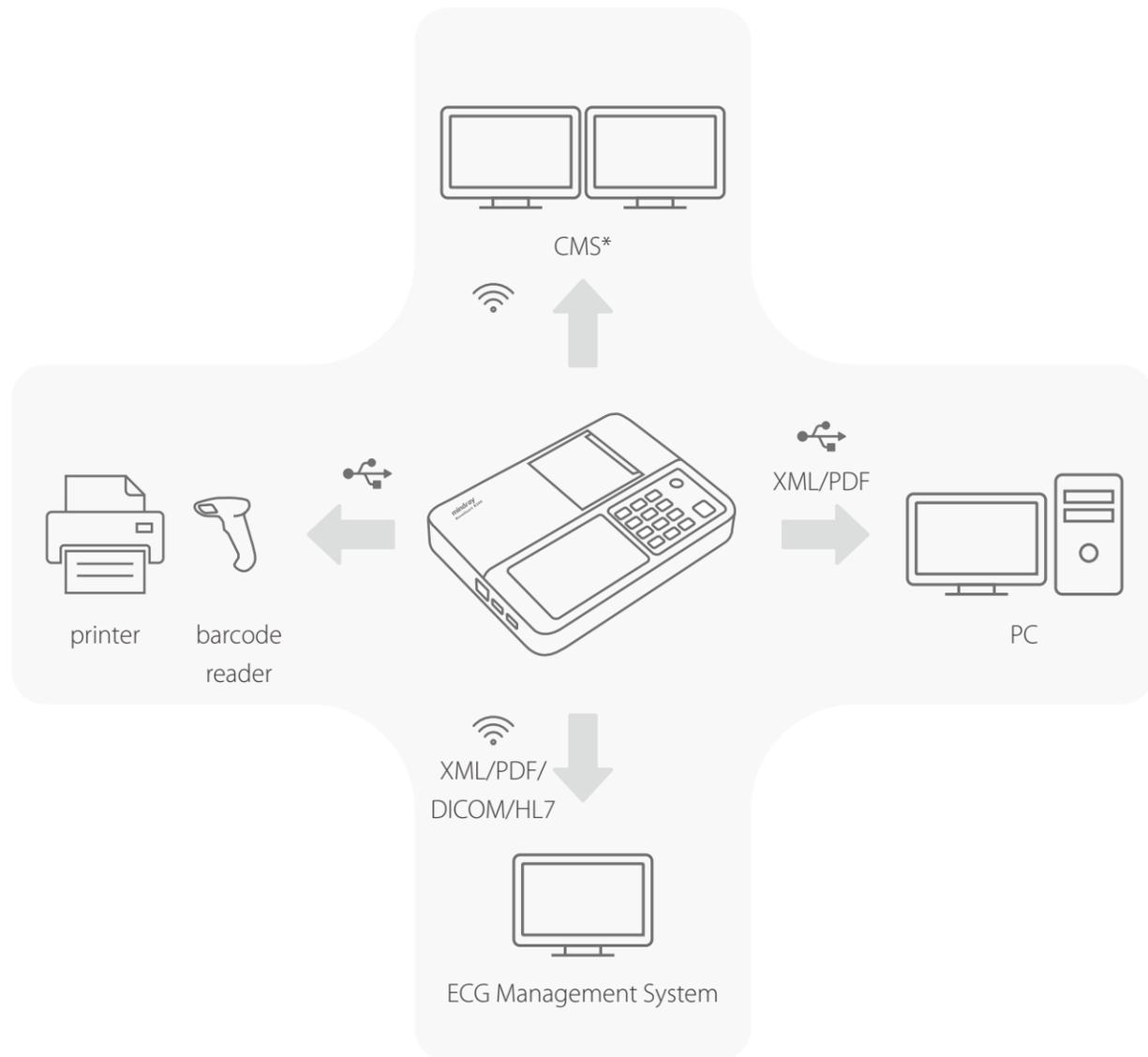
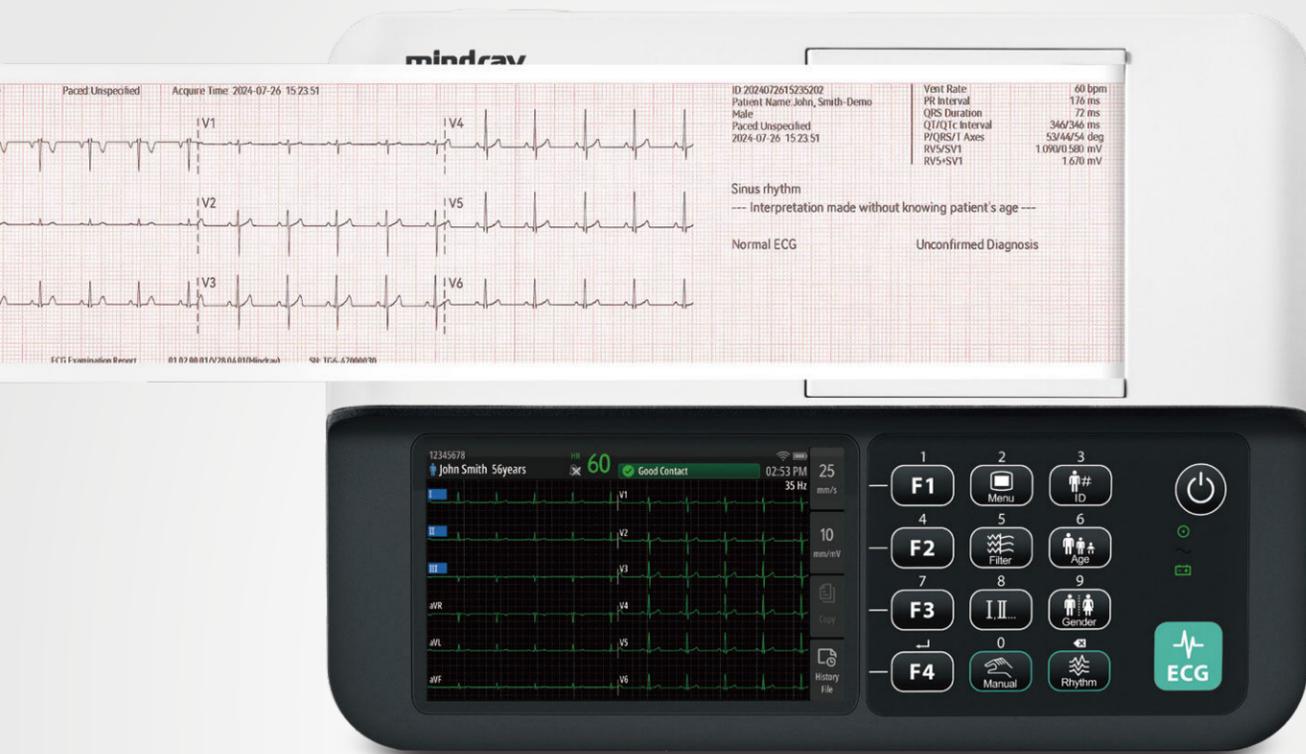


