


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 °C~45 °C
Relative Humidity:	≤85 %, no condensation
Atmospheric pressure:	860 hPa~1060 hPa
Power Supply:	DC 1.5 V

Transport and Storage Environment

Environment Temperature:	-40 °C~+55 °C
Relative Humidity:	≤85 %, no condensation
Atmospheric pressure:	860 hPa-1060 hPa

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(32 bit)/Windows 7(32 bit)
Microsoft Windows 2000(64 bit)/XP(64 bit)/Vista(64 bit)/Windows 7(64 bit)

Display: Color display with the resolution 1024×768 or advanced

Resolution of printer: 600DPI

1.2 Product Feature and Anticipative Purpose

Product feature:

This system contains recorder & analysis software. Recorder is an easy-to-use unit, which collects 12-lead ECG waveform synchronously and records at least 24 hours continuously. With the clear operating interface, analysis software is easy for you to use, which can play back and classifying dispose ECG waveform stored in recorder and achieve kinds of analysis functions, such as arrhythmia, HRV, QTD, TWA, etc.

Anticipative purpose:

This system can be used for dynamic monitoring of the heart disease, such as arrhythmia, coronary heart disease, and so on. It can record ECG signal for human body at least 24 hours, store the signal without compression, provide diagnosis basis for doctors by effective analysis software.

1.3 Safety

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



Warning:

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 °C).

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 LR03 AAA 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 expected 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.

	The protection categories against electric shock of the patient connections are: This symbol indicates that the instrument is IEC 60601-1 Type BF equipment.
	USB interface.
	reclaimable icon.
IP22	Degree of protection against ingress of water: 2 Degree of protection against ingress of dust: 2
	Serial number

	<p>Refer to instruction manual/booklet.</p>
	<p>This item is compliant with Directive 93/42/EEC of 14 June 1993 concerning medical devices; Including, at 21 March 2010, the amendments by Council Directive 2007/47/EEC.</p>
	<p>European Representative</p>
	<p>Manufacturer</p>
	<p>Date of manufacture</p>
	<p>Temperature limit</p>
	<p>Humidity limitation</p>
	<p>Atmospheric pressure limitation</p>

	Keep dry
	Fragile,handle with care
	UP
	Recycling regeneration mark

1.4 Cleaning and Maintenance

It is recommended that you check if there is any damage on the recorder or leads wires before monitoring on the patient. If you find any damage, stop using it, and contact the biomedical engineer of the hospital or our Customer Service immediately.

In addition, the overall check of the recorder, including the safety check, should be performed only by qualified personnel once every 12 months.

The recorder can be cleaned with hospital-grade ethanol and dried in air or with dry and clean cloth. Please take out the batteries if the recorder is not in use for a long time and proper safekeeping.

Chapter 2 Frame Character of Product

2.1 Sketch Map for Every Orientation

2.1.1 Front View

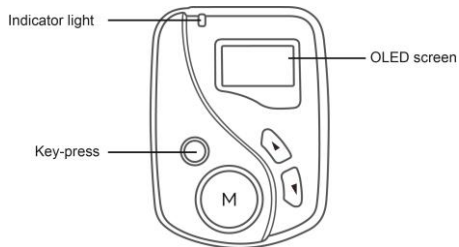


Fig.2-1 Front view

2.1.2 Top View

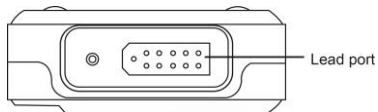


Fig.2-2 Top view

2.1.3 Bottom View

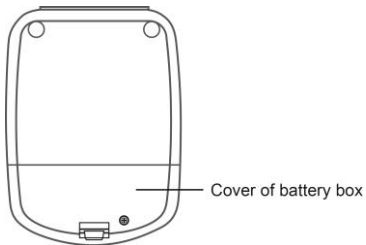





Fig.2-3 Bottom view

2.2 Definition of Keys and Indicator Light

 /  or  Function key: Power on/Power off/Menu/Return

 Function key: OK

 Function key: Up

 Function key: Down

Indicator light: glint every 8 seconds in the process of ECG signal collection.

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.

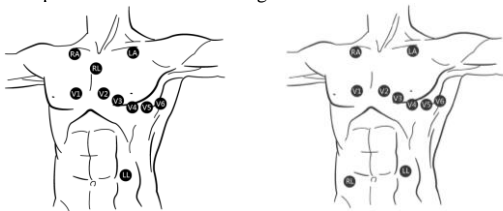


Fig.3-1

◆ 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

Please ensure to install battery properly according to the marking in the battery box, as shown in Figure 3-2.

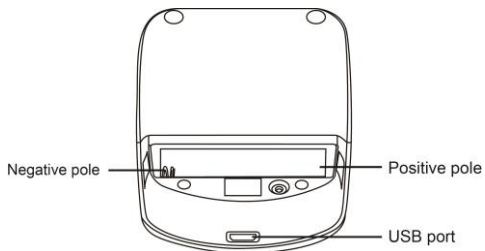


Fig.3-2

Warning:

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

Warning:

Don't use chargeable battery, otherwise the electric quantity may display inaccurately or the recording time may be not 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 or if it won't be not used long 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.




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

4.1 Record Operation

Long press  /  or  button to open the recorder (long press this button can also close the recorder). After opening the recorder, display the international standard I-lead waveform as Fig.4-1.

Press up button  and down button  to switch waveform between the twelve leads. After all the waveforms can display normally by switching, long press , a prompt of start recording will appear, as shown in Fig. 4-2.


If you don't want to record the data, please release  before the prompt of start recording appear, and the recorder will return to the interface as Fig.4-1.




Fig.4-1



Fig.4-2

The start recording interface will last about 5 or 6 seconds, then the screen will turn black

completely, and the recorder will enter the saving-power mode. When recording, the indicator light on the top left corner of the recorder will glitter one time every 8 seconds, it means that the record state is normal.

When recording, if the patient feels uncomfortable suddenly, please long press  to mark. After recording, when the PC software analyses the recording data, the PC software can display the marked waveform, and the doctor can analyses the problem according to the marked waveform more exactly.





When recording, if the user wants to end the recording by hand, please long press  /  or  button about 3 seconds, then the recorder will display the interface as Fig.4-3. The interface is used to affirm whether to end recording or not.




Fig.4-3



Fig.4-4

If the user want to end recording, long press  at the interface as Fig.4-3, then the screen will display the information as Fig.4-4. The interface lasts about 2 seconds, then return to the interface as the Fig.4-1.

4.2 System Setting

In the interface as Fig.4-1, press  or  to enter system setting interface as Fig.4-5 and Fig.4-6.

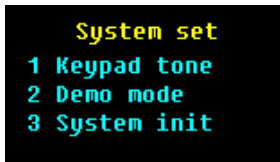


Fig.4-5

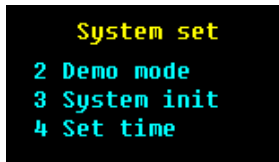





Fig.4-6

Press up button  and down button  to choose the item, and press  to affirm the selective setting item.

