IMPORTANT NOTICE

MEDICAL DEVICE WARRANTY

DailyCare Biomedical Inc. 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 and labor costs when, upon examination by the manufacturer, the device is determined to be in fact defective. In order to implement the provisions of warranty repair, the purchaser must notify DailyCare Biomedical Inc 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 www.dcbiomed.com.

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 Inc 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 Inc has agreed to and provided a written exception to this policy.

ATTENTION!

DailyCare Biomedical Inc assumes no responsibility for any personal injuries or damages sustained by or through use of this product.

CheckMyHeart

- will NOT tell you if you have heart problems. Only your physician can do that. You should NOT interpret the measurement results yourself.
- is NOT a diagnostic device. It is only an ECG recorder.
- is NOT a substitute for a traditional ECG diagnosis.
- is NOT recommended for users with pacemakers.

What you should not do:

- Do NOT operate CheckMyHeart while using other electrical devices.
- Do NOT connect CheckMyHeart to the PC via USB cable when acquiring ECG.
- Do NOT use accessories other than those provided by the manufacturer. Do NOT use USB cable other than that supplied by manufacturer.
- Do NOT subject the device to water and liquid spillage. Do NOT clean with alcohol, acetones or any other flammable chemical agents. Do NOT use with any lotions.
- Do NOT place the device and its accessories under direct sunlight and harsh environments.
- Do NOT disassemble CheckMyHeart. It may cause device malfunction, device failure or damage and you will loose all warranty.

ATTENTION!

Please use the device properly by following standard operating procedure. **(Please refer to Section 2.2.1 Page 5)** Improper use of the device will cause inaccurate representation of measured results. NOISE indicator may appear if the device is not operated correctly. If you readings are NOT within the reference range, multiple readings are recommended.

As a rule, if you are feeling uncomfortable, regardless of the numbers and symbols on the device, please consult your physicians immediately!

Table of Contents

INTRODUCTION

CheckMyHeart handheld ECG user's manual is designed to help you quickly get started using CheckMyHeart. This chapter explains the indications for use of CheckMyHeart, along with warnings, cautions, requirements, and installation information for using the software. The remainder of this manual provides more specific information about the hardware and the software of this product, as well as some reference information.
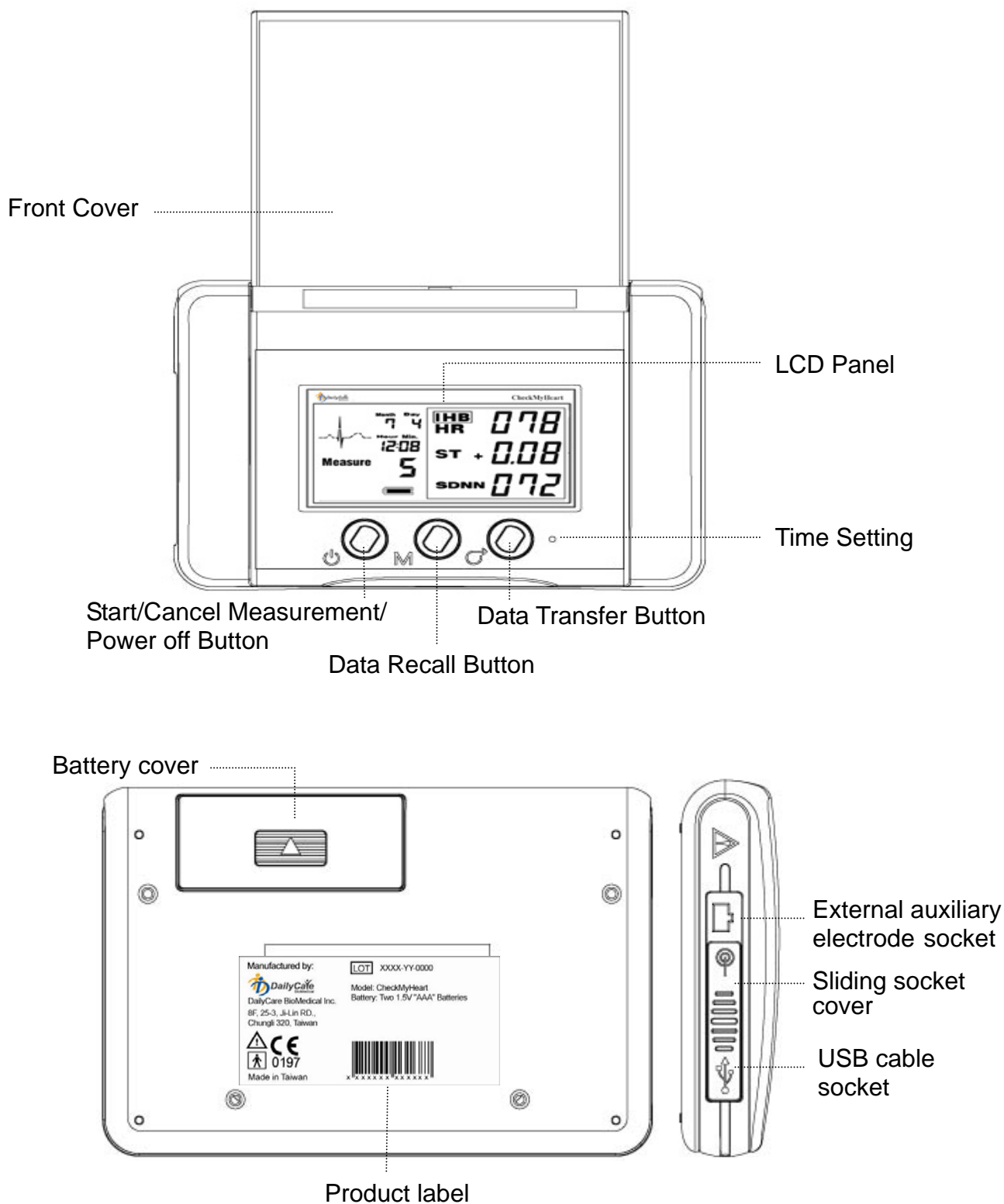
1.1 Purpose of the device (Indications for use)

CheckMyHeart is intended to record, recall, store and transfer Lead I ECG signals for home health care use. The intended users are adults above 20 years old. This device is not intended to substitute for a hospital diagnostic ECG device. This device is also not intended for recording and transmission of user's ECG signals simultaneously.

PRODUCT DESCRIPTION

2.1 Product Design

2.1.1 Main Unit

Front Cover

LCD Panel

Measure

Time Setting

Start/Cancel Measurement/
Power off Button

Data Transfer Button

Data Recall Button

Battery cover

Manufactured by:
DailyCare
DailyCare BioMedical Inc.
8F, 25-3, Ji-Lin RD.,
Chungli 320, Taiwan

LOT XXXX-YY-0000

Model: CheckMyHeart
Battery: Two 1.5V "AAA" Batteries

CE
0197
Made in Taiwan

External auxiliary
electrode socket

Sliding socket
cover

USB cable
socket

Product label

2.1.2 Control Buttons

Control Button Descriptions

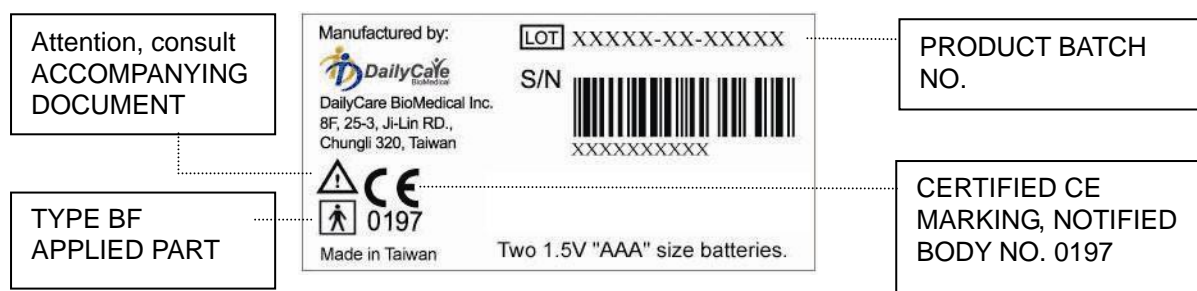| Buttons	Descriptions
⏻ (Button 1)	**Start / Cancel Measurement / Power off Button** ~Press once to start measurement. ~Hold for 3 seconds to power off. ~After measuring, press again to start another measurement.
Ⓜ (Button 2)	**Data Recall button** ~Press once to enter data recall mode. The latest data recorded will be displayed. ~Press again to recall other recorded data, starting from the first. ~Hold for 3 seconds, or press any other button, to leave data recall mode.
⊘ (Button 3)	**Data Transfer Button / Data Clearance** ~Connect CheckMyHeart to PC with USB cable and press once to start transferring of stored data. ~ Hold ⊘ for 3 seconds to manually clear all stored data.
• (Hidden Button)	**Time Setting** ~When the device is on, press once to set the right time. ~Press Button 2 Ⓜ to select month/date/time. ~Press Button 3 ⊘ to adjust value.

