BeneHeart D3/BeneHeart D2

Defibrillator/Monitor

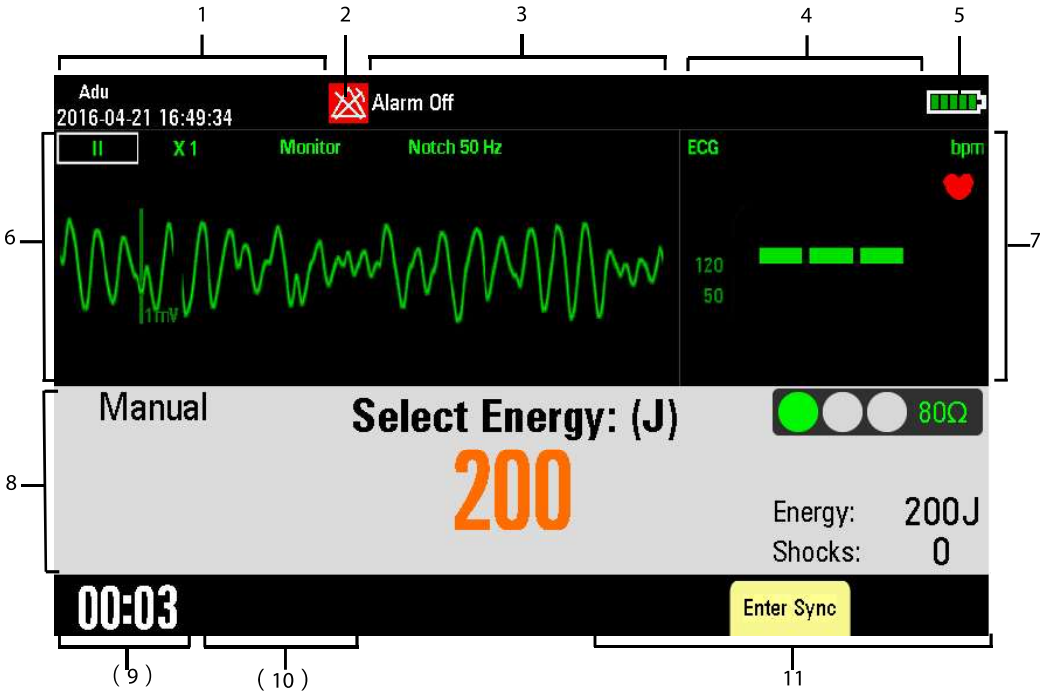
Operator’s Manual

CE 0123

- Release time: January 2019
- Revision: 8.0

2.4 Display Views

A typical screen in Manual Defib Mode is shown below.



1. Patient Information area

   This area shows patient name, patient category, paced status, and current date and time.

   - : indicates that the patient has an implanted pacemaker.

2. Alarm status symbols

   indicates alarms are paused.

   indicates alarm are reset.

   indicates alarm sounds are turned off.

   indicates the system is in alarm off status.

3. Physiological Alarm area

   This area shows physiological alarm messages. When multiple alarms occur, they will be displayed circularly.

4. Technical Alarm area

   This area shows technical alarm messages and prompt messages. When multiple messages come, they will be displayed circularly.

5. Battery Status indicator

   It indicates battery status. Refer to chapter *23 Batteries* for details.

6. Waveform area

   This area shows measurement waveforms. The waveform label is displayed at the upper left corner of the waveform.

7. Parameter area

   This area shows measurement parameters. Each measurement module has a parameter block and the parameter name is displayed at the upper left corner.

8. Manual Defib information area

   This area shows the selected defibrillation energy, shock counter as well as prompt related to manual defibrillation.

5 Alarms

Alarms triggered by a vital sign that appears abnormal or by technical problems of the equipment, are indicated to the user by visual and audible alarm indications.

