	KF-0656-4-0018		
	0656		

Summary of safety and clinical performance

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3.3.1

3.3.2Accessories not included but necessary for use

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Item	Energy	Sequence of events	Hazardous situation	harm	Control Measure	Risk level

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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	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

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%

If the accuracy of any value displayed on the equipment, CMS, or printed on a graph strip or report is questionable,	CP-2014-021、CP17-JH0052	0.005%

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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

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		20
		27
		64
		68
		185

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	124
	52
	177

		1
		21
		50
		40
		63
		176

			success

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	52
	168
	220

		7
		23

		36
		54
		67
		33
		220

Number of total Cases	success cases	success
150	140	93.3%

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	139
	77
	216

		1
		2
		12
		78
		122
		216

			success

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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

	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?** 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?**

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
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?**

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?** 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.	

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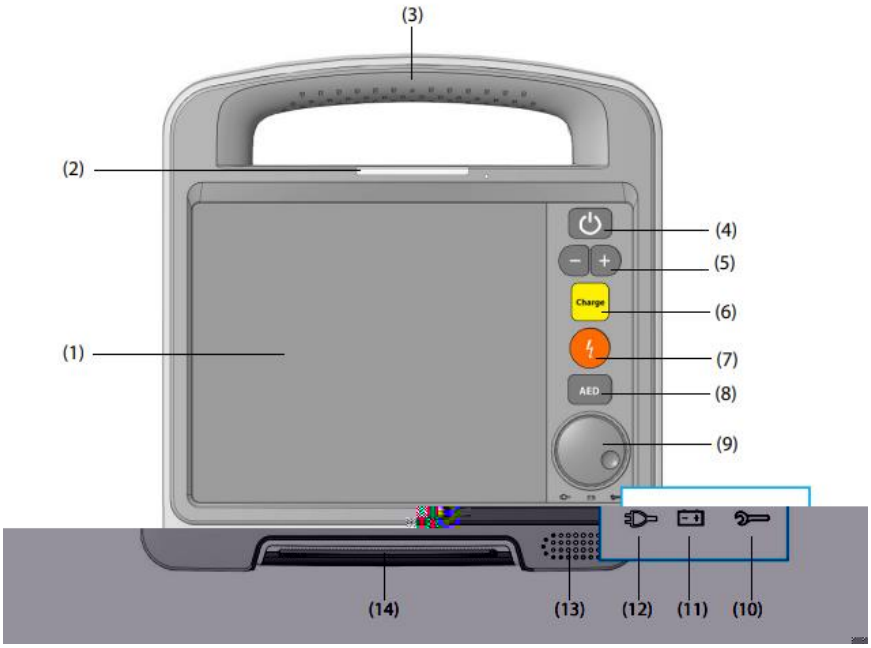

