QUANTA COMPUTER INC. HUAYA PLANT

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Wearable ECG Monitoring Device
User Manual

Ver. 1.0

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CI2418-01_2A

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Warnings and Reminders

Warnings:

- The NYA Quanta Wireless Home Health Management System is to be used for clinical assessment and reference only. The NYA Quanta Wireless Home Health Management System is not intended for diagnostic use.

- The NYA Quanta Wireless Home Health Management System consists entirely of sophisticated medical electrical devices so maintenance can only be carried out by professional technicians. Unauthorized disassembly of the device by the user is not allowed.

- The NYA Quanta Wireless Home Health Management System must be used with the specified "accessories" and "electrodes". The use of accessories and electrodes from other brands may lead to faulty readings.

- Do not allow the metal connectors to come into contact with any kind of power source during use.

- Before using the NYA Quanta Wireless Home Health Management System. Please make sure that all of the machine's indicator lights are clearly readable in the current usage environment.

- Damaged or faulty accessories and electrodes should not be used.

- When the NYA Quanta Wireless Home Health Management System experiences an error, it will automatically stop taking measurements and the corresponding indicator lights will blink.

- When the NYA Quanta Wireless Home Health Management System is low on power, it will automatically stop taking measurements and the corresponding indicator lights will be blink.

- When the NYA Quanta Wireless Home Health Management System is taking measurements, please try and avoid using any instruments or devices that may affect the accuracy of the readings (e.g. the use of the blood pressure meter will affect the measurement of the pulse).

- When the NYA Quanta Wireless Home Health Management System is taking measurements, please try and avoid using other electronic devices nearby. If it must be used with other electronic devices simultaneously, please check to make sure that the NYA Quanta Wireless Home Health Management System is continuing to take measurements normally.

- NYA-specific accessories are defined in this user guide. The use of accessories from other brands may damage the device.

- Do not use the NYA Quanta Wireless Home Health Management System in a flammable environment.

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Reminders:

- Please read through this user guide carefully before using the NYA Quanta Wireless Home Health Management System.

- If the NYA Quanta Wireless Home Health Management System must be used to take measurements over an extended period of time, please inspect the contact point of the electrodes at least once every 8 hours to make sure that the electrodes are in the right position and there is no allergic skin reaction from the user.

- Do not use medical electrical equipment such as "defibrillators" when using the NYA Quanta Wireless Home Health Management System.

- When the NYA Quanta Wireless Home Health Management System is taking measurements, if a stable reading cannot be taken then stop taking the measurement right away (not everyone is suitable for monitoring with the NYA Quanta Wireless Home Health Management System).

- The NYA Quanta Wireless Home Health Management System can only take measurements when the subject is stationary (e.g. while sitting or lying down) or engaging in ordinary exercise. Any activities not permitted by the attending physician may affect the accuracy of the measurements.

- Do not use the NYA Quanta Wireless Home Health Management System in an excessively humid environment and never submerge it directly under water.

- Do not clean or wipe the NYA Quanta Wireless Home Health Management System with corrosive and abrasive cleaning agents.

- The NYA Quanta Wireless Home Health Management System consists entirely of sophisticated medical electrical devices so maintenance can only be carried out by professional technicians. Unauthorized disassembly of the device by the user is not allowed.

- When the NYA Quanta Wireless Home Health Management System is low on power, please insert it in the charger for re-charging as soon as possible.

- The disposal of the NYA Quanta Wireless Home Health Management System and its accessories should comply with the relevant local regulations.

- The NYA Quanta Wireless Home Health Management System has been tested and certified to international electro-magnetic compatibility (EMC) standards for medical equipment (EN 60601-1 and EN 60601-1-2) for the user's peace of mind.

- The NYA Quanta Wireless Home Health Management System and its accessories should be disposed of properly. If you are uncertain about the proper disposal method, please contact customer service at Quanta Computer Inc. Huaya Plant for assistance.

- The accuracy of the medical electrical equipment may be affected if used near high-frequency communications equipment.

- Battery Caution

  Risk of explosion if battery is replaced by an incorrect type.

  Dispose of used batteries according to the instructions

- **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.

  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.

  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.
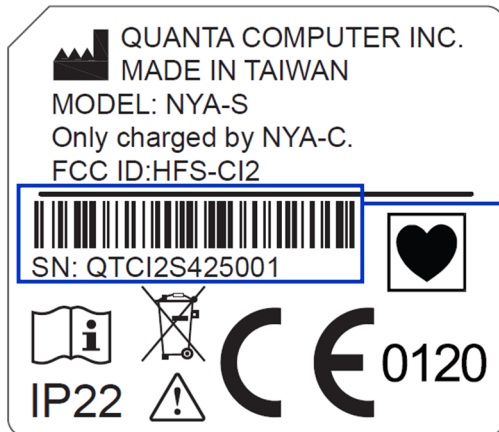 This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment 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.
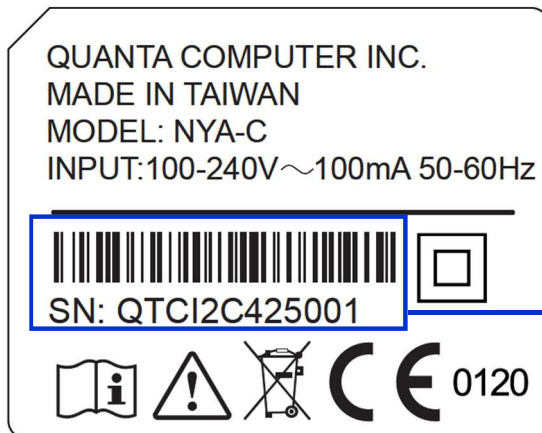
  .

Year of Manufacture

The year of manufacture label and format of the wireless home health management system's body monitor, charger and ECG electrodes are shown below:

● Sensor

QUANTA COMPUTER INC.
MADE IN TAIWAN
MODEL: NYA-S
Only charged by NYA-C.
FCC ID:HFS-CI2
SN: QTCI2S425001
IP22

SN: QTCI2C425001

In the serial number on the product label, the 7th character starting from the left ("14" in the shown example) represents the sensor and charger's year of manufacture.