WARNING

- **A potential hazard exists if different alarm presets are used for the same or similar device in any single area, e.g. an intensive care unit or cardiac operating room.**
- **If the equipment is connected to a CMS, remote suspension, inhibition, silence and reset of monitoring alarms via the CMS may cause a potential hazard. For details, refer to the operator's manual of the CMS.**
- **Do not rely exclusively on the audible alarm system for monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always make sure that the audio alarm volume level is adequate in your care environment. Always keep the patient under close surveillance.**

5.1 Alarm Categories

By nature, the equipment's alarms can be classified into three categories: physiological alarms, technical alarms and prompt messages.

1. Physiological alarms

   Physiological alarms, also called patient status alarms, are triggered by a monitored parameter value that violates set alarm limits or by an abnormal patient condition. Physiological alarm messages are displayed in the physiological alarm area. In AED mode, no physiological alarm will be presented.

2. Technical alarms

   Technical alarms, also called system status alarms, are triggered by a device malfunction or a patient data distortion due to improper operation or system failure. Technical alarm messages are displayed in the technical alarm area.

3. Prompt messages

   As a matter of fact, prompt messages are not alarm messages. Apart from the physiological and technical alarms, the equipment also shows some messages indicating system status. Messages of this kind are usually displayed in the prompt area. Therapy-related prompts are shown in corresponding information area. Some special prompts are shown in dialog boxes.

5.2 Alarm Levels

By severity, alarms can be classified into three categories: high level alarms, medium level alarms and low level alarms.

	Physiological alarms	**Technical alarms**
High level	Indicate that your patient is in a life threatening situation, such as Asystole, Vfib/Vtac and so forth, and an emergency treatment is demanded.	Indicate a severe device malfunction or an improper operation, which may result that the equipment cannot detect critical patient status or may cause therapy failed, and thus threaten the patient's life, such as low battery.
Medium level	Indicate that your patient's vital signs appear abnormal and an immediate treatment is required.	Indicate a device malfunction or an improper operation, which may not threaten the patient's life but may compromise patient monitoring or therapy.
Low level	Indicate that you patient's vital signs appear abnormal and an immediate treatment may be required.	Indicate a device malfunction or an improper operation, which may compromise a certain function but will not threaten the patient's life.

5.3 Alarm Indicators

When an alarm occurs, the equipment indicates it to the user through visual or audible alarm indications.

- Alarm lamp
- Alarm tones
- Alarm message
- Flashing numeric

NOTE

- **When multiple alarms of different levels occur simultaneously, the equipment will select the alarm of the highest level and give visual and audible alarm indications accordingly. Alarm messages will be displayed circularly.**
- **Some physiological alarms, such as Asystole, are exclusive. They have identical alarm tones and alarm lights with normal high level physiological alarms, but their alarm messages are displayed exclusively. That is to say, when an exclusive physiological alarm and a normal high level physiological alarms are triggered simultaneously, only alarm message of the exclusive physiological alarm is displayed.**

5.3.1 Alarm Lamps

If an alarm occurs, the alarm lamp will flash. The color and flashing frequency match the alarm level as follows:

- High level alarms — the lamp quickly flashes red.
- Medium level alarms — the lamp slowly flashes yellow.
- Low level alarms — the lamp lights yellow without flashing.

5.3.2 Audible Alarms

The equipment uses different alarm tone patterns to match the alarm level:

- High level alarms — triple + double + triple + double beeps.
- Medium level alarms — triple beeps.
- Low level alarms — single beep.

5.3.3 Alarm Message

When an alarm occurs, the alarm message will appear in the technical or physiological alarm area. For physiological alarms, the asterisk symbols (*) before the alarm message match the alarm level as follows:

- High level alarms — ***
- Medium level alarms — **
- Low level alarms — *

Additionally, the alarm message has different background color which matches the alarm level.

For physiological alarms

- High level alarms — red
- Medium level alarms — yellow
- Low level alarms — yellow

For technical alarms

- High level alarms: — red
- Medium level alarms: — yellow
- Low level alarms: — blue

19 Data Management

19.1 Introduction

The data management function enables you to:

- Edit patient information;
- Review patient events; and
- Export patient data to USB memory.

