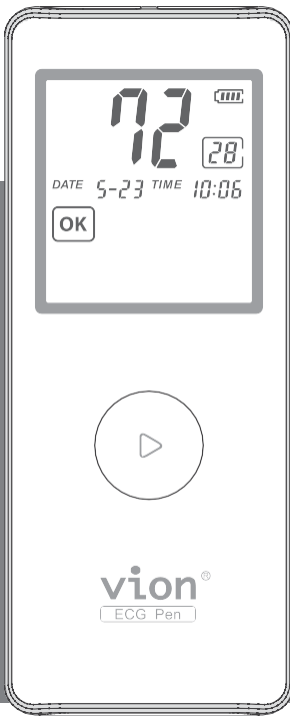


# vion®

ECG Pen / 880E  
870E

Instruction for Use ▶

Version /V1.2EN



Thank you for purchasing Vion.880E.  
Please read the instructions before use.

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## + General Notes

1. This Instruction for Use is for Vion.880E/870E.
2. This is an Electrocardiogram (ECG) device that provides referential data that could be taken into consideration by medical professionals and enables self-health monitoring.
3. Self diagnosis or treatment is dangerous behavior. Please don't use the electrocardiogram or data generated by the device to diagnose yourself. Consult with medical professionals if you notice any change in your condition, regardless of the measurement results.
4. The measurement result provided by the device only reflects the measurement taken at the moment.
5. The electrocardiogram cannot show all variations and symptoms of the heart disease, please consult with medical professionals when feeling discomfort with your heart.
6. Please follow the national requirement to dispose unit/accessories/waste products/residues/batteries etc.

## + Signs and Symbols

Following signs and symbols are used in the Instruction for Use, on the packaging and label of the device and accessories :

	Type CF applied part		The product is with Bluetooth function
	ATTENTION, should read the Instruction for Use		Protection against solid foreign objects of 12.5 mm Ø and greater and against vertically falling water drops when enclosure tilted up to 15°
	Consult Instruction for Use		
			This way up
	Manufacturer		Fragile
	Date of manufacture		Keep dry
	Reference number		Keep away from sunlight
	Serial number		Permissible operating temperature and humidity
	Batch number		Permissible storage/transport temperature and humidity

**INDICATION FOR USE**

Vion. ECG Pen (Model: 880E/870E) is intended to be used in measuring heart rate, recording and analyzing ECG signal, then storing and displaying general information for adult population who are concerned about their heart conditions during everyday life. This Vion ECG Pen 880E/870E allows users to record transient cardiac events up to 9 leads voluntarily anytime or at the time of symptomatic cardio discomfort (when used under the instructions of a physician). The recorded ECG signals can be promptly transferred to personal mobile devices such as computers(870E not applicable) or cellular phones. At the same time, these data can be transmitted to physician as reference immediately, during office visits, or for telemedicine purpose. This device is capable of measuring and displaying up to 9

**INDICATION FOR USE**

individual channels of electrocardiogram (ECG) rhythms. Vion ECG Pen 880E/870E can also detect the presence of atrial fibrillation, bradycardia, tachycardia, and normal sinus rhythm (when prescribed or used under the care of a physician). This device is intended to be used by healthcare professionals, patients with known or suspected heart conditions, and healthy individuals. While Vion ECG Pen 880E/870E is a state of the art home-use ECG medical device for self-monitoring and record-keeping of users' cardio conditions, but it is not intended to substitute a conventional 12 leads ECG diagnostic tool. Users with implanted pacemakers are not recommended to use this device.

## + Important Safety Notes

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- It is not recommended to use this device with a cardiac pacemaker or other implanted devices. Be sure to follow your doctor's instruction if necessary.
  - Do not use this device during an MRI scan.
  - Do not use this device with a defibrillator.
  - Do not expose this device to static electricity. Always disperse any static electricity from your body before handling this device.<sup>1</sup>
  - Do not submerge (or immerse) the device in water or liquid. Do not clean the device with acetone, or other volatile solution.
  - Do not put the device in autoclaves, or gas sterilization devices.
  - Avoid hitting, dropping, stamping, shaking of the device.
  - Do not disassemble this device that may result in damage, malfunction, or abnormal operation.
  - Do not use this device on people with sensitive skin or allergies.
  - Do not use the device if there are wounds on your contacted area or skin irritation/inflammation on/near the contacted area while performing measurement
- 

- Do not use this device for children weighing less than 10 kgs.
- The electrodes of this device should not come in contact with other electrically conductive parts, including earth ground.
- Do not store/expose the device in the following environments: Locations exposed to direct sunshine, high temperature or humidity, heavy dirt, near water or fire, and under high electromagnetic influence.
- Do not use other USB extension cord besides the companion USB extension set to connect the device with computer. The companion USB extension set is especially designed for avoiding electrical shock if come in
- direct contact with electrodes when connecting to computer.(870E N/A)
- Do not leave this device unattended with infants or persons who cannot express their consent.
- Do not operate this device in a moving vehicle (car, airplane).
- Do not use mobile phones, or other devices that emit electromagnetic fields near this device which may result in incorrect operation of the device.
- Remove batteries if won't be using this device for some time, to prevent battery to expand, leak and possibly destroy the device.