1 keypad tone setting



Set keypad tone on/off.

2 Demo mode



Choose on, and the user can see the demo waveform as Fig.4-7.



Fig.4-7

Press up button  and down button  to switch lead, and look on the waveform of different lead.

3 System initialization

Press  to enter initialization interface as Fig.4-8. Press  again to initialize system as Fig.4-9.

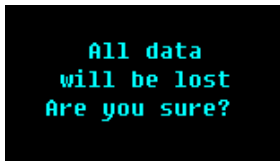


Fig.4-8

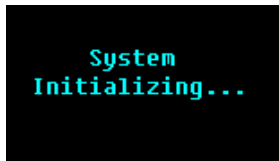



Fig.4-9

Notice:all the data in TF card will be lost after running the System initialization, please use carefully!

4 Time setting

Press  to enter the time setting interface as Fig.4-10.

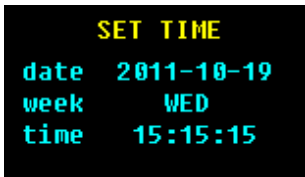








Fig.4-10

Press  to choose the item to set (the week needn't set). Press up button  and down button  to change the value. After setting, press / or  to save the setting and return the the superior menu.

4.3 Record Replay

Take off the electrodes on the patient, and Using an USB cable to connect the recorder with the PC, then an icon will appear on the PC, as shown in Figure 4-11.

Note: Please make sure the recorder is already powered off before connecting the USB cable. Remove batteries first, then insert the USB cable.

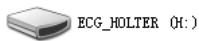


Fig.4-11

Open the disk, and find the file "ECG_WAVE.BIN" as Fig.4-12.



Fig.4-12

Select this file in the analysis software and perform replay.

Note: 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 Problems 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 a gain.

The recording time on the recorder is different with the practical recording time.	1.The quality of the battery is poor. or the battery has been put for a long time.	Change another high-quality new battery.
	2.Because the characteristic and brand of the battery are different, large internal resistance influence operating voltage and discharging current.	Change another new battery.
The data can't be cleared away.	1.Some part of the recorder may be damaged because the electrolyte in the battery flows out.	Please contact our company.

5.3 Problems 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 Problems 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 has much false error, and the quality of ECG signal is poor.	1. The cable isn't connected well or has not enough buffer length or is fixed improperly.	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
- Version naming rules: V<major version No.>.<minor 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.

Start the analysis software for this system. The main interface is shown as Fig.6-1.

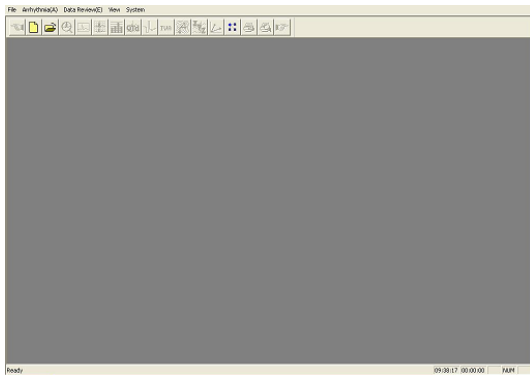

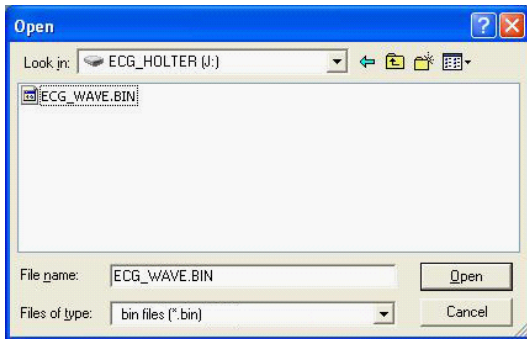


Fig.6-1

Replay HOLTER recorder

Connect the HOLTER recorder with PC. Click the "New" in the menu of "File" or click , and input the new patient information.

If the recorder use SD memory, please choose the collection file ECG_WAVE.BIN (as Fig.6-2 up). Certainly you could also copy the case history to other place, then choose. If the recorder use Flash memory, please turn to Fig.6-2 below.



New Case

Patient Information

Name:	<input type="text"/>	Sex:	Male	▼	Pacemaker:	No	▼				
Age:	<input type="text"/>	Admission No.:	<input type="text"/>								
ID:	0000002	Report No.:	<input type="text"/>								
Department:	<input type="text"/>	Bed No.:	<input type="text"/>								
Height:	<input type="text"/>	cm	Weight:	<input type="text"/>	kg						
Doctor Name:	<input type="text"/>	Doctor Tel.:	<input type="text"/>								
Date:	7	/	4	/	2016	Time:	10	:	32	:	10
	MM		DD		YYYY		hh		mm		ss
Hospital Title:	<input type="text"/>										

Connect recorder and press button...

Fig.6-2

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

After the patient's data input, to click , and the computer begins to read data from the recorder. The prompt (as Fig.6-3) will pop up when the communication finishes. Here click to enter the interface of arrhythmia analysis (as Fig.6-5), and click 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).

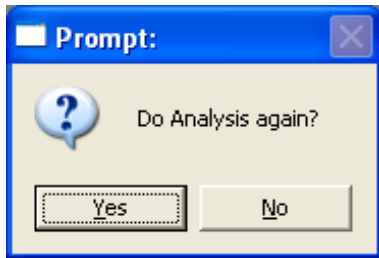


Fig.6-3

Attention: If the patient takes a pacemaker, the pace maker parameters setup interface (as Fig.6-4) will pop up before arrhythmia analysis interface appears. Here doctors need modify the following items according to patient's pace maker 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".

Pace Maker Parameters

Parameters:

Implanted Date: 2008 Year 7 Month 7 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 \div 0.1ms

Pulse Height: High Common Low

OK Cancel

Fig.6-4

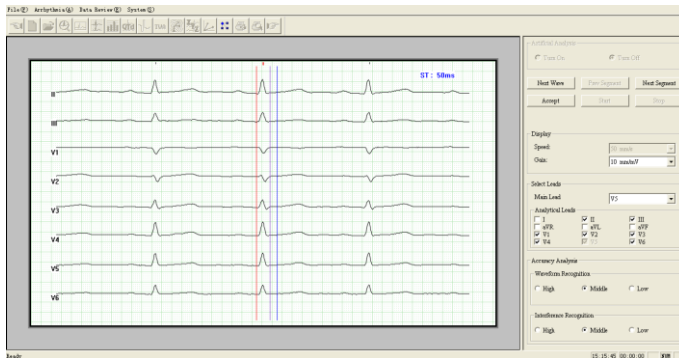


Fig.6-5

The left side of the interface (as Fig.6-5) 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.6-6) 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's wave is too low, please choose "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.

