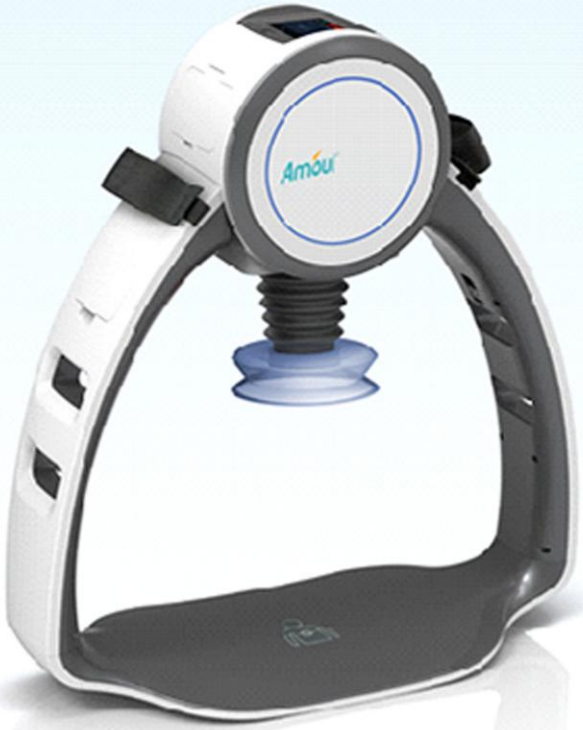
Amoul




E5E6

# Safety and Performance Information
# CPR System

www.amoulmed.com

# Contents

# Product Information

Thank you for choosing the Amoul CPR System. The Amoul chest compression system is a state-of-the-art medical device designed to provide consistent, high-quality chest compressions during cardiopulmonary resuscitation (CPR). This manual provides detailed instructions on the setup, operation, and maintenance of the CPR System, ensuring its effective use in emergency situations. The system is engineered to enhance the delivery of life-saving compressions, maintaining optimal blood flow to vital organs during cardiac arrest. By following the guidelines outlined in this manual, healthcare providers can maximize the efficiency and reliability of the CPR System, ultimately improving patient outcomes.

Before using the equipment, please read this manual carefully and understand the information contained in it to operate it properly. Keep this manual in an accessible place for consultation whenever needed.

| |
|---|
| Product name: CPR System |
| Model: E5, E6 |
| 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 |
| Tel: +86-755- 26072210 Fax: +86-755-23016012 |
| Website: www.amoulmed.com E-mail: service.intl@amoulmed.com |
| Version: 1.1 |
| Revision date: 2024.07.29 |

**Attention:**
This medical device is not intended for any homecare use.

CE 2797

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Ambulanc reserves the right to modify this manual without prior notice.

Ambulanc reserves the right to change related technology without prior notice.

Ambulanc reserves the right to alter product specifications without prior notice.

Ambulanc makes no warranty in any form concerning this manual, including (but not limited to) a guarantee for implied marketability and adaptability for a specific purpose.

Ambulanc will, at its own discretion, take responsibility for the safety, reliability and performance of the instrument in one of the following cases:

- Any assembly, expansion, readjustment, improvement and repair operations are performed by any professional authorized by Ambulanc;
- Related electrical equipment is in compliance with national standards;
- The instrument is used in accordance with the operation instructions.

Ambulanc will not be responsible for safety, reliability and operation condition of the product in one of the following cases:

- Any component is dismantled, expanded or re-adjusted;
- The instrument is not repaired or changed by any personnel authorized by Ambulanc;
- The product is not used correctly in compliance with this Operation Manual.

# Maintenance service

**Scope of charge-free service:**

- Charge-free service is provided for any device in the scope of Ambulanc's warranty terms.

**Scope of paid service:**

- Paid service is provided for any device beyond the range of Ambulanc's warranty terms.

As well as in one of the following cases, even during the warranty period:

- Damage caused by personal fault;
- Improper use;
- Grid voltage beyond the limits;
- Irresistible natural disaster;
- Use of spare part or consumables not approved by the manufacturer, or services performed by personnel that are not authorized by Ambulanc.

**Warning:**

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

# Warranty

**Manufacturing Process and Raw Material:**

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 Unit

After-Sales Service Unit., Ambulanc (Shenzhen) Tech. Co., Ltd.

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

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Website: http://www.amoulmed.com

Email: service.intl@amoulmed.com

# Return

## Return procedure

Any return as necessary shall comply with the following procedure:

- Obtaining the right of return: Contact the Customer Service Department of Ambulanc, and inform them of the product series number, which is marked on the outer shipping box. If the series number is not legible, the return will not be accepted. Please specify the product model number and briefly explain the reason for the return.