● Charger

QUANTA COMPUTER INC.
MADE IN TAIWAN
MODEL: NYA-C
INPUT:100-240V～100mA 50-60Hz
SN: QTCI2C425001

Example:

If the serial number is "QTCI2C425001"

The 7th characters is mean "14"

Then the year of manufacture is 2014 AD.

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● ECG Electrodes

The effective date of the ECG electrodes is labeled along the lower edge of the packaging in impact type (not printed) as shown below:

Example: 220801X 2015-07

Explanation: 220801X ➔ Manufacturer lot number

2015-07 ➔ Valid before July 2015

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Supplier's Declaration

The NYA Quanta Home Health Management System conforms to the international EN 60601-1 and EN 60601-1-2 standards for electromagnetic compatibility with medical electrical devices and systems.

Emission Testing	Compliant Standard	Electromagnetic Environment Guidelines
The recommended electromagnetic environment for this instrument is shown in the table below. The customer or user should ensure that this instrument is used in the described environment.		
RF Emissions CISPR 11	Group 1	Radio-frequency is only used by the internal functions of this instrument. The emission energy is also very low and does not interfere with nearby electronic instruments.
RF Emissions CISPR 11	Class B	This instrument is suitable for home use (including residential or other mixed residential/public low-voltage power grids)
Harmonic Emissions	IEC 61000-3-2	
Voltage Fluctuations/ Flicker Emissions	IEC 61000-3-3	

Testing	IEC 60601-1-2 testing	Compliant Standard	Electromagnetic Environment Guidelines
The recommended electromagnetic environment for this instrument is shown in the table below. The customer or user should ensure that it is used in the described environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	The floor should be timber, concrete or ceramic tile. If the floor is covered in a synthetic material then it should have a relative humidity of at least 30%.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency and magnetic field in representative commercial or hospital environments.

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Supplier's declaration and guidelines—Electromagnetic Immunity

Testing	IEC 60601-1-2 testing	Compliant Standard	Electromagnetic Environment Guidelines
The recommended electromagnetic environment for this instrument is shown in the table below. The customer or user should ensure that it is used in the described environment.			
No part of the NYA Quanta Wireless Home health management System should be placed near portable and mobile radio-frequency communications equipment. The recommended safety distance can be calculated using the radio frequency and the following formula.			
Radio-frequency IEC 61000-4-6	3 V/m 150 kHz to 80 MHz	[3] V	Recommended safety distance $d=1.17\sqrt{P}$
Radio-frequency IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[3] V/m	$d=1.17\sqrt{P}$ 80 MHz to 800MHz $d=2.33\sqrt{P}$ 800MHz to 2.5 GHz *P* is the maximum output of the transmitter (Unit: Watt) *d* is the recommended safety distance (Unit: Meter) The field intensity of the fixed RF transmitter (after an EM site survey) should be lower than the recommended values for the above frequency ranges. Interference may be produced near instruments that have the following symbol:

The field intensity of fixed RF transmitters (e.g. radio, mobile phone, ham radio, FM and AM radio broadcasts and TV stations) cannot be predicted from the frequency alone.   To evaluate the EM field intensity of the environment, an EM site survey may be necessary.   If the measured field intensity for a region exceeds the above recommended range, the device should be observed or checked to make sure it operates normally.   If abnormal operation is observed, further action such as adjusting the direction or re-positioning of the equipment should be taken.

Attention: For frequencies between 80 MHz and 800 MHz, use the higher frequency range.

Attention: These guidelines may not be applicable to all situations.   Electromagnetic waves can be absorbed or reflected by buildings, objects and people.

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Recommended safety distance

The following table lists the recommended safety distance between the device and mobile RF communications equipment.

The recommended EM environment for the NYA Quanta Wireless Home Health Management System is where RF interference is controlled. The user should maintain the recommended safety distance with the devices and portable/mobile RF communications equipment listed in the following table (corresponding to the maximum output of the RF transmitter).			
	Recommended Safety Distance (corresponding to RF transmitter output)		
Maximum output of RF transmitter (Watt)	150 kHz to 80 MHz $d=1.17\sqrt{P}$	80 MHz to 800 MHz $d=1.17\sqrt{P}$	800 MHz to 2.5 GHz $d=2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

If the maximum output of the transmitter is not shown in the above table, use the formula to derive the recommended safety distance _d_ (Meter) with _P_ (Watt) being the maximum output of the transmitter.

Attention: For frequencies between 80 MHz and 800 MHz, use the higher frequency range.

Attention: These guidelines may not be applicable to all situations.   Electromagnetic waves can be absorbed or reflected by buildings, objects and people.

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Regulatory Marks

The Wireless Home Health Management System conforms to the following regulatory requirements.

Administrative Regulations on Low Power Radio Waves Radiated Devices (930322)

Article 12

Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to an approved low power radio-frequency devices.

Article 14

The low power radio-frequency devices shall not influence aircraft security and interfere with legal communications.   If found, the user shall cease operation immediately until no interference is achieved.

The said legal communications means radio communications is operated in compliance with the Telecommunications Act.   The low power radio-frequency devices must be susceptible with the interference from legal communications or ISM radio wave radiated devices.

CE 0120	CE Mark: Indicates that the body monitor has been certified and conforms to EC Directive 93/42/EEC on medical devices.
♥	Type CF applied part
	Indicates that the body monitor is classified as electrical or electronic equipment requiring proper disposal (WEEE Directive)
REF	Indicates the manufacturer's catalogue number **Attention: Catalogue number may also be referred to as the reference number or reorder number.**
SN	Indicates the manufacture's serial number.
	Indicates the manufacturer's name and address
∿	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.

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⚠	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
📖	Indicates the need for the user to consult the instructions for use.
▣	Indicates the identification of CLASS II EQUIPMENT only

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Introduction

- "Electrocardiogram" (ECG) Waveform

| Required equipment		Remarks
Smart phone (E)＋ NYA body monitor (G)		
ECG electrode (I) ＋ Accessory (H)	Body Monitoring Shirt(J)	Choose one of the two measurement options on the left based on the usage requirements, nursing personnel's requirements or user's personal preference.

Equipment

A.NB / PC

Functions

The device requires a commercially available personal computer (NB/PC) with Bluetooth capabilities. In addition to the basic functions of a computer, the installation provides an exclusive application (UI, as below) capable of performing electrocardiogram (ECG) measurements. Doctors and medical staff can effectively monitor health information by uploading the measurements to the main server via Bluetooth.