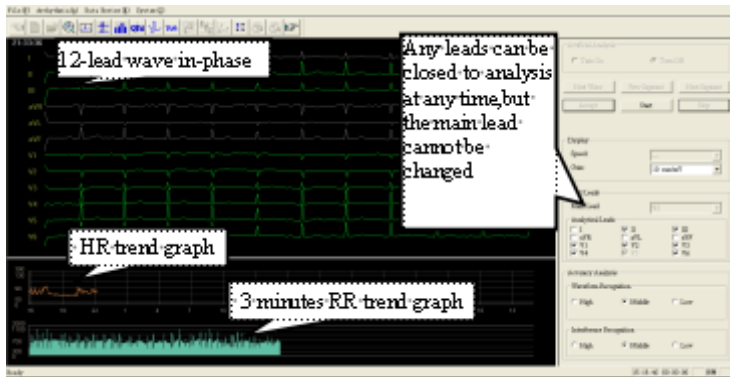


Fig.6-6

Click "Stop", the system will stop temporarily. User can browse the 12 lead ECG through " $\leftarrow \uparrow \rightarrow \downarrow$ " 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.6-7). When the analysis stopped, press " $\leftarrow \uparrow \rightarrow \downarrow$ " on the keyboard to go back to certain point to analyze again if necessary.



Fig.6-7

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

Scroll bar usage


Click the "▲▼" at the right side of the Window or scroll bar to change the content shown in the window.

Click "▲" to roll up a row and click "▼" to roll down a row, click the point between "▲▼" to page up or down.

Change window size

Move the mouse arrowhead to the side of box, when the arrowhead turn to " \leftrightarrow " or " \updownarrow ", press the left keypad of mouse and don't set free until drag to the wanted location.

Screen interface distributing

Click  into the template replay module (as Fig.6-8)

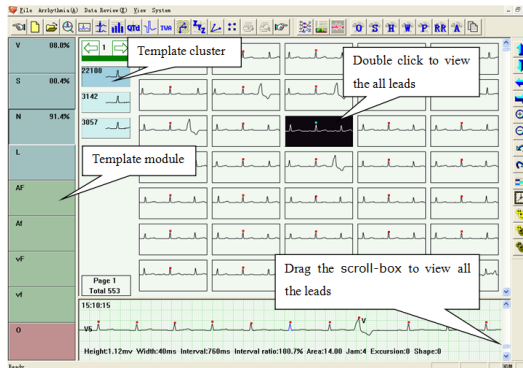


Fig.6-8

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

The top right window is display window for the selected template in the template cluster, which displays every waveform.

The bottom right window is the waveform show window, which displays the detailed information of the waveform which the mouse is pointing.



Classify all the beats by shape.



Classify parameter adjustment function (as Fig.6-9).

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.

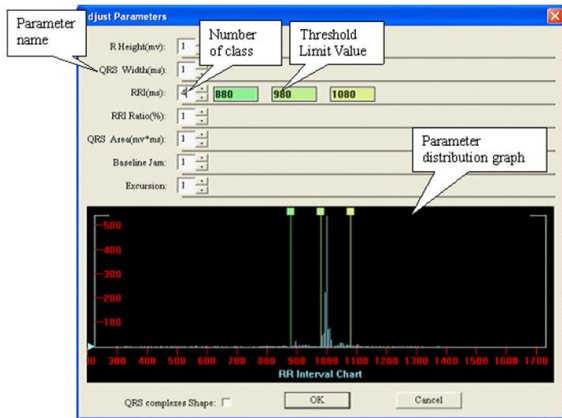


Fig.6-9

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

Fig.6-10 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.

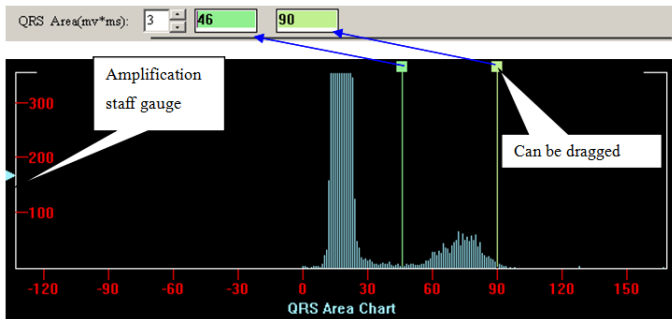
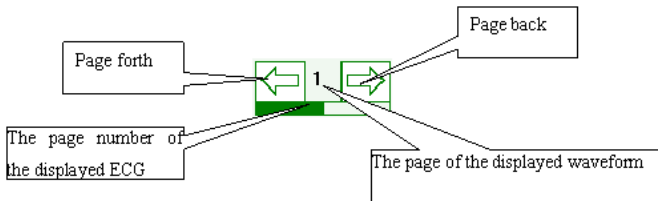


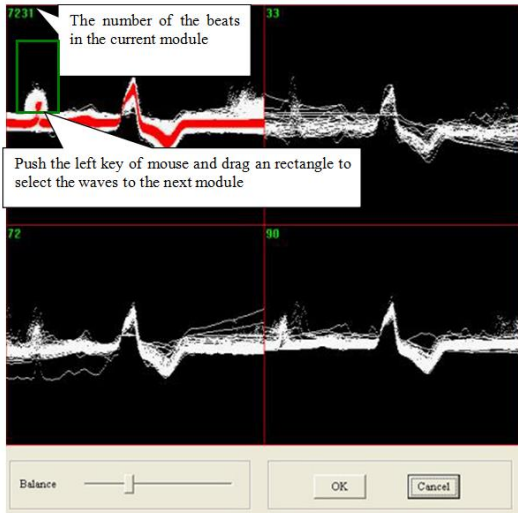
Fig.6-10

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




Classify all the selected beats by Demix.

Enter the Demix analyze all the selected beats are shown in the first module, the density of the wave is more higher and the color is more darker. Use the balance scroll-box to regulate the color of density of the wave. Click the button "OK" can classify the selected beats.



Quick classify




Classify by the shape of the Baseline jam, click the button  to change the default parameters;




Classify by the shape of the wave's shape;




Classify by the shape of the R wave's height, click the button  to change the default parameters;




Classify by the shape of the QRS width, click the button  to change the default parameters;




Classify by the shape of the RR Interval, click the button  to change the default parameters;



Classify by the shape of the RR Interval Ratio, click the button  to change the default parameters;



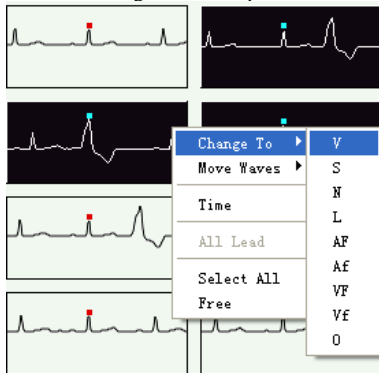
Classify by the shape of the QRS's Area($\text{mv} \cdot \text{ms}$), click the button  to change the default parameters.



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.

Right button editor menu

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.

"Page up", "Page down", "home", "end", "↑", "↓" mean page up, page down, to the beginning of the page, to the end of the page, up and down.

Control graph display key



Remove the ECG in the left window up



Remove the ECG in the left window down



Remove the ECG in the left window left



Remove the ECG in the left window right



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



Click the button and enter order replay module (as Fig.6-11).