- Store the device in safe place to avoid small parts swallowed by children in any circumstances.
- Under the environment temperature of 40°C, the temperature of applied part (ECG electrodes) will reach 42°C highest.

- This device has not been validated for use on pregnant patients.

- Keep the components of the device out of the reach of infants, toddlers or children. This device contains small parts(such as batteries) that may cause a choking hazard if swallowed by infants, toddlers or children.

*1Static electricity may cause damage to the electronic components. To prevent electrostatic damage to the device, ensure your body is free of static electricity before using the device. Contact with earthed objects or devices, increase humidity, and moisturize skin can effectively reduce the cause of electrostatic damage.*

# + Product Description

## Main Features

Vion. 880E/870E can record personal electrocardiogram (ECG) for approximately 30 seconds of an adult individual.

### ■ Instant Feedback after Measurement

This device automatically provides referential results analyzed from the recorded 30 seconds ECG data.

### ■ Handheld ECG Measurement

The handheld ECG design provides great convenience for home use. This patented ergonomic design not only makes detection easier, but also enables signals to be acquired with better resolution and be more conducive for analysis.

### ■ Multifunctional Software(870E not applicable)

BP ECG Studio software can assist you to :

- Download ECG data.
- Configure your device.
- Review measurement records in chronicle order.
- Display ECG waveforms to doctors for reference.

### ■ Bluetooth 4.0

With Bluetooth 4.0 technology, this device ideally provides real-time display of your measurement on Smartphones/Tablets for a great portability of reviewing your records anytime, anywhere.

## Package Contents

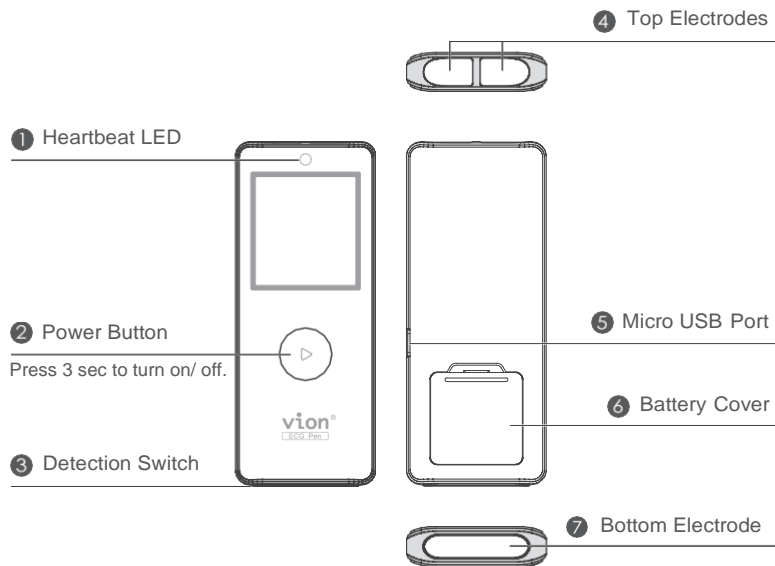
Your package should include the following items.

Main Unit	Vion.880E/870E
Accessories	USB extension set (870E not applicable) <sup>1</sup>
	Instruction for Use
	2 x coin-typed batteries (trial use)
	BP ECG Studio CD(870E not applicable)

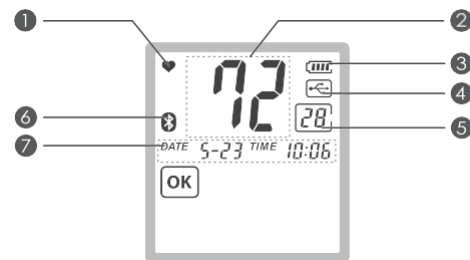
<sup>1</sup> The USB extension set is for downloading ECG data to your computer. Do not use other USB extension cord besides the companion USB extension set to connect the ECG Pen with computer. The companion USB extension set is especially designed for avoiding electrical shock if come in direct contact with electrodes when connecting to computer.

