Amoul

E7E8 Safety and Performance Information
CPR System

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Table of Contents

Product Information

Description

Thank you for purchasing the CPR System.

Please read and understand the contents of this manual carefully before using the device . Keep this manual properly after reading it, place it in the correct location, and make it available if needed.

Note: The manual is mainly based on E8; the only difference between E8 and E7 is that E7 is not equipped with a hand-held terminal, while E8 has a hand-held terminal. This manual is applicable for both E8 and E7.

Product name:	CPR System
Specifications /Model:	E7, E8
Manufacturer:	Ambulanc (Shenzhen) Tech. Co., Ltd.
Manufacturer 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
Contact information	Tel: +86-755- 26072210 Fax:+86-755-23016012 Website:http://www.amoulmed.com E-mail:service.intl@amoulmed.com
Version	1.1
Revision date:	2024.07.29

Caution:

The device is not designed for home use.

CE 2797

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Ambulanc (Shenzhen) Tech. Co., Ltd. is responsible for the safety, reliability, and performance of the device only under the following circumstances, namely:

- The assembly operation, extension, re-adjustment, improvement, and repair are carried out by the personnel authorized by Ambulanc (Shenzhen) Tech. Co., Ltd.
- The relevant electrical equipment meets the national standards;
- The device should be used according to the manual.
- Ambulanc (Shenzhen) Tech. Co., Ltd. shall not be responsible for the safety, reliability, and operation of the products in the following situations:
- Components are disassembled, stretched, and readjusted;
- The device repaired or modified by personnel who are not authorized by Ambulanc (Shenzhen) Tech. Co., Ltd.;
- Not used correctly according to the manual.

Maintenance service

Warranty service :

The warranty service is available for all devices that meet the criteria of the warranty service policy of Ambulanc (Shenzhen) Tech. Co., Ltd.

Scope of fee-based services:

Ambulanc (Shenzhen) Tech. Co., Ltd. will provide fee-based services for the device that exceed the scope of the warranty service policy of Ambulanc (Shenzhen) Tech. Co., Ltd..

Even during the warranty period, the product may need fee-based maintenance due to the following reasons:

- Artificial damage;
- Improper use;
- Grid voltage exceeds the specified range of the device;
- Unavoidable natural disasters;
- Parts or consumables that are not licensed by Ambulanc (Shenzhen) Tech. Co., Ltd. or the machine was repaired by personnel who are not authorized by Ambulanc (Shenzhen) Tech. Co., Ltd.

Warnings:

Failure to implement a proper repair or maintenance plan may result in the device being abnormal and may endanger the patients' health.

Warranty

The manufacturing process and raw materials:

Ambulanc (Shenzhen) Tech. Co., Ltd. guarantees to provide charge-free service for the production process and raw material failures during the warranty period under normal operation and maintenance conditions.

After-sales Service

After-sale service department: Ambulanc (Shenzhen) Tech. Co., Ltd.

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

Toll-free service hotline: 400-9969-120

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

Website:http://www.amoulmed.com

Email:service.intl@amoulmed.com

Return

Return procedure

If the products need to be returned to Ambulanc (Shenzhen) Tech. Co., Ltd., please follow these steps:

- To obtain the right of return: contact the customer service department of Ambulanc (Shenzhen) Tech. Co., Ltd., provide the number of Ambulanc product series numbers marked on the outer shipping box; if the number is not clear enough to be identified, the return will not be accepted. Please indicate the product model and briefly describe the reason for the return.

•Cost of shipping: the user shall bear the shipping costs (including customs charges) of transporting the device to Ambulanc (Shenzhen) Tech. Co., Ltd. for the return of the device.

Important information

1. After purchasing this product, the customer is fully responsible for the maintenance and management of the product.

2. Even during the warranty period, the quality guarantee does not include the following contents:

•Damage or loss caused by wrong or rough operating;

•Damage or loss caused by force majeure such as fire, earthquake, flood, or lightning.

•Failure to meet the use conditions specified in this system, such as damage or loss caused by insufficient power supply, incorrect installation or unsatisfactory environmental conditions.

•Transportation damage caused by improper packing when returning goods.

•Damage or loss caused by failure to use the system without a license.

•Damage or loss of systems not purchased from Ambulanc (Shenzhen) Tech. Co., Ltd. or its authorized dealers or agents.

3. Only qualified medical personnel with professional qualifications are allowed to operate this device.

4. Unauthorized modification of the software, hardware, or any other parts of this product is prohibited.

5. Under any circumstances, Ambulanc (Shenzhen) Tech. Co., Ltd. will not be responsible for any problems, damages, or losses caused by the re-installation, modification or repair of this system by personnel not designated by Ambulanc (Shenzhen) Tech. Co., Ltd.

