Document type	Development Document	Confidentiality	Confidential
Document No.	KF-0654-6-0069-04		
Scope	0654		

Summary of safety and clinical performance

Related Document(s)

Document No.	Document Name	Version
KF-0654-6-0069-01	Clinical Evaluation Report	/
KF-0654-6-0069-17	PMCF Plan	/
KF-0654-6-0018-02	Periodic Safety Update Report	/
KF-0654-2-0007	Risk Management Report	/

Revision History

Ver.	Revision description (including the evaluation path)	Revisor	Effective Date
1.0	Initial version	wangsiyang	2022-11-10
2.0	Revise the Chapter 5.1	wangsiyang	2022-12-27
3.0	Add the requested information	wangsiyang	2023-07-26

Table of Contents

1. Identification the device and the manufacturer

Device details	
Name of device	Automated External Defibrillator
Model and type	BeneHeart C1/BeneHeart C1A/BeneHeart C2/BeneHeart C2A/BeneHeart S1/BeneHeart S1A/BeneHeart S2/BeneHeart S2A/BeneHeart C1 Fully Automatic/BeneHeart C1A Fully Automatic/BeneHeart C2 Fully Automatic/BeneHeart C2A Fully Automatic/BeneHeart S1 Fully Automatic/BeneHeart S1A Fully Automatic/BeneHeart S2 Fully Automatic/BeneHeart S2A Fully Automatic
Basic UDI-DI	69449040AB010000423E
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.
Address	Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
SRN	CN-MF-000014156
Authorized 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 equipment is intended for semi-automated external defibrillation and automated external defibrillation. It also provides CPR feedback.

2.2 Indications

The equipment is intended for patients with ventricular fibrillation, pulseless ventricular tachycardia and ventricular flutter.

2.3 Contraindications

The equipment 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

Automated external defibrillation(AED)

Biphasic impedance compensation algorithm:

Biphasic waveform parameter is automatically adjusted according to impedance of a patient to ensure safety and effectiveness of treatment waveform in different patients' impedance conditions. When the impedance is low, to avoid damage to myocardial cells, reduce the phase I discharge inception voltage and also the discharge duration. When the impedance is high, to achieve sufficient treatment effect, increase the phase I discharge inception voltage and also the discharge duration.

Algorithm of heart rhythm recognition detector

Allows analysis of the ECG signal acquired from a patient to accurately determine whether defibrillation treatment is required. If ECG signal of the patient is suitable for defibrillation, the algorithm suggests defibrillation and guides an operator to perform defibrillation treatment on the patient. If defibrillation conditions are not met, the algorithm suggests not performing defibrillation to prevent an operator to carry out unnecessary defibrillation on the patient.

CPR Feedback

Detect CPR compressions based on the change of the chest impedance signal which comes from multifunction electrode pads and calculate the compression rate. First, the peaks of the impedance signal are detected, then the peak-to-peak intervals within 5 seconds are averaged, and this average value is used as the compression rate value.

3.2 Overview of the previous generations device

Device Name: Automated External Defibrillator

Model: BeneHeart D1

The comparison with the previous generation of the device is as below:

1. Technical Characteristics			
Technical characteristics	**Device 1 (subject device) Description of characteristics and reference to specifying documents**	**Device 2(marketed device) Description of characteristics and reference to specifying documents**	**Technical characteristics**
1.1 Device is of similar design	 The device can be divided into hardware and software. The hardware module can be divided into main board, battery, pads. Main board contains power management, main control and parameter circuit. Each circuit has the corresponding function software as the carrier for its signal processing and transmission.	 The device can be divided into hardware and software. The hardware module can be divided into main board, battery, pads. Main board contains power management, main control and parameter circuit. Each circuit has the corresponding function software as the carrier for its signal processing and transmission.	Although the main control circuit in hardware design is different, the parameter circuit and power management circuit in hardware design are the same. The functions are mainly determined by the parameter circuit and power management circuit.
1.2 Used under similar conditions of use	The equipment is to be used in public places and facilities by persons who have been trained in its operation. The operator should be trained in basic life support or other emergency medical response.	The equipment is intended for use in pre-hospital or hospital 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. The equipment is also intended for use in public places and facilities by personnel trained in the operation of the equipment and qualified by training in basic life support, advanced cardiac life support or other emergency medical response.	The subject device is the subset of the marketed device.
1.3Similar specifications and properties including		Defibrillatior	Beneheart C &S series do not have 1-9J energy level

physiochemical properties	Defibrillatior 	Energy \ Impedance	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω
---	---	---	---	---	---	---	---
10 J	9.7	10	9.7	9.3	8.9	8.5	8.1
15 J	15	15	15	14	13	13	12
20 J	20	20	20	19	18	17	16
25 J	24	25	24	23	22	21	20
30 J	29	30	29	28	27	25	24
50 J	49	50	49	47	45	43	41
70 J	68	70	68	65	62	60	57
100 J	97	100	97	93	89	85	81
120 J	116	120	116	111	106	101	97
150 J	146	150	146	140	134	128	122
170 J	166	170	166	159	151	145	138
200 J	195	200	195	187	178	170	163
300 J	292	300	292	280	267	255	244
360 J	351	360	350	336	321	306	293 | Accuracy: ±2J or±10%, whichever is greater Waveform: Biphasic truncated exponential (BTE) waveform Defibrillation Discharge software: auto-compensation according to patient impedance CPR compression Compression rate: from Electrodes		Energy \ Impedance	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω
---	---	---	---	---	---	---	---
1 J	1	1	1	0.9	0.9	0.9	0.8
2 J	2	2	2	1.9	1.8	1.7	1.6
3 J	2.9	3	2.9	2.8	2.7	2.6	2.4
4 J	3.9	4	3.9	3.7	3.6	3.4	3.2
5 J	4.9	5	4.9	4.7	4.5	4.3	4.1
6 J	5.8	6	5.8	5.6	5.3	5.1	4.9
7 J	6.8	7	6.8	6.6	6.3	6	5.7
8 J	7.8	8	7.8	7.4	7.1	6.8	6.5
9 J	8.8	9	8.8	8.4	8	7.7	7.3
10 J	9.7	10	9.7	9.3	8.9	8.5	8.1
15 J	15	15	15	14	13	13	12
20 J	20	20	20	19	18	17	16
30 J	29	30	29	28	27	25	24
50 J	49	50	49	47	45	43	41
70 J	68	70	68	65	62	60	57
100 J	97	100	97	93	89	85	81
150 J	146	150	146	140	134	128	122
170 J	166	170	166	159	151	145	138
200 J	195	200	195	187	178	170	163
300 J	292	300	292	280	267	255	244
360 J	351	360	350	336	321	306	293	 Accuracy: ±2J or±15%, whichever is greater Waveform: Biphasic truncated exponential (BTE) waveform Defibrillation Discharge software: auto-compensation according to patient impedance CPR compression Compression rate: Measurement range: 40 to 160 cpm (compressions per minute)	which Beneheart D1 has. The Beneheart C &S series is to be used in public places and facilities by persons who have been trained in its operation. The Beneheart C &S series do not need 1-9J energy level based on its Intended Medical Conditions. Beneheart C &S series have 25J and 120J energy level which Beneheart D1 does not have. But these two energy levels are within the scope of the 2021 ERC guidence which the scope is in 1-360J range. Also, 25J and 120J are same with certified Beneheart D6 in MDR.

	Measurement range: 60 to 200 cpm (compressions per minute) from CPR Sensor Measurement range: 40 to 160 cpm (compressions per minute)		So Beneheart C &S series defibrillator energy level is the similar with marked device. The measurement range of CPR Compression rate from electrodes of Beneheart C &S series is different with Beneheart D1 from CPR sensor. But the measurement range satisfies 2020 AHA guidance.
1.4 Principles of operation	Automated external defibrillation: Biphasic impedance compensation algorithm: Biphasic waveform parameter is automatically adjusted according to impedance of a patient to ensure safety and effectiveness of treatment waveform in different patients' impedance conditions. When the impedance is low, to avoid damage to myocardial cells, reduce the phase I discharge inception voltage and also the discharge duration. When the impedance is high, to achieve sufficient treatment effect, increase the phase I discharge inception voltage and also the discharge duration. Algorithm of heart rhythm recognition detector Allows analysis of the ECG signal acquired from a patient to accurately determine whether defibrillation treatment is required. If ECG signal of the patient is suitable for defibrillation, the algorithm suggests defibrillation and guides an operator to perform defibrillation treatment on the patient. If defibrillation conditions are not met, the algorithm suggests not performing	Automated external defibrillation: Biphasic impedance compensation algorithm: Biphasic waveform parameter is automatically adjusted according to impedance of a patient to ensure safety and effectiveness of treatment waveform in different patients' impedance conditions. When the impedance is low, to avoid damage to myocardial cells, reduce the phase I discharge inception voltage and also the discharge duration. When the impedance is high, to achieve sufficient treatment effect, increase the phase I discharge inception voltage and also the discharge duration. Algorithm of heart rhythm recognition detector Allows analysis of the ECG signal acquired from a patient to accurately determine whether defibrillation treatment is required. If ECG signal of the patient is suitable for defibrillation, the algorithm suggests defibrillation and guides an operator to perform defibrillation treatment on the patient. If defibrillation conditions are not met, the algorithm suggests	Both device have same impedance compensation algorithm and heart rhythm recognition detector.

	defibrillation to prevent an operator to carry out unnecessary defibrillation on the patient. CPR Feedback: from Electrodes Detect CPR compressions based on the change of the chest impedance signal which comes from multifunction electrode pads and calculate the compression rate. First, the peaks of the impedance signal is detected, then the peak-to-peak intervals within 5 seconds are averaged, and this average value is used as the compression rate value. from CPR Sensor Identify user compress based on the force signal, measure the acceleration value based on the accelerometer, and perform quadratic integration of the measured acceleration value to calculate the displacement. Then, calculate the compress rate and interruption time according to the compress interval, and calculate the compress depth according to the displacement during compression.	not performing defibrillation to prevent an operator to carry out unnecessary defibrillation on the patient. CPR Feedback: Identify user compress based on the force signal, measure the acceleration value based on the accelerometer, and perform quadratic integration of the measured acceleration value to calculate the displacement. Then, calculate the compress rate and interruption time according to the compress interval, and calculate the compress depth according to the displacement during compression.	The subject device can provide CPR feedback of CPR rate through CPR sensor based on CPR movement measurements which is the same as the marketed device and is a class IIa functionality. The subject device can also provide a subset (CPR rate only) feedback of CPR movement based on the change of thoracic impedance which is a developed technology as discussed in the SOTA.
1.5 Critical performance standards	EN ISO 14971 EN ISO 20417 EN ISO 15223-1 EN ISO 10993-1 IEC 60601-1	EN ISO 14971 EN 1041 EN ISO 15223-1 EN ISO 10993-1 IEC 60601-1	The subject device is the subset of the marketed device.

<table>
<tr>
<td></td>
<td>IEC 60601-1-2
IEC 60601-1-6
IEC 60601-2-4
IEC 60601-1-10
IEC 60601-1-11
IEC 60601-1-12
EN 62304
IEC 62366-1
EN 1789
EN 13718-1
IEC 60086-4</td>
<td>IEC 60601-1-2
IEC 60601-1-6
EN 60601-1-8
IEC 60601-2-4
IEC 60601-2-27
IEC 60601-2-49
IEC 60601-1-10
IEC 60601-1-11
IEC 60601-1-12
EN 62304
IEC 62366-1
EN 1789
EN 13718-1
IEC 60086-4</td>
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<tr>
<td>1.6 similar clinical performance</td>
<td>Test results on IEC 60601-2-4 requirements are shown below.
<table>
<tr><th>Rhythm category</th><th>Requirement</th><th>Test result</th></tr>
<tr><td>Shockable (sensitivity):
Coarse VF
Rapid VT</td><td>
>90%
>75%</td><td>
Met
Met</td></tr>
<tr><td>Nonshockable (specificity)</td><td>>95%</td><td>Met</td></tr>
<tr><td>Positive predictive value</td><td>Report only</td><td>>98%</td></tr>
<tr><td>False positive rate</td><td>Report only</td><td><2%</td></tr>
</table>
Test results on AHA recommendations are shown below.</td>
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<tr><td>False positive rate</td><td>Report only</td><td><2%</td></tr>
</table>
Test results on AHA recommendations are shown below.</td>
<td>The rhythm analysis algorithm performance of the subject device is same with the marketed device.</td>
</tr>
</table>

Rhythm category	Minimum sample size (cases)	Performance goal	Sample size tested (cases)	Test result
Shockable (sensitivity):				
Coarse VF	200	>90%	205	Met
Rapid VT	50	>75%	80	Met
Nonshockable (specificity):	300			
Normal sinus rhythm	100	>99%	171	Met
Asystole	100	>95%	180	Met
Other nonshockable rhythms	30	>95%	385	Met
Intermediate:				
Fine VF	25	Report only	27	66.67% shockable
Other VT	25	Report only	42	76.19% nonshockable

Rhythm category	Minimum sample size (cases)	Performance goal	Sample size tested (cases)	Test result
Shockable (sensitivity):				
Coarse VF	200	>90%	205	Met
Rapid VT	50	>75%	80	Met
Nonshockable (specificity):	300			
Normal sinus rhythm	100	>99%	171	Met
Asystole	100	>95%	180	Met
Other nonshockable rhythms	30	>95%	385	Met
Intermediate:				
Fine VF	25	Report only	27	66.67% shockable
Other VT	25	Report only	42	76.19% nonshockable

2. Biological characteristics

Biological characteristics (add a separate row for each of the assessed characteristics)	**Device 1 (subject device)** **Description of characteristics and reference to specifying documents**	**Device 2(marketed device) Description of characteristics and reference to specifying documents**	**Identified differences or conclusion that there are no differences in the characteristic**

2.1 Uses the same materials or substances in contact with the same human tissues or body fluids	Not applicable There are no accssories contact with human tissues or body fluids included in this MDR submission.	Not applicable	Same.
2.2 Similar kind and duration of contact with the same human tissues or body fluids	Not applicable There are no accssories contact with human tissues or body fluids included in this MDR submission.	Not applicable	Same.
2.3 Similar release characteristics of substances including degradation products and leachables	Not applicable There are no accssories contact with human tissues or body fluids included in this MDR submission.	Not applicable	Same.
2.4 Biocompatibility Standard	Not applicable There are no accssories contact with human tissues or body fluids included in this MDR submission.	Not applicable	Same
3. Clinical Condition			
Clinical characteristics (add a separate row for each of the assessed characteristics)	**Device 1 (subject device)** **Description of characteristics and reference to specifying documents**	**Device 2(marketed device) Description of characteristics and reference to specifying documents**	**Identified differences or conclusion that there are no differences in the characteristic**
3.1 Intended Use	**Intended Purpose Statement** The equipment is intended for semi-automated external defibrillation and automated external defibrillation.	**Intended Use** The equipment configured with AED, manual defibrillation and ECG monitoring functions is intended for automatic defibrillation (AED) and	D1 supports semi-automated external

	Indication for Use The equipment is intended for patients with ventricular fibrillation, pulseless ventricular tachycardia and ventricular flutter. **Intended Users** The operator should be trained in basic life support or other emergency medical response. **Intended Patient Population** The equipment is intended to be used on adults and pediatric patients in a sudden cardiac arrest. The patients must be: ■ Unresponsive ■ Not breathing or not breathing normally **Intended Medical Conditions** The equipment is to be used in public places and facilities by persons who have been trained in its operation. **Contra-indications** The equipment is contraindicated in the treatment when the patient is showing any of the following: ◆ Consciousness ◆ Breathing ◆ Detectable pulse or other signs of circulation **Side-effects** Through clinical data from literature and clinical data from post-market surveillance activity of subject device, there is no side-effects identified.	manual defibrillation treatments. It guides operators through Cardiopulmonary resuscitation (CPR) and can also be used for ECG monitoring. The equipment configured with only AED function is intended for AED. It also guides operators throughout CPR. **Intended Users** The equipment is intended for use in pre-hospital or hospital 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. The equipment is also intended for use in public places and facilities by personnel trained in the operation of the equipment and qualified by training in basic life support, advanced cardiac life support or other emergency medical response. **Intended Medical Conditions** The equipment is intended for use in pre-hospital or hospital 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. The equipment is also intended for use in public places and facilities by personnel trained in the operation of the equipment and qualified by training in basic life support, advanced cardiac life support or other emergency medical response. **Intended Patient Population** The AED mode is to be used only on cardio arrest patients who must be: • Unresponsive • Not breathing or not breathing normally Manual Defibrillation Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. Synchronous defibrillation is intended for termination of atrial fibrillation. ECG	defibrillation and manual defibrillation. The subject device supports semi-automated external defibrillation and automated external defibrillation. The difference between semi-automated external defibrillation and automated external defibrillation is only the difference of discharge key. The AED algorithm and defibrillation waveform are the same. D1 is intended for use in pre-hospital, hospital or public places and facilities while C&S series is intended for use in public places and facilities.

		The ECG monitoring function is used to monitor and/or store the patient's ECG waveform and heart rate. CPR Feedback The CPR sensor can be connected to the equipment to provide real-time CPR feedback, including the chest compression depth, rate and interruption time.	The data of D1 used in this report comes from public places and facilities that supports semi-automated external defibrillation, which is the same as the conditions of use and users of the subject device. The subject device is similar with the marketed device.
3.2 Clinical condition or purpose, including similar severity and stage of disease	The device is designed for treating life-threatening heart beat irregularities	The device is designed for treating life-threatening heart beat irregularities	**Same**
3.3 Site in the body	The site of defibrillation is at the bottom of the heart and the tip of the heart, the base of the heart refers to the 2nd-3rd intercostal of the right edge of the sternum, and the tip of the heart is the intersection between the front line of the left axillary and the fifth rib on the left side. The site of CPR function is in the middle of the chest, on the lower half of the sternum.	The site of defibrillation is at the bottom of the heart and the tip of the heart, the base of the heart refers to the 2nd-3rd intercostal of the right edge of the sternum, and the tip of the heart is the intersection between the front line of the left axillary and the fifth rib on the left side. The site of CPR function is in the middle of the chest, on the lower half of the sternum.	**Same for defibrillation and CPR function**
3.4 Intended uers	The operator should be trained in basic life support or other emergency medical response.	The equipment is intended for use in pre-hospital or hospital 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.	The subject device is the subset of the marketed device.

		The equipment is also intended for use in public places and facilities by personnel trained in the operation of the equipment and qualified by training in basic life support, advanced cardiac life support or other emergency medical response.	
3.5 Patient population	The device is intended to be used on adults and children in a sudden cardiac arrest. The patients must be: ■ Unresponsive ■ Not breathing or not breathing normally	The device is intended to be used on adults and children in a sudden cardiac arrest. The patients must be: ■ Unresponsive ■ Not breathing or not breathing normally	**Same**
3.6 Clinical application scenario	AED mode can help people with sudden cardiac arrest. Combined with CPR, give people chance to survive.	AED mode can help people with sudden cardiac arrest. Combined with CPR, give people chance to survive. In manual defibrillation mode, asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. Synchronous defibrillation is intended for termination of atrial fibrillation. The ECG monitoring function is used to monitor and/or record the patient's ECG waveform and heart rate	The subject device is the subset of the marketed device.
Summary Based on the comparison from technical, biological and clinical perspectives, slight differences are found, which cannot affect the safety and clinical performance of the device			

3.3 Accessories

3.3.1Accessories included

None.

3.3.2Accessories not included but necessary for use

3.3.2.1 Others

For the other devices, see as below:

Accessories	Description	Model	Applicable patient	Remark
Therapy Accessories	Multifunction electrode pads	MR60	Adult, Child	Disposable (5 sets/pack)
		MR61	Child	
		MR62	Adult, Child	Disposable (5 sets/pack), the adult pads are automatically detected, the pediatric pads need to be manually selected
		MR63	Child	Disposable (5 sets/pack), the pediatric pads are automatically detected
	CPR sensor	MR6401	/	Reusable, without a battery
	CPR sensor cable	MR6801	/	Reusable
	CPR adhesive tape	MR6921	/	Disposable (3 sets/pack)

3.3.2.2 Other products that are not devices

- Disposable battery

3.4 Another device

None.

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	Energ	Sequence of events	Hazardous situation	Harm	Control Measure	Risk level
C3.2.1	Energy hazards	High current flows through	The discharge current is large, causing damage to the	The patient's myocardium is	The MINDRAY biphasic truncated exponential	AFAP

		the myocardium during defibrillation therapy.	cardiomyocytes.	injured by electric shock during defibrillation therapy.	waveform is used, and the waveform parameters can be adjusted according to the patient impedance.	

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.

Risk and Benefit Analysis：

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 Warnings and Precautions required by the manufacturer

- Check for mechanical damages before each use. If case of any damage, do not apply it to patients.
- 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.
- The equipment is not intended to be used within the Magnetic Resonance (MR) environment.
- Do not open the equipment housings. All servicing and future upgrades must be carried out by the service personnel.
- This equipment is used for single patient at a time.
- Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation.
- Do not defibrillate a patient who lies on wet ground.
- For the treatment of patients with implantable pacemakers, place the electrode pads away from

internal pacemaker generator if possible to help prevent damage to the pacemaker.

- To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to reduce risk of entanglement or strangulation by patients or personnel.
- Do not touch device connectors or other live equipment if in contact with the patient; otherwise patient injury may result.
- Do not touch the patient and live parts simultaneously. Otherwise patient injury may result.
- Package material may contaminate the environment. Properly dispose of the package material according to applicable waste control regulations and keep it out of children's reach.
- Keep a distance of at least 20cm away from the equipment when the wireless function is in use.

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 C&S series Automated External Defibrillator.

In the final collection results, the adverse event rate was 0% and the complaint rate was 0.003%. 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	CP2204-JH02865	2022	BeneHeart C1	China	300 AED training machines were not individually packaged, and there were no Chinese voice packages in the software. Deviations in understanding occur during the communication between the mindray business personnel and customers, and the error PO(purchasae order) is placed. It has been explained to the customer that this batch of products has been handled to the satisfaction of the customer.	/	NO	N No malfunction was involved, no clinical risk was involved.

2	CP2203-JH02836	2022	BeneHeart C2	China	The product name in the FQC report of the equipment was external defibrillator, the customer thought that the name of the FQC report was wrong, and the customer asked for an explanation. The product name in the FQC report is the abbreviation of the series of products used by our company for unified management. Mindray products comply with regulatory requirements. The letter of explanation has been made clear to the customer and no actual product	/	NO No actual product problem is involved.	N No malfunction was involved, no clinical risk was involved.

					problem is involved.			
3	CP2112-JH02689	2021	BeneHeart C1	China	After the customer purchased the electrode pads, he found that the validity period was less than one year, and the replacement has been carried out. The pads can be used normally within the validity period. Therefore, no risks are involved.	Defibrillation discharge failed	NO The pads can be used normally within the validity period.	Y; Risk items: KF-0654-2-0007 Risk Management Report: 3.24.3 Current Control Measure: The validity period of pads included in the design control device self-test. The expiration date is marked on the accessories. It is indicated in the manual that the pads should be used within the validity period. Risk Level After Control Measure: Acceptable

4.4 Complaint rates of the specific warning and precautions

Warnings and precautions	Complaint No.	Complaint rates
Check for mechanical damages before each use. If case of any damage, do not apply it to patients.	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%
The equipment is not intended to be used within the Magnetic Resonance (MR) environment.	0	0.000%
Do not open the equipment housings. All servicing and future upgrades must be carried out by the service personnel.	0	0.000%
This equipment is used for single patient at a time.	0	0.000%
Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation.	0	0.000%
Do not defibrillate a patient who lies on wet ground.	0	0.000%
For the treatment of patients with implantable pacemakers, place the electrode pads away from internal pacemaker generator if possible to help prevent damage to the pacemaker.	0	0.000%
To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to reduce risk of entanglement or strangulation by patients or personnel.	0	0.000%
Do not touch device connectors 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. Otherwise patient injury may result.	0	0.000%
Package material may contaminate the environment. Properly dispose of the package material according to applicable waste control regulations and keep it out of children's reach.	0	0.000%
Keep a distance of at least 20cm away from the equipment when the wireless function is in use.	0	0.000%

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 automatic external defibrillator 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 AED function can also meet the safety and effectiveness of European users.

5.1 Summary of post-market clinical data

Since the defibrillation module development of the subject device is based on the previous generation products, based on the comparison from technical, biological and clinical perspectives, slight differences are found, which cannot affect the safety and clinical performance of the device, and the post-market clinical follow-up is conducted on the technology of the previous generation products to obtain the clinical data.

The automated external defibrillators of BeneHeart C1/BeneHeart C1A/BeneHeart C2/BeneHeart C2A/BeneHeart S1/BeneHeart S1A/BeneHeart S2/BeneHeart S2A/BeneHeart C1 Fully Automatic/BeneHeart C1A Fully Automatic/BeneHeart C2 Fully Automatic/BeneHeart C2A Fully Automatic/BeneHeart S1 Fully Automatic/BeneHeart S1A Fully Automatic/BeneHeart S2 Fully Automatic/BeneHeart S2A Fully Automatic are thus determined to be as safe and effective as the equivalent devices including BeneHeart D1.

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 C & S series Automated external defibrillator	BeneHeart D1 Automated external defibrillator	Not applicable

Post-clinical follow-up data from 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**

247 clinical cases have been collected until 2023.7, all cases came from public places and facilities, with details as follows:

Age Distribution of the Cases:

Age	Number of Cases
＜8 years	2
≥8 years	245
Total	247

Defibrillation success rate:

Number of total Cases	success cases	success rate
161	154	95.7%

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

AED	results of Expert diagnostic with ECG		Total
	Positive	Negative	/
Positive	497	7	504
Negative	8	1205	1213
Total	505	1212	1717

Sensitivity

A/(A+C)*100%=98.4%

Specificity

D/(B+D)*100%=99.4%

The inappropriate analyses:

1-1702/1717*100%=0.9%

The Delivered shock with incorrect shock advice:

1-1205/1212*100%=0.6%

95% Confidence Interval Calculation:

For the defibrillation success rate of the device in question:

This PMCF collects 161 cases and 154 cases are successful, the final result of defibrillation success rate is 95.7%. Based on Confidence interval calculation formula:

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

When α=0.05，$Z_{\alpha/2} = 1.96$

Finally, the two-sided 95% confidence interval of 95.7% is calculated as follows:(92.6%, 98.8%), the lower limit 92.6% is above the target value 87.9%.

For the sensitivity of the device in question:

This PMCF collects 505 shockable rhythms cases and 497 correct identification cases, the final result of sensitivity is 98.4%. Based on Confidence interval calculation formula:

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

When α=0.05，$Z_{\alpha/2} = 1.96$

Finally, the two-sided 95% confidence interval of 98.4% is calculated as follows:(97.3%, 99.5%), the lower limit 97.3% is above the target value 90%.

For the specificity of the device in question:

This PMCF collects 1212 non-shockable rhythms/conditions cases and 1205 correct identification cases, the final result of specificity is 99.4%. Based on Confidence interval calculation formula:

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

When α=0.05，$Z_{\alpha/2} = 1.96$

Finally, the two-sided 95% confidence interval of 99.4% is calculated as follows: (99.0%,99.8%), the lower limit 99.0% is above the target value 95%.

- **Conclusion:**

The result of defibrillation success rate is 95.7% (95%Cl: 92.6%, 98.8%), the lower limit 92.6% is upper than the target value 87.9%.

The result of sensitivity rate is 98.4% (95%Cl: 97.3%, 99.5%), the lower limit 97.3% is upper than the target value 90%.

The result of specificity rate is 99.4% (95%Cl: 99.0%,99.8%), the lower limit 99.0% is upper than the target value 95%.

The result of the inappropriate analyses is 0.9%, lower than the result from SOTA(8.8%).

The result of the delivered shock with incorrect shock advice is 0.6%, lower than the result from SOTA(2.4%)

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

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.

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

N/A.

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

N/A.

5.4 An overall summary of the clinical performance and safety

Automated external defibrillator is intended to be used for defibrillator. For a patient with ventricular fibrillation (VF)/ventricular tachycardia (VT), the effective and timely two-way defibrillation treatment presents high success rate of treatment.

Automated external defibrillation (AED)

The primary endpoint is the defibrillation success rate and sensitivity/specificity, a total of 247 cases of the use of the BeneHeart series of defibrillation monitors were collected until 2023. 154 of 161 cases are successful defibrillated, the result of defibrillation success rate is 95.7% (95%Cl: 92.6%,98.8%), the lower limit 92.6% is upper than the target value 87.9%.

The result of sensitivity rate is 98.4% (95%Cl: 97.3%, 99.5%), the lower limit 97.3% is upper than the target value 90%.

The result of specificity rate is 99.4% (95%Cl: 99.0%, 99.8%), the lower limit 99.0% 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.

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	**Assessment**
Assessment of Benefits of Devices	
Type of benefit(s)	**Using real world data or other available data, what is the medical device's impact on clinical management and patient health?** The automated external defibrillator is intended for semi-automated external defibrillation and automated external defibrillation. Automated external defibrillation (AED) can directly improve patient survival, relieve symptoms and improve patient quality of life. During defibrillation, the CPR could standardize the chest compression procedure based on the measurement of compression depth range and compression rate.
Magnitude of the benefit(s)	**What is the medical device's impact on patient health and clinical management?**

	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%. The magnitude of this benefit is either life or death.
Probability of the patient experiencing one or more benefit(s)	**From the data of PMCF:** The result of defibrillation success rate is 95.7% (95%Cl: 92.6%, 98.8%), the lower limit 92.6% is upper than the target value 87.9%. The result of sensitivity rate is 98.4% (95%Cl: 97.3%, 99.5%), the lower limit 97.3% is upper than the target value 90%. The result of specificity rate is 99.4% (95%Cl: 99.0%,99.8%), the lower limit 99.0% 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.
Duration of effect(s)	N/A.
Assessment of risks of Devices	
Medical device-related deaths and serious injuries	The risk management report has assessed the severity and probability of hazard occurrence and the combined residual risk is acceptable and the product is safe and effective. Since the automated external defibrillator was launched, there are no device related deaths and serious injuries from the information collected from customers and after-sales service engineers
Medical device-related nonserious adverse events	Since the automated external defibrillator was launched, there are no device related nonserious adverse events from the information collected from customers and after-sales service engineers
Procedure-related complications	Not found yet.
Likelihood of Risk	The risks have been appropriately identified and measures has been taken to mitigate the potential risks. From the data of PMS activity and PMCF survey study, no adverse events related to the device are found.
Risk from false-positive or false negative results for diagnostics	N/A.

Conclusion	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
Automated external defibrillation (AED)	Semi-automated defibrillation	manual defibrillation
CPR feedback	CPR feedback	CPR metronome

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 – discharge	– automatic arrhythmia analysis and charge – press button according to the prompt (Semi-automatic AED) or automatic discharge (Fully automatic AED)

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.

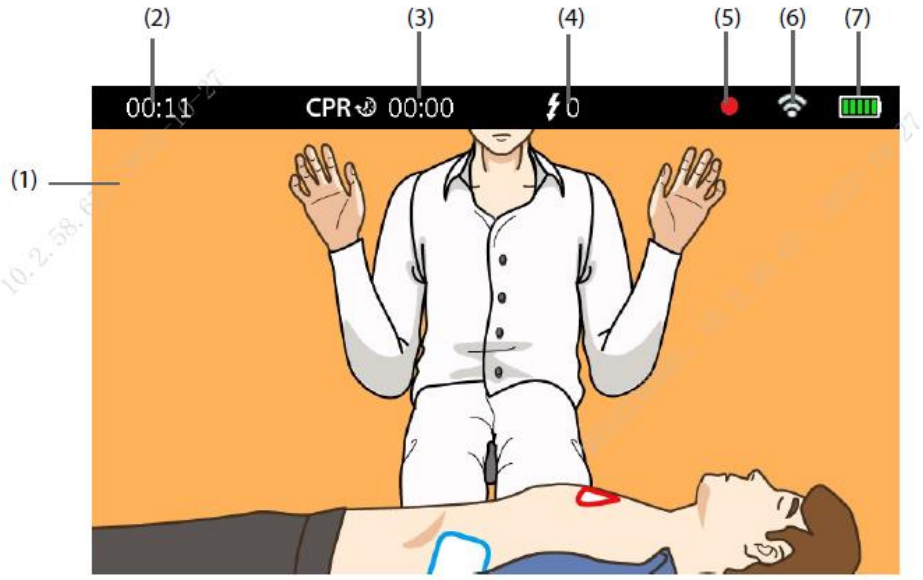
7. Suggested profile and training for users

The equipment is intended for use only by person who trained in basic life support or other emergency medical response.

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.**

Screen Display:



(1) ECG rhythm: displays one ECG waveform acquired from the electrode pads if ECG Display is set to On.

(2) Runtime area: displays the equipment's operating time since powered on.

(3) CPR time

(4) Number of delivered shocks

(5) Record icon: available when the sound recording function is enabled.

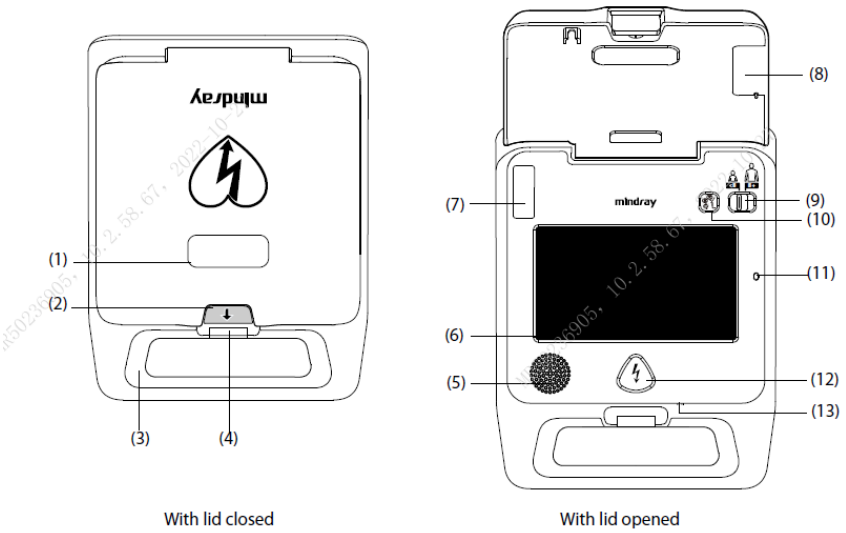
(6) Network type indicator

• : indicates the equipment is configured with the Wi-Fi module, and is connected to the AED ALERT system through the Wi-Fi network.

• 4G: indicates the equipment is configured with the cellular module, and is connected to the AED ALERT system through the cellular network.

(7) Battery status indicator: indicates battery status.

Top View:



With lid closed With lid opened

(1) Pad expiration window: checks the expiration date of pads.

(2) Latch: opens or closes the lid.

(3) Handle

(4) Status indicator

- Green: the equipment is turned on, and can work correctly.
- Flashing green: the equipment is in the standby status, and is ready for operation at any time.
- Flashing red: auto test failure is detected on the equipment.
- Off: no battery is installed or the battery is malfunctioning.

(5) Speaker: the equipment automatically adjusts the volume depending on surrounding noise levels by default.

(6) Display screen (for equipment configured with the screen)

(7) Pads connector: connects the electrode pads.

(8) Pads package holder: stores the electrode pads.

(9) Adult/Child mode switch: flip right or left to switch between adult and child.

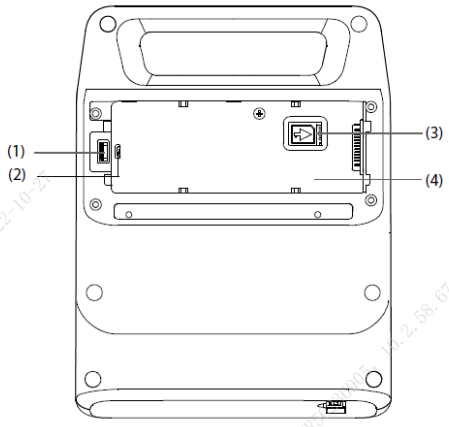
(10) Language button: press to switch between the configured languages.

(11) Optical sensor (for equipment configured with the screen): the equipment automatically adjusts the screen brightness depending on surrounding light by default.

(12) Shock button (for semi-auto model): press to deliver a shock to the patient.

(13) Microphone: records voices. It is available only when the record function is enabled.

Bottom View:



The battery compartment provides the following connectors.

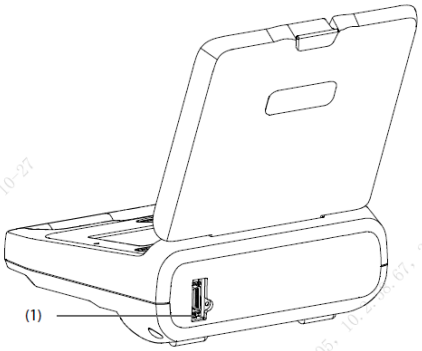
(1) USB connector: connects the USB flash memory.

(2) micro USB connector: connects the computer.

(3) Network connector (for equipment configured with the cellular module): connects the SIM card.

(4) Battery compartment: stores the battery.

Back View:



Multifunction connector (for equipment configured with the CPR sensor: connects the CPR sensor.

Pads cable, pads, test load:

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

Modify Configuration:

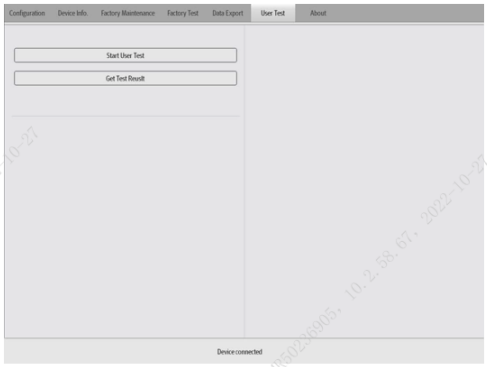
● Modify Configuration — AED Tool Installation and Use Guide

Basic Operations

1. After the device is connected to the AED Tool, enter the **Configuration page, click Read Device Configuration, and the prompt "Reading the configuration file successfully!" appears.**
2. Close the above prompt box, edit **System Time, Language, Shock Series, WLAN Setup, and other items, click Write Device Configuration, and the prompt "Writing successfully! Effective after the device is restarted" appears.**
3. Restart the AED device and the written configurations takes effect.

User Test:

User Test — AED Tool Installation and Use Guide



1. With the device lip opened, enter the User Test page.
2. Click Start User Test, the device starts the user test, and you should perform user test followed the voice and text prompts.
3. After the test is completed, click Get Test Result to read the test results.

Other ways to receive voice test result

Start user test in one of the following ways:

- Long press the language switch button, after 5s, dial the patient selection switch twice.
- Long press the shock button, after 5s, dial the patient selection switch twice.

Battery Loading Test:

Battery Loading Test

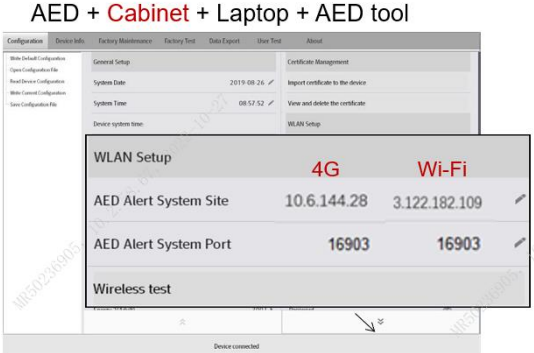
Confirm the external defibrillator, the buttons, the horn, the pads and the batteries can work normally. Follow this procedure to perform the test:

1. Close the upper cover of the external defibrillator.
2. After removing the batteries for 3 minutes, re-install the batteries to the battery compartment of the external defibrillator and enter the battery loading self-test mode.
3. Perform the auto test, audio test and button test according to the voice prompts of the external defibrillator.
4. Test whether the device is abnormal according to the voice test results. If any item fails, the status indicator will flash red when the device is turned off.

Network Test:

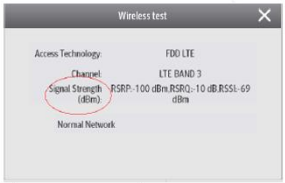
Network Test — SN not imported in Alert

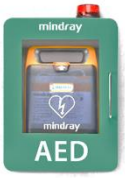
AED + Cabinet + Laptop + AED tool



- Network test is after User test
- After User test, put AED in Cabinet
- Wait till Status indicator flash normal

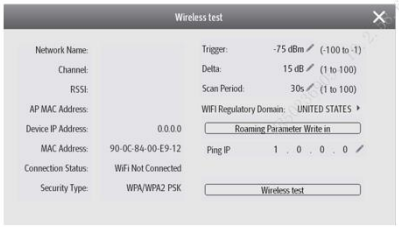
4G module

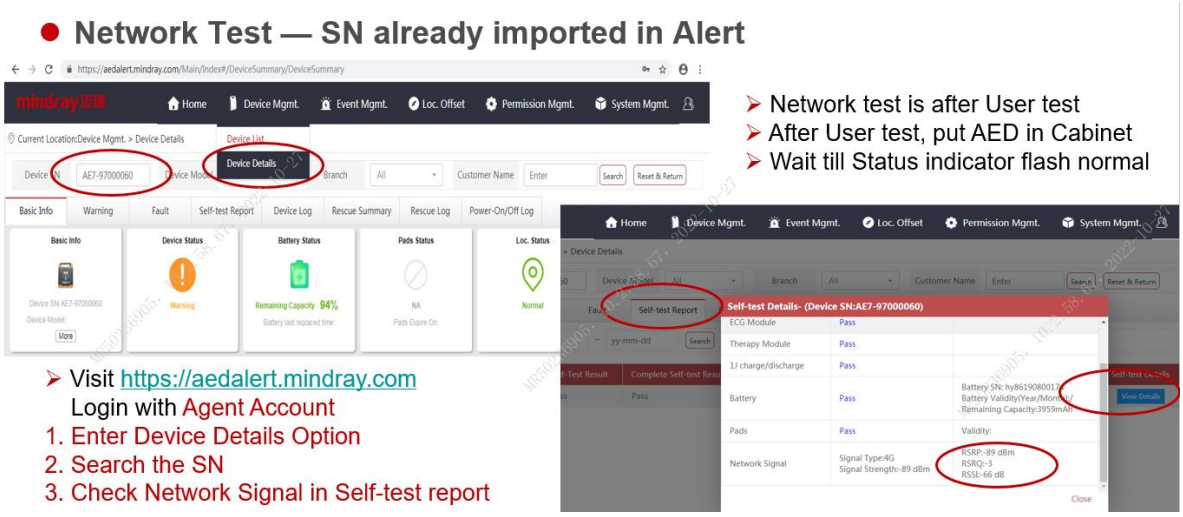




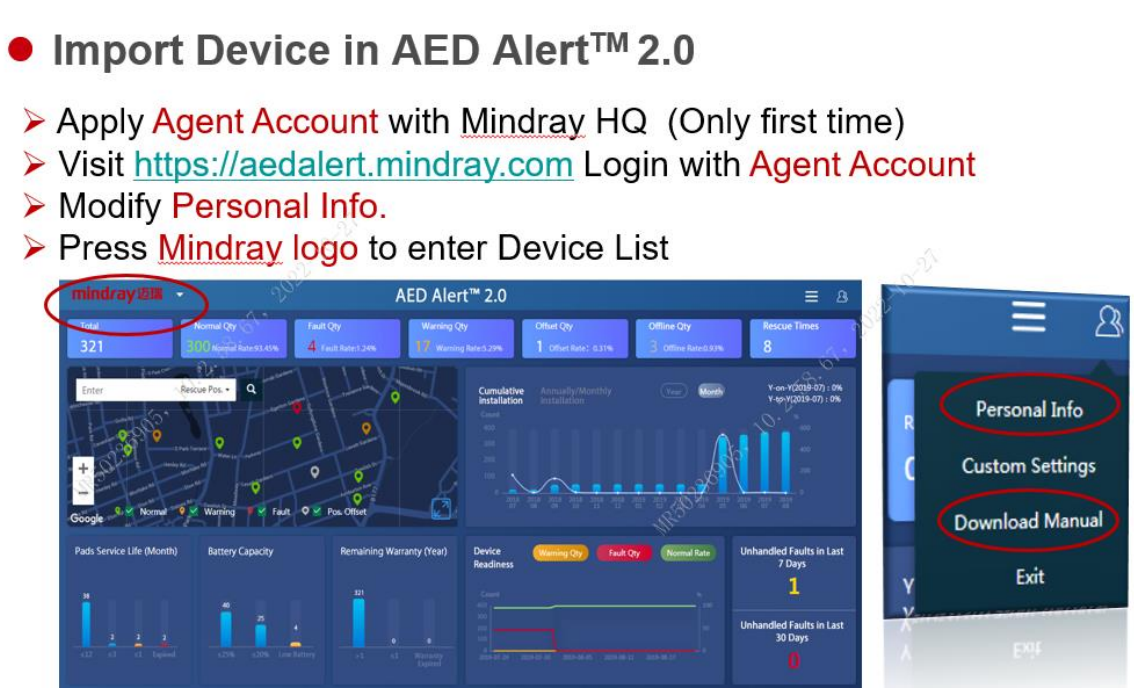
Index	Accept criteria	Explanation
Access Technology	TDD LTE or FDD LTE	Acceptance criteria are met to indicate that the location can be use to install AED, otherwise you need to consider find another location.
Singal Strength	RSRP>-100dBm and RSRQ>-14dB	
4G function test result	Normal Network	

Wi-Fi module



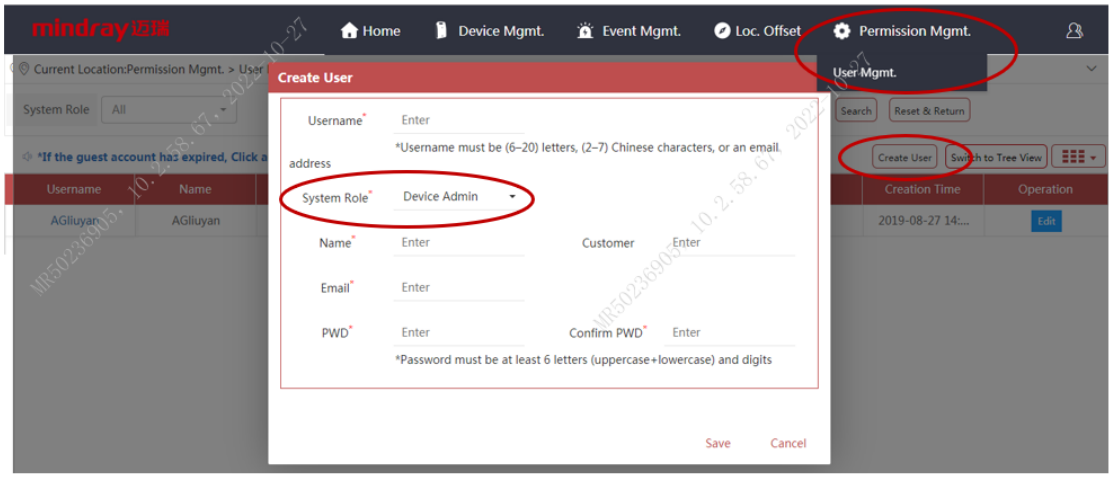


Import Device in AED Alert 2.0:



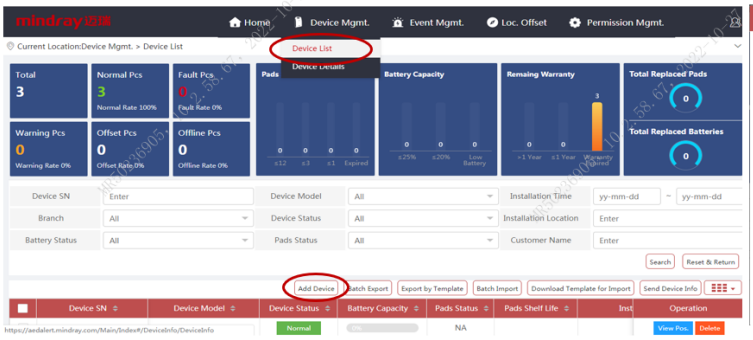
Import Device in AED Alert™ 2.0

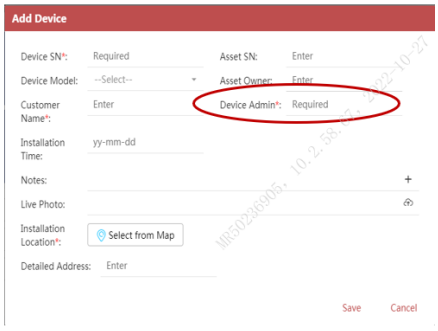
- Enter Permission Mgmt. -> User Mgmt. -> Create User
- Create Device Admin Account



Import Device in AED Alert™ 2.0

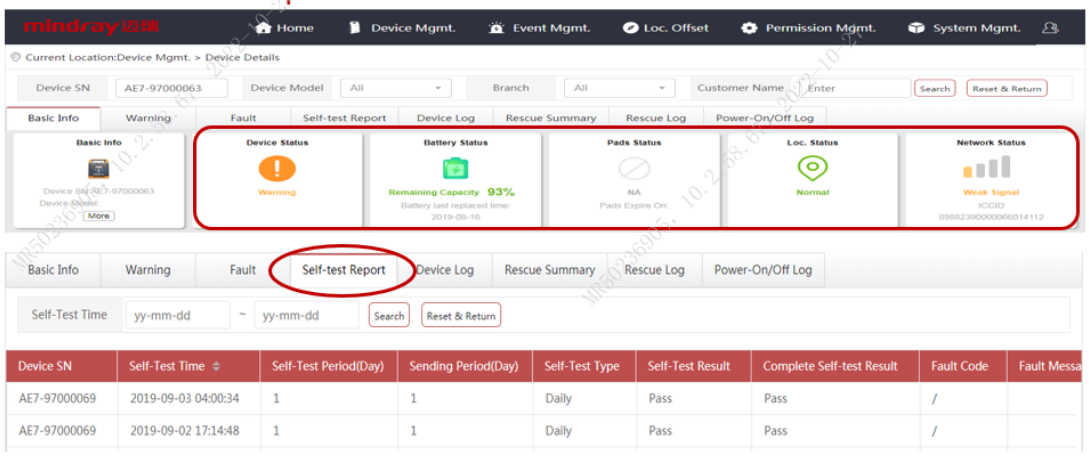
- Enter Device Mgmt. -> Device List
- Press Add Device to import AED (Recommended)
- Associate Device with Device Admin





Import Device in AED Alert™ 2.0

- Enter Device Mgmt. -> Device Details
- Check All Device Status
- Check Self-test Report is received

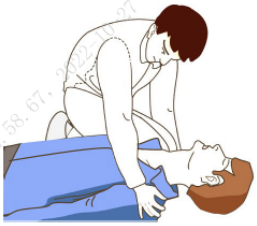


➢ Introduction of the function operation of the product.

AED:

You should perform the general steps for a rescue.

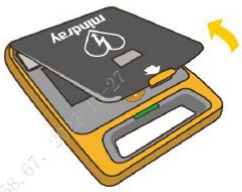
1 Assess the Patient



Confirm that the patient is both:
- Unresponsive,
- Not breathing or not breathing normally

CALL EMERGENCY MEDICAL SERVICE!

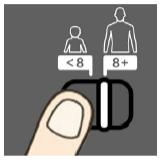
2 Turn on the Equipment



Open the lid.

You hear:
Powered on. Stay calm. Follow the instructions.

3 Check Patient Category



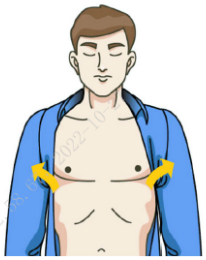
Flip the Adult/Child mode switch left or right:
- For an adult: 8 years and older or over 25kg

You hear:
Adult mode

- For a child: under 8 years old or under 25kg

You hear:
Child mode

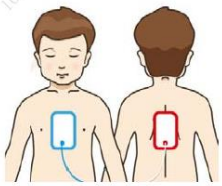
4 Prepare the Patient



Expose the patient's bare chest:
- Ensure the patient's skin is clean and dry.
- Dry the patient's chest and shave excessive hair if necessary.

You hear:
Remove clothing from patient's chest. Apply pads as shown on Pads.

5 **Apply the Electrode Pads**



Apply the electrode pads to the patient as directed on the pads package.

For an adult:

- Blue (apex) pad placement: place the blue pad as the blue area (below left nipple, on the left anterior axillary line) illustrated in the picture
- Red (sternum) pad placement: place the red pad as the red area (below the clavicle, lateral to the sternum) illustrated in the picture

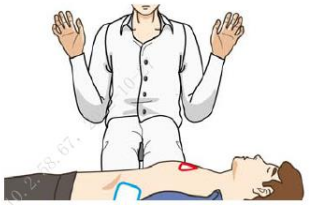
For a child:

- Blue (apex) pad placement: place the blue pad as the blue area (on the chest middle line) illustrated in the picture
- Red (sternum) pad placement: place the red pad as the red area (on the back middle line) illustrated in the picture

You hear:

Apply pads firmly to patient's bare chest as shown on Pads.

6 **Analyze Heart Rhythm**



Do not touch the patient, waits for heart rhythm analysis.

You hear:

Do not touch the patient. Analyzing heart rhythm.

7 **Deliver a Shock**

If Shock Advised

- For fully automatic models:

The equipment automatically shocks the patient.

You hear:

Shock advised. Shock will be delivered in: 3, 2, 1

- For semi-automatic models:

Press the Shock button within the configured time.

You hear:

Shock advised. Press flashing shock button.

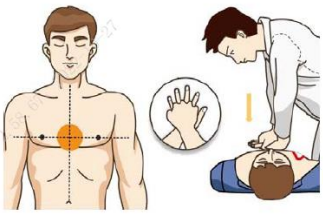
If No Shock Advised

Go to Step 8.

You hear:

No shock advised.

8 **Perform CPR**



Perform CPR according to the prompts.

- If the CPR time expires, repeat Step 6.
- If the patient is conscious and breathing normally, wait for emergency medical services to arrive.

8. Harmonized standards and CS applied

EN	ISO	Medical devices - Application of risk management to medical devices

14971:2019/A11:2021	
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
IEC 60601-1:2005+A1:2012+A2:2020	Medical electrical equipment--Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance-- Collateral standard: Electromagnetic compatibility--Requirements and tests
IEC 60601-1-6:2010+A1:2013+A2:2020	Medical electrical equipment-part 1-6: general requirements for basic safety and essential performance--collateral standard: usability
IEC 60601-2-4:2010+A1:2018	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators
IEC 62366-1:2015+A1:2020	Medical devices – Part 1： Application of usability engineering to medical devices
EN 1789:2020	Medical Vehicles and Their Equipment - Road Ambulances
EN 13718-1:2014+A1:2020	Medical vehicles and their equipment-Air ambulances-Part 1: Requirements for medical devices used in air ambulances
IEC 60601-1-10:2007+A1:2013+A2:2020	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
IEC 60601-1-11:2015+A1:2020	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
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
IEC 60086-4:2019	Primary batteries – Part 4: Safety of lithium batteries
EN 62304:2006/A1:2015	Medical device software - Software lifecycle processes

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1.0	2022.10.25	Initial version	☒ Yes Validation language: English ☐ No
2.0	2022.12.27	Revise the Chapter 5.1	☒ Yes Validation language: English ☐ No
3.0	2023.07.26	Add the requested information	☒ Yes Validation language: English

			☐ No