

Training Excellence

# BeneHeart R3

Advanced User Guide





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# Section 1 Safety Notes

- Before using, the operator must verify that the equipment, connecting cables and accessories are clean and in correct working order.
- Do not open the equipment housing. All servicing and upgrades must be carried out by fully trained and authorised personnel.
- This equipment is not intended to be used with high frequency surgical units.
- Keep away from fluid. If liquids have entered the equipment remove the device from use and have it checked by service personnel.
- For paced patients, the equipment may mistake a pace pulse for a QRS complex if several adverse conditions exist simultaneously. Always keep these patients under close surveillance.
- Magnetic and electrical fields are capable of interfering with the performance of the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
- Please note: the physiological data and waveforms displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.



# Section 2 Battery

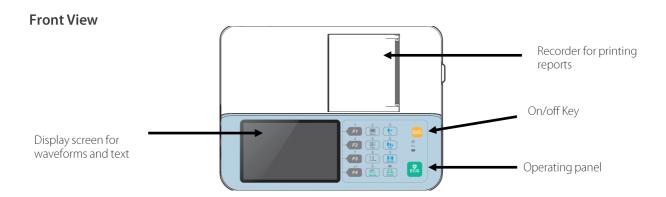
• The battery indicator on the operating panel will be unlit if the device is mains powered or lit green if using battery power.

Battery type	Rechargeable lithium-ion
Run time, when powered by a new fully charged battery	≥ 500 Auto measurement reports or 2 hours continuous recording or 6 hours of measurement without recording
Charge Time (with power off)	≤ 3 hours to 90% capacity ≤ 3.5 hours to 100% capacity
Shutdown delay (after a low battery message first occurs)	Minimum 5 minutes

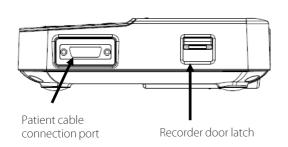
- The battery is charged whenever the device is connected to an AC power source, regardless of whether the device is switched on.
- On-screen battery symbols (top right corner of display) indicate battery status as follows:
- Indicates that the battery works correctly. The solid green portion represents the current battery charge level. Each block represents a charge of approximately 20% capacity.
- Indicates that the battery has a low charge level and needs to be charged. In this case, the LED turns yellow and the message [**Low Battery**] is shown at the bottom of the screen.
- Indicates that the battery is almost depleted and needs to be charged immediately
- Indicates that no battery is installed, or the battery fails to charge
- Exchange or conditioning of the battery should be carried out by authorised personnel only. Please refer to the **BeneHeart R3 Operators Manual** for more information.

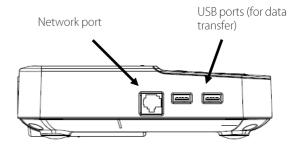


# Section 3 Equipment Overview

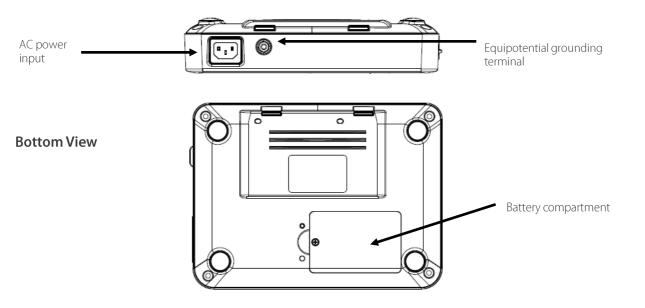


## **Side Views**





### **Back View**



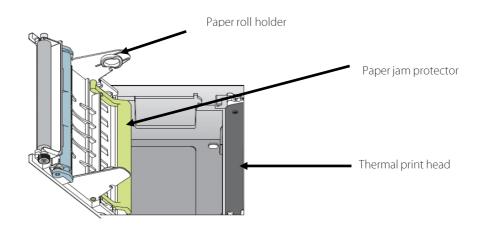


# Section 4 Device Setup

# **Loading Paper**

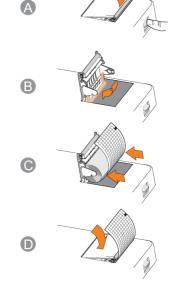
- Before printing ECG reports, ensure that thermal recording paper is loaded. The equipment supports both roll paper and Z-fold paper.
- The setting of [PaperType] in the [Maintenance] menu must correspond with the paper used, otherwise the system will prompt "Paper Type Error". This should be done on initial setup of the device as a password is required. Speak to your Medical Engineering Department for more information.
- The default setting is [**Roll**] and this is generally the preferred option as there is little risk of a paper iam.

