patient, please wait
Shock delivered
No shock advised

No shock delivered
Start CPR
Stop CPR
Visual alarm signal
Shock indicator
Visual information signals
Battery indicator
Energy indicator

Recommended accessories

It is always good to have a spare battery and a spare pads set.

Other things that are advised to be kept with the AED include:

- Scissors — for cutting the patient’s clothes if needed
- Disposable gloves — to protect the operator
- A disposable razor — to shave the chest hair if it prevents good pads contact
- A pocket mask or face shield — to protect the user
- A towel or absorbent wipes — to dry the patient's skin for good pads contact.

3. Using the AED

This chapter provides the information for using the AED.

Note: *To help ensure the safe use of the defibrillator, completely read the* ***General Warnings and Cautions*** *section from Chapter 1.*

Overview

The common operating procedures of the AED include the following steps:

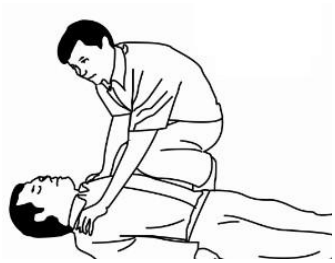
- Call your emergency service provider
- Quickly bring the AED to the patient side and power on. If there is any delay to get defibrillator, check the patient and perform CPR if needed until the defibrillator is available.
- Attach the AED pads to the patient
- ECG analyzing
- Charging procedure
- Deliver shock
- CPR

Determine to Use AED

If there is someone that you think him/her maybe in SCA, act quickly and calmly. If someone else is available, ask him/her to call for emergency medical service while you get AED.

Before using the AED, you must check the following conditions:

1. Unconsciousness; and
2. Absence of normal breathing; and
3. Absence of a pulse or signs of circulation.



When the above three points are met, then don't hesitate to use the AED!

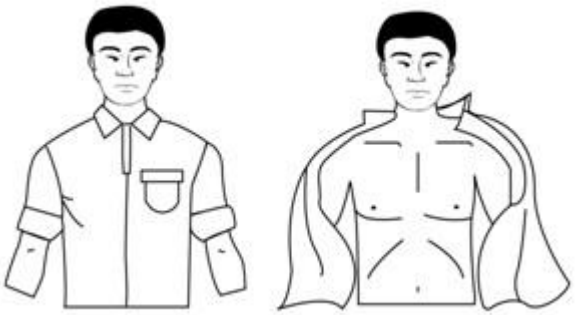
Using the AED

There are three simple steps to use an AED to treat the patient who may be in SCA.

Step 1

Step 1: Press the green ON/OFF button, and prepare the patient.
Press the green ON/OFF button for 2 seconds to start the AED, then the power indicator will turn on.
Press the Set button, according to the patient's age and weight, choose the proper mode. The default energy sequence is **Adult mode** 150J, 150J, 200J.

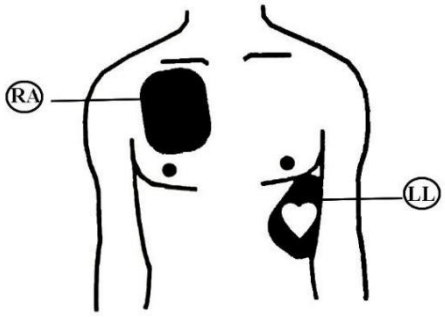
Follow the LED and voice instruction. And meanwhile, remove all the clothing from the patient’s chest. If it is necessary, rip or cut off the clothing to bare the patient’s chest.



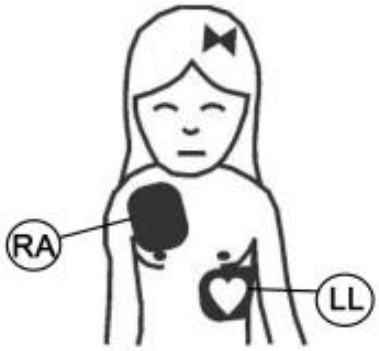
Step 2

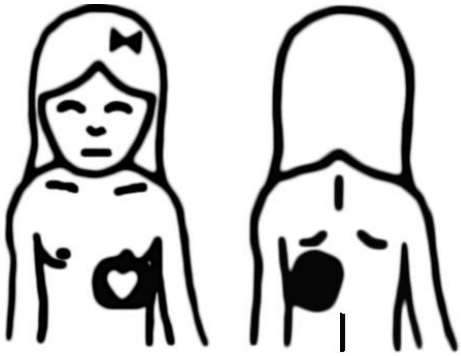
Step 2: Firstly, Remove the pads from the pad package by tearing the package along the dotted line near the top of the package. Peel away the backing from the pads and attach the pads to the patient’s bare chest following the illustration on the pads. Plug the pads connector into the AED, and follow the voice instructions.