BeneHeart R300
Electrocardiograph



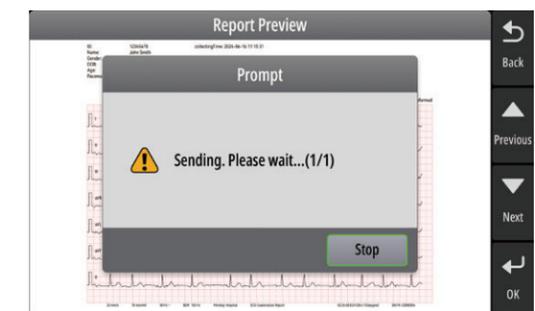
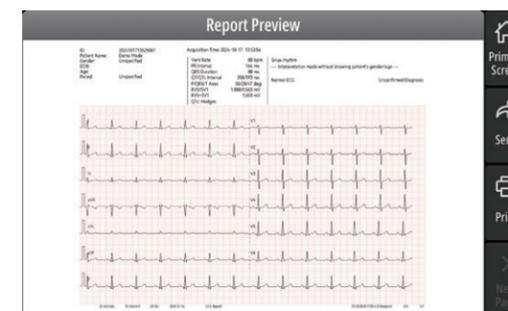
* Will be available in future updates





Convenient Operation

The user-friendliness of BeneHeart R300's interface provides several paper-saving features, the report preview (before printed), re-analysis (if the patient information is modified) and E-report transmission.



Clear display

5" color screen for real-time waveforms observing



Versatile recorder

Support both rolling and Z-fold paper



Light weight

Only 1.28kg (with battery) and compact size



Large capacity

Store over 1000 reports



Longer operating time

At least 10 hours of paperless recording



Great mobility

The trolley makes R300 mobile to wherever needed

Reliable Analysis



R300 supports both the University of Glasgow 12-lead ECG analysis program and Mindray 12-lead resting ECG analysis algorithm for adults and pediatrics, both of which provide accurate and reliable analysis references to give you more confidence in diagnosis.

The Glasgow algorithm is the first to be based on specific variables, including age, gender, race, medication, and class in order to maximise the accuracy of the ECG interpretation.

Mindray has accumulated and inherited more than 20 years of experience in the field of ECG analysis. It has used tens of thousands of clinical ECG data for development and iteration, passed the internationally authoritative CSE evaluation, and achieved more balanced algorithm performance (sensitivity & specificity).

Note: Some functions are optional, please consult your local sales representative for availability.

BeneHeart R300

Electrocardiograph



Technical Specifications	
Physical Specifications	
Height	≤60 mm
Width	≤210 mm
Length	≤270mm
Weight	≤1.5 kg
Measurement Specifications	
Frequency response	0.01~500Hz
ECG sampling rate	64000 samples/s (A/D)
Pacer sampling rate	96000 samples/s (A/D)
Common mode rejection	≥ 140 dB (AC filter on) ≥ 123 dB (AC filter off)
Time constant	≥3.2 s
ADC	24 bits
A/D resolution	0.1192 μV/LSB
Input impedance	≥ 100 MΩ (10 Hz)
Display sensitivity	Auto, 1.25 mm/mV, 2.5 mm/mV , 5 mm/mV, 10 mm/mV, 20 mm/mV , 10/5 mm/mV, 20/10 mm/mV, (± 5%)
Electrode offset potential tolerance	±900mV, ± 5%
Minimum signal	20 μV p-p(10Hz)
Calibration signal	1mV ± 1%
Noise level	≤12.5 μV (p-p)
Baseline filter	0.01Hz, 0.05 Hz, 0.56 Hz
EMG filter	20 Hz, 35 Hz, OFF
Lowpass filter	150 Hz, 270 Hz, 350 Hz
Notch filter	50 Hz, 60 Hz, OFF
Rejection on power frequency interference	≥20 dB
Input signal range	±10 mVpp
Accuracy of signal reproduction	In compliance with the requirements of IEC 60601-2-25
Defibrillation proof	Enduring 5000V (360 J) charge without data loss or corruption
Baseline recovery time	<5 s (after defibrillation)
Electrode polarization recovery time	<10 s
Defibrillation energy absorption	≤10% (100Ω load)
AC overload protection	10 s
Channel crosstalk	≤0.5mm
Time deviation between channels	< 100μs
Pacer detection	Amplitude: ±500 μV to ±700 mV Width: 30 μs to 2ms
HR measurement range	30 to 300 bpm
HR accuracy	±1% or ±1bpm, whichever is greater
HR resolution	1 bpm

Display	
Display type	Color TFT LCD
Display size	5 inches
Display resolution	800×480 pixels
Display data	patient ID, patient name, gender, age, heart rate, pacemaker, warning messages, information messages, time, battery power indicator, network, waveforms, lead labels, pace annotations, speed, gain
Power	
Power supply	AC input (without external power adaptor) or battery operation
AC Power	
Input voltage	100 to 240 VAC ±10%
Input current	1.0 to 0.5A
AC frequency	50/60 Hz
Battery	
Battery type	Rechargeable lithium-ion battery, 2600mAh
Charge time	Less than 3 hours to 90% and less than 3.5 hours to 100% with equipment turned off.
Battery capacity	At least 500 auto reports, or 2 hours of continuous paper recording, or 6 hours of paperless recording.
Shutdown delay	at least 5 minutes after the low battery alarm first occurs
Recorder	
Recorder type	High-resolution thermal recorder
Paper speed	5 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. (± 5%)
Printing resolution	Horizontal 32 dots/mm (25 mm/s) , Vertical 8 dots/mm
Paper type	80mm×20m (rolled paper) 80mm×70m×200 pages (folded paper)
Software	
Measurement and interpretation	Supports <i>the University of Glasgow 12-lead ECG analysis program</i> and <i>Mindray 12-lead Resting ECG Analysis Algorithm</i> for adults and pediatrics
Resting ECG mode	Records and prints 12-lead resting ECG with 10-second duration
Internal storage	1200 ECGs
<p>www.mindray.com</p> <p>P/N:ENG-R300 datasheet -210285X2P-20240911</p> <p>©2024 Shenzhen Mindray Bio-Medical Electronics Co.,Ltd. All rights reserved.</p>	
 mindray healthcare within reach	

BeneHeart R300/BeneHeart R30

Electrocardiograph

Operator's Manual



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Release time: November 2024

Revision: 3.0

2 Equipment Overview

2.1 Intended Use

2.1.1 Intended Purpose Statement

The equipment is intended for clinical electrocardiographic diagnosis and study.