Quanta ECG Monitor Application UI (for use on NB / PC)

Functions

The application (UI) can be installed on any personal computer (NB /PC) to provide ECG data measurement functions. With the Quanta ECG Monitor device (B), body monitoring accessories (D), ECG electrode patches (C) , measured data will be uploaded to the server via Bluetooth so doctors and medical staff can conduct carry out remote monitoring.
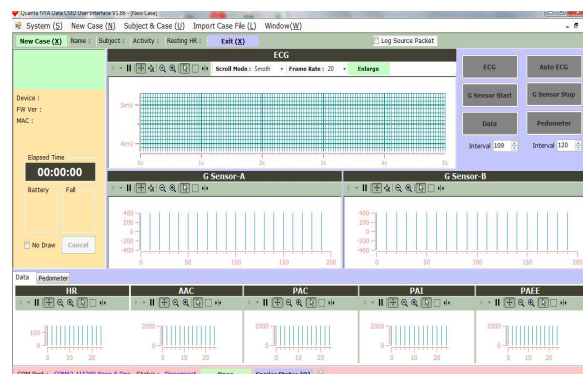
B. NYA Body Monitor

Function

The ECG signal measured through this device is wirelessly transmitted using low-power Bluetooth technology to the smart phone for processing. The data is then uploaded via 3G wireless network to the cloud server.

This device requires the ECG Electrodes (C) in order to take measurements.

C. NYA Body Monitor Accessory

Function

When the electrodes are used, this accessory is used to attach the NYA Body Monitor (B) and transmit the ECG signal between electrodes.
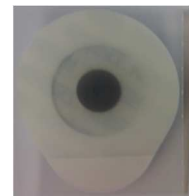
 Back

 Front

D. ECG Electrodes

Function

Attach to the designated location on the chest in order to capture physiological ECG signal for the NYA Body Monitor (B) for processing and upload.

E. NYA Charger

Function

Used for charging the NYA Body Monitor (B). The charger has two slots that allow it to charge two Body Monitor (B) units at the same time.

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Equipment Operating Instructions

A. Personal Computer (NB/ PC)

According to the specifications of individual personal computers (NB / PC).

Operating Instructions:

- Start up the computer

  After starting up your personal computer (NB / PC), users can access the available functions.

- Shut down the computer

 To shut down your personal computer (NB / PC), click Shut Down.

- Bluetooth Functions
  - Install a Bluetooth dongle on your personal computer (NB / PC).
  - Plug in your Bluetooth dongle to the USB port to turn the Bluetooth functions on or off.
  - Upon selecting and launching Bluetooth, the Bluetooth interface will be displayed. Click to search for the device.
  - Your device name will be displayed in the Bluetooth selection field. Click on your device name to add it to the system.
  - The configuration and connection status will be shown on top of the device name in your list of Bluetooth devices.

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B. Quanta ECG Monitor application, NYA- Data- CMD [for use on personal computers (NB / PC)]

Operating Instructions:

- Ensure that you have completed the installation of the Quanta ECG Monitor. Please refer to the next chapter, "G.   Quanta ECG Monitor Body Monitoring Device" for the instructions and diagrams.

- On your computer's desktop, click the NYA-Data-CMD UI icon, as shown, to launch the application.

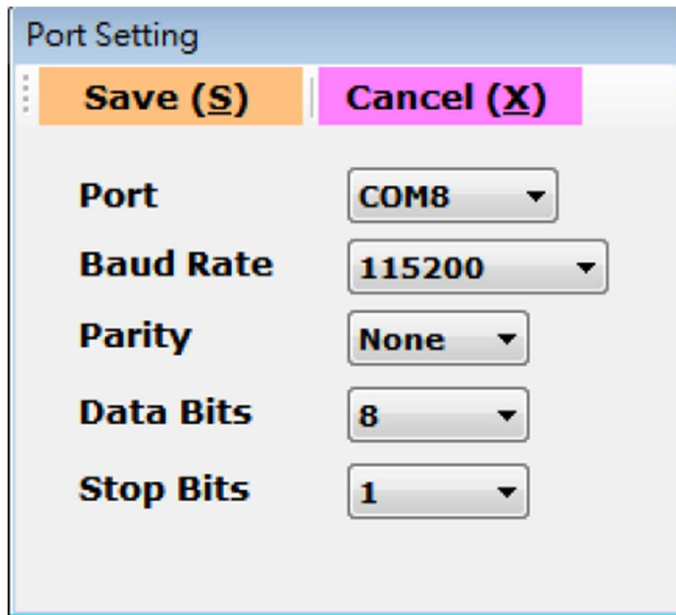- The following window will be displayed upon launching the application.
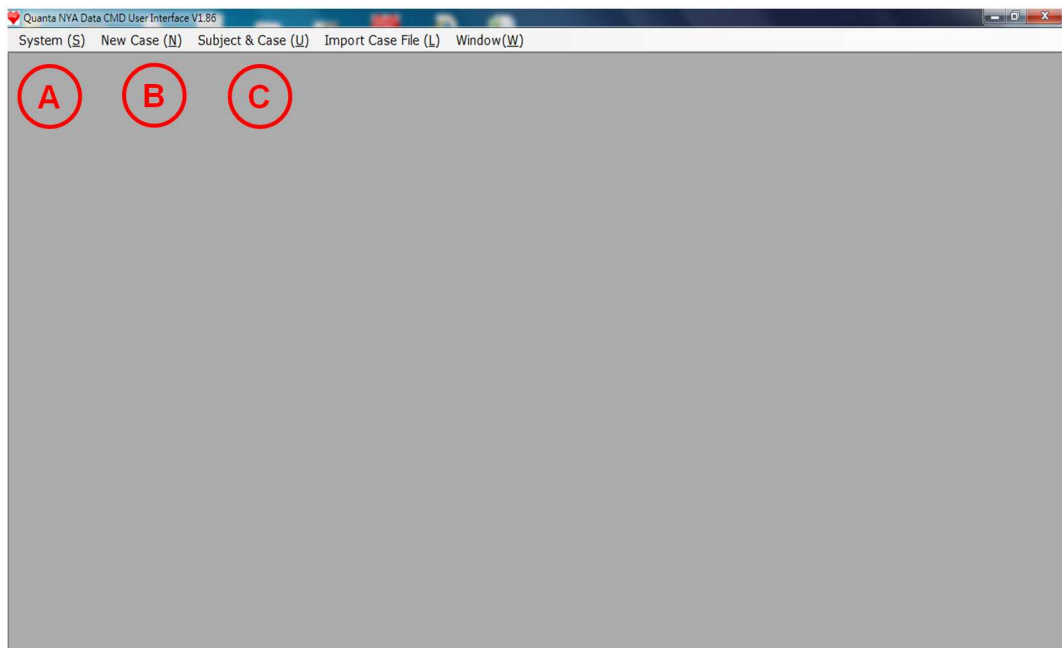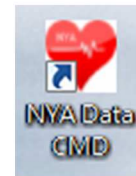
Button	Function
A	Communication Port Settings
B	Create New Case
C	Subject & Case Management

1. Communication Port Settings

   Set up the com port to receive Vital Sign Sensor data.
   Click "System" → "Com Port Setting" to open the following window.