2.1.3 Product Package

Standard Package:

☑	CheckMyHeart device	x 1
☑	CheckMyHeart Heart rate Variability (HRV) analysis Software CD	x 1
☑	CheckMyHeart User's Manual	x 1
☑	Carrying Case	x 1
☑	USB Cable	x 1
☑	Auxiliary Electrode Cable	x 1

Not Included:

1) Electrode gel pad. These pads can be purchased at local drug stores.
2) AAA alkaline battery. CheckMyHeart needs two to operate.

2.1.4 Product Label

CheckMyHeart is TYPE B EQUIPMENT WITH F-TYPE APPLIED PART IN EN IEC60601-1 STANDARD
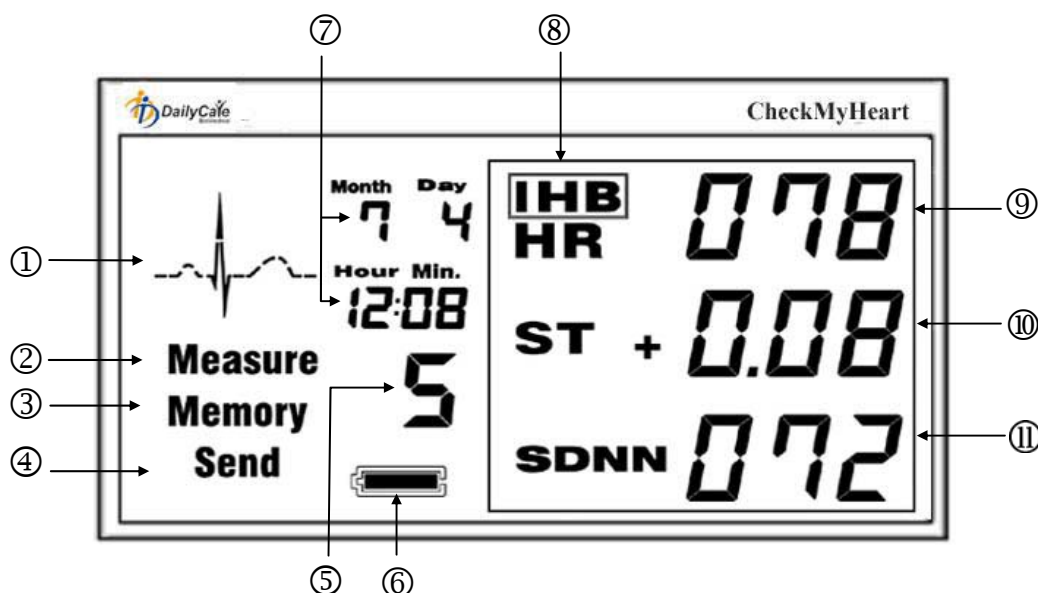
2.2 Taking a Measurement

2.2.1 Steps of Measurement

Steps	Descriptions
	Slide the socket cover to expose the auxiliary electrode cable socket and connect one end of the cable to the device. Connect the split ends of the cable to the adhesive ECG electrode pads. (Users can buy qualified electrode pads from qualified medical device and pharmacy stores.) **Place the RED electrode on the right arm and the BLUE electrode on the left arm as shown.**
	Press the ⏻ button once to start measurement. - "Measure" will appear and measurement will take **300** seconds. You can stop recording by pressing the ⏻ button for 2 seconds. - ⎍ will flash on the LCD panel during recording. Do NOT move or talk during recording to get good stable signals. - Data will be saved automatically after each recording. The device can store 6 data files. - Hold the ⏻ button for 3 seconds to power off the device. The device has an auto-off design if it is left idle for more than 2 minutes.

NOTE: Both auxiliary electrode and USB sockets on the device are to be used only with the standard accessories provided. Warranty will NOT cover damages that result from failure to comply with these instructions.

2.3 Display Panel

2.3.1 LCD Display

LCD display panel

Reference Range of Measured Results

	Reference Range	Warning Sign
HR	60 < HR＜100 bpm	**Flash**
ST	-2 < ST＜+2 mm	**Flash**
SDNN	A mathematical calculation of heart rate variability. There is NO reference range.	
(IHB) Irregular Heart Beat	Please consult your physician for advice if **IHB** indicator appears frequently.	

Attention: The information above is for reference ONLY. If the measured parameters fall within the reference range and user feels any discomfort, user should contact a physician. Measured data by CheckMyHeart may be provided to a physician for reference, monitoring, or further analysis.

2.3.2 LCD Display Description

#	Item	LCD Panel Descriptions
①		Flashes when recording is in progress. Flashing stops when recording is completed. **NOTE:** This is a simulated ECG tracing, NOT a recorded ECG tracing.
②	**Measure**	Displays when the device is in ECG recording mode. One measurement requires 300 sec.
③	**Memory**	Displays when the device is in data recall mode.
④	**Send**	Displays when the device is transferring data.
⑤	Data files	Press data recall button to view other files stored in the device. Up to **6** data can be stored in device memory.
⑥	Battery Condition	▭ indicates the battery power is normal. ▭ indicates the battery power is low.
⑦	Date/Time	Month/Day/Hour/Minute
⑧	**IHB**	Irregular heart beat (IHB) indicator. Displays when the device detects large variation in RR interval during measurement. **NOTE:** IHB is not based on morphology of ECG. IHB may also appear if signals are too NOISY. Please measure again following SOP strictly.
⑨	**HR**	Average Heart Rate of 300 seconds. **Flashes** right after measurement when the numbers are out of reference range.
⑩	**ST**	ST segment. **Flashes** right after measurement when the numbers are out of reference range.
⑪	**SDNN**	Standard deviation of all normal to normal intervals. **NOTE:** SDNN is mathematical analysis of HRV and is not a diagnostic value. Recently research has been shown that the HRV is a technology for the assessment of cardiac autonomic status.

2.4 Product Specifications

|	
Input impedance	> 10M Ohm
Input dynamic range	+/- 2 mV
Bandwidth	0.15 ~ 40 Hz
CMRR (Common Mode Rejection Ratio)	> 60 dB
A/D conversion	12 bits
Sampling frequency	250 samples/sec
Measurement Time	300 seconds
Display	LCD display panel
Input	External auxiliary electrodes and conductive adhesive ECG pads
Output	USB interface
Power Supply	1.5V (AAA) X 2
Size	12 × 8 × 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

CheckMyHeart SOFTWARE

3.1 System Requirements

Operating System: Windows 98/98SE/2000/XP/Vista

Hardware Requirements:

➢ CPU: Pentium III and above

➢ Memory: 100MB and above

➢ Hard Disk capacity: 100MB and above

➢ Data transmission media: Universal Serial Bus (USB)

➢ Screen resolution: 1024 x 768

3.2 Installation
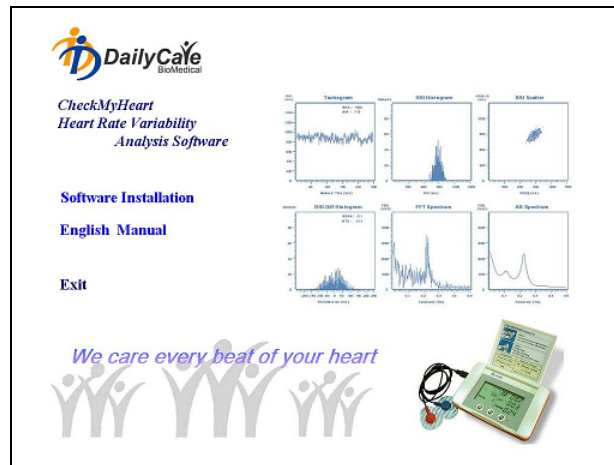
CheckMyHeart software main page

Insert CheckMyHeart software CD into the CD-ROM. Select "Software Installation" from the main page and setup will run automatically. If auto-installation does not start, double click on the "autorun.exe" application file in the CD to install manually. Follow the Setup Wizard instruction on the screen.

