PROFESSIONAL MEDICAL PRODUCTS

ECG HOLTER WITH SOFTWARE

Use and maintenance book

GIMA 35130

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Made in China

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CE 0123

IP22

MD

-40°C +55°C 86kPa 106kPa 0% ≤85%

M35130-EN-Rev.4-02.26

Foreword

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 must be noted, the procedures may result in abnormal, 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 and 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.

The content in this user manual complies with real product. For software upgrade and some modifications, the content in this user manual is subject to change without prior notice, and we sincerely apologize for that.

Note: Please read the user manual carefully before use, and operate the device strictly following the procedures in the user manual.

Warnings

Before using this product, the safety and effectiveness described in the following shall be considered:

- Type of protection against electric shock: internally powered equipment.

- Degree of protection against electric shock: type BF applied part.
- Working mode: continuous operating device.
- Protection classification of shell: IP22.
- Measurement results shall be described by qualified doctors combined with clinical symptoms.
- The using reliability depends on whether the operation guide and maintenance instructions in this manual is followed.
- The device is not applicable for infants weighting less than 10Kg.
- Contraindications: none.
- The device can not work directly on human heart.
- Date of manufacture: see the label.

Warning: To ensure safety and effectiveness, please use the accessories recommended by our company. Repair and maintenance shall be carried out by professional personnel approved by our company. Replacement of accessories that are not supplied by our company may result in errors. Any maintenance personnel who has not been trained by our company or other authorized service organization should not attempt to maintain the product.

Responsibility of operator

- The device should be operated by a professionally trained medical staff, and kept by a special person.

- The operator must carefully read the User Manual before using this product, and strictly follow the operating procedure described in the User Manual.
- The safety requirements have been fully considered in product designing, but the operator should not ignore the observation on patient and the state of device.
- The operator shall provide the use condition of the product to our company.

Responsibility of our company

- Our company supplies qualified products to users.
- Our company provides services of installation, debugging and technically training according to the contract.
- Our company performs device repair in warranty period (one year) and maintenance after warranty period.
- Our company is responsible to respond to users' requirements in time.

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Chapter 1 Introduction

1.1 Environment Condition and Applicable People

The environment requirement of operation, transport and storage for this System.

Operation Environment

Environment Temperature:	10 ℃~45 ℃
Relative Humidity:	10%～95%,no condensation
Atmospheric pressure:	700hPa~1060hPa
Power Supply:	DC 3 V

Transport and Storage Environment

Environment Temperature:	-40 ℃~+55 ℃
Relative Humidity:	10%～95%,no condensation
Atmospheric Pressure:	700hPa~1060hPa

Computer Configuration and Printer Requirement for Software

CPU:	Pentium III, Celeron(CYON)800 or advanced
EMS memory:	256 M or above
Hard disk:	40G or above
CD-ROM:	CD-ROM or advanced
I/O port:	more than four USB2.0 ports

Operating System:	Microsoft Windows 2000(32 bit)/XP(32 bit)/Vista(32bit)/Windows 7(32 bit) Microsoft Windows 2000(64 bit)/XP(64 bit)/Vista(64bit)/Windows 7(64 bit)
Display:	Color display with the resolution1024×768 or advanced
Resolution of printer:	600DPI

1.2 Product Feature and Intended Purpose

1.2.1 Product feature:

This device contains recorder & analysis software. The device can be used for dynamic monitoring of ECG signals. It can record human ECG signals for at least 24 hours, store ECG signals without compression, provide effective analysis software and provide diagnostic basis for doctors.

1.2.2 Intended purpose:

The device is used to record and analyze the dynamic ECG signal for clinical diagnosis and research.

1.2.3 Device Indications:

The device is suitable for heart diseases such as arrhythmia and coronary heart disease.

1.2.4 Intended Users:

The device is used in hospitals and various professional medical institutions. It is operated and

used by professional medical personnel to record ECG of patients.

The ME EQUIPMENT or ME SYSTEM is suitable for home health care environments.But the patient can only worn,it is not operable.

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise,degradation of the performance of this equipment could result.

1.3 Safety

The design of this system accords with the international safety standard IEC60601-2-47.

Warning:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established。

Please don't use this device with the defibrillation device.

Please don't operate this device in environment containing flammable gas.

Do not use the device under interference by high-power equipment, such as high voltage cable, X ray, ultrasonic machine, MRI machine or electrotherapy machine, and keep it away from mobile phone and other radiation source.

The device should not be used together with any defibrillation device.

Please don't use device with electromagnetic radiation in the vicinity of the recorder.

Please don't use this device in high temperature environment (advised highest temperature:45 ℃).

NO modification of equipment.

Please read this user manual carefully before using the product, and operate according to this manual strictly.

This system must be operated by the personnel who has been trained and authorized and safe kept by the person specially assigned.

Please open the back cover with the screwdriver,and install batteries as the + - logo.The battery to be used must be high-quality LR6 AA alkaline battery.

The environment where the device will be used should be kept away from vibration, dust, corrosive or combustible matter, and shun extreme temperature and humidity, and so on.
Doctor must tell patient monitored by recorder not to do much movement.
Please insert the batteries properly in the right direction for the improper insertion may damage the device.
For protecting environment, please deal with the scrap batteries according to the local rule of law.
The useful life of the product rests with the useful life of components, which are 5 years generally.
Maintenance and repair are not allowed during using the device.
The materials selected for the design and manufacture of the device shall meet its excepted service life. Any corrosion, aging, mechanical wear or degradation of biological materials caused by bacteria, plants, animals, etc. will not degrade the mechanical properties of the device.
Avoid contact with water. Avoid using or storing the device in places where excessive air pressure, humidity or temperature exceeds the specified standard, poor ventilation or dusty.
Pay attention to battery's positive and negative anodes when replacing.
Dispose of packaging materials, waste batteries and end-of-life products in accordance with

local laws and regulations. User should perform proper treatment to the waste products and materials according to the regulations and try to classify the waste for recycling.
The manufacturer bears responsibility for software maintenance and debugging.
The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes needs to be determined by a clinician.
Gain Accuracy:The output signal is equivalent to the input signal ,and the maximum error isAccuracy±10%.
To avoid the risk of strangulation and suffocation, keep infants and children away from the device.

	Type BF applied part
	USB interface
	WEEE disposal
IP22	Covering Protection rate
SN	Serial number

	Follow instructions for use
CE 0123	This item is compliant with Regulation(EU)2017/745 of the European Parliament and of the Council of April 2017.
EU REP	Authorized representative in the European Union
	Manufacturer
	Date of manufacture
	Temperature limit
	Humidity limit
	Atmospheric pressure limit
	Keep in a cool, dry place
	Fragile,handle with care

	UP
	Recycling regeneration mark
	Medical device
	Unique device identifier
	General warning sign NOTE ： Background col our:Yellow Triangular band: Black
	Product code
	Lot number
	Imported by
	Caution: read instructions (warnings) carefully

1.4 Cleaning and Maintenance

Cleaning：

The reusable lead wire that contact with the patient need to be cleaned after each use:

Recommended cleaner:

Solution of isopropyl alcohol(70%)

When cleaning reusable lead wire:

1.Clean the places (such as gaps and grooves) that are not easy to wipe on the surface of the reusable lead wire with a medical brush dipped in cleaner (no liquid drips from the brush), brush for three minutes; take a clean and soft cloth and dip it into the cleaner, then wring it dry, and use it to thoroughly wipe all outer surfaces of the reusable lead wire, and wipe for two minutes, avoid wiping the interface of the lead wire to the host. Repeat this step for three times, until there is no obvious residue.

2.After cleaning, wipe the extra cleaner with a new cloth or a paper towel soaked in water until there is no obvious detergent residue.

3.Put the reusable lead wire in a cool and well ventilated place to let it dry naturally and thoroughly.

Disinfection：

To avoid long-term damage to the device, it should be disinfected in accordance with the rules and regulations of the hospital.

Recommended disinfectant for the reusable lead wire:

Solution of isopropyl alcohol(70%)

When disinfecting reusable lead wire:

1.Clean the places (such as gaps and grooves) that are not easy to wipe on the surface of the reusable lead wire with a medical brush dipped in disinfectant (no liquid drips from the brush),brush for three minutes; take a clean and soft cloth and dip it into the disinfectant, then wring it dry, and use it to thoroughly wipe all outer surfaces of the reusable lead wire, and wipe for two minutes, avoid wiping the interface of the lead wire to the host. Repeat this step for three times, until there is no obvious residue.

2.After cleaning, wipe the extra cleaner with a new cloth or a paper towel soaked in water until there is no obvious detergent residue.

3.Put the reusable lead wire in a cool and well ventilated place to let it dry naturally and thoroughly.

Chapter 2 Frame Character of Product

2.1 Sketch Map for every Orientation

2.1.1 Front view

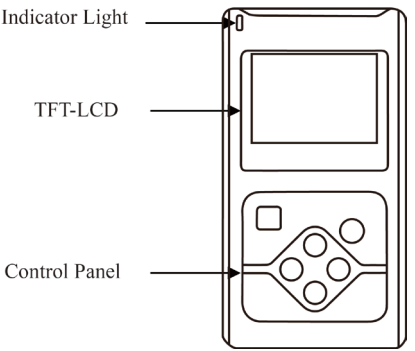


Fig.2-1 Front view

2.1.2 Side view

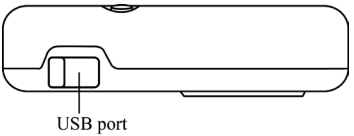


Fig.2-2 Side view

2.1.3 Bottom view

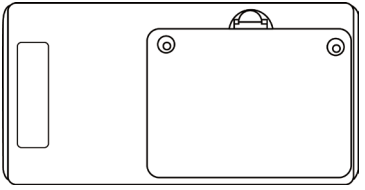


Fig.2-3 Bottom view

2.2 Definition of Keystoke, Interface and Indicator Light

 or  function key: menu/cancel/turn on/off

 function key: marker/affirmance/choice

 direction key: left

 direction key: right

 direction key: go up

 direction key: go down

Indicator light: (glint every 4 seconds when collecting ECG signal)
Show date communication status when connecting with the computer.

Chapter 3 Preparing Work before Using

3.1 Electrode Placement

Notice:

The placement of electrode is the basic of holter recorder collecting ECG data signal. The quality and position of electrode affect the quality of ECG signal. Please read this chapter carefully before first operation.

The conductive part (applied part) of electrode should not contact with other conductive parts or the earth.

Signal input/output part can be connected with the specified instrument only, please contact our company for any replacement.

Position of the electrode placement is shown (as **Fig.3-1**).

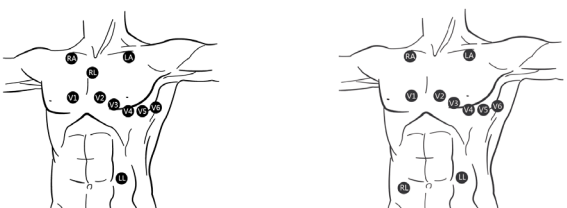


Fig.3-1

◆ Deal with the skin

When attaching and placing the electrode, we need to deal with the skin at first, and be sure to clean the skin. Use 95% alcohol to scrub the skin, after the alcohol evaporates, use abrasive paper attached to the electrode to wipe the attached place to remove cuticula on the surface of the skin in order to reduce the resistance from the skin and the disturbance from the EMG. People who have much hair need to shave it to ensure the skin well connected with the electrode. The skin of old patients is dry and has many crinkles, so we have to clean the skin and make the attached place flat. If the attached place is near the bosom of the woman patient, electrode and cables should be covered by the bra and then fixed well.

◆ Place the electrode

Use high-quality ECG electrode to attach the right place and connect with the correspond electrode. To prevent the electrode drop and the baseline excursion caused by pulling, use the medical adhesive belt or plaster to fix every electrode and cable properly. Don’t use the common adhesive belt to attach the cables for fear of dirtying, corroding the cables and reducing the usage life span. If use the device in the environment of high temperature or easy perspiring, "EKG Medical Gel" could be wiped on the skin around the electrode beforehand.(or follow the electrode factory introductions to use).

3.2 Battery Installation and Notice

3.2.1 Open the battery cover according to the direction which the arrowhead on the cover indicates. Follow as **Fig.3-2**.

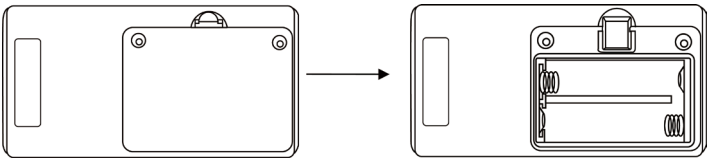


Fig.3-2

3.2.2 Please insert the batteries properly in the right direction, and then close the cover. Follow as **Fig.3-3**.

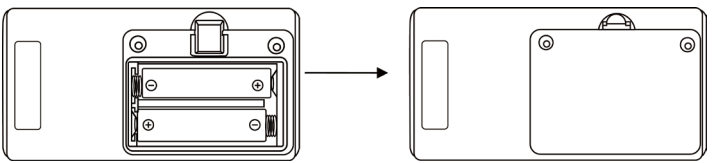


Fig.3-3

3.2.3 The state of battery and working requirements are shown as Table 3-a1.

	The batteries are full, the device could run in gear.
	The batteries are insufficient, suggest not record.
	The batteries are almost drained, please replace the battery immediately.

Table 3-a1

When the batteries are almost drained and not replaced, the recorder will show the interface (as **Fig.3-4**), and turn into protected mode.

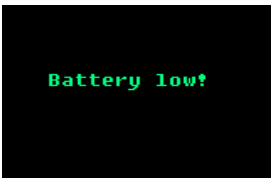


Fig.3-4

When the energy of battery is low, the recorder turn into protected mode in order to protect the recorder from damaging. Under protected mode the device don't run until the device is electricized by USB or the batteries are full.

Warning:

The batteries should be full when the device collects new information, otherwise the recording time could not last long enough.

Notice:

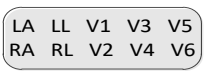
Please confirm all electrodes and lead wires are connected well to patient. Otherwise, interference in waveform at the beginning of record may lead to failure analysis.

Notice:

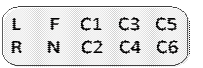
Please take off the battery after monitoring in order to protect the recorder from damaging because of battery leak.

Instructions:

The electrode indicator and pictures in this direction take example for usually American, if there is some difference in the actual use,please operate and use refer to following usually European indicator.