- Port

  The system will automatically detect and list the current Com Ports on the computer. Select the Port to connect to.

- Baud Rate

  Select 115200.
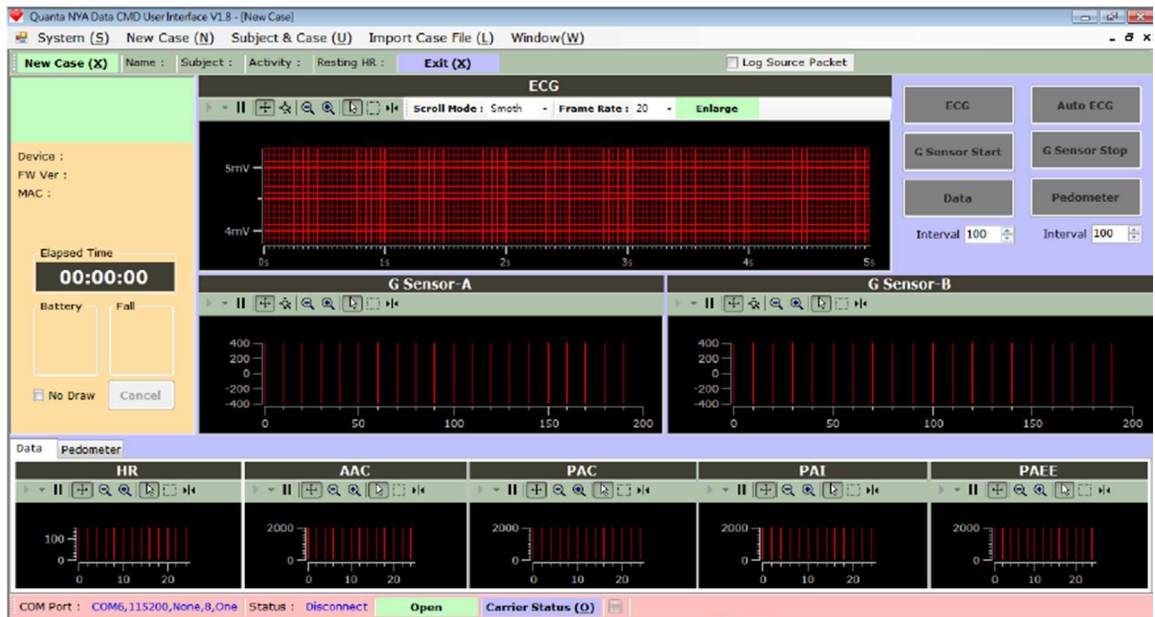
- Parity

  Select None.

- Date Bits

  Select 8.

- Stop Bits

  Select 1.

  ◆ After making the changes, click "Save" to complete. The changes will not take effect if you cancel and exit the screen.
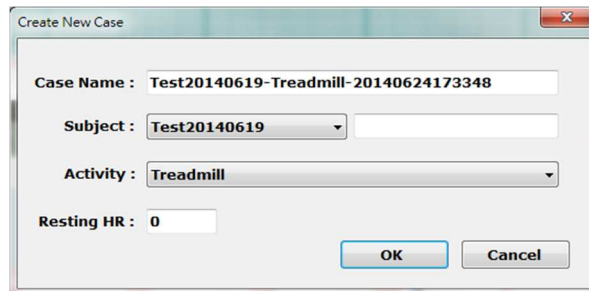
2. Create New Case

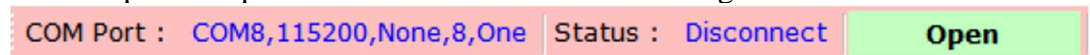Clicking "New Case" will display the following window:

Create a New Case as follows:

a. Click "New Case" to display the following window.

Confirm the subject in the Subject field. Enter the Resting HR of the Subject and click "OK".

b. Ensure Bluetooth has been properly connected to the Serial Port of the hardware.

c. Click "Open" to open the Com Port as shown in the diagram below.


If correctly launched, the Status will change to Connected as shown in the diagram below. To close the Com Port, click "Close". If during the measurement process, the Com Port connection disconnects due to instability, the system will close the Com Port automatically.
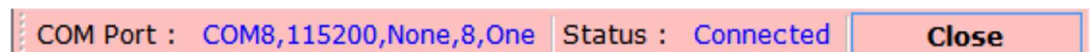

d. Click "Start" on the left of the screen to connect to the hardware, send out the initializing data and prepare to receive the test data.

e. To end the test, click "Stop" on the right of the screen. Upon clicking "Stop", the data automatically save to the database.