3.3 Transmit Data

All data files recorded in CheckMyHeart can be transferred to PC for analysis through the USB port on the left side of CheckMyHeart as shown below. Slide the socket cover to expose the USB socket.

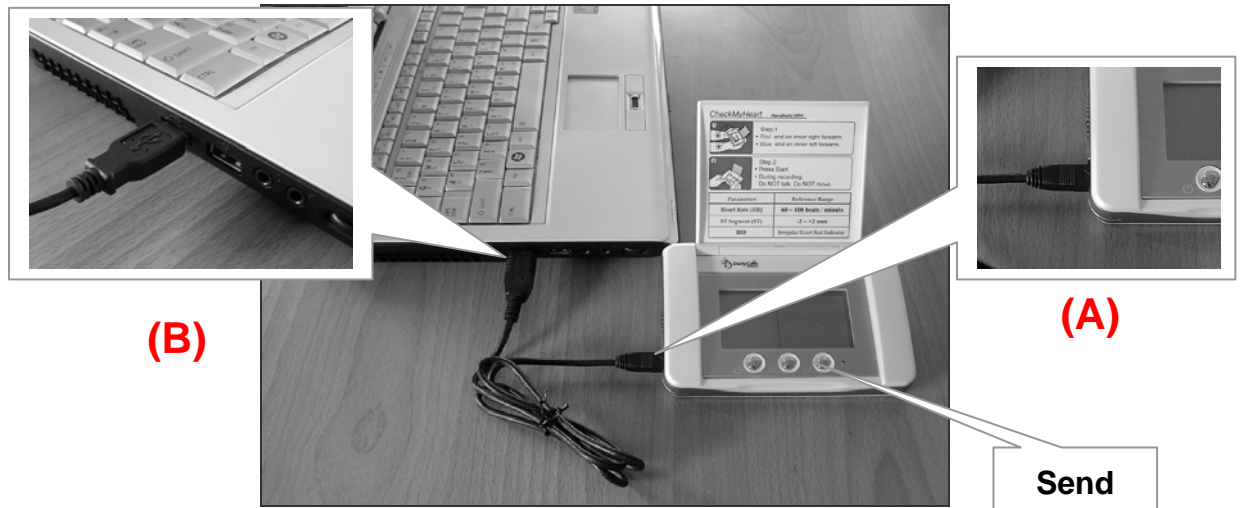**Only use USB cable provided by manufacturer to transmit data.**
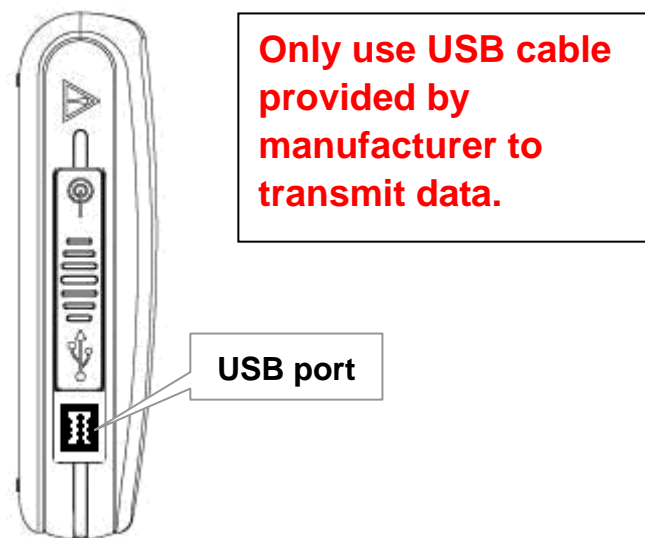
USB port

CheckMyHeart USB port

Steps for file transfer.   Please follow the following steps:

1. Start the CheckMyHeart software by selecting DailyCare Biomedical Inc → CheckMyHeart from the File Menu or by clicking on the   on your desktop.

2. A "Disconnected" status will be shown initially on the bottom left of the main menu.

   Connect one end of the USB cable (small) to the USB socket

on the hardware first (A). Then connect the other end of the

USB cable to the USB port on the computer (B).

(B)

(A)

Send

Connection of USB cable

3. When the USB connection detected, it will be indicated on the

bottom left corner of the software screen.
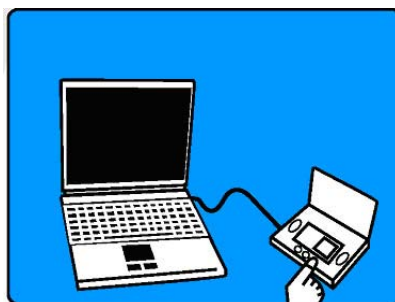
Only use USB cable provided by manufacturer to transmit data.

4. Press ⊘ on CheckMyHeart and **Send** will appear on the LCD display, indicating a transfer of the data files to the PC. The number below **Send** is the serial number of the data files currently downloading to the PC. A transmission window will appear on the PC to show data transmission in progress as shown below.
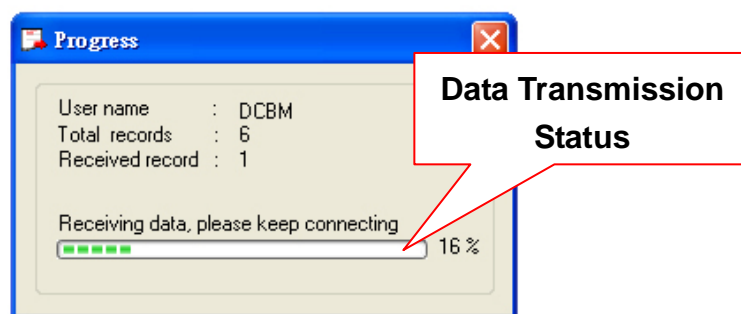

Data transmission progress window

Note: Please select the right user before you transfer the data into the user's file.

Note: After data files have been successfully transferred to the PC and when you start your next measurement, **CheckMyHeart hardware will erase its memory automatically.**

Note: If **Send** flashes after pressing ⊘ or during file transfer, it means the connection between CheckMyHeart and the PC has failed. Please close and then re-start the software again, and/or reconnect the USB cable.

