Amoul®

Operator's Manual
Automatic External Defibrillator

www.amoulmed.com

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Product Information

Thank you for purchasing the Amoul Automatic External Defibrillator.

Before using the equipment, please read and understand the contents of this operator's manual carefully so as to use the instrument correctly. Keep this manual properly after reading and keep it in a place where it is easily accessible.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

Product name:	Automatic External Defibrillator
Specifications and models:	i9，i7, LS1 Semi Automatic, LS1 Pro Semi Automatic
Name of manufacturer:	Ambulanc (Shenzhen) Tech. Co., Ltd
Production address:	3rd and 8th Floor, Block C, Building #5, and 1st to 10th Floor, Building #8, Skyworth Innovation Industry Park, Tangtou 1st Road, Shiyan, Baoan District, Shenzhen, Guangdong 518108, China
Date of manufacturer:	See the label on main unit
Service life:	10 years
Release version of the manual:	1.0
Revision date of the manual:	2024.11.07
Defibrillation mode	Semi automatic

Product name:	Automatic External Defibrillator
Specifications and models:	i9 Plus，i7 Plus, LS1 Fully Automatic, LS1 Pro Fully Automatic
Name of manufacturer:	Ambulanc (Shenzhen) Tech. Co., Ltd
Production address:	3rd and 8th Floor, Block C, Building #5, and 1st to 10th Floor, Building #8, Skyworth Innovation Industry Park, Tangtou 1st Road, Shiyan, Baoan District, Shenzhen, Guangdong 518108, China
Date of manufacturer:	See the label on main unit
Service life:	10 years
Release version of the manual:	1.0
Revision date of the manual:	2024.11.07
Defibrillation mode	Fully automatic

EC REP EC-Representative

CE 2797

EC-Representative: Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg, Germany

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Unless otherwise specified, Automatic External Defibrillator is referred to as "the/this defibrillator" or "the/this equipment/instrument/device/product" in this manual.

The product pictures in this manual are for reference only and may differ from the actual product, and the actual product prevails.

Ambulanc (Shenzhen) Tech. Co., Ltd is responsible for the effects on safety, reliability and performance of this product, only if:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by Ambulanc (Shenzhen) Tech. Co., Ltd authorized personnel;
- Relevant electrical equipment complies with national standards;
- The product is used in accordance with the instructions for use.
- In case of any of the following circumstances, Ambulanc (Shenzhen) Tech. Co., Ltd shall not be responsible for the safety, reliability and operation of the product:
  - Components are disassembled, stretched and debugged again;
  - Non-authorized personnel of Ambulanc (Shenzhen) Tech. Co., Ltd repair or change instruments;
  - The product is not used correctly in accordance with the instructions for use.

Maintenance Services

Free Service Scope:

All equipment that meets the requirements of the warranty service regulations of Ambulanc (Shenzhen) Tech. Co., Ltd can enjoy free service.

Paid Service Scope:

For equipment beyond the scope of the warranty service regulations of Ambulanc (Shenzhen) Tech. Co., Ltd, Ambulanc (Shenzhen) Tech. Co., Ltd shall implement the paid service;

Even during the warranty period, the product needs to be repaired due to the following reasons:

- Man-made damage;
- Improper use;
- The grid voltage exceeds the specified range of the equipment;
- Irresistible natural disasters;
- Replace the accessories and consumables without the permission of Ambulanc (Shenzhen) Tech. Co., Ltd, or repair the machine by non-authorized personnel of Ambulanc (Shenzhen) Tech. Co., Ltd.

Guarantee

Manufacturing Process and Raw Materials:

Ambulanc (Shenzhen) Tech. Co., Ltd guarantees that in normal use and maintenance, the instrument will have no production process and raw material failure during the warranty period.

After-Sales Service Unit

User Service Department of Ambulanc (Shenzhen) Tech. Co., Ltd

Address:Building #8, Skyworth Innovation Industry Park, Tang Tou 1st Road, Shiyan, Baoan District, 518108, Shenzhen, China

Zip code: 518108

Free service hotline: 400-9969-120

Tel: +86-755 26072215 Fax: +86-755 23016012

Website: http://www.amoulmed.com

E-mail: service.intl@amoulmed.com

Returns

Return Procedure

If you really need to return the product to Ambulanc (Shenzhen) Tech. Co., Ltd, please follow the following steps:

- Obtain the right to return the goods: contact the customer service department of Ambulanc (Shenzhen) Tech. Co., Ltd and inform the Ambulanc product series number, which has been marked on the outer shipping box. If the series number is not clearly identifiable, the return will not be accepted. Please indicate the product model and briefly describe the reason for return.
- Freight: The user shall bear the freight, including customs fees, incurred by the return of instrument to

Ambulanc (Shenzhen) Tech. Co., Ltd.