# + Product Description

## Hardware Description



## LCD Display



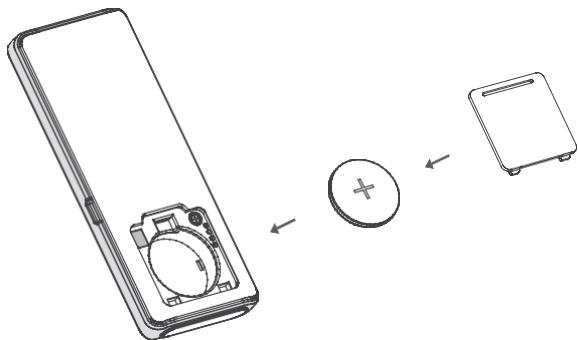
- 1 **Heartbeat Indicator:** Flashes in sync with heartbeats during measurement.
- 2 **Heart Rate:**  
During recording: Displays the real-time heartbeat.  
During reviewing: Displays the average heart rate of each measurement.
- 3 **Battery Level Indicator:** Shows current battery level.
- 4 **USB Connection:** Displays the status of USB connection. (870E not applicable)
- 5 **Digits Display:**  
During ECG Recording : Displays the 30 seconds count down.  
During Reviewing : Displays the sequence numbers of stored records.
- 6 **Bluetooth Connection:** Displays the status of Bluetooth connection.
- 7 **Time:** Displays date and time.



# + Preparation before Taking Measurement

## Battery Installation

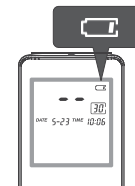
- 1 Turn the device upside down.
- 2 Remove the battery cover by inserting the tip of your finger into the opening of the cover.
- 3 Install two CR2032 coin-typed batteries by following the + (positive) and - (negative) polarities indicated on the battery compartment.
- 4 Slide back the battery cover until it clicks into place.



## Battery Life and Replacement

- 1 Install or replace the batteries by following the + (positive) and- (negative) polarities indicated on the battery compartment.
- 2 When the battery level indicator appears only with 1 bar left, the batteries are nearly running out, please replace new batteries timely.

**Note:** Turn the device off before replacing batteries.



- 3 Two new “CR2032” coin-typed batteries will last for approximately 500 measurements.
- 4 Please use same brand and type of batteries and replace all batteries at the same time. Avoid using used and new batteries together.
- 5 Do not use rechargeable batteries.
- 6 Remove batteries if won't be using this device for some time, to prevent the device from being damaged.
- 7 Please dispose waste batteries according to applicable local regulations.

# + Preparation before Taking Measurement

## Cautions before Taking Measurement

**Please read the cautions below to correctly measure your personal ECG :**

- Do not attempt to use this device over or through clothing.
- If the electrodes are dirty, please use a soft cloth or a cotton swab moistened with disinfectant alcohol to clean dirt from the surface.
- If your skin or hands are dry, moisten them with damp cloth before taking measurement.
- Do not let your right hand in contact with your body during the measurement, and avoid heavily pressing the top and bottom electrodes to influence the accuracy of measuring.
- Do not use the device in upside down position.
- Do not move or talk while taking measurement and keep the balance of your body to avoid influencing the accuracy of measurement result
- Ideally perform the measurement either sitting down or lying down. Do not stand up to take the measurement.

## +Taking Measurement

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### Operation Procedure

There are three different methods of taking the measurement. Start with measurement method A, “right index finger-chest.” If this method does not deliver measurements, or delivers only unstable measurements (“EE” is frequently displayed), switch to method B “left index finger-chest” and, if necessary, to method C “left hand-right hand.”

The most suitable method/ procedure depends on the heart configuration (shape of the heart) of each individual user. If it is not possible to take stable measurements using a given measurement method, this could have a harmless cause such as the shape of the heart. However, the cause may also be an illness or disease.

**Note:** Measurement method C offers maximum comfort, but offers a much lower measurement stability than methods A or B.

Press the on/ off button for about three seconds to turn the device on. The device shows the full display.

### WARNING

If segments are missing, stop using the device and immediately contact customer services. To test whether the full display is completely displayed, hold the On/Off button when switching on the device.

## +Taking Measurement

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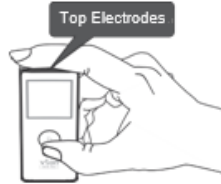
### Measurement Method A

“right index finger-chest” (approximately corresponds to “lead 2”)

1. Press the power button for 3 seconds to turn on your ECG Pen.
2. Lay your right index finger on the two top electrodes of the device and hold the ECG Pen face up in your hand.

3. You can determine the correct position for placing the lower electrode of the device against your chest using the following methods:

- Place the bottom electrode of the ECG Pen on bare skin about 5 centimeters (2 inches) below your left nipple supported by the ribcage, and press it **GENTLY** until you hear the click sound.
- Draw an imaginary line from the front of your armpit downwards. At the same time, draw an imaginary line going up 10cm from the lowest rib on the left side of your body. Place the lower electrode of the device at the point where these two lines meet.
- Draw an imaginary line from the bottom of the centre of your chest (sternum) to the left. At the same time, draw an imaginary line from the front of your armpit downwards. Place the lower electrode of the device at the point where these two lines meet.



