English

PCECG-500
Electrocardiograph
Operator’s Manual

I Preface

Declaration

We make no warranties of any kind, including (but not limited to) implied warranties of merchantability and fitness for a particular purpose. We assume no responsibility for any errors that may appear in this document, or for incidental or consequential damage in connection with the furnishing, performance or use of this material.

We will make continuous improvement in features and functions for future publication of new equipment without prior notice.

Copyright

General Notes

- *Italic* text is used to indicate prompt information or quote the referenced chapters or sections.
- [XX] is used to indicate the character string in the software.
- → is used to indicate operational procedures.
- All illustrations in this manual serve as examples only and may differ from what is actually seen.

Special Notes

The warnings, cautions and tips in this manual are used to remind readers of some specific information.

⚠ Warning

Indicates a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury.

❗ Caution

Indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property.

☞ Note

Provides important tips regarding the operation or function of the device.

II Manufacturer's Liability and Warranty

Manufacturer's Liability

The manufacturer is responsible for the safety, reliability and performance of the device, only if:

- Assembly operations, expansions, re-adjustments, improvements and repairs of this device are performed by authorized personnel;
- The electrical installation of the relevant room complies with the applicable national and local requirements;
- The device is used in accordance with the instructions in this manual.

The manufacturer shall not be responsible for direct, indirect or ultimate damage or delay caused by:

- The device is disassembled, stretched and re-adjusted;
- Maintenance or modification of the device is conducted by unauthorized personnel;
- Subsequent damage caused by improper use or maintenance;
- Replacement or removal of serial number label and manufacture label;
- Mis-operation caused by the neglect to the instructions in this manual.

Warranty

The warranty period is subject to the terms in the sales contract.

The warranty covers all device failures caused by material, firmware or production process. Any faulty parts can be repaired and replaced free of charge during the warranty period.

- **Manufacturing Process and Raw Materials**

The manufacturer warrants that there is no defect in raw material and manufacturing process. During warranty period, the manufacturer will repair or replace the defective part(s) free of charge if the defect has been confirmed as raw material or manufacturing process defect under normal operation and maintenance conditions.

- **Software or Firmware**

Software or firmware installed in the products of the manufacturer will be repaired by replacing the software or devices upon receipt of reports proving that the software or firmware are defective, but the manufacturer cannot guarantee that the use of the software or devices will not be interrupted or error free.

- **Circuit Diagram**

Upon request, the manufacturer may provide necessary circuit diagrams, component part lists, and other technical information to assist qualified service personnel in parts repair.

Note: Freight and other charges are excluded in the above warranty.

Manufacturer's Information

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Table of Contents

Chapter 1 Safety Guidance

This chapter provides important safety information related to the use of the device. In other chapters, it also contains relevant safety information for specific operations. In order to use the device safely and effectively, please read and strictly observe all of the safety information described in this manual before use.

1.1 Safety Warnings

1.1.1 Device Warnings

⚠ Warning

This device is not designed for direct cardiac application.

⚠ Warning

This device is not intended for treatment.

⚠ Warning

This device is intended to be used by personnel professionally trained. The operator should be familiar with the contents of this Operator's Manual before operation.

⚠ Warning

Replacement of components by unauthorized personnel may lead to unacceptable risks.

⚠ Warning

Do not open the device housings while the power is connected.

⚠ Warning

EXPLOSION HAZARD - Do not use the device in the presence of flammable anesthetic mixture with oxygen or other flammable agents.

⚠ Warning

Do not use the device adjacent to or stacked with other device. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.

⚠ Warning

This device cannot be used with diathermy related device.

⚠ Warning

This device cannot be used with high frequency surgical equipment.

⚠ Warning

Do not use this device in the presence of high static electricity or high voltage device which may generate sparks.

⚠ Warning

Auxiliary equipment connected to the analog and digital interfaces must be certified according to IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of IEC 60601-1. If in doubt, consult our technical service department or your local distributor.

⚠ Warning

The summation of leakage current should never exceed leakage current limits while several other devices are used at the same time.

⚠ Warning

Only the ECG cable and other accessories supplied by the manufacturer can be used. Otherwise, the performance, electric shock protection or defibrillator protection cannot be guaranteed.

⚠ Warning

Make sure that all electrodes are connected to the patient correctly before operation.

⚠ Warning

Make sure that the conductive parts of electrodes (including neutral electrodes) and lead wires, do not come in contact with earth or any other conducting objects.

⚠ Warning

Do not use dissimilar metal electrodes.

⚠ Warning

Indication of abnormal operation of the device: When the DC voltage at the input terminal is increased to ±1V, the device will display lead off.

⚠ Warning

Check the device, ECG cable and electrodes before operating the device. Replace the parts of evident defectiveness or aging which may impair the safety or performance before use.

⚠ Warning

Do not touch the patient and live parts simultaneously. Otherwise patient injury may result.

⚠ Warning

Do not carry out maintenance and repair of the device in use.

⚠ Warning

The frequency setting of AC filter should be consistent with the frequency of local mains supply, otherwise, the anti-interference performance of the device will be seriously affected.

⚠ Warning

Do not use sharp objects such as pens to touch the display screen, otherwise it may damage the display screen.

1.1.2 Defibrillator and Pacemaker Warnings

⚠ Warning

When used with a defibrillator or pacemaker, all electrodes connected and not connected to the patient and the patient should not be grounded.

⚠ Warning

Before defibrillating, make sure the patient is completely isolated and avoid touching any metal part of the device in case of electric shock.

⚠ Warning

Before defibrillating, remove all electrodes, gel or cloth from the patient in case of any possible burnt. When the electrode paddle of defibrillator is in direct contact with these materials, the discharge capacity will cause severe electric burn of patients.

⚠ Warning

Before defibrillating, enable the ADS function and select 0.67Hz filter.

⚠ Warning

Use ECG cable (98ME01EC030) with defibrillator protection specified by the manufacturer while defibrillating. Otherwise there might be electric burnt of the patient or damage of the device. After

defibrillation, under the standard sensitivity setting, the ECG waveform will return to 80% of the normal amplitude within 5 seconds.

⚠ Warning

During defibrillation, use disposable electrodes and ECG adapter wires specified by the manufacturer and use them in accordance with their instructions for use.

⚠ Warning

After defibrillation, the ADS filter is set at 0.67Hz, and the cardiogram is displayed and maintained within 10 seconds.

⚠ Warning

Use only the ECG cable and electrodes supplied by the manufacturer while defibrillating.

⚠ Warning

For patient with a pacemaker, since this device has a pacing signal suppression function, under normal circumstances, pacing pulses will not be included in the pulse rate detection and calculation. However, if the width of the pacing pulse exceeds 2ms, it is still possible to continue counting the pacing pulse. To reduce this possibility, the operator should closely observe the changes in the ECG waveform on the screen, and do not rely on the indications of the device itself, when the device is used for such patients.

1.1.3 Battery Warnings

⚠ Warning

Improper operation may cause the lithium battery (hereinafter called battery) to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. It is necessary to read this manual carefully and pay more attention to warning information.

⚠ Warning

Danger of explosion - Do not reverse the anode and the cathode when installing the battery.

⚠ Warning

Do not use the battery near a fire source or in the place where the temperature exceeds 60℃. Do not heat the battery or throw it into fire. Do not expose the battery to liquid.

⚠ Warning

Do not gouge the battery with metal, hammer or drop the battery or destroy the battery by other means, otherwise it will cause the battery over-heated, smoking, distorted or burning, even in danger.

⚠ Warning

When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

⚠ Warning

If the battery shows signs of damage, signs of leakage, or the battery fails, replace it with a new one immediately.

⚠ Warning

Please replace the battery if its operating time is significantly lower than the specified time, see *A.3 Physical and Hardware Specifications*.

⚠ Warning

Only batteries of the same model and specification provided by the manufacturer should be used.

Warning

Stop using the battery when it reaches the end of its service life or any abnormal phenomenon is found from the battery, and dispose the battery according to local regulations.

Warning

Replace the battery if it has been used for more than three years.

Warning

Remove or install the battery only when the device is powered off.

Warning

Remove the battery from the device when the device is not used for a long time.

Warning

If the battery is stored alone and not used for a long time, we recommend that the battery should be charged at least once every 6 months to prevent over discharge.

1.2 Cautions

1.2.1 General Cautions

Caution

Avoid water splashing on the device.

Caution

Avoid high temperature, the device should be used in the temperature between 5℃ to 40℃ during operation.

Caution

Do not use the device in a dusty environment with bad ventilation or in the presence of corrosive materials.

Caution

Make sure that there is no intense electromagnetic interference source around the device, such as radio transmitters or mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. is likely to bring electromagnetic interference.

Caution

Do not detach the electrodes from the patient during ECG analysis.

Caution

Disposable electrodes cannot be reused.

Caution

The device and accessories are to be disposed of according to local regulations after their service lives.

Caution

The results given by the device should be examined based on the overall clinical condition of the patient, and they cannot substitute for regular checking.

1.2.2 Cleaning and Disinfection Cautions

Caution

Turn off the device, disconnect the USB cable and remove the ECG cable before cleaning and disinfection.

