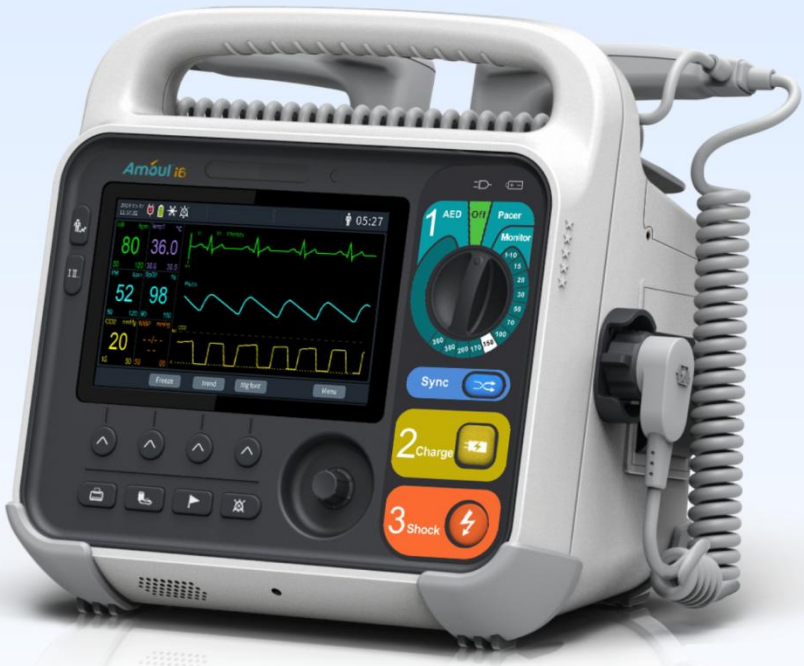
Amoul®



Instruction Manual
Defibrillator / Monitor

www.amoulmed.com

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Product Information

Thank you for purchasing the Amoul Defibrillator/Monitor series products.

Before using the equipment, please read and understand the contents of this operation 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.

Note: The i2 model differs from the i6 model only by eliminating the temperature detection function, so the manual is mainly based on the i6 model, and also applicable to the i2 model products.

Product name:	Defibrillator/Monitor
Specifications and models:	i2, i6
Registered address:	Rm A1302,13th Floor,Block A,Shenzhen National Engineering Laboratory Building,No20,Gaoxin 7th Road South,Yuehai Sub-district,Nanshan District, Shenzhen,Guangdong Province, China.
Name of manufacturer:	AMBULANC (SHENZHEN) TECH. CO., LTD
Production address:	3rd Floor,Block C,Building #5,Skyworth Innovation Industry Park, Tang Tou 1st Road,Shiyan,Baoan District,518108,Shenzhen,People's Republic of China
Date of manufacture:	See the host label
Service life:	8 years
Software name:	Defibrillator/Monitor software
Software release version:	V1.0
Release version of the manual	1.0
Revision date of the manual	2022.12

Note:

This instrument is not designed for home use.

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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.

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- 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.

Warning:

Failure to implement a satisfactory repair/maintenance program for each hospital or institution responsible for the use of this instrument may result in abnormal instrument failure and may endanger personal health.

Guarantee

Manufacturing Process and Raw Materials:

AMBULANC (SHENZHEN) TECH. CO., LTD guarantees that the instrument is in normal use and maintenance, and there is 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: Amoul Building, Building 8, Skyworth Innovation Industry Park, Tang Tou 1st Road,Shiyan,Baoan District,518108,Shenzhen,People's Republic of 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: info@amoulmed.com

Returns

Return Procedure

If you really need to return goods 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. Only qualified medical personnel with professional qualifications are allowed to use this equipment.

4. Unauthorized modification of the software or hardware or any other part of the product is prohibited.

5. 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.

6. The system aims to provide doctors with auxiliary tools needed for clinical treatment.

7. Doctors are responsible for the treatment process. Amoul is not responsible for the treatment process.

8. Be sure to back up important data on external storage media, such as external memory, clinical records, notebooks, etc.

9. 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.

10. AMBULANC (SHENZHEN) TECH. CO., LTD shall not be responsible for any damage caused by defects in the equipment itself or damage caused by user error.

11. 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.

12. If the warranty request is rejected, AMBULANC (SHENZHEN) TECH. CO., LTD shall not be responsible for the round-trip transportation costs.