## +Taking Measurement

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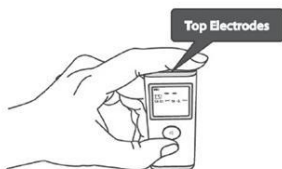
**Press it GENTLY until you hear the click sound.**

**Note:** Do not press the electrodes hardily. Excessive muscle tension will cause unnecessary noise.

### **Measurement Method B**

**“left index finger-chest” (approximately corresponds to “lead 3”)**

1. Press the power button for 3 seconds to turn on your ECG Pen.
2. Lay your left index finger on the two top electrodes of the device and hold the ECG Pen face up in your hand.

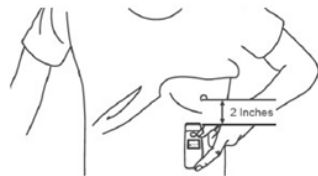


## +Taking Measurement

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**3.** You can determine the correct position for placing the lower electrode of the device against your chest using the following methods:

- Place the bottom electrode of the ECG Pen on bare skin about 5 centimeters (2 inches) below your left nipple supported by the ribcage, and press it **GENTLY** until you hear the click sound.
- Draw an imaginary line from the front of your armpit downwards. At the same time, draw an imaginary line going up 10cm from the lowest rib on the left side of your body. Place the lower electrode of the device at the point where these two lines meet.
- Draw an imaginary line from the bottom of the centre of your chest (sternum) to the left. At the same time, draw an imaginary line from the front of your armpit downwards. Place the lower electrode of the device at the point where these two lines meet.



**Press it GENTLY until you hear the click sound.**

**Note:** Do not press the electrodes hardily. Excessive muscle tension will cause

## Taking Measurement

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*unnecessary noise.*

### **Measurement Method C**

**“left hand-right hand” (approximately corresponds to “lead 1”)**

1. Press the power button for 3 seconds to turn on your ECG Pen.
2. Place your right index finger on the two top electrodes of the device.

Place a finger of your left hand on the lower electrode.

3. Press the lower electrode until you hear or feel a click.



Press it **GENTLY** until you hear the click sound.

**Note:** *Do not press the electrodes hardly. Excessive muscle tension will cause unnecessary noise.*

**Note:** *Please note that there must be no skin contact between your right and left hand (measurement method C) or hand and chest (measurement methods A/B). Otherwise, the measurement cannot be taken correctly. Do*

## Taking Measurement

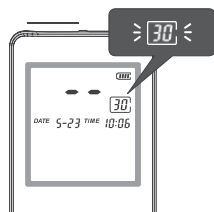
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*not move during the measurement, do not speak and hold the device still. Movements of any kind will falsify the measurements.*

# + Taking Measurement

## Operation Procedure

- 4 The device starts beeping, and the Digits Display flashes for a few seconds, indicating the measurement is about to start.



**Note:** If the bottom electrode is released within 3 seconds at the beginning of your measurement, the measurement will be aborted.

- 5 The measurement will be completed after 30 seconds, and you may see the results shown on the LCD.

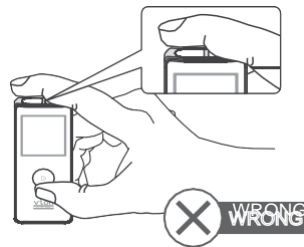


**Note:** The latest measurement will replace the oldest one when the memory is full (36 measurements).

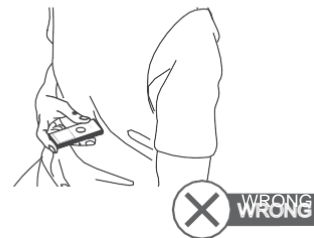
## Common Wrong Operations

Please avoid the following operations:

- The right index finger is not in sufficient contact with top electrodes.



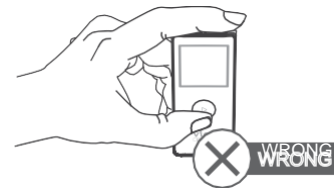
- Measuring over or through clothing.



- Holding the device in the wrong direction.









- Holding the device with left hand.

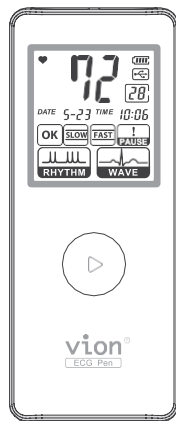


# + Result Display

## Measurement Results

The ECG measurement result will display as follows :

-  : Normal Result
-  : Slow Heart Rate (<60 bpm)  
Bradycardia
-  : Fast Heart Rate (>100bpm)  
Tachycardia
-  : Paused Heartbeat
-  : Irregular Rhythm
-  : Abnormal Waveform






Please retake the measurement if the displayed heart rate is flashing, which indicates ECG signals are unstable or weak.