Caution

Prevent the detergent from seeping into the device when cleaning. Do not immerse the device and accessories into liquid under any circumstances.

Caution

Do not clean the device and accessories with abrasive fabric and avoid scratching the electrodes.

Caution

Any remainder of detergent should be removed from the device and the ECG cable after cleaning.

Caution

The device shall be disinfected if it is touched by infected patient or suspected patient.

Caution

Do not use high temperature, high pressure steam and ionizing radiation for disinfection.

1.3 Device Symbols

Symbol	Description	Symbol	Description
	ECG cable connector		USB connector
	Type CF applied part		Caution! Consult accompanying documents
	Serial number		Batch code
	Manufacturer		Date of manufacture
	No reliance on installation protective measures		Non-ionizing electromagnetic radiation
	The symbol indicates that the device		Authorised representative in

Symbol	Description	Symbol	Description
	complies with the European Council Directive 93/42/EEC concerning medical devices.		the European Community
UK RP	UK responsible person	CH REP	Authorised representative in Switzerland
	Follow WEEE regulations for disposal		Refer to Operator's Manual (Background: blue; Symbol: white)
	General warning sign (Background: yellow; Symbol and line: black)		Packaging can be recycled, don't throw it away! (Only applicable for French market)
	Battery can be recycled, don't throw it away! (Only applicable for French market)		

☞ **Note**

Your device does not necessarily have all of the above symbols.

☞ **Note**

This manual is printed in Black and White.

Chapter 2 Product Introduction

2.1 Intended Use

The PCECG-500 Electrocardiograph (hereinafter referred to as the “device”) is a portable ECG analysis device, which is used to acquire resting ECG signals from adult and pediatric patients through body surface ECG electrodes, and analyze the ECG data for clinical diagnosis and research.

The device is to be used in medical institutions by qualified clinical professionals or under their guidance. The operators must have received adequate training and be fully competent in the use of the device.

2.2 Contraindication

No contraindication.

2.3 Product Composition

The product consists of the device, USB cable, battery, ECG cable and electrodes.

2.4 Product Accessories

Accessory	Model/Type	Quantity
USB cable	Type C	1
ECG cable	98ME01EC030	1 set
Disposable ECG electrodes	915W50	20 pcs
Rechargeable lithium battery	A-EMSH	1
Type-C USB Flash Disk	32G	1

The accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1. For details about the accessories, refer to the instructions for use provided with the accessory.

⚠ Warning

Although the accessory material that contacts patients has been evaluated biologically and the biological safety meets the requirements of ISO 10993-1, very few people may have allergic reaction, and those with allergic reaction should stop using it!

⚠ Warning

Please use the accessories provided by the manufacturer. Using other accessories may cause damage to the device or not meet the claimed specifications in this manual.

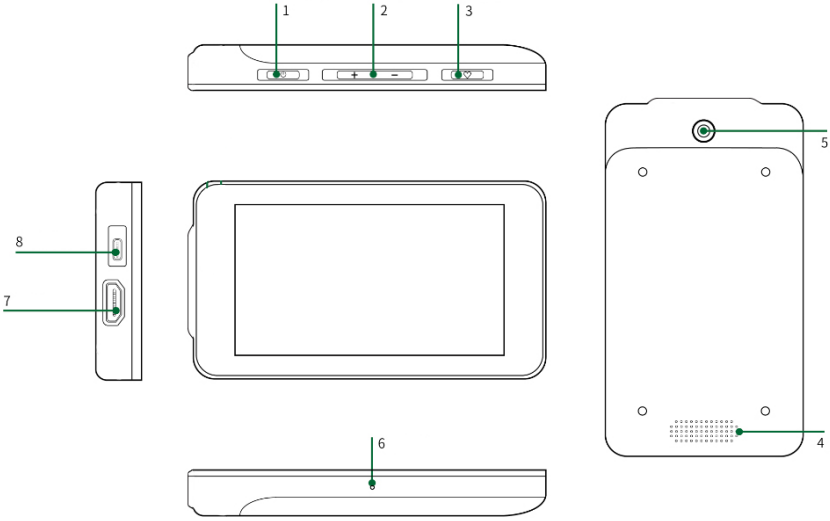
⚠ Warning

Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.

⚠ Warning

Reuse of disposable accessories may cause a risk of contamination and reduce the performance of the device.

2.5 Product View



1 Power On/Off key

- Power On: In the shutdown state, press and hold this key until the startup screen pops up.
- Power Off: In any state of power on, long press this key will bring up the power off confirmation screen. If you select “OK”, the display screen turns black after the device has been turned off.
- In standby mode, press this key to rest or light up the screen.

2 Volume adjustment key

- Press and hold the volume key “+”, the volume can be adjusted to the maximum.
- Press and hold the volume key “-“, the volume can be adjusted to mute.

3 Acquisition button

Press this button to start ECG acquisition.

4 Speaker holes

Give notification tone, heartbeat tone, etc.

5 Camera

Scan the code type supported to input patient information.

6 Microphone

Voice microphone, reserved function.

7 ECG cable connector

Connect the ECG cable for ECG acquisition.

8 USB connector

- Connect a USB drive for data transmission.
- Connect a USB printer.
- Charge the polymer lithium battery.

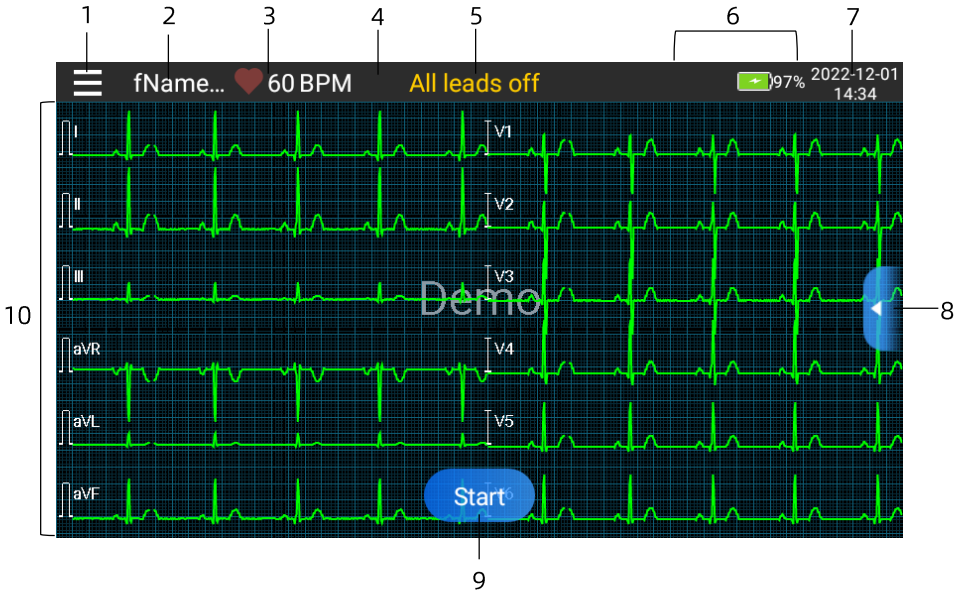
2.6 Function Features

- Portable design, compact in size with low weight, easy for carry.
- Color touch screen, easy to operate.
- Can be powered by an external DC power supply or a built-in rechargeable lithium battery.
- Support synchronous acquisition and display of 6-lead / 12-lead waveform, as well as heart rate detection.
- Provide ECG algorithm to automatically analyze the acquired ECG waveform, output measured values and diagnosis results.
- Support auto mode and R-R mode.
- Provide 4 sampling modes: pre-sampling, real-time sampling, periodic sampling and trigger sampling.
- Support automatic pacing detection and marking.

- Support ADS (Anti-drifting system) and EMG (electromyograph) interference.
- Accurately identify the electrode with poor contact and give instructions.
- Input patient information via full keyboard and barcode scanning.
- Freeze the ECG waveform on the screen.
- Output files in multiple formats, such as Carewell ECG, PDF, BMP, DAT.
- Auto-saving function: save the ECG data when the report is printed.
- Store, preview, review, edit, export, print and search patient data.
- Support wireless transmission of ECG data via Wi-Fi network.
- Print ECG reports through an external printer.
- Export patient data to USB drive via USB connector.

2.7 Screen Display

After turning on the device, the ECG acquisition screen is displayed, as shown in the figure below:



1 Menu Expand / Hide button

Click the [☰] button in the upper left corner of the main screen to open the system menu. After the menu is expanded, click the [☰] button again to hide the menu.

In the expansion window, you can perform the following operations:

- Freeze

  After clicking the [Freeze] button, the ECG waveforms stop refreshing and scrolling.

  You can switch the speed, sensitivity and lead of the frozen waveform, as well as manually add or modify diagnosis results, store and print ECG reports. For more information, see *4.5 Freezing Waveforms*.

- File

  Click the [File] button to enter the patient file management screen, where you can add and modify patient information, re-sample for the patient, view, query, export and print ECG report. For more information, see *4.9 File Management*.
- Setup

  Click the [Setup] button to set the device comprehensively. For more information, see *Chapter 5 System Setup*.