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f. Screen description:
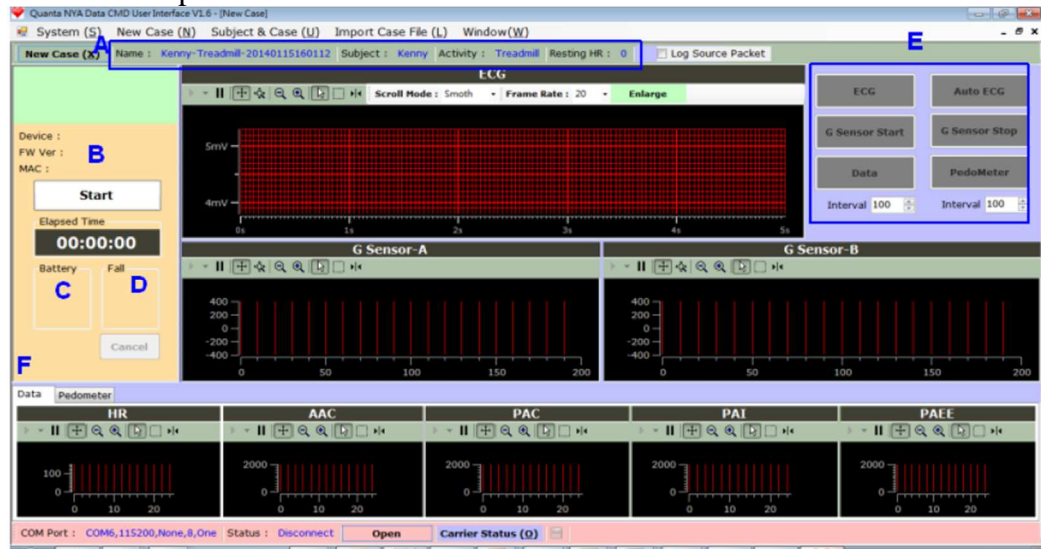
A. Displays the basic information of the case.
B. Displays the time elapsed for the test.
C. Displays the battery life of the hardware.
D. Displays whether a Fall Event occurs. Click "Cancel" to execute Cancel Fall Event command.
E. Auto ECG command. By clicking "Auto ECG", the ECG waveform will update every 3 seconds; HR, AAC, PAC, PAI, PAEE and battery will update every 15 seconds; and Steps, Stride, Speed, Calories, and Distance will update every 60 seconds.
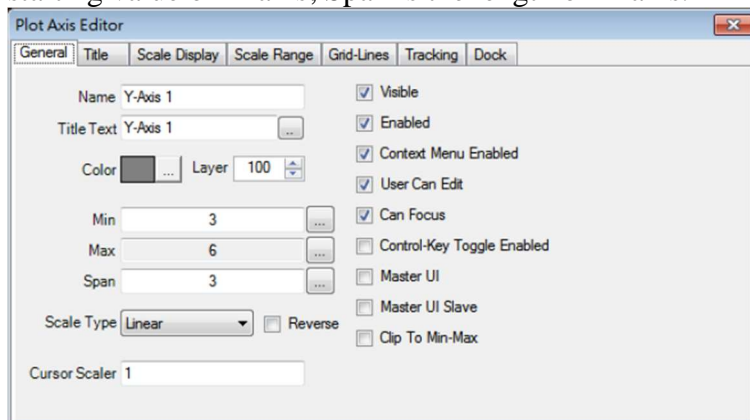
◆ ECG waveform display
Enlarge will enlarge the ECG waveform measured.
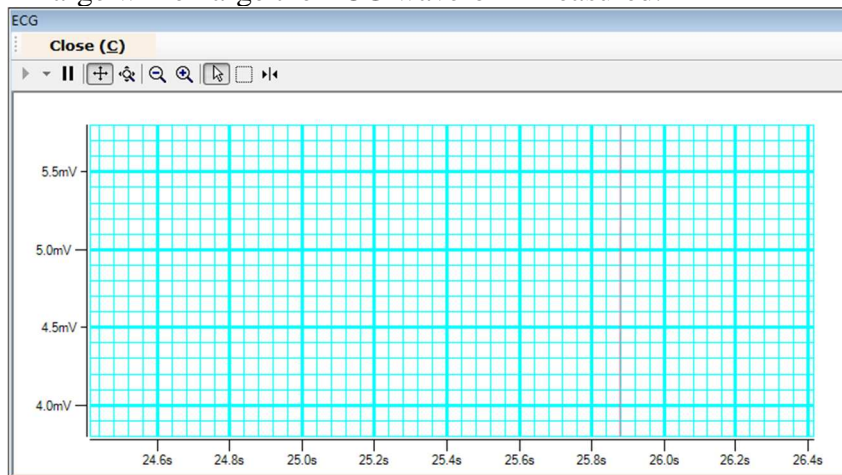
◆ Change Y-axis range of ECG display
On the Y-axis range, right-click to display a selection list. Select Edit as shown in the diagram right.

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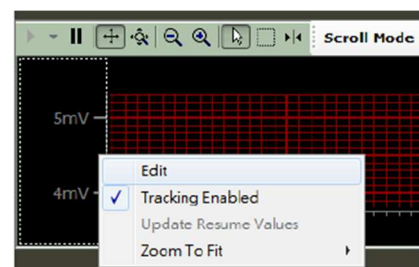
Correct the two values, Min and Span, on the General Tab. Min is the starting value of Y-axis; Span is the length of Y-axis.

◆ Battery life display of monitoring device

Under normal connection and usage, the battery life symbol will display as follows. Different battery bars represent different battery life.

| High battery life, estimated usage time of 12 to 16 hours.	Medium battery life, estimated usage time of 7 to 11 hours.	Low battery life, estimated usage time of 2 to 6 hours.	Critical battery life, with less than 1 hour of battery life. Please charge immediately.
4 bars (full)	3 bars	2 bars	1 bar

Note: The above battery life display and usage time is for reference only, as the data is obtained by testing on a new product. The actual usage time will defer with different conditions such as charging conditions, number of times used, environmental temperature, distance from base station, connectivity, etc.

| Condition	Possible Reason	Recommended Actions
Data disconnected or omitted while sleeping.	The subject turns over or sleeps on one side causing the Quanta ECG Monitor to detach from the accessories or causing poor connection due to pressure from the body.	We recommend putting on the physiological monitoring clothing while sleeping.
	The Quanta ECG Monitor monitoring device is a safe and low power Bluetooth device. The electric wave emitted is weak. If the subject sleeps on one side or wraps one's arms around the body while sleeping, the device may easily become disconnected or obstructed by the body.	While sleeping, put the handphone on your headboard or within 1 to 2 meters of the bedside. We recommended placing the handphone at a position higher than the bed. Do not put the handphone on the floor. Refrain from placing the handphone at a position lower than or at the end of the bed.