3-5 usually American



3-6 usually European

The usually American indicator is match up to the usually European indicator one by one, the relationship of them are listed in the following table:

usually American	usually European
LA	L

RA	R
LL	F
RL	N
V1	C1
V2	C2
V3	C3
V4	C4
V5	C5
V6	C6

Chapter 4 Recorder Operation Explanation

Press  or  for about 3 seconds to turn on the recorder (press  or  for about 3 seconds to turn off the recorder on the main interface), the main interface is shown in **Fig.4-1**.

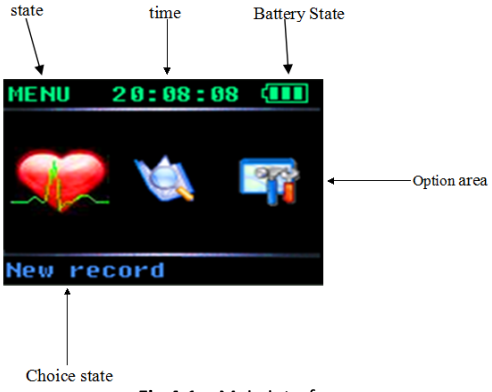


Fig.4-1 Main interface

4.1 New Record

Use ◀ or ▶ to choose ♥ on main interface, press ! to enter new record operation, display interface is as **Fig.4-2**.

On the interface, press ▲ or ▼ to change the gain, press ◀ or ▶ to switch lead status.

After recording one time, press  if you want to continue to record, here the interface will show the information "Last record will be covered! Are you sure?" as **Fig.4-3**.

Fig.4-2

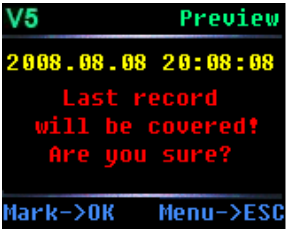


Fig.4-3

Press  or  to cancel recording and return to the main interface.

Press  to continue to record and the interface will show the information "Starting record" as **Fig.4-4**.

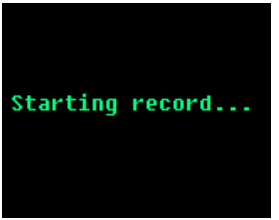


Fig.4-4

The interface as **Fig.4-4** will last 2 seconds, then the recorder enter stand-by mode. The blue indicator on the top left corner of recorder will glitter one time every 4 seconds to show the state in gear.

Press  for about 3 seconds to record event marker when recording, in the meanwhile, the beep from recorder indicates you have succeeded in event marker.

Press  or  for about 3 seconds when recording if you want to end recording manually, then the recorder will show the information as **Fig.4-5** to affirm whether the recording operation will be stopped.

Fig.4-5

If you confirm that you want to terminate recording, please press  for about 3 seconds according to the information shown on the interface, at the same time the screen will display the information as **Fig.4-6**. This interface will last about 2 seconds, then return to the main interface.

Fig.4-6

4.2 Review Record

Use or to choose on main interface, press to enter review record operation interface, if the recorder has storage record, there will be a interface as **Fig.4-7**.

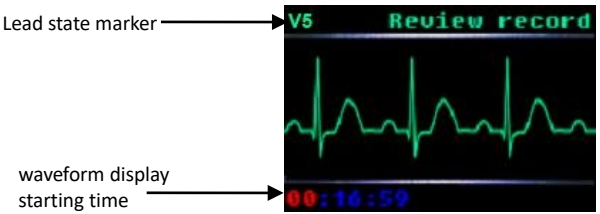


Fig.4-7

Under this interface, use or to change lead marker (Ⅰ, Ⅱ, Ⅲ, AVR, AVL, AVF, V1, V2, V3, V4, V5, V6), press to switch between hour, minute and second, the red one shows the option which has been chosen, use or to change the value.

If the recorder hasn't storage record, there will be a "No record" information on the screen as **Fig.4-8**, and the interface will return main interface automatically after 2 seconds.

Fig.4-8

4.3 System Set

Use  or  to choose  on main interface, press  to enter the "system set" interface as **Fig.4-9**.

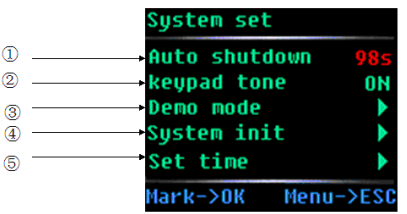


Fig.4-9

Use or to choose the option, use or to set the option which has been chosen or enter the inferior menu, the red one shows the option which has been chosen.

① Auto shutdown set

The time scope of auto shutdown is 3~98 seconds, if setting 99s, the recorder will open forever.

② Keypad tone set

Under this option, you can decide the keypad tone "ON/OFF".

③ Demo mode

Under the item, the demonstration waveform is shown in **Fig.4-10**.

Fig.4-10

Press to switch ECG lead waveform.

④ System initialization

Press ▶ to enter the interface as shown in **Fig.4-11**.

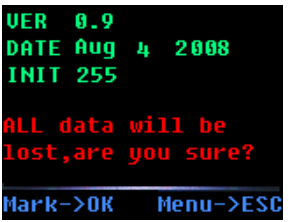


Fig.4-11

⚠ **Notice:**

Detailed edition information depends on current recorder.

Press ! to enter the initialization interface as shown in **Fig.4-12**.

⑤ Time set

Press ▶ to enter the time set interface as **Fig.4-13**.

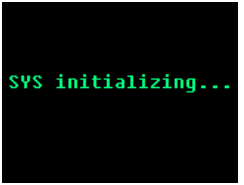


Fig.4-12

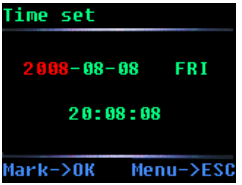


Fig.4-13

Use or to choose the option, use or to change the value, press to save the setting and return superior menu. Press or to cancel setting and returning superior menu.

4.4 Replay Record

Please remove electrodes from patient, and then connect recorder to PC with USB cable. It is recommended that batteries should be remained in the recorder. The indicator light is on, and the interface displays the information as **Fig.4-14** if the connection is normal.

Fig.4-14

In "My computer" of PC, there is a symbol as **Fig.4-15**.

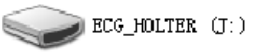


Fig.4-15

Open the disk, you can see a file named ECG_WAVE.BIN (as **Fig.4-16**).

Fig.4-16

Please choose this file of analyse software to perform the replaying operation.

Notice:

Please refer to the information of chapter 6 for the detail.

After replaying, please Safely remove USB Mass Storage Device as **Fig.4-17**, then pull out USB connecting line to avoid damaging the device.

Fig.4-17

After cutting the connection with PC, this device will go back to the main interface.

Notice:

The USB interface of recorder is USB2.0, please choose the USB2.0 interface in PC to connect in order to make sure the speed of data communication.

During the connection process, if the PC crashed or powered off accidentally caused by a sudden blackout or other reasons, please disconnect the recorder and PC and wait for the PC working well, then connect it with the recorder to upload cases.

Chapter 5 Malfunction Analysis and Troubleshooting

5.1 Daily Maintenance

5.1.1 Maintenance after use

Long press  or  to turn off the device.

Unplug lead cables, please hold the plug part and do not pull the wire with force.

Clean the device and accessories.

Place the device in a cool and dry environment.

Do not soak the device into detergent for cleaning. Before cleaning the shell, please do turn the device off. It is recommended to use neutral cleanser to wipe the recorder for its cleaning, then air dry or use a clean and dry cloth to wipe it.

5.1.2 Inspection and Maintenance of Lead cables and Electrodes

Use a multimeter to detect the connectivity of the lead cable by checking whether each wire of the lead cable is in good contact. The resistance of each wire from the electrode plug to the corresponding pin in the lead cable plug should be less than 2Ω. The integrity of the lead cable must be checked regularly. Any lead wire damage will cause a false waveform of the corresponding lead or all leads on the ECG. The lead cable can be cleaned with water or neutral solvent. Do not use the detergent or germicide containing alcohol (Please do not immerse the lead cables in liquid for

disinfection).

Bending or knotting will shorten the service life of lead cable. When using it, please straighten the lead cable first.

The lead cable should be replaced if it shows broken or corrosion phenomenon. The maintenance of lead cable depends on its using frequency.

5.2 The Problem Related to the Battery

Problem	Cause	Correction
The recorder has no response and the indicator isn't light after the battery is put in.	1.The battery is used up.	Change another battery.
	2.The battery can't connect with the reed very well. The height of "+" of some brand of battery is too low.	Change another brand of battery. or put a thick of metal piece in the place between the "+" of battery and reed.
	3.The direction of the battery is wrong.	Install the battery correctly once again.
The recording time on the recorder is	1.The quality of the battery is poor. or the battery has been put for a long time.	Change another high-quality new battery.

different with the practical recording time.	2. Because the characteristic and brand of the battery are different, large internal resistance influence operating voltage and discharging current.	Change another new battery.
	1. Some part of the recorder may be damaged because the electrolyte in the battery flows out.	Please contact our company.

5.3 The Problem Related to the Skin and the Electrode

Problem	Cause	Correction
The wave is disturbed; the quality of the ECG signal is poor.	1. The skin can't be cleaned well, or the electrode isn't attached right.	Clean the skin and attach once more.
	2. The quality of the one-off electrode is poor, or the electrode has been stored for a long time.	Use new,high-quality electrode.
	3. The movement of the patient's upper limbs is too severe.	Ask the patient to avoid severe movement when monitoring.
The amplitude of some ECG wave is small, which is difficult for analysis.	The cable is broken.	Change a new cable.

5.4 The Problem Related to the Cable and the Input Plug

Problem	Cause	Correction
The output wave of the recorder is a straight line.	1. The recorder isn't connected well.	Please check if the needles of the plug is curved, broken or lack. If the plug is well, please connect once again.
	2. The cable is broken.	Please contact our company.
	3. The recorder is broken.	Please contact our company.
Some ECG wave is disturbed a lot, and the quality of ECG signal is poor.	1. The cable isn't connected well	Connect the cable once again according to the operation manual.
	2. Lead cable is broken.	Please change a new one.
	3. The quality of the one-off electrode is poor.	Please change new, high-quality electrode.

5.5 Other Problems

Problem	Cause	Correction
The communication of data is failed.	There is something wrong with the USB cable.	Change another USB cable.

Chapter 6 Instructions for Analysis Software

Overview

- PC software name: 12 Channels ECG Holter System_L
- PC software specification: no

- PC software version: V5.5
- Version naming rules: V<major version No.>.< major version No.>.<revised version No.>.<revised version No.>

  PC software version can be obtained from PC software.
- Algorithm:

  Name: refer to Annex II

  Type: ECG waveform processing algorithm

  Purpose: be used for the check of waveform data analysis and calculation.

  Clinical function: the algorithm is used to analyze and calculate the ECG waveform data of the patient, provides the basis for diagnosis.

6.1 Welcome for using the software

When the software is run for the first time, a “Welcome” window pops up for prompt. If secure login is not enabled, click the Continue button in the welcome window to enter the main interface of the software. If secure login is enabled, clicking the Continue button will take you to the user management function interface (see the User Management section). Click the Exit button to exit the software.

6.2 User Management

This section applies to situations where secure login is enabled.

6.2.1 Administrators

When the software enables secure login function and no regular user is created, the administrator

login window will be displayed after starting the software.

✧ **Administrator login**

Input administrator password and click the “Log in” button.

Default administrator password: **Holter20250218**

Prompt: To ensure system security, please change the default password immediately after logging into the administrator account for the first time.

❖ **Error prompt:**

When the password input is incorrect, a prompt “Password error, please re-enter” will appear.

✧ **Modifying administrator password**

Click the “Modify” button, then the “New password” and “Confirm password” edit boxes become available, where you can input the new password, and the “Log in” button changes to “Confirm” button.

Input the old password in the “Password” edit box, the new password in the “New password” and “Confirm password” edit boxes, and click “Confirm” to complete administrator password modification and log in the administrator account.

Attention: the password is 8-16 characters long and must be composed of letters and numbers.

❖ **Error prompt:**

No.	Prompt	Error
1	Password cannot be empty!	No old password is input.
2	Password error, please re-enter.	The old password is input incorrectly.

3	The new password cannot be empty!	No new password is input.
4	Please enter a confirmation password!	No confirmation password is input.
5	The confirmation password you entered is incorrect. Please re-enter it!	The confirmation password is not consistent with the new password.

6.2.2 User management

After the successful login of administrator account, a “User Management” window appears, which is used for adding and deleting users.

✧ **Add new users:**

Input account information in corresponding locations and click the “Save” button. When the “Success” is prompted, the new user is added successfully.

“Account” limit: 1-32 characters, composed of letters or numbers.

“Password” and “Confirm password” limit: 8-16 characters, composed of letters and numbers.

❖ **Error prompt:**

No.	Prompt	Error
1	Please enter an account and try again.	No account is input.
2	Password cannot be empty!	No password is input.
3	Please enter a confirmation password!	No confirmation password is input.
4	The confirmation password you entered is incorrect. Please re-enter it!	The confirmation password is not consistent with the new password.

✧ **Modify user information:**

When the account input already exists, click the “Save” button to modify user information.

✧ **Delete users:**

Select the account to be deleted in the account pull-down list, and click “Delete” to delete it.

✧ **Return to “User Login”:**

After the user management is completed, click the “OK” button to return to the “User Login” interface.

6.2.3 User Login

After the account is added, the “User Login” interface is entered. Select the login account, and input the password, then click “Log in”.

Click the “Administrators” button to recall the “Administrator Login” function.

Click the “Exit” button to close the software.

6.3 Main Interface

After successful login, enter the main interface of the software.

Function explanation of edit module

Represent: Arrhythmia analysis module, Template replay module, Order replay module, HRV analysis module, QTD analysis module, HRT module, TWA module, VCG module, VLP module, TVCG module and Parameter definition module.

 Go to the previous operation  Go to the next operation

6.4 Replay HOLTER recorder

Connect the HOLTER recorder with PC. Then click the "New" menu button under the "File" menu in the main window, or click the  button in the main toolbar. Please enter patient information in the pop-up new case window (as Fig. 6-1).