To access data management: press the Main Menu button on the front panel to enter the Main Menu, and then select [**Others>>**] → [**Archives>>**] → [**Yes**].

Only in Monitor, Manual Defib and Pacer mode can you access archive mode. When you enter the Archives Main screen, patient monitoring and therapy automatically end and the patient last admitted will be saved as the latest archived patient.

19.2 Reviewing Patient Events

To view patient events, select a patient in the Archives Main screen, and then press the navigation knob to confirm the selection. In this case, you can select the [**Return**] soft key to return to the Archives Main screen.

To edit patient information, select the [**Patient Info**] button and change the patient information as desired. Then you can select the [**Review Events**] button to return to the Review Events screen or the [**Return**] soft key to return to the Archives Main screen.

19.3 Exporting Data

In the Archives Main screen,

1. Select [**Export Data**] to enter the Export Data screen, in which select [**USB Memory**]. Then, the system starts searching for USB memory and enters the data export screen if the memory is found.
2. Select the data you want to export and then press the [**Export**] button.

During data export, the message "**Exporting Data. Please Wait...**" appears in the prompt information area and a progress bar is displayed. If an exception happens, data export stops automatically and the reason for interruption is presented in the prompt information area.

After the data is completely exported, you can select the [**Return**] soft key to return to the Archives Main screen.

NOTE

- **Do not remove the USB flash memory from the equipment before data is completely exported.**

20 Recording

20.1 Using a Recorder

The thermal recorder records patient information, measurement numerics and waveforms.

20.2 Recording Types

By the way recordings are triggered, they can be classified into the following categories:

1. Manually-triggered realtime waveform recordings.
2. Event-triggered recordings.
3. Alarm recordings triggered by an alarm limit violation or an arrhythmia event.
4. Manually-triggered, task-related recordings.

The task-related recordings include:

- Frozen wave recording
- Tabular trends recording
- Event recording
- Parameter alarm recording
- Event review recording
- Event Summary Report
- Check report
- Configuration recording

For details about alarm recording, refer to *5 Alarms*.

For details about task-related recordings, refer to respective sections of this manual.

20.3 Starting and Stopping Recordings

To manually start a recording, you can either

- Press the hardkey on the front of the recorder,
- Select the [**Record**] button from the current menu or window.

At the completion of recording, two columns of "*" marks will be printed to indicate the end of recording.

Automatic recordings will be triggered in the following conditions:

- If both [**Alarm**] and [**Alm Rec**] for a measurement are switched on, an alarm recording will be triggered automatically as an alarm occurs.
- When related event is triggered.

To manually stop a recording, you can press the hardkey again.

Recordings stop automatically when:

- A recording is completed.
- The recorder runs out of paper.
- The recorder has a failure.
- Operating mode is changed.

NOTE

- **If you change the ECG Lead, Gain or Filter during recording, the recorded ECG waveform changes accordingly, but the label of Lead, Gain or Filter recorded remains unchanged.**

Description	Applicable patient	Remark	PN
CapnoLine H O2Adult(008180)	Adult	Disposable	0010-10-42575
CapnoLine H O2Pediatric(008181)	Pediatric		0010-10-42576
NIV-Line Adult(008174)	Adult		0010-10-42577
NIV-LinePediatric(008175)	Pediatric		0010-10-42578

26.5 Therapy Accessories

Description	Model	Applicable patient	Remark	PN
External paddles	MR6601	Adult, pediatric	Reusable	0651-30-77001
Multifunction electrode pads	MR60	Adult	Disposable (5 sets/pack)	0651-30-77007
	MR61	Pediatric		0651-30-77008
	MR62	Adult		040-002608-00
	MR63	Pediatric		040-002609-00
Pads cable	MR6701	/	Reusable	0651-20-77031
Conductive gel	15-25	/	Consumable	0000-10-10775
Internal paddles	MR6501	Neonate	Reusable	0651-21-77043
	MR6502	Neonate	Reusable	0651-21-77044
	MR6503	Adult	Reusable	0651-21-77045
CPR sensor	MR6401	/	Reusable, with a battery	115-044836-00
CPR sensor cable	MR6801	/	Reusable	040-003096-00
CPR adhesive tape	MR6921	/	Disposable (3 sets/pack)	040-003123-00