Clean and dry the patient's skin, and if necessary, shave off chest hair to ensure good AED pads connection with the bare skin. Use **Adult mode** for adults or children aged 8 or above who weigh 25kg (55 pounds) or more, and **Pediatric mode** for children aged 1-7 who weigh less than 25Kg (55 pounds).
Not for use on infant patients.



Adult pads





Pediatric pads

Apply the AED pads to the patient's bare chest according to the package instructions of AED pads. Be sure to press firmly so that the pads adhere to the patient's chest completely.

The AED pads are CE certified, and fully comply with the related requirements of biocompatibility.

Deliver Shock

The AED will analyze the patient's ECG after detecting that the pads have been attached to the patient. During the analysis, the AED will instruct you not to touch the patient in case of analysis error. And also the AED will indicate when the ECG analysis is finished.

For an AED with a new battery and between 20°C to 30°C temperature, it will take 16 seconds from the initial rhythm analysis with a clear ECG signal to a shock prompt.

If a shock is needed, the voice prompt you do not touch patient, the orange shock LED lights and give shock automatically. After shock is delivered, the voice will instruct you to start Cardiopulmonary resuscitation (CPR).

After delivering a shock, the AED will enter the CPR for about 2 minutes. After that the AED will analyze ECG rhythm again. Don't touch the patient during this period. If a shockable rhythm is detected, the defibrillation procedure will start again.

If no shock is needed, the voice prompt will tell you "no shock advised" as well.

DANGER

- *DO NOT TOUCH the AED pads surfaces, the patient, and any conductive material touching the patient during ECG analysis or defibrillation.*
- *Always stand clear of the patient when delivering a shock.*
- *Possible explosion and fire hazard may occur if used in the presence of flammable agents or in an oxygen enriched atmosphere.*

WARNING

- *Not for use on infant patients.*
- *According to the patient's age and weight, choose the right mode and select the proper energy.*
- *Disconnect other electrical equipment which have no DEFIBRILLATION-PROOF applied parts from the patient before defibrillation.*
- *Improperly placed pads may lead to incorrect analysis and an inappropriate shock or no shock decision.*

NOTE

- *To help ensure the safe use of the defibrillator, please completely read the **General Warnings and Cautions** section from Chapter 1.*

Charging and Discharging Process

Charging Process

If the AED determines that the patient should have a defibrillation after ECG analysis, the charging process will start.

When the charging procedure starts, the pads checking continue, if the electrode is improperly connected, the AED will start an internal discharging and give a voice prompt to the operator.

NOTE

- *The charging time depends on the energy of defibrillation.*

Discharging Process

When the charging process finished, the AED will enter the discharging procedure and give voice prompts to the operator.

During the discharging process, the voice prompt you do not touch patient, the orange shock LED lights and give shock automatically.

After delivering a shock, the AED will enter the CPR procedure for about 2 minutes. After that the AED will analyze ECG rhythm again. Don't touch the patient during this period. If a shockable rhythm is detected, the defibrillation procedure will start again.

NOTE

- *To help ensure the safe use of the defibrillator, please completely read the **General Warnings and Cautions** section from Chapter 1.*

Cardiopulmonary Resuscitation (CPR)

The AED will enter CPR procedure, when the condition below occurred:

- During the analyzing period, if the heart rhythm is not considered to be a shockable rhythm by the AED, a CPR will start.
- If the patient is unconscious and absent of normal breathing, a cardiopulmonary resuscitation should be performed on the patient immediately.
- After delivering each shock, the AED will enter the CPR procedure.

The 2020 AHA guidelines for CPR recommendation, for patients in cardiac arrest, CPR providers should give 30 compressions, reopen the airway after 30 compressions, then give 2 effective rescue breaths. CPR providers should ensure that the chest compressions are deep enough (for adult at least 5 cm but not more than 6 cm, for children at least one third of the anterior-posterior dimension of the chest or 5cm).

