

Edition: VER1.0B1



**HANDHELD**  
**ECG Monitor**

**INSTRUCTION  
MANUAL**

**MD100B**

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## Notes on Safety

This device monitors and records ECG waveforms, it is not intended for medical diagnosis. Please refer any recordings to a qualified physician for medical interpretation. This device is not a substitute for seeking medical attention. If you believe you are experiencing any adverse medical event, you are to seek medical attention immediately.

The recordings should be used as a reference for analyzing cardiac rhythm by doctors only. Always consult your doctor.

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

### Warnings!

- ✧ Not intended for use on individuals with a cardiac pacemaker.
- ✧ Not intended for use with an implanted 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 use on individuals with significant resting tremors.
- ✧ Do not use on individuals with dermatological conditions.
- ✧ Intended for adult user only.
- ✧ Do not use batteries of a type other than that specified in this manual.
- ✧ Do not take measurements where the device will be exposed to strong electromagnetic forces.

### 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, remove hair at the electrode contact point.

**General**

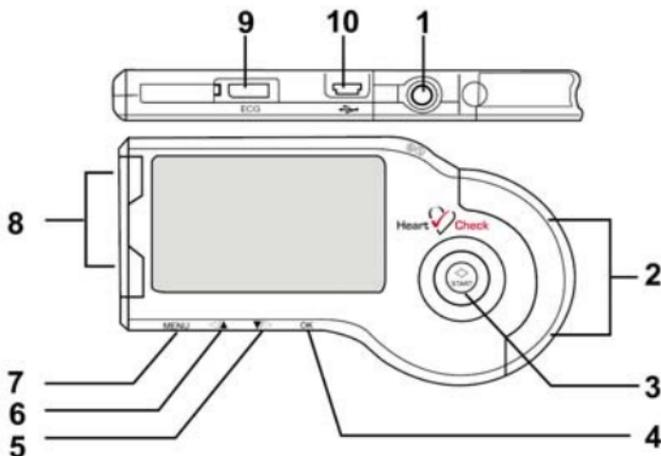
- ✧ Avoid extremes in temperature and humidity. Do not use this device in locations subject to high or low temperatures or humidity.
- ✧ Use at a temperature within 5°C to 40 °C and below 80% RH.
- ✧ Do not sterilize this device in an autoclave or gas sterilizer (EOG, formaldehyde, high density ozone 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 accessories according to applicable local regulations.

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## 1. General Description

### 1.1 Know Your Device



Picture 1-1

#### Description of Picture 1-1:

- ① **POWER** button: Power on or off the device.
- ② **Right Metal Electrodes**: Hold these two with right index finger when taking a measurement.
- ③ **START** button: The shortcut key for ECG measurement.
- ④ **OK** button: Press this button to confirm the selection or set date and time when in the Date and Time Setting Mode.
- ⑤ **▼/▶** Button: Press this button to move the cursor to your desired menu or change the number, or move the wave form to the left.
- ⑥ **◀/▲** Button: Press this button to move the cursor to your desired menu or change the number, or move the wave form to the right.
- ⑦ **MENU** button: Return to the previous menu by pressing this button.
- ⑧ **Left Metal Electrodes**: Place this against the center of left palm or chest when taking a measurement.
- ⑨ **ECG cable socket**: When taking a measurement by ECG cable, connect the ECG cable with this port.

- ⑩ **USB interface:** Transmit data to the PC through this interface.

## 1.2 Product Features

- ✧ Small, portable and easy to use.
- ✧ Choice of two measuring modes.
- ✧ USB data transmission.
- ✧ Fast measurement in just 30 seconds.
- ✧ Up to 200, 30 seconds ECG Strips recorded.
- ✧ Measurement of one channel ECG anytime, anywhere you like.
- ✧ Display of ECG waveform, heart rate, ECG quality result and battery status on the backlit LCD screen.
- ✧ Auto power-off.
- ✧ Two AAA batteries.
- ✧ PC Software provided to review recordings.

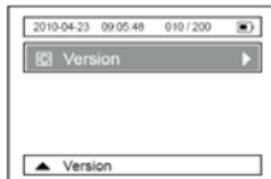
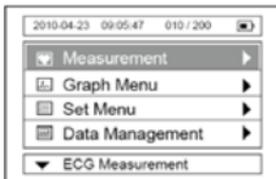
## 1.3 Intended Use

The MD100 ECG monitor is a handheld device intended for use in non-invasively recording and displaying of ECG waveforms for self recording of adults in daily life under physician direction to provide the physician with relevant data on the heart condition of their patient. The MD100 is a patient triggered event recorder which makes available to patients the ability to manually record transient cardiac events. The MD100 is suitable for patient and professional use. The MD100 ECG monitor allows the recorded ECG data to be saved to the device memory and to later display the ECG data on a computer. An ECG report can be printed from the computer.

