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Chapter 1: Introduction to ReadMyHeart

Thank you for purchasing ReadMyHeart.

This manual provides guidance on how to use this product, as well as reference information on its components.

Purpose of the device (Indications for use)

ReadMyHeart is intended to record, display, store, recall, and transfer electrical heart activity for home health care use. The intended users are adults over the age of 20. This device is not intended to substitute for a hospital diagnostic ECG (ElectroCardiograph) device. This device is also not intended for recording and transmission of user's ECG signals simultaneously.

Important safety notice

Caution: The ECG graphic displayed on the LCD is an idealized tracing, and NOT your recorded ECG tracing.

Warning: ReadMyHeart is NOT a diagnostic device, it is only an ECG recorder and it CANNOT serve as a substitute for a traditional ECG diagnosis.

Warning: ReadMyHeart will NOT tell you if you have heart problems. Consult your physician for a diagnosis, do NOT interpret the numbers yourself.

Caution:

Do NOT operate ReadMyHeart concurrently with other electrical devices.

Do NOT connect the device to your computer via USB cable while recording

Do NOT record with a dirty or greasy hand surface

Do NOT move, talk, or breathe deeply while recording

Do NOT press too hard on the dry conduction electrode pad

Do NOT use creams, gels, moisturizers etc. on your hands prior to using the device

Caution: If your measurement values do NOT fall within the reference range, multiple recordings are recommended.

Introduction: what do ECGs do?

The function of our heart is so important. It has its own automatic nervous (electrical) system to keep it running independently, without control from the brain. Electrical waves travel through the heart chambers to charge and trigger heartbeats. Each chamber contracts with perfectly synchronized timing to circulate blood effectively. If the chambers are not synchronized, the blood will not circulate effectively, which can be the symptom or the cause of cardiovascular diseases. For more information on irregular heartbeats or arrhythmias, please visit the American Heart Association's website: www.americanheart.org

How does ReadMyHeart work?

The micro-current generated during heartbeats passes through the thumbs, which is where the device records it. Like the electronic cardiograph, it records the heart's electrical activity and counts the related cardiograph parameters for the users. These measurements compose the ECG tracing (like the model picture on the LCD screen) which doctors use to check for arrhythmias and other cardiovascular diseases.

Chapter 2: Getting started

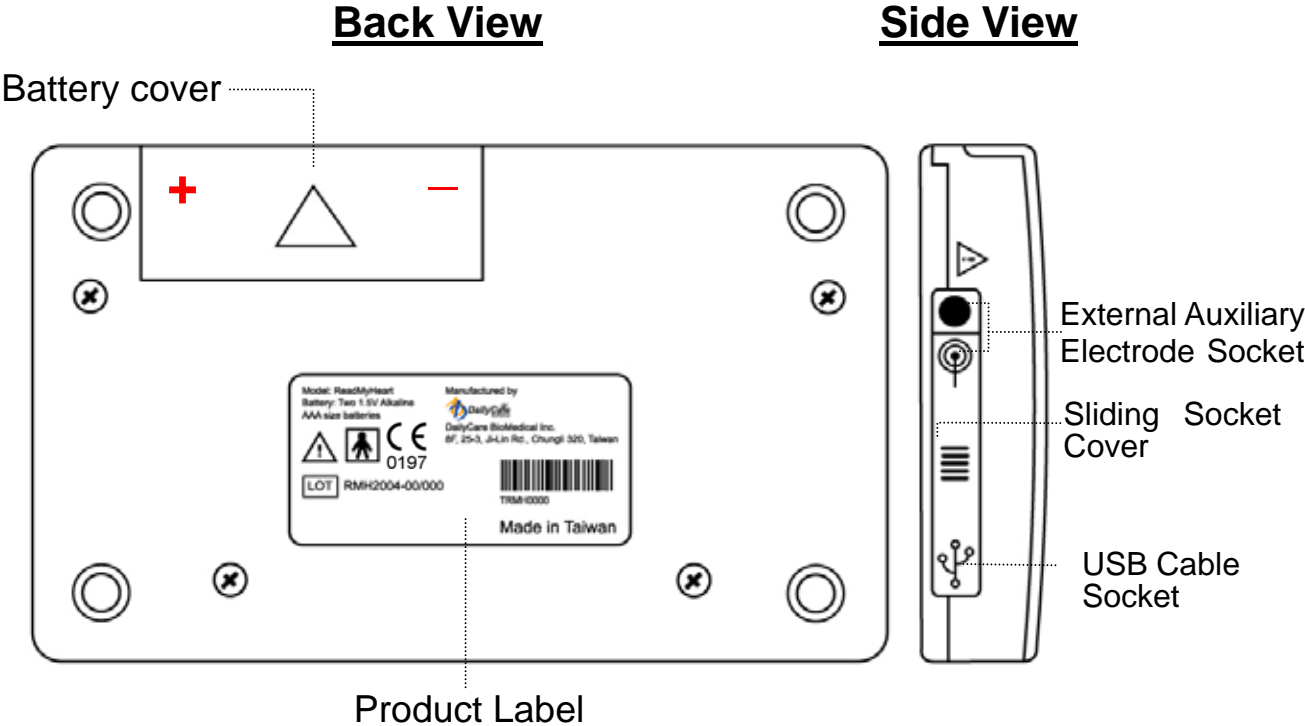
Product Package contents

<input checked="" type="checkbox"/>	ReadMyHeart	X 1
<input checked="" type="checkbox"/>	USB Cable	X 1
<input checked="" type="checkbox"/>	ReadMyHeart Software CD	X 1
<input checked="" type="checkbox"/>	ReadMyHeart User's Manual	X 1
<input checked="" type="checkbox"/>	External Auxiliary Electrode Cable	X 1