6. The doctor is liable for the treatment process. Ambulanc (Shenzhen) Tech. Co., Ltd. shall not bear any responsibilities for the treatment process.

7. Be sure to back up important data to external storage media such as clinical records and notebooks.

8. Ambulanc (Shenzhen) Tech. Co., Ltd. shall not be responsible for damage not caused by defects in the device itself or damage caused by user error.

9. Ambulanc (Shenzhen) Tech. Co., Ltd. shall not be responsible for the damage caused by the continued use of this device after exceeding its service life.

10. Ambulanc (Shenzhen) Tech. Co., Ltd. shall not be responsible for the return shipping costs if the warranty claim is denied.

11. This manual contains warnings about foreseeable potential hazards. We should keep strong vigilance against unspecified dangers at any time. Ambulanc (Shenzhen) Tech. Co., Ltd. shall not be liable for any damage or loss caused by negligence or disregard of the precautions specified in this manual.

12. Once the administrator of this system changes, this manual must be handed over.

13. 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.

14. This CPR System meets the requirements of RTCA DO-160G Environmental Conditions and Test Procedures for Airborne Equipment S20, S21 and it can be used on helicopters.

1.Safety Instructions

Please read these safety instructions carefully. These safety instructions are inseparable parts of the device and must always be available. For safety reasons, please pay attention to the following matters:

A routine check must be performed before using this device (see Section 8.1).

Please follow the instructions stipulated in Section 6 to prevent infection or bacterial contamination.

1.1. Security Information

Safety instructions are marked in this manual as follows:

Marker Prompt	Relevant description
⚠**Warnings**:	Warning about the risk of injuries for patients and users.
⚠**Caution:**	Warnings are given for situations that will cause device damage and may cause the wrong therapeutic effect.
⚠**Tips:**	Provide useful tips.
⚠**Warnings**:	[Training] The CPR System can not be operated if you have not received medical training and technical instruction on it, as improper use may result in serious physical injury. [Never leave the patient alone during the use of the device] It is strictly forbidden to leave the patient alone while using the device to allow for a timely response to minimize patient injury in the event of an emergency (e.g., aggregated condition of the patient or machine malfunction). [High-pressure chambers] Never use the device in high-pressure applications (high-pressure chambers). [Fire hazard] Do not use the CPR System in an oxygen-rich environment or with flammable reagents or flammable anesthetics. [Scope of Application] Use the CPR System only for the intended purpose (see Section 2.2). [Qualification of Maintenance Personnel] Maintenance, such as inspection and repairs, shall be only carried out by the manufacturer Ambulanc (Shenzhen) Tech. Co., Ltd., or by its authorized professionals. [Do not open] Do not open the CPR System case. Do not replace or change the external or internal parts of the CPR System.
⚠**Caution**:	[Other Devices] When the CPR System and a device emitting high-frequency radiation (e.g., mobile phone, radio, and high-frequency electrosurgical) are used at the same time, please keep them apart at a distance of more than one meter,

Marker Prompt	Relevant description
	otherwise it may cause malfunction. [Other equipment] This equipment should not be used in a strong magnetic environment (e.g.,an MRI system). Failure to place the device in a strong magnetic environment may cause the device to malfunction. [External Power Supply] When an external power source is used to supply power to the CPR System, please always connect it to a connector that is easy to plug and unplug, so that you can unplug it quickly in case of failure. [External power supply] When using an external power source to supply power to the CPR System, please ensure that the power cord will not be tripped over or obstructed. Do not use an external power source when not necessary, instead, use the battery inside the CPR System to power it. [Liquid] Do not immerse the CPR System in liquid. If fluid enters the enclosure, it may damage the device. [Environmental Protection] This product may produce some waste or wear parts when it is used or after its service life is exceeded, and disposing of these wastes may cause serious pollution to the environment or cross-infection. It should be managed according to the local laws. It cannot be disposed of in the same way as normal waste.

1.2. Accessories/Spare Parts

Caution:

Only the manufacturer, Ambulanc (Shenzhen) Tech. Co., Ltd., or its authorized professionals may perform maintenance measures, such as inspection and repair operations.

For protection from sunlight, please take proper measures to protect silicone and rubber parts from UV light and prolonged direct sunlight; otherwise, these parts will become brittle.

The use of accessories by other manufacturers will lead to failures and incompatibilities. Please keep in mind that failure to use the recommended accessories in the manual or the original spare parts will void the warranty rights and responsibilities.

1.3. Battery

Warnings:

[Low battery] When the prompt for low battery appears, please take any of the following actions:

Replace the battery with a fully charged one.

Connect the CPR System to the external power supply.

Caution:

In order to operate the CPR system in an emergency, batteries must always be installed, even when it is powered by an external power supply.

To minimize disruption, we recommend including a fully charged spare battery in the carrying case.

1.4. Operation

Warnings:

[Unsatisfactory position] If the CPR System cannot be placed safely and correctly on the patient's chest, please perform manual CPR again.

[Incorrect position on the chest] If the silicone pad is not positioned correctly relative to the sternum, there is an increased risk of injury to the chest cavity and internal organs. It may also affect the patient's blood circulation.

[Position changes during operation] If the position of the pressed head changes during operation or defibrillation, please adjust the patient’s position, and reposition it. Always use the stabilization strap of the CPR System to help ensure proper positioning.

[ECG device interference] Chest compressions may interfere with the analysis of the ECG device. Before starting the analysis with the ECG device, first press the pause button to temporarily stop chest compressions to shorten the interruption time as much as possible, and then press the start button to restart compressions when the heart rate analysis is finished.

[Electric shock] Remove and replace the external power cord (optional accessory) immediately to avoid electric shock or fire hazards, if it is damaged.

[Maintain care] Never leave the patient or the CPR System while CPR is being performed. Only by doing this are you able to respond quickly if the patinet deteriorates, the CPR System malfunctions, or the inside battery supply is at a lower level. The late response of medical personnel may lead to serious bodily harm to the patients.

[Malfunction] If there is an interruption during the operation, the pressure is not sufficient, or abnormal conditions occur, press the pause button and then long press the power button for 3 seconds to stop the CPR System and remove the device. Start performing manual chest compressions immediately.

Caution:

[Gel present on the chest] If there is gel on the patient's chest (e.g., used during an ultrasound examination), the position of the silicone pad may shift during use. Remove all gel before placing the silicone pad int the proper position.

[Application of fixing straps] If the use of CPR System fixing straps may prevent or delay treatment for the patient, then, please fix the straps later on.

[Adjunctive therapy] Using other medical devices or drugs with the CPR System can affect the effectiveness of treatment. Please refer to the instructions and make sure the other devices are appropriate for use with the CPR System.

[Venous Access] Ensure that the venous access is unobstructed.

[Device alarm] If any malfunction occurs during operation, the alarm indicator will light up and an alarm will sound. Refer to Section 7.

[Do not use fixing straps to lift the patient] Do not use patient restraint straps or fixing straps to lift the patient. Patient restraint straps and fixing straps are only used to secure the patient to the CPR System.

2.Device Description

2.1. Operating principle

The CPR System is electrically controlled to adjust the depth of compression and mode.

2.2. Intended use

It aims to conduct external chest compression to adult patients suffering from acute cardiac arrest (loss of autonomous respiration, pulse beat and consciousness). It can be used when external chest compression is helpful for patients.

2.3. Intended use environment

Applicable to uninterrupted CPR of patients before admission and within the hospital, as well as during patient transport.

2.4. Patient population

Adult patients who are suitable for use of the device:

- Chest circumference: 70 cm to 150 cm

The use of the CPR System is not limited by the patient's weight.

⚠ **Note:**

•The patient is too small: automatic positioning cannot be completed; or after the automatic positioning is completed, when the compression is started, the alarm information bar and voice alarm prompt "Fail to position".

•Patient is too large: The body part of the CPR System cannot be locked to the back panel without pressing on the patient's chest.

2.5. Indications

The CPR System is applicable for patients with acute cardiac arrest.

2.6. Contraindications

Pregnancy, trauma, or traumatic cardiac arrest.

2.7. Side effects

Side effects include Rib fracture, Sternum fracture, External chest wall bruising or abrasion, Nerve injury, Flail chest, Liver laceration, Hemothorax, Mediastinal injuries, Pneumothorax, Pulmonary edema, Spine fracture, Spleen injury, Subcutaneous emphysema, Chest laceration, Blood in mouth and Gastric contents reflux.

2.8. Intended User

Persons using the CPR System shall be qualified to have the following certifications:

•Operators with medical technology, such as first responders, first-aid personnel, nurses, physicians or medical staff.

•Trained for clinical application of the CPR System approved by Ambulanc (Shenzhen) Tech. Co., Ltd.;

•Learned CPR courses in accordance with the American Heart Association, the European Resuscitation Council guidelines, or similar guidelines.

Warning :

Improper use can cause serious injury to people (operators and patients).

3.Operation and use

3.1. Adjust and activate compression

Warnings:

If the pressed head is not positioned correctly relative to the sternum, there is an increased risk of injury to the chest cavity and internal organs, as well as an impact on the patient's blood circulation.

If the patient is too obese to lock the main unit to the straps, the CPR System is not suitable for that patient. Stop using the CPR System and switch to manual compressions immediately.

Warning:

If the CPR System cannot be placed safely and correctly on the patient's chest, perform manual CPR immediately.

If the patient is too small, the strap may not be able to secure the main unit on the chest of the patient.

Never leave the patient alone while the CPR System is working. Only by doing this are you able to respond quickly in case the patient's condition deteriorates, the CPR System malfunctions, or the battery nearly runs out. Late responses by medical personnel may lead to serious bodily harm.

If there is an interruption during the operation, the pressure is not sufficient, or abnormal conditions occur, please press the pause button and then press the power button for 3 seconds to stop the CPR System and remove the device from the patient. Start performing manual chest compressions immediately.

When the prompt for low battery appears, please take any of the following steps:

Replace the battery with a fully charged one.

Connect the external power supply.

Caution:

If the main unit is shut down due to an abnormality during operation and the silicone pad fails to return to its original position, please stop using the machine, remove its main unit in the first time, and manually push the silicone pad back to its original position.

If the gel is present on the patient's chest (e.g., it is used during an ultrasound examination), the position of the silicone pad may change during use; therefore, all gel needs to be removed before placing the silicone pad.

3.2. Use the patient fixing straps

Caution:

Do not fix the straps if this may prevent or delay the treatment.

3.3. Moving patients

Caution:

Do not use fixing straps to lift the patient. Fixing straps are only used to secure the patient to the CPR System.

Ensure the venous access is unobstructed.

Caution:

If the position of the silicone pad shifts during operation or defibrillation, manually adjust the positions of the patient's chest and the silicone pad immediately, and use the patient fixing strap to help keep the patient in the correct position.

3.4. Replacing the power source during use

3.4.1.Replace the battery

Tips:

When the alarm light flashes red, the main unit will still work and will last for about 15 minutes. To minimize interruptions, it is recommended to replace the battery with a new one or connect an external power source to charge the battery when the battery is low on power.

3.4.2.Connection to the external power supply

Caution:

For the CPR System to operate, batteries must always be installed, even when powered by an external power supply.

3.5. Charging the Battery

Caution:

Only the accessories approved by Ambulanc (Shenzhen) Tech. Co., Ltd. are allowed to be used with the CPR System. If you are using an unapproved accessory, the CPR System may not operate properly.

Only use a battery and power supply suitable for the CPR System. If other batteries or power supplies are used, permanent damage may be caused to the CPR System and the warranty may be voided.

3.6. Adjunctive therapy

Caution:

Using other medical devices or drugs with the CPR System can affect the treatment effect. For other devices or drugs, please be sure to refer to their instruction manual to ensure

that they are suitable for use with CPR.

4.Sanitization

⚠**Caution:**

Always disconnect the device from the power supply before cleaning or performing routine maintenance.

Do not immerse the CPR System in a liquid. If liquid enters the hood, it will cause damage to the equipment. Allow the CPR System to dry before wrapping it.

5.Service

5.1. Routine Inspection

⚠**Warnings:**

If the external power cord (optional accessory) is damaged, remove and replace it immediately to avoid electric shock or fire hazards.

5.2. Remove and recharge the Battery

⚠ **Caution:**

For the CPR System to operate, batteries must always be installed (even when powered by an external power supply). To minimize disruption, we recommend including a fully charged spare battery in the carrying case.

⚠**Warnings:**

The use of accessories by other manufacturers will lead to failures and incompatibilities. Please keep in mind that failure to use the recommended accessories in the manual or the original spare parts will void the warranty rights and responsibilities.

6.Medical Device Management Class

Medical Device Management Class	
Class	Class IIb according to Regulation 2017/745

7.EMC

⚠**Caution:**

This CPR System meets the requirements of IEC 60601-1-2 and RTCA DO-160G

Environmental Conditions and Test Procedures for Airborne Equipment S20, S21.

The user should install and use the machine according to the electromagnetic compatibility information provided by the documents that come with the machine.

Portable and mobile RF communication equipment may affect the performance of the CPR System, avoid strong electromagnetic interference such as being close to mobile phones and microwave ovens when using;

The guidelines and the manufacturer's statement are detailed in the annex.

⚠Warning:

This CPR System should not be used nearby or stacked with other equipment, and if it must be neared or stacked with, it should be observed to verify that it will operate properly in the configuration in which it is used.

Except for cables sold as spare parts for internal components by the manufacturer of the CPR System, the use of accessories and cables other than those specified may result in increased emissions or reduced interference resistance of the CPR System.

⚠Caution:

Be sure to give full consideration to the EMC of the environment in which this device is installed and used by the above guidance;

Other device on or near this device, even if it complies with the emission requirements of CISPR, may still interfere with this device. Please confirm the device operates properly before you can apply it on the patient;

The use of any unauthorized parts on this device may weaken the electromagnetic immunity of the system and may also increase the electromagnetic emissions of this device.

Ambulanc(Shenzhen)Tech.Co.,Ltd.

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