The waves of main analysis lead is displayed in the window as default. The red point is the heart beat mark.

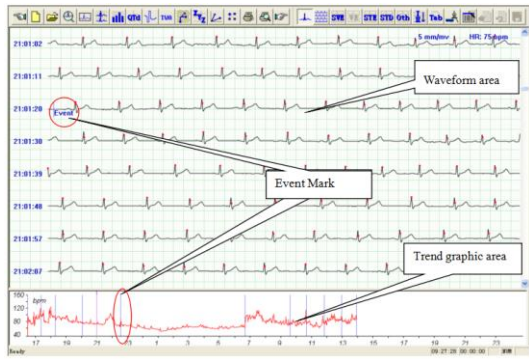


Fig.6-11

Event marker, including the blue lines and "Event" 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.

Trend graph display area:

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.

Click the right key of mouse in the window to call up the menu (as Fig.6-12).



Fig.6-12

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 Trend: display RR 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".

Click  to choose the item "Draw trend type".

Continuous mode:

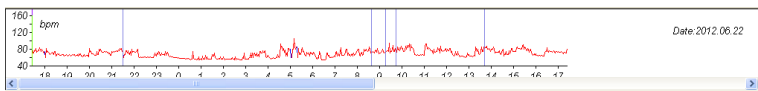


Fig.6-13

As Fig.6-13, rolling bar will appear in the continuous mode in the bottom of window and time will appear on the right. You can drag the rolling bar to change the beginning time of trend graph, meanwhile time display and ECG waveform will change, too.

Contrast mode:

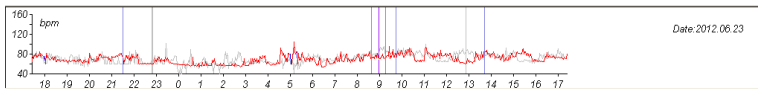


Fig.6-14

As Fig.6-14, many curves in 24 h are plotted, the red curve is the current selected one, other curves show the HR change of other time.

Click curve with the left key of mouse, and the curve will turn red. Synchronously time mark line, date display and ECG waveform will change, too.

Waveform display area:

Click on the ECG by the right key of mouse, the menu (as Fig.6-15) will appear. Doctor can check and analyze patient's ECG as required.

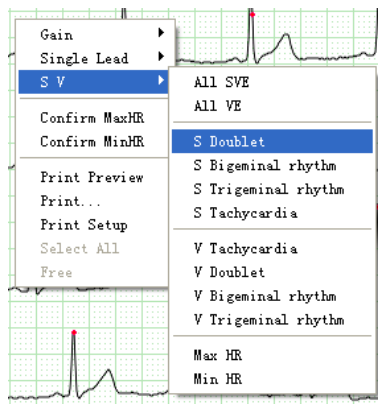


Fig.6-15

Click "Gain" to adjust the wave's gain, viz. Amplification factor.

Click "single lead" to change the lead no. and display the ECG of appointed lead.

Click "SV" to display all the strip graph of the appointed kinds in the current ECG.

Click "Max HR" to select ECG as Max HR ECG.

Click "Min HR" to select ECG as Min HR ECG.

Prompt:

The strip graph is such a graph that it can plot a single lead ECG wave in a quadrate area and mark the beginning time and average heart rate. The wave of 3.5 s after the beginning time is the main wave.

Pressing "Ctrl" key on the keyboard and clicking the left key of mouse on some a strip graph can select it to change the attribute or delete. The background of the selected strip graph will turn black. The same operation can also cancel the selection.

The following is the introduction taking example for "Max HR".

Click "Max HR" in the menu as Fig.6-15, and the strip graph of the max heart rate will appear, which is for the main analytical lead. Of course, the physician can choose other lead according to the

needs by  button (as Fig.6-16).

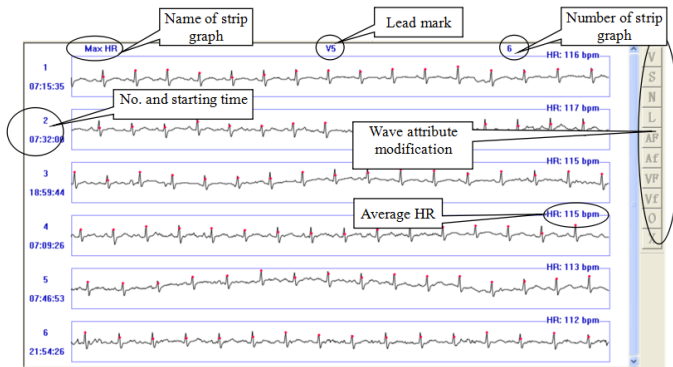


Fig.6-16

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

In this interface, the software selects no1 strip graph 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 strip graphs 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 strip graph and add to the display, as Fig.6-17.

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.

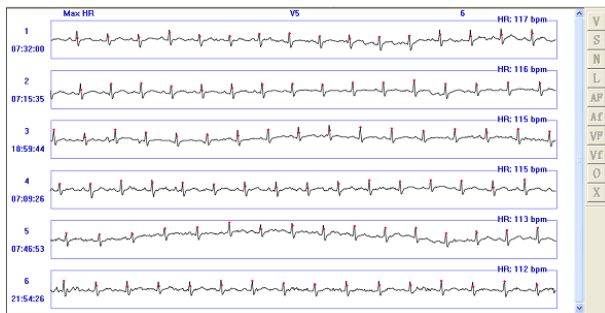


Fig.6-17



Click  button, show the multi-lead ECG from the starting time (as Fig.6-18).



Fig.6-18

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

Click  button, show the strip graph of supra ventricular electrocardiogram (as Fig.6-19).

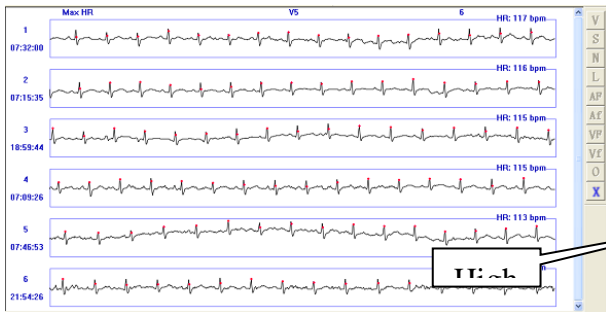



Fig.6-19

Click  button, show the strip graph of ventricular electrocardiogram (as Fig.6-20).

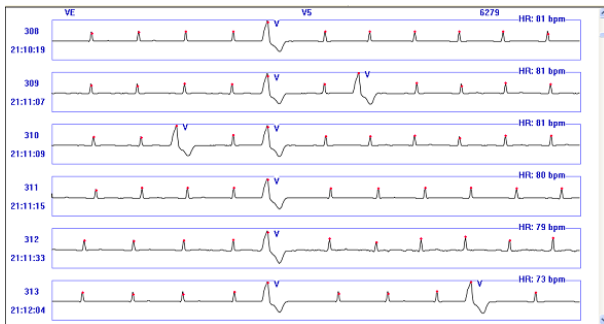








Fig.6-20

Attention: the strip graph of  and  can be modified on attribute in the selected state, while the strip graph of ,  and  can only be deleted.