Important Information

1. After purchasing this product, the customer is fully responsible for the maintenance and management of this product.
2. Even during the warranty period, the warranty does not cover the following:
   - Damage or loss caused by misuse or rough use.
   - Damage or loss caused by Force majeure such as fire, earthquake, flood or lightning.
   - Failure to meet the specified service conditions of the system, such as damage or loss caused by insufficient power supply, incorrect installation or unsatisfactory environmental conditions.
   - Transportation damage caused by improper packaging at the time of return.
   - Damage or loss resulting from the use of this system in the region where it was not originally purchased.
   - Damage to or loss due to not purchasing a regular system from Amoul or its authorized dealer or agent.
3. Unauthorized modification of the software or hardware or any other part of the product is prohibited.
4. Under any circumstances, Amoul shall not be responsible for any problems, damages or losses caused by reinstallation, alteration or maintenance of this system by non-Ambulanc designated personnel.
5. Ambulanc (Shenzhen) Tech. Co., Ltd shall not be responsible for the loss of data stored in the system due to the operator's error or abnormal situation.
6. Ambulanc (Shenzhen) Tech. Co., Ltd shall not be responsible for any damage caused by the continued use of the equipment after the expiration of the service life of the equipment.
7. This operator’s manual contains warnings about foreseeable potential hazards. Be on high alert at all times for unexplained dangers. Ambulanc (Shenzhen) Tech. Co., Ltd shall not be responsible for any damage or loss caused by negligence or disregard of the precautions specified in this operator’s manual.
8. Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics.
   Links to the summary of safety and clinical performance: https://ec.europa.eu/tools/eudamed
   Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Safety Instructions

Please read this safety instruction carefully. This safety instruction is an integral part of the equipment and must be accessible at all times. For safety reasons, please pay attention to the following:

Mark Prompt	Definition
Danger:	Indicates an imminent hazard that, if not avoided, will result in death, serious personal injury, or property damage.
Warning:	Indicates a potential hazard or unsafe practices that, if not avoided, could result in death, serious personal injury or property damage.
Caution:	Indicates a potential hazard or unsafe practices that, if not avoided, could result in minor personal injury or product/property damage.
Note:	Emphasizes important precautions, provides instructions or explanations to ensure that you get the most from your product.

Security Information

Safety instructions are marked in this operator's manual as follows:

Mark Prompt	Related Information
Dangers:	The defibrillator can produce high voltages when performing defibrillation that can cause significant injury or death, so the defibrillator should be used by a professional clinician, or a trained first-aid provider. Personnel using this defibrillator should be adequately trained. No person without authorization, or without training, shall perform any operation. Do not use this equipment in an oxygen-rich environment, or in an environment where flammable or explosive substances such as anesthetics are placed to prevent fire or explosion; At the same time, the defibrillator and its surrounding area should be kept clean and dry. During defibrillation, keep enough distance from the patient and from metal objects connected to the patient so as to avoid electric shocks. Do not open the equipment housings, otherwise there may be a risk of electric shock. All servicing and future upgrades must be carried out by the service personnel trained and authorized by the Company.
Warnings:	The device must be inspected for mechanical damage before use, and if there is any malfunction, it should not be attached to the patient. Always check the device, cables and accessories before use to ensure that it can work properly and safely. Use of damaged or ineffective accessories may cause the automated external defibrillator to perform abnormally and/or injure the patient or the user. Never allow the electrode pads to come into contact with other electrodes or metals that come into contact with the patient. This device can only use disposable batteries provided by the Company. This defibrillator can only be used by a single patient at a time. This defibrillator is not intended for use in an Magnetic Resonance (MR) environment. Do not use this defibrillator in an oxygen-rich environment or in an environment where flammable or explosive materials such as anesthetics are placed to prevent fire or explosion. Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation. Do not defibrillate a patient who lies on wet ground. The alarm volume should be set according to the actual situation of the patient.

