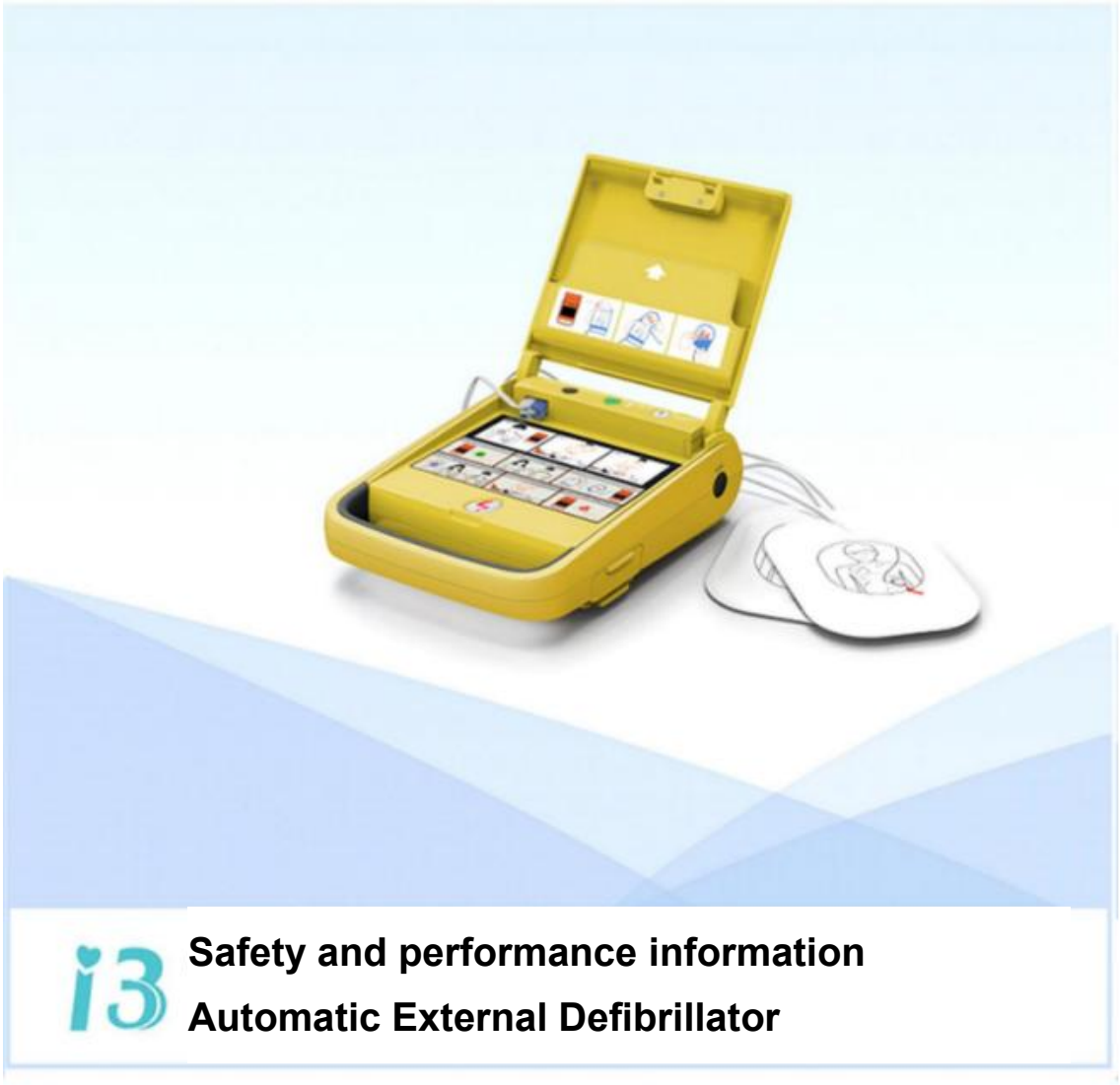
Amoul



i3 Safety and performance information
Automatic External Defibrillator

www.amoulmed.com

CE 2797

Release Version：1.1

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Contents

Product information

Thanks for purchasing i3 Automatic External Defibrillator.

To use the instrument correctly, please carefully read and understand the Manual before using. Keep the manual properly after reading and put it in an accessible position.

Product name:	Automatic External Defibrillator
Model:	i3
Manufacturer name:	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

⚠ Notes:

The instrument is not designed for family use.

