

HANDHELD ECG MONITOR

INSTRUCTION

MANUAL

Customer Instructions

Dear users, thank you for purchasing our product Handheld ECG Monitor. Please be sure to read the manual carefully before using this device for the first time. Failure to follow these instructions may cause measuring abnormality, equipment damage or personal injury. We assume no responsibility for personal injury or damage sustained by or through use of this product.

No part of this manual may be photocopied, reproduced, modified or translated into another language without the prior written consent. We reserve the right to improve and amend it at any time without prior notice.

In case of modifications, you will NOT be advised with a Modification Notice. The information in this manual should NOT be regarded as the promise of our company.

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Notes on Safety

This device is intended to monitor the ECG waveform, not for medical diagnosis. **Never use the device in critical situations!**

- Self-diagnosis and treatment is dangerous.

The measurement results are reference for analyzing the cardiac rhythm of patients by doctors only, and should never be used as a basis for starting or modifying treatment without independent confirmation by medical examination. **Do not** make diagnosis by yourself according to the measurement and analysis results; always consult your doctor if abnormal information is presented frequently.

- The values displayed by the device are the values at the time of measurement.

Medical conditions can change suddenly. If you notice any change in your condition, consult your doctor, regardless of the measurement results.

- Do NOT Use the device for treatment; we will not be responsible for the suddenness happened during a measurement.



Warnings!

- ✧ Do not use with a cardiac pacemaker.
- ✧ Do not use with a defibrillator.
- ✧ Do not use in the presence of flammable anesthetics, drugs or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent).
- ✧ Do not attempt self-diagnosis of the measurement results and analysis. Always consult your doctor.
 - Self-diagnosis may lead to deterioration in your condition.
- ✧ Do not use on patients with significant resting tremors.
- ✧ Do not use on people with sensitive skin or allergies.
 - This may result in exanthema, skin irritation, or eczema.
- ✧ Keep out of reach of small children and people who cannot express their consent.
- ✧ Do not use for any purpose other than obtaining an electrocardiograph.
- ✧ Do not expose the device to strong shocks or vibrations, or drop or step on the device.
- ✧ Do not use batteries of a type other than that specified in this manual.

- ✧ Do not apply over clothing.
- ✧ Do not take measurements when there are drops of water on your skin, such as from sweat or after bathing.
- ✧ Do not take measurements where the device will be exposed to strong electromagnetic forces.
- ✧ Chemicals from a broken LCD display panel are toxic when ingested. Use caution when the monitor has a broken display panel.
- ✧ The user should operate the equipment according to the EMC information provided in the accompanying documents.
- ✧ Portable and mobile RF communications equipment can affect medical electrical equipment.
- ✧ This equipment should not be used adjacent to or stacked with other equipment.
- ✧ The Handheld ECG oximeter is not intended for use during patient transport outside the healthcare facility

Caution!

- ✧ Do not expose the device to static electricity. Always disperse any static electricity from your body before handling the device.
- ✧ Do not take measurements in a moving vehicle.
- ✧ Do not use a cellular phone near the device.
- ✧ Do not disassemble, repair, or modify the device.
- ✧ Do not insert batteries with their polarities reversed.
- ✧ The chest electrode will be impeded by excessive body hair, regularly remove hair at the electrode contact point.

General

- ✧ Avoid extremes in temperature and humidity. Do not use this device in locations subject to high or low temperatures or humidity.
Use at a temperature within 5°C to 40 °C and below 80% RH.
- ✧ Do not sterilize this device in an autoclave or gas sterilizer (EOG, formaldehyde, high density ozone etc.)
- ✧ Do not wash this device with water.
- ✧ Do not store the device in the following ambient conditions.
 - Locations exposed to direct sunlight.
 - Locations subject to high temperatures and high humidity.
 - Wet or damp locations where water may get on the device.

- Dusty locations.
 - Near fires or open flames.
 - Locations exposed to strong vibration.
 - Locations exposed to strong electromagnetic fields.
- ✧ Dispose of the device and its accessory according to applicable local regulations.

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1. General Description

1.1 Know Your Device

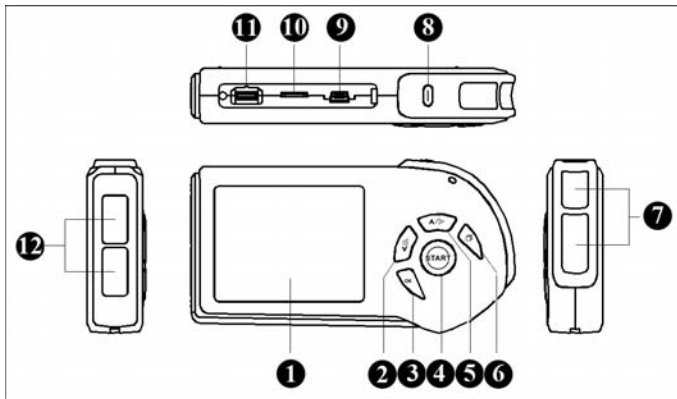


Fig.1-1

Description of Fig. 1-1:

①. LCD display: Display the parameters include the current date and time, battery power indicator, etc.	⑦. Metal Electrodes: Hold these two with right index finger when taking a measurement.
②. Left/Down Button: Press this button to move the cursor/ waveform to the left or change the number.	⑧. POWER button: Power on/off.
③. OK button: Press this button to confirm the selection and enter the submenu or confirm the setting and select the next item.	⑨. USB interface: Transmit data to the PC through this interface.
④. START button: Shortcut key for taking a measurement.	⑩. SD card socket: A SD card is intended to be inserted this socket.
⑤. Up/Right Button: Press this button to move the cursor/waveform to the right or change the number.	⑪. ECG cable interface: Connect the ECG cable with this port.
⑥. MENU button: Return to the previous menu by pressing this button.	⑫. Metal Electrodes: Place this against the center of left palm or chest when taking a measurement.

1.2 Product Features

- ✧ Easy to use
- ✧ Convenient to carry
- ✧ High-definition color display
- ✧ User Friendly interface
- ✧ Two optional measurement modes
- ✧ Support using Micro-SD Card saving more data records.
- ✧ The saving records can be uploaded to PC for review or management.

1.3 Intended Use

The MD100E-B ECG monitor is a handheld device indicated for use in non-invasively detecting and displaying ECG waveform for self testing of adult in daily life; otherwise it also can provide the doctor with relevant data on the heart condition of the patient in hospital. It is available to manually record transient cardiac events immediately at any time, suitable for patient and professional use, helpful in determining cardiac aetiology of symptomatic events. This ECG monitor allows the consumer to record their ECG data into the device memory and displays the ECG data to the healthcare professional during office visits.

NOTE: The product is not suitable to monitor patient continuously.

1.4 Main Menu

Main Menu Screen:



Fig.1-2

**ECG Measurement:**

In this menu, there are three options “Easy Mode”, “Continuous Mode” and “Bluetooth Switch”

**Records Review:**

Entering this menu, there are data records and ECG waveform stored available.

**System unit Settings:**

Entering this menu, there are six submenus:

1. Date and Time Settings
2. Brightness Settings
3. Beep Settings
4. User ID Settings
5. Wave scale Settings
6. Auto power off Settings

**Data Management:**

Entering this menu, the records stored in the monitor can be deleted or copied to an SD card.

**Factory Settings:**

The factory settings can be restored or not according user needs.

**Version:**

The user can acquire the version, SN serial number and register information.

2. Inserting and Replacing Batteries

2.1 Open the battery cover on the back panel of the device.

2.2 Insert two AA batteries lightly as indication of the polarity sign: (refer to Fig. 2-1).



Make sure the polarities of the batteries are correct.

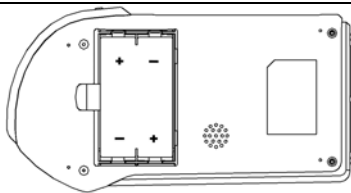


Fig. 2-1

2.3 Close the battery cover.

Battery life and replacement:

When the “Battery power is low please change with new ones in time.” message appears, replace batteries with new ones immediately.

- ✧ Always turn off the device before replacing the batteries.
- ✧ Dispose of the used batteries according to the applicable local regulations.

Battery life:

- ✧ Two new AA batteries will last for about 500 measurements. (If measurements are performed once a day at room temperature (22°C).)
- ✧ The batteries enclosed in the package are used for demonstration purpose. It is possible that these batteries will not last for 500 measurements.
- ✧ The battery life can be confirmed in the upper right of the LCD display.




Full power



low power



no power

When the sign “” appears, it means the battery power is not sufficient, and the device will show information as Fig. 2-2. It is suggested that users replace the batteries with new ones in time.

Battery power is low please change with new ones in time.

Fig. 2-2

Warning!

If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult doctor immediately.

Cautions!

- ✧ Do not use batteries not specified for this device. Do not insert the batteries with the polarities in the wrong direction.
- ✧ Do not dispose of batteries in fire.
- ✧ If battery fluid should get on your skin or clothing, immediately rinse with plenty of clean water.
- ✧ Remove batteries from this device when you are not going to use it for a long period of time (approximately three months or more).
- ✧ Do not use batteries of a different type together.
- ✧ Do not use new and used batteries together.


3. Setting the ID, Date and Time

Always set the ID number, Date and Time before using the device for the first time.

Set the ID number for different user. Make sure the date and time are correct before using the device, reset them if necessary. The ID number, date and time are important indicators when a measurement is taken.

3.1 Date and time setting

Note: The date and time information will be displayed on the screen in format of “Year-Month-Date”; “Hour: Minute: Second”.

3.1.1 Press the  Power button to turn on the device.

3.1.2 Select [System unit settings] → [Data and Time settings]. Press the OK button to select the item which you want to adjust.