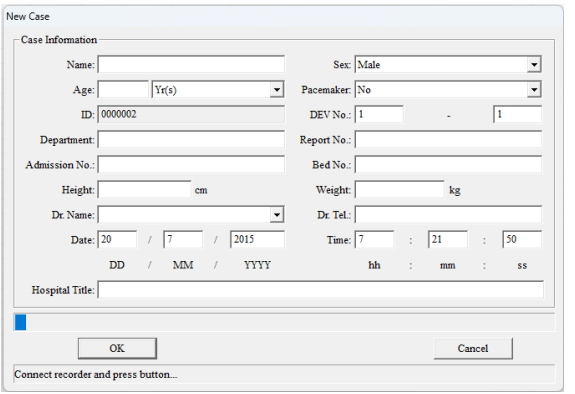


Fig. 6-1

Attention: If the patient takes a pacemaker, choose "Yes" in the item "Pacemaker", then the system can add the function of pacing analysis.

After the patient's data input, to click “OK”, and the computer begins to read data from the recorder. The prompt will pop up when the communication finishes. Here click “Yes” to enter the interface of arrhythmia analysis (as Fig.6-3), and click “No” to enter the template replay interface (for the case which has been analyzed) or the order replay interface (for the case which has not been analyzed).

Attention: If the patient takes a pacemaker, the pacemaker parameters setup interface (as Fig.6-2) will pop up before arrhythmia analysis interface appears. Here doctors need modify the following items according to patient's pacemaker parameters. The accuracy of pacing pulse analysis relates to the "high" or "low" of pacing pulse, usually it should be "common", if the pulse is very low, please choose the "high".

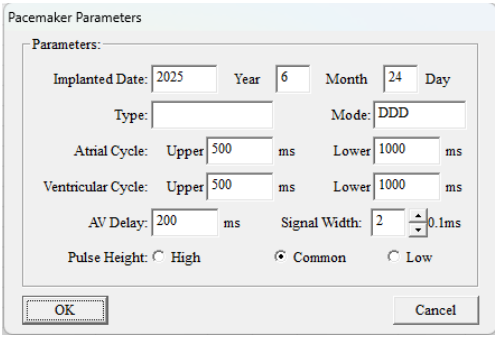

Pacemaker Parameters
Parameters:
Implanted Date: 2025 Year 6 Month 24 Day
Type:
Mode: DDD
Atrial Cycle: Upper 500 ms Lower 1000 ms
Ventricular Cycle: Upper 500 ms Lower 1000 ms
AV Delay: 200 ms
Signal Width: 2 0.1ms
Pulse Height: High Common Low
OK
Cancel

Fig. 6-2

6.5 Arrhythmia Analysis

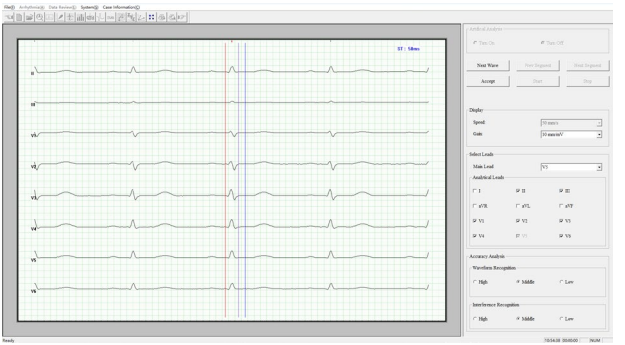


Fig.6-3

The left side of the interface is the waveform display window, displaying the waves of all analyzed leads. Here operators need choose a meaningful wave to diagnose and adjust the value of ST segment. Look at the picture. The three colored lines from left to right are baseline point, ST segment beginning point, and ST segment ending point. If you want to adjust a line, click this line to select it, and then move it through "←→" on the keyboard.

The right side of the picture is the control view, the "Artificial Analyze" option is designed for extending function.

If the current wave is good, please click the "Accept" button, and then the system enters the arrhythmia analysis (as Fig.6-4) automatically. If the user wants to exit this program, please close direct. If the current wave is not good, please click the "Next Wave" or "Next Segment" button, then the system will show the waves constantly until you click "Accept" to enter the arrhythmia analysis.

Click the "▼" button at the right of "Main Lead" to choose main analytical lead.

Click the options under the "Analytical Leads" to decide which leads to be analyzed, the default is 8-lead.

When the amplitude of the case waveform is too low, please select "high" in the "Waveform Recognition" option.

When the case meets much disturbance, please choose "High" in the "Interference Recognition" Option. The options "Accuracy Analysis" don't need to adjust generally. The user can choose according to the actual circumstances.

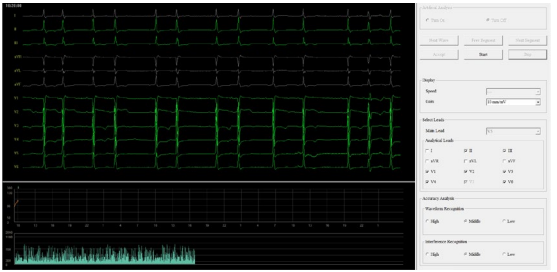


Fig. 6-4

Click "Stop", the system will stop temporarily. User can browse the 12 lead ECG through "←↑→↓" on the keyboard. In the HR trend graph, there is a green symbol line, which represents the place of the current wave. User can go back to a point, change condition ("Leads Analyzed", "Height", "distinguish O"), click "Start", the part starting at the green sign will be analyzed again. (as Fig.6-5).

When the analysis stopped, press "←↑→↓" on the keyboard to go back to certain point to analyze again if necessary.

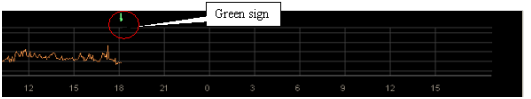


Fig.6-5

6.6 Template Replay

Click  into the template replay module (as Fig.6-6)

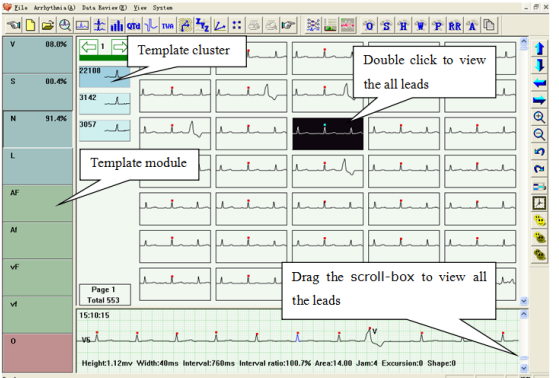


Fig.6-6

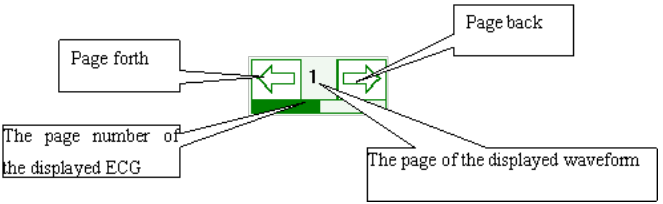
The left window is the template window. Every button is a template. The letter in the button represents the type (for example: V means ventricular premature beat, S means atrial premature beats), the percentage means what percentage this kind is in the total. No percentage means no wave.

V: ventricular premature beat template	AF: atrial flutter template
S: supra premature beat template	Af: atrial fibrillation template
N: normal beat template	VF: ventricular flutter template
L: pause template	Vf: ventricular fibrillation template
O: Interference template	

The window in the upper right corner is the display window for the selected template in the template cluster, displaying each waveform.

The bottom right window is the waveform show window, which displays the detailed information of the waveform which the mouse is pointing. Double clicking the left mouse button in this window will bring up the lead selection window. Select the leads to be displayed in this window and click "OK". The electrocardiogram in the waveform display window will change the leads accordingly.

You can also set default values on the "Display" page of parameter definition, that is, clicking the “Select” button in "Template" will bring up a window for lead selection. After selecting the lead, click "OK".



6.6.1 Classification Parameter Adjustment

 Classification parameter adjustment function (as Fig.6-7).

Parameter name: the name of the parameter to be classified.

Number of class: set how many classes the parameter will be classified. It can be increased or decreased by "▲" or "▼" buttons. When it increases 1, the numbers of both the threshold limit value at its right and the boundary in the parameter distribution graph will also increase 1, and the reverse is true. The number of class should be among 1 and 7.

Threshold Limit Value: the value of the corresponding boundary in the parameter distribution graph.

Parameter distribution graph: take example for the area distribution graph of QRS wave.

QRS complexes shape: select it to classify the waves according to QRS shape.

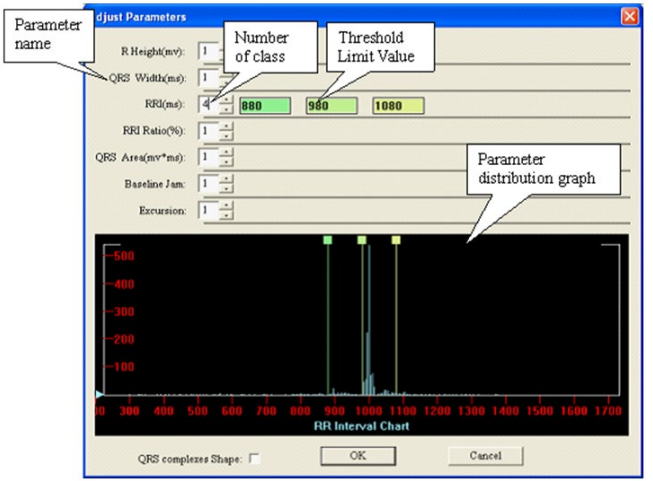

Parameter name
Number of class
Threshold Limit Value
djust Parameters
R Height(mv):
QRS Width(ms):
RRI(ms):
RRI Ratio(%):
QRS Area(mv*ms):
Baseline Jam:
Excursion:
880
980
1080
Parameter distribution graph
500
400
300
200
100
300 400 500 600 700 800 900 1000 1100 1200 1300 1400 1500 1600 1700
RR Interval Chart
QRS complexes Shape:
OK
Cancel

Fig.6-7

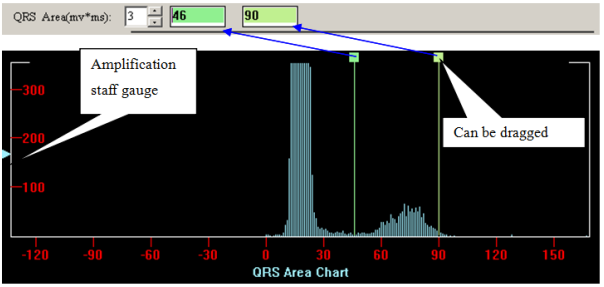


Fig. 6-8

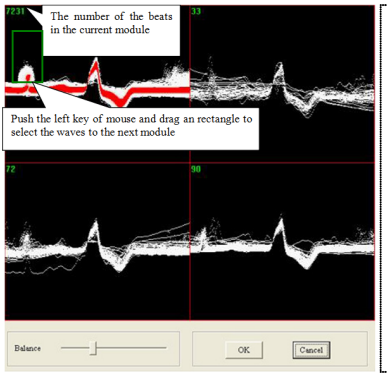
Fig.6-8 shows the distributing graph of the wave. The y-axis is the number of QRS wave, the abscissa is the value of wave. The classified line corresponds to the editor box above. Move the line by dragging the pane on it to change its threshold limit value. The blue triangle on the left is the amplification staff gauge, you can change the magnification factor of the y-axis the by dragging it up and down with the left key of the mouse.

6.6.2 Classify By Form


Classify all heartbeats according to waveform morphology.

6.6.3 Classify By Demix

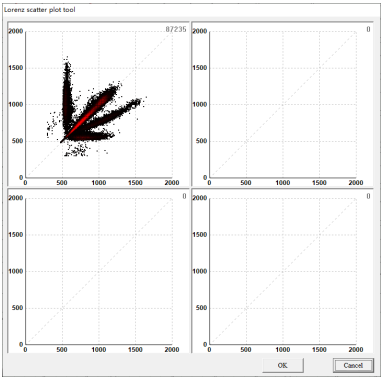
Use Demix tool to classify heartbeats in the template cluster.



There are 4 class templates in the window, and the number of heart beats in each category is displayed in the upper left corner of each template. Press the left mouse button in the template and drag the mouse to bring up a rectangular box. The selected ECG waveforms within the rectangular box will be assigned to the next template.

6.6.4 Scatter Plot Classification

Use scatter plot tool to classify heartbeats in the template cluster.



There are 4 scatter plot templates in the window. After pressing the left mouse button on the scatter plot and moving the mouse, the trajectory of the mouse movement forms an area. After lifting the left mouse button, the heartbeats in this area will be selected and automatically assigned to the next template.

6.6.5 Quick Classification

Use default parameters to classify heartbeats in the current template:

Baseline Jam

QRS complexes shape

R Height

 QRS Width

 RRI

 RRI Ratio

 QRS Area

6.6.6 Add New Class

 Add a new class: When click this button, the window "Class Name" as the following figure will appear. Input the class name, viz. name of the new template that you want to add in the blank, and click "OK", a new template will appear in the "template window" at the left side.

6.6.7 Other Functions

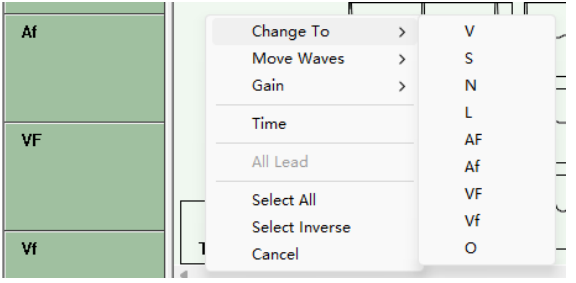
 Switch the waveform leads in the template cluster.

 Save ECG segment.

 Delete saved electrocardiogram segments.

6.6.8 Right Click Menu and Shortcut Keys

Select the beats and click the right key of the mouse to show the menu, can change the attribute of the beats. Then the selected beats are changed into the specified module.



Shortcut key

"V", "S", "N", "L" are the shortcut key to put the chosen wave into that class.

Control graph display key

 Move up the ECG in the left window

 Move down the ECG in the left window

 Move left the ECG in the left window

 Move right the ECG in the left window

 Amplify the ECG in the left window

 Lessen the ECG in the left window

 Cancel the edit operation

 Recover the edit operation

 Display or hide the statistics

 Display or hide the time

 Choose all the ECG in the left window

 Reverse choice the wave in the left window

 Cancel choice in the left window

 Delete selected heartbeat

6.7 Order Replay

Click the  button and enter order replay module (as Fig.6-9).