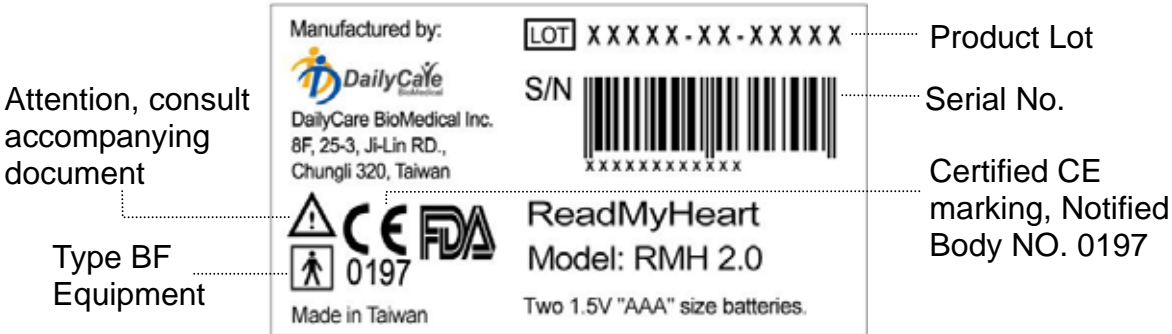
Note: The following accessories are not included:

1. **AAA alkaline batteries:** Two batteries are needed to operate ReadMyHeart.
2. **Electrode gel pad:** Pads for external auxiliary electrode cable may be purchased at www.dailycareusa.com or your local drug stores. Please check at your local drug store for more information. Use only FDA cleared ECG electrode gel pads.

Product Back View & Side View



Product Label

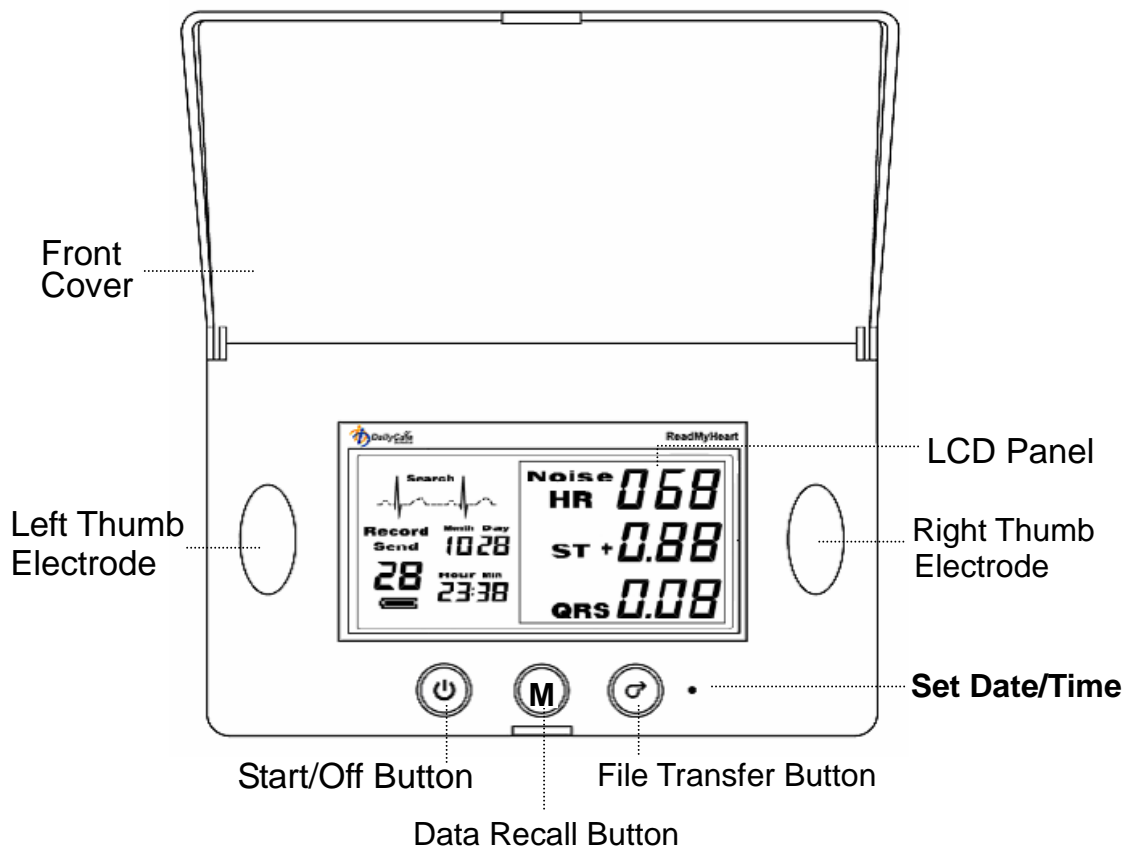


Battery Installation

Slide the battery cover open, and insert two AAA alkaline batteries, making sure the poles of the batteries are inserted correctly.