Allow the chest to recoil completely after each compression and minimize interruptions in compressions. When providing rescue breaths/ventilations
rescuers spend approximately 1s inflating the chest with sufficient volume to ensure the chest rises visibly. Then continue with chest compressions and rescue breaths in a ratio of 30:2.

At the end of the CPR, the AED will give a prompt to indicate that the operator must stop CPR and not touch the patient so that the defibrillator can restart a heart rhythm analyzing and determine if a shockable rhythm exists.

NOTE

- *To help ensure the safe use of the defibrillator, please completely read the **General Warnings and Cautions** section from Chapter 1.*

An Emergency Cancellation

If any unpredictable situation occurs, the operator can use ON/OFF button to make an emergency cancellation.

The unpredictable situation may be described as below:

- The movement of the patient during the discharging period.
- Other dangerous situations.

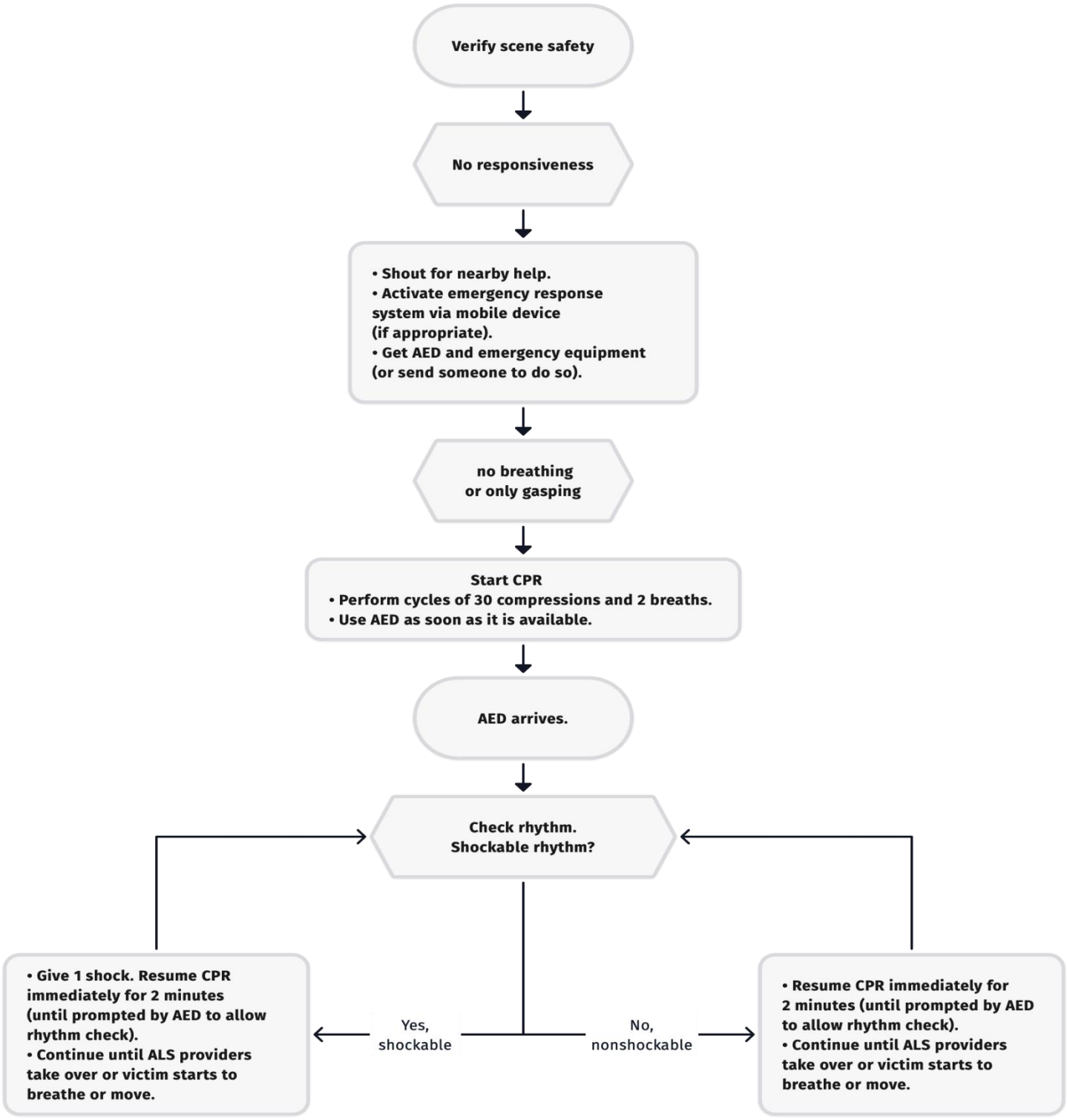
If unpredictable situations occur, the operator should press the ON/OFF button for 3 seconds to shut down the AED and internally discharge all the power in the defibrillator.