3.4 Software Interface
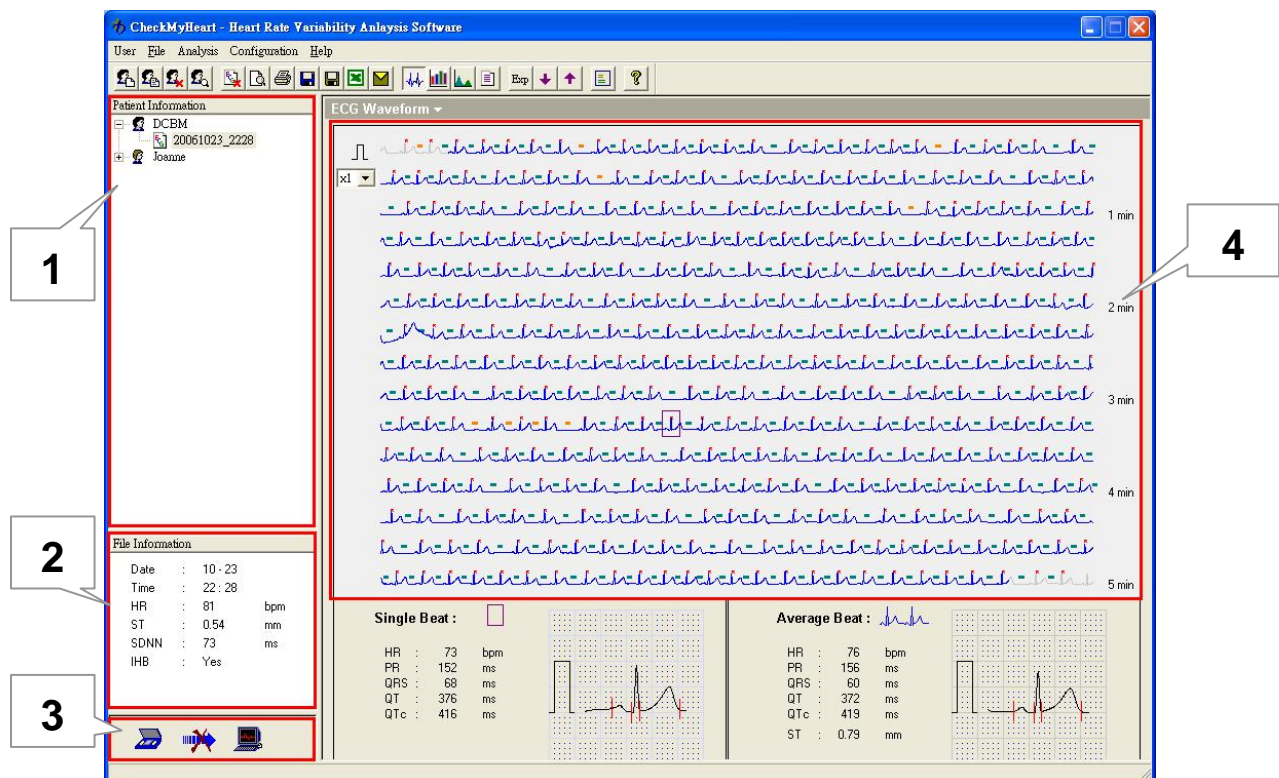
CheckMyHeart software and database interface details

This analysis and database management system is divided into four main parts:

1.   User and file management;

2.   Average ECG parameters display and remarks;

3.   Connection status of CheckMyHeart to PC;

4.   Five minute ECG trace and HRV analysis report

3.5 User and file Management

User and file management   Data analysis
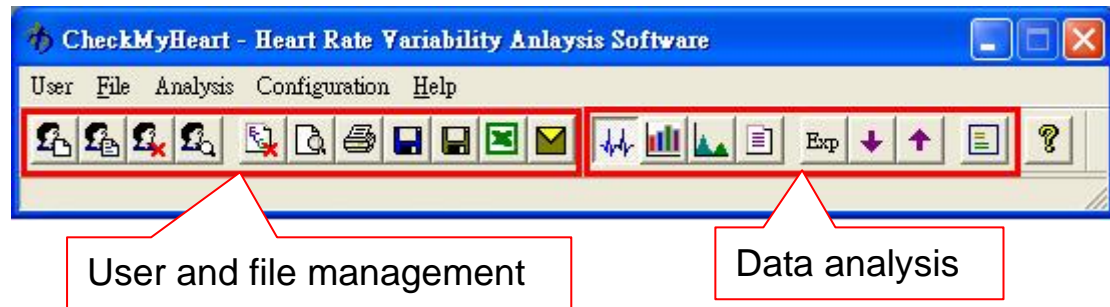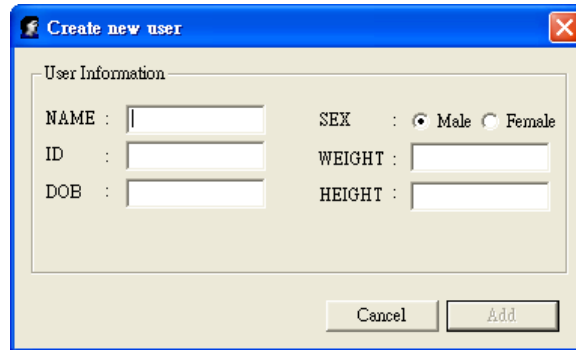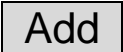
Function Keys	Description
🧑	Add a new user
🧑	Display and change user's information
🧑	Delete selected user
🧑	Search for user
🗐	Delete selected file
🗐	Preview HRV analysis report for printing
🖨	Print HRV analysis report and 5 min ECG waveform
💾	Save HRV analysis report as graphic file
💾	Save 5 min ECG waveform as graphic file
📊	Export HRV result in Excel format
✉	Email ECG data

Detailed descriptions of Function Keys are as follows:

3.5.1 Add a New User

1. Click on [icon] function key to add a new user,. The "Create new user" window will appear as shown below.

2. Enter user information such as name, sex, ID, weight, date of birth (DOB) and height. **NOTE:** Name has to be keyed to create a new user.

3. Click on ☐ Add ☐ and a new user will be added to the user information list. Name of user must be keyed. Otherwise, a warning window will appear.

4. Repeat step 1 and 2 to add more new users.

5. Click on ☐ X ☐ to close the user management window.

3.5.2 Display or Change User's Information

1. Select a file/user first.
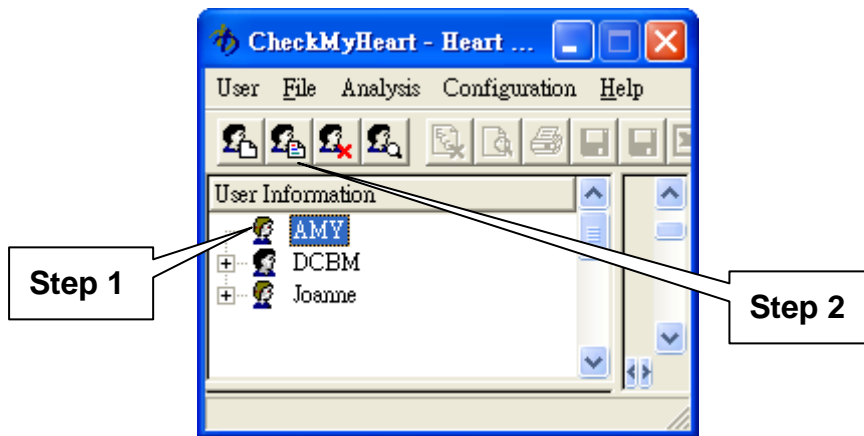
2. Click 🔁 function key. The user's information will appear as shown below.
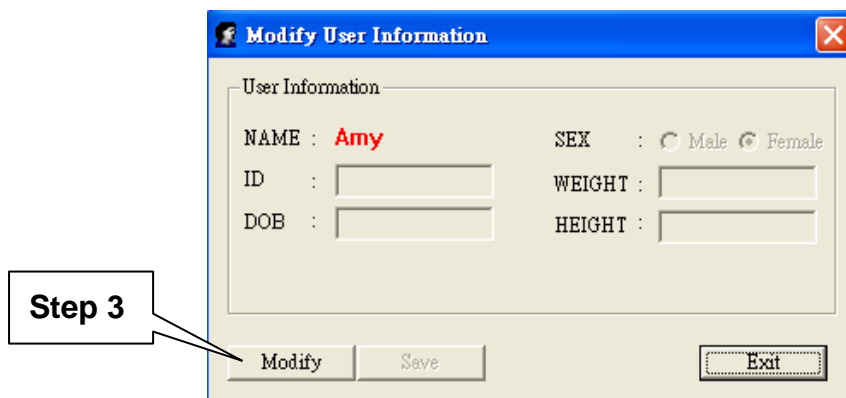
You can modify the values on the table after click | Modify |.

Then click | Save |, all the modified values will be saved automatically. Click | Exit |, The values will NOT be changed.

3.5.3 Delete Selected User

1. Select the user to be deleted by clicking on the name.

2. Click 🔁 function key. A warning window will appear.

3. Select | OK | to delete. Select Cancel to cancel the deletion.

Note: Default user "DCBM" cannot be deleted.

Note: ALL FILES under the user will be deleted if the user is

   deleted.

3.5.4 Search for User

1. Click 🔍 function key. A window will appear. You can search

   by "User Name" or by "ID". Please type in your search

   characters in the String field.
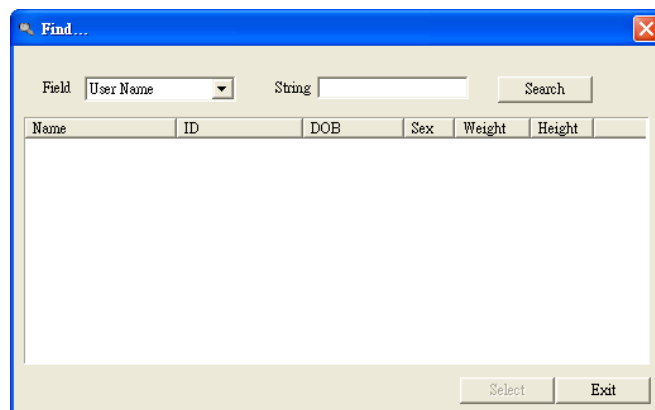
2. Select Find to start finding. If the user is found, the name

   will be highlighted.

