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3.3.1.1

3.3.1.4

3.3.2.1

Module type	**Applicable patient**	**Remark**	**Manufacturer**
Mindray SpO_2 module	Adult, pediatric, neonate	/	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Masimo SpO_2 module		8 pins, purple connector	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
		7 pins, white connector	Shenzhen Mindray Bio-Medical Electronics

			Co., Ltd
Nellcor SpO_2 module		/	Shenzhen Mindray Bio-Medical Electronics Co., Ltd

3.3.2.2

3.3.3.1

Type	Applicable patient	Manufacturer
Reusable	Adult, pediatric	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
	Neonate	

3.3.3.2

Type	Model	Applicable patient	Applied site	Limb Circumference (cm)	Bladder Width (cm)	Manufacturer
Reusable	CM1201	Infant	Upper arm	10 to 19	9.2	Shenzhen

	CM1202	Pediatric		18 to 26	12.2	Mindray Bio-Medical Electronics Co., Ltd
	CM1203	Adult		24 to 35	15.1	
	CM1204	Large adult		33 to 47	18.3	
	CM1205	Adult	Thigh	46 to 66	22.5	
	CM1301	Infant	Upper arm	10 to 19	7.2	
	CM1302	Pediatric		18 to 26	9.8	
	CM1303	Adult		25 to 35	13.1	
	CM1304	Large adult		33 to 47	16.5	
	CM1305	Adult	Thigh	46 to 66	20.5	
Single patient	CM1500A	Neonate	Upper arm	3.1 to 5.7	2.2	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
	CM1500B			4.3 to 8	2.9	
	CM1500C			5.8 to 10.9	3.8	
	CM1500D			7.1 to 13.1	4.8	
	CM1501	Infant		10 to 19	7.2	
	CM1502	Pediatric		18 to 26	9.8	
	CM1503	Adult		25 to 35	13.1	
	CM1504	Large adult		33 to 47	16.5	
	CM1505	Adult	Thigh	46 to 66	20.5	

3.3.4.1

Type	**Model**	**Applicable Temp probe**	**Manufacturer**
Reusable	MR420B	MR411, MR412	Shenzhen Mindray Bio-Medical Electronics Co., Ltd

3.3.4.2

Description	**Applicable patient**	**Remark**	**Manufacturer**
Nasal sampling line	Pediatric	Disposable	Oridion Medical1987 Ltd.
Nasal sampling line, plus O_2	Adult		Oridion Medical1987 Ltd.
Nasal sampling line, plus O_2	Pediatric		Oridion Medical1987 Ltd.
Nasal sampling line, long, plus O_2	Adult		Oridion Medical1987 Ltd.
Nasal sampling line, long, plus O_2	Pediatric		Oridion Medical1987 Ltd.
Nasal sampling line, long	Adult		Oridion Medical1987 Ltd.
Nasal sampling line, long	Pediatric		Oridion Medical1987 Ltd.

Nasal sampling line, long	Neonate		Oridion Medical1987 Ltd.
Nasal sampling line, long, plus O_2	Adult		Oridion Medical1987 Ltd.
Nasal sampling line, long, plus O_2	Pediatric		Oridion Medical1987 Ltd.
Nasal sampling line	Adult		Oridion Medical1987 Ltd.
Nasal sampling line	Pediatric		Oridion Medical1987 Ltd.

3.3.6.2

Description	Model	Manufacturer
Carrying case	/	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Conducting gel mount kit	/	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Charger Station kit (International)	BatteryFeed 20	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Charger Station kit (US)		Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Charger Station kit (Indian)		Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Charger Station kit (EU)		Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Charger Station kit (Brazilian)		Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Charger Station kit (UK)		Shenzhen Mindray Bio-Medical Electronics Co., Ltd

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

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BeneHeart D5/ BeneHeart D6

iPM 12 Patient Monitor and BeneView T5 patient monitors.