26.6 Miscellaneous

Description	Model	PN
Rechargeable lithium ion battery	LI24I005A	115-049328-00
	LI24I001A	115-007858-00
Test load	MR6901	0651-20-77032
Test load	MR6905	040-000413-00
Analog output cable	/	009-008524-00
Cable of electrode pads with test load (50 ohm)	MR6702	040-000545-00
Synchronous defibrillation input cable	/	009-008523-00
Grounding cable	UL1015/14AWG	1000-21-00122
DC/AC adapter	/	0010-30-12471
Patient data management software kit	/	0651-30-77145
Carrying case and shield cover	/	115-018610-00
D3 back pouch	/	115-008708-00
Conducting gel mount kit	/	115-007857-00
Pothook kit	/	115-007587-00

A Specifications

A.1 General Specifications

Type of protection against electrical shock	Class I, equipment energized from an external and internal electrical power source. If you suspect the integrity of the external protective earthing or the protective earthing wire, you should run the equipment on internal electrical power supply (battery).
Degree of protection against electric shock	Type BF defibrillation proof for CO_2 monitoring and external defibrillation.
	Type CF defibrillation proof for ECG, SpO_2, NIBP, internal defibrillation and CPR sensor.
Mode of operation	Continuous
Degree of protection against harmful ingress of solid	IP4X
Degree of protection against harmful ingress of water	IPX4 (when running on battery) IPX1 (when running on AC power supply)
Degree of mobility	Portable

Size	
Width × depth × height	288×203×275 mm

Maximum Weight
6.1 kg, including a battery, external paddles and 3-leadwire.

Display	
Type	TFT Color LCD
Size	7 inch
Resolution	800×480 pixels
Viewed waveforms	Max. 3
Wave viewing time	Max. 16s (ECG)

Equipment connectors	
USB connector	Connects USB flash memory
Multifunctional connector	Connects a cable for analog output or a cable for defibrillator synchronization.
RJ45 connector	Connects standard network cable.

Audio Indicator	
Speaker	Gives alarm tones (45 to 85 dB), key tones, QRS tones; Supports PITCH TONE and multi-level tone modulation; Alarm tones comply with IEC60601-1-8.
Multifunctional connector	
Standard	Meets the requirements of EN60601-1 for short-circuit protection and leakage current
Output impedance	Typically 50Ω
ECG Analog Output (only ECG lead set)	
Bandwidth (-3 dB; reference frequency: 10 Hz)	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Therapy mode: 1 to 20 Hz
Maximum QRS delay	25 ms (in diagnostic mode, and with Notch off)
Sensitivity	1 V/mV ±5%
Pace enhancement	Signal amplitude: V_{oh}≥2.5V Pulse width: 10ms±5% Signal rising and falling time: ≤100μs
Synchronous input	
Input signal range	0 to 5V (TTL level)
Input impedance	≥10 kΩ
Pulse width	>5 ms
Alarm output (Network connector)	
Alarm delay time from the equipment to other remote equipment	The alarm delay time from the equipment to other remote equipment is ≤4 seconds, measured at the equipment signal output connector.