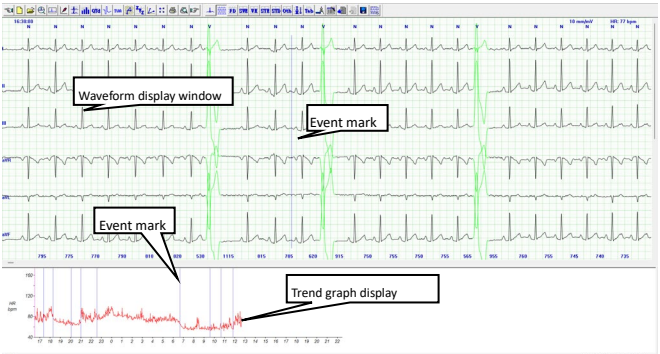


Fig.6-9

6.7.1 ECG

Display a single lead ECG. The red dots in the picture are heartbeat markers.

Click on the ECG by the right key of mouse, the menu will appear. Doctor can check and analyze patient's ECG as required.

Menu items:

Gain: to adjust the wave's gain, viz. Amplification factor.
Single Lead: to change the lead no. and display the ECG of appointed lead.
SV: to display all the bar chart of the appointed kinds in the current ECG.
Confirm Max HR: Select the current ECG as Max HR ECG.
Confirm Min HR: Select the current ECG as Min HR ECG.
Event marker:
Including the blue lines in the waveform area and the blue lines in the trend graph area, shows the operator has press the event button on this position and recorded an event.

6.7.2 Trend Charts

HR trend graph is displayed in the trend graph display area as default. Erect purple line is time mark, corresponding to the starting time of the waveform in the Waveform display area. Click the left key of mouse on the trend graph, the position of the erect line and the starting time of waveform will change. Right click on the window and a selection menu will appear.
Menu items:
ST: display ST trend graph of each lead;
T: display T trend graph of each lead;
SVE Trend: display SVE trend graph;
VE Trend: display VE trend graph;
R-R Trend: display R-R interval Trend graph;

L Trend: display pause trend graph

If the collecting time is longer than 30 h, the trend graph will be plotted according to the mode selected in "Parameters".

Continuous mode:

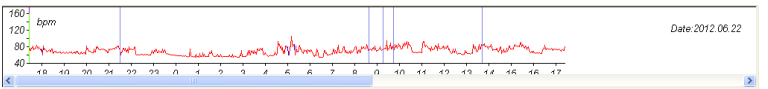


Fig.6-10

As Fig.6-10, when continuous mode is used, a scroll bar appears below the window and a time display appears on the right. You can drag the scroll bar to change the start time displayed on the trend graph, and the date display on the right and the ECG waveform displayed in the waveform display window will change accordingly.

Contrast mode:

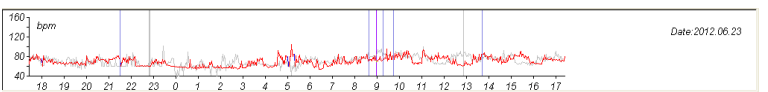


Fig.6-11

As shown in Fig. 6-11, the graph displays multiple curves with a 24-hour time interval. The red curve represents the currently selected heart rate change curve, while other colors represent heart rate change curves for different time intervals.

Click the left mouse button on the curve, and the curve will turn red. At the same time, the time marker line, date display, and ECG waveform will also change accordingly.

6.7.3 Bar Chart

A bar chart is a type of ECG waveform diagram that plots a single-lead ECG waveform within a rectangular area, indicating the start time and average heart rate. The waveform starting 3.5 seconds after the start time is the primary waveform represented by this bar chart.

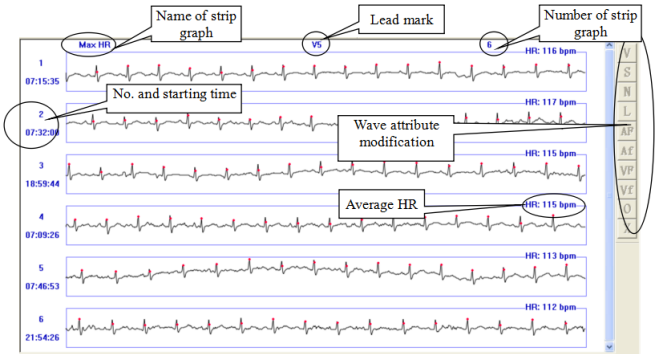


Fig.6-12

V: Change type into ventricular premature beat	S: Change type to supra ventricular premature beat
N: Change type to normal beat	L: Change type to pause
AF: Change type to atrial flutter	Af: Change type to atrial fibrillation
VF: Change type to ventricular flutter	Vf: Change type to ventricular fibrillation

O: Change type to interference	X: Delete

Hold down the 'Ctrl' key on the keyboard and click the left mouse button on a bar chart to select it for property modification or deletion. The background of the selected bar chart will turn black. The same operation can be used to deselect a previously selected bar chart.

The following explanation uses Max HR as an example.

Click the "Max HR" option under the 

button. The bar charts of maximum HR will be displayed in the window. Users can use  button to switch the leads of the waveform in the bar chart as needed.

In this interface, the software selects no.1 bar chart as Max HR automatically. If you want to change into other graph manually, click the right key of mouse on that graph and select "confirm Max HR", then this graph will be set as Max HR and changed into the no1 graph, following that, Max HR in the main report will also change.

Attention: for Max HR, default 6 bar charts are displayed. If all of that 6 graphs are interference waves or false error, select a graph and delete it. Then the software will automatically analyze and get a new Max HR bar chart and add to the display, as Fig.6-13.

Attention: it is similar between Min HR and Max HR in display and operation, so there will be no extra introduction in the following content.

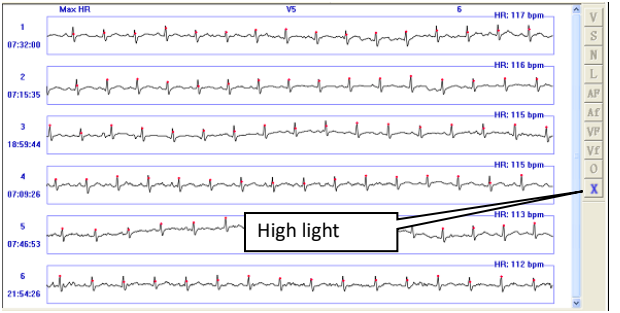


Fig.6-13

Attention: in the display interface of the bar chart, double click a bar chart with the left key of mouse to switch it to the multi-lead cardiogram on the same time.

Click SVE or VE button, show the bar charts of supra ventricular premature beat or ventricular premature beat (as Fig.6-14).

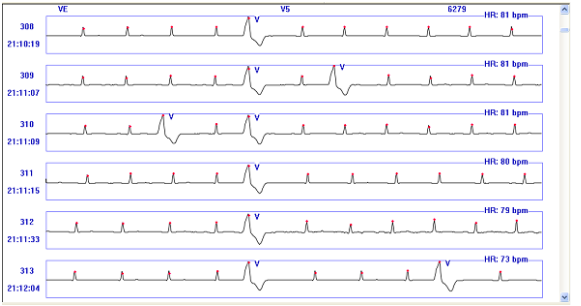
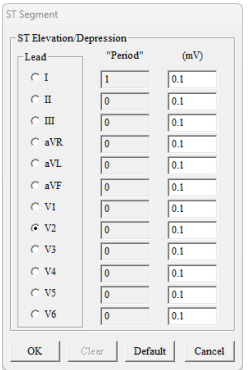


Fig.6-14

Click the 

or 

button, enter ST elevation or ST depressions ECG analysis function interface.



The Physician can select a lead and enter parameter as needed. The parameter range should be between 0.01 and 0.3.

After selecting the lead, click the 'OK' button to show the bar charts of all ST segment elevations or depressions in this lead, as shown in Fig 6-15:

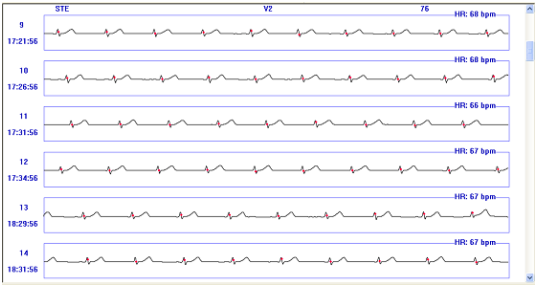


Fig.6-15

Attention:

- **This software can perform ST segment analysis on all leads when using any or all calibration signals.**
- **The parameters displayed in the "ST segment change" window are the analysis parameters used for the "STE" (ST segment elevation) and "STD" (ST segment depression) analysis functions. Physicians can modify the analysis parameters here to perform ST segment analysis on this lead again.**
- **This software has the function of myocardial ischemia analysis, which can analyze ST segment depression events, display ST segment depression fragments of all leads in the myocardial**

ischemia data table, and provide printed reports.

Click  button, display other classified bar chart: S Pair, S Bigeminal rhythm, S Trigeminal rhythm, S Run; V Run, V Pair, V Bigeminal rhythm, V Trigeminal rhythm, R-R Pause, A Flutter, A Fibrillation, A Escape beat, V Flutter, V Fibrillation, V Escape beat, Max HR, Min HR, Bradycardia, Max R-R.

Before performing the above operation to display the ECG for each category, if the refresh  button (highlighted) indicates that the data needs to be refreshed, click the button to refresh the data.

6.7.4 Data Table

Click  button, display data tables.

✧ **Arrhythmia Table:**

Display the arrhythmia statistic for every hour, as Fig.6-16.

Av.HR: Average HR	Min HR: minimum HR
Max HR: maximum HR	V: ventricular premature beat
V Pair: ventricular couplet	V Short run: ventricular short run
V Long run: ventricular long run	V Big.: ventricular bigeminy
V Trig.: ventricular trigeminy	S: supra ventricular premature beat
S Pair: supra ventricular couplet	S Short run: supra ventricular short run

S Long run: supra ventricular long run	S Big.: supra ventricular bigeminy
S Trig.: supra ventricular trigeminy	L: pause
BC: bradycardia	

Click the left mouse button on any data in the "Av. HR", "Min HR" and "Max HR" columns to modify the data. Click ‘OK’ to save the changes.

Click on any data in the "Min HR" or "Max HR" column to display the electrocardiogram waveform of the Minimum or Maximum HR during that time period below the arrhythmia data table.

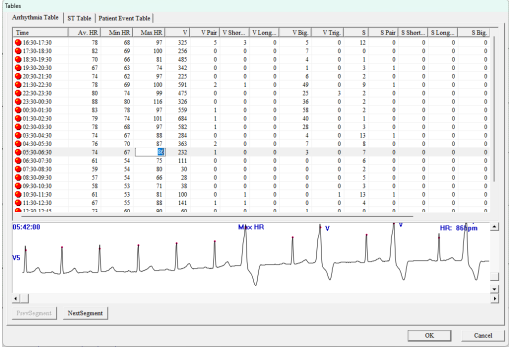


Fig.6-16

✧ **ST Table:**

Display the average ST voltage for each lead per hour.

Click the left mouse button on any data in the columns from 'I_ST' to "V6_ST" to modify the data. Click 'OK' to save the changes.

✧ **Patient Event Data Table:**

During the case collection process, if the patient manually records events, a Patient Event Data Table will be generated. Display the time and remarks of the event in the data table.

Select one of the records in the data table, fill in the comments for the event below, and then click the modify button to add or modify the comments for the event.

Click the 'OK' button to save this modification.

Double click on an event record to view its electrocardiogram.

6.7.5 ECG data export

In the order replay interface, click on the "Arrhythmia" menu and select the " Export ECG Data" option. Right click on the electrocardiogram to display the menu shown in Figure 6-17.

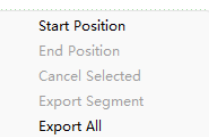


Fig. 6-17

Firstly, determine the starting and ending positions on the electrocardiogram, and then choose to export the electrocardiogram data within that segment. Alternatively, you can directly choose to export the entire data.

After selecting to export ECG data, you need to specify the file save path.

Attention: This function can only be activated in the sequential playback interface and is not available in other functional interfaces.

6.7.6 Other Functions

 Screen Measurement

Hold down the left mouse button on the electrocardiogram and drag to adjust the rectangular box to cover the area to be measured; After releasing the left mouse button, the measurement results will automatically be displayed in the list on the electrocardiogram.

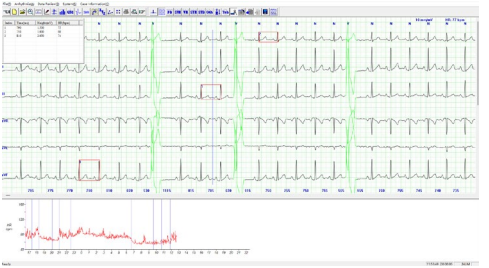
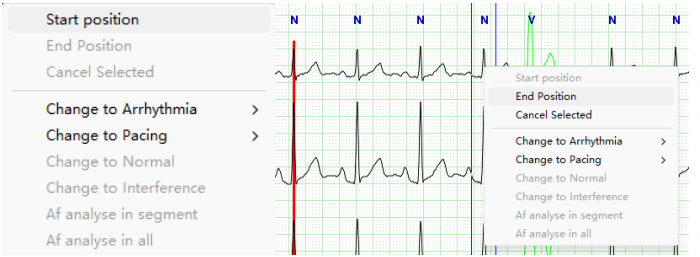


Fig. 6-18

 Modify QRS Complex Type

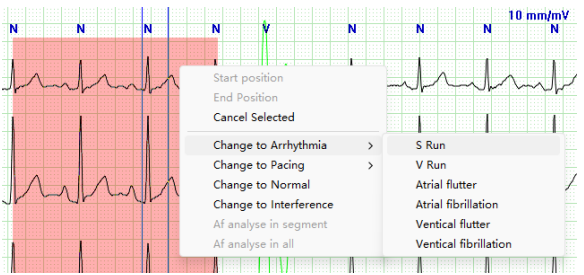
Move the mouse and place the rectangular box on the QRS complex. Click the left mouse button to cycle through the QRS complex type. Place the rectangular box in the unmarked QRS complex and click the left mouse button to insert a heartbeat of type N.

Right click on the electrocardiogram to use the menu to specify the start and end positions, and change all heartbeats within that range to the specified type.



Choose the start position

Choose the end position



Modify the heartbeat type within the area


Switch Single Lead display.


Full Disclosure ECG.


Store the current electrocardiogram in the print selection queue.


Delete all of the manually selected ECG segment in the print queue.


Update arrhythmia analysis results.


ScreenShot

6.8 Myocardial Ischemia Analysis (STLE)

Click "STLE" item inside of "Arrhythmia" item, show ST adjusting window as Fig.6-19.