Intellectual Property Right

This product and its operating manual are the intellectual property of Ambulanc (Shenzhen) Tech. Co., Ltd., including but not limited to patent right, trademark right and copyright.

Ambulanc has the final right to interpret this manual.

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Statement

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 specification without prior notice.

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

Unless otherwise specified, "Ambulanc" and "the Company" in this Operation Manual refer to Ambulanc (Shenzhen) Tech. Co., Ltd.

The product pictures in this instruction manual are for reference only and are not exactly the same as the actual product, everything is subject to the actual product.

Ambulanc will, at its own discretion, take responsibility for 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 approved 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 repaired or changed not by any personnel approved by Ambulanc;
- The product is not used correctly in compliance with this Operating Manual.

Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics.

Links to the summary of safety and clinical performance:
https://ec.europa.eu/tools/eudamed

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Maintenance Service

Scope of Charge-Free Service：

Charge-free service is provided for any equipment in the range of Ambulanc warranty terms.

Scope of Paid Service：

Paid service is provided for any equipment beyond the range of Ambulanc 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/ consumables not approved or machine service performed by personal not authorized by Ambulanc.

⚠Warning：

Failure to implement a set of satisfactory service/maintenance plan by any hospital or institute responsible for using this instrument may cause malfunction of it or even endanger body health.

Return

Return Procedure

Any return as necessary shall comply with the following procedure:

- Acquire right of return: Contact Ambulanc customer service, and provide the product ID labeled on external packaging of the instrument, which must be legible for return approval. Indicate product model and describe the reason for return.
- Freight: Any expenses (including customs fee) incurred in transporting the instrument to Ambulanc shall be paid by the user.

Important Information

1. After purchase of the product, the customer shall take full responsibility for maintenance and management of it.
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 system, such as insufficient power supply, improper installation or unfavorable environmental conditions;
- any damage caused by improper packaging when returning to Ambulanc;
- any damage or loss incurred due to use of the system in the region not initially intended for it;
- any damage or loss caused due to purchase from any unauthorized dealer or agent.

3. This equipment can be used only by certified medical staff.
4. Any software or hardware of this product must not be changed or modified without authorization.
5. In any case Ambulanc will take no responsibility for problem, damage or loss resulted from re-installation, change or repair of the system performed not by personnel authorized by Ambulanc.
6. This system is intended to provide the data required for clinical diagnosis for physicians. The physician takes responsibility for diagnosis process. Ambulanc takes no responsibility for any diagnosis process.
7. Be sure to back any key data to external storage medium, such as clinography and notes.
8. Ambulanc takes no liability for loss of data stored in the system due to the operator's fault or any exceptional condition.
9. This manual contains warnings for foreseeable potential hazards. User shall keep watch at any time for any hazard not stated in the manual.
10. Ambulanc is not responsible for damage caused by defects in the equipment itself or damage caused by mistakes made by the user.

11. Ambulanc will not be responsible for any damage caused by the use of this equipment after the service life of the equipment is exceeded.
12. Ambulanc will not bear the cost of transportation if the warranty request is rejected.
13. The Ambulanc takes no responsibility for damage or loss resulted from negligence or failure to observe the preventive measures stated in this manual.
14. This manual must be handed over to the successor when the system administrator is changed.

Safety Description

Please read these safety instructions carefully. These safety instructions are an integral part of the equipment and must be kept accessible for review whenever necessary. For purpose of safety, the following information must be paid attention to.

Warning、Attention and tips

The following safety marks are used in this manual:

⚠ Danger：

Warn the patient and the user of the risk of serious personal injury or even death.

⚠ Warning：

Warn of the danger of potential personal injury or even death to patients and users.

⚠ Attention：

Indicating potential equipment damage and undesired treatment effect.

⚠ Tip：

Giving useful indicative information.

⚠ Danger：

- This device emit high power during defibrillation. This electrical energy can cause

serious personal injury or death if not used correctly in accordance with the operating instructions in this manual. Observe all operating instructions in this manual when using this device. Do not operate this equipment until you are familiar with all operating instructions.

- If this equipment is used near a flammable agent or in an oxygen-rich environment, an explosion or fire may occur as the equipment may cause an arc discharge during a defibrillation shock.
- During defibrillation, keep a sufficient distance from the patient and the metal objects connected to the patient to avoid electric shock.