3.1.3 Press the up/right or left/down button to increase or decrease the number.

3.1.4 In the same way, set the month, day, hour, minute and second.

3.1.5 Press the MENU button to return to the previous menu.

3.2 ID settings

NOTE: ALWAYS set different ID number for every user before taking a measurement.

3.2.1 Select [System unit settings]→[User ID Setting], then press the “OK” button to enter.


3.2.2 Press the up/right or left/down button to adjust the ID number. Its range is from 1 to 255. After setting, press “OK” button to confirm the setting and return to the previous menu.

4. Using SD Card

The monitor includes an SD card for storing ECG data, which can be viewed by your doctor later. This section describes how to insert and eject an SD card, and how to format a card so it can be used to store ECG data.

NOTE: DO NOT store data other than ECG data from the monitor on the card.

4.1 Inserting an SD card

The SD () mark is displayed in the top right corner of the screen while the SD memory card is inserted, and the monitor is turned on.

4.1.1 Open the cover on the side of the monitor and insert the SD card in its slot. Insert the card until it clicks into position.

Caution! When inserting the SD card, do not try to force the card into the slot. Be sure that the side with silk faces upwards. Otherwise, that could damage the card or the unit itself.

4.1.2 Close the SD card slot cover.

4.2 Ejecting the SD card

4.2.1 Open the SD card slot cover and press the card. The lock is released and the card is ejected lightly.

4.2.2 Remove the SD card, and then close the SD card slot cover.

4.3 Formatting an SD card

Insert the SD card into the SD card reader; then connect the SD card reader with a computer's USB interface. In the right mouse button menu, select the "fat" item to start formatting the SD card.

NOTE:

- It is recommended to use the approved micro-SD cards and Readers.
- If the prompt information "Do not support this file system. Please format SD card with fat16" appears, format the SD card on a computer.

5. Taking a measurement

The methods of measurement include palm measurement, chest measurement and cable measurement. The measurement modes include Easy Mode and Continuous Mode.

Important Notes on Taking a Measurement

In order to obtain a good ECG reading, it is important that measurements are taken correctly. Please read the instructions carefully before taking a measurement for the first time, and follow the instructions each time you take a measurement.


- ✧ Make sure that the electrodes are directly touching your skin.
- ✧ If your hands or skin are dry, wipe them with a damp towel so that they are slightly moist.
- ✧ If the electrodes are dirty, wipe any dirt off with a soft cloth moistened with disinfectant alcohol or a cotton swab.
 - Take care not to use too much disinfectant alcohol when cleaning the electrodes.
 - Do not wipe or get disinfectant alcohol on parts other than the electrodes.

✧ Do not move during measurement.

- Movement, including talking, coughing or sneezing, during measurement can affect the measurement results.

✧ If the position of your finger or arm is inappropriate during measurement, the results may be unreliable, so be sure to check their position before taking a measurement.

✧ After taking a measurement, disinfect the electrodes by wiping them with a soft cloth or cotton swab moistened with disinfectant alcohol. If you do not disinfect the electrodes there is a risk of skin disease.

5.1 Press the  Power button for about 3 seconds to turn on the device and 4 seconds to turn off.

Note: If you forget to turn the device off, it will automatically shut down within 4 minutes (default).

Users can set the auto power off time “OFF, 1 min, 2 min...10 min” in the [System Settings] menu.




There are three options in the [Measurement mode] menu  “Easy Mode”  “Continuous Mode” and  “Bluetooth Switch”. Choose “Easy Mode”, then click “OK” button. When the device counts down from six to zero, the measurement will start.



Fig. 5-1

5.2 Make sure that you are in a relaxed position. Then press the “START” button to start a measurement, and the measuring mode depends on your

selection in the [Measurement Mode] menu.

Before you take a measurement, the ideal posture is one where you are seated comfortably with your back straight and hands on your legs.

Note: You can also take a measurement while you are standing or while lying down.

5.3 Palm Measurement

Make sure hold the “7” metal electrodes of the device with right index finger firmly, and place the “12” electrodes against the center of the left palm. While maintaining the same posture, press the START button. (Refer to Fig. 5-2)



Fig. 5-2

Measuring Screen (Easy Mode):



Fig. 5-3

Description of Fig. 5-3:

“2009-05-08”: The current date.

“14:07:40”: The current time.

“36/100”: The device can store 100 records.

The current measurement record is the 36th one.



With SD card, it displays this icon; without SD card, it doesn't display this icon.



Indication of the power of battery



: ECG amplitude bar



The ECG waveform

×1: ECG waveform scale. You can set the displaying scale (x0.5, x1, x1.5, or x2) in the [System unit Settings].



Beep is OFF.



: The status bar of measurement progress.


13: Indication of measurement time.



The sign of heartbeat, it twinkles synchronously with the heartbeat.

It takes 30 seconds to complete the measurement. During the measurement, the device will beep synchronously with the heartbeat, the screen displays the ECG waveform and progress bar at the bottom of the screen indicates the measurement progress.