Post-use Procedure

After the AED has been used on a patient, the unit should be prepared for the next use.

1. Check the appearance of the AED for signs of damage, dirt, or contamination.
2. Replace with a new set of AED pads.
3. Perform a self-test manually.
4. Turn off the AED by pressing the ON/OFF button.
5. Return the AED to its installed place so it will be ready for use when needed.

Emergency Treatment of Cardiac Arrest



WARNING *When responding to cardiac arrest in a child:*

• Provide child CPR while a bystander calls emergency medical services (EMS) and get the AED

• If no bystander is available, perform approximately 2 minutes of CPR (cycles of 30 compressions and 2 breaths) before calling EMS and retrieving the AED.

• If you witnessed the child's collapse, call EMS immediately and then get the AED. Alternatively, follow your local protocol.

4. Maintenance of AED

Maintenance

Although the AED is a device designed with very low frequency maintenance, but periodically maintenance are needed for optimized operation of the AED. The actual inspection period depends on the use frequency.

The Frequency of Inspection

Usually, we recommend inspecting the AED once a week or twice a month, but if used frequently, more inspections should be performed.

Frequency of Use (n/month)	Inspection
1/month	Once a week
2~3/month	Twice a week
Infrequent use (1~2 a year)	Once a month

The Battery

The AED will perform daily, weekly and monthly self-test to ensure that it is ready to work at any time. The AED charges the energy storage device automatically and discharges through the internal discharge circuit during monthly self-test. And these kinds of self-tests will consume battery power. So, it is very important to check whether the battery still works during the inspection as mentioned above.

Check the Indicator and the Voice

NOTE

The operator should follow the rules to perform the inspection, and improper inspection may cause damage to the AED.

If the AED starts without AED pads connection, the indicator of “CHECK PAD” will be flickering and a voice prompt will be broadcasted. If neither of the two conditions appears, contact authorized service personnel for professional inspection.

WARNING

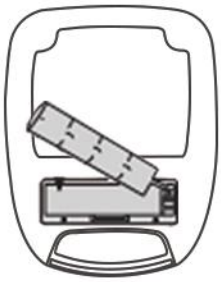
If the conditions above are observed during the inspection, the AED must be returned for further inspection and do not use to any patient before it is ready.

Check the Battery

The AED will automatically check the capacity of the battery when it starts. If the battery capacity is low, the ON/OFF indicator will be flashing.

If the AED is out of battery, replace the old battery with a new one.

Open the battery compartment (located at the bottom of the AED) by removing the screws and then sliding the battery cover back.



1. Screw out and remove the screws to open the battery compartment.
2. Take out the old battery, and replace new one.
3. Slide the battery cover back and make sure the screw holes are aligned. Fasten the screws.

WARNING *The spare battery that doesn't match the standard battery parameters may cause serious damage to the AED.*

Follow the replacement instructions. It is best to have the battery replaced by trained person.
Please remove the battery, if you are sure that the AED will not be used for a period.

Check the AED Pads

Inspect the packaging of any disposable AED Pads to ensure that the seal is intact and within its validity date.
Inspect the cables carefully to ensure there are no defects.

Replace the AED pads after 24 hours from their application on the patient's skin. The AED pads are disposable, if the pads are not effective, please do not use again.

The AED pads are CE certified and fully comply with the related requirements of biocompatibility.

Cleaning and Disinfecting

Cleaning

CAUTION *Do not clean any part of the defibrillator or accessories with bleach, bleach dilution, or phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the*

defibrillator or its accessories.

