



GIMA

PROFESSIONAL MEDICAL PRODUCTS

CONTEC 8000 WIRELESS ECG WORKSTATION - 12 CHANNELS

User manual

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

Gima 33316



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PEOPLE'S REPUBLIC OF CHINA
Made in China



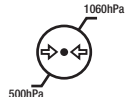
CONTEC8000G



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Preface

Please read the User Manual carefully before using this product. The operating procedures specifies in this User Manual should be followed strictly.

This manual describes in detail the operation steps which must be noted, the procedures which may result in abnormality, and possible damage to the product or users. Refer to following chapters for details. Failed to follow the User Manual may cause measuring abnormality, device damage or personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues of such results due to user's negligence of this manual for using, maintenance or storage. The free services and repairs does not cover such faults either.

For product upgrade, the device you received may not exactly in keeping with the description in this user manual, and we sincerely apologize for that.

Caution

Please consider the security and validity before putting the product into use:

- Type of protection against electric shock: internally powered equipment
- Degree of protection against electric shock: type CF with defibrillation-proof
- Working mode: continuous working equipment
- Degree of protection against of ingress of liquid: IPX0
- Measurement results should be explained by professional doctor combined with clinical symptoms.
- The reliability of this product depends on whether the operator's operation is in accordance with the operating and maintenance instructions of this manual.
- The service life of product is 3 years.
- Contraindications: no.



Warning: To ensure safety and validity, please use the accessories recommended by our company. Repair and maintenance shall be carried out by professional personnel approved by our company.

Responsibility on the user

- This equipment should be used by the physicians who have received professional training, and kept by special personnel.
- The user should read this user manual carefully before operating, and operate it in accordance with the manual.
- Although the device has been designed with a view to safety requirement enough, the user should not neglect the state of the equipment and patient observation.
- The user is responsible to supply the use situations of device to our company.

Responsibility of Our Company

- Our company supplies the qualified product to the user in accordance with enterprise standard.
- Our company installs and debugs the equipment and trains the physicians by contract.
- Our company performs device repair in warranty period (a year) and maintenance after warranty period.
- Our company is responsible to respond to users' requirements in time.

The user manual is written by our company. All rights reserved.

Statement

Our company owns all rights to this unpublished work and intends to maintain it as confidential information. This publication is used only for reference of operation, maintenance, or repair of our equipment. No part of this can be disseminated to others. Our company will not take any consequences or responsibilities for using of this manual for other purpose.

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Our company has the final interpretation of this manual. The content of this manual is subject to change without prior notice.

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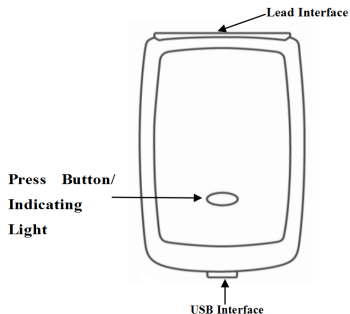
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Chapter 1 General Information

1.1 General

The device can be used for 12-lead simultaneous ECG sample, replay, automatic analyses and diagnose, Frequency Cardiogram (FCG), High Frequency ECG, QT interval Dispersion analyse, Heart Rate Variability (HRV) analyse, myocardial ischemia (STLE) analyse, Heart rate turbulence (HRT) analyse, Pacing ECG analyse, Vector Cardiogram (VCG), Time Vector Cardiogram (TVCG) and SAEKG, etc., which reflects user's heart locomotion circumstance, providing credible evidence for doctors to diagnose.



Appearance of Recorder

- **Indicator**
It is used to indicate the device's working state.
- **Lead interface**
Connect according to the lead number indicated on the panel. The part of the ECG lead wire that comes into contact with the patient is the applied part.

➤ USB interface

Charge for the device by connecting with USB in computer or 5V adapter with the data line.

1.2 Technical Specification

1. Operating conditions

- a). Ambient temperature: $+5^{\circ}\text{C}\sim+40^{\circ}\text{C}$
- b). Relative humidity: 25 % ~ 95 % (no condensation)
- c). Power supply: rechargeable lithium battery, 3.7 V, 900 mAh
- d). Atmospheric pressure: 700 hPa~1060 hPa

Storage conditions

- a). Ambient temperature: $-40^{\circ}\text{C}\sim+55^{\circ}\text{C}$
- b). Relative humidity: $\leq 95\%$
- c). Atmospheric pressure: 500 hPa~1060 hPa

2. Sampling frequency: 1000Hz

3. Sampling accuracy: 24-bit

4. Lead: 12-lead

5. Input dynamic range: $\pm 5\text{ mV}$

6. Gain: 5, 10, 20 mm/mV, accuracy: $\pm 5\%$

7. Gain control: continuous variation is available

8. Gain switch: When the gain changes, there is indication for the recording output.

9. Gain stability: After startup for 1 minute, the gain variation per minute shall be less than 0.33%. The total variation within 1 hour of the constant gain at each level shall be less than $\pm 3\%$.

10. Time base: 12.5 mm/s, 25 mm/s, 50 mm/s

11. Time base accuracy: within 0.2 s~2.0 s, the allowable error shall be less than $\pm 5\%$.

12. Channel width: the display width of each channel shall be more than 40mm.

13. Track width: $< 1\text{ mm}$

14. System error: $\pm 5\%$

15. Lead weight factor: accuracy within $\pm 5\%$

16. Calibration voltage: 1 mV, deviation within $\pm 5\%$

17. Input impedance: $> 40\text{ M}\Omega$

18. Patient-electrode DC current: $< 0.1\text{ }\mu\text{A}$

19. System noise: $\leq 15 \mu\text{Vp-p}$
20. Minimum detection signal: detect the sinusoidal signal deflected to 10 Hz, 20 μV (peak-to-peak value)
21. CMRR: $> 115 \text{ dB}$
22. Pacemaker detection channel: standard lead II
23. Amplitude-frequency characteristic:

Rated input amplitude	Input frequency and waveform	Relative output response
1.0	0.67 Hz ~ 40 Hz, sinusoidal	$\pm 10\%^a$
0.5	40 Hz ~ 100 Hz, sinusoidal	+10%, -30% ^a
0.25	100 Hz ~ 150 Hz, sinusoidal	+10%, -30% ^a
0.5	150 Hz ~ 500 Hz, sinusoidal	+10%, -100% ^a
1.5	$\leq 1 \text{ Hz}$, 200 ms, triangular	+0%, -10% ^b
^a Output relative to 10 Hz		
^b Output relative to 200 ms		

24. Safety classification:

Type of protection against electric shock: internally powered equipment

Degree of protection against electric shock: type CF with defibrillation-proof

25. Defibrillation voltage: $\pm 5 \text{ kV}$

1.3 Function and Speciality

The ECG workstation connects with matched software by means of Bluetooth, it can help doctors to analyze, diagnose and print patients' ECG. It can be used in ECG rooms, sickrooms and community hospitals. The software's characteristics are as following:

1. The sampling template adopts real-time sampling, display and store mode, which is clear and perspicuous. It not only has functions like real-time analyzing QRS wave, calculating heart rate and real-time print, but also has three filtering methods: baseline filtering, frequency filtering, EMG filtering.
2. Advanced arithmetic is adopted in the software, so that it is more perfect when the computer is seeking points, and it can obtain reliable auto-recognizing sort of arrhythmia, which can make the analyzing report and conclusion more valuable.
3. The problem of wave over-lapped, caused by baseline shift or excessive crest is solved by adjusting the leads position.

The leads position can be arranged automatically.

4. Thoroughly new orientation diagnosis function for coronary heart disease is finer to analyze abnormal Q wave.
5. The QTD template is provided to display the Chromatogram Map. It can also show the 12-lead ECG waves in high fidelity in order to adjust the points' position exactly.
6. HRV supports to analyze and print for long case. You can select the analyzing time conveniently by pressing left button of the mouse.
7. It can analyse heart rate turbulence, myocardial ischemia, pacing ECG at the same time.
8. The shortcut replay function of tridimensional vector loop can make you review the trend of vector loop more clearly.
9. The Print Preview and Print functions which adopt "What You See Is What You Get" can be found in every template. The A4, B5 two different sizes of paper are supported, so you can use it conveniently.
10. The "shortcut print" function can help you quickly preview or print all of the analytical reports, and save the reports in your computer with multimedia format (BMP, PNG, PDF or JPG format) according to factual need, so that you can turn over them more conveniently and intuitively in the future.
11. High-sampling rate (1000Hz) ensures ECG waves have no distortion and fine resolution in display and print function, make the details of ECG waves more perfect.
12. Strong and perfect base management of case makes it convenient to exceed, lookup, delete, backup, recovery and modify the case history data, and sustain combined conditions query function.
13. Abundant setting items are provided in system setting. You can set basic information, the operation of software, sampling data, wave analysis, database management, printing course ect according to your need.
14. The indicator light on the recorder can prompt charging, low battery and bluetooth working status. After the device startup, the indicator light will brighten in green color. It turns orange when the device is charging, if the device battery is low, the orange light will flicker. During sampling, the light will flicker in blue color with aptotic frequency.
15. Built-in rechargeable large capacity lithium battery.

Chapter 2 Safety Precautions

- 2.1 Make sure the device is placed on a flat surface before use, and avoid strong vibration or shock when moving.
- 2.2 Complete power supply system and proper grounding should be provided.
- 2.3 The design of this device has mature consideration of security, but operator should never neglect attention to device state and patient's observation. If necessary, unplug the data line or remove the electrodes in order to protect the patient.
- 2.4 Do not contact the device with water. Do not use or store the device in places where atmospheric pressure is too large, humidity, temperature exceeds the required standards, poor ventilation or dusty place.
- 2.5 It is forbidden to use the device in place containing flammable anesthetic gas or other flammable chemicals, otherwise there is a danger of fire.
- 2.6 It is strictly prohibited to use this device in medical hyperbaric oxygen chamber, otherwise there is a danger of explosion or fire.
- 2.7 Do not use the device under the environment within interference from high-voltage cable, X-ray, ultrasound machine, electrotherapy and other high frequency equipments. Keep the device away from emission sources such as cell phone or portable telephone.
- 2.8 Modification of the equipment is prohibited without the manufacturer's permission.
- 2.9 EMC

If the device appears improper functional phenomenon during using, please be sure to remove the adverse effects before continue to use. In response to this situation, the manual gives corresponding preventive measures.

- The device or system should not be used close to or stacked with other equipment, and if it is necessary to do so, please guarantee that the device is functioning properly in its using configuration.
- Use of unspecified accessories, transducers and cables other than those sold by manufacturers of device or system as spare parts for internal components may result in decreasing of gain and immunity of the device or system.
- Effect of radiated electromagnetic waves:
The use of mobile phones may affect the operation of the device. When installing medical electrical equipment, please do remind all personnel to turn off mobile phones and small radio equipment.
- Effect of static electricity:

Static electricity in a dry environment (indoors) may affect the operation of the device, especially in winter. Before using, make the room air wet, or discharge the static electricity from the cable and ECG recorder personnel.

■ Effect of thunder and lightning:

During charging, if thunder and lightning is present in the vicinity, a voltage surge may be caused in the device. If you are concerned about the danger, then you can unplug the data line to stop charging.

2.10 ECG waveform measurement and analysis

2.10.1 Identification of P wave and Q wave is not always reliable with intensive EMG or AC interference. Neither are the ST segment and T wave with baseline drift.

2.10.2 Winding and unclear end position of S wave and T wave may cause error in measurement.

2.10.3 When R wave is uninspected caused by some leads off or QRS wave low voltage, the heart rate measurement may deviate greatly from the correct.

2.10.4 In case of QRS low voltage, ECG axis calculation and border-point identification of QRS wave are not always reliable.

2.10.5 Occasionally, frequent ventricular premature complexes may be identified as dominant beat.

2.10.6 Merging of versatile arrhythmias may result in unreliable measurement because of the difficulty in distinguishing P wave in such situation.

2.10.7 The device is designed with auto analysis function, which only analyses the ECG waveforms it gathered and does not reflect all patient's states. Its analysis results may be not in accordance with doctor's diagnoses. Therefore, the final conclusion concerning each patient is up to the doctor basing on analysis results , patient symptoms, and other examinations together.

2.11 The device is intended for use on young people and adults aged 12 to 87.

2.12 The device does not have an anti-burn device when together with high-frequency surgical equipment. When the device is used in conjunction with high-frequency surgical equipment, the electrodes of the device should be kept away from the contacts of the high-frequency equipment to prevent burning and electrode wire burnout caused by high-frequency sparks.

2.13 If multiple instruments are connected to a patient ,the sum of the leakage currents may exceed the limits given in the IEC/EC 60601-1 and may pose a safety hazard.

2.14 The device is not designed for intracardiac use or direct cardiac application.

2.15 The device has been safety tasted with the recommended accessories, peripherals, and leads, and no hazard is found when the device is operated with cardiac pacemakers or other stimulators.

2.16 Disposable electrodes must be used during defibrillation.

2.17 Defibrillation lead cable (BIT0371) must be used during defibrillation. The protection of the defibrillation effect of a cardiac defibrillator depends on the use of appropriate cable.

2.18 Do not touch the patient, bed, table or the equipment while using the ECG together with a defibrillator.

Note: After defibrillation, the ECG waveform becomes unstable. Before collecting the ECG waveform, it should be left to stand for at least 5seconds until the ECG waveform stabilizes.

2.19 Ensure the device is only connected to devices authorized/approved by manufacturer. Users should operate all system deployed and supported by manufacturer within specifications authorized by manufacturer, including software, software configuration, security configuration, etc. approved by manufacturer.

2.20 The device is isolated from the mains power through connectors or power plugs. The device should be placed at a location where it is easy for the user to disconnect the mains power.

2.21 The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results. Disconnect the patient data cable from the electrocardiograph, or detach the leads from the patient prior to performing any procedure that uses high frequency surgical equipment.

Chapter 3 Warranty Provisions

3.1 Under normal use, namely operate it according to the User Manual and notices, if there is any trouble, please contact our customer service department. Our company has the factory record and user files for each device, user has free maintenance service from purchasing date according to the following terms and conditions. Please return the warranty card to us in time, which is convenient for us to provide comprehensive and efficient service for you.

3.2 We may take the guide, expressing companies, home warranty and other forms to fulfill commitments.

3.3 Even in the free warranty period, in principle, you will also pay the money for repair if you have the following instance:

3.3.1 Malfunction or damage arising from failure to operate the equipment according to the User Manual and notices.

3.3.2 Malfunction or damage arising from dropping when moving it after purchasing.

3.3.3 Malfunction or damage arising from repair, alteration and decomposition not implemented by our company.

3.3.4 Malfunction or damage arising from improper storage or force majeure after purchasing.

3.4 The free warranty period for accessories and the wear parts is six months. User manual and packaging are not contained in the scope of the warranty.

3.5 Our company is not liable for that the failure of the product directly or indirectly leads to other connected devices in

the failure.

3.6 If it is found that the protection labels have been destroyed, the agreement of free maintenance service will become invalid immediately.

3.7 In the warranty period, maintenance charges, the company proposed to continue the use of "Maintenance contract system". Please contact our customer service department advisory for more details.

Chapter 4 Device Operation Precautions

4.1 Precautions before use

4.1.1 For safe and effective use, please read the user manual carefully before operation.

4.1.2 Read the contents of installation and startup described in User Manual before installing, to avoid equipment damage.

4.1.3 Make sure the installation condition meets requirements, otherwise the software may work or display abnormally.

4.1.4 Check that the device is in good condition.

4.1.5 The device shall be placed on a flat surface, and moves gently to avoid strong vibration or shock.

4.1.6 Check that the lead cables are correctly connected before starting.

4.1.7 Choose a location that is easily grounded in the room. Do not allow the patient and the patient's wire to come into contact with other conductor parts, including the earth or a well-grounded hospital bed.

4.1.8 Clean the lead wire Clean with a neutral solvent. Do not use alcohol-based cleaners or germicides.

4.1.9 Ensure that the device is operating within the normal ambient temperature range of +5°C to +40°C. If the device is stored at a higher or lower temperature, keep it in the operating environment for approximately 10 minutes before using it on order to ensure the normal work.

4.2 Precautions during operating

4.2.1 During using, the doctor should observe the patient carefully without leaving the operation site. If necessary, turn off the power or remove the electrode to ensure patient safety.

4.2.2 The patient and the device can only be connected via lead wires through the electrodes, in order to avoid the patient touches other parts of device or conductors.