13. This operation 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 operation manual.

Please keep this operation manual properly. Once the administrator of this equipment system changes, this operation manual must be handed over properly.

Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, d eclaration 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

A notice to the user and/or patient:Any serious incident that has occurred in relation to the de vice should be reported to the manufacturer and the competent authority of the Member State in w hich the user and/or patient is established.

1. 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:

1.1. Security Information

Safety instructions are marked in this operation manual as follows:

Mark Prompt	Related Instructions
⚠**Danger:**	Alerts patients and users of a potential risk of death or serious personal injury.
⚠**Warning:**	Alerts patients and users of a potential risk of injury.
⚠**Note:**	Alerts of conditions that may cause damage to the equipment and may result in wrong therapeutic effects.

1.1.1. Danger

The device will release a large amount of electrical energy during defibrillation, which may result in serious injury or even death. When using this equipment, all operating instructions in this manual must be observed. Do not operate this equipment until you are familiar with all functions and all operating instructions.

Do not open the equipment enclosure to avoid the possibility of electric shock. The repair or upgrade of the equipment can only be carried out by the qualified and authorized maintenance personnel trained by the company.

Avoid using this equipment in the vicinity of combustible agents or in an oxygen-rich environment to prevent explosion or fire. In addition, the Defibrillator/Monitor and its surrounding area should be kept clean and dry.

During defibrillation, keep a sufficient distance from the patient and metal objects connected to the patient to avoid electric shock.

1.1.2. Warning

Before use, the operator must check whether that the equipment, connecting cables and accessories are in correct operating condition. Do not use this equipment if a fault is found.

Make sure the synchronous input system is applied to this Defibrillator/Monitor and the input signal is correct if necessary.

This equipment is used for single patient at a time.

The equipment is not intended to be used within the Magnetic Resonance (MRI) environment.

Only the battery and power cord provided by our company can be used for this equipment.

Do not disassemble the Defibrillator/Monitor to prevent electric shock.

The multifunction electrode pads shall be closely adhered to the skin of the patient without leaving a gap. If necessary, use a tool to scrape the hair on the chest of the patient.

If you wish to use this equipment with equipment not mentioned in this manual, please consult the relevant manufacturer and Amoul.

During operation, keep the equipment away from sources of electromagnetic interference (such as motors, generators, X-ray equipment, radio transmitters, cellular mobile telephones, magnetic resonance imaging and other equipment) that may interfere with the signals being collected and analyzed. For more information, see Chapter 16: EMC.

Do not operate the equipment in water. Do not immerse any part of the equipment in water or spill any liquid on it. If the equipment is wet, dry it.

Do not store or use the equipment in a humid environment. If the equipment is damp, please use a dry towel to dry the surface of the equipment, and put the equipment in a dry, 20°C environment for a period of time, until the equipment is completely dry before use.

Always have a fully charged and properly maintained backup battery on hand. When the device displays a low battery warning, charge or replace the battery promptly. Failure to do so may cause the device to be shut down.

During defibrillation, disconnect all other devices that do not have defibrillation protection from the patient.

The alarm volume and alarm limit shall be set according to the actual situation of the patient. It is not possible to rely solely on an audible alarm system for patient monitoring. A small alarm volume setting may result in a missed judgment or cause danger to the patient.

When the device is connected to the patient, it is not allowed to perform any functional check to avoid accidental electric shock to the patient.

When using this device for treatment, attention should always be paid to the actual condition of the patient. If there is a delay in delivering a shock, it is possible that a heart rhythm that has been analyzed as shockable may be converted to a non-shockable heart rhythm, resulting in an incorrect delivery of a shock.

When treating patients with implantable pacemakers, the multifunction electrode pads or external paddles should be placed as far as possible away from the area where the pacemaker is implanted.

Please carefully place the power cord and the cables of various accessories to prevent the patient from being entangled or suffocated, or the cables from being entangled and subject to electrical interference.

Do not touch the patient and the equipment interface, the thermal head of the recorder or other live equipment at the same time to avoid injury to the patient.

During the charging and discharging process of the machine, the operator shall not touch the patient and the conductive part of the equipment at the same time.

To avoid danger or environmental pollution, relevant local laws and regulations or the waste disposal procedures of the hospital must be observed when handling the main unit, accessories and packaging materials. The main unit, accessories and packaging materials must be kept out of the reach of children.

Do not make any modifications to this equipment.

Maintenance measures such as inspection and overhaul work can only be carried out by the manufacturer AMBULANC (SHENZHEN) TECH. CO., LTD, or by its authorized professionals.

