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Product Information

Description

Thank you for purchasing the CPR System.

Please read and understand the contents of this instruction manual carefully before use to operate the device correctly. Maintain this Manual properly after reading, and place it in a convenient location.

Note: since E7 is different from E8 only in that E7 is not equipped with a hand-held terminal, so the manual is based on E8, which is also applicable to E7.

<table>
<thead>
<tr>
<th>Product name:</th>
<th>CPR System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specifications /Model:</td>
<td>E7, E8</td>
</tr>
<tr>
<td>Manufacturer:</td>
<td>AMBULANC(SHENZHEN)TECH.CO.,LTD.</td>
</tr>
<tr>
<td>Manufacturer address:</td>
<td>3rd Floor, Block C, Building #5, Skyworth Innovation Industry Park, Tang Tou 1st Road, Shiyan Town, Baoan District, Shenzhen 518108, China</td>
</tr>
<tr>
<td>Contact information</td>
<td>Tel: +86-755- 26072210  Fax:+86-755-23016012 Website:www.ambulgroup.com E-mail:<a href="mailto:manager@ambulanc.com">manager@ambulanc.com</a></td>
</tr>
<tr>
<td>Date of manufacture</td>
<td>See the label on the main unit</td>
</tr>
<tr>
<td>Service life:</td>
<td>8 years</td>
</tr>
<tr>
<td>Software release version</td>
<td>V1</td>
</tr>
<tr>
<td>Instruction manual version</td>
<td>1.0</td>
</tr>
<tr>
<td>Manual revision date:</td>
<td>7/20/2022</td>
</tr>
</tbody>
</table>

⚠️ Caution:

The device is not designed for home use.
**Intellectual property**

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**Statement**

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AMBULANC(SHENZHEN)TECH.CO., LTD. reserves the right to change the technology without prior notice.

AMBULANC(SHENZHEN)TECH.CO., LTD. reserves the right to modify product specifications without prior notice.

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Unless otherwise specified, "Ambulanc" and "the Company" in this Instruction Manual all refer to AMBULANC(SHENZHEN)TECH.CO., LTD.

The product images in this instruction manual are for reference only and are not identical to the actual product, and everything is subject to the actual product.

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 approved by AMBULANC(SHENZHEN)TECH.CO., LTD.;
- The relevant electrical equipment meets the national standards;
- The device should be used according to the Instruction Manual.
- AMBULANC(SHENZHEN)TECH.CO., LTD. shall not be responsible for the safety, reliability and operation of the products in case of the following situations:
Components are disassembled, tensioned 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 Instruction Manual.

**Maintenance service**

**Free service scope:**

The free service is available for all devices that meet the scope of warranty service regulations of AMBULANC(SHENZHEN)TECH.CO.,LTD.

**Scope of fee-based services:**

AMBULANC(SHENZHEN)TECH.CO.,LTD. will implement fee-based services for the equipment that exceeds the scope of warranty service regulations of AMBULANC(SHENZHEN)TECH.CO.,LTD.;

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

- Artificial damage;
- Improper use;
- Grid voltage exceeds the specified range of the device;
- Unavoidable natural disasters;
- Replace parts or consumables that are not licensed by AMBULANC(SHENZHEN)TECH.CO.,LTD. or have the machine repaired by personnel who are not authorized by AMBULANC(SHENZHEN)TECH.CO.,LTD.

⚠️ **Warnings:**

Failure to implement a satisfactory repair/maintenance program for each hospital or institution responsible for using this device may result in abnormal device failure and endanger human health.

**Assurance**

**The manufacturing process and raw materials:**

AMBULANC(SHENZHEN)TECH.CO.,LTD. guarantees that the equipment will be free of the production process and raw material failures during the warranty period under normal operation and maintenance conditions.

**After-sales service is provided by**

After-sale service department of AMBULANC(SHENZHEN)TECH.CO.,LTD.

Address: 3/F, Building C, 5# Skyworth Innovation Valley, No.1 Tangtou Road, Shiyian Street, Baoan District, Shenzhen

Zip code: 518108

Toll-free service hotline: 400-9969-120

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

Website: http://www.amouled.com
Email: manager@amoulmed.com

Return

Return procedure

If the products need to be returned to AMBULANC(SHENZHEN)TECH.CO., LTD., please use the following steps:

- To obtain the right of return: contact the customer service department of AMBULANC(SHENZHEN)TECH.CO., LTD. to provide the number of Ambulanc product series 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 handling;
   - 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 the 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 in the initial purchase area.
   - 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 or 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 the loss of data stored inside the system due to operator errors or abnormal circumstances.