Notes:

- ✧ During a measurement the device will only respond to the “MENU”, “START” or “POWER” buttons.
 - ✧ If the contact between electrodes and skin becomes loose, or the conditions change during the measurement, the result may be unreliable.
 - ✧ When the electrodes are contacted not well during the measurement, the device will remind you with “” icon flashing at the bottom of the screen.
 - ✧ Keep still and do not move until the measurement is complete.
- Wrong Operation Methods:
- A. Both hands move at will.
 - B. Both hands contact with electrodes loosely during the measurement.
 - C. No palm/finger touches electrodes.

A measurement result message is displayed when the measurement has been completed (refer to Fig. 5-4 for details).



Fig. 5-4

Description of Picture 5-4:

“**2009-05-08**”: The current date.

“**14:13:35**”: The current time.

“**37/100**”: The current measurement record is the 37th one.

: Indication of the power of battery.

“**HR 090 bpm**”: The heart rate is 90 beats per minute.

“**2009-05-08**”: The record storage date.

“**14:07**”: The record storage time.

“**ID: 002**”: The ID number is 002.

The results will be stored automatically within 5 seconds. The monitor can memorize 100 pieces of records at most.

When the records are full, the message “**Storage is full**” will appear on the centre of the screen. If you want to store another record, the system will remind you that the record cannot be stored, until the user deleted the unnecessary records. Or **copy** the records to a **SD card** to be stored, and **then delete the records in the monitor**. After that the new measurement records can be stored.

Caution!

DO NOT make any direct diagnostic or analytical decision according to the result, but use it for reference **ONLY**.

5.4 Chest measurement

If palm measurement is not ideal, please adopt chest measurement.

5.4.1 Measurement for Male:

Hold the device with the right hand; make sure that the right index finger makes contact with the “7” metal electrodes sufficiently. Place the “12” electrodes against left chest on bare skin about 5cm below your left nipple. While maintaining the same posture, press the START button. (Refer to Fig. 5-5)



Fig. 5-5

Note: If you have problems in applying the device so that the “12” metal electrodes are flat against your chest, please ask your doctor for advice.

5.4.2 Measurement for Female

Locate the ECG monitor at the lower end of breastbone and move horizontally to the middle of the left part of the chest. If necessary, gently lift the breast and place the “12” electrodes under the left breast. Unless the electrodes come in contact with the brassiere, it is NOT necessary to remove it; if you are unsure **please consult your doctor**.



Fig. 5-6

To obtain the high quality ECG, users can adopt the cable measurement.

Note: The small open circle indicates the proper position of electrodes, as shown in Fig. 5-6.

Improper Operation Methods:

- A. The touching point of the “12” electrodes do NOT contact left chest.
- B. The handhold gesture is NOT correct.
- C. The “12” electrodes do not contact fully the skin. (E.g. the monitor is impeded by clothes while taking a measurement)

Notes:

- ✧ Make sure that you are relaxed and that your chest is free of tension.
- ✧ Press the electrodes close against your bare chest. Do not place the electrodes on clothing as this will result in an inaccurate measurement.
- ✧ If measuring in dry circumstance, which might cause weak heart pulse signal, please wet your skin or hands with some diluted salt water or clean water. This would strengthen the heart pulse signals, and make the recording much more accurate.
- ✧ When doing chest measurement, if you have problems applying the device so that the “12” metal electrodes are flat against your chest, please ask your doctor for advice.
- ✧ **Keep still and do not move until the measurement is complete.**

5.5 Leg Measurement

Besides palm and chest measurement, user can adopt leg measurement. As shown in the following picture. Touch the electrodes on the right side of the monitor with right hand and get the left side electrodes touched with left ankle.

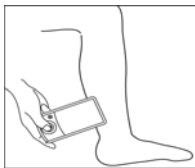


Fig. 5-7

5.6 Cable Measurement

If palm measurement is not ideal and it is not convenient to adopt chest measurement, the cable measurement will be recommended. Connect the cable and the unit effectively through the lead port. The position for placing the cable electrode is shown in Fig. 5-8.

NOTE:

- ✧ Make sure that you are relaxed and that your chest is free of tension.
- ✧ Press the chest electrodes close against your bare chest. Do not place the electrodes on clothing as this will result in an inaccurate measurement.

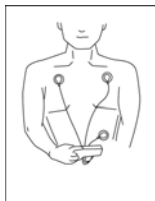


Fig. 5-8

AHA:

White (right arm RA) electrode — put it under the clavicle ,next to the right shoulder.

Black (left arm LA) electrode — put it under the clavicle ,next to the left shoulder.

Red (left leg LL) electrode — put it at the left of the underbelly.

IEC:

Red (right arm R) electrode — put it under the clavicle ,next to the right shoulder.

Yellow (left arm L) electrode — put it under the clavicle ,next to the left shoulder.

Green (left leg F) electrode — put it at the left of the underbelly.

Wrong Operation Methods:

- A. Connect wrong cable mount.
- B. Electrodes contact wrong position of the body.



Warnings! Very Important!

Users are strictly prohibited to attach the lead cable electrodes on their body if the lead cable is not connected with the device. Before measurement, firstly the lead cable should be connected with the device, secondly the lead cable electrodes should be attached to your body; After measurement, firstly the lead cable electrodes should be removed from body, secondly the lead cable should be disconnected with the device.

5.7 Continuous Mode

In the [Measurement Mode] menu you can select the “Continuous Mode” for long term measuring. The measurement can last for about 6 hours with two new batteries.



Fig. 5-9

“090”: The inspected Heart rate is 90 bpm.

Note: In the continuous Mode, the measurement results cannot be saved in the monitor, but can be saved into SD card. The measurement results can be real-timely displayed on a computer by the data transmission software after connecting the monitor with computer via the USB data cable or the USB adapter.

5.8 Bluetooth Switch

In the [Measurement Mode] menu you can select the “Bluetooth Switch” for measuring.

When you select the “Bluetooth Switch”, you enter the following interface.



Fig. 5-10

Select “ON” and you can take a measurement. The following figure is the measurement interface.



Fig. 5-11

“090”: The inspected Heart rate is 90 bpm.

**There is an analysis result of a measurement in the continuous mode.
The function is optional, so the user should purchase for applying.**

No.	Abbr.	Analysis
1	ASYSTOLE	Suspected Sinus halted beat
2	TAHY	Suspected fast beat

3	BRADY	Suspected slow beat
4	MISSBEAT	Suspected missing beat
5	RUNPVC	Suspected Repeating early beat
6	TRIGEMIN	Suspected trigeminy
7	BIGEMINY	Suspected bigeminy
8	R On T	Suspected R wave on T wave
9	COUPLET	Suspected Twin early beat
10	PVC	Suspected early beat

Cautions!

- ✧ Please note that while the measurements from an ECG monitor are a useful guide for your doctor, they cannot detect all changes in heart conditions. Always consult your doctor if you notice any changes in your condition, regardless of the measurement results. Consult a doctor even if “Stable waveform” is displayed as the measurement result, if you have been diagnosed with a heart condition.
- ✧ The values displayed by the device are the values at the time of measurement. Medical conditions can change suddenly. If you notice any change in your condition, consult your doctor, regardless of the measurement results.

6. ECG Data Display

6.1 Reviewing records

Select [Records Review] in the main menu, and then press “OK” button. And the saved records are displayed in graph as show in the Fig. 6-1.



Fig. 6-1

NOTE: If the device does NOT have stored records ever, it will show the prompt information “No record!”, when entering the [Records Review] menu.

6.2 Reviewing ECG waveforms

Select a record in the records list, and press the “OK” button. The corresponding waveform will be displayed. (Refer to Fig.6-2). Press the Navigation buttons to move the waveform forward or backward.



Fig. 6-2

Description of Fig. 6-2:

“036/100”: It means that the device can store one hundred records and the current record is the 36th one.

⌋ : ECG amplitude ruler

⌋ : ECG waveform

▬ : Measurement progress bar

“4”: The interval of the current ECG waveform.

Every piece of stored ECG data is displayed with date, time and a character representing the measured waveform.

Measuring result depiction: After reviewing the certain ECG waveform, press the “OK” button to enter the corresponding result depiction, refer to Fig. 6-3.







Fig. 6-3

In the current menu press navigation button to select YES, NO, or the KEY icon, and then press the “OK” button to reserve, delete or lock the result.

Deleting or locking ECG records

Deleting: Under the Fig. 6-3 menu, press up/right or left/down button to select the “YES” item, you will delete the current ECG record.

Locking: Select the  icon, the current ECG record will be locked. The mark  will be displayed besides this record. Select the  icon again and press the “OK” button, the record will be unlocked with the icon  appearing.

NOTE: The locked records can NOT be deleted.

7. System Settings

In the [System unit Settings] menu, there are six options as follow:



Date and Time Settings



Brightness Settings



Beep Settings



User ID Settings



Wave scale Settings



Auto poweroff Settings

7.1 ID, Date and Time Settings

Please refer to the section “3. Setting the Date and Time”.

7.2 Brightness Settings

1. Select [System unit Settings] → [Brightness Settings], then press the “OK” button to enter.
2. Press up/right or left/down button to set the backlight. And press the “OK” or MENU button return to the previous menu.

7.3 Beep Settings

1. Select [System unit Settings] → [Beep Settings], then press the “OK” button to enter.
2. Press up/right or left/down button to select “ON” or “OFF”, then press “OK” button to confirm your settings.

7.4 Wave Scale Settings

1. Select [System unit Settings] → [Wave scale Settings], then press the “OK” button to enter.
2. Press up/right or left/down button to select “x0.5, x1, x1.5, x2”, then press “OK” button to confirm your settings.

7.5 Auto Power off Settings

1. Select [System unit Settings] → [Auto power off Settings], then press the “OK” button to enter.
2. Press up/right or left/down button to set the time limit “OFF, 1 Min. 2 Min...10 Min”, and press “OK” button to confirm your settings.

8. Data Management

8.1 Erase all data

In the main menu screen, Press up/right or left/down button to select [Data Management] and then press the “OK” button to enter.

Select [Erase all data], there are two options “Clear local data” and “Clear

SD card data". Select your desired one, and then press the "OK" button.

8.2 Copy to SD card

Select [Data Management] → [Copy to SD card], and then press the "OK" button. All the data in the monitor will be copied into the SD card.


8.3 SD card status

When you insert the SD card, you can choose the SD card status. Select [Data Management] → [SD card status]. You can enter the following the interface.



Fig. 8-1

9. Factory Settings

The  factory settings can be restored or not according to user needs. The settings include that the Measurement Mode is Easy Mode; the Brightness is the second level; Beep is ON; the ID number is 1; the Wave scale is X1 and the time of Auto power off is 4 min.

10. Data Transmission

Before data transmission, make sure to turn the device on and connect it with a computer by the data cable attached. The operations refer to the **User Manual** of the data transmission **Software**. During data transmitting, the following figure will appear on the screen.



Fig. 10-1

FCC Warnings!

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

11. Version

In the main menu, press up/right or left/down button to select the [Version], you will get the monitor information.













Actually ECG arrhythmia analysis function is embedded in the device, but this function could only be initiated with a register Code. If arrhythmia analysis function is really in need, please contact the local supplier for the Register Code.

Note: The Register Code will be surcharged.

12. Trouble Shooting

Problem	Cause	Solution
The device can NOT be turned on.	1 The batteries are worn out. 2. The batteries are inserted incorrectly. 3. The device might be broken out.	1. Replace batteries with new ones. 2. Reinstall batteries with their polarities correctly. 3. Please contact the local service center.
The device is failed to measure heart rate.	1. The electrodes are not made good contact with your body. 2. Move when measuring 3. Electromagnetic interference 4. The signal is too weak	1 Place the electrode correctly. 2. Keep motionless and avoid moving when measuring 3. Keep away from electromagnetic interference 4. Change another method of measurement. (e.g. Chest/Cable measurement)
ECG waveform unstable or too much irrelevant waveforms exist.	1. Your skin is dry. 2. Electrode and the body does not contact well 3. Your body is too tense.	1. Cleaning skin with soap and water and moisten your skin with damp towel. 2. Check the instructions and repeat measurement. 3. Relax and repeat the measurement.

13. Key Symbols

Symbol	Meaning	Symbol	Meaning
	Heart rate (Device: BPM-beat per minute.)		The safe class of this device is type CF.
	Operating instructions	SN	Serial number
	Power button		Navigation buttons
	MENU button		Key icon
	Lead off		Lock/Unlock icons
	Low battery voltage	START	Start a measurement.
	Follow operating instructions		Caution

14. Technical specifications

Classification:

According to the type of protection against electric shock, it can be classified as internally power equipment. Its application type is CF and it is the movable common facility with no defibrillator or protection.

Operating Environment:

Power supply: 2 AA batteries

Operation Voltage: DC 3V (+0.3V, -0.8V);

Operation Temperature: 5°C ~ 40°C

Operation Humidity: ≤80%

Atmosphere Pressure Range: 86kPa-106kPa

Storage Environment

Storage Temperature: -20°C ~ 55°C

Storage Humidity: ≤93%

Atmosphere Pressure Range: 50kPa-106kPa

ECG Measurement:

Channel amount: 1 (differential input)

Measuring electrodes: Four integrative metal electrode, or three ECG electrode pieces connected to the ECG cable mount with selected ECG cable.

Three Measuring parts: The signals measured can be I lead and approximate II lead and III lead.

Signal bandwidth: 0.5Hz-75Hz (+0.4dB, -3.0dB)

Sampling rate: 250Hz

Heart rate measuring range: 30bpm-240bpm

Heart rate accuracy: 30~100bpm: ± 2 bpm; 101~240bpm: ± 4 bpm or 2 % (the smaller)

Display Mode:

Display screen type: TFT

The dimension of display area: 60mm×45mm

Backlight: LCD backlight

Data Storage:

Every record stores ECG data for 30 seconds.

The device can store 100 items of ECG strips records at most.