Administrative	**Device 1 (subject device)** Description of characteristics and reference to specifying documents	**Device 2 (marketed device)** Description of characteristics and reference to specifying documents	**Device 3(marketed device)** Description of characteristics and reference to specifying documents	**Device 4(marketed 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	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD	Same.
Device Trade Name	BeneHeart D5/ BeneHeart D6 Defibrillator/Monitor	BeneVision N12 Patient Monitor	iPM 12 Patient Monitor	BeneView T5 patient monitor	Not applicable

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		2
		3
		17

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		20
		27
		64
		68
		185

			success

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	125
	52
	177

		1
		21
		50
		40
[redacted]		63

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	52
	168
	220

[redacted]

	220

Number of total Cases	success cases	success
150	140	93.3%

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	13900044>-4004 6/MCID 2MCI/F6 10.56]TJ 8.264 reW 139
	77
	216

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	o What was the magnitude of 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	All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following: pediatric patients only. 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?**

	experience the benefit value it?	

	- Are patients willing to accept the probable risk of the harmful event, given the probable 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?** All adverse events are reversible and not harmful to human body. They are temporary effects. 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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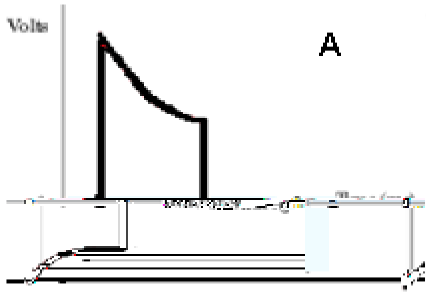
Volts
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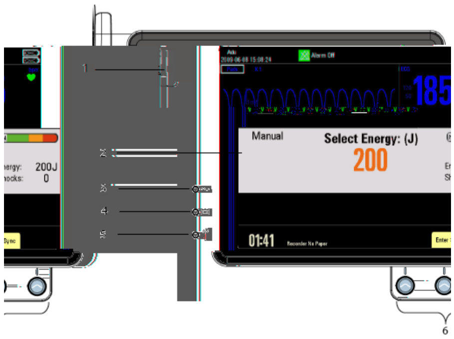
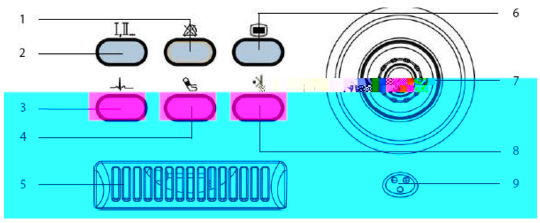
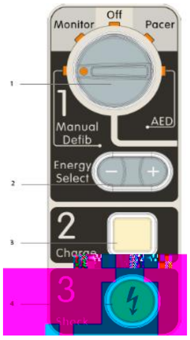
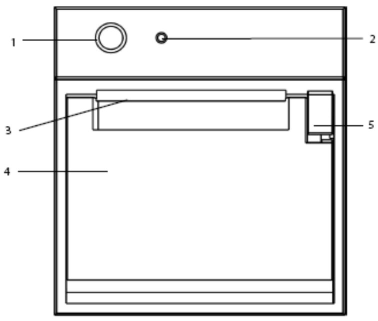
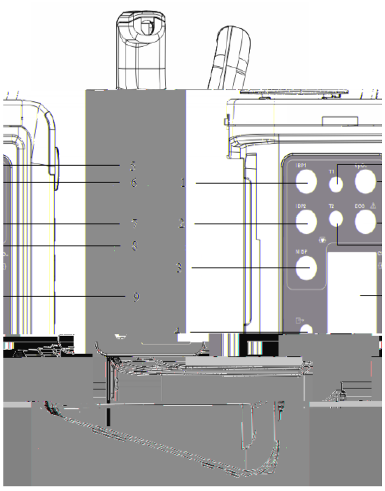