# Inside the Printer Compartment



#### To Load Roll Paper

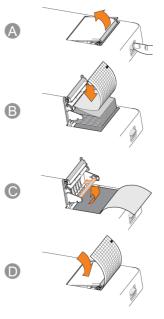
- A. Press down the recorder door latch to open the recorder door.
- B. Check that the paper jam protector is secured flat against the recorder door (i.e. not clipped into the paper roll holder).
- C. Insert a new paper roll into the paper roll holder, with the grid side facing the thermal print head.
- D. Unroll the beginning of the paper and close the recorder door. Overlap the unrolled paper on the recorder door. Make sure the grid side is facing up.





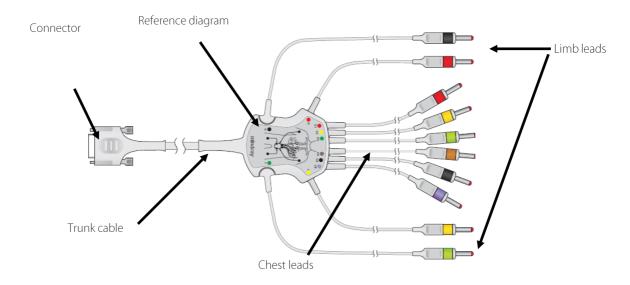
## To Load Z-Fold Paper

- A. Press down the recorder door latch to open the recorder door.
- B. Place the Z-fold paper pack into the paper compartment.
- C. Lift the paper jam protector and click it into the openings at the bottom of the paper roll holder. Unfold the first page of the Z-fold paper pack. Make sure the grid side faces the thermal print head.
- D. Close the recorder door. Overlap the unfolded paper on the recorder door. Make sure the grid side is facing up.



# Connecting the Patient Cable

The patient cable consists of a connector, a trunk cable, 4 limb lead wires and 6 chest lead wires. The lead wires are colour-coded and a reference diagram can be seen on the trunk cable.



- Plug the patient cable to the connector on the right side of the equipment. Ensure the connector on the cable is arrow-side up.
- Tighten the screws to securely attach the patient cable to the equipment.
- Attach the crocodile clips to the end of each lead wire to enable connection to the electrodes.



# Section 5 System Setup

#### Accessing the Main Menu

- Press the [Menu] key (number 2) on the operating panel to access the main menu.
- Press [F2] or [F3] to select the desired menu item.
- Press [F4] to confirm the selection.
- You can return to previous menu by pressing [F1].



In the main menu you can:

- Configure waveforms
- Configure recordings
- Manage files
- Customise patient information
- Perform system setup

The settings in the main menu are saved as user defaults and remain effective even after the equipment is turned off.

Changes made to the Speed or Gain using the [F1] and [F2] quick keys will return to the main menu settings when the device is switched off. Therefore it is advisable to use these keys to make changes for individual patients in order to leave the default settings unaltered.

Please see the **BeneHeart R3 Operators Manual** for the full list of menu functions.



# Section 6 Advised Setup

Below are the advised initial setup steps. The options suggested are in addition to the existing selections in the default configuration unless otherwise stated. Following these steps before the first use will ensure the most effective default configuration for the majority of users.

If your device has already been configured, skip this section and move to **Section 8: Patient Demographics.** 

#### **Set Patient Information**

- On the operating panel select [Menu].
- Use [F3] to scroll down to [Basic Setup].
- Press [F4] Enter.
- Select [Patient Info Setup].
- Press [**F4**] Enter.
- First select [**Detailed Patient Info**]. This allows you to decide which details can be included when the Patient ID key is pressed. (Basic information of ID, name, gender and age included as default).
- Use [F2] and [F3] to scroll through the menu, followed by [F4] to make your selections.
   \*Advised selections: [DOB] and [V3 Placement]
- Next select [**Required Patient Info**]. This creates a prompt to input the Patient ID (Hospital Number) when the ECG key is pressed, ensuring all recordings are labelled.
- Press [Enter].
- On completion select [F1] Back to return to the previous menu.