Mark Prompt	Related Information
	Audible alarm systems cannot be relied upon alone to monitor patients. When the alarm volume is set to a lower level, it may cause danger to the patient. When the defibrillator is connected to the patient, no functional tests should be performed to prevent the patient from accidental electric shock. When using this defibrillator for treatment, you should always pay attention to the actual situation of the patient. If the delivery of the shock is delayed, a situation may occur in which the heart rhythm that has been analyzed to be shockable changes to a non-shockable rhythm, resulting in the shock being delivered incorrectly. When the main unit analyzes the heart rhythm, CPR or other processing of the patient or moving the patient may cause analysis errors or delay in analysis time. If the main unit notifies you that a shock is recommended while you are handling or moving the patient, stop CPR and let the patient be as still as possible for 15 seconds so that the main unit has time to reanalyze before notifying the shock. For the treatment of patients with implantable pacemakers, place the electrode pads away from internal pacemaker generator if possible to help prevent damage to the pacemaker. Please carefully place the cables with various accessories to avoid entanglement or suffocation, entanglement of cables, or electrical interference. Do not touch the patient with the device interfaces or other live equipment at the same time as to avoid injury to the patient. For patient safety, use the accessories specified in this operator's manual. In order to avoid hazards or environmental pollution, packaging materials must be handled in accordance with relevant local regulations or hospital waste disposal systems. Packaging materials must be kept out of the reach of children. The operator must not touch both the patient and the conductive part of the defibrillator. Do not use dry-out electrode pads because they do not fit closely with the skin, and do not allow the electrode pads to come into contact with other electrodes, wires, etc., otherwise, an electric current may be generated and burn the skin during the shock, and the current flowing to the patient's heart may be diverted to other parts.
 Caution:	Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force. Do not mix different types and brands of electrode pads. Mixing electrode pads may result in large baseline drift or longer baseline recovery time after defibrillation. In order to avoid polluting the environment, contaminating other equipment or infecting people, the equipment and its accessories that have reached the end of its service life must be disposed of in accordance with relevant local regulations or hospital rules and regulations. Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phones, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation. For more information, see the EMC section. Pay special attention to the type of electrode pad used, as some electrode pads may have large potential shifts due to polarization. The recovery time after the defibrillation pulse needs to be particularly considered. The extruded spherical electrode, which is commonly used in diagnostic ECG recordings, is more prone to this effect.

Mark Prompt	Related Information
 Notes:	Please place this manual near the equipment so that it can be easily and promptly accessed when operating the equipment. During normal use, the operator shall stand in a location where the equipment can be easily viewed and operated. To prepare the equipment for use, install the battery in advance and connect the electrode pad plugs. If the equipment has been dropped or mishandled, perform a user test. If any item fails, do not use the equipment again and contact the authorized service personnel in time for repair.

Explanation of Symbols and Terms

The following table describes the symbols used on this equipment or in this manual.

Symbol	Description in English	Symbol	Description in English
	Consult instructions for use or consult electronic instructions for use		Caution
	Date of manufacture		Serial number
	Use-by date		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
	Medical device		Refer to instruction manual/ booklet
	The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it. * For system products, this label may be attached to the main unit only		Dust-tight Protected against water jets
	Adult/Child mode switch		ON/OFF button
	Language Switch/Mute button		Manufacturer
	Voice recording icon		Do not expose the battery to high heat or open flames; do not incinerate the battery
	Do not mutilate the battery or open the battery case		Do not crush the battery
	Shock button		Environmental protection service life of electronic products (20 years)
	Non-ionizing electromagnetic radiation		USB connector
	Wi-Fi network indicator	4G	4G network indicator

The following table introduces the English abbreviations used in this manual.

English Abbreviation	English Full Name
AED	Automatic External Defibrillator
CPR	Cardiopulmonary Resuscitation
ECG	Electrocardiograph
AHA	American Heart Association
ERC	European Resuscitation Council
EMC	Electromagnetic Compatibility
MRI	Magnetic Resonance Imaging

Accessories/Spare Parts

Note:

Only the manufacturer Ambulanc (Shenzhen) Tech. Co., Ltd or authorized professionals can be allowed to carry out maintenance measures, such as inspection and overhaul work.

The use of accessories from other manufacturers can lead to malfunctions and incompatibilities. Please keep in mind that warranty rights and responsibilities will be void if you do not use the accessories recommended in the manual or if you do not use the original spare parts.