4.2.3 Patient can not move when operating the device.

4.2.4 When a patient is using the device, neither the device itself nor its components should be maintained or serviced.

4.3 Precautions after use

4.3.1 Cut off the power, gently remove the electrodes and limb clips, then remove the lead cables, do not pull with strong force.

4.3.2 Clean the device and all accessories, and store them for the next use.

4.4 Interpretation of symbols

	Type CF with defibrillation-proof
	USB interface
	Refer to instruction manual/booklet
	WEEE (2002/96/EC)
	This item is compliant with Regulation(EU)2017/745 of the European Parliament and of the Council of 5 April 2017.
	Atmospheric pressure limitation
	Humidity limitation
	Temperature limitation

	This side UP
	Fragile, handle with care
	Keep dry
	Stacking limit by number
	Manufacturer
	Date of manufacturer
	Batch code
	Catalogue number
	Serial number

	Caution! Refer to the accompanying document.
	General warning sign NOTE : Background colour: yellow Triangular band: Black
	Quality control pass
	Medical Device
	Unique Device Identification
	Authorized representative in the European Community
	Imported by

Chapter 5 Install and Start

5.1 System Configurations and Software Explanations

CPU: above 2.0 GHz

Memory: above 1G

Main board: support USB2.0, main board with Intel chips group is recommended.

Hard disk: 40G or above

Operating System: Microsoft WindowsXP/7/8/10/11

Resolution: above 1024*768

Printer: 600 dpi laser printer

Interface: USB2.0

The setting can be modified at display attribute in Windows operating System. If you have any question about modifying the system setting, please refer to the help of Windows operating system.

5.2 Software Installation

First, get the installation package or USB flash disk of ECG workstation. Then run ECG Workstation.exe. (As Figure 1)

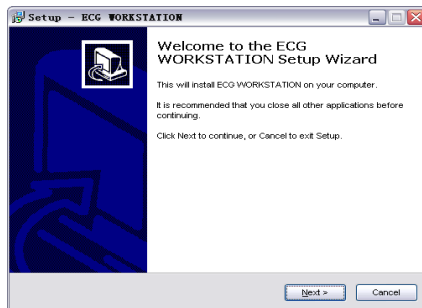


Figure 1

Click "Next", then the interface shown as Figure 2, Figure 3 will appear.

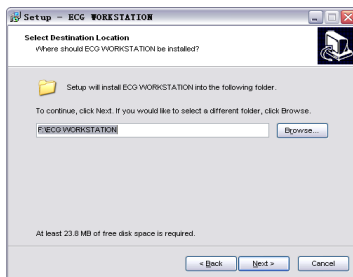


Figure 2

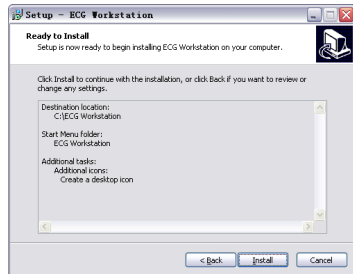


Figure 3

Click "Install", then the interface shown as Figure 4, Figure 5, Figure 6 will appear.

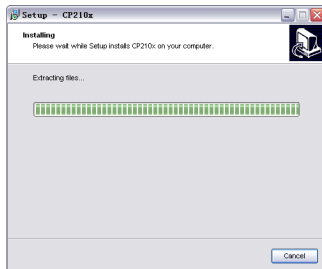


Figure 4

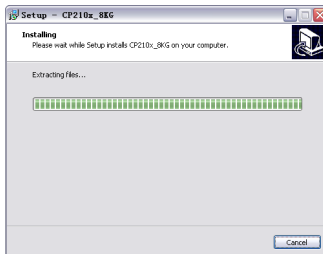


Figure 5

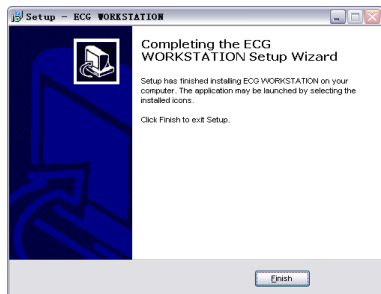


Figure 6

After installing, please set printer, display resolution, etc. in your computer according to "5.1 System Configurations and Software Explanations" and restart the computer. Then the software has been installed on PC and can be used.

5.3 Add Bluetooth equipment

Please start the ECG workstation device first before adding the bluetooth equipment. Long press the button on the front of device for one second to start it. It indicates that it can add the bluetooth equipment when the indicator is green. If the indicator is orange, the bluetooth equipment can not be added, please charge to the device in time.

5.3.1 Non-Bluetooth Low Energy (BLE) connection method

Please search and add the bluetooth equipment before start collecting, installation processes are as following:

- 1) Connect the bluetooth adapter with the USB interface in computer.

- 2) A icon  will display on the right bottom corner  of computer screen.

- 3) Double click the icon, it will pop up a dialogue box as shown in **Figure 7**.

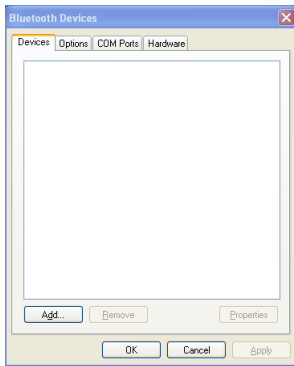


Figure 7

- 4) Click "Add" button, the dialogue box shown in Figure 8 will pop up.

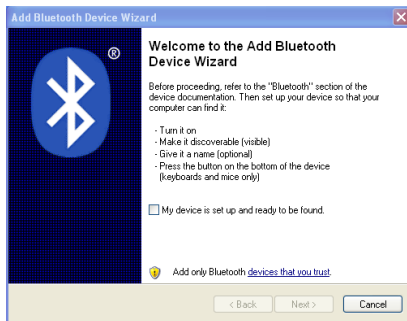


Figure 8

- 5) Tick the "My device is set up and ready to be found ", then the "Next" button is available to choose, click it to pop up dialogue box as Figure 9

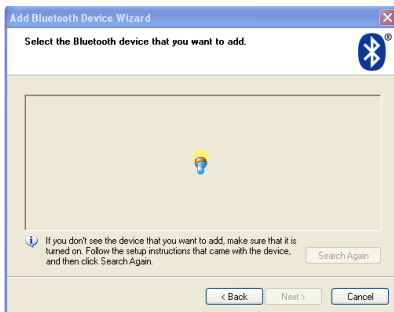


Figure 9

The bluetooth adapter will automatically search for bluetooth devices around. All available devices will be displayed on the interface shown as Figure 10 once searched.

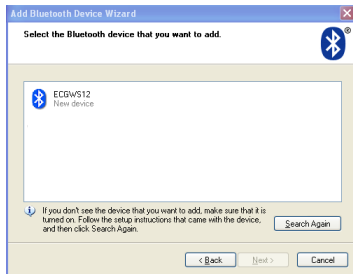


Figure 10

- 6) Select the bluetooth symbol, then the "Next" button is available to choose, click it to pop up a dialogue box as Figure 11:

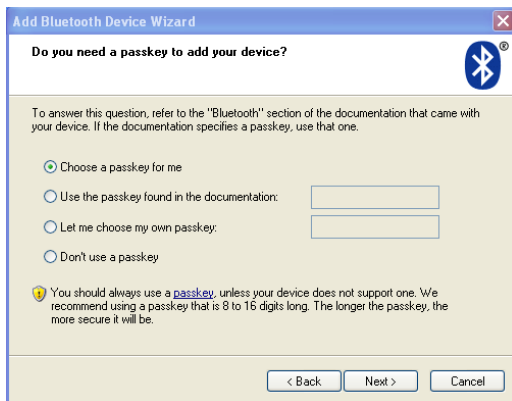


Figure 11

- 7) Choose "Let me choose my own passkey", input the password "7762" in the textbox on right side, then click "Next", the dialogue box as Figure 12 will pop up.

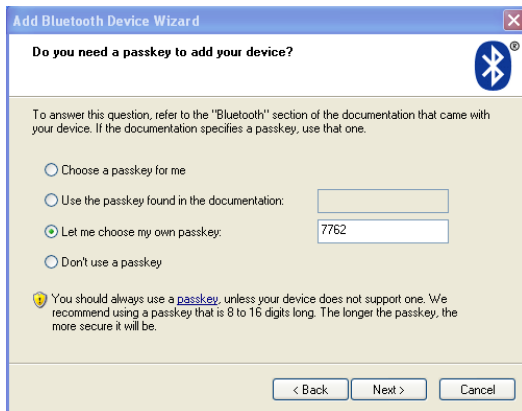


Figure 12

- 8) Please wait for its installation, then a dialogue shown as Figure 13 pops up after finishing.



Figure 13

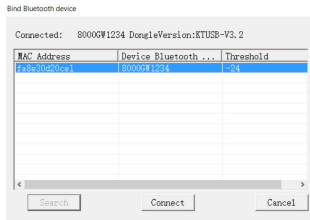
9) Click "Finish" to complete the installation.

You can start collecting ECG data after doing all the works above.

5.3.2 BLE Bluetooth version connection method

1 Plug the BLE Bluetooth dongle into the USB port of the computer.

2 Open ECG WORKSTATION .When you open ECG WORKSTATION for the first time, a Bluetooth connection interface will pop up as shown in the following picture.



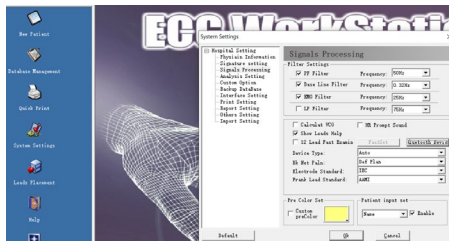
3 Select the name of the device to be connected. For example, CONTEC8000G1234, where 1234 is the serial number on the back of the device.

4 After clicking the connect, you will enter the main interface of the program. The connection has been successful.

Change the connection device

1 Open ECG WORKSTATION .

2 Click on System setting->Signals processing->Bluetooth device



5.4 Startup the ECG Workstation

First, please make sure that you have added the bluetooth device. Resolution needs to be set above 1024*768, and the font of windows appearance needs to be set as normal.

Double click ECG Workstation icon on the desktop to start the ECG workstation.

5.5 Uninstall the Software

Choose "Start" -> "Program" -> "ECG Workstation", and click "Uninstall ECG Workstation". Then the dialog as Figure 14 will appear.

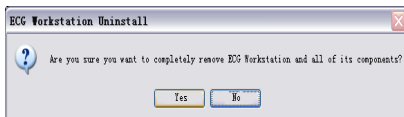


Figure 14

Click "Yes", then all components will be deleted automatically, and the dialog shown as Figure 15 will appear, click "OK" to finish uninstalling.



Figure 15

Chapter 6 Electrode Installation

6.1 Wilson Lead System

In this manual, all involved lead identifiers are displayed in accordance with the U.S.A. Standard. The standard can be set in "signals processing" under "system settings". The correspondence for lead identifiers and colors between European Standard and U.S.A. Standard as following:

System	European Standard		U.S.A. Standard	
	Patient electrode connection identifier	Color	Patient electrode connection identifier	Color
Limbs electrode	R	Red	RA	White
	L	Yellow	LA	Black
	F	Green	LL	Red
	N	Black	RL	Green
Chest electrode for Wilson lead	C1	White/Red	V1	Brown/Red
	C2	White/Yellow	V2	Brown/Yellow
	C3	White/Green	V3	Brown/Green
	C4	White/Brown	V4	Brown/Blue
	C5	White/Black	V5	Brown/Orange
	C6	White/Violet	V6	Brown/Violet
Frank lead	I(C1)	Light blue/Red	I(V1)	Orange/Red
	E(C2)	Light blue/Yellow	E(V2)	Orange/Yellow
	C(C3)	Light blue/Green	C(V3)	Orange/Green
	A(C4)	Light blue/Brown	A(V4)	Orange/Brown
	M(C5)	Light blue/Black	M(V5)	Orange/Black
	H(C6)	Light blue/Violet	H(V6)	Orange/Violet

The electrode placement positions of Wilson Lead System are shown as Figure 16.

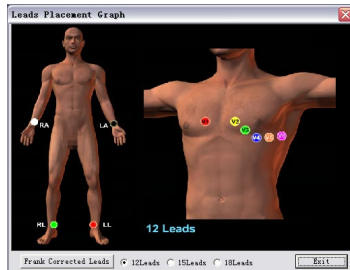


Figure 16

Chest electrodes placement positions are as followings:

- V1: Right margin of Sternum, and the fourth ribbing clearance.
- V2: Left margin of Sternum, and the fourth ribbing clearance.
- V3: The mid-point of the line between V2 and V4.
- V4: The fifth ribbing clearance of left side, and the midline of left clavicle.
- V5: The font line of left armpit, and the same plane of V4.
- V6: The midline of left armpit, and the same plane of V4.

Limbs electrodes placement positions are as followingS:

- RA: Right arm
- LA: Left arm
- LL: Left leg
- RL: Right leg

6.2 Frank Lead System

The electrodes placement positions of Frank Lead System are shown as Figure 17.

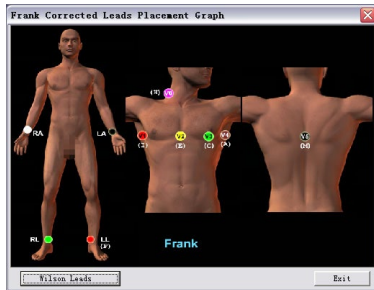


Figure 17

Chest electrodes installation positions are as followings:

V1: The midline of right armpit, and the fifth ribbing clearance.

V2: The font midline, and the fifth ribbing clearance level.

V3: The mid-point of the line between V2 and V4.

V4: The midline of left armpit, and the fifth ribbing clearance.

V5: The back spine line, and the fifth ribbing clearance level. Use electrode piece as electrode and join the lead lines by connection line

V6: The right scruff

Limbs electrodes placement positions are as following:

RA: Right arm

LA: Left arm

LL: Left leg

RL: Right leg

6.3 Electrode Installation Instructions and Precautions

- ◆ Make sure to insert lead cables following the sequence labeled on the recorder.
- ◆ As the weather of the north in the winter is cold, the skin exposed in the air easily produces the muscle tremble. So the best temperature indoor is above 16°C to reduce EMG interference.
- ◆ During installing electrodes, we propose to install the chest electrodes first, then the limbs electrodes.
- ◆ When placing the electrodes of chest lead, use proper force to avoid the balls' falling off during sampling and gore instance to the patient after sampling.
- ◆ When placing the electrodes of chest lead, clean the chest skin with alcohol to remove the skin oil and fat. In the North or the dry air circumstance, it is better to lay a little conductive paste to enhance the conductivity capability. Smear conductive paste to the 25mm-diameter range and the verge of electrode absorbing bowl. Press absorbing balls of chest electrodes to fix the chest electrodes to certain place.
- ◆ Conductive paste coat should be separated from each other, chest electrodes should not be contacted each other to avoid short-circuit.
- ◆ The left leg need not share an electrode with the right one.
- ◆ When the limbs electrodes are installed, the electrodes should be fixed to tenderness skin of feet and hands. Clean the skin where the electrode is fixed with alcohol, then lay a little conductive paste to the skin. The side which has sheet metal should be placed to the inside of the limbs (As Figure 18).

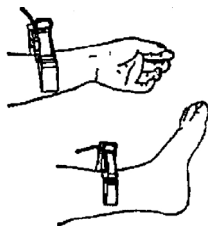


Figure 18

- After placing the electrodes, patients should keep relaxed. Muscle should not be forced to avoid EMG interference.
- Do not mix old and new electrodes, or mix reusable electrodes with disposable electrodes. Do not use electrodes with dissimilar metals at same time. If different types of electrodes are used together, electrocardiogram recording will be seriously affected.
- Electrodes and lead cable comparison table:

Electrode position	Electrode symbol
Right arm	RA/R
Left arm	LA/L
Left leg	LL/F
Right leg	RL/N
Breast	VI/CI
Breast	V2/C2
Breast	V3/C3
Breast	V4/C4
Breast	V5/C5
Breast	V6/C6

Chapter 7 Software

When you have completed and fully understood all the contents mentioned above, you can really start to use this system integrating Wilson system and Frank system into a whole.

Notice: The device is a standard 12-lead sync sampling device, so it always chooses "12-lead" under any interface that need to choose from Wilson "12-lead", "15-lead" or "18-lead".