2.1.2 Indication for Use

The equipment is intended to acquire, analyze, display, store, and record electrocardiographic information for adult and children of any age from birth upwards for clinical diagnosis and study.

2.1.3 Intended Users

The equipment must be used by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on it.

2.1.4 Intended Patient Population

The equipment can be used in both adult, pediatric and neonatal patients.

2.1.5 Intended Medical Conditions

The equipment is for use in hospital and other professional medical institutions.

2.1.6 Contra-indications

None.

2.1.7 Side-effects

None.

According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed.

2.1.8 Clinical Benefit

The clinical benefit using the equipment to complete an ECG test is assisting the medical professionals in diagnosis and evaluation of patient's heart conditions in a non-invasive, cost-effective, and fast-enough way.

2.2 Applied Parts

The applied parts of the equipment are:

- ECG electrodes
- Patient cable

2.3 Main Unit and Connectors

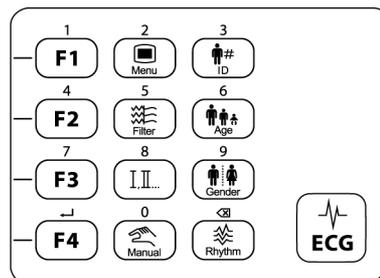
2.3.1 Top View



- (1) Display screen
- (2) Recorder
- (3) Power switch
 - ◆ When powered on, press it to turn on the equipment.
 - ◆ When turned on, press and hold it for 3 seconds to turn off the equipment.
- (4) Indicators:
 - Power-on indicator 
 - ◆ Illuminated: the equipment is turned on.
 - ◆ Off: the equipment is turned off.
 - AC power indicator 
 - ◆ Illuminated: the AC power is connected.
 - ◆ Off: the AC power is not connected.
 - Battery indicator 
 - ◆ Steady green: the battery is fully charged.
 - ◆ Flashing green: the equipment operates on battery power.
 - ◆ Steady orange: the battery is being charged.
 - ◆ Flashing orange: the battery fails.
 - ◆ Off: the battery is not installed.

Hard keys

Hard keys are located on the front panel, used for operating the screen, inputting information or acquiring an ECG. For details on using hard keys, see 3.8.1 *Using the Hard Keys*.

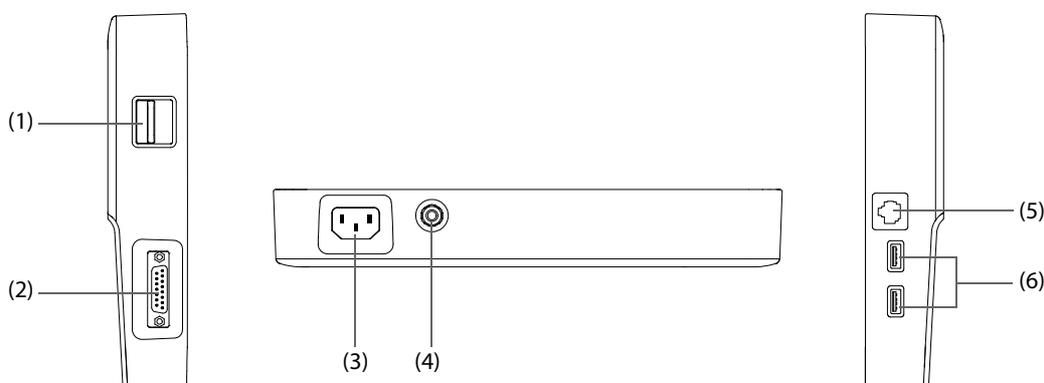


The following table lists all hard keys on the equipment.

Label	Description
0 to 9	Numeric key. When inputting the age, press it to input a corresponding number.
←	When inputting information, press it to confirm the entry.
✕	When inputting information, press it to delete the previous character.
F1 to F4	Function key. Press it to perform a operation corresponding with option on the screen at the left side.
Menu	<ul style="list-style-type: none"> Accesses the main menu. Exits the main menu or the current menu.
Filter	Switches the frequency of muscle artifact filter in the Auto mode.
Lead	Switches the leads to be recorded in the Manual mode.
Manual	Starts or stops acquiring an ECG in the Manual mode.
ID	Opens the ID window, and the cursor is switched to the textbox of patient ID.
Age	The cursor is switched to the patient age on the main screen.
Gender	Switches the patient gender.
Rhythm	Starts or stops acquiring a rhythm ECG.
ECG	Starts or stops acquiring an ECG.

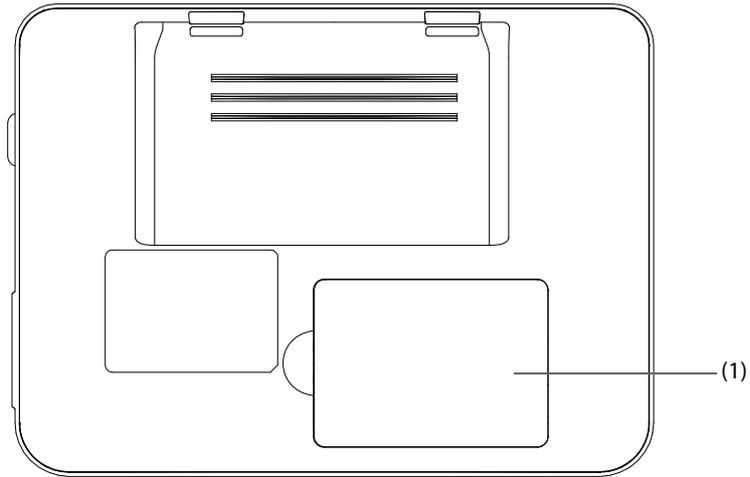
2.3.2 Side View

The following pictures are right, back and left views of the equipment from left to right.



- (1) Recorder door latch: opens the recorder door.
- (2) Patient cable connector: connects the patient cable for ECG acquisition.
- (3) AC power input
- (4) Equipotential grounding terminal
When the equipment and other devices are to be used together, their equipotential grounding terminals should be connected together to eliminate the potential difference between them.
- (5) Network connector: is a standard RJ45 connector which connects the equipment to the central monitoring system (CMS) or other network devices.
- (6) USB connector: connect USB devices, for example USB drive or barcode reader.

2.3.3 Bottom View



(1) Battery compartment: stores the battery.

2.4 Input Devices

The equipment allows data entry through hard key and barcode reader. You can only use Mindray specified input devices.

2.5 Printing Devices

You can use a build-in recorder to print patient report. When the equipment is connected to a Mindray specified printer through networks, you can also use the printer for printing.

3.5 Turning on the Equipment

Before turning on the equipment, perform the following inspections:

1. Check the equipment for any mechanical damage. Make sure that the patient cable is properly connected.
2. Connect the equipment to the AC power supply. Make sure the battery power is sufficient if the equipment is powered by the battery.

Press the power switch to turn on the equipment. After the start-up screen is displayed, the equipment automatically enters the main screen.

CAUTION

- **Do not use the equipment on a patient if you suspect it is not working properly, or if it is mechanically damaged. Contact the service personnel or Mindray.**
-

3.6 Making Settings for First Use

Before putting the equipment into use for the first time, you should make settings for the equipment. Otherwise, the equipment cannot be started.

To make settings for first use, follow this procedure:

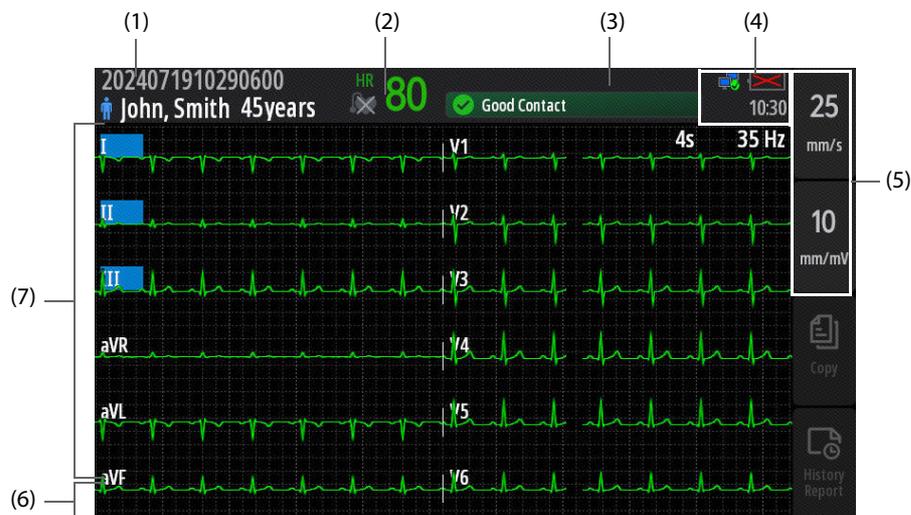
1. Turn on the equipment. The equipment automatically display the **Basic Setup** menu.
2. Select the system language, and then select **Next**.
3. Select the system date and time, and then select **Next** to turn to the **Network Setup** menu. For details about the setup, see *3.8.2 Setting the Date and Time*.
4. Make network settings, and then press the **F1** hard key to return to the **Basic Setup** menu. For details about the setup, see *10.2.11 Network Setup Menu*.
5. Set **Notch Frequency** and **ECG Standard**. For details about the setup, see *10.2.2.2 Filter Setup Tab* and *10.2.2.3 Lead Setup Tab*.
6. Select **Next**, and then restart the equipment.

NOTE

- **If you do not complete settings for all items except network settings, the equipment will not save the settings and still display the Basic Setup menu for next startup.**
-

3.7 Main Screen Display

The following figure shows the main screen display.



- (1) Patient information area: displays gender icon, patient name, patient ID and age by default.
- (2) Patient status area: displays HR value and paced status.
 - If pacemaker pulses are detected,  is displayed.
 - If no pacemaker pulses are detected,  is displayed.
- (3) Message area: displays Message 1 in top row and Message 2 in bottom row.
For more information, see *C.2 Messages*.
- (4) System information area: displays the network status, battery status and system time. For more information, see *3.7.1 On-screen Symbols*.
- (5) Waveform setup area: sets waveforms to be displayed and acquired. For more information, see *6.2 Configuring Displayed Waveforms*.
- (6) Pacemaker pulse marker area: when **Paced** is set to **Yes** or **Unspecified** and pacing signals are detected, displays pacemaker pulse marker and corresponding lead label.
- (7) Waveform area: displays waveforms and lead labels.

3.7.1 On-screen Symbols

The following table lists the on-screen symbols.

Symbol	Description	Symbol	Description
	Male (with a blue background)		Female (with a pink background)
	Unspecified gender (with a white background)		No battery is installed.
	The battery works correctly. The green portion represents the remaining charge.		The battery is being charged.
	The battery has low power and needs to be charged.		The battery has critically low charge and needs to be charged immediately. Otherwise, the equipment will soon automatically shut down.
	Wired network is connected.		Wired network is not connected.
	Wireless network is connected. The solid part indicates network signal strength.		Wireless network is not connected.

6.3 Acquiring ECG

The equipment provides multiple modes for acquiring an ECG.

6.3.1 Auto Mode

In the Auto mode, the equipment acquires 10 seconds of ECG data and provides measured values and diagnostic results. Either Mindray or Glasgow algorithm can be configured for the equipment. For more information about the algorithm, see the physician's guide to corresponding algorithm

After acquiring ECG data, the equipment automatically prints out the report. You can configure to preview the report before the printing. The switch setting of **Report Preview** can be changed in the **Maintenance** menu only. For more information, see *10.2.3.1 Record Setup Tab*.

To start acquiring 12-lead ECG in the Auto mode, follow this procedure:

1. Check that patient information is correct.
2. Press  **ECG**.
3. If needed, set the equipment to acquire 10 seconds of ECG data before the acquisition. The pre-acquisition function is disabled by default. The switch setting of **Pre-acquisition** can be changed in the **Maintenance** menu only. For more information, see *10.2.3.1 Record Setup Tab*.
4. After acquiring 10 seconds of ECG data, the equipment automatically starts analysis and prints out the report.

During the acquisition, press the **F4** hard key to interrupt it at any time.

6.3.2 Manual Mode

In the Manual mode, the equipment continuously acquires the real-time ECG waveforms. The Manual mode does not provide measured values and diagnostic results.

To start acquiring an ECG in the Manual mode, follow this procedure:

1. Press .
2. Press  or the **F4** hard key to complete the acquisition.

The equipment starts acquiring ECG data, and automatically prints out the report at the same time. You can configure to preview the report after completing the acquisition. The switch setting of **Report Preview** can be changed in the **Maintenance** menu only. For more information, see *10.2.3.1 Record Setup Tab*.

6.3.3 Rhythm Mode

In the Rhythm mode, the equipment acquires 30 minutes of ECG data at most for the rhythm lead. The Rhythm mode does not provide measured values and diagnostic results.

To start acquiring an ECG in the Rhythm mode, follow this procedure:

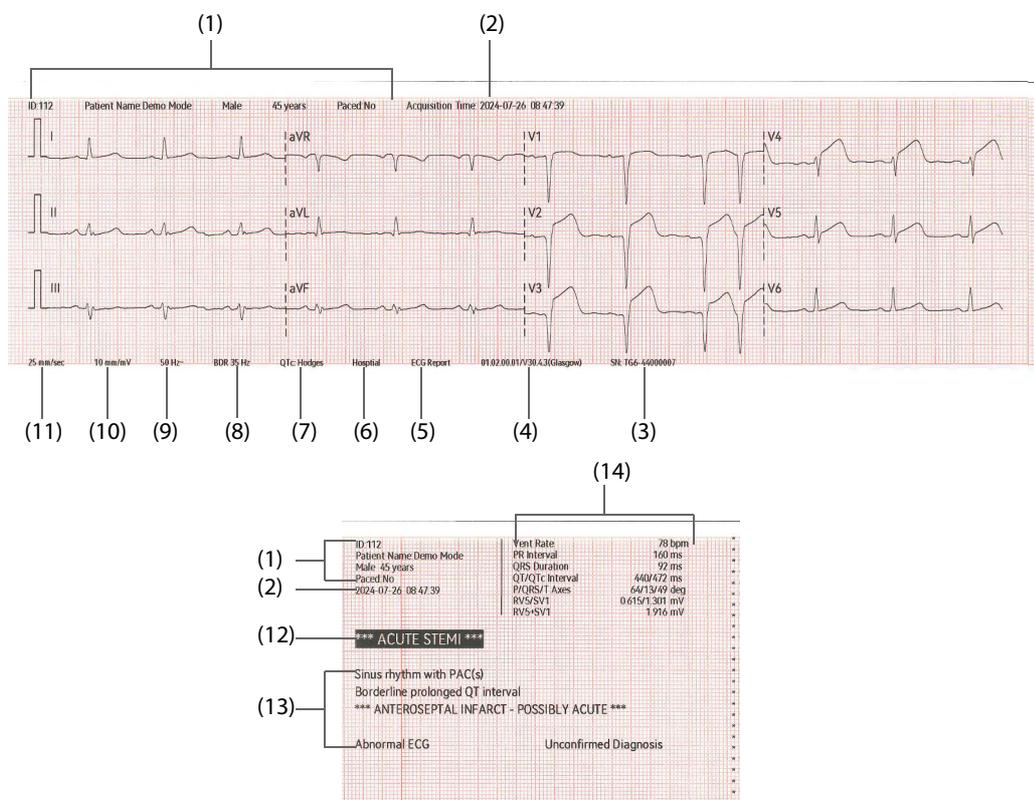
1. Press .
2. Press  or the **F4** hard key to complete the acquisition.

After completing the acquisition, the equipment automatically prints out the report. You can configure to preview the report before the printing. The switch setting of **Report Preview** can be changed in the **Maintenance** menu only. For more information, see *10.2.3.1 Record Setup Tab*.

6.6 Viewing Printed Reports

Items added into the print report can be changed in the **Maintenance** menu only. For more information, see *10.2.3.3 Added in Report Setup Tab*.

The following figure shows a standard 12-lead ECG report in the Auto mode



- | | |
|---|---|
| (1) Patient information | (2) Acquisition time |
| (3) Equipment SN | (4) System software version/algorithm version |
| (5) Report name | (6) Institution name |
| (7) QTc formula | (8) Frequency range |
| (9) Notch filter | (10) Gain |
| (11) Paper speed | |
| (12) Critical values: includes "Consider Acute STEMI", "Acute MI/Ischemia", "Extreme Tachycardia", "Extreme Bradycardia", "Significant Arrhythmia". | |
| (13) Diagnostic results | |
| (14) Measured values: include heart rate, PR interval, QRS duration, QT/QTc interval, P/QRS/T axes, RV5/SV1, RV5+SV1. | |

10.2.2 Waveform Setup Menu

10.2.2.1 Display Setup Tab

Menu Item	Default	Description
Waveform Layout	6x2	Sets the waveform layout. Take "3x4+1" as an example, ECG waveforms are displayed in 3 lines and 4 columns followed by a rhythm lead waveform.
Wave Refresh Sequence	Sequential	Sets the refreshing method of ECG waveforms. <ul style="list-style-type: none">• Sequential: ECG waveforms of all leads are refreshed one by one in order.• Synchronize: ECG waveforms of all leads are refreshed at the same time.
MainScreen Grid	On	Sets whether waveforms are displayed with gridlines on the main screen.

10.2.2.2 Filter Setup Tab

Menu Item	Default	Description
Muscle Artifact Filter	35 Hz	Muscle artifact filter attenuates noise in the waveform by restricting the included frequencies. The muscle artifact filter is a low-pass filter. Signals exceeding the set frequency are filtered out. <ul style="list-style-type: none">• 35 Hz: only signals at 35 Hz or less are displayed.• 20 Hz: only signals at 20 Hz or less are displayed.• Off: signals at 350 Hz or less are displayed.
Lowpass Filter	150 Hz	Signals exceeding the set frequency are filtered out.
Baseline Drift Removal	0.56 Hz (BDR 0.56 Hz)	The baseline drift removal suppresses most baseline drift interference and also is able to preserve the fidelity of the ST-segment level.
Notch Filter	On	The notch filter removes the line frequency interference.
Notch Frequency	50 Hz	Sets notch filter frequency according to the power line frequency of your country.

10.2.2.3 Lead Setup Tab

Menu Item	Default	Description
Rhythm Lead 1	II	Sets the first rhythm lead to be displayed.
Lead Sequence	Standard	Sets the ECG waveform layout. <ul style="list-style-type: none">• Standard: the waveform sequence is I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6.• Cabrera: the waveform sequence is aVL, I, -aVR, II, aVF, III, V1, V2, V3, V4, V5, V6.
ECG Standard	AHA	Sets the ECG standard according to the leadwires you are using.

10.2.2.4 Advanced Setup Tab

Menu Item	Default	Description
Pacing Sampling	Normal	<ul style="list-style-type: none"> • Normal: samples waveforms at an amplitude of ± 2 mV to ± 700 mV, width of 0.1 ms to 2.0 ms. • High Sensitivity: samples waveforms at an amplitude of ± 500 μV to ± 700 mV, width of 30 μs to 2.0 ms.
Reversal Lead Prompt	On	Sets whether the equipment prompts limb electrodes are reversal in the Auto mode.