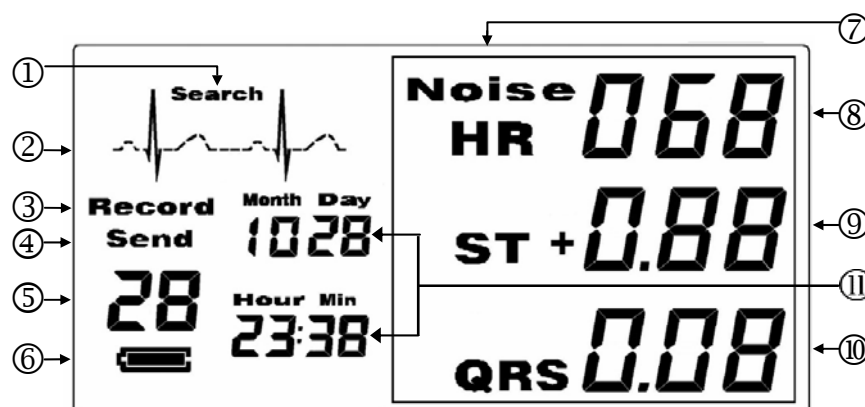
Note: If the batteries are inserted incorrectly, it may cause the temperature of ReadMyHeart to rise suddenly. In the event of a sudden rise in device temperature, immediately remove the batteries and reinsert them correctly. Please allow the device to drop to room temperature before taking a new recording.




Top View



LCD panel description

(See p. 9 'Recording ECG Parameters' to obtain the screen below)



#		LCD Panel Descriptions
①	Search	Displayed when detecting heart electrical signals.
②		Flashes when recording is in progress. Flashing stops when recording is completed. NOTE: This is an idealized ECG tracing, NOT a real-time recorded ECG tracing. It does not represent your actual ECG.
③	Record	Displayed when in data record mode.
④	Send	Displayed when transferring data.
⑤	Record #	It is the total # of records stored or the number of the records being displayed in data recall mode. A blinking record # indicates that the memory is (almost) full; Note: If this number reaches 30, you cannot take any more measurements until you delete the stored records or transfer them to a PC (see page 18/21).
⑥	Battery Condition	 indicates the battery power is normal.  indicates the battery power is low.


⑦	Noise	<p>Noise is displayed when signal recorded is noisy or beyond the device's testing range.</p> <p>Note: Inaccurate parameters will still be displayed on LCD and stored. They will appear in RED on your heart trend when displayed on the software (See Ch. 6 on Software Features)</p>
⑧	HR or Noise Level	<p>During the recording, the number represents</p> <ul style="list-style-type: none"> • the “noise” level in the electrodes, indicating insufficient conductivity (if it changes abruptly) or • the instant heart rate reading <p>When the recording is complete, it displays the average Heart Rate of the measurement. Number flashes when signal recorded is >100, or <60.</p> <p>Note: If noise is present during recording then the HR shown is not accurate.</p>
⑨ ⑩	ST, QRS	<p>Not displayed at the time of recording.</p> <p>When the recording is complete, displays the key parameters recorded by the device. Numbers flash when signal recorded is outside reference range.</p>
⑪	Date/Time	Month/Day/Hour/Minute

Turning the power on

Press any button once to turn the power on.

The **main menu** will show items ① through ⑥ on the LCD display.

Turning the power off

Hold the  button for 3 seconds to turn off the device.

The device also has an auto-off design that will automatically switch the device off if it is left idle for more than 2 minutes.



Setting Date/Time

When the device is showing the main menu:

1. Use a thin pointed object (like a toothpick) to click the • indented button. Do NOT use a sharp object as this could damage the device. The number under Month on the LCD panel will start to flash. See step 3 below to change value.
2. Press again to go to the Day. Press **(M)** button to go to Hour. Press **(M)** button again to go to Min (Minutes).
3. Press the **(↻)** button when the numbers are flashing to change to your desired value.
4. Press **(M)** button to go back to the main menu.

Recording Heart Function (ECG) parameters

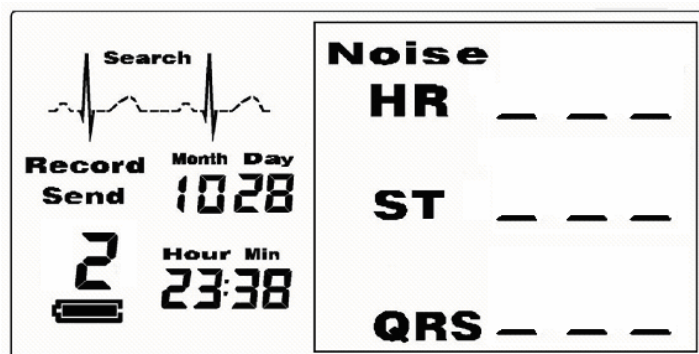
1. Wash your hands with soap and water then towel dry before using the device. DO NOT use a hand dryer. DO NOT use creams or moisturizers.
2. Sit on a chair, your back straight, feet on the ground, with your shoulders relaxed.
3. Relax and breathe calmly.
4. Hold the device in your hand and rest it on your lap.