1. Equipment Introduction

1.1. Intended purpose

To treat people who have cardiac arrest (SCA). The following are the symptoms of SCA:

- No activity or reaction during shaking
- Inability to breathe normally.

1.2. Contraindication

Do not treat them with AED for patients who has the following signs:

- Able to move and react when shaking
- Able to breathe normally

1.3. Patient Population

The defibrillator can be used with standard defibrillation pads only on adults and children who are no less than 8 years old or whose weight no less than 25 kg (55 lbs). The defibrillator may be used on children who are less than 8 years old or weigh less than 25 kg (55 lbs) with Infant/Child Reduced Energy Defibrillation Electrodes.

1.4. Intended User

The user of AEDs shall be proved to satisfy the following conditions:

- Received training in cardiopulmonary resuscitation and automatic external defibrillator.
- Received training in basic life support or advanced life support resuscitation courses or other physician-authorized emergency response programs.

1.5. Structural Composition

The equipment consists of a main unit, a disposable lithium manganese dioxide battery and multifunctional electrode pads.

1.6. Function

In working status, AED automatically analyzes the patient's heart rhythm, gives a hint on whether to deliver a shock, and prompts or automatically administers a shock to the patient. Both types of models guide the operator through the defibrillation process with voice instructions, and the display screen of i9 and i9 Plus also provides information via sound and light.

2. Installation and Setup

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier, your local distributor or the manufacturer.

If the packing case is intact, open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage. If you have any question, please contact your local distributor or the manufacturer.

Warning:

- This product must be installed by a person designated by the Company.
- The software version of this product belongs to the Company, and any organization or individual shall not carry out infringement acts such as tampering, copying or exchange by any means without permission.
- When you connect this product with other electrical equipment into a combination with specific functions, if you cannot determine whether the combination is dangerous (for example, the risk of electric shock caused by the accumulation of leakage current), please contact the Company or the relevant experts of the hospital in time to ensure the safety of all equipment in the combination.
- The use of accessories beyond those specified in the manual may increase electromagnetic emission or reduce the electromagnetic immunity of the defibrillator. Always use spare parts or consumables provided by the Company or its authorized representatives.

Note:

To ensure that the equipment is ready to use, install the battery in advance and connect the electrode pads connector.

2.1. Environmental Requirements

Do not operate, store or transport the equipment beyond the environmental specifications in the manual.

Do not store the equipment in direct sunlight.

Do not store the equipment in an area with a large temperature difference.

Do not store the equipment near any heating equipment.

Do not store the equipment in an area with strong vibrations.

Do not operate or store the equipment in an environment filled with flammable gases or anesthetics.

Do not operate or store the equipment in a dusty environment.

Note:

Please ensure that this equipment is under the specified environmental requirements, otherwise it will not be able to meet the technical specifications claimed in this manual, and may cause unforeseen consequences such as equipment damage.

Do not open the sealed electrode pads package when the equipment is not in use to prevent the AED electrode pads from drying out.

2.2. Battery Installation

1. As soon as you open the package, check all materials against the packing list.

2. Be familiar with the controls and characteristics of the main unit. Study the functionality of buttons, switches, indicators, and connector ports.

3. Install the battery (for details, see 8.4 Replacing the Battery).

After the battery is installed, the main unit automatically performs an auto-test to verify that the rescue operation is ready. The status LED flashing green indicates that the main unit has passed the battery installation test.

4. Store the defibrillator according to the emergency response plan. When storing, you must consider the following:

- The conditions of the storage area must be within the environmental limits of the defibrillator.

1. It must be easy to check the status indicator of the defibrillator.

3. Cleaning and Disinfecting

3.1. Cleaning

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your location, the equipment should be cleaned more frequently.

Recommended cleaning agents are:

- Water
- Sodium hypochlorite bleach (10%, Sodium hypochlorite)
- Hydrogen peroxide (3%)
- Ethanol (75%)
- Isopropyl alcohol (70%)

To clean your equipment, follow these rules:

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

After each cleaning, perform the following functional checks:

- Run the battery installation test, refer to Chapter 7.Troubleshooting
- Verify and confirm that the status LED is flashing green to indicate that the device is ready for rescue operations.