Before cleaning the AED, make sure that the unit has been powered off, because any cleaning with the equipment powered on may cause a shock hazard to the cleaning personnel.

The appearance of the AED can be cleaned with a soft cloth dampened in water.

CAUTION *Don't let water get into the AED when cleaning the AED, because these liquids may cause some damage to the AED or a shock hazard to the cleaning personnel.*

Disinfecting

It is recommended to use alcohol with a concentration of 75% to disinfect the AED, which is easy to get from hospitals and clinics.

CAUTION *Never use the following cleaning agents to the AED: Acetone, Ammonia cleanser, Glutaraldehyde.*

Troubleshooting

This section explains possible problems that may occur to the AED. The indicator and voice prompts will also indicate the possible problems to the operator.

CAUTION *The operator can try to solve problems that occur before or during the operation based on the following troubleshootings.*

1. Q: The voice prompt of "Plug in cable", "Attach pads to patient's bare chest" or "Check AED pads" is still playing when the pads have been attached to the patient and the pads connector has been connected to the socket of the AED.
   A:
   - If the AED pads are dry, damaged or expired, replace the current pads with new ones and try again.
   - Ensure that the AED pads have been properly adhered to the patient. If not, wipe off the water or moisture from the chest and shave off chest hair, then press the pads firmly on the patient's chest.
   - Make sure that the two pads do not come into contact with each other.
   - If the pads connector is not fully connected to the AED socket, firmly push the connector into the socket.

2. Q: The analyzing is interrupted during the analyzing procedure, and

the voice prompt of “Plug in cable”, “Attach pads to patient’s bare chest” or “Check AED pads” is being played.

A:

- Power off the AED and check the pads placed on the patient, if they are not properly connected, firmly press the pads on the patient’s chest, then start the AED again.
- If the patient has body actions during the analyzing procedure, power off the AED and check if defibrillator is suitable for the patient.

3. Q: The charging stopped during the charging procedure, and the voice prompt of “Plug in cable”, “Attach pads to patient’s bare chest” or “Check AED pads” is being played.

   A:

   - Power off the AED and check the pads connector. If the connector is not fully connected to the socket of the AED, firmly push the connector into the socket; or
   - Power off the AED and check the pads connecting with the patient’s bare chest. If the pads are poorly attached, wipe off the air hole and firmly press the pads on the patient’s chest.
   - Make sure that the two pads don’t come into contact with each other.

4. Q: During the operation of the AED, the ON/OFF indicator is flashing.

   A: Power off the AED and replace the battery with a new one.

A. Technical Specifications

1. The Main Unit General

Category	Specification
Dimensions	300 x 240x 80mm
Weight	1.9 ±0.2kg
LCD Screen size	3.5inch
LCD resolution	320(RGB)×240
Equipment Type	transportable equipment
Operating Temperature	0°C to 50°C
Operating Humidity	15% to 95% R.H. (non-condensing)
Atmospheric pressure	50kPa~106kPa
Storage Temperature	-20°C to 55°C
Storage Humidity	Up to 93% (non-condensing)
Transport Temperature	-20°C to 55°C
Transport Humidity	Up to 93% (non-condensing)
Transient operating Temperature	-20°C to 50°C
Transient Operating Humidity	15% to 90% R.H. (non-condensing)
Design Standard	EN ISO13485:2016 EN ISO14971:2012 EN1041:2008+A1:2013 EN ISO 15223-1:2016 EN 60601-1:2006/A1:2013 Type BF, Internally Powered, Continuous operation, Defibrillator Proof Operation EN 60601-2-4:2011 EN 62304:2006+A1:2015 EN 62366-1:2015 EN 60601-1-6:2010 EN 60601-1-2:2015 EN ISO 10993-1:2009/AC2010 EN 60601-1-12:2015 EN 60601-1-8:2007/A11:2017

NOTE *No time is needed for warming or cooling the AED form the min. or max. storage temperature.*

