# “Wegene” Wireless ECG Patch (WG-103) Operation Manual

## Ver. 2.0

## Wegene Technology Inc.

# Table of Contents

# 1. Safety Information

Please read the following items before using the ECG Patch.

## Warnings

- Do *NOT* use ECG Patch in an environment with flammable materials.
- Do *NOT* use ECG Patch with MRI (magnetic resonance imaging) environment.
- Do *NOT* use ECG Patch with a defibrillator, an electro-cautery, cardiac pacemakers or other stimulators together.
- To prevent possible explosion hazard. Do *NOT* use ECG Patch in the presence of flammable anesthetics.

## Caution

- It’s necessary to read this user’s manual carefully before using this product.
- Make sure that ECG Patch is on the right position of chest and confirm the correctly signal source.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and components.
- Please handle ECG Patch with care. Hitting or dropping the device may stop it from working. If there is any damage resulting from abnormal use, please contact service personnel.
- It is not recommended to use ECG Patch to diagnose children under 12 or expectant mothers.
- The electrodes are for single use only.
- Portable and mobile wireless communications device (RF, radio frequency) maybe affect the ECG Patch.
- Please do not disassemble the ECG Patch and direct contact with the dealers and Leadtek if have any questions about maintenance and repair.
- The electrodes of ECG Patch  approved ISO10993 test.

# 2. Introduction

ECG Patch has some features, that including: small size, light weight, power-saving, no signal cable, battery-powered, wireless transmission, real-time ECG and immediate heart rate. It can also have long-term monitoring in those applications: academic research, sports training, home care, and clinical research.

ECG Patch can measure single lead ECG and use advanced physiological analysis technology to evaluate the function of the autonomic nervous system from heart rhythms. The collected ECG signals are analyzed by frequency spectrum to discover minor fluctuations in the heart rate variability data. The fluctuations can be categorized into 3 distinct patterns, namely High Frequency, Low Frequency and Very Low Frequency, as follows:

1. The High Frequency (HF) component is synchronized with respiration, also called the respiration component, which represents the function of the parasympathetic nerves.
2. The Low Frequency (LF) component is related to vasomotion or the baroreflex. The ratio of the LF component to the HF component can reflect the activity of the sympathetic nerves.
3. The meaning of the Very Low Frequency (VLF) component is not yet clearly understood. It has been confirmed that the function of the autonomic nervous system can be determined by using HRV analysis. Its sensitivity greatly exceeds that of the conventional detection approach for the autonomic nerves. For results measured by an ordinary nerve conduction

instrument (NCI), only the value of the R-R interval is given, but no standard value is provided for reference. Contrary to ordinary NCI, this device can not only obtain the average heart rate (including the average R-R interval) and the Standard Deviation of NN interval (SDNN), but also the integral function of autonomic nerve, functions of sympathetic nerve and parasympathetic nerve. Meanwhile, the obtained values can be used to compare with the standard values in the database composed of different age and gender groups at a later stage. Hence, ECG Patch will become a new tool for measuring the function of IHR, HRV index.

# 3. Specifications

3.1 Electrocardiogram:

- Lead I ECG
- Immediate heart rate (IHR)
- Heart rate variability (HRV) parameters: SDNN, LF, HF, LF%
- Frequency: 250 Hz
- Resolution: 8 bits