#### **Set Date and Time**

- On the operating panel select [Menu].
- Use [F3] to scroll down to [Basic Setup].
- Press [F4] Enter.
- Use [F3] and [F4] to scroll to required menu item, e.g. day, month or year.
- Press [F4] Enter.
- Use [F2] and [F3] to until desired option is reached.
- Press [F4] Enter.

The highlighted area will now automatically move onto the next field. Continue with this process until all date and time settings are correct.



- For [Lead Notation] select [IEC].
- Choose your preferred selections for [Auto Standby] and [Auto Shutdown].
- Press [Back] to return to the previous menu.

# **Waveform Setup**

• No recommended changes to default setup.

## **Report Setup**

• Select [**Extend Record**]. The device automatically performs a rhythm measurement and prints a rhythm report if critical values "Extreme Tachycardia", "Extreme Bradycardia", or "Significant Arrhythmia" are detected at the completion of auto measurement.

## File Management

• Select [**Preview**]. This allows the ECG to be checked before printing to ensure ECG paper is not wasted.

#### Maintenance

• No recommended changes to default setup, unless Z-Fold paper is to be used.



# Section 7 Configuration

# Managing the Configuration

Select [Menu]  $\rightarrow$  [Maintenance]  $\rightarrow$  enter the required password $\rightarrow$  [System Setup].

Functions available:

- Load configuration
- Export configuration
- Print configuration
- Return to default configuration

# **Loading Configuration**

You can import a configuration file stored on a USB memory stick into the device's internal memory.

- 1. Insert the USB stick into the USB connector on the left side of the equipment.
- 2. Select [Menu]→[Maintenance]→[Load Config].
- 3. Follow the on-screen instructions.

# **Exporting Configuration**

You can export the configuration file stored in the equipment's internal memory to a USB memory.

- 1. Insert a USB memory into the USB connector on the left side of the equipment.
- 2. Select [Menu]→[Maintenance]→[Export Config].
- 3. Follow the on-screen instructions.



# Section 8 Patient Demographics

Some patient information may directly affect ECG analysis. Complete and correct patient information is helpful for accurate diagnosis and treatment of the patient.

For a new patient, enter patient information before taking an ECG measurement.

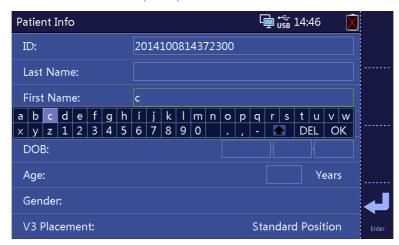
• You can quickly enter patient information by pressing the [ID] key, [Age] key, or [Gender] key.

## **Typing Numbers**

- Use the numerical keys on the operating panel.
- Use [X] on the operating panel to delete.

## **Typing Letters**

- Select the relevant field i.e. "Last Name" to activate the on-screen keyboard.
- Use [F3] and [F4] to navigate the keyboard.
- Press [**F4**] Enter to select a letter.
- Press [**Del**] to delete a letter.
- Press [**OK**] to move onto the next field.
- When all required information is complete press either [F1] Back or [ECG] to start analysis.



The device will prompt the user to input patient details when the [**ECG**] button is pressed. Please see **Set Patient Info** for setup details.

The paediatric lead placement V4R is recommended if the patient is under 16 years of age. Please record V4R using the V3 electrode (see **Patient Preparation**). This is normal practice for a patient of this age. This requires the **[V3 Placement]** setting to be changed to **[V4R Position]** in the **[Patient Info Setup]** menu.

The device will discharge a patient when switched off. However, if you are moving directly to another patient please ensure the device is cleaned and the new patient's details are entered by selecting [ID], [Age] or [Gender].



# Section 9 Patient Preparation

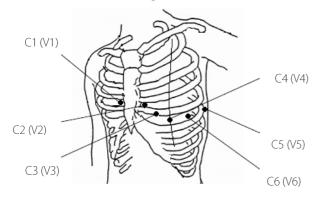
• Lay the patient on a bed with arms resting at their side and legs lying flat and not touching. Ensure the patient is comfortable and relaxed.

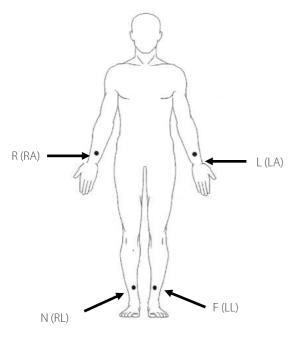
# Prepare the Skin

Careful skin preparation is the key to high-quality ECG signals.

- 1. Expose the chest and electrode sites on the limbs.
- 2. Shave hair from each electrode site.
- 3. Degrease each electrode site with alcohol and abrade slightly with dry gauze to remove dead skin cells.
- 4. Ensure the skin is completely dry.

## **Electrode Positioning**





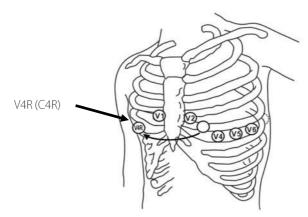
Lead	Lead	Electrode Placement
(IEC)	(AHA)	Electrode Placement
C1	V1	4th intercostal space at the right sternal border
C2	V2	4th intercostal space at the left sternal border
C3	V3	Midway between C2 and C4 electrode positions
C4	V4	5th intercostal space at the left mid-clavicular line
C5	V5	Left anterior axillary line, horizontal with the C4 electrode position
C6	V6	Left mid-axillary line, horizontal with the C4 electrode position
R	RA	Above right wrist
L	LA	Above left wrist
N	RL	Above right ankle
F	LL	Above left ankle



• Limb electrodes may be placed more proximally on the limb if required, but wherever possible the opposite limb lead should be positioned to match.

#### Paediatric Placement

When acquiring a paediatric ECG, an alternative to the standard V3 (C3) placement may be used. Place the sensor in the V4R (C4R) position, on the right side of the chest in a position corresponding to V4 (C4).



• If this placement is used [V4R Position] should be selected in the [Patient Info] menu for correct lead-wire labelling. Please see Section 8: Patient Demographics.

## **Applying Electrodes**

- 1. Ensure disposable electrodes are in date and have been stored inside the packet to avoid the drying out of conductive gel.
- 2. Place the electrodes on the sites as shown above. To obtain a high-quality ECG signal, make sure that the electrodes firmly contact the skin.
- 3. Route the lead wires to avoid twisting. Connect the lead wires with the electrodes.
- 4. Make sure the patient cable is tightly connected to the device and electrodes are correctly connected with the lead wires.
- When placing the chest electrodes, ensure that the electrodes do not touch each other and conductive gel from one site does not touch another site.
- Limb electrodes should be placed on fleshy areas above the inside wrists and ankles, not on the bone.

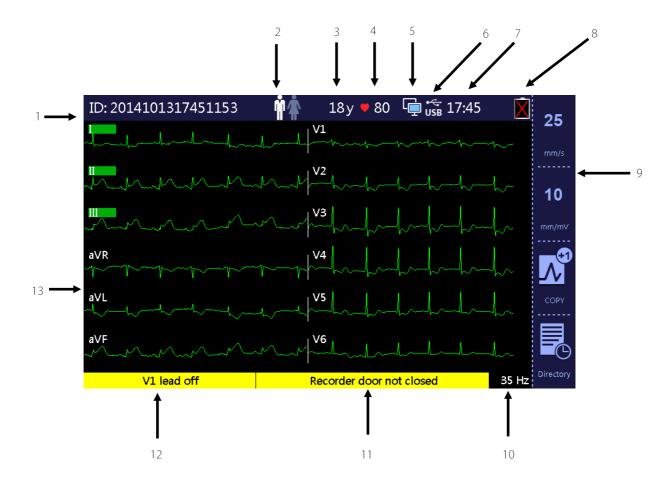
#### Lead Off

The system will prompt "Lead Off" when electrodes are detached, any of the lead wires are poorly connected with the electrode, or the patient cable becomes detached from the device.

- When any of the limb electrodes or leads are detached, excluding the right leg (N/RL) electrode, the system will respectively prompt "LA Lead Off", "LL Lead Off", or "RA Lead Off".
- When any of the chest electrodes or leads are detached the system will respectively prompt "V(X) Lead Off", in where (X) represents lead 1-6.
- When the right leg (N/RL) electrode or lead is detached, two or more limb leads are detached together, or the patient cable detaches from the equipment, the system will prompt "Limb Lead Off".



# Section 10 Main Screen



- 1. Patient ID display
- 2. Gender icon: the display will show or
- 3. Age: the unit can be set to [Years], [Months] or [Days].
- 4. Heart rate
- 5. Network status icon
- 6. USB device status icon
- 7. System time
- 8. Battery status icon
- 9. Soft key area: shows the labels of function keys located to the right
- 10. Muscle artefact filter setting: displays the setting of muscle artefact filter. If the filter is disabled in the [Waveform Setup] menu, the display shows 150Hz.
- 11. Message area 1: displays "Lead Off" and noise information
- 12. Message area 2: displays all other messages
- 13. Waveform display area



## **Setting the Waveform**

On the main screen:

- Repeatedly press [F1] to select the current waveform speed.
   Default Setting: 25mm/s
- Repeatedly press [F2] to select the current waveform gain.
   Default Setting: 10mm/mV
- Press the [**Filter**] (number 5) key to set the the current frequency of muscle artefact filter. Default Setting: 35 Hz
- Press the [Lead] (number 8) key to select the leads for manual recording.
   Default Setting: I, II, III

You can also configure the ECG waveforms by accessing the [**Wave Setup**] menu, however be aware that any changes made in the menus will be retained when the device is switched off, whilst changes made with function keys will be reset to the default configuration.

## **Setting ECG Report**

The format and content of the ECG report is configurable in the [**Report Setup**] menu. Please refer to the **BeneHeart R3 Operators Manual** for a full list of options.



# Section 11 Acquiring an ECG

#### **Auto Measurement**

In auto measurement mode, the equipment automatically acquires 10 seconds of 12-lead ECG, starts analysis at the completion of ECG acquisition, then prints the ECG report as per system setup.

To start an auto measurement:

- 1. Prepare the patient as described in Patient Preparation.
- 2. Enter patient information as described in Patient Demographics.
- 3. Adjust waveform speed, waveform size, and the frequency of muscle artefact filter as described in Setting the Waveform.
- 4. If required, check other waveform and report settings by selecting [Menu] → [Waveform Setup] and [Report Setup].
- 5. Press the [ECG] key to start an auto measurement.

If the [**Preview**] option is disabled, the equipment automatically prints the ECG report after ECG data is acquired and analysed.

If the [Preview] option is enabled, the preview of the ECG report displays. You can then:

- Press [**F1**] to discard the report and return to the normal screen. From here you may press [**ECG**] if you wish to try again.
- Press [F2] to send the report to the external device, if connected.
- Press [**F3**] to print the report.
- Press [F4] to display the next page of the report, if there is any.

The equipment automatically stops recording when the ECG report has been printed. You can also press [F4] to interrupt printing.

#### Manual Measurement\*

In manual measurement mode, the equipment continuously records the ECG waveforms of the selected lead(s) in real time. You can select the [**Lead**] (number 8) key to change the lead(s) to be recorded. The labels of selected leads are highlighted with a green background on the screen.

To generate a Manual report:

- 1. Follow steps 1 to 4 of Auto Measurement above.
- 2. Press the [Manual] key to start recording.
- 3. Press [F4] to stop recording.

In manual measurement mode, press [F3] to place a 1mV square wave on the printout.

\*Please note that in manual measurement mode no analysis of the waveforms will be made by the device.



## Rhythm Measurement\*

In rhythm measurement mode, the device acquires 60 seconds of data then prints the waveforms of the rhythm lead.

In the rhythm ECG report, ECG waveforms are displayed in 3 cascade lines, with each line including 10 seconds of waveform.

You can change the lead to be recorded in the rhythm report by selecting [Menu]  $\rightarrow$  [Report Setup] $\rightarrow$  [Rhythm Lead].

To generate a rhythm report:

- 1. Follow steps 1 to 4 of Auto Measurement above.
- 2. Press the [Rhythm] key to start a rhythm measurement.

The device will start acquiring ECG data and display a countdown. When 60 seconds of data has been collected printing will start automatically.

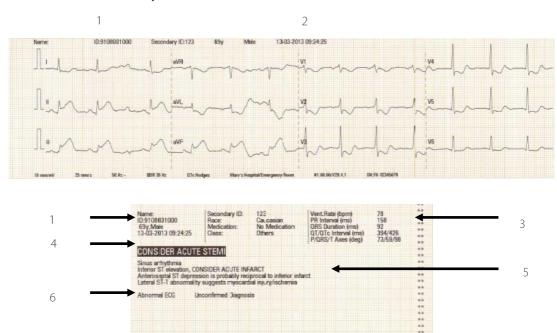
The rhythm mode automatically stops when the report is finished. You can also press the [**Rhythm**] key to manually interrupt it.