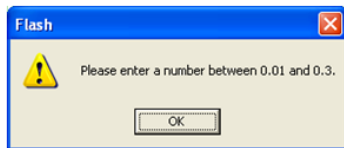
Click the  button, enter ST elevation ECG analysis.



The "ST Segment" dialog box is titled "ST Elevation/Depression". It contains a list of leads with radio buttons and input fields for "Period" and "Q/T". Lead V2 is selected. At the bottom are "OK", "Default", and "Cancel" buttons.

Lead	Period*	Q/T
<input type="radio"/> I	0	0.2
<input type="radio"/> II	0	0.2
<input type="radio"/> III	0	0.2
<input type="radio"/> aVR	0	0.2
<input type="radio"/> aVL	0	0.2
<input type="radio"/> aVF	0	0.2
<input type="radio"/> V1	0	0.2
<input checked="" type="radio"/> V2	0	0.2
<input type="radio"/> V3	0	0.2
<input type="radio"/> V4	0	0.2
<input type="radio"/> V5	0	0.2
<input type="radio"/> V6	0	0.2

The physician can "choose lead" according to what he needs to input the parameter. The parameter should be between 0.01 and 0.3. If the input number is out of the range, the computer will display:



Click "ok", and input the parameter again.

Select a lead and click "OK", and in the background window all of the STE strip graphs of this lead, as Fig.6-21.

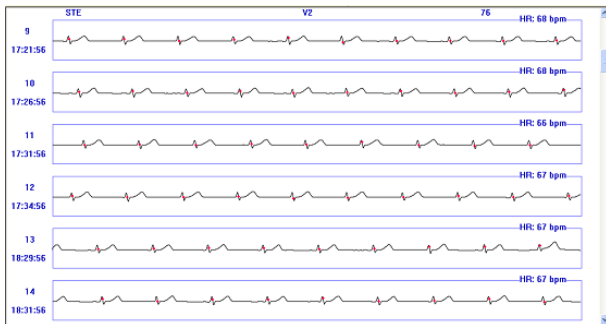


Fig.6-21

Select a lead and click "OK", and in the background window all of the STD strip graphs of this lead, as Fig.6-22.

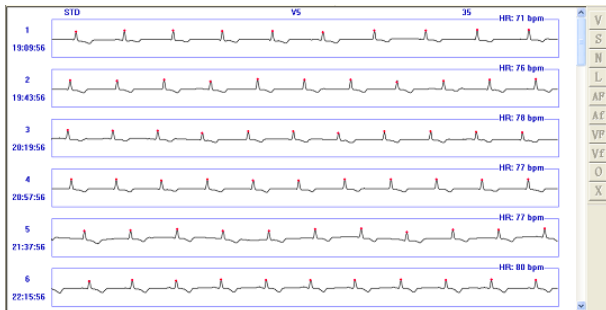





Fig.6-22

Click  button, display other classified strip graph: S Couplet, S Bigeminal rhythm, S Trigeminal rhythm, S Run; V Run, V Couplet, V Bigeminal rhythm, V Trigeminal rhythm, R-R Pause, Atrial flutter, Atrial fibrillation, V Flutter, V Fibrillation, Max HR, Min HR, Bradycardia.

Before above the classified ECG display operations, if refresh button  (high bright) means the data need refresh, click this button to refresh data.

Click  button to display single lead ECG waveform or change the lead displayed in the strip graph.

Click  button, display chart.

Arrhythmia Table: display the arrhythmia statistic for every hour, as Fig.6-23.

Av.HR: Average HR	Min HR: minimum HR
Max HR: maximum HR	V: ventricular premature beat
V Couplet: 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 Couplet: 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 any a data among the row of "Av. HR" "Min HR" and "Max HR" with the left key of mouse to modify it, and click "OK" to save this modification.

Time	Av. HR	Min HR	Max HR	V	V Cos	V Short	V Long	V Big	V Trig	S	S Coups	S Short	S Long
16:30-17:30	88	69	122	9	0	0	0	0	0	2	0	0	0
17:30-18:30	96	77	127	6	0	0	0	0	0	1	0	0	0
18:30-19:30	88	78	102	1	0	0	0	0	0	0	0	0	0
19:30-20:30	87	74	105	0	0	0	0	0	0	1	0	0	0
20:30-21:30	78	69	89	0	0	0	0	0	0	0	0	0	0
21:30-22:30	84	69	107	2	0	0	0	0	0	0	0	0	0
22:30-23:30	75	63	90	2	0	0	0	0	0	3	0	0	0
23:30-00:30	65	57	74	0	0	0	0	0	0	1	0	0	0
00:30-01:30	59	51	68	7	2	0	0	0	0	11	0	0	0
01:30-02:30	60	54	68	2	0	0	0	0	0	12	0	0	0
02:30-03:30	67	62	74	0	0	0	0	0	0	1	0	0	0
03:30-04:30	70	60	82	0	0	0	0	0	0	4	0	0	0
04:30-05:30	65	58	75	0	0	0	0	0	0	7	0	0	0
05:30-06:30	67	59	77	1	0	0	0	0	0	9	0	0	0
06:30-07:30	82	63	116	8	0	0	0	0	0	6	0	0	0
07:30-08:30	93	76	123	6	0	0	0	0	0	0	0	0	0
08:30-09:30	83	69	105	0	0	0	0	0	0	1	0	0	0
09:30-10:30	76	66	89	1	0	0	0	0	0	0	0	0	0
10:30-11:30	83	64	117	8	0	0	0	0	0	5	0	0	0
11:30-12:30	79	63	107	2	0	0	0	0	0	5	5	0	0
12:30-13:30	86	73	106	0	0	0	0	0	0	2	0	0	0
13:30-13:59	91	75	115	2	0	0	0	0	0	2	0	0	0
All	77	51	127	57	2	0	0	0	0	73	0	0	0
Unit	bpm	bpm	bpm	n	n	n	n	n	n	n	n	n	n

Fig.6-23

ST Table: display the average ST voltage of each lead for every hour. As Fig.6-24.