## 1.4 Display

The device screen is used to display the ECG waveform, a confirmation of the ECG quality, other parameters, such as time & date, battery status and the status of data storage in memory.

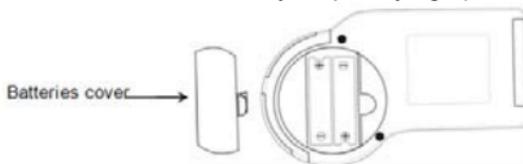
### Menu interfaces



- “ **Measurement**”: Enter this menu to select the measurement mode and take a measurement.
- “ **GRAPH Menu**”: Enter this menu to review, delete, and lock the detected ECG waveform and ECG quality result.
- “ **SET Menu**”: Enter this menu to set the Date & Time, Brightness, Beep Tone On/Off, Automatic Power-off, Assign ECG ID Number and set Wave Scale.
- “ **Data Management**”: Enter this menu to delete data.
- “ **Version**”: Enter this menu to review the device's information.

## 2. Battery Installation

- 2.1 Open the battery cover on the back panel of the device.
- 2.2 Insert two AAA batteries as indicated by the polarity sign (refer to Picture 2-1) .



Picture 2-1

- 2.3 Replace the battery cover on the back panel of the device.



**Ensure the polarity of the batteries is correct, otherwise the device will not function correctly.**

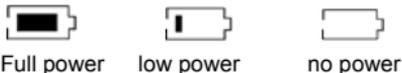
### Battery life and replacement

When the “Battery power is low please replace with fresh new batteries” message appears, replace batteries with new ones.

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

## Battery life

- ◇ Two new AAA batteries will last for approximate 400 measurements.
- ◇ The batteries enclosed in the package are used for demonstration purposes. It is possible that these batteries will not last for 400 measurements.
- ◇ The battery life can be confirmed in the upper right of the LCD display.



When the sign "⎓" appears, it means the battery power is not sufficient, and the device will display the information as in picture 2-2. We suggest users replace the batteries with new ones.

Battery power is low  
please replace with fresh  
new batteries

Picture 2-2 Low power

## CAUTION!

- ◇ 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 you come into contact with battery fluid, seek immediate medical attention.
- ◇ Remove batteries from this device during periods of non use.
- ◇ Disposal of the batteries should comply with local laws and regulations.

## 3. Setting Date and Time

**Always set the date and time before using the device for the first time.**

Routinely check whether the date and time are correct before using the device and reset if necessary. The date and time are important indicators when a measurement is taken.

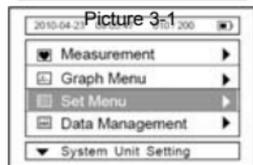
### 3.1 Date and time setting

**Note:** The date and time information will be displayed on the interface in the format of "Year/Month/Date"; "Hour/Minute/Second".

1. Press the Power button for 3 seconds to turn on the device.

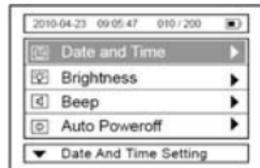


2. Select the “Set Menu” item, as shown in Picture 3-2. And then press the “OK” button to enter.



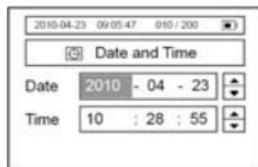
Picture 3-2

3. Select the “Date and Time” item, as shown in Picture 3-3, then press the “OK” button.



Picture 3-3

4. Press the “OK” button to highlight an item, and press  $\blacktriangledown/\blacktriangleright$  or  $\blacktriangleleft/\blacktriangleup$  button to adjust each date and time value. Press the “MENU” button to confirm your settings.



Picture 3-4

## 4. Taking a Measurement

### 4.1 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 quality of the measurement results.

◇ Incorrect positioning of the device during measurement may cause the results to be inaccurate, be sure to check the position before taking a measurement.

◇ To ensure the device remains in good working order, keep the electrodes clean. Disinfect the electrodes by wiping them with a soft cloth or cotton swab moistened with disinfectant alcohol.