SD Card type: Micro-SD card

Dimension and Weight:

Dimension: 140mmX75mmX26mm (Length × Width × Height)

Weight: 125g (without batteries)

Accessories:

Battery (AA).....	2 pieces
Pouch.....	1 piece
USB data cable	1 piece
Software CD.....	1 piece
Instruction manual.....	1 piece
Quick Operation Guide.....	1 piece
Micro-SD Card.....	1 piece
SD Card reader (optional).....	1 piece
ECG cable (optional).....	1 piece
ECG Electrode (optional).....	1 package

Notes:

- ✧ **Specifications may be changed without prior notice.**
- ✧ **Disposal of this product and used batteries should be carried out in accordance with the local regulations for the disposal of electronic products.**
- ✧ **Please use the approved accessories supplied by our company, change other accessories may cause degrading the safety performance.**

**Guidance and Manufacturer's declaration – electromagnetic
emissions-For Handheld ECG Monitor**

1	Guidance and Manufacturer's declaration - electromagnetic emission
2	The MD100E-B Handheld ECG Monitor is intended for use in the electromagnetic environment specified below. The customer or the

	user of MD100E-B Handheld ECG Monitor should assure that it is used in such an environment.		
3	Emission test	Compliance	Electromagnetic Environment – guidance
4	RF emissions CISPR 11	Group 1	The MD100E-B Handheld ECG Monitor 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 equipment.
5	RF emissions CISPR 11	Class B	
6	Harmonic emissions IEC 61000-3-2	Not applicable	
7	Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	The MD100E-B Handheld ECG Monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's declaration – electromagnetic immunity- For Handheld ECG monitor

Guidance and Manufacturer's declaration - electromagnetic immunity			
The MD100E-B Handheld ECG Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the MD100E-B Handheld ECG Monitor 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	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be

			at least 30%.
Electrostatic transient / burst IEC 61000-4-4	$\pm 2\text{kV}$ for power supply lines $\pm 1\text{kV}$ for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 1\text{ kV}$ differential mode $\pm 2\text{ kV}$ common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MD100E-B Handheld ECG Monitor requires continued operation during power mains interruptions, it is recommended that the MD100E-B Handheld ECG Monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristics 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 Handheld ECG monitor that are not LIFE-SUPPORTING

Guidance and Manufacturer's declaration - electromagnetic immunity

The MD100E-B Handheld ECG Monitor is intended for use in the electromagnetic environment specified below.

The customer or the user of the MD100E-B Handheld ECG Monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic Environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the MD100E-B Handheld ECG Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is

			<p>the recommended separation distance in meters (m).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with following symbol:</p> 
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NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

a Field strengths from fixed transmitters, such as base station 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 the Handheld ECG Monitor (MD100E-B) should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting of the relocating the Handheld ECG Monitor (MD100E-B).

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

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMS - For Handheld ECG monitor that are not LIFE-SUPPORTING

Recommended separation distances between

portable and mobile RF communications equipment and the MD100E-B Handheld ECG Monitor

The MD100E-B Handheld ECG Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MD100E-B Handheld ECG Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MD100E-B Handheld ECG Monitor as recommended below, according to the maximum output power of the communications equipment

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 meters (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.

15. Maintenance and Storage

- ✧ Clean the device with a cloth lightly dampened with water, disinfectant alcohol or detergent, and then wipes it dry with a dry cloth.

- ✧ Wipe the electrodes using a cloth dampened with disinfectant alcohol.
- ✧ Do not wipe the device with benzene, gasoline, paint thinner, concentrated alcohol, or other volatile detergents.
- ✧ Do not place objects on top of the device. This could damage the device.
- ✧ Do not disassemble the device. There are no user serviceable parts. Repairs should only be carried out by authorized personnel.
- ✧ Do not sterilize this device in an autoclave, ultraviolet sterilizer or gas sterilizer (EOG, formaldehyde, high density ozone etc.)
- ✧ This device does not require calibration during the expected life cycle.
- ✧ When display the low voltage mark "", please change the batteries in time. Dispose the used batteries according to the applicable local regulations.
- ✧ Please remove the batteries if the device is not to be used for a long period of time.
- ✧ The environment temperature for transport or storage of the packaged device is $-4^{\circ}\text{F} \sim 131^{\circ}\text{F}$ ($-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$), and the humidity is $\leq 93\%$.

Caution:

- ✧ Keep operating environment clean, quiet, no erodent and no flammable material. Do not use this device in the environment with too high or too low temperature and humidity
- ✧ If this device is splashed or contaminated by water drop, please stop operating.
- ✧ Please do not use the device at once when it is moved from cold place to the warm and moist place.
- ✧ Please do not use sharp tools to operate any of buttons.
- ✧ Do not immerge the device into liquids or clean the surface with organic liquid, and do not splash liquids on the device.

15.1 Service Method

Service support: Our Company will offer user telephone and e-mail support as well as in-house repair at our facility

Parts replacement: Our Company will replace parts, accessories, free of

charge during the warranty period.

Our company will update the system software free of charge.

15.2 Exempt and limitation

a) Our company isn't responsible for such damage caused by force majeure. For example: fire, thunder flash, flood, cyclone, hail, earthquake, house collapse, commotion, plane failing and traffic accident, deliberate damage, lack of fuel or water, labor and capital bother, strike and stop-working etc.

b) No-service offer

The corresponding charge and insurance charge of disassembling, refurbishing, repackaging and moving the oximeter or the part of it.

The damage caused by the third company not commended by our company to adjust, install, replace the parts of the oximeter.