1. Mode Select knob
2. Energy Select button
3. Charge button
4. Shock button





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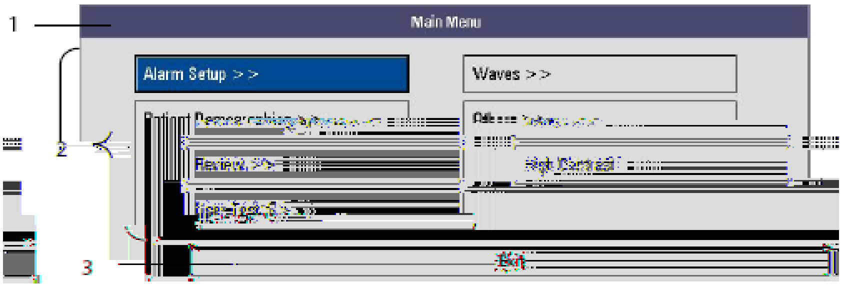
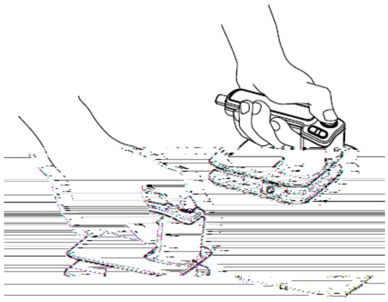
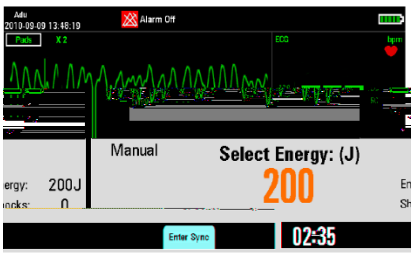
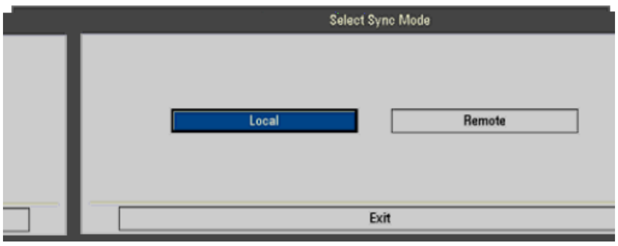
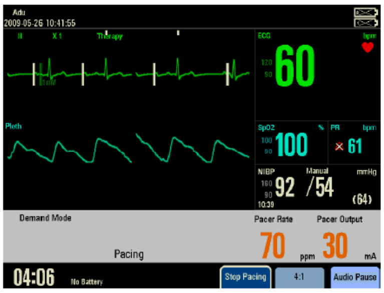

1
2
3
Main Menu
Alarm Setup > >
Waves > >
Exit


Adu
2010-09-09 13:48:19
Alarm Off
Pads
X 2
ECG
bpm
Manual
Select Energy: (J)
200
Energy:
Shocks:




Adu
2010-09-09 13:48:19
Alarm Off
Pads
X 2
ECG
bpm
Manual
Select Energy: (J)
200
200J
0
Enter Sync
02:35


Select Sync Mode
Local
Remote
Exit



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PACER INPUT
(50Ω - 1500Ω)
DEFIB
PACER
275 V MAX
SETUP


No Battery
Manual
Select Energy: (J)
200
SYNC
Energy: 200J
Shocks: 1
02:40

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EN ISO 14971: 2012 Medical devices - Application of risk management to medical devices

EN 1041:2008+A1:2013 Information supplied by the manufacturer with medical devices

ISO 15223-1:2016: Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied

EN ISO 10993-1: 2009/AC:2010 Biological evaluation of medical devices - Part 1: Evaluation and testing

EN 60601-1:2006/A1:2013 Medical electrical equipment--Part 1:General requirements for basic safety and essential performance

EN 60601-1-2: 2015 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: 2013 Medical electrical equipment-part 1-6: general requirements for basic safety and essential performance--collateral standard: usability

EN 60601-1-8: 2012 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

IEC 60601-2-4: 2018 Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators

IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

IEC 60601-2-27: 2011 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

IEC 80601-2-30:2018 Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

ISO 81060-2: 2018 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: 2011 Medical electrical equipment Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment

ISO 80601-2-61:2011 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

ISO 80601-2-55: 2018 Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors

EN 62304: 2015 Medical device software - Software lifecycle processes

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

EN 1789: 2007+A2:2014 Medical Vehicles and Their Equipment - Road Ambulances

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