BeneHeart D3/BeneHeart D2

Defibrillator/Monitor

Operator's Manual

CE 0123

- Release time: January 2019
- Revision: 8.0

6 Monitoring ECG

6.1 Overview

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it as waveforms and numerics. The equipment enables ECG monitoring through 3-, 5-lead ECG sets, external paddles and multifunction electrode pads. If both ECG sets and paddles/pads are connected, the configured ECG waveforms are displayed in the waveform area.

6.2 Safety

WARNING

- **ECG monitoring is not suitable for direct cardiac application.**
- **Periodically inspect the electrode application site to ensure skin quality. If the skin quality changes, replace the electrodes or change the application site.**
- **Use defibrillation-proof ECG cables during defibrillation.**
- **When monitoring a patient implanted with a pacemaker, be sure to select correct paced status. Otherwise, the pacing pulses may be counted in the case of cardiac arrest or some arrhythmias. Do not completely rely on the heart rate reading or the heart rate alarms. Always keep paced patients under close surveillance.**
- **PACEMAKER PATIENTS – 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.**

CAUTION

- **Interference from a non-grounded instrument near the patient and electrosurgery interference can cause problems with the waveform.**

NOTE

- **When connecting electrodes and/or patient cables, make sure that the connectors never come into contact with other conductive parts, or with earth. Particularly make sure that all of the ECG electrodes are attached to the patient.**
- **If selected lead cannot provide valid ECG signals, a dash line is shown in the ECG waveform area.**
- **Avoid using external paddles for ECG monitoring if possible.**
- **Use the same type of ECG electrodes when monitoring ECG through ECG lead set.**

6.3 Monitoring View

You can access Monitor mode by switching the Mode Select knob to the Monitor position. When operating in Monitor mode, the equipment displays up to two ECG waveforms, the heart rate reading, other available parameter values and active alarm settings.

6.4 Preparing to Monitor ECG

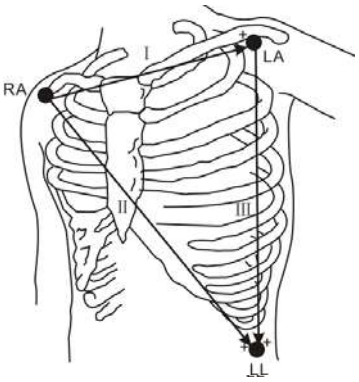
6.4.1 ECG Monitoring with Electrodes

1. Prepare the patient's skin. Proper skin preparation is necessary for good signal quality at the electrode, as the skin is a poor conductor of electricity. To properly prepare the skin, choose flat areas and then follow this procedure:
   - Shave hair from skin at chosen sites.
   - Gently rub skin surface at application sites to remove dead skin cells.
   - Thoroughly clean the sites with mild soap and water. We do not recommend using ether or pure alcohol, because this dries the skin and increases the resistance.
   - Dry the skin completely before applying the electrodes.
2. Attach the clips or snaps to the electrodes before placing them.
3. Place the electrodes on the patient.
4. Attach the lead wires to the ECG trunk cable and then plug the trunk cable into the equipment's ECG connector.
5. Connect the ECG trunk cable to the equipment.
6. Switch the Mode Select knob to Monitor.

6.4.1.1 Placing Electrodes

3-Lead Placement

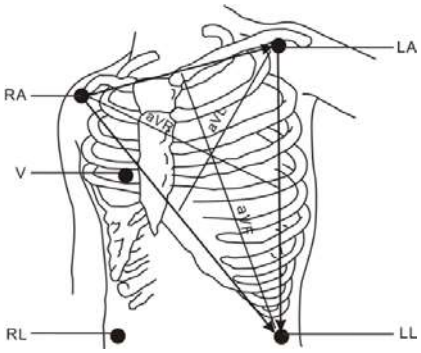
The following is a typical AHA electrode placement for a 3-lead ECG set:



- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- LL placement: on the left lower abdomen.

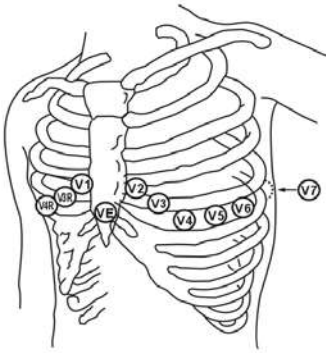
5-Lead Placement

The following is a typical AHA electrode placement for a 5-lead ECG set:



- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- RL placement: on the right lower abdomen.
- LL placement: on the left lower abdomen.
- V placement: on the chest.

The chest (V) electrode can be placed on one of the following positions:



- V1 placement: on the fourth intercostal space at the right sternal border.
- V2 placement: on the fourth intercostal space at the left sternal border
- V3 placement: midway between the V2 and V4 electrode positions.
- V4 placement: on the fifth intercostal space at the left midclavicular line.
- V5 placement: on the left anterior axillary line, horizontal with the V4 electrode position.
- V6 placement: on the left midaxillary line, horizontal with the V4 electrode position.
- V3R-V6R placement: on the right side of the chest in positions corresponding to those on the left.
- VE placement: over the xiphoid process.
- V7 placement: on posterior chest at the left posterior axillary line in the fifth intercostal space.
- V7R placement: on posterior chest at the left posterior axillary line in the fifth intercostal space.