5. Press the  button to start recording.
6. Immediately place your thumbs gently on the dry electrode pads and make sure that they cover the whole electrode pad.
7.  will animate on the LCD panel during the recording.
8. The device will record for around 25 -27 seconds. Do not move, talk, or breathe deeply during recording time.
9. If “Noise” appears on the LCD screen and the HR value varies rapidly from time to time, the conductivity of the dry electrodes is insufficient for a recording. See Chapter 3 for instructions on improving the accuracy of the measurements.

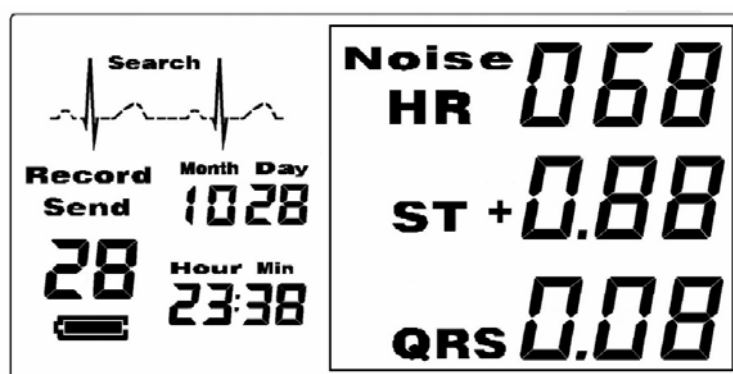
Note:

1. You cannot stop a recording that is already in progress. Please let the device run the full 25 -27 seconds before starting a new recording.
2. Data will be saved automatically after each recording. The device can store up to 30 records.

When it is done if the conductivity is very poor, then the LCD panel will look like this:



If the measurement is completed despite disturbed conductivity, the screen will look like this:



Note:

In the screen above, even though the numbers are displayed, the measurements are inaccurate. Please take a new measurement as described from Step 1. Note that the “**Noise**” measurements will appear in **red** when displayed by the software (see Ch. 6 on software features).

Heart Function (ECG) parameters

The ReadMyHeart hardware displays 3 heart function (ECG) parameters: the average heart rate (HR), the ST segment (ST), and the QRS interval (QRS), displayed on the LCD after each recording. The reference range of the parameters is shown below. If the recorded value falls out of the range, the recorded numbers will flash.

Parameters	Reference Range	Warning when out of range/inaccurate
HR	$60 < \text{HR} < 100$ bpm	
ST	$-2 < \text{ST} < +2$ mm	Flashing numbers
QRS	$0.08 < \text{QRS} < 0.12$ sec	

Attention: The information above is for reference ONLY. Do NOT interpret the numbers without consulting a physician. If the measured parameters frequently and/or consistently fall outside the reference range, consult your physician immediately. **Regardless of whether the numbers fall within or outside the reference range, see your physician if you experience any abnormal symptoms (e.g acute chest pain, palpitations, dizziness...).** Recorded data by ReadMyHeart may be provided to a physician for reference.

Chapter 3: Improving Recording Quality

“Noise” appears during the recording time

If the conductivity is too poor for an accurate reading, the following may apply:

- “Noise” appears on the LCD
- HR numbers change rapidly/ abruptly during recording
- You may feel that the heart rate measured (after recording is complete), is higher than what you have perceived.

The conductivity between your thumbs and the dry electrodes may be too poor because:

- Thumbs are greasy or too dry.
- Contact pressure between the thumbs and the dry electrodes may be too strong.

If this is the case, please review the next section to improve conductivity.

Why should you wash your hands with soap?


The conductivity between your thumbs and the dry electrodes is crucial for the device to clearly detect the micro-current generated during the heartbeats. Common factors can affect the conductivity and therefore, the accuracy of the measurement:

- your thumbs may be covered by dirt, oil, or layers of residue
- the skin of your thumbs may be too dry
- the skin on your thumbs may be very thick

By washing your hands with soap, you will not only remove any dirt or oil but also moisturize the surface, improving the conductivity of your thumbs. The micro-current generated during a heartbeat is then able to properly travel through your thumbs and be recorded by the dry electrode.

Step by step recording procedures

To improve the accuracy of a recording you need to adhere to the following procedures:

1. Wash your hands with soap and water then towel dry before using the device. Fingers need to be slightly moist. DO NOT use cream or moisturizers. DO NOT use an electric hand dryer.
2. Sit on a chair, your back straight, feet on the ground, your shoulders relaxed.
3. Relax and breathe calmly.
4. Hold the device in your hand and rest it on your lap.
5. Open the cover and press the  button to start recording.

6. Place your thumbs gently on the dry electrode pads and make sure that they cover the whole electrode pad.
7. Do not move, talk, or breathe deeply during the 25 -27 second period of recording.

How do I know if there was a conductivity problem?