9. 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.

10. 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.

11. AMBULANC(SHENZHEN)TECH.CO.,LTD. shall not be responsible for the return shipping costs if the warranty claim is denied.

12. 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 instruction manual.

13. Once the administrator of this system changes, this Manual must be handed over.
1. Safety Instructions

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

A routine check must be performed before using this device (see "8.1 Routine Inspection").

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

1.1. Security Information

Safety instructions are marked in this Instruction Manual as follows:

<table>
<thead>
<tr>
<th>Marker Prompt</th>
<th>Relevant description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Warnings]</td>
<td>Warn patients and users of the risk of injuries.</td>
</tr>
<tr>
<td>![Caution]</td>
<td>Warnings are given for situations that will cause device damage and may cause wrong therapeutic effect.</td>
</tr>
<tr>
<td>![Tips]</td>
<td>Provide useful tips.</td>
</tr>
<tr>
<td>![Warnings]</td>
<td>[Trained] CPR System can not be operated if you have not received medical training and technical instruction on CPR equipment, as improper use may result in serious physical injury. [Never leave the patient during the use of the device] It is strictly forbidden to leave the patient alone during the use of the device to allow for a timely response to minimize patient injury in the event of an emergency (e.g., aggregated condition of 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 &quot;2.2 Intended use&quot;). [Qualification of Maintenance Personnel] Maintenance measures, such as inspection and repairs, may only be carried out by the manufacturer, Ambulanc (Shenzhen) Tech.Co., Ltd. or by its authorized professionals. [Do not open] Do not open the CPR System housing. Do not replace or alter the external or internal parts of the CPR System.</td>
</tr>
<tr>
<td>Marker Prompt</td>
<td>Relevant description</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------</td>
</tr>
<tr>
<td></td>
<td>[Other Devices] When a CPR System and a device emitting high-frequency radiation (e.g., mobile phone, radio, and high-frequency electrosurgical unit) are used at the same time, please keep them apart at a distance of more than one meter, otherwise it may cause malfunction.</td>
</tr>
<tr>
<td></td>
<td>[Other equipment] This equipment should not be used in a strong magnetic field environment (e.g. MRI system). Failure to do so may cause the malfunction of this device.</td>
</tr>
<tr>
<td></td>
<td>[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.</td>
</tr>
<tr>
<td></td>
<td>[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.</td>
</tr>
<tr>
<td></td>
<td>[Liquid] Do not immerse the CPR System in liquid. If fluid enters the enclosure, it may damage the device.</td>
</tr>
<tr>
<td></td>
<td>[Environmental Protection] This product may produce some waste or wearing 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, and should be managed and treated according to local laws and regulations and other relevant provisions. It cannot be disposed in the same way as normal waste.</td>
</tr>
</tbody>
</table>

## 1.2. Description of symbols and terms

The following table describes the symbols used on this device or in this Manual.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>English Instructions</th>
<th>Symbol</th>
<th>English Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Warning" /></td>
<td>Refer to the documents provided</td>
<td><img src="image" alt="Information" /></td>
<td>Refer to the Instructions for Use</td>
</tr>
<tr>
<td><img src="image" alt="Date" /></td>
<td>Date of manufacture</td>
<td><img src="image" alt="Person" /></td>
<td>Type BF application part</td>
</tr>
<tr>
<td><img src="image" alt="Don't throw" /></td>
<td>Don't throw it away in household garbage can at will</td>
<td><img src="image" alt="Radio" /></td>
<td>Non-ionizing radiation</td>
</tr>
<tr>
<td><img src="image" alt="Refer" /></td>
<td>Refer to the attached Handbook/Instructions</td>
<td><img src="image" alt="Switch" /></td>
<td>Main unit switch</td>
</tr>
</tbody>
</table>
The following table describes the terms used in this manual

<table>
<thead>
<tr>
<th>English abbreviation</th>
<th>Full name in English</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPR</td>
<td>Cardiopulmonary Resuscitation</td>
</tr>
<tr>
<td>CISPR</td>
<td>International Special Committee on Radio Interference</td>
</tr>
<tr>
<td>EMC</td>
<td>Electro-Magnetic Compatibility</td>
</tr>
<tr>
<td>ILCOR</td>
<td>International Liaison Committee on Resuscitation</td>
</tr>
<tr>
<td>PC</td>
<td>Personal Computer</td>
</tr>
</tbody>
</table>

### 1.3. Software

A large number of quality assurance measures have been taken when developing the device software, and the risks caused by software defects are minimal.