⚠ Warning:

- Check that the equipment, cables and accessories are working properly before use. Do not use this device if you find a problem.
- This device can only be used with primary batteries supplied by the company.
- Do not disassemble the defibrillator, otherwise there is a danger of electric shock. This device does not contain any parts that can be removed by the user.
- The electrode sheet needs to be closely adhered to the patient's skin, and there is no gap left. If necessary, the patient's chest hair should be scraped off with a tool.
- If you would like to use this device with equipment not mentioned in this manual, please consult the manufacturer.
- Keep i3 away from sources of electromagnetic interference (such as motors, generators, X-ray equipment, radio transmitters, cellular mobile phones, nuclear magnetic resonance, and other equipment) as it may interfere with the signals being collected and analyzed during operation. . For details, see Chapter 9, "EMC"。
- Do not immerse any part of the device in water or other liquids. Also avoid spilling any liquid on the device or accessories. Do not use formaldehyde or other flammable reagents for cleaning, as this may cause an explosion or fire. Do not autoclave or disinfect this equipment or accessories unless otherwise stated.
- Always have a spare battery that is fully charged and properly maintained. When the device displays a low battery warning, replace the battery, as this may cause the device to shut down.
- Disconnect all other devices without defibrillation protection from the patient during defibrillation.

- Do not modify this device.
- Only the manufacturer AMBULANC (SHENZHEN) TECH.CO.,LTD. or its authorized professionals can perform maintenance measures such as inspection and maintenance work.

⚠ Attention：

- Please keep this equipment in a safe place to prevent it from falling, colliding, being subjected to strong shocks or other mechanical external forces.
- Do not mix electrodes of different types and brands. Mixing electrodes can cause large baseline drift or lead to longer baseline recovery time after defibrillation。
- In order to avoid contamination or infection of personnel, the environment or other equipment, equipment and its accessories that meet the service life must be disposed of in accordance with relevant local regulations or hospital systems.

⚠ Tip:

- Keep this manual near the equipment and make it easy to get it when you operate the equipment.
- When operating this device, the user should stand in front of the device.
- In order to prepare the equipment for use at any time, please install the battery in advance and connect the electrode plug.
- User detection should be performed once the device has been dropped or improperly operated. If any malfunction is detected, do not use the equipment and contact the designated service personnel for repairs.

⚠ Residual risk

Even if we've figured out a lot of ways to prevent risk, it could happen:

- May burn skin during use

Accessories/spare parts

⚠ Attention:

- Maintenance measures can only be taken by manufacturer (Ambulanc (Shenzhen) Tech. Co., Ltd.) or its authorized professionals, such as inspection and overhaul.
- Use of accessories of other manufacturers may result in faults and incompatibility. Please remember the warranty right and responsibility will be invalid in the following cases: not using the accessories recommended in the Manual or the original spare parts.

1. Equipment description

1.1. Purpose

i3 is an Automatic External Defibrillator. Simple and direct voice prompt and indication are provided for direct rescue operation. The equipment is light, powered by battery and convenient to carry. i3 aims to treat ventricular fibrillation (VF) and ventricular tachycardia, and these two symptoms are the most common cause for sudden cardiac arrest (SCA). When SCA occurs, the patient's heart will stop beating suddenly, and such situations will suddenly appear in any age group and there is no sign of it. Defibrillation is the only effective treatment for this symptom.

1.2. Intended use

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

- No activity or reaction during shaking
- inability to breathe normally

1.3. Patient population

The defibrillator may be used with standard defibrillation pads only on adults and children who are 8 years old or more or who weigh more than 25 kg (55 lbs). The defibrillator may be used on children who are less than 8 years old or weigh less than 25 kg (55 lbs) with Infant/Child Reduced Energy Defibrillation Electrodes.

1.4. Contraindication

Please don't use i3 when the patient has the following signs:

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

1.5. Application

i3 for emergency responders, medical staff, or trained non-professional in or outside the hospital.

1.6. User qualification

The Automatic Defibrillator i3 is intended to used by properly trained personnel in basic or advanced life support, or by personnel authorized by physicians to treat emergency defibrillation in patients with cardiac arrest.

2. Installation and setting

⚠Warning:

Using of accessories not specified in the manual may increase electromagnetic radiation or reduce the electromagnetic immunity of i3. Use the alternative accessories and consumables of Ambulanc or those supplied by its authorized representatives.

2.1. Setting i3

⚠Notes:

Please don't open the sealing electrode container if you don't plan to use it, to prevent drying of AED electrode.