\*Please note that in rhythm measurement mode no analysis of the waveforms will be made by the device.



# Section 12 ECG Reports

# **Auto Measurement ECG Report**



- 1. Patient information
- 2. Time of acquisition
- 3. Global measurements
- 4. Critical value
- 5. Diagnosis statement
- 6. Conclusion

# **Resting 12 Lead ECG Analysis**

The device is configured with the University of Glasgow algorithm or the Mindray algorithm to provide an interpretation of the resting 12-lead ECG. The system automatically starts analysis at the completion of ECG acquisition.

Both algorithms provide the following analysis:

#### Measurements

- Vent. Rate (bpm)
- PR Interval (ms)
- QRS Duration (ms)
- QT/QTC Interval (ms)
- P/QRS/T Axes (°)



- RV5/SV1 (mV)\*
- RV5+SV1 (mV)\*

#### Critical Values

- Consider Acute STEMI
- Acute MI/Ischemia
- Extreme Tachycardia
- Extreme Bradycardia
- Significant Arrhythmia
- Prolonged QTc Interval

## Diagnoses

Median Complex\*

Measurement Matrix\*

\* Starred values are not set as default and, if required, should be selected from [**Report Analysis Setup**], within the [**Report Setup**] menu.

For full details of resting 12-lead ECG analysis with the Glasgow algorithm refer to **12-Lead ECG Interpretive Program Physician's Guide**.

For full details of resting 12 lead ECG analysis with the Mindray algorithm refer to *Mindray Resting 12-Lead ECG Analysis Algorithm Physician's Guide*.



# Section 13 Managing Patient Archives

If you have enabled [**Auto Save**] in the [**File Management**] menu, the system automatically creates and saves a patient file at the completion of each auto measurement. You can search, review, export, delete and print historic archives.

The internal memory can store up to 800 ECG reports.

## **Print a Copy**

A copy of the last report may be printed by pressing key [F3] whilst viewing the normal screen, unless the device has been switched off since the report was originally generated.

#### **Access the Directory**

It is possible to access previous reports via the Directory. The Directory list will be shown in date and time order, with the most recent at the top.

- To access the Directory select key [F4] on the normal screen.
- Scroll through the list using the [F2] and [F3] keys.
- Select the required report with [F4] Enter.
- Choose to go [Back] to the normal screen, or [Delete], [Review] or [Print] the selected report using keys [F1] to [F4] respectively.

#### Search for a Report

To search for a previous patient's report you may search by date or patient ID.

- Select [Menu].
- Select [File Management].
- Select [Search by Date] or [Search by ID].
- Enter the search parameters.
- If you are searching by date set [**Start Date**] and [**End Date**]. If you are searching by ID enter the ID, or part of the ID.
- Select [Search] to see a list of qualifying reports.
- Select the desired report to [**Delete**], [**Review**] or [**Print**] as above.

#### **Exporting Files**

In certain circumstances it is possible to export records from the device. Please see **BeneHeart R3 Operators Manual** for details.



# Section 14 Troubleshooting

Please see **BeneHeart R3 Operators Manual** for a full list of messages.

Symptom	Possible Cause	Corrective Action
The device does not power up	<ol> <li>The equipment is not connected to AC mains</li> <li>Battery is not installed or has no charge</li> </ol>	<ol> <li>Check that the power cord is securely connected</li> <li>Check that the battery is installed and has sufficient charge.         Otherwise, connect the equipment to AC mains to run the equipment and charge the battery.     </li> </ol>
ECG data displays unacceptable noise	<ol> <li>Patient movement</li> <li>Improper filter setting</li> <li>Poor skin preparation</li> <li>Electrode problem</li> <li>Patient cable problem</li> <li>Wrong accessories are used or mix electrode types and brands</li> </ol>	<ol> <li>Request the patient lies still during ECG acquisition</li> <li>Check the settings of the filters are appropriate</li> <li>Prepare the patient before ECG acquisition</li> <li>Verify the electrodes are applied correctly. Check for defective or expired electrodes.</li> <li>Check for defective, broken or disconnected patient cable</li> <li>Use specified accessories. Do not mix electrode types or brands.</li> </ol>
The recorder does not work	<ol> <li>Paperless recording is enabled</li> <li>Recording paper is not loaded</li> <li>Recorder door is not properly closed</li> <li>Print head is too hot</li> <li>Recorder is disabled due to depleted battery</li> </ol>	<ol> <li>Select [Menu]→[Report Setup] and check [Paperless Recording]</li> <li>Verify recording paper is properly loaded</li> <li>Verify recorder door is properly closed</li> <li>Wait till the print head cools down</li> <li>Connect the equipment to AC mains to run the equipment and charge the battery</li> </ol>