A.2 Defibrillator Specifications

Standards	Meet standards of IEC 60601-2-4
Defibrillation mode	Manual defib, synchronous cardioversion, AED
Defibrillation waveform	Biphasic truncated exponential (BTE) waveform, auto-compensation according to patient impedance
Defibrillation electrodes	External paddles set coming with pediatric paddles included, multifunction electrode pads and internal paddles
Controls and indicators on external paddles	Charge button, Shock buttons, Energy Select buttons and charge done indicator

Range of selected energy	
External defibrillation	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 150, 170, 200, 300, 360 J
Internal defibrillation	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50 J

Patient impedance range	
External defibrillation	25 to 300 Ω
Internal defibrillation	15 to 300 Ω

A.4 Pacer Specifications

Standards	Meet standards of IEC 60601-2-4
Pacing mode	Demand, fixed
Output waveform	Monophasic square wave pulse pulse width 20 ms or 40 ms Accuracy: ±5%
Pacing rate	30ppm to 210ppm Accuracy: ±1.5% Resolution: 5 ppm
Pacing output	0mA to 200mA, Accuracy: ±5% or ±5mA, whichever is greater Resolution: 1mA, 2mA or 5mA
Refractory period	200 to 300 ms (depending on pacing rate)
4:1 pacing	Pacing pulse frequency reduced by factor of 4 when this function is activated.
Output protection	The equipment has no sign of damage after defibrillation-proof test.

A.5 Monitor Specifications

ECG (from ECG lead set)	
Standards	Meet standards of IEC 60601-2-27
Patient connection	3-lead ECG cable, 5-lead ECG cable
ECG inputs	3-lead ECG set: I, II, III 5-lead ECG set: I, II, III, aVR, aVL, aVF, V
Gain	2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40mm/mV (×4), Auto. Error less than ± 5%
Paper speed	6.25mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error no more than ± 5%
Bandwidth (-3dB)	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Therapy mode: 1 to 20 Hz
Common mode rejection	Diagnostic mode: >90 dB Monitor mode: >105 dB Therapy mode: >105 dB
Notch filter	50/60Hz, In Monitor, Therapy modes: notch filter turns on automatically In Diagnostic mode: notch filter is turned on manually
ECG signal range	±8mV (peak-to-peak value)
Calibration signal	1mV (peak-to-peak value) ±5%
Differential input impedance	≥5 MΩ
Electrode offset potential tolerance	±500mV
Defibrillation protection	Enduring 5000V (360 J) charge without data loss or corruption Baseline recovery time: <2.5 s (after defibrillation) Polarization recovery time: <10 s Defibrillation energy absorption: ≤10% (100Ω load)
ESU protection	Cut mode: 300 W Coagulate mode: 100 W Recovery time: ≤10 s In compliance with the requirements in clause 202.6.2.101 of IEC 60601-2-27
Pace Pulse	

Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs
Pace pulse rejection	When tested in accordance with the IEC 60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs Input slew rate: 2.2 V/s ± 15% RTI
HR	
Measurement range	Neonate 15 to 350 bpm Pediatric 15 to 350 bpm Adult 15 to 300 bpm
Accuracy	±1% or ±1bpm, which ever is greater
Resolution	1 bpm
Sensitivity	200 µV (lead II)
Heart rate averaging	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, the following method is used: If the last 3 consecutive RR intervals are greater than 1200 ms, the 4 most recent RR intervals are averaged to compute the HR. Otherwise, heart rate is computed by subtracting the maximum and minimum ones from the most recent 12 RR intervals and then averaging them. The HR value displayed on the screen is updated every second.
Response time to heart rate change	Meets the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 5). From 80 to 120 bpm: less than 11 s From 80 to 40 bpm: less than 11 s
Time to alarm for tachycardia	Meets the requirements in Clause 201.7.9.2.9.101 b) 6) of IEC 60601-2-27. Waveform 4ah - range: 11 s 4a - range: 11 s 4ad - range: 11 s 4bh - range: 11 s 4b - range: 11 s 4bd - range: 11 s
Arrhythmia Analysis Classifications	Asystole, V-Fib/V-Tach, V-Tac, Vent. Brady, Extreme Tachy, Extreme Brady, PVCs/min, PVC, Couplet, VT>2, Bigeminy, Trigeminy, R on T, Tachy, Brady, Missed Beat, PNP, PNC, Vent. Rhythm, Multif. PVCs, Nonsus. Vtac, Pause, Irr. Rhythm, Afib
Tall T-wave rejection capability	When the test is performed based on Clause 201.12.1.101.17 of IEC 60601-2-27, the heart rate meter will reject all 100 ms QRS complexes with less than 1.2 mV of amplitude, and T waves with T-wave interval of 180 ms and those with Q-T interval of 350 ms.
Lead-off detection current	Measuring electrode: ≤0.1 µA Drive electrode: ≤1 µA
Baseline recovery time	<2.5 s (after defibrillation, in monitor mode and therapy mode)
Response to irregular rhythm	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the heart rate after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy (3a): 80±1 bpm Slow alternating ventricular bigeminy (3b): 60±1 bpm Rapid alternating ventricular bigeminy (3c): 120±1 bpm Bidirectional systoles (3d): 90±2 bpm