2.2. CPR setting

⚠Tips:

Under the Countdown mode, i3 provides voice prompt (1min and 30s, 1min, 40s and 20s) of rest time till the next cycle of defibrillation (start from ECG analysis).

Under Countdown mode, press the flashing blue "i" within 20s after CPR start to switch into Voice mode.

3. Defibrillation

3.1. CPR guide

⚠Tips:

i3 can be used for children under 8 years old.

- Please use the pediatric low-energy defibrillator electrode supplied by Ambulanc for children under 8 years old or the weight is less than 25Kg. (Please don't use the pediatric low-energy defibrillator electrode supplied by Ambulanc for adult patients.)
- For the children above 8 years old, American Heart Association (AHA) suggests the application of adult "Life chain" and resuscitation sequence (2020 AHA guide for cardiopulmonary resuscitation and emergency cardiac care).

3.2. Preparation for rescue

⚠Tips:

Please don't waste time on taking off the patient's clothes. Please tear or shear off the patient's clothes when necessary.

⚠Warning:

Check whether the electrode is damaged and whether the gel is dried.

If the electrode is damaged or the gel is dried, please change a new electrode.

3.3. Main rescue sequence

⚠Warning:

- Please don't put the electrode (defibrillation pole) on the implanted pacemaker or cardioverter-defibrillator. Keep the electrode away from the implanted equipment.

The electrode piece needs to be closely attached to the patient's skin, and there is no gap left. If necessary, use a tool to scrape the patient's chest hair.

- Please don't put the electrode (defibrillation pole) on the transdermal drug patch directly, otherwise, it may result in skin burn.
- During ECG signal collection and analysis, the patient shall keep static and reduce the motion artifact to the maximum.

- When using i3, disconnect the connection between the patient and the medical electrical equipment without the defibrillation parts.
- Keep the electrode far away from the other electrodes or metal parts.
- Prevent the patient's body (such as the head or the naked skin of limbs) and conducting flow (such as gel, blood or saline) from contacting with metal (such as bedstead or stretcher), and residual channels will be provided for defibrillation current.
- Excessive Energy Delivery.

For children less than 8 years of age or 55 lbs (25 kg), use child electrodes. Do not use Adult electrodes; these electrodes do not attenuate the energy.

⚠Tips:

Though i3 is charging after detecting the shockable rhythm, it can collect and analyze the ECG of patient continuously. If the ECG heart rhythm is changed into non-shockable rhythm, i3 will release automatically.

⚠ Warning:

After pressing "shock", no one should touch the patient. The defibrillation shock will result in injury of operator or bystander.

3.4. CPR guide

⚠Warning:

- i3 will stop analyzing the patient's ECG during CPR.
- It will recover the ECG analysis automatically after CPR.
- If it is necessary to use other defibrillators for the patient, please disconnect i3 from the patient. Before using other defibrillators, please disconnect the connection between i3 and the patient.

3.5. Data storage

⚠Warning:

- Please don't remove the battery when i3 collects data, otherwise, you will lose the special rescue data. If it is necessary to remove the battery, please shut down i3 correctly before removal by pressing "Start/shutdown".

- i3 has ≥16G memory capacity for recording ECG and rescue data. If the collected data exceeds the capacity during rescue, it will cover the earlier data automatically.

4. Sanitary treatment

⚠Notes:

- Please don't soak the parts of i3 in the liquid.
- If i3 is soaked in water, please contact with Ambulanc or its authorized representative to provide maintenance service.
- Please prevent liquid from entering the equipment box.
- Please prevent liquid from splashing on the equipment box.
- Please don't use powerful acetone cleaner when cleaning the equipment.
- Please don't use rough materials when cleaning the device
- Please don't disinfect i3.

5. Maintenance

5.1. Battery

⚠Warning:

- Only the battery recommended and supplied by the manufacturer can be used. Use of battery not recommended and supplied by the manufacturer may result in abnormal operation.

5.2. Battery replacement

⚠Warning:

- Please don't open or remove the battery case.
- Please prevent battery from contacting with open fire and other heat sources, and don't discard it in the fire.
- Please prevent terminal short circuit of battery.
- Please prevent the battery from serious physical influence, and prevent hammer

from knocking.