Paper jammed or misaligned	<ol> <li>Unapproved paper is used</li> <li>Recording paper is not properly loaded</li> </ol>	<ol> <li>Use approved recording paper.         Take out the paper and tear off the jammed part.     </li> <li>Reload the paper as described in Section 4: Device Setup</li> </ol>
Partially missing printout or printout not clear.	<ol> <li>Dirty print head</li> <li>Some thermal points on print head are damaged</li> </ol>	<ol> <li>Clean the print head as described in <i>Section 15: Care and Maintenance</i></li> <li>If the problem persists, contact your service personnel</li> </ol>
The equipment automatically shuts down	1. Auto shutdown is enabled 2. The battery is depleted when the equipment runs on battery power	<ol> <li>Check the setting of [Auto Shut Down] by selecting         [Menu]→[Basic Setup]. If any limb lead is detached, the equipment will automatically shut down when there has been no operation within the preset time.</li> <li>Connect the equipment to AC mains to run the equipment and charge the battery</li> </ol>
The display is completely blank	1. Auto Standby is enabled	1. If a limb lead is detached and there has been no operation for the defined time, the device will automatically turn off the display to save power. To exit the standby mode, press any key.
The screen display is too dark to be seen clearly	1. The setting of brightness is low	1. Adjust screen brightness



# Section 15 Care & Maintenance

## **Cleaning and Disinfecting**

Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

- Always dilute the cleaning and disinfecting agent according to the manufacturer's instructions or use lowest possible concentration.
- Do not immerse any part of the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

Recommended cleaning agents for the equipment are: Sodium hypochlorite bleach (diluted) Hydrogen peroxide (3%) Ethanol (75%) Isopropanol (70%)

For the recommended cleaning agents for the reusable accessories, refer to the instructions for use delivered with the accessories.

## **Cleaning the Equipment**

Your equipment should be cleaned on a regular basis. Before cleaning the equipment, consult your hospital's regulations.

Cleaning the BeneHeart R3 Device

- 1. Shut down the equipment and disconnect the power cord, accessories, and other devices that are connected to the equipment.
- 2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
- 3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaning agent.
- 4. Wipe off excess moisture with a dry cloth.
- 5. Dry your equipment in a ventilated, cool place.

Cleaning Patient Cables and Lead Wires

- 1. Remove cable and lead wires from the equipment before cleaning.
- 2. Gently wipe the cables and lead wires with a soft cloth dampened with ethanol, avoiding the metal connectors.
- 3. Wipe off excess moisture with a dry cloth.
- 4. Dry the cables and lead wires in a ventilated, cool place.



Cleaning the Thermal Print Head

- 1. Turn off the device.
- 2. Open the recorder door with the latch.
- 3. Remove the recording paper.
- 4. Gently wipe the print head with cotton swabs, dampened with ethanol, to remove the dust and foreign particles.
- 5. Wipe off excess moisture with dry cotton swabs.
- 6. When the print head is completely air dried, reload the recording paper and close the recorder door.

Printing quality may be affected by a dirty print head. Clean the print head once per month, or as needed. Check the printout to ensure the printing is legible and dark. Light printing may indicate a dirty print head.

# Disinfecting

Disinfection may cause damage to the equipment and is therefore not recommended for this device, unless otherwise indicated by your hospital's servicing schedule. Cleaning the device before disinfecting is recommended.

The recommended disinfectants for the equipment include: Ethanol 75% Isopropanol 70% Perform® classic concentrate OXY

For recommended disinfectant agents for the reusable accessories refer to the instructions for use, delivered with the accessories.

## Sterilisation

Unless otherwise specified in the instructions for specific accessories, do not sterilise the equipment.