1.1.3. Cautions

Please keep the equipment properly to prevent the equipment from falling, collision, strong shock or other mechanical damage.

Do not mix different types and brands of electrode pads. The use of mixed electrode pads may result in greater baseline drift or longer baseline recovery time after defibrillation.

To avoid contamination or infection of personnel, the environment, or other equipment, equipment and accessories that have reached the end of their service life must be disposed of in accordance with the relevant local regulations or the relevant system of the medical institution.

Please place this manual near the equipment so that it can be easily and timely obtained and accessed when operating the equipment.

When operating the equipment, the operator should stand in front of the equipment.

In order to keep the equipment available at any time, please install a fully charged battery in advance and connect the multifunctional electrode pad plug.

A user test should be performed after the device has been dropped or improperly operated. If any fault is detected, do not use the equipment again and contact the company's authorized after-sales service personnel or designated maintenance personnel for maintenance.

Please install this equipment in a location where it is easy to see, operate, and maintain.

1.2. Security Overview

A functional check must be carried out before using the equipment (see Chapter "12Check and Maintenance").

Follow the instructions in the Chapter "11Cleaning and Disinfecting" to prevent infection or bacterial infection.

2. Introduction

2.1. Intended Purpose

The Defibrillator/Monitor is intended for external defibrillation, internal defibrillation, synchronized cardioversion and semi-automated external defibrillation (AED). It can also be used for non-invasive external pacing as well as ECG, SpO2, Resp, PR, NIBP, CO2 monitoring and Temp monitoring.

2.2. Intended User

The equipment is intended to be used by qualified medical personnel trained in the operation of the equipment and qualified by training in basic life support, advanced cardiovascular life support or defibrillation.

2.3. Indication

AED Mode:Sudden Cardiac Arrest (SCA)

Manual Defib Mode: Ventricular Fibrillation (VF),Ventricular Tachycardia (VT)

Noninvasive Pacing Mode: symptomatic bradycardia, asystole

synchronized cardioversion: atrial fibrillation

2.4. Contraindication

Contraindications:

1. Manual Defib Mode: Person with Reactive, autonomously breathing, palpable pulse.
2. AED Mode: Person with reactive and breathing normally.
3. Noninvasive Pacing Mode: For the treatment of ventricular fibrillation.

2.5. Patient Population

1. Adults and Pediatric;
2. Patients with ventricular fibrillation and ventricular tachycardia;
3. Suspected cardiac arrest;
4. atrial fibrillation;
5. symptomatic bradycardia, asystole.

3. Installation and Use

Warning:

The Defibrillator/Monitor shall be installed by professionals or personnel authorized by the company.

The software copyright of the Defibrillator/Monitor is solely owned by the company. No organization or individual shall resort to juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.

All analog and digital devices connected to the Defibrillator/Monitor must be certificated according to the applicable IEC standards (such as IEC60601-1 Safety of Medical Electrical Equipment), and all devices shall be connected in accordance with the requirements of the valid version of IEC60601-1-1 system standard. The personnel responsible for connecting the additional equipment to the input and output signal ports are responsible for the compliance of the system with the IEC60601-1-1 standard. If you have any questions, please contact our company.

If it is not evident from the equipment specifications whether a particular combination is hazardous, for example, due to summation of leakage currents, please consult the company or an

expert in the field, to ensure the necessary safety of all devices concerned will not be impaired by the proposed combination.

The use of accessories beyond those specified in the manual may increase electromagnetic emissions or reduce the electromagnetic immunity of the Defibrillator/Monitor. The replacement parts and consumables provided by AMBULANC (SHENZHEN) TECH. CO., LTD or its authorized representative must be used.

3.1. Unpacking and Checking

Note

Please save the packing case and packing materials for future transportation or storage.

Warning

Packing materials may cause pollution to the environment. When disposing of packing materials, the relevant local regulations or the hospital's waste disposal system must be observed. Keep packing materials out of the reach of children.

The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.

3.2. Environmental Requirements

Note

Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could be caused.

3.3. Turning On the Equipment

Warning

Do not use the Defibrillator/Monitor for any monitoring or therapy procedure on a patient if it is not working properly, or if it is mechanically damaged. Contact your service personnel.

4. Interface Description

4.1. Limit Setting

Warning:

Please check whether the alarm limit setting is suitable for the patient before starting monitoring.