2. Defibrillator

<table>
<tr><th>Category</th><th colspan="4">Specification</th></tr>
<tr><td>Waveform</td><td colspan="4">Biphasic Truncated exponential</td></tr>
<tr><td>Energy Sequence</td><td colspan="4">Adult mode:150J, 150J, 200J
Adult mode:120J, 120J, 150J
Pediatric mode:50J, 50J, 75J
Pediatric mode:30J, 30J, 50J</td></tr>
<tr><td colspan="5">Charge Time (20℃ of ambient temperature)</td></tr>
<tr><td rowspan="2"></td><td colspan="2">From initiation of rhythm Analysis to charge done</td><td colspan="2">From initial power on to charge done</td></tr>
<tr><td>Adult</td><td>Pediatric</td><td>Adult</td><td>Pediatric</td></tr>
<tr><td>With a new,fully charged battery</td><td>14sec. (120J)
16sec. (150J)
20sec. (200J)</td><td>10sec. (30J)
11sec. (50J)
13sec. (75J)</td><td>19sec. (120J)
21sec. (150J)
24sec. (200J)</td><td>15sec. (30J)
17sec. (50J)
19sec. (75J)</td></tr>
<tr><td>With a new,fully charged battery,depleted by 6 times discharges</td><td>14sec. (120J)
16sec. (150J)
20sec. (200J)</td><td>10sec. (30J)
11sec. (50J)
13sec. (75J)</td><td>19sec. (120J)
21sec. (150J)
25sec. (200J)</td><td>15sec. (30J)
17sec. (50J)
19sec. (75J)</td></tr>
<tr><td>Analysis Time</td><td colspan="4">9 sec.</td></tr>
<tr><td>The maximum time from the initiation of rhythm analysis to readiness for discharge with a new battery.</td><td colspan="4">MAX. 25 seconds</td></tr>
<tr><td>The maximum time from the initiation of rhythm analysis to readiness for discharge after 6 shocks.</td><td colspan="4">MAX. 35 seconds</td></tr>
<tr><td>The maximum time from initially switching power on to readiness for discharge.</td><td colspan="4">MAX. 30 seconds</td></tr>
<tr><td>Instruction</td><td colspan="4">Voice and Visual Prompts</td></tr>
<tr><td>Controls</td><td colspan="4">Three buttons -ON/OFF, SHOCK, SET</td></tr>
<tr><td>The time required for the AED to warm from the minimum storage temperature between uses until the AED is ready for its INTENDED USE when the ambient temperature is 20 °C</td><td colspan="4">8 hours</td></tr>
<tr><td>the time required for the AED to cool from the maximum storage temperature between uses</td><td colspan="4">4 hours</td></tr>
</table>

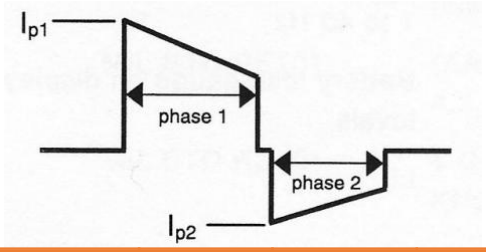
until the AED is ready for its INTENDED USE when the ambient temperature is 20 °C	
The Maximum Voltage	1050±50V
Output disabled when the PATIENT impedance is outside limits	25Ω to 175Ω

Energy Level（J）	Specified energy（J）	Load resistance（Ω）	Output Energy Accuracy
30	30	25	±15%
	30	50	
	30	75	
	30	100	
	25.5	125	
	25.5	150	
	22.5	175	
50	50	25	
	50	50	
	50	75	
	50	100	
	42.5	125	
	42.5	150	
	37.5	175	
75	75	25	
	75	50	
	75	75	
	75	100	
	63.8	125	
	63.8	150	
	56.3	175	
150	150	25	
	150	50	
	150	75	
	150	100	
	127.5	125	
	127.5	150	
	112.5	175	
200	200	25	
	200	50	
	200	75	
	200	100	
	170	125	

	170	150	
	150	175	

3. Waveform Specifications

The table below provides details of the biphasic truncated exponential waveform delivered by the AED (set to 200J) when connected to resistive loads of 25 through 175 Ohms. The waveforms are characterized by typical values for peak current (Ip), duration of the first output phase, and duration of the second output phase.