2 Patient information area

- The patient information area displays the patient name, which is not displayed if no name is entered.
- Click the patient information area to enter the Patient Info screen to view and edit the detailed patient information.

3 Heart rate (HR) area

- Display the heartbeat symbol and real-time HR value and unit. The refreshing speed of the dynamic icon is the same as the heart beating speed.
- When the HR exceeds the detectable HR range, the HR value area is displayed as "-".
- 0 means cardiac arrest, displayed as 0.
- When all leads / rhythm leads fall off, the HR will be displayed as "-" by default.

4 Lead indication area

Click this area to view the electrode connection diagram and connection status in the popup window.

The identifier and position of the electrodes that fell off are displayed in yellow, and that not fell off are displayed in green.

5 Prompt information area

Display prompt information such as "All leads off", "HR overrange".

6 Status display area

Display the current network, internal battery, external power, and external USB device connection status of the device.

- Wireless networks

  If a Wi-Fi wireless network is connected, the Wi-Fi icon and signal strength will be displayed.

  Not displayed when not connected.

- Battery

  If a battery is installed, the battery icon and the percentage of remaining battery power will be displayed.

  Not displayed when not installed.

- Power supply

  If a DC power supply is connected, the DC power icon will be displayed.

  Not displayed when not connected.

- USB device

  If a USB device, such as USB printer, USB flash disk, etc., is connected, the USB device icon will be displayed.

  Not displayed when not connected.

7 System time area

Displays the system date and time. The time format can be set to 12h or 24h.

8 Quick key menu

At the middle right side of the main screen, there is expand/hide quick key menu, you can perform quick setting of low-pass filter, sensitivity and speed.

9 Start / Stop button

- Click the [Start] button to start the acquisition and printing operation immediately.
- During acquisition and printing, click the [Stop] button to stop the acquisition or printing operation immediately.

10 Waveform area

- Displays the ECG waveform.
- The waveform layout is the same as the waveform display format set in different working modes.

2.8 Operating Modes

2.8.1 Routine Use

When the device is turned on, it automatically enters the routine use mode, which is most frequently used clinical mode. In this mode, you can perform ECG test, record waveforms, measured values and analysis results, set up the system, print and export ECG reports.

2.8.2 Standby Mode

When there is no user operation and all leads off within the set time, the device automatically enters the standby mode if the device is inactive for a predefined time limit.

To set the time to automatically enter the standby mode, follow the steps below:

1. Click [] button in the upper left corner of the main screen to open the menu screen.
2. Click the [Setup] button to enter the setting screen.
3. Click [System Setup] → [Other Setup] → [Auto Standby].
4. Set the time to automatically enter standby mode.

In the standby mode, the display screen is black, and the device enters the power saving state.

To exit the standby mode, short press the Power On/Off key or click the touchscreen.

2.8.3 Demo Mode

In this mode, the device can demonstrate its main functions when a patient or patient simulator is not connected.

To enter the demo mode, follow the steps below:

1. Click [] button in the upper left corner of the main screen to open the menu screen.
2. Click the [Setup] button to enter the setting screen.
3. Click [System Setup] → [Demo].
4. Select [Normal ECG] or [Abnormal ECG].

When the demo mode is enabled, both the waveform area of the acquisition screen and the parameter information area at the bottom left of the printed report display the word "Demo".

To exit the demo mode, click the exit button in expand/hide quick key menu in the middle right side of the screen.

⚠ Warning

The Demo mode is mainly used to show the performance of the device and to train users. In clinical use, do not set the device to Demo mode when connecting patients, to avoid mistaking the Demo waveform for patient's waveform, which may result in delayed diagnosis and treatment.

2.9 Date of Manufacture and Service Life

The service life of the device is 5 years. Please refer to the label on the back of the device for the date of manufacture.

Chapter 3 Operation Preparations

3.1 Unpacking and Checking

Before unpacking, examine the packaging carefully for signs of damage. If any damage is found, please contact the carrier immediately.

If the packaging is intact, perform unpacking inspection according to the following steps:

1. Open the package and take out the device and accessories carefully.
2. Check all materials according to the packing list.
3. Check the device for any mechanical damage.
4. Check the accessories for scratches or defects.

Contact us in case of any problems.

> ⚠ **Warning**
>
> **Keep the packaging materials out of the reach of children. When disposing of the packaging materials, be sure to comply with your local waste control regulations or the hospital's waste disposal system.**

3.2 Preparing the Device

The device preparation includes the following steps:

1. Using the Battery
2. Using the DC Power Supply
3. Connecting the ECG Cable
4. Inspections Before Power-On
5. Turning On the Device
6. Setting Up the Device
7. Connecting the Printer

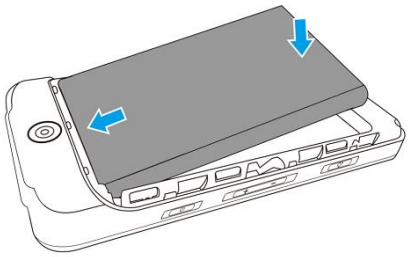
3.2.1 Using the Battery

The device can be powered by a rechargeable lithium battery. When a battery is installed, the device will automatically run from battery power in case of power failure of the DC power supply.

- Installing the Battery

To install or replace the battery, follow the steps below:

1. Press and hold the device's back cover, and pull it down to remove the back cover.
2. Place the battery at the corresponding position of the battery compartment, as shown in the following figure.



3. Reinstall the back cover and push to snap it in place.

- Charging the Battery

Because of the power consumption during the storage and transportation, the battery capacity may not be full, so it is necessary to charge the battery before using it for the first time.

The battery is charged whenever the device is connected to a DC power source regardless of whether or not the device is currently turned on.

When the device is on, the battery power icon in the upper right corner of the main screen will dynamically display the charging state of the battery.

For charge time and run time of the battery, see *A.3 Physical and Hardware Specifications*.

3.2.2 Using the DC Power Supply

To connect the DC power supply to the device, follow the steps below:

1. Plug the USB cable Type-A connector into the USB power supply connector.
2. Insert the USB cable Type-C connector into the USB connector of the device.

> ☞ **Note**
>
> **When the battery is fully charged, the charging indication symbol will stop rolling. In this case, disconnect the USB cable Type -C connector from the device and then disconnect the USB cable Type -A power supply connector.**

3.2.3 Connecting the ECG Cable

Connect the ECG cable to the ECG cable connector of the device.

> ⚠ **Warning**
>
> **As the ECG cable connector uses a universal HDMI connector, to ensure accurate ECG data acquisition, the ECG cable provided by the manufacturer must be used to avoid misuse.**

3.2.4 Inspections Before Power-On

To ensure the safe and effective operation of the device, perform the following inspections before power-on and operation.

- Operating Environment:

Make sure that there is no electromagnetic interference source around the device, such as electrosurgical device, ultrasonic diagnostic device, radioactive device, etc. Switch off these devices when necessary.

- Battery:

Check that the battery is installed and fully charged.

- ECG Cable:

Make sure that the ECG cable is firmly connected to the device.

3.2.5 Turning On the Device

Press the Power On/Off key for less than 2 seconds to turn on the device, it will enter the startup screen, and then enter the main screen.

3.2.6 Setting Up the Device

Set up the device before using it for the first time:

1. Click the [] button in the upper left corner of the main screen to open the menu screen.
2. Click the [Setup] button to enter the setting screen.
3. Set the system date and time, touch tone and other items as required.

For more information about device settings, see *Chapter 5 System Setup*.

3.2.7 Connecting the Printer

To use an external printer, select [Setup] → [Record Setup], and set [Print Device] to [Network Printer] or [USB Printer].

- When selecting [Network Printer], you need to set the IP address and port number of the network printer, and use it after the connection is successful.

- When selecting [USB Printer], plug the USB cable supplied with the printer into the USB adapter which has been inserted into the device. Make sure the USB printer is connected successfully.

3.2.8 Turning Off the Device

Follow the steps below to turn off the device:

1. Confirm that the patient's ECG test has been completed.
2. Remove the electrodes from the patient.
3. Press and hold the Power On/Off key for about 3 seconds, the screen displays a prompt message, and the device shuts down after your power off confirmation.

Caution

Press and hold the Power On/Off key for no less than 6 seconds to forcibly shut down the device if it could not be shut down normally. However, this operation may cause data loss or corruption, please proceed with caution.

3.3 Preparing the Patient

3.3.1 Setting Patient Information

Certain patient information directly affects ECG analysis, correct and complete patient information is helpful to the accuracy of analysis and treatment of the patient. Patient information is classified as required information and detailed information. The required information must be entered. In the [Patient Info] screen, an asterisk (*) is placed behind the required information. The detailed information helps you to know more about the patient.

To set patient information, follow the steps below:

1. In the main screen, click [] → [Setup] to enter the setting screen.
2. Click [Patient Info] to enter the patient information setting screen.
3. Select the required information items, patient ID generation mode, etc.

For specific setting information, see *5.2 Patient Info Setup*.

3.3.2 Entering Patient Information

Use any of the following methods to enter patient information before taking an ECG test.