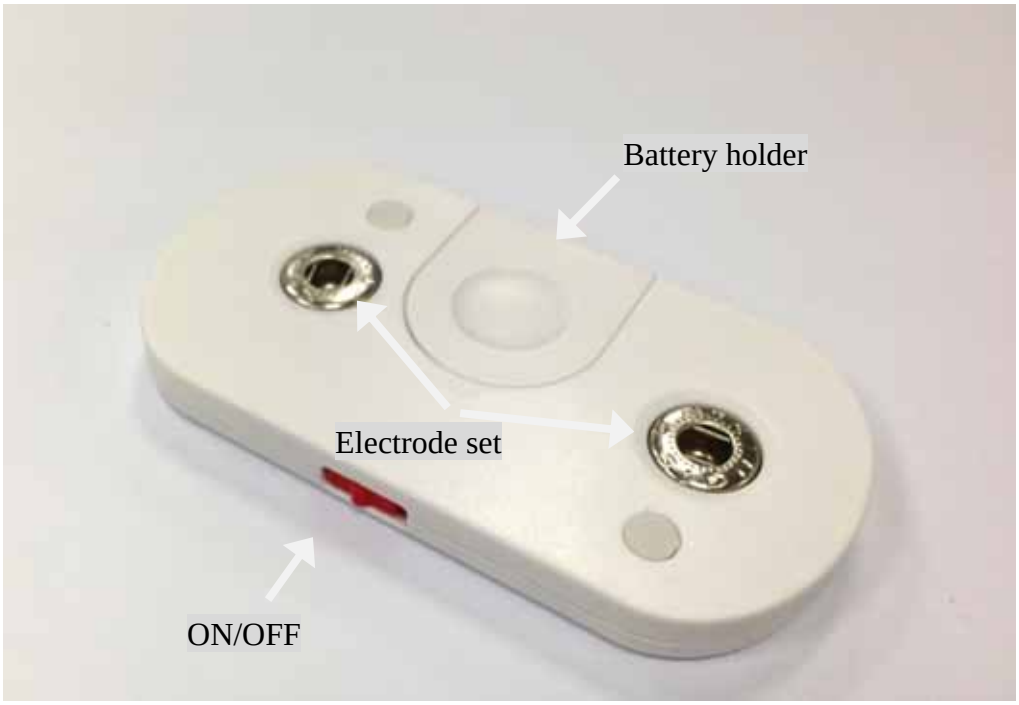
3.2 Wireless:

- Channel: 2.401 GHz- 2.480 GHz
- Transmission distance: < 10M

3.3 Appearance:

- Dimensions: 80 x 40 x 8 mm
- Weight: 19g (include battery)
- Power consumption:
  Operating at full capacity: 1mA-3mA
  Standby: 10 $\mu$ A
- Battery: CR2032

3.4 I/O Port Descriptions:



3.5Package contents:

The product is shipped with the following parts: main device*1, ECG electrode*10, USB RF Dongle*1 and CD*1, 4 parts in total.

| No. | Item | Picture |
|---|---|---|
| 1 | main device |  |
| 2 | ECG electrode |  |
| 3 | USB RF Dongle |  |

| | | |
|---|---|---|
| 4 | CD |  |



3.6 Disc content:

- ECG Patch Operation Manual .pdf
- How to Use ECG Patch .pdf
- Dongle Driver
  \USB Driver\CDM 2.04.16.exe
- Patch test
  ECG_Patch_Monitor.exe
- Patch test (2)
  \Multiple Patch Monitor Demo Program \ HRVIC_test.exe

3.7 System requirement of PC for data transmission:

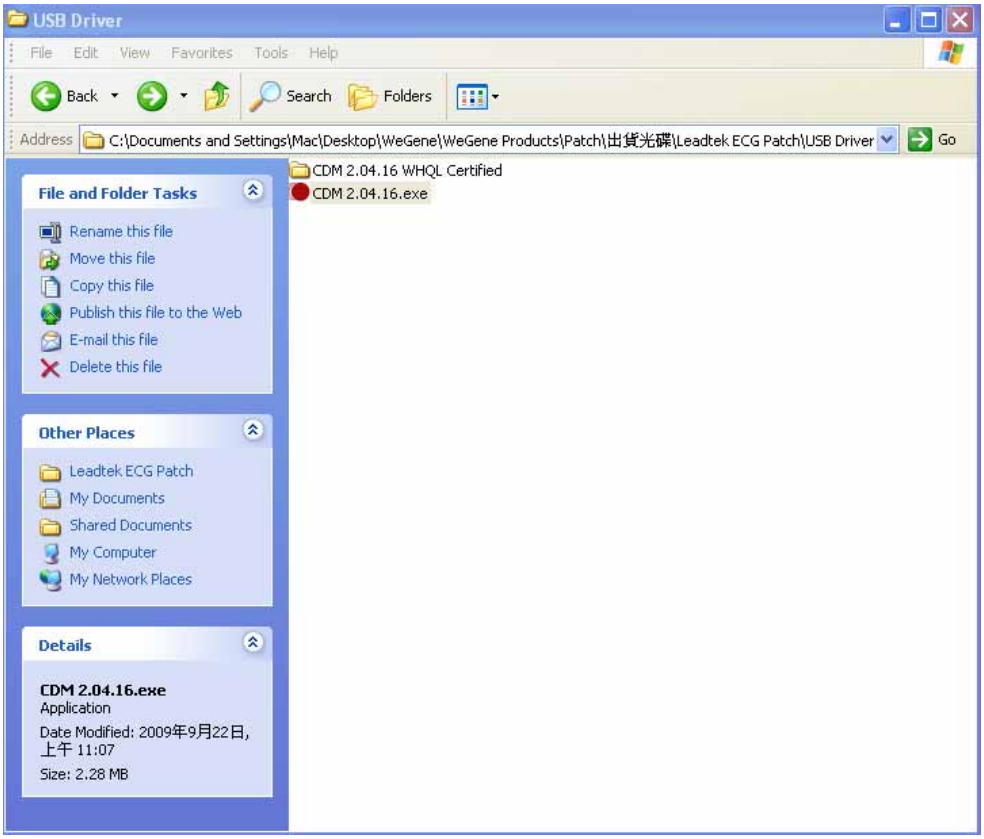
Hardware requirement: CD ROM, USB Port, CPU: 1.50GHz or upper
Software requirement: windows 2000 (SP4), WIN XP, windows vista