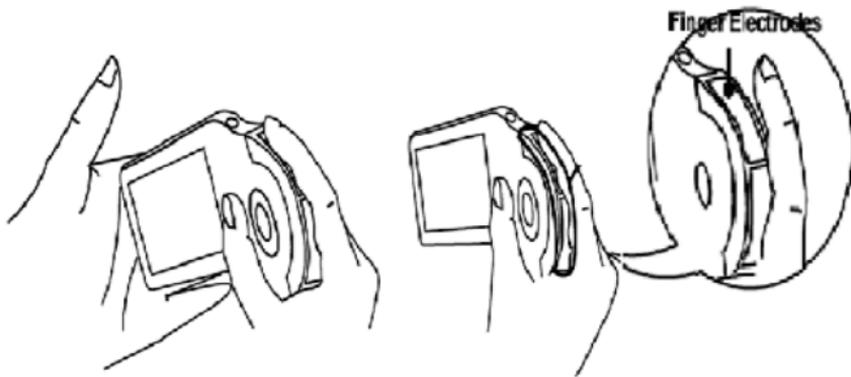
## 4.2 Measurement Methods:

There are three ways to record an ECG using this device; palm measurement, chest measurement and cable measurement.

The ideal posture for any of the methods listed above is to be seated comfortably with your back straight. You can also take a measurement while you are standing or while lying down. Be sure to stay as still as possible until the measurement is complete.

### 4.2.1 Palm Measurement

Make sure to hold the right metal electrodes of the device with right index finger firmly, and place the left metal electrodes against the center of the left palm. (Refer to Picture 4-1)



Picture 4-1

**Notes:**

- ◇ During measurement, the device will only respond to the “MENU” or “OK” button to discontinue the measurement.
- ◇ If the contact between the electrodes and skin becomes loose, or the conditions change during measurement, the recording may be inaccurate.
- ◇ If the electrodes do not have good contact during the measurement, the device will show the “” icon at the bottom right of the screen. Repeat recording.
- ◇ Keep still and do not move until the measurement is complete.
- ◇ If you experience difficulties using the palm measurement method please try one of the alternative methods outlined below or consult your physician.

**Wrong Operation Methods:**

- A. Hand contact with the electrodes become loose during the measurement.
- B. Palm or fingers are not covering the electrodes.

**4.2.2 Chest measurement**

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

**(1) Measurement for Male:**

Hold the device with the right hand; make sure that the index finger makes contact with the right metal electrodes sufficiently. Place the left metal electrodes against left side of your chest on bare skin about 5 cm below your left nipple. (Refer to Picture 4-2)

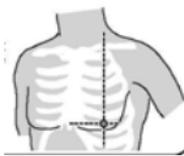


Picture 4-2

**Note:** If you experience problems placing the device’s left metal electrodes flat against your chest during chest recordings, **please ask your doctor for advice.**

**(2) Measurement for Female**

Locate the ECG monitor at the lower end of the breastbone and move horizontally to the middle of the left part of the chest. If necessary, gently lift the breast and place the left metal electrodes under the left breast. If the electrodes come in contact with under garments, move the device slightly until it has made contact with the skin. It is **NOT** necessary to remove the under garments; if you are unsure, **please consult your doctor**.



Picture 4-3

**Note:** The proper position of the left metal electrodes is shown in Picture 4-3.

**Improper Operation Methods:**

- A. The left metal electrodes are not in contact with the left chest.
- B. The hand positioning is not correct on the right metal electrodes.

**Notes:**

- ✧ Make sure that you are relaxed.
- ✧ Press the electrodes against your bare skin. Do not try and take a recording through clothing.
- ✧ If your skin is very dry, your recording may not be accurate.
- ✧ If you experience problems applying the device so that the left metal electrodes are flat against your chest when taking the chest measurement, **please ask your doctor for advice**.

### 4.2.3 Cable Measurement

If palm measurement is not ideal and it is not convenient to adopt the chest measurement, the cable measurement is recommended. 1. Place the electrode patches on the appropriate body areas as depicted in Picture 4-4. Connect the cables to the patches with the matching colour ends. 2. Connect the leads to the device through the lead port.



Picture 4-4

(1) The position for placing the cable electrodes is shown in Picture 4-4.

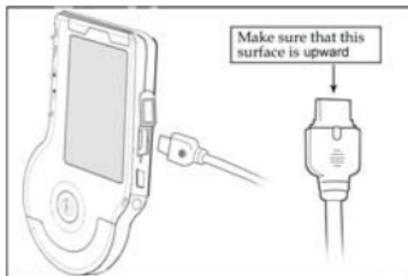
**White** (right arm RA) electrode — under the clavicle next to the right shoulder.