- Enter patient information manually
- Read patient ID with the device's camera
- Read patient ID with a barcode reader

✦ **Entering Patient Information Manually**

To manually enter the patient information, follow the steps below:

1. Access the Patient Info screen in either of the following ways:
   - Click the patient information area in the main screen to open the Patient Info screen.
   - Click [] → [File] → [Patient Info] to enter the patient information screen.
2. Enter the patient information.
3. Click the [OK] button to save the patient information.
4. Click the [Reset] button to clear and re-enter the patient information.
5. Click the [Cancel] button to exit without saving the patient information.

Note

You can save patient information only when all the required patient information is entered.

✦ **Reading Patient ID with the Device's Camera**

To read the patient ID with the built-in camera of the device, follow the steps below:

1. Click the [] button beside the patient ID input box.
2. Use the device's camera to scan the linear barcode or QR code to enter the decoded content into the patient ID input box.
3. Enter other patient information manually.
4. Click the [OK] button to save the patient information.

✦ **Reading Patient ID with a Barcode Reader**

To read the patient ID with the barcode reader, follow the steps below:

1. Connect the barcode reader to the USB connector of the device.
2. Press down the button on the reader handle, and target the reader to the barcode. Then the [Patient Info] menu pops up with the patient ID entered.

Warning

After scanning, please check the scanning result to ensure that the correct patient information is entered.

3.3.3 Preparing the Patient Skin

The patient's emotions and body conductivity can obviously affect the quality of ECG. To properly preparing the patient, follow the steps below:

1. Ask the patient to lie down comfortably and be relaxed.

2. Remove the clothing from the patient where the electrode was placed.
3. Clean the skin where the electrodes are placed with alcohol. Shave hair from electrode sites, if necessary. Excessive hair prevents a good connection.

3.3.4 Applying Electrodes

The quality of ECG waveform will be affected by the contact resistance between the patient and the electrode. In order to get a high-quality ECG, the skin-electrode resistance must be minimized when you attach electrodes to patients.

To apply electrodes, follow the steps below:

1. Prepare the skin as describe in *3.3.3 Preparing the Patient Skin*.
2. Attach the snaps to the electrodes prior to placement.
3. Place the electrodes firmly on the correct sites. See *3.3.5 ECG Electrode Placement* for details.

Caution

To ensure accurate ECG test, please select the appropriate electrode type and pay attention to the placement position of the electrodes.

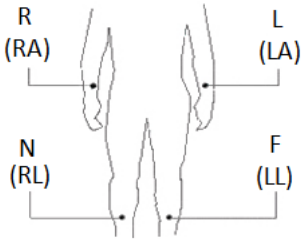
Caution

If any side-effect such as allergic or itchy reaction is found, remove the electrodes from the patients immediately.

3.3.5 ECG Electrode Placement

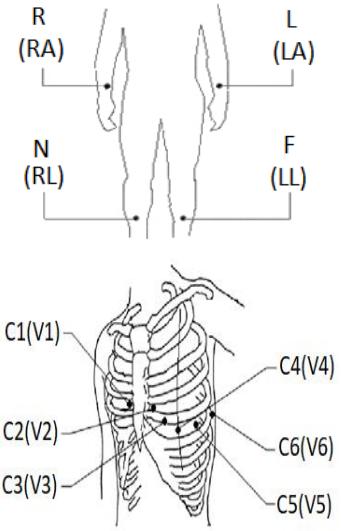
Place the electrodes on the patient according to the lead type you have chosen. The following figures show the typical position of electrode placement.

✦ **6-lead Electrode Placement**



IEC Standard		AHA Standard		Electrode Placement Position
Identifier	**Color Code**	**Identifier**	**Color Code**	
R	Red	RA	White	Right arm
L	Yellow	LA	Black	Left arm
F	Green	LL	Red	Left leg
N	Black	RL	Green	Right leg

✦ **12-lead Electrode Placement**



IEC Standard		AHA Standard		Electrode Placement Position
Identifier	Color Code	Identifier	Color Code	
R	Red	RA	White	Right arm
L	Yellow	LA	Black	Left arm
F	Green	LL	Red	Left leg
N	Black	RL	Green	Right leg
C1	White/ Red	V1	Brown/ Red	On the fourth intercostal space at the right sternal border.
C2	White/ Yellow	V2	Brown/ Yellow	On the fourth intercostal space at the left sternal border.
C3	White/ Green	V3	Brown/ Green	Midway between C2 (V2) and C4 (V4) electrode position.
C4	White/ Brown	V4	Brown/ Blue	On the fifth intercostal space at the left midclavicular line.
C5	White/ Black	V5	Brown/ Orange	On the left anterior axillary line, horizontal with the C4 (V4) electrode position.
C6	White/ Violet	V6	Brown/ Violet	On the left midaxillary line, horizontal with the C4 (V4) electrode position.

Caution

For actual use, please place the electrodes according to the physician's advice.

Chapter 4 Operation Instructions

4.1 Selecting the Lead Mode

The device supports 2 lead modes: 6-lead and 12-lead.

To select the lead mode, follow the steps below:

1. In the main screen, click [] → [Setup] to enter the setting screen.
2. Click [ECG Setup] to select the required [Lead Mode].
3. Return to the main screen after setting.

4.2 Selecting the Sampling Mode and Time

To select the sampling mode and set the sampling time, follow the steps below:

1. In the main screen, click [] → [Setup] to enter the setting screen.
2. Click [ECG Setup] → [Sampling Mode] to set the sampling mode.
3. Click [Sampling Setup] to set the sampling time as needed.
4. Return to the main screen after setting.

The device supports 5 sampling modes: Real-time, Pre-sampling, Periodic, Trigger and R-R.

- When sampling mode is set as [Real-time], 10s ECG data acquired from the time of pressing the [Start] button will be recorded.
- When sampling mode is set as [Pre-sampling], 10s ECG data acquired before pressing the [Start] button will be recorded.
- When sampling mode is set as [Periodic], after the periodic printing interval and periodic printing length have been

set, the waveform, patient information, data measurement and analysis results will be automatically printed at regular intervals until the end of the periodic printing time.

- When sampling mode is set as [Trigger], if an arrhythmia occurs during the examination, the device will automatically trigger the printing and print out the waveform of the arrhythmia.
- When sampling mode is set as [R-R], you can perform waveform acquisition and data analysis for a lead for up to 180s, which is convenient for physicians to make detailed observations.

4.3 Setting ECG Waveform and Report

Set the ECG waveform and report before starting an ECG test.
Operation procedures:

1. Click the quick keys at the middle right side of the main screen to set the low-pass filter, sensitivity and speed respectively.
2. Click [Setup] → [ECG Setup] and [Record Setup] to check other waveform setting items and report setting items, and make relevant settings as needed.

For more information, see *Chapter 5 System Setup*.

4.4 Acquisition and Analysis

After the ECG waveform is stable, click the [Start] button, the device starts recording the ECG waveform. After the ECG data is acquired for the set time period, the device automatically starts analysis, and selects whether to print ECG report according to the settings.

If the [Preview] option in the [ECG Setup] screen is disabled, the device automatically prints the ECG report after ECG data is acquired and analyzed.

If the [Preview] option in the [ECG Setup] screen is enabled, the preview of waveforms displays after ECG data is acquired and analyzed. You can do the following operations in the preview screen:

- Select [I] in the lead selection area in the lower left corner of the thumbnail area to switch the lead whose waveform needs to be observed.
- Select [10mm/mV] in the expand menu to modify the amplitude of the waveform.
- Select [25mm/s] in the expand menu to modify the display speed of the waveform.
- Select [Diagnosis] in the expand menu to re-analyze or modify the diagnosis results, or confirm the auto analysis result.
- Select [Save] in the expand menu to save the report.
- Select [Print] in the expand menu to print the report.
- Select the return icon in the upper left corner of the screen to return to the main screen.

Caution

The isoelectric segments within the QRS are included in the Q-, R- or S-waves. The isoelectric parts (I-wave) after global QRS-onset or before global QRS-offset (K-wave) are included in the duration measurement of the respective adjacent waveform.

4.5 Freezing Waveforms

You can freeze the currently displayed waveforms on the screen. The frozen waveform is the 130 seconds waveform

before pressing the freeze button. If the data are less than 130 seconds, the waveform of the actual duration from the beginning of waveform refresh to the time when the button is clicked is displayed. If the ECG data is less than 10 seconds before freezing, it is necessary to wait for the device to collect enough data for 10 seconds before freezing.

In the main screen, click [] → [Freeze] to enter the waveform freezing screen. You can do the following operations:

- Slide the waveform left and right for a careful observation.
- Select [I] in the lead selection area in the lower left corner of the thumbnail area to switch the lead whose waveform needs to be observed.
- Select [10mm/mV] in the expand menu to modify the amplitude of the waveform.
- Select [25mm/s] in the expand menu to modify the display speed of the waveform.
- Select [Diagnosis] in the expand menu to edit the analysis result.
- Select [Save] in the expand menu to save the report.
- Select [Print] in the expand menu to print the report.
- Select the return icon  in the upper left corner of the screen to return to the main screen.

4.6 Printing Reports

You can print ECG reports through an external printer. See *3.2.7 Connecting the Printer* for methods for connecting the printer to your device.