# 4. Installation

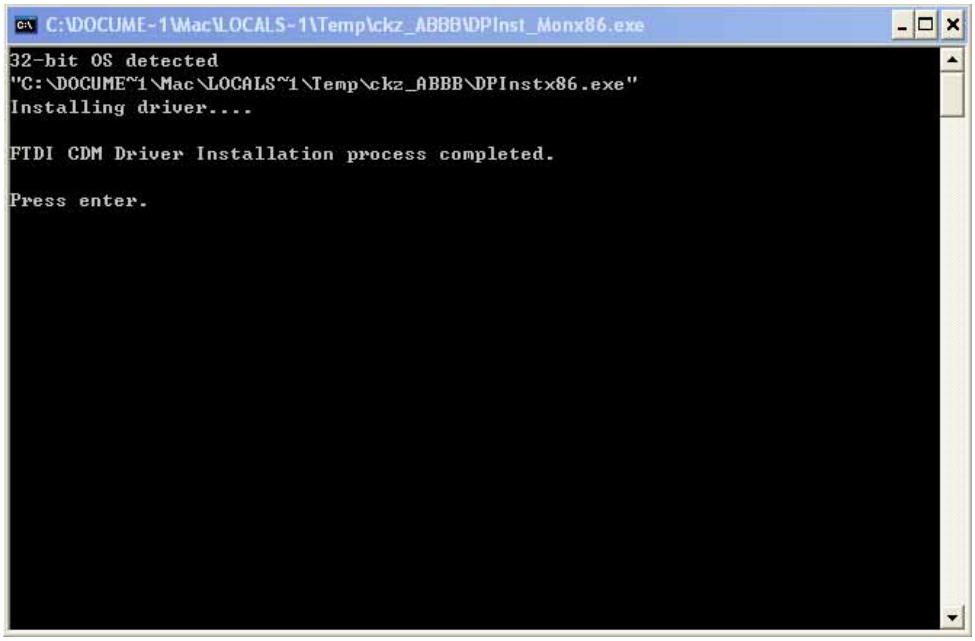
## 4.1 Installation of ECG Patch:

### 4.1.1 Install the driver of RF Dongle:

Press Driver program(CDM 2.04.16.exe) from CD-ROM.



Complete the installation after press “enter” key from the below screen.




4.1.2 How the start the ECG Patch

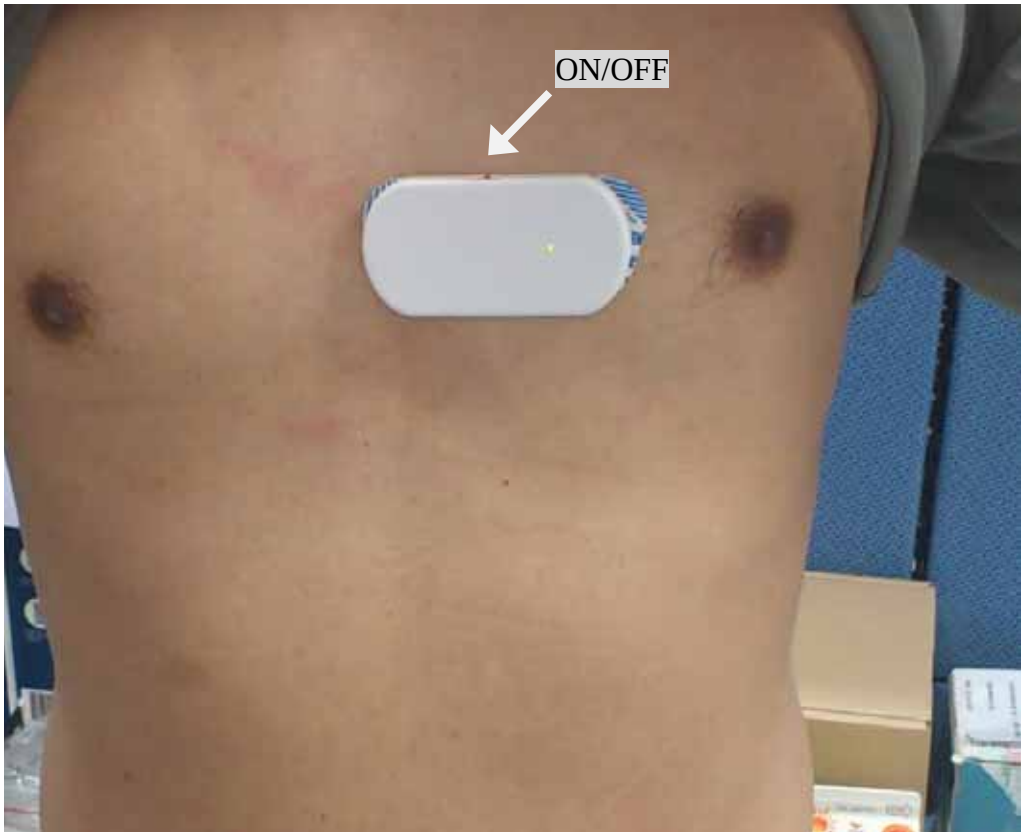
Before using the ECG Patch, please prepare the applications first.

Put into the battery (CR2032)

Button up the electrodes (both size)

Turn on (Green light)

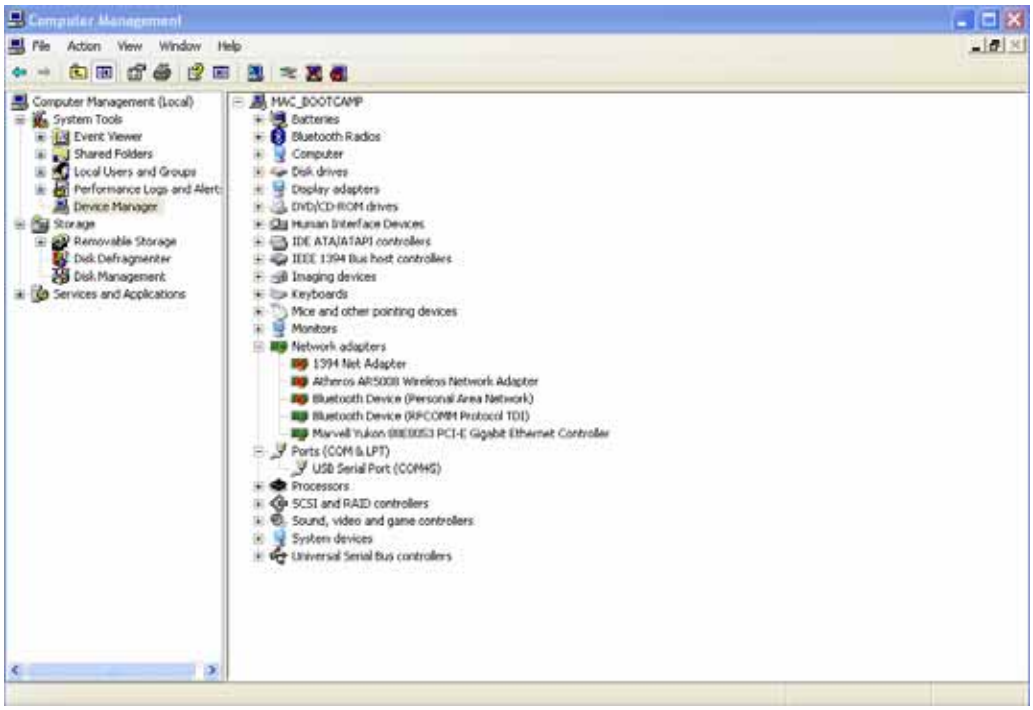
Note: Turn on the ECG Patch, after the setting of application Program /Software is ready.



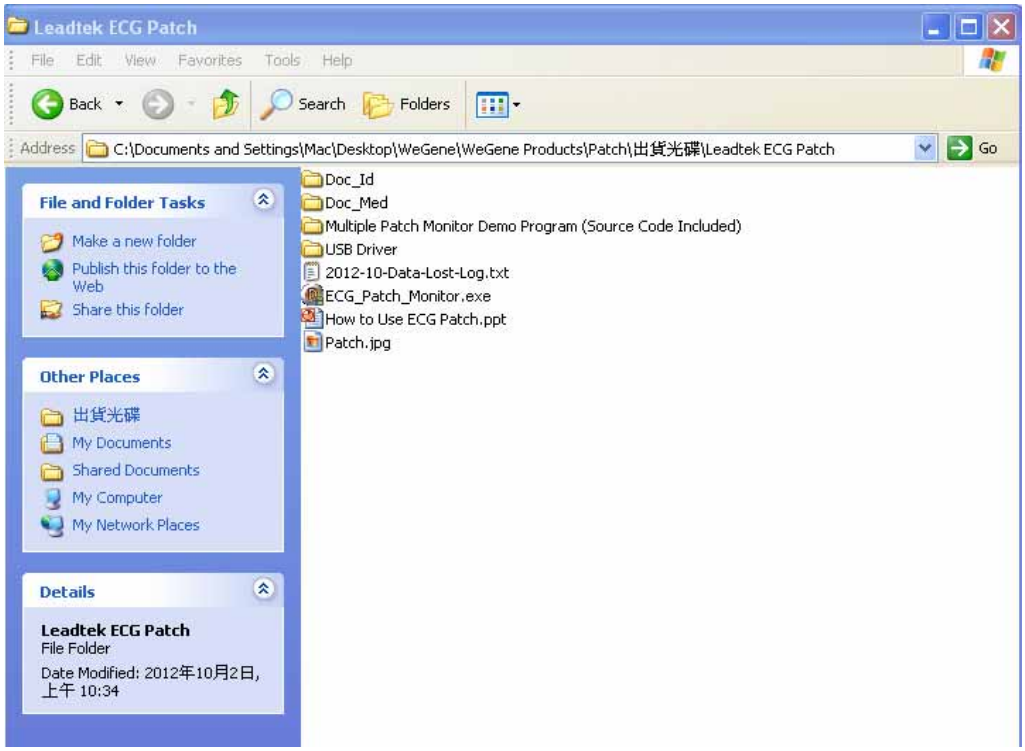

4.1.3 Application Programs

Patch test (1)

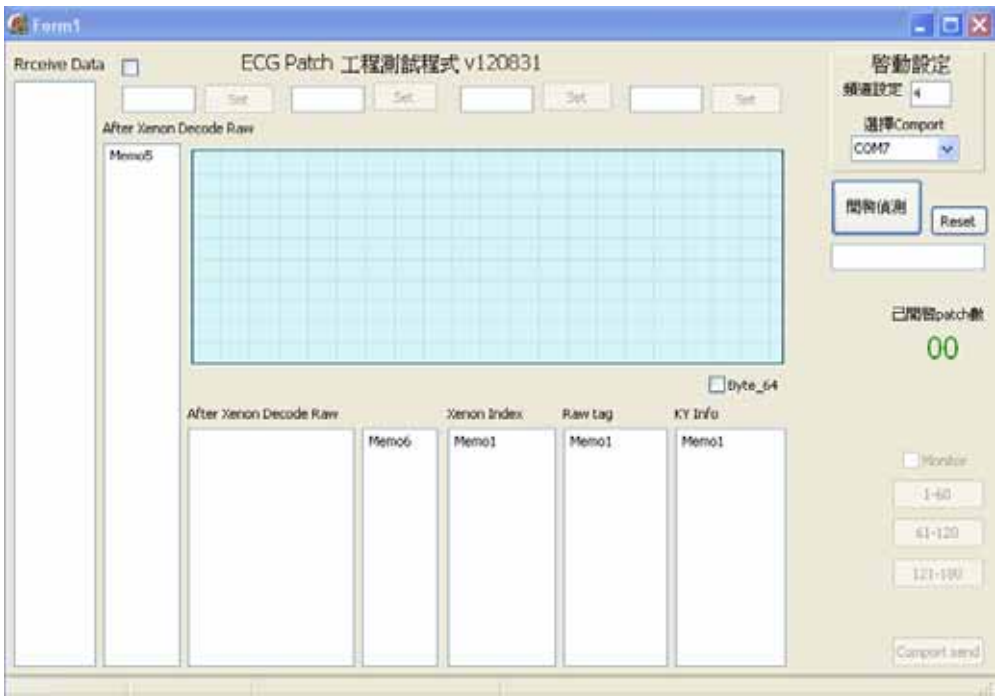
Computer Management >Device Manager > Check the USB Serial Port



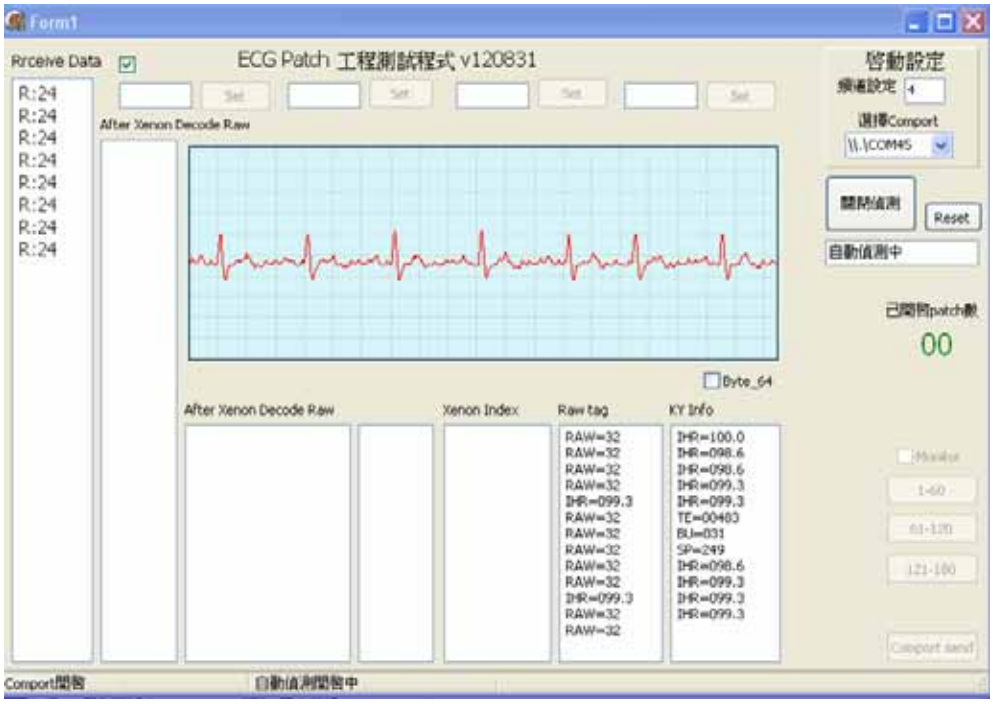

Open the program, “ECG_Patch_Monitor.exe”




Choose Comport and Channel (Default = 7). Press ”開始檢測” (Start).

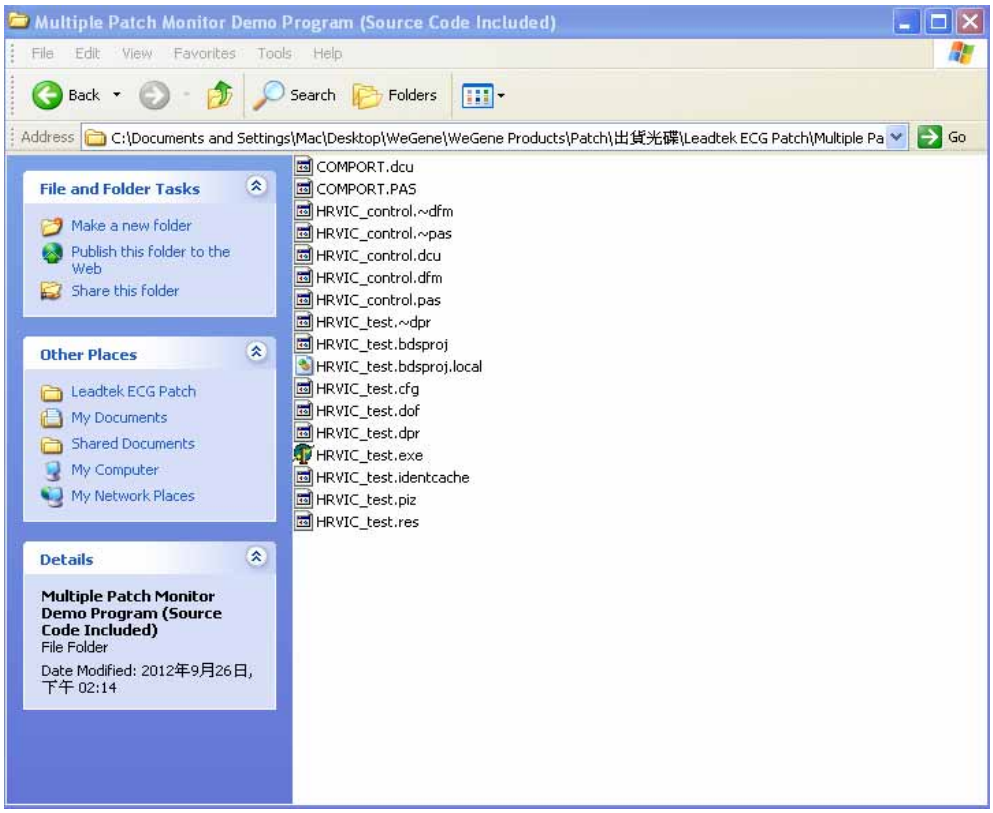



View receiver data

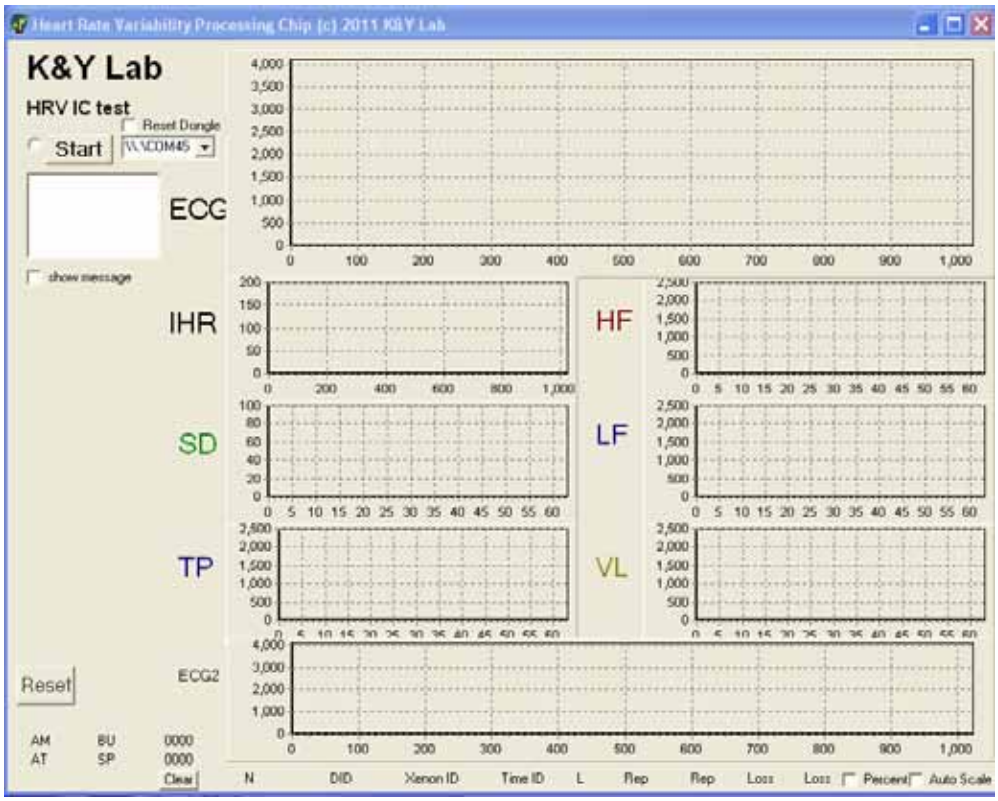


Patch test (2)

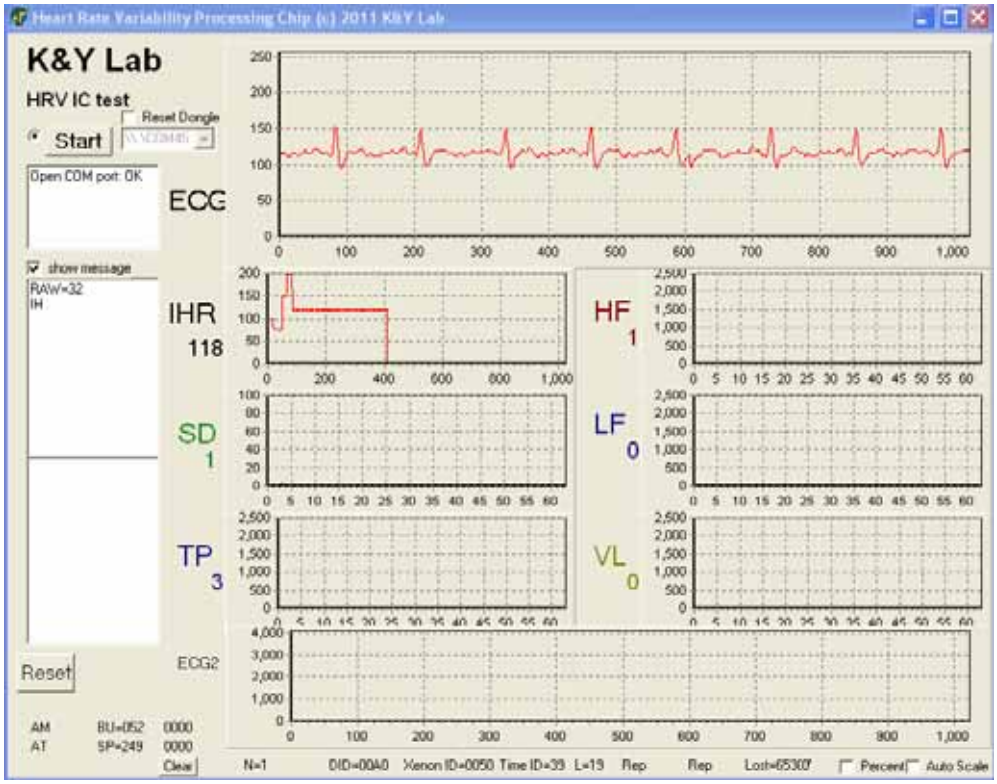
Open “HRVIC_test.exe” and repeat 3.1action.




Select right Comport and press the “Start” button




View receiver data(ECG waveform, HR, HRV index)



# 5. Contact Information

If you are not able to solve a problem, please contact your retail seller. You can also contact our technical support personnel by phone or mail, according to the following contact information:

1. Toll-free service call: +886 (02)82265800#765

2. Address: 18F., No. 166, Jian-Yi Rd., Chung-Ho Dist., New Taipei City 23511, Taiwan, R.O.C.

# 6. Warranty

Leadtek Research Inc. provides a one-year warranty, starting from the purchasing date, to the original purchaser for repairing any product failure due to fabrication error or defective parts. Within the limited range of the warranty, defective products shall be fixed or replaced by Leadtek Research, Inc. This warranty is not transferable. Damage due to negligence, accident, abuse, misapplication, modification, mailing to the seller, or repairs not made by Leadtek Research Inc., is not covered by the warranty. Within the coverage of the warranty, the delivery fee for mailing to the retail seller or the direct store is not covered within the scope of the warranty.

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Wegene Technology Inc.
18F., No. 166, Jian-Yi Rd., Chung-Ho Dist., New Taipei City 23511, Taiwan, R.O.C.
Tel: +886 (02)8226-5800 Fax: +886 (02) 8226-5471

Email：louishsiao@wegene.com.tw

Website: www.wegene.com.tw

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**Federal Communication 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 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 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.

**15.21**

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

**15.19**

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.

**FCC RF Radiation Exposure Statement:**

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

NCC 警語

低功率電波輻射性電機管理辦法

第十二條經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

第十四條低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。

前項合法通信，指依電信規定作業之無線電信。

低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。