**Black** (left arm LA) electrode —under the clavicle next to the left shoulder.

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

**Note:** Ensure the electrode patches are placed in the correct positions and are well attached before pressing the “START” button.

(2) Connecting the device using the ECG lead cable. (Refer to picture 4-5).



Picture 4-5

Make sure the ECG cable connector is inserted fully into the device.

If the measurement has failed, please check the placement of electrode patches

or the connection of the unit and lead cable.

#### Wrong Operation Methods:

- A. Cables are mounted incorrectly.
- B. Electrode patches have been placed on the body incorrectly.

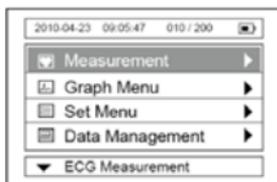
### 4.3 Measurement Mode:

There are two measurement modes for your selection easy mode and continuous mode.

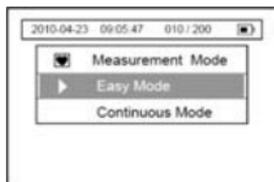
#### 4.3.1 Measuring in Easy Mode:

Press the  Power button for about 3 seconds to turn on the device.

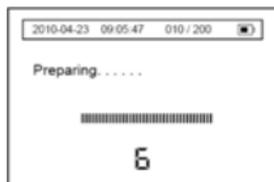
Enter the menu interface as shown in Picture 4-6 and select the “Measurement” item, the interface switches to the one as shown in Picture 4-7. Measurement Modes include Easy Mode and Continuous Mode. Choose the “Easy Mode” item, and click the “OK” button. The interface will appear as shown in Picture 4-8. After the count down from six to zero, the measurement will start.



Picture 4-6



Picture 4-7

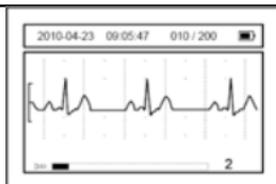


Picture 4-8

Additionally, you can press the START button to quickly start a measurement, based on the measuring mode selected in the “Measurement” Menu. Before measuring, make sure that you are in a relaxed position.

#### Measuring interface in Easy Mode:

It takes about 30 seconds to complete the ECG measurement. During the measurement, the device will beep synchronously along with the heart beat.



Picture 4-9

Description of Picture 4-9:

**"2010-04-23"**: The current date.

**"09:05:47"**: The current time.

**"010/200"**: Indicates that ten measurement results have been saved in the device and the device may store up to a maximum of 200 records.

 : Indication of the power level of the battery.

**E** : ECG amplitude ruler.

 : The examined ECG waveform.

**x1**: ECG waveform scale. You can select the displaying scale (x 0.5, x 1, x 1.5 or x 2) in the "SET Menu".

 : Speaker status – On or Off.

 : The status bar showing measurement progress.

**2**: Indication of measurement time.

 : The sign of heartbeat, it flashes on and off synchronously with the heart beat.

A measurement result message is displayed when the measurement has been completed (Refer to Picture 4-10 & 4-11 for details).



Picture 4-10



Picture 4-11

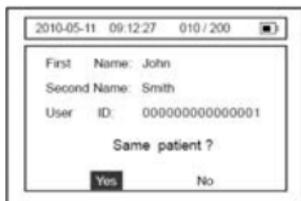
## Description of Picture 4-11:

"2010-04-23":	The current date
"09:05:47":	The current time
"010/200":	Indicates ten measurement results have been saved in the device and the device can store up to 200 records.
 :	Indication of the power level of the battery.
"HR 080 bpm":	The heart rate is 80 beats per minute.
"2010-04-23":	The record storage date
"09:05":	The record storage time

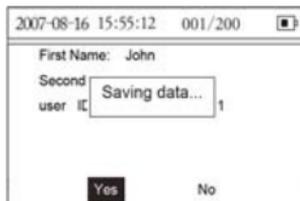
To cancel this ECG recording, press  button once to move the cursor to the "Cancel" item. Press OK button to return the Menu interface.

**To save the ECG result, please perform the following steps:**

To save the ECG press the OK button when the "Save" item is highlighted, or it will be saved automatically within 3 seconds. The screen then switches to the user information interface (Refer to Picture. 4-12). The user information is shown to allow the user to confirm the patient's identity.



Picture 4-12



Picture 4-13

If the patient's information is correct select the "Yes" item and press the OK button. The data will be saved under this patient.