3.5.5 Delete Selected ECG File

1. .Select the file to be deleted by clicking on the file name.

2. Click 🗑 to delete the selected file. Only one file can be

   deleted in one time.

3.5.6 Preview and Print HRV analysis report and ECG waveform

1. Select the file that you want to preview or print.

2. Click ▣ preview function, and a preview window will appear as shown.

Preview HRV analysis report and ECG

3. Select 🖶 , printer selection window will appear. Choose printer and print options accordingly. After printing, the window will close and return to the main page.

3.5.7 Save HRV analysis report as graphic file

1. Click the file name you want to save HRV report as graphic file.
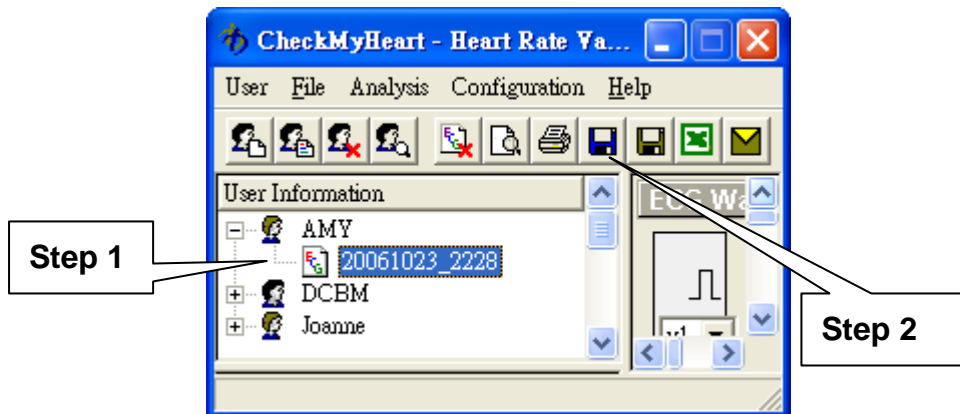
2. Select 🖫 and the file selection window will appear. The file will have **.jpg** extension.

3.5.8 Save 5 min ECG waveform as graphic file

1. Click the file name you want to save 5 min ECG waveform as graphic file.

2. Select 🖫 and the file selection window will appear. And the 5 min ECG waveform will be saved in **.jpg** file.

3.5.9 Export HRV result in Excel format

1. Click the file name you want to export the HRV analysis result.

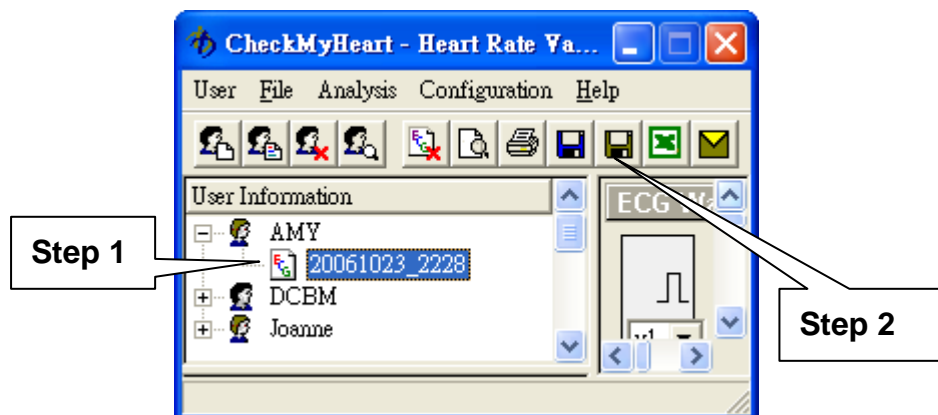2. Select ![Excel icon] and the file selection window will appear. HRV analysis summary including time/frequency domain analysis result will be saved in Excel file (extension.xls).
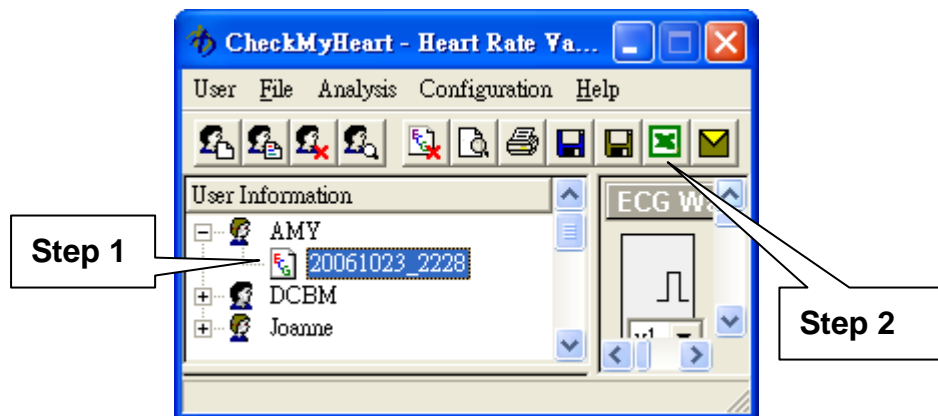
3.5.10 Email ECG data

1. Click the file name you want to E-mail.

2. Click ![Email icon] E-mail function, then the selected files will automatically be attached in the email for sending to the addressed receiver. The email will include two attached files at the same time. One is the 5 min ECG waveform, and the other is the HRV report.

3.6 Data analysis

The functions keys for data analysis are described as follows:

Function Keys	Description
⊣⊩	Review 5 min ECG
ⅢⅢ	Time Domain Analysis
▲▲	Frequency Domain Analysis
📄	HRV Analysis Summary
Exp	Export RR Interval raw data as text file
⬇ ⬆	Import and Export of CheckMyHeart file
☰	Analysis Configuration Setting

Detailed descriptions of Function Keys are as follows:

3.6.1 View 5 minute ECG waveform

1. Click on the file that you want to view.
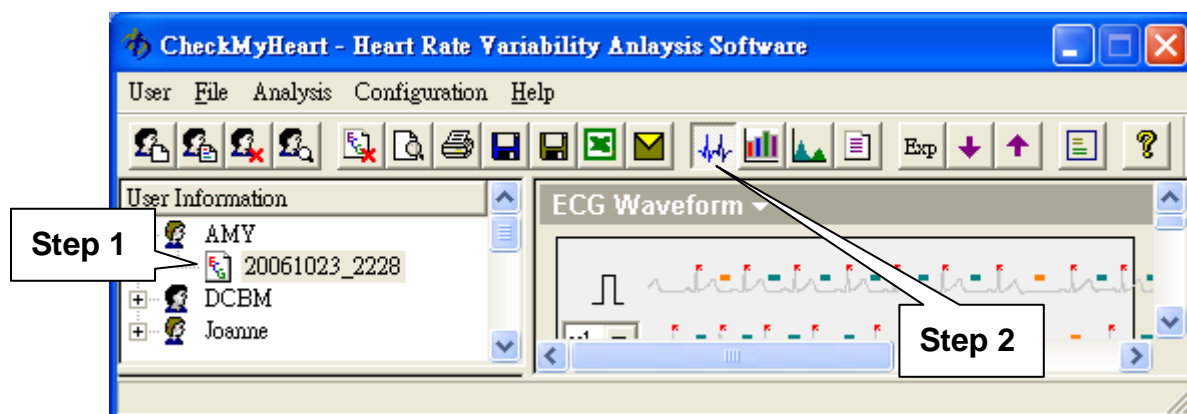
2. Select and 5 minute ECG waveform will be displayed in the window. Left click on each QRS complex to display single beat at lower left corner. Use right clicks on QRS complex to select a range to display average beat at lower right corner.
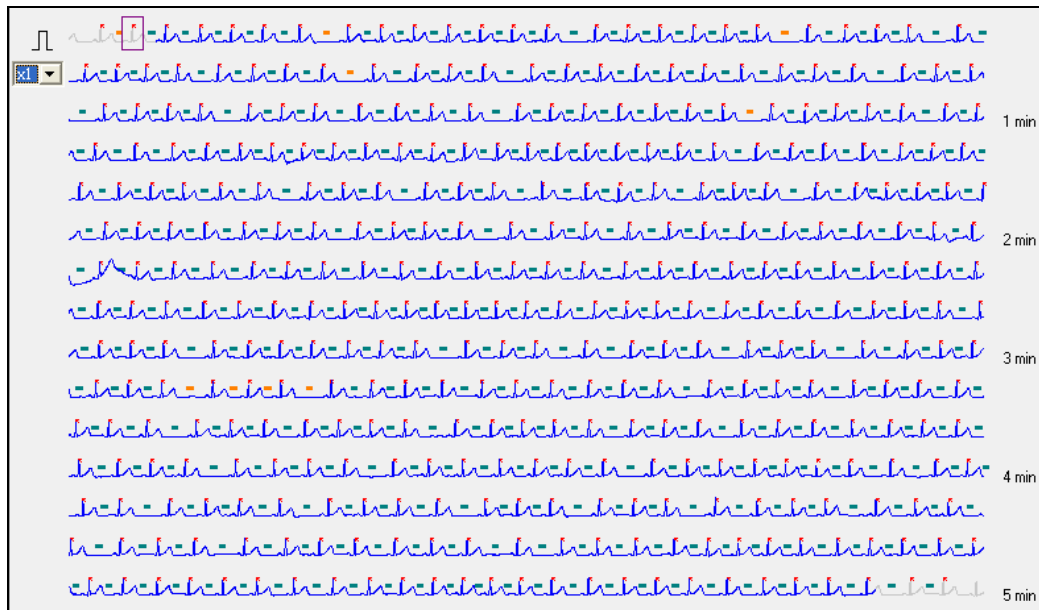
5 minute ECG Waveform
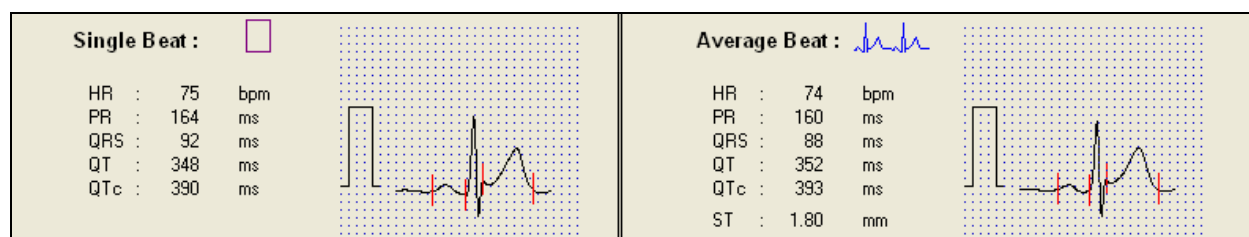
Single beat and average beat display

3.6.2 Edit R Wave

1. Click on the file you want to view.

2. Double left click on the QRS complex that you like to edit. The first and last 2.5 seconds of ECG will be shown as below.
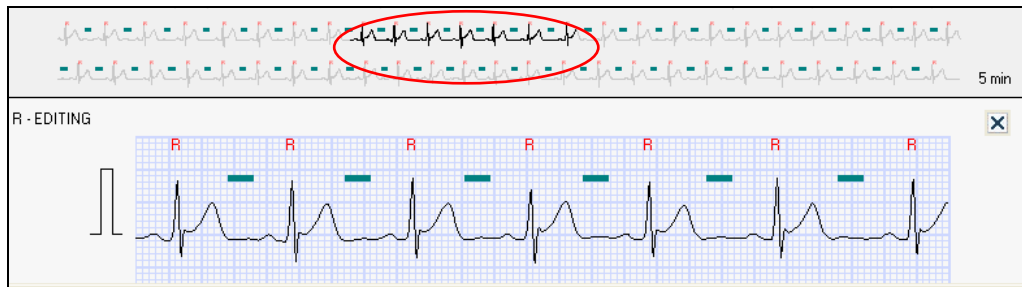
R wave editing display

3. Left click on the ECG wave to add or delete R wave. The green bar means the RR interval is included in the calculation of HRV. The orange bar means the RR interval is not included in the calculation of HRV.

4. To exit the R-editing function, or save, simply click on the ☒ on the right corner of R-editing section.

3.6.3 View HRV time domain analysis

1. Click on the file that you want to view.
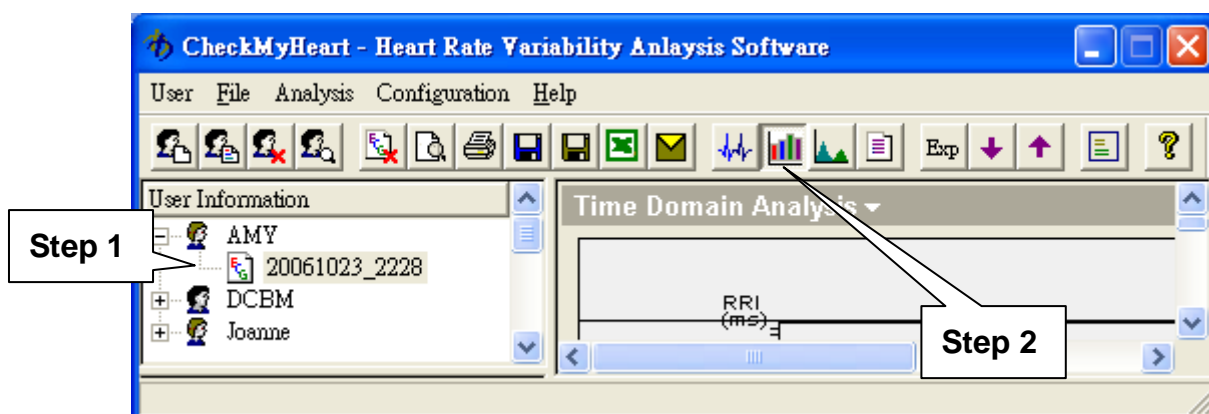
2. Select ▥ and time domain analysis (RRI and Heart Rate Tachogram, RRI and HR Histogram and RRI Scatter plot) will be shown as below.
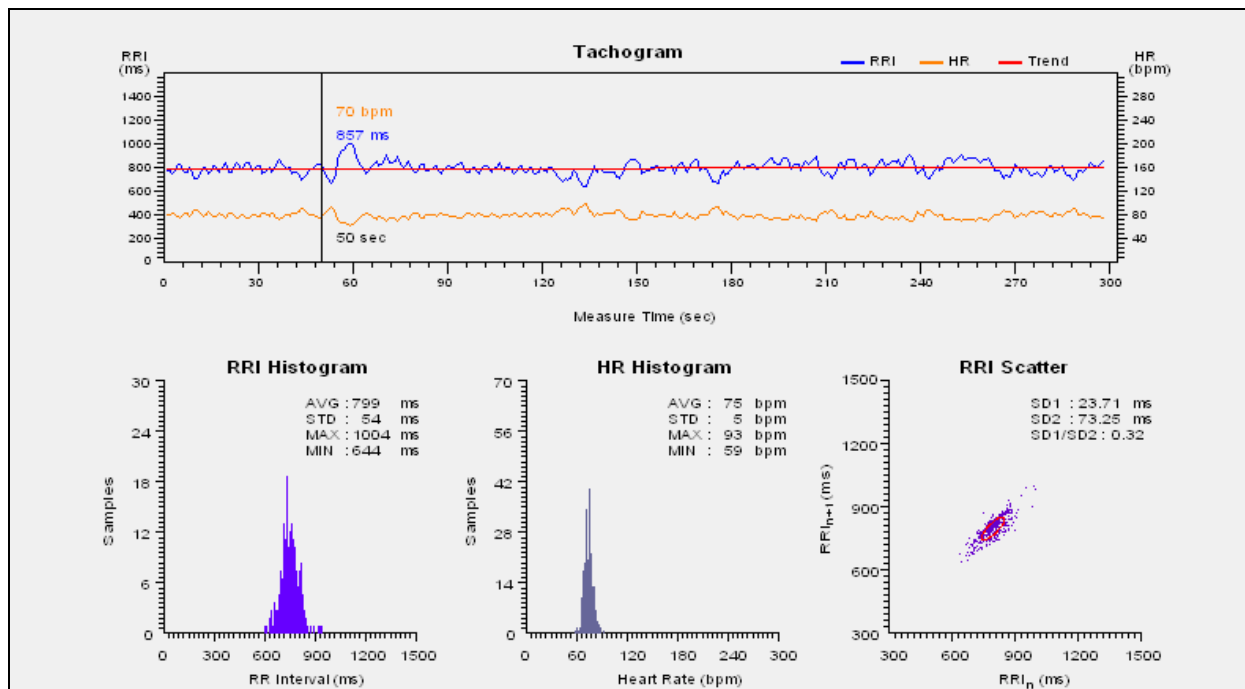
RRI Tachogram: The RR durations versus number of progressive beats. It can be used to show the variation of beat-to-beat durations. The blue line is the value of RR-interval (ms) and the red line is the progressive average of RR-interval (ms).