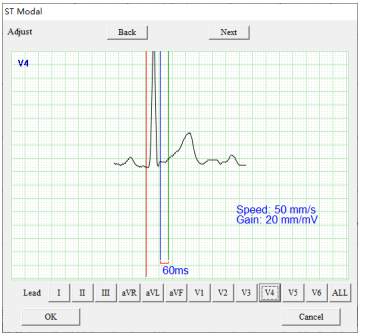


Fig.6-19

Back: display the previous heartbeat waveform;

Next: display the next heartbeat waveform;

Lead: select a single lead from I to V6 or click "ALL" to display all the ECG waveforms.

Adjust the position of reference line: place the mouse cursor near the line you want to adjust, click the left mouse button, and the line will move to the mouse click position.

After adjusting the reference line, click the "OK" button, and the software will start analyzing the ST segments of all heartbeats. The analysis results will be displayed in the myocardial ischemia data table (STLE table).

Click  button, display STLE table.

Each row in the table represents each arrhythmia episode with ST segment depression in the lead. The data in the table includes: Start Time, Length, Av.HR, Max HR, ST, STLE, V, S.

Users can directly delete selected episodes in the table. After clicking the "OK" button, the modified file will be saved.

Users can double-click a row in the table. After double-clicking, the multi-lead waveform will be displayed in the “Order Replay” window. The start time of the waveform is the same as the "Start Time" of the row.

If the user double-clicks a row in the table without clicking "OK" after deleting the episode, the program prompts the user to save the changes to the file.

Choosing "Yes" will save the changed file, choosing "No" will not save.

6.9 Heart Rate Deceleration Analysis (DC)

Select the "DC analysis" option in the "Arrhythmia" menu to enter the heart rate deceleration analysis function interface, as shown in Fig. 6-20:

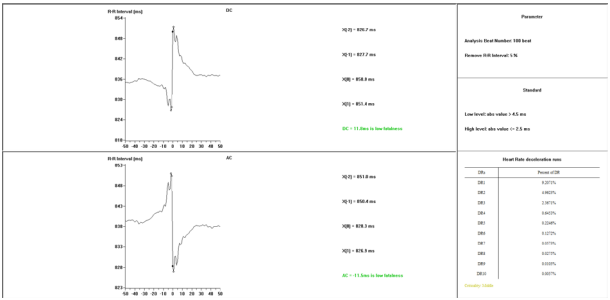


Fig. 6-20

The concept of the deceleration capacity of rate think that in the 24 hours record of the Holter ECG information, in all the adjacent R-R interval when the next R-R interval compare to the last R-R interval has the extension, the rate appeared reduction, and it can be regarded as the vagus nerve negative frequency effect on heart rate adjustment result, it is the vagus nerve function and disorder of quantitative index. Determination of the deceleration capacity of rate, the slow cycle of the Holter record will be treatment mathematical serialize. First the different heart rate will be aligned by order, and calculate the average of the correspond number of R-R interval, then the average into heart rate reduction force (DC) calculation formula and computing DC value.

①>4.5 ms: low level of fatalness;

②2.6 ms~4.5 ms: middle level of fatalness;

③<2.6 ms: high level of fatalness;

Click the  button to call up the settings function and adjust the analysis parameters.

✧ **Analysis Beat Number:** set the number of the R-R interval.

✧ **Remove R-R Interval:** in order to reduce the error of the manual work, when the next R-R interval compare to the last R-R interval extend or shorten beyond by the setting percent value, then the last R-R interval will be removed.

✧ **Low level of fatalness:** shows the vagus nerve effect make the deceleration capacity of rate strengthen.

✧ **High level of fatalness:** shows the patient's vagus nerve effect's expand ability become lower, the ability of regulation the deceleration capacity of rate becomes lower. So, the function of protected the heart decrease evidently. It has practical value in prewarning and screening the high-risk acute myocardial infarction.

 Edit the conclusion of the heart rate deceleration report.

6.10 QT Dispersion Analysis (QTd)

Click  button, enter QTD analysis function interface, as shown in Fig. 6-21.

QT dispersion main incarnate the differentia of the QT Interval between 12 leads, it is the difference between Max value and Min value which are the QT Interval between 12 leads.

It`s main function is to reflect the inconsistency of ventricular repolarization, indicate the degree of inconsistency in the recovery time of ventricular excitability, or indicate the degree of difference in ventricular refractory period.

For increasing precision and reducing error, the system adopts the method that got the mean value, which was based on each interval produced in the 3 continuous cardiac cycles. The result will show on the right of the interface. Using three arrows betwixt the interface to mark the three continuous heart beats. You can move the heart beat which needs to be measured with the "left" or "right" key, or adjusting the start or end position of Q, S and T wave of the chosen heart beat in the left view.

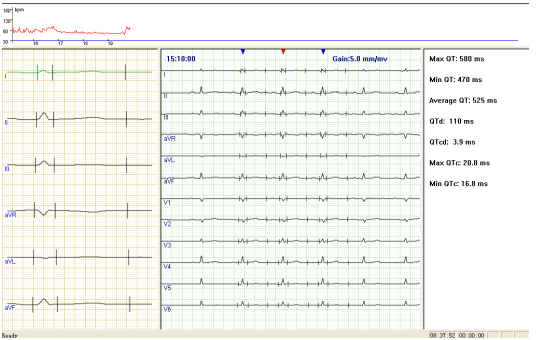


Fig.6-21

Click the left view, by using the up and down key to choose some lead waveform, the waveform will become green, which shows that you have pitched on the waveform of the heart beats. Then you can adjust the position of Q, S or T by pressing the "Tab" key. If the upright line on the waveform is red, showing that you can adjust its position with the left or right key. The data in the data view on the right will change automatically.

There are two buttons on the toolbar, one is limb lead, and the other is the chest lead. Each of them stands for several waveforms of leads, which show in the left view. Under the default situation, it displays the limb 6-lead.

Prompt: The HR trend graph can help you select the waveform of QTD, which need to be analyzed quickly.

6.11 Heart Rate Turbulence Analysis (HRT)

Click  button, enter HRT analysis module.

HRT could be quantification expressed by two parameters, the two parameters are TO and TS. Ventricular premature beat causes artery blood pressure brief foul-up. When the adjustable function is natural, this transitory change will be represented by the form of HRT immediately; when the adjustable function is injured, the change will weaken or disappear as Fig.6-22.

The position marked "HRT beginning" is the beginning position of wave that satisfies HRT judged condition, the third QRS wave after this position is ventricular premature beat, you can see the R-R interval trend graph in the whole HRT occurring term in the left below graph, which have signed the TO, TS segment with red line to make the user more convenient to judge.

Click the  button in toolbar will display the wave that satisfies last HRT analysis condition, Click the  button will display the wave that satisfies next HRT analysis condition.

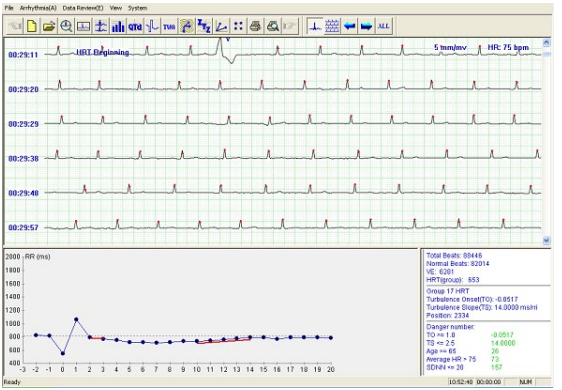


Fig.6-22

Click the ALL button will display the HRT waveform after superposition on the left below window graph as Fig.6-23.

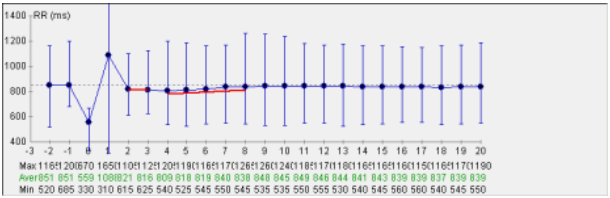


Fig.6-23

The erect line on the dot express R-R interval is the maximal value and minimal value on different period of time.

The three-row number below graph express the R-R interval the maximal value, the average and minimal value for the corresponding dot.

The graph on the right below window is the conclusion.

Before seeing the whole case report, the option such as "Normal Beats" will show the word "Not Judge". When the result is in the range that "Danger number" indicates, the corresponding result will turn to red to remind the user.

 Edit the conclusion of the heart rate turbulence report.

6.12 T Wave Alternation Analysis (TWA)

Click 

button to enter the T Wave alternation analysis module.

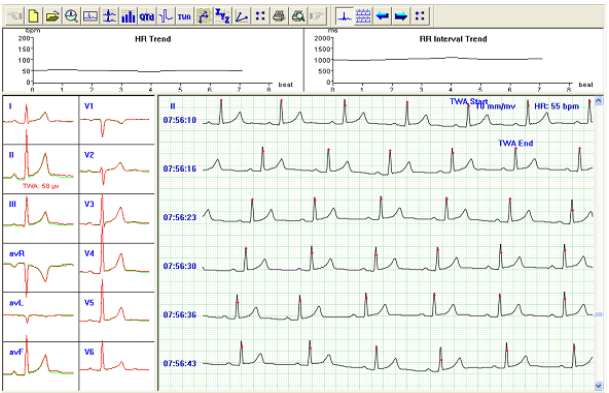


Fig.6-24

T wave alternation (TWA) is a periodic beat-to-beat variation in the amplitude or shape of the T wave in an electrocardiogram, and the variation of the amplitude is ≥0.1 mV. TWA is a important index on judging and preventing Arrhythmia.

The analysis adopts TWA measure basing on the maximum of T wave. The general method is: choose continuous 8 (16, 32, ……128) waveforms, number QRS waveform from the first one, such as 1, 2, 3, ……, 8, then compare the maximum of T wave; if the difference of T wave is larger than the range that has preestablished, there is TWA phenomena. After comparing, carry out superposition of the singular number (1, 3, 5……) wave and superposition of dual number (2, 4, 6……) wave respectively, then draw the result after superposition, it will be more obvious as Fig.6-24.

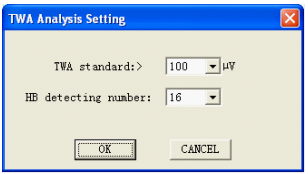
The position marked "TWA beginning", "TWA end" is the section of wave that satisfies TWA judged condition. On the left, it is the superposition graph of the singular number wave and dual number wave. The green line is the superposition wave of the singular number; the red line is the superposition wave of the dual number. If there are red words below wave, it means there is TWA phenomenon for this lead (such as II-lead on above picture). The number express the height difference after superposition of the singular number wave and superposition of dual number wave. Click the rectangle where the wave is, the right wave graph will turn to single-lead wave of the appointed lead. "HR trend", "R-R interval trend" above express the heart rate of TWA segment and the mutative trend of R-R interval.

Click the  button in toolbar will display the wave that satisfies last TWA analysis condition.

Click the  button will display the wave that satisfies next TWA analysis condition.

 and  express the switch between single lead and multi-lead for the current displaying waves.

 is the setting button, click it, then the following dialog box will appear:



The user can set the TWA judging standard and the heart beat detecting number. The range for TWA judging standard is 40~100 μV, HB detecting number is:8~128 Beat. The purpose of setting is analysis convenience and reducing mistake.

 Edit the conclusion of the T wave alternation report.

6.13 Atrial Fibrillation Analysis

In the “Order Replay” interface, select the "Atrial Fibrillation" in the "Arrhythmia" menu. The atrial fibrillation analysis function will enter the interface as Fig.6-25 automatically.

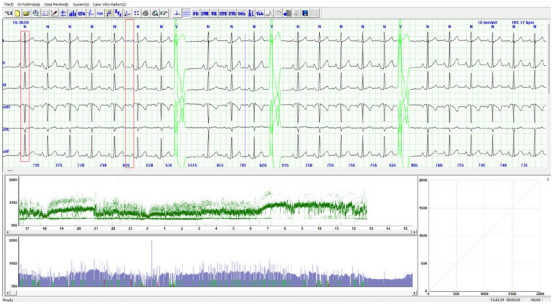


Fig. 6-25

The interface defaults to displaying electrocardiogram, time scatter plot, R-R interval trend plot, and Lorenz scatter plot. After automatic analysis or manual determination of atrial fibrillation segments, the interface will display a list of atrial fibrillation events.

✧ **ECG:** Multi lead ECG is displayed, and focal Dim sum beats are marked with shaded rectangle box, corresponding to the position marks in time scatter plot and R-R interval trend plot.

✧ **Time scatter plot:** displays the distribution of R-R intervals per minute of heartbeats each column.

✧ **R-R interval trend plot:** represents one minute, and by observing the degree of divergence of data points, the time period of occurrence of arrhythmias such as atrial fibrillation can be quickly identified.

✧ **Lorenz scatter plot:** used to display the R-R interval distribution of all heartbeats within a selected segment or event segment, and to assist in determining the type and characteristics of abnormal events through scatter plot morphology.

Users can set the starting and ending positions of the analysis segment through the right-click menu in the time scatter plot or R-R interval trend chart. After selecting a segment, you can manually specify segment attributes, perform automatic atrial fibrillation analysis, or choose to perform automatic atrial fibrillation analysis on the entire data.

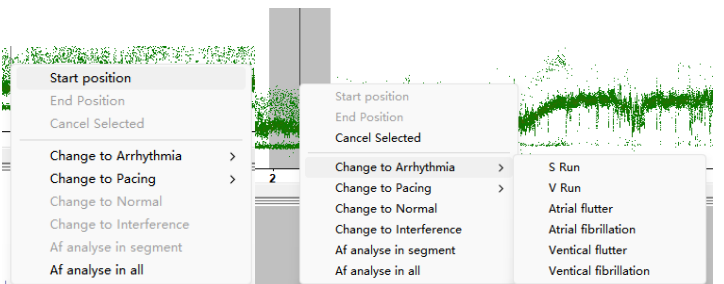


Fig.6-26

After automatically analyzing atrial fibrillation events or manually specifying atrial flutter, atrial fibrillation, ventricular flutter, and ventricular fibrillation segments, an event list will be displayed on the interface, including information such as event type, start time, duration, and heart rate, to help users eliminate artifacts.

6.14 HRV Analysis

Click  button, enter the **HRV** analysis module.

Notice:

Click  button, the system enters sinus beats HRV analysis. Which is the default analysis. Click  button, the system enters all beats HRV analysis.