1. If you see the Noise/Heart Rate vary quickly (e.g, going above 200) during the recording, then the conductivity is too poor. To improve the conductivity and accuracy, adjust the amount of pressure your thumbs exert onto the dry electrode (not too hard). Make sure you have washed your hands and followed the procedures. It may take a few practice recordings to stabilize the noise/heart rate readout and take an accurate recording.
2. If you cannot hold the device steadily, do NOT have clean hands, have thick skin on your hands, or have persistent trouble recording through your thumbs, you may need to use an external electrode (see next section).

Alternative recording method

The device can take measurements through an external auxiliary electrode cable. This cable and ECG conductive adhesive electrodes (ECG pads) are included, but replacement of ECG pads are optional accessories, available for purchase separately.




Note: Use only FDA approved ECG pads.

To record using external electrodes, please follow this procedure (as seen on the QuickGuide):

1. Auxiliary electrode Socket  is located on the left of the device (see page 18). Slide the socket cover to expose the external electrode socket on the device.
2. Connect the external auxiliary electrode cable to the device.
3. Place the sticky electrode pads on the middle of the inner forearms, RED electrode on the right arm and BLUE electrode on the left.
4. Press the  button to start recording.
5. Don't move, talk, or breathe deeply during the 25 -27 second period of recording. Do not touch the dry electrodes.

Chapter 4: Viewing records on ReadMyHeart




Operation of ReadMyHeart hardware only requires the four basic control buttons as described below:



Buttons	Descriptions
	Start recording / Power Off*
	Recalling Data
	Transfer Data / Delete Data
•	Set Date / Time

* Touch any key to switch power on. Note that ReadMyHeart will automatically turn off if left idle for 2 min.

Recalling Data



From the device panel main menu (see page 8).

1. Press the  button to see recorded data. The latest data will be displayed. Press the  button again to show the first data stored in the device. Press again to show the following data.
2. When in recall data mode, pressing the  button for 3

seconds, pressing  or pressing  clears the parameter box on the right hand side of the LCD and return to the main menu (see page 7 to know about the main menu).

Note: The ReadMyHeart hardware can store 30 records in its memory. If the memory has stored more than 25 records, the number will flash three times after each recording. This is to remind you to transfer the data to your PC. Note: If the memory is full, ReadMyHeart will stop taking measurements until records are deleted or transferred onto a PC.

Deleting data

Press the  and  simultaneously for 3 seconds to **delete all** the data stored in ReadMyHeart

Note: Transferring the data to a PC will automatically delete all records from ReadMyHeart.

Chapter 5: Installing ReadMyHeart software

There are some advanced functions available with the software provided. Before learning about those functions, you will need to install the software onto a PC with CD Rom drive.

System requirements

To install and use the components of the ReadMyHeart software, your computer system must meet the following requirements:

- Operating system: Windows 98/98SE/2000/XP
- CPU: Pentium III and above
- Memory: 100MB and above
- Hard disk capacity: 100MB and above
- CD-ROM drive
- Data transmission media: Universal Serial Bus (USB)
- DPI of screen: 1024 x 768

Software installation instructions

The following instructions will guide you through installing the ReadMyHeart software from the CD-ROM included in the package.

First, check that your PC meets the System requirements (p.19).

To install ReadMyHeart software:

1. Exit all open programs.
2. Insert the ReadMyHeart CD-ROM into the computer's CD-ROM drive.
3. The software should start running automatically.
4. If auto-installation does not start, browse CD Rom drive for the menu and open "autorun.exe" If you do not know how to browse for the CD Rom drive, consult a PC expert.
5. When the software screen appears, select "Software Installation" and follow the on-screen instructions to complete installation.

Software registration and upgrade information

To register your ReadMyHeart, please go to

<http://www.dcbiomed.com/web/register>

Transferring data from ReadMyHeart to a PC

(information also available on ReadMyHeart QuickGuide)

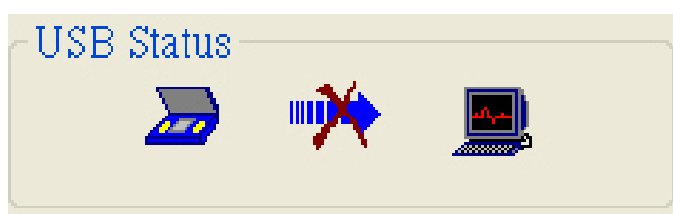
You need to have installed the software onto your PC as shown above. Start the ReadMyHeart software by clicking on the

ReadMyHeart icon:  on your desktop,

or use Windows Explorer to locate and run

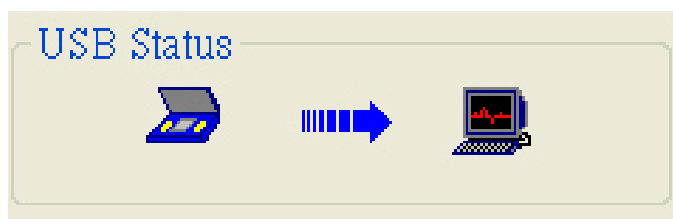
[“Program Files\DailyCare BioMedical\ReadMyHeart OTC\
ReadMyHeart.exe”](#)


A “Disconnected” status will be shown initially on the bottom left of the software screen on the PC monitor as follows:

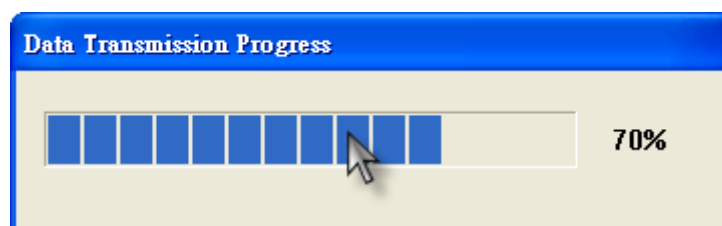


1. Connect one end of the USB cable to the USB socket on the device (see Product Back View & Side View page 5). Connect the other end of the USB cable to the USB port on the computer.


2. When the USB connection is detected, this icon will appear on the bottom left corner of the software screen on the PC monitor:





3. Press the  button on ReadMyHeart device to transfer data from the hardware to the computer.
4. **Send** will appear on ReadMyHeart's LCD panel, indicating transfer of the data is occurring. A data transmission progress window will pop up on the PC monitor:



Note:

1. The number below **Send** on the device's LCD panel is the serial number of the records currently downloading to the PC.
2. If **Send** flashes after pressing  or during file transfer, it

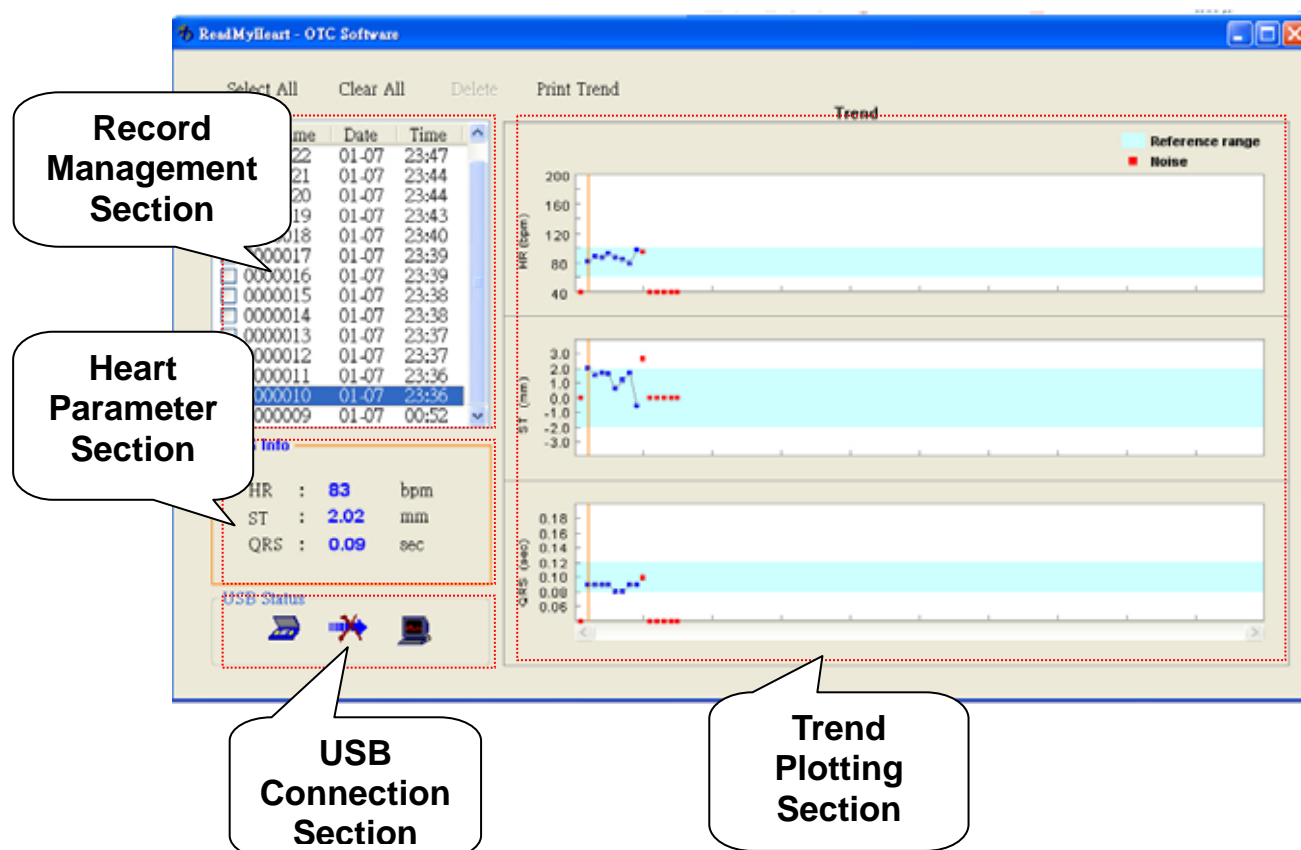
means the connection between ReadMyHeart and the PC has failed. Please close and start the software again, and/or reconnect the USB cable.

3. If you have successfully transferred your data to the software, even if you press the  button again, the software will not receive and duplicate the same data.
4. If the number 0 appears below **Send** after pressing , it indicates there are no more records left in ReadMyHeart to transfer.

After the records have successfully transferred to the PC, all records will be erased from the ReadMyHeart's internal memory. The recorded data is now stored in your PC, where the provided software will enable you to view and print the trends in heart function parameters. To learn how to use ReadMyHeart software, read the next chapter.

Chapter 6: Using ReadMyHeart software

READMYHEART has a simple displaying interface. This display and data management system is divided into four main sections:



ReadMyHeart software automatically shows you the past 14 records on the **Record Management section** (1) and the past 100 records on the **Trend Plotting Section** (4) (see software screen above)

Viewing Heart Parameters and Data Files

To view an individual record, you can:

- click on its date, time, or record number on the **Record Management section (1)**
- or you can select one point on the **Trend Plotting Section (4)**, and it will show you the corresponding record date, time, and number in the left box - **Record Management Section (1)**
- For the individual record selected, the recorded parameter numbers are displayed in the left box - **Heart Parameter Section (2)** of the screen.

Viewing Heart Parameters Trend Graphic

ReadMyHeart automatically shows the most recent 100 recordings on the **Trend Plotting Section (4)**. If the data does not have more than 100 recordings, the curve will show all records.

Click on any point on the trend curve and the filename, date, time, will be highlighted on the **Management section (1)** and its corresponding HR, ST, QRS values will be shown on **Heart Parameter Section (2)**

Note: Data which showed “noise” during recording or which has parameter values outside of the reference range (see Heart Function (ECG) parameters p.12) will appear in RED on the trend curve.

Deleting a Record

To Delete a record, simple check the record you wish to delete and click “Delete”. You may check several records and delete them simultaneously. Note that all deletions are permanent and that ReadMyHeart does NOT keep a copy of the record once it is transferred onto a PC.

Printing Heart Function Trend

If more than 100 records are in store, use the scroll bar to choose the trend curve you wish to Print. Then click “Print” to print the trend currently on the screen and follow the on -screen instructions to complete printing.

Chapter 7: Care and Maintenance

Cleaning the dry electrodes

When the dry conduction electrodes on ReadMyHeart are used regularly, grease and dirt may accumulate, possibly affecting the recording of the heart function parameters. Please use a clean wiping cloth to remove grease and dirt. DO NOT use any cleaning solutions or organic solvents as they will damage the device.

Caution: Do NOT use accessories other than those provided by the manufacturer.

Caution: Do NOT expose the device to water and liquid spillage. Do NOT clean with alcohol, acetones, or any other flammable chemical agents. Do NOT autoclave, steam or sterilize the device and its accessories.

Caution: Do NOT place the device and its accessories under direct sunlight, at temperatures inferior to 40°F or superior to 105°F or to harsh environments.

Caution: Do NOT disassemble ReadMyHeart, as it may cause device malfunction, device failure, or damage to the device. DO NOT apply any conducting gel or other fluids to avoid damaging the thumb electrodes and the device.

Product registration, updates, newsletters:

For registration and software upgrade please see “Software registration and upgrade information“ on page 20.

FDA and Health Canada Licence Numbers

USA FDA 510K Clearance: K042814

Health Canada Lic # 66589

Descriptions of the device

The ReadMyHeart hardware has an LCD panel protected by an open cover. There are three control buttons for: recording, recalling, and transferring ECG data plus one additional button for setting time and date. Both of your thumbs are placed on the left and right electrode to start the measurement of ECG. The external auxiliary electrode cable socket and USB cable socket are located on the side of the hardware. There is a sliding socket cover to prevent the use of the sockets at the same time.

Product Specifications

Input impedance	> 10 Mohm
Input dynamic range	+/- 2 mV
Bandwidth	0.15 – 40 Hz
CMRR (Common Mode Rejection Ration)	> 60 db
A/D conversion	12 bit
Sampling frequency	250 samples/sec
Measurement Time	~25-27 seconds
Display	LCD display panel
Input	Dry conduction electrodes and/or external auxiliary electrodes
Output	USB interface
Power Supply	1.5V (AAA) X 2
Size	4.7 x 3.1 x 0.8 in (12 x 8 x 2 cm)
Weight	116 g (Not including batteries)
Environmental Conditions:	
Storage temperature	-4°F ~122°F (-20°C~ 50°C)
Operating temperature	50°F~104°F (10°C ~ 40°C)
Humidity	25% ~ 95%
Measurement Range:	
Average heart rate	45 to 180 bpm
ST segment	-3 to +3 mm
QRS interval	< 0.20 sec

Medical Device Warranty

DailyCare BioMedical warrants each new device to be free from defects in material and workmanship. This warranty is not transferable. This warranty is effective for a continuous period of one year from initial date of shipment against the original order to the original purchaser. This warranty covers parts, labor, and transportation costs when, upon examination by the manufacturer, the device is determined to be defective. In order to implement the provisions of warranty repair, the purchaser must notify DailyCare BioMedical concerning suspected defects and then, if so instructed, ship the instrument to the designated facility, correctly packed in an appropriate shipping container, for examination and servicing.

