Product Name: Automatic External Defibrillator

Product Model: F3 /F5

Company Name: Shenzhen Comen Medical Instruments Co., Ltd.

Address: Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China.

Introduction

This document summarizes the product's safety and performance information.

1.1 Safety Information

⚠ Danger

- Indicates an imminent danger that, if not avoided, may result in death, serious personal injury, or property damage.

⚠ Warning

- Alerts you to situations that may result in serious consequences or adverse events or endanger personal safety. Failure to observe the warning information may cause severe injury or even death of the user or patient.

⚠ Caution

- Alerts you to potential dangers or unsafe operations, which, if not avoided, may result in minor injury, product failure or damage, or property damage, or cause more serious injury in the future.

⚠ Note

- Emphasizes important considerations and provides instructions or explanations for better use of the product.

⚠ Danger

- The defibrillator generates high voltage during defibrillation, which may cause serious injury or death. Therefore, the defibrillator must be used by or under the guidance of professional clinicians. Personnel using this defibrillator must have adequate training. Any unauthorized or personnel without training shall not perform any operations.
- Do not open the housing of the defibrillator to avoid potential hazards of electric shock. Any repairs and upgrades to the defibrillator must be performed by service personnel trained and authorized by Comen.
- Do not use the device in an oxygen-rich environment, or in an environment where flammable and explosive materials such as anesthetics are stored, to avoid explosion or fire.
- During defibrillation, the operator shall not come into contact with the patient, the supporting table or the device. Before reusing the cables, confirm that their functions are normal.

⚠ Warning

- Before using, the user must check the device and its accessories to ensure that they can work properly and safely.
- Do not conduct therapy on patients lying on wet ground.
- When conducting therapy on patients with a pacemaker, the defibrillation electrodes shall be placed away from the pacemaker.
- Alarm volume and high/low alarm limits should be set depending on the patient. When a patient is monitored, do not exclusively rely on the audible alarm system. If the alarm volume is set too low or is completely turned off, the alarm will not be heard, and the patient may be put in danger. Paying close attention to the patient's actual clinical conditions is the most reliable monitoring method.
- Observe the local laws and regulations or the waste disposal rules of the hospital when disposing of packaging materials. Keep the packaging materials out of the reach of children.
- Do not use the device in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- To ensure safety, avoid stacking multiple equipment or placing anything on the defibrillator during operation.
- Carefully place accessory cables to avoid entanglement, potential strangulation, and electrical interference to the patient.
- To avoid the risk of electric shock, please remove the sensor connected and completely disconnect the device before cleaning.
- For patients with pacemakers, the cardiotachometer may be used to record pacemaker pulse in the event of asystole or arrhythmia. Do not completely rely on the alarm function of the cardiotachometer. Patients with pacemakers must be closely monitored. For the pacemaker inhibiting function of the device, please refer to the relevant section in this Manual.
- Keep the patient under close surveillance when using this device to conduct therapy. If the shock is delayed, the shockable rhythm may change to non-shockable rhythm, leading to delivering an incorrect shock.
- Any equipment without defibrillation protection shall be disconnected from the patient during defibrillation.
- During defibrillation the operator should not come into contact with the patient, the monitor or the supporting table.
- Before reusing the cables, confirm that their functions are normal.
- In order to avoid burns (resulting from electrical leakage) to the patient, ensure that the device's sensors and sensor cables never come into contact with any high-frequency electrosurgical equipment.
- The physiological waveform and parameter, alarm message and other information displayed by the device are only for reference by physicians, and not directly used as a basis for clinical treatment.
- Electromagnetic fields can affect the performance of this device. Therefore, equipment used in the vicinity of this device must meet the corresponding EMC requirements. For example, mobile phones and X-rays are potential sources of interference since they all transmit high-intensity electromagnetic radiation.
- In normal use, please do not touch the signal I/O port, other live equipment, and the patient simultaneously, otherwise the patient may be injured.

- Do not use the device in an MRI environment.
- After defibrillation, the waveform baseline will recover within 2s.
- The user must not make any modifications to the equipment.
- The operating as well as the transportation and storage environment of this device must comply with the environmental specifications in this User Manual, otherwise the device's precision may be affected.
- Do not repair or maintain the device when it is being used.
- Only approved analog or digital equipment in accordance with the specified IEC standards (like IEC 60950 safety standards for Information Technology Equipment, IEC 60601-1 safety standards for medical electrical equipment, etc.) are allowed to be connected to the device. All configurations should comply with the valid version of the standard IEC 60601-1. Personnel who connect external equipment to the signal I/O ports of the device should verify that medical system complies with IEC 60601-1 requirements, before configuring the medical system and connecting the external equipment. If there is any doubt, please contact our company.
- If more than one piece of equipment is connected to the device at one time through the patient cable connector, network connector or other signal ports, the total leakage current caused must comply with the requirement specified in IEC 60601-1.
- If the use of the device is delayed or interrupted during a first aid process, implement CPR treatment for the patient first.
- Defibrillation may cause myocardial injury. Select an appropriate energy for the patient, especially for pediatric patients.
- Any serious incident that has occurred in relation to the device should be reported to Comen and the competent authority of the Member State in which the user and/or patient is established.