Before printing a report, check that the paper is properly loaded. To load the paper for the external printer, refer to the printer's accompanying instructions for use.

See *0Appendix C* Supported Printers for the printer models supported by the device.

You can also export reports from the device to a USB flash disk, and then import them to your computer for storage or printing.

> ☞ **Note**
>
> **If the [Printout] option in the [Record Setup] screen is disabled, click the [Start] button to save but cannot print the ECG report.**

4.7 Saving a Report

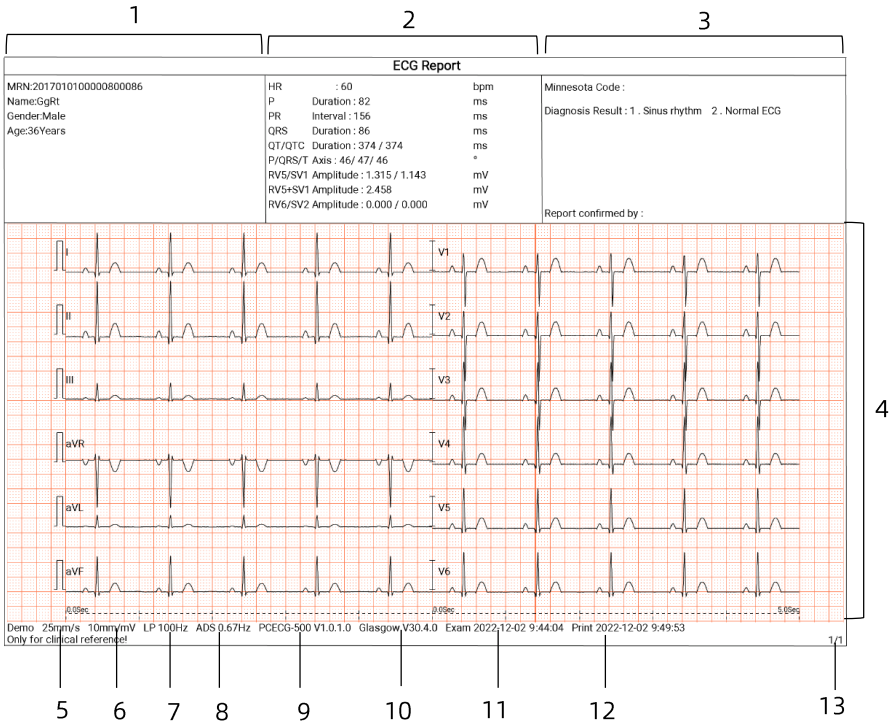
If the [Auto Save] option in the [ECG Setup] screen is enabled, a patient record is automatically created and saved at the completion of each measurement. You can search, review, print, send, export or delete the historic patient records from the [File] screen. Refer to *4.9 File Management* for details.

If [Auto Save] is disabled, you can select [Save] in the preview window to manually save a report.

4.8 ECG Report

- **Example 1**

The following figure takes a 6x2 real-time sampling ECG report under the 12-lead mode as an example to illustrate the elements in the report.



1 Patient information area

2 Measurement parameters area

3 Diagnosis result area

4 Waveform area

5 Speed

6 Sensitivity

7 Lowpass filter
8 ADS filter
9 System software version
10 Algorithm software version
11 Examination date and time
12 Print data and time
13 Page information

A report usually includes waveform area, patient information area, measurement parameter area, diagnosis result area. You can also select to print the average template (only available for 6-lead) and measurement matrix information.

Measurement parameters include:

HR (Heart rate) (bpm), P Duration (ms), PR Interval (ms), QRS Duration (ms), QT/QTc Duration (ms), P/QRS/T Axis (°), RV5/SV1 Amplitude (mV), RV5+SV1 Amplitude (mV), RV6/SV2 Amplitude (mV)

Diagnosis result:

Shows the auto diagnosis result.

Average template:

Gives the average value of 10s acquired ECG signal of each lead.

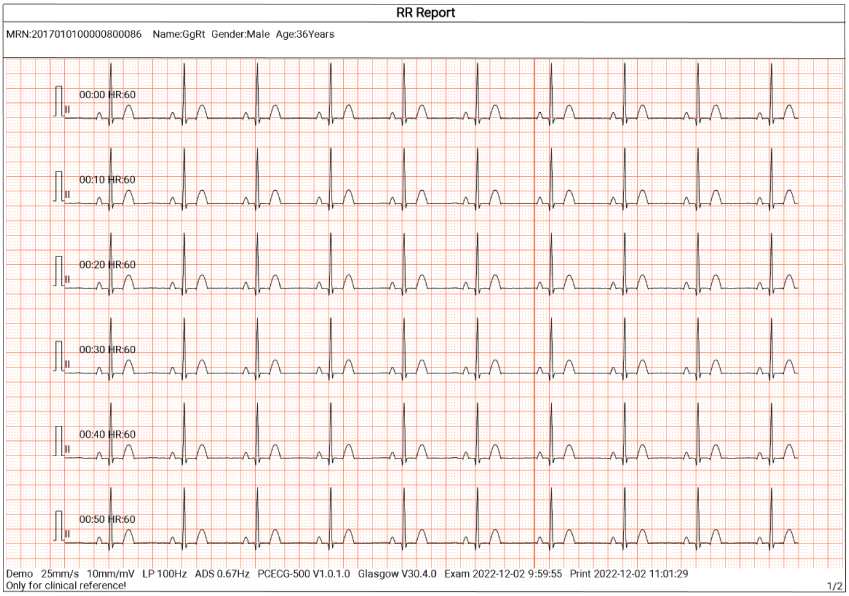
Measurement matrix:

Gives 14 measurements of each lead, including:

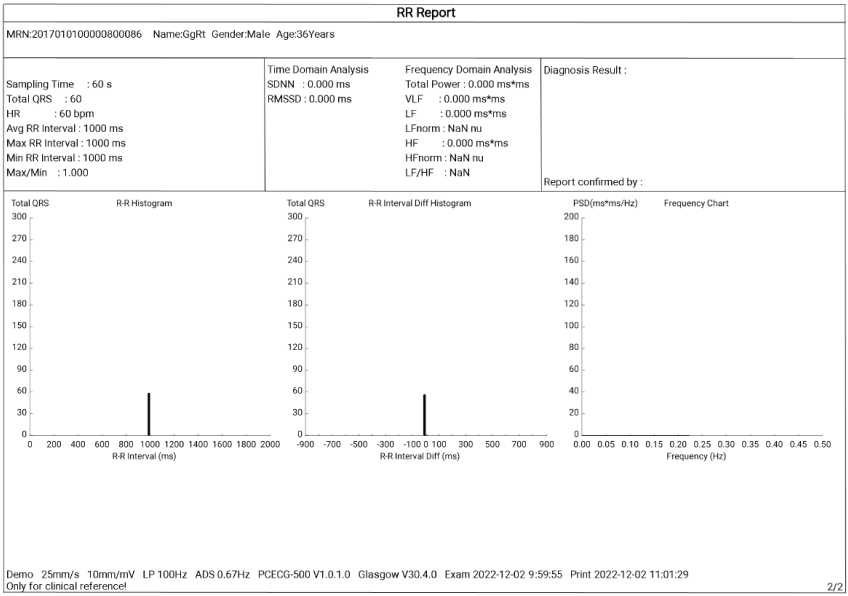
P amplitude (mV), Q amplitude (mV), R amplitude (mV), S amplitude (mV), T amplitude (mV), ST1 amplitude (mV), STJ amplitude (mV), ST20 amplitude (mV), ST40 amplitude (mV), ST60 amplitude (mV), ST80 amplitude (mV), Q duration (ms), R duration (ms), S duration (ms)

- **Example 2**

The following is a sample of single lead ECG record in the R-R mode.



Page 1 - 1min rhythm waveform of lead II



Page 2 – R-R measurement and analysis result

In the R-R mode, ECG analysis provides:

Measurement parameters include:

Sampling Time (s), Total QRS, HR (bpm), Average RR Interval (ms), Max RR Interval (ms), Min RR Interval (ms), Max/Min (Ratio of Maximum RR Interval to Minimum RR Interval)

Time-domain analysis index:

SDNN (Standard Deviation of Normal to Normal Intervals) (ms)

RMSSD (The Root Mean Square Successive Difference) (ms)

Frequency-domain analysis index:

Total Power (ms*ms), VLF (extremely low frequency, ms*ms), LF (low frequency, ms*ms), LFnorm (nu), HF (high frequency ms*ms), HFnorm (nu), LF/HF

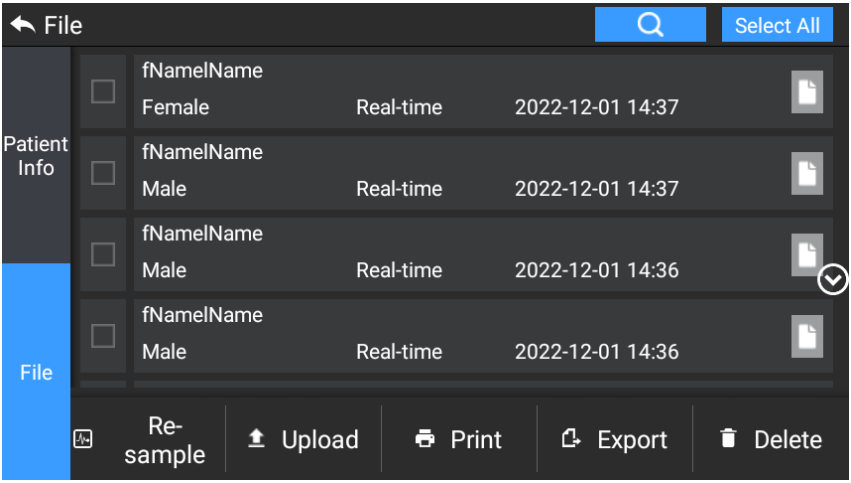
RR Histogram

RR Interval Diff Histogram

Frequency Chart

4.9 File Management

In the main screen, click [☰] → [File] to enter the patient file management screen, as shown in the figure below.