Note:

- Always dilute following the manufacturer's instructions or use lowest possible concentration.
- Do not immerse part of the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).
- If the equipment has been immersed in water, please contact the manufacturer or an authorized representative to provide maintenance services.
- Do not use rough materials to wipe the surface of the device.

3.2. Disinfecting

Disinfection may cause some damage to the equipment. Disinfect the equipment as required in your facility servicing schedule. Cleaning equipment before disinfecting is recommended.

Recommended disinfectants are:

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

3.3. Sterilization

Sterilization of this defibrillator, related products or accessories is not recommended.

4. Maintenance

4.1. Routine Maintenance and Condition Monitoring

This equipment is extremely easy to maintain and it can automatically perform auto-test in standby status. If the battery is installed and the status LED is blinking green, it means that the equipment is in standby status. Auto-tests are performed daily, weekly and monthly. If a fault is detected during auto-tests, the main unit will issue an alarm. Check the main unit's status LED regularly to ensure that the equipment is always ready for first-aid.

4.2. Regular Check

In addition to the tests recommended after using the defibrillator, you will regularly perform the following tests:

- Check if the status LED flashes green, if there is an abnormality, please refer to Section 7.Troubleshooting;
- Replace all used, broken or expired accessories;
- Check the appearance, if there is any damage, please contact the after-sales service department of the Company;
- Record the results of each regular check.

4.3. Battery

If the defibrillator has been installed and the main unit is in standby status, in order to facilitate monitoring the condition of the defibrillator and save rescue time, it is recommended to install the battery into the main unit at this time.

If the defibrillator is stored in a warehouse or in transit, in order to save battery power, it is recommended that the main unit and the battery be placed separately.

The main unit will always monitor the battery level during standby status and working status, and the user can check the battery level through the battery display, and the full charge is 4 bars. When the battery level is too low, the battery display will show 0 bar, and the status indicator will turn red, indicating that the user needs to replace the battery immediately.

The new disposable battery is able to provide 300 times of 200 Joules defibrillation discharges, or 4 hours of normal work time. Turning on the defibrillator consumes battery power. When the battery is installed in the defibrillator, the battery level decreases due to the battery's own normal discharge rate and the energy used by the defibrillator's self-test function. If the defibrillator is not used during this time, the standby life of the battery is detailed in Section 9.4.Battery Specifications. Whether due to the use of a defibrillator on a patient or for training, the standby life and the battery life are reduced.

If stored at the right temperature, the new non-rechargeable battery has a lifespan of 7 years. The battery is gradually discharged when stored outside the defibrillator, and if it is placed in the defibrillator, the service life of the defibrillator will be shortened, depending on the length of time it has been stored.

To properly maintain a non-rechargeable battery:

- Do not attempt to recharge;
- Do not make electrical connections between battery contacts;

- Please use and store the battery at the temperature specified in this manual, high temperatures will accelerate power loss and shorten battery life, and low temperatures will reduce battery capacity.

Warning:

- Use only batteries recommended and provided by the manufacturer, otherwise it may result in abnormal operation.
- When trying to charge a disposable battery, an explosion, fire or toxic gases may occur.
- When the low battery alarm occurs, please replace the disposable battery with a new one immediately.

5. Specifications

5.1. Safety Specifications

Safety specifications	
Type of protection against electrical shock	Internally Powered ME Equipment
Degree of protection against electric shock	Type BF defibrillation proof

5.2. Physical Specifications

Main unit model	
Semi-automatic model	i9、i7
Fully-automatic model	i9 Plus、i7 Plus
Size and weight	
Size	Length: 289mm Width: 217mm Height: 91mm
Weight	About 2.35 kg

6. EMC

The equipment meets the requirements of electromagnetic emissions and immunity specified in IEC 60601-1-2.

The basic performances of EMC are as follows: During EMC testing, the screen can display normally without false alarm, and the equipment can operate without faults.

6.1. Warning

Touching with the pins of connectors marked with ESD warning symbol should be avoided, and unless the ESD protection measures are taken, the connection to these connectors also should be avoided.

Portable and mobile RF communications equipment may affect the running of this equipment.

Use of this device adjacent to or stacked with other device should be avoided. But if such use is necessary, this device and the other device should be observed to verify that they are operating normally.

6.2. Cautions

The equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the delivered file.

The operators are advised to recognize to ESD warning symbols.

The operators must receive the training of basic contents on ESD protection measures.