⚠ Caution

- To avoid instrument damage and ensure the patient's safety, only use the accessories specified in this user manual.
- Please install or handle the instrument carefully to avoid damage caused by dropping, collision, strong oscillation or other external mechanical forces.
- Before powering on the device verify that the supply voltage and frequency conform to the requirements specified on the nameplate or in this manual.
- At the end of the service life of the device and the accessories, they must be disposed of in accordance with relevant local laws and regulations or the hospital's rules and regulations. When disposing of the device, please remove the battery, otherwise there may be a risk of electric shock.
- Dry the device immediately if it is exposed to rain.
- Check the cables and functional accessories periodically. If there is any sign of aging or damage, please stop using them immediately.

⚠ Note

- Place the device at a position where observation, operation and maintenance are convenient and not obstructed.

- This manual is based on the maximum configuration; therefore, some contents may not be applicable to your device.
- Keep this user manual available for easy and convenient reference.
- The device is not intended for home use.
- The device can only be used for one patient at a time.
- In normal use, the operator must be positioned within one meter of the device.

1.2 Installation

Warning

- This device must only be installed by personnel specified by the company.
- With copyright reserved, any person shall not falsify, photocopy or exchange the software in any manner whatsoever without the prior written permission of the company.
- When the device is connected with other electrical equipment for a specific function, if users cannot confirm the combination is without risk (for example, the electric shock hazard caused by the accumulated leakage current) from the specifications of each equipment, please contact a specialist from Comen or the hospital to ensure the combination is safe.

Note

- Condensation means gas or liquid condenses when it cools. For example, water vapor is changed into water when it cools, and the water is changed into ice when it cools. The lower the temperature, the faster the condensation goes.

Note

- Do not damage the packaging of defibrillation electrodes. If the package is damaged, please replace the defibrillation electrodes immediately.

Warning

- If there is any evidence of failure or any error messages are displayed, disconnect the device from the patient. Contact a service technician of Comen.

Note

- When the defibrillator is transferred from the minimum or the maximum storage temperature to an ambient temperature of 20 °C, it takes 10 minutes for the device to achieve its intended use.

1.3 Alarms

Warning

- Use of different configurations on different devices in one area (e.g., ICU or OR) may cause potential danger.

Note

- The device retains the latest alarm settings in the event of power loss, and the settings shall not change with the duration of the power interruption.

Note

- The status indicator will light up in red if a fault is detected in auto-test.

Warning

- When multiple alarms of different levels are triggered simultaneously, the device will activate the warning sound and light for the highest level alarm, and the alarm text messages are displayed in turn.
- Certain physiological alarms, such as asystole and respiratory arrest, are exclusive. The sound and light expression of this type of alarm is the same as that of the high-level alarm, but the alarm information is displayed in an exclusive manner, that is, when the general physiological alarm and the exclusive physiological alarm occur simultaneously, only the text alarm information of the exclusive physiological alarm is displayed.

Note

- The pressure level of alarm sound generated by the device is 45-85db.
- The alarm sound for special system alarms is set to be high and cannot be changed by the setup of alarm volume.

Warning

- If the alarm volume is turned off, the device cannot sound an alarm if a new alarm is generated.

Therefore, you should be careful with this operation.

- Do not rely only on the audible alarm. Otherwise, the patient's safety may be at risk if the alarm volume is low. Pay close attention to the patient's actual clinical conditions.

⚠ Note

- If alarm reset is activated and a new alarm occurs, the alarm is generated normally.

⚠ Warning

- Make sure the current alarm limits are applicable to the current patient before monitoring.
- When setting upper and lower alarm limits, make sure the patient type (ADU or PED) is correct.

1.4 Configuration Management

⚠ Note

- The configuration in [Edit Config.] can only be changed under the guidance of authorized personnel.

⚠ Note

- Configurations such as date, time and language and items in network setup cannot be reset to factory default.

1.5 AED

⚠ Danger

- Do not conduct defibrillation in the presence of oxygen-rich atmospheres to avoid fire or explosion. When conducting defibrillation on a patient with an oxygen catheter, place the oxygen catheter correctly.
- During defibrillation, do not allow the defibrillation electrodes to touch each other or touch the ECG electrodes, lead wires, dressings, etc. Otherwise electrical arcing and patient skin burns could occur.
- Before shock, make sure that no one is in contact with the patient and any equipment (including the bed or stretcher) connected with the patient to avoid potential injury and death.
- During defibrillation, do not touch the patient, conductive liquid or any metal to avoid forming a

current path.

⚠Warning

- During defibrillation, any bubbles in the conductive gel between the electrodes and the patient's skin will cause patient skin burns. Make sure that the pads are tightly placed against the patient's skin to avoid bubbles.
- Do not use the defibrillation electrodes if they are dry. Use the electrodes immediately after unpacking them.
- Do not use expired defibrillation electrodes.
- AED is only applicable to patients more than eight years old. Only conduct defibrillation on children below 8 years of age in manual defibrillation mode.

⚠Caution

- For the patients with pacemaker, the sensitivity and specificity of AED analysis may be lower.
- Improper handling of the pads during storage or before use will damage the defibrillation electrodes. Do not use damaged electrodes.
- Dispose of expired or damaged accessories in accordance with local laws or relevant regulations of the hospital.

⚠ Note

- Keep the patient still during cardiac rhythm analysis in order to prevent misdiagnosis and delayed diagnosis.
- The electric shock is only delivered after the Shock button is pressed.
- High levels of impedance could have a great impact on the patient's therapy. If a prompt message [High Impedance. Cancel Shock.] appears, please check whether the patient's skin is prepared correctly. If the prompt message is still present, please replace the defibrillation electrodes.
- For safety reasons, certain heart rhythms with low amplitude or low frequency and some ventricular fibrillation rhythms may not be recognized as shockable rhythms.

⚠Warning

- CPR metronome doesn't indicate the current condition of the patient. The operators should assess the patient's condition constantly because the patient's condition may vary in a very short period.
- Do not perform CPR on patients with response and normal breathing.

⚠ Note

- CPR metronome can be affected by the on/off state of the AED voice prompt and the settings of voice volume.

1.6 Manual Defibrillation

⚠ Danger

- Do not conduct defibrillation in the presence of oxygen-rich atmospheres to avoid fire and explosion. When conducting defibrillation on a patient with an oxygen catheter, place the oxygen catheter away from the defibrillation electrodes.
- During defibrillation, do not allow the defibrillation electrodes to touch each other or touch the ECG electrodes, lead wires, dressings, etc. Otherwise, electrical arcing and patient skin burns could occur.
- Before shock, make sure that no one is in contact with the patient and any equipment (including a bed or stretcher) connected with the patient to avoid potential injury and death.
- During defibrillation, do not touch the patient, conductive liquid or any metal to avoid forming a current path.

⚠ Warning

- To ensure personal safety, do not attach the defibrillation electrodes to your body to verify whether the electrodes are correctly connected.
- Do not use the electrodes if the packaging or the electrodes show signs of damage or the electrode service life has expired.

⚠ Caution

- Before defibrillation, any medical device which has no defibrillation protection shall be disconnected from the patient.

⚠ Note

- High levels of impedance could have a great impact on the patient's therapy. If a prompt message [High Impedance. Cancel Shock.] appears, please check whether the patient's skin is prepared correctly. If the prompt message is still present, please replace the defibrillation electrodes.
- Successful resuscitation is dependent on the patient's physiological conditions and the circumstances on site. Failure to revive a patient does not necessarily indicate a problem in device performance. The muscular response of the patient during defibrillation is not a reliable indicator of energy delivery.

⚠ Note

- A 200J energy level is recommended for defibrillation for an adult.
- Use pediatric defibrillation electrodes for patients below 8 years of age. If no pediatric electrodes are available, set the patient type to pediatric and apply the adult defibrillation electrodes as instructions on the screen.
- The user can choose ECG lead wires to conduct ECG monitoring during defibrillation and any available lead can be selected to display.

⚠ Note

- The alarms will be enabled automatically after entering synchronized cardioversion.
- If the R wave is not detected in 5 seconds, the prompt message [R Wave Not Detected] will be displayed in the defibrillation information area.

⚠ Note

- The defibrillation can be conducted when the contact impedance is high. To achieve better therapy, it is recommended to conduct defibrillation when the contact impedance is normal.

⚠ Warning

- Only use detergents and disinfectants recommended in this manual. Using other detergents and disinfectants may result in damage to the equipment or other risks.
- Do not use EtO (ethylene oxide) to disinfect the device.
- Do not leave any disinfectant residue on the surface and accessory of the monitor. Use a wet cloth to clean it immediately.
- It is not allowed to use a detergent mixture; otherwise hazardous gases may be generated.
- This chapter only introduces the methods for cleaning reusable accessories. Disposable accessories should not be reused after cleaning and disinfection to avoid cross infection.
- To protect the environment, disposable accessories must be recycled or properly disposed of.
- After cleaning, if the sensor cable is damaged or shows any evidence of ageing, it should be replaced with a new cable.
- High-temperature sterilization of the device and all accessories is not allowed.
- Do not use any cleaning solution that is not recommended in this manual; failure to do so may result in permanent damage to the equipment, sensor or cable.
- Do not soak the sensor or connector in any solution for cleaning or disinfection.
- If you accidentally pour liquid on the device or accessories, please contact the maintenance personnel immediately.

⚠ Warning

- If the hospital or agency who uses this device does not follow a satisfactory maintenance schedule, the device may become damaged and personal safety may be endangered.
- If the device is affected by moisture, please place the device in a well-ventilated environment and contact the maintenance personnel or the company immediately.
- When the device is connected to a patient, do not conduct any functional inspection and maintenance to avoid potential electric shocks.

⚠ Note

- When the device is turned off, auto test can be performed only when the battery is installed.

⚠ Warning

- Make sure that the patient is not connected to the device when conducting a user test.

⚠ Warning

- Do not disassemble or modify this device and accessories.

1.7 EMC

⚠ Warning

- The F3/F5 Automatic External Defibrillator must not be used close to or stacked with other equipment. If it must be used close to or stacked with other equipment, observe and verify that it can operate normally for the configuration used.
- Except for the cables sold by the manufacturer of the F3/F5 Automatic External Defibrillator as spare parts of internal components, the use of accessories and cables other than those specified may result in an increase in the emission or a decrease in electromagnetic immunity of the F3/F5 Automatic External Defibrillator.
- Operation of the F3/F5 Automatic External Defibrillator below the minimum amplitude or minimum value specified in the product specifications may cause inaccurate consequences.
- Even if other equipment meets the emission requirements of the corresponding national standards, the F3/F5 Automatic External Defibrillator may still get interference from other equipment.

⚠ Note

- The F3/F5 Automatic External Defibrillator complies with the relevant requirements for electromagnetic compatibility of IEC 60601-1-2 and IEC 60601-2-4.
- Users must install and use the electromagnetic compatibility information provided in the accompanying documents.
- Portable and mobile RF communication equipment may affect the performance of the F3/F5 Automatic External Defibrillator. Avoid strong electromagnetic interference when using, such as near mobile phones, microwave ovens, etc.
- See the Annex for the guidance and manufacturer's declaration.

1.8 Cybersecurity

⚠ Warning

- Improper use of the automatic external defibrillator could cause hazards to patients and device performance.
- For embedded device, the security update is integrated with the software application program update. The update is only allowed locally by authorized users.
- When the automatic external defibrillator reaches the end of service, do erase patient data and configuration data before enforcing disposal policy.
- Before connecting the automatic external defibrillator to other instruments, ensure that any connected device is free of malware.

⚠ Note

- The automatic external defibrillator is intended to be used in professional healthcare facilities by professional healthcare personnel.
- No software installation required for the embedded device.
- We will make available on request of software bill of materials.

⚠ Note

Steps that can be taken to safeguard this information and the general security of the automatic external defibrillator:

- Physical Access: Limit use of the defibrillator to authorized users. Keep the device under physical control.
- Active Use: Users of the defibrillator should take measures to limit patient data storage. Patient data should be removed from the defibrillator after a patient is discharged and patient monitoring has ended.
- Network Security: The facility must take measures to ensure the security of any shared network to

which the defibrillator may be connected to.

- Device Security: Only connect the device to the manufacturer indicate compatible and ensure that any connected device is free of malware.
- Keep the device updated.
- Use good password.
- Act on or follow-up on alerts, inconsistencies, strange behavior of a device and let the responsible organization (Health Delivery Organizations, HDOs) knows.

Chapter2 **Performance Information**

1). Product Classification

Name	Type	
Type of protection against electric shock	Internally powered	
Degree of protection against electric shock	Type CF applied part	ECG
	Type BF applied part	Defibrillation
Degree of protection by enclosure	IP55	
Mode of operation	Continuous operation	
Mobility	Portable	
Degree of explosion protection	Not category AP/APG	

2). Environmental Specifications

Name		Type	
Operating environment	F5/F3	Ambient temperature	0 °C~50 °C (The device can work for at least 60min after entering an environment of -20°C from room temperature.)
		Relative humidity	0%~95%, non-condensing
		Atmospheric pressure	570 hPa~1062 hPa
	Charger Station	Ambient temperature	0 °C~45 °C
Transient operating environment		Ambient temperature	-20°C ~50°C (-20°C Normal work for 1 hour)
		Relative humidity	0%~95%, non-condensing
		Atmospheric pressure	570hPa~1062hPa
Transportation and storage environment		Transportation and storage temperature	-30 °C~70 °C
		Relative humidity	0%~95%, non-condensing
		Atmospheric pressure	570 hPa~1062 hPa
		During the transportation, the device must be protected from severe shock, vibration, and rain and snow.	

3). Physical Specifications

Model	Size (length × width × height)	Weight
F5/F3	295mm×210mm×75.6mm	≤2.6kg

Item	Size (length × width × height)
Battery	160mm×78mm×26.5mm

4). Battery Specifications

Name	Type		
Rechargeable battery (a new fully-charged battery at an ambient temperature of 20 °C)			
Battery type	Rechargeable lithium-ion battery		
Battery specification	CMLI2X4I003B: 14.4 V⎓ 5000 mAh		
Charging time	Charge the battery with the charger station: it takes less than 2 hours to charge to 90% and less than 3 hours to charge to 100%.		
Operating hours	**Operating mode**	**Operating hours**	**Test condition**
	ECG monitoring	Not less than 12h	The screen is in low-light mode, the wireless function is disabled, defibrillation charging and discharging are not performed, and recording is disabled.
	Defibrillation	Not less than 310 times of discharge	200J, with a charge and discharge frequency of 3 times/min
	Defibrillation	Not less than 210 times of discharge	360J, with a charge and discharge frequency of 3 times/min
Battery capacity meter	There is a multi-segment LED battery level indicator on the battery that can be used to quickly assess battery power.		
Low battery alarm	After the alarm occurs, ECG monitoring can be performed continuously for 30 min (operating conditions are as follows: the screen is in low-light mode, the wireless function is disabled, defibrillation charging and discharging are not performed, and audio is turned off), and at least ten times of 200 J defibrillation discharge or at least six times of 360 J defibrillation discharge can be performed.		
Disposable battery (a new fully charged battery at an ambient temperature of 20 °C)			
Battery type	Disposable maintenance-free non-rechargeable battery		
Battery specification	CMLM3X4I001B: 12 V⎓ 4200 mAh CMLM1X5I001B: 15 V ⎓5600 mAh		
Operating hours	**Operating mode**	**Operating hours**	**Test condition**
	ECG monitoring	Not less than 12h	The screen is in low-light mode, the wireless function is disabled, defibrillation charging and

			discharging are not performed, and recording is disabled.
	Defibrillation	Not less than 310 times of discharge	200J, with a charge and discharge frequency of 3 times/min
	Defibrillation	Not less than 210 times of discharge	360J, with a charge and discharge frequency of 3 times/min
Battery capacity meter	There is a battery power indicator on the screen, which can be used to quickly evaluate the battery power		
Low battery alarm	After the alarm occurs, ECG monitoring can be performed continuously for 30 min (operating conditions are as follows: the screen is in low-light mode, the wireless function is disabled, defibrillation charging and discharging are not performed, and audio is turned off), or at least ten times of 200 J defibrillation discharge or at least six times of 360 J defibrillation discharges can be performed.		
Battery standby life	Time	Test condition	
	> 4 years	20 °C±5 °C ambient temperature, a new battery installed in the device without turning on the device, daily self-test performed and no self-test results are transmitted.	
	> 3 years	20 °C±5 °C ambient temperature, a new battery installed in the device without turning on the device, daily self-test performed and self-test results are transmitted once a week via Wi-Fi/ cellular mobile network.	
	> 2 years	20 °C±5 °C ambient temperature, a new battery installed in the device without turning on the device, daily self-test performed and self-test results are transmitted every day via Wi-Fi/ cellular mobile network.	

5). Other Specifications

Name	Type
Voltage, frequency and current of the charger station	AC: 220V, 50HZ/60HZ±1HZ, 1.0-0.5A DC: 12V, 6A
Access control	Enter the maintenance menu with the password provided by the supplier or administrator to modify the setup to modules.

6). Display Specifications

Name	Type
Screen type	TFT display screen

Operating mode	Automatic, Indoor, and Outdoor. In the automatic mode, the device automatically adjusts the screen brightness according to the ambient light.
Size	7 inch
Resolution	800 pixels × 480 pixels
Waveform	1 waveform

7). Data Management

Name	Type
Data storage	512MB
Patient file	Up to 100 files
Waveform storage	Up to 8 hours of continuous ECG waveform
Event record	Support storage of 1500 alarm events and event annotations
Self-test reports	1500 files
Recording time	Up to 3 hours
Data export	The data can be exported through USB flash drives.

8). Network Specifications

Name	Type
Device interface	Type: USB port; quantity: ≥1; protocol: USB protocol
Wired/wireless communication protocol	TCP/IP
WI-FI	
Modulation type	IEEE802.11 a/b/g/n
Transmission frequency	IEEE 802.11b/g/n (2.4G): 2.412GHz ~ 2.472GHz IEEE 802.11a (5G): 5.18GHz ~ 5.24GHz, 5.745GHz ~ 5.825GHz
Frequency characteristic	IEEE 802.11b/g/n (2.4G) :2400 MHz~2500 MHz IEEE 802.11a (5G): 4900 MHz~5845 MHz
Cellular mobile network (2G/3G/4G)	
Modulation type	3GPP E-UTRA Release 11: LTE-FDD/LTE-TDD/WCDMA/TD-SCDMA/CDMA/GSM
Transmission frequency	LTE-FDD B1: 1920MHz ~ 1980MHz, 2110MHz ~ 2170MHz LTE-FDD B3: 1710MHz ~ 1785MHz, 1805MHz ~ 1880MHz LTE-FDD B5: 824MHz ~ 849MHz, 869MHz ~ 894MHz LTE-FDD B8: 880MHz ~ 915MHz, 925MHz ~ 960MHz LTE-TDD B38: 2570MHz ~ 2620MHz LTE-TDD B39: 1880MHz ~ 1920MHz LTE-TDD B40: 2300MHz ~ 2400MHz LTE-TDD B41: 2555MHz ~ 2655MHz

	CDMA BC0: 824MHz ~ 849MHz, 869MHz ~ 894MHz WCDMA B1: 1920MHz ~ 1980MHz, 2110MHz ~ 2170MHz WCDMA B8: 880MHz ~ 915MHz, 925MHz ~ 960MHz TD-SCDMA B34: 2010MHz ~ 2025MHz TD-SCDMA B39: 1880MHz ~ 1920MHz EGSM900: 880MHz ~ 915MHz, 925MHz ~ 960MHz DSC1800: 1710MHz ~ 1785MHz, 1805MHz ~ 1880MHz
Frequency characteristic	Bandwidth: 1.4/3/5/10/15/20 MHz
Radiated power	Class 3 (23dBm±2dB) for LTE FDD Class 3 (23dBm±2dB) for LTE TDD Class 2 (24dBm+1/-3dB) for TD-SCDMA Class 3 (24dBm+1/-3dB) for WCDMA Class 3 (24dBm+2/-1dB) for CDMA BC0 Class E2 (27dBm±3dB) for EDGE 900MHz Class E2 (26dBm±3dB) for EDGE 1800MHz Class 4 (33dBm±2dB) for EGSM900 Class 1 (30dBm±2dB) for DCS1800
Cellular mobile network (5G)	
Modulation type	3GPP Release 13, 3GPP Release 14: LTE-Cat NB1
Transmission frequency	B1: 1920MHz ~ 1980MHz, 2110MHz ~ 2170MHz B3: 1710MHz ~ 1785MHz, 1805MHz ~ 1880MHz B5: 824MHz ~ 849MHz, 869MHz ~ 894MHz B8: 880MHz ~ 915MHz, 925MHz ~ 960MHz B20: 791MHz ~ 821MHz, 832MHz ~ 862MHz
Radiated power	23 dBm ±2 dB

9). Defibrillation Specifications

Name	Type
Applicable standards	IEC 60601-2-4
Defibrillation mode	Manual asynchronous defibrillation, synchronous defibrillation and AED defibrillation
Defibrillation waveform	BTE waveform. Waveform parameters can be automatically compensated according to patient impedance.
Defibrillation electrode type	The multi-function defibrillation electrodes support adult/pediatric type, and the type of the multi-functional electrode pad can be automatically identified.
Shock delivery	Deliver a shock through the multi-function defibrillation electrodes
Local synchronous discharge delay	Less than 60ms (from the R wave spike)
Energy output accuracy	Under 25, 75, 100, 125, 150 and 175Ω loads, the maximum deviation does not exceed ±2J or ±10%, whichever is greater. Under a 50Ω load, the deviation between the release energy and the rated release energy value of the defibrillator does not exceed ±1.5J or ±10% (whichever is greater).

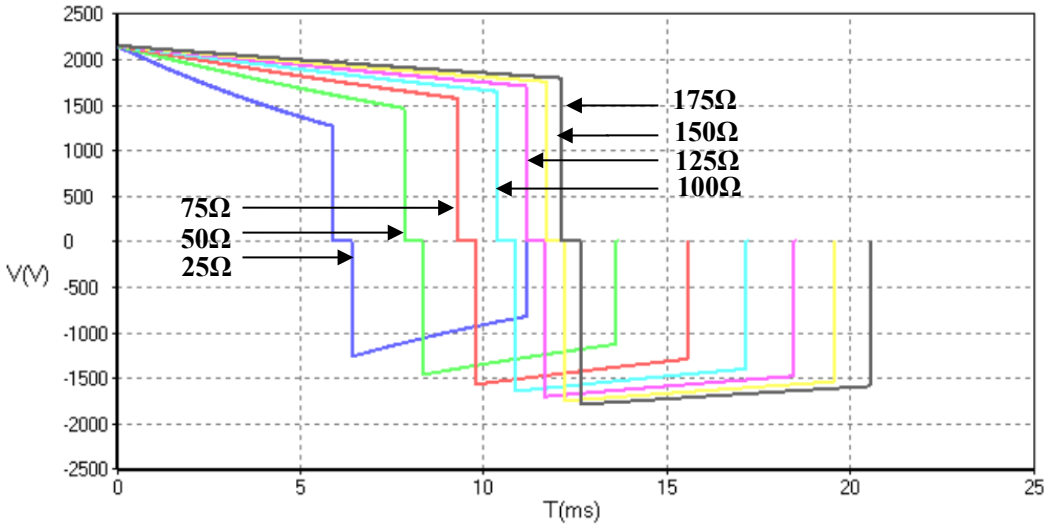
Impedance range	20~300Ω

Energy selection range	
Manual defibrillation	1/2/3/4/5/6/7/8/9/10/15/20/30/50/70/100/120/150/170/200/220/250/270/300/360J

AED defibrillation	
Electric shock sequence	Electric shock energy (adult): 100~360J configurable; options: 100J, 150J, 170J, 200J, 300J and 360J Electric shock energy (pediatric): 50~100J configurable; options: 50J, 70J and 100J Number of electric shocks: once, twice, and 3 times configurable The default configuration complies with AHA:2020 First Aid Guide
Shockable heart rate	VF and VT

AED algorithm performance complies with the requirements of IEC 60601-2-4 and AAMI DF80 and suggestions of AHA		
Heart rhythm classification	Specification requirement	Remark
Shockable heart rhythm VF	Sensitivity >90%	Complies with the requirements of IEC 60601-2-4 and AAMI DF80 and suggestions of AHA (sensitivity > 90%)
Shockable heart rhythm VT	Sensitivity >75%	Complies with the requirements of IEC 60601-2-4 and AAMI DF80 and suggestions of AHA (sensitivity > 75%)
Non-shockable heart rhythm	>95%	Complies with the requirements of IEC 60601-2-4 and AAMI DF80 and suggestions of AHA (specificity > 95%)

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



Energy accuracy									
Impedance / Energy	50Ω	Accuracy	25Ω	75Ω	100Ω	125Ω	150Ω	175Ω	Accuracy
1J	1	±1.5J	1	1.1	1	1	0.9	0.8	±2J
2J	2	±1.5J	2	2	2	2	1.8	1.8	±2J
3J	3	±1.5J	2.8	3	2.8	3	2.7	2.5	±2J
4J	4	±1.5J	3.8	4.1	3.8	4	3.6	3.5	±2J
5J	5	±1.5J	4.8	5.0	4.8	4	4.5	4.2	±2J
6J	6	±1.5J	5.8	5.9	5.9	5	5.4	5.3	±2J
7J	7	±1.5J	6.8	6.9	6.9	6.8	6.3	6.0	±2J
8J	8	±1.5J	7.8	8	8.0	7.5	7.2	7.0	±2J
9J	9	±1.5J	8.8	9	8.6	8.5	8.1	7.7	±2J
10J	10	±1.5J	9.6	9.9	9.6	9.3	9.0	8.4	±2J
15J	15	±10%	15	15	14	14	13	13	±10%
20J	20	±10%	19	20	19	18	17	17	±10%
30J	30	±10%	29	30	29	27	26	25	±10%
50J	50	±10%	49	49	48	45	44	42	±10%
70J	70	±10%	68	69	66	63	60	58	±10%
100J	101	±10%	98	98	95	90	86	83	±10%
120J	122	±10%	118	119	114	109	104	100	±10%
150J	152	±10%	148	148	142	136	130	124	±10%
170J	172	±10%	167	168	160	151	147	140	±10%
200J	203	±10%	197	198	189	180	173	165	±10%
220J	224	±10%	217	218	209	199	190	182	±10%
250J	254	±10%	245	247	237	226	216	207	±10%
270J	275	±10%	267	267	256	244	233	223	±10%
300J	305	±10%	297	296	284	270	258	247	±10%
360J	363	±10%	356	354	339	324	310	296	±10%

Charging time; note: at 20 °C							
Battery Status		Manual defibrillation		AED defibrillation			
Rechargeable lithium ion battery		Charging time		From the beginning of the analysis to charging completion		From power-on to charging completion	
		200J	360J	200J	360J	200J	360J
	With a new, fully charged battery	<4s	<7s	<10s	<10s	<17s	<17s

	With a new, fully charged battery, depleted by 15 times of 360 J discharge	<4s	<7s	<10s	<10s	<17s	<17s
Disposable battery	With a new, fully charged battery	<7s	<13s	<10s	<17s	<17s	<24s
	With a new, fully charged battery, depleted by 15 time of 360 J discharge	/	/	<10s	<17s	<17s	<24s