Double-click "ECG Workstation" icon on the Desktop to enter to the interface shown as Figure 19.

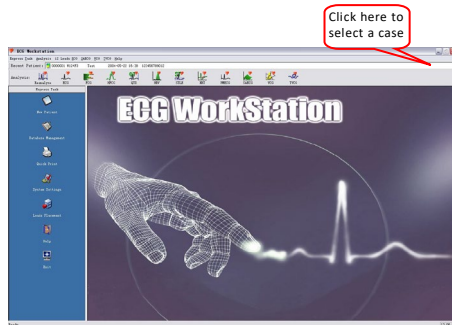


Figure 19

Let's see each part in the main interface. First, at the top of the software is the menu, including "Express Task", "Analysis" and "Help". These menus are corresponding with the various function buttons in the main interface one by one.

The "Recent Patient" shows the information of the patient analyzed at present. The column contains the patient number,

name, time and remarks, etc. You can click the downwards arrow  on the right of columns to choose the other

patients checked to review and analyze.

The "Analysis" lists all the analysis projects you can do. It indicates that the analysis item can't be used if it shows gray (As Figure 20), because the record does not meet conditions or has not yet been analyzed.



Figure 20

In "Express Task" column, we provide you with a number of functions beyond the ECG analysis, including collection, database management, quick print, system settings, help and so on. These functions can help you to use the software faster and better. Their features are as followings:

The "New Patient" allows you to enter the patient information interface before sampling, and start sampling from this interface. After clicking the button, you can choose the lead system, set the collection time, input basic information of patient.

You can not only use the "Database Management" to search, modify, backup, recover and update all cases checked, but also to review the cases.

The "Quick Print" can help you to print the reports without entering the specific analysis item. You can also save the information to your own computer by different formats (PDF format or JPG format).

The "System Settings" provides you a series of options. By simple setting, you can use and operate the software.

The "Leads Placement" and the "Help" can help you quickly resolve the problems appearing during using the software.

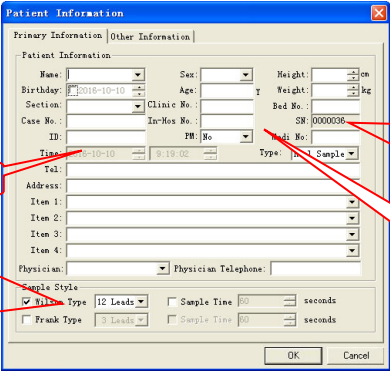
The "Exit" button allows you to exit the software in the normal way without worrying about losing data.

Chapter 8 New Patient Sampling

You can use our product after installing the software and hardware and knowing the electrode placement.

8.1 Input New Patient Information

Click "New patient"  button (As Figure 21) to input relative information.



The screenshot shows the "Patient Information" dialog box with the "Primary Information" tab selected. The form contains various fields for patient data. Red callout boxes provide additional context for specific fields:

- Current examined time:** Points to the "Time" field, which displays "8-10-10".
- It is created automatically, it is a unique ID for patient:** Points to the "ID" field, which displays "0000036".
- Pacemaker detection:** Points to the "Sample Style" section, specifically the "12 Leads" option under the "Wile" type.
- Click it to change the lead system and set the sample time:** Points to the "Sample Time" field, which is set to "60" seconds.

The form includes fields for Name, Sex, Height, Birthdate, Age, Weight, Section, Clinic No., Bed No., Case No., In-Mos No., SW, ID, PW, Medi No., Time, Tel., Address, Item 1-4, Physician, and Physician Telephone. The "Sample Style" section has checkboxes for "Wile" and "Frank" types, each with a "Leads" dropdown and a "Sample Time" field.

Figure 21

You can input patient information in this dialog, which is convenient to manage and query the case in future. You can also input the items you want, or input nothing to enter the sampling module directly. The item of time is always the current time. You can select sample type in "Sample Style", or set it in "System Settings", which can get the default sample type in next sampling and time you want to sample. Note: Item1/Item2are user-defined items. You can define them in "System Settings" dialog. For example, patient telephone number can not be printed in report. But if you change "Item1" to "patient telephone number" in "user-defined" setting, and select "Print", this information will be printed. (Refer to "customized settings" in 9.1.4 "System Settings")

Turn on Pacemaker detection when selecting PM as yes.

The following is the sample selection information. Click the mouse to select the sample style you want(as Follow).

Sample Style

☒ Wilson Type	18 Leads ▼	☐ Sample Time	60	seconds
☐ Frank Type	12 Leads 15 Leads 18 Leads	☐ Sample Time	60	seconds

Wilson: 12 leads Wilson can be selected to test 12 leads ECG, FCG, HFECG, QTD, HRV, STLE, HRT and PMECCG. Sample time must be more than 3s. It is recommended that sample time should be set to more than 20s when performing FCG analysis. Frank: it is usually used to test VCG, SAECG and TVCG. The sample time is generally more than 3s. It is recommended that the sample time should be set to more than 5min when performing SAECG.

You can set time sampling and select sample time, when it arrives to the time, the system will automatically stop sampling. Remark can be added in the "Other information" dialog, convenient to query (As Figure 22).

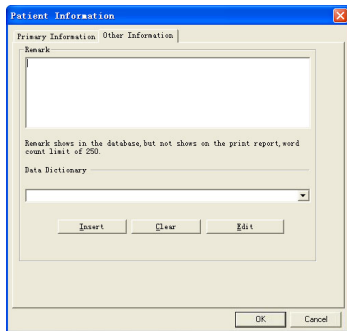


Figure 22

Click "OK" to enter sampling template to sample the case.



Caution: All electrodes must be placed properly before clicking "OK", to avoid interference waveform.

8.2 ECG Sampling

There is a delay for more than 20s before sampling to balance potential between skin and device (In fact, it takes you more than 20 seconds to input the patient information). Click "OK" in Figure 20 or Figure 22, then enter to the interface shown as Figure 23.

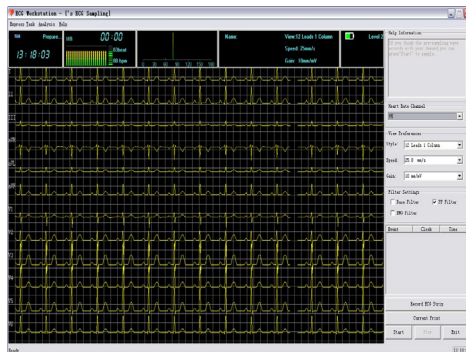


Figure 23

If the connection between the collecting box and the computer has problem, for example, the Bluetooth is connected unsuccessfully or disconnected, then the system will prompt “Connection error”(as Figure 24). Then please check the connection of the Bluetooth.

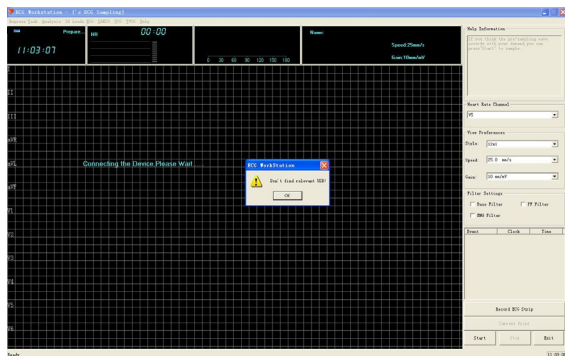


Figure 24

If the lead cable doesn't contact with body well or does not connect with patient, the system will prompt "Leads fell off" or "OL or Satu" (As Figure 25), and the correlative channel will draw a straight line. Overload and lead off are abnormal working conditions. For the instance, please check whether the connection between the lead cable and the patient is proper, and the connection line is good.



Figure 25

During pre-sampling phase, the wave is yellow, waveform quality can be observed, the positions of electrodes and leads can also be adjusted. If the waveform interference is too big, then adjust by “Filter Settings” to get stable and clear waveform.

In some cases, the quick print is required. Click "Real time print" to print directly. Notice: if the ECG data is deficient for one page, the "Real time print" button will be gray and not be used.

Click "Start" button to sample after wave is clear (As Figure 26).

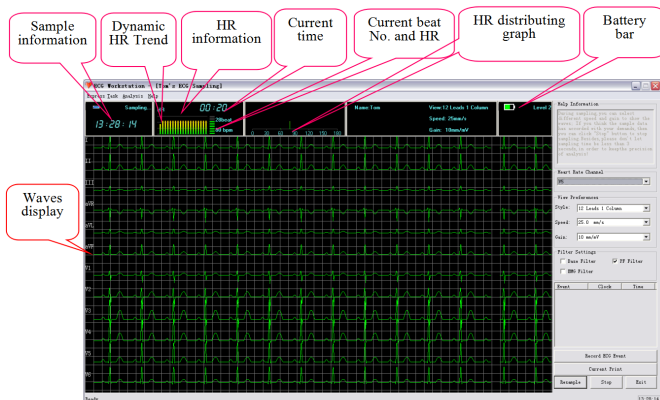


Figure 26

During collecting process, battery power displayed on the collecting interface in real-time, which also called the battery bar. In the following picture, the battery bar means "battery level is two", and its color is green. When the color turns to red, it means "the battery is low". Please charge the device, as the collecting can't be continued in low battery. The device will prompt low battery during pre-collecting process, as shown in Figure 27, while during formal sampling process, the prompt interface is shown in Figure 28.



Attention: Please use the USB cable provided by our company to charge the device. You can connect it with a computer or use a power adapter of 5V rated voltage and rated current no more than 1A for charging.

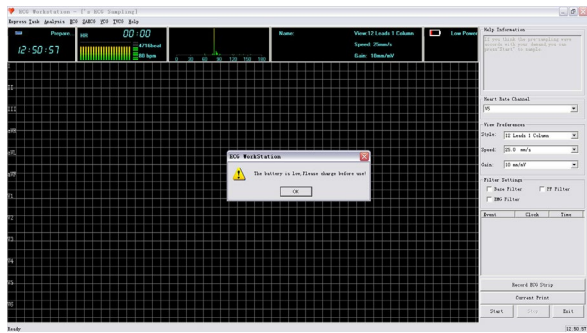


Figure 27

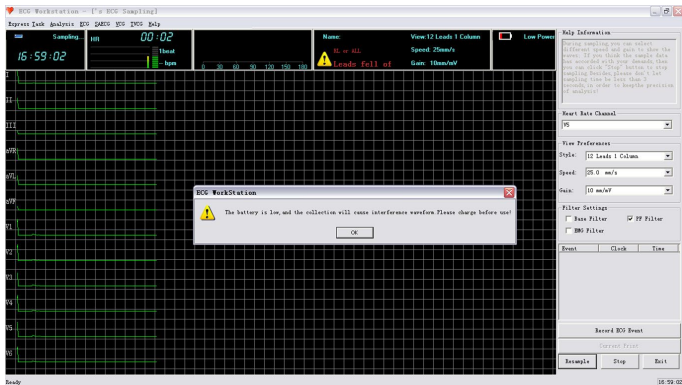


Figure 28

It indicates that it is in sampling phase when the waveform color is green.

- ◆ In this phase, the system can sample and calculate HR at the same time, but if the lead voltage selected in “Heart Rate Channel” is a little lower, QRS waveform may not be found rightly, so the HR can not be calculated accurately, then the HR can not be displayed normally, please select the lead in “Heart Rate Channel” with higher voltage to calculate the HR.
- ◆ If there is large interference source near the system, please select “PF Filter” in “Filter Settings”.
- ◆ If there is serious baseline drift, please select “Base Filter” in “Filter Settings”.
- ◆ If there is large EMG interference from patient, please select “EMG Filter” in “Filter Settings”.
- ◆ If the waveform can’t meet with requirements, click “Resample”.

- ◆ If "Sample Time" is set before sampling, the system will automatically stop sampling when it arrives to the time, and turn to next function.
- ◆ If "Sample Time" is not set, you can press "Stop" and "Close" to finish sampling after sampling for some time (more than 3s)
- ◆ "Current Print" can be used in real sampling.
- ◆ If both "Wilson Type 12 Leads" and "Frank 3Leads" are selected, systems will pop up dialog (As **Figure 28**) after clicking "close" button in **Figure 29**.

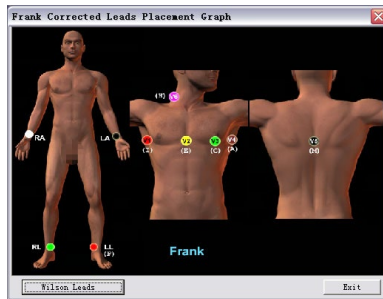


Figure 29

Place the electrodes according to Figure 29, then click "Start" button to enter the interface shown as Figure 30.

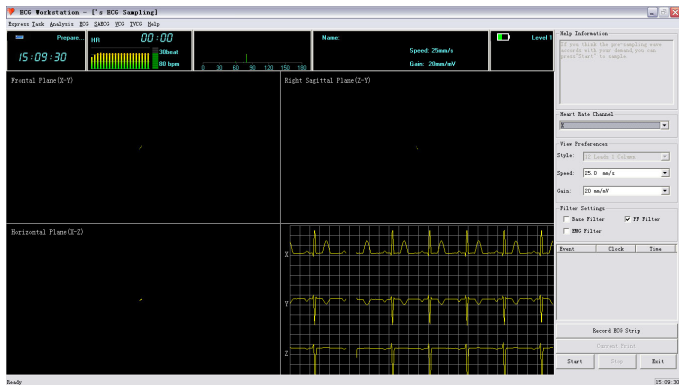


Figure 30

The operation is the same as "Wilson Type 12 Leads". Keep the sampling time more than 5 minutes for analyzing SAECS.

8.3 Analysis

When the sampling is over, the interface shown as Figure 31 will appear.

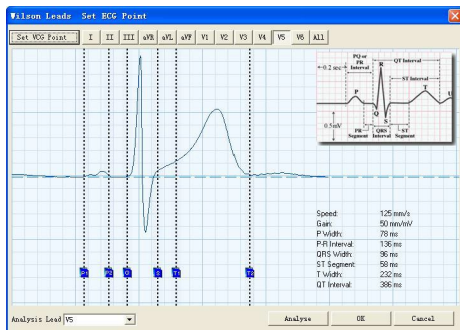


Figure 31

Put the cursor on the dashed lines, press the left key of mouse and drag them to proper positions. Attention: Press "Set VCG Measurement Point", then switch to Frank. Click "OK" button to return to the main interface after all the calibration operations have been completed. Then you can enter other items to analyse.

For more detailed explanations about calibration interface, please refer to "9.2.1 Reanalyse".

Chapter 9 Functions Explanation

9.1 Shortcut task



New Patient

9.1.1 New Patient

This contents have been explained in "8.1 Input patient information", so we won't explain here.



9.1.2 Case database management

It supports the function of automatically storing original data for each patient, you can check patient's basic information by this function, query, select or delete patient information according to the combined conditions(As Figure 32).

The screenshot shows the 'Patient Database' application window. It features a top section for query input with fields for Name, Sex, Section, Case No., SN, Age, Time, Doctor, Item1-4, Remark, and VerCount. A 'Run Query' button is at the bottom left. The right side contains action buttons like 'Load Selected Patient', 'Delete Selected Patient', 'Modify Selected Patient', 'Update Database', 'Backup Case', 'Resume Case', 'Compare Case', and 'Label Manage'. There are also 'Load Style' and 'Case Style' sections with radio buttons for selection. The bottom part of the window displays a table of patient records.

Input conditions to query

Click "Time" check box, then you can query by time

Click here to select 12 leads or 3 leads case

Click here to select the case style

Case display

Page turning or locate pages for database.

SN	Name	Sex	Age	Check Date	Case No.
0000001	Test	41T		2004-05-22	13543513
0000033				2016-11-16	
0000034				2016-11-16	
0000035				2016-11-16	

Figure 32

In case display area, we list latest 100 groups of cases met conditions, which is convenient for user to query conveniently and quickly. User can turn pages by the button or the edit box.

It displays the information which have patients' cases, and case style can be selected, including "Deleted", "Undeleted" and "All".

The icons displayed in front of the cases indicate the type of cases. The icon  indicates the case has been deleted, the icon  indicates that the patient only has Frank case file, the icon  indicates that the patient only has Wilson case file, and the icon  indicates that the patient has both Frank and Wilson case files. You can double click the case item to open it.

