BeneHeart D3/BeneHeart D2

Defibrillator/Monitor

Operator’s Manual

CE 0123

- Release time: January 2019
- Revision: 8.0

WARNING

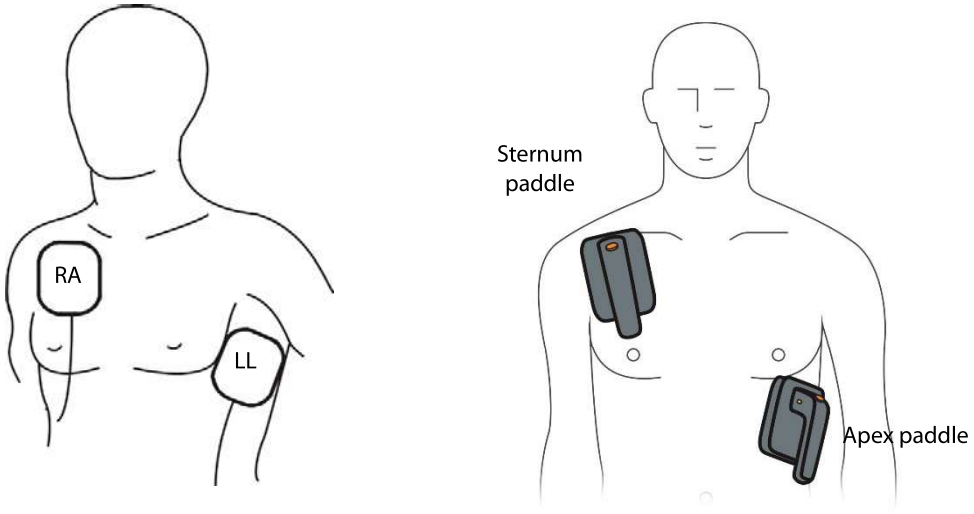
- **When using electrosurgical units (ESU), place ECG electrodes between the ESU and its grounding plate to prevent unwanted burns. Never entangle ESU cable and ECG cable together.**
- **When using electrosurgical units (ESU), never place ECG electrodes near to the grounding plate of the ESU, as this can cause a lot of interference on the ECG signal.**

6.4.2 ECG Monitoring with Paddles/Pads

1. Prepare the patient's skin.
2. Apply the paddles/pads to the patient.
   - ◆ If multifunction electrode pads are used, apply pads according to the instructions for use indicated on pads package. Use anterior-lateral placement.
   - ◆ If external paddles are used, remove the paddle set from the paddle tray by grasping the handles and pulling them straight up. Apply conductive gel to paddle electrodes. Place the paddles to the patient's chest using the anterior-lateral placement.
3. If multifunction electrode pads are used, connect the pads to the pads cable.
4. Connect paddles/pads cable with the equipment if not connected.

Anterior-lateral Paddles/Pads placement

1. Place the RA pad or Sternum paddle on the patient's upper right torso, lateral to the sternum and below the clavicle, as shown below.
2. Place the LL pad, or Apex paddle to the patient's left nipple in the midaxillary line, with the center of the electrode in the midaxillary line, if possible. See the figure below.



NOTE

- **Anterior - lateral placement is the only placement that can be used for ECG monitoring with paddles/ pads accessories.**

6.4.3 Checking Paced Status

It is important to set the paced status correctly when you start monitoring ECG. The paced symbol is displayed when the [**Paced**] is set to [**Yes**]. The pace pulse markers "?" are shown on the ECG wave when the patient has a paced signal.

To change the paced status, you can select either:

- ■ [**Main Menu**] → [**Patient Demographics>>**] → [**Paced**], or
- ■ The ECG parameter window to enter the [**ECG Setup**] menu, and then, select [**Others>>**] → [**Paced**], and toggle between [**Yes**] and [**No**].

WARNING

- **For paced patients, you must set [Paced] to [Yes]. If it is incorrectly set to [No], the equipment could mistake a pace pulse for a QRS and fail to alarm when the ECG signal is too weak. Do not rely entirely on rate meter alarms when monitoring patients with pacemakers. Always keep these patients under close surveillance.**
- **For non-paced patients, you must set [Paced] to [No]. If it is incorrectly set to [Yes], the equipment may be unable to detect premature ventricular beats (including PVCs).**
- **On ventricular paced patients, episodes of Ventricular Tachycardia may not always be detected.**
- **Do not rely entirely upon the system's automated arrhythmia detection algorithm. Keep pacemaker patients under close surveillance.**

6.5 ECG Display

The figure below shows the ECG monitoring view in 5-lead mode. It is for reference only. Your display may be configured to look slightly different.

PVCs values is shown only when arrhythmia analysis is switched on. When external paddles or multifunctional electrode pads are used for ECG monitoring, the PVCs values is shown as "---".

6.6 Changing ECG Settings

6.6.1 Change Lead Setting

6.6.1.1 Selecting Lead Type

1. Select the ECG parameter area to enter the [**ECG Setup**] menu.
2. Select [**Lead Set**] and toggle between [**3-lead**] and [**5-lead**].

You can also set lead type in the configuration mode:

1. Press the Menu button on the equipment's front panel. In the Main Menu, select [**Others >>**] → [**Configuration >>**] → enter the required password to enter the Configuration Main menu.
2. Select [**ECG Setup**] → [**Lead Set**] and toggle between [**3-lead**] and [**5-lead**].

The settings changed in configuration mode will be saved when the equipment is turned off.

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.