Setting the alarm limit to the limit value may make the alarm system invalid. For instance, the high oxygen level makes premature infants prone to retrobody fibroplasia. If the upper alarm for SpO_2 alarm is still set to 100%, the upper alarm will not be triggered.

4.2. Event Review

Note

- Suspending or closing an alarm will not be saved as an event.
- The events already stored will not be affected by power down.
- If the events stored reach the storage limit, the events newly stored will automatically overwrite the earliest ones.

4.3. Archives Management

Note

- Do not remove the USB flash disk before the completion of data export.
- The Defibrillator/Monitor can enter the main interface of archives management through the main menu only in the monitoring, manual defibrillation and pacing modes. After entering the main interface of archives management, the Defibrillator/Monitor automatically ends the monitoring and treatment of the patient, with the last patient as the latest historical patient.

4.4. User Test

Note

A user detection is suggested at each shift turnover.

Note

During key test, the keys already detected are in green.

The key test does not detect the off gear of the knob in the mode. If the time for the user switches to the off gear exceeds 7s, the system will be turned off.

The system will save the results of conventional test, high energy test and key test for review. Select [Recap History] in the main interface of user detection to enter the history review interface and check the results of user test.

The system can save up to 800 detection records in the order of test time from top to bottom. You can select a test record by rotating the knob and press the knob to view the detailed test report for the current test.

Note

If there is no historical test report, [Recap History] will not be displayed in the main interface of user test.

5. AED Mode

5.1. Overview

Warning:

- During defibrillation, the bubbles between the skin and multifunctional electrodes may cause burns to the patient's skin. Ensure that multifunctional electrodes are fully attached to the skin to avoid bubbles.
- Do not use dry multifunctional electrodes.
- During the defibrillation, do not touch the patient and keep adequate distance from the patient.

Note:

For patients with a pacemaker, the sensitivity and specificity of AED analysis algorithm may be relatively lower.

5.2. AED Steps

5.2.1. Defibrillation Operations

Note:

- When performing defibrillation in pediatrics below 8, the multifunctional electrodes for pediatrics are recommended. When no multifunctional electrodes for pediatrics are available, the multifunctional electrodes for adults may be used. Besides, patient type should be set to [Pediatric].
- The supporting multifunctional electrodes of the Defibrillator/Monitor are disposable accessories. Do not reuse them.
- During analyzing the heart rhythm, the patient should be kept immobile to avoid misdiagnosis or delayed diagnosis.
- The Defibrillator/Monitor will not release shock automatically. Shocks will be released only when the shock button is pressed.
- Avoid affecting the treatment of patients due to high impedance. In case of the prompt information "no shock is released due to excessive impedance", please check whether the patient's skin is clean and dry. If this information does not disappear, please replace the multifunctional electrode or cable of electrode pads.

5.3. CPR Operation

Warning

The CPR metronome does not indicate the current condition of patients. Since patients' condition may change in a very short time, the operator needs to frequently evaluate patients' condition. CPR should not be performed on patients with normal response and respiration.

Note

The CPR metronome is affected by the "on/off" of AED voice prompt and the setting of voice volume.

6. Manual Defibrillation Mode

6.1. Overview

Warning:

When performing manual synchronous defibrillation, if the ECG waveform is monitored via external paddles, the artifact caused by the movement of electrode paddles may be similar to R wave and trigger defibrillation shocks.

Do not use liquid conductive agent. Only the conductive paste designated or allowed by the company can be used.

When treating patients with external paddles, the paddles should be smoothly attached to the patient and evenly pressed. Do not press too hard to cause other harm to the patient.

When performing defibrillation on pediatric patients, an appropriate energy level should be selected.

Do not attach external paddles on yourself to confirm that they are effectively connected.

6.2. Manual Defibrillation Interface

Note:

Defibrillation should be performed on the patient when the contact impedance indication is normal. Defibrillation is also allowed when the contact impedance is high.

6.3. Steps of Manual Defibrillation

6.3.1. External Defibrillation

Warning:

1．During defibrillation, avoid touching the parts other than the insulated parts such as the handle of external paddles.

2．Turn on the Defibrillator/Monitor and enter manual defibrillation mode.

3．Select energy: set the required energy by the knob switch of the Defibrillator/Monitor. If external electrode paddles are used, the energy may also be set by pressing the energy selection buttons on the electrode paddles.

4．Charge the device.