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C   Subject & Case Management
 After executing "Subject & Case", the following screen will be displayed:
 A. Click "New Subject" button.
 B. Enter Name, Sex, Birthday, Height and Weight.
 C. Click "Save All" to save into the database. If the Name entered already exists, the system will display the following alert message as shown in the diagram.
 D. Select the Subject Name in the "Subject Name" field. The subject's test cases will display in the case list below.
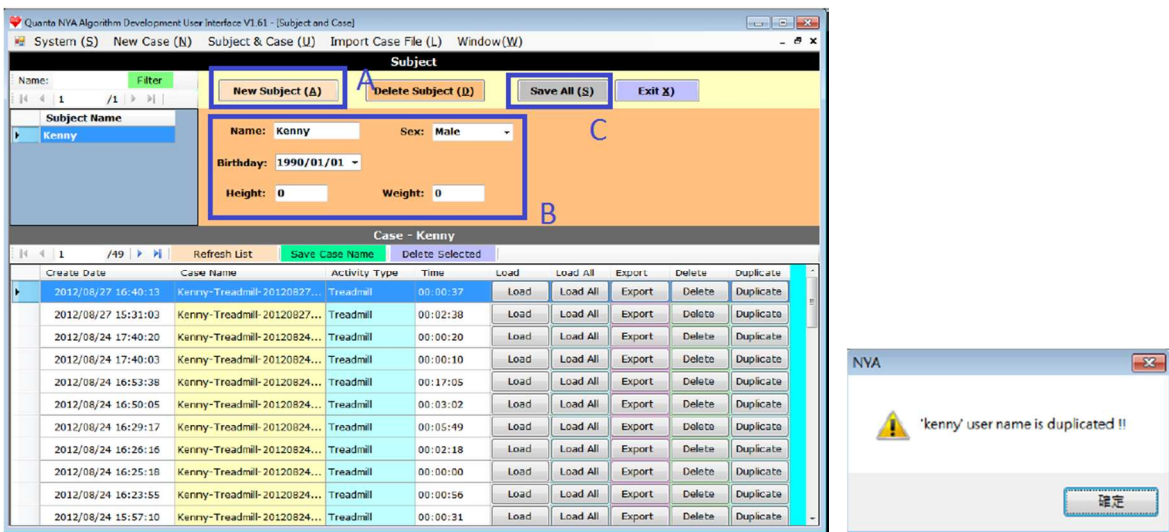
C. NYA Body Monitor

● External guide to body monitor:

Front of Body Monitor

Back of Body Monitor

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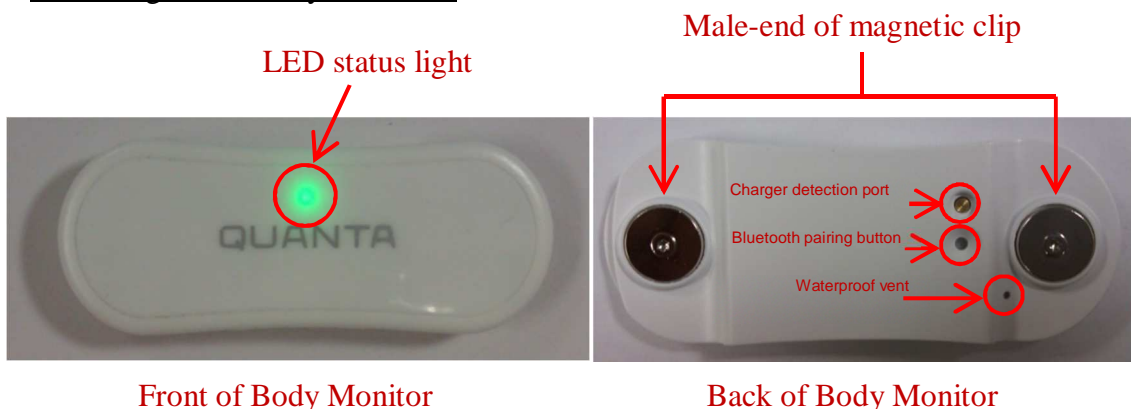
- Bluetooth matching (These settings will be set by the service representative)

    (1) When the "Smart Phone" or "NYA Monitor" is used for the first time or updated they must be paired.

    (2) Open the smart phone and make sure that it has Bluetooth enabled (See E. Smart Phone Instructions).

    (3) Use the pin to press the Bluetooth pairing button on the "NYA Monitor" to start pairing.

    (4) During the pairing process, the LED status light will alternatively blink green/orange for 1 minute.

    (5) Once pairing is successful, the green LED will stay lit for 5 seconds and the mobile phone will show that it is connected.

    (6) If pairing fails, the LED status light on the monitor will alternatively blink green/orange for 1 minute then stop pairing and searching. All lights will then go out.

- Instructions for the Body Monitor

    (1) Clip the ECG electrode's male connector to the female connector on the accessory as shown below:
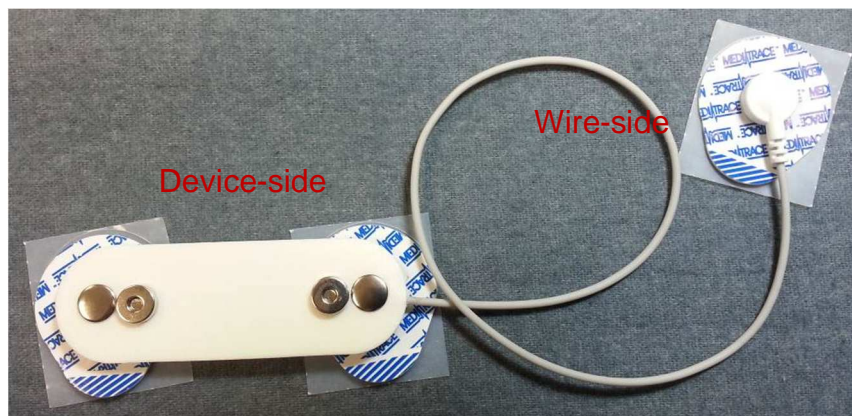
    (2) Remove the paper strip from the ECG electrode. For step 1, attach the device-side to the lower edge of the left chest. For step 2, attach the wire-side to the lower edge of the right collarbone as shown below:


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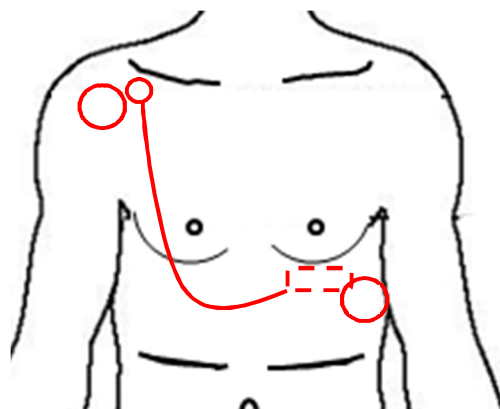
Attention: The ECG electrodes and accessory must not be worn in the following manner for an extended period of time. This prevents the dangling end from short-circuiting with any power supply.