Function:

Query: Enter query item on the left, then press the "Run Query" button, all cases that meet the conditions will be displayed in the table. You can query the file location, case No., patient name, sex, check date, physician and so on. The fuzzy query is supported for all of the query. Only input a character, all items met conditions will be listed. For example: input "Wang" in "Name" and click "Run Query", all patients whose name include "Wang" will be displayed. Input "APB" in "Remark", all patients with the remark information including "APB" will be listed. The method to edit remark, please refer to "Modify selected patient".

Clear query: Clear all previously entered conditions.

Load selected patient: Select the patient to be examined, click "Load selected patient", the patient will become the current patient and its data will be loaded in memory for processing. You can also double-click the case with the left key of mouse to load patient.

Delete selected patient: Select the case to be deleted, click "Delete selected patient" to delete it. **Attention: The case can't be recovered after deleting, but "Patient information" of this case will be saved.**

Lead style: "Wilson" indicates 12 leads sampling mode, "Frank" shows 3 leads sampling mode, and "W&F" is both 12 leads and 3 leads mode.

Case style: You can check the information of undeleted, deleted or all patients.

Modify selected patient: Select the case to be modified, press "Modify Selected Patient" to modify. After modifying, click "OK" button to save, As Figure 20.

Update database: Resume database files, or some other operation may cause that the database files do not match with the

actual cases, for example, although case has been deleted but it shows that it still has not been deleted in case database management, or case records document exists, but it is still listed in deleted case in case database management, which may cause wrong query results. Click "Update database" button to check the database information, match the case database and documents to show the correct query results.

Backup case: Choose the case to be backup by clicking the left button of the mouse in the case display area, or dragging the mouse in this area, then click "Backup Case" button, the interface shown as Figure 33 will appear. You should select the saving path and press "OK" to save. If the operation is successful, the dialog box as Figure 34 will appear.



Figure 33



Figure 34

Resume case: resume case function can resume the backup case to the existing database. The interface shown as Figure 35 will appear after clicking "Resume Case" button.

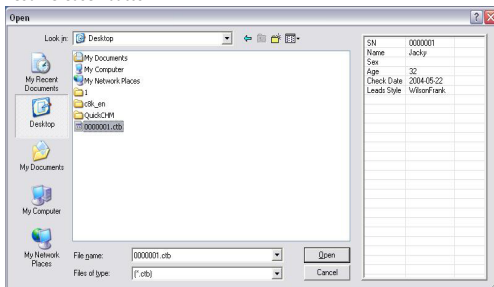


Figure 35

Click "Backup Case", the relevant information will be listed in the right. Select all cases you need to resume, click "Open" button, then the backup cases will resume to the current database.

If the record has already existed in current database, the interface shown as Figure 36 will appear. Choose according to your actual need.

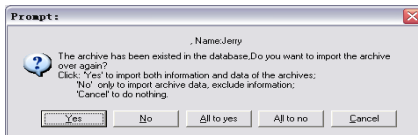


Figure 36

Statistic: Case statistics function can count the items in lateral or longitudinal shown as Figure 37. The statistics result will be displayed in a list.

Patient Database

Query Item: Name: [] Sex: []
Case No.: [] Section: []
SR: [] to []
Age: 50 to 50
Time: 2004-5-22 to 2016-12-15
Doctor: [] Label: []
12333: []
Item 2: []
Item 3: []
Item 4: []
Remark: []
VerCount: By office [] HorCount: By time []
Run Query Clear Query Statistic

Buttons: Load Selected Patient, Delete Selected Patient, Modify Selected Patient, Update Database, Backup Case, Restore Case, Compare Case, Label Manage, Exit

Lead Style: ☐ Wilson, ☐ Frank, ☐ NAF, ☒ All

Case Style: ☒ Modeleted, ☐ Deleted, ☐ All

	2004-05--2016-12	Total
Other	5	5
2013-1	1	1
2013-2	1	1
2013-6	1	1
2015-6	1	1
2016-1	1	1
456789012345	1	1

Export

Figure 37

Compare Case: Choose two cases of Wilson system in the case list, select case comparing function, the interface shown as Figure 38 will appear.



Figure 38

Label Manage:Any combination of query criteria is available and can be saved as a tag. You can add, delete and modify the tag, as shown in Figure 39.

Query Lable [X]

Query Item

Name: Sex:

Case No.: Section:

SN: to

☐ Age: to

☐ Time: to

Doctor:

Item1:

Item2:

Item3:

Item4:

Remark:

Lead Style

☐ Wilson ☐ Frank

☐ W&F ☒ All

Label List

Label Manage

Modify Default

Add Save

Delete DelDefault

OK

Figure 39



9.1.3 Quick print

This function allows you to print the record quickly without entering each analysis items (As Figure 40).

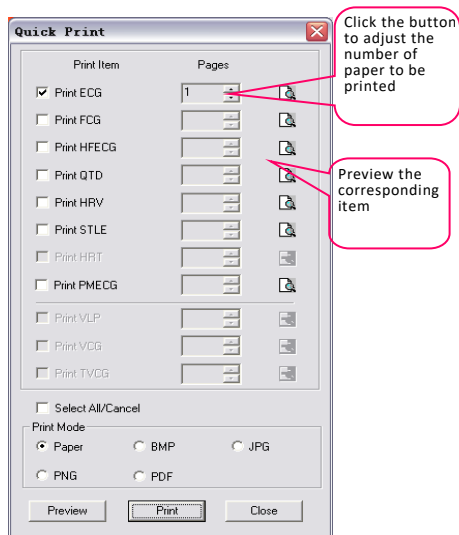


Figure 40

You can select or cancel the items by clicking the selecting box in the front of every print item, adjust the print pages

according to your need, and preview the corresponding report by clicking the button  in the last line.

"Select All / cancel" button can help you select or cancel all of the print items quickly.

Choose proper print form in ""Print mode" according to the actual need. Select "Paper", project report will be printed in the form of paper. Select "BMP", "JPG", "PNG" or "PDF", report will be saved in computer. When you select one way and click "Print" to save, save path can be selected through "Print Setting" in the "System Settings". Refer to "9.1.4 System Settings".

"Preview" button can help you preview all print items selected. "Print" button can print or save the print item selected according to "Pages" and "Print Mode".

It is need to say that, quick print function is to provide convenience for users. So when you enter into any project for analysis, the system will automatically save the item status exited the analysis item, and quick print according to the last status. As the print function of the system follows the principle of "What You See Is What You Get", in any analysis item, you only need choose the most suitable view. The record will be printed conveniently by quick print after exiting.

If some item becomes gray, as Figure 41, it indicates that this analysis item can not be printed or met the print requirement. For example, if "FCG analysis" item can't be used, it indicates the data doesn't meet the length required by analyzing the spectrum ECG. If the "HRT analysis" item can't be used, it indicates that there is no "HRT" in the case or the current case dissatisfies the condition of analyzing HRT.



Figure 41



9.1.4 System Settings

Hospital name, hospital telephone, hospital fax can be set in "Hospital Information" (As Figure 42).

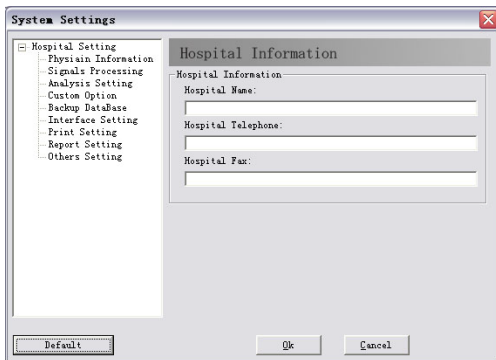


Figure 42

Physician name, physician telephone and section information can be set in "Physician Information" (As Figure 43). Herein, up to 50 sections and 10 physician names can be input and recorded automatically. The physician item in "Patient information" is related with this item, and it will be printed in the diagnosis reports.

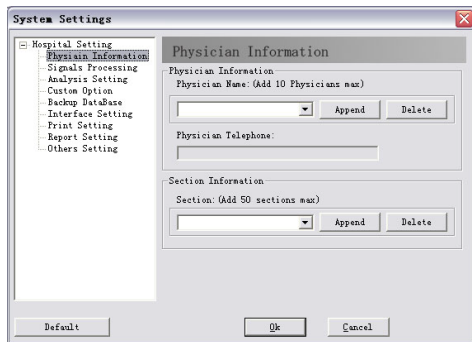


Figure 43

Enable filter, baseline filter, EMG filter, HR prompt sound, calculate VCG, device type, Bk Net Pain and Lead Standard can be set in "Signals Processing" shown as Figure 44.

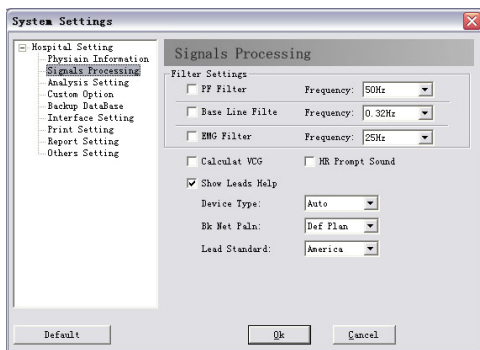


Figure 44

The interference arisen from AC can be filtered after selecting "AC filter". If "Baseline Filter" and "EMG filter" are selected, the ECG wave will be better, but at the same time they will affect the ECG signal in some degree. So we propose to choose them cautiously.

The items set in "Signals Processing" will be applied to actual sampling automatically and regarded as the default selection, but it does not mean that we can't change the settings during sampling. You can also change them manually before or during sampling (Refer to "8 New Patient Sampling").

In "Analysis Setting" (As Figure 45), you can set the heart rate channel, arrhythmia parameters and the print form of diagnostic conclusions, etc.

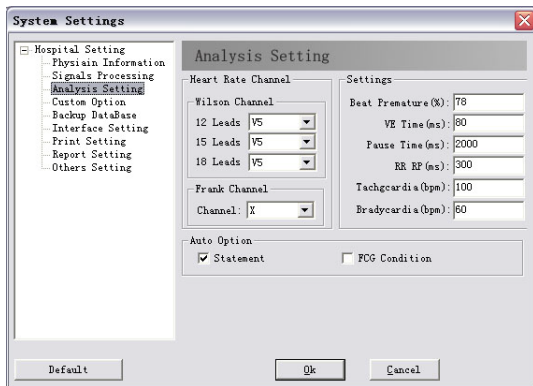


Figure 45

During sampling, the system analyses heart rate according to the chosen channel, which can also be modified at any time (refer to "8 New Patient Sampling").

In "Custom Option" (As Figure 46), you can edit custom items and select whether to print.

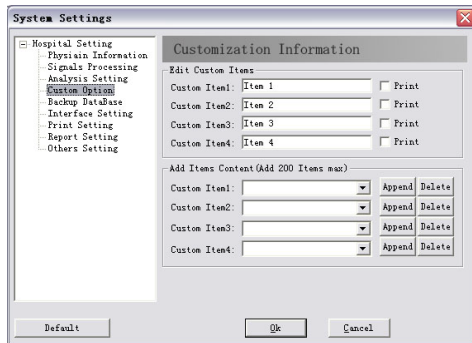


Figure 46

The items corresponding to "New Patient" can be modified by modifying customer item. For example, change the content in "Custom Item 1" to "Examination No.". When you click the button "New patient" on main interface, the former item 1 will become "Examination No.". You can add the items according to your need. If you choose "Print", the corresponding custom item will be shown on the top of the report.

In the "Backup DataBase" (As Figure 47), you can set up auto backup time, resume methods, save path. You can also resume the backup database file to the current file by "Select Film" (As Figure 48).

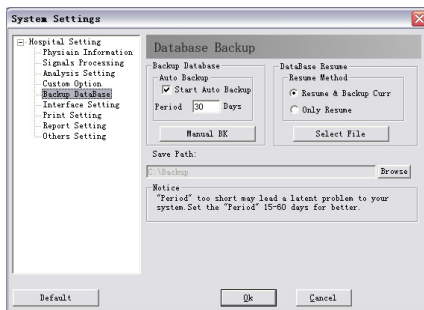


Figure 47

database backup consistent when choosing file to resume.

When you resume the database, you'd better update in "Case Management" (refer to "9.1.2 Case database management") to keep the database and case file consistent.

In "Interface Setting" (As Figure 49), you can set the main interface, show waves, language, database management and age precision, etc.

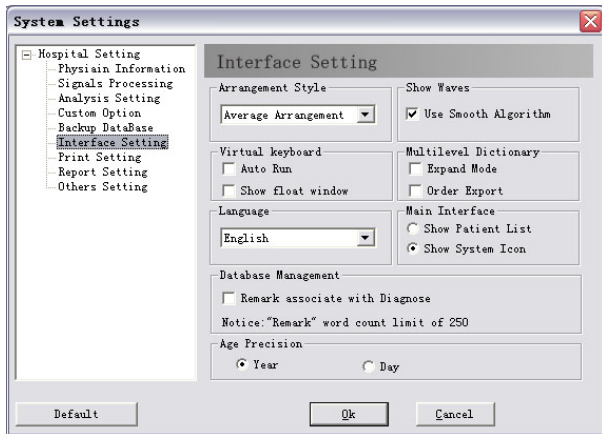


Figure 49

In "Interface Setting", if you choose "Show Patient List", the main interface will be shown as Figure 50.

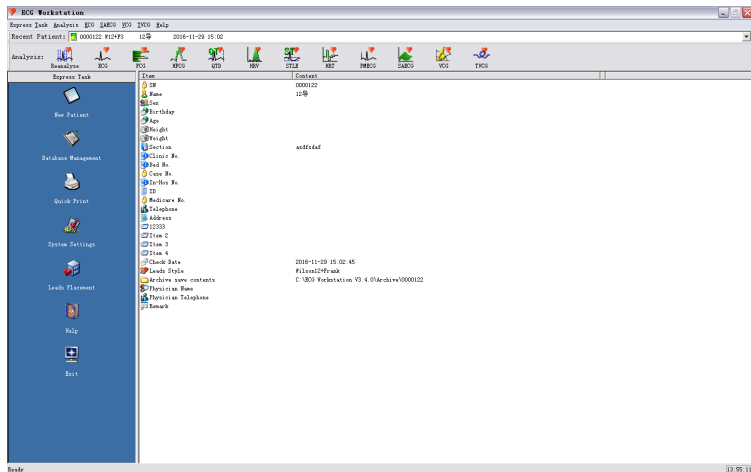


Figure 50

63

If you choose "Use Smooth Algorithm" in "Show Waves", the ECG waves will become smoother. As Figure 52, Figure 53:

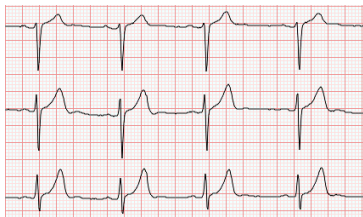


Figure 52 Use smooth algorithm

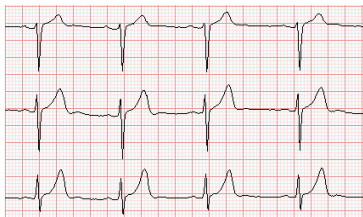


Figure 53 Not use smooth algorithm

"Language" can switch the language between Chinese and English. "Arrangement style" can change the default arrangement style in "12 leads ECG" (refer to the leads arrangement explanation in "9.2.2 ECG"), which includes "Smart Arrangement" and "Average Arrangement". "Database management" can help you to associate the remark with the diagnosis information, that is the diagnosis information will be saved in the database as a part of remark. In "Print Setting", you can choose the paper type, printing arrangement style, and whether print diagnostic information or scale signal (As Figure 54).

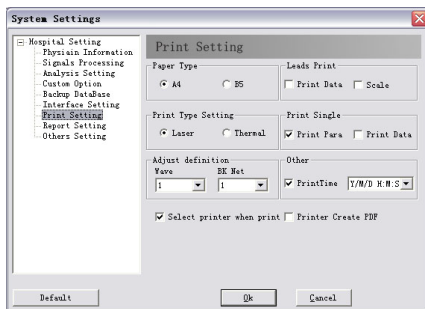


Figure 54

You can change the default save path of reports (PDF/JPG/PNG/BMP) by clicking "Save Path". The information about how to generate reports of PDF/JPG/PNG/BMP form, please refer to "9.1.3 Quick print". The software provides two save types in accordance with "Date" and "Case". The "Date" type represents that all print reports will be classified and saved by testing date. For example, an ECG is sampled on May 20th, 2008, and its serial number is 0000002, if the case report is exported to PDF on May 28th, 2008, the report will be saved in a specified path naming "20080528". While if you selects "Case" for save type, the report will be saved in a specified path naming "0000002". You can choose the print type from two different types of "laser print" and "thermal print". Also, the bold level of waveform and background can be set.