In this screen, all files are listed in chronological order, and the latest files are displayed on the top. You can re-acquire, upload, preview, edit, export, print, query and delete the stored historical files.

Button	Description
Re-sample	Click to re-acquire ECG for the selected patient.
Upload	Click to upload one or more selected patient reports to the FTP server.
Print	Click to print one or more selected patient reports.
Export	Click to export the currently selected report. The system supports exporting reports to USB drive in any format of Carewell ECG, PDF, BMP and DAT.
Delete	Click to delete one or more selected patient data.

Button	Description
	The search condition setting window pops up after clicking this button. You can set relevant search conditions for precise search.
Select All / Unselect All	Click to select all / deselect all patient data.

4.10 Sending Reports

The device can be connected with the FTP server through the wireless network to send the patient's ECG reports. When an ECG report is generated, it will be sent to the FTP server automatically.

To connect the FTP server, follow the steps below:

1. In the main screen, click [] → [Setup] to enter the setting screen.
2. Select [Comm. Setup].
3. Enable [WLAN] and connect the network.
4. Set the FTP communication, including the IP address, port, username and password of the FTP server.
5. Click the [Test] button in the top right corner of the FTP Setup screen to test whether FTP communication is successful.
6. Set the file format of the reports uploaded to the FTP server.
7. Set the path mode. Options: Auto, Manual.
8. Set the path to which reports are uploaded if [Path Mode] is set to [Manual].

☞ **Note**

The upload path format is default to yyyy/MM/dd/id (where id refers to the patient ID) and cannot be modified when the [Path Mode] is set to [Auto].

You can manually send the patient's reports in the following way:

1. In the main screen, click [] → [File] to enter the patient file management screen.
2. Select the patient report(s) to be sent.
3. Select [Upload] to send the selected report(s) to the FTP server.

Chapter 5 System Setup

In the main screen, click [] → [Setup] to enter the setting screen.

☞ **Note**

The underlined options in the following table are the system default settings.

5.1 ECG Setup

Menu Items	Description
Sampling Mode	Real-time, Pre-sampling, Periodic, Trigger, R-R
Lead Setup	
Lead Mode	6-lead, 12-lead
Layout	Waveform display format of the corresponding lead mode. For 6-lead: 6×1, 3×2 For 12-lead: 6×2
Lead Standard	IEC, AHA
Lead Sequence	Standard, Cabrera Standard: the sequence is I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6. Cabrera: the sequence is aVL, I, -aVR, II, aVF, III, V1, V2, V3, V4, V5, V6.
Rhythm Setup	
Rhythm Type	Single Lead, Three Leads

Menu Items	Description
Rhythm Lead 1	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Rhythm Lead 2	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Rhythm Lead 3	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Display Setup	
Speed	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s
Sensitivity	2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV
Filter Setup	
ADS Filter	0.05Hz, 0.32Hz, 0.67Hz
EMG Filter	25Hz, 35Hz, 45Hz, Off
Lowpass Filter	75Hz, 100Hz, 150Hz, Off
Other Setup	
Preview	On, Off
Auto Save	On, Off

5.2 Patient Info Setup

Menu Items	Description
Patient Info Configuration	
Required Patient Info	Patient ID, Last Name, First Name, Gender, Age, Date of Birth

Menu Items	Description
Detailed Patient Info	Height, Weight, Blood Pressure, Medication, Medical History
Basic Setup	
Height/Weight Unit	cm/kg, inch/lb
Blood Pressure Unit	mmHg, kPa
Patient ID	Auto Accumulation, Manual Input

5.3 Sampling Setup

Menu Items	Description
Sampling Time Setup	
Periodic	Manually enter an integer number in minutes into the text box The input range is 1-60 Min, and the default value is 60 Min
Periodic Interval	Manually enter an integer number in minutes into the text box The input range is 1-60 Min, and the default value is 1 Min ☞ **Note** **The periodic interval cannot be greater than the total time of periodic sampling.**
RR	1 Min, 3 Min

5.4 Record Setup

Menu Items	Description
Print Setup	
Print Sequence	Synchronous, Sequential
Layout	Waveform display format in the generated report. For 6-lead: 6×1, 3×2 For 12-lead: 12x1, 6x2, 6x2+1R, 3x4, 3x4+1R, 3x4+3R ☞ **Note** **The options are Single Lead and Three Leads for R-R mode.**
Printout	On, Off
Print Device	Network Printer, USB Printer
Network Printer	
Network IP	When [Network Printer] is selected for [Print Device], set the network IP and port.
Port	
Test	Click this button to test whether the network printer is connected successfully.
Printout Grid	On, Off
Report Setup	
Measurement Parameters	Select whether Measurement Parameters are included in the ECG report generated by auto measurement. Checked by default.

Menu Items	Description
Average Template	Select whether Average Template is included in the ECG report generated by auto measurement. Unchecked by default.
Diagnosis Result	Select whether Diagnosis Result is included in the ECG report generated by auto measurement. Checked by default.
Minnesota Code	Select whether Minnesota Code is included in the ECG report generated by auto measurement. Unchecked by default.
Print Time	Select whether Print Time is included in the report. Checked by default.
Measurement Matrix	Select whether Measurement Matrix is included in the ECG report generated by auto measurement. Unchecked by default.
Time Scale	Select whether Time Scale is included in the ECG report generated by auto measurement. Checked by default.

5.5 Communication Setup

5.5.1 WLAN

Turn on or turn off the [WLAN] switch to enable or disable the WLAN.

When [WLAN] is enabled, the device starts to search for available wireless networks in the area. Select the one you would like to connect. If the wireless network is secured, a window requiring password will pop up. Enter the correct

password, then click [Connect]. In a short while, a wireless connection is set up.

5.5.2 FTP Setup

Menu Items	Description
IP Address	Enter the IP address of the FTP server.
Port	Enter the FTP port.
Username	Enter the FTP username.
Password	Enter the FTP password.
Upload Format	PDF, BMP, Carewell ECG, DAT
Path Mode	Auto, Manual
Upload Path	Enter the path to which reports are uploaded if [Path Mode] is set to [Manual]. The upload path format is default to yyyy/MM/dd/id and cannot be modified when the [Path Mode] is set to [Auto].

5.6 System Setup

Menu Items	Description
Display & Sound	
Language	Select the UI language.
Demo	Options: Off, Normal ECG, Abnormal ECG
Low Battery Beep	On, Off
Print End Beep	On, Off

Menu Items	Description
Lead Off Beep	On, Off
Touch Tone	On, Off
QRS Beep	On, Off
Date & Time	
Current Date	Set the current date
Current Time	Set the current time
Date Format	Options: yyyy-mm-dd, mm-dd-yyyy, dd-mm-yyyy
Time Format	Options: 12h, 24h
Other Setup	
Auto Standby	Set the time for the device to automatically enter standby mode. Options: Close, 5 Min, 10 Min, 20 Min, 30 Min, 60 Min When you select [Close], the device will not automatically enter the standby mode.
Institution Name	Enter the name of the medical institution.
Other function	
System Upgrade	Click to upgrade the system via USB flash disk files.
Restore Default Settings	Click to confirm whether to restore the default settings. This operation will restore all settings to their default values (record data will not be deleted).

5.7 System Maintenance

In the setting screen, click [System Setup] → [System Maintenance] to enter the system maintenance screen.

Menu Items	Description
AC Frequency	Options: Off, 50Hz, 60Hz
SCP	It can be enabled after entering the correct authorization key for this format.
HL7	It can be enabled after entering the correct authorization key for this format.
DICOM	It can be enabled after entering the correct authorization key for this format.
QR Code Setting	Set the start address and end address of each field, as well as the gender code. You can add other field according to your actual need by clicking +.