Wire-side hanging loose   Device-side hanging loose
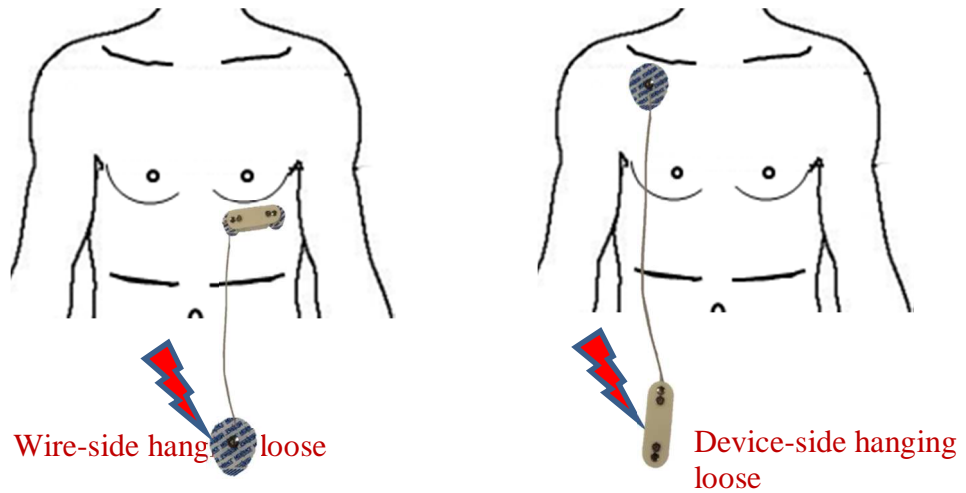
(3) Clip the male magnetic male connector on the monitor to the female connector on the accessory as shown below.   Note: The circular red or blue mark on the monitor must point upwards and must not be upside-down. Please see below.

Circular mark pointing upwards

(4) Launch the NYA-Data-CMD Application" on the PC/NB (Please see the previous section B.) shown below:

NYA-Data-CMD
Application icon
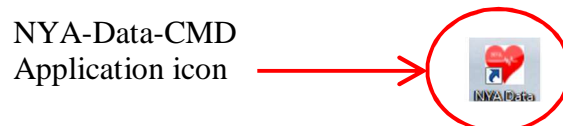
Note: Before launching the application, only one body monitor can be used/activated at any time.   Using two monitors at the same time will cause the App system to fail.

(5) Once the app is running, please see the instructions in section B.
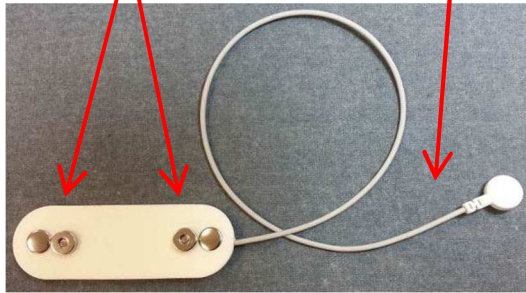
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● Other body monitor information:

  (a) If the monitor has a low battery, the orange LED light will blink.

  (b) When the monitor is placed on the accessory (or body monitoring shirt), the green LED light on the monitor will blink for 5 seconds before going out.

  (c) During standby and measurement, the monitor's status light will not be shown except when power is blow.

  (d) When the monitor is being charged in the charger, the status lights will remain off.

  (e) As long as the monitor is not on the accessory, tapping the monitor twice will cause the green LED to come on. The monitor will then start transmitting data (the smart phone app must be running and connected). Once the transmission is complete, the green LED light goes out. If the smart phone does not have the app running, the green LED will stay on for two minutes then go out.

  (f) When the ECG electrode falls from the user or the monitor becomes detached from the accessory, the green LED on the monitor blinks once every 3 seconds.
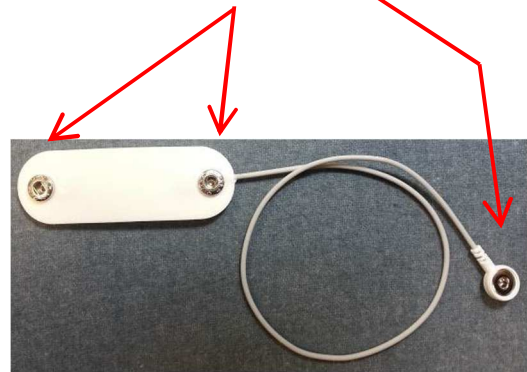
D. NYA Body Monitor Accessory

Used for connecting the body monitor and ECG electrodes so the best ECG signal can be acquired. Please see the previous section ""G. NYA Body Monitor" for further information and graphics.
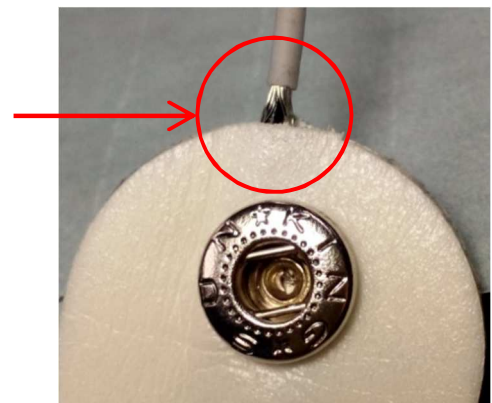
Magnetic Clip Female Connector   Pressure Clip Female Connector

ECG wiring

Front of accessory   Reverse of accessory

Attention:

If any wear or damage to the wire cladding is found during use, replace immediately.

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E. ECG Electrodes

The ECG Electrodes are conductors placed on the skin of the chest for transmitting the signal generated by the beating of the heart. The signal is transmitted to the body monitor for amplification and processing into the ECG signal.