Caution: In "Print Setting", "Scale Signal" is valid when the "Arrangement Style" is set to "Average Arrangement"(Refer to "Interface Setting" in "9.1.4 System Setting").

In "Report setting"(as Figure 55), you can set Report Title,Report Head,Print SN and Small Net.

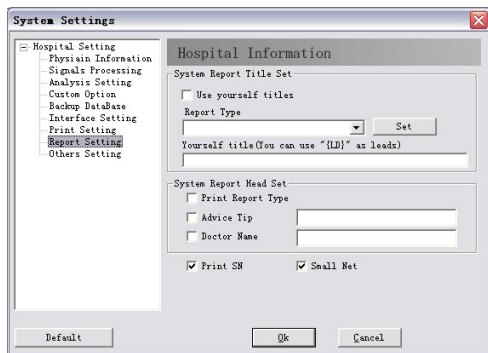


Figure 55

Patient information to be checked, files save path and name, create files can be set in "Others Setting" (As Figure 56).

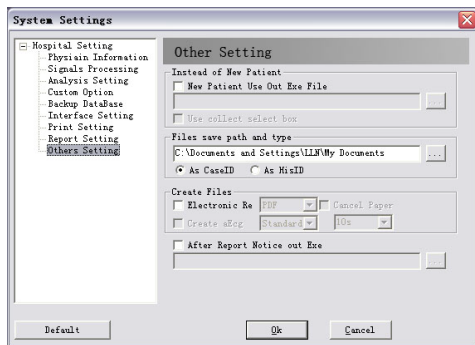


Figure 56

In “Others Setting”, “Instead of New Patient” can be input by “...” to select external procedure. “Use collect select box” can be used after selecting “New Patient Use Out Exe File”, then the dialog box of collection type will appear.

“Files save path and type” is used to set the electronic report. Its path can be changed by “...” on the right of “Files save path and type”. “Create Files” is used to set created mode and whether to create aEcg files. After selecting “Electronic Re”, electronic report formats(PDF, JPG, BMP or PNG) can be selected. Paper report can be printed if “Cancel Paper” is not selected, otherwise it only prints electronic report. It only prints paper report if “Electronic Re” is not selected. “After Report Notice out Exe” is used to connect with external procedure and inform it to process the report.



9.1.5 Lead Placement

Lead placement graph can be checked at any moment by this function. The specified method can be found in "Electrode placement".

Wilson connection is shown as Figure 57.

Frank connection is shown as Figure 58.

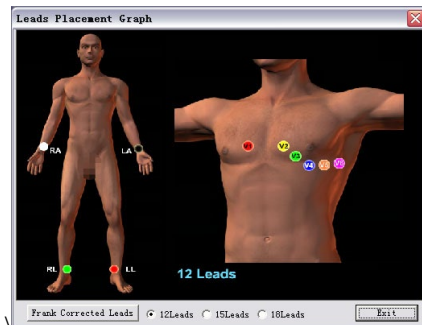


Figure 57

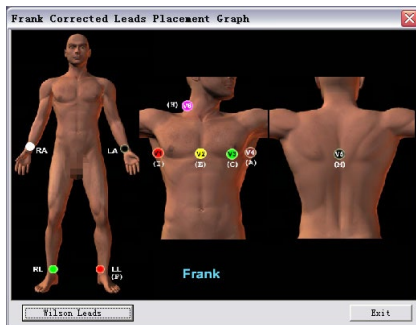


Figure 58



9.1.6 Help

Click it to run the help system.



9.1.7 Exit

Click it to exit and close the system.

9.2 Analysis



9.2.1 Reanalyse

Click this button to enter the "Reanalyse" interface (Wilson and Frank Leads analysis: Figure 59/ Figure 60, Wilson Leads analysis: Figure 61, Frank Leads analysis: Figure 62). Or "Reanalyse" interface will automatically appear after collecting (Wilson and Frank Leads analysis: Figure 61/ Figure 62, Wilson Leads analysis: Figure 61, Frank Leads analysis: Figure 62).

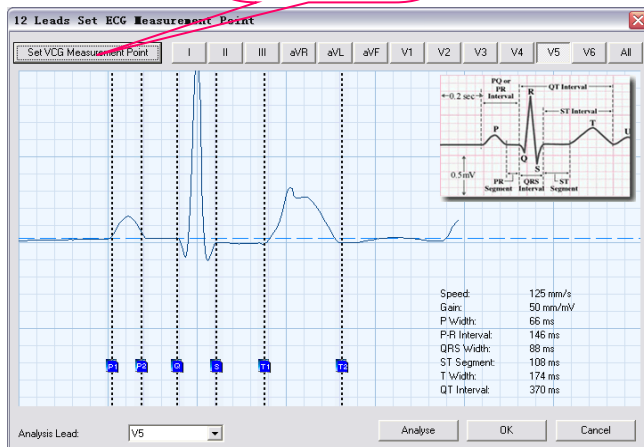


Figure 59

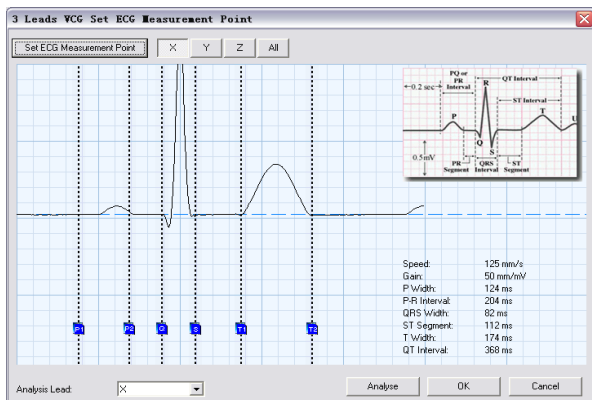


Figure 60

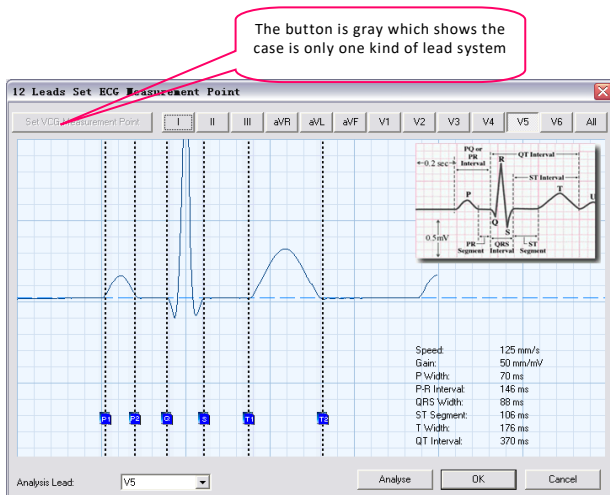


Figure 61

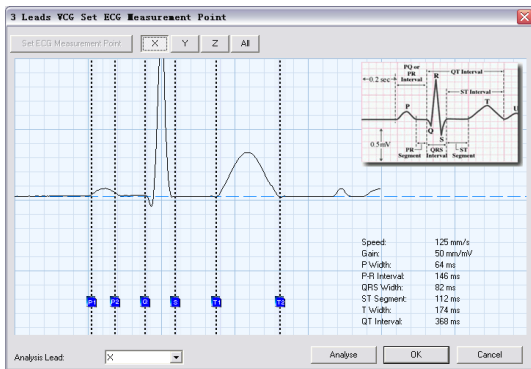


Figure 62

The methods to solely analyze Wilson or Frank lead style are similar. When sampling by Wilson and Frank at the same time, you can switch to Wilson lead style by clicking "Set ECG Measurement Point" or switch to Frank lead style by clicking "Set VCG Measurement Point".

You can choose the main analysis lead by clicking the "Analysis lead" on the left bottom.

You can adjust the beginning and end points of P wave and T wave, the beginning point of Q wave and the end point of S wave by adjusting line P1, P2, Q, S, T1, T2. If the positions of the six points are exact, the analysis result will be more accurate. The data on the right bottom includes P Width, P-R Interval, QRS Width, ST-Segment width, T Width, QT Interval. You can click "I", "II", "III", "aVR", "aVL", "aVF", "V1", "V2", "V3", "V4", "V5", "V6" or "X", "Y", "Z" at the right of lead to display corresponding lead. Select "All" to display all leads. The main analysis lead is displayed as default



Figure 64

Click the icon in the bottom-right corner of the diagnostic interface to lock the diagnostic interface, so it will no longer be restricted by the area where the mouse is located, as shown in Figure 65.



Figure 65

- **Wave Property:** 12-lead sync waves are shown in this template. There is an arrowhead on every wave, the red one indicates the wave has been enabled, and the gray indicates the wave hasn't been enabled. If there is no arrowhead above a QRS wave, it represents the QRS wave has not been analyzed automatically. Here you should click "Edit" to add it. If the QRS wave is abnormal, for example, APB or VPB, there are red letters to mark its attribute, which are listed as following:

"S": APB

"V": VPB

"L": Long Intermission

"O": Interference

"P": Pacemaker

The numbers between two arrowheads denote RR interval of the QRS wave and HR calculated according to the RR interval.

- **Lead Position Adjustment:** This module supports lead position adjustment. Click left button of mouse on the lead

label, then drag to move waves. Click right button of mouse on the lead label to hide corresponding waves, and click again to recover them. Click right button of mouse on blank place of lead label, the lead arrangement menu will appear, you can set it to "Smart Arrangement" or "Average Arrangement" (the default arrangement can be modified in "System Settings"). You can also click "Show All" to display all of the hidden leads.

As Figure 66:

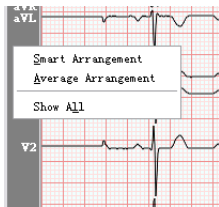


Figure 66

- Speed and gain adjustment: adjust gain to display in one page or several pages (As Figure 67).

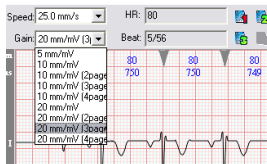


Figure 67



Figure 68

- **"Previous":** Select the previous beat.
- **"Next":** Select the next beat.
- **"ECG":** select wave arrangement mode during wave review, as Figure 69:

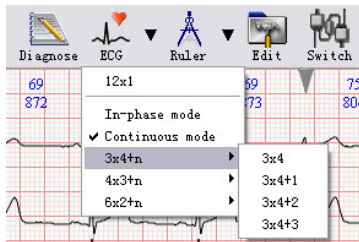


Figure 69

- **"Ruler":** the cursor will become ruler-like. Click the left key of mouse and drag to draw a blue rectangle, whose length between left and right shows time(ms) interval and length between up and down shows voltage(mv). These measure results will be displayed after you release the left button.
- **"Edit"**(As Figure 70): edit the attribute of the chosen beat. Here a blue rectangle will appear, in which is the current chosen wave. Press corresponding keys ---"V", "S", "L", "O", "D", "P", "N" to modify the property of wave.

The meanings of keys are: "S": APB, "V": VPB, "L": Long Intermission, "O": Interference, "P": Pacemaker, "D": Del, "N": Normal. It can also add beats.



Figure 70

- **"Switch":** the lead with error can be switched.
- **Magnifier:** waveform can be magnifier, convenient to check.
- **"Diagnose"** (As Figure 71): Turn to diagnosis interface. At first, it will enter the wave superimposition interface.

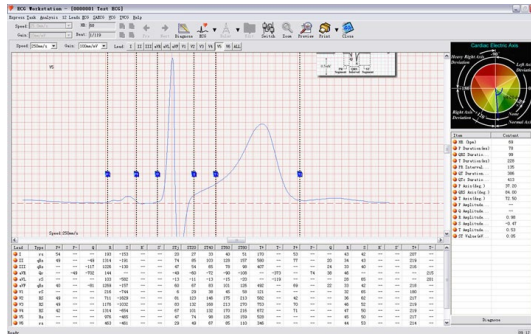


Figure 71

Main functions for this interface: display superimposition wave, display and modify the position of mark points, display ECG axis graph, calculate and display relative diagnosis data.

You can choose to superpose the beats of a single lead or of all leads. The superposition of all leads makes the position of the 6 mark points more accurate. (As Figure 72)

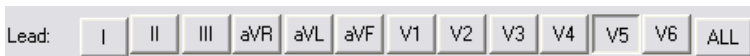


Figure 72

6 mark points are as followings:

P1: the start position of P wave

P2: the end position of P wave

Q: the start position of QRS wave

S: the end position of QRS wave

T1: the start position of T wave

T2: the end position of T wave

When you adjust these points, the corresponding results will change. When you think that the current case is not Sinus bradycardia, you can superpose or exchange P1 and P2, then the data related to P wave will be cleared. Notice: don't confuse the sequence of the six mark points.

You can adjust gain and speed to magnify the waves on the screen to observe waves more conveniently. (As Figure 73)

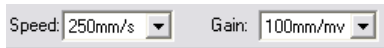


Figure 73

The data which are read automatically or recalculated are displayed in the list box in the bottom right corner, including:

1. Heart rate (bpm)
2. P duration (ms)
3. QRS duration (ms)
4. T duration (ms)
5. PR interval (ms)
6. QT interval (ms)
7. QTc interval (ms)
8. P axis (degree)
9. QRS axis (degree)
10. T axis (degree)
11. P wave amplitude (selected lead, mV)
12. Q wave amplitude (selected lead, mV)
13. R wave amplitude (selected lead, mV)
14. S wave amplitude (selected lead, mV)
15. T wave amplitude (selected lead, mV)
16. ST value (selected lead, mV)

The data results via superposing will be given in Data Table, these parameters are:

Table 1:

Item	Unit	Item	Unit	Item	Unit
HR	BPM	P duration	ms	QRS duration	ms
T duration	ms	PR interval	ms	QT interval	ms
QTc interval	ms	P axis	degree	QRS axis	degree
T axis	degree	P amplitude	mV	Q amplitude	mV

R amplitude	mV	S amplitude	mV	T amplitude	mV
ST value	mV				

Table 2:

QRS type(12-lead), P wave amplitude (positive and negative) (12-lead, μV), Q wave amplitude (12-lead, μV), R wave amplitude (12-lead, μV), S wave amplitude (12-lead, μV), R' amplitude, S' amplitude, J point ST amplitude (12-lead, μV), 20ms ST amplitude (12-lead, μV), 40ms ST amplitude (12-lead, μV), 60ms ST amplitude (12-lead, μV), 80ms ST amplitude (12-lead, μV), T wave amplitude (positive and negative) (12-lead, μV), P duration (positive and negative, 12-lead, ms), Q duration (12-lead, ms), R duration (12-lead, ms), S duration (12-lead, ms), R' duration (12-lead, ms), S' duration (12-lead, ms), T duration (positive and negative) (12-lead, ms).

- **Data Dictionary:** The data dictionary of 12-lead interface includes secondary data dictionary and multilevel data dictionary. Use "Data Dictionary" to insert diagnostic terms.

You can add your own technical terms or arrange the sequence of terms according to your need. (As Figure 74). Multi-row display is supported.

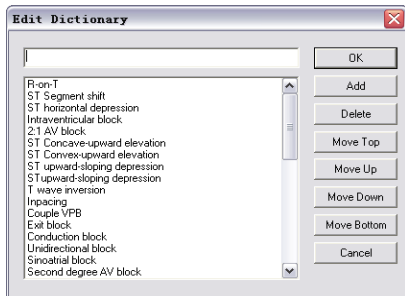


Figure 74

Here we introduce how to edit directory.

"Add" can add the term you entered in the blank into directory.

"Delete" can delete the selected term from the directory.

"Move top" can put the selected term to the first line of the directory. By the operation, you can place the common terms on the top of the directory conveniently.

"Move up" can move the selected term to one order upward.

"Move down" can move the selected term to one order downward.

"Move bottom" can move the selected term to the bottom of the directory. For the terms which are not usually used, you can place them on the bottom of the directory conveniently.

For your convenience, we add intelligent arranging function. The terms which are often used will be arranged at the top of the directory. The terms which are not often used will be arranged at the bottom of the directory.