- Freight: The user is responsible for the freight for the return of the device to Ambulanc (including customs fees).

# Important information

1. After purchasing the product, the customer shall take full responsibility for its maintenance and management.

2. Quality assurance will not cover the following, even during the warranty period:

- Any damage or loss resulted from improper use or misuse of the product;

- Any damage or loss caused by force majeure such as fire, earthquake, flood or lightning;

- Any damage or loss attributed to failure to meet any operating condition required for the device, such as insufficient power supply, improper installation or unfavorable environmental conditions;

- Any damage or loss incurred due to the use of the device in the region not initially intended for it; and

- Any damage or loss caused by a purchase from any unauthorized dealer or agent.

3. This device can be used only by certified medical staff.

4. Any software or hardware of this product shall not be changed or modified without authorization.

5. In any case, Ambulanc will not take responsibility for any problems, damage or loss resulting from the re-installation, change or repair of the device performed by personnel who are not authorized by Ambulanc.

6. This device is intended to provide the data required for clinical diagnosis by physicians. The physician takes responsibility for the diagnosis process. Ambulanc is not liable for any diagnostic results.

7. Be sure to back up any key data to an external storage medium, such as clinical records and logs.

8. This manual contains warnings for foreseeable potential hazards. The user shall keep watch at any time for any hazard that is not published in the manual. Ambulanc takes no responsibility for damage or loss resulting from negligence or failure to observe the preventive measures stated in this manual.

9. This manual must be handed over to the successor when the device administrator is changed.

10. 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.

# 1. Safety information

Please read this manual carefully. This manual is an integral part of the device and must be consulted at any time. For the sake of safety, the following information shall be paid attention to.

## 1.1. Warning, Attention and Tips

The following safety marks are used in this manual:

**Warning:**
Provides early warning of situations that do harm to patients and users.

**Attention:**
Warning about situations that may cause damage to the device and may result in incorrect treatment results.

**Tips:**
Provides useful information.

## 1.2. Overview

- Regular check must be performed before use of the device (refer to Section 8.1 - Regular check).

- Please observe the instructions in Section 6 to prevent cross contamination.

**Warning:**

- **Training required**: The CPR System can be operated only after you have received proper training from a certified professional with technical expertise in cardiopulmonary resuscitation device. Improper use may result in serious bodily injury.

- **Fire hazard**: Do not use the CPR System in an oxygen-rich environment or with flammable reagents or flammable anesthetics.

- **Scope of use**: Use the CPR System solely for its intended purpose, as specified in Section 2.1.

- **Maintenance qualification**: Maintenance measures should only be performed by Ambulanc (Shenzhen) Tech. Co., Ltd. or its authorized professionals.

- **Do not open**: Do not open the CPR System shield. Do not replace or modify the external or internal parts of the CPR System.

**Note:**

- **External power supply**: When using an external power supply for the CPR System, always connect it to an easy-to-plug interface to ensure it can be swiftly disconnected in case of a malfunction with the power supply.

- **External Power Supply**: When using an external power supply to power the CPR System, make sure that the power cord is not caught or obstructed. If the external power supply is not available, please use the battery.

- **Liquid exposure**: Do not immerse the CPR System in a liquid. If liquid enters the hood, it will damage the device.

## 1.3. Accessories and Spare Parts

**Note:**

- **Preventing exposure to sun**: Take measures to prevent silica gel and rubber parts from being exposed to ultraviolet light and prolonged direct sunlight, as this can cause these parts to become brittle.

- **Use only authorized accessories**: Using accessories from other manufacturers can cause malfunctions and incompatibilities. Please note that in such cases, the rights and responsibilities of the warranty will be void. Only use accessories recommended in the manual and only use original spare parts.

## 1.4. Battery

**Warning:**

Battery Low: When a low battery alarm occurs, do one of the following:

- Replace the battery with a fully charged one.
- Connect an external power supply.

**Note:**

- Keep the battery installed: In order to operate the CPR System in an emergency, the battery must always be installed (even when it is powered by an external power supply).

- To minimize interruptions, we recommend always having a spare fully charged battery in the carrying case.

## 1.5. Operation

**Warning:**

- **Improper placement**: If the CPR System cannot be safely and correctly placed on the patient's chest, perform manual cardiopulmonary resuscitation immediately.

- **Incorrect position on the chest**: If the relative position of the suction cup to the sternum is incorrect, it increases the risk of damage to the chest and internal organs and adversely affects the patient's blood circulation.