10). ECG Specifications

Name	Type
ECG input	3-lead ECG lead wire and multi-function defibrillation electrodes
Available leads	Defibrillation electrodes 3-lead: I, II, III
ECG gain	Support at least 1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40 mm/ mV (×4), and automatic gain; the error is less than ± 5%
Electrode polarization voltage	With a DC polarization voltage of 850 mV, the sensitivity varies by ±5%.
Sweep speed	25 mm/s and the error is not more than ±10%
Frequency characteristics (ECG lead)	Monitoring mode: 0.5 Hz ~ 40 Hz (-3.0 dB ~ +0.4 dB) Treatment mode: 1 Hz ~ 20 Hz (-3.0 dB ~ + 0.4 dB)
Frequency characteristics (defibrillation electrodes)	Treatment mode: 1 Hz ~ 20 Hz (-3.0 dB ~ + 0.4 dB)
Common mode suppression ability (ECG lead)	Monitoring mode: >105 dB Treatment mode: >105 dB
Common mode suppression ability (defibrillation electrodes)	Treatment mode: >105 dB
Power frequency notch	a) Power frequency interference suppression capability ≥20 dB. b) Monitoring and therapy modes: support 50/60 Hz notch function.
Differential input impedance (ECG lead)	≥ 5MΩ
Differential input impedance (defibrillation electrodes)	Treatment mode: ≥5MΩ
ECG input signal range	±8 mV (peak-to-peak value)
Input signal accuracy	According to ANSI/SSMI EC13, use method A and method B to determine the total error and frequency response of the system
Lead detachment detection and active noise suppression	Measuring electrode: < 0.1 μA Drive electrode: < 1 μA
System noise (p-v RTI)	The noise level converted to the input shall be no more than 25μV (peak-to-peak value).
Calibration voltage	1 mV, with an error range of ±5%
Noise suppression of electrotome	ECG lead wire conforming to the standard is used, relative to ECG baseline, peak-to-peak noise ≤ 2 mV
ECG HR measurement range	Adult: 15 bpm~300 bpm
	Pediatric: 15 bpm~350 bpm
HR measurement accuracy	±1 bpm or ±1%, whichever is higher
Resolution	1 bpm

HR alarm range and accuracy	a) Adult: HR alarm setting range: upper limit: (lower limit + 2 bpm) ~ 300 bpm, lower limit: 15 bpm ~ (upper limit - 2 bpm). b) Pediatric: HR alarm setting range: upper limit: (lower limit + 2 bpm) ~ 350 bpm, lower limit: 15 bpm ~ (upper limit - 2 bpm). c) The alarm accuracy is: ±1 bpm
Baseline recovery time	≤ 2s after defibrillation
Level trigger threshold for HR detection	200μV
Type of arrhythmia (ECG lead)	27 arrhythmia analysis results and alarms are provided: Asystole, Vfib/VT, PVCs/min too high, R on T, Run PVCs, COUPLET, PVC, BIGEMINY, TRIGEMINY, tachycardia, bradycardia, extreme tachycardia, extreme bradycardia, MISSED BEATS, multiform PVC, VT, NSVT, ventricular rhythm, heartbeat pause, Pauses/min too high, irregular rhythm, ventricular bradycardia, atrial fibrillation, PNC, PNP, irregular rhythm end, and atrial fibrillation end
Threshold setup of arrhythmia (ECG lead)	The threshold of the following arrhythmia shall be set up: PVCs/min, Tachy (HR high limit), Brady (HR low limit), Extreme Tachy, Extreme Brady, Asystole Delay, V-Tach Rate, V-Tach PVCs, V-Tach Rate, V-Tach PVCs, Multi PVCs Window, Heart Pause Time, Pauses/min and AF/IrrRhy Stop Time.
Type of arrhythmia (defibrillation electrodes)	5 arrhythmia analysis results and alarms are provided: Asystole, VF, VT, PNC, and PNP
Threshold setup of arrhythmia (defibrillation electrodes)	The threshold of asystole delay and V-Tach rate shall be set up.
Time to alarm for high and low HR	11s
Time to alarm for cardiac arrest	11s
Tall T-wave rejection capability	1.2 mV
Input dynamic range	DC bias voltage up to ±850mV
Mean HR	As required in Section 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, the HR is calculated as follows. If all of the last 3 RR intervals are longer than 1200ms, the average of the last 4 RR intervals is the HR. Otherwise, the average of the last 12 RR intervals (with the longest interval and shortest interval excluded) is the HR.
HR meter accuracy and response to irregular rhythm	According to the requirements of Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the HR value displayed after the 20-second stabilization period is: Figure 3 a) (BGM) 80±1 bpm. Figure 3 b) (slow change BGM) 60±1 bpm. Figure 3 c) (fast change BGM) 120±1 bpm Figure 3 d) (two-way contraction) 90±2 bpm.
HR change response time	According to the requirements of Clause 201.7.9.2.9.101 b) 5) of IEC 60601-2-27, HR increases from 80 to 120 bpm: less than 11 s; HR decreases from 80 to 40 bpm: less than 11 s
Time to alarm for tachycardia	Waveform as required by Section 201.7.9.2.9.101 b) 6) of IEC 60601-2-27: Figure 4 a) 1-range: 11 s. Figure 4 a) 0.5-range: 11 s. Figure 4 a) 2-range: 11 s. Figure 4 b) 1-range: 11 s. Figure 4 b) 0.5-range: 11 s. Figure 4 b) 2-range: 11 s.

Pacing pulse	
Pacing mark	PACE identification is marked on the screen for PACE pulses that meet the following conditions: Amplitude: ±2 mV~±700 mV Width: 0.1 ms~2 ms Rise time: 10 µs~100 µs
Pacing suppression	Suppress pulses comply with the following conditions: Amplitude: ±2~±700 mV Width: 0.1~2 ms Rise time: 10~100 µs Minimum input slew rate: 10 V/s RTI, non-overshoot