Time	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
16:30-17:30	0.04	0.11	0.08	-0.07	-0.02	0.10	-0.07	0.04	0.28	0.22	0.11	0.07
17:30-18:30	0.04	0.10	0.06	-0.07	-0.01	0.08	-0.05	0.04	0.28	0.21	0.10	0.06
18:30-19:30	0.04	0.14	0.10	-0.09	-0.03	0.12	-0.04	0.12	0.35	0.24	0.11	0.07
19:30-20:30	0.04	0.14	0.10	-0.09	-0.03	0.12	-0.02	0.17	0.36	0.25	0.11	0.08
20:30-21:30	0.04	0.16	0.12	-0.10	-0.03	0.14	-0.01	0.16	0.36	0.24	0.11	0.08
21:30-22:30	0.04	0.11	0.08	-0.07	-0.02	0.09	-0.02	0.07	0.29	0.19	0.09	0.06
22:30-23:30	0.04	0.12	0.09	-0.08	-0.02	0.11	0.04	0.20	0.31	0.18	0.09	0.06
23:30-00:30	0.03	0.11	0.08	-0.07	-0.02	0.09	0.05	0.21	0.33	0.20	0.09	0.07
00:30-01:30	0.03	0.10	0.07	-0.07	-0.01	0.08	0.04	0.17	0.30	0.22	0.11	0.07
01:30-02:30	0.03	0.10	0.07	-0.06	-0.02	0.08	0.04	0.16	0.30	0.19	0.10	0.07
02:30-03:30	0.03	0.11	0.08	-0.07	-0.03	0.10	0.02	0.15	0.30	0.19	0.09	0.06
03:30-04:30	0.03	0.10	0.07	-0.06	-0.02	0.08	0.02	0.18	0.30	0.19	0.09	0.06
04:30-05:30	0.03	0.09	0.05	-0.06	-0.01	0.07	0.02	0.16	0.28	0.24	0.13	0.07
05:30-06:30	0.03	0.10	0.07	-0.06	-0.02	0.08	0.04	0.21	0.29	0.17	0.07	0.05
06:30-07:30	0.03	0.06	0.03	-0.04	0.00	0.04	-0.03	0.07	0.25	0.17	0.07	0.04
07:30-08:30	0.03	0.09	0.06	-0.06	-0.01	0.08	-0.05	0.06	0.27	0.19	0.08	0.05
08:30-09:30	0.03	0.12	0.09	-0.08	-0.03	0.10	-0.05	0.07	0.28	0.21	0.10	0.07
09:30-10:30	0.03	0.12	0.09	-0.07	-0.03	0.11	-0.05	0.05	0.29	0.23	0.11	0.07
10:30-11:30	0.03	0.11	0.08	-0.07	-0.02	0.09	-0.04	0.05	0.29	0.22	0.10	0.06
11:30-12:30	0.03	0.10	0.07	-0.06	-0.02	0.08	-0.04	0.07	0.28	0.20	0.09	0.06
12:30-13:30	0.04	0.10	0.06	-0.07	-0.01	0.08	-0.01	0.12	0.31	0.18	0.08	0.05
13:30-13:59	0.04	0.09	0.05	-0.06	-0.01	0.07	-0.01	0.11	0.31	0.19	0.09	0.06
All	0.03	0.11	0.07	-0.07	-0.02	0.09	-0.01	0.12	0.30	0.21	0.10	0.06
Unit	mV	mV	mV	mV	mV	mV	mV	mV	mV	mV	mV	mV

Fig.6-24

Double click any a data in the row from "I" to "V6" with the left key of mouse to modify it, and click "OK" to save this modification.

STLE analysis

Click "STLE" item inside of "Arrhythmia" item, show ST adjusting window as Fig.6-25.

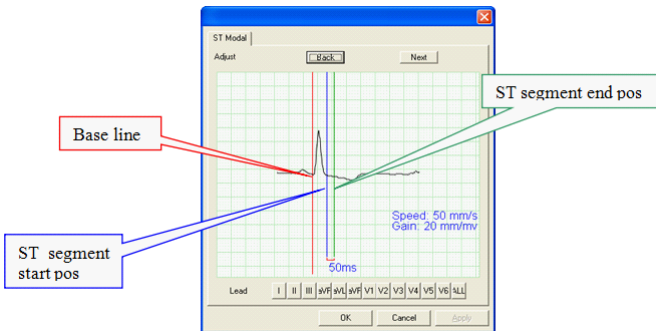


Fig.6-25


Back: display the former beat waveform;

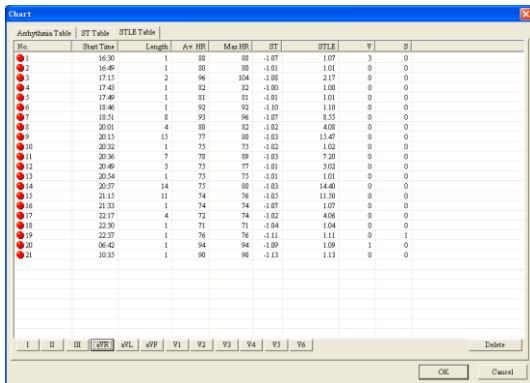
Next: display the next beat waveform;

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

Adjust the position of baseline: set the mouse cursor about the line you want to adjust, click the left of mouse, this line will move to the position of the mouse cursor.

Click "OK" after adjusting well, the software will operate all beats ST analysis, and display the analyzing result in the myocardium ischemia table.

Click  button, display STLE table, as Fig.6-26.



No.	Start Time	Length	Av HR	Max HR	ST	STLE	V	S
1	16:30	1	80	80	-1.07	1.07	3	0
2	16:49	1	80	80	-1.01	1.01	0	0
3	17:15	2	96	104	-1.08	2.17	0	0
4	17:43	1	82	82	-1.00	1.00	0	0
5	17:49	1	81	81	-1.01	1.01	0	0
6	18:46	1	92	92	-1.10	1.10	0	0
7	18:51	8	93	96	-1.07	8.55	0	0
8	20:01	4	80	82	-1.02	4.08	0	0
9	20:15	15	77	80	-1.03	15.47	0	0
10	20:32	1	75	75	-1.02	1.02	0	0
11	20:36	7	78	89	-1.03	7.20	0	0
12	20:49	3	75	77	-1.01	3.02	0	0
13	20:54	1	75	75	-1.01	1.01	0	0
14	20:57	14	75	80	-1.03	14.40	0	0
15	21:15	11	74	76	-1.05	11.50	0	0
16	21:33	1	74	74	-1.07	1.07	0	0
17	22:17	4	72	74	-1.02	4.06	0	0
18	22:30	1	71	71	-1.04	1.04	0	0
19	22:37	1	76	76	-1.11	1.11	0	1
20	06:42	1	94	94	-1.09	1.09	1	0
21	10:35	1	90	90	-1.13	1.13	0	0

Fig.6-26

Each row in the table stands for each period of time of ST depression of display lead. The data of table contains: Start time, lasting Length, Av.HR, Max HR, ST, STLE, V, S.

User could delete some periods of time in table directly, knock "ok", the changed file will be saved.

User could double click the row in the table, then the order review window will display multi-leads waveform, the beginning time of waveform is the same as "beginning time" of the row as Fig.6-27.