Output Energy (J)	Patient Impedance (Ω)	Ip1 (Amps)	Ip2 (Amps)	Phase1 (ms)	Phase2 (ms)	Interval (ms)
30	25	20.7	13.5	5.5	3.2	0.7
	50	10.3	6.8	10.6	6.5	0.7
	75	6.9	4.5	16.1	8.8	0.7
	100	5.2	3.4	19.5	9.5	0.7
	125	4.1	2.7	20.1	11.1	0.7
	150	3.4	2.3	21.5	10.2	0.7
	175	2.9	1.9	21.7	11.2	0.7
50	25	26.7	17.4	5.6	3.2	0.7
	50	13.3	8.7	10.7	6.5	0.7
	75	8.9	5.8	16.2	8.8	0.7
	100	6.7	4.4	19.5	9.5	0.7
	125	5.3	3.5	20.1	10.8	0.7
	150	4.4	2.9	21.5	10.3	0.7
	175	3.8	2.5	21.7	11.0	0.7
75	25	32.7	21.4	5.5	3.3	0.7
	50	16.3	10.7	10.9	6.6	0.7
	75	10.9	7.1	16.3	8.9	0.7
	100	8.2	5.3	19.7	9.6	0.7
	125	6.5	4.3	20.5	11.2	0.7
	150	5.4	3.6	21.6	10.4	0.7
	175	4.7	3.1	21.8	11.2	0.7
150	25	46.1	31.0	5.6	3.2	0.7
	50	23.9	15.1	10.7	6.5	0.7
	75	15.7	10.3	16.2	8.8	0.7
	100	11.5	7.7	19.5	9.5	0.7
	125	9.0	6.2	20.2	10.8	0.7
	150	7.4	5.2	21.4	10.3	0.7

	175	7.2	5.2	21.6	11.0	0.7
200	25	53.6	36.0	5.5	3.3	0.7
	50	27.8	17.5	10.9	6.6	0.7
	75	18.2	12.0	16.3	8.9	0.7
	100	13.4	9.0	19.7	9.6	0.7
	125	10.5	7.2	20.5	11.2	0.7
	150	8.6	6.0	21.6	10.4	0.7
	175	8.2	6.1	21.8	11.2	0.7

4. Electrical Isolation

Category	Specification
Power	Unit operates on internal battery only
External Electrical Connections	No external devices are attached to the unit
Risk Current Category	Internally powered equipment with defibrillator-proof BF type patient applied part (as per definition of EN 60601-1 standard)

5. Battery

Category	Specification
Non-Rechargeable	MDT10001 LiMnO2 12V, 3.2 Ah (Those accessories, which are not specified by Manufacturer, should not be used)
Capacity	20 discharge cycles at the maximum energy sequence (**Adult mode**) or 120 discharges at 200J; or 150 discharges at 150J (at 20°C ambient temperature)
Shelf Life (25℃±15℃)	5 years storage + 4 years standby 4 years standby (after installation)

NOTE

Battery capacity measured according to EN 60601-2-4, clause 201.102.3.2 at room temperature. Capacity may be diminished at operating temperature extremes, or when the available battery charge is used in multiple Power ON/OFF cycles.

6. AED Pads

Category	Specification
Life in use	disposable
Use-by date	See the packaging label
Storage Temperature	To be stored in a day place, with temperature between +5°C to +35°C. The storage at extreme temperatures must be limited to short periods(24 hours at -30°C or +65°C).
Operating Temperature	0°C to 50°C

B. Rhythm Recognition Performance

The AED algorithm meets the requirements of ANSI/AAMI DF39-1993 section 3.3.18 and the sensitivity and specificity levels recommended by the AHA Automated External Defibrillators for Public Access Use: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance. The test database includes shockable rhythms consisting of ventricular fibrillation rhythms (>200uV) and wide-complex ventricular tachycardia at a rate greater than 180 BPM. Non-shockable rhythms include various sinus rhythms including supraventricular tachycardia, atrial fibrillation, atrial flutter, sinus rhythm with PVC's, asystole, pacemaker rhythmsa, and ventricular tachycardia with a rate less than 180 BPM and/or narrow complexes.

Rhythms	Performance Goal	Conclusion
Shockable: VF	＞90% sensitivity	Meets the AAMI DF39 requirement and AHA recommendation
Shockable: VT	＞75% sensitivity	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: NSR	＞99% sensitivity (AHA)	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: asystole	＞95% sensitivity	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: all other rhythms	＞95% sensitivity	Meets the AAMI DF39 requirement and AHA recommendation

According to EN 60601-2-4 201.7.9.3.103

	VF and VT	All other ECG rhythms
Shock	1004	320
No Shock	85	29591

The sensitivity of the device for shockable rhythms is 92.2%. The true predictive value is 75.8%. The specificity of the device for non-shockable rhythms is 98.9%. The false positive rate is 1.1%.