- Press the charging button on the panel or on the electrode paddles. When the Defibrillator/Monitor is being charged, the charging progress bar will be displayed in the operation prompt area. There will be a charging sound. When the device is fully charged, there will be a charging completion sound.

- If the selected energy needs to be changed during or after charging, the desired energy may be selected by energy selection buttons. When the energy value is changed, the charging button should be pressed again to charge the device.

- The energy being charged or already charged may be discharged internally by pressing [Release] soft key. If the shock button is not pressed within the set Time to Auto Disarm, the Defibrillator/Monitor will perform automatic release. The [Time to Auto Disarm] can be set in General Setups.

5．Shock;

- Shock: confirm that the current patient requires shocks and that the Defibrillator/Monitor has been charged. Ensure that no one is touching the patient or the accessories or equipment connected to the patient. Shout loudly and clearly "stand aside".

- If electrode pads are used: press the shock button on the machine panel to release a shock to the patient.

- If external electrode paddles are used: press the shock button on both electrode paddles to release shocks to the patient.

Note:

- Defibrillation is generally performed by electrode paddles or multifunction electrode pads. However, during defibrillation, ECG leads can be selected for ECG monitoring. If ECG leads have been connected, any available leads can be displayed selectively.

- The recommended energy for adult defibrillation is 150J.

- When performing defibrillation on pediatrics patients, electrode paddles for pediatrics should be used. The recommended energy is 50J. The maximum energy is 100J.

- When performing defibrillation in pediatrics below 8, the multifunction electrode pads for pediatric are recommended. When no multifunction electrode pads for pediatrics are available, the multifunction electrode pads for adults may be used. Besides, patient type should be set to [Pediatric].

6.3.2. Internal Defibrillation

Note:

- When internal defibrillation electrode paddles are used, the selectable maximum energy is automatically limited to 50J to avoid any heart damage due to high energy.

- Internal defibrillation electrode paddles must be sterilized before use, or severe cross infection may be caused.

- Internal defibrillation electrode paddles must be cleaned and sterilized after each use.

6.4. Manual synchronous defibrillation

6.4.1. Steps of Manual Synchronous Defibrillation

Note:

- After entering synchronous cardioversion, the alarm of Defibrillator/Monitor will be automatically resumed.
- When delivering a synchronous shock, the shock button (or the discharge button on the external paddles) should be pressed and held until shocks are released. The Defibrillator/Monitor releases a shock on the next R wave monitored.

7. Monitoring Mode

7.1. ECG Monitoring

7.1.1. Overview

Warning:

- The skin sites at ECG electrodes, multifunction electrode pads or external paddles should be regularly checked. In case of signs of allergy, electrodes should be replaced, or the position of multifunction electrode pads or external defibrillation paddles should be changed.
- If defibrillation of the patient is required, an anti-defibrillation type ECG cable should be used.
- The patient's pacing status should be properly set, otherwise the pacemaker pulses may be counted during cardiac arrest and certain arrhythmias in patients with built-in pacemakers. Close attention should be paid to patients with pacemakers. Do not rely solely on the heart rate alarm and the displayed heart rate.

Note:

- Ensure that no other conductive parts or the ground is contacted when attaching electrodes or connecting cables. Ensure that all ECG electrodes are connected to the patient.
- The interference from ungrounded instruments near the patient and ESU interference may cause distortion of the ECG waveform.
- If the selected ECG signal source cannot obtain effective ECG signal, the ECG waveform is displayed as a dotted line.
- ECG monitoring with external paddles should be avoided as far as possible.
- When performing ECG monitoring with ECG leads, the electrodes used must be of the same type.
- When performing ECG monitoring, this Defibrillator/Monitor cannot be used for direct cardiac contact.

7.1.2. Steps of ECG Monitoring

7.1.2.1. Lead Monitoring Operation

Note:

- The supporting ECG electrodes of the Defibrillator/Monitor are disposable ECG electrodes. Reuse is not allowed.

7.1.2.2. Placement of Lead Electrodes

Warning:

When electrosurgery unit (ESU) is used, the ECG electrodes should be attached in the middle position between the earth plate of the ESU and the electrosurgical knife to avoid burns. The cable of the ESU cannot be intertwined with the ECG cable.

When the ESU is used, do not place electrodes near the earth plate of the ESU, or a lot of interference to ECG signal may be caused.

7.1.2.3. Check of Pacing Status

Warning

- For patients with a pacemaker, the [Pacing Analysis Switch] must be set to [On]. When the pacing analysis is on, the arrhythmias associated with premature ventricular beats (including PVCs counts) will not be detected. Besides, ST segment will not be analyzed.

- For patients without a pacemaker, the [Pacing Analysis Switch] should be set to [Off]. Otherwise the system cannot detect the arrhythmias associated with premature ventricular beats (including PVCs counts). Some pacemakers may cause false alarms of low heart rate or arrest due to pacemaker artifact. For instance, pacemaker overshoot may override the true QRS.

7.2. CO_2 Monitoring

7.2.1. Mainstream CO_2 Module

Note:

- The mainstream CO_2 module is only suitable for patient undergoing mechanical ventilation (trachea cannula).

- It should be zeroed upon the first use, which takes about 15 - 20s.

- The mainstream CO_2 module adopts disposable gas circuit connector that should not be re-sterilized or reused.

- The battery capacity should be kept above 1300 mAh during the normal operation of the CO2 module.

- Do not collide or shake the CO_2 module.

7.2.2. Influencing Factors for Measurement

The following factors may affect the accuracy of measurement:

- Leakage or internal leakage of sampling gas:
- Mechanical shock;
- Circulating pressure higher than 10 kPa (100 cmH_2O) and abnormal pressure changes in the gas circuit;
- Other sources of interference (if any).

7.3. SpO_2 Monitoring

7.3.1. SpO2 Monitoring Display

Warning

- Only the pulse oximetry probes specified in this IFU can be used by referring to the IFU for the sensor.
- Before use, the operator should verify the compatibility among the Defibrillator/Monitor, pulse oximetry probe and oximetry cable, or harms may be caused to patients.
- In case of a tendency of anoxia, the blood-gas analyzer should be used to analyze the blood sample so as to fully grasp the patient's condition.
- Do not use this device and pulse oxygen saturation probe when using MRI device for the induced current may cause serious burns to patients.
- When patients are monitored for prolonged periods of time, the pulse oximetry probe attachment should be checked every 2 hours and moved appropriately in case of skin changes or every 4 hours. Some patients, such as patients with perfusion disorder or skin sensitivity, should be checked more frequently. The reason is that continuous prolonged monitoring may increase unexpected skin changes, such as allergies, redness, blistering, or compression necrosis.

Note:

Functional test devices or oxygen simulators cannot be used to verify the accuracy of oxygen saturation monitors and pulse oxygen saturation probes. The accuracy of oxygen saturation monitors and pulse oxygen saturation probes should be verified by clinical data.

The pulse oxygen saturation probe and probe extension cord used in combination with this Defibrillator/Monitor are used with this monitor to confirm and test the conformance to EN ISO 80601-2-61:2019.

7.4. NIBP Monitoring

7.4.1. Overview

Warning

- The type of patient must be confirmed before the measurement. Wrong settings may endanger patient's safety for high settings for adults are not suitable for pediatrics.

- Do not measure the NIBP of patients who suffer from sickle cell disease, have or are expected to have skin injury.

- For patients with severe thrombotic disease, whether to perform automatic blood pressure measurement must be decided according to the clinical situation for there is a risk of hematoma on the limb where the cuff is used.

- Do not attach the cuff on the limb with intravenous infusion or intubation for damage to the tissues around the catheter may be caused when the infusion is slowed down or blocked during the cuff inflation.

- The measuring part, patient position, exercise, and physiological status may affect the reading of NIBP. If you doubt the accuracy of measurements, please first check the patient's vital signs by other means, and then check whether the Defibrillator/Monitor is functioning properly.

7.4.2. NIBP Measurement Procedures

7.4.2.1. Preparations

Note:

- Incorrect size of or bent NIBP cuff may result in inaccurate measurements.

- During NIBP measurement, do no touch or squeeze the cuff or the gas-guide tube, or inaccurate measurements may be caused.

7.4.2.2. Measurement Mode

Warning

In the automatic measurement mode, if the measurement lasts too long, purpura, ischemia or nerve injury may be caused by the friction between the cuff and the body. When monitoring the patient, the color, warmth and sensitivity of the distal limb should be frequently checked. Once any abnormality is observed, the cuff should be bound on another position; or the blood pressure measurement should be stopped.

7.4.3. Setting of Initial Pressure

Note:

- The initial inflation pressure cannot be set during the NIBP measurement.

- After the NIBP module is reset or the patient type is changed, the initial inflation pressure value is restored to the default for the current patient type.

7.5. TEMP Monitoring

7.5.1. Overview

Warning

Check whether the cable of the temperature probe is normal before starting temperature

monitoring. When the temperature probe cable in channel 1 or 2 is unplugged from the temperature probe port, a technical alarm will be triggered; and a prompt message will be displayed on the screen.

7.5.2. TEMP Measurement Procedures

Note

This Defibrillator/Monitor supports surface and cavity probes. Appropriate body temperature probes may be selected according to the patient type and measurement needs.

7.6. RESP Monitoring

7.6.1. Overview

Warning:

When monitoring the patient's respiration, the electrotome-resistant ECG cables cannot be used.

Respiratory measurement cannot identify obstructive and mixed apnea. It can only detect after the last respiration. If the next respiration is not detected after the preset time, an alarm is triggered. The safety and effectiveness of breathalymetric methods in detecting apnea, especially in premature infants and infants, has not been verified.

7.6.2. Placement of Respiration Electrodes

Note:

In order to obtain the optimal respiratory waves, when respirations are measured with Lead I, the RA and LA electrodes should be horizontally placed. When Lead II is selected, the RA and LL electrodes should be diagonally placed. See the figure below:

Note

Respiration monitoring is not suitable for the patients who are very active, as this will cause false alarms.

8. Noninvasive Pacing Mode

8.1. Overview

Note:

- Use demand pacing mode whenever possible. Use fixed mode pacing if noise or artifact interferes with proper sensing of R-wave or when monitoring electrodes are not available.
- During fixed mode pacing, R-wave markers do not appear on the paced beats.
- During demand mode pacing, if the patient's heart rate is above the pacing rate, pace pulses are not delivered and, therefore, pace markers do not appear.
- In pacing mode, arrhythmia analysis is supported, and available arrhythmia alarms are asystole, ventricular fibrillation and ventricular tachycardia.
- If pacing is interrupted for any reason, the [Start Pacing] soft key must be pressed to

resume pacing.

- In the case that electrode pads poorly contact the patient, the alarm "Pacing Stopped Abnormally" and "Pads Falling Off" may be presented.

- Electrode pads are not an available option for the source of ECG waveform in pacing mode.

Warning:

Heart rate displays and alarms function during pacing, but they can be unreliable. Observe the patient closely while pacing. Do not rely on the indicated heart rate or heart rate alarms as a measure of the patient's perfusion status.

8.2. Pacing Procedure

Note:

- Use care when handling the electrode pads on the patient to avoid shock hazard during pacing.

- When you are using the pacing function with battery power, if the "Low Battery" alarm is presented, you should connect the equipment to external power or install a fully charged battery.

- The monitoring or pacing function may be unstable in the presence of electric scalpel or other electronic devices.

9. Recording Setting

9.1. Usage of Recorder

Note

If you change the ECG Lead, Gain or Filter during recording, the recorded ECG waveform changes accordingly, but the label of Lead, Gain or Filter recorded remains unchanged.

9.2. Loading Paper

Note:

- It is recommended to use the thermal paper provided by the Company. Otherwise, it may cause damage to the recorder's print head, the recorder may be unable to print, or poor print quality may result.
- Never pull the recorder paper with force when a recording is in process. Otherwise, it may cause damage to the recorder.
- Do not leave the recorder door open unless you have to reload paper or remove troubles.

9.3. Cleaning of the Recorder

Note:

- Do not use anything that may destroy the thermal element, such as sand paper.
- Do not add unnecessary force to the thermal head.

10. Battery Management

10.1. Overview

Warning:

- Keep the batteries out of reach of children.
- Use only specified batteries by the manufacturer.
- The batteries should be charged in this equipment or in a device approved by the Company.

Note:

- Whether the equipment is in use or not, always connect the equipment to AC mains whenever it is possible.
- Always install a fully charged battery in the equipment.
- After long term use and aging, the power capacity indicated by the battery symbol may be different from the actual capacity. Please refer to the system alarm message.

10.2. Checking Battery Performance

Note:

Life expectancy of a battery depends on how frequent and how long it is used. When properly stored, the lithiumion battery has a service life of approximately two years. If improperly used, its life expectancy can be shortened. We recommend replacing batteries every two years.

To keep the battery in a good performance, the fully discharged (or nearly fully discharged) battery must be charged as soon as possible.

Battery operating time depends on the device configuration and operation. For example, measuring NIBP repeatedly will shorten the battery operating time.

10.3. Storage of Battery

Note:

- Remove the battery from the equipment if the equipment is not used for a prolonged time.
- Do not store the battery at 38°C (100°F) or above for a long time to avoid shortening the life expectancy of the battery.

10.4. Recycling of Batteries

Warning:

Do not disassemble, incinerate or short circuit batteries. Otherwise, they may ignite, explode, or leak, causing personal injury.

11. Cleaning and Disinfecting

Warning:

You must shut down the equipment, remove the batteries and disconnect the power cord and socket before cleaning the equipment.

Note:

- Please dilute detergent and disinfectant according to the manufacturer's instructions or use lowest possible concentration.
- Do not immerse the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Keep the paddles clean. After each use or before user checks, thoroughly clean the paddles and paddle tray.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish), or any erosive cleaners (such as acetone or acetone-based cleaners).
- To clean or disinfect reusable accessories, refer to the instructions for use delivered with the accessories.

12. Check and Maintenance

12.1. Routine Maintenance

Warning:

If the external power cable is damaged, you should remove and replace it immediately to avoid electric shock or fire hazards.

12.2. Maintenance

Note:

After the equipment has been successively used for 12 months, or after the equipment is upgraded or repaired, a thorough inspection should be performed by the skilled maintenance personnel authorized by the Company to ensure the reliability of the equipment.

Damageable critical parts, such as handle, cable, etc. should be checked after each use. And it is recommended to replace them every three years at least.

13. Alarms

Note:

- A potential hazard exists if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.
- When the alarm system is powered off, the equipment will save the alarm before the power failure. The stored alarm message does not change with the time of outage.

14. Technical Data

14.1. Medical Device Management Category

Medical Device Management Category	
Category	Class III,Rule 22
Electrical Safety Classification	
Shock-proof Type	Type I, a device with internal power supply
Degree of protection against electric shock	Type BF defibrillation proof: CO_2 monitoring and external defibrillation Type CF defibrillation proof: ECG, RESP, TEMP, SpO_2, NIBP and internal defibrillation
Degree of protection against ingress of dust & water	IP54
Mode of operation	Continuous

14.2. Main Unit Specifications

Overall Dimensions		
Dimensions at installation	L: 290 mm W: 205mm H: 297mm	
Weight (including battery)	5.8 kg	
Display screen		
Type	TFT Color LCD	
Size	7 inch	
Resolution	800x480 pixels	
Feature	Non-touch screen	
Power Specifications		
Main power	Input voltage	100-240V
	Input frequency	50 Hz/60 Hz

<table>
<tr><td></td><td colspan="2">Input current</td><td>2.0-1.0 A</td></tr>
<tr><td colspan="4">Battery Specifications (the specifications are based on a fully charged new battery and at 20°C of ambient temperature)</td></tr>
<tr><td>Type</td><td colspan="3">Rechargeable lithium ion battery</td></tr>
<tr><td>Battery capacity</td><td colspan="3">3500mAh</td></tr>
<tr><td>Battery voltage</td><td colspan="3">14.8 V of nominal voltage</td></tr>
<tr><td rowspan="4">Run time</td><td>Operating mode</td><td>Run time</td><td>Testing condition</td></tr>
<tr><td>Defibrillation</td><td>≥100 times</td><td>Maximum defib. energy, discharge at interval which is large than 1 min, without recording</td></tr>
<tr><td>Pacer</td><td>≥2h</td><td>50 Ω load impedance, pacing rate 80 bpm, pacing output 60 mA, without recording</td></tr>
<tr><td>Monitor</td><td>≥3h</td><td>ECG is set to the typical operation status, and the screen brightness is set to the lowest level without recording</td></tr>
<tr><td>Charge time</td><td colspan="3">Less than 3 hours to 100% with equipment power off;
Less than 4.5 hours to 100% with equipment power on;</td></tr>
<tr><td>Low battery alarm</td><td colspan="3">After the low battery alarm occurs, 20 minutes of vital signs monitoring (operation conditions
are: connected with SpO2 probe, ECG cable, without recording, and other configurations are set to the factory default), and at least 6 discharges of defibrillation at the max energy can be performed</td></tr>
</table>

15. 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.

15.1. 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.

15.2. 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.

15.3. EMC Information of this Equipment

Guideline and Manufacturer's Declaration - Electromagnetic Emissions		
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.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emission CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The equipment is suitable for use in all facilities, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 60601-1-2 IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 60601-1-2 IEC 61000-3-3	Complies	

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.

16. Storage and Transport

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.

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