Use of accessories and cables other than those sold by the manufacturer of this defibrillator as spare parts for internal components could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device.

6.3. EMC Information of this Equipment

Guideline and Manufacturer's Declaration - Electromagnetic Immunity			
The equipment is suitable for use in the electromagnetic environment specified below. The customer and the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should meet the requirements of use in a typical commercial or hospital environment.
Surge IEC 61000-4-11	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should meet the requirements of use in a typical commercial or hospital environment

Voltage dips, voltage interruptions and voltage changes on the power input line IEC 61000-4-11	< 5% U_T for 0.5 cycles (>95% of dip at U_T)	< 5% U_T for 0.5 cycles (>95% of dip at U_T)	Mains power quality should meet the requirements of use in a typical commercial or hospital environment. If the user of this defibrillator requires continued operation during power mains interruptions, it is recommended that it is powered from an uninterruptible power supply or a battery
	40% U_T for 5 cycles (>60% of dips at U_T)	40% U_T for 5 cycles (>60% of dips at U_T)	
	70% U_T for 25 cycles (>30% of dips at U_T)	70% U_T for 25 cycles (>30% of dips at U_T)	
	< 5% U_T for 5 seconds (>95% of dips at U_T)	< 5% U_T for 5 seconds (>95% of dips at U_T)	
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	3 0A/m	Power frequency magnetic fields should have level characteristics of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Guideline and Manufacturer's Declaration - Electromagnetic Immunity			
The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - Guidance**

Conduced RF IEC 61000-4-6 Radiated RF IEC61000-4-3	3 V (RMS) 150 kHz - 80 MHz (Except for ISM bands [a]) 10 V (RMS) 150 kHz - 80 MHz (ISM bands [a]) 10V/m 80MHz - 2.5GHz	3 V (RMS) 10V (RMS) 20V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ $d = \left[\frac{12}{V2}\right]\sqrt{P}$ $d = \left[\frac{12}{E1}\right]\sqrt{P}$ 80 MHz~800 MHz $d = \left[\frac{23}{E1}\right]\sqrt{P}$ 800 MHz~2.5 GHz Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer; 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.

a. The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz, and 40.66 MHz to 40.70 MHz.

b. Compliance level in the ISM frequency bands between 150 kHz to 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that portable/mobile communication equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in computing 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

d. Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Equipment

The equipment is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment, according to the maximum output power of the communication equipment.

Rated Maximum Output power of Transmitter Watts (W)	Separation Distance According to Frequency of Transmitter (m)			
	150 kHz to 80 MHz (Except for ISM bands) d = $1.2\sqrt{P}$	150 kHz to 80 MHz (ISM bands) d = $1.2\sqrt{P}$	80MHz to 800MHz d = $0.6\sqrt{P}$	800MHz to 2.5GHz d = $1.15\sqrt{P}$
0.01	0.12	0.12	0.060	0.12
0.1	0.38	0.38	0.19	0.37
1	1.2	1.2	0.6	1.2
10	3.8	3.8	1.9	3.7
100	12	12	6.0	12

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined 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 higher frequency range applies.

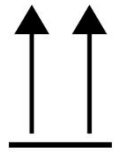
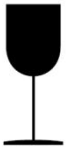
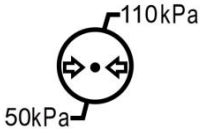
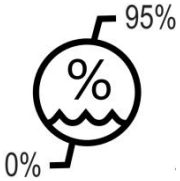
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 3: The ISM bands between 50 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 4: Factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz to 80 MHz and in the frequency range 80 MHz to 2.5 GHz, so as to decrease the likelihood that portable/mobile communication equipment could cause interference if it is inadvertently brought into patient areas.

7. Storage and Transportation

After packaging, the product can be transported in a common way. During the transportation, it should be protected from moisture, sunlight and impact. See the chart below:

Graphic Symbol	Description	Graphic Symbol	Description
	This way up		Fragile; Handle with care
	Keep dry		Stacking limit by number: 5
	Temperature limitations: -30°C to 70°C		
	Atmospheric pressure limitations: 50 kPa to 110 kPa		
	Humidity limitations: 0%~95%		

Warning:

The product should be placed in the standard environment for 8 hours or above before use in cases: the storage conditions exceed the requirements of operation environment; switch into use status from storage status.

It is recommended not to install the battery into the main unit during storage and transportation.

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