LEPU MEDICAL

Holter Recorder

(Model: TH3 / TH12)

Operator’s Manual

I Foreword

Declaration

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As Carewell will continue to improve the device, the configuration and performance of subsequent models will be changed without notice.

Copyright

Revision

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General Notes

- All illustrations in this manual are only for explanatory purposes and may differ from what is actually seen.
- For buttons, menu items, and text to be entered, use bold format (e.g. **bold**).
- For screen displayed text, prompt information, use italics format (e.g. *italics)*.

II Manufacturer's Liability and Warranty

Liability of Manufacturer

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

- Assembly operations, expansion, readjustment, improvement and repair are performed by personnel authorized by Carewell.
- The electrical device related to the product conforms to national standards.
- Use the device as instructed.

Carewell 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 by personnel not authorized by Carewell.
- Damage caused by abnormal use or beyond specified conditions of use.
- Serial number labels or manufacturing marks are replaced or removed.
- Mis-operation caused by the neglect to the instruction on this manual.

Warranty

✦ Manufacturing Process and Raw Materials

Carewell warrants that the device is manufactured with the required raw materials and processes. In the normal operation and maintenance condition, if Carewell receives reports of manufacturing processes and material failures, it will repair or replace the hardware products.

- **Software or Devices**

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

Shipping and other charges are not included in the above warranty.

Production Date and Service Life

The service life of Holter Recorder is 5 years. Please see the label on the back of main unit for production date.

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Safety Instruction

This manual uses three special messages to highlight information or indicate potential risks to operator or device.

⚠ Warning

Indicates that you should be aware of information about avoid possible injury to the person being examined and medical personnel.

❗ Caution

Indicates that you must strictly follow the procedures to avoid data loss or corruption of the software application files.

☞ Note

Comments provide additional information, such as extended explanations, hints, or reminders.

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Content

Chapter 1 Safety Guideline....1
1.1 Safety Instruction....1
1.2 Precautions....1
Chapter 2 Overview....5
2.1 Intended Use....5
2.2 Contraindications....5
2.3 Intended Users....6
2.4 Structure and Composition....6
2.5 Product Accessories....6
2.6 Symbol Description....7
Chapter 3 Device Appearance....9
3.1 Main Unit....9
3.1.1 Screen....9
3.1.2 Button Description....9
3.1.3 Buzzer....10
3.2 Ports....10
3.2.1 Lead Wire Ports....10
3.2.2 USB Ports....10
3.3 Back of Main Unit....10
Chapter 4 Recording Preparation....11
4.1 Battery Selection....11
4.2 Installation of Accessories....11
4.3 Electrode Slice Placement....13
4.3.1 Electrode Slice Usage....13
4.3.2 Electrode Slices Placement....14
4.3.3 Electrode Slice Replacement....17
4.4 Check before Startup....17
Chapter 5 ECG Recording....18
5.1 Start ECG Recording....18

5.1.1 Starting Steps 18
5.1.2 Waveform Interface 19
5.1.3 Setting Parameters 21
5.2 Recording Process 22
5.3 Stop Recording 22
5.3.1 Stop Recording before the Pre-set Recording Time 22
5.3.2 Record Ends Automatically 23
5.3.3 Take Off the Recorder After Record Ends 24
5.4 Data Replay 24
5.5 Power On/Off 24
Chapter 6 Cleaning, Disinfection and Maintenance 25
6.1 Cleaning 25
6.2 Disinfection 25
6.3 Daily Maintenance 25
Chapter 7 Common Problems and Solutions 27
Appendix A Technical Specifications 28
A.1 Standards 28
A.2 Classification 28
A.3 Environmental Specifications 29
A.4 Performance Specifications 29
A.5 Physical Specifications 30
Appendix B EMC Information 31

Chapter 1 Safety Guideline

1.1 Safety Instruction

For the safe and effective usage of Holter Recorder, please read the operator's manual carefully to avoid possible injury. Before operation, please be familiar with its performances and fully understand the correct operating methods and precautions.

The device must be maintained by qualified engineers authorized by Carewell, otherwise Carewell will not take any responsibilities for its safety, reliability and performance.

Any serious medical incident should be reported to the local competent authority and European representative of our company.