If the patient's information is incorrect, move the cursor to the "NO" item and press the OK button to enter the correct patient information as shown in Pic.4-14.

Picture 4-14

To input the first name, press  $\blacktriangledown/\triangleright$  or  $\blacktriangleleft/\triangleleft$  button to change the character from A to the required letter (such as J in John) and then press the OK button to move the cursor to the next space. Set each character of the first name based on the afore mentioned steps. When the first name is complete, press the MENU button to move the cursor to the “Second Name” field.

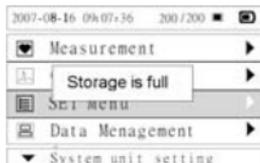
Enter the second Name and User ID following the steps used for the First Name selection (see instructions above).

**Note:** Each field is large enough to accommodate 15 characters or numbers.

Picture 4-15

To save the information, press the MENU button to move the cursor to the “Save” location and then press the OK button to save patient information and exit the current interface.

The device can save 200 30-second ECG records. When the device memory is full, the icon “ $\blacksquare$ ” will appear on the upper right of the LCD screen (shown in Picture 4-16 & Picture 4-17). Once the device memory is full an alert will be shown to indicate that no further records can be stored (shown as Picture 4-17). Before being able to record new ECGs delete unnecessary records from the device memory.



Picture 4-16



Picture 4-17

**To turn off the device press the  button for three seconds**

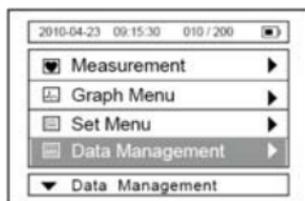
**Note:** If you forget to turn the device off, it will automatically shut down within one minute. Users can set the auto power off time limit (1 minutes, 2 minutes...10 minutes) in "System Settings"

### Caution!

- ✧ 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, even if "Stable waveform" is displayed as the measurement result.
- ✧ 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 prior measurement results.

### 4.3.2 Continuous Mode

The device must be connected to a computer prior to the start of a recording. In the "Measurement Mode" you can select the "Continuous Mode" for longer term monitoring. New batteries are expected to support approximately 6 hours of recordings in Continuous Mode.



Picture 4-18

**Note:** In Continuous Mode, the device must be connected to the computer as Continuous Mode measurement results cannot be saved in the device. The measurement results can be displayed in real-time on a computer by using the data

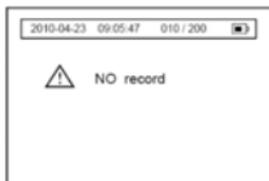
transmission software. To use the data transmission software connect the device to a computer by using the data cable provided. Recordings may be saved in the software on the computer once the transmission is complete.

## 5. Displaying an ECG

The "GRAPH Menu" is used to display, lock, or delete the list of ECG data stored.

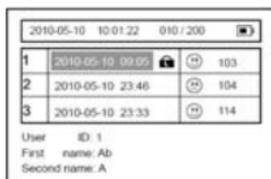
### Displaying ECG Waveform

1. Press the  button to select the "Graph Menu" when the main menu appears, and then press the "OK" button to confirm. If the device does NOT have stored records, it will show the following information as shown in Picture 5-1 when users enter into the "Graph Menu" screen.



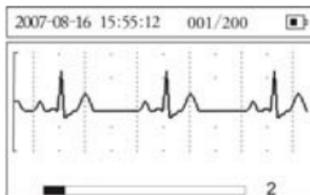
Picture 5-1

2. Press the  button to select the "Graph Menu" when the main menu appears, and then press the "OK" button to confirm. Refer to Picture 5-2.



Picture 5-2

3. Press the  or  button to select the ECG data you wish to view from the ECG data list, then press the OK button to display the detailed view of the waveform (Refer to Picture 5-3). Press the  or  button to move forward/backward through the waveforms, Press the "MENU" button to exit from the current menu.



Picture 5-3

Description of picture 5-3:

**"001/200"**: It indicates one measurement has been saved in the device and the device can store up to 200 records.

**E** : ECG amplitude ruler

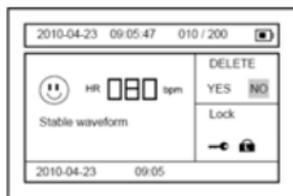
 : ECG waveform

 : Measurement progress bar

**2** : The interval of the current ECG waveform.

**Note:** Every stored ECG data is displayed with date, time and a character representing the measured waveform.

**Measuring result depiction:** After reviewing a certain ECG waveform, press the "OK" button to enter in to the corresponding ECG quality result depiction. (Refer to Picture 5-4).