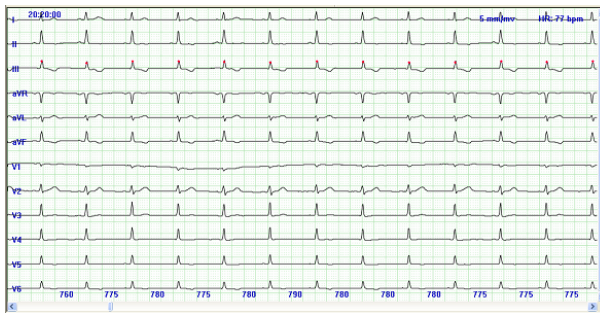
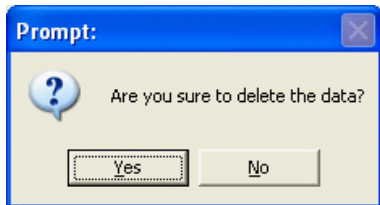


Fig.6-27

After deleting the some periods of time, if user don" knock "ok" before double click the row in the table, program will remind user to save the changed file or not with the dialog box below.



Choosing will save the changed file, choosing will not save.

Click "DC analysis" item inside of "Arrhythmia" item, show the deceleration capacity of rate analyzing window (as Fig.6-28).

The concept of the deceleration capacity of rate think that in the 24 hours record of the Holter eeg information, in all the adjacent RR interval when the next RR interval compare to the last RR 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 RR interval, then the average into heart rate reduction force (DC) calculation formula and computing DC value.

- ① >4.5 ms: low level of fatalness;
- ② 2.6 ms~4.5 ms: middle level of fatalness;
- ③ <2.6 ms: high level of fatalness;

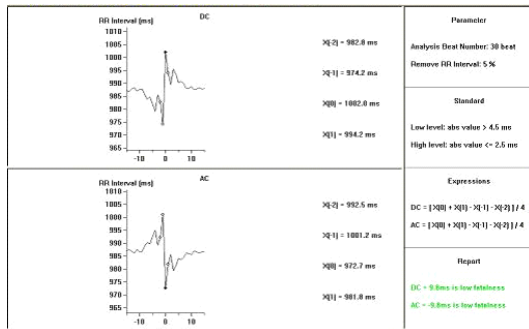



Fig.6-28

Click  button, call the parameters setting window (as Fig.6-29).

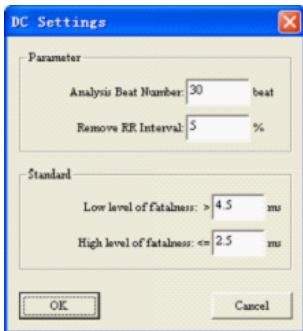


Fig.6-29


Analysis Beat Number: set the number of the RR interval;

Remove RR Interval: in order to reduce the error of the manual work, when the next RR interval compare to the last RR interval extend or shorten beyond by the setting percent value, then the last RR 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 become lower. So the function of protected the heart decrease evidently. It has practical value in prewarning and screening the high-risk acute myocardial infarction.

Knocking  button, enter QTD analysis system.

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 reflecting Ventricle Repolarization inconsistency, and denote inconsisten degree of Ventricular excitability resumptive time, or denote difference degree of Ventricular Refractory period.

QT dispersion graph is as Fig.6-30.

For increasing precision and reducing error, the system adopts the method that got the mean value, which was based on the 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. 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 beat. 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.

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

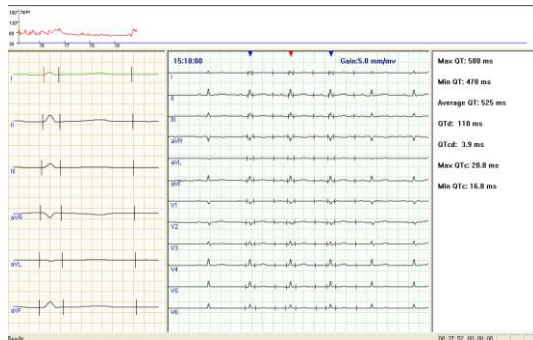


Fig.6-30



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.6-31:

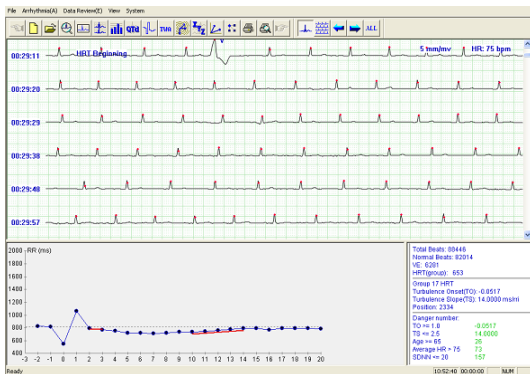



Fig.6-31

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 RR 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, click  will display the HRT waveform after superposition on the left below window graph as Fig.6-32:

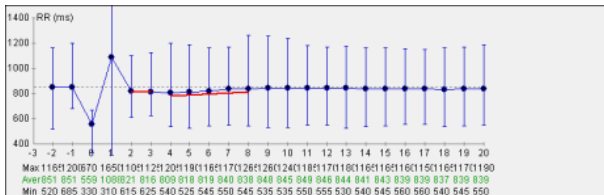


Fig.6-32

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

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

The graph on the right below window is the conclusion as Fig.6-33:

Total Beats: 88446	
Normal Beats: 82014	
VE: 6281	
HRT(group): 653	
Average HRT	
Turbulence Onset(TO): -0.0380	
Turbulence Slope(TS): 7.4000 ms/rri	
Position: 68	
Danger number:	
TO >= 1.0	-0.0380
TS <= 2.5	7.4000
Age >= 65	26
Average HR > 75	73
SDNN <= 20	157

Fig.6-33

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.

Click  button to enter the T Wave alternation analysis module.

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 an 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.6-34:




Fig.6-34

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", "RR interval trend" above express the heart rate of TWA segment and the mutative trend of RR interval.

Click  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:

TWA Analysis Setting


TWA standard:> 100 μ V

HB detecting number: 16

OK CANCEL

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



Click  button to measure RR and PR interval. Put the red point on the wave, pressing the left key and drag to draw an rectangle, then get the measure result;


Measure Result ✕

Result

Time: ms

Height: mv

Convert To HR: bpm

Click  button to modify the type of QRS wave.



Put the mouse pointer which has the blue rectangle on the wave of QRS that need to modify, then you can click the left button to modify the wave.

For example: put the blue rectangle on the S that need to modify in the left picture, click the left button and the S will change to V, then continue click the left button, you will get the O.

Under such situation, the waveform could be modified continuously. Move the mouse to the beginning of the waveform which needs modification, click the right button to choose the start position, then move to the end, click the right button again to make sure the end position. Now the segment can be modified.

Start position
End Position
Cancel Selected
Change to S Run
Change to V Run
Change to Atrial flutter
Change to Atrial fibrillation
Change to Ventical flutter
Change to Ventical fibrillation
Change to Normal
Change to Interference
Af analyse in segment
Af analyse in all

Choose the start pos

Start position
End Position
Cancel Selected
Change to S Run
Change to V Run
Change to Atrial flutter
Change to Atrial fibrillation
Change to Ventical flutter
Change to Ventical fibrillation
Change to Normal
Change to Interference
Af analyse in segment
Af analyse in all

Choose the end pos

Start position
End Position
Cancel Selected
Change to S Run
Change to V Run
Change to Atrial flutter
Change to Atrial fibrillation
Change to Ventical flutter
Change to Ventical fibrillation
Change to Normal
Change to Interference
Af analyse in segment
Af analyse in all

Modify the waveform in series

In the order replay interface, select the "Atrial Fibrillation" in the "Arrhythmia" menu to analyze the atrial fibrillation of the case that the arrhythmia has been construed. The atrial fibrillation analysis system will enter the interface as Fig.6-35 automatically.

