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Summary of safety and clinical performance

Related Document(s)

Document No.	Document Name	Version
KF-0656-4-0012	Clinical Evaluation Report	2.0
KF-0656-4-0015	PMCF Plan	2.0
KF-0656-4-0008	Periodic Safety Update Report	1.0
KF-0656-2-0009	Risk Management Report	5.0
KF-0651-4-0020	PMCF Report	1.0

Revision History

Ver.	Revision description (including the evaluation path)	Revisor	Effective Date
1.0	Initial version	wangsiyang	2022-06-24
2.0	Update the chapter2 Intended use	wangsiyang	2022-12-21
3.0	Revised the content of Chapter 7 and update the Chapter 8	wangsiyang	

Table of Contents

1. Identification the device and the manufacturer

Device details	
Name of device	Defibrillator Monitor
Model and type	BeneHeart D20/ BeneHeart D20A/ BeneHeart D20C/ BeneHeart D30 BeneHeart D50/ BeneHeart D50A/ BeneHeart D50C BeneHeart D60 BeneHeart DX/ BeneHeart DM
Basic UDI-DI	69449040AB010000102Z
Nomenclature	NA
Classification	III （According to Rule 22 of MDR Annex VIII）
CND code	Z120305
Manufacturer details	
Manufacturer name	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Adress	Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
SRN	CN-MF-000014156
Authorised Representative	
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
SRN of the EC-Representative	DE-AR-000000001
Notified Body	BSI Group The Netherlands B.V.
NB’s single identification number	CE 2797
First CE certification date	/

2. Intended use

2.1 Intended purpose

The Defibrillator/Monitor is intended for external defibrillation, internal defibrillation, synchronized cardioversion and semi-automated external defibrillation. It can also be used for non-invasive external pacing, CPR Feedback as well as ECG, Resp, SpO2, PR, NIBP, CO2, IBP and Temp monitoring.

The intended purpose of BeneHeart D30/BeneHeart D20/BeneHeart D20A/BeneHeart D20C does not include IBP and Temp monitoring.

2.2 Indications

■ External defibrillation/AED/internal defibrillation：

The external defibrillation, AED and internal defibrillation modes are intended for patients with ventricular fibrillation, pulseless ventricular tachycardia and ventricular flutter.

■ Synchronized cardioversion：

Synchronized cardioversion is intended for the treatment of atrial fibrillation and atrial flutter.

■ Non-invasive external pacing:

Non-invasive external pacing is intended for the treatment of bradycardia and asystole.

■ CPR Feedback:

CPR Feedback is intended for patients with cardiac arrest.

■ Monitoring：

Monitoring is intended for the monitoring of ECG, Resp, SpO2, PR, NIBP, IBP, Temp and CO2 parameter.

2.3 Contra-indications

■ AED

The AED mode is contraindicated in the treatment when the patient is showing any of the following:

◆ Consciousness

◆ Breathing

◆ Detectable pulse or other signs of circulation

■ Manual Defibrillation

Manual defibrillation is contraindicated in the treatment when the patient is showing any of the following:

◆ Consciousness

◆ Breathing.

◆ Detectable pulse or other signs of circulation

3. Description of the device

3.1 Description of the device

External Defibrillation

The manual defibrillation feature uses exponential-truncated biphasic defibrillation technology and performs automatic compensation according to impedance of a patient. The biphasic defibrillation technology has been proved to be advantageous over the monophasic one and extensively applied in the defibrillation industry.

Semi-automated external defibrillation (Semi-AED)

The AED function uses the exponential-truncated biphasic defibrillation technology and the algorithm of a heart rhythm recognition detector to guide operators whether to perform defibrillation treatment.

CPR Feedback

The cardio-pulmonary resuscitation (CPR) sensor analyzes and calculates the compression rate by using

the pressure sensor to measure the change of the compress force; The displacement waveform is obtained by quadratic integration of the acceleration signal acquired by the acceleration sensor, recognized, and analyzed and calculated to obtain the compress depth and recovery data.

The compression rate can also be obtained by calculating the change of the chest impedance, which comes from multifunction electrode pads

CPR Filter is a technology that filters the CPR artifact from the ECG to allow users to see a close approximation of a patient's underlying ECG rhythm during CPR compressions, reducing interruptions in CPR.

Noninvasive Pacing

The external pacing function imposes the pulse of fixed width on patients at a certain current intensity and frequency. This technology is universal in external pacing currently and is widely applied in defibrillator monitors. The circuit composed of the MCU and operational amplifier is a constant-current source circuit. The MCU, based on the DAC level output and frequency, can control the magnitude and frequency of current flowing through a patient's thoracic impedance.

ECG

An electrocardiogram (ECG) is a variation curve recording the electrical activity of the heart over a cardiac cycle using electrodes placed over the skin, and acquiring the heart's electrical signal to analyze and calculate heart rate (HR) and arrhythmia (ARR). 12 lead ECG interpretation is a widely used technology to diagnose different heart conditions like arrhythmia, structural heart disease, myocardial infarction etc. by analyzing 12 lead ECG waveform.

NIBP

NIBP measures the peripheral arterial blood pressure based on the principle of oscillation.

SpO2

Pulse blood oxygen monitoring uses the spectrophotometry to monitor blood oxygen (measuring based on the different wavelengths of light absorbed by tissues).

Temp

The TEMP module measures body temperature based on the temperature resistance characteristics of the thermistor.

CO2

CO2 gas has a strong absorption peak around the 4.26μm infrared light. Based on non-dispersive infrared spectroscopy (NDIR), the absorption volume of signals in the band is measured using the Lambert-Beer law to determine the CO2 concentration during human respiration. Where, I0 and I are the infrared light intensity before and after absorption; α is the absorption coefficient of the measured gas at the wavelength; L is the effective absorption optical length of the measured gas; and C is the concentration of the measured gas. Make that ABS = ln(I0) - ln(I) = αLC. Then, ABS is the CO2 signal absorption volume of the infrared light in the 4.26μm band when passing through the CO2 gas at a concentration of C. By calculating the absorption volume, the CO2 gas concentration can be calculated.

IBP

Invasive blood pressure (IBP) measurement directly measures intravascular pressure by means of fluid coupling.

Resp

The RESP module measures the respiration rate using the chest impedance pneumography method.

3.2 Overview of the previous generations device

Previous device：BeneHeart D5/BeneHeart D6 Defibrillator/Monitor

Manufacture: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Description:

BeneHeart D5/BeneHeart D6 is the first defibrillator/monitor of Mindray, have got the CE mark since 2008, the medical device registration certificate of China was obtained in 2010.

The BeneHeart D20/ D20A/ D20C/ D30/ D50/ D50A/ D50C/ D60 /DX/ DM defibrillators/monitors are developed based on predecessor products BeneHeart D5/BeneHeart D6. The key core functions and software core algorithms of the Defibrillator/Monitor are completely the same as those of the predecessor products. The therapy module and multi-parameter monitor module (including hardware principle and software core algorithm) fully use predecessor product schemes.

The design and development of the new generation of Defibrillator/Monitor is based on feedback from market users of predecessor products. The main differences lie in appearance, hardware, and software.

In terms of appearance, the appearance of the device under application is upgraded to be smaller and lighter, which greatly reduces the weight and is convenient for the users to carry.

In terms of hardware, the equipment has been updated to touchscreen, and the screen size is upgraded to a large screen, which is convenient for use. The subject devices support both the built-in multi-parameter monitoring module (BeneHeart D20/ D20A/ D20C/ D30/ D50/ D50A/ D50C/ D60) and the external multi-parameter monitoring module (BeneHeart DX/ DM), giving users multiple options.

In terms of software, the core functions of the software are completely the same as those of the predecessor products. The subject equipment cooperates with the touch screen upgrade and modified the software function.

3.3 Accessories

3.3.1 Accessories included

None.

3.3.2 Accessories not included but necessary for use

3.3.2.1 Others

For the other devices, see as below:

Accessories	Description
ECG	ECG Electrodes
	3-lead ECG Leadwires
	5-lead ECG Leadwires
	12-lead ECG Leadwires
	12-Pin Separable Trunk Cables
	12-Pin Integrative Trunk Cables
SpO2	SpO2 Sensors
	Extension Cables
NIBP	NIBP Hoses
	Cuffs
TEMP (Applicable to D60/D50A/D50/D50C/DX/DM)	Temp Cable
	Temp Probes
IBP (Applicable to D60/D50A/D50/D50C/DX/DM)	IBP Accessories
	ICP Accessories
CO2	Reusable CO2 adapter
	airway sampling line
	nasal sampling line
	Airway adapter
	Mask
	Cable management straps
	Sensor holding clips
	CO2 sensor
Therapy Accessories	External defibrillation paddles
	Electrode gel
	Multifunction electrode pads
	pads cable with 50Ω test load
	CPR sensor
	Internal defibrillation paddles

3.3.2.2 Other products that are not devices

- Transport dock
- AC power adapter

- Analog output cable
- Synchronous defibrillation input cable
- Wi-Fi to 4G router kit
- Charger station
- Barcode reader
- Recorder paper, 50 mm×20 m
- Recorder paper, 112 mm×20 m
- Rechargeable lithium-ion battery

3.4 Another device

The equipment can be connected to a Central Monitoring System (hereinafter called CMS) through wired and wireless networks. The CMS uses the software system of Mindray and the general hospital surgical network.

4. Residual risks and undesirable effects, warnings and precautions

4.1 Residual risks and undesirable effects

Residual risks：

With complete product risk analysis and control, only one residual risk assessment belongs to the "AFAP" level. The table below gives the residual risk and benefit analysis of these hazards:

Item	Energy	Sequence of events	Hazardous situation	harm	Control Measure	Risk level
6.8.4	Energy hazards	High current flows through the myocardium during defibrillation therapy.	The discharge current is large, causing damage to the cardiomyocytes.	The patient's myocardium is injured by electric shock during defibrillation therapy.	The MINDRAY biphasic truncated exponential waveform is used, and the waveform parameters can be adjusted according to the patient impedance.	AFAP

undesirable effects:

Through clinical data from post-market surveillance activity (including adverse event report analysis and post-marketing clinical follow-up), there is no undesirable effects identified.

After search the literature of similar device, the results of SOTA evaluation shown that undesirable effects may include myocardial damage and skin burns.

Quantitative data

According to the requirements of MDCG 2019-19, the risk information in the SSCP should include quantification.

Through SOTA research, the clinical risk about residual risk and undesirable effects has been published quantitative data in CER, which has been related with clinical data of the subject device.

We included the results of the SOTA study as an acceptance criterion for Residual risks and undesirable effects evaluation. We collected clinical data from subject device initial CE marked, to prove that the probability of occurrence of harm of our devices is much lower than the average level in the industry.

The evaluation of Residual risks and undesirable effects per CEP has been summarized as below:

State of the Art Acceptance Criteria		**PMS data from subject device and equivalent devices**	**Clinical data from subject device and equivalent devices**	**Evaluation result**
Myocardial damage (Synchronized Cardioversion)	2%	No Myocardial damage is reported in the PMS data. Please refer to chapter 4.4	No myocardial injury or other adverse events are reported. For details see KF-0651-4-0020 PMCF Report Chapter 3.2	Better than SOTA
Myocardial damage (Internal Defibrillation)	2%	No Myocardial damage is reported in the PMS data. Please refer to chapter 4.4	No myocardial injury or other adverse events are reported. For details see KF-0651-4-0020 PMCF Report Chapter 3.3	Better than SOTA
Skin burns (Non-invasive External Pacing)	5.26%	According to the literature search in Chapter 3, there may be a risk of skin burn on the Defibrillator/ Monitor in the industry. The main failure cause may be the equipment's over-temperature. The occurrence probability is about 3%. The post-market surveillance activities of the applicant device and equivalent device show that, **no adverse events and complaints related to skin burns is reported in the PMS data.**	We have actively investigated this clinical risk in the post-market clinical follow-up activities. The post-market clinical follow-up report indicates that, no skin burns or other adverse events were reported. For details see KF-0651-4-0020 PMCF Report Chapter 3.5.	Better than SOTA

		In conclusion, the PMS data proves that the device does not involve the above clinical risks. For more details, please refers to chapter 4.4 Clinical data from Post-Market surveillance (PMS).		

It means that the subject device's acceptability of residual risks and undesirable effect is better than SOTA.

Risk and Benefit Analysis:

Through the parameter monitoring, medical staff have established sufficient conditions to provide patients with a better medical monitoring environment, and the benefits are obvious.

Although there is also the possibility of false positives and false negatives in parameter monitoring, the impact of false positives and false negatives is limited and will not cause substantial harm to patients.

In addition, the parameter monitoring of the monitor has the advantages of simplicity of equipment, convenient operation, timeliness, economy, etc. compared with other known ones.

Therefore, from the perspective of benefit and risk, monitor parameter monitoring has obvious benefits, controllable risks, and has strong clinical application popularization characteristics.

Defibrillators are life-saving devices used in emergency situations. They have been shown to have a high benefit for patients with underlying diseases that remain undetected until sudden cardiac arrest occurs. The time from collapse to defibrillation is critical in-patient survival. For every minute that passes between collapse and defibrillation, survival rates from VF SCA decrease 7% to 10%.

In conclusion, given the available information above, the defibrillator's support for patients in cardiac arrest who are unconscious, not breathing, or without circulation the probable benefits outweigh the probable risks.

4.2 Warning

- This equipment is used for single patient at a time.
- The equipment is not intended to be used within the Magnetic Resonance (MR) environment.
- Do not disassemble the equipment. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.
- Before connecting the equipment to the external power supply, check that the voltage and frequency ratings are the same as those indicated on the equipment's label or in this manual.
- To avoid risk of electric shock, the equipment must only be connected to mains power with protective earth. If a protective earth conductor is not provided, operate it on battery power, if

possible.

- Do not use the multiple portable socket outlets (MPSO) or AC mains extension cords. Insure that the sum of the individual ground leakage currents does not exceed the allowable limits.
- Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.
- Do not exclusively rely on audible alarms for patient monitoring. Adjusting alarm volume to a low level or turning off alarm sound may result in patient hazards. Customize alarm settings according to patient situations and keep patients under close surveillance.
- Physiological data and alarm messages provided by the equipment should not be used as the sole basis for diagnosis or therapy decisions. They must be used in conjunction with clinical signs and symptoms. Misinterpreting measured values or other parameters may result in patient hazards.
- Do not place the equipment or accessories in any position that might cause it to fall on the patient.
- Do not start or operate the equipment unless the setup was verified to be correct.
- Place and secure cables and tubings carefully to prevent from stumbling, entanglement and patient strangulation.
- The software equipment copyright is solely owned by Mindray. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.
- Disconnect the non-defibrillation-proof devices from the patient during defibrillation.
- Make sure the synchronous input system is applied to this equipment and the input signal is correct if necessary.
- Do not defibrillate a patient who lies on the wet or metal ground.
- Do not perform any functional check if the equipment is connected with a patient. Otherwise the patient might be shocked.
- Always keep the patients under close surveillance when delivering the therapy. If there is a delay in delivering a shock, the rhythm that has been analyzed as shockable may be converted to a nonshockable rhythm, which may result in an incorrect shock delivery.
- For the treatment of patients with implantable pacemakers, place electrode pads or paddles away from internal pacemaker generator if possible to help prevent damage to the pacemaker.
- Do not touch device connectors, recorder print head, battery connector or other live equipment if in contact with the patient. Otherwise patient injury may result.
- Do not touch the patient and live parts simultaneously.

4.3 Post-Market surveillance (PMS）database research

According to Regulation (EU) 2017/745 Article 84, Mindray has established the post-market surveillance system and actively gathering relevant data. By now, there is no serious incidents or field safety corrective action (FSCA) and no corrective action preventive action (CAPA) reported about BeneHeart D5/D6 Defibrillator/Monitor.

In the final collection results, the adverse event rate was 0% and the complaint rate was 0.06%.