 Display the comprehensive results of HRV analysis on 5-minute electrocardiogram segments, and select the starting time of the segment through the heart rate trend chart below.

 Display the comprehensive results of HRV analysis on 1-hour electrocardiogram segments, and select the starting time of the segment through the heart rate trend chart below.

 Display the histogram of the R-R interval throughout the entire process.

Display the histogram of the R-R interval difference throughout the entire process.

Display the Poincare of the R-R interval throughout the entire process.

Display the Poincare of the R-R interval difference throughout the entire process.

Display the frequence graph throughout the entire process.

Display the frequence 3D graph throughout the entire process.

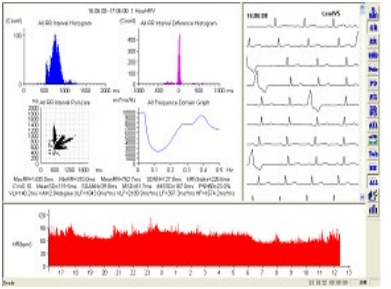
Display the results of comprehensive analysis throughout the entire process.

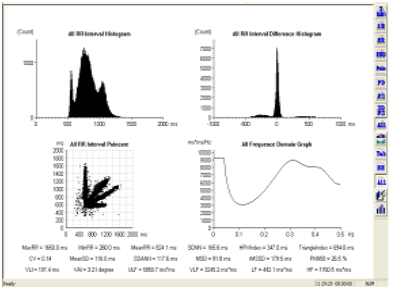

Display the full HRV trend chart.

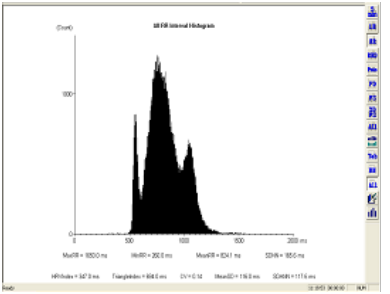
Display the full HRV data table.

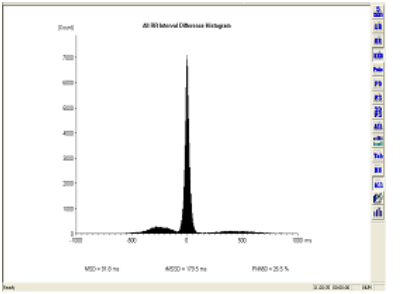

Edit the conclusion of the HRV analysis report. This function is only activated in the HRV comprehensive analysis function.

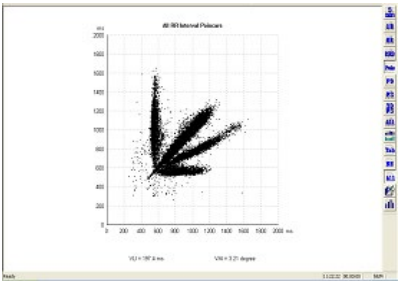
Partial functional interface display:

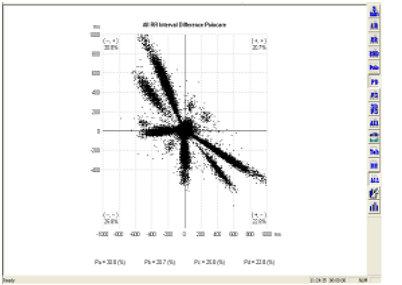


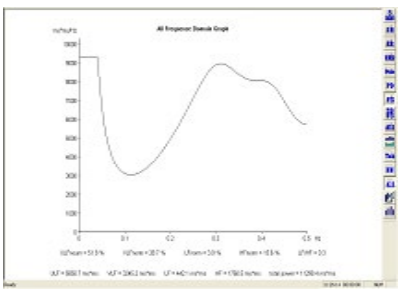


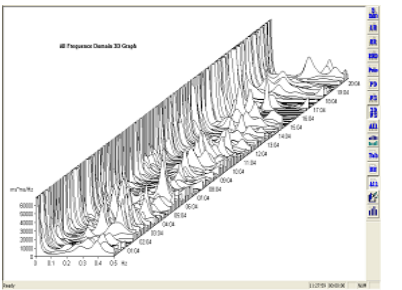


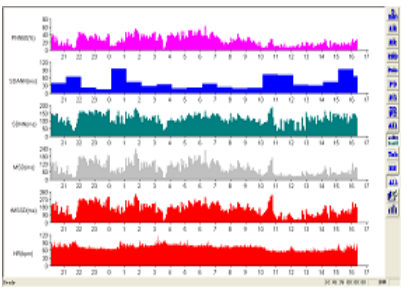


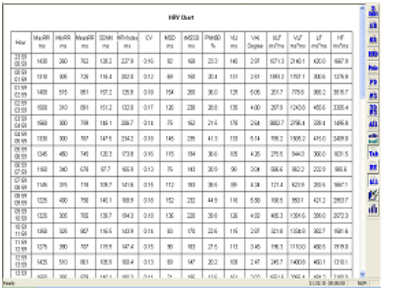

dd RR Interval Poincare
ms
2000
1800
1600
1400
1200
1000
800
600
400
200
0
0 200 400 600 800 1000 1200 1400 1600 1800 2000 ms
VLI = 197.4 ms
VAI = 3.21 degree


dd RR Interval Difference Poincare
ms
1000
800
600
400
200
0
-200
-400
-600
-800
-1000 -800 -600 -400 -200 0 200 400 600 800 1000 ms
(- , +)
28.8%
(+ , +)
20.7%
(- , -)
28.8%
(+ , -)
21.6%
Pa = 22.8 (%)
Pb = 28.7 (%)
Pc = 25.8 (%)
Pd = 22.8 (%)


dd Frequency Domain Graph
ms²/ms/Hz
1000
900
800
700
600
500
400
300
200
100
0
0.1
0.2
0.3
0.4
0.5 Hz
VLF mean = 51.5%
LF mean = 28.7 %
HF mean = 19.8 %
LF/HF = 2.0


dd Frequency Domain 3D Graph
ms²/ms/Hz
60000
50000
40000
30000
20000
10000
0
0 0.1 0.2 0.3 0.4 0.5 Hz





6.15 Report Editor

Click  button to display the Main report, Additional report and Sleeping duration (as Fig.6-27).

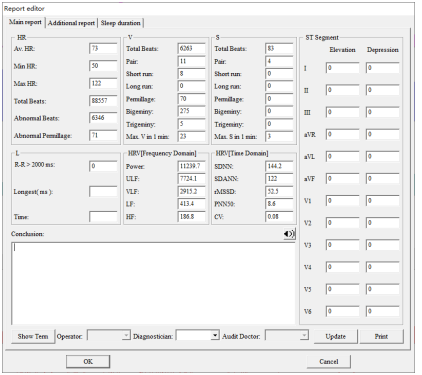


Fig. 6-27

➢ **Main report:** The window is used to modify the data of main report and fill in the diagnostic conclusion.

✧ **Show Term:** A professional terminology library used as a diagnostic result. Click the Show Term button, right-click on the pop-up terminology library interface, and select "Add, Modify, Delete" from the menu to perform corresponding operations on the terminology.

✧ **Operator/Diagnostician/Audit Doctor:** According to the settings, the corresponding doctor can be

selected and their electronic signature can be added to the report.

✧ **Update:** Update statistical results.

✧ **Print:** After clicking the OK button, immediately print the overall report.

Diagnosis conclusion voice broadcast: Click the  button to pop up the diagnosis conclusion dialog box, and you can hear the voice broadcast of the diagnosis conclusion. This function is only available on Windows 7 and compatible operating systems.

Attention: If a diagnostic conclusion has been written without clicking "OK" before "Compute" -> "OK" operations, this conclusion will not be saved.

➢ **Additional report:** edit the data in the Additive analysis report.

➢ **Sleep duration:** fill the factual time of sleep and wake to perform the dormancy asphyxia analyze.

Attention: please fill in the sleep time according to factual situation to ensure the analyze accurate.

6.16 Select Printing

Click  button on the right side of the report editing button to display the "Select Printing" window, where the physician can select the required report to print.

✧ **Report:** select "Main Report" to print.

✧ **ST Table:** select "ST Table" in "Order Replay" to print.

✧ **Bradycardia:** select "Bradycardia Table" to print.

✧ **Patient Event:** select the patient event data table to print.

✧ **Arrhythmia Table:** select "Arrhythmia Table" in "Order Replay" to print.

✧ **Flutter & Fib:** select "Atrial Fibrillation "report to print.

✧ **STLE Table:** select "STLE table" (Myocardial ischemia total load table)of a single lead to print.

✧ **HRV FD Report:** select the HRV frequency domain report to print.

✧ **HRV Table:** select "HRV Table" to print.

✧ **Pacing Report:** select "Pacing Report" to print.

✧ **V Run Table:** select "V Run Table" to print.

✧ **Trend:** select “HR Trend”, “VE” trend, “SVE” trend, and trend chart of ST segment and T wave in each lead to print.

✧ **HRV Trend:** select "HRV Trend" to print, including: PNN50, SDANN, SDNN, MSD and rMSSD.

➢ **HRV Graph:**

✧ **R-R Bar:** R-R interval histogram;

✧ **R-R DBar:** R-R interval dispersion histogram;

✧ **Poincare:** R-R interval Poincare;

✧ **SDP:** R-R interval dispersion Poincare;

✧ **FS:** frequence graph;

✧ **3DF:** frequence 3D graph.

✧ **Dormancy asphyxia analyze:** select dormancy asphyxia analyze report to print, including: the reports of trend, multi parameters balance and dangers analyze.

➢ **ECG segment selection:**

Click  button to remove the single time in the left frame into the right and wait to print.

Click  button to remove all the time in the left frame into the right and wait to print.

Click  button to remove the single time in the right frame into the left and cancel the print.

Click  button to remove all the time in the right frame into the left and cancel the print.

✧ **All:** select all reports.

✧ **Inverse:** cancel all of the reports you have selected, and select all of the reports you didn't select.

✧ **Default:** select some primary reports.

✧ **OK:** save this selection.

✧ **Cancel:** cancel selection.

Attention:

Flutter & Fib is not selective to print in the lack of the Atrial Fibrillation analyze.

STLE Table is not selective to print in the lack of the STLE analyze.

HRV Table can only be selected for printing after viewing it in the HRV analysis function.

Pacing Report is selective to print only for the case with pacing.

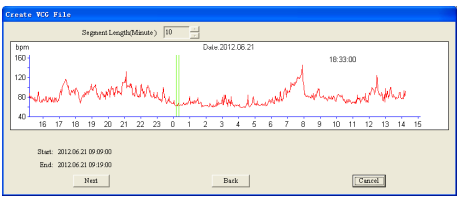
Modify the name of the ECG segment in the selective print queue by double click it.

After clicking "OK", click  in the HRV analyze interface to print the report directly or click  to preview it.

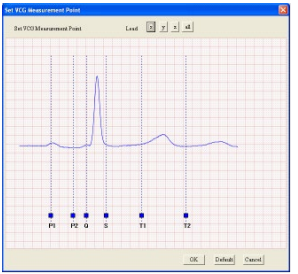
6.17 Vectorcardiogram

Choosing  button and enter the vectorcardiogram module.

First the screen will appear dialog box about converting file.



Press "Shift" or "Ctrl" key and click the ECG at the same time to choose the start and end times, click "Next" button to display the QRS wave start position correction diagram.



Put the mouse pointer on the blue rectangle, keep the left button down, the mouse pointer will turn to the crisscross cursor, drag the blue rectangle left or right to setting the incept position of each wave over again.

Click "OK" button and enter three-lead VCG graph As Fig.6-28.

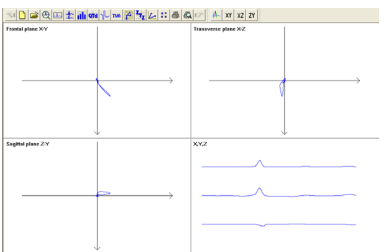


Fig. 6-28

Click  button and enter Set VCG Measurement Point.

Click “XY” button and enter Frontal plane X-Y graph (as Fig.6-29).

Click “XZ” button and enter Transverse plane X-Z graph (as Fig.6-29).

Click “ZY” button and enter Sagittal plane Z-Y graph (as Fig.6-29).

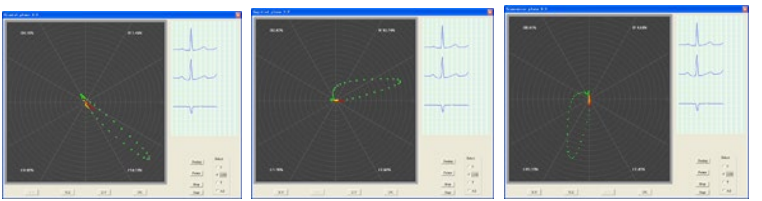


Fig. 6-29

6.18 ventricular late potential (VLP)

Click  button and enter VLP analytical module (as Fig.6-30).

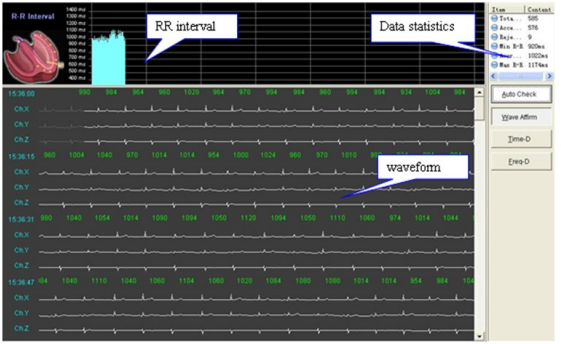


Fig.6-30

Data statistics

The statistical result of VLP analyze is displayed in "Wave Affirm" interface as following:

Total Beats: the total number of beats for the selected time in "File conversation"

Accepted Beats: the total number of beats in "Wave Affirm";

Rejected Beats: the number of rejected beats in "Wave Affirm";

Min R-R: Minimal R-R interval;

Av. R-R: Average R-R interval;

Max R-R: Maximal R-R interval.

6.18.1 Auto check

Auto filter ECG waves. Click the button to call up the "R-R Range" window.

✧ **Maximal R-R Limit:** set a percentage value, the ECG waveform with R-R interval more than average R-R interval by this percentage value will be rejected.

✧ **Minimal R-R Limit:** set a percentage value, the ECG waveform with R-R interval less than average R-R interval by this percentage value will be rejected.

Note: Auto check function is useable in the interface of wave affirm.

6.18.2 Wave Affirm

Waves can be filtrated by "auto check" or manual (as Fig.6-30).