Electrode Placement for Surgical Patients

The surgical site should be taken into consideration when placing electrodes on a surgical patient, e.g. for open-chest surgery, the chest electrodes can be placed on the lateral chest or back. To reduce artifacts and interference from electrosurgical units, you can place the limb electrodes close to the shoulders and lower abdomen and the chest electrodes on the left side of the mid-chest. Do not place the electrodes on the upper arm. Otherwise, the ECG waveform will be very small.

WARNING

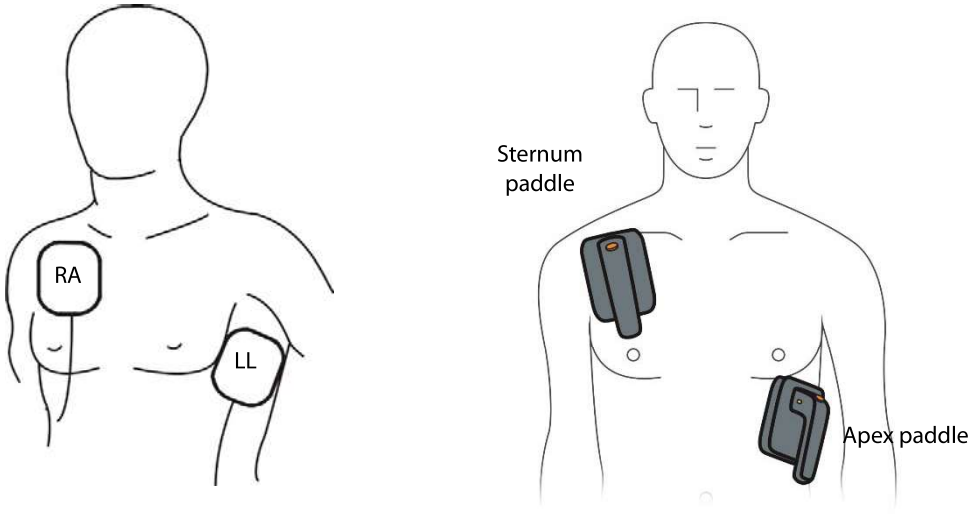
- **When using electrosurgical units (ESU), place ECG electrodes between the ESU and its grounding plate to prevent unwanted burns. Never entangle ESU cable and ECG cable together.**
- **When using electrosurgical units (ESU), never place ECG electrodes near to the grounding plate of the ESU, as this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

- **Never connect the equipment with the patient while performing configuration management.**

22.3.1 General Setup Menu

Menu Item		Options/Range	Default	Remark
Device Name		20 characters	/	The characters are included in the keyboard. Restoring factory default configurations does not change these items.
Institution Name		20 characters	/	
Department		20 characters	/	
Bed No.		20 characters	/	
Patient Cat.		Adu, Ped, Neo	Adu	/
Height Unit		cm, inch	cm	/
Weight unit		kg, lb	kg	/
Language		Chinese, English, French, German, Italian, Polish, Spanish, Portuguese, Russian, Czech, Turkish, Dutch, Hungarian, Korean	/	/
Data Format		yyyy-mm-dd, mm-dd-yyyy, dd-mm-yyyy	yyyy-mm-dd	/
Time Format		12 h, 24 h	24 h	/
System Time	Year	2007 to 2099	2007	/
	Month	01 to 12	01	[**Month**] is 01 to 05 when [**Year**] is set to [**2099**].
	Day	01 to 31	01	/
	Hour	24 h: 00 to 23 12 h: 12AM to 11PM	24 h: 00 12 h: 12AM	/
	Minute	00 to 59	00	/
	Second	00 to 59	00	/

22.3.2 Manual Defib Setup Menu

Menu Item		Options/Range	Default	Remark
Manual Therapy Access		Direct, Confirmed, Password	Direct	[**Set Password**] is active only when [**Manual Therapy Access**] is set to [**Password**].
Set Password		4 digits	0000	(0000-9999)
Pads Default	Adult	100, 150, 170, 200, 300, 360 J	200 J	/
	Pediatric	10, 15, 20, 30, 50, 70, 100 J	50 J	/
Internal Default		2, 5, 10, 20, 30, 50	10 J	/
Time to Auto Disarm		30s, 60s, 90s, 120s	60s	/
Syn After Shock		Yes, No	No	/
Remote Sync		On, Off	Off	/
Monitor Para.		SpO_2, NIBP, CO_2, Off	Off	/
Charge Tone Vlm		High, Med, Low	Med	/
Contact Impedance Indicator		On, Off	Off	/
Maximum Defib. Energy		360 J	360 J	/

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

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