- **Change in position during operation**: If the position of the patient’s chest relative to the suction cup changes during operation or defibrillation, adjust the patient's position and reposition the suction cup. Always use the CPR System stabilization belt to ensure the correct position.

- **ECG interference**: Chest compression can interfere with ECG analysis. Pause the CPR System before starting the ECG analysis. Minimize interruption time as much as possible. Press the "Start" button to resume chest compressions.

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

- **Constant monitoring**: Never leave the patient alone when the CPR System works during cardiopulmonary resuscitation. Only by doing this can you respond quickly in case the patient's condition deteriorates, the CPR System fails, or the battery alarm shows a low battery level. A slow response from a medical professional may result in serious bodily injury.

• **Malfunction**: If an interruption occurs during operation, the compression is insufficient, or an abnormal condition arises, press the "pause" button for 3 seconds to stop and remove the device. Begin manual chest compressions immediately.

**Note:**

• **Gel on the chest**: If there is gel on the patient's chest (e.g., from an ultrasound examination), the position of the suction cup may change during use. Remove all the gel before placing the suction cup

• **Use of the stabilization belt**: If using the stabilization belt will prevent or delay CPR, proceed with using the CPR System without the belt.

• **Auxiliary Therapy:** Using other medical devices or drugs in conjunction with the CPR System may affect treatment. Please refer to their instructions to ensure compatibility and suitability for use with the CPR System.

• **Keep Your Hands Safe**: Do not place your hands on or beneath the suction cup while the CPR system is in operation. Ensure your hands are clear of the lock button when attaching the upper part or lifting the patient.

• **Venous Access**: ensure unobstructed venous access for the patient.

• **Device cooling**: Ensure the air hole under the hood is not obstructed, as blocking it may cause the device to overheat.

• **Device Alarm**: If a malfunction occurs during operation, the alarm light will illuminate, and an alarm will sound. Refer to Section 7: Troubleshooting for further guidance.

• **Fixing Belt Usage**: Do not use the fixing belt to lift the patient. The fixing belt is designed solely for securing the patient to the CPR System.

• **Skin Burns**: The temperature of the cover and battery may rise above 118°F (48°C). Avoid prolonged contact with these surfaces to prevent skin burns. Ensure the fixing belt is removed from the patient's hands.

# 2. Device description

## 2.1. 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.

## 2.2. Patient population

Adult patients suitable for use with equipment:
• Sternal height from 160 to 310 mm
• Maximum chest width: 455 mm
The use of the CPR System is not subject to the patient's weight limit.

**Note:**

• The patient is too small: automatic positioning cannot be performed; the alarm prompt "Fail to position" will be voiced. .

• 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.

## 2.3. Indications

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

## 2.4. Intended use environment

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

## 2.5. Contraindications

Pregnancy, trauma, or traumatic cardiac arrest.

## 2.6. 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.

## 2.7. 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.

⚠ **Improper Use Warning:**

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

# 3. Operation

## 3.1. Positioning the CPR System on the patient

⚠ **Attention:**

• Pull up and confirm the grip position: When pulling the E6 up to confirm correct attachment of the top, hold the E6 by the grip opening (top opening) and not by the bottom opening, which contains the lock button, as shown in the following figure. This avoids accidentally pressing the locking button and releasing the upper part.

**Warning:**

- **Patient is too large**: If the patient is too large, such that (i) it is not possible to attach the upper part to the backplate or (ii) when attaching the upper part to the backplate, the suction cup presses on the patient's chest even before starting compressions, then the CPR System is not suitable for this patient. You should stop using the CPR System and proceed with manual CPR compressions immediately.

## 3.2. Adjusting the CPR System and Starting Compressions

**Warning:**

- **Risks** of **incorrectly positioning** the suction cup: Poor positioning relative to the sternum increases the risk of injury to the thoracic cavity and internal organs, as well as jeopardizing the patient's blood circulation.

**Warning:**

- **Incorrect position:** If the CPR System cannot be positioned safely and correctly on the patient's chest, stop using the device and proceed with manual compressions immediately.

- **Patient is too small:** If the patient is too small for the device, the CPR System emits 3 quick alarm signals when lowering the suction cup and you will not be able to enter the setting of the pressing depth and pressing mode. In this case, stop using the device and proceed with manual compressions immediately.

- **Total care for the patient**: Never leave the patient unattended while the chest compression system is operating. Keep yourself alert to respond quickly to any changes in the patient's condition and respond to the device's prompts. Delay in response can result in serious physical harm to the patient.

- **Malfunction**: If there is an interruption during operation, inadequate compressions, or any abnormal condition, long press the On/Off button for 3 seconds to stop the CPR System. Remove the device from the patient and begin manual chest compressions immediately.

**Low battery**: If a low battery warning appears, either replace the empty battery with a fully charged one or connect the E6 to an external power source.

**Attention:**

- **Watch your hands**: Do not place your hands on or under the suction cup when the CPR System is operating. Keep your hands away from the fixation lock when connecting the equipment to the backplate or when lifting the patient.

- **Remove gel from the patient's chest:** If there is gel on the patient's chest (e.g., from an ultrasound examination), it can affect the position of the suction cup. Remove all the gel before positioning the suction cup.

- **Do not block the air outlet**: In order to prevent the unit from overheating, ensure the air outlet located below the equipment cover is not blocked.

## 3.3. Using the stabilization belt

**Attention:**

- Application of Stabilization Belt: If the use of stabilization belts will prevent or delay any treatment, the device should be used later on.

## 3.4. Moving the patient

### 3.4.1.Fixing the patient's arms to the CPR device

**Note:**

- **Do not use the fixing straps to lift the patient:** Do not use the fixing straps to lift the patient. The belt is only used to secure the patient to the CPR System.

- **Skin burns:** The temperature of the cover and battery may rise above 118°F (48°C). If it is too hot, do not touch it for a long time to prevent skin burns. The patient fixing straps are removed from the patient's hands.

- **Vein Path:** Ensures unobstructed venous access.

### 3.4.2.Move patient

**Note:**

- **Position changed during operation:** If the position of the suction cup changes during operation or defibrillation, immediately press the adjustment button to adjust the position. Always use the stabilization belt to help ensure the correct position.

## 3.5. Change battery during operation

### 3.5.1.Change battery

**Note:**To minimize disruption, we offer a dual battery design. It is recommended to replace the new battery or connect the external power supply to charge the battery after a battery has a low battery alarm. Try to avoid the situation where only one battery is left.

### 3.5.2.Connect with external power

**Note:**

- Keep battery installed: In order for the CPR System to operate, the battery must always be installed (even when it is powered by an external power supply) .

Use the power cord:

- Connect the power cord to the CPR System.

- Connect the power cord to a wall outlet (100-240V, 50/60 Hz).

Use the vehicle charging cord:

- Connect the vehicle charging cord to the CPR System.
- Connect the vehicle charging cord to the car outlet (24-25 V DC).

### 3.5.3. Charging battery

**Note:**

- Keep battery installed: In order to operate the CPR System in an emergency, the battery must always be installed (even when powered by an external power supply).

- **Use only approved accessories**: Only accessories approved by the Ambulanc company are allowed to be used with the CPR System. If you are using an unauthorized attachment, the CPR System will not operate correctly. Use only batteries and power supplies suitable for the CPR System. If you use a different battery or power source, it may cause permanent damage to the CPR System, and the warranty will become invalid.

## 3.6. Concurrent treatment

**Note:**

- **Concurrent treatment:** The use of other medical device or drugs in conjunction with the CPR System can affect the effectiveness of treatment. Please be sure to refer to the instructions of the other medical device, and make sure they are suitable for use with CPR.

# 4. Cleaning

## 4.1. General cleaning procedures

**Note:**

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. Maintenance

## 5.1. Regular check

**Warning:**

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

## 5.2. Remove battery and charge

**Note:**

• Keep battery installed: In order for the CPR System to operate, the battery must always be installed (even when powered by an external power source). To minimize interruptions, we recommend always having a fully charged spare battery in the carrying case.

**Warning:**

• **Use only approved accessories:** Using accessories from other manufacturers can cause malfunctions and incompatibilities. Please keep in mind that in these cases, the rights and responsibilities of the warranty will be void: Do not use the accessories recommended in the instructions or the original spare parts.

# 6. Medical Devices Management Category

| **Medical Devices Management Category** | |
|---|---|
| Category | Class IIb according to Regulation 2017/745 |

# 7. EMC

Note:

- The CPR System meets the requirements of IEC 60601-1-2.
- Users should install and use the electromagnetic compatibility information provided by the random file.
- Portable and mobile RF communication equipment may affect the performance of the CPR System, avoiding strong electromagnetic interference when used near mobile phones, microwave ovens, etc.
- The guide and the manufacturer's statement are in the attachment.

Warning:

- The CPR System machine should not be used close to or stacked with other equipment. If it must be, it should be observed to be able to operate normally in its configuration.
- In addition to the cables sold by the manufacturer of the CPR System as spare parts for internal components, the use of extra-standard accessories and cables may result in the CPR System increased working or reduced immunity.

Ambulanc(Shenzhen)Tech.Co.,Ltd.

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