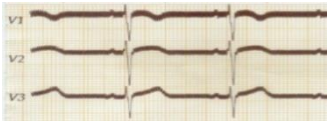
5.8 Factory Maintenance

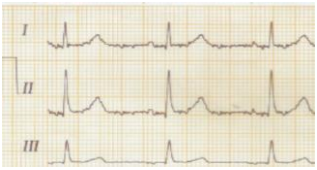
In the setting screen, click [System Setup] → [System Maintenance] → [Factory Maintenance], enter the required password to access the factory maintenance menu. You can:

- Export Log
- Factory Upgrade
- Restore Factory Settings

Chapter 6 Prompt Messages and Troubleshooting

No.	Messages or Troubles	Solutions
1	*XX lead off (All leads off)*	1. Check the corresponding electrode(s). Re-apply or replace the electrode(s) if necessary. 2. Check that the ECG cable is properly connected to the device.
2	*Low battery!*	Charge the battery immediately.
3	*Battery depleted. Power off soon.*	Connect the DC power supply to power the device and charge the battery immediately.
4	*Export failed*	Check the USB device and export data again.
5	*Insufficient memory space*	Delete unwanted historical files or change the storage device / location.
6	Some Lead without Waveform Printout	If you acquire the ECG data immediately after the leadwires are applied to the patient, the ECG traces may not display because the ADS is not stable yet. Normally it is necessary to wait for the waveform of each lead to be

No.	Messages or Troubles	Solutions
		stable if all leads are in good contact before ECG test.
7	AC Interference Symptom: There is an overlap of 50Hz sine wave with certain amplitude and regularity on the ECG traces, and obvious jitter appears on the ECG baseline.  	Check the following aspects of the device for solving problems: ● The device is properly grounded. ● The electrodes and leadwires are correctly connected. ● Enough conductive paste is applied to the electrodes and the patient's skin. ● Patient bed is properly grounded. ● Patient not come into contact with conducting objects such as metal parts of the patient bed. ● Nobody is touching the patient. ● There is no powerful electrical equipment operating nearby, such as X-ray machines or ultrasonic instruments. ● The patient is not wearing glass or diamond ornaments.

No.	Messages or Troubles	Solutions
		• AC filter frequency is properly set. **If the interference cannot be cleared after the above measures, use an AC filter, and the recorded waveform is slightly attenuated.**
8	EMG Interference Symptom: The ECG has irregular fluctuation while the baseline demonstrates no change. 	Check the following aspects of the device for solving problems: • The room is uncomfortable? • The patient is nervous or feels cold? • The bed is too narrow? • The patient is talking? **If the interference cannot be cleared after the above measures, use an EMG filter, and the recorded waveform is slightly attenuated.**
9	Baseline drift. Symptom: The printed ECG baseline irregularly moves up and down.	Check the following aspects of the device for solving problems: • The electrodes are firmly attached? • The lead wires are properly connected to the electrodes?

No.	Messages or Troubles	Solutions
		● The electrodes and the patient's skin are clean? ● Whether enough conductive paste is applied to the electrodes and the patient's skin. ● During the recording, the patient moves or breathes. ● Mixed use of old and new electrodes. **If the interference cannot be cleared after the above measures, use an ADS filter.**

Chapter 7 Cleaning, Disinfection and Maintenance

Sterilization is not recommended for this device and its accessories, but they should be kept clean. If the device has become contaminated, clean it before disinfection.

7.1 Recommended Cleaning Agents

Supported cleaning agents: water, neutral soap solution, ethanol solution (volume ratio: 70% to 80%).

Supported cleaning tools: cotton ball, soft gauze, soft brush and soft cloth.

7.2 Cleaning

7.2.1 Cleaning the Device

Clean the exterior surface of the device monthly or more frequently if needed. Before cleaning the device, consult your hospital's regulations for cleaning the device.

To clean the device, follow the steps below:

1. Turn off the device and disconnect it from the power cable and ECG cable.
2. Clean the surface of the device with a clean soft cloth moistened with one of the recommended cleaning agents.
3. Wipe off all the cleaning agent residue with a clean dry cloth. Dry your device in a ventilated, cool place.

7.2.2 Cleaning the ECG cable

Before cleaning the ECG cable, remove it from the device.

For the cleaning of the ECG cable, refer to its instructions for use delivered with it.

7.3 Disinfection

Disinfection of the device is not necessary. To avoid permanent damage to the device, disinfection can be performed only when it has been considered as necessary according to your hospital's regulations. Before disinfection, clean the device first.

For the disinfection of the ECG cable, refer to its instructions for use delivered with it.

7.4 Care and Maintenance

To ensure the performance and safety of the device and its accessories, routine care and maintenance should be carried out.

7.4.1 Device

Follow the below guidelines to maintain the device:

- Avoid excessive temperature, sunshine, humidity and dirt. Prevent shaking it violently.
- Prevent any liquid from penetrating into the device, otherwise the safety and performance of the device cannot be guaranteed.
- Regularly check the device's performance by the medical device service department.

7.4.2 ECG cable

Follow the below guidelines to maintain the ECG cable:

- Regularly check the integrity of the ECG cable. Make sure that it is conductible.
- Do not drag or twist the ECG cable with excessive stress while using it.

- Hold the connector plug instead of the cable when connecting or disconnecting the ECG cable.
- When the ECG cable is not to be used, coil it with a larger diameter or hang it up to avoid twisting or folding at acute angles.
- Once damage or aging of the ECG cable is found, replace it with a new one immediately.
- For the replacement cycle of the ECG cable, refer to its instructions for use.

7.5 Viewing System Information

When performing maintenance for the device, you may need to check the system information.

In the main screen, click [] → [Setup] → [System Setup], under [My Device], you can view the software version, algorithm version, memory space, scan to input the unique device identifier (UDI) of the device, perform system upgrade and system maintenance, as well as restore default settings.

Appendix A Technical Specifications

A.1 Safety Specifications

Standards	MDD 93/42/EEC	Medical Device Directive
	IEC 60601-1: 2005+A1:2012+A2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	IEC 60601-2-25: 2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
	IEC 60601-1-2: 2014+A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
Classifications	Anti electric-shock type:	Class II
	Anti electric-shock degree:	Type CF applied part

	Degree of protection against harmful ingress of water:	IPX0
	Installation and use:	Portable, not permanent installation device
	Working mode:	Continuous operation
	EMC:	Group I, Class B
	Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas

A.2 Environment Specifications

Environment	Temperature	Relative Humidity (non-condensing)	Atmospheric Pressure
Operating	0℃-40℃	15%-85%	700hPa-1060hPa
Transport & Storage	-20℃-+55℃	15%-95%	700hPa-1060hPa

A.3 Physical and Hardware Specifications

Main unit	Dimensions	134mm × 74mm × 17mm (Width × Depth × Height)
	Weight	About 250g, including the main unit and battery
	Display	4.46 inches, color LCD touch screen Resolution: 480 × 854 pixels
		Rated voltage: 3.8V

Power supply	Built-in rechargeable lithium-ion battery	Rated capacity: 6000mAh
		Run time: When using only the internal battery, under normal conditions, when the battery is fully charged, the device can continuously acquire and send ECG data for more than 24 hours.
		Charge time: Charge the battery for at least 8 hours before using it for the first time. For a depleted battery with the device power off: ≤ 8h to 90% capacity ≤ 10h to 100% capacity

A.4 ECG Specifications

HR Measurement	Method	Peak-peak detection
	Measurement range	30bpm-300bpm
	Accuracy	±1bpm
Main unit	Leads	6/12-lead synchronous acquisition and analysis
	A/D conversion	24 bits
	Sampling rate	2000 samples / sec
	Skew between channels	No skew

	Amplitude quantisation	0.95 μV/LSB
	Common mode rejection ratio (CMRR)	≥100dB (AC filter on)
	Time constant	≥3.2s
	Frequency response	0.05Hz-150Hz $^{+0.4dB}_{-3.0dB}$, 10Hz
	Sensitivity	2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV Accuracy: ±5%
	Filter	AC filter: 50Hz, 60Hz, Off
		EMG filter: 25Hz, 35Hz, 45Hz, Off
		ADS filter: 0.05Hz, 0.32Hz, 0.67Hz
		Lowpass filter: 75Hz, 100Hz, 150Hz, Off
	Speed	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s Accuracy: ±3%
	Input impedance	≥50MΩ (10Hz)
	Calibration voltage	1mV±5%
	Depolarization voltage	±500mV
	Noise	≤30μVp-p

	Pacing pulse display	Pacing pulse with amplitude of 2mV~250mV, duration of 0.1ms~2.0ms, rise time of less than 100μs, and frequency of 100/min can be displayed on the ECG recording.
	ECG input signal range	≤±5mVp-p
	Minimum detectable signal	20μVp-p
Analysis algorithm	CWECG-SLA ECG analysis program (6-lead) Glasgow Resting ECG Analysis Program (12-lead)	

Appendix B EMC and Radio Regulatory Compliance

B.1 EMC Compliance

Basic performance: The device can acquire ECG data normally.

Caution

Users shall use the device according to the EMC information provided in this manual.

Caution

Mobile or portable RF communication equipment may affect the performance of the device. Avoid strong electromagnetic interference when in use, such as microwave ovens, etc.

Caution

When the input signal amplitude is lower than the minimum amplitude (20μVp-p) specified in the technical specifications, the measurement result may be inaccurate.

Caution

The customer or the user of the device should assure that the device is used under the electromagnetic environment specified below, otherwise the device may not work normally.