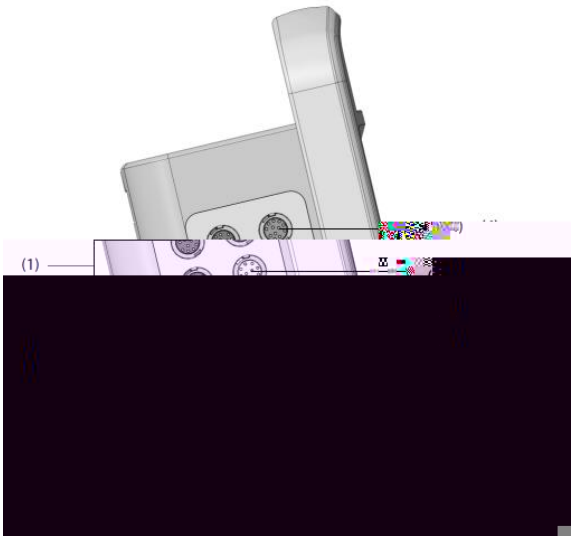

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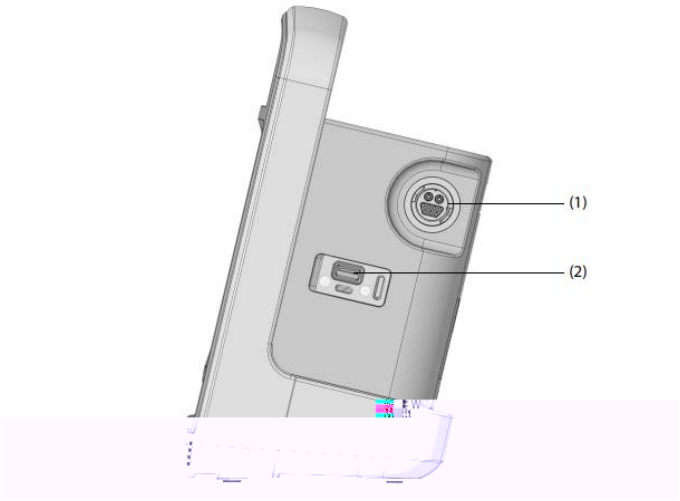

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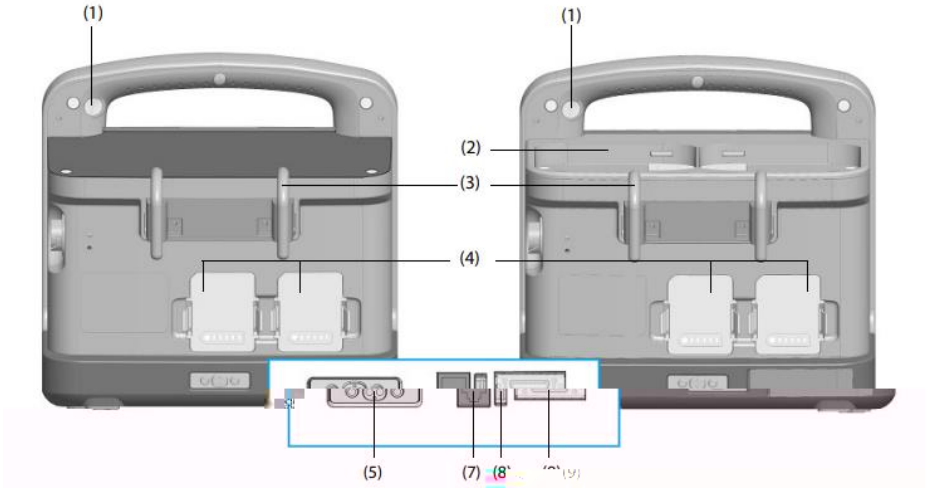

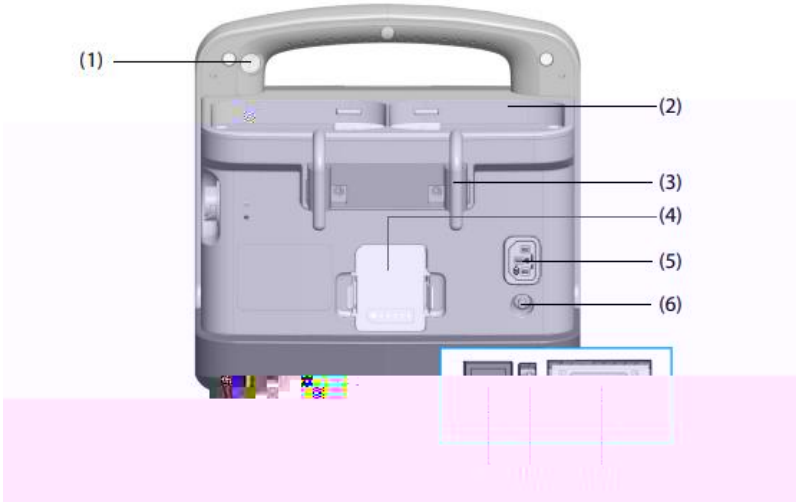

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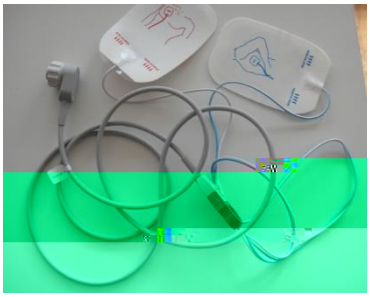