✧ **R-R interval:** display R-R interval trend graph of all accepted beats in waveform window.

✧ **Waveform:** display 3 leads waves after file conversation. Herein the white curves denote accepted waves, and the grey waves denote rejected waves. Click the left key of mouse on waveform

✧ to change the selection state of into accepted or rejected state beat on this position.

6.18.3 Time Domain (Time-D)

Click this button to enter the time domain analysis interface (as Fig.6-31).

The content of "Statistics data" in this interface is as following:

✧ **Standard QRS:** the time between two erect line in standard unfiltered window.

✧ **Total QRS:** the time between two erect line in FIR filter window.

✧ **Under 40uV:** the duration of waves with the amplitude less than 40 μV at the end of QRS waves after filtering and Superposition.

✧ **Last 40 ms:** root meat square of the amplitude in the last 40 ms of QRS waves after filtering and Superposition.

✧ **Filter Frequency:** transmission bands of filter;

✧ **Superimposition Numbers:** the number of superposition beats.

✧ **Standard unfiltered:** Unfiltered superposition waves is displayed in this window. Two erect lines denote the start position and end position of standard QRS wave. Click one with the left key of mouse and it will turn blue which shows it has been selected. Here adjusts its position with "←" and "→" on keyboard, meanwhile the data of standard QRS will change, too.

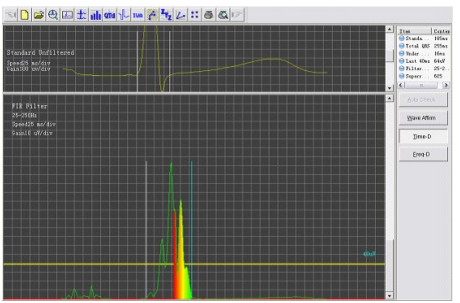


Fig.6-31

Click the right mouse in the window to call up the menu where you can select the superposition wave you want to check. Multiply selection is supported.

✧ **FIR filter:** the superposed wave after filtering is displayed in this window. Two erect lines denote the start position and end position of standard QRS wave. Click one with the left key of mouse and it will turn blue which shows it has been selected. Here adjust its position with "←" and "→" on keyboard, meanwhile the data of standard QRS will change, too. When the end position of QRS wave is adjusted, the data of "Under 40 μV" and "Last 40 ms" will also change.

Click the right key of mouse to call up the setting menu.

✧ **25 Hz~250 Hz:** select the transmission band 25 Hz~250 Hz;

✧ **40 Hz~250 Hz:** select the transmission band 40 Hz~250 Hz;

✧ **10 uV/div:** select the gain 10 uv/div;

✧ **5 uV/div:** select the gain 5 uv/div.

6.18.4 Frequency Domain (Freq-D)

Click this button to enter the interface of frequency domain analysis (as Fig.6-32).

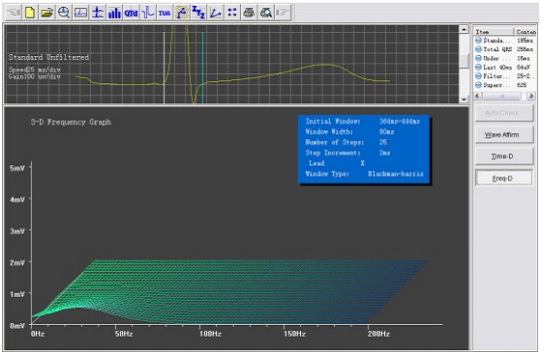


Fig.6-32

The content of data statistics is accordant with time domain analysis in this interface.

Standard unfiltered: in "Freq-D" window a single-lead unfiltered superposed wave is display in this window. Click the right key of mouse to call up a menu without multiply selection. When the end position of QRS wave is adjusted, 3-D frequency graph will also change.

3-D frequency graph: display 3-D frequency graph of the single-lead superposed wave.

Click  to print and click  to preview the VLP analyze report in VLP analytical module.

6.19 Time Vector Electrocardiogram (TVCG)

Click  button and enter TVCG analysis module.

Click R point by mouse, VCG graph will display at the left of the screen.

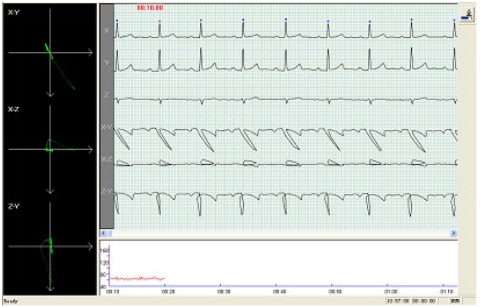
Click  can measure R-R or PR interval and so on.

Waveform window: Display the time vector waveform diagram, mark the currently selected R point with a red dot, and mark the unselected point with a blue dot. Click on the R point with the mouse, and the corresponding electrocardiogram vector diagram will be displayed on the left side of the screen.

Vector Loop Window: Display the vector loops of the frontal plane, transverse plane, and sagittal plane of the currently selected heartbeat.

HR trend chart window: displays the average HR trend chart every ten seconds. The purple vertical line in the chart is a time marker, corresponding to the starting time of the waveform chart drawn in the waveform display window. When clicking the left mouse button on the trend chart, the position of the vertical line changes accordingly, and the starting time of the waveform chart also changes accordingly.

Select heartbeat: Use the up and down arrow keys on the keyboard to browse waveforms, and use the left and right arrow keys to select heartbeat and redraw vector loops.



6.20 Parameter settings

Click  button and enter the parameter setting operation.

6.20.1 Analysis page

The various parameters used when setting up automatic analysis mainly include:

- **R-R Pause:** a standard of judging pause module;
- **Premature beat:**

✧ Maximum R-R interval ratio: used to determine the R-R interval advance rate for premature beats.

✧ Ventricular beat minimum time limit of QRS: QRS wave duration used to distinguish between atrial premature beats and ventricular premature beats.

➢ **Bradycardia:**

✧ Duration time: the shortest time limit of bradycardia segment.

✧ Maximum HR: the highest HR of bradycardia segment.

➢ **Analysis of arrhythmia:**

✧ Refractor period: the minimum interval of two heart beats.

✧ Min. cycle of long run: set the standard for judging whether it is a long run or short run.

✧ Default Classify Method: set the template classification method.

✧ Automatic re-classification: select the types that need to be retained when reclassifying.

➢ **Atrial fibrillation analysis:**

✧ Minimum length: the minimum length of atrial fibrillation fragments.

✧ Minimum HR: the minimum HR of atrial fibrillation fragments.

✧ Min-rate of change: the minimum rate of change in the R-R interval of each heartbeat within the atrial fibrillation segment.

➢ **QTD:** choose the calculation formula for QT discretization analysis.

6.20.2 Display page

Trend chart: select the display method for the trend chart of long cases (more than 1 day).

➢ **Electrocardiogram:**

✧ AC filter: enable power frequency filtering when drawing an electrocardiogram.

✧ Baseline filter: enable baseline filtering when drawing an electrocardiogram.

✧ Smooth display: enable smoothing when drawing an electrocardiogram.

✧ Waveform 6 Leads * 2(10 mm/mV): the multi-lead ECG uses a 6 * 2 display mode with a gain of 10 mm/mV.

✧ Wave color: set color markings for different types of heartbeats on the ECG.

✧ Template: set the default lead for displaying ECG in the template review interface.

✧ Age: set the display format for age.

6.20.3 Print page

➢ **Electrocardiogram:**

✧ Print type: select a type for printing ECG waves;

✧ Wave definition: select a definition for printing ECG waves;

✧ Segment/Page: set the number of ECG segments to be printed per page.

✧ Horizontal print ECG: electrocardiogram fragments turned into horizontal printing.

➢ **General Report:**

✧ Print effective time: the main report has been changed to the 'effective duration' mode.

✧ Print ST result: the main report includes the results of ST segment analysis.

✧ Print long N-N: the main report includes statistical results of long N-N intervals.

✧ Af enters S: the main report includes atrial fibrillation data in atrial premature beats.

✧ Print HRV Result: the main report includes the results of HRV analysis.
✧ Print longest R-R interval: print the statistical results of the longest R-R interval in the main report.
✧ Print first report time: print the time of the first report issued in the main report.
✧ Operator: print operator information in the main report.
✧ Audit Doctor: print the information of the audit doctor in the main report.
➢ **Doctor title:** Select the title of 'Physician Signature' in the main report. You can also add or remove titles.
➢ **Auto-report:** select the automatic description in the diagnostic conclusion.
✧ Custom report title: set the title and subheadings of the main report.
✧ Custom footer comments: customize the footer of the main report.
✧ Print E-report: select to print electronic report.
✧ Print paper report: choose to print the paper report.
✧ Page size: select the type of printing paper.
✧ Short age format: use short format when printing patient age.
✧ Print HR segment length: print the length of heart rate segments in the main report and arrhythmia data table.
✧ Sort segment by time: in the selection print window, electrocardiogram segments are sorted by time.

6.20.4 System page

➢ **Language:** set the interface's language of the software.

✧ Enable welcome window: check this option to display the welcome window after turning on the software.

✧ Enable secure login: check this option to enable the user management and user login functions.

Note: when checking or unchecking two options above, a "Administrators Verification" dialog box will pop up, then input the correct password and click "OK" to complete the operation.

6.21 Case Management

Open the "Maintain" item in the "File", or click  button on main toolbar, enter the case management function.

6.21.1 Modify the display status of the list

 Display all cases or only show cases that have not been deleted.

6.21.2 Modify case information

 Modify the information of a single case.

6.21.3 Delete the selected case

 Selected cases can be deleted, and multiple selections can be made in the case list for simultaneous deletion.

Attention:

Cannot delete the case being reviewed.

Deleting a case is an irreversible operation and cannot be restored after deletion. Please confirm carefully before proceeding with the operation.

6.21.4 View report

 Display electronic reports of a case.

6.21.5 Export case

 Selected cases can be exported, supporting multiple selections in the case list and exporting simultaneously.

The exported file is generated by lossless compression of case data and information, with a smaller size and easier storage and management. If you need to view the exported content, you can restore and open it through the 'Import Cases' function.

Attention:

Before exporting the case, please confirm that the target disk space is sufficient.

After the case is exported, its original data is still saved in the software. After confirming that the exported case file is correct, users need to manually delete the case using the "Delete Case" function.

6.21.6 Import case

 Re import the exported cases into the software for easy review and analysis.

The import window provides a case information preview function to help users confirm the selected case.

If the software detects duplicate cases during import, a prompt window will appear with the following message:

"Yes": the current file will be imported to cover with the same one;

"No": the current file will not be imported;

"All to Yes": all the cases will be imported to cover with the same one;

"All to No": all the same cases will not be imported;

"Cancel": cancel to import the file.

Attention:

Please choose carefully according to the actual situation to avoid the loss of important data.

6.21.7 Page switching

 Page up.

 Page down.

6.21.8 Search for cases

 Search for cases.

6.22 Pacing Analysis

When the data contain pacing signal, the system can identify it automatically and add the pacing analyze function.

After recorder replay, the pacemaker parameters setting window will appear, about its function, please refer to "replay HOLTER recorder".

There are 11 templates windows in the template replay function (as Fig.6-33). One button is for a template. The letters on the button are the name of its template (for example, D is Dual chamber pacing). The percent on the button is the percentage of this kind of waves in total, and here nothing shows the lack.

D: Dual chamber pacing	AP: Atrial Pacing
AUS: Atrial Under Sense	AOS: Atrial Over Sense
AOO: Atrial asynchronous pacing	VP: Ventricular pacing
VUS: Ventricular Under Sense	VOS: Ventricular Over Sense
VFB: Ventricular fusion beat	VO: Ventricular Pseudofusion
VOO: Ventricular asynchronous pacing	

Notice: The blue line under the ECG wave is marker for pacing, shows the position of the pacing signals on the ECG wave.

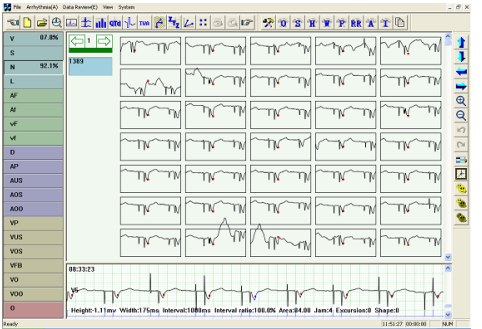


Fig.6-33

Enter the order replay, click the 

button and appear the "Chart" dialog box which added the "Pacemaker Table" (as Fig.6-34).

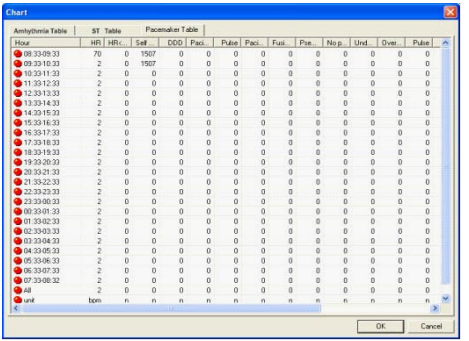


Fig.6-34

6.23 Sleep Breath Pause Syndrome Analysis

In case report  please fill the correct sleep time and wake time about sleeping time segment (as Fig.6-35).

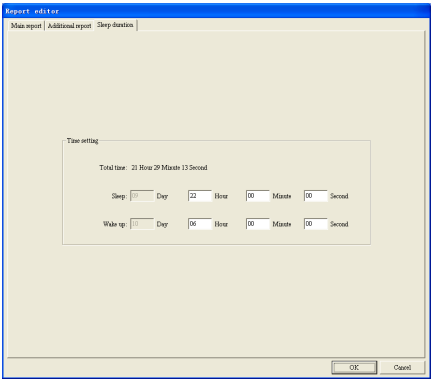


Fig.6-35

Last, in "Select Printing" window  , select "Trend", Multiparameter balance", Dangers analyse" about the option of "Dormancy asphyxia analyse" (as Fig.6-36).

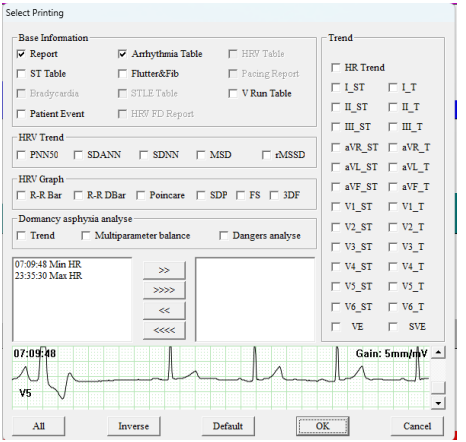


Fig.6-36

Once confirmed, a sleep apnea analysis report can be printed. By comparing and analyzing heart rate variability during sleep and wakefulness periods, a final assessment of the likelihood of sleep apnea syndrome can be made.