The guidelines and manufacturer's declaration are detailed in the following tables:

Table 1

Guidance and Manufacturer's Declaration – Electromagnetic Emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Clause 5

Table 2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines
Surge IEC61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
Immunity Test	IEC 60601 Test Level	Compliance Level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

Guidance and Manufacturer's Declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity Test	IEC60601 Test Level				Compliance Level
	Test Frequency	Modulation	Maximum Power	Immunity Level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation : 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation : 217Hz	0.2 W	9 V/m	9 V/m

	810 MHz 870 MHz 930 MHz	**Pulse Modulation : 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation : 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation : 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation : 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

B.2 Radio Regulatory Compliance

The wireless module used in this device is in compliance with IEEE 802.11 ac/b/g/n (2.4G & 5G), and does not cause harmful interference.

Warning

Keep a distance of at least 20cm away from the device when Wi-Fi function is in use.

Appendix C Supported Printers

The device supports the following printers:

Brand	Model
Brother	Brother DCP-L2550DW, Brother HL-5595DNH, Brother DCP-L2535DW, Brother HL-3160CDW, Brother DCP-B7520DW, Brother HL-3190CDW, Brother DCP-B7535DW, Brother DCP-9030CDN, Brother HL-2595DW, Brother MFC-9150CDN, Brother DCP-7195DW, Brother MFC-9350CDW, Brother MFC-B7720DN, Brother MFC-1816, Brother DCP-B7530DN, Brother MFC-1819, Brother DCP-B7500D, Brother MFC-7470D, Brother HL-B2050DN, Brother MFC-9340CDW, Brother MFC-L8900CDW, Brother MFC-9140CDN, Brother MFC-8540DN, Brother DCP-9020CDN, Brother MFC-8535DN, Brother MFC-7895DW, Brother MFC-8530DN, Brother DCP-8060, Brother MFC-7880DN, Brother DCP-8070D, Brother DCP-7180DN, Brother DCP-8085DN, Brother DCP-L8400CDN, Brother DCP-B7535DW, Brother MFC-L8650CDW, Brother HL-2250DN, Brother HL-L9310CDW, Brother HL-2560DN, Brother HL-L8260CDN, Brother HL-5340D, Brother HL-5595DN, Brother HL-5350DN, Brother HL-5590DN, Brother HL-5370DW, Brother HL-5585D, Brother HL-5595DN (H), Brother HL-5580D, Brother MFC-7840N, Brother HL-L9200CDW, Brother MFC-7860DN, Brother HL-6180DW, Brother MFC-8370DN, Brother HL-5450DN, Brother MFC-8460N, Brother HL-5440D, Brother MFC-8510DN, Brother HL-5445D, Brother MFC-8515DN, Brother HL-3170CDW, Brother MFC-8520DN, Brother DCP-7190DW, Brother MFC-8860DN, Brother DCP-7090DW, Brother MFC-8880DN
HP	HP Color LaserJet 2820, HP Color LaserJet 2840, HP COLOR LASERJET MANAGED MFP E77428DN, HP COLOR LASERJET MANAGED MFP E77422DN, HP Color LaserJet CM1015 MFP, HP Color LaserJet CM1017 MFP, HP LASERJET MANAGED MFP E72430DN, HP LASERJET MANAGED MFP E72425DN, HP LaserJet 3050, HP LaserJet 3050z, HP LaserJet 3052, HP LaserJet 3055, HP LaserJet 3390, HP COLOR LASERJET FLOW MFP E87660Z,

Brand	Model
	HP COLOR LASERJET MANAGED MFP E87660DU, HP COLOR LASERJET FLOW MFP E87650Z, HP COLOR LASERJET MANAGED MFP E87650DU, HP COLOR LASERJET FLOW MFP E87640Z, HP LaserJet M3027 MFP, HP LaserJet M3035 MFP, HP COLOR LASERJET MANAGED MFP E87640DU, HP LASERJET FLOW MFP E82560Z, HP LaserJet M4345 MFP, HP LaserJet M5025 MFP, HP LASERJET MANAGED MFP E82560DU, HP LASERJET MANAGED MFP E82550DU, HP LaserJet M5035 MFP, HP Color LaserJet 4730mfp, HP LASERJET MANAGED MFP E82540DU, HP LASERJET MFP M72625DN, HP LASERJET MFP M42525DN, HP Color LaserJet 9500mfp, HP LaserJet 4345mfp, HP LASERJET MFP M42525N, HP LaserJet 9040mfp, HP LASERJET MFP M42523DN, HP LaserJet 9050mfp, HP LASERJET MFP M42523N, HP Color LaserJet 2605, HP LASERJET MFP M439NDA, HP Color LaserJet 2700, HP LASERJET MFP M439DN, HP Color LaserJet 5550, HP LASERJET MFP M439N, HP LASERJET MFP M437NDA, HP LaserJet 1320, HP LaserJet 5200Lx, HP LaserJet 5200, HP LaserJet 5200L, HP LASERJET ENTERPRISE FLOW M830Z MFP, HP LASERJET MFP M437DN, HP LASERJET MFP M437N, HP LaserJet 5200n, HP LaserJet 5200dtn, HP LaserJet 5200tn, HP COLOR LASERJET ENTERPRISE FLOW M880Z, HP LaserJet 9040, HP LASERJET MFP M72630DN, HP LaserJet 9050dn, HP LaserJet 9050n, HP COLOR LASERJET PRO M454DW, HP COLOR LASERJET PRO M454DN, HP COLOR LASERJET PRO M454NW, HP LASERJET PRO M405DW, HP LaserJet 9050, HP Deskjet F388, HP LASERJET PRO M405DN, HP LaserJet P2015, HP LaserJet P3005, HP LASERJET PRO M405D, HP LaserJet M1005, HP LASERJET PRO M305DN, HP LASERJET PRO M305D, HP LASERJET PRO M227FDW, HP LASERJET PRO M405N, HP COLOR LASERJET PRO MFP M479FDW,

Brand	Model
	HP LASERJET PRO M280NW, HP LASERJET PRO M180N, HP COLOR LASERJET PRO MFP M479FNW, HP LASERJET PRO M154A, HP COLOR LASERJET PRO MFP M479DW, HP LASERJET E78325DN, HP LASERJET PRO MFP M429FDW, HP LASERJET E78330Z, HP LASERJET PRO MFP M429FDN, HP LASERJET E78325Z, HP LASERJET PRO MFP M429DW, HP LASERJET E78323Z, HP LASERJET PRO MFP M329DN, HP LASERJET E78330DN, HP LASERJET PRO MFP M329DW, HP LASERJET E78323DN, HP LASERJET PRO M435NW, HP LASERJET E78228DN, HP LASERJET MFP M436N A3, HP LASERJET E78223DN, HP LASERJET MFP M436NDA A3, HP LASERJET PRO M227SDN, HP LASERJET PRO M154NW, HP LASERJET ENTERPRISE 700 MFP M725F, HP LASERJET PRO M254NW, HP LASERJET PRO M254DW, HP LASERJET ENTERPRISE 700 MFP M725Z, HP LASERJET ENTERPRISE 700 MFP M725DN, HP LASERJET PRO M181FW, HP LASERJET PRO M281FDW, HP COLOR LASERJET ENTERPRISE MFP M776DN, HP COLOR LASERJET ENTERPRISE FLOW MFP M776ZS, HP COLOR LASERJET ENTERPRISE FLOW MFP M776Z, HP LASERJET PRO MFP M227D, HP COLOR LASERJET MFP E77830DN, HP LASERJET PRO MFP M227FDN, HP LASERJET PRO M203D, HP COLOR LASERJET FLOW MFP E77830Z, HP M148fdw, HP M148dw, HP COLOR LASERJET MFP E77825DN, HP LASERJET FLOW MFP E82540Z, HP LASERJET MFP E72535DN, HP LASERJET FLOW MFP E82550Z, HP LASERJET FLOW MFP E72535Z, HP M202dw, HP M283FDW, HP LASERJET MFP E72530DN, HP LASERJET FLOW MFP E72530Z, HP LASERJET MFP E72525DN, HP LASERJET FLOW MFP E72525Z

Brand	Model
Epson	Epson M15188, Epson WF-C579Ra, Epson L15188, Epson WF-C20590c, Epson WF-6093, Epson WF-M20590a, Epson WF-6593, Epson WF-C17590c, Epson WF-C869Ra, Epson WF-M20590B, Epson WF-C20590a, Epson WF-M20590c, Epson WF-C17590a, Epson WF-C879Ra, Epson WF-C5790a, Epson WF-C878Ra, Epson WF-C5290a, Epson WF-M21000a, Epson WF-C8190a, Epson WF-M21000c, Epson WF-C8690a
Canon	Canon LBP162dw, Canon LBP722Cx, Canon MF543dw, Canon LBP223dw, Canon LBP225dn, Canon LBP228x, Canon MF449dw, Canon MF443dw, Canon MF441dw, Canon MF643Cdw, Canon MF645Cx, Canon LBP623Cdn, Canon LBP623Cdw, Canon LBP663Cdw, Canon MF266dn, Canon MF269dw, Canon LBP710Cx

☞ Note

For more details about the printer, refer to the document accompanying the printer. With product upgrades, the device may support additional printers without prior notice.