Limitations and Exclusions

This warranty does not cover repairs necessitated by any damage to equipment caused by mishandling, neglect, abuse, customer modification or failure of the user to follow the published operating instructions. Repaired devices are warranted for a period of 30 days and are subject to the limitations and exclusions described in

this document. **DailyCare BioMedical reserves the right to make design changes in its products without incurring the obligation to incorporate these changes in products previously delivered.** This warranty applies unless DailyCare BioMedical has agreed to and provided a written exception to this policy.

Chapter 8: User Assistance and Trouble Shooting

Frequently Asked Questions

Q1 Why does the “Start” button not activate a new recording?

A:

1. If you see that the Record # on the device LCD is blinking (see page 7 for a panel description), then the memory is full. See page 20 for help with “Deleting Data” and “Transferring data onto a PC”.
2. The “Start” button will not start a recording during “Setting Time/Date” Mode. Press the **(M)** button to get out of the Date/Time setting menu.
3. The “Start” button will not start a recording if a recording is already in progress. Let the recording time elapse and try again.

Q2: What is ReadMyHeart?

A: See “Descriptions of the device” on page 28

Q3: Why does “Noise” appear during measurement?

A: See page 13

Q4: The parameters measured by ReadMyHeart do not correspond with my condition

A: In case of an emergency physical condition, users should immediately contact emergency services.
See “Noise” appears during the Recording on page 13.

Q5: Why are the 3 parameters values showing “- - -“ ?

A: If the conductivity is too poor and the parameters are meaningless then none of the parameters will be shown. Please see “Noise” appears during the Recording page 13.

Q6: Will static electricity affect the measurement of ReadMyHeart?

A: ReadMyHeart is CE certified and has passed electromagnetic interference and compatibility tests. Under normal circumstances, static electricity will not affect the operation of ReadMyHeart.

Q7: Can ReadMyHeart use another external power supply?

A: No. READMYHEART is to be operated ONLY by two replaceable 1.5V (AAA) alkaline batteries. Please DO NOT use other external power supply, as it may be hazardous and may damage the system and the device.

Q8: Can ReadMyHeart connect to accessories other than the ones provided in the standard package?

A: All standard package accessories meet special specifications of medical device regulations. Please DO NOT use any other accessories other than the ones provided in the standard package to avoid hazards and subsequent damage to the device.

Q9: Can conducting gel or other fluids be used when using ReadMyHeart?

A: ReadMyHeart is designed to be operated without any conducting gel or other fluids. DO NOT apply any conducting gel or other fluids to avoid damaging the device.

Q10: Can any other fingers be used to take measurements?

A: Noise signals may be larger if fingers other than the thumbs are used. It is recommended that you use optional auxiliary electrodes for measurement if you cannot use the thumbs.

Q11: Can ReadMyHeart be used while standing up, sitting down, or lying down?

A: For optimal accuracy, it is recommended that you be in a stable sitting position to take the recording.

Q12: After exercising, can I measure heart parameters? Will the measurement be correct?

A: Yes, heart parameters can be recorded after exercising. During the measurement, please remain in a stable position to insure quality of recording or use the external cables.

Q13: Can ReadMyHeart be used during commuting?

A: During commuting, if a stable sitting position can be maintained, ReadMyHeart can be used to measure heart parameters. DO NOT use the device while operating any vehicle.

Q14: Why does the data recorded in the ReadMyHeart disappear after the batteries are replaced?

A: When ReadMyHeart is not connected to batteries, data will be erased from the memory after approximately 2 minutes.

“How to ...?”, “What...?” and “ Where...?”

Q15: How to install or change the batteries.

A: See “Battery Installation” page 6

Q16: How to setup the date and time.

A: See “Setting Date/Time” page 9

Q17: How do I install the software?

A: See “Software installation instructions” on Page 19

Q18: How to turn off the power on the device.

A: See “Turning the power off” page 8

Q19: How to recall, delete or transfer data to a PC.

A: See “recall, delete or transfer data” page 18/21.

Q20: How to use the optional external auxiliary electrode cable.

A: See “How do I know if there was a conductivity problem?”
and “Copyrights and Trademarks Notice “ on page 15 & 16

Q21: How to maintain ReadMyHeart ?

A: See “Cleaning the dry electrodes” page 27

Q22: What are the system requirements to use the software?

A: See “System requirements” page 19

Q23: What are the device technical specifications?

A: See “Product Specifications” page 29

Q24: What do the 3 parameters displayed on the LCD mean?

A: See “Heart Function (ECG) parameters” page 12 and
“References” page 36

Contact DailyCare

Headquarters contact information

DailyCare BioMedical Inc.

8F, 25-3, Ji-Lin Rd, Chungli 32062, Taiwan

Email: info@dcbiomed.com

Website: www.dcbiomed.com

USA contact information

DailyCare USA Inc.

44888 Osgood Rd. Fremont CA 94539

Tel: 1-800-970-8620

FAX: 1-510-683-8662

References

American Heart Association

www.americanheart.org

National Heart, Lung and Blood Institute

www.nhlbi.nih.gov

ECG Library

www.ecglibrary.com

EMedicine

www.emedicine.com