1.2 Precautions

⚠ Warning

Holter Recorder cannot be used for infants weighing less than 10kg.

⚠ Warning

It will result in explosion if Holter Recorder is operated in an environment with flammable anesthetics.

⚠ Warning

Do not use the device while taking a shower as it is not waterproof.

⚠ Warning

Do not use the device in the presence of high-voltage device or high static electricity environment. Otherwise, sparks may occur due to instantaneous discharge.

⚠ Warning

Only authorized maintenance engineers can open the device casing.

⚠ Warning

Please use the lead wires and other matching accessories provided by Carewell. It may damage the device and affect its performance and safety if other types of accessories are used.

⚠ Warning

Holter Recorder can only upload the data to computer via the USB cable provided by Carewell. During uploading data, Holter Recorder cannot be applied to human body. Holter Recorder cannot be used for connection with other devices except uploading data. Superimposed leakage current may exceed the limit.

⚠ Warning

Please ensure all electrode slices are connected to correct position of the subject's body. Avoid the electrode slices (including neutral electrode slices) and subject from contacting any other conductive parts or the ground.

⚠ Warning

Before using the device, please check if the device, lead wires and electrode slices exist any damage that may affect the safety of subjects. Please replace the parts with obvious damages or aging before operation.

⚠ Warning

After reaching the service life, the device and reusable parts should be returned to manufacturer for recycling or disposed according to local regulations.

⚠ Warning

Subjects allergic to lead wires or electrode slices are forbidden to use Holter Recorder.

⚠ Warning

To avoid risk of electric shock, do not touch the patient cable connector during ECG recording.

⚠ Warning

Ensure that the electrode slice not detached from the patient, otherwise it may lead to a hazardous situation.

⚠ Warning

This device is intended to be used by trained clinical professionals. They should be familiar with the contents of this Operator's Manual before operation.

❗ Caution

Please read the relevant operation in this manual. Incorrect operation will result in the loss of all ECG data.

❗ Caution

Please disconnect the lead wire from the subject during defibrillation.

❗ Caution

When the subject is wearing a cardiac pacemaker during the recording, it may generate false positive or negative pacing recording results. Poor electrode slice connection or electrical interference of nearby device may result in pacing pulse misidentification. During bipolar pacing, weak pacing pulse signal from the subject's skin may result in pacing pulse omission.

❗ Caution

Please dispose the waste batteries in accordance with relevant local laws.

Caution

When Holter Recorder is not likely to be used for some time, or there is leakage from the battery, please remove the battery. Battery corrosion will damage Holter Recorder.

Caution

Subjects must stay away from large electrical device or other electromagnetic interference to obtain the best record result. Such as electric blankets and heating pads.

Caution

Please use the accompanying lead wire and SD card. Any damages or accidents caused by using lead wire and SD card unconfirmed by Carewell, Carewell will not be responsible for the safety and other joint liability.

Caution

Please use a compatible SD card confirmed by the manufacturer. The usage of a SD card unconfirmed by the manufacturer may result in abnormal record or incomplete record. Please contact the manufacturer for SD card replacement.

Caution

If the operator ignores the low battery alarm and continues to start recording, Holter Recorder may not record the data for 24 hours.

Chapter 2 Overview

Holter Recorder is intended to record the dynamic electrocardiogram. It can continuously record the electrocardiogram of the subject's different postures in daily life for a long time. Holter is not limited by the detection distance, time, environment, subject activity and posture. In addition to a large amount of detection information storage, it can also detect the transient myocardial ischemia and capture the transient arrhythmia.

TH3 can continuously record 8-lead ECG data for 24 hours. And TH12 can continuously record 12-lead ECG data for 24 hours.

Both TH3 and TH12 Holter Recorders are powered by an AAA battery (1.5V, 700mAh), SD card is used as a memory medium, and LCD display screen provides parameters setting, checking and confirmation of waveform quality.

2.1 Intended Use

Holter Recorder is used by medical institutions for dynamic ECG recording of subjects. It is intended to be used with AI-ECG Tracker or cardiac remote mobile monitoring system.

Caution

The intended use of Holter Recorder stated above only provides a reference for medical diagnosis, but not replace the clinician to make a diagnosis.

2.2 Contraindications

No contraindication.

2.3 Intended Users

The intended users of this recorder include all people except for the infants whose weight is less than 10kg.

2.4 Structure and Composition

Holter Recorder is mainly composed of recorder and ECG lead wires.

2.5 Product Accessories

No.	Name	Model	Quantity
1	ECG lead wire (button)	98ME01AC011(TH12)/ 98ME01AC124(TH3)	1 piece
2	Disposable ECG electrode slices	915W50	1 packet
3	Shoulder strap	/	1 piece
4	leather case	/	1 piece
5	Card reader	/	1 piece
6	SD card	16GB	1 piece

⚠ Warning

Please use the lead wires and other matching accessories provided by Carewell. It may damage the device and affect its performance and safety after use other types of accessories.

⚠ Warning

The disposable ECG electrode slices meet YY/T0196 or ANSI/AAMI EC12 standard.

⚠ Warning

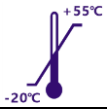
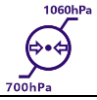
The lead wires and disposable ECG electrode slices should be CE-marked.

Caution

Please contact the manufacturer for more accessories information.

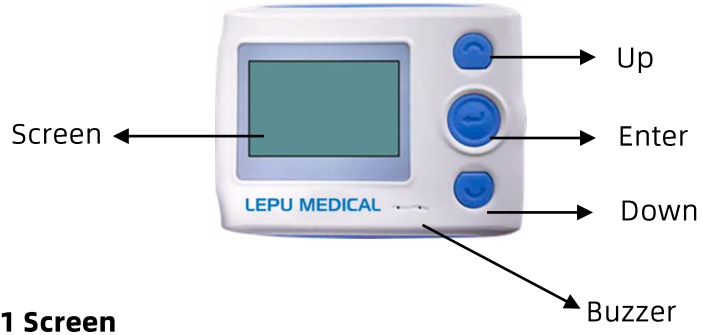
2.6 Symbol Description

Symbol	Description	Symbol	Description
+	Positive pole of the battery	-	Negative pole of the battery
	SD card socket		Symbol for "CAUTION, CONSULT ACCOMPANYING DOCUMENTS"
CE 0123	CE symbol		Please read the manual instruction before use
	Type BF applied part		Recovery and recycling
EC REP	Authorized Representative in the European Community		Manufacturer
UK RP	UK Responsible Person		Date of manufacture
LOT	Batch code	SN	Serial number
	Handle with care		Upward
	Stacking layers limit		Keep away from rain

Symbol	Description	Symbol	Description
	Humidity limit		Temperature limit
	Atmospheric pressure limit		

Chapter 3 Device Appearance

3.1 Main Unit



3.1.1 Screen

The screen is a liquid crystal screen (LCD).

3.1.2 Button Description

The instruction of each button and buttons combination as follows:

Button or Buttons Combination	Function
Up button	Switch to the previous lead. Reduce the setting value. Move the cursor up/left.
Down button	Switch to the next lead. Increase the setting value. Move the cursor down/right.
Enter button	Enter the setting value. Enable the "Recording Operation" page. Mark the events during recording.
Down button + Enter button	Enable the "Exit Recording" page.

3.1.3 Buzzer

During the recording process, when the lead falls off, the buzzer will continuously buzz for 30 seconds. After 30 seconds, if the lead still falls off, the buzzer no longer buzzes, but the screen still prompts the message about lead dropping.

If you want to eliminate the prompt tone immediately, please reattach the dropped lead, the prompt tone will automatically disappear.

3.2 Ports

3.2.1 Lead Wire Ports

The ports are used for connecting the ECG lead wires.

3.2.2 USB Ports

After connecting the Holter Recorder to the computer via the USB port, the ECG analysis system can read the recorded data in the recorder.

3.3 Back of Main Unit

Chapter 4 Recording Preparation

4.1 Battery Selection

Please install a new alkaline battery into Holter Recorder. The recording time of tested battery as follows:

Battery Type	Recording Time
AAA alkaline battery (1.5V, 700mAh)	24 hours

Warning

Incorrect replacement of batteries leads to an unacceptable risk.

Caution

Do not use rechargeable batteries to avoid danger.

Caution

If the battery is exhausted, please replace it immediately to avoid affecting data recording.

4.2 Installation of Accessories

Please install the SD card, battery and lead wires before recording the ECG data. Please install as the following steps:

1. Insert the SD card. Please ensure the SD card is not in the write-protected status, and insert the SD card in the correct direction and method.

Caution

Please use a compatible SD card confirmed by the manufacturer. The usage of SD card unconfirmed by the manufacturer may result in abnormal record or incomplete record. Please contact the manufacturer for SD card replacement.

Caution

Please confirm the SD card lock switch is turned on. Otherwise, the subject waveform information cannot be recorded.

2. Connect the lead wire to ECG recorder.

Caution

Please insert the lead wire correctly as shown in the figure above, ensure the lead wire plug is fully inserted into the interface and the casing is closed correctly.

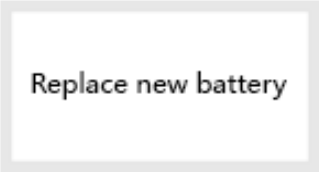
3. Install new batteries and ensure its positive and negative poles are correct. After the battery is correctly installed, the recorder will start up automatically and the screen will display the startup interface.

Caution

If the operator ignores the low battery alarm (as the figure below) and continues to start recording, Holter Recorder may not be able to record the data for 24 hours.

Caution

When the system detects the battery level is too low to supply the device for operation, the system prompts that "*Please replace the new battery!*" (as shown in the figure below) before allowing any other operation.



4.3 Electrode Slice Placement

4.3.1 Electrode Slice Usage

1. Fasten the disposable electrode slice into the electrode joint of lead wire.
2. Remove the protective packaging on the back of the disposable electrode slice.
3. Place the electrode slices correctly in accordance with the electrode slices placement illustration in the operator's manual or the physician's guidance, and ensure the electrode slices are firmly pasted on the subject's skin.

Note

Please use under the guidance of professional medical personals. It is recommended that the electrode slices be placed by personel with professional medical training.

☞ **Note**

The correct pretreatment of the subject's skin is essential to obtain a good ECG record. Please refer to the electrode slices manufacturer's instruction for skin pretreatment technology.

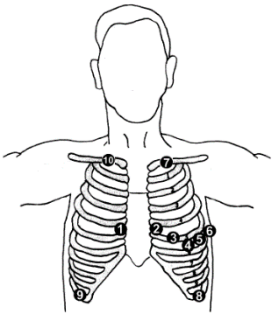
☞ **Note**

Please use ECG electrode slices specially used for long-distance recording Holter Recorder, and the ECG electrode slices should be equipped with a valid registration certificate for medical appliance. All electrode slices must be produced by the same manufacturer.

4.3.2 Electrode Slices Placement

✦ **12-lead Electrode Slices (10 Lead Wires) Placement**

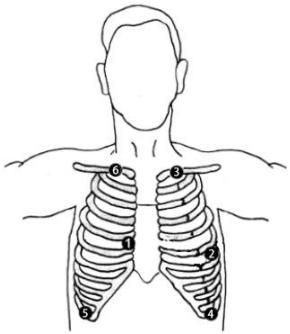
Place 10 lead wires in different colors on the human body in accordance with the corresponding position for 12-lead ECG recording. The following diagram shows the typical position of electrode slices placement. You can also refer to the position recommended by the analysis system and physician for electrode slices placement.



	AHA Color	AHA Label	IEC Color	IEC Label	Position
1	Brown/ Red	V1	White/ Red	C1	The fourth intercostal space at the right edge of sternum
2	Brown/ Yellow	V2	White/ Yellow	C2	The fourth intercostal space at the left edge of sternum
3	Brown/ Green	V3	White/ Green	C3	The position between V2 and V4
4	Brown/ Blue	V4	White/ Dark brown	C4	Midclavicular line at the fifth intercostal space
5	Brown/ Orange	V5	White/ Light blue	C5	Anterior axillary line at the same level as V4
6	Brown/ Purple	V6	White/ Purple	C6	Midaxillary line at the same level as V4 and V5
7	Black	LA	Yellow	L	Left shoulder
8	Red	LL	Green	F	The lower edge of rib cage, or the level of the navel at the position of middle clavicle line.
9	Green	RL	Black	N	The lower edge of rib cage, or the level of the navel at the position of middle clavicle line.
10	White	RA	Red	R	Right shoulder

✦ **8-lead Electrode Slices (6 Lead Wires) Placement**

Place 6 lead wires in different colors on the human body in accordance with the corresponding position for 8-lead ECG recording. The following diagram shows the typical position of electrode slices placement. You can also refer to the position recommended by the analysis system and physician for electrode slices placement.



	AHA Color	AHA Label	IEC Color	IEC Label	Position
1	Brown/ Red	V1	White/ Red	C1	The fourth intercostal space at the right edge of sternum
2	Brown/ Orange	V5	White/ Light Blue	C5	Anterior axillary line at the same level as V4
3	Black	LA	Yellow	L	The left shoulder
4	Red	LL	Green	F	The lower edge of rib cage, or the level of the navel at the position of middle clavicle line.
5	Green	RL	Black	N	The lower edge of rib cage, or the level of the navel at the position of middle clavicle line.
6	White	RA	Red	R	Right shoulder

4.3.3 Electrode Slice Replacement

Before recording, wipe the corresponding skin of human body, fasten the button between the electrode slice and lead wire. Tear down the protective plastic film and paste the electrode slice on the corresponding position of human body.

After the recording ends, remove the whole electrode slice from the human body. Separate the button between the electrode slice and lead wire. Dispose the waste electrode slice in accordance with the local laws and regulations.

4.4 Check before Startup

Please check the following items before startup to ensure the safe operation of the device:

- **Environment:** During the operation, please keep away from a space environment with strong interference for a long time, such as near a radiation machine.
- **Battery:** The battery is installed or not.
- **Lead:** Please check the lead wire plugs are firmly connected or not, and avoid the lead wires close to the AC power cord. Check whether the lead wire is correctly connected to the corresponding electrode slice.
- **Electrode slice:** Check whether the electrode slices are installed firmly and the electrode slices, especially the thoracic electrode slices, are in contact with each other.
- **Subject:** Do not touch the metal, which may cause interference.

Chapter 5 ECG Recording

5.1 Start ECG Recording

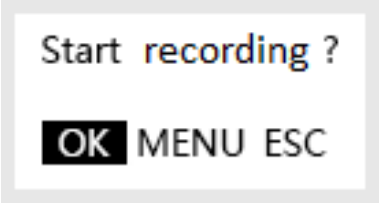
Caution

Every time the ECG recording is started, Holter Recorder will automatically format the SD card. Before start ECG recording, please ensure data in the SD card have been safely transferred to ECG analysis system.

5.1.1 Starting Steps

When the leads have been correctly connected to the subject's body, start the ECG recording in the following steps:

1. Press the **Enter** button to access the recording operation interface as follows:



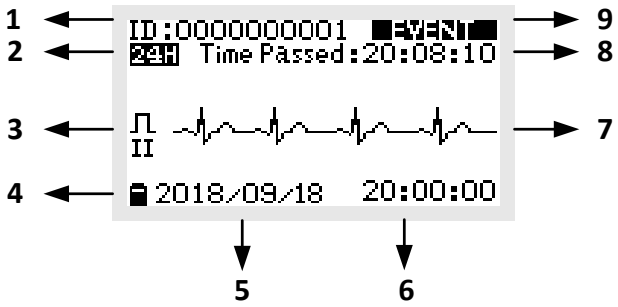
2. If the device needs to be configured, press the **Down** button to move the cursor to the position of "**MENU**". And then press **Enter** button to access the MENU interface. Please refer to **5.1.3 Setting parameters** for the setting of specific parameters.
3. If no configuration is required, when the cursor locates in the position of "**Enter**", press **Enter** button to access the subject ID confirmation interface.

4. Confirm the subject ID. If the ID number needs to be modified, please modify it on this interface.
5. Please wait for the system to complete the SD card formatting automatically. After formatting, the system will automatically access the recording interface.
6. Put the Holter Recorder into a leather case and wear it with the belt or shoulder strap.

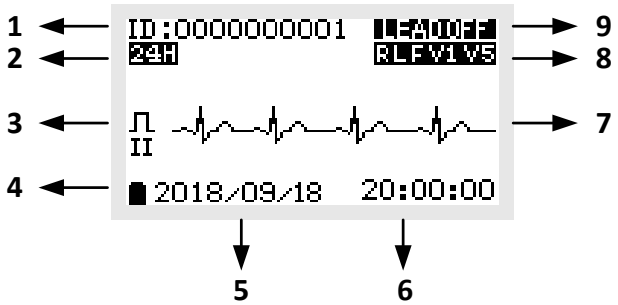
5.1.2 Waveform Interface

After starting the ECG recording, the following interface will be displayed:

- **Normal recording interface**



- **Lead-off interface**



No.	Description
1	Subject ID number
2	Pre-set total recording time
3	Current lead label
4	The battery level will display the following status: : Current remaining battery. : The icon flashes, which means low battery.
5	Current date
6	Current time
7	Current waveform
8	Dropped lead or recording time. During the recording process, the recording time is displayed, as shown in the above diagram of normal recording interface. When the lead falls off, the name of dropped lead is displayed first, as shown in the lead-off interface diagram above.
9	The information area will display the following prompt information: **LEADOFF**: The lead falls off. **EVENT:** The current period is marked as an event. **END:** The recording ends.

☞ **Note**

In the waveform interface, if no button is pressed for 15 seconds, the system will automatically switch to blank screen. Press the Enter button  , the system screen will display again.

5.1.3 Setting Parameters

In the recording operation interface, move the cursor to the "Setting" position and press "Enter" button to access the parameters setting interface. In the parameters setting interface, you can perform the following operations:

View Waveform

- Return to the main waveform interface.
- After other settings are completed, you can select this option to return to the main waveform interface.

Recording Mode

- **Recording Gain:** Options include 0.5, 1, 2. The gain settings are applicable to all leads and only affect the display of information on the screen interface.
- **Recording time:** 1 day, recording will stop automatically after 24 hours.
- **Return:** Return to the previous menu.

Settings

- **Language:** Set the display interface to Chinese or English.
- **ID number:** Enter the subject ID number.
- **Date/Time:** The date display format is [YYYY]-[MM]-[DD], the time display format is HH:mm:SS.

Date/Time Settings	Description
YYYY	Year, 4 digits, such as 2010
MM	Month, 2 digits, Range 01-12
DD	Day, 2 digits, Range 01-31
HH	Hour, 2 digits, Range 00-23
Mm	Minute, 2 digits, Range 00-59
SS	Second, 2 digits, Range 00-59

- **Return:** Return to the previous menu.

5.2 Recording Process

Caution

For a better recording effect, please remind the subject to stay in a resting state during the recording process, activities with a small amount of exercise are allowed, such as walking. Do not perform exercises such as thoracic exercises, swinging arms and so on.

In the recording process, you can perform the following operations:

Mark an Event

On the waveform interface, press the **Enter** button  to mark an event. The system only records an event if the Enter button is pressed again within 8 seconds.

Switch Display of ECG Waveform

In the waveform interface, press **Up** button  , **Down** button  to switch the waveform display of each lead.

5.3 Stop Recording

Holter Recorder will automatically stop recording at the pre-set recording time. You can also stop recording in advance in accordance with requirements.

5.3.1 Stop Recording before the Pre-set Recording Time

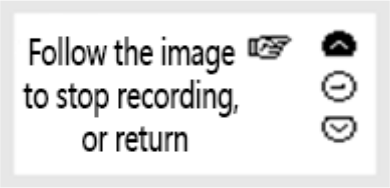
Caution

Stopping the recording must be performed by a professional and trained person before the end of recording.

In the waveform recording process, follow the steps below to stop recording before the pre-set recording time:

1. In the waveform interface, press the **Down** button + **Enter** button to access the protective interface of stopping recording.
2. According to the screen tips, press the button indicated by the icon ☞ to unlock the interface. The unlocking operation steps as follows:

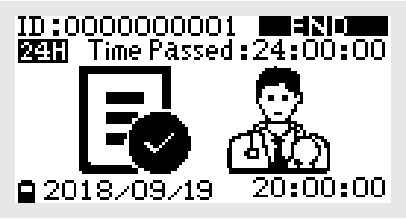
   Press **Up** button > **Down** button > **Up** button > **Enter** button



3. On the unlocked interface, stop the recording.

5.3.2 Record Ends Automatically

After the record ends, the screen will display the record end interface, buttons will be invalid, the clock will stop refreshing, and the END characters will be displayed in the upper right corner.



5.3.3 Take Off the Recorder After Record Ends

After record ends, the professional medical staff takes off the recorder according to the following steps:

1. Remove the waste battery and dispose it appropriately in accordance with the local law.
2. Press the SD card and it will automatically pop up.
3. Remove the electrode slices from the subject and separate the lead wires from the electrode slices.

Caution

Do not pull the cable forcibly; otherwise, the wires inside the insulation layer will be damaged. When removing the electrode slices from the subject, please grasp the insulator at the end of the lead wire terminal to pull out the terminal.

5.4 Data Replay

Perform data replay in the following steps:

1. Access to the ECG analysis system installed on the computer.
2. Transfer ECG data in the SD card to the computer analysis system.

Caution

Please confirm the ECG data has been successfully imported into the analysis system, and the SD card can be taken out for the next subject's record.

5.5 Power On/Off

- Power On: Install the battery to power on the recorder.
- Power Off: Take out the battery to power off the recorder.

Chapter 6 Cleaning, Disinfection and Maintenance

The cleaning and disinfection introduced in this chapter only involves the main unit of the recorder. For the cleaning and disinfection of lead wires or other accessories, please refer to their corresponding instructions or follow the regulations of medical institutions.

6.1 Cleaning

Please clean the main unit of Holter Recorder in the following steps:

1. Mix the water and mild detergent together to make mixed liquor.
2. Soak the soft cloth with the mixed liquor.
3. Clean the main unit of Holter Recorder with a soft cloth.
4. Use a mild detergent to clean the adhesive on the subject's lead wires.

☞ **Note:**

Please clean the main unit after usage.

6.2 Disinfection

It is recommended to sterilize the main unit shell with the 75% ethanol after usage.

6.3 Daily Maintenance

Maintenance of Main Unit

- The record box should be away from high temperature, sunlight, moisture, dust or impact. Please store it properly to prevent liquid from permeating into the inside of the

device, which will affect the performance and safety of the device.

Maintenance of Lead Wires

- Before usage, please check the integrity of lead wire and ensure it is in good conduction.
- During the usage, please straighten out the lead wires as much as possible to avoid knotting and small angle bending.
- The core wire or shielding layer of the lead wire is easy to be damaged, especially the plugs at both ends. During the usage, do not pull or twist the lead wire, please hold the plug with your hand for operation.
- Cables and leads should be coiled into a large disc for storage, or suspended to avoid twisting or folding at an acute angle.
- If the cables and lead wires are damaged or aged, please replace the new one.

Chapter 7 Common Problems and Solutions

Problems	Solutions
No display	Check the battery direction Install new battery
Low battery	Check the battery case and clean the contacting points of two poles if necessary Install new battery
The battery cannot supply for 24 hours	Please use new battery. After testing, AAA alkaline battery (1.5V, 700mAh) can supply the recorder for 24 hours. Other batteries have not been tested and cannot guarantee 24 hours power supply.
Noise and artifacts of ECG signal	Ensure all electrode slices reliably contact the subject Ensure all lead wires are connected Replace the lead wires
Card damaged message	The used SD card cannot be used for this recorder, please use the Sandisk SD card. If the same problem still exists after replacing multiple cards, please contact the after-sales service department of Carewell.

Appendix A Technical Specifications

A.1 Standards

- Meet the requirements of IEC 60601-1:2005+AMD1:2012 CSV Medical electrical equipment - Part 1: General requirements for basic safety and essential performance,
- Meet the requirements of IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- Meet the requirements of IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

A.2 Classification

Electric shock protection class	BF device
Electric shock type	Internal power supply (using the battery)
Liquid-proof Degree	IPX0, common device without waterproof capability
Operating mode	Continuous operation
Gas mixture of flammable anesthetic gas and air or oxygen or nitrous oxide	Non-AP/APG type
Installation and usage classification	Non-permanent installation device

Electromagnetic compatibility is classified in accordance with IEC/CISPR 11	Group I Class B
Pollution degree	2

A.3 Environmental Specifications

	Transportation/Storage	Operating Environment
Temperature	-20℃~+55℃	0℃~+45℃
Relative Humidity	10%~95% (no condensation)	10%~95% (no condensation)
Atmospheric Pressure	700hPa~1060hPa	700hPa~1060hPa

A.4 Performance Specifications

Number of Channels	12 leads
Sampling Frequency	250Hz
Sampling Accuracy	24 bits
Input Dynamic Range	≤±5mV
Input Impedance	＞10MΩ
Common Mode Rejection	≥80dB
System Noise	≤50μV(p/v)
Frequency Response	(0.67Hz～40Hz)（+3dB～-3dB）
Time Constant	≥3.2s
Polarization Resistance Voltage	±300mV

Storage	Equipped with SD card, which can store 24 hours record.
Duration of contact for all applied parts and accesible parts	t≥1min
Temperature rise of the applied parts	Not exceed 1°C

A.5 Physical Specifications

Size of Main Unit	75×58×17mm (Length × Width × Height)
Screen	Liquid crystal screen (LCD), size: 1.4", resolution 128*64
Weight	62g (including main unit and battery)
Ports	Lead wire port: HDMI, it is used for connecting the ECG lead wires. USB Port: It is used for connecting USB cable.
Power Supply	1 AAA alkaline battery, 1.5V, 700mAh support 24 hours record

Appendix B EMC Information

Holter Recorder conforms to the relative EMC requirements of IEC60601-2-47:2012 and IEC60601-1-2:2014. User should install and use the device according to the EMC information provided in the accompanying documents. Please see the following table for the guidance and manufacturer's declaration.

Basic performances: Holter Recorder can normally collect the ECG signals.

Caution

Holter Recorder should not be stacked with or used near other devices. Otherwise, user should observe and verify whether the device can operate normally under its configuration.

Caution

Except for the cables sold out as a spare part of internal components by the manufacturer, other accessories or cables may result in the increase of electromagnetic emission and decrease of immunity.

Caution

Portable and mobile RF communication devices may influence the performances of Holter Recorder, please avoid strong electromagnetic interference (e.g. cellphone, microwave oven, etc.) during the usage.

Caution

The minimum amplitude of physiological signals of Holter Recorder is 50μV. It will result in the inaccurate data if the Recorder operates in the minimum amplitude.

Name	Length	Shield or Not
ECG cable	1m	No

Guidance and manufacturer's declaration – electromagnetic emission – for all DEVICE AND SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group I	Holter Recorder uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic device.
RF emissions CISPR 11	Class B	Holter Recorder suits for all facilities, including domestic facilities and public low voltage supply network connected to the family houses.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity – for all DEVICE and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±15 kV air	± 8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable	Not applicable

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	Not applicable	Not applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m, 150/180Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – for DEVICE and SYSTEM that are not LIFE-SUPPORTING

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">Holter Recorder is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF</td><td>3 V (effective value)
150 kHz to 80 MHz

3 V/m</td><td>3 V (effective value)

3 V/m</td><td>Portable and mobile RF communications devices should be used no closer to any part of Holter Recorder including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
d = $1.2\sqrt{P}$
d = $1.2\sqrt{P}$ 80 MHz～800 MHz
d = $2.3\sqrt{P}$ 800 MHz～2.5 GHz
where p is the maximum output power rating of the</td></tr>
</table>

IEC 61000-4-3	80 MHz to 2.5 GHz		transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a) should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of device marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Holter Recorder is used exceeds the applicable RF compliance level above, Holter Recorder should be observed to verify normal operation. If abnormal performance is observed, additional			

measures may be necessary, such as reorienting or relocating Holter Recorder.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications device and the DEVICE or SYSTEM - for DEVICE and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications device and Holter Recorder			
Holter Recorder is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications device (transmitters) and as recommended below, according to the maximum output power of the communications device.			
Rated maximum output of transmitter/W	Separation distance according to frequency of transmitter/m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the			

transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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