Pressure Clip Male
Connector

Front of electrodes

Back of electrodes

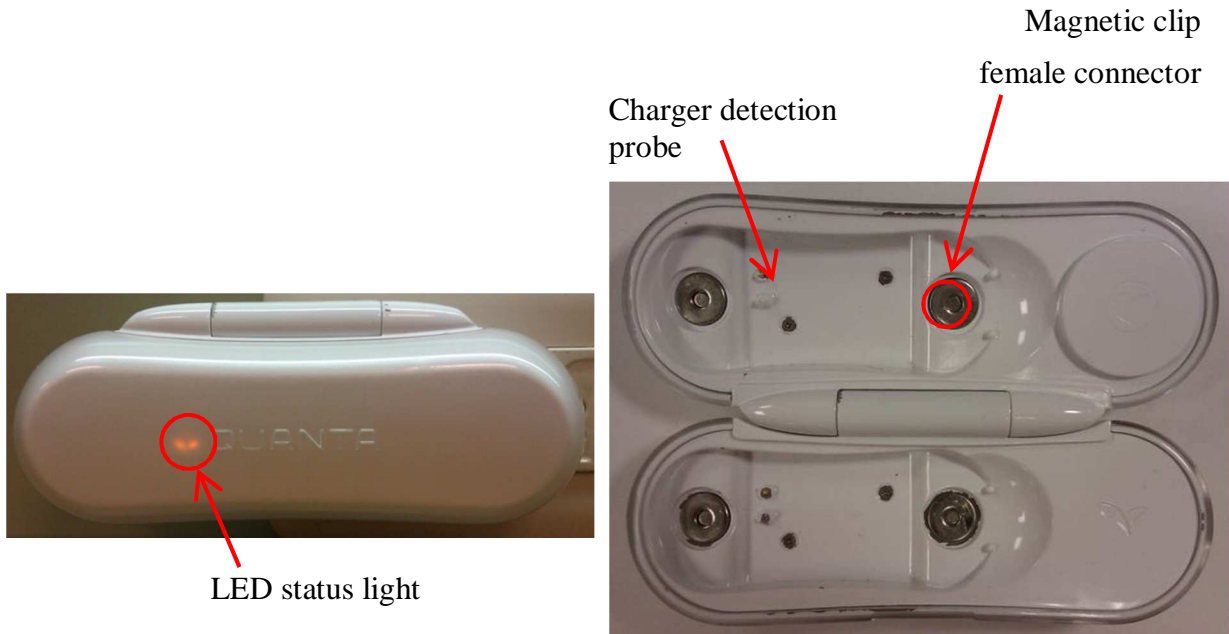Attention:

- Before attaching the ECG electrodes, make sure that the skin surface is clean. It may necessary to wipe the skin clean with a wet towel or alcohol swabs then wait for it to dry before attachment.

- Electrodes are not re-usable.

- If the skin at the attachment point shows signs of a rash/blisters/reddening or other discomfort, please contact the medial personnel or physician.

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F. NYA Charger

Charger function:

LED status light

Charger detection probe

Magnetic clip female connector

(1) The magnetic clip male-connector on the monitor and the magnetic clip female connector of the charger clips with each other. Pay attention to the direction when placing the monitor on the charger. The charger detection port on the monitor must be aligned with the charger detection probe on the charger as shown below.

Charger detection probe

Charger detection port
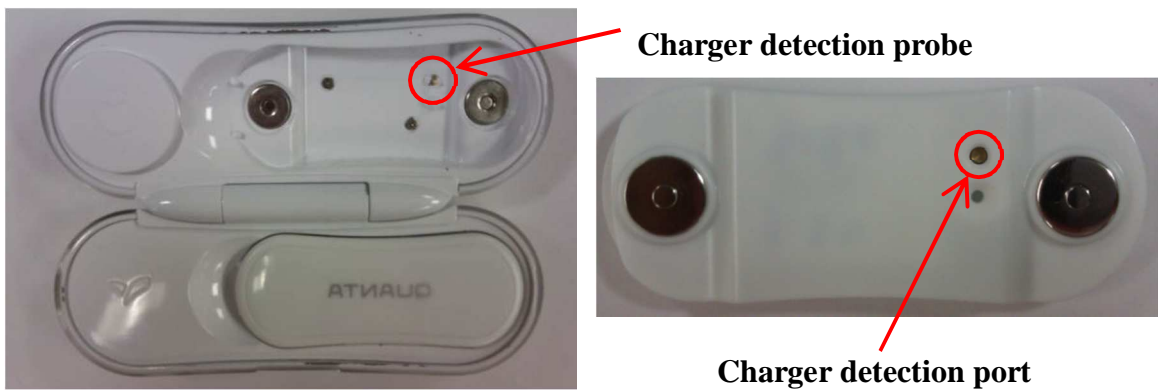
(2) When the charger is closed and plugged into power mains, the orange LED will light up when it is charging normally as shown below.

During charging the orange LED stays on.

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(3) Once the monitor is fully charged, the orange LED on the charger goes out and the green LED comes on. Remove the charger from the socket, open the cover of the charger and insert finger into the ventral groove to pick up the monitor for use as shown below:

The green LED lights up after charging

Insert finger into ventral groove and pick up monitor.

Other charger functions

(1) When the charger is plugged into the socket by itself (with no monitors), the orange LED light lights up for two seconds.

(2) Place the monitor on the charger and connect the transformer to the power socket. The orange LED light on the charger will now light up.

(3) Once the monitor has been fully charged, the orange LED is extinguished and the green LED slights up.

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Cleaning of the Wireless Home Health Management System

Item	Model Name	Cleaning Method
Body Monitor	NYA Target	Wipe with dry cloth
Charger	NYA Charger	Wipe with dry cloth
Accessory (S)	NYA Patch S	Wipe with damp cloth
Accessory (M)	NYA Patch M	
Accessory (L)	NYA Patch L	

Product Specifications

HR Monitor	- Measuring Lead : Lead I - HR Range : 30~240 - Frequency response : 0.1~40Hz - Heart rate accuracy : ±3 or ±3% - Sampling rate : 256Hz
Activity	- G-sensor (3 axis) : ±8g - G-sensor sampling rate : 52Hz
Radio	- Bluetooth 3.0+EDR - Tx: 0 dbm - Transmission range : 10 meters
Battery	- Lithium polymer battery 3.7V/140 mAh - Battery life : about 15 hours under measuring mode (Based on link with iPhone and App on)
Operating Temperature	5°C ~ 40°C

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Product List

Part Name/Model	Part Description