- If there is leakage or abnormal odor, please keep the battery away from the fire so as to prevent fire of leaked electrolyte.
- Please put battery in the place inaccessible to children.
- If the battery leaks or the leaked liquid enters the eyes, please wash with clean water and consult a doctor.
- Please don't put battery in direct sunlight pace or high-temperature area.
- Please prevent battery from contacting with water.
- Put battery in the place far away from direct sunlight, high temperature and humidity.
- Please dispose battery according to the local laws and regulations.
- Please don't put i3 battery in unsafe environment.

5.3. Defibrillator electrode

⚠Warning:

- Only the electrodes supplied by the manufacturer can be used for supporting i3. Use of electrodes not specified by the manufacturer may affect the defibrillation effect.

6. Technical parameter

6.1. Management category of medical equipment

Management category of medical equipment	
Category	Class III medical equipment according to Regulation EU 2017/745

7. EMC

7.1. Declaration of magnetic radiation

i3 can be used for the following specific electromagnetic environment, and the user shall use the equipment in the following specified electromagnetic environment.

Radiation test	Compliance test	Electromagnetic environment guide
RF radiation (CISPR 11)	First group	i3 only uses the RF energy when running the internal functions. Therefore, the RF radiation is extremely low and has little electromagnetic interference on the electronic equipment nearby.
RF radiation (CISPR 11)	Class B	i3 is applicable to all facilities, including the household and the residential public LV supply network directly connected with the house.
Harmonic radiation (IEC6100-3-2)	N/A	
Voltage fluctuation and twinkle emission (IEC6100-3-3)	N/A	

7.2. Declaration of electromagnetic immunity - Requirements for all equipment systems

i3 can be used for the following specific electromagnetic environment, and the user shall use the equipment in the following specified electromagnetic environment.

Category of immunity	IEC 60601-1 test level	Compliance level	Electromagnetic environment guide
Electrostatic discharge (ESD)	Contact discharge: ±6kV Air discharge:	Contact discharge: ±6kV Air discharge:	The ground shall be wood, concrete or ceramics. If the ground is paved

(IEC 61000-4-2)	±8kV	±8kV	with composite materials, the relative humidity shall be at least 30%.
Electrical fast transient burst (IEC 61000-4-4)	To power cord: ±2kV To long I/O cable: ±1kV	N/A	The power level shall be at least typical commercial or medical environment level.
Surge (IEC 61000-4-5)	Differential mode: ±1kV Common mode: ±2kV	N/A	The power level shall be at least typical commercial or medical environment level.
Power frequency magnetic field (50/60Hz) (IEC6100-4-8)	3A/m	3A/m 50/60HZ	Power frequency magnetic field shall have the horizontal characteristics of power frequency magnetic field in typical commercial or medical environment.
Voltage drop, short interruption and voltage change (IEC6100-4-11)	＜5%UT(drop: ＞95%, UT), 0.5 cycle	＜5%UT(drop: ＞95%, UT), 0.5 cycle	The power level shall be at least typical commercial or medical environment level. It is suggested to supply power with UPS so that the product can keep operation even during AC power outage.
	40%UT (60% drop, UT), 5 cycles;	40%UT (60% drop, UT), 5 cycles;	
	70%UT (30% drop, UT), 25 cycles; ＜5%UT (drop: ＞95%, UT), 5s;	70%UT (30% drop, UT), 25 cycles; ＜5%UT (drop: ＞95%, UT), 5s;	

7.3. Declaration on guide and manufacturer - Electromagnetic immunity

The purchaser or user shall use i3 in the following specified electromagnetic environment:

Immunity test	IEC 60601 test level	Conformance level
RF transmission	3V (effective value) 150kHz-80MHz (except the medical	3V (effective value)

IEC6100-4-6 RF radiation IEC6100-4-3	engineering frequency banda)	
	10V (effective value) 150kHz-80MHz (the medical engineering frequency banda)	10V (effective value)
	10V/m 80 MHz-2.5 GHz	30V/m

Electromagnetic environment guide

The portable and mobile RF communication equipment shall not be used near i3 than the recommended isolation distance, including cable. The distance is calculated according to the formula of transmitter frequency.

Recommended isolation distance:

$$d = \left[\frac{3.5}{V1}\right]\sqrt{P} \qquad d = \left[\frac{12}{E1}\right]\sqrt{P} \quad 80\ \text{MHz}\sim 800\ \text{MHz}$$

$$d = \left[\frac{12}{V2}\right]\sqrt{P} \qquad d = \left[\frac{23}{E1}\right]\sqrt{P} \quad 800\ \text{MHz}\sim 2.5\ \text{GHz}$$

Wherein:

P -According to the maximum rated output power of transmitter manufactured by the transmitter manufacturer (unit: W);

d-Recommended isolation distance (unit: m).