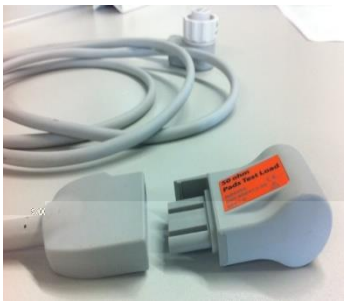

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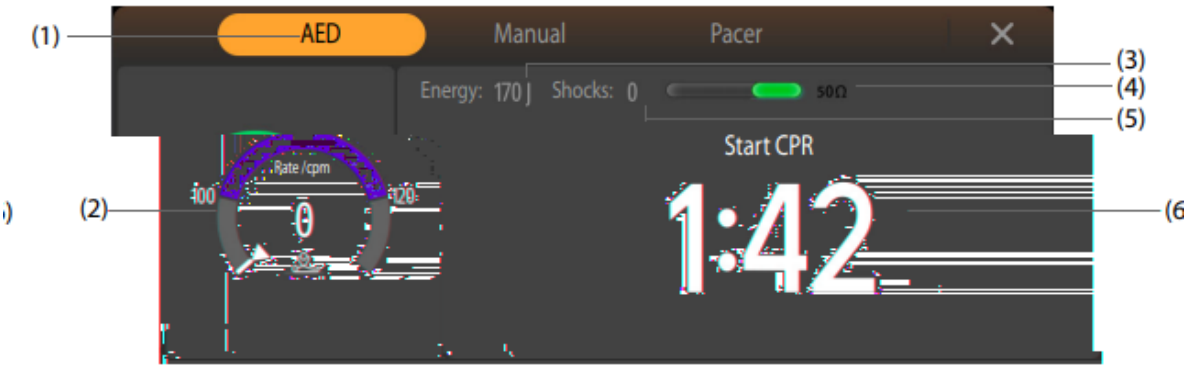
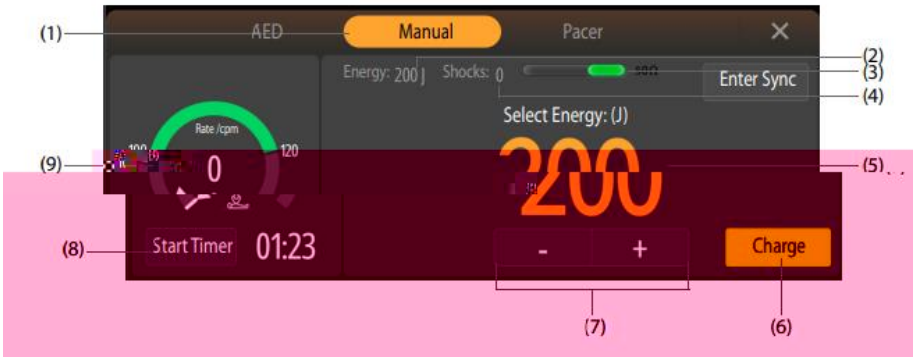

(1)
AED
Manual
Pacer
(3)
Energy: 170 J
Shocks: 0
50Ω
(4)
(5)
Start CPR
(2)
Rate /cpm
100
120
1:42
(6


(1)
AED
Manual
Pacer
(2)
Energy: 200 J
Shocks: 0
(3)
Enter Sync
(4)
Select Energy: (J)
(9)
Rate /cpm
100
120
0
200
(5)
(8)
Start Timer
01:23
-
+
Charge
(7)
(6)


II
X 2
Therapy
(1)
1 mV
SYNC
200
Charge

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

8.

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 b81 210.2397881 210.292.7( )90880.29 Tm/6464 81.6

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

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