Attention: if the sample time is longer than 30 h, the dormancy asphyxia analysis will be disabled, and the "Dormancy asphyxia analyse" option will not appear in the "Select Printing" window.

6.24 Additional Functions

6.24.1 Waterfall Chart

Select the "Waterfall Chart" option in the "Arrhythmia" menu to enter the waterfall chart interface, as shown in Figure 6-37.

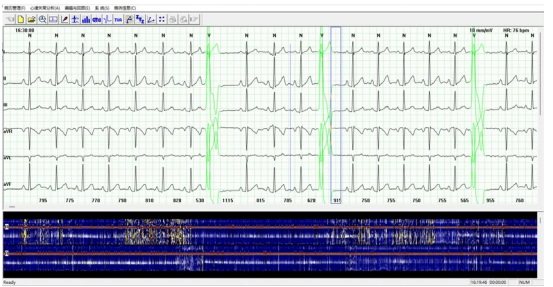


Fig. 6-37

The interface includes an electrocardiogram display window and a waterfall chart display window.

Left click in the waterfall chart window to locate the corresponding heartbeat in the ECG, and then

modify the heartbeat type in the ECG window through left click or right-click menu.

In the waterfall chart window, you can also use the right-click menu to switch leads.

6.24.2 P-R Trend

Select the "P-R Trend" item in the "Arrhythmia" menu to enter the P-R Trend Chart interface, as shown in Figure 6-38.

The interface includes an ECG display window and a P-R trend chart display window.

Left click in the P-R trend chart window to locate the corresponding heartbeat in the electrocardiogram, and then modify the heartbeat type in the electrocardiogram window through left click or right-click menu.

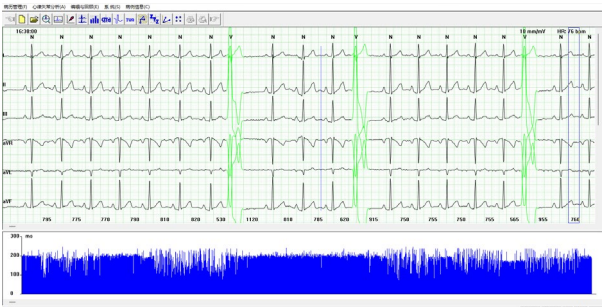


Fig. 6-38

6.24.3 ST_3D Trend

In the “Order Replay” function interface, select the "ST_3D Trend" item from the "Arrhythmia" menu, and the ST Segment 3D Trend Chart window will pop up, as shown in Figure 6-39.

Its main functions include:

✧ **Red color:** the values represented by the red area in the figure.

✧ **Blue color:** the values represented by the blue area in the figure.

✧ **Style:** you can choose whether the current display is a "surface" composed of 3D surfaces or a "frame" composed of curves.

✧ **Quality:** select the quality of the image.

✧ **Color:** adjustable background and coordinate axis colors. Double click on the color block and set it in the pop-up color selection window.

✧ **Show projection:** display the projection of the trend chart onto the base of the coordinate system.

✧ **Smooth:** smooth the image.

✧ **Show Standard:** display standard comparison chart.

✧ **Reset:** restore the trend chart to its initial state.

✧ **Cruise:** dynamic display of trend chart.

✧ **Forward:** push the viewport forward to zoom in on the trend chart.

✧ **Backward:** move the viewport backwards to zoom out of the trend chart.

✧ **Rotate the Trend Chart:**

Upward Downward Towards the left Towards the right

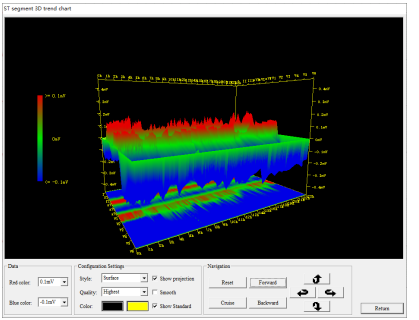


Fig. 6-39

6.25 Case Information

The case information menu item in the main window includes the following functions:

✧ View: display basic information of the current case.

✧ Modify: modify the basic information of the current case.

✧ Preset: store the case information in the record box, and automatically fill in the saved case information when using the " Replay HOLTER recorder " function.

Appendix Ⅰ

Table 1 Accessories

Name	Quality	Type
Disposable ECG Electrodes	1 box	
ECG cable	1 set	Holter one-piece typeA 12leadwire,IEC,TPU,gold-plated button
		Holter one-piece typeA 12leadwire,American standard,TPU,gold-plated button

Table 2 Device combinations

Name	Quality	Type
Host	1 pc	TLC5000
Disposable ECG Electrodes	1 box	
ECG cable	1 set	Holter one-piece typeA 12leadwire,IEC,TPU,gold-plated button
		Holter one-piece typeA 12leadwire,American standard,TPU,gold-plated button
USB2.0 cable	1 pc	HGP0062
PC software	1 pc	V5
Backpack	1 pc	60*25*115mm
User manual	1 pc	140*105mm

Notes:

Please follow the instructions on the package when opening the package.

After unpacking, please check the accessories and accompanying documents in accordance with the packing list, then start inspecting the device.

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

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.

The package shall be kept properly for future use in regular maintenance or device repair.

Product Performance

Lead mode:12 lead

Record time:no less than 24 hours

Common≥60 dB

Gain accuracy:≤10%

Gain stability:≤3%

System noise:≤50 μV

Scan speed：25mm/s

Frequency response:for sin signals with frequency from 0.05 Hz to 40 Hz,the response amplitude

should be between 140% to 70% of the response amplitude at 5 Hz(+3dB to -3dB)
Min detection signal: the min value of physiological signal that can be monitored is 50 μV

Appendix II

Heart rate calculation method: The non-interference heart rate in the ECG picture segment is N, and the heart rate (HR) calculation formula is as follows

HR = 60000 / Sum of R-R interval of N heartbeats / N)

Arrest recognition method: According to the pause maximum heart rate or minimum RR interval set by the user in the "parameter definition" function, compare the RR intervals of non-interference heartbeats, and the eligible heartbeats are classified as long Pause intermittently.

Supplementary explanation of ST segment analysis;

This software can analyze the elevation or depression of the ST-segment average voltage (ie ST-segment displacement) for all leads.

The user can calibrate the ST segment of the ECG waveform in the "Arrhythmia Analysis" function, and in the "Sequence Review" function

Click the "STE" button to set the judgment standard for ST-segment elevation in each lead, or click the "STD" button to set the judgment standard for ST-segment depression in each lead, that is, to change the judgment standard for ST-segment elevation or depression in each lead. voltage range.

The user can view the number of ST-segment elevation and depression in each lead in the "Report", that is, the number of fragments that occurred in each lead segment of the mouth.

This software provides the hourly ST-segment average voltage output of all leads in the "ST-segment data sheet". After using the "Myocardial Ischemia Analysis" function, a total emergency ischemia load table is generated, and the start time and the start time of the ST segment depression segment in each lead of the whole case are counted.

Duration, average heart rate, maximum heart rate, average ST segment voltage, total load, number of premature ventricular and premature events.

The heart rate range and ST segment displacement range of each segment are not counted.

Appendix III

This section provides special tips for electromagnetic compatibility.Install and use the holter according to the electromagnetic compatibility information provided inthis section.

Portable and mobile radio frequency communication devices may affect the use of holter.It is recommended to keep the portable and mobile radio communication devices away from the holter or turn them off when using the holter normally.

The connection cable provided by our company must be used.

Warning:the use of accessories other than those provided by us may result in increased emission or decreased immunity of the holter.

The holter should not be used in close proximity to or on top of other devices with the same or similar operating frequency.If it must be used in close proximity to or in excess of other devices,it should observed and verified that it can operate properly under the configuration used.

Basic performance:the device can display,record.

In order to ensure the normal operation of the holter and ensure that its emission is not increased and its immunity is not reduced,please use the connection cable and related accessories provides by our company.

Use of non-specified accessories,transducers,or cables with the holter may result in increased emission or reduced immunity of the device or system.

 warning

Active medical device are subject to special EMC precaution and must there be installed in accordance with these guidelines and use.

 warning

Portable and mobile communication radio frequance devices may affect the use of medical electrical equipment.

 warning

The use of accessories,transducers,and cables other than those sold by the manufacturer of the equipment or system as spare for internal components may result in an increase in emission or a

decrease in immunity of the equipment or system.

Electromagnetic emissions:

 warning:the device or system should not be in close proximity or overflow with other equipment.if it must be used in close proximity or overflow,it should be observed and verified that it works properly under the configuretion used.

Guidance and manufacturer's declaration-electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	Not applicable
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable
Power frequency magnetic Field IEC 61000-4-8	30A/m 50Hz/60Hz	30A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz–80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and	3 V 0,15 MHz–80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and

	80 MHz 80 %AM at 2 Hz	80 MHz 80 %AM at 2 Hz
Radiated RF IEC61000-4-3	10 V/m 80 MHz–2,7 GHz 80 %AM at 2 Hz	10 V/m 80 MHz–2,7 GHz 80 %AM at 2 Hz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity						
	Test Frequency (MHz)	**Band** (MHz)	**Service**	**Modulation**	**IEC 60601-1-2 Test Level** (V/m)	**Compliance level** (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY To RF wireless Communicat ions equipment)	385	380-390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430-470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	28	28
	710	704-787	LTE Band 13,17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800-960	GSM	Pulse	28	28

	870 930		800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	modulation 18 Hz		
	1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	28	28
	2450	2450-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	、28
	5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity				
Radiated RF	**Test**	**Modulation**	**IEC**	**Compliance**

IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	**Frequency**		**60601-1-2 Test Level** (A/m)	**level** (A/m)
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 MHz	Pulse modulation 50 kHz	7,5	7,5

Appendix IV

In normal use condition that user strictly following the user manual and operation precautions to use, if the device shows any problem, please contact our customer service department. Our company has factory records and user profiles for each device, according to the warranty period and conditions specified below, user enjoys free maintenance services for one year from the date of purchase. In order to facilitate us to provide you with a comprehensive and efficient maintenance service, please be sure to return the warranty card when you need repair service.

Our company may adopt remote guidance, express delivery, visiting service or other methods to carry out the maintenance service.

Even in the period of free maintenance, we may charge for repair in the following situations:

- Faults or damages caused by not following the user manual and operation precautions.
- Faults or damages caused by dropping accidentally when moving the device.
- Faults or damages caused by repair, reconstruction or decomposition, etc. by others except our company.
- Faults or damages caused by improper storage or force majeure.

The free maintenance period for accessories and wear-out parts is half a year. The user manual and packaging materials are excluded.

Our company is not responsible for any malfunction of other connecting instruments directly or indirectly caused by the failure of this device.

The free maintenance service is valid only when the protection label is intact.

For paid maintenance beyond the warranty period, our company recommends to continue to obey the "Maintenance contract regulation". Please consult our customer service department for specific situation.

Others

Do not open the device enclosure to avoid from possible electric shock.

The device associated circuit schematics and critical parts list are only available to authorized service station or maintenance personnel, who is responsible for maintenance of the device.

The device belongs to measuring instrument. User should send the device to national designated inspection institution for inspection according to requirements. The device shall be inspected at least

once per year, and all the accessories should be inspected and maintained at least once every six months.

Software Installation Instructions

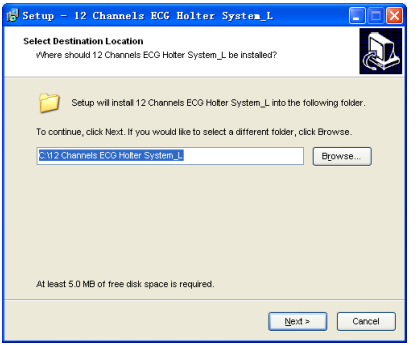
NOTE: This software should be installed by a designated person authorized by the company.

Double-click the installation package, when the window “User Account Control” pops up, select “YES” for the option “Do you want to allow this app from an unknown publisher to make changes to your device?”.

1) After entering the installation, if the software supports several languages, then “Select Setup Language” interface as shown below will pop up.

Click “OK” after selecting a language from the drop-down list.

2) Then enter the selection window for the installation position as the Figure below.

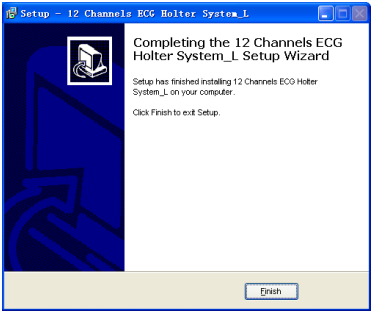


Click “Browse” to select a destination location, it is recommended to install it in a non-system disk.

Click “Next” in the “Select Start Menu Folder” window.

3) Click “Install” in “Ready to Install” window.

4) Installation complete.



Click “Finish” in the prompt window.

Security advice

To protect the security of patients' personal health information, we provide the following security advice:

1. Automatic screen lock: Set up a screen saver that displays the login interface when resumed, shorten the automatic logout interval when the system is idle, and recommend that users log out or shut down the computer when leaving;

2. Users can use Windows user accounts and passwords, or the secure login provided by this software

(see the User Management section). If using Windows user accounts and passwords, please note the following two points:

(1) Set complex passwords and change them regularly. We recommend enabling Windows password policies;

(2) Disable administrator and guest accounts. Each user should have a unique identity;

3. Install security software and antivirus software, and enable the firewall and automatic updates. Run antivirus software regularly;

4. Ensure the physical security of all devices storing personal information (excluding removable media), meaning they cannot be removed without tools;

5. This software contains personal health information and medical records that require protection and confidentiality. Do not copy patient health information and medical records to removable storage media. If copied, ensure the physical security of the medium at all times;

6. Take antivirus measures before using USB storage devices, such as scanning the USB device for viruses;

7. Disable default services such as Windows Remote Desktop, Telnet, and file sharing;

8. Secure environment:

This product is designed to be used in an environment with the following expected privacy and security safeguards:

(1) The computer on which this software is installed should be physically protected to prevent

unauthorized users from accessing it;
(2) External media containing patient data, reports, and logs should be protected. When no longer in use, data should be securely deleted and/or the media should be safely removed;
(3) The display of computers on which this software is installed should be positioned so that only authorized users can view the screen content.

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