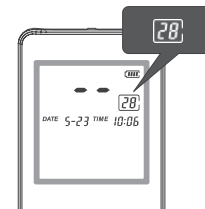
**Note1:** Method of determining a PAUSE-Indicate one or more pauses in the cardiac cycle, each of which is longer than 2 seconds.

**Note2:** Method of calculating heart rate-Take the R-R duration between two identical points of consecutive ECG waveforms and divide it into 60.  
The resulting equation: Heart Rate = 60/(R-R interval)

## Reviewing Results

For reviewing the previous records, you may:

- 1 Press the  button for 3 seconds to turn on the device. The LCD displays the total number of records stored.
- 2 Press the  button again, and the LCD displays the average heart rate of the latest measurement and the Digits Display shows the sequence number of stored records.
- 3 By pressing the  button repeatedly, the result will be shown in a cyclic order.



## System Requirements

Before installing BP ECG Studio, please check the system requirements listed below.

Operating System	Windows 7 or higher
Recommended Hardware	Intel Core i3-3220 3.30 GHz or higher
	1 GB of RAM or more
	1 GB of hard disk free space or more
	Screen Resolution: 1280 x 1024 or higher

## Installation

Please use the companion CD to install BP ECG Studio.

- 1 Insert the CD to your computer.
- 2 Browse the CD and double click Setup.exe to start the installation.

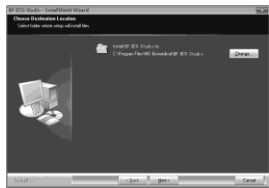


- 3 Select language and continue the process.
- 4 Read and accept the license agreement.

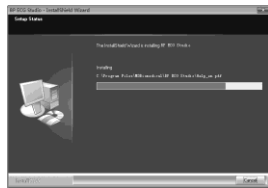




- 5** Select the folder for installing BP ECG Studio.



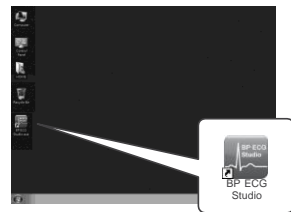
- 6** Click [Install] to start the installation process.



- 7** Click [Finish] to complete the installation process.

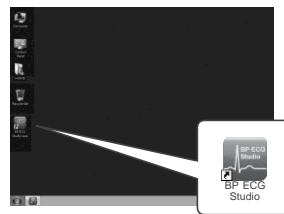


- 8** Then, the icon will be shown on the desktop.

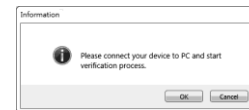


The process of system authentication will be needed as BP ECG Studio is executed for the first time.

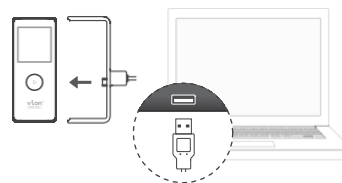
- 1** Double click the icon to run BP ECG Studio.



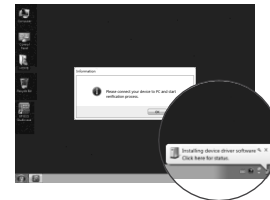
- 2** The following message will be displayed.



- 3** Connect the USB extension set with your device and plug it into the USB port of your computer.

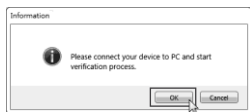


- 4** The system will automatically check the presence of your device.

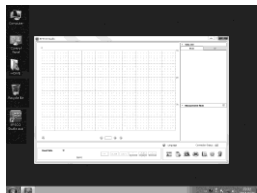


## System Authentication

- 5 Click [OK] to complete the authentication process.



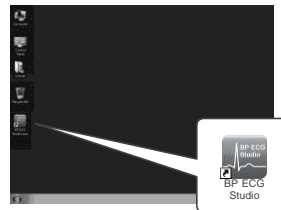
- 6 Then, the main window of BP ECG Studio will be launched.




## Downloading ECG Data to Computer

To download ECG data to your computer:

- 1 Run BP ECG Studio.



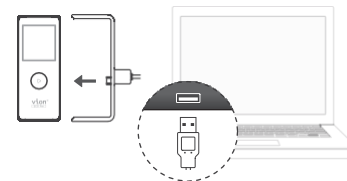
- 2 Create a new user account by clicking  <sup>1</sup>.