Complaint handling and risk control (individual complaint records and trend analysis of complaints) as below:

No.	Complaint No.	Complaint Initiation Year	Product Model	Country	Problem description	Dangerous situations	Whether it is related to the product	Risk involved (Y/N)
1	CP14-JH0068	2014	BeneHeart D6	France	French hospitals complain that the 12-lead ECG accessory of D6 is prone to damage. After multiple communication with the hospital, the detailed information of the exception cannot be obtained and investigation cannot be conducted.	The ECG information cannot be obtained, or the ECG information is incorrect.	NO After multiple communication with the hospital, the detailed information of the exception cannot be obtained and investigation cannot be conducted.	N
2	CP-2014-021	2014	BeneHeart D6	Germany	During resuscitation, the equipment specified above displayed a false ECG rhythm. According to the display screen, a wide complex tachycardia was present, with a frequency of 180/min. The LP 15 Physio-Control ECG device from the Langenhoven (80-31) emergency vehicle present at the scene	The ECG information cannot be obtained, or the ECG information is incorrect.	NO There is a serious deviation between the information provided by the user and the device log. The user is unwilling to provide the exact information and	N

					was used in parallel with the ECG device named above (D6). This led to significant deviations in the rhythm. The LP 15 Physio-Control presented asystole cardiac arrest and the ECG device (D6) continued to display wide complex tachycardia. The crew from the Langenhoven emergency vehicle are also due to provide a statement. The device has been taken out of service as a result of this error report. There is a serious deviation between the information provided by the user and the device log. The user is unwilling to provide the exact information and cannot perform further investigation.		cannot perform further investigation.	
3	CP-2014-028	2014	BeneHeart D6	Germany	The ECG measurement is inaccurate due to interference. Not a product problem.	The ECG information cannot be obtained, or the ECG information is incorrect.	NO The R&D department combined with the product log analysis indicates that the error may be caused by poor contact of the electrode pads or movement of the patient. Not a product problem.	N

4	CP15-JH0323	2015	BeneHeart D6	Ecuador	The battery of BeneHeart D6 failed in less than one month.	During a patient use event， the device inappropriately shut down or restarted itself.	YES When the battery energy is low, the device generates an alarm.	Y; Risk items: KF-0656-2-0009 Risk Management Report: 6.1.2.1、6.1.2.9 Current Control Measure: Real-time battery capacity detection, status display, and low battery alarm. Risk Level After Control Measure: Acceptable
5	CP16-JH0017	2016	BeneHeart D6	UK	A British hospital has 40 newly installed BeneHeart D6, 9 of them failed in self test.The confirmed problem is that the impedance detection error is large due to incorrect calibration (zero calibration and gain calibration) by the user, and the measured value exceeds the detection threshold during self-test. After the customer uses the calibration method recommended by the Mindray manual for calibration, the problem is solved and the device works normally.	Defibrillation cannot discharge	NO The customer did not perform self-test according to the manual requirements, resulting in poor self-test of the device. This device is not faulty.	N

6	CP16-JH0040	2016	BeneHeart D5	China	The client complains that the device Beneheart D5 does not discharge when the synchronous defibrillation therapy is used for the AF patient. Analysis on the device shows that the discharge operation fails due to automatic release, which may be related to external factors such as the electrode plate is not in good contact with the human body during discharge, and the device functions properly.	Defibrillation cannot discharge	NO The panddle is not in good contact with the human body during the discharge, so the device cannot discharge. Unrelated to the device.	N
7	CP16-JH0089	2016	BeneHeart D6	China	Beneheart D6 cannot discharge on the patient. According to the analysis and test, the device function is normal. It is speculated that the customer feedback that the device cannot be discharged on the patient may be related to the automatic disarming (too high impedance) caused by such external factors as electrode plate contamination and improper contact between the electrode plate and the human body during the discharge.	Defibrillation cannot discharge	NO The panddle is not in good contact with the human body during the discharge, so the device cannot discharge. Unrelated to the device.	N
8	CP16-JH0090	2016	BeneHeart D6	China	High energy charging failure occurred in March, 2016 for Beneheart D6. The device returns to the R&D department for analysis. The function of the device is normal and the problem information complained by the user cannot be reproduced. The device log also has no exception record.	Defibrillation cannot discharge	NO The customer feedback information is incorrect. In combination with the product record log, there is no adverse event reported by the customer. No	N

							problem with this device.	
9	CP16-JH0568	2016	BeneHeart D6	China	Discharge failure during D6 defibrillation in Beijing sanluju hospital. According to the investigation, the problem is that the hospital does not use the conductive paste according to the manual requirements, but uses the ultrasonic coupling agent so that the impedance is too high to be discharged. The device is detected to be normal.	Defibrillation cannot discharge	NO The hospital does not use the conductive paste according to the manual requirements, but uses the ultrasonic coupling agent.No problem with this device.	N
10	CP16-JH0497	2016	BeneHeart D6	China	No discharge during the rescue using BeneHeart D6. According to the investigation, the problem is that the hospital does not use the conductive paste according to the manual requirements, but uses the ultrasonic coupling agent so that the impedance is too high to be discharged. The device is detected to be normal.	Defibrillation cannot discharge	NO The hospital does not use the conductive paste according to the manual requirements, but uses the ultrasonic coupling agent.No problem with this device.	N

11	CP17-JH0052	2017	BeneHeart D6	China	Suspect no discharge during the rescue using BeneHeart D6. Communicate with the hospital and learn that the patient has asystole and there is no ventricular fibrillation waveform before the BeneHeart D6 defibrillation monitor is used to rescue the patient. The BeneHeart D6 operator's manual specifies that the defibrillation function is applicable to patients with ventricular fibrillation and ventricular tachycardia without respiration and pulse. The BeneHeart D6 defibrillation monitor works properly.	Defibrillation cannot discharge	NO The patient has asystole and there is no ventricular fibrillation waveform before the BeneHeart D6 defibrillation monitor is used to rescue the patient. Not an indication for Intended Use of this device.No problem with this device.	N
12	CP17-JH0110	2017	BeneHeart D6	Mexico	The device cannot be turned on. The battery has a burning smell. The BeneHeart D6 in Mexico. Occasional battery-related faults occur. The equipment is made of flame-retardant materials and will not burn. This problem may cause startup failure.	During a patient use event，the device inappropriately shut down or restarted itself.	YES	Y; Risk items: KF-0656-2-0009 Risk Management Report: 7.3.7.1、6.8.3 Current Control Measure: Design fireproof materials for equipment enclosure Risk Level After Control Measure: Acceptable

13	CP17-JH0116	2017	BeneHeart D6	China	The customer reported that "sparking" occurred when AC power was connected. When the AC power supply is no longer plugged in, change to battery power and the device can be started normally.This problem is caused by that the customer removes the anti-off hook and the plug connection is unstable during long-term use.	During a patient use event , the device inappropriately shut down or restarted itself.	NO This problem is caused by that the customer removes the anti-off hook and the plug connection is unstable during long-term use.No problem with this device.	N
14	CP17-JH0124	2017	BeneHeart D6	China	Using D6 defibrillation monitor in Ya'an people's Hospital, The department doctor judges that multiple shocks have no effect based on "the patient's body and skin do not respond to the shock," and hopes the manufacturer to conduct an investigation. Mindray has performed functional and performance tests on the device, and all functions are normal without device exception. The records of multiple defibrillation discharges mentioned by the customer indicate that all the discharges were successful. The absence of obvious limb response after defibrillation discharge may be related to the patient's physical condition at that time.	Defibrillation cannot discharge	NO The records of multiple defibrillation discharges mentioned by the customer indicate that all the discharges were successful. The absence of obvious limb response after defibrillation discharge may be related to the patient's physical condition at that time.No problem with this device.	N
15	CP1904-JH00657	2019	BeneHeart D6	China	Henan Provincial Employee Hospital reported that during the out-of-hospital emergency treatment, it was found that the BeneHeart D6 12-lead ECG still had waveforms after the	The ECG information cannot be obtained, or the ECG information is	NO This is ECG mechanical disconnection.No problem with this device.	N

					patient died. This is ECG mechanical disconnection. Not caused by Mindray products.	incorrect.		
16	CP1906-JH00767	2019	BeneHeart D6	China	During defibrillation in the intervention Department of Ya'an people's Hospital of Sichuan Province, the Department of the hospital said that during the use of 200J defibrillation, the patient's response was weak after discharge, and the ECG had no response. It is confirmed that the information reported by the hospital is incorrect, and there is no "invalid shock, resulting in patient death" event. In addition, the hospital did not raise any problems with the device and only required to replace the device.	Defibrillation cannot discharge	NO There is no "invalid shock, resulting in patient death" event. In addition, the hospital did not raise any problems with the device and only required to replace the device. No problem with this device.	N
17	CP1911-JH01050	2019	BENEHEART D6	China	Ya'an People's Hospital of Sichuan Province The hospital thinks that the defibrillator does not discharge. After the investigation, it is confirmed that the user misoperates the shock when it is not fully charged. When the impedance is too high, the shock is released. The device is normal.	Defibrillation cannot discharge	NO The user misoperates the shock when it is not fully charged. When the impedance is too high, the shock is released.No problem with this device.	N

18	CP1910-JH01012	2019	BENEHEART D6	France	D6 - Batt failed The D6 is not capable to see the complete battery status and cannot see the real battery status. The user does not detect and maintain the battery regularly as required by the manual, and does not replace the battery for 2 years as required by the manual.	During a patient use event , the device inappropriately shut down or restarted itself.	NO The user does not detect and maintain the battery regularly as required by the manual, and does not replace the battery for 2 years as required by the manual.No problem with this device.	N
19	CP2011-JH01757	2020	BeneHeart D6	China	Sparks on the BENEHEART D6 handle of Jiaokou County Hospital of Traditional Chinese Medicine. After checking the device, the handle is cracked, which should be caused by the customer's falling down during use. The liquid penetrates the handle through the crack, causing the client phenomenon.	Unexpected release of defibrillation energy	NO The handle is cracked, which should be caused by the customer's falling down during use. The liquid penetrates the handle through the crack, causing the client phenomenon.No problem with this device.	N

20	CP2011-JH01729	2020	BeneHeart D6	Germany	Feedback from German office: The nurse felt the hand was shocked during the user test. After testing, all the functions of the monitor are normal. 1. The function test is normal. 2. The test results of the contact impedance and leakage current meet the standards, and the safety test is normal.	Unexpected release of defibrillation energy	NO After testing, all the functions of the monitor are normal. 1. The function test is normal. 2. The test results of the contact impedance and leakage current meet the standards, and the safety test is normal. No problem with this device.	N
21	CP2101-JH01908	2021	BeneHeart D6	China	The D6 waveform is still normal after the patient asystole. This is ECG mechanical disconnection. Not caused by Mindray products.	The ECG information cannot be obtained, or the ECG information is incorrect.	NO This is ECG mechanical disconnection. Not caused by Mindray products.	N

22	CP2112-JH02590	2021	BeneHeart D6	China	According to Baoan Central Hospital, D6 cannot discharge. After testing the product functions and checking and analyzing the device logs, the device is normal. Finally, confirmed the device with the medical personnel in the hospital,The discharge function of the device is normal.	Defibrillation cannot discharge	NO The device cannot discharge due to incorrect operation by the customer.No problem with this device.	N
23	CP2101-JH01881	2021	BENEHEART D6	China	Defibrillation Failure in Affiliated Hospital of Shanxi College of Traditional Chinese Medicine. The R&D analyzed the returned log and found that the defibrillator successfully discharged five times on the day of the incident . No exception was found to the devices. The failure of defibrillation rescue is unrelated to the defibrillator and electrode pads, and may be related to the patient's physiological status and rescue time.	Defibrillation cannot discharge	NO The R&D analyzed the returned log and found that the defibrillator successfully discharged five times on the day of the incident . No exception was found to the devices. The failure of defibrillation rescue is unrelated to the defibrillator and electrode pads, and may be related to the patient's physiological status and rescue time. No problem with this device.	N

4.4 Complaint rates of the specific warning and precautions

Warnings and precautions	Complaint No.	Complaint rates
• Only use parts and accessories specified in this manual. Follow the instructions for use and adhere to all warnings and cautions.	CP16-JH0568、CP16-JH0497	0.005%

• This equipment is used for single patient at a time.	0	0.000%
• The equipment is not intended to be used within the Magnetic Resonance (MR) environment.	0	0.000%
• Do not disassemble the equipment. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.	0	0.000%
• Before connecting the equipment to the external power supply, check that the voltage and frequency ratings are the same as those indicated on the equipment's label or in this manual.	CP14-JH0068、CP16-JH0089	0.005%
• Before each use, the operator must check the equipment condition to ensure that the equipment is ready for operation.	CP15-JH0323、CP17-JH0110、CP1910-JH01012、CP2011-JH01757、CP16-JH0090	0.013%
• To avoid risk of electric shock, the equipment must only be connected to mains power with protective earth. If a protective earth conductor is not provided, operate it on battery power, if possible.	CP17-JH0116	0.003%
• Do not use the multiple portable socket outlets (MPSO) or AC mains extension cords. Insure that the sum of the individual ground leakage currents does not exceed the allowable limits.	0	0.000%
• Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.	0	0.000%
• Do not exclusively rely on audible alarms for patient monitoring. Adjusting alarm volume to a low level or turning off alarm sound may result in patient hazards. Customize alarm settings according to patient situations and keep patients under close surveillance.	0	0.000%
• Physiological data and alarm messages provided by the equipment should not be used as the sole basis for diagnosis or therapy decisions. They must be used in conjunction with clinical signs and symptoms. Misinterpreting measured values or other parameters may result in patient hazards.	CP-2014-028、CP1904-JH00657、CP2101-JH01908、CP17-JH0124	0.010%

• Do not place the equipment or accessories in any position that might cause it to fall on the patient.	0	0.000%
• Do not start or operate the equipment unless the setup was verified to be correct.	CP16-JH0017、CP16-JH0040、CP1911-JH01050	0.008%
• Place and secure cables and tubings carefully to prevent from stumbling, entanglement and patient strangulation.	0	0.000%
• The software equipment copyright is solely owned by Mindray. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.	0	0.000%
• Disconnect the non defibrillation-proof devices from the patient during defibrillation.	0	0.000%
• Make sure the synchronous input system is applied to this equipment and the input signal is correct if necessary.	0	0.000%
• Do not defibrillate a patient who lies on the wet or metal ground.	0	0.000%
• Do not perform any functional check if the equipment is connected with a patient. Otherwise the patient might be shocked.	0	0.000%
• Always keep the patients under close surveillance when delivering the therapy. If there is a delay in delivering a shock, the rhythm that has been analyzed as shockable may be converted to a non-shockable rhythm, which may result in an incorrect shock delivery.	0	0.000%
• For the treatment of patients with implantable pacemakers, place electrode pads or paddles away from internal pacemaker generator if possible to help prevent damage to the pacemaker.	0	0.000%
• Do not touch device connectors, recorder print head, battery connector or other live equipment if in contact with the patient. Otherwise patient injury may result.	0	0.000%
• Do not touch the patient and live parts simultaneously.	CP2011-JH01729	0.003%

• If the accuracy of any value displayed on the equipment, CMS, or printed on a graph strip or report is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly.	CP-2014-021、CP17-JH0052	0.005%

5. The summary of clinical evaluation and post-market clinical follow-up (PMCF)

The data from the current technology of defibrillation waveforms, standard compliance testing, post-marketing clinical follow-up in China and Europe. It can fully prove that defibrillation monitor can meet clinical safety and effectiveness.

After marketing in EU, we will formulate a detailed post-marketing clinical follow-up plan to collect a certain amount of cases according to statistical requirements to ensure that the External Defibrillation, synchronized cardioversion, Internal Defibrillation, AED, and the Non-invasive external pacing function of the defibrillator can also meet the safety and effectiveness of European users.