Introduction of multilevel data dictionary is shown as below (as Figure 75):

There are a lot of technical terms added in the data dictionary. Select the terminology you need, and then click "OK" button, these terms will be imported into the prompt list, which greatly improves the efficiency for doctor's diagnosis. Click "Font" to set the font and color of data dictionary, "Add" to add new terms, "Modify" to re-edit the term, "Delete" to delete the term, "Move up" and "Move down" to adjust the position of the current term, "Move top" to place the selected term to the first row of the directory, "Move bottom" to move the selected term to the bottom of the dictionary. All modifications to the data dictionary shall be saved after clicking "Save" button, or it will return to the initial state when software restarted.

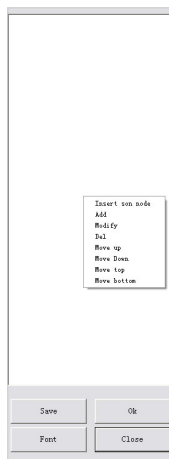


Figure 75

- **Print** and preview: the functions are same as the "Print" and "Preview" in "Diagnosis", it can print report with 12-lead ECG. Attention: in this dialog box, there are two print methods ("Horizontal", "Vertical"). See figure



9.2.3 FCG



FCG is to distill some reference information hidden from 12-lead ECG waves.

FCG is used to diagnose the patient with myocardial infarction history by analyzing the abnormal Q waves and locating comparing them according to the theory that Q wave is no more than 1/4 of the main wave and Q duration is less 0.04s.

FCG analysis interface is shown as Figure 76:

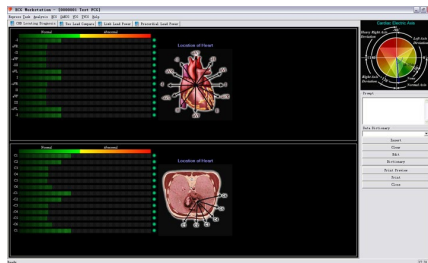


Figure 76

The upper part of interface is the analysis for the front side of the heart, where the leads include: I, -aVR, II, aVF, III, -aVL, -I, aVR, -II, -aVF, -III and aVL. Here the negative sign before lead shows the direction of that lead is reverse with the lead without negative sign. The lower part of interface is the analysis for the transverse plane of the heart, where the leads include: V1, V2, V3, V4, V5, V6, -V1, -V2, -V3, -V4, -V5 and -V6. In normal conditions, the mark light at the right of the chromatogram for corresponding lead is green. If chromatogram is abnormal according to the above standard, the light will turn red for caution. You can modify or add interpretation according to your diagnosis, which is shown in the diagnosis report.

Power Spectrum Analysis, as Figure 77.

Through comparing the peaks, the power spectrum of 12 leads can help doctors to diagnose. You can click the buttons to check limb lead power spectrum or precordial lead power spectrum. Click "Print Preview" or "Print" to preview or print reports.

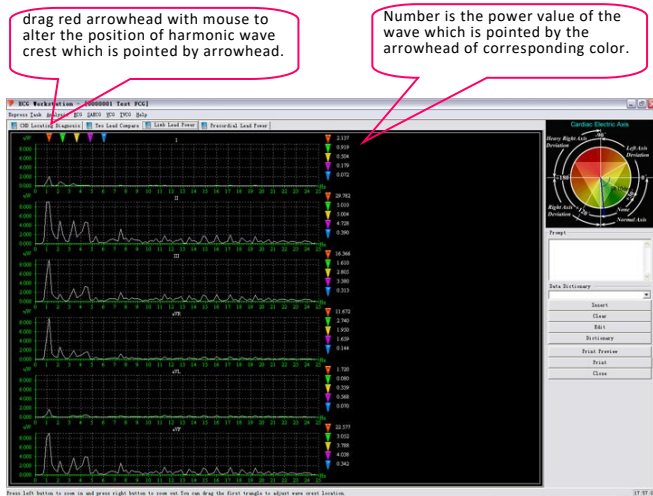


Figure 77

On "Limb Lead Power" and "Precordial Lead Power" analysis graph, there are five triangular arrowheads with different color which point to the harmonic peaks of five conjoint power, you can use the mouse to move the first red arrowhead to change the five arrowheads indicated the location of the harmonic peaks of power spectrum.

In the power waveform drawing area, you can click the left button to amplify the graphic and click the right button to reduce it.

The figure following the vertical arrows at the right interface indicates the values of power spectrum curves which are pointed by corresponding arrowheads.

Corresponding analysis for the two leads is shown as Figure 78.

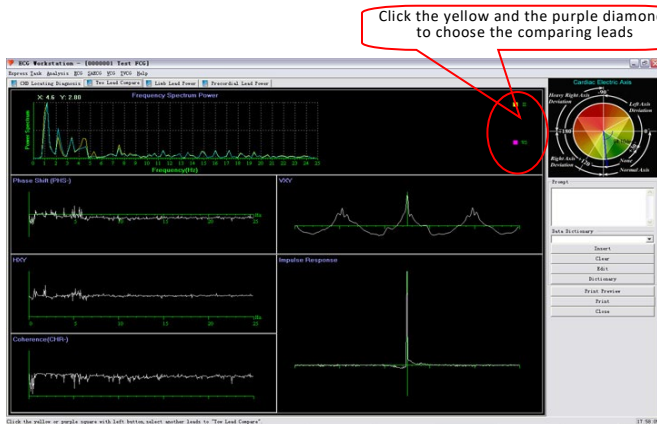


Figure 78

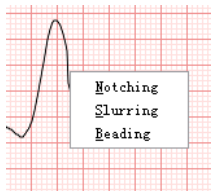


Figure 80

- The statistic table on the left-bottom corner of the screen displays the number of notching, slurring and beading in all 12 leads. Click the right key of the mouse on the waves, the shortcut menu will appear, then click corresponding items to modify wave attribute (As Figure 80). After modifying, your selection will be displayed at the left of waves (As Figure 81), and the number of attribute in the data statistics table will be changed.

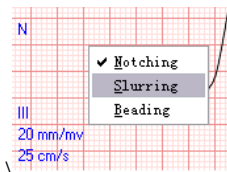


Figure 81

- In default, enlarged wave of six-lead single beat displays on the screen so that you can observe whether the enlarged beats have notching, slurring and beading. You can click "Leads combination style" to select which leads to be displayed in six panes. In order to observe conveniently, a list box is given below the HR trend graph for gain adjustment, where you can select the enlargement factor for single beat.

- In the middle part of HFCG interface, which displays continuous wave, you can select which beat wave will be enlarged in below six panes by pressing "Next" or "Preview" to move the green erect line frame or fill in the number to be checked in "Jump to".
- You can also print and preview the HFCG report. Both case report and ECG waves can be printed, so that patient or hospital can save for long time.



9.2.5 QTD

QTD(QT dispersion, QTd) is the difference between the max and the min value of the QT interval in 12-lead ECG, which reflects the inhomogeneity of ventricular myocardium repolarization mainly, and which stands for difference of refractory period in ventricular myocardium (As Figure 82).

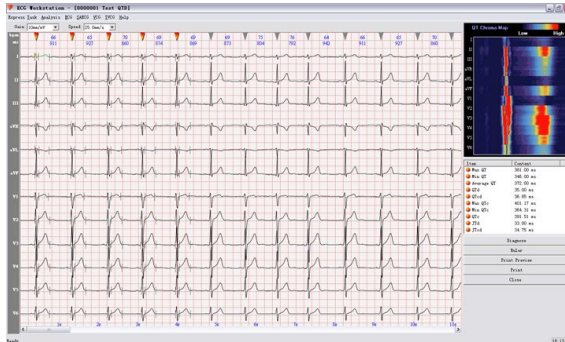


Figure 82



HRV

analysis i

HRV analysis is shown as Figure 83 and Figure 84.

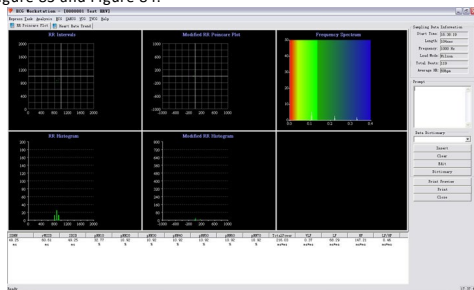


Figure 83

Attention: HRV makes sense for the case more than 5min.

HRV graphs include RR interval histogram, RR interval dispersion histogram, RR interval poicare, RR interval dispersion poicare, RR interval trend graph and HR trend graph.

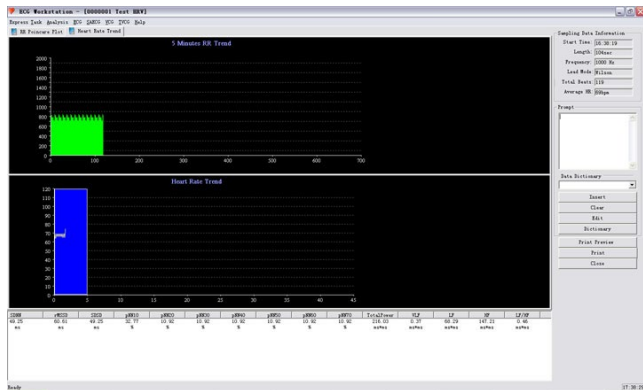


Figure 84

- ◆ RR Interval Histogram is a graphic mode which reflects the distribution of the RR interval at a period of time (such as 1 hour, 12 hours, 24 hours). The horizontal axis expresses the R-R interval, and the vertical axis expresses the corresponding number of heartbeats. The shape of RR Interval Histogram intuitively reflects circumstance of HRV. When the histogram is high and narrow, it demonstrates the value of HRV is smaller than the normal. On the contrary, the value is larger than the normal. The RR Interval Histogram has single peak value. But most of persons

with double peaks even multi-peak are normal, which mostly appears in the normal persons with bigger HRV.

- ◆ The statistics of RR interval dispersion histogram is on the basis of the margin of two neighboring RR Interval from sinus node (unit: ms). The horizontal axis is the margin of two neighboring RR Interval from sinus node, the center is 0. The later RR Interval is longer than the former one, the margin is plus, whereas the margin is negative. And the vertical axis is the numbers of heartbeat.
- ◆ The RR interval dispersion histogram reflects the difference of RR interval, namely, the extent of Arrhythmia.
- ◆ The RR interval histogram reflects the macroscopical degree of heart rate change.
- ◆ The horizontal axis of the RR interval poincare graph(it reflects the whole change of heart rate) is the RR which is the previous R-R interval length of two adjacent sinus cardiac cycle. And the vertical axis is the next one. It has four shapes: (1) the comet shape (2) the torpedo shape (3) the anomalous shape (4) the fan shape. The last three cases are exceptional graphs.
- ◆ The horizontal axis of RR interval dispersion poincare is the difference of previous neighboring RR Interval from sinus node, and the vertical axis is the difference of next neighboring RR Interval from sinus node. The values distribute in the four quadrants around the center. The more it's in the second and fourth quadrants, the larger extent of dispersion it shows and the larger HRV is.



9.2.7 STLE

Myocardial ischemia will appear when coronary artery can not meet the energy need of the cardiac muscle. It can be divided into two types, myocardial demand oxygen increase and oxygen supply Reduce. In fact, myocardial ischemia is the result of the two types. The main interface is as following (As Figure 85).

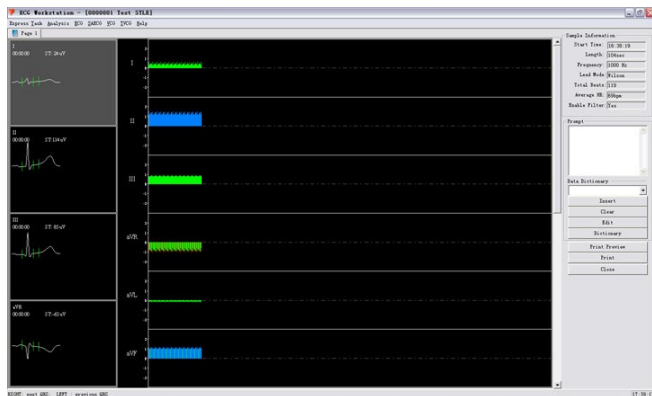


Figure 85

The size of each heartbeat ST-segment of 12-lead displays in the central of this interface, which marks with red (ST-segment is too low), green (ST-segment is in the normal range) and blue (ST-segment is high). In this interface, you can choose "Setting Compare" or "Delete Compare" by clicking the right button of the mouse at current histogram (the location of vertical line) (As Figure 86).

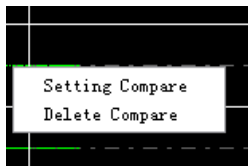


Figure 86

At the right of the interface, you can choose the current QRS index by double clicking the left button of mouse. You can also use the key P or N to achieve this function. P shows the previous of current index, N shows the next of current index. The left interface of Myocardial ischemia shows the QRS wave corresponding to the current index, it shows the four leads (I/II/III/aVR) in default. You can also select the lead to be checked by the right key (As Figure 87).

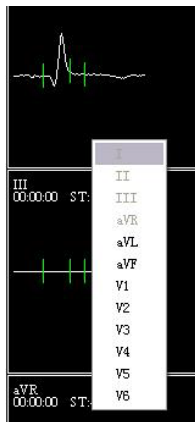


Figure 87



9.2.8 HRT

HRT is a kind of bidirectional physiological response of sinus node to ventricular premature contraction. It shows the short-time heart rate acceleration and following heart rate deceleration. HRT can be expressed by two parameters(TO and TS). Premature ventricular beat can lead to the blood pressure turbulence of artery (low amplitude premature beat and the following normal heartbeat of high amplitude). When the auto-adjustment function of human body is natural, the short-lived change will be shown in the form of HRT immediately. When the auto-adjustment function of the human is damaged, this change will weaken or even disappear (As Figure 88).

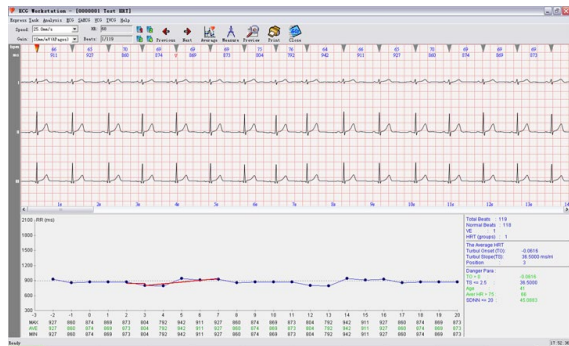


Figure 88

The 12 leads ECG is shown on the top, which are displayed in four pages in default. You can click    to choose QRS wave to be checked. You can also superpose all possible HRT, then the superimposition wave will display at the bottom of the interface, shown as Figure 89.

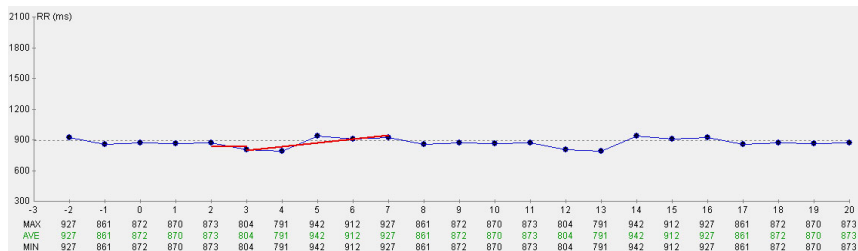


Figure 89

The vertical lines on upper and lower location of dots, express the largest or the smallest RR interval for the same point on the HRT wave at the different time.

The data showed below the figure denotes the largest, the average and the smallest RR interval of corresponding point.

The conclusion display area locates in the lower right corner(As Figure 90):

Total Beats	: 119
Normal Beats	: 118
VE	: 1
HRT (groups)	: 1
The Average HRT	
Turbul Onset (TO):	-0.0621
Turbul Slope(TS):	36.7000 ms/mri
Position	: 3
Danger Para :	
TO > 0 :	-0.0621
TS <= 2.5 :	36.7000
Age :	41
Aver HR > 75 :	66
SDNN <= 20 :	45.2819

Figure 90

When the results arrives "Risk index", the corresponding data would turn red to alert users. If you don't check the whole case report, "Normal beats" will show "No judge".