- 3 Fill in user information.<sup>2</sup>



- 4 Plug the connector of USB extension set into USB port of your computer.

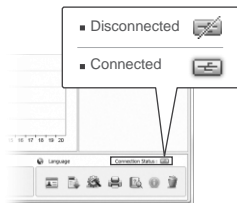


<sup>1</sup> You need to select a user account to log in every time. You may also delete the user account by clicking .

<sup>2</sup> The mandatory fields marked with "\*" CANNOT be changed once been set.

## Downloading ECG Data to Computer

- 5 Make sure the connection is established.



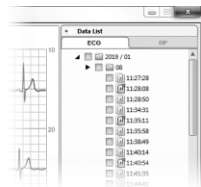
- 6 Click  to enter data download.



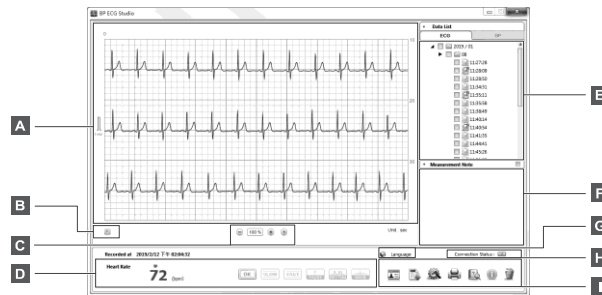
- 7 Click [Download] to download data from the device.<sup>1</sup>



- 8 Records will be added into Data List at the right column.




## Main Window



- A Electrocardiogram Trace

- B Grid Color Options

Click  to change the grid color into green or red.

- C Scale Adjustment

Zoom in  / Zoom out  / Reset  the scale of signals.

- D Result Display

<sup>1</sup> If you want to delete the data after downloading, please select "Delete data after download complete". Note: Please be aware that MD Biomedical will not be responsible for the loss of data and/or information in your computer.

### **E** Data List

### **F** Measurement Note

Note your symptoms, Medications or activities related to the measurement for further reference.

### **G** Multilingual Converter

Click  to change the interface to preferred languages.

### **H** USB Connection Status

Disconnected  / Connected 

### **I** Functions Menu

#### **User information**

Edit the user information.

#### **Download**

Download data from the device to computer.

#### **Configure**

Configure your device.

#### **Print**

Print out the ECG/ BP data in a report format.

#### **Help**

Open the on-line Instruction for Use of BP ECG Studio.

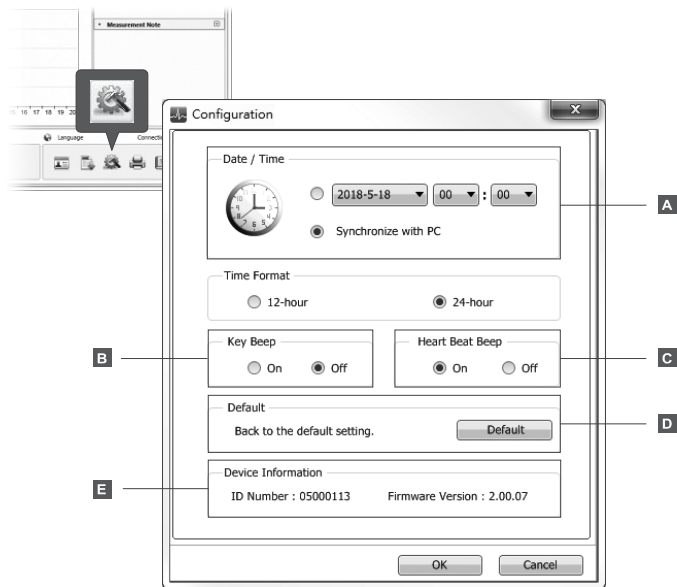
#### **Delete**

Delete the selected ECG data from computer.

#### **About**

Provide version and copyright information.

To configure your device, click  to open the configuration window.



In the configuration

### **A** window: Date/ Time

You can set the date/ time manually or set it to sync with the computer.

### **B** Key Beep

You can enable/disable the beep sound when the device is operating.

### **C** Heart Beat Beep

You can enable/disable the beep sound during your ECG measurement.

### **D** Default

By clicking [Default], you can reset your device to factory default settings.

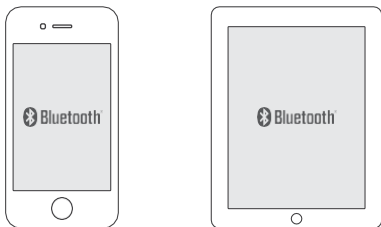
### **E** Device Information

You can acquire the information of ID Number and Firmware Version.

## + APP Download

### System Requirements :

Smartphones or Tablets which support Bluetooth4.0 (BLE)



Please scan the QR code to enter APP introduction web page, and follow the instructions to download and use the APP.



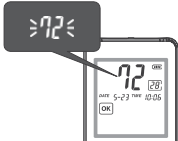
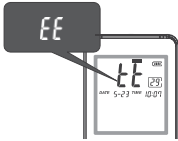
Note: Please be aware that MD Biomedical will not be responsible for the loss of data and/or information in your APP.

## + Cleaning and Maintenance

- Do not use any abrasive or volatile cleaners.
- Please clean the device with a soft cloth dampened with water, then wipe them with a dry cloth.
- If electrodes are dirty, please use a soft cloth or a cotton swab moistened with 70~75% alcohol to clean the electrodes.
- Do not use alcohol to clean any other parts, and use it only to clean electrodes.
- Do not wash or immerse the device or other components in water.
- Do not use gasoline, thinners or similar solvents to clean the device or other components.

\*Note: For best personal hygiene, please clean the device by following above instructions at least every 7 days after using.

## + Messages

Message Shown	Possible Cause	Suggestion
<ul style="list-style-type: none"> <li>The measurement result of averaged heart rate keeps flashing.</li> </ul> 	Unstable or weak ECG signals.	Please follow the instructions on page 11~14 to retake the measurement.
<ul style="list-style-type: none"> <li>Measurement result shows EE.</li> </ul> 	Failure analysis resulted from insufficient contact, an interruption, or high noise level during measurement.	Please follow the instructions on page 11~14 to retake the measurement.

## + Trouble Shooting

Problem	Possible Cause	Suggestion
<ul style="list-style-type: none"> <li>The device cannot be turned on after pressing the power button for 3 seconds.</li> </ul>	<ol style="list-style-type: none"> <li>Battery power is low.</li> <li>Batteries are installed with wrong direction.</li> </ol>	<ol style="list-style-type: none"> <li>Replace with new batteries.</li> <li>Please ensure the polarities of batteries are matched with the ones indicated on the battery compartment.</li> </ol>
<ul style="list-style-type: none"> <li>The measurement does not start after the electrodes touching skin.</li> </ul>	Press too lightly.	Make sure to press the bottom electrodes with sufficient force.
<ul style="list-style-type: none"> <li>Measurement records disappear from the device storage.</li> </ul>	Old records are overwritten by new ones due to storage overload.	Download data periodically to your smartphones/tablets for records keeping.
<ul style="list-style-type: none"> <li>Message shows the system authentication failed while running the BP ECG Studio. (870E N/A)</li> </ul>	The device is not connected with the computer or the installation of BP ECG Studio failed.	Make sure the device is well connected with the computer and restart the BP ECG Studio again.

## + Warranty Information

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MD Biomedical warrants your *Vion FCG Pen 880F / 870F* to be free from defects in workmanship and materials within 1 (one) year from the date of the purchase receipt under normal usage according to the Instruction for Use. This warranty is not transferable.

This warranty covers repair or replace without charge, at our option, upon examination. Repair or replacement is our only responsibility and your only remedy under the above warranties.

The warranty does not cover :

- If the warranty sticker was changed or damaged.
- Accidental fall or collision during usage or transport.
- Damage caused by heavy fall, damp, liquids immersion, foreign objects or materials intrusion, or voltage abnormality.
- Damage caused by lack of reasonable maintenance or personal negligence on the part of the customer.
- Damage caused by improper operations, storage or transport without following the Instruction for Use.
- If the device has been opened by unauthorized repair shops or workshops.
- Wearing parts.
- Damage caused by force majeure, such as natural disaster.

## + Warranty Information

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MD Biomedical shall not be liable for loss of use or any other incidental, consequential or indirect costs, expenses or damages in any way linked with the device or use of the device.

To obtain warranty service, the purchaser must notify the authorized distributors, agents or representatives of MD Biomedical concerning suspected defects to get the address of the repair location, pack the device carefully to avoid damage in transit, and then ship the device to the designated address.



## + Technical Specifications


### Vion ECG Pen

Model	Vion.880E/870E
Induction System	single channel, bipolar
Bandwidth	0.05 ~ 40Hz
Sampling Rate	256Hz
Heart Rate Range	5 ~ 199 beats/min
Memory	36 memory spaces
Power Source	two CR2032 coin-typed batteries
Battery life	500+ measurements with 2 new coin-typed batteries
Operation Temperature/Humidity/atmosph here	5 ~ 40°C, 15~90% RH, 700hPa~1060hPa
Storage/Transport Temperature/Humidity	-25~70°C, ≤90% RH, 700hPa~1060hPa
Weight	30g (without batteries)
Dimensions	93 mm x 38 mm x 10.5 mm

Input signal range	-400mV < Signal (DC+AC) < 400mV
Input Impedance	> 10M Ohms
A/D resolution	16 bits
Interface	USB or Bluetooth 4.0
Service Life	3 years (5 times per day)
IP classification	IP22
Protection against electric shock	Internally powered ME equipment

# Technical Specifications

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1. Technical information is subject to change without notification to allow for updates. ↵
  2. Patent No.: TWI307273, TWM460636, CN100546539C, CN101953686B, US8644915, EP2477541, WO2011006356 ↵
  3. This device complies with IEC 60601-1-2 and is subject to special precautionary measures regarding electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit. ↵
  4. **About a wireless communication interference** ↵

This device operates in an unlicensed ISM band at 2.4 GHz. In the event this device is used near other wireless devices such as microwave and wireless LAN, which operate on the same frequency band as this Product, there is a possibility that interference may occur. ↵

If interference occurs, stop the operation of the other devices or relocate this device away from other wireless devices before attempting to use it. ↵
  5. The safety class of this device is CF. ↵

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6. If any parts of the device are loosen, damaged or deformed, please contact the qualified distributor or the manufacturer MD Biomedical, Inc. to replace
  7. MD biomedical will provide limited warranty and support updates of PC software and mobile device applications during the life cycle of the device. However, please be aware that MD biomedical will not be responsible for the loss of data and/or information in the app or personal computer.
  8. If any cybersecurity vulnerability or incident is detected, please follow the suggestion of Messages and Trouble Shooting parts in the instruction manual first. If problem still exists, please contact MD biomedical for further processing and assistant.

# EMC Information

## Important information regarding Electromagnetic Compatibility (EMC)

This device manufactured by MD Biomedical, Inc. conforms to IEC60601-1-2 Electromagnetic Compatibility (EMC) standard. Nevertheless, special precautions need to be observed:

\*The use of accessories and cables other than those specified or provided by MD Biomedical, Inc. could result in increased electromagnetic emission or decreased electromagnetic immunity of the device and result in improper operation.

\*During measurement, the use of the device adjacent to or stacked with other device should be avoided because it could result in

improper operation. In case such use is necessary, the device and other device should be observed to verify that they are operating normally.

\*During measurement, Portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by MD Biomedical, Inc. Otherwise, degradation of the performance of the device could result.

\*Refer to further guidance below regarding the EMC environment in which the device should be used.

# EMC Information

Table 1 - EMISSION Limits and Compliance<sup>Ⓢ</sup>

Phenomenon <sup>Ⓢ</sup>	EMISSION Limits <sup>Ⓢ</sup>	Compliance <sup>Ⓢ</sup>
Conducted and radiated RF EMISSIONS <sup>Ⓢ</sup>	CISPR 11 <sup>Ⓢ</sup>	Group1, Class B <sup>Ⓢ</sup>

Table 2 - IMMUNITY TEST LEVELS<sup>Ⓢ</sup>

Phenomenon <sup>Ⓢ</sup>	Basic EMC standard <sup>Ⓢ</sup>	IMMUNITY TEST LEVELS <sup>Ⓢ</sup>
Electrostatic discharge <sup>Ⓢ</sup>	IEC 61000-4-2 <sup>Ⓢ</sup>	±8 kV contact <sup>Ⓢ</sup> ±2 kV, ±4 kV, ±8 kV, ±15 kV air for enclosure port <sup>Ⓢ</sup>
Radiated RF electromagnetic fields <sup>Ⓢ</sup>	IEC 61000-4-3 <sup>Ⓢ</sup>	3 V/m <sup>Ⓢ</sup> 80 MHz to 2.7 GHz <sup>Ⓢ</sup> 80% AM at 1 kHz for enclosure port <sup>Ⓢ</sup>
Proximity fields from RF wireless communications equipment <sup>Ⓢ</sup>	IEC 61000-4-3 <sup>Ⓢ</sup>	Ⓢ See table 3 <sup>Ⓢ</sup>
Rated power frequency magnetic fields <sup>Ⓢ</sup>	IEC 61000-4-8 <sup>Ⓢ</sup>	30 A/m <sup>Ⓢ</sup> 50 Hz and 60Hz for enclosure port <sup>Ⓢ</sup>

## +FCC Statement

### CAUTION:

To assure continued FCC compliance:

Any changes or modifications not expressly approved by the grantee of this device 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 harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FEDERAL COMMUNICATIONS COMMISSION

### INTERFERENCE STATEMENT

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

## +FCC Statement

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.

Exposure to Radio Frequency Radiation:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meet FCC radio frequency(RF) Exposure Guidelines.

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

 **MD Biomedical, Inc.**

8F., No.222, Sec 4, Chengde Rd., Taipei City 111, Taiwan

[www.mdbiomedical.com](http://www.mdbiomedical.com)