5.1 Summary of clinical data related to equivalent device (if applicable)

The Defibrillator/Monitor belongs to the combination of Manual defibrillation, monitor, pacer and AED module, these modules are independent of each other and will not affect other modules when a single module works.

Since the defibrillation module and monitor module of the defibrillation monitor are independent of each other, and the module development of the subject device is based on the previous generation products, the technical characteristics, biological characteristics and clinical technical characteristics of the device are completely the same, and the clinical trial is conducted on the technology of the previous generation products to obtain the clinical data.

The monitor module of BeneHeart D20/ D20A/ D20C/ D30/ D50/ D50A/ D50C/ D60 /DX/ DM defibrillators/monitor is thus determined to be as safe and effective as the equivalent devices including BeneHeart D5/ BeneHeart D6.

Administrative	**Device 1 (subject device)** Description of characteristics and reference to specifying documents	**Device 2 (equivalent device)** Description of characteristics and reference to specifying documents	**Identified differences or conclusion that there are no differences in the characteristic**

Manufacturer	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD	Same.
Device Trade Name	BeneHeart D50/ BeneHeart D60 Defibrillator/Monitor	BeneHeart D5/ BeneHeart D6 Defibrillator/Monitor	Not applicable

Post-clinical follow-up data from BeneHeart D5/ BeneHeart D6：

External Defibrillation

- **Objective**

  To demonstrate the performance and safety of external defibrillation function, identifying previously unknown side-effects and ensuring the continued acceptability of the benefit-risk ratio.

- **General clinical Information**

  1. Subject Selection

  - Ages eligible for selection: Adult and pediatric.
  - Sexes eligible for selection: All
  - Subjects have already used the External Defibrillation function of Mindray defibrillator monitors

  2. Sample Size Calculation

  This PMCF adopts the single-group design method, the OPC (Objective performance criteria) is set to 87.9 % (P0), Pt set to 95%. We also determine α=0.05，β=0.2，power (1-β)=0.8, clinical drop-out rate γ= 0.05. Based on the Formula for Estimating Sample Size of a Single Group Target Value Test, a minimum of 142 clinical cases are expected to be collected in this PMCF.

  3. Process

  Mindray will continuously collect clinical cases from at least 2 hospitals. The clinical cases will be recorded and filled in the PMCF form by the medical staff according to the actual treatment conditions. Submit the signed PMCF form to Mindray for confirmation and statistics.

- **Adopted Statistical Analysis Method and Acceptance Criteria**

1. Statistical Analysis Method

The defibrillation success rate equals the total number of success cases divided by the total number of tracked cases. Descriptive statistics of baseline parameters such as patient age, gende are also collected.

2. Acceptance Criteria

The final result of defibrillation success rate is obtained and its two-sided 95% confidence interval is calculated. If the lower limit of the confidence interval is above the target value 87.9%, the clinical performance of the product under application shall be proved to meet the requirement of recognized level in the industry.

- **Result**

174 clinical cases have been collected from 50 hospitals until 2022, with details as follows:

Gender Distribution of the Cases:

Gender	Number of Cases
Male	125
Female	49
Total	174

Age Distribution of the Cases:

populations	Age	Number of Cases
pediatric	1 month -<3 year	2
	3-<12 year	2
	12-<18 year	3
adult	18-<40 year	17
	40-<60 year	60
	≥60 year	90
Total		174

Indications Distribution of the Cases:

Indications	Number of Cases
Ventricular fibrillation	148
Pulseless ventricular tachycardia	19
Others	7
Total	174

Successful/Failed Cases:

Successful Cases	Failed Cases	Total	success rate
164	8	174	94.3%

This PMCF collects 174 cases and 164 cases are successful, the final result of defibrillation success rate is 94.3%. Based on Confidence interval calculation formula:

$$\mathrm{p} \pm z_{\alpha/2}\sqrt{p(1-P)/n}$$

When α=0.05，$Z_{\alpha/2} = 1.96$

Finally, the two-sided 95% confidence interval of 94.3% is calculated as follows:(90.9%, 97.7%), the lower limit 90.9% is above the target value 87.9%.

The final result of defibrillation success rate is 94.3% (95%Cl: 90.9%, 97.7%). the lower limit 90.9% is above the target value 87.9%, the clinical performance of the external defibrillation function of the product in question has been proved to meet the requirement of recognized level in the industry.

No adverse events related to the device are found through surveys.

Synchronized Cardioversion

- **Objective**

  To demonstrate the performance and safety of synchronized cardioversion function, identifying previously unknown side-effects and ensuring the continued acceptability of the benefit-risk ratio.

- **General clinical Information**

1. Subject Selection

- Ages eligible for selection: Adult and pediatric.
- Sexes eligible for selection: All
- Subjects have already used the Synchronized Cardioversion function of Mindray defibrillator monitors

2. Sample Size Calculation

This PMCF adopts the single-group design method, the OPC (Objective performance criteria) is set to 88.9% (P0), Pt set to 95%. We also determine α=0.05，β=0.2，power (1-β)=0.8, clinical drop-out rate γ= 0.05. Based on the Formula for Estimating Sample Size of a Single Group Target Value Test, a minimum of 181 clinical cases are expected to be collected in this PMCF.

3. Process

Mindray will continuously collect clinical cases from at least 2 hospitals. The clinical cases will be recorded and filled in the PMCF form by the medical staff according to the actual treatment conditions. Submit the signed PMCF form to Mindray for confirmation and statistics.

➢ **Adopted Statistical Analysis Method and Acceptance Criteria**

1. Statistical Analysis Method

The cardioversion success rate equals the total number of success cases divided by the total number of tracked cases. Descriptive statistics of baseline parameters such as patient age, gender are also collected.

2. Acceptance Criteria

The final result of cardioversion success rate is obtained and its two-sided 95% confidence interval is calculated. If the lower limit of the confidence interval is above the target value 88.9%, the clinical performance of the product under application shall be proved to meet the requirement of recognized level in the industry.

➢ **Result**

185 clinical cases have been collected from 4 hospitals until 2022, with details as follows:

Gender Distribution of the Cases:

Gender	Number of Cases
Male	104

Female	81
Total	185

Age Distribution of the Cases:

populations	Age	Number of Cases
pediatric	1month -<3 year	2
	3-<12 year	4
	12-<18 year	20
adult	18-<40 year	27
	40-<60 year	64
	≥60 year	68
Total		185

Indications Distribution of the Cases:

Indications	Number of Cases
Atrial fibrillation	130
Others	55
Total	185

Successful/Failed Cases:

Successful Cases	Failed Cases	Total	success rate
175	10	185	94.6%

This PMCF collects 185 cases and 175 cases are successful, the final result of defibrillation success rate is 94.6%. Based on Confidence interval calculation formula:

$$\mathbf{p} \pm z_{\alpha/2}\sqrt{p(1-P)/n}$$

When α=0.05，$Z_{\alpha/2} = 1.96$

Finally, the two-sided 95% confidence interval of 94.6% is calculated as follows:(91.4%, 97.8%), the lower limit 91.4% is above the target value 88.9%.

The final result of defibrillation success rate is 94.6% (95%Cl: 91.4%, 97.8%). the lower limit 91.4% is above the target value 88.9%, the clinical performance of the external defibrillation function of the product in question has been proved to meet the requirement of recognized level in the industry.

No adverse events related to the device are found through surveys.

Internal Defibrillation

- **Objective**

To demonstrate the performance and safety of internal defibrillation function, identifying previously unknown side-effects and ensuring the continued acceptability of the benefit-risk ratio.

- **General clinical Information**

1. Subject Selection

- Ages eligible for selection: Adult and pediatric.
- Sexes eligible for selection: All
- Subjects have already used the Internal Defibrillation function of Mindray defibrillator monitors

2. Sample Size Calculation

This PMCF adopts the single-group design method, the OPC (Objective performance criteria) is set to 94.2 % (P0), Pt set to 95%. We also determine α=0.05，β=0.2，power (1-β)=0.8, clinical drop-out rate γ= 0.05. Based on the Formula for Estimating Sample Size of a Single Group Target Value Test, a minimum of 135 clinical cases are expected to be collected in this PMCF.

3. Process

Mindray will continuously collect clinical cases from at least 2 hospitals. The clinical cases will be recorded and filled in the PMCF form by the medical staff according to the actual treatment conditions. Submit the signed PMCF form to Mindray for confirmation and statistics.

- **Adopted Statistical Analysis Method and Acceptance Criteria**

1. Statistical Analysis Method

The defibrillation success rate equals the total number of success cases divided by the total number of tracked cases. Descriptive statistics of baseline parameters such as patient age, gender are also collected.

2. Acceptance Criteria

The final result of defibrillation success rate is obtained and its two-sided 95% confidence interval is calculated. If the lower limit of the confidence interval is above the target value 94.2%, the clinical performance of the product under application shall be proved to meet the requirement of recognized level in the industry.

- **Result**

176 clinical cases have been collected from 4 hospitals until 2022, with details as follows:

Gender Distribution of the Cases:

Gender	Number of Cases
Male	124
Female	52
Total	177

Age Distribution of the Cases:

populations	Age	Number of Cases
pediatric	1 month -< 3 year	1
	3-<12 year	1
	12-<18 year	21
adult	18-<40 year	50
	40-<60 year	40
	≥60 year	63
Total		176

Indications Distribution of the Cases:

Indications	Number of Cases
Ventricular fibrillation	140
Ventricular tachycardia	13
Others	23
Total	176

Successful/Failed Cases:

Successful Cases	Failed Cases	Total	success rate
172	4	176	97.7%

This PMCF collects 177 cases and 173 cases are successful, the final result of defibrillation success rate is 97.7%. Based on Confidence interval calculation formula:

$$\mathrm{p} \pm z_{\alpha/2}\sqrt{p(1-P)/n}$$

When α=0.05，$Z_{\alpha/2} = 1.96$

Finally, the two-sided 95% confidence interval of 97.7% is calculated as follows:(95.5%, 99.9%), the lower limit 95.5% is above the target value 94.2%.

The final result of defibrillation success rate is 97.7% (95%Cl: 95.5%, 99.9%). the lower limit 95.5% is above the target value 94.2%, the clinical performance of the Internal Defibrillation function of the product in question has been proved to meet the requirement of recognized level in the industry.

Semi-automated external defibrillation (AED)

- **Objective**

  To demonstrate the performance and safety of Semi-automated external defibrillation function, identifying previously unknown side-effects and ensuring the continued acceptability of the benefit-risk ratio.

- **General clinical Information**

1. **Subject Selection**
   - Ages eligible for selection: Adult and pediatric.
   - Sexes eligible for selection: All
   - Subjects have already used the Semi-automated external defibrillation function of Mindray defibrillator monitors

2. **Sample Size Calculation**

For the defibrillation success rate

This PMCF adopts the single-group design method, the OPC (Objective performance criteria) is set to 87.9 % (P0), Pt set to 95%. We also determine α=0.05，β=0.2，power (1-β)=0.8, clinical drop-out rate γ= 0.05. Based on the Formula for Estimating Sample Size of a Single Group Target Value Test, a minimum of 142 clinical cases are expected to be collected in this PMCF.

For the sensitivity

This PMCF adopts the single-group design method, the OPC (Objective performance criteria) is set to 90 % (P0), Pt set to 95%. We also determine α=0.05，β=0.2，power (1-β)=0.8, clinical drop-out rate γ= 0.05. Based on the Formula for Estimating Sample Size of a Single Group Target Value Test, a minimum of 251 clinical cases are expected to be collected in this PMCF.

For the specificity

This PMCF adopts the single-group design method, the OPC (Objective performance criteria) is set to 95 % (P0), Pt set to 99%. We also determine α=0.05，β=0.2，power (1-β)=0.8, clinical drop-out rate γ= 0.05. Based on the Formula for Estimating Sample Size of a Single Group Target Value Test, a minimum of 172 clinical cases are expected to be collected in this PMCF.

3. **Process**

Mindray will continuously collect clinical data of Semi-automated external defibrillation function. Mindray exports the clinical data from the device for analysis and statistics.

➢ **Adopted Statistical Analysis Method and Acceptance Criteria**

1. Statistical Analysis Method

According to the PMCF Plan, this clinical follow-up mainly verifies the defibrillation success rate and sensitivity/ specificity of the device in question, and must include at least 180 shockable rhythms cases and 10 non-shockable rhythms/conditions cases.

The defibrillation success rate equals the total number of success cases divided by the total number of tracked cases. Descriptive statistics of baseline parameters such as patient age, gende are also collected.

The sensitivity of device is the number of true positive shockable rhythms that have been correctly classed as shockable, expressed as a percentage of the total number of shockable rhythms: A/(A+C)*100%.

The specificity is the number of organized or perfusing rhythms that have been correctly classed as non-shockable rhythms/conditions by the algorithm, and expressed as a percentage of the total number of non-shockable rhythms/conditions: D/(B+D)*100%.

2. Acceptance Criteria

The final result of defibrillation success rate is obtained and its two-sided 95% confidence interval is calculated. If the lower limit of the confidence interval is above the target value 87.9%, the clinical performance of the product under application shall be proved to meet the requirement of recognized level in the industry.

The final result of sensitivity and specificity is obtained and its two-sided 95% confidence interval is calculated. If the lower limit of the sensitivity confidence interval is above the target value 90% and the lower limit of the specificity confidence interval is above the target value 95%, the clinical performance of the product in question shall be proved to meet the requirement of recognized level in the industry.

- **Result**

220 clinical cases have been collected until 2022, with details as follows:

Gender Distribution of the Cases:

Gender	Number of Cases
Male	52
Female	168
Total	220

Age Distribution of the Cases:

populations	Age	Number of Cases
pediatric	1 month -< 3 year	7
	3-<12 year	23

	12-<18 year	36
adult	18-<40 year	54
	40-<60 year	67
	≥60 year	33
Total		220

Defibrillation success rate:

Number of total Cases	success cases	success rate
150	140	93.3%

Positive: shockable rhythms cases. Negative: non-shockable rhythms/conditions cases.

AED	results of Expert diagnostic with ECG		Total
	Positive	Negative	/
Positive	419	16	435
Negative	19	1205	1224
Total	438	1221	1659

Sensitivity

A/(A+C)*100%=95.7%

Specificity

D/(B+D)*100%=98.7%

95% Confidence Interval Calculation:

For the defibrillation success rate of the device in question:

This PMCF collects 150 cases and 140 cases are successful, the final result of defibrillation success rate is **93.3%**. Based on Confidence interval calculation formula:

$$\mathrm{p} \pm z_{\alpha/2}\sqrt{p(1-P)/n}$$

When α=0.05，$Z_{\alpha/2} = 1.96$

Finally, the two-sided 95% confidence interval of 92.9% is calculated as follows:**(89.3%, 97.3%)**, the lower limit **89.3%** is **above** the target value **87.9%.**

For the sensitivity of the device in question:

This PMCF collects 438 shockable rhythms cases and 419 correct identification cases, the final result of sensitivity is **95.7%**. Based on Confidence interval calculation formula:

$$\mathrm{p} \pm z_{\alpha/2}\sqrt{p(1-P)/n}$$

When α=0.05，$Z_{\alpha/2} = 1.96$

Finally, the two-sided 95% confidence interval of 95.7% is calculated as follows:**(93.9%, 97.5%)**, the lower limit **93.9%** is **above** the target value **90%.**

For the specificity of the device in question:

This PMCF collects 1221 non-shockable rhythms/conditions cases and 1205 correct identification cases, the final result of specificity is **98.7%**. Based on Confidence interval calculation formula:

$$\mathrm{p} \pm z_{\alpha/2}\sqrt{p(1-P)/n}$$

When α=0.05，$Z_{\alpha/2} = 1.96$

Finally, the two-sided 95% confidence interval of 98.7% is calculated as follows: **(98.1%, 99.3%)**, the lower limit **98.1%** is **above** the target value **95%.**

- **Conclusion:**

The result of defibrillation success rate is 93.3% (95%Cl: **89.3**%, **97.3**%), the lower limit **89.3%** is upper than the target value **87.9**%.

The result of sensitivity rate is 95.7% (95%Cl: **93.9**%, **97.5**%), the lower limit **93.9**% is upper than the target value **90**%.

The result of specificity rate is 98.7% (95%Cl: **98.1%, 99.3%**), the lower limit **98.1%** is upper than the target value **95**%.

The clinical performance of the AED function of the product in question has been proved to meet the requirement of recognized level in the industry.

Non-invasive external pacing

- Objective

To demonstrate the performance and safety of Non-invasive external pacing function, identifying previously unknown side-effects and ensuring the continued

acceptability of the benefit-risk ratio.

- General clinical Information

1. Subject Selection

- Ages eligible for selection: Adult and pediatric.
- Sexes eligible for selection: All
- Subjects have already used the Non-invasive pacing function of Mindray defibrillator monitors

2. Sample Size Calculation

This PMCF adopts the single-group design method, the OPC (Objective performance criteria) is set to 58.9 % (P0), Pt set to 95%. We also determine α=0.05，β=0.2，power (1-β)=0.8, clinical drop-out rate γ= 0.05. Based on the Formula for Estimating Sample Size of a Single Group Target Value Test, a minimum of 190 clinical cases are expected to be collected in this PMCF.

3. Process

Mindray will continuously collect clinical cases from at least 2 hospitals. The clinical cases will be recorded and filled in the PMCF form by the medical staff according to the actual treatment conditions. Submit the signed PMCF form to Mindray for confirmation and statistics.

- Adopted Statistical Analysis Method and Acceptance Criteria

1. Statistical Analysis Method

The pacing success rate equals the total number of success cases divided by the total number of tracked cases. Descriptive statistics of baseline parameters such as patient age, gender are also collected.

2. Acceptance Criteria

The final result of pacing success rate is obtained and its two-sided 95% confidence interval is calculated. If the lower limit of the confidence interval is above the target value 58.9%, the clinical performance of the product under application shall be proved to meet the requirement of SOTA criteria in the industry.

- Result

216 clinical cases has collected from 2 hospitals until 2022, with details as follows:

Gender Distribution of the Cases

Gender	Number of Cases

Male	139
Female	77
Total	216

Age Distribution of the Cases

populations	Age	Number of Cases
pediatric	1month-< 3 year	1
	3-<12 year	1
	12-<18 year	2
adult	18-<40 year	12
	40-<60 year	78
	≥60 year	122
Total		216

Indications Distribution of the Cases:

Indications	Number of Cases
Bradycardia	148
Asystole	68
Total	216

Results

Successful Cases	Failed Cases	Total	success rate
184	32	216	85.2%

This PMCF collects 216 cases and 172 cases are successful, the final result of pacing success rate is 85.2%. Based on Confidence interval calculation formula:

$$\mathrm{p} \pm z_{\alpha/2}\sqrt{p(1-P)/n}$$

When α=0.05，$Z_{\alpha/2} = 1.96$

Finally, the two-sided 95% confidence interval of 85.2% is calculated as follows:(80.5%, 89.9%), the lower limit 80.5% is above the target value 58.9%.

The final result of pacing success rate is 85.2% (95%Cl: 80.5%, 89.9%). the lower limit 80.5% is above the target value 58.9%, the clinical performance of the Non-invasive external pacing of the product in question has been proved to meet the requirement of SOTA criteria in the industry.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking (if applicable).

SpO2:

Objectives of the study

Though clinical trials to verify the effectiveness and accuracy of the SPO2 measurement function of Mindray's SPO2 module in clinical applications.

Summary of study methods

According to the test method recommended by the ISO80601-2-61:2011 SpO2 professional clinical standard, the SpO2 measurement results were compared with the invasive blood gas analysis measurement values.

Inclusion criteria:

1. Subjects must understand clinical trials and participate voluntarily.
2. Meet the ASA classification I of the Anesthesia Association.
3. The subjects are healthy adults COHb<3%, MetHb<2%, ctHb>l0g/dL.
4. Healthy adult subjects need to be able to withstand the minimum medical risk of controlled oxygen reduction to the specified level in the clinical trial protocol.

Exclusion criteria:

1. The subject has any systemic disease.
2. Subject is methemoglobin.
3. Subjects do not understand clinical trials and their risks.
4. Smoker
5. Pregnancy
6. Subject has symptoms or history of peripheral ischemia
7. The age of the subject must not be less than 18 years old
8. Other unqualified conditions identified by cliniciants

Primary and secondary endpoint

The acceptance criteria and data analysis are as follows:

Accuracy: The measurement range of SpO2 is 0%~100%, and the measurement error is ±3% in the range of 70%~100%. And the measurement range of PR is 20~300bpm, and the measurement error is ±3bpm in the range of 20~300bpm.

Requirements for patients: Each probe should test at least 10 subjects, and a total of at least 200 sets of comparative data are obtained for each type of subjects.

Results

A total of 20 subjects were completed in this trial, and each subject was subject to 20 comparison tests. The results are as follows:

Table**1** Analysis of SpO2 clinical trial data

SpO2 probe	Probe Type	Probed Site	Index	Accuracy	Acceptance Criterion	Conclusion
512F	Adult	Finger	SPO2	1.1013	≤ 2	Meet the requirement
			PR	2.4619	≤ 3	Meet the requirement
512H	Pediatric	Finger	SPO2	1.1529	≤ 2	Meet the requirement
			PR	2.3752	≤ 3	Meet the requirement
512E	Adult	Finger	SPO2	1.2572	≤ 2	Meet the requirement
			PR	2.1972	≤ 3	Meet the requirement
512G	Pediatric	Finger	SPO2	1.3547	≤ 2	Meet the requirement
			PR	1.2057	≤ 3	Meet the requirement
518B	Neonate	Foot	SPO2	1.3804	≤ 2	Meet the requirement
			PR	1.5186	≤ 3	Meet the requirement
520A	Adult	Foot	SPO2	1.2773	≤ 2	Meet the requirement
			PR	2.1689	≤ 3	Meet the requirement

SpO2 probe	Probe Type	Probed Site	Index	Accuracy	Acceptance Criterion	Conclusion
520P	Pediatric	Foot	SPO2	1.1658	≤ 2	Meet the requirement
			PR	2.2028	≤ 3	Meet the requirement
520I	Infant	Toe	SPO2	1.3123	≤ 2	Meet the requirement
			PR	2.3677	≤ 3	Meet the requirement
520N	Neonate	Foot	SPO2	1.3577	≤ 2	Meet the requirement
			PR	2.1644	≤ 3	Meet the requirement

Conclution

The effectiveness and accuracy of the SPO2 measurement function of Mindray's SPO2 module meet the ISO 81060-2:2013 SPO2 professional clinical standard.

NIBP:

Objectives of the study

Though clinical trials to verify the safety and effectiveness of the NIBP measurement function of Mindray's NIBP module in clinical applications.

Summary of study methods

According to the trial method recommended in the ISO81060-2:2013 NIBP professional clinical standard, the data of adult/pediatric group (3 years old and older) and neonate group (3 years old and younger) were compared with invasive blood pressure.

Group	Attributes	Abstract
adult/pediatric (3 years old and older)	Inclusion criteria	1. Select people aged 3 years and over who have undergone arterial intubation due to clinical needs for diagnosis to participate in clinical trials.

compared with invasive blood pressure		2. Subjects need to understand the clinical trial and agree to participate. 3. If the subject is underage or the subject does not have the cognitive ability, the legal guardian of subject must understand the clinical trial and agree to the subject to participate. If the subject has cognitive ability, he should also understand the content of the trial and participate voluntarily.
	Exclusion criteria	Subjects with severe shock, use of a heart lung machine, upper extremity infection heart or arterial malformations (excluding those after surgical correction).
	Number of the cases	According to the trial method compared with invasive blood pressure recommended in the ISO 81060-2:2013 NIBP professional clinical standard, the number of Subjects for adult/pediatric group (3 years old and older) must not be less than 20 cases.
adult/pediatric (3 years old and older) compared with auscultation	Inclusion criteria	1. Select people aged 3 years and over who have undergone arterial intubation due to clinical needs for diagnosis to participate in clinical trials. 2. Subjects need to understand the clinical trial and agree to participate. 3. If the subject is underage or the subject does not have the cognitive ability, the legal guardian of subject must understand the clinical trial and agree to the subject to participate. If the subject has cognitive ability, he should also understand the content of the trial and participate voluntarily.
	Exclusion criteria	Subjects with severe shock, use of a heart lung machine, upper extremity infection heart or arterial malformations (excluding those after surgical correction)
	Number of the cases	According to the trial method compared with auscultation recommended in the ISO 81060-2:2013 NIBP professional clinical standard, the number of Subjects for adult/pediatric group (3 years old and older) must not be less than 85 cases included at least 35 subjects aged 3~12 years.
Neonate (3 years old and younger) compared with invasive blood	Inclusion criteria	1. Select people aged 3 years and younger who have undergone arterial intubation due to clinical needs for diagnosis to participate in clinical trials. 2. The legal guardian of subject must understand the clinical trial and agree to the subject to participate. If the subject has cognitive ability, he should also understand the content of the trial and participate voluntarily.

pressure	Exclusion criteria	Subjects with severe shock, use of a heart lung machine, upper extremity infection heart, arterial malformations (excluding those after surgical correction) or severe arrhythmia.
	Number of the cases	According to the trial method compared with invasive blood pressure recommended in the ISO 81060-2:2013 NIBP professional clinical standard, the number of Subjects for group (3 years old and younger) must not be less than 18 cases.

Main evaluation index: The absolute value of the mean of the difference between the systolic/diastolic/mean pressure measured by the tested device and the reference device does not exceed 5.0 mmHg, and the standard deviation does not exceed 8.0 mmHg. If results do not comply with any one of the two criteria, the tested device does not meet the requirement in ISO81060-2:2013 (E).

Results

A total of 20 subjects including11men and 9 women in the adult/pediatric group are tested, and the gender and age distribution of the subjects meet the standard requirements. The results are as follows:

Table2 NIBP clinical trial data analysis for adults/pediatric

All Data		**Number of Data Groups**	Range (mmHg)	**Mean Deviation (mmHg)**			**Standard Deviation (mmHg)**		
				Results	**Acceptance Criterion**	**Conclusion**	**Results**	**Acceptance Criterion**	**Conclusion**
Tested method vs invasive blood pressure	SBP	**200**	**86~191**	-3.9	Absolute value ≤ 5.0	Meet the requirement	1.4	≤ 8.0	Meet the requirement
	DBP	200	40~113	-3.7	Absolute value ≤ 5.0	Meet the requirement	1.3	≤ 8.0	Meet the requirement
	MBP	200	62~135	-3.8	Absolute value ≤ 5.0	Meet the requirement	1.1	≤ 8.0	Meet the requirement

A total of 85 subjects including 30 men and 55 women in the adult/pediatric group are tested, and the gender and age distribution of the subjects meet the standard requirements. The results are as follows:

Table3 NIBP clinical trial data analysis for adults/pediatric

All Data	**Number of Data Groups**	**Range (mmHg)**	**Mean Deviation (mmHg)**			**Standard Deviation (mmHg)**		
			Results	**Acceptance Criterion**	**Conclusion**	**Results**	**Acceptance Criterion**	**Conclusion**

Tested method vs auscultation	SBP	255	75~218	4.0	Absolute value ≤ 5.0	Meet the requirement	5.5	≤ 8.0	Meet the requirement
	DBP	255	34~121	-1.9	Absolute value ≤ 5.0	Meet the requirement	4.6	≤ 8.0	Meet the requirement

A total of 18 subjects in the neonate group are tested, and the gender and age distribution of the subjects meet the standard requirements. The results are as follows:

Table**4** NIBP clinical trial data analysis for neonate

All Data		**Number of Data Groups**	**Range (mmHg)**	**Mean Deviation (mmHg)**			**Standard Deviation (mmHg)**		
				Results	**Acceptance Criterion**	**Conclusion**	**Results**	**Acceptance Criterion**	**Conclusion**
Tested method vs invasive blood pressure	SBP	180	40~117	4.5	Absolute value ≤ 5.0	Meet the requirement	1.8	≤ 8.0	Meet the requirement
	DBP	180	21~80	4.1	Absolute value ≤ 5.0	Meet the requirement	1.7	≤ 8.0	Meet the requirement
	MBP	180	27~93	4.7	Absolute value ≤ 5.0	Meet the requirement	2.0	≤ 8.0	Meet the requirement

Conclution

The effectiveness and accuracy of the NIBP measurement function of Mindray's NIBP module meet the ISO 81060-2:2013 NIBP professional clinical standard.

ECG:

Objectives of the study

Though clinical trials to verify the safety and effectiveness of the ECG measurement function of Mindray's ECG module in clinical applications.

Summary of study methods

1) Use the Mindray's ECG module (Device Under Test (DUT)) to monitor ECG for selected subjects, and use the Monitoring devices that have been on the market for a long time (Reference Device (RCT)) to monitor the above parameters at the same time. Through this clinical trial, determine the consistent equivalence of the DUT and RCT in terms of the monitoring performance of the ECG parameters.

2) Record clearly and in detail: The information of the experimental subjects of the clinical trial; the environmental information of the monitoring; the information of the time and place of the trial (see the clinical trial record form).

3) ECG monitoring. On the subject's body, proceed as follows:

- Attach two sets of cardiac electrodes adjacent to each other according to the five-lead connection method; or attach two sets of cardiac electrodes adjacent to each other according to the three-lead connection method;
- Then connect the ECG lead wires of the DUT and the RCT respectively.
- Turn on the ST segment analysis and arrhythmia monitoring functions of the DUT and the RCT.
- Turn on the DUT and the RCT and observe the ECG waveform of lead II. During the observation process, you can switch to other leads to evaluate the overall situation of ECG monitoring.
- Record the HR value and the ST segment values of all leads every 3 to 5 minutes, and obtain 20 sets of data.

Results

Trial data and processing results:

HR (General monitoring)

Statistic results of respiratory rate

Statistical item	Number of Data Sets	Mean deviation (bpm)	Standard deviation (bpm)	Mean ± SD Data within range	Mean±SD~ Mean±2SD Data within range	Mean±2SD Data outside range
HR	1340	0.034	0.51	1119 (83.5%)	98 (7.3%)	123 (9.2%)

HR (Diagnosis mode)

HR statistical results in diagnosis mode

Statistical item	Number of Data Sets	Mean deviation (bpm)	Standard deviation (bpm)	Mean ± SD Data within range	Mean ± SD~ Mean±2SD Data within range	Mean±2SD Data outside range
HR	1340	0.028	0.64	1053 (78.6%)	208 (15.5%)	79 (5.9%)

ST segment

Statistical results of ST segment

Statistical item	Number of Data Sets	Mean deviation (mV)	Standard deviation (mV)	Mean ± SD Data within range	Mean ± SD~ Mean±2SD Data within range	Mean±2SD Data outside range
ST- I	1300	0	0.01	1270 (97.7%)	0	30 (2.3%)

ST-II	1300	0	0.01	1255 (93.6%)	0	45 (3.4%)
ST-III	1300	0	0.01	1255 (93.6%)	0	45 (3.4%)
ST-aVR	1300	0	0.01	1259 (94.4%)	0	41 (3.1%)
SP-aVL	1300	0	0.01	1265 (95.4%)	0	35 (2.6%)

Conclusions

During the clinical trial, all subjects are in good condition, and none of the subjects have discomfort symptoms or adverse reactions due to the use of Mindray's ECG module for monitoring. Therefore, it can be considered safe to use the Mindray ECG module for related parameter monitoring. Clinical performance of ECG function meets SOTA benchmark.

IBP:

Objectives of the study

Though clinical trials to verify the safety and effectiveness of the IBP measurement function of Mindray's IBP module in clinical applications.

Summary of study methods

(1) Use the IBP module (Device Under Test (DUT)) to monitor IBP for selected subjects, and use the Mindray's Monitoring devices that have been on the market for a long time (Reference Device (RCT)) to monitor the above parameters at the same time. Through this clinical trial, determine the consistent equivalence of the DUT and RCT in terms of the monitoring performance of the IBP parameters.

(2) Record clearly and in detail: The information of the experimental subjects of the clinical trial; the environmental information of the monitoring; the information of the time and place of the trial (see the clinical trial record form).

(3) IBP monitoring. On the subject's body, proceed as follows:

- Learn the blood supply of the branch before puncture and catheterization. For subjects who underwent radial artery puncture, perform the AllenS test, and perform radial artery puncture for those with normal Allen-S test results. For subjects who underwent dorsal pedis artery puncture, learn the blood supply of the posterior tibial artery, and perform the dorsal pedis artery puncture only after ensuring that the blood supply is good.
- Before the first comparative measurement, calibrate the. pressure for the DUT and RCT.
- Fill the tubing system of the pressure tube and sensor with normal saline, making sure there are no air bubbles in the tubing.
- Perform arterial puncture (radial artery or dorsal pedis artery, as noted on the record form), and connect a manometric tube containing a heparin solution.
- Connect the pressure measuring tube to the pressure tubes and sensors of the DUT and the RCT respectively through the three-way valve switch,
- and zero the pressure sensors of the DUT and the RCT respectively.
- At the same time, directly measure the arterial blood pressure, and record synchronous measurement data of systolic blood pressure, mean blood pressure and diastolic blood pressure every 3 to 5 minutes; obtain 20 sets of data.

Results

Acceptance Criteria：

- **IBP: Mean deviation ≤ ± 1mmHg, standard deviation ≤ 5mmHg.**
- **IBP PR: Mean deviation ≤ ±1bpm, standard deviation ≤ 2 bpm.**

Trial data and processing results:

Systolic pressure

- **Statistic results of IBP systolic pressure**

Statistical item	Number of Data Sets	Mean deviation (rpm)	Standard deviation (rpm)	Mean ± SD Data within range	Mean±SD~ Mean±2SD Data within range	Mean±2SD Data outside range
IBP-sys	1340	0.24	2.39	1076 (80.3%)	141 (10.5%)	123 (9.2%)

MBP

Statistic results of IBP MBP

Statistical item	Number of Data Sets	Mean deviation (rpm)	Standard deviation (rpm)	Mean ± SD Data within range	Mean±SD~ Mean±2SD Data within range	Mean±2SD Data outside range
IBP-mean	1340	0.22	2.53	1063 (79.3%)	176 (13.2%)	101 (7.5%)

DBP

Statistic results of IBP DBP

Statistical item	Number of Data	Mean deviation (rpm)	Standard deviation (rpm)	Mean ± SD	Mean±SD~ Mean±2SD	Mean±2SD

	Sets			Data within range	Data within range	Data outside range
IBP-dia	1340	0.21	2.61	1069 (79.8%)	181 (13.5%)	90 (6.7%)

Conclusions

During the clinical trial, all subjects are in good condition, and none of the subjects have discomfort symptoms or adverse reactions due to the use of Mindray's IBP module for monitoring. Therefore, it can be considered safe to use the Mindray IBP module for related parameter monitoring. Clinical performance of IBP function meets SOTA benchmark.

Temp:

Objectives of the study

Though clinical trials to verify the safety and effectiveness of the Temp measurement function of Mindray's TEMP module in clinical applications.

Summary of study methods

(1) Use the TEMP module (Device Under Test (DUT)) to monitor Temp for selected subjects, and use the Mindray's Monitoring devices that have been on the market for a long time (Reference Device (RCT)) to monitor the above parameters at the same time. Through this clinical trial, determine the consistent equivalence of the DUT and RCT in terms of the monitoring performance of the Temp parameters.

(2) Record clearly and in detail: The information of the experimental subjects of the clinical trial; the environmental information of the monitoring; the information of the time and place of the trial (see the clinical trial record form).

(3) Body temperature (Temp) monitoring.

- For subjects who need body temperature monitoring clinically, use the body surface temperature probe to compare body temperature.
- Adhere the body temperature probes of the DUT and the RCT adjacent to the subject's body (The axilla is the first choice, and other parts should be indicated in the case report form).
- Record a pair of body temperature values every 3 to 5 minutes. Obtain 20 pairs of data.

Results

Trial data and processing results:

Body temperature

Statistic results of body temperature

Statistical item	Number of Data Sets	Mean deviation (°C)	Standard deviation (°C)	Mean ± SD Data within range	Mean±SD~ Mean±2SD Data within range	Mean±2SD Data outside range
Temp	1340	-0.01	0.09	806 (60.1%)	403 (30.1%)	131 (9.8%)

Conclusions

During the clinical trial, all subjects are in good condition, and none of the subjects have discomfort symptoms or adverse reactions due to the use of Mindray's Temp module for monitoring. Therefore, it can be considered safe to use the Mindray Temp module for related parameter monitoring. Clinical performance of Temp function meets SOTA benchmark.

CO2:

Objectives of the study

Though clinical trials to verify the safety and effectiveness of the CO2 measurement function of Mindray's CO2 module in clinical applications.

Summary of study methods

(1) Use the CO2 module (Device Under Test (DUT)) to monitor CO2 for selected subjects, and use the Mindray's Monitoring devices that have been on the market for a long time (Reference Device (RCT)) to monitor the above parameters at the same time. Through this clinical trial, determine the consistent equivalence of the DUT and RCT in terms of the monitoring performance of the CO2 parameters.

(2) Record clearly and in detail: The information of the experimental subjects of the clinical trial; the environmental information of the monitoring; the information of the time and place of the trial (see the clinical trial record form).

(3) CO2 monitoring. On the subject's body, proceed as follows:

- Set the operation mode to measurement mode, and set the flow rate, gas compensation, and humidity compensation correctly.
- Select the correct type of water tank to connect the sampling tube, connect it to the CO2 module, and connect the DUT and the RCT to the respiration airway at the same time through a three-way valve.
- After the CO2 module finishes preheating and enters the measurement state, record a set of EtCO2, InsCO2 and aWRR values every 3 to 5 minutes and obtain 20 sets of data.

Results

Acceptance Criteria: Consistency requirements of EtCO2 and InsCO2 measurement results: Mean deviation ≤±2mmHg, standard deviation ≤5 mmHg.

Trial data and processing results:

Statistical results of ETCO2 measurements

Statistical item	Number	Mean deviation	Standard deviation	Mean ± SD	Mean±SD~	Mean±2SD

	of Data Sets	(rpm)	(rpm)	Data within range	Mean±2SD Data within range	Data outside range
EtCOi	1340	-0.029	0.71	1102 (82.2%)	144 (10.7%)	94 (7.0%)

Statistical results of InsCO2 measurements

Statistic results of InsCO2

Statistical item	Number of Data Sets	Mean deviation (rpm)	Standard deviation (rpm)	Mean ± SD Data within range	Mean±SD~ Mean±2SD Data within range	Mean±2SD Data outside range
InsCOi	1340	-0.05	0.49	994 (74.2%)	194 (14.5%)	152 (11.3%)

Statistical results of awRR measurements

Statistical item	Number of Data Sets	Mean deviation (rpm)	Standard deviation (rpm)	Mean ± SD Data within range	Mean±SD~ Mean±2SD Data within range	Mean±2SD Data outside range

InsCOi	1340	0.06	0.28	1221 (91.2%)	0	119 (8.8%)

Conclusions

During the clinical trial, all subjects are in good condition, and none of the subjects have discomfort symptoms or adverse reactions due to the use of Mindray's CO2 module for monitoring. Therefore, it can be considered safe to use the Mindray CO2 module for related parameter monitoring. Clinical performance of CO2 function meets SOTA benchmark.

RESP:

Objectives of the study

Though clinical trials to verify the safety and effectiveness of the CO2 measurement function of Mindray's RESP module in clinical applications.

Summary of study methods

(1) Use the RESP module (Device Under Test (DUT)) to monitor RESP for selected subjects, and use the Mindray's Monitoring devices that have been on the market for a long time (Reference Device (RCT)) to monitor the above parameters at the same time. Through this clinical trial, determine the consistent equivalence of the DUT and RCT in terms of the monitoring performance of the RESP parameters.

(2) Record clearly and in detail: The information of the experimental subjects of the clinical trial; the environmental information of the monitoring; the information of the time and place of the trial (see the clinical trial record form).

(3) RESP monitoring. On the subject's body, proceed as follows:

- Attach two sets of cardiac electrodes adjacent to each other according to the five-lead connection method; or attach two sets of cardiac electrodes adjacent to each other according to the three-lead connection method;

- Then connect the ECG lead wires of the DUT and the RCT respectively.
- Turn on the DUT and the RCT and record the respiratory rate (RR) value every 3 to 5 minutes to obtain 20 sets of data.
- Select the respiratory lead I or II, observe the respiratory waveform of the corresponding lead, and record the selected respiratory lead in the case report form.

Results

Trial data and processing results:

Respiratory rate

Statistic results of respiratory rate

Statistical item	Number of Data Sets	Mean deviation (rpm)	Standard deviation (rpm)	Mean ± SD Data within range	Mean±SD~ Mean±2SD Data within range	Mean±2SD Data outside range
RR	1340	0.06	0.32	1192 (88.9%)	0	148 (11.1%)

Conclusions

During the clinical trial, all subjects are in good condition, and none of the subjects have discomfort symptoms or adverse reactions due to the use of Mindray's RESP module for monitoring. Therefore, it can be considered safe to use the Mindray RESP module for related parameter monitoring. Clinical performance of RESP function meets SOTA benchmark.

5.3 Summary of clinical data from other sources (if applicable)

N.A.

5.4 An overall summary of the clinical performance and safety

Defibrillator/monitor is intended to be used for monitoring, defibrillator and alarming. When unsatisfactory physiological PATIENT states, unsatisfactory functional states of the patient monitor or hazards to the patient or operator due to the patient monitor exists, the Defibrillator/monitor detects alarm conditions and generate alarm signals. For a patient with ventricular fibrillation (VF)/ventricular tachycardia (VT), the effective and timely two-way defibrillation treatment presents high success rate of treatment.

External Defibrillation

The defibrillation success rate is the primary endpoint, a total of 174 cases of the use of the BeneHeart series of defibrillation monitors were collected until 2022. 164 cases are successful, the final result of defibrillation success rate is 94.3% (95%Cl: 90.9%, 97.7%). The lower limit 90.9% is above the target value 87.9%, the clinical performance of the external defibrillation function of the product in question has been proved to meet the requirement of recognized level in the industry.

Synchronized Cardioversion

The cardioversion success rate is the primary endpoint, a total of 185 cases of the use of the BeneHeart series of defibrillation monitors were collected until 2022. 175 cases are successful, the final result of defibrillation success rate is 94.6% (95%Cl: 91.4%, 97.8%). The lower limit 91.4% is above the target value 88.9%, the clinical performance of the Synchronized Cardioversion function of the product in question has been proved to meet the requirement of recognized level in the industry.

Internal Defibrillation

The defibrillation success rate is the primary endpoint, a total of 176 cases of the use of the BeneHeart series of defibrillation monitors were collected until 2022. 173 cases are successful, the final result of defibrillation success rate is 97.7% (95%Cl: 95.5%, 99.9%). The lower limit 95.5% is above the target value 94.2%, the clinical performance of the Internal Defibrillation function of the product in question has been proved to meet the requirement of recognized level in the industry.

Semi-automated external defibrillation (AED)

The primary endpoint is the defibrillation success rate and sensitivity/specificity, a total of 220 cases of the use of the BeneHeart series of defibrillation monitors were collected until 2022. 140 cases are successful, the result of defibrillation success rate is 93.3% (95%Cl: 89.3%, 97.3%), the lower limit 89.3% is upper than the target value 87.9%.

The result of sensitivity rate is 95.7% (95%Cl: 93.9%, 97.5%), the lower limit 93.9% is upper than the target value 90%.

The result of specificity rate is 98.7% (95%Cl: 98.1%, 99.3%), the lower limit 98.1% is upper than the target value 95%.

The clinical performance of the AED function of the product in question has been proved to meet the requirement of recognized level in the industry.

Non-invasive external pacing

The defibrillation success rate is the primary endpoint, a total of 216 cases of the use of the BeneHeart series of defibrillation monitors were collected until 2022. 172 cases are successful, the final result of defibrillation success rate is 85.2% (95%Cl: 80.5%, 89.9%). The lower limit 80.5% is above the target value 58.9%, the clinical performance of the Non-invasive external pacing of the product in question has been proved to meet the requirement of SOTA criteria in the industry.

Monitor and defibrillator technology has a long history of acceptable and well-understood performance and risk. It can compatible with a high level of protection of health and safety and acceptable according to current knowledge/the state of the art. Based on the clinical data of the equivalent equipment and similar equipment, there are no residual risks and uncertainties or unanswered questions identified, the device is the useful medical equipment that the benefit to weight against the risk of the identified hazards is acceptable.

According to the conclusion of residual risks evaluation, for the intended patients, myocardial damage and skin burns can occur during or after the use of the medical device.

Factor	**Question to consider**	**Notes**
Assessment of Benefits of Devices		
1. Type of benefit(s)	- What primary endpoints or surrogate endpoints were evaluated? - What key secondary endpoints orsurrogate endpoints were evaluated? - What value do patients place on the benefit?	monitors are intended to be used for monitoring, displaying, reviewing, storing, alarming and transferring of multiple physiological parameters. Patient monitor improves the efficiency of medical staff in monitoring the physiological parameters of patients Patients put a high value on this treatment because it has the potential to save their lives. Patients are therefore willing to accept the risks of this treatment to achieve the benefit. If the treatment provides timely successful defibrillation, the patient will survive a life threatening cardiac arrest situation and will be able to seek further treatment.
2. Magnitude of the benefit(s)	- For each primary and secondary endpoint or surrogate endpoints evaluated: o What was the magnitude of	The patient monitor complies with the standard test, bench test and usability test to approve the accuracy during monitoring

	each treatment effect? - What scale is used to measure the benefit? o How did the benefit rank on that scale?	According to the AHA Recommendations Defibrillators are recommended to treat tachyarrhythmias requiring a shock,the Recommendations level is CLASS I (STRONG) Benefit >>> Risk,based on B-NR LEVEL (QUALITY) OF EVIDENCE; Defibrillators using biphasic waveforms are preferred over monophasic defibrillators for treatment of tachyarrhythmias , the Recommendations level is CLASS IIa (MODERATE) Benefit >> Risk,based on LEVEL B-R (Randomized).
3. Probability of the patient experiencing one or more benefit(s)	- Was the study able to predict which patients will experience a benefit? - What is the probability that a patient for whom the device is intended will experience a benefit? - How did the benefits evaluated vary across sub-populations? (If the study was sufficiently powered for subpopulations, note specific subpopulations, nature of difference and any known reasons for these differences.) - Was there a variation in public health benefit for different populations? - Even if the benefit is in a small portion of the population, do those patients who would experience the benefit value it?	All the parameters can be monitored on single adult, pediatric, and neonatal patients. a) **Can this study predict which patients will benefit?** Sudden death is the first manifestation of cardiovascular disease. Prompt discovery and shock defibrillation and cardiopulmonary resuscitation can save a significant proportion of sudden deaths; The probability of patient survival decreases by about 7 %~10%% every 1 min delay from falling to defibrillation. b) **What is the probability of the expected benefit to the patient?** The successful definition defined in the AHA cardiopulmonary resuscitation guide in 2015 is that ventricular fibrillation is terminated within 5s after electric shock is applied. When the defibrillation success rate is in the range of 85% to 95%, it is considered that the product design meets expectations. c) **Are public health benefits vary among different groups?** Ventricular fibrillation can occur in any population, and the most immediate treatments for ventricular fibrillation are defibrillation and cardiopulmonary resuscitation. There is no evidence from the AHA guidelines that de<unk> brillation outcomes vary between populations with regard to ventricular fibrillation.

4. Duration of effect(s)	- Could the duration, if relevant, of each treatment effect, including primary and secondary endpoints be determined? If so, what was it? - Is the duration of the benefit achieved of value to patients?	Patients can be continuously monitored during the hospitalization period and benefit continuously If the treatment provides timely successful defibrillation, the patient will survive a life threatening cardiac arrest situation and will be able to seek further treatment.
Assessment of risks of Devices		
5. Severity, types, number and rates of harmful events (events and consequences):		
· Device-related serious adverse events	- What are the device-related serious adverse events for this product?	According to section 4.3, No serious adverse events
· Device-related non-serious adverse events	- What are the device-related non-serious adverse events for this product?	According to section 4.3, the non-serious adverse events had been all solved and we did risk control measurement.
· Procedure-related complications	- What other procedure-related complications may a patient be subject to?	Not found yet
6. Probability of a harmful event	- What percent of the intended patient population would expect to experience a harmful event? - What is the incidence of each harmful event in the study population? - How much uncertainty is in that estimate? - How does the incidence of harmful events vary by subpopulation (if applicable)? - Are patients willing to accept the probable risk of the harmful event, given the probable benefits of the device?	a) **What is the probability of adverse events in the intended users?** Since the market release of BeneHeart D5/D6 defibrillator/monitor, 131917 sets of them have been sold, and 25 sets of them have been reported to have the adverse events mentioned above. So the probability of adverse events is 25/131917 b) **Is the patient willing to accept the risk of possible adverse events while considering the possible benefits of the device?** The magnitude of this benefit is either life or death.So,patients put a high value on this treatment because it has the potential to save their lives. Patients are therefore willing to accept the risks of this treatment to achieve the benefit.

7. Duration of harmful events	- How long does the harmful event last? - Is the harmful event reversible? - What type of intervention is required to address the harmful event?	a) **Is the adverse event reversible?** All adverse events are reversible and temporary damages except myocardial damage. b) **What measures should be taken for adverse events?** Mindray PMS will regularly collect, analyze, correct and prevent post-marketing adverse events.
8. Risk from false-positive or false-negative results for diagnostics	- What are the consequences of a false positive? - What are the consequences of a false negative? - Is this the only means of diagnosing the problem, or is it part of an overall diagnostic plan	According to section 4.4.1, 4.4.2, 4.4.3, the consequences of a false positive or false negative are identified and verificated with safety test, bench test, usability test risk control measurement
Conclusion	Through the parameter monitoring, medical staff have established sufficient conditions to provide patients with a better medical monitoring environment, and the benefits are obvious. Although there is also the possibility of false positives and false negatives in parameter monitoring, the impact of false positives and false negatives is limited and will not cause substantial harm to patients. In addition, the parameter monitoring of the patient monitor has the advantages of simplicity of equipment, convenient operation, timeliness, economy, etc. compared with other known ones. Therefore, from the perspective of benefit and risk, patient monitor parameter monitoring has obvious benefits, controllable risks, and has strong clinical application popularization characteristics. Defibrillator are life-saving devices used in emergency situations. They have been shown to have a high benefit for patients with underlying diseases that remain undetected until sudden cardiac arrest occurs. The time from collapse to defibrillation is critical in-patient survival. For every minute that passes between collapse and defibrillation, survival rates from VF SCA decrease 7% to 10%. In conclusion, given the available information above, the defibrillator's support for patients in cardiac arrest who are unconscious, not breathing, or without circulation the probable benefits outweigh the probable risks.	

5.5 Ongoing or planned post-market clinical follow-up

After the product is marketed in the Europe, Mindray will continue to track the success rate of defibrillators to ensure the long-term safety of the product. In the CE region, China, and ROW, we will select several hospitals for follow-up (the content here will be refreshed after the hospital are confirmed). The PMCF is organized and carried out by Mindray's clinical engineers, who will control the quality and progress of data collection. During the clinical follow-up process, we will summarize the clinical follow-up results every year until the collection of cases is completed to ensure that the product is safe and effective in the clinic.

If there are any emerging risks, complications or unexpected device failures have been detected, the summary of safety and clinical performance shall be updated throughout the life cycle of the device.

6. Possible diagnostic or therapeutic alternatives

Function	Manufacturer's	Alternatives
External Defibrillation	biphasic waveforms defibrillators	Monophasic waveform defibrillators
Synchronous cardioversion	Electrical cardioversion	1. pharmacological cardioversion 2. radiofrequency ablation
Internal Defibrillation	internal defibrillation	None
Semi-automated external defibrillation (AED)	Semi-automated defibrillation	manual defibrillation
Non-invasive external pacing	external pacing	1. transcutaneous pacing 2. transvenous pacing 3. percussion pacing 4. epicardial pacing
CPR feedback	CPR feedback	CPR metronome
ECG	ECG	1. PR (SPO2) 2. Ultrasound Cardiogram （UCG）
IBP	Invasive Blood Pressure	Noninvasive Blood Pressure
TEMP	Continuous body temperature monitoring	Infrared temperature
CO2	CO2	1. colorimetric CO2 2. PaCO2
RESP	ECG-derived respiration	1. Visual respiratory assessment

		2. Acoustic respiratory assessment 3. PPG-derived respiration
SPO2	pulse oximetry (SpO2)	arterial oxygen saturation (SaO2)
NIBP	Oscillometric blood pressure	1. Auscultatory blood pressure 2. invasive blood pressure (IBP)

External Defibrillation

Modern defibrillators are classified according to 2 types of waveforms: monophasic and biphasic. Monophasic waveform defibrillators were introduced first, but biphasic waveforms are used in almost all AEDs and manual defibrillators sold today. Energy levels vary by type of device and manufacturer. [1-3]

Defibrillators with monophasic waveform deliver current in one polarity and were the first to be introduced. They can be further categorized by the rate at which the current pulse decreases to zero. If the monophasic waveform falls to zero gradually, the term damped sinusoidal（MDS）is used. If the waveform falls instantaneously, the term truncated exponential（MTE）is used (figure 1) [1-8].

Few monophasic waveform defibrillators are being manufactured, but many are still in use, and most use MDS waveforms. As noted above, no specific waveform characteristic (either monophasic or biphasic) is consistently associated with a greater incidence of ROSC or higher survival to hospital discharge rates after cardiac arrest [1-8].

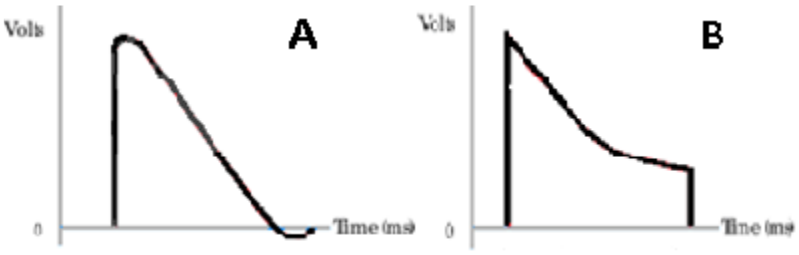


Figure 1. Monophasic waveforms. A. Damped sinusoidal wave (A) and truncated exponential (B).

Biphasic waveform defibrillator was developed later. The delivered current flows in a positive direction for a specified time and then reverses and flows in a negative direction for the remaining duration of the electrical discharge (figure 2). With biphasic waveforms there is a lower defibrillation threshold (DFT) that allows reductions of the energy levels administrated and may cause less myocardial damage. The use of biphasic waveforms permits a reduction in the size and weight of defibrillators. [1-8]

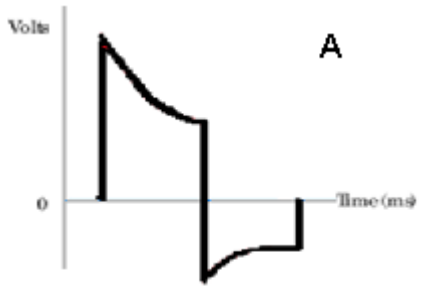


Figure 2. A. Biphasic waveform.

	Biphasic	Monophasic
Volume and Weight	lighter and smaller	– Heavy, Unportable
Current market share	– Majority MEDs – Almost all AEDs	– small part of historical inventory
Easy of use	– Simple, easy	– old products, not updated – old technology, difficult to use
shock success rate	– equivalent or higher	/
myocardial damage	– less	/
energy	– 200 J to 360 J escalating energy (BTE) for Adult	200 J to 360 J escalating energy (MDS) for adult 200 J to 360 J escalating energy (MTE) for adult

Synchronous cardioversion

Drug cardioversion or pharmacological cardioversion is to convert an abnormal and potentially dangerous heart rhythm (atrial fibrillation or atrial flutter etc.) into a normal sinus rhythm using oral or intravenous agents (amiodarone, flecainide, ibutilide, propafenone, and vernakalant etc.). Pharmacological cardioversion is a conventional therapy. The main advantages of pharmacological cardioversion are cost effective, avoiding the resource intensive procedural sedation and corresponding risks due to anesthesia procedures comparing to electrical cardioversion. While electrical cardioversion usually has a higher success rate than pharmacological cardioversion in the short-term.

Radiofrequency ablation uses an electric current through wires into the heart to heat up a small area in the atrial chamber tissue to stop it from sending disorder electrical signals to generate the arrhythmias like atrial fibrillation or atrial flutter and restore the rhythm back to normal sinus. Radiofrequency ablation is a more complex and expensive clinical practice than electrical or pharmacological cardioversion. It's usually a scheduled invasive procedure and not suitable for emergency cases unlike cardioversion. Despite being currently the most effective therapeutic option, radiofrequency ablation has not shown desirable results in all patients. The addition of pharmacologic therapy to the routine strategy of catheter ablation

enhances the overall success of the procedure.

In clinical practice, electrical or pharmacological cardioversion is a more effective way to restore the patient rhythm in a short-term especially in emergency situations than radiofrequency ablation. For long-term rhythm control, radiofrequency ablation is most effective while the choice of radiofrequency ablation or pharmacologic therapy or a hybrid therapy shall be determined by clinical professionals according to the different conditions of individual patients.

Internal Defibrillation

Cardiac surgery is usually performed on a nonbeating heart; ventricular fibrillation may occur or may be deliberately induced during operation. If a regular rhythm does not spontaneously resume at the end of operation, an electric shock is applied directly to the fibrillating heart to restore rhythmic contraction. Similarly, during thoracotomy, because traditional external defibrillation pads or paddles cannot be placed, only option is to place defibrillation paddles on the surface of the heart for internal defibrillation.

According to our current cognition, the use of internal defibrillation is the only safe, effective and convenient option for ventricular fibrillation during thoracotomy, cardiac surgery or large abdominal surgery.

Semi-automated external defibrillation

Manual defibrillation is designed for health professionals, Professional medical staff judge the patient's vital signs parameters by themselves, and complete the entire defibrillation process (ECG analysis, energy adjustment, charging and discharging) as needed. AED are designed to be used by laypersons who ideally should have received AED training at some point in the past. Generally, AED are designed very intuitive and user-friendly so that even untrained bystanders can perfectly employ them to deliver an electric shock to a VF victim. In contrast with AED, the more sophisticated manual defibrillation used by health professionals can perform other functions but require a skilled operator able to interpret electrocardiograms.

	MED	AED
intended users	– health professionals	– laypersons received AED training
Key different Point	– interpret electrocardiograms manually	– automatic arrhythmia analysis
Easy of use	– interpret electrocardiograms – Set energy and charge – dischage	– automatic arrhythmia analysis and charge – press button according to the prompt (Semi-automatic AED) – Shorter hands-off period for rhythm confirmation

Non-invasive external pacing

Technological developments have provided transcutaneous, transvenous, percussion, epicardial approaches to temporary cardiac pacing in addition to the refinement of external pacing. All approaches, however, are based on the provision of rate support from an external pulse generator via an electrode or electrodes which can be removed easily after a short period of pacing, as many of the situations requiring temporary pacing are transient and resolve spontaneously or have a correctable underlying cause.

Compare with different pacing mode are as follows:

pacing mode	transcutaneous pacing	transvenous pacing	percussion pacing	epicardial pacing
position	chest wall via adhesive electrodes	pacing wires are inserted into the veins via an introducer sheath, and passed through the venous system to the heart	pacing wires are fixed directly to the myocardium (ventricular and often atrial) and are exposed through the skin on the chest wall	middle or lower two thirds of the patient's sternum
use condition	patients cannot be moved or staff with transvenous pacing experience are not immediately available	patients with persistent hemodynamically unstable bradycardia refractory to medical therapy	temporizing measure in exceptional circumstances such as witnessed, monitored in-hospital arrest (eg, cardiac catheterization laboratory) for bradyasystole before a loss of consciousness and if performed without delaying definitive therapy	profound bradycardia resulting in clinical cardiac arrest. p-wave asystole (ventricular standstill).

CPR feedback

Currently, during CPR, doctors mainly use the following two methods to improve CPR compression accuracy:

1. Use the CPR metronome guidance to improve CPR compression accuracy;
2. Use the CPR feedback technology to improve CPR compression accuracy.

For the first method, because there is no audiovisual feedback, when the CPR compression rate is inaccurate, the user cannot be reminded, and the method can only help the user improve the accuracy of the compression rate，but cannot improve the accuracy of the compression depth.

The second method, because there is feedback, users can adjust the frequency and depth of compressions in real time through the feedback information and achieve optimal compression.

ECG

Treatments	Advantages	Disadvantages
ECG	ECG monitoring is the most common and accessible and continuous heart rate monitoring method. It can also provide observation of ECG waveform changes, diagnosis of myocardial damage, myocardial ischemia and electrolyte disturbance. ECG remains the gold standard to continuously monitor an infant's HR in the neonatal intensive care unit (NICU). ECG gets reliable signals more quickly than PR.	Delay in signal acquisition due to skin cleaning (all infants are wet at delivery) and lead placement as well as skin fragility in extremely premature infants. There is also the potential of pulseless electric activity, which could be interpreted as HR on an ECG
PR（SPO_2）	PR is continuous and visible to the whole team, and more precise then palpation and auscultation.	Delay in HR display sometimes up to 2 min, which could potentially delay resuscitation efforts, and inaccuracy of HR measurements due to motion artefacts or poor tissue perfusion
Ultrasound Cardiogram（UCG）	UCG is faster than palpation, auscultation and PO HR, UCG is more accurate than auscultation and palpation HR, and the Whole team can hear HR	UCG HR is difficult to record, and All measurements were performed by the same examiner Needs an extra staff member. UCG Can interfere with resuscitation efforts in terms of crowding

IBP

Treatments	Invasive Blood Pressure (IBP)	Noninvasive Blood Pressure (NIBP)
Measurement method	Invasive blood pressure is a blood pressure monitoring method in which the blood pressure is monitored by direct methods by inserting a cannula into a suitable artery.	Noninvasive blood pressure is a way of monitoring the blood pressure indirectly using a special apparatus.
Clinical intervention	Required: the cannula is inserted into a suitable vein during the invasive blood pressure monitoring	Not required: a cuff is used which is wrapped around the arm and connected to a monitor during the noninvasive blood

		pressure monitoring.
Application	Intensive Care Unit (ICU), Operating theater	Out-patient, tentative diagnosis
Accuracy	Invasive blood pressure monitoring is a highly accurate method.	Noninvasive blood pressure monitoring is a less accurate method
Advantages	Accurate measurement of beat-to-beat pressure fluctuations can be used to monitor the blood pressure of patients in a critical health condition.	Noninvasive hence not prone to infections, or clinical manifestation caused by unsterilized needles.
Disadvantages	/	Noninvasive blood pressure monitoring is not very accurate and error-prone.

TEMP

The methods used in body temperature measurement are divided into instrumental methods and mathematical methods. The instrumental approach directly utilizes body temperature measurements from temperature-sensitive sensors and electronics by combining actual and predictive measurements, invasive and non-invasive measurements. From the literature we searched, body temperature measurement mainly includes continuous contact measurement methods, as well as discontinuous measurement methods, including digital thermometers, infrared thermometers, zero heat flux thermometers, and thermal imaging . Temperature monitoring technology mainly includes continuous body temperature monitoring technology and spot measurement technology. Continuous body temperature monitoring, as a means of continuous monitoring of human body temperature, continuously measures the temperature. Spot measurement is used for temperature screening, which is suitable for different scenarios and has no possibility of substitution. Therefore, the two measurement techniques will coexist for a long time.

TEMP	Continuous temperature	Point measurement technology			
		digital	infrared	zero heat flux	thermal imaging
Site	rhinitis, esophagus, bladder, rectum	oral 、armpit 、rectum	Ear	Forehead	Face
Distance	Contact	Contact	Contact	Contact	10 cm/50 cm
Speed	continuous temperature	6 s	1 s	1 s	1 s
Recordability	Yes	No	No	No	No
Clinical Accuracy	±0.1 °C	±0.1 °C	±0.2 °C	±0.23 °C	±3 °C

CO2

Treatment	Sidestream CO2	colorimetric CO2	PaCO2
Measurement method	continuous	continuous	non-continuous
Invasive	Non- invasive	Non- invasive	Invasive
Quantitative	Quantitative	Qualitative and semi-quantitative	Quantitative
Reuse	Reuse device	Single-use device	Reuse device
Target patients	Intubated and non-intubated patient	Intubated patient	Intubated and non-intubated patient
Real-time	Several seconds delay	Real-time	Time delay
Sampling gas	yes	no	no

RESP

There are some kinds of respiration rate measurement methods, some methods have high accuracy, some methods are easy to use and some methods are inexpensive. All of which have their own advantages and disadvantages.

	Impedance respiration	Visual respiratory assessment	Acoustic respiratory assessment	ECG-derived respiration	PPG-derived respiration	Tidal volume
Accuracy	High	High	High	Medium	Medium	High
Easy of use	Easy to use	Professional staff	Professional staff	Easy to use	Easy to use	Difficult to use
Time-consuming	Less	More	More	Less	Less	Less
Monitoring coherence	Continuous	Spot Check	Spot Check	Continuous	Continuous	Continuous
Cost	Less	High	High	Less	Less	High

SPO2

The primary purpose of intensive care is to ensure adequate oxygen supply to the organ systems, and the assessment of the patient's oxygen status is usually by drawing the patient's arterial blood to calculate oxygen saturation. Clinically, it is also known as the gold standard for SpO2[12-2].

Compared with SaO2, SpO2 monitoring has obvious advantages. It can display results conveniently,

quickly, and accurately, and conduct continuous non-invasive monitoring. In some cases, it has the function of trend review. It is especially suitable for monitoring the critically ill patients in ICU and during and after the operation, helping the medical staff to find the abnormal results in time, actively find the causes, and make corresponding treatment.

	SpO2	SaO2
Continuity	Continuous	Non-continuous
Operation	Convenience	Complex
Traumatic	non-invasive	invasive
Accuracy	Approximate	Gold standard

NIBP

Blood pressure can be measured in two ways: Invasive and non-invasive. The invasive blood pressure is mainly measured through an intra-arterial catheter. The NIBP measurement is classified into intermittent NIBP measurement (mainly including manual auscultatory blood pressure and automatic cuff oscillometric blood pressure measurement) and continuous NIBP measurement (such as photoplethysmography (PPG) blood pressure measurement and pulse transmission time (PTT) blood pressure measurement) based on whether NIBP is measured continuously

In combination with the maturity of the technology, detailed comparisons are made between the oscillometric NIBP measurement, auscultatory NIBP measurement, and IBP measurement. The results are as follows.

Item	Oscillometric blood pressure	Auscultatory blood pressure	IBP
Measurement method	Non-invasive	Non-invasive	Invasive
General measurement media	Cuff-based	Cuff-based	Catheter-based
Measurement Continuity	Intermittent	Intermittent	Continuous
Measurement Process	Manual	Automatic	Automatic
Operation complexity	Difficult	Easy	More Difficult
Target patients	Adults, pediatrics and neonates	Adults, pediatrics and neonates	Adults, pediatrics and neonates
General measurement site	Upper arm	Upper arm	Arterial
Clinical investigation	Not required	Clinical investigation shall be carried out according to ISO 80601-2	Not required

Measurement reliability	Higher	High	Higher

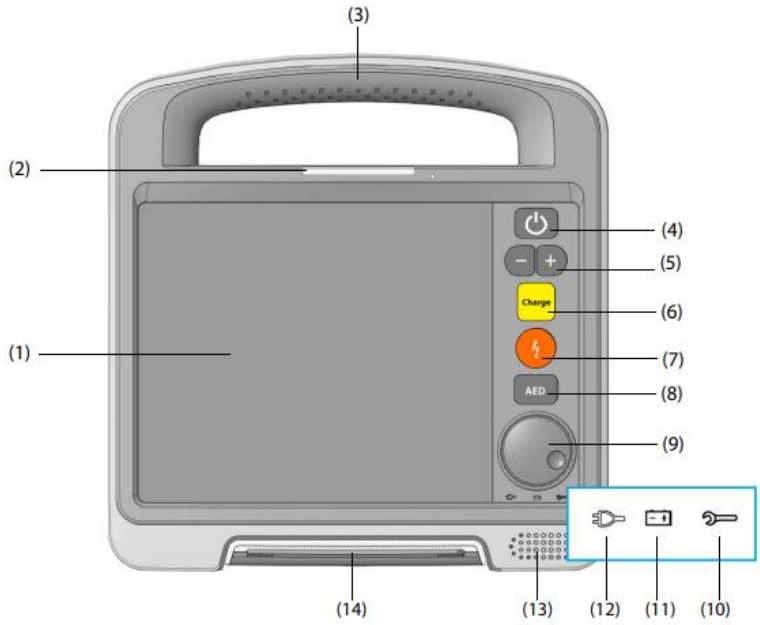
7. Suggested profile and training for users

The equipment is intended for use only by clinical professionals who have a clinical education background or under their guidance. It must only be used by qualified medical personnel trained in the operation of the equipment and qualified by training in basic life support, advanced cardiac life support or defibrillation.

For clinical users who install the machine for the first time, the engineer will provide clinical users with practical demonstrations and functional explanations of the machine. In addition to the training of clinical roles, there is also an introduction to the equipment installation function when the engineer is installed, the training content is as follows:

- **Introduction of the main unit of the product.**

Area 1:



(1) Display screen

(2) Alarm lamp: flashes in different color and frequency to match the alarm level.

(3) Handle

(4) Power switch

◆ When powered on, press it to turn on the equipment.

◆ When turned on, press and hold it for 3 seconds to turn off the equipment.

(5) Energy Selection buttons

◆ When turned on, press it to enter the Manual Defib mode.

◆ In the Manual Defib mode, press it to select the desired energy level. (6) Charge button

◆ When turned on, press it to enter the Manual Defib mode.

◆ In the Manual Defib mode, press it to charge the equipment to the desired energy level. (7) Shock button

◆ When turned on, press it to enter the Manual Defib mode.

◆ In the AED or Manual Defib mode, press it to deliver a shock to the patient. It flashes when the equipment is charged and ready.

(8) AED button: accesses the AED mode when the equipment is turned on.

(9) Navigation knob: provides the screen-related operations.

(10) Status indicator

■ Steady green:

◆ external power supply is connected, and the equipment operates properly.

◆ only battery is connected for power supply, the equipment is turned on and operates properly.

■ Flashing green:

◆ only battery is connected for power supply, the equipment is turned off and operates properly.

■ Flashing red

◆ auto test fails, or a failure is detected on the equipment.

◆ DC power supply connected is overcurrent or overvoltage.

◆ only one battery is connected for power supply, and the battery has a low power or battery fails.

◆ only two battery are connected for power supply, both batteries have a low power or either of batteries fails.

◆ only external power supply is connected for power supply, and No Battery is set to Status Indicator On.

■ Off: external power supply and battery are not connected.

(11) Battery indicator

◆ Yellow: the battery is being charged.

◆ Green: the battery is fully charged or the equipment operates on battery power.

◆ Off: battery is not installed or battery fails.

(12) Power indicator

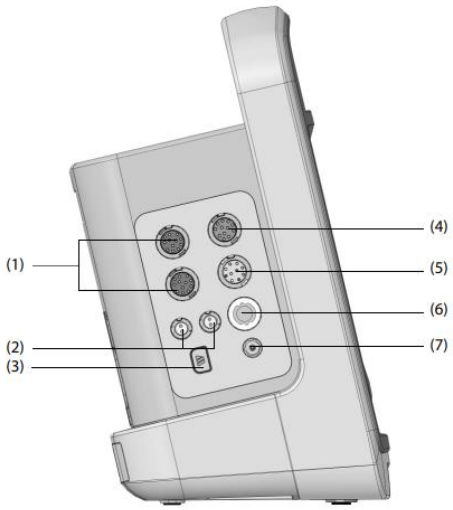
◆ Illuminated: the external power supply is connected.

◆ Off: the external power supply is not connected.

(13) Speaker

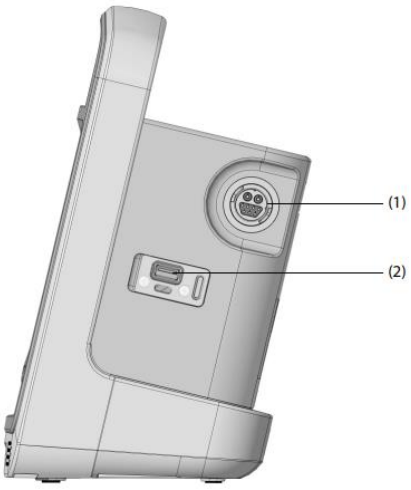
(14) Recorder

Area 2:



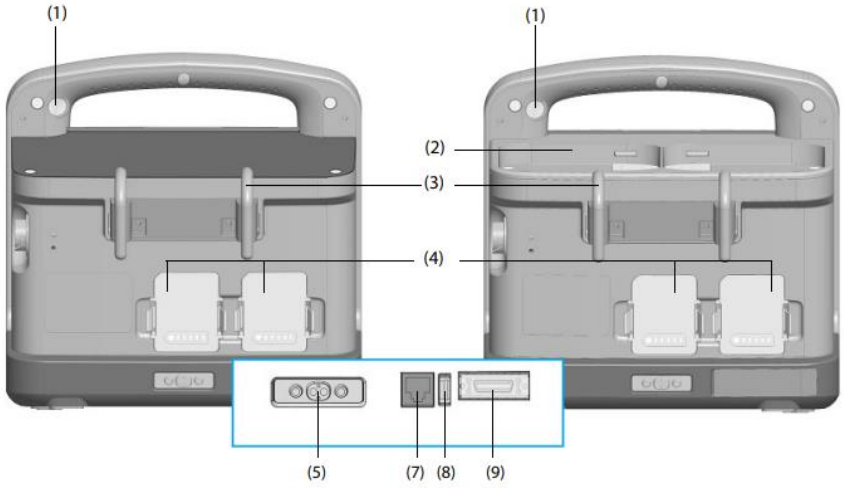
(1) IBP sensor connector (2) Temp probe connector (3) CO2 connector (4) ECG cable connector (5) SpO2 sensor connector (6) NIBP cuff connector (7) Gas outlet

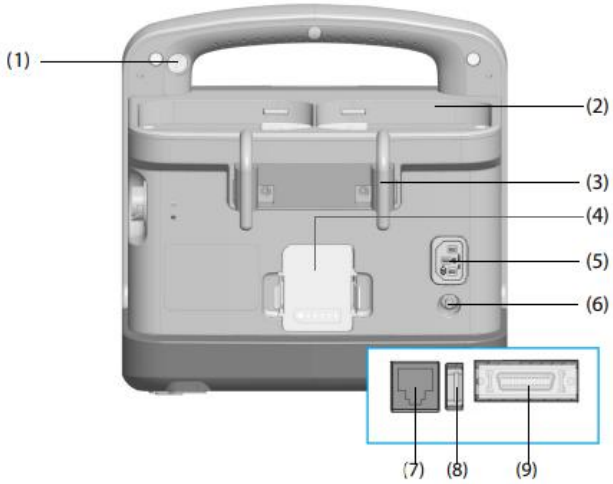
Area 3:



(1) Therapy port: connects the therapy cable. (2) USB 3.0 connecto

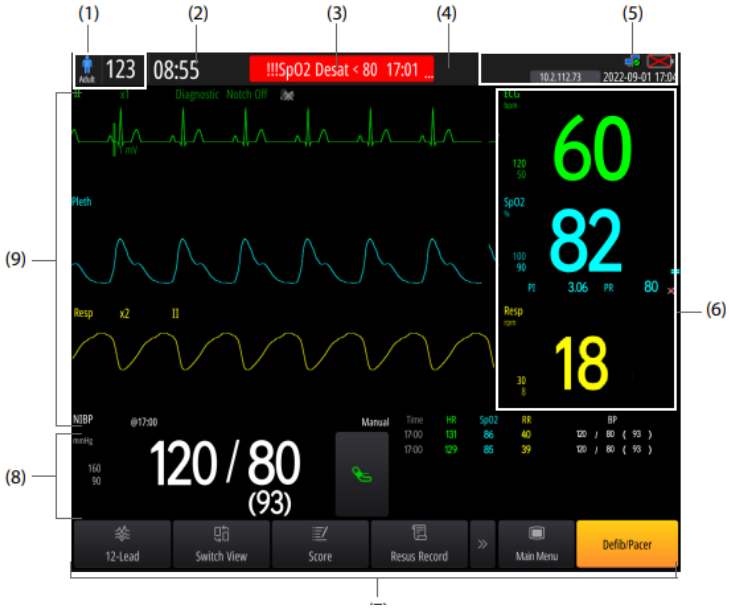
Area 4:





(1) Camera: captures for rescue scene. (2) Paddle tray: places external paddles. (3) Hook: holds the cables. (4) Battery (5) Power input: connects an external power supply. (6) Equipotential grounding terminal When the equipment and other devices are to be used together, their equipotential grounding terminals should be connected together to eliminate the potential difference between them. (7) Network connector: is a standard RJ45 connector. (8) USB 2.0 connector: connects the USB drive. (9) Multifunctional connector: connects a CPR sensor, or a cable for analog output or synchronized cardioversion.

Area 5:



(1) Patient information area: displays patient name/bed number (configurable) and patient category. The display of Patient Name and Bed No. can be configured in the Configuration mode only.

(2) Runtime area: displays the operating time since equipment is turned on.

(3) Alarm information area: displays the physiological alarms, technical alarm messages and prompt messages.

(4) Alarm status area: displays the alarm status symbol.

(5) System information area: displays the network status, battery status, voice recording symbol, IP address of the connected CMS and system time.

(6) Parameter numerics area: displays parameter values, units, alarm limits, and alarm status. This area also displays the parameter list. Selecting a parameter numeric area enters corresponding parameter menu. Selecting the parameter list enters the Tabular Trends review page.

(7) Quick key area: provides a quick access to general operations. The locations of Main Menu and Defib/Pacer quick keys are unchangeable.

(8) Parameter waveform area The following table lists the on-screen symbols displayed in the system information area:

◆ Parameter waveform area: displays parameter waveforms and parameter alarms. Select a waveform enters the corresponding parameter menu.

◆ Parameter numerics area: displays parameter values, units, alarm limits, and alarm status. This area also displays the parameter list. Selecting a parameter numeric area enters corresponding parameter menu. Selecting the parameter list enters the Tabular Trends review page.

(9) Parameter waveform area: displays parameter waveforms and parameter alarms. Select a waveform enters the corresponding parameter menu.

External Paddles:

1.Shock button with indicator 2. Charge button 3. Energy Select button

Pads cable, pads, test load:

➢ Introduction of the basic operation/setting of the product.

Using the Touchscreen

Gestures for Quick Operation

You can use the following gestures to take a quick operation.

■ Tapping the screen

◆ To select an item from menus or lists, tap on the item with your finger.

◆ To select a quick key, tap on the key with your finger.

◆ To enter a parameter menu, tap corresponding parameter numeric area or waveform area.

■ Swiping across the screen with a single finger:

◆ To scroll through a list and a menu, swipe up and down.

■ Swiping across the screen with two fingers:

◆ To switch between the screens, swipe left or right across the screen.

Locking the Touchscreen

To avoid misuse, you can temporarily disable the touchscreen. To do so, choose either of the following

ways:

■ No operation is taken within 5 minutes. The setting of Screen Lock Duration can be changed in the Configuration mode only.

■ Select the Main Menu quick key → from the Common column select Screen Lock.

■ Press and hold the Main Menu quick key to display , swipe the slider up as instructed. on the Main Menu quick key indicates that the touchscreen is disabled. To unlock the touchscreen, select anywhere on the screen to display and swipe the slider up as instructed.

Setting the Date and Time:

Before putting the equipment into use for the first time, you should set the time zone and system time in accordance with your local time.

To set the system date and time, follow this procedure:

1. Access System Time in either of the following ways:

◆ Select the Main Menu quick key → from the System column select Time.

◆ Select the system information area of the main screen.

2. Set the system date.

◆ Date Format: sets the system date format.

◆ Date: sets the system date.

3. Set the system time.

◆ 24-Hour Time switch: if the 12-hour mode is needed, switch it off.

◆ Time: sets the system time.

4. Set the Daylight Savings Time switch.

If the daylight savings time is needed, switch it on.

Adjusting the Screen Brightness:

To adjust the screen brightness, follow this procedure:

1. Access Display in either of the following ways:

◆ Select the Main Menu quick key → from the Display column select Screen Setup → select the Display tab.

◆ Select the Main Menu quick key → from the Display column select Brightness.

2. Set the screen brightness

Changing Volume:

To adjust the system volume, follow this procedure:

1. Select the Main Menu quick key → from the Common column select the Volume tab.

2. Respectively set Alarm Volume, QRS Volume and Key Volume

Selecting High Contrast Mode:

The equipment provides the high contrast for a better view in a high light ambient.

To enable the high contrast display, select the Main Menu quick key and select High Contrast from the Common column.

To disable the high contrast display, select the Main Menu quick key and select Full Color from the Common column.

The high contract display remains when you change the operating mode.

However, the setting of the high contrast display will not be saved after the equipment is turned off.

➢ Introduction of the function operation of the product.

AED:

1. Access the patient and make sure the patient is suitable for AED.

2. Connect the therapy cable to the equipment, and then connect the therapy cable and electrode pads.

3. Prepare the patient skin.

4. Apply the electrode pads to the patient as indicated on the pads package.

5. Check the patient category symbol in the patient information area.

6. The default energy level is automatically changed according to the patient category setting.

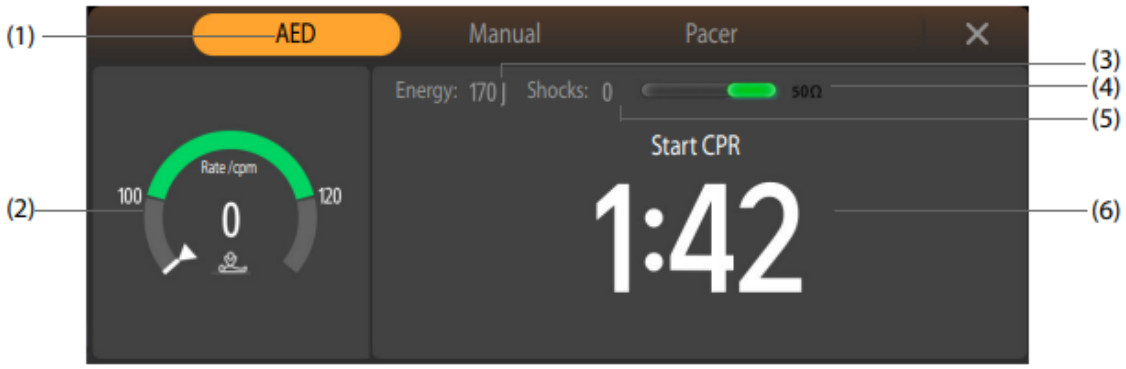
7. Do not touch the patient, wait for the heart rhythm analysis.

8. ◆ If non-shockable rhythm is detected, the equipment prompts “No Shock Advised!” and enters the CPR status by default.Then perform step 10

9. Deliver a shock.

10. Perform CPR.

The following figure shows the AED window.



(1) Operating mode

(2) Connection prompt/CPR dashboard:

◆ Connection prompt: if the therapy cable is not connect, a prompt is displayed.

◆ CPR dashboard: provides instructions in chest compressions, including compression rate, interruption time and relevant CPR prompts.

(3) Selected energy

(4) Patient contact indicator and impedance value (configurable): indicates the contact status between the patient and electrode pads.

(5) Shock counter

(6) Therapy message: instructs the therapy operations

Manual Defibrillation:

To perform the external defibrillation, follow this procedure:

1. Access the patient and make sure the patient is suitable for the external defirbillation.

2. Connect the therapy cable to the equipment, and then connect the therapy cable and external paddles.

3. Prepare the patient skin.

4. Apply electrode gel on the paddle electrodes.

5. Apply the external paddles to the patient by using the anterior-lateral placement. ◆ Place the sternum paddle on the patient's upper right torso, lateral to the sternum and below the clavicle. ◆ Place the apex paddle to the patient's left nipple in the midaxillary line, with the center of the electrode in the midaxillary line.

6. Check the patient category symbol in the patient information area. If needed, select the patient category symbol and change the setting of Patient Category.

7. The default energy level is automatically changed according to the patient category setting. ◆ For the

adult patients, the recommended energy level for the first shock is 200 J. ◆ For the pediatric patients, the recommended energy level for the first shock is 50 J.

8. Select the energy level in any of the following ways: ◆ Press the Energy Selection button on the equipment. ◆ Press the Energy Selection button on the Apex paddle. ◆ Select the Energy Selection key in the Manual Defib window. Selecting and holding it provides a quick selection.

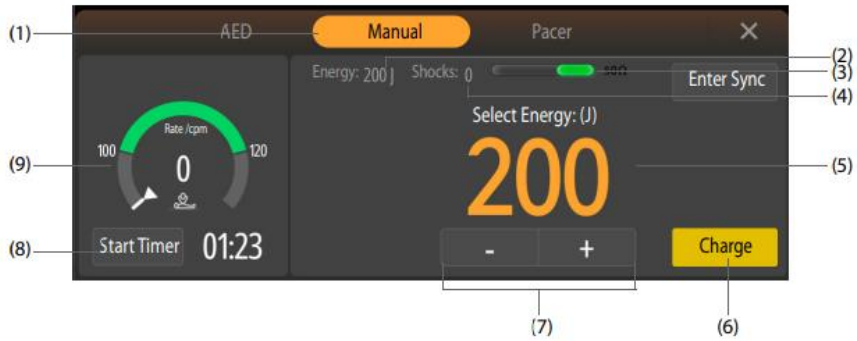
9. Charge the equipment in any of the following ways: ◆ Press the Energy Selection button on the Apex paddle. ◆ Press the Charge button on the equipment. ◆ Select Charge in the Manual Defib window.

10. Wait for the equipment charging to the desired energy level. The equipment gives a charging tone and changing progress bar.

11. Simultaneously press the Shock buttons both on the external paddles. If you do not press the Shock buttons within the configured time, the equipment automatically disarms itself.

12. Perform CPR. If needed, select Start Timer to enable CPR countdown

The following figure shows the Manual Defib window



(1) Operating mode

(2) Selected energy

(3) Patient contact indicator and impedance value (configurable)

(4) Shock counter

(5) Therapy message

(6) Charge key: charges the equipment to the desired energy level.

(7) Energy Selection key: selects the desired energy level.

(8) CPR timer: starts or stops CPR countdown.

(9) Connection prompt/CPR dashboard:

◆ Connection prompt: if the therapy cable is not connect, a prompt is displayed.

◆ CPR dashboard: provides instructions in chest compressions, including CPR timer, compression rate and interruption time.

Synchronized Cardioversion:

To perform sychronized cardioversion, follow this procedure:

1. Access the patient and make sure the patient is suitable for sychronized cardioversion.

2. Connect the therapy cable to the equipment, and then connect the therapy cable and external paddles.

3. Prepare the patient skin.

4. Apply the ECG electrodes to the patient.

5. Enable sychronized cardioversion.

6. Select a lead. The selected lead should have a clear signal and a large QRS complex.

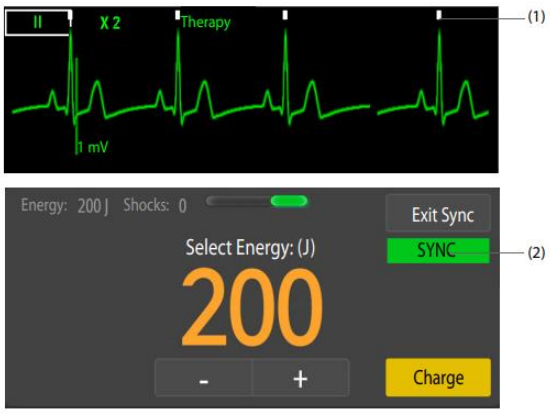
7. Check that a white R-wave marker appears above each R-wave. If the R-wave markers do not appear or do not coincide with the R-waves, for example above the T-waves, select another lead.

8. Press the Energy Selection button on the Apex to select the energy level.

9. Press the Charge button the Apex paddle.

10. Simultaneously press the Shock buttons on both the external paddles.

11. Press and hold the Shock buttons on both the external paddles until the shock is delivered



(1) R-wave marker (2) SYNC marker

Noninvasive Pacing:

To perform demand mode pacing, follow this procedure:

1. Access the patient and make sure the patient is suitable for the demand mode pacing.

2. Connect the therapy cable to the equipment, and then connect the therapy cable and electrode pads.

3. Prepare the patient skin.

4. Apply the ECG electrodes to the patient.

5. Access the Pacer mode, and select Demand Mode in the Pacer window.

6. Select a lead with an easily detectable R-wave.

7. Check that a white R-wave marker appears above each R-wave. If the R-wave markers do not appear or do not coincide with the R-waves, for example above the T-waves, select another lead.

8. If needed, change settings of Pacer Rate and Pacer Output.

9. Select Start Pacing to start pacing. The prompt "Pacing" is displayed.

10. Check that white pacing markers appear on the ECG waveform.

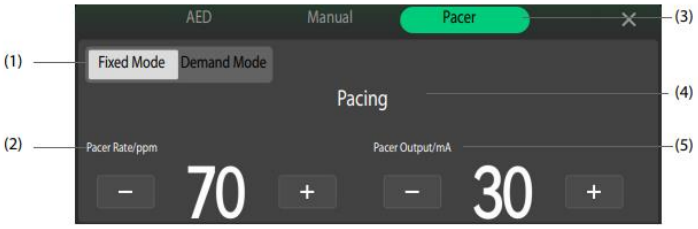
11. Adjust the pacer output until cardiac capture occurs (capture is indicated by the appearance of a QRS complex after each pace marker), and then decrease the output to the lowest level that still maintains capture.

12. Select and hold 4:1 to temporarily pause pacing.

13. Use the patient's femoral artery, right brachial or radial artery for palpating pulse, make sure the presence of a peripheral pulse. Releasing 4:1 can resume pacing.

14. Select Stop Pacing to stop pacing

The following figure shows the Pacer window



(1) Pacer mode (2) Pacer rate (3) Operating mode (4) Prompt message (5) Pacer output

➢ Introduction of the maintenance of the product.

Manual Defibrillation Test:

1. Remove the batteries and connect the equipment with AC mains. Turn the Mode Select knob to Manual Defib.

2. Connect the external paddles to the equipment and Remove the paddle from the paddle base. Place the paddle on the defibrillator/pacer analyzer.

3.Enter the Configuration-Main screen. In the Record Setup menu, set Shock Event to On so that shock events can be recorded automatically if happened.

4.Set the analyzer to Energy Measurement mode. In this case, the energy value should be displayed as 0 or blank.

5.Select the energy level to 1 J.

6. Charge/discharge the equipment to verify the energies measured by the analyzer meet the following accuracy:

Preset Energy (J)	Measured Value (J)
1	0 to 3
100	90 to 110
360	324 to 396

7.Set the energy to 100 J and 360 J respectively. Repeat step 6.

8. Run the equipment on fully charged battery. Move the Mode Select knob to Manual Defib. Repeat steps 5 to 7.

9. Use pads. Repeat step 5 to 7.

10.Verify that the equipment records the shock events automatically and correctly.

Synchronous Defibrillation:

1. Insert the pads/paddle cable to the therapy interface of the equipment, and connect the pads/ external paddles correctly to the defibrillator/pacer analyzer.

2. Connect ECG cables with the equipment and connect the leads to the defibrillator/pacer analyzer.

3.Set the mode of the defibrillator/pacer analyzer to Synchronized Cardioversion and output normal sinus rhythms, e.g. amplitude value 1 mV and HR 60 bpm.

4.Enter the Configuration Main menu, and choose Therapy Setup>Manual Defib Setup.

5.Set Sync After Shock to On.

6.Select the energy level to 10 J.

7.Press the Enter Sync soft key to start synchronized cardioversion. If Remote Sync is set to On, press the

Enter Sync soft key, and then select Local in the menu displayed to start synchronized cardioversion.

8.Select Pads or Paddles as the ECG source and begin charging.

9. When charging finishes, hold down the Shock key to deliver a shock. • Verify that synchronous discharge succeeds and the delivery energy measured by the analyzer is 10 J±2 J. • Verify that the delay time of synchronous defibrillation measured by the analyzer is less than 60 ms. • Verify that the synchronous discharge mark appears on the R wave. • Verify that the prompt messages are correct during testing.

10.Select lead II as ECG source and perform charging. Repeat step 9

8. Harmonized standards and CS applied

EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices

EN ISO 20417:2021 Information supplied by the manufacturer with medical devices

EN ISO 15223-1:2021: Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied

EN 60601-1:2006/A1:2013+A2:2021/IEC 60601 1: 2005 +A1:2012+A2: 2020 Medical electrical equipment--Part 1:General requirements for basic safety and essential performance

EN 60601-1-2: 2015+A1:2021 Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance-- Collateral standard: Electromagnetic compatibility--Requirements and tests

EN 60601-1-6:2010/A2:2021 Medical electrical equipment-part 1-6: general requirements for basic safety and essential performance--collateral standard: usability

EN 60601-1-8:2007/A2:2021 Medical electrical equipment - part 1-8: general requirements for basic safety and essential performance - collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

EN 60601-2-4:2011/A1:2019 Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators

IEC 60601-2-25:2015 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

IEC 60601-2-27: 2014 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

IEC 80601-2-30:2019 Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

ISO 81060-2: 2013 Non-invasive sphygmomanometers - part 2: clinical validation of automated measurement type

IEC 60601-2-34: 2011 Medical electrical equipment - part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment

IEC 60601-2-49: 2019 Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment

EN ISO 80601-2-61:2019/ISO 80601-2-61:2017（Corrected version 2018-02） Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment

ISO 80601-2-56: 2017 Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

EN ISO62304:2018 Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors

IEC 62366-1: 2015/A1:2020 Medical devices - Application of usability engineering to medical devices

EN 1789: 2020 Medical Vehicles and Their Equipment - Road Ambulances

ISO 17664-2:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices (ISO 17664-2:2021)

IEC 60601-1-12:2014/AMD1:2020 Medical Electrical Equipment — Part 1-12: General requirements for

basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment

EN 60601-1-10:2008+A2:2021 Medical electrical equipment Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1.0	2021.06.23	Initial version	☒ Yes Validation language: English ☐ No