When the records did not find HRT, the hint "None HTR found!" will be shown at the bottom of the interface, at the same time the top function buttons are not available (As Figure 91):



Figure 91



9.2.9 PMECG

PMECG is a kind of surface electrocardiogram after implanting artificial heart pacemaker. As the pacing region and the pacing type are different, the recording ECG is different. PMECG includes P-QRS-T-wave group and pacing signal. The familiar pacing width is 0.4~0.5ms. In the 25mm/s ECG, pacing signal is a short vertical line which is called linear waves, named S signal, whose amplitude has the larger differences in various leads. Pacemaker detection channel: standard lead II. The pacing impulses collected on the remaining leads are regarded as pacing markers.

The module of the PMECG is shown as Figure 92:



Figure 92

It shows the basic waves of PMECG at upper half of interface. S signal can be found in the waves. The bottom half part of the interface lists the pacing signal's proportion in the form of list table. The explanations of pacing type are as following:

DD: double antrum beat

VO:ventricular false fusion wave range

VFB:ventricular fusion beats

VOS:ventricular over sense

VP:ventricular full pacing

VUS:ventricular under sense

AP:atrial pacing wave

AOS:atrial over sense

Pacing module provides the function of parameter settings (As Figure 93).

Pace Maker Parameters

Parameters:

Implanted Date: 2015 Year 5 Month 12 Day

AV Delay: 200 ms Signal Width: 2 ms

Type: DDD Mode:

Atrial Cycle:

Upper: 500 ms Lower: 1000 ms

Ventricular Cycle:

Upper: 500 ms Lower: 1000 ms

OK

Figure 93

You can set the specific time of implanting pacemaker, pacemaker models, pacing type, timing period of atrial and ventricular, AV delay, signal width, etc. After setting, click “OK” to save. If you modify the parameters, the system will calculate the pacing proportion according to the new parameters.

9.2.10 SAECG

VLP is a sharp wave that appears at the end of QRS waves and ST Segment, which has the characteristic of high frequency and low amplitude with an equipotential activity sometimes. Most of circumstance, VLP almost appears on patient with myocardial infarction.

The interface of SAECG is shown as Figure 94:

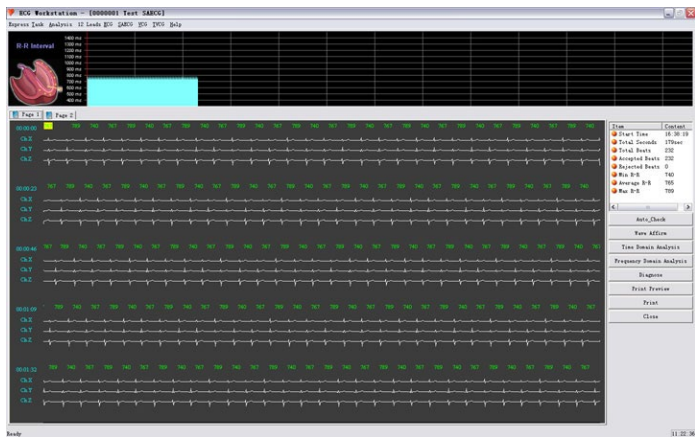


Figure 94

R-R interval graph is plotted at the upper interface. You can select a beat in the bottom interface by clicking the left key of mouse, or clicking directly on the waves to select it, which can select to accept or reject heartbeat to analyze. In this figure, the white wave denotes the wave is accepted, the gray wave denotes the wave is rejected. On the right table, some statistical data will be displayed automatically.

Click "Auto-Check", you can set the percent higher or lower than average heart rate. The default value is 10% (As Figure 95).

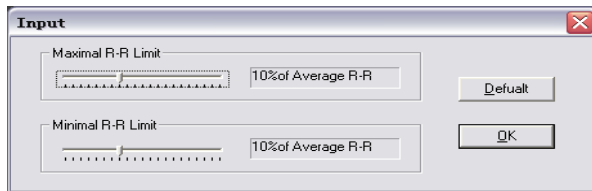


Figure 95

Click the "Time Domain Analysis" and "Frequency Domain Analysis" button to enter their sub-menu.

The small waves at the upper interface are superposition waves. You can adjust the position of window by clicking the left key of mouse. The default is 20ms point after the end of QRS wave.

Frequency Domain Analysis is changed when the QRS ending point of the unfiltered wave is changed.

Frequency Domain Analysis is shown as Figure 96.

You can select the vertical line using the left button, and adjust the position of the line by using the left and right key on the keyboard.

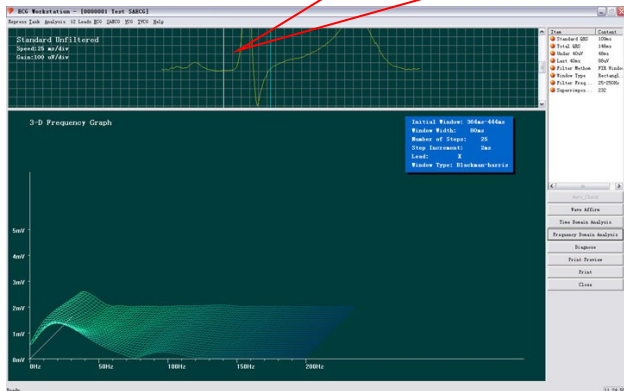


Figure 96

You can select the vertical line by using the left button and adjust the position of the line by using the left and right key on the keyboard. Then the following "Three-dimensional spectrum graph" will also be changed. Time Domain Analysis is shown as Figure 97:

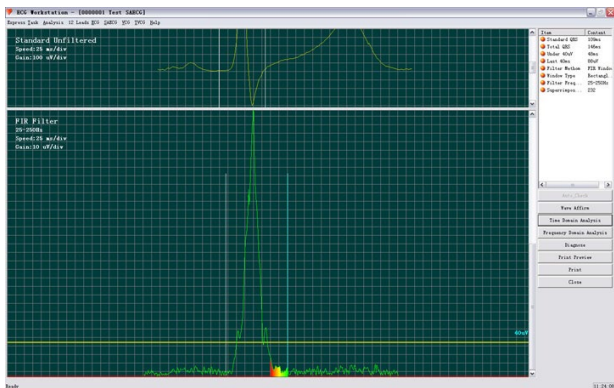


Figure 97

In this interface, you can also adjust the vertical line of "No filter wave". You can also use the same method to adjust characteristic point position of the waves after filtering.

In "Time Domain Analysis" interface, the upper is single-lead ECG waves via superimposition, the bottom half part is filtered single-lead ECG waves via superimposition. You can select and mark by clicking the left key of mouse.

1. You can move QRS start point of unfiltered wave by pressing the left or right key.
2. You can move QRS end point of unfiltered wave by pressing the left or right key.
3. You can move QRS start point of filtered wave by pressing the left or right key.
4. You can move QRS end point of filtered wave by pressing the left or right key.

Here you can preview and print the VCG report, or print every vector loop and amplificatory VCG of all planes (As Figure 98).

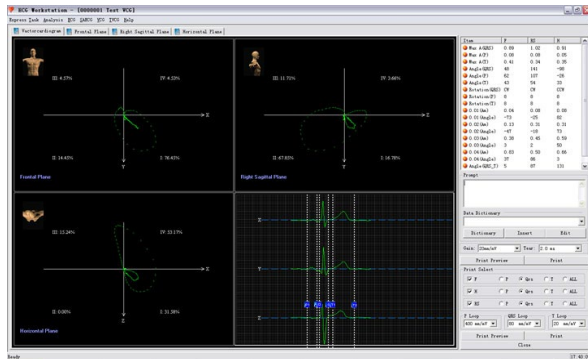


Figure 98

Double-click the figure show area of the Frontal plane (the Right Sagittal plane or Horizontal plane), you can enter the amplified Frontal plane (the Right Sagittal plane or Horizontal plane) (As Figure 99).

You can select and set the format of the report to be printed at lower right area of the interface. The "Report of Print vector total" includes three-vector rings and integrated data. You can also select which vector and which vector ring will be

printed in the "Print Select" region (P ring, Qrs ring and T ring).

The percentage of QRS area which falls in II, III, IV or I phases are displayed in the edge of that phase.

VCG parameters are as follows:

Max A (QRS) maximal amplitude of QRS loop (mV)

Max A (P) maximal amplitude of P loop (mV)

Max A (T) maximal amplitude of T loop (mV)

Angle (QRS) angle of the max QRS amplitude (degree)

Angle (T) angle of the max T amplitude (degree)

Angle (P) angle of the max P amplitude (degree)

Rotation (QRS) rotation direction of QRS loop

CW - clockwise

CCW - counter clockwise

"8" - 8 shape loop

Rotation (P) - rotation direction of P loop

Rotation (T) - rotation direction of T loop

0.01 (Am) - amplitude at 0.01 second from beginning of QRS loop (mV)

0.01 (Angle) - angle at 0.01 second from beginning of QRS loop (degree)

0.02 (Am) - amplitude at 0.02 second from beginning of QRS loop (mV)

0.02 (Angle) - angle at 0.02 second from beginning of QRS loop (degree)

0.03 (Am) - amplitude at 0.03 second from beginning of QRS loop (mV)

0.03 (Angle) - angle at 0.03 second from beginning of QRS loop (degree)

0.04 (Am) - amplitude at 0.04 second from beginning of QRS loop (mV)

0.04 (Angle) - angle at 0.04 second from beginning of QRS loop (degree)

Angle(QRS-T) included angle that between the max amplitude of QRS and T

MaxA(QRS/T) ratio that between the max amplitude of QRS and T

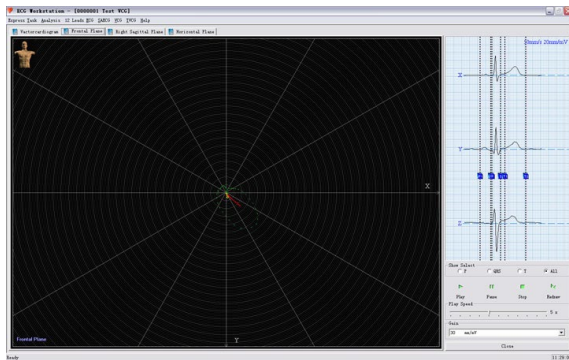


Figure 99

After setting the gain, you can replay the process of the curve forming. P loop is yellow, QRS loop is green and T loop is red. In this interface, click the blue pane at the top and right of the interface and drag the mouse to adjust the start and end point of P, QRS or T waves, and the amplified graph will be plotted again according to the adjusted position.



9.2.12 TVCG

TVCG is a kind of VCG considering the time factor, which is also called the continuous ECG vector. Same as the ambulatory electrocardiography (AECG), it can record and observe every cardiac cycle. This module shows not only the complete TVCG wave, but also waves of X, Y, Z three leads.

The interface is shown as Figure 100:



Figure 100

You can use the toolbar on the left of the screen to change the speed and the gain. Press the little triangle above the wave, or press "Previews", "Next" button to set the current wave. The vector loop of the current wave is shown on the right of the screen.

Measurement button. If you want to measure the period and amplitude of a wave, firstly, press the measurement button, secondly, press the left button of the mouse at the beginning of the wave you want to measure, and move it to the end point of that wave, then release the button. The result will be shown on the screen.

When the button is pressed again, the function will be finished.

The print function can help you to print the TVCG wave.

The "Select" function is mainly to reanalyse and superpose a part or all of the QRS waves according to your selection. The waves and data via superposition can be read in the VCG module. If you do not select, system will superpose all QRS waves

in default. Specific operations: click "Select" button on the toolbar, when the button is in active state, namely arrowhead turns purple to yellow, you can click the left button of the mouse on the arrowhead at the top of the QRS wave to choose it and click "Select" again to change the arrowhead from yellow into purple or exit the TVCG module, system will analyze and superpose again according to your selection (As Figure 101). Then you can read it in VCG module. You can also use the menu, which pops up by right-click on the arrowhead above waves at the selection state, to perform the quick choice.



Figure 101

Chapter 10 Maintenance

10.1 Battery maintenance

- The power supply equipment should be capable of providing a 5V DC voltage.
- The device installed full sealed and maintenance-free rechargeable lithium batteries inside, which adopts perfect automatic charging/discharging monitoring system. It will charge automatically if connected with USB cable. Battery status displayed on the top right corner of the sampling interface after startup. When the device is fully discharged, connect it with a computer by USB cable about 3.5 hours to achieve full charging, 3 hours to achieve 90% charging. If use a power adapter of 5V rated voltage and 1A rated current for charging, about 2.5 hours is enough, 2 hours to achieve 90% charging.
- The device can continuously collecting above 6 hours after fully charged. It will automatically shut down when battery is low, to avoid permanent damage to the battery which is arisen from over discharge.
- Please charge the battery as soon as possible after used up. It shall be charged per three months if you may not use for a long time. Following the direction to use can greatly extend the battery service life.
- Please replace the battery if it is rapidly used up after fully charged or can't be recharged.



Attention

- Don't disassembly the battery privately, failure to properly train personnel in battery replacement can lead to fires. In case of replacement, use only the battery provided by our company. Do not allow anyone but the qualified service personnel authorized by our company to replace the battery. Insert the battery plug in the direction indicated by the battery socket, with the red wire connected to "+" and the black wire to "-".
- Do not contact the positive and negative terminal by the lead, to avoid fire.
- Do not use the battery in environment of fire source nearby or temperature over 60°C, and avoid heating it or throwing it into fire, water or splashing by water.
- Do not destroy the battery, such as chisel, hammer or beat, to avoid producing risk which is arisen from battery

heating, smoking, deformation or burn.

- Please immediately keep away from the battery when it leaks liquid or gives off bad smell. Please wash with clean water immediately when the electrolyte leaks to skin or clothes. If the electrolyte oozes and enters into eyes, please do not massage and wipe eyes, wash with clean water and go to hospital at once.
- Please stop using the battery immediately if it reaches to service life, smelly, shape or color changed or distorted. Please deal with it obeying local regulations and laws.

10.2 Maintenance after use

10.2.1 When unplugging lead cables, please hold the plug instead of the cable to pull it out gently.

10.2.2 Clean the device, wipe the accessories, and cover them with a dust shield.

10.2.3 Place the device in a cool, dry place, and avoid strong vibration when moving.

10.2.4 When cleaning the device, do not immerse it into the cleaning agent. Before cleaning device enclosure, the power supply must be cut off. Use neutral solvent to clean the device. Do not use alcohol-based cleaners or fungicides.

10.3 Inspection and Maintenance of lead cables and electrodes

10.3.1 The conduction of lead cables can be detected by using a multimeter through checking each lead cable. The resistance of each cable from the electrode plug to the semi-circular interface of lead cable connector should be less than 10 Ω . The integrity of the lead cables must be checked regularly, and any damage to them will cause a false waveform on the ECG for corresponding lead or all leads. Clean the lead wires with neutral solvent. Do not use alcohol-containing cleaning agents or fungicides (do not immerse lead wire in the liquid for disinfection).

10.3.2 Bending or knot will shorten the service life of the lead wire, please straighten out the lead wire before connecting the electrode.

10.3.3 Electrodes shall be kept properly. After long-term use, due to corrosion and other reasons, the electrode surface will be oxidized discoloration and then affecting signal acquisition, the electrode shall be replaced.

10.4 Disposal of the product after scrapping

The disposal of packaging materials and end-of-life products must follow the local laws and regulations. User shall dispose

the scrap products and materials properly according to local laws and regulations and try to support the classification recycling.

10.5 Disinfection

To avoid permanent damage to the equipment, it is recommended that disinfection is performed only when it is considered as necessary according to your hospital's regulations.

The validated disinfectant for disinfecting is:

Isopropanol(70%)



Caution:

- 1. do not use high-temperature vapour or ionizing radiation as disinfection methods.**
- 2. Do not use chloric disinfectant such as chloride, sodium hypochlorite etc.**

10.6 Others

10.6.1 Do not open the device enclosure to avoid possible hazard.

10.6.2 Relevant schematic circuit diagram and detailed list of key components are only provided to the qualified service station or maintenance personnel recognized by our company, the relevant maintenance personnel is responsible for the maintenance of devices.

10.6.3 The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- 1) Inspect the equipment and accessories for mechanical and functional damage.
- 2) Inspect the safety related labels for legibility.
- 3) Verify that the device functions properly as described in the instructions for use.
- 4) Test the essential performance according to IEC/EN 60601-2-25, or methods recommended by the hospital or local distributor.