10.2.3 Report Setup Menu

10.2.3.1 Record Setup Tab

Menu Item	Default	Description
Printing Device	Recorder	Sets the output device to print the reports.
Pre-acquisition	Off	<p>In the Auto mode, sets whether the equipment acquires an ECG before you press :</p> <ul style="list-style-type: none"> • On: if more than 10 seconds of ECG data has been acquired, the equipment immediately displays report preview after you start the acquisition; if less than 10 seconds of ECG data has been acquired, the message “ECG acquiring... The printing will be started after acquisition.” is displayed. • Off: the equipment displays report preview after you start the acquisition and 10 seconds of ECG data is acquired.
Acquisition Duration for Rhythm/ Manual Report	1 min	Sets the duration for acquiring an ECG in the Manual and Rhythm modes.
Report Print	On	<p>Sets whether the equipment immediately starts printing after acquiring an ECG.</p> <p>If Report Preview is switch on:</p> <ul style="list-style-type: none"> • On: the equipment automatically displays the report preview and saves a file after the acquisition. • Off: the equipment automatically displays the report preview after the acquisition. A file is saved after you close the report preview. <p>If Report Preview is switch off:</p> <ul style="list-style-type: none"> • On: the equipment automatically starts printing after the acquisition. A file is saved after the printing. • Off: the equipment automatically saves a file after the acquisition.
Report Preview	Off	Sets whether the ECG report is previewed before being printed.
Thermal Paper Report Format	3x4	<p>Sets the format of ECG report generated in the Auto mode.</p> <ul style="list-style-type: none"> • 3x4: ECG waveforms are displayed in 3 lines and 4 columns, followed by median complex, measurement matrix, measurements and diagnoses. • 3x4+1: is available when Printout Sequence is set to Sequential. ECG waveforms are displayed in 3 lines and 4 columns, followed by a line of rhythm lead, median complex, measurement matrix, measurements and diagnoses. • 3x4 Compact: is available when Printout Sequence is set to Sequential. ECG waveforms are displayed in 3 lines and 4 columns, measurements and diagnoses are displayed on top of waveforms. Median complex and measurement matrix will not be included.

10.2.3.3 Added in Report Setup Tab

Menu Item	Default	Description
Measurements/Interpretation/ Interpretation Summary/RV5/SV1	Selected	Sets the item to be added in the report. <ul style="list-style-type: none"> • Measurements: includes heart rate, PR interval, QRS duration, QT/QTc interval, P/QRS/T axes, RV5/SV1, RV5+SV1. • Median Complex: displays a median complex waveform for each lead and a lead II waveform of 10 seconds in 3x4+1 format. • Measurement Matrix (for Glasgow algorithm): provides 32 measurements of each lead, including Pon (ms), Pdur (ms), QRSON (ms), QRSdur (ms), Qdur (ms), Rdur (ms), Sdur (ms), R'dur (ms), S'dur (ms), P+dur (ms), QRSdef (ms), P+amp (μV), P-amp (μV), QRSp2p (μV), Qamp (μV), Ramp (μV), Samp (μV), R'amp (μV), S'amp (μV), STamp (μV), 2/8STT (μV), 3/8STT (μV), T+amp (μV), T-amp (μV), QRSarea (μV*ms), Rnotch, DWconf (%), STslope (deg), Ton (ms), Tdur (ms), T+dur (ms), QTint (ms). • Measurement Matrix (for Mindray algorithm): provides 30 measurements of each lead, including Pon (ms), Pdur (ms), QRSON (ms), QRSdur (ms), Qdur (ms), Rdur (ms), Sdur (ms), R'dur (ms), S'dur (ms), P+dur (ms), QRSdef (ms), P+amp (μV), P-amp (μV), QRSp2p (μV), Qamp (μV), Ramp (μV), Samp (μV), R'amp (μV), S'amp (μV), STamp (μV), T+amp (μV), T-amp (μV), QRSarea (μV*ms), STslope (deg), Ton (ms), Tdur (ms), T+dur (ms), QTint (ms), STTmid (μV), STTend(μV).
Median Complex/Measurement Matrix	Unselected	

10.2.3.4 Export Tab

Menu Item	Default	Description
File Type	PDF	Sets the default format of exported file.

10.2.4 Patient Management

10.2.4.1 Displayed Information Setup Tab

Menu Item	Default	Description
Middle Name/Secondary ID/Race/V3 Placement/Department/Room No/Bed No/Physician/Technician/ Indication/Medication/Weight/BP	Unselected	Sets the default item displayed on New Patient and Edit Patient ID pages of the Patient Management window.

10.2.4.2 Reserved Information Setup Tab

Menu Item	Default	Description
Race/Physician/Technician/ Department/Room No	Unselected	Sets the item remaining information for the next patient.

10.2.4.3 Required Information Setup Tab

Menu Item	Default	Description
Patient ID/Patient Name/Gender/ DOB/Age/Paced	Unselected	Sets the item required on New Patient and Edit Patient ID pages of the Patient Management window.

14 Accessories

The accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.

WARNING

- **Use accessories specified in this chapter. Using other accessories may cause damage to the equipment or not meet the claimed specifications.**
- **Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.**

CAUTION

- **The accessories may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If accessory performance is degraded due to aging or environmental conditions, contact your service personnel.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
- **Use the accessories before the expiry date if their expiry date is indicated.**
- **The disposable accessories shall be disposed of according to hospital's regulations.**

14.1 ECG Accessories

Model	PN	Description	Applicable Patient
EC6408**	040-001642-00	12-pin integrative patient cable, reusable, AHA, Φ 4 banana plugs, defibrillation-proof	Adult
EC6409**	040-001643-00	12-pin integrative patient cable, reusable, AHA, clip (MR), defibrillation-proof	Adult, Pediatric
EC6410**	040-001644-00	12-pin integrative patient cable, reusable, IEC, Φ 4 banana plugs, defibrillation-proof	Adult
EC6411**	040-001645-00	12-pin integrative patient cable, reusable, IEC, clip (MR), defibrillation-proof	Adult, Pediatric
ECG-FD09X4	040-007423-00	12-pin integrative patient cable, reusable, AHA, Φ 4 banana plugs, defibrillation-proof	Adult
ECG-FD10X4	040-007643-00	12-pin integrative patient cable, reusable, IEC, Φ 4 banana plugs, defibrillation-proof	Adult
ECG-FJ01	040-007640-00	Multifunction limb electrode, reusable, IEC, copper alloy (MR)	Adult
ECG-FJ01	040-007641-00	Multifunction limb electrode, reusable, IEC, Ag/AgCl (MR)	Adult
ECG-FJ02	040-007639-00	Multifunction limb electrode, reusable, AHA, copper alloy (MR)	Adult
ECG-FJ02	040-007642-00	Multifunction limb electrode, reusable, Ag/AgCl (MR)	Adult
ECG-FQX41	040-007428-00	Multifunction chest electrode, reusable	Adult
ECG-FQX42	040-007429-00	Multifunction chest electrode, reusable	Adult
SF06	040-002711-00	Disposable electrode, 5 pcs/package	Adult