ECG (from defibrillation electrodes)	
Patient connection	paddles or multifunction electrode pads
ECG inputs	pads/paddles
Gain	2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40mm/mV (×4), Auto. Error less than ± 5%
Paper speed	6.25mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error no more than ± 10%
Bandwidth (-3dB)	Therapy mode: 1 to 20 Hz
Common mode rejection	Therapy mode: >105 dB
Notch filter	50/60Hz In Therapy mode: notch filter turns on automatically
ECG signal range	±8mV (peak-to-peak value)
Calibration signal	1mV (peak-to-peak value) ±5%
Differential input impedance	≥5 MΩ
Electrode offset potential tolerance	±1V
Defibrillation protection	Enduring 5000V (360 J) charge without data loss or corruption Baseline recovery time: <2.5 s (after defibrillation) Polarization recovery time: <10 s Defibrillation energy absorption: ≤10% (100Ω load)
ESU protection	Cut mode: 300 W Coagulate mode: 100 W Recovery time: ≤10 s In compliance with the requirements in clause 202.6.2.101 of IEC 60601-2-27
Pace Pulse	
Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs
Pace pulse rejection	When tested in accordance with the IEC 60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs
HR	
Measurement range	Pediatric 15 to 350 bpm Adult 15 to 300 bpm
Accuracy	±1% or ±1bpm, which ever is greater
Resolution	1 bpm
Sensitivity	200 µV
Heart rate averaging	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, the following method is used: If the last 3 consecutive RR intervals are greater than 1200 ms, the 4 most recent RR intervals are averaged to compute the HR. Otherwise, heart rate is computed by subtracting the maximum and minimum ones from the most recent 12 RR intervals and then averaging them. The HR value displayed on the screen is updated every second.
Response time to heart rate change	Meets the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 5). From 80 to 120 bpm: less than 11 s From 80 to 40 bpm: less than 11 s

Mindray SpO_2 Module		
*Measurement accuracy verification: The SpO_2 accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO-oximeter measurements.		
Standard	Meet standards of ISO 80601-2-61	
Measurement range	0 to 100%	
Resolution	1%	
Accuracy	70 to 100%: 70 to 100%: 0% to 69%:	±2% (in adult/pediatric mode) ±3% (in neonate mode) Not specified
Refreshing rate	≤2 s	
PR		
Measurement range	20 to 300 bpm	
Resolution	1 bpm	
Accuracy	±3 bpm	
Response time	<20 s (SpO_2 value sudden changes from 70% to 100%) <20 s (PR value sudden changes from 25 to 240 bpm)	

Masimo SpO_2 Module		
Standard	Meet standards of ISO 80601-2-61	
Measurement range	1 to 100%	
Resolution	1%	
Accuracy	70 to 100%: 70 to 100%: 70 to 100%: 1% to 69%:	±2% (measured without motion in adult/ pediatric mode) ±3% (measured without motion in neonate mode) ±3% (measured with motion) Not specified
Refreshing rate	≤2 s	
PR		
Measurement range	25 to 240 bpm	
Accuracy	±3 bpm (measured without motion) ±5 bpm (measured with motion)	
Response time	≤20 s (SpO_2 value sudden changes from 70% to 100%) ≤20 s (PR value sudden changes from 25 to 220 bpm)	