If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

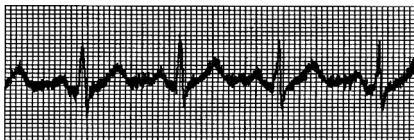
Chapter 11 Troubleshooting

11.1 AC Interference



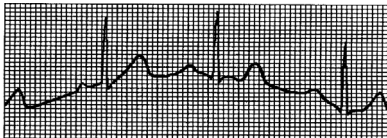
- ① Whether or not the device is grounded reliably?
- ② Whether or not the electrodes and skin are daubed enough conductive gel?
- ③ Whether or not the metal bed is grounded reliably?
- ④ Whether or not the patient has touched the wall or metal parts of the bed?
- ⑤ Whether or not the patient has touched other people?
- ⑥ Whether or not there is high-power electric equipment working nearby? Such as X-ray machine or ultrasonic device, etc.

11.2 EMG Interference



- ① Whether or not the room is comfortable?
- ② Whether or not the patient is nervous?
- ③ Whether or not the bed space is narrow?

11.3 Baseline Drift

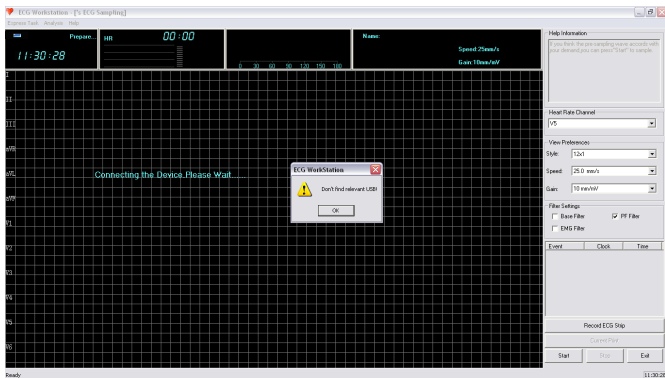


- ① Whether or not the electrode placement is stable?
- ② Whether or not the electrodes or lead cables are connected reliably?
- ③ Whether or not the electrodes and patient skin are cleaned and are daubed enough conductive gel?
- ④ Whether or not it is caused by patient's movement and breath?
- ⑤ Whether or not the electrodes or leads are in bad connection?

If you can not clear the interference after taking all the measures above, please use filter.

11.4 Sampling Failure

The dialog box "Don't find relevant USB!" as following figure appears.



Check whether the connection between the device and the recorder(namely the Bluetooth equipment) is correct and reliable. Make sure there is no obstructions between the recorder and the Bluetooth equipment.

"Read Data Error" will appear, shown as below figure.



Check whether there are some reasons caused the abnormal connection of Bluetooth during sampling.

11.5 Troubleshooting

Phenomenon	Reason	Solution
Too large interference, disorderly waveform	Lead cable is not solid enough to connect the two ends.	Check lead cable. Do a good job in dealing with patients.
	Interference from AC.	Check electrical equipment around the equipment.
	Patient is too tension, not quiet.	Start sampling again after patient is stable.

	Start sampling before the lead cable is connected well, the electric potential between body and sampling equipment has been not balanced.	Connect lead cable well, start sampling after the patient is stable.
	Inadequate skin treatment or incorrect electrodes placement.	Please reprocessing and installation, it is advised to use saline or medical alcohol to wipe each electrode placement (in the north or in the winter dry skin, this step is important), the left and right leg electrodes should not placed on the left leg, then click "Resample".
Baseline burr	AC interference is large.	Improve the environment. If it is the steel bed, it should be replaced. Sampling equipment is too close to other high-power equipment or power supply.
	EMG interfere is large.	Let patients relax. Keep the indoor temperature above 16 °C.
No sampling waves	Bluetooth adapter or lead cables are damaged	Check or replace the Bluetooth adapter or lead cables
Irregular waveform, with too great wave or beeline	Bad electrode conductivity. Bad connection between electrode and skin. The plug between lead cable and PC is not tight enough. Bad connection between lead cable and electrode.	Use alcohol of good quality. Use alcohol to clean electrode and the skin under electrode.
Unstable baseline	Patient movement.	Let the patient keep calm.
Normal operations but data cannot be collected.	Some lead cable falls off.	Check or connect the lead cable again.
	An improper lead cable in specification or the lead cable with bad quality has been used.	Replace the lead cable.
Waveform of some lead is small in amplitude	Lead cable is broken.	Replace the lead cable.
Equipment connection	Software was not turned off normally after last use.	Please connect recorder and PC again and restart the software.

failure	PC has recovered from sleep state, in sleep state, the power will be cut off.	
	The Bluetooth adapter is damaged.	Check and replace the Bluetooth adapter.
	The Bluetooth equipment is not connected correctly.	Add the Bluetooth equipment again according to the user manual.
Print failure or wrong format of report	There is no printer connected or no printer driver installed	Please let professional technical personnel to install the printer again, and set the accuracy of printer as 600 dpi according to the user manual.
	Improper print setting.	
The interface of software can't be displayed entirely.	Resolution of display is too low.	Adjust the resolution of display to more than 1366*768 according to the requirement described in the User Manual.

Chapter 12 Packing List

12.1 Accompanying accessories

When device leaves factory, a complete packaging shall contain the followings:

Items	Qty.
ECG sampling facility	1set
ECG workstation installation USB flash disk(including User Manual).	1pcs
ECG lead cable	1set
ECG lead extension cable (to electrode)	2pcs
Data line	1pcs
Suction ball	6pcs
Limb electrode clamp	4pcs
Lead cable clamps	2pcs
Packing receipt	1pcs

12.2 Attention

12.2.1 Please follow the instructions when opening the package.

12.2.2 After unpacking, please check the accessories and accompanying documentation in accordance with the packing list, then start checking the device.

12.2.3 If the packing content does not meet the requirement or the device does not work properly, please contact with our company immediately.

12.2.4 Please use the accessories provided by our company, otherwise the performance and safety of the device may be affected. If accessories provided by other company need to be used, please first consult the after-sales service of our company, or we will not responsible for any caused damages.

12.2.5 The package shall be kept properly in case of using during regular maintenance or device repair.

Chapter 13 Principle and Clinical Application

13.1 The matched ECG sampling clip gathers the change of heart's integrated potential, which is periodically changed with the cardiac cycle, from the skin surface, then form the dynamic curves, namely ECG. After that analyze based on it.

Steps are as following:

The 8-lead ECG signal is switched to numeric signal through A/D conversion, and it stores data and displays waveform via magnifying and filtering. Then examine QRS waves and P waves, identify the dividing point of P, QRS and T waves, measure parameters and distill the characters. At last, come to the data forms and diagrams after calculating.

Clinical application:

- Sinus P-QRS-T characters.
- Atrial P'-QRS-T characters. If atrial P' wave appears, it can be diagnosed to be atrial beat.
- Basic characters of junctional P-QRS-T waves group. If junctional pacemaker is provided agitatedly and abnormally, it will come into being junctional arrhythmia.
- Basic characters of ventricular QRT-T waves group, if myocardial infraction waveform shows up, it can be diagnosed to be myocardial infraction.
- Niveau diagnosis of Ventricular proiosystole.
- Niveau diagnosis of Ventricular tachycardia. It can be variant angina pectoris, acute myocardial infarction(AMI), rheumatic valvulitis, cardiomyopathy, congenital cardiopathy, diabetes mellitus, cerebrovascular disease, cardiopathy postoperation, cardiac failure. Digitalis toxis, crucial electrolyte disturbance and mitral valve prolapse syndrome etc.
- VT RFCA post MI, to determine whether RFCA treatment is doable.
- Niveau diagnosis of dominant bypass ECG, to raise the success rate of catheter-induced ablation.
- Differential diagnosis of broad QRS wave groups.
- Diagnosis of Q-T internal Dispersion, P waves Dispersion and coronary artery disease.

The product is to diagnose coronary heart disease (CHD), angina pectoris (AP), MI, rheumatic heart disease, mitral stenosis, irrhythmia, myocarditis, coronary artery insufficiency, organic cardiopathy, congenital cardiopathy and so on.

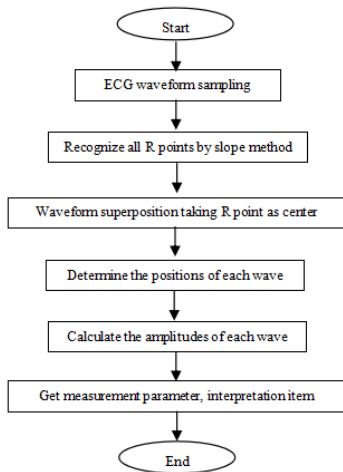
13.2 Algorithm description

This section describes the algorithm, formulas and judgment conditions for interpretation items related to functions of ECG automated measurement and automated interpretation.

The 12-lead sync ECG waveform passes through the filter (AC, EMG, DFT (if has, and open)) into the module of automated measurement and automated interpretation.

The module of automated measurement and automated interpretation mainly includes process of find the cardiac impulse location, find the beginning/end for each wave, amplitude calculation, parameters calculation, and interpretations judgment based on known parameters.

The workflow is shown as below:



13.2.1 Find the cardiac impulse location

1) Data preprocessing, obtain the absolute value trend of slope for each lead; then superimpose each absolute value, obtain the superimposed graph of absolute value of slope.

2) Smoothing filter the superimposed graph on average of width 80ms, obtain the analytical data source DDD.

3) Find the cardiac impulse location, give an initial threshold for searching, orderly scan the data in the analytical data source DDD, then compare it with the threshold value:

When the value is greater than the threshold, it may be the beginning of qrs-complex. If the distance from the previous qrs-complex to the current location is less than 150ms, then give up the location.

Otherwise, take the 1/4 of threshold value as a reference, find the beginning of qrs-complex within 100ms before the current location.

When the value is less than the threshold value, it may be the end of qrs-complex. Take the 1/4 of threshold value as a reference, find the end of qrs-complex.

If the found qrs-complex is wide, this qrs-complex shall be excluded. Otherwise, save the found qrs-complex.

4) Locate: after found the qrs-complex, search the max value point between the beginning point and end point in the ecg original data, mark the point as cardiac impulse location.

5) Dynamically threshold adjustment: after found the cardiac impulse location, use the value at the cardiac impulse location for the dynamically adaptive adjustment of the threshold value. Define the threshold value as 1/3 of the average of the nearest three cardiac impulses.

6) After found the cardiac impulse location, compute the RR-interval and accumulate it with the previous RR-intervals, then count the number of accumulated RR-intervals.

7) Continue searching until the end of data, and calculate the global average value for RR-intervals at the same time.

13.2.2 Find the beginning/end for each wave

The beginning/end of qrs-complex has been approached in above cardiac impulse locating process, but it is mainly in order to assist to find the cardiac impulse location; in addition, the location is searched based on the slope threshold value, which is imprecise. Here, according to the found cardiac impulse location, the beginning/end of qrs-complex will be sought accurately. Name the cardiac impulse location as the peak of R-wave.

1. Read data

1) Read one data of qrs-complex: take the peak of R-wave as reference, locate directly to the original ecg file, read a piece of data containing the qrs-complex.

- 2) Preprocessing: superimpose the absolute value of slope for 12-lead signals.
 - 3) Use the preprocessed data to carry on the searching of QRS-complex, P-wave and T-wave as the followings.
 - 4) Read the next data of qrs-complex, repeat step 2 and step 3 until the analyzing of all qrs-complex are finished.
2. Find QRS-complex
 - 1) Calculate the threshold value of S-wave: search the minimal value within 200ms after the peak of R-wave, take the value that equals to minimal value plus 0.4, as the threshold value for finding the end of S-wave.
 - 2) Find the beginning of Q-wave: take 0.5 as the threshold value, search forwardly starting from R-wave, a point that less than the threshold value, within 0ms-200ms before the peak of R-wave, which is the beginning of Q-wave.
 - 3) Find the end of S-wave: search backwardly starting from R-wave, a point that less than the threshold value of the end of S-wave, within 0ms-200ms after the peak of R-wave, which is the end of S-wave.
 3. Find P-wave
 - 1) Peak of P-wave: search the max value within 30ms-100ms before the beginning of Q-wave, temporarily mark the point as the peak of P-wave.
 - 2) Find the end of P-wave: search the minimal value between the peak of P-wave and the beginning of Q-wave, the minimal value plus 0.05 is the threshold value, use the threshold value to find the end of P-wave.
 - 3) Find the beginning of P-wave: search the minimal value within 150ms before the peak of P-wave, the minimal value plus 0.06 is the threshold value, use the threshold value to find the beginning of P-wave.
 - 4) If the found P-wave is narrow, research the P-wave according to the following steps.
 - 5) Change the searching range of 30ms-100ms to 100ms-350ms in step 1, repeat step 1-4.
 - 6) If the found P-wave is still narrow, it means that P-wave doesn't exist.
 4. Find T-wave
 - 1) Peak of T-wave: search the max value within 30ms-300ms after the end of QRS-complex, save it as the peak of T-wave.
 - 2) Threshold value of the beginning of T-wave: search the minimal value within 0ms-100ms after the end of QRS-complex, the minimal value plus 1/10 of the peak value of T-wave is the threshold for finding the beginning of T-wave.
 - 3) Threshold value of the end of T-wave: search the minimal value within 200ms after the peak of T-wave, the minimal value plus 1/10 of the peak value of T-wave is the threshold for finding the end of T-wave.
 - 4) Find the beginning of T-wave: in the range between the minimal value in step2 and the peak of T-wave, find a point that less than the threshold value of the beginning of T-wave, the point is the beginning of T-wave.

5) Find the end of T-wave: in the range between the minimal value in step3 and the peak of T-wave, find a point that less than the threshold value of the end of T-wave, the point is the end of T-wave.

5. Explanation of equipotential segment

In searching the QRS-complex, this algorithm adopts the analysis method of superposition of the slopes for all leads, therefore, the equipotential segments before and after the QRS-complex are partly included in the start and end points of the QRS-complex. It is depends on the number of leads containing equipotential segments. If there are more leads containing equipotential segments, the slope value will be smaller after superposition, so it is difficult to meet the threshold condition, and only a small part of the equipotential segments is counted to the start and end points of the QRS-complex. On the contrary, if there are less leads containing equipotential segments, a large part of the equipotential segments will be counted to the start and end points of the QRS-complex. Anyway, the equipotential segments before and after the QRS-complex are partly included in the QRS-complex duration.

13.2.3 Amplitude measurement

After finding the position of each wave, i.e. the start and end points of P wave, QRS complex and T wave, use the following method to measure P, Q, R, S, ST and T waves of each lead.

1.P-wave

Calculate the average value of the data 20ms before the start point of P wave, and use this average value as the baseline of P wave. Find the max value between the start point and end point of P wave, the difference between the max value and the baseline would be the amplitude of P wave.

2.Q/R/S wave

Calculate the average value of the data 10-30ms before the start point of QRS complex, and use this average value as the baseline of QRS complex. Search boundary points that exceeding the baseline from the start point of Q wave to the end point of S wave. Each adjacent two boundary points forms a sub-wave. Determine whether each sub-wave is a recognizable minimum wave (see the definition below). If it is a recognizable minimum wave, first identify its direction. If it is above the QRS baseline, it is R wave, if it is below the baseline, it is Q wave or S wave. Find the extreme value of this wave, and the difference between the extreme value and the baseline is the amplitude of Q/R/S wave.

Note: If there is only one downward wave, its amplitude should be respectively recorded in the amplitude of Q wave and S wave.

3.ST segment

Take above baseline of QRS complex as the ST baseline. Calculate the differences between the ST baseline and the points at 40ms and 60ms after the end point of QRS complex, and calculate the average value of these two differences, the average value is the amplitude of ST segment.

4.T-wave

Calculate the average value of the data 20-50ms after the end point of T wave, and average this value with the QRS baseline in 2, then use the result as the baseline of T wave. Find the max value between the start point and end point of T wave, the difference between the max value and the baseline would be the amplitude of T wave.

5.Recognition of minimum wave

The minimum wave can be recognized by the algorithm according to the requirement of IEC60601-2-51:2003 Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs, Annex GG, Clause GG.5 Definition of waveforms, measurement of minimum waves. The wave that meet the following conditions is the minimum wave that can be recognized by the algorithm.

- 1) The signal part under consideration shows clearly two opposite slopes with at least one turning point in between;
- 2) The signal part under consideration deviates at least $30\mu\text{V}$ from the reference level for a duration of at least 6ms;
- 3) The minimum observable duration of wave under consideration is 12ms and amplitude $\geq 30\mu\text{V}$.



Disposal: *The product must not be disposed of along with other domestic waste.*

The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies