文件类型	技术文件	项目编号	205
文件编号	H-1.601.00223	打印要求	彩色 ☐ 黑白

205 用户使用说明书（英文）

制定		审核		批准	
日期	2023.03.08	日期	2023.03.08	日期	2023.03.08

参 考 资 料

文件编号	说明

修 订 记 录

版本	ECR/PCN TCN	更 改 内 容	制 定	批准日期
A1.0	ECR20201121	新增	谢荣锋	2020.11.25
A2.0	ECR20211142	修改页码形式	李楚伦	2021.09.28
2.0	ECR20220318	修改公司信息	谢荣锋	
3.0	ECR20220619	1.增加相关图形符号 2.增加英文缩略语解释表 3.增加软件发布版本、说明书版本、修订日期 4.封面加上 CE 标识、说明书版本、修订日期，封底加上制造商标识 5.修改全文字体大小及格式，AHA 指南年份改为 2020 年 6.EMC 章节适用法规条例改成国际标准	蓝海花	2022.07.19
4.0	ECR20221004	1.增加 CPR 指导界面说明，增加 PC 端连接说明 2.增加治疗病人阻抗测量范围：满足 0Ω～300Ω 3.增加低电量报警后至少还可持续 30 分钟工作时间 4.增加“设备的内部存储容量≥16GB，可存储不少于 3000 份自检报告” 5.增加录音功能、增加音量和亮度自动调节	蓝海花	2022.10.18
5.0	ECR20230218	修改触摸屏面板语言切换、一体式电极片相关信息和图片	蓝海花	2023.03.08
发放部门		☐ 生产部 采购部 品质部 ☐ 市场部 ☐ 研发系统		
存档方式		电子文档 纸文档 ☐ 其它：		

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

Amoul



i5 User Manual

Semi-automatic External Defibrillator

Release Version: 5.0

Revision date:2023-03

www.amoulmed.com

深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)

CE 2797

深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)

Contents

1. Equipment description 1
    1.1. Purpose 1
    1.2. Intended use 1
    1.3. Contraindication 1
    1.4. Application 1
    1.5. User qualification 1
    1.6. Function 1
    1.7. Equipment view 2
2. Interface description 5
    2.1. Interface composition 5
    2.2. Description for interface settings 5
    2.3. CPR Operation Instructions 10
3. Data Export 15
    3.1. Connect with APP 15
    3.2. Download from the data folder 16
    3.3. Download from the selfcheck folder 17
    3.4. View the files downloaded to the local 18
    3.5. View the downloaded list.txt file and H1.i file 20
    3.6. Generate report 21
    3.7. Connect with PC 22
4. Installation and setting 25
    4.1. Setting i5 25
    4.2. CPR setting 26
5. Defibrillation 28
    5.1. CPR guide 28
    5.2. Preparation for rescue 29
    5.3. Main rescue sequence 31
    5.4. CPR guide 33
    5.5. Data storage 35
    5.6. Quick reference 35
6. Sanitary treatment 36
7. Fault and its removal 37
    7.1. Automatic test 1 37
    7.2. Equipment status 37
    7.3. Fault removal 38
8. Maintenance 41
    8.1. Equipment state monitoring 41
    8.2. Battery 41
    8.3. Battery replacement 41
    8.4. Defibrillator electrode 42
9. i5 supply configuration 44
    9.1. Standard configuration 44

深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)

9.2. Optional configuration 44
10. Technical parameter 45
10.1. Management category of medical equipment 45
10.2. Physical specification 45
10.3. Environmental specification 45
10.4. Battery specification 46
10.5. Defibrillator 46
10.6. Output waveform of adult patient (200 J) 47
10.7. ECG 52
10.8. Self-diagnosis test 53
10.9. Defibrillating electrode 54
11. EMC 55
11.1. Declaration of magnetic radiation 55
11.2. Declaration of electromagnetic immunity - Requirements for all equipment systems 55
11.3. Declaration on guide and manufacturer - Electromagnetic immunity 56
11.4. Recommended isolation distance 58
12. Descriptions for classification of toxic and harmful substance 60
13. Storage and transportation 61

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

Product information

Thanks for purchasing i5 Semi-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:	Semi-Automatic External Defibrillator
Model:	i5
Registrant name:	AMBULANC (SHENZHEN) TECH. CO., LTD.
Registrant domicile:	Rm A1302,13th Floor,Block A,Shenzhen National Engineering Laboratory Building,No20,Gaoxin 7th Road South,Yuehai Sub-district,Nanshan District, Shenzhen,Guangdong Province, China.
Manufacturer name:	AMBULANC (SHENZHEN) TECH. CO., LTD.
Manufacturer address:	3rd Floor, Block C, Building #5, Skyworth Innovation Industry Park, Tang Tou 1st Road, Shiyan, Baoan District, Shenzhen 518108, China
Date of manufacturing	See label on main unit
Service life:	8 years
Software Version:	V1.0
Release Version:	4.0
Revision date:	2022-10

Notes:

The instrument is not designed for family use.

EC REP EC-Representative

EC-Representative：Shanghai International Holding Corp. GmbH(Europe)

Eiffestrasse 80 20537,Hamburg,Germany

Contact pers：Qiming Cheng

Telephone: +49-40-2513175 Fax: +49-40-255726

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

Intellectual Property Right

© 2022 AMBULANC (SHENZHEN) TECH.CO.,LTD. All rights reserved.

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.

Ambulanc has the right to handle this manual as confidential material. Without prior written approval of Ambulanc, any individual or organization shall not disclose nor access all or parry of the information in this manual in any way, nor handle this manual in any other way, including but not limited to, publishing, modifying, copying, issuing, leasing, recomposing and translating.

Amoul This is the registered trademark or trademark of AMBULANC (SHENZHEN) TECH.CO.,LTD., and these trademarks and related Ambulanc logo are intangible property owned by AMBULANC (SHENZHEN) TECH.CO.,LTD. Use of any other trademarks or logos in this manual is for edition only, rather than any other purpose, and they are owned by their respective owners.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

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.

深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)

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.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

Warranty

Manufacturing Process and Raw Material：

Ambulanc warrants that no failure will be resulted from any defect in manufacturing process or raw material when this instrument is used and serviced correctly.

After-Sales Service Unit

After-Sales Service Dept., AMBULANC (SHENZHEN) TECH.CO.,LTD.

Address: 3rd Floor, Block C, Building #5, Skyworth Innovation Industry Park, Tang Tou 1st Road, Shiyan , Baoan District, Shenzhen 518108, P.R.China

Service Hot Line：400-9969-120

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

Web site: http://www.amoulmed.com

E-MAIL: manager@amoulmed.com

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 Ambulancanc shall be paid by the user.

深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)

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; and
- 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.

深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)

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. 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 releases a lot of 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.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

- 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 disposable 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 i5 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 10, "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.

深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)

- 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.

Software

Since a lot of quality assurance measures were taken during equipment and software development, the risk caused by software defects is negligible.

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.

Symbol description

The table below introduces the symbols on the equipment or in the manual.

Symbol	Description	Symbol	Description
	Refer to the attached documents		Refer to the Manual
	Date of production	SN	S/N

深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)

Symbol	Description	Symbol	Description
	Expiring date		BF defibrillation equipment
	Don't discard the equipment in garbage can arbitrarily		Check the accompanied manual/instruction
	"Shock"		"Start/shutdown"
	"i"		Manufacturers
	EC-Representative		Waterproof level
	"CE 2797"		Adult and child mode switch
	Medical Device		
	The product contains some harmful substances, and it can be used at easy within the environment-friendly use period but shall enter the recycle system if exceeding the period (environment-friendly use period: 20 years).		

The table below introduces the abbreviations on the equipment or in the manual.

Abbreviations	Description
AED	Automated External Defibrillator
CPR	Cardiopulmonary Resuscitation
ECG	Electrocardiograph
AHA	American Heart Association
EMSS	Emergency Medical Service System
EMC	Electro-Magnetic Compatibility

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

1. Equipment description

1.1. Purpose

i5 is a Semi-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. i5 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

i5 is used 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. Contraindication

Please don't use i5 when the patient has the following signs:

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

1.4. Application

i5 for emergency responders, medical staff, or trained non-professional in or outside the hospital.

1.5. User qualification

The user of i5 shall be proved to satisfy the following conditions:

- Received training on equipment.
- Received training on cardiopulmonary resuscitation or other physician-authorized emergency response programs.

1.6. Function

i5 is composed of host, defibrillator electrode and battery. Ambulanc has designed i5 as the components for a defibrillation system.

深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)

1.7. Equipment view

1.7.1. Host-front view

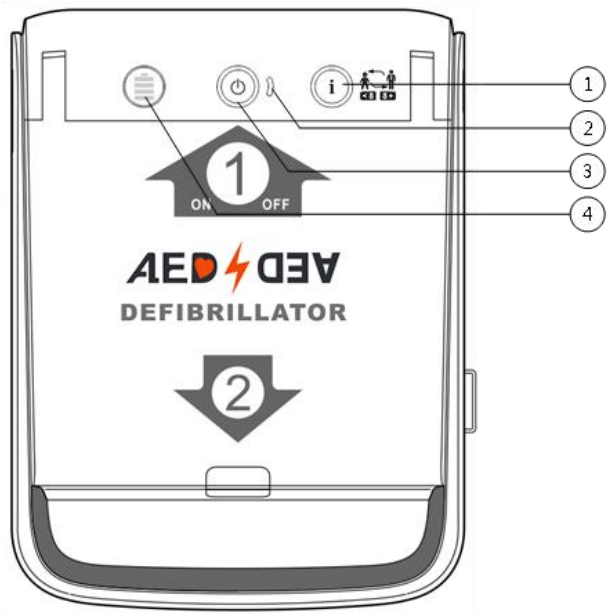


Figure 1Host (front view - when the cover is closed)

Parts	Description
1 "i"	1) Long press this button in the power off state to enter the management mode for parameter setting 2) Short press this button in the power on state to change the adult or pediatric defibrillation mode.
2 Status LED	Indicate the state of i5. • Green light flashing: indicate that i5 is in the standby mode, the machine is normal and can be used for rescue. • Green light on: indicate that i5 is in the work mode. • Red light flashing: indicate that system errors are detected or the battery is low when i5 is in the standby mode. • Red light on: indicate that the machine has faults or the battery is low when i5 is in the work mode. • Blue light on: indicate that i5 is in self-test. • White light on: indicate that i5 is in the management mode.
3 "Start/Shutdown"	The button is used to start or shut down i5.
4 Battery display	Display the battery level in real time

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

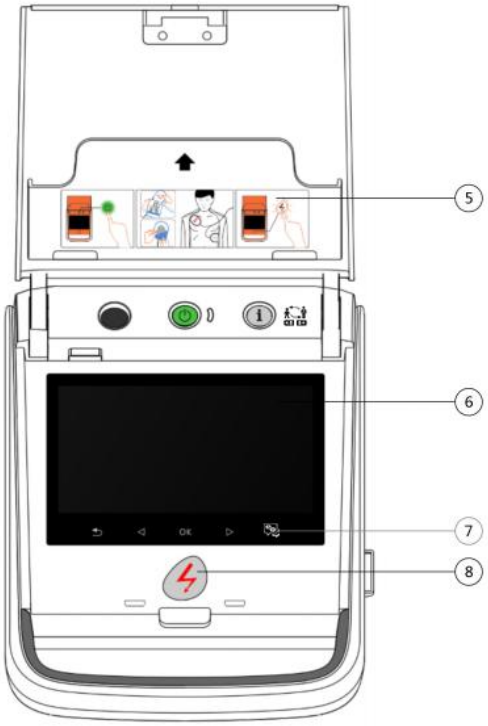


Figure 2 Host (front view - when the cover is opened)

Parts	Description
5 Operating steps	Main rescue steps
6 Display screen	Display rescue procedures
7 Touch buttons	Return, left arrow, confirm, right arrow, language switching (only switch under rescue mode or when the electrodes are not connected, and long press the button to switch).
8 "Shock"	Press it to give electric shock

1.7.2. Host-rear view

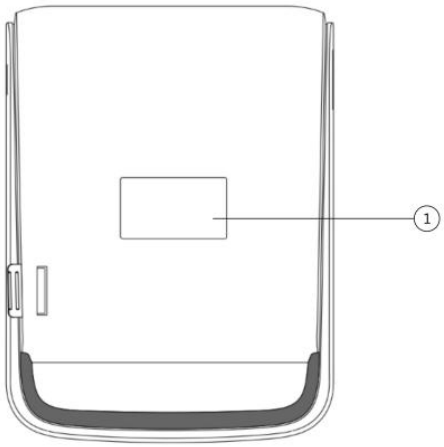


Figure 3 Host (rear view)

Parts	Description
1 Host tag	For marking the host information.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

1.7.3. Host - left view and right view

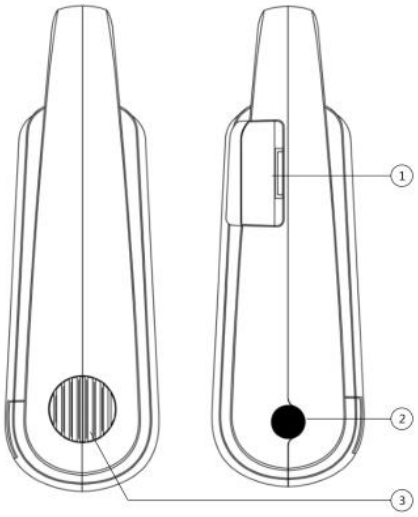


Figure 4 Host (left view and right view)

Parts	Description
1 Battery	Provide power supply for the host (self-test will be started at once after inserting the battery)
2 Empty (saved for future use)	\
3 Horn	For voice prompt or sound alarm

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

2. Interface description

2.1. Interface composition

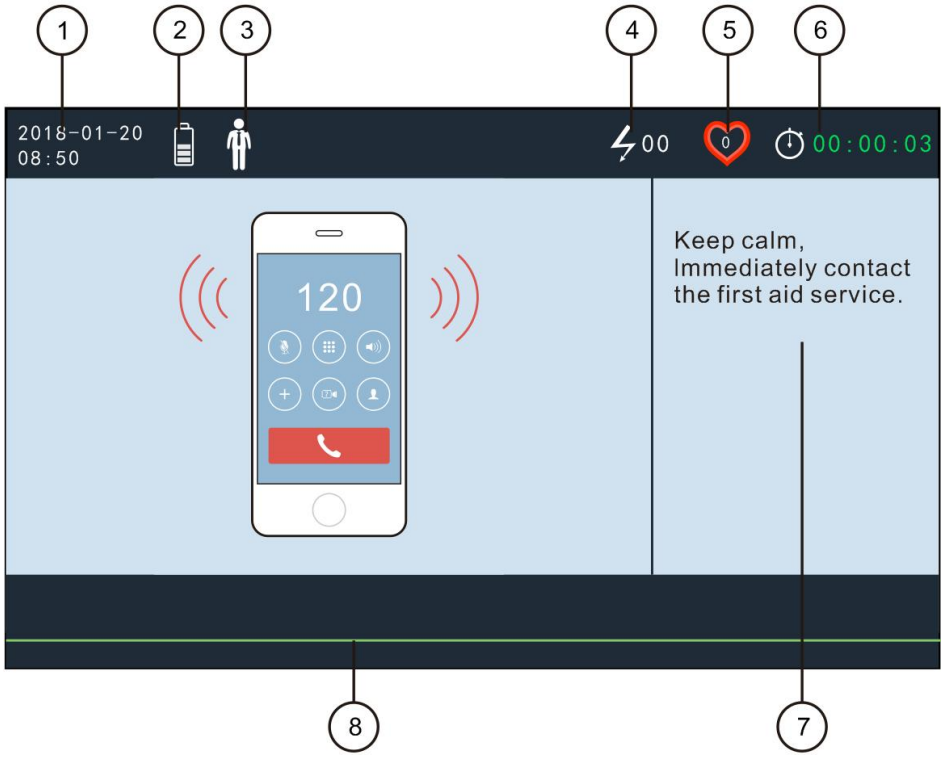


Figure 5 Main Interface

Parts	Description
1 System date and time	Display the current date and time
2 Battery level	Display the current battery level
3 Patient type	Display the currently-selected patient type (adult/pediatric)
4 Times of shock	The times of shock from startup to current time under normal operation; The total times of shock of i5 under management mode after delivery.
5 Heart rate	Display the current heart rate
6 System timing	The working time of equipment from startup to current time under normal operation; The total using time of i5 under management mode after delivery.
7 First-aid info area	Display the first-aid prompts, eg.CPR parameters.
8 Waveform area	Display the real-time ECG wave.

2.2. Description for interface settings

You can optimize the host setting on the setting interface to adapt to different applications, long press <i> mechanical button under shutdown state to enter the setting

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

interface and call the actual setting interface with the navigation soft key.

2.2.1. Mode setting

Press < ▷ > to choose < Mode > and enter the mode setting interface (as the figure below).

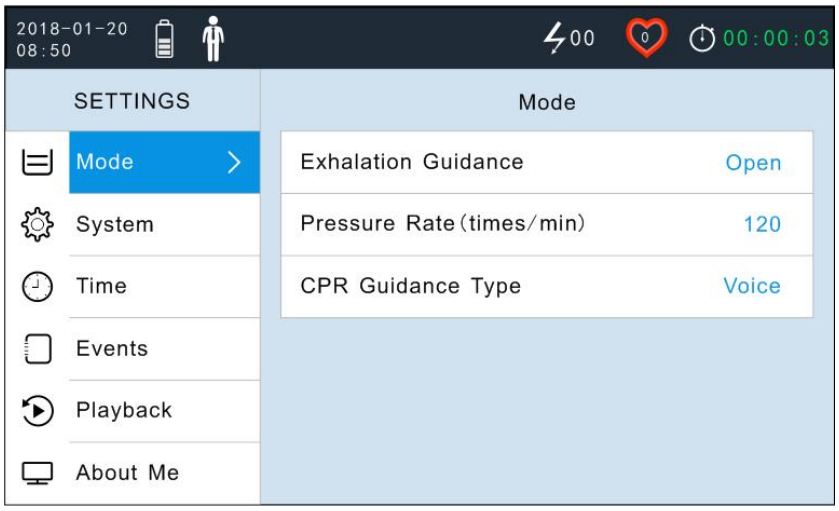


Figure 6 Mode Setting Interface

Parts	Description
1 Exhalation Guidance	Default: Open. Adjustable: Open / Close
2 Pressing Rate (times/min)	Default:110. Adjustable: 100, 110 and 120
3 CPR Guidance Type	Default: Countdown. Adjustable: Voice guide and Countdown

⚠ Notes:

1. Exhalation Guidance open: CPR prompt pressing mode is 30:2.
2. Exhalation Guidance close: CPR prompt pressing mode is continuous press.
3. The unit of pressing rate is times/min, for example, 100 means that the pressing rate is 100 times per minute.
4. When CPR guidance type is Voice guide: it enters CPR voice guide directly, without the need of manual intervention.
5. When CPR guide type is Countdown mode: when it is necessary to enter the CPR guide mode, the blue i button flashes and prompts the user to press the button to obtain the CPR guide; if the button is not pressed within 20s, the equipment will reanalyze the rhythm of the heart after the end of 2 min countdown.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

2.2.2. System setting

Press < ▷ > to choose <System > and enter the system setting interface (as the figure below).

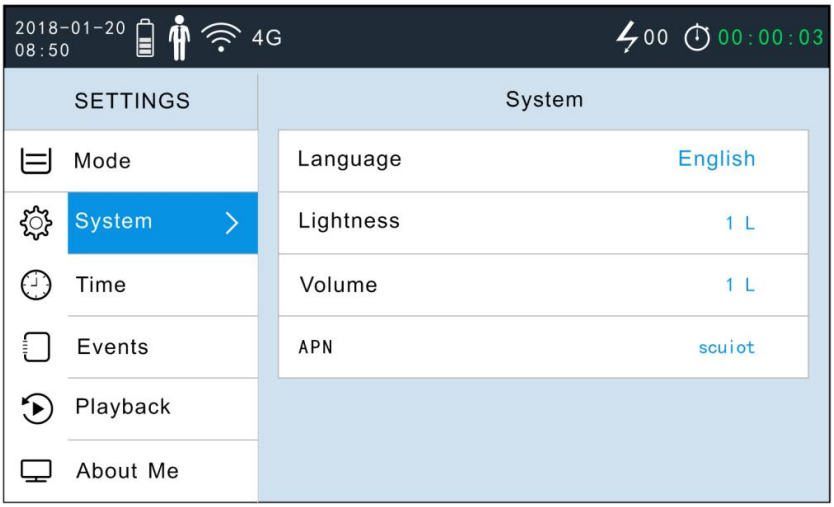


Figure 7 System Setting Interface

Parts	Description
1 Language	Default: English. Adjustable: Chinese , English and Cantonese.
2 Lightness	The screen lightness can be adjusted automatically according to the ambient light intensity, adapting to use in the strong light environment in the wild. Default to Level 2. Adjustable: Level 1-5.
3 Volume	It can automatically adjust the volume according to the noise level of the environment. Default to Level 3. Adjustable: Level 1-3.
4 APN	Set the APN type of network.

2.2.3. Time

Press < ▷ > to choose <Time> and enter the time setting interface (as the figure below).In this interface, it can be set the system time, as well as the expiration date and expiration reminder of electrode

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

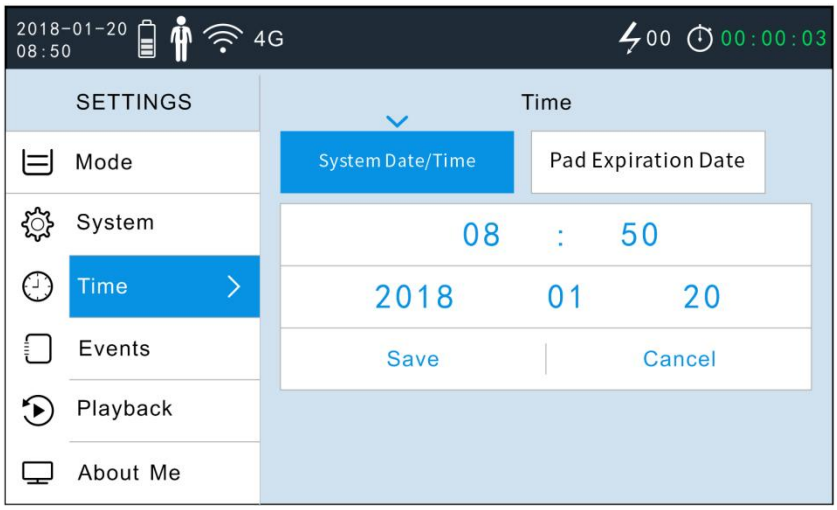


Figure 8 Time Setting Interface

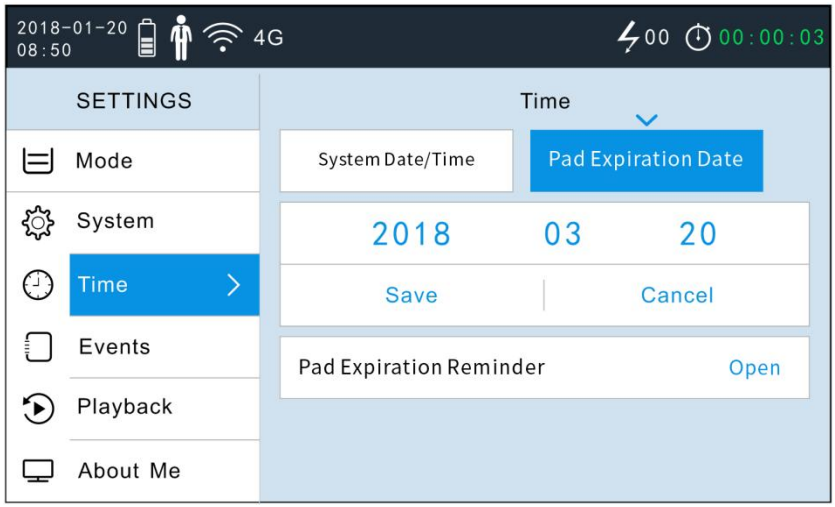


Figure 9Set the expiration date of the electrode

When the expiration date of the electrode is less than 3 months, the i5 device will send a reminder message, then it can be checked through the logs interface, APP terminal and PC terminal

2.2.4. Events

Press < ▷ > to choose <Events> to check the system log (as the figure below).

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

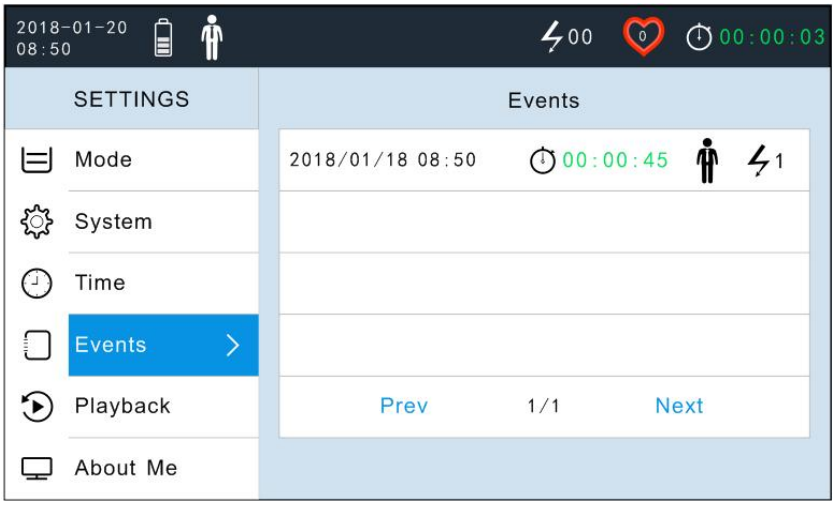


Figure 10 Log Interface

Currently, the system can support the memory of 1000 logs at most. When the log information reaches the upper limit, the newer log will cover the older logs. i5 only records the log of shock. When checking logs, pay attention to the following points:

- Log information structure: log time + rescue stopwatch + patient type + shock times.
- Log time: log recording time, that is, the startup time of i5 when shock occurs.
- Emergency stopwatch: the time from startup of i5 to the shock.
- Patient type: display as adult or pediatric
- Shock times: record the sequence of shock. (For example: "1" indicates the first shock after startup, and "2" indicates the second shock after startup).

2.2.5. Playback

Press < ▷ > to choose <Playback> and view playback files (as the figure below).

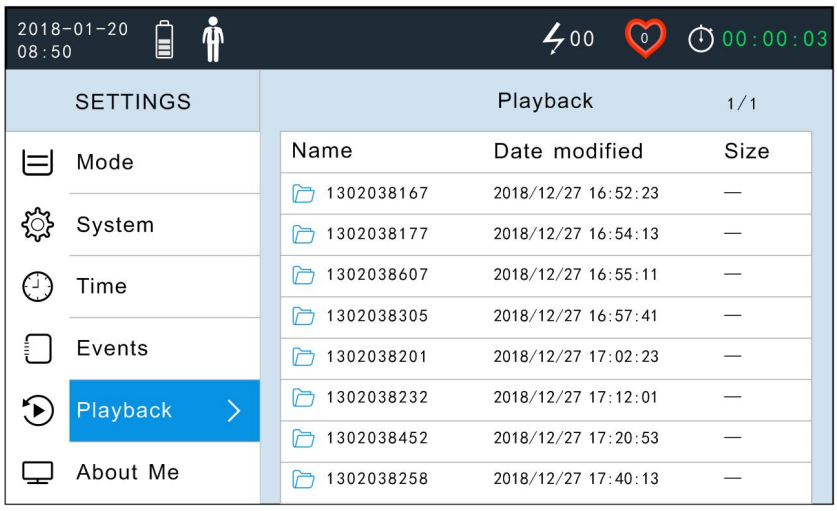


Figure 11 Playback

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

2.2.6. About Me

Press < ▷ > to choose <About Me> and check the software and hardware version (as the figure below).

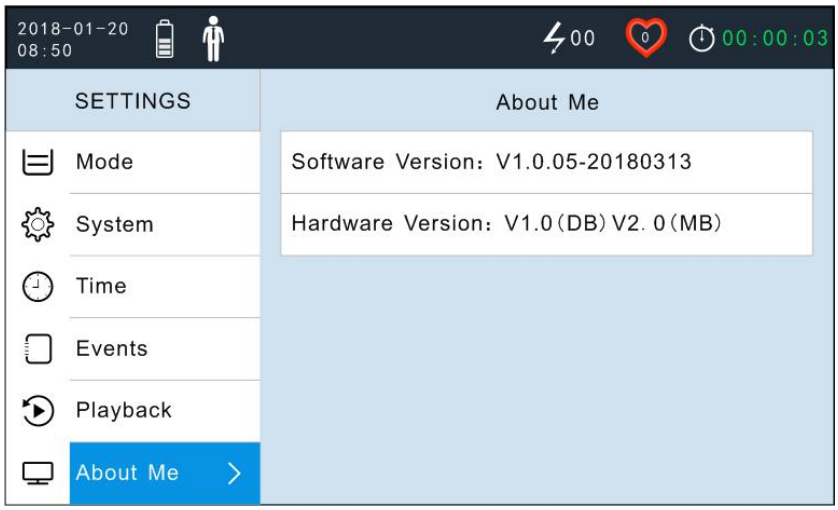


Figure 12 About the Machine Interface

2.2.7. Save the setting

When finishing time parameter setting, adjust the cursor at "Save" to save, and click OK for setting successfully; If save is not needed, choose "Cancel" on the interface.

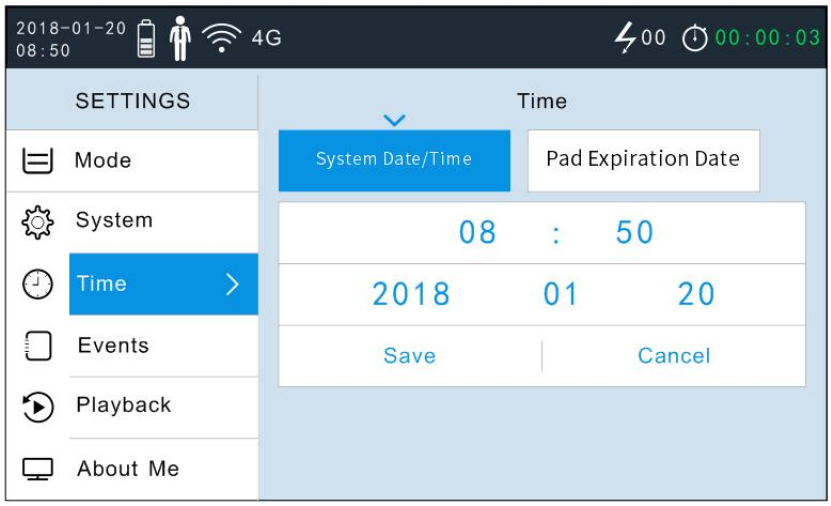


Figure 13 Interface of Time Parameter Save and Cancel

To save other parameters setting, click Save for setting successfully.

2.3. CPR Operation Instructions

After opening the device cover, the system automatically prompts “Keep calm，Immediately contact the first aid service”, and displays the corresponding instructions on the screen.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

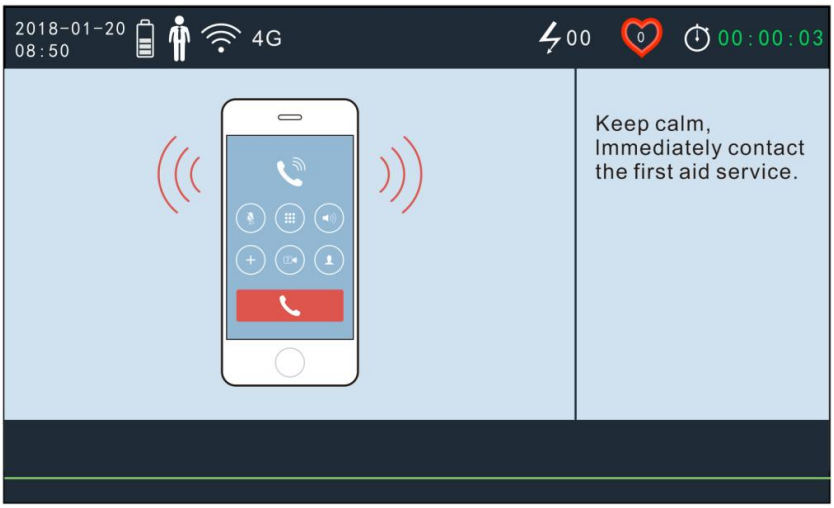


Figure 14 Contact the first aid service

Rescuers should operate AED device according to the prompts “Tear off the electrode packing, insert the electrode connector into the device”.

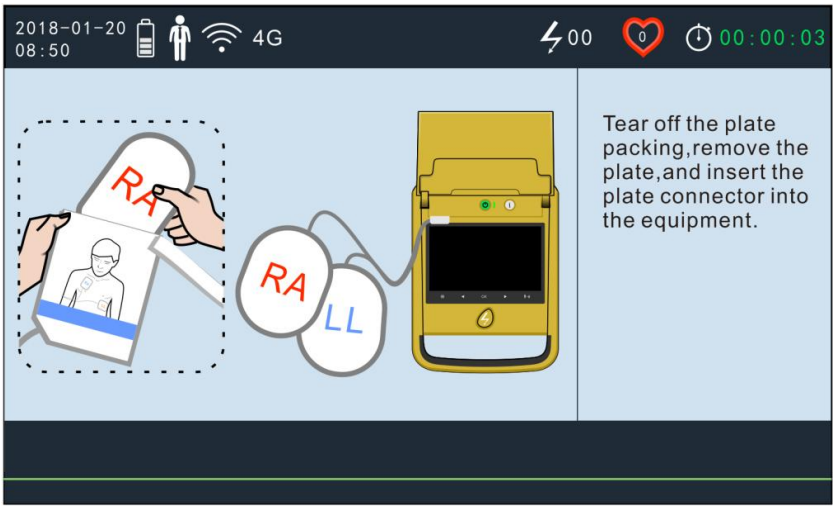
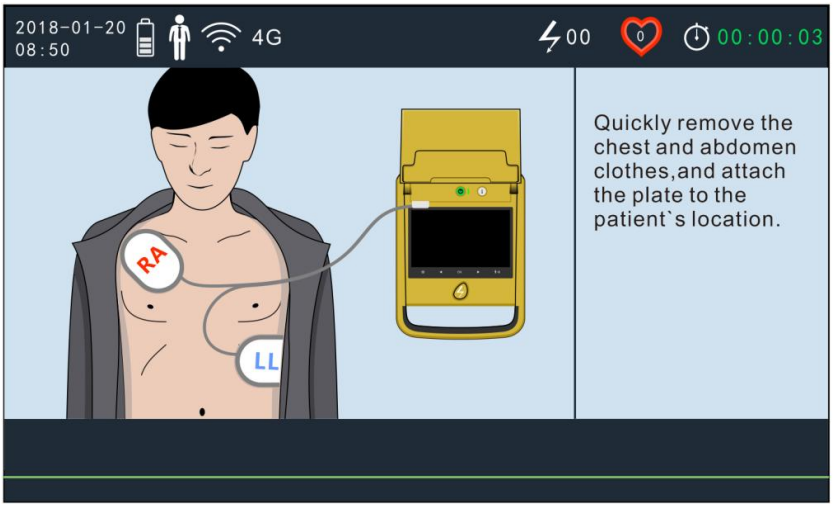


Figure 15 Insert the plate connector into the equipment

Follow the voice prompts “Quickly remove the chest and abdomen clothes, and attach the electrode to the patient correct positions” to continue to operate the AED device.



深圳市安保医疗科技股份有限公司
受控文件 副本号( )

Figure 16 Attach the plate to the patient’s body(adult)

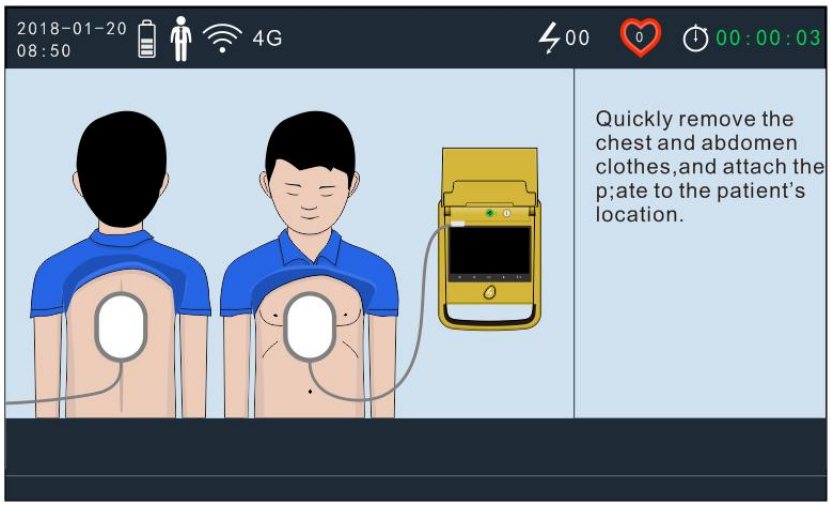


Figure 17 Attach the plate to the patient’s body(Children)

When heart rhythm analysis is in progress, anyone should not touch the patient to avoid inaccurate analysis of the device

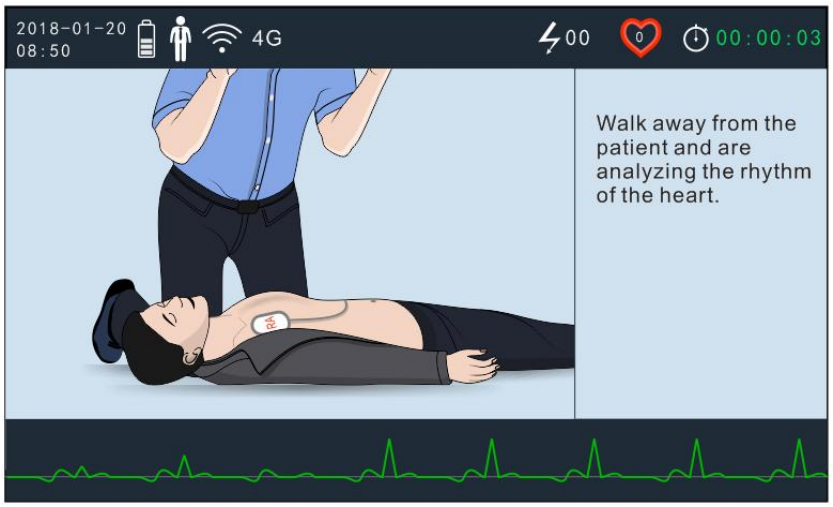


Figure 18 heart rhythm analysis

When the voice prompts "Now safe to touch the patient. Please press patient chest following the metronome", you can follow the instructions appear on the screen to perform CPR

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

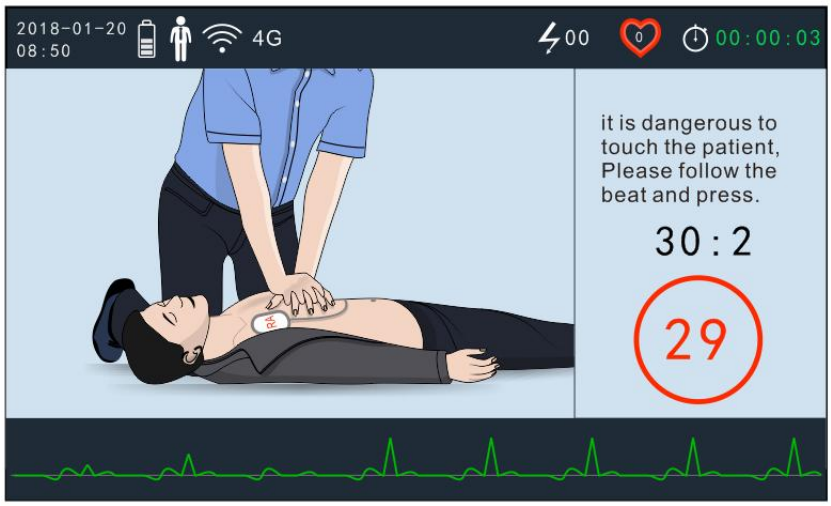


Figure 19 perform CPR

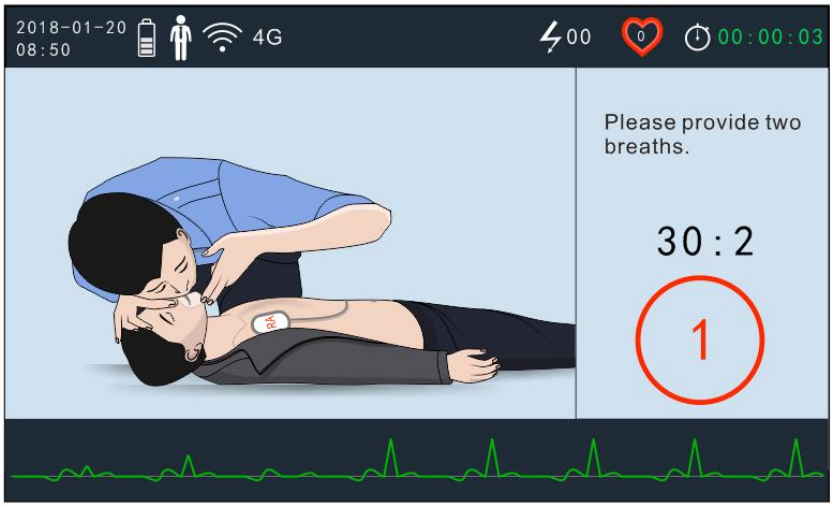


Figure 20 Provide two breaths

When the screen shows charging, please stand by and warn anyone don't touch the patient.



Figure 21 Charging

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

After charging, follow the voice prompts and press the flashing orange button to give a shock to the patient.

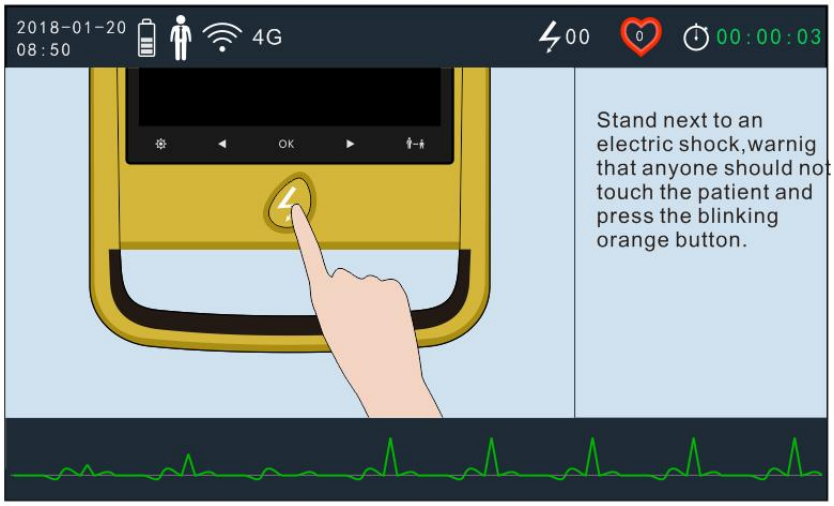


Figure 22 Give a shock to patient

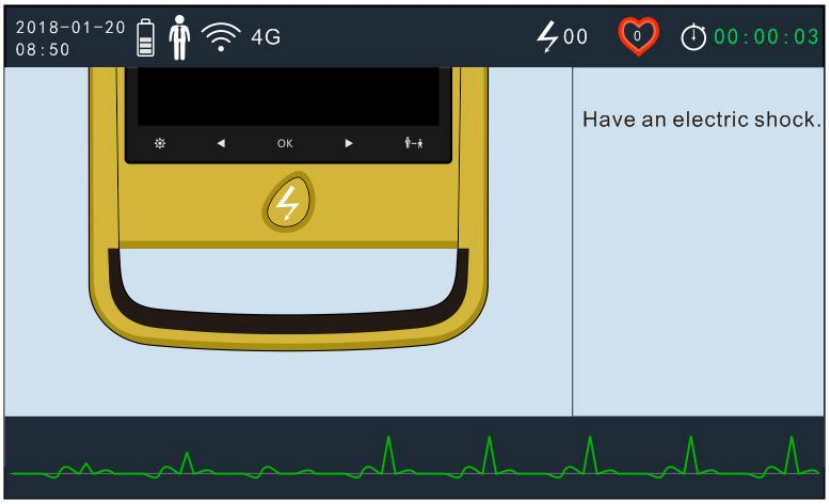


Figure 23 Complete an electric shock

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

3. Data Export

i5 provides the data export function, you can use it to export the current self-inspection reports, and data of recording ECG and emergency activities etc.

3.1. Connect with APP

1. After AED device is turned on, open WiFi and close mobile data function of the mobile phone.

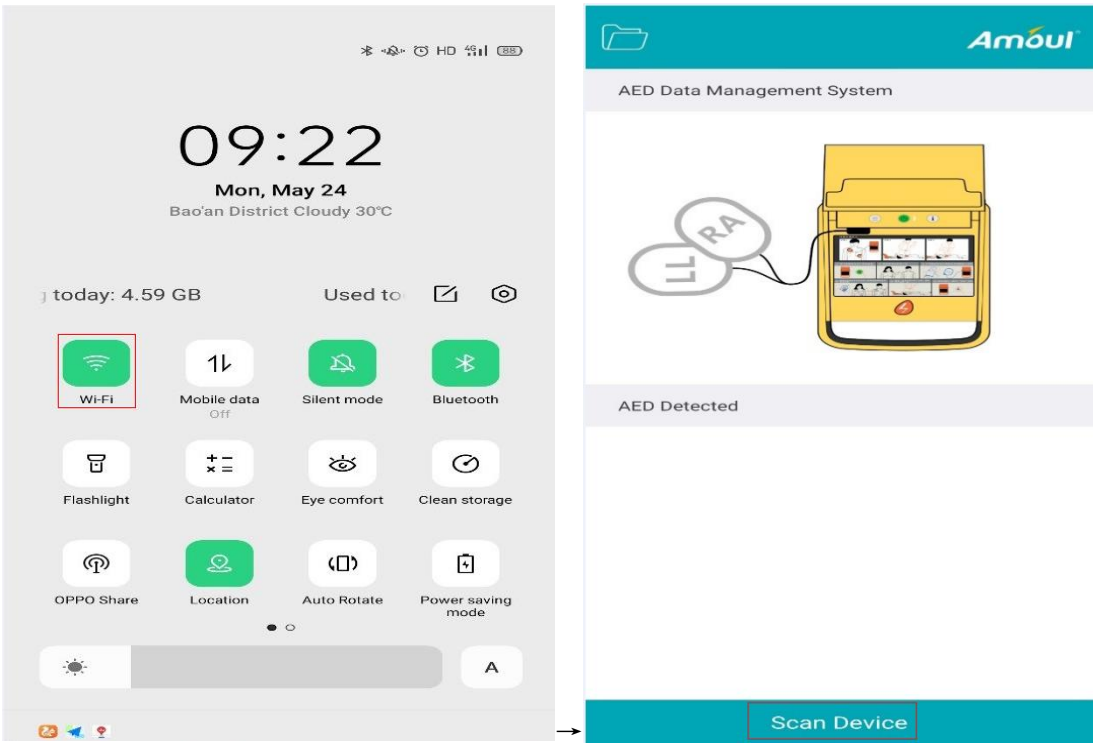


Figure 24 open WiFi and close mobile data functio

2. Run the APP, click "Scan Device" button.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

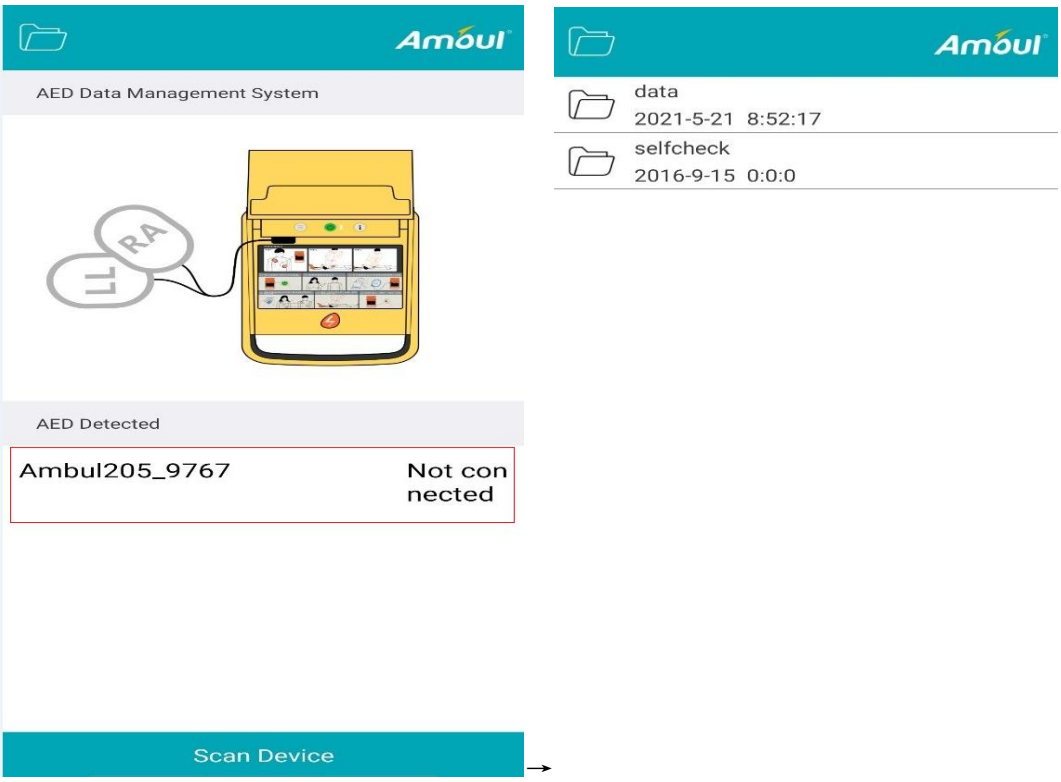


Figure 25 Scan Device

3．Choose the device scanned, and click it to enter the management interface to see 2 folders: data and selfcheck.

3.2. Download from the data folder

1．Click on the data folder.

2．Click on the sub folder wanted. Each sub folder is generated by the device from boot to shutdown. There are event files list.txt (generated at boot) and H1.i files of ECG data (.i files are generated only after use of the device, thus there may be null, or multiple .i files).

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

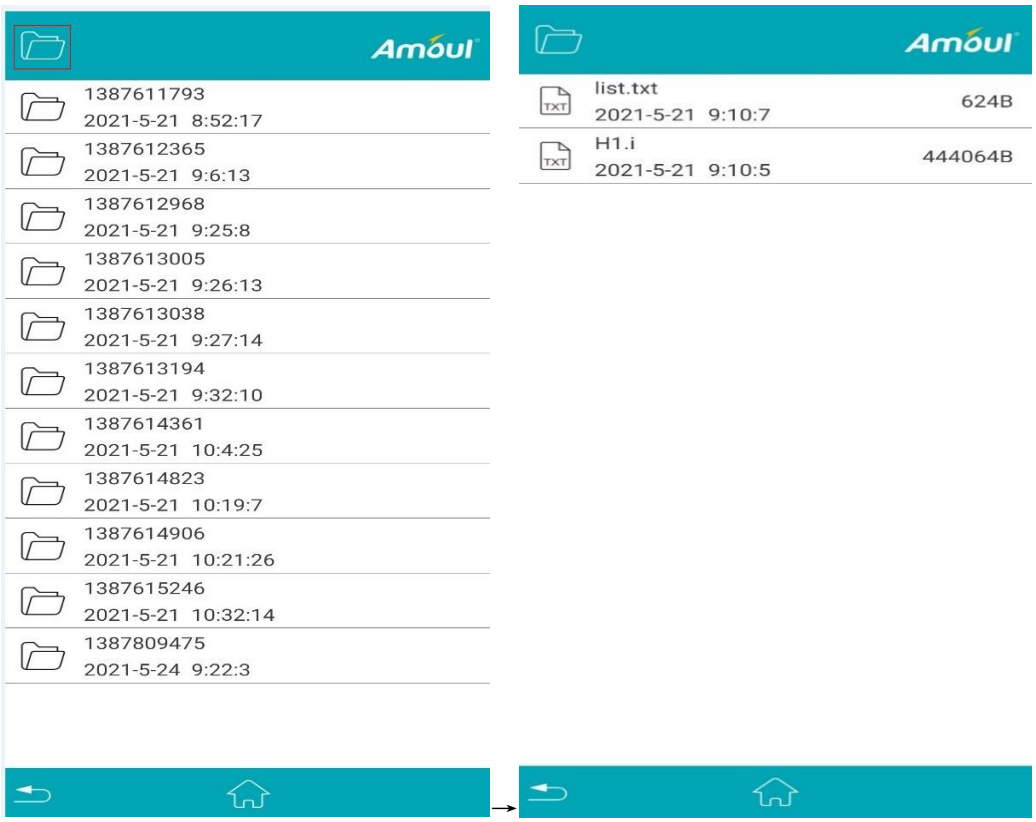


Figure 26 Download the file

3. Click to download the list.txt file and the H1.i file. (Note: files can only be download one by one, multiple clicks at the same time create empty files thus useless).

Download of list.txt file is fast. After completion, a downward arrow icon will appear (indicating that the file has been downloaded); if click again, it means another download.

Download of H1.i files is slow, the larger the data, the slower it takes.

3.3. Download from the selfcheck folder

1. Click selfcheck to enter the selfcheck folder.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )



Figure 27 Download the selfcheck folder

2. Click to download the selfcheck file wanted.

(seflcheck files record the events and status of the AED device, such as device turned on, start CPR).

3.4. View the files downloaded to the local

1. Click the folder icon in the upper left corner to enter the local files interface, where user can see folders named by the device name (each device connected before will create a folder named after the device name, which is convenient to manage the data of each device).

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

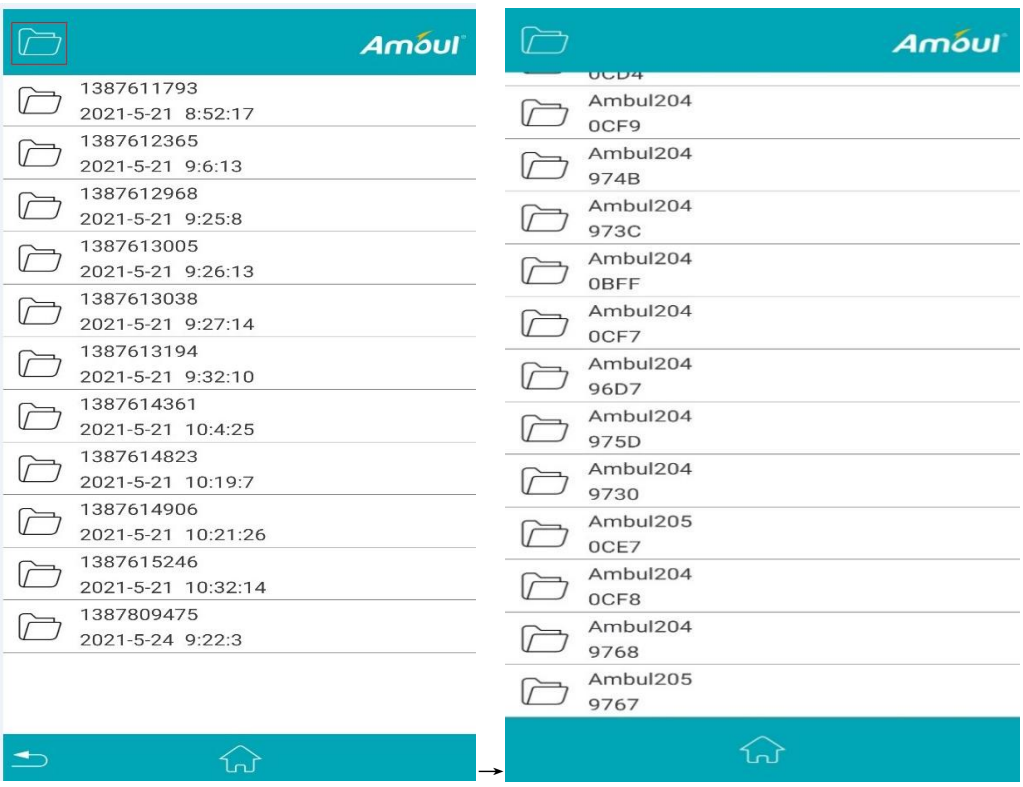


Figure 28

2. Click on the name of the device you just connected (eg, Ambul205_9767) to view the data.

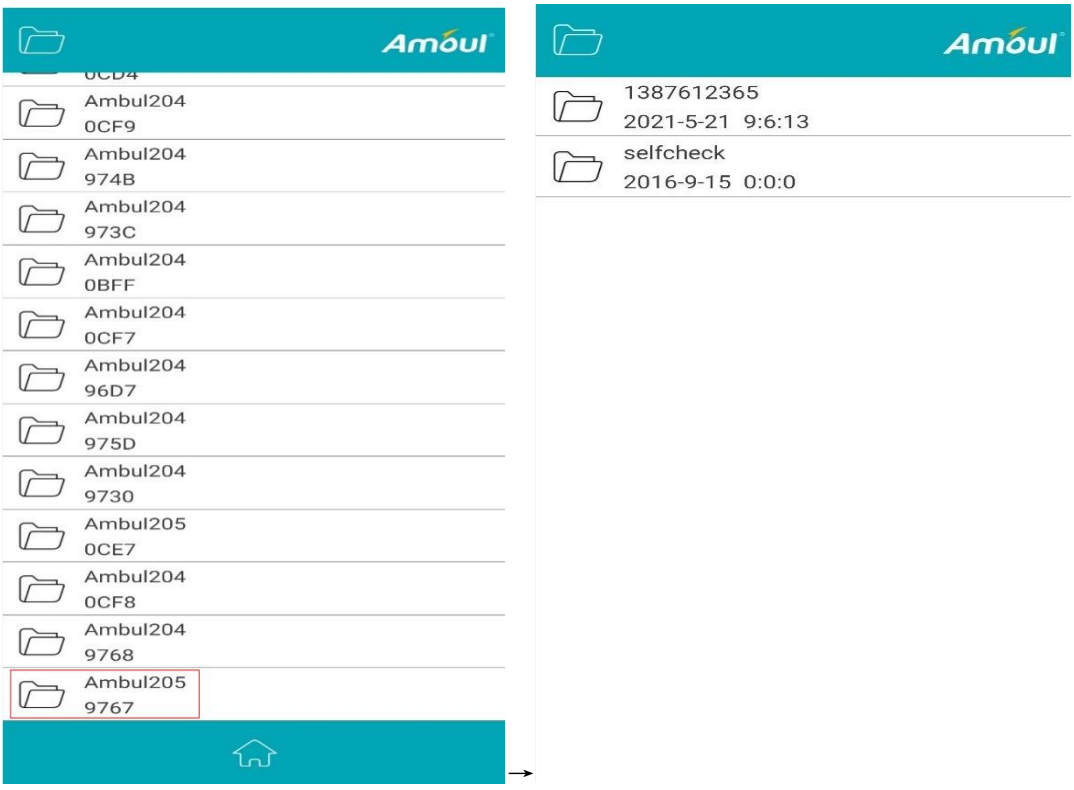


Figure 29

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

3.5. View the downloaded list.txt file and H1.i file

1. Click on the data file (eg. 1387612365) to view the downloaded files.

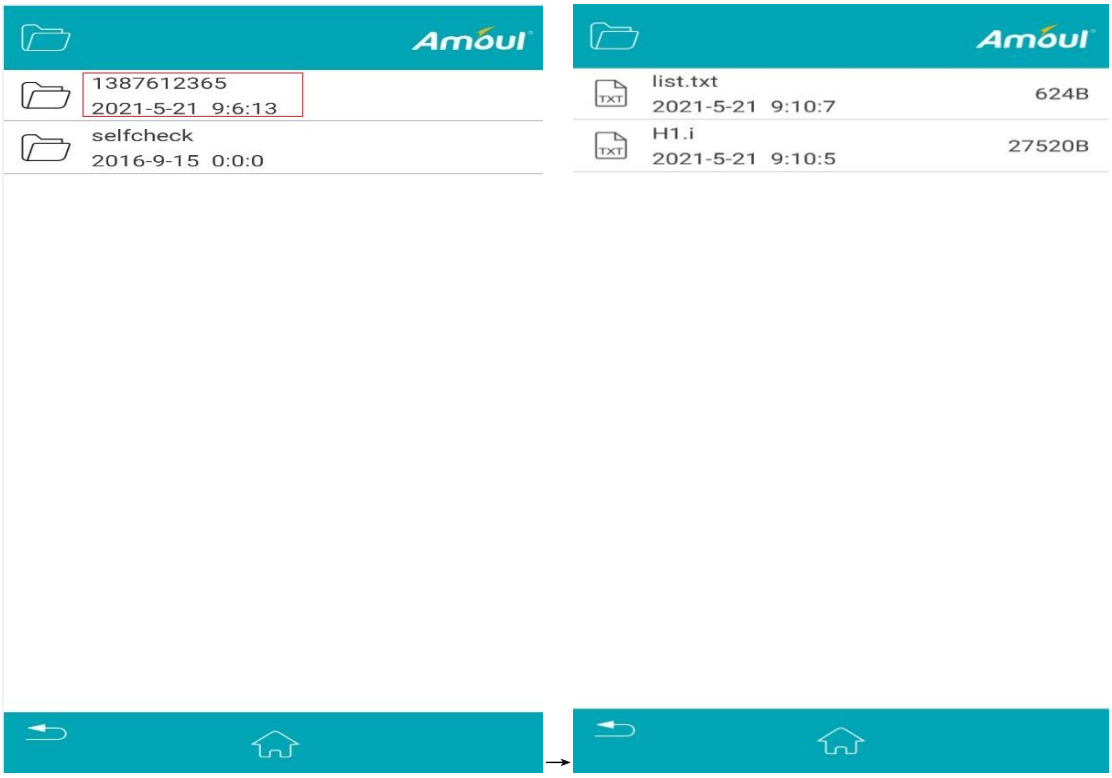


Figure 30

2. To view the event file (list.txt), click list.txt.

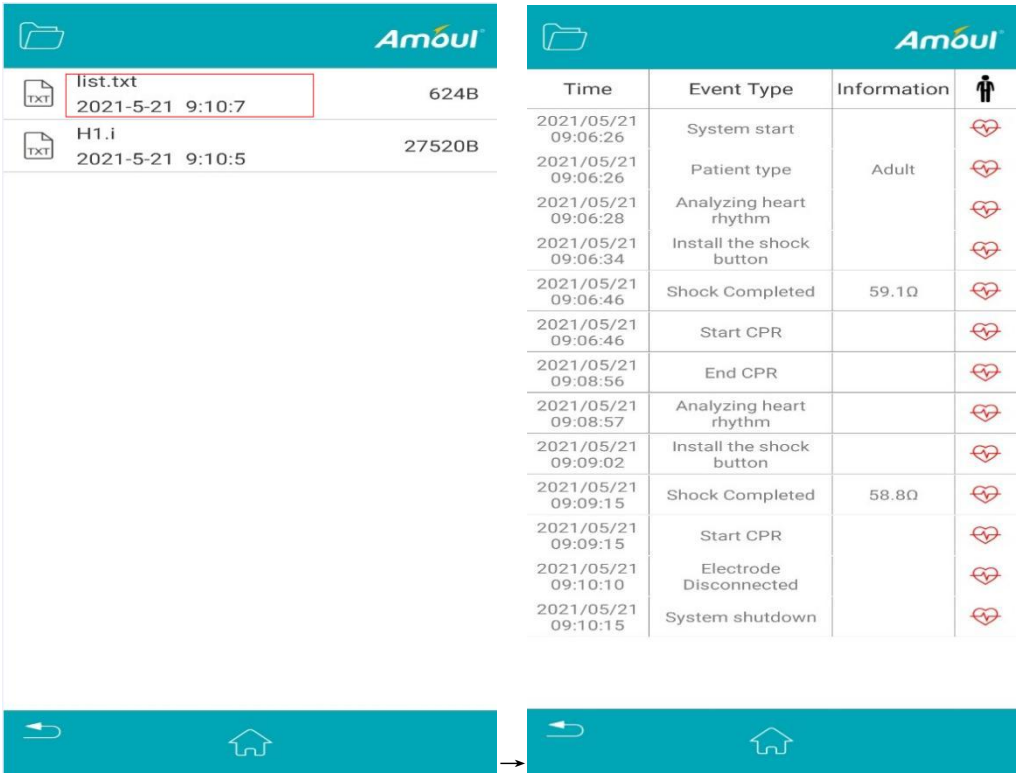


Figure 31

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

3．To view the H1.i file for ECG waveform, click the H1.i file.

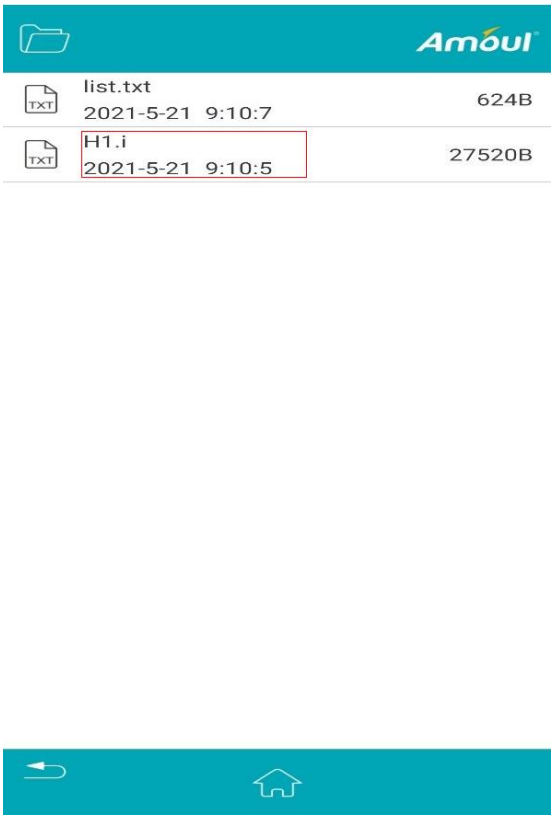


Figure 32

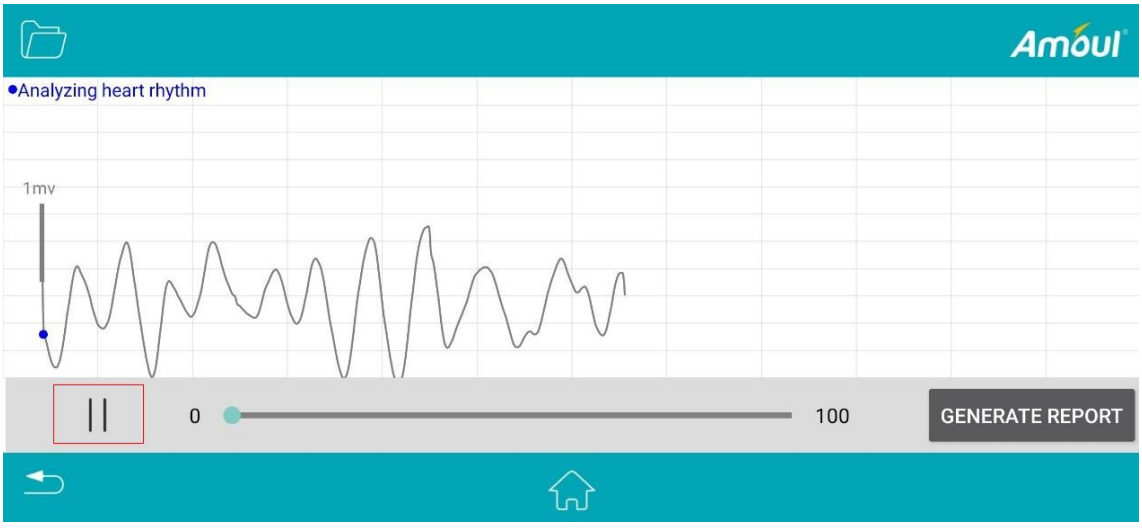


Figure 33

3.6. Generate report

1．Following the Step 3 of Chapter2.5, click “Generate report” button at ECG waveform displaying interface to generate a report in PDF format.

2．To view the report, click .pdf file at the corresponding data file (eg. 1384992776) (after report generated) or open it at the location:

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

\Android\data\com.amoul.homeActivity4G\cache\ambuls\Ambul204_7081\1384992776_2021-4-13　10:0:8）

3.7. Connect with PC

1．After AED device is turned on, check whether there is a WiFi name of the device in WiFi list of the computer. If it does not appear, it means the AED device is not turned on or the distance is too far. Please refresh the WiFi list again until you see the device's WiFi name after troubleshooting.

2．Use the computer to run the AED data management platform software, as shown in the figure below



Figure 34 Login AED data management platform

3．The AED data management platform software automatically searches for i5 devices nearby and displays the corresponding WiFi name, as shown in the figure below

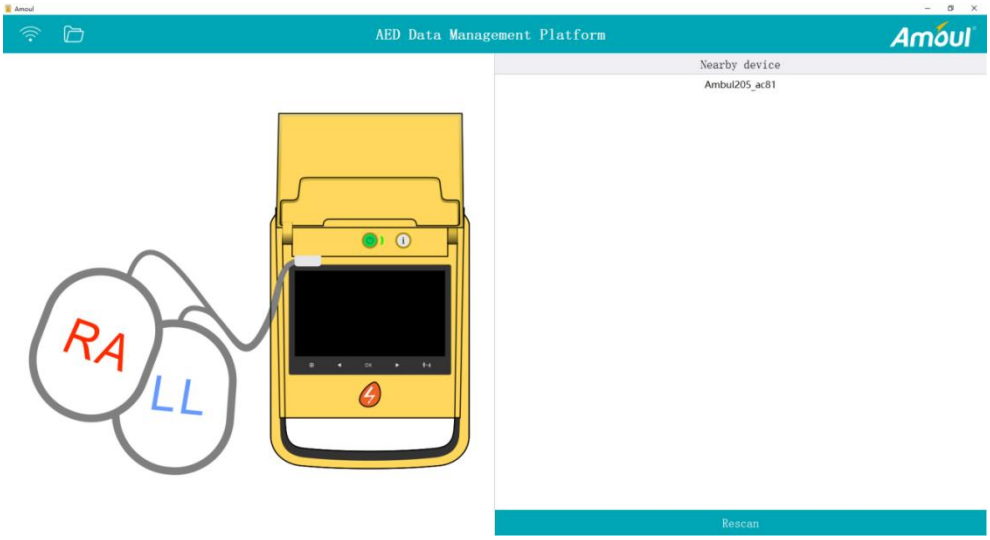


Figure 35 AED Connect interface

4．If there is no i5 device nearby or the device is not turned on, the AED data

深圳市安保医疗科技股份有限公司
受控文件　副本号(　)

management platform software will prompt "device not scanned !", as shown in the figure below, you need to check the status of the i5 device, and then click the [Rescan] button

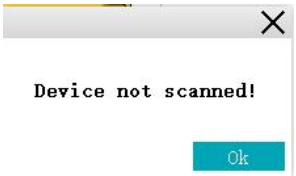


Figure 36 device not scanned

5. After scanning to the device, double-click the WiFi name (such as "Ambul205_ac81") to connect the device and enter the management interface;

6. Click the operating data or self-test information on the left side of the interface, and select a corresponding time to view the event and status information such as device startup, CPR function, ECG waveform, etc.;

7. Click the [ ] icon to open the data saved locally;

8. Click the [PDF] icon to generate the corresponding pdf report.

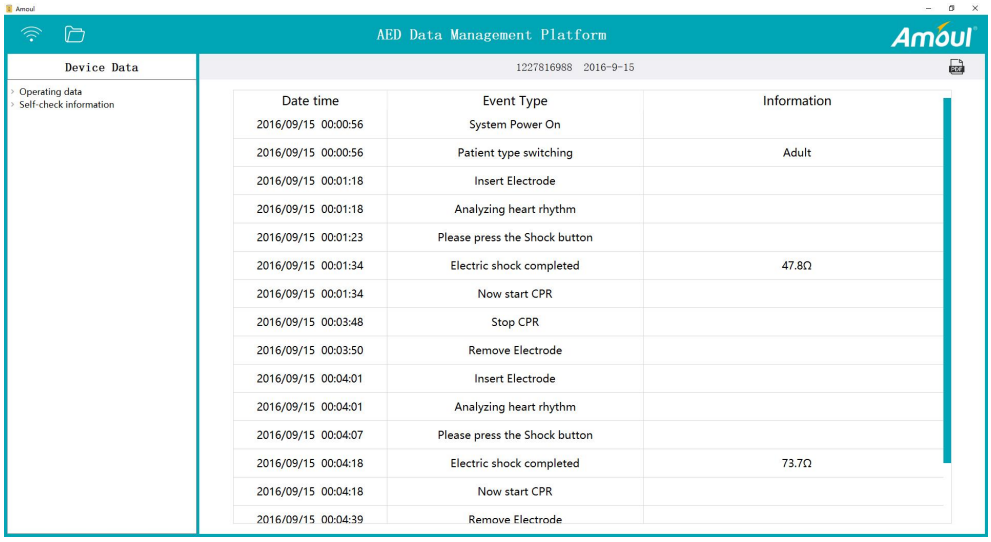


Figure 37 Operating data

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

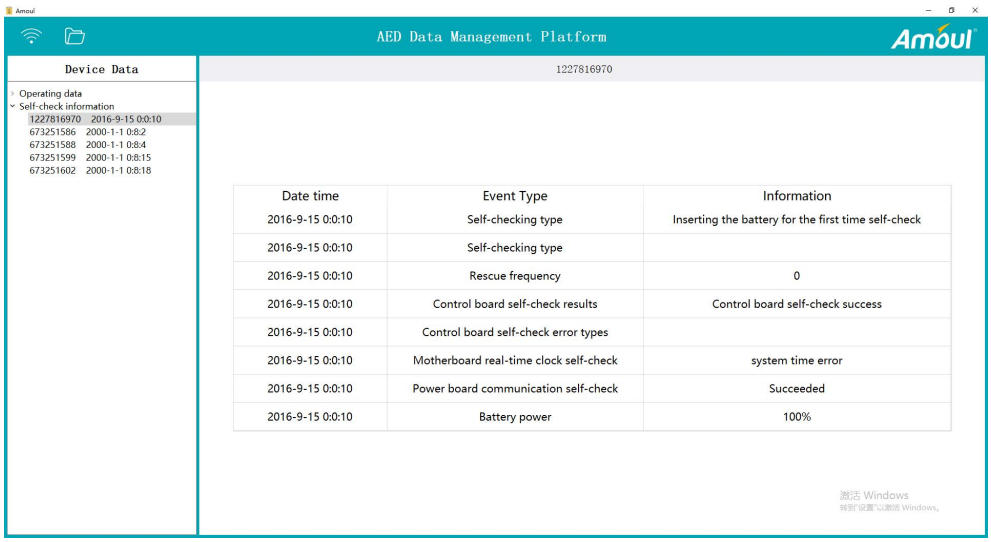


Figure 38 Self-inspection reports

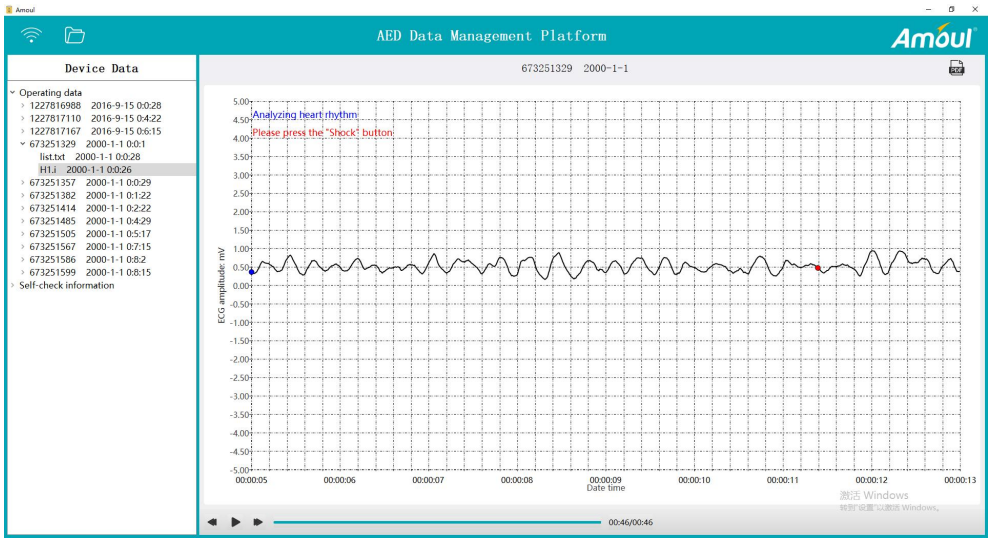


Figure 39 ECG waveform

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

4. Installation and setting

The packing box of i5 contains the following objects: i5 semi-automatic external defibrillator, user manual, battery and disposable defibrillator electrode.

⚠Warning:

- Using of accessories not specified in the manual may increase electromagnetic radiation or reduce the electromagnetic immunity of i5. Use the alternative accessories and consumables of Ambulanc or those supplied by its authorized representatives.

4.1. Setting i5

1. After opening the packing box, please verify whether all goods listed on the packing list are included.

2. Be familiar with the controls and characteristics of i5. Study the functions of button, switch, indicator and connection port.

3. Place the package of defibrillator electrode according to the figure below. Please don't open the packing bag of electrode if you don't plan to use it.



Figure 40 Packing Bag Placement of Defibrillator Electrode

4. Install the battery.

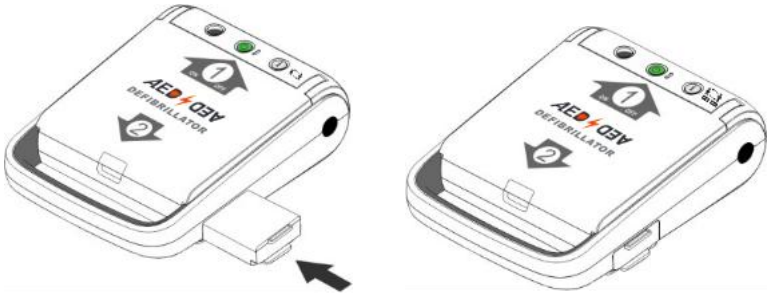


Figure 41 Battery Installation

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

After inserting the battery, i5 will start self-test automatically and comfirm that rescue operation is ready. It indicates that the battery insertion test is passed if the green light of state LED flashes.

5. If you have purchased the optional accessories, please put i5 in the suitcase.

6. Store i5 according to the emergency response plan. When storing i5, consider the following items.

- The conditions of storage area shall not exceed the environment limit of i5.
- Use the indicator for checking i5 so as to get ready for first aid.
- Place the telephone near the storage area so that you can contact with the emergency medical service.

⚠Notes:

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

4.2. CPR setting

CPR plan depends on the following setting:

CPR plan setting			
Parameter	Settings	Default value	Instruction
Exhalation Guidance	Open / Close	Open	Voice prompt for guiding breathing time
Pressing Rate (times/min)	100, 110 or 120	110	The equipment provides the compression rate so as to facilitate time setting for external chest compression.
CPR Guidance Type	Voice guide / Countdown mode	Countdown mode	Guide type during CPR. Provide gradual guide under the voice guide mode in the whole process of CPR. Count down the rest time under the pause time countdown mode till the next cycle of defibrillation.
Pressing - breathing ratio	Fixed.	30:2 (30 times of pressing and 2 times of breath)	Proportion between pressing times and breathing times.

⚠Tips:

i5 provides voice prompt (1min and 30s, 1min, 40s and 20s) of rest time under the Countdown mode till the next cycle of defibrillation (start from ECG analysis).

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

Under the Countdown mode, press the flashing blue "i" within 20s after start of CPR to choose the Voice guide mode.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

5. Defibrillation

5.1. CPR guide

If you see someone is suffering from sudden cardiac arrest, please take actions suggested in "Life chain" in AHA so as to make emergency response to sudden cardiac arrest.



Figure 42 Life Chain

1. Identify and start the emergency response system immediately.

Pat the patient's shoulder, shout at the patient and check whether there is any response.

Start the community emergency response system (for example, call 120 or ask for local similar service).

2. Carry out CPR as soon as possible.

3. Defibrillate as soon as possible: adopt i5.

The use of i5 can be summarized as three steps: after pressing the power switch,

Step 1: paste the electrode.

Step 2: if there is prompt, please press "Shock".

Step 3: Carry out CPR.

4. Carry out effective advanced life support and care to recover natural circulation.

5. Comprehensive nursing care after sudden cardiac arrest, and transfer the patient to medical institution or professional clinic.

⚠Warning:

Please don't use i5 for pediatric below 1 year old.

⚠Tips:

i5 can be used for children at the age of 1-8.

- Please use the pediatric low-energy defibrillator electrode supplied by Ambulanc for children at the age of 1-8 or the weight is less than 25Kg. (Please don't use the

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

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).

5.2. Preparation for rescue

1. Press "Start/shutdown" to start i5.

i5 starts the following indication and voice prompt (brief voice instruction) in sequence:

Status LED: Turn into blue light to indicate the self-test is started.

Buzzer: send transient and continuous buzzing.

Status LED: Turn into green light to indicate the rescue is started.

Voice prompt: " Make sure the white electrode plate has been connected to the equipment".

You will hear this voice prompt until i5 is connected with the patient.

2. Open the i5 cover.

Open the main unit cover and press the "i" button to change the adult or pediatric defibrillation mode. For example, if the patient is an adult, briefly press the "i" button until the device says "Adult mode". If the patient is a child (body weight less than 25 kg or age less than 8 years), press the "i" button until the device gives the voice prompt "Pediatric mode".



Figure 43 i5 Cover Opening

3. Take off the patient's clothes.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )



Figure 44 Patient's Clothes Taking Off

Tips:

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

4. Tear off the package of electrode.

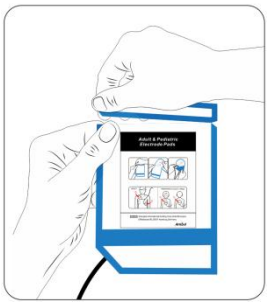


Figure 45

5. Take the electrode from the package

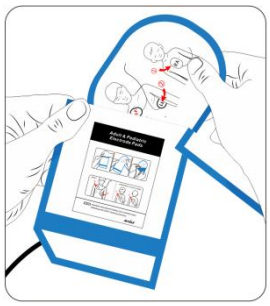


Figure 46

6. If the electrode connector is not connected with the connector port in advance, please connect it immediately.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

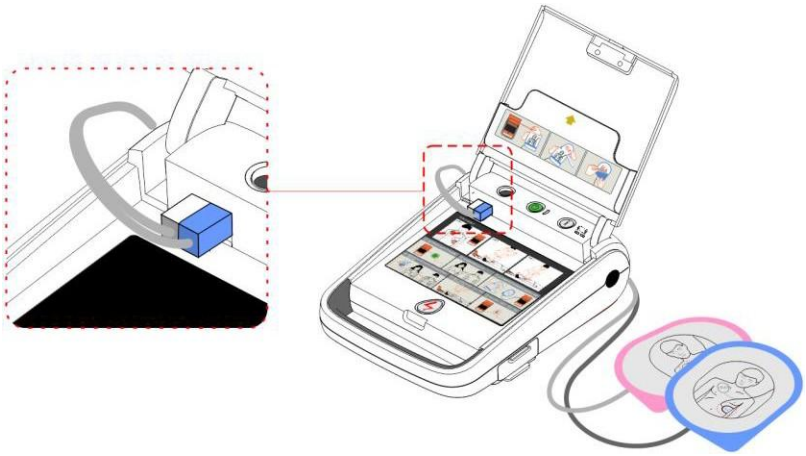


Figure 47 Electrode Connector Connecting

7. Check the figure at the back of electrode. The graph indicates the pasting position of electrode on the patient's body.

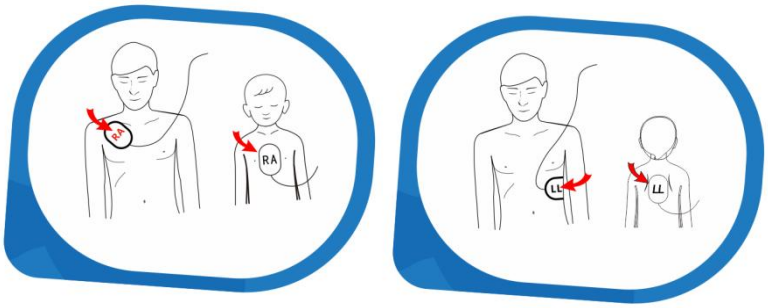


Figure 48 Adult and Child Electrode

8. Uncover the protective layer of electrode.



Figure 49

⚠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.

5.3. Main rescue sequence

Step 1: paste the electrode.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

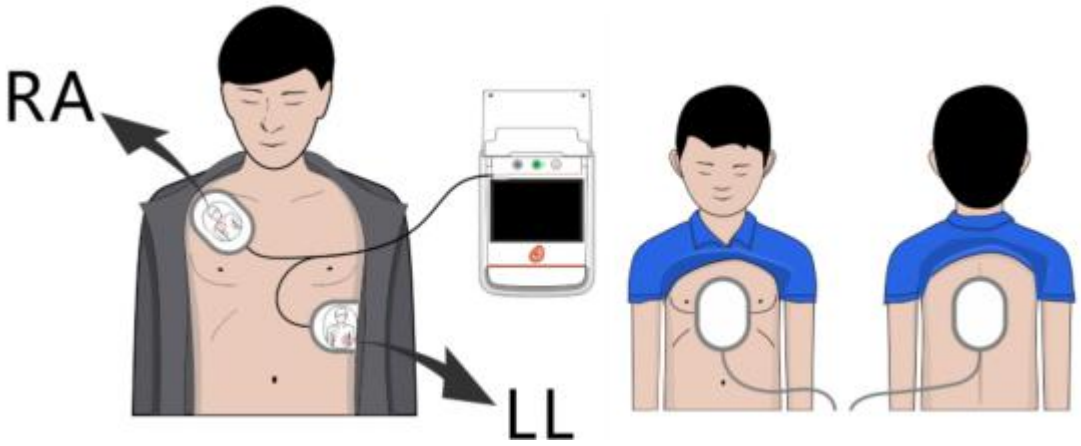


Figure 50 Electrode Pasting

If i5 senses the connection with the patient, it will prompt "Keep away from the patient".

When placing the pads, please note the following special circumstances：

- For patients with obesity, try to place the electrodes on the flat part of the chest.
- For patients with thin skin, the electrode should be placed close to the contour between the ribs and the ribs to maximize the adhesion of the electrodes to the skin.
- For patients implanted with pacemakers, the electrodes should be kept away from the generator of the implantable pacemaker. Please treat such patients as patients requiring urgent care.

⚠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 i5, 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.

深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)

Step 2: if there is prompt, please press "Shock".

i5 will start cardiac rhythm collection and analysis after being connected with the patient.

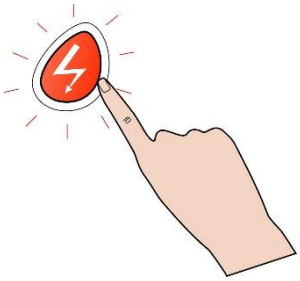
i5 will have the voice prompt "cardiac rhythm is being analyzed, please stand by side" during cardiac rhythm analysis

After cardiac rhythm analysis, i5 will determine whether the patient needs the shock.

Case I, if needed, the indication and voice prompt are shown as follows:

- Voice prompt: "Stand by side for shock. Warning! No one should touch the patient."
- Buzzer: Sends buzzing continuously till "Shock" is pressed or released within 15s.
- Voice prompt: "Press flashing orange button for shock immediately."
- Backlight of "shock": orange light flashes.

It indicates that you should press "shock" for the shock.



- If you press "shock", i5 will conduct defibrillation shock. Tell you the shock condition through voice prompt: "Shock is completed."
- If you don't press "Shock" within 15s, i5 will release automatically and enter the CPR guide. The voice prompt is: "Fail to press 'shock'.

Case II, if not needed, the indication and voice prompt are shown as follows:

- Voice prompt: "Shock is not recommended".

⚠Tips:

Though i5 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, i5 will release automatically.

⚠Warning:

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

Step 3: Carry out CPR.

i5 will guide you to carry out CPR after shock.

Please refer to the following CPR guide for other indications and voice prompt.

5.4. CPR guide

i5 provides voice guide prompt when CPR management starts.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

Brief voice instruction
Conduct shock on the ECG heart rhythm of patient or the shock is conducted already, or shock should not be conducted or no shock is conducted. • Voice prompt: "Please start CPR now". • CPR guide: convey through loudspeaker according to the CPR plan.
Detailed voice instructions
Conduct shock on the ECG heart rhythm of patient or the shock is conducted already, or shock should not be conducted or no shock is conducted. • Voice prompt: " It's safe to touch the patient. Now start CPR ". • CPR guide: convey through loudspeaker according to the CPR plan.

Press the flashing blue "i" within 20s after the start of CPR, you can switch the CPR guide mode from Countdown mode into Voice guide mode. The table below describes the guide sequence under the Voice guide mode.

Steps	Instruction	Your actions
1	Voice prompt: "Please start CPR now". Or " It's safe to touch the patient. Now start CPR".	• Put your hands between the nipples of the patient, with one hand placing on the other hand. • Press the chest by 5cm at least.
2	Compression Rate: The compression rate is 110 times/min (default value). The proportion between pressing and breathing is set as 30:2, that is, 30 compressions and 2 breaths.	• Please press the patient's chest hard timely and quickly when i5 provides t he heartbeat. 
3	Voice prompt: "Provide two breaths."	• Open the respiratory tract with the h ead inclined and the jaw upward.
4	Voice prompt: "Exhale."	• Provide two breaths. • Each breath lasts for 1s. • Each breath should be enough so a s to enable the chest to protrude obvio usly. • Provide two breaths within 5s. 
5	Circulation: Cycle the step 1-4 for 5 times.	• Cycle the CPR steps for 5 times wit hin 2min.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

⚠Warning:

- i5 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 i5 from the patient. Before using other defibrillators, please disconnect the connection between i5 and the patient.

5.5. Data storage

i5 will store the following data automatically during rescue.

- ECG data
- Rescue data, which including system power on/off,patient type, patient Impedance Range, insert/remove electrode, start/stop CPR, analyzing heart rhythm, electric shock,etc..

The data is stored in the memory of i5. The memory of i5 belongs to non-volatile equipment, so the stored data is still in the memory even i5 is shut down.

⚠Warning:

- Please don't remove the battery when i5 collects data, otherwise, you will lose the special rescue data. If it is necessary to remove the battery, please shut down i5 correctly before removal by pressing "Start/shutdown".
- i5 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.

5.6. Quick reference

The rescue measures are as follows:

1. Start up and open the cover.

2. Take off patient’s shirts.

3. Open the package of electrode and insert the electrode connector in the machine.

4. Uncover the back liner of electrode and past the two electrodes on the indication position of the patient.

5. After the prompt "heart rhythm is being analyzed" occurs, please wait and stand by side.

6. if there is prompt, please press "Shock".

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

6. Sanitary treatment

i5 shall be subjected to sanitary treatment after using to remove dirt. After sanitary treatment, please conduct the following functional inspection.

- Conduct battery insertion test by referring to Chapter 6 "Fault and its removal".
- Verify and confirm whether the green light of state LED flashes, which indicates that i5 is ready for the rescue.

Please clean i5 with soft cloth dipped with certain solution:

- Diluted soap water
- Diluted chlorine bleach and water mixture (30ml bleach/1L water)
- Diluted ammonia detergent
- Diluted hydrogen peroxide

i5 needs to be cleaned every six months.

Notes:

- Please don't soak the parts of i5 in the liquid.
- If i5 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 (especially the infrared optical filter at IrDA port).
- Please don't disinfect i5.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

7. Fault and its removal

If the fault is not removed at once, please contact with Ambulanc or the authorized distributor. To prevent unnecessary injury, please don't use the machine continuously.

7.1. Automatic test 1

i5 is subjected to the following test so as to verify and confirm that the emergency rescue is ready:

Test	Detailed information of test
Battery insertion test	Operate after battery insertion. Carry out the test in the following case: • When using i5 for the first time. • When replacing the battery. • When you doubt that i5 is damaged. Please don't perform the test when it is about to rescue, since the test may take some time. If new battery is inserted during rescue, please press "Start/shutdown" to avoid the test, wait for the shutdown of i5, press "Start/shutdown" again to start i5, and test the "shock" and "i" of i5 during the test; you should press the button one by one under the prompt of i5. If fault is not detected, the prompt is as follows: "Press the flashing orange 'i'." "Press the flashing blue 'i'." i5 will enter the standby mode, and the green light of state LED will flash. If fault is detected, i5 will prompt "System fault, press the flashing red 'i'."
Startup test	Operate after starting i5.
Operation time test	Operate after using i5 during rescue. Monitor the performance of key components.
Daily, weekly and monthly test	Operate every day, week and month so as to check the functions of important subsystem.

7.2. Equipment status

The following indicator indicates the current state of i5:

- Status LED:
- "i":
- "Shock"

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

- Buzzer

Indicator/indication	Indication
Status LED: Green light flashes	Indicate that i5 is in the standby mode and ready for rescue
Status LED: Green light is on	Indicate that i5 is being used for rescue normally
Status LED: Red light flashes	Indicate that i5 has system fault or the battery power is low in the standby state
Status LED: Red light is on "i": the red light flashes Voice prompt: "System fault, press the flashing red 'i'."	• Indicate that fault is detected by i5 during batter y insertion test. • Indicate that fault is detected by i5 in the defibril lation state
Status LED: Red light is on	Indicate that i5 detects the low battery power during working
Status LED: Blue light is on	Indicate that i5 is under the self-test
Status LED: White light is on	Indicate that i5 starts the management mode.
Status LED: Purple light flashes	Indicate that you can choose and set parameters under the management mode of i5.
Graphic rescue guide: 1	Indicate that you should connect the electrode with the patient and i5.
Graphic rescue guide: 2	i5 is analyzing the ECG of patient.
Graphic rescue guide: 3	Carry out CPR.
"i": Red light flashes	Indicate that error occurs Press "i" to obtain more information.
"Shock": Orange light flashes Buzzer: buzzing continuously.	Press "Shock" to shock the patient.

7.3. Fault removal

Carefully study the following guide, and accept the suggestions at appropriate time.

7.3.1. Fault removal during first aid

Indication	Possible reasons	Remedial action
Equipment mode: standby Status LED: Red light flashes	• The battery power is low.	• Replace i5 battery with new o ne.
	• Detect the errors of i5.	• Replace i5 with effective defib rillator. Send the failure equipme nt to the Maintenance Center fo r repair.
Equipment mode:	• The battery power	• When the battery low alarm o

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

operation Status LED: Red light is on	is low.	ccurs for the first time, i5 can provide at least 10 shocks or can work continuously for 30 minutes, please replace the i5 battery with new one. • If there is no available new battery or other defibrillators, please examine the patient and carry out CPR before EMS team arrives as needed.
Equipment mode: operation Status LED: Red light is on "i": Red light flashes	• Detect the errors of i5 • i5 cannot be used for rescue in this case.	• Carry out CPR on the patient. • Use other defibrillators. • If there is no available defibrillator, please carry out CPR before EMS team arrives.
Voice prompt: "Fail to press 'shock' ".	• Press "Shock" when you don't send the prompt of "Shock ".	• If you want to give shock to patient, please press "Shock" after receiving the prompt of "Shock".
	• You have pressed the "Shock", but it has defect.	• Replace with effective defibrillator.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

7.3.2. Fault removal in non-emergency time

Indication	Possible reasons	Remedial action
Equipment mode: standby Status LED: Red light flashes	• The battery power is low. • Detect the errors of i5.	• Press "Start/shutdown". • If the battery power is low, i5 will prompt you as follows after startup: "The battery power is low, please change battery." • If there are errors due to system fault, i5 will prompt you as follows after startup: "System fault, press the flashing red 'i'." After pressing "i", i5 will send the following prompt: " error code XXX." XXX here refers to an error code (range: 1 - 512). • If error occurs due to low battery power, please change the battery. Only the battery of Ambulanc can be used. • If error occurs due to system fault, please send i5 to the authorized maintenance center.
Equipment mode: operation Status LED: Red light is on	• The battery power is low.	• When the battery low alarm occurs for the first time, i5 can provide at least 10 shocks or can work continuously for 30 minutes, please replace the i5 battery with new one. • Only the battery of Ambulanc can be used.
Equipment mode: operation Status LED: Red light is on "i": Red light flashes	• Detect the errors of i5. • i5 cannot be used for rescue in this case.	• i5 prompts you that: "System fault, press the flashing red 'i'." • After pressing the flashing red "i", i5 will send the following prompt: " error code XXX." XXX here refers to an error code (range: 1 - 512). • Send i5 to the authorized maintenance center.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

8. Maintenance

8.1. Equipment state monitoring

i5 is in the automatic self-test under the standby mode. If the battery is inserted and the green light of state LED flashes, it indicates that i5 is in the standby state. The automatic self-test is performed every day, week and month. If fault is detected during automatic self-test, i5 will send alarm. Check the state LED of i5 periodically(every six months) so that i5 can be ready for first aid all the time.

8.2. Battery

When i5 is stored in standby mode, the battery shall be monitored.

- If the battery power of i5 is low, please change the battery.
- Ensure that the alternative battery is in the validity period.

⚠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.

8.3. Battery replacement

1. Remove the exhausted battery. Press the battery latched device and pull the battery from the slot to release the latch. As shown below.

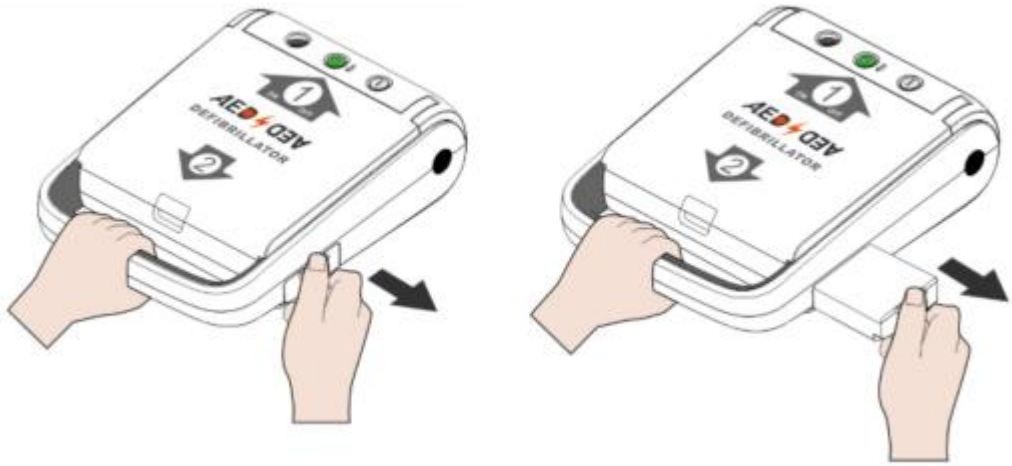


Figure 51 Battery Pulling Out

2. Insert the new battery and push it inward till the latch device has a click sound.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

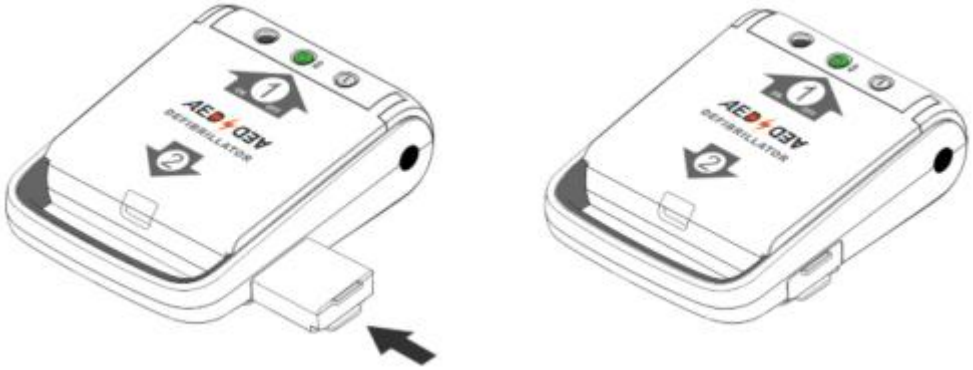


Figure 52 Battery Insertion

⚠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 i5 battery in unsafe environment.

8.4. Defibrillator electrode

When storing i5 in the standby mode, monitor the defibrillator electrodes.

- Check the validity period of defibrillator electrodes periodically. Ensure that the whole set of defibrillator electrodes stored together with i5 is not expired.
- Check the package integrity of defibrillator electrodes.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

- Check whether the electrode cable connected in advance has possible defects.

⚠Warning:

Only the electrodes supplied by the manufacturer can be used for supporting i5. Use of electrodes not specified by the manufacturer may affect the defibrillation effect.

8.4.1. Replacement of defibrillator electrodes

1. Verify and confirm whether the alternative electrode is expired or not. The tag has effective date as follows.

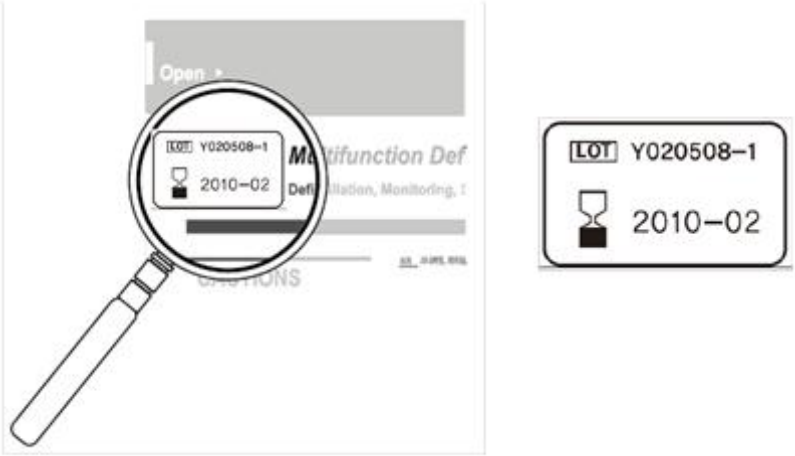


Figure 53 Effective Date of Electrode

2. Put the AED electrode on the front cover of i5, and cover the front cover.



Figure 54 Electrode Putting

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

9. i5 supply configuration

9.1. Standard configuration

No.	Name	Material code	Unit	Quantity	Remarks
1	i5 host	2.205.00001	Set	1	
2	Adult & Pediatric Electrode Pads(disposable)	5.000.01116	Bag	1	
3	Battery	2.204.00042	Piece	1	
4	i5 User Manual	1.601.00223	Piece	1	

9.2. Optional configuration

No.	Name	Material code	Unit	Remarks
1	Adult & Pediatric Electrode Pads(disposable)	5.000.01116	Bag	optional

Notes:

Configuration is subject to specific packing list.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

10. Technical parameter

10.1. Management category of medical equipment

Management category of medical equipment	
Category	Category IIb medical equipment according to 93/42/EEC Regulations

10.2. Physical specification

Dimension of complete machine	
Outline dimension	Length: 289mm Width: 217mm Height: 91mm
Weight	About 2.5Kg
Display screen	
Type	Color screen TFT
Size	7-inch
Resolution	Pixel: 800 x 480
Memory	
Memory capacity	≥16G, it can store > 1000 pieces of logs data for recording ECG and emergency activities,or > 3000 pieces of self-inspection reports. i5 has recording function,that will be automatic recording when i5 powers on. The memory capacity can store 60 minutes recording data for rescue scene (This function is optional)

10.3. Environmental specification

Working environment	
Temperature	0℃-50℃
Humidity	10%-95% (no condensation)
Air pressure	70kPa-110kPa
Storage environment (Host machine)	
Temperature	-30℃-70℃
Humidity	10%-95% (no condensation)
Air pressure	70kPa-110kPa
Storage environment (electrode pads)	
Temperature	0℃-50℃

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

Humidity	20%-80% (no condensation)

10.4. Battery specification

Battery specification	
Type	Parameter: DC 12V 4.5Ah Li-MnO2 battery Non-rechargeable model: SZAB I5DC Factory: AMBULANC (SHENZHEN) TECH. CO., LTD
Capacity	At least 300 shocks or work for 8 hours
Temperature range	Operating state: 0℃-50℃ Storage state: -30℃-70℃

10.5. Defibrillator

Defibrillator		
Classification	Nominal specification	
Operation mode	Continuous operaiton	
Waveform	Two-phase e-cube (attenuation index chopped wave type): impedance compensation	
Patient Impedance Range	0Ω~300Ω	
Output energy	See 10.6	
Charging control	Automatic control of software (arrhythmia detection system and charging control)	
Heart rhythm analysis time	Less than 5 s. (temperature 20℃)	
Energy storage and charging time	Less than 7s	Applicable to fully-charged new battery. (temperature 20℃)
Time from analysis start to shock preparation	Less than 9s	Applicable to fully-charged new battery.(temperature 20℃)
Time from startup to shock preparation	Less than 9s	Applicable to fully-charged new battery.(temperature 20℃)

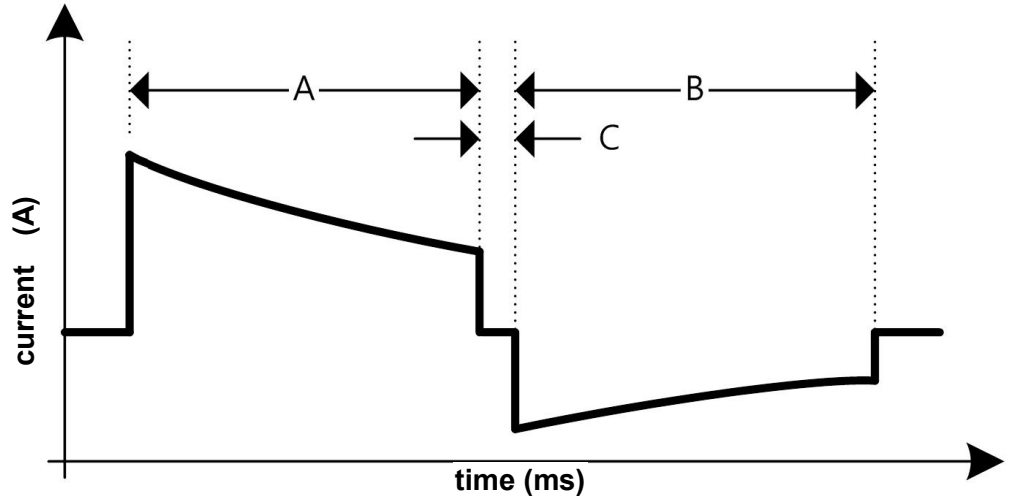
深圳市安保医疗科技股份有限公司
受控文件 副本号( )

Charging completion indication	• Voice prompt "Press flashing orange button for shock immediately." • The backlight of "Shock" flashes. • The buzzer buzzing continuously.
Time interval from CPR to shock	The time from CPR completion to shock is 6s
Released	After charging, i5 can be released automatically in the following cases: • The heart rhythm of patient is changed into non-shockable rhythm; or • Fail to press "Shock" within 15s after charging; or • Press "Start/shutdown" to shut down i5; or • Remove the defibrillator electrode or electrode connector from the patient to disconnect from i5.
Shock provision	Provide shock when pressing "Shock" after starting i5.
Shock provision carrier	Use adult defibrillation electrode in the front (Lead II) or use the low-energy pediatric electrode in front and at back.
All parts Patient isolation	Defibrillation electrode BE (defibrillation)

10.6. Output waveform of adult patient (200 J)

Adult electrode pads：

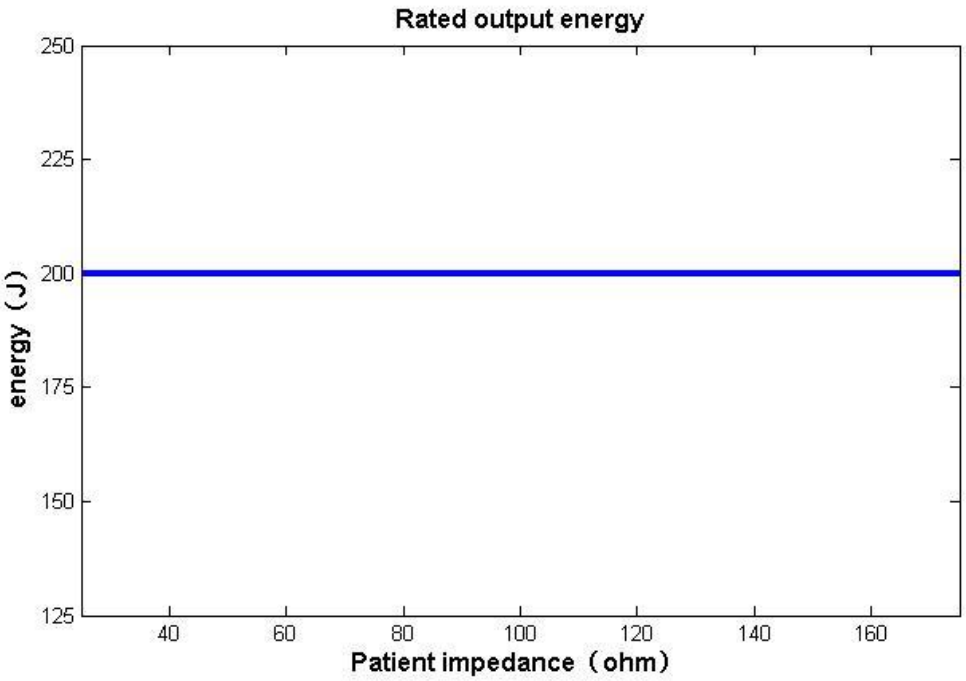
The defibrillation waveform is shown below：



Patient impedance (Ω)	Duration on Phase I ms)	Duration on Phase II (ms)	Interphase duration (ms)	Energy (J)	Energy precision （J）

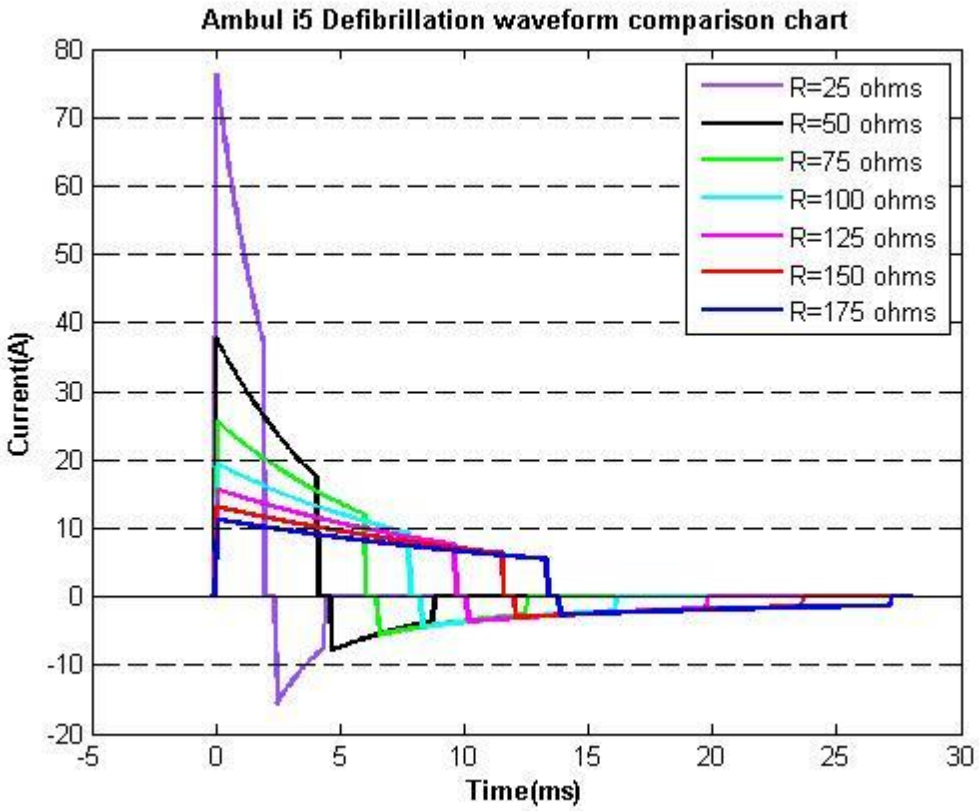
深圳市安保医疗科技股份有限公司
受控文件 副本号( )

25	1.9	2	0.5	200	200(±15%)
50	3.8	3.8	0.5	200	200(±15%)
75	5.6	5.6	0.5	200	200(±15%)
100	7.6	7.6	0.5	199	200(±15%)
125	9.3	9.4	0.5	199	200(±15%)
150	11.2	11.3	0.5	200	200(±15%)
175	13	13.1	0.5	200	200(±15%)



200J defibrillation waveform (load impedance is 25Ω, 50Ω, 75 Ω, 100 Ω, 125 Ω, 150 Ω and 175 Ω)

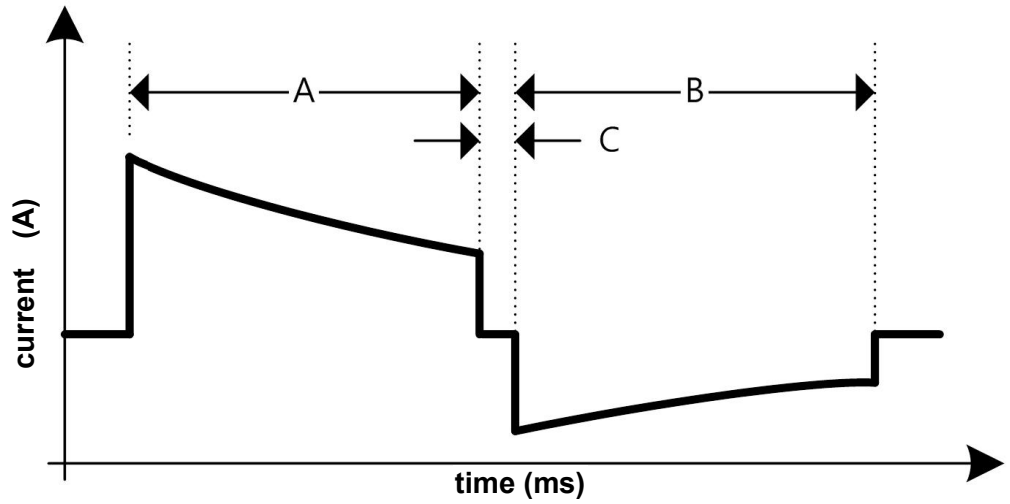
深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)



深圳市安保医疗科技股份有限公司
受控文件 副本号( )

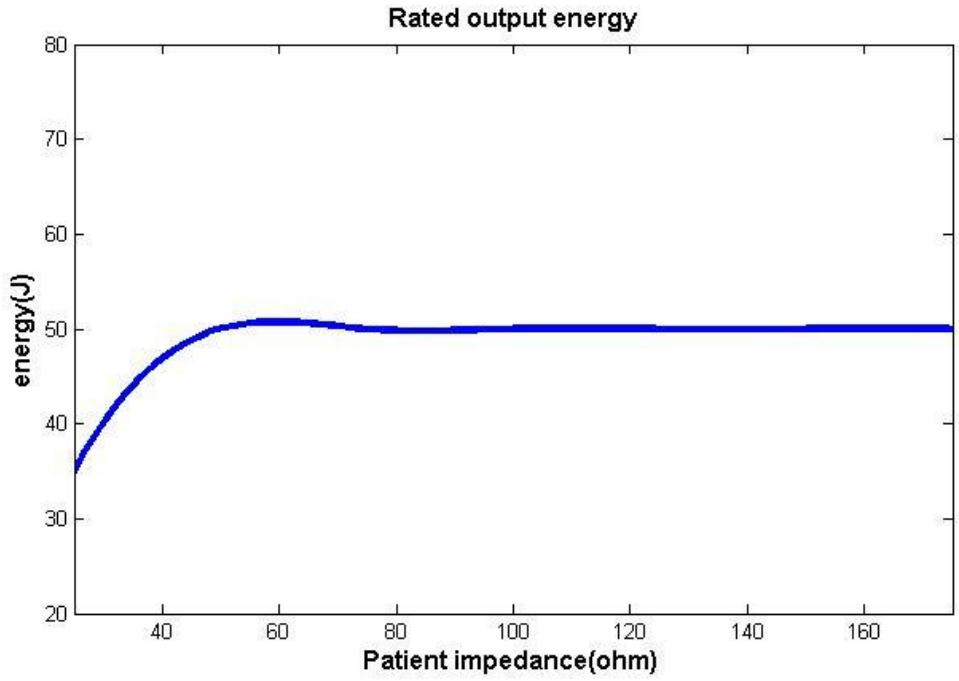
Pediatric electrode pads：

The defibrillation waveform is shown below：

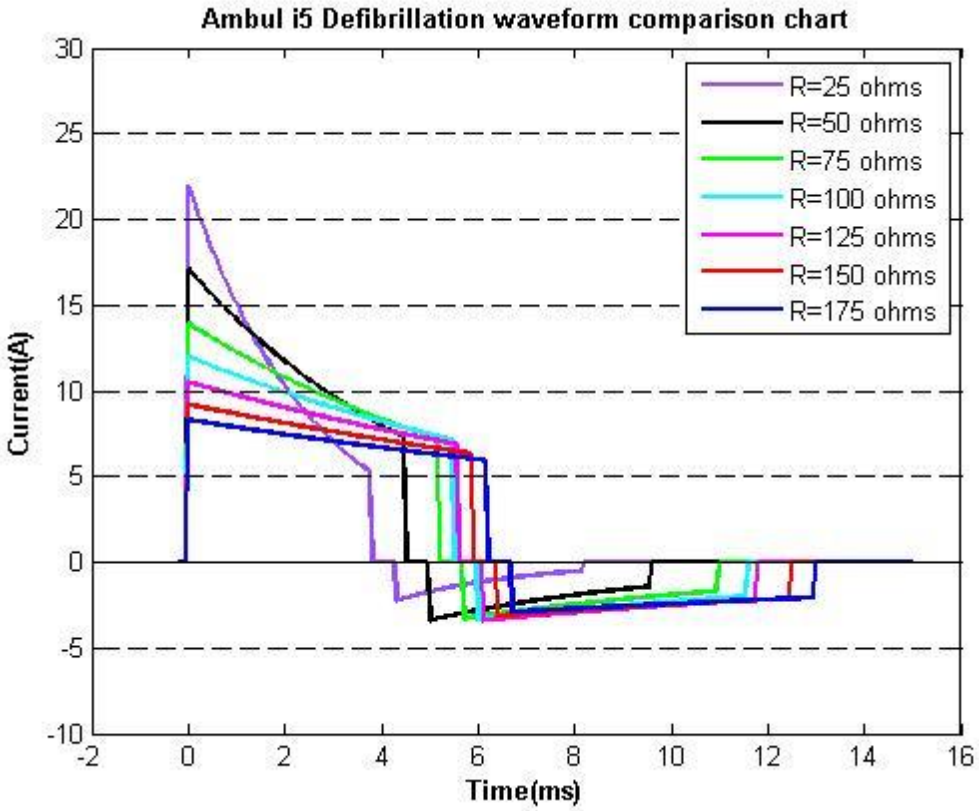


Patient impedance (Ω)	Duration on Phase I (ms)	Duration on Phase II (ms)	Interphase duration (ms)	Energy precision （J）
25	3.8	3.9	0.5	35(±15%)
50	4.5	4.6	0.5	50(±15%)
75	5.2	5.3	0.5	50(±15%)
100	5.5	5.6	0.5	50(±15%)
125	5.6	5.7	0.5	50(±15%)
150	5.9	6.1	0.5	50(±15%)
175	6.2	6.3	0.5	50(±15%)

深圳市安保医疗科技股份有限公司
受控文件　　副本号(　)



50J defibrillation waveform (load impedance is 25Ω, 50Ω, 75 Ω, 100 Ω, 125 Ω, 150 Ω and 175 Ω):



深圳市安保医疗科技股份有限公司
受控文件 副本号( )

10.7. ECG

ECG acquisition	
Classification	Nominal specification
Collected ECG lead	Lead II
Frequency response	1Hz-30Hz
ECG analysis system	
Classification	Nominal specification
Function	Determine the patient impedance and evaluate the patient's ECG so as to determine whether it is shockable.
Impedance range	25Ω - 175Ω
Shockable rhythm	Ventricular fibrillation or ventricular tachycardia
Non-shockable rhythm	ECG rhythm in addition to ventricular fibrillation or ventricular tachycardia
Analysis scheme	Prepare shock and suspend to carry out CPR, depending on the analysis result.
Sensitivity and specificity	Conform to the ANSI/AAMI DF80 / IEC60601-2-4:2010 guide.

Heart rhythm	Minimum sample size	Experimental samples	Shock decision	Non-Shock Decision	Actual performance	Target performance	Actual 90% Unilateral Confidence Lower Limit	Target 90% Unilateral Confidence Lower Limit
Coarse ventricular fibrillation	200	220	217	3	Sensitivity=98.6%	Sensitivity＞90%	97.6%	87%
Ventricular tachycardia	50	55	53	2	Sensitivity=96.4%	Sensitivity＞75%	93.1%	67%
Normal sinus rhythm	100	110	0	110	Specificity=100%	Specificity＞99%	100%	97%
asystole	100	110	0	110	Specificity=100%	Specificity＞95%	100%	92%
Other Non-shock	210	230	2	228	Specificity=9	Specificity＞	98.3%	88%

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

heart rhythm					9.1%	95%		
The Value of Real Forecast：98.18% false positive rate：0.44%								

Other Non-shock heart rhythm include:Sinus rhythm characterized by ventricular extrasystole (PVC) 、 Supraventricular tachycardia, sinus bradycardia, atrial fibrillation/flutter, cardiac conduction block, ventricular autonomic rhythm, pacemaker rhythm.

Obtain all ECG waveform test results

	VF and VT	All other ECG rhythms
Shock	270 cases	2 cases
Non-shock	5 cases	448 cases

The sensitivity of electroshock cardioversion device was as follows: A/(A+C): 98.18% (270/275)

The actual predicted value of the equipment is: A/(A+B): 99.26% (270/272)

The device specificity of non-electric cardioversion is as follows: D/(B+D): 99.56%(448/450)

The false alarm rate of electroshock cardioversion device is: B/(B+D): 0.44%(2/450)

10.8. Self-diagnosis test

Automatic	
Power-on self-test	Battery power
	Memory
	Communication between mainboard and HV board
	Charging condition of defibrillation capacitor
	Release condition of defibrillation capacitor
	Relief condition
Run time self-test	Battery power
	Communication between mainboard and HV board
	Charging condition of defibrillation capacitor
	Release condition of defibrillation capacitor
	Relief condition
Daily self-test	Battery power
	Memory
	Electrode status test (optional)

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

Weekly self-test	And daily self-test
	Charging condition of defibrillation capacitor
	Relief condition
Monthly self-test	And weekly self-test
	Release condition of defibrillation capacitor
Manual (by the user)	
Battery insertion test (finish directly when the user inserts the battery in the battery jar of equipment)	Battery power
	Memory
	Communication between mainboard and HV board
	Charging condition of defibrillation capacitor
	Release condition of defibrillation capacitor
	Relief condition
	"Shock" and "i"

10.9. Defibrillating electrode

Specification of adult defibrillation electrode	
Type	For adult (the defibrillation electrode is applicable to the patient at the age of 8 or above or the weight is heavier than or equal to 25Kg) Adhesive, disposable and non-polarized defibrillation electrode
Electrode area	About 110cm2 for each
Cable length	About 1.2m
Guarantee period	24 months (calculated since the production date)
Specification of child defibrillation electrode	
Type	For pediatric department (applicable to the children below 8 years old or in the weight of less than 25Kg) Adhesive, disposable and non-polarized defibrillation electrode
Electrode area	About 80cm2 for each
Cable length	About 1.5m
Guarantee period	24 months (calculated since the production date)

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

11. EMC

11.1. Declaration of magnetic radiation

i5 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	i5 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	i5 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	

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

i5 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) (IEC 61000-4-2)	Contact discharge: ±6kV Air discharge: ±8kV	Contact discharge: ±6kV Air discharge: ±8kV	The ground shall be wood, concrete or ceramics. If the ground is paved with composite materials, the relative humidity shall be at least 30%.
Electrical fast transient burst	To power cord: ±2kV	N/A	The power level shall be at least

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

(IEC 61000-4-4)	To long I/O cable: ±1kV		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	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%U_T(drop: ＞95%, U_T), 0.5 cycle	＜5%U_T(drop: ＞95%, U_T), 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%U_T (60% drop, U_T), 5 cycles;	40%U_T (60% drop, U_T), 5 cycles;	
	70%U_T (30% drop, U_T), 25 cycles; ＜5%U_T (drop: ＞95%, U_T), 5s;	70%U_T (30% drop, U_T), 25 cycles; ＜5%U_T (drop: ＞95%, U_T), 5s;	

11.3. Declaration on guide and manufacturer - Electromagnetic immunity

The purchaser or user shall use i5 in the following specified electromagnetic environment:

Immunity test	IEC 60601 test level	Conformance level
RF transmission IEC6100-4-6 RF radiation IEC6100-4-3	3V (effective value) 150kHz-80MHz (except the medical engineering frequency band[a])	3V (effective value)
	10V (effective value) 150kHz-80MHz (the medical	10V (effective value)

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

	engineering frequency band[a])	
	10V/m 80 MHz-2.5 GHz	30V/m

Electromagnetic environment guide

The portable and mobile RF communication equipment shall not be used near i5 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

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

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 i5 is higher than the RF conformance level, observe i5 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 i5.

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

11.4. Recommended isolation distance

i5 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 i5.

Recommended isolation distance between the portable and mobile RF and i5 anfangcommunication equipment and i5				
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-800 MHz $d = 0.4\sqrt{P}$	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.				

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

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.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

12. Descriptions for classification of toxic and harmful substance

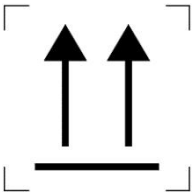
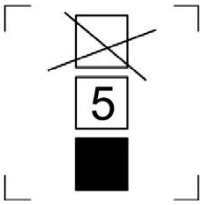
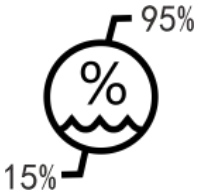
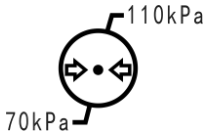
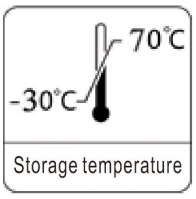
Name and content of toxic and hazardous substance or element							
Document name		**Cadmium Cd**	**Mercury Hg**	**Plumbum Pb**	**Hexavalent chromium Cr(VI)**	**Polybrominated biphenyls PBB**	**Polybrominated diphenyl ethers PBDE**
Battery		×	×	×	×	×	×
Packaging materials		○	×	×	○	×	×
Host	PCBA	○	○	×	○	○	○
	Internal connecting line	○	○	○	○	○	○
	Machined parts	○	○	○	×	○	○
Machine casing	Button	○	○	○	○	○	○
	Label	○	○	○	○	○	○
	Front casing	○	○	○	○	○	○
	Rear casing	○	○	○	○	○	○
Appendix	Power cord	○	○	○	○	○	○
	Connecting part	○	○	○	×	○	○

×: Represent that at least the content of hazardous substance or element exceeds the limit requirement of SJ/T11363-2006 in a certain homogeneous material of the parts.
○: Represent that at least the content of hazardous substance or element is within the limit requirement of SJ/T11363-2006 in all homogeneous materials of the parts.

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

13. Storage and transportation

Packed products can be transported through highway, aviation or railway. Prevent impact and violent vibration during transportation. See the instruction in table below:

Graph and symbol	Description	Graph and symbol	Description
	Upward		Handle with Care
	Keep Dry		Limit of stacking layers: 5
	Temperature range: 15%-95%		Pressure range: 70kPa-110kPa
	Storage temperature: -30-70℃		

⚠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 8h

深圳市安保医疗科技股份有限公司
受控文件 副本号( )

AMBULANC(SHENZHEN)TECH.CO.,LTD

Add: 3th Floor,Block C,Building #5,Skyworth Innovation Industry Park,Tang Tou 1st Road,Shiyan,Baoan District,518108 Shenzhen,China
Tel: +86-755 26072210 Fax: +86-755 23016012
Web site: www.amoulmed.com E-mail:manager@amoulmed.com

深圳市安保医疗科技股份有限公司
受控文件 副本号( )