Nellcor SpO_2 Module		
Standard	Meet standards of ISO 80601-2-61	
Measurement range	0 to 100%	
Resolution	1%	
Accuracy	70 to 100%: 70 to 100%: 0% to 69%:	±2% (in adult/pediatric mode) ±3% (in neonate mode) Not specified
Refreshing rate	≤2 s	
PR		
Measurement range	20 to 300 bpm	
Resolution	1 bpm	
Accuracy	±3 bpm (20 to 250 bpm) Not specified (251 to 300 bpm)	

NIBP					
Standards	Meet standard of ISO 80601-2-30				
Technique	Oscillometry				
Mode of operation	Manual, Auto and STAT				
Auto mode repetition intervals	1, 2, 2.5, 3, 5, 10, 15, 20, 30, 60, 90, 120, 180, 240 or 480 min				
STAT mode cycle time	5 min				
Static pressure measurement range	0mmHg to 300mmHg				
Static pressure measurement accuracy	±3mmHg				
Maximum measurement time	180s for adult and pediatric patients 90s for neonatal patients				
Initial cuff inflation pressure range	Adult: 80 to 280 mmHg Pediatric: 80 to 210 mmHg Neonate: 60 to 140 mmHg				
Measurement range			Adult	Pediatric	Neonate
	Systolic	mmHg	25 to 290	25 to 240	25 to 140
	Diastolic	mmHg	10 to 250	10 to 200	10 to 115
	Mean	mmHg	15 to 260	15 to 215	15 to 125
Software overpressure protection	Adult:	297±3 mmHg			
	Pediatric:	297±3 mmHg			
	Neonate:	147±3 mmHg			
Measurement accuracy	Max mean error: ±5 mmHg Max standard deviation: 8 mmHg				
Resolution	1 mmHg				

*Measurement accuracy verification: In adult and pediatric modes, the blood pressure measurements measured with this device are in compliance with the Standard for Non-invasive sphygmomanometers (ISO 81060-2)in terms of mean error and stardard deviation by comparing with intra-arterial or auscultatory measurements (depending on the configuration) in a typical patient population. For auscultatory reference, the 5th Korotkoff sound was used to determine the diastolic pressure.

In neonatal mode, the blood pressure measurements measured with this device are in compliance with the American National Standard for Non-invasive sphygmomanometers (ISO 81060-2) in terms of mean error and stardard deviation by comparing with intra-arterial measurements (depending on the configuration) in a typical patient population.

A.7 Recorder Specifications

Method	High-resolution thermal dot array
Number of waveforms	Max. 3
Paper speed	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error no more than ± 5%
Paper width	50 mm
Grid lines	The operator can choose to print grid lines or not
Auto record	Charge events, shock events, marked events, auto test report, parameter alarms, ARR alarms, if configured on

A.8 Alarm Specifications

Alarm Levels	High, medium, low level alarms, complying with IEC60601-1-8
Alarm Categories	Physiological alarms, technical alarms; Latched alarms and unlatched alarms.
Alarm lamp	Independent alarm LED
Parameter alarm setting	Alarm properties of all available parameters can be set simultaneously in the Para. Alarm menu
Auto alarm limits	Parameter alarm limits can be automatically adjusted according to currently measured vital signs

A.9 Data Management Specifications

Data Storage	1G Bytes
Marking Events	16 types of events, user customized
Event recording	At least 1000 events for each patient.
Waveform storage	At least 24 hours of consecutive ECG waveform
Voice recording	At least 180 minutes in total, more than 60 minutes for each patient
Tabular Trends	At least 72 hours of all measured parameters; resolution:1 min
Data Export	Data can be export to a PC through a USB flash memory
Patient archives	Up to 100

