



Cardio Care
ECG/EKG Recorder ►►

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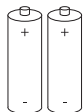
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Package Content and Know Your Unit

Package Content



Instruction Manual



AAA Batteries

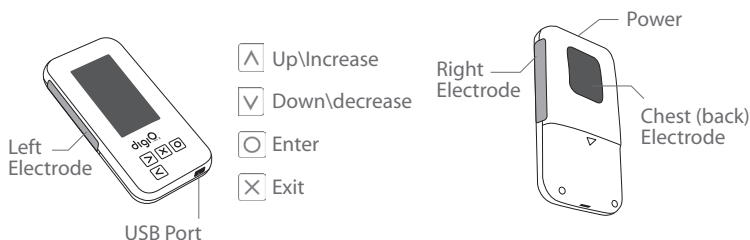


Cardio Care Unit

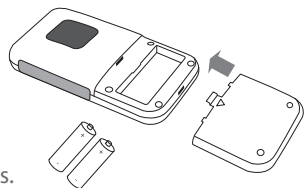


Protective Pouch

Main Unit



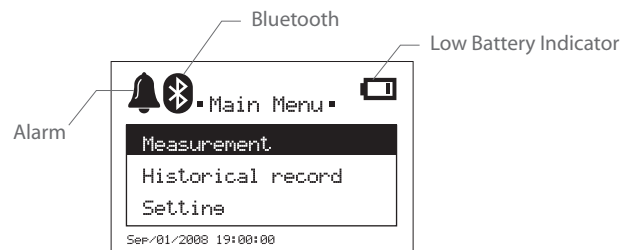
Battery Replacement



1. Remove the battery cover.
2. Put 2 new 1.5V AAA alkaline batteries.
3. Put the battery cover back.

Getting Started

The LCM Display



Introduction

The Principle of ECG/EKG

Human heart is able to beat as the electrical impulse passes across and through it, and the beat accompanies producing electric activity. An ECG/EKG does not measure the movement of your heartbeat but rather the electrical activity, it is recorded by measuring the potential difference of particular surface part of body by the electronics instrument.

Intended use


Cardio Care is a non-invasive and easy to use electrocardiograph unit that you can use indoor environment. It records and stores electrocardiogram (ECG) measurements of your heart rhythm of each 30 second period. These ECG readings can monitor your condition more easily. Cardio care unit is designed for prescription purpose, record, store and display the ECG waveform and heart rate that it can help doctor to know the patient's condition. This unit is intended for use on the adult population over 20 years old.

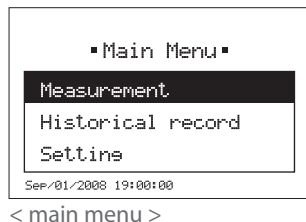
<NOTE>

Please note that while the measurement from an ECG/EKG recorder is an 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.

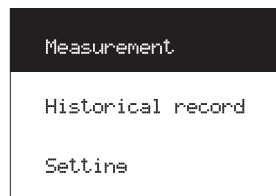
Operating Instructions


Power on / off

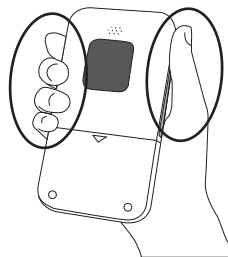
Press  to turn on / off Cardio Care. After the welcome message, You will enter main menu automatically, where you can proceed on taking measurement, checking historical record or adjusting setting.





Measurement

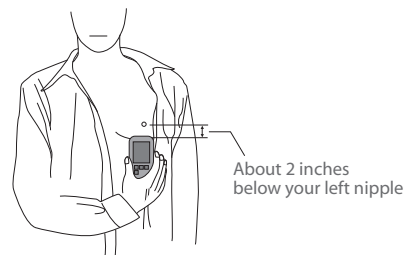



Press button  and start to measurement.





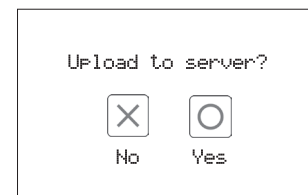
- A. Make sure to be in a relaxed condition. The ideal posture of being seated comfortably with your back straight is suggested. However, measurement can still be made while you are standing, lying down or in other comfortable positions.
- B. Use your right hand to hold the unit properly with your fingers gently pressed on the side electrodes. Please refer to the figure.

- C. Press  and it will start measuring with a beep sound after 5 seconds. Place the unit with the back end electrode against the spot slightly below your chest, The measurement will stop after 30 seconds of recording automatically and is accompanied with a beep sound, The heart rate will be shown on the page and press .



After press  the device will show the loading page, and then start to measurement.

- D. The unit will ask automatically if you want to upload the record to server, press  to upload or  to skip.



- E. After selection, it will go into the page of showing historical record list immediately. More details about the record reading will be shown in the "Historical Record" section.

<NOTE>

Please use ONLY your right hand to take the measurement

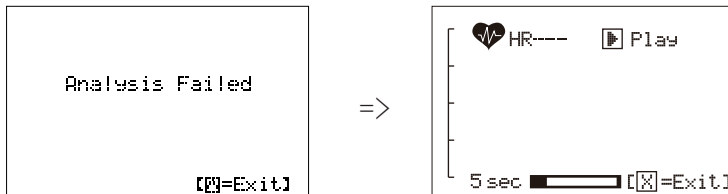
Important Notes on Taking Measurement

In order to obtain an accurate ECG/EKG reading, it is important that measurement is taken correctly. Before taking measurement for the first time, read these instructions carefully and make sure you observe the following points each time you take measurement.

- Make sure that the electrodes are directly touching your skin.
- If your hand or skin is 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 or a cotton swab moistened with disinfectant alcohol.
- Do not use disinfectant alcohol to clean the unit except 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 inaccurate, so be sure to check their positions before taking a measurement.
- After taking 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.

<NOTE>

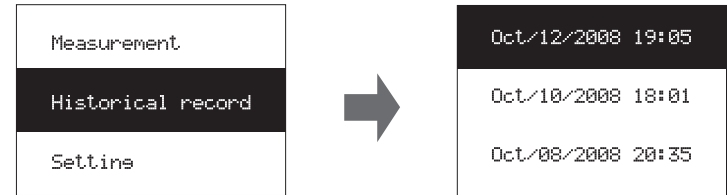
If the ECG is interfered by electrostatic discharge, the LCM may show "analysis failed" as follow:



Please wait 30 seconds and then measure again.

Historical Record

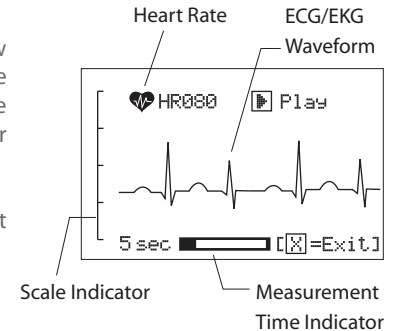
Historical record page can be accessed directly after measurement or through Menu selection.



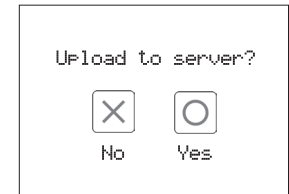
• Review Measurement Record

Historical record page will show all record that is stored within the device, press to select the desired record for clearer ECG/EKG data.

The ECG/EKG record will start playing automatically, press to slow down, press to pause /resume and to exit.




Please note that if the record hasn't been uploaded, it will confirm repeatedly.




· Delete Record

(A) Delete All Record

Please go to the historical record page, then press and hold key  for 2 seconds to delete all record stored in this unit.

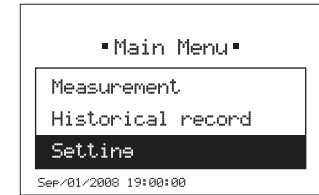
(B) Delete Single Record

Press and hold key  for 2 seconds to delete while playing the record.

 Warning: Erased record can not be restored.



Setting

Setting page can be accessed directly through Menu selection.



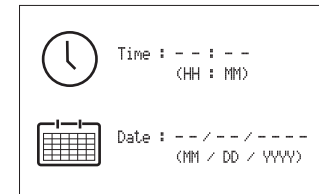
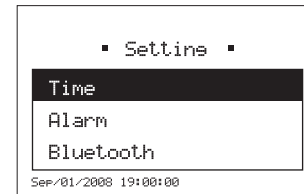
· Date and Time:



Press   to set date and time and  to confirm. Press  to return to the previous step.

Press  to decrease the number.





Press  to increase the number.

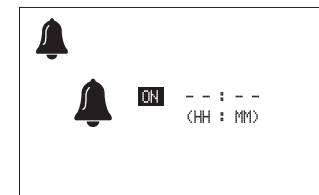
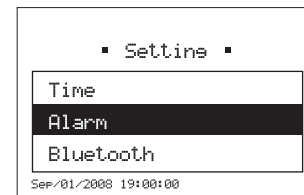


· Alarm:



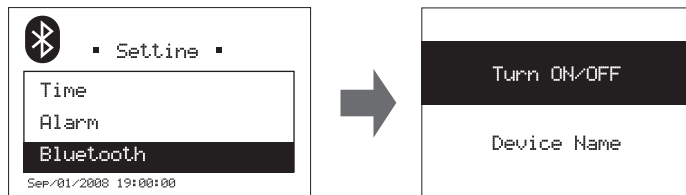
Press   to set the alarm time. Press  to decrease the number. Press  to increase the number.




Please press   to select ON/OFF and  to confirm. Press  to return to the previous step.

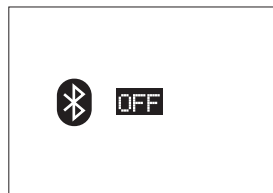


Bluetooth

(A) Turn ON/OFF






Press   to select ON/OFF and  to confirm.



(B) Device Name

Users are allowed to modify the device name by changing the last digit(0-9)to avoid device search collision situation.

Please press   to select the number from 0 to 9 and  to confirm.



Bluetooth: (Upload record to PC/server)

1. Download "My Cardio Care"

Please download and install "My Cardio Care" from our website <http://www.digio2.com> before uploading record to PC/server.

Go to <http://www.digio2.com>

-> Press "Download"




-> Press "Healthcare Device"

-> Press "My Cardio Care"

(Download and install "My Cardio Care" to your PC)

2. Setting Device Name

Users are allowed to modify the device name by changing the last digit(0-9)to avoid device search collision situation.

Please press   to select the number from 0 to 9 and  to confirm.



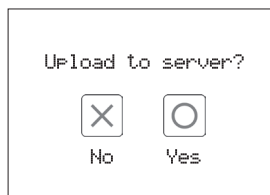
3. Connect Bluetooth

When you see the Bluetooth device has been connected then key in '0000' as passkey.

4-1. Go to the device's Historical record page



4-2. Press ☐ to enter the desired record for upload. The screen will show "Upload to Server?"



4-3. Press ☐ to upload the record to PC/ server.

4-4. If the upload is complete, the PC/ server monitor will show ECG/EKG waveform.

USB: (Upload record to PC/server)

1. Download "My Cardio Care"

Please download and install "My Cardio Care" from our website <http://www.digio2.com> before uploading record to PC/server.

Go to <http://www.digio2.com>

-> Press "Download"

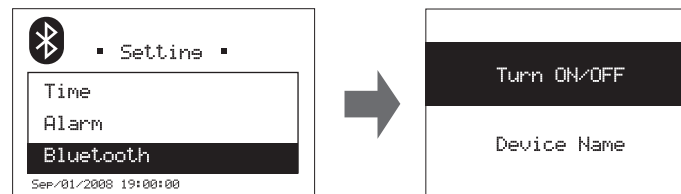
-> Press "Healthcare Device"

-> Press "My Cardio Care"

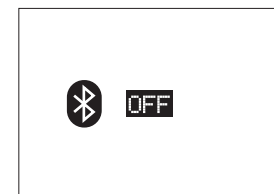
(Download and install "My Cardio Care" to your PC)

2. Turn Off Bluetooth

Make sure the Bluetooth of Cardio Care is turned off.

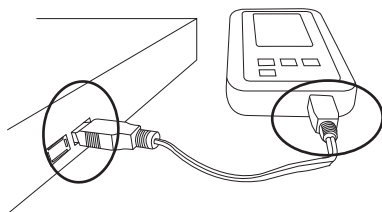


Press to select ON/OFF and ☐ to confirm.



3. Connect Mini USB cable

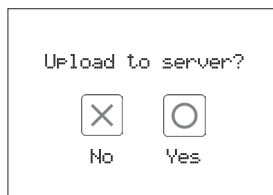
- Prepare one Mini USB cable
- Please connect Mini USB/USB cable to Cardio Care.



4-1. Go to the device's Historical record page



4-2. Press ☐ to enter the desired record for upload. The screen will show "Upload to Server?"



4-3. Press ☐ to upload the record to PC/ server.

4-4. If the upload is complete, the PC/ server monitor will show ECG/EKG waveform.

<NOTE>

If user connect the ECG with PC by USB cable, the ECG will not has measurement function, and user can only transfer the data to PC.

Important Safety Note

Safety Labels Used in this Manual

"⚠ Warning" indicates a potentially hazardous situation which, if not avoided, could result in serious injury.

⚠ Warning:

- The device is not design intended for complete diagnosis of cardiac conditions. The device measure heart rate and heart rhythm only
- Do not use this unit if you have a cardiac pacemaker or other implanted devices.
- Do not use this unit with a defibrillator or HF surgical equipment.
- Do not strong shock, drop and vibrations
- Do not use this unit during an MRI Scan. (Contraindications for undergoing an MRI scan for spine-related pain in the back, neck or leg include: Patients who have a heart pacemaker, a metallic foreign body (metal sliver) in their eye, and who have an aneurysm clip in their brain.)
- Do not attempt self-diagnosis or self-treatment based on the measurement results and analysis. Always consult your doctor. Self-diagnosis or self-treatment may lead to deterioration in your condition.
- Do not use this unit on people with sensitive skin or allergies.
- Do not attempt to use the unit over or through clothing.
- Do not attempt to use the unit with your left hand.
- Do not use for any purpose other than obtaining an electrocardiograph.
- Do not use batteries of a type other than that specified in this manual.
- Do not measure if dust is on the electrodes. Clean them first.

- 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 unit will be exposed to strong electromagnetic forces.
- In order to achieve accurate measurements, please replace new batteries when low battery indicator is on.
- Safety hazard may occur in case the final system does not provide sufficient insulation to mains and earth, however, the equipment can be safely connected to other IEC/EN 60601-1 approved equipment that has all its connectors intended for connection to this unit separated from earth by basic insulation.
- Do not use this product in combination with non IEC/EN 60601-1 approved computers/adaptors.
- Any ECG/EKG record erased from the unit cannot be recovered.
- Do not wash this unit with water.
- Do not store the unit in the following ambient conditions:
 - (1) Locations exposed to direct sunlight.
 - (2) Locations subject to high temperatures and high humidity.
 - (3) Wet or damp locations where water may get on the unit.
 - (4) Dusty locations.
 - (5) Near fires or open flames.
 - (6) Locations exposed to strong vibration.
 - (7) Locations exposed to strong electromagnetic fields.
- Parts of electrodes and other connectors should not contact other conductive parts including earth.
- The medical system that will connect to this unit or another equipment shall comply with IEC/EN 60601-1-1.
- When ECG transfer data through USB cable to PC, the ECG is no power no function, to avoid any electronic shock, please do not use ECG to measure when USB cable is connecting PC.

Maintenance and Storage

- Clean the unit with a cloth dampened with water or mild detergent, then wipe it dry with a dry cloth.
- Wipe the electrodes using a cloth dampened with ethyl alcohol (75% v/v).
- Do not wipe the unit with benzene, gasoline, paint thinner, concentrated alcohol, or other volatile detergents.
- Do not place objects on top of the unit. It could damage the unit.
- Do not disassemble the unit. Repairs should only be carried out by digiO2 authorized personnel.
- There is no sensor in the ECG/EKG; therefore, this unit does not require calibration.
- Remove the batteries from this unit when you are not going to use it for a long period of time (approximately three months or more).

Troubleshooting

Problem	Cause	Solution
Nothing happens when you press the power button	The batteries are worn out. The batteries are inserted incorrectly.	Replace both batteries with new ones. Insert the batteries with their polarities correctly aligned.
Measurement finishes but result is abnormal.	The electrodes are not making good contact with your finger or chest.	Check the instructions and repeat the measurement.
	Your body is too tense.	Relax and repeat the measurement.
	Electrode contact was broken before 30 seconds of data has been recorded.	Make sure that your finger and chest maintain contact with the electrodes for the full 30 seconds of the measurement.
	The chest electrode has been applied over clothing.	Apply the chest electrode to bare skin.
	Your skin is dry.	Moisten your skin with a damp towel or wash your hands in advance, but don't use the unit in wet hands.
	The ECG signal is too weak.	Make sure that the electrodes are applied correctly. However, for some individuals measurement may not be possible.

Warranty Information

Your Cardio Care unit is warranted to be free from defects in materials and workmanship appearing within 1 year from the date of purchase, when used in accordance with the instructions provided. The above warranties extend only to the original retail purchaser.

Manufacture Date

According manufacture date, please see product's CE label SN number, the SN coding principles are as below.



SN Coding principles :

The first to fourth codes 0009 are the product part number, A9800009, last four codes.

The fifth to sixth codes "YY" are the last 2 codes of A.D.

The seventh code "M" is month (1~9, Oct=A, Nov=B, Dec=C)

The eighth to ninth code "DD" are manufacture date

The tenth to fourteenth code "XXXXXX" are serial number

The fifteenth code "R" is the version of the product (A9800009)

Sings and Symbols :

	Type B Equipment		An item that poses no known hazards in all MR environments.
	Caution/Warning. Consult accompanying documents		Consult instruction for use
	CE-European Conformity. This device conforms to the standards for products sold in the European Economic Area.		
	Interference may occur in the vicinity of equipment marked.		

Specifications

ECG/EKG Specifications	ECG-10X
Power Supply	1.5V AAA Battery*2
Standard Sensitivity	10mm/mV \pm 5%
Input Impedance	>10M ohms
Input Dynamic Range	+ / - 2mV
Bandwidth	0.005 ~ 40 Hz
CMRR	> 95 dB
AD Conversion	12 bits
Sampling Frequency	256 samples/sec
Measurement Time	30 sec.
Dimensions (WxDxH) unit: mm	125x64x27
Weight(with batteries)	144g
Environmental Conditions	
· Storage Temp.	-20°C ~ 50°C
· Operating Temp.	10°C ~ 40°C
· Humidity	25% ~ 95%
Data Transmission	USB/Bluetooth
Waveform Output	USB/Bluetooth
Display	60mm x 32.5mm LCM display panel

<NOTE>

- Specifications may be changed without prior notice.
- Disposal of this product, the optional accessories and used batteries should be carried out in accordance with the national regulations for the disposal of electronic products. Unlawful disposal may cause environmental pollution.
- This product complies with medical device standards IEC 60601-1 with Amendments 1&2.
- This product meets EMC standards IEC60601-1-2:2001+A1:2004. Using this device with or near other medical/electrical equipment could produce mutual interference. Be sure to read the Instruction Manual for correct installation and use. Also, be sure to read the Instruction Manuals for all other electronic equipment nearby.

FCC Statement-Potential for Radio/Television Interference (for U.S.A. only)

- This product 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 environment. The product generates, uses, and can radiate radio frequency energy and, if not 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 condition. If the product does cause harmful interference to radio or television reception, which can be determined by turning the product on and off, 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 product and the receiver.
 - Connect the product 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.

Manufactured by digiO2 International Co., Ltd.

Made in Taiwan

Distributed by:

digiO2 International Co., Ltd.

4F-13, No. 79, Sec. 1, Hsin Tai Wu Rd., Hsi-Chih, Taipei Hsien 221, Taiwan

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Regulation Number: 870.2340



= Type B

Federal Communications Commission (FCC) Statement

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

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.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) this device may not cause interference and
- 2) this device must accept any interference, including interference that may cause undesired operation of the device.

FCC RF Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

End users must follow the specific operating instructions for satisfying RF exposure compliance.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

ECG-10X wireless system configuration and operation:

1. Quality of service: BQB test
2. Security requirements: Key in Pin code "0000".
3. If users paired with PC was unsuccessful, the data was not shown it on the LCM. Users can repairing and upload the it again.