- **RRI Histogram:** The distribution of number of events versus RR-interval (ms).

- **RRI Scatter:** The Poincaré plot, a geometrical method of HRV analysis, is a diagram (scattergram) plotting each RR interval as a function of the previous RR interval. These plots can be interpreted visually and quantitatively.

Note: You can select detrending method. The detrend value will be automatically calculated.

RRI Series Detrending

Detrending Method :
⦿ First Order Polynomial
◯ Second Order Polynomial
◯ Smooth priors : Lamda [200]

3. Time Domain Measurements Table

Time Domain Measurements

Variable	Non-detrend Value	Detrend Value
Mean	799.31 ms	---
SDNN	54.44 ms	54.37 ms
RMSSD	33.53 ms	33.54 ms
NN50	44.00	44.00
pNN50	11.83 %	11.83 %
SD1	23.71 ms	23.72 ms
SD2	73.25 ms	73.14 ms
SD1/SD2	0.32	0.32

- **MEAN (ms):** The time average of RR-intervals

- **SDNN (ms):** Standard deviation of all the normal to normal (NN) intervals.

- **RMSSD (ms):** The square root of the mean of the sum of the squares of differences between adjacent NN intervals

- **NN50:** Number of pairs of adjacent NN intervals differing by more than 50ms in the entire recording; three variants are possible counting all such NN intervals pairs or only pairs in which the first or the second interval is longer.

- **pNN50 (%):** NN50 count divided by the total number of NN intervals

- **SD1:** Standard deviation of the scatter distribution along the direction perpendicular to the y=x line

- **SD2:** Standard deviation of the scatter distribution parallel to the y=x line

-25-

3.6.4 View HRV frequency domain analysis

1. Click on the file that you want to view.
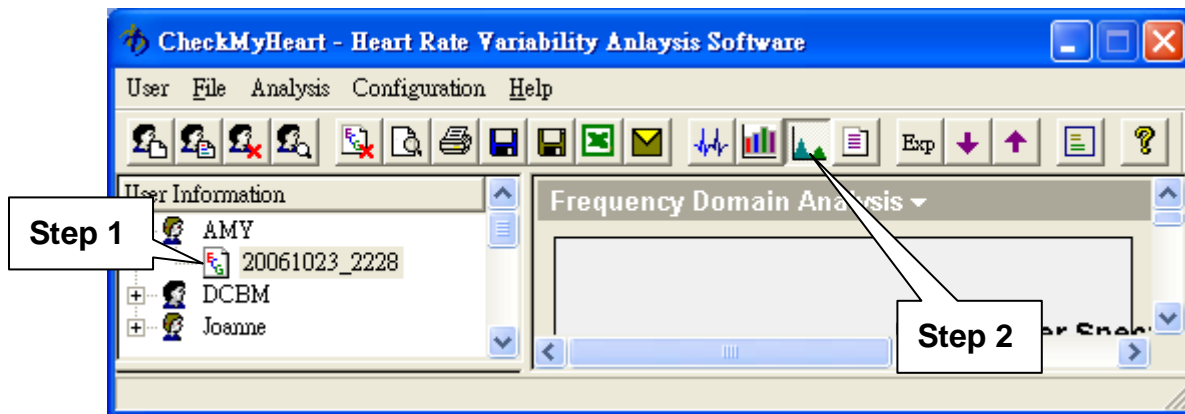
2. Select [icon] and frequency domain analysis (FFT – Power Spectral [non-detrend] and AR – Power Spectral [non-detrend]) will be plotted out and summarized as shown below.
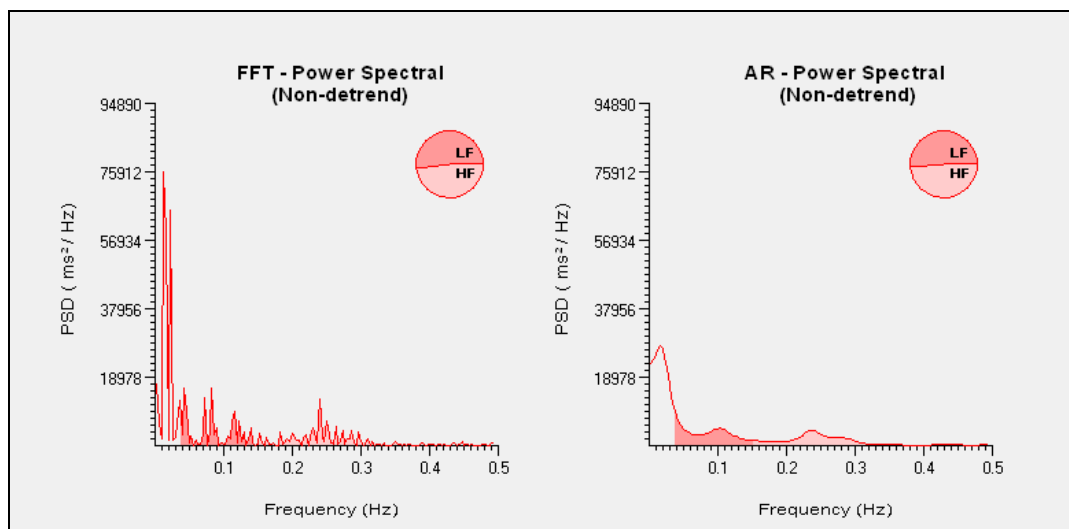
3. Analysis Table

Frequency Band Range

VLF	0.04	~ 0.04	Hz
LF	0.04	~ 0.15	Hz
HF	0.15	~ 0.4	Hz

The Order of AR Model 16

◉ Display Non-detrend Power Spectral
○ Display detrend Power Spectral

Frequency Domain Measurements

Variable	Non-detrend		Detrend		Units
	FFT	AR	FFT	AR	
VLF power	0	0	0	0	ms
LF power	423	418	422	417	ms
HF power	387	393	387	392	ms
Total power	1651	1698	1558	1593	ms
LF norm	25.67	24.63	27.08	26.18	nu
HF norm	23.50	23.17	24.85	24.61	nu
LF/HF	1.09	1.06	1.09	1.06	

- **VLF:** Very low frequency

- **LF:** Low frequency

- **HF:** High frequency

- **AR Model:** Order range (1~99)

- **FFT spectrum**: Fast Fourier transform spectrum.

- **AR spectrum:** Auto-regressive power spectrum.

Note: You can change the VLF, LF, HF frequency band range accordingly. And also choose to display non-detrend or detrend power spectral.

3.6.5 View analysis summary

1. Click on the file that you want to view.
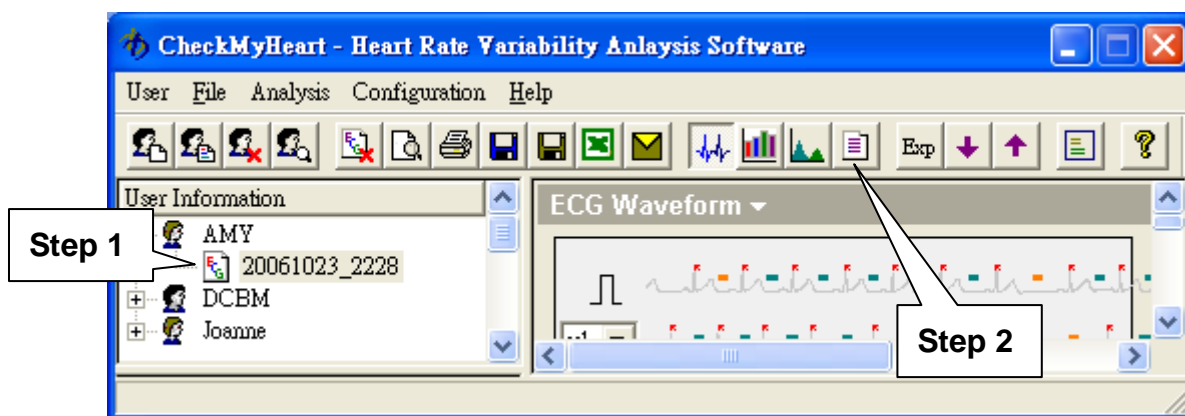
2. Select 📄 and analysis summary will be shown as below. You can also make your own notes by typing in the "Finding" section.