A.10 Wi-Fi Specifications

Wi-Fi Technical Specifications	
Protocol	IEEE 802.11a/b/g/n
Modulation mode	DSSS and OFDM
Operating frequency	IEEE 802.11b/g/n (at 2.4G): 2.4 GHz to 2.495 GHz IEEE 802.11a/n (at 5G): 5.15 GHz to 5.825 GHz
Channel spacing	IEEE 802.11b/g/n (at 2.4G): 5 MHz IEEE802.11a/n (at 5G): 20 MHz
Wireless baud rate	IEEE 802.11b: 1 Mbps to 11 Mbps IEEE 802.11g: 6 Mbps to 54 Mbps IEEE 802.11n: 6.5 Mbps to 72.2 Mbps IEEE 802.11a: 6 Mbps to 54 Mbps
Output power	<20dBm (CE requirement: detection mode- RMS) <30dBm (FCC requirement: detection mode- peak power)
Operating mode	Infrastructure
Data security	Standards: WPA-PSK, WPA2-PSK Encryption: TKIP, AES

Measurement	Alarm Message	L	I	Cause and solution
SpO_2	SpO_2 Sensor Off	L*	B	The SpO_2 sensor has become detached from the patient or the module, or there is a fault with the SpO_2 sensor, or an unspecified SpO_2 sensor has been used. Check the sensor application site and the sensor type, and make sure the sensor is not damaged. Reconnect the sensor or use a new sensor.
	SpO_2 Sensor Fault	L	C	
	SpO_2 No Sensor	L	B	
	SpO_2 Unknow Sensor	L	C	
	SpO_2 Sensor Incompatible	L	C	
	SpO_2 Too Much Light	L	C	There is too much light on the SpO_2 sensor. Move the sensor to a place with lower level of ambient light or cover the sensor to minimize the ambient light.
	SpO_2 Low Signal	L	C	The SpO_2 signal is too low or too weak. Check the patient's condition and change the sensor application site. If the error persists, replace the sensor.
	SpO_2 Weak Signal	L	C	
	SpO_2 Weak Pulse	L	C	
	SpO_2 Low Perf	L	B	
	SpO_2 Interference	L	C	The SpO_2 signal has been interfered. Check for any possible sources of signal noise form the area around the sensor, and check the patient for excessive motion.
	SpO_2 Non-Pulsatile	L	C	
	SpO_2 Board Fault	L	C	There is a problem with the SpO_2 measurement board. Do not use the module and contact your service personnel.
NIBP	NIBP Loose Cuff	L	A	The NIBP cuff is not properly connected, or there is a leak in the airway.
	NIBP Air Leak	L	A	
	NIBP Pneumatic Leak	L	A	Check the NIBP cuff and pump for leakages.
	NIBP Cuff Type Wrong	L	A	The cuff type applied mismatches the patient category. Verify the patient category and replace the cuff.
	NIBP Air Press. Err	L	A	An error occurred to the air pressure. Verify that the equipment application site meets the environmental requirements and check if there is any source that affects the air pressure.
	NIBP Weak Signal	L	A	The patient's pulse is weak or the cuff is loose. Check the patient's condition and change the cuff application site. If the problem persists, change the cuff.
	NIBP Sig. Saturated	L	A	The NIBP signal is saturated due to excess motion or other sources.
	NIBP Overrange	L	A	The patient's NIBP value may be beyond the specified measurement range.
	NIBP Excessive Motion	L	A	Check the patient's condition and reduce the patient motion.
	NIBP Equip Err	H	A	An error occurred during NIBP measurement and therefore the equipment cannot perform analysis correctly. Check the patient's condition and NIBP connections, or replace the cuff.
	NIBP Time Out	L	A	
	NIBP Measure Failed	L	A	
	NIBP Reset For Err	L	A	An illegal reset occurred during NIBP measurement. Check if the airway is occluded.