### 1.4. 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 of 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.

1.5. Battery

⚠️ Warnings:

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

Replace the battery with a fully charged one.
Connect the external CPR System power supply.

⚠️ 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 to include a fully charged spare battery in the carrying case.

1.6. 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 compression 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 compressor 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 machine interference] Chest compressions may interfere with the analysis of the ECG machine. Before starting the analysis with the ECG machine, 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 hazard, if it is damaged.

[Maintenance care] Never leave away from the patient or the CPR System while CPR is being performed. Only then will you be able to respond quickly if the patient's condition deteriorates or if indications are given that the CPR System malfunctions or runs low on battery power. Slow response of medical personnel may lead to serious bodily harm.

[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.

⚠️ Caution:

[Defibrillation electrodes] Locate the defibrillator electrodes and wires to ensure that they are not under the compressor head. If the electrodes are already placed on the patient, make sure they are not under the compressor head. If it is located under the compressor head, a
new electrode must be used.

[Gel present on the chest] If the gel is present on the patient's chest (e.g., used during an ultrasound examination), the position of the compressor head may change during use. Remove all gel before placing the compressor head at the proper position.

[Application of fixing straps] If the use of CPR System fixing straps would prevent or delay any treatment to the patient, then, the use of this device should be postponed.

[Adjunctive therapy] Using other medical devices or drugs with the CPR System can affect the therapeutic effect. For other devices and/or medications, be sure to refer to their instructions for use to ensure that they are appropriate for use with CPR.

[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 7.1 for troubleshooting.

[Do not use fixing straps to lift the patient] Do not use patient restraint straps and 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 compressions 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. Contraindications

Do not use the CPR System chest compressions device if the following conditions occur:

- Patients suffer severe chest trauma, pneumothorax, rib or sternal fractures and cardiac rupture, as well as those who are no longer eligible to perform manual CPR.
- Patients with congenital or acquired chest deformities;
- For adults with excessively thin bodies: the depth of the compressor head to the chest may be too large during compression;
- For obese adults: the patient restraint strap may not be able to effectively bind the machine to the patient;
- Infants, children and pregnant patients.
- Patients who are considered inappropriate by the attending physician to receive chest compressions, or who have no obvious characteristics that suggest chest compressions can help restore their vital signs, must follow local and international guidelines for CPR when using E8/E7.

2.5. Side effects

The International Resuscitation Liaison Committee (ILCOR) stated that cardiopulmonary resuscitation has the following side effects:

“In view of death from cardiac arrest, rib fractures and other injuries are common and acceptable outcomes of cardiopulmonary resuscitation. After resuscitation, all patients should be reassessed to determine if there is any recovery-related injury.”

In addition to the above symptoms, chest embolism and pain are common in the use of the E6 cardiopulmonary resuscitation machine.

2.6. Intended User

Persons using E6 must be verified to have the following conditions:

- Operators with medical technology, such as: first responders, ambulance personnel, nurses, physicians or medical staff;
- Trained for clinical application of E6 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 can cause serious injury to people (operators and patients).

2.7. Structure Composition of the Device

E8/E7 CPR System is composed of the main unit (battery included), patient restraint straps and fixing straps, and power a adapter.

Note: CPR System model E8 comes with a hand-held terminal, whereas the E7 model has no hand-held terminal.
3. Operation and use

3.1. Adjust and activate compression

⚠️ Warnings:

If the compressor 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 and the use of the CPR System should be stopped and manual compressions should be performed.

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

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

Never leave away from the patient or the CPR System while CPR is being performed. Only then will you be able to respond quickly if the patient's condition deteriorates or if the CPR System malfunctions or runs low on battery power. Slow response of medical personnel may lead to serious bodily harm.

If there is an interruption during the operation, or 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. Start performing manual chest compressions.

⚠️ Caution:

If the main unit is shut down due to abnormality during operation, and the compressor head fails to return to its original position, please first stop using the machine and remove its main unit, and manually push the compressor head 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 compressor head may change during use; therefore, all gel needs to be removed before placing the compressor head.

3.2. Use the patient fixing straps

⚠️ Caution:

If the use of CPR System fixing straps would prevent or delay any treatment to the patient, the use of this device should be postponed or not used.

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.

If the position of the compressor head changes during operation or defibrillation, manually adjust the positions and angle of the patient's chest and the compressor head immediately and use the patient fixing strap to help maintain the correct position.
3.4. Replacing the power source during use

⚠️ Tips:
When the alarm light flashes red, the main unit will still work continuously for about 15 minutes. To minimize interruptions, it is recommended that the battery is replaced with a new battery or is connected to an external power source to recharge the battery promptly after a low battery indication.

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

- Use the power cord:
  1. Connect the power cord to the main unit.
  2. Connect the power cord to a wall outlet (100-240V, 50/60 Hz)

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 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 therapeutic effect. For other devices and/or medications, be sure to refer to their Instruction Manual to ensure that they are appropriate 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 liquid. If fluid enters the enclosure, it may damage the device. Allow the CPR System to dry before it is packaged.

When disinfecting the whole machine, it is forbidden to fumigate with peracetic acid and formaldehyde;

The disinfectant is configured according to the manufacturer's instructions, and the disinfection method is based on: GB 26373-2010 Ethanol Disinfectant Hygiene Standards.
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 hazard.

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 of 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. Technical Parameters

6.1. Medical Device Management Class

<table>
<thead>
<tr>
<th>Medical Device Management Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class</td>
</tr>
</tbody>
</table>

6.2. Physical specifications

<table>
<thead>
<tr>
<th>Dimensions of the main unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions when assembled</td>
</tr>
<tr>
<td>Weight (Battery included)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hand-held terminal dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions when assembled</td>
</tr>
<tr>
<td>Weight</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hand-held terminal display</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
</tr>
<tr>
<td>Size</td>
</tr>
<tr>
<td>Resolution</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
</tr>
<tr>
<td>Storage capacity</td>
</tr>
</tbody>
</table>
7. EMC

⚠️ Caution:
This CPR System meets the requirements of IEC 60601-1-2.

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 near to 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.

<table>
<thead>
<tr>
<th>The guidelines and the manufacturer's statement - Electromagnetic emission</th>
</tr>
</thead>
<tbody>
<tr>
<td>The E8/E7 CPR System is intended for use in the following specified electromagnetic environments, which the purchaser or user should ensure that it is used in such an environment:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Emission Test</th>
<th>Conformance</th>
<th>Electromagnetic Environment - Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emission CISPR11</td>
<td>Group 1</td>
<td>The E8/E7 CPR System uses RF energy only for its internal functions. As a result, its RF emissions are low and the potential for interference with nearby electronic equipment is low</td>
</tr>
<tr>
<td>RF emission CISPR11</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Harmonic emission</td>
<td>Class A</td>
<td>The E8/E7 CPR System is suitable for use in all facilities, both non-domestic and not directly connected to the public low voltage power grid for residential use.</td>
</tr>
<tr>
<td>Harmonic emission IEC 60601-1-2 EN 61000-3-2</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

Guidelines and Manufacturer's Statement - Electromagnetic Immunity

The E8/E7 CPR System is intended for use in the following specified electromagnetic environments, which the purchaser or user should ensure that it is used in such an environment:

<table>
<thead>
<tr>
<th>Interference Resistance Test</th>
<th>IEC 60601 test level</th>
<th>Coincidence Level</th>
<th>Electromagnetic Environment - Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge</td>
<td>±8 kV contact discharge</td>
<td>±8 kV contact discharge</td>
<td>The floor shall be covered with wood, concrete or ceramic tiles, and if the floor is covered with synthetic material, the relative humidity shall be at least 30%</td>
</tr>
<tr>
<td>-------------------------</td>
<td>------------------------</td>
<td>------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>IEC6100-4-2</td>
<td>±15 kV Air discharge</td>
<td>±15 kV Air discharge</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient burst</td>
<td>±2 kV pairs of power cords</td>
<td>±2 kV pairs of power cords</td>
<td>Grid power shall be of a typical commercial or hospital quality</td>
</tr>
<tr>
<td>IEC6100-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV wire-to-wire</td>
<td>±1 kV wire-to-wire</td>
<td>Grid power shall be of a typical commercial or hospital quality</td>
</tr>
<tr>
<td>IEC6100-4-5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage sag, short interruption and voltage change on power input line</td>
<td>&lt;5 % UT for 0.5 weeks (on UT, &gt;95% of sag) 40 % UT for 5 weeks (on UT, 60% of sag) 70 % UT for 25 weeks (on UT, 30% of sag) &lt;5 % UT for 5s (on UT, &gt;95% of sag)</td>
<td>&lt;5 % UT for 0.5 weeks (on UT, &gt;95% of sag) 40 % UT for 5 weeks (on UT, 60% of sag) 70 % UT for 25 weeks (on UT, 30% of sag) &lt;5 % UT for 5s (on UT, &gt;95% of sag)</td>
<td>Grid power shall be of a typical commercial or hospital quality. If the user of the E8/E7 CPR System needs continuous operation during a power interruption, it is recommended that the E8/E7 CPR System be powered by an uninterruptible power supply or battery.</td>
</tr>
<tr>
<td>IEC6100-4-11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency magnetic field (50/60Hz)</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>The power frequency magnetic field should have the level characteristics of that in typical places such as commercial or medical environments</td>
</tr>
<tr>
<td>IEC6100-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: $U_T$ means AC network voltage before test voltage is applied.

**Guidelines and Manufacturer’s Statement - Electromagnetic Immunity**

The E8/E7 CPR System is intended for use in the following specified electromagnetic environments, which the purchaser or user should ensure that it is used in such an environment:
<table>
<thead>
<tr>
<th>Interference Resistance Test</th>
<th>IEC 60601 Test</th>
<th>Coincidence Level</th>
<th>Electromagnetic Environment - Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radio frequency conduction</td>
<td>3V (valid value)</td>
<td>3V (valid value)</td>
<td>Portable and mobile RF communication equipment should not be used closer to any portion of the E8/E7 CPR System than the recommended separation distance, including cables. The distance is calculated according to a formula corresponding to the transmitter frequency. Recommended Separation Distance</td>
</tr>
<tr>
<td>IEC6100-4-6</td>
<td>150 kHz ~ 80 MHz (Except ISM band a)</td>
<td>10V (Valid value)</td>
<td>( d = 1.2\sqrt{P} )</td>
</tr>
<tr>
<td>Radio frequency radiation</td>
<td>150kHz ~ 80MHz (ISM band a)</td>
<td>10V/m</td>
<td>( d = 0.4\sqrt{P} ) 80 MHz ~ 800 MHz</td>
</tr>
<tr>
<td>IEC6100-4-3</td>
<td>80 MHz ~ 2.5 GHz</td>
<td>10V/m</td>
<td>( d = 0.8\sqrt{P} ) 800 MHz ~ 2.5 GHz</td>
</tr>
</tbody>
</table>

wherein, 
\( P \) According to the maximum rated output power of transmitter in watts(W) provided by transmitter manufacturer; 
\( d \) - recommended separation distance, in meters (m) b. 
The field strength of the fixed RF transmitter is determined by surveying c of electromagnetic field, and it should be lower than the coincidence level in each frequency range \( d \). Interference may occur in the vicinity of the equipment marked with the following symbols.

Note 1: at 80 MHz and 800 MHz frequencies, the formula for the higher frequency band is used.
Note 2: these guidelines may not be appropriate for all situations where electromagnetic propagation is affected by absorption and reflection from buildings, objects, and the human body.