C. Guidance and manufacturer's declaration

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS –for The AED

Guidance and manufacturer's declaration – electromagnetic emissions		
The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The AED 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 CISPR 11	Class B	The AED is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions EN 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Not applicable	

Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for The AED

Guidance and manufacturer's declaration – electromagnetic immunity			
The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment–guidance**
Electrostatic discharge (ESD) EN 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for LIFE-SUPPORTING the AED

Guidance and manufacturer's declaration – electromagnetic immunity			
The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.			
Immunity test	**EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF EN 61000-4-6 Radiated RF EN 61000-4-3	3Vrms 150KHz to80 MHz 20V/m 80 MHz to 2.5 GHz	3V 20V/m	Portable and mobile RF communications equipment should be used no closer to any part of the AED, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V1}\right]\sqrt{P}$ 150KHz to80 MHz $d = \left[\frac{12}{E1}\right]\sqrt{P}$ 80MHz to 800 MHz $d = \left[\frac{23}{E1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) and d is the recommended separation distance in meters (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [c], should be less than the compliance level in each frequency range [d]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
b The compliance levels in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges. c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AED is used exceeds the applicable RF compliance level above, the AED should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AED.			

Table 4 – Recommended separation distances between portable and mobile RF

communications equipment and the AED – for LIFE-SUPPORTING the AED

Recommended separation distances between portable and mobile RF communications equipment and the AED			
The AED is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AED as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150KHz to80 MHz $d = \left[\frac{3,5}{V1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{12}{E1}\right]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = \left[\frac{23}{E1}\right]\sqrt{P}$
0,01	0.12	0,06	0,115
0,1	0.38	0,19	0,364
1	1.2	0,6	1,15
10	3.8	1,90	3,637
100	12	6	11,5
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2. An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. NOTE 3. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

D.Glossary of Symbols

Consult operation Manual.

Attention: Consult accompanying documents.

Defibrillation protected Type BF patient connection

Dangerous Voltage

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.

Manufacturer

Date of manufacturer

Serial Number

IP55 Dust-protected and water jetting-protected

Use-by date

AED Pads plug socket indicator icon

Batch code

Catalogue number

Non-sterile

Do not use if package is damaged

Keep away from sunlight

Temperature limit

Humidity limitation

Atmospheric pressure limitation

Do not re-use

Operating temperature range 0℃-50℃

For more than 8 years age and weight range from 25kg

Meets the requirements of the European Medical Device.

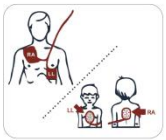
Non-ionizing radiation

When stacking, the number of layers does not exceed 2 layers

Fragile, handle with care

Keep up

Keep dry



Indication of the AED pads connected to the patient's chest

E. Glossary of terms

AED	Automated external defibrillator
ALS	Advanced life support
Arrhythmia	An unhealthy, often irregular, beating of the heart.
Cardiac arrest	Cessation of the heart muscle
CPR	Cardiopulmonary resuscitation
Defibrillation	High-energy pulse of electricity (shock) delivered to the heart muscle to restore normal cardiac activity
ECG	Electrocardiogram
Electrocardiograph	Instrument used to record electrical currents associated with heart muscle activity
Fibrillation	Rapid twitching movements that replace the normal rhythmic contraction of the heart and may cause a lack of circulation and pulse
Joule	The amount of energy delivered during defibrillation, related to the intensity of the shock delivered.
Non-shockable rhythm	Patient heart rhythms that are not a candidate for defibrillation pulse
NSR	Normal sinus rhythm
RF	Radio frequency
SCA	Sudden cardiac arrest
Self-test	Automatic test performed at system power-up to check readiness of battery, internal circuitry, main processor, and defibrillator
Shock	Defibrillation electrical pulse
Shockable rhythm	Abnormal heart rhythm which is a candidate for defibrillation pulse
Tachycardia	An abnormally fast heart rate
Time-stamped event	Any change in heart rhythm or any shock delivered by the defibrillator