Picture 5-4

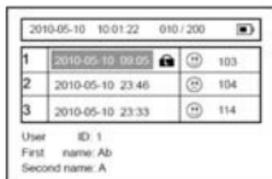
In the current menu press the  or  button to select YES, NO, or the  icon, and then press the "OK" button to delete save or lock the result.

### Deleting or locking the ECG data record

**Deleting:** Under the interface, such as in Picture.5-4, press the  or  button to select the "YES" item, you will delete the current ECG records.

**Locking:** Press the  or  button to select the  icon, you will lock the current ECG record being indicated by the  icon (Refer to Picture 5-5). The locked

record can NOT be deleted. To unlock the records, select the  icon again and press the "OK" button.



Picture 5-5

## 6. System Settings

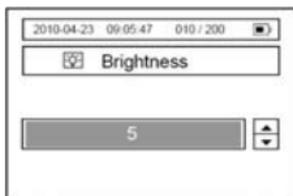
Select "Set Menu" in the main menu by pressing the  button, and then press the "OK" button to enter.

### 6.1 Date and Time Setting

Please refer to section 3 "Setting Date and Time".

### 6.2 Brightness Setting

6.2.1 Press the  button to select the "Brightness" item, and then press the "OK" button to enter. Press the  button or  to select the backlight level from "Off" to "1, 2, 3...7". Refer to Picture. 6-1.

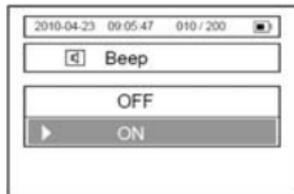


Picture 6-1

6.2.2 Press the "OK" button to confirm, and return to the previous menu.

### 6.3 Beep Setting

6.3.1 Press the  button or  to select the "Beep" item. Then press the "OK" button to enter, Select "On" or "Off" by pressing the  or  button, refer to picture 6-2.



Picture 6-2

6.3.2 Press the “OK” button to save the settings, and to return to the previous interface.

## 6.4 Auto Power-off Setting

6.4.1 Press the  $\blacktriangledown/\blacktriangleright$  button to select the “Auto Power off” item, and then press the “OK” button to enter. Press the button  $\blacktriangledown/\blacktriangleright$  or  $\blacktriangleleft/\blacktriangleup$  button to select “off” or to set the time limit “1 Min. 2 Min.... 10 Min.”, refer to Picture 6-3.

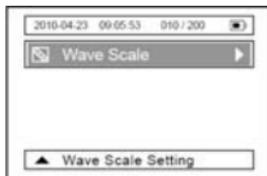


Picture 6-3

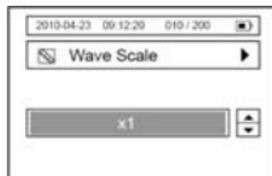
6.4.2 Press the “OK” button to confirm, and to return to the previous menu.

## 6.5 Wave Scale Setting

6.5.1 Press the  $\blacktriangledown/\blacktriangleright$  button to select the “Wave Scale” item, and then press the “OK” button to enter. Press the  $\blacktriangledown/\blacktriangleright$  button or  $\blacktriangleleft/\blacktriangleup$  button to select x0.5, x1, x1.5 or x2. refer to Picture 6-5.



Picture 6-4

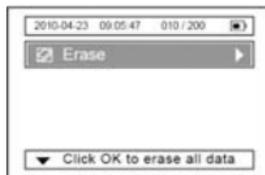


Picture 6-5

6.5.2 Press the “OK” button to confirm, and to return to the previous menu.

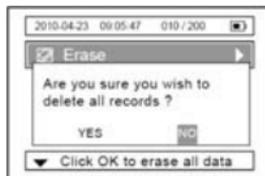
## 7. Data Management

In the main menu interface, press the  $\blacktriangledown/\blacktriangleright$  button to select the “Data Management” item, and then press the “OK” button to enter into the sub menu. Refer to the following picture.



Picture 7-1

Press the “OK” button to erase all data.



Picture 7-2

Select either “YES” or “NO” by using the  $\triangleleft/\blacktriangle$  &  $\blacktriangledown/\triangleright$  buttons. If selecting “YES” all data on the device will be deleted. Selecting “NO” will cancel the function.

## 8. Version

In the main menu, press the  $\blacktriangledown/\triangleright$  button to select the “Version”, item, information about the device will be displayed.

## 9. Data Transmission

Before data transmission, make sure that the device is on and connected to a computer by the data cable.

For data transmission operations refer to the accompanying **Software User Manual**.

## 10. Trouble Shooting

Problem	Cause	Solution
The device can NOT be turned on	<ol style="list-style-type: none"> <li>1. The batteries are drained or almost drained.</li> <li>2. The batteries are not inserted properly.</li> <li>3. The device is broken</li> </ol>	<ol style="list-style-type: none"> <li>1. Change batteries.</li> <li>2. Reinstall batteries</li> <li>3. Please contact the local service center.</li> </ol>

	out.	
The device is failure in measuring heart rate.	<ol style="list-style-type: none"> <li>1. The electrodes have not made good contact with your body.</li> <li>2. Movement occurred when measuring</li> <li>3. Electromagnetic interference</li> <li>4. The signal is too weak</li> </ol>	<ol style="list-style-type: none"> <li>1. Place the electrodes correctly.</li> <li>2. When measuring, please keep quiet and avoid moving.</li> <li>3. Keep away from electromagnetic source.</li> <li>4. Change to another method of measurement (e.g. Chest/Cable measurement).</li> </ol>
ECG waveform excursion or strong irrelevant waveform	<ol style="list-style-type: none"> <li>1. Your skin is too dry or oily.</li> <li>2. Electrode and body does not contact tightly.</li> <li>3. Your body is too tense.</li> </ol>	<ol style="list-style-type: none"> <li>1. Clean the skin thoroughly with soap and water prior to use.</li> <li>2. Press the electrode with a certain force.</li> <li>3. Relax and repeat the measurement.</li> </ol>

## 11. Key Symbols

Symbol	Meaning	Symbol	Meaning
	Type CF applied part.		Record is locked
	Caution. May indicate important information.		Record is full
	Heart rate (Unit: BPM(beat per minute))		Power button
	LI ECG Lead is disconnected	<b>SN</b>	Serial number
	Low battery		USB interface
	Manufacturer		The device is susceptible to electro static discharge (ESD).
	Date of Manufacture		The packaging for this device is recyclable.
	Is not AP category Equipment.		European union approval
	Authorized representative in the European community.		

## 12. Technical Data

### Classification:

According to the type of protection against electric shock, it can be classified as internally powered equipment. The device's application type is CF and it is a movable common facility with no defibrillator or protection.

### Operating Environment:

Operation Temperature: 5°C~40°C;

Atmosphere Pressure Range: 86kPa-106kPa;

Operation Humidity: ≤80%, no condensation;

Operation Voltage: DC 3V (+0.3V, -0.8V); 2 AAA batteries.

### Storage Environment

Storage Temperature: -20°C~55°C

Storage Humidity: ≤93%, no condensation

### ECG Measurement:

**Channel amount:** 1 (difference input)

**Measuring electrodes:** Four integrated metal electrodes.

**Three Measuring parts:** The signals measured can be lead [I] (between right and left hand) and approximate lead [II] or lead [III] (between both hands and the chest).

**Note:** The signals measured by the device positioned from the right hand and left hand is lead [I] on a standard surface ECG. The signals measured by the device positioned from the right hand and left chest best approximates a frontal plane lead such as lead [II] on a standard surface ECG.

**Signal bandwidth:** 0.5Hz-75Hz

**Sampling rate:** 250Hz

**Heart rate measuring range:** 30bpm-240bpm

**Heart rate measuring accuracy:** 30~100bpm: ±2bpm; 101~240bpm: ±4bpm

### Display Mode:

Display screen type: 160 × 240 dot - matrix single color LCD.

The dimension of display area: 70mm×45mm

Backlight: LCD backlight

### Data Storage:

Every record stored holds 30 seconds of ECG data.

The device can store 200 ECG recordings.

### Dimension and Weight:

Dimension: 136mm×84mm×21mm (Length × Width × Height)

Weight: 120g (Not including Two AAA batteries)

### Product Accessories:

AAA Batteries-----	2 pieces
Protective Pouch-----	1 piece
Software CD-----	1 piece
Instruction Manual-----	1 piece
Quick Start Guide-----	1 piece
Service Policy Label-----	1 piece
Packing List-----	1 piece
USB cable-----	1 piece
3 Lead ECG Cable-----	1 piece
Electrodes-----	1 Packet
Certificate of Quality-----	1 piece

### 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 accessories provided with the equipment, use of other accessories will render the warranty null and void.**

## 13. Maintenance and Storage

- ◇ Clean the device with a cloth lightly dampened with water, disinfectant alcohol or detergent, and then wipe 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.
- ◇ 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 displaying the low voltage mark "", please change the batteries. 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  $\leq 93\%$ , no condensation.

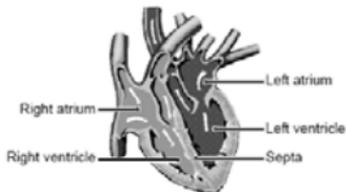
**CAUTION:**

- ◇ Keep operating environment clean, quiet, no erodent and no flammable material. Do not use this device in an environment with too high or too low temperature and humidity.
- ◇ Please do not use the device when it is moved from a cold place to a warm and moist place. The device should be given some time to adjust to the change in temperature.
- ◇ Please do not use sharp tools to operate any of the buttons.
- ◇ Do not immerge the device into liquids or clean the surface with organic liquid, and do not splash liquids on the device.

## 14. 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 sides by the septa. 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.

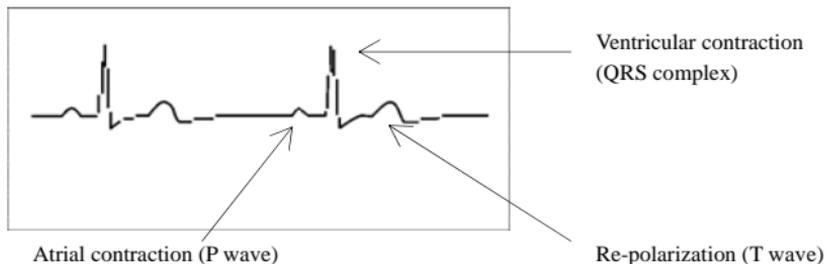
The electrical impulse that causes the heart to beat spreads across the atria, causing the left and right atrium to contract and pump blood into the left and right ventricles respectively. The two ventricles then contract and pump blood out of the heart. The heart muscle then relaxes, or re- polarizes,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



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.



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) heart rate. These may be caused by such conditions as heart disease, aging, physical predisposition, stress, lack of sleep, and fatigue. Arrhythmias can only be diagnosed by a doctor.

## 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.

## Appendix

### Guidance and manufacture's declaration- electromagnetic immunity for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration - electromagnetic immunity			
The Handheld ECG Monitor is intended for use in the electromagnetic environment special below. The customer or the user of 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) IEC610004-2	$\pm 6\text{kV}$ contact $\pm 8\text{kV}$ air	$\pm 6\text{kV}$ contact $\pm 8\text{kV}$ air	Floors should be wood, concrete or ceramic tile. If floor are converted with synthetic material, the relative humidity should be at least 30%
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**Guidance and manufacture's declaration - electromagnetic immunity for  
EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

**Guidance and manufacture's declaration - electromagnetic immunity**

The Handheld ECG Monitor is intended for use in the electromagnetic environment special below. The customer or the user of Handheld ECG monitor should assure that it is used in such an environment.

<b>Immunity Test</b>	<b>IEC 60601 Test level</b>	<b>Compliance Level</b>	<b>Electromagnetic environment guidance</b>
61000-4-6 Radiated RF IEC 61000-4-3	3V/m 80Hz To 2.5 GHz	3V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Handheld ECG monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = \frac{3.5}{E_1} \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = \frac{7}{E_1} \sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$ <p>Where P is the maximum output power rating of the transmitter in Watts (W) according separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> 
<p><b>Note1:</b> At 80MHz and 800MHz, the higher frequency range applies.</p>			
<p><b>Note2:</b> These guideline may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

- <sup>a</sup> Field strengths from fixed transmitters, such as base situation 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 is used exceeds the applicable RF compliance level above, the Handheld ECG monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Handheld ECG monitor.
- <sup>b</sup> Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING**

**Recommended separation distances between portable and mobile RF communications equipment and the Handheld ECG monitor**

The Handheld ECG monitor is intended for use in an electromagnetic environment in which radiated RF disturbance is controlled. The customer or the user of the MD100 Handheld ECG monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Handheld ECG monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	80MHz to 800 MHz $d = \frac{3.5}{E_1} \sqrt{P}$	800MHz to 2.5 GHz $d = \frac{7}{E_1} \sqrt{P}$
0.01	0.1167	0.2334
0.1	0.3689	0.7378
1	1.1667	2.3334

10	3.6893	7.7386
100	11.6667	23.3334

For transmitters rated at a maximum output power not listed above, the recommended separation distance 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.

**NOTE1** At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

**NOTE2** 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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