a The ISM (industrial, scientific, and medical radio) band between 150 kHz and 80 MHz refers to 6.765 MHz-6.795 MHz, 13.553 MHz-13.567 MHz, 26.957 MHz-27.283 MHz, and 40.66 MHz-40.70 MHz.
b The compliance level in the ISM (industrial, scientific, and medical radio) band between the 150 kHz-80 MHz and the 80 MHz-2.5 GHz frequency range is used to reduce the possibility of interference when mobile/portable communication devices are accidentally brought into the patient area. For this purpose, the additional factor 10/3 is used to calculate the recommended separation distance of the transmitter over these frequency ranges.
c. The field strength of fixed transmitters such as base stations of wireless (cellular/cordless) phones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts and TV broadcasts, cannot be accurately predicted theoretically. To evaluate the electromagnetic environment of a fixed RF transmitter, the survey of electromagnetic fields should be considered. If the measured field strength of the place where the E8/E7 CPR System is positioned is higher than the above-mentioned applicable RF compliance level, observe the E8/E7 CPR System to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as readjusting the direction or position of the E8/E7 CPR System.

d. In the whole frequency range from 150 kHz to 80 MHz, the field strength should be lower than 3 V/m.

Recommended separation distance between portable and mobile RF communication equipment and the E8/E7 CPR System

The E8/E7 CPR System is expected to be used in electromagnetic environment with controlled RF radiation disturbance. Based on the maximum rated output power of communication equipment, the purchaser or user can prevent electromagnetic interference by keeping the minimum distance between portable and mobile radio frequency communication equipment (transmitter) and E8/E7 CPR System as recommended below.

<table>
<thead>
<tr>
<th>Separation distance corresponding to different frequencies of transmitter (m)</th>
<th>150 kHz ~ 80 MHz (except ISM band)</th>
<th>150 kHz ~ 80 MHz (ISM band)</th>
<th>80 MHz ~ 800 MHz</th>
<th>800 MHz ~ 2.5 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>d = 1.2√P</td>
<td>d = 1.2√P</td>
<td>d = 1.2√P</td>
<td>d = 2.3√P</td>
<td></td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
<td>0.12</td>
<td>0.04</td>
<td>0.08</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
<td>0.38</td>
<td>0.12</td>
<td>0.24</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
<td>1.2</td>
<td>0.4</td>
<td>0.8</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
<td>3.8</td>
<td>1.2</td>
<td>2.4</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
<td>12</td>
<td>3.8</td>
<td>7.7</td>
</tr>
</tbody>
</table>

For the maximum rated output power of the transmitter not listed in the above table, the recommended separation distance d in meters (m) can be determined by the formula in the corresponding transmitter frequency column, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer in watts (W).

Note 1: at 80 MHz and 800 MHz frequency points, the formula for the higher frequency band is used.

Note 2: The ISM (industrial, scientific, and medical radio) band between 150 kHz and 80 MHz refers to 6.765 MHz-6.795 MHz, 13.553 MHz-13.567 MHz, 26.957 MHz-27.283 MHz, and 40.66 MHz-40.70 MHz.

Note 3: additional factor 10/3 is used to calculate the recommended separation distance for the transmitters in the 150 kHz-80 MHz ISM (industrial, scientific, and
medical radio) band and 80 MHz-2.5 GHz frequency range to reduce the possibility of interference when portable/mobile RF communication equipment is accidentally brought into the patient area.

Note 4: these guidelines may not be applicable in all cases. Electromagnetic propagation is influenced by the absorption and reflection of buildings, objects and human bodies.

### Basic EMC performance of E8/E7 CPR System

E8/E7 CPR System can operate properly on correct parameter settings. See Section 5 of the Instruction Manual for details. Alarms may be issued based on real-time monitoring of the CPR System status. It also guarantees the accuracy of the following parameters in the electromagnetic compatibility environment of the CPR System:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compression depth</td>
<td>30-55mm, ±3mm, 50mm by default setting, continuously adjustable (the default for E7 is 50mm, not adjustable)</td>
</tr>
<tr>
<td>Compression frequency</td>
<td>110±3 compressions per minute</td>
</tr>
<tr>
<td>Mode (optional for operators)</td>
<td>30:2 (30 compressions followed by a 3-second ventilation pause)</td>
</tr>
<tr>
<td></td>
<td>Continuous compression</td>
</tr>
</tbody>
</table>

#### EMC Wire Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adapter’s input power cord</td>
<td>2.0±0.01m</td>
</tr>
<tr>
<td>Adapter’s output power cord</td>
<td>1.2±0.05m</td>
</tr>
</tbody>
</table>

⚠️ **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.