The damage and failure caused by user or its representative doesn't comply with the operator's manual.

c) The oximeter is installed or connected with such external device without our company permission as printer, computer, netline and lead to oximeter failure. Our company will charge for the maintenance.

d) Responsibility limitation

During the period of maintenance contract validity, if user changes the parts manufactured by other manufacturers without our company permission, our company is entitled to stop contract.

15.3 User Guarantee

a) Please read user manual carefully before operation.

b) Please operate and make daily maintenance as request of manual and guarantee.

c) Power supply and environment.

15.4 No-guarantee principle

- There is no-dispelled smut and not-original mark in the crust.
- There is physical damage on oximeter and its accessory.
- There are liquid leftover and eyewinker on oximeter, which may lead to short circuit and plug board failure.
- All the probe and accessories belong to consumption and beyond free change range.

- Such damage of probe caused by mechanical force doesn't belong to free change range.
- During measurement of SPO₂, principle leads to measuring value difficultly or inaccurate measurement.
- Not-original package leads to damaging oximeter during transportation
- Not our company professionals or authorized personnel disassemble oximeter and lead to oximeter failure.
- Not carefully read manual and so wrong operation lead to oximeter damage and failure.

15.5 User's Special Request for Guarantee Time

Our guarantee constitution for oximeter complies with electronic product after-sale service standard regulated by national laws. We regulate the guarantee time of hoist board is one year and all the accessories are three months. If users request the guarantee time beyond our regulated guarantee time, we should take it into consideration. Because electronic product has such character of quick changing, for such user asking more than three years guarantee time, our company will not sell oximeter parts during maintenance. Our company will upgrade oximeter or change new maintenance methods, for this, we charge the lowest price for new oximeter with user permission.

15.6 Repackage

- Take all the accessories and put them into plastic cover
- Try to use original package and packing material. User will be responsible for such damage caused by bad package during transportation.
- Please offer guarantee list and copy of invoice to standby with the period of guarantee.
- Please describe failure phenomenon in detail and altogether offer oximeter.
- Pack the product with the hard bag, and put the foam between the inner box and the carton to alleviate the shake.

16. General information about the Heart and ECG Measurements

The heart is a muscular pump controlled by electrical impulses generated by the body. It is divided into two by the septa and each side has two chambers—an atrium and a ventricle-linked by a one-way valve. The left atrium and

ventricle control oxygenated blood, and the right atrium and ventricle control de-oxygenated ("used") blood.

The electrical impulse that causes the heart to beat spreads across the atria, causing the left and right atrium to contract and pump blood into the left and right ventricles respectively. The two ventricles then contract and pump blood out of the heart. The heart muscle then relaxes, or re-polarises, allowing blood to fill up the heart again.

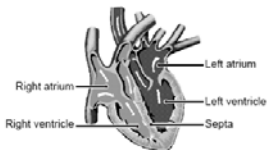


Fig. 16-1

An ECG monitor is able to measure the electrical impulse as it passes across and through the heart, causing the heart to beat. An ECG does not measure the movement of your heartbeat, but rather the electrical activity that causes the heart to beat. The measurements recorded by an ECG monitor, when combined with a medical examination, can help your doctor monitor your heart condition. The ECG measurements recorded by the device are NOT designed or intended for medical diagnosis. Conditions such as arrhythmia and Ischemia can only be diagnosed by a doctor through a special examination.

About the ECG Waveform

The ECG waveform shows the rhythm of your heartbeat during the 30-second measurement and displays the electrical activity causing the heart to beat. The waveform for each heartbeat shows the progress of the electrical impulse across and through the heart.

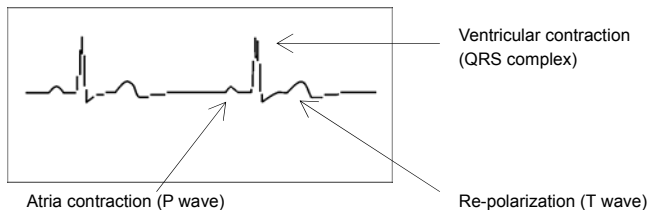


Fig. 16-2

The first peak indicates the spread of the impulse over the atria and the beginning of their contraction. This is known as the P wave. The second peak indicates the spread of impulse over the ventricles and the beginning of their contraction. This is known as the QRS complex. The third peak indicates the activity as the heart relaxes (re-polarization), and is known as the T wave.

What is Arrhythmia?

Arrhythmia is a condition where the heartbeat rhythm is abnormal due to flaws in the bio-electrical system that drives the heartbeat. Typical symptoms are skipped heartbeats, premature contraction, an abnormally rapid (tachycardia) or slow (bradycardia) pulse. This can be caused by heart disease, ageing, physical predisposition, stress, lack of sleep, fatigue etc. Arrhythmia can only be diagnosed by a doctor through a special examination.

What is Ischemia?

Ischemia is a condition in which insufficient oxygen is supplied to parts of the heart or other parts of the body. This is usually due to a blockage or partial blockage of an artery.

Ischemia can only be diagnosed by a doctor through a special examination.

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