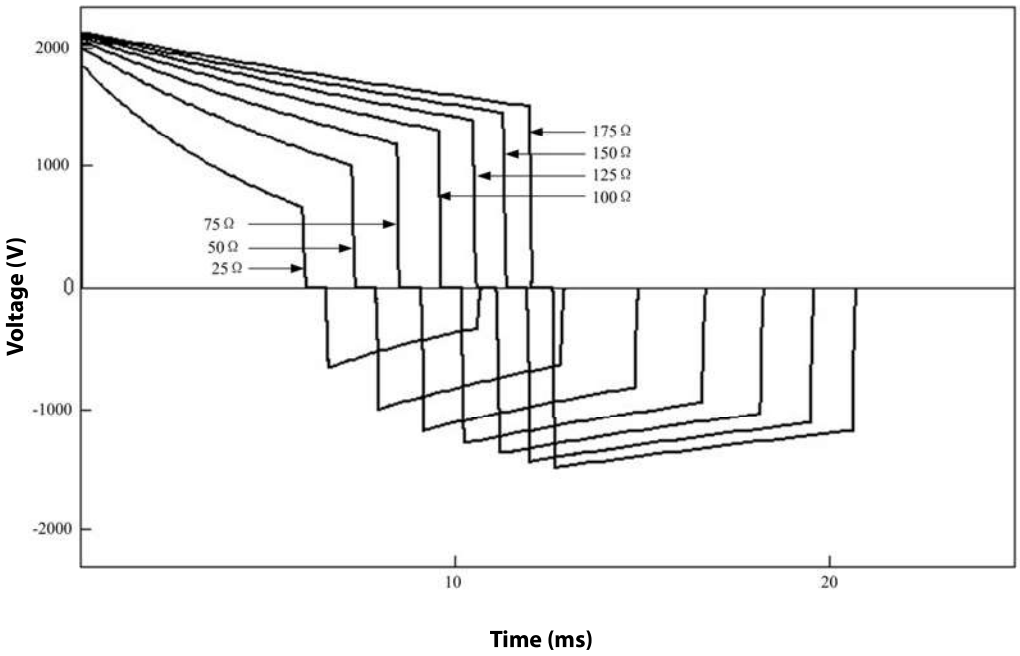
A.2 Defibrillator Specifications

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

360 J defibrillation waveform into impedance of 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 175Ω



Selected energy accuracy								
Impedance / Energy	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω	Accuracy
1 J	1	1	1	0.9	0.9	0.9	0.8	±2J
2 J	2	2	2	1.9	1.8	1.7	1.6	±2J
3 J	2.9	3	2.9	2.8	2.7	2.6	2.4	±2J
4 J	3.9	4	3.9	3.7	3.6	3.4	3.2	±2J
5 J	4.9	5	4.9	4.7	4.5	4.3	4.1	±2J
6 J	5.8	6	5.8	5.6	5.3	5.1	4.9	±2J
7 J	6.8	7	6.8	6.6	6.3	6	5.7	±2J
8 J	7.8	8	7.8	7.4	7.1	6.8	6.5	±2J
9 J	8.8	9	8.8	8.4	8	7.7	7.3	±2J
10 J	9.7	10	9.7	9.3	8.9	8.5	8.1	±2J
15 J	15	15	15	14	13	13	12	±15%
20 J	20	20	20	19	18	17	16	±15%
30 J	29	30	29	28	27	25	24	±15%
50 J	49	50	49	47	45	43	41	±15%
70 J	68	70	68	65	62	60	57	±15%
100 J	97	100	97	93	89	85	81	±15%
150 J	146	150	146	140	134	128	122	±15%
170 J	166	170	166	159	151	145	138	±15%
200 J	195	200	195	187	178	170	163	±15%
300 J	292	300	292	280	267	255	244	±15%
360 J	351	360	350	336	321	306	293	±15%

Charge time (Note: at 20 ±5 °C of ambient temperature)												
	Manual Defib						AED					
	Charge time		From initial power on (from cold start) to charge done		From initial power on (from fast startup mode) to charge done		From initiation of rhythm analysis to charge done		From initial power on (from cold start) to charge done		From initial power on to charge done	
	200J	360J	200J	360J	200J	360J	200J	360J	200J	360J	200J	360J
With a new, fully charged battery	<3 s	<7 s	<11 s	<14 s	<6 s	<10 s	<10 s	<12 s	<21 s	<26 s	<13 s	<15 s
With a new, fully charged battery, depleted by 15 360 J discharges	<4 s	<8 s	<12 s	<15 s	<7 s	<11 s	<11 s	<13 s	<23 s	<27 s	<14 s	<16 s
With 90% to 100% rated mains voltage	<4 s	<7 s	<11 s	<14 s	<7 s	<10 s	<11 s	<12 s	<22 s	<24 s	<14 s	<15 s

Synchronized discharge delay	
Local synchronized discharge delay	< 60ms (from the peak of R-wave)
Remote synchronized discharge delay	< 25ms (from the rise edge of synchronous signal)

AED	
Shock series	Energy level: 100 to 360J, configurable for adult; 10 to 100J, configurable for pediatric Shocks: 1, 2, 3, configurable; Meeting AHA guidelines 2015 by default.

AED ECG Analysis Performance

For more information, refer to *B Mindray Shockable Rhythm Analysis Algorithm*.

A.3 CPR Compression Specifications

Compression depth	Measurement range: 0.0 to 8.0 cm Effective range: 1.5 to 8.0 cm Accuracy (for effective range): ±0.5 cm or ±10%, whichever is greater Resolution: 0.1 cm Refreshing rate: ≥0.5Hz
Compression rate	Measurement range: 40 to 160 cpm (compressions per minute) Effective range: 40 to 160 cpm (compressions per minute) Accuracy: ±2 cpm (compression per minute) Resolution: 1 cpm Refreshing rate: ≥0.5Hz
Interruption time	Measurement range: 0 to 300 s Effective range: 0 to 300 s Resolution: 1 s Refreshing rate: ≥0.5Hz

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