Information					
Name : DCBM		Sex : Male		Filename : 20060102_2246	
ID : R20060311		Weight : 100		Measure Date : 01 / 02	
DOB : 2004.03.01		Height : 180		Measure Time : 22 : 46	

HRV Analysis Results

Time Domain Measurements

Variable	Non-detrend Value	Detrend Value
Mean	731.57 ms	---
SDNN	72.28 ms	71.41 ms
RMSSD	82.68 ms	82.70 ms
NN50	31.00	31.00
pNN50	7.60 %	7.60 %
SD1	58.46 ms	58.48 ms
SD2	83.85 ms	82.33 ms
SD1/SD2	0.70	0.71

Frequency Domain Measurements

Variable	Non-detrend		Detrend		Units
	FFT	AR	FFT	AR	
VLF power	600	450	526	378	ms²
LF power	1058	1269	1066	1273	ms²
HF power	756	776	755	776	ms²
Total power	2415	2497	2348	2428	ms²
LF norm	58.34	62.03	58.55	62.11	nu
HF norm	41.66	37.97	41.45	37.89	nu
LF/HF	1.40	1.63	1.41	1.64	

Detrend method : second order polynomial

VLF : 0.00 ~ 0.04 Hz
LF : 0.04 ~ 0.15 Hz
HF : 0.15 ~ 0.40 Hz

The Order of AR Model : 16

Finding

3.6.6 Export RR interval raw data

1. Click on the file that you want to export RR data.
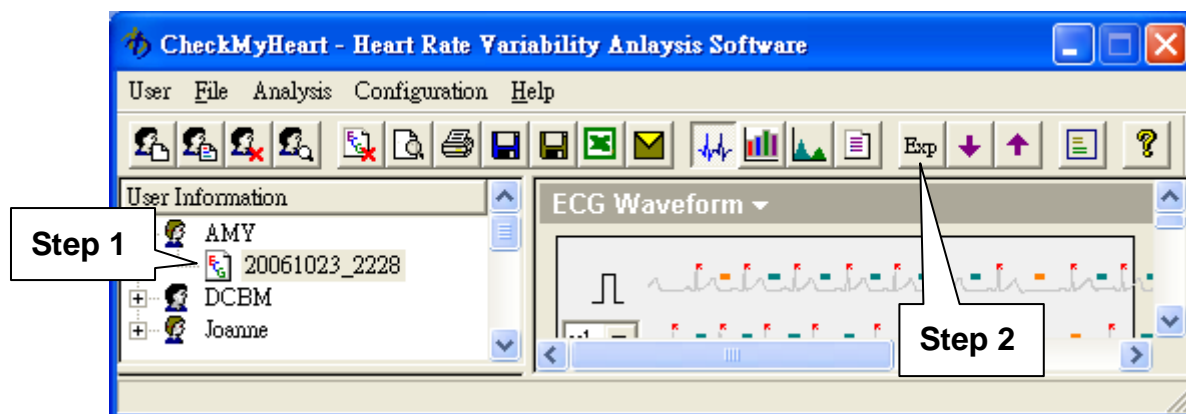
2. Select [Exp] and you will be asked to save the RR interval data

in text file (extension .txt).

3.3.7 Export and Import User Data

1. You can have your ECG database in several computers with CheckMyHeart software. Click on [↑] export key and save a user's ECG data for export. The file will have **.cmh** extension. Please save the file for export.
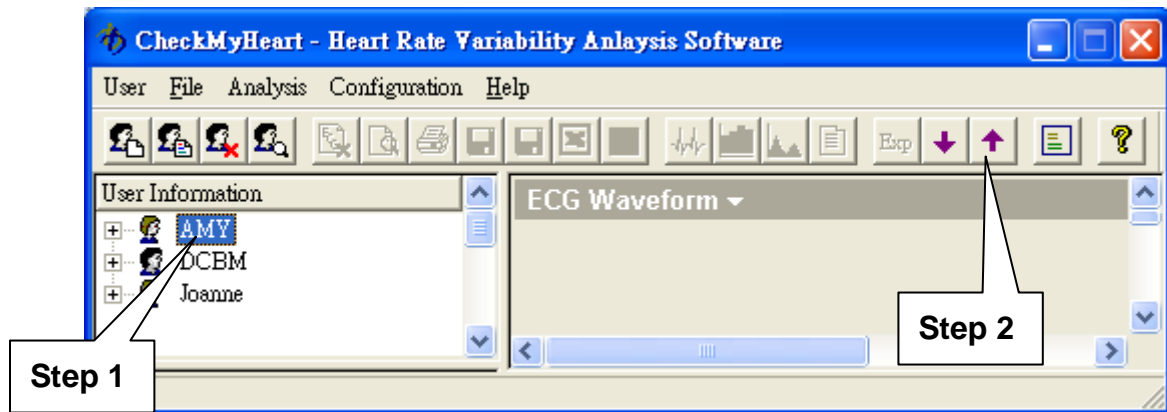
2. Choose the computer you want to import the database. Please make sure CheckMyHeart software is installed. Click on [↓] import key. Choose and open the file name with .cmh extension to import the user's data.

Frequently asked questions

Q1:	What is CheckMyHeart?
A1:	CheckMyHeart is a device intended to record, recall, store and transfer ECG signals. You can record your 5 min ECG tracing easily.
Q2:	What are the factors that may affect the measurement by CheckMyHeart?
A2:	Do not move and talk during measurement. Please make sure adhesive conductive ECG pad is in good contact wit you skin. Please make sure the external electrode cable is connected properly with the ECG pad and the hardwar.
Q3:	Will static electricity affect the measurement of CheckMyHeart?
A3:	CheckMyHeart is CE certified and has passed electromagnetic interference and compatibility tests. Under normal circumstances, static electricity will not affect the operation of CheckMyHeart.
Q4:	How do you manage ECG signals if multiple people use a single CheckMyHeart device?
A4:	Data cannot be managed on the CheckMyHeart device directly. If there is more than one user, please use the software provided for data management. For detailed information, please refer to the User's Manual.
Q5:	Can the parameters measured by CheckMyHeart be used for clinical diagnosis?
A5:	The ECG tracings recorded by CheckMyHeart ARE NOT for clinical diagnostic purposes but for a physician's reference only.
Q6:	Why do the data recorded in the CheckMyHeart disappear after the batteries are replaced?
A6:	Data will remain in the memory for approximately 2 minutes only during battery replacement. Thus, please replace batteries as quickly as possible to preserve data.

Q7:	Can CheckMyHeart use other external power supply?
A7:	No. CheckMyHeart is to be operated by two replaceable 1.5V (AAA) alkaline batteries. Please DO NOT use other external power supply which may be hazardous and may damage the device.
Q8:	Can CheckMyHeart use accessories other than the ones provided in the standard package?
A8:	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:	What to do if the parameters measured by CheckMyHeart do not correspond to the user's condition?
A9:	In case of an emergency physical condition, users should contact emergency services immediately, or go report immediately to the hospital. If the measured parameters do not correspond to user's condition, please make sure all standard operating procedures are followed. If not, please contact a physician for further check up.
Q10:	Can CheckMyHeart be used while the user is standing up, sitting down, or lying down?
A10:	Yes, but DO NOT move or talk during recording.
Q11:	After exercising, can ECG be measured using CheckMyHeart? Will the measurement be correct?
A11:	Yes, ECG can be recorded after exercise. During measurement, please remain in a stable position to avoid noise interference.
Q12:	Can CheckMyHeart be used during commuting?
A12:	During commuting, if user is able to keep a stable position, CheckMyHeart can be used to measure ECG. DO NOT use the device during the operation of any vehicle.

CONTACT INFORMATION

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