The field intensity of fixed RF transmitter is determined according to the survey of electromagnetic field, and it should be lower than the conformance level in each frequency range.

Interference may appear near the equipment marked in the following symbols:

Note 1:

For the frequency of 80MHz and 800MHz, use the formula in higher frequency band.

Note 2:

The guide may not be applicable to all situations, and the electromagnetic propagation is affected by the building, object and human absorption and reflection.

a. The medical engineering frequency band between 150kHz and 80MHz refers to 6.765MHz-6.795MHz, 13.553MHz-13.567MHz, 26.957MHz-27.283MHz and 40.66MHz-40.70MHz.

b. The conformance level on the medical engineering frequency band (150kHz-80MHz) and the frequency of 80MHz-2.5GHz is used for reducing the probability of interference caused by mobile/portable communication device when being taken to the patient area occasionally. Therefore, additional factor 10/3 is used for calculating the recommended isolation distance of transmitter in the frequency range.

c. Fixed transmitter, such as: radio (honeycomb/wireless) telephone and ground mobile radio base station, amateur radio, amplitude and FM radio broadcast and TV broadcast, and the field intensity cannot be predicated accurately theoretically. To evaluate the electromagnetic environment of fixed RF transmitter, consider the survey of electromagnetic place. If the field intensity of i3 is higher than the RF conformance level, observe i3 to verify whether it can work normally. If normal performance is observed, the supplementary measures may be necessary, for example, readjust the direction or position of i3.

d. The field intensity shall be less than 3V/m in the whole frequency range of 150kHz-80MHz.

7.4. Recommended isolation distance

i3 shall be used in the electromagnetic environment where the RF radiation interference is controlled. According to the maximum rated output power of communication equipment, the purchaser or user can prevent electromagnetic interference by keeping the following recommended minimum distance between the portable and mobile RF communication equipment (transmitter) and i3.

Recommended isolation distance between the portable and mobile RF and i3 an fang communication equipment and i3				
Rated maximum output power W of transmitter	Isolation distance /m corresponds to different frequencies of transmitter			
	150kHz-80MHz (Except the medical engineering frequency band) d = $1.17\sqrt{P}$	50kHz-80MHz (Medical engineering frequency band) d = $1.2\sqrt{P}$	80MHz-800MHz d = $0.4\sqrt{P}$	800 MHz-2.5 GHz d= $0.767\sqrt{P}$
0.01	0.12	0.12	0.04	0.08
0.1	0.38	0.38	0.13	0.24
1	1.2	1.20	0.40	0.77
10	3.8	3.80	1.30	2.40
100	12.00	12.00	4.00	7.70
Note 1: For the frequency of 80MHz and 800MHz, use the formula in higher frequency band. Note 2: The medical engineering frequency band between 150kHz and 80MHz refers to 6.765MHz-6.795MHz, 13.553MHz-13.567MHz,				

26.957MHz-27.283MHz and 40.66MHz-40.70MHz.

Note 3:

Additional factor 10/3 is used for calculating the recommended isolation distance of transmitter on the medical engineering frequency band (150kHz-80MHz) and in the frequency range of 80MHz-2.5GHz, so as to reduce the probability of interference caused by portable/mobile RF communication equipment when being taken to the patient area.

Note 4:

The guides may not be suitable for all situations. Electromagnetic propagation is affected by the building, object and human absorption and reflection.

For the maximum rated output power of transmitter not listed in the above table, the recommended isolation distance d (unit: m) can be determined by the formula in the frequency column of transmitter, and "P" (unit: W) here is the maximum rated output power of transmitter provided by the transmitter manufacturer.

⚠Notes:

- Please fully consider the electromagnetic compatibility of the equipment installation and using environment according to the above guide;
- Though the equipment or other equipment near the device meets the emission requirement of CISPR, it may still interfere with the equipment, so please verify whether the equipment can work normally before using.
- Using of unapproved parts on the equipment may reduce the electromagnetic immunity of system or increase the electromagnetic emission of equipment.

8. Storage and transportation

⚠Warning:

- When the storage condition exceeds the working environment requirement and the storage state is converted into use condition, use the product after placing it in standard environment for more than 8.