Model	PN	Description	Applicable Patient
SF07	040-002833-00	Disposable electrode	Pediatric, Neonate
TJ-V001A-P	040-001646-00	Multifunction electrode adapter	Adult, Pediatric
15-25	0000-10-10775	Reusable electrode gel	All

14.2 Others

PN	Description
022-000600-00	Rechargeable lithium-ion battery
1000-21-00122	Grounding cables
095-002708-00	Recorder paper, folded, 80mm×70m×200 pages
095-003380-00	Recorder paper, folded, 80mm×70m×200 pages
095-003386-00	Recorder paper, rolled, 80mm×20m
M002-10-69954	Recorder paper, rolled
009-016580-00	Power cord
009-016581-00	Power cord, American
009-016582-00	Power cord, UK
009-016583-00	Power cord, European
009-007190-00	Power cord, Indian
009-001791-00	Power cord, South African
009-001075-00	Power cord, Brazil
009-007191-00	Power cord, Swiss
009-002636-00	Power cord, Australian
009-016788-00	Power cord, Korean
045-001370-00	Barcode reader mounting kit
115-008393-00	1D barcode reader kit
023-002134-00	2D barcode reader
025-000038-00	RFID handheld 2D barcode reader
025-000256-00	Medical-grade 2D barcode reader
048-003791-00	Reusable carrying case
045-006372-00	Trolley
115-032940-00	CardioVista ECG Viewer software kit

Recorder paper	Paper type: rolled paper, folded paper Paper size: 80 mm×20 m (rolled paper), 80mm×70m×200 pages (folded paper)
Paper speed	5 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error no more than ± 5%

A.4.3 LEDs

Power-on LED	1 (green)
AC power LED	1 (green)
Battery LED	1 (two color-coded: orange and green)

A.4.4 Audio Indicators

Buzzer	Gives power-on tone, heartbeat tone, acquisition done tone and failure tone
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A.4.5 External Connectors

Power input	1, AC power input with equipotential grounding terminal, connects the external power supply.
Network connector	1 RJ45 connector, 100 Base-TX, IEEE 802.3, connects a standard network cable.
USB connector	2 USB 2.0 connectors, connects the USB drive and barcode reader.
Patient cable connector	1, connects patient cable for ECG acquisition.

A.5 Data Storage

Data stored in the equipment is not affected by a power failure.

The equipment store 1200 ECG reports.

A.6 Wi-Fi Specifications

Protocol	IEEE 802.11a/b/g/n/ac/ax
Modulation mode	BPSK, QPSK, 16QAM, 64QAM, 256QAM, 1024QAM
Operating frequency	2400 MHz to 2483.5 MHz 5150 MHz to 5250 MHz, 5250 MHz to 5350 MHz, 5470 MHz to 5725 MHz, 5725 MHz to 5850 MHz, 5925 MHz to 7125 MHz
Wireless baud rate	IEEE 802.11a: 6 Mbps to 54 Mbps IEEE 802.11b: 1 Mbps to 11 Mbps IEEE 802.11g: 6 Mbps to 54 Mbps IEEE 802.11n: MCS0-MCS7 IEEE 802.11ac: MCS0-MCS9 IEEE 802.11ax: MCS0-MCS11
Output power	≤ 20 dBm (CE requirement: detection mode- RMS)
Operating mode	As station, access AP for data transmission
Data security	Standards: WPA/WPA2-PSK, WPA/WPA2-EAP, WPA3-OWE, WPA3-SAE, WPA3-EAP EAP method: EAP-TTLS, EAP-TLS, PEAP-MsChapV2, PEAP-TLS, PEAP-GTC, LEAP, EAP-FAST Encryption: TKIP, AES
Distinct vision distance	The distinct vision distance between the equipment and the AP: ≥ 50 m.

Symptom	Possible Cause	Corrective actions
ECG waveforms display unacceptable noise.	<ul style="list-style-type: none"> • Patient movement during ECG acquisition. • AC interference from external devices or improper notch filter setting. • Muscle artifact or improper muscle artifact filter setting. • Poor skin preparation. • Electrode problems. 	<ul style="list-style-type: none"> • Make sure the patient keep still during ECG acquisition. • Turn of the adjacent devices or move this equipment away from the interference if possible. Properly set the notch filter. • Properly set the muscle artifact filter. • Prepare the patient skin as described in <i>5.3 Preparing the Skin</i>. • Make sure electrodes are correctly applied as described in <i>5.5 Applying Electrodes</i>. Check for defective or expired electrodes. Replace with disposable electrodes if necessary.
The equipment automatically shuts down.	<ul style="list-style-type: none"> • The auto shutdown function is enabled. • The battery is depleted when the equipment runs on battery power. 	<ul style="list-style-type: none"> • Turn on the equipment. • Connect the equipment to AC power to run the equipment and charge the battery.
Partially missing or not clear printout.	<ul style="list-style-type: none"> • Dirty print head. • Some thermal points on print head are damaged. 	Clean the print head. If the problem persists, contact your service personnel.
The display is too dark to be seen clearly.	The setting of brightness is low.	Adjust screen brightness as described in <i>3.8.3 Adjusting the Screen Brightness</i> .

C.2 Messages

The equipment provides two types of messages in the message area.

- Message 1: locates in top row of the message area. It displays other messages except messages relevant to lead status and noise existence.
- Message 2: locates in bottom row of the message area. It displays messages relevant to lead status and noise existence.

NOTE

- **When multiple messages occur, they will be displayed circularly.**
- **The equipment always gives a reminder if failure-related message occurs. For details on configuring the reminder tone, see *3.8.4 Adjusting the Volume*.**

C.2.1 Message 1

Message	Possible Cause	Corrective actions
Low Battery	The battery power is too low.	Connect the equipment to the AC power to run the equipment and charge the battery.
Critically Low Battery	The battery power is almost depleted.	Immediately connect the equipment to the AC power to run the equipment and charge the battery.
Battery Error. Please contact your service personnel.	Failure is detected when the battery is being charged.	Contact your service personnel.
Recorder Unavailable	Communication with the recorder fails or the recorder does not work.	<ol style="list-style-type: none"> 1. Make sure that the recorder paper is properly loaded. 2. Make sure that the print head is not overheat. 3. If the problem persists, contact your service personnel.
Recorder Head Hot: Please Wait	Print head becomes too hot due to heavy use.	Stop printing and wait until the print head cools down.

Message	Possible Cause	Corrective actions
Recorder Door Open	Paper tray is open.	Push the paper tray back in position and start the printing again.
Recorder Out Of Paper	The thermal recorder runs out of paper.	Load the paper as described in 3.4.3 <i>Loading the Paper</i> .
Paper Type Error	<ul style="list-style-type: none"> Unspecified paper is used. The black mark on the recorder paper cannot be detected. 	<ol style="list-style-type: none"> Make sure the specified paper is used. Load the paper as described in 3.4.3 <i>Loading the Paper</i>.
Printer Unavailable	<ul style="list-style-type: none"> The printer is not turned on. The printer model is not the specified one. The printer automatically shuts down. Communication with the printer fails. 	<ol style="list-style-type: none"> Turn on the printer. Make sure the printer model is the specified one. Disable the auto shutdown function on the printer. Disable the smart drive installation function on the printer. Make sure the printer is properly connected with the equipment. If the problem persists, contact your service personnel.
ECG Module Error. Please contact your service personnel.	Damaged ECG board or software failure causes ECG communication error or communication stops.	Contact your service personnel.
Device Voltage Abnormal. Please contact your service personnel.	The voltage of PCBA power supply is abnormal.	Contact your service personnel.
Storage Error	The internal storage is damaged.	Restart the equipment. If the problem persists, contact your service personnel.
USB drive not found.	The system fails to find the USB drive.	<ol style="list-style-type: none"> Make sure that the USB drive is properly connected to the equipment. If the problem persists, contact your service personnel.
Storage space is nearly full	Less than 10 files can be stored.	Delete useless files to release storage space.
RT Clock Reset Required. Please contact your service personnel.	The real-time clock displays the initial value because button cell failed and reset, or button cell is not available.	Contact your service personnel.
Acquiring...	The equipment is acquiring an ECG in the Rhythm mode.	Wait until countdown is reached. If needed, press  or F4 to stop.
ECG acquiring... The printing will be started after acquisition.	The pre-acquisition function is enabled, and acquired ECG data is less than 10 seconds before you start acquiring an ECG.	Wait until sufficient data is acquired.
Analyzing...	The algorithm is analyzing acquired ECG data in the Auto mode.	Wait until analysis is completed.
Analysis Failed	The algorithm fails to analyze acquired ECG data and is unable to give diagnostic results.	See the physician's guide to corresponding algorithm.
Reanalyzing...	The equipment is reanalyzing ECG data after you modify patient information.	Wait until reanalysis is completed.
Generating Preview...	The equipment is generating a preview of the ECG report.	Wait until the preview is generated.
Printing...	The report is being printed out.	Wait until the printing is completed. If needed, press the F4 hard key.
Printing Stopped	Printing is manually stopped.	/
Printing Retry:	The printing fails, the equipment try to start printing again.	Wait until the printing is completed.

Message	Possible Cause	Corrective actions
Printing Failed:	The external printer runs out of paper or cannot be connected.	Check the printer, and start printing again.
Sending....	Files are being transmitted to an external system.	Wait until all files have been transmitted.
Sent Successfully	The files are successfully transmitted to an external system.	/
Sending Failed	The files fail to be transmitted to the an external system.	<ol style="list-style-type: none"> 1. Check network connection and network settings. Then try again. 2. If the problem persists, contact your service personnel.
Configurations exported successfully.	Configuration is successfully exported.	/
Exporting configurations failed.	Configuration fails to be exported.	<ol style="list-style-type: none"> 1. Make sure that the USB drive is properly connected to the equipment and file system is not damaged. 2. Make sure that the USB drive has sufficient space.
Configurations imported successfully.	Configuration is successfully imported.	/
Importing configurations failed.	Configuration fails to be imported.	<ol style="list-style-type: none"> 1. Make sure that the USB drive is properly connected to the equipment and file system is not damaged. 2. If the problem persists, contact your service personnel.
Connection failed, please check network.	The server cannot be connected when files are transmitted to the server.	<ol style="list-style-type: none"> 1. Check network connection and network settings. Then try again. 2. If the problem persists, contact your service personnel.
Incorrect username or password	Wrong user name or password is entered.	Enter the correct user name and password.
LAN1 IP Address Conflict	IP address conflict.	<ol style="list-style-type: none"> 1. Check network connection and network settings. Then try again. 2. If the problem persists, contact your service personnel.
WLAN IP Address Conflict		
System is shutting down...	The system is shutting down.	Wait until the equipment shuts down.

C.2.2 Message 2

Message	Possible Cause	Corrective actions
Good Contact	All electrodes and leadwires are properly connected.	/
Limb Lead Off	<ul style="list-style-type: none"> • RL lead off or more than one limb lead off. • Patient cable is detached from the equipment. 	<ol style="list-style-type: none"> 1. Check corresponding electrodes and leadwires. Re-apply the electrodes or reconnect the leadwires if necessary. 2. Make sure that patient cable is properly connected to the equipment.
Lead Off: XX*	The referred lead is off.	Check corresponding electrodes and leadwires. Re-apply the electrodes or reconnect the leadwires if necessary.

D.3 Device Labeling

Check the labels provided by the manufacturer or the healthcare facilities are present and legible.

- Main unit label
- Integrated warning labels

D.4 Protective Earth Resistance

1. Plug the probes of the analyzer into the device's protective earth terminal and protective earth terminal of the AC power cord.
2. Test the earth resistance with a current of 25 A.
3. Verify the resistance is less than limits.

LIMITS

For all countries, $R = 0.2 \Omega$ Maximum

D.5 Earth Leakage Test

Run an Earth Leakage test on the device being tested before performing any other leakage tests.

The following outlet conditions apply when performing the Earth Leakage test:

- normal polarity (Normal Condition)
- reverse polarity (Normal Condition)
- normal polarity with open neutral (Single Fault Condition)
- reverse polarity with open neutral (Single Fault Condition)

LIMITS

For UL60601-1,

- ◆ 300 μ A in Normal Condition
- ◆ 1000 μ A in Single Fault Condition

For IEC60601-1,

- ◆ 500 μ A in Normal Condition
- ◆ 1000 μ A in Single Fault Condition

D.6 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements have a true RMS only

The following outlet conditions apply when performing the Patient Leakage Current test.

- normal polarity (Normal Condition)
- reverse polarity (Normal Condition)
- normal polarity with open neutral (Single Fault Condition)
- reverse polarity with open neutral (Single Fault Condition)
- normal polarity with open earth (Single Fault Condition)
- reverse polarity with open earth (Single Fault Condition)

LIMITS

For CF  applied parts

- ◆ 10 μ A in Normal Condition
- ◆ 50 μ A in Single Fault Condition