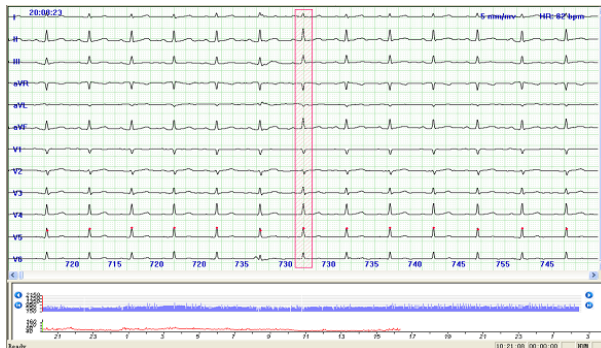






Fig.6-35

It is similar to the interface of order replay, but add the azury diagram above the HR trend. It is the RR interval of the current position that displayed. At the same time, there is a red rectangle appear

on the multi channel graph. The waveform that the red rectangle indicates corresponds to the waveform indicated on the RR interval graph.

The user can choose any parts of RR interval to scan by using the HR trend at the bottom. User also can click directly. Use the   to roll forwards or backwards and use the   to turn over the page. During this process, the multi-channel graph and the green line on the HR trend will change at the same time.

You will see that there are azury, navy-blue, gray and some white lines on the RR interval graph. Their meaning is as follows:

The azury is general waveform; The navy blue means the continuous S, V, AF, Af, VF, Vf (the concrete meaning see the template elucidation part) etc.; Gray means the continuous artefacts; The white lines means interference segment.

System support keyboard to view RR interval trend graph. Click the view below, passing the "→" "←" can view the RR interval forward or backward, passing the "Page Up", "Page Down", can turn over the page backward or forward, you can also pass the "↑" "↓"to play the RR interval automatically, and press any key to stop playing.

The user can judge the atrial fibrillation occurrence time and length assumably by using RR interval graph.(as Fig.6-36). Combining the multi channel graph, if make sure that the segment is AF; pop up the menu as follows by clicking the right button on the RR interval: set "Start position" and "End position" to choose a segment, then the segment turn red, its attribute can be modified to S

Tachycardia, V Tachycardia, Atrial flutter, Atrial fibrillation, Ventricle flutter, Ventricle fibrillation, Normal, interference. At the same time, user also can choose automatic atrial fibrillation analysis ("AF analyze in segment") for this segment. You also can choose the whole automatic atrial fibrillation analysis at the beginning ("AF analyze in all").

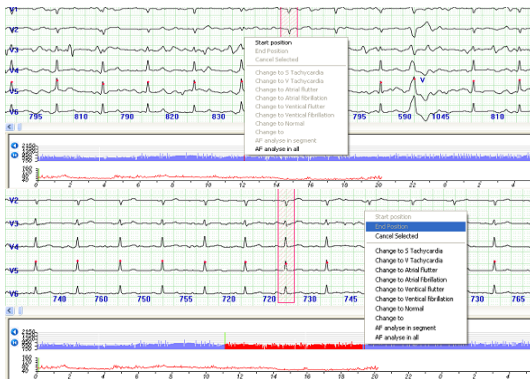







Fig.6-36


Click  button to store ECG of the current time in the print selective queue, as Fig.6-60


Click  button to delete all of the manually selected ECG segment in the print queue

Click  button to refresh data.

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 analyze all beats HRV analysis.

Click  button, display sinus beats HRV analysis results in 5 minutes.

The frequency domain, time domain and the integration electrocardiogram in 5 minutes. You can print them, can change the starting time by clicking in the below trend graph, and change page by moving the scroll bar in the top right window (as Fig.6-37).



Click button to display the all beats HRV analysis results in 5 minutes (as Fig.6-38).

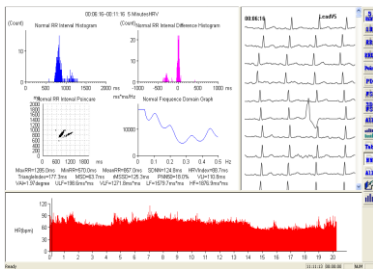


Fig.6-37

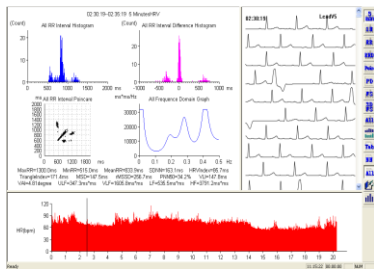




Fig.6-38

Click  button to display sinus beats HRV analysis results in an hour.

The frequency domain, time domain and the integration electrocardiogram in one hour. You can print them, can change the starting time by clicking in the below trend graph, the change page by moving the scroll bar in the top right window (as Fig.6-39).

Click  button to display the all beats HRV analysis results in an hour (as Fig.6-40).

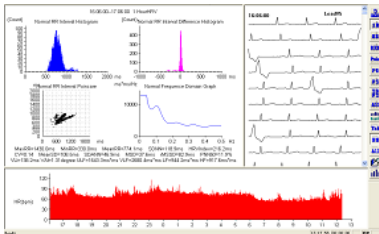


Fig.6-39

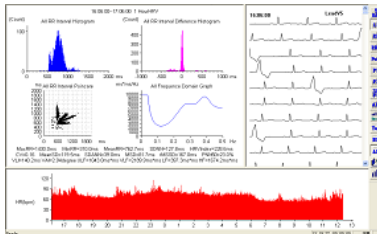




Fig.6-40

Click  button to display the whole process of the sinus beats RR interval histogram (as Fig.6-41).

Click  button to display the all beats RR interval histogram (as Fig.6-42).

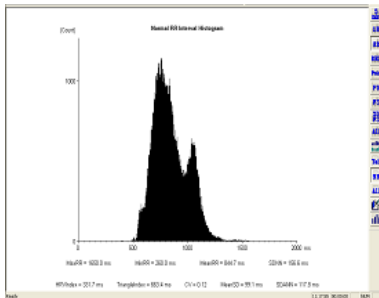


Fig.6-41

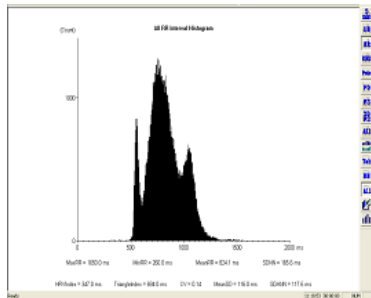



Fig.6-42

Click  button to display the whole process of the sinus beats RR interval dispersion histogram (as Fig.6-43).

Click  button to display the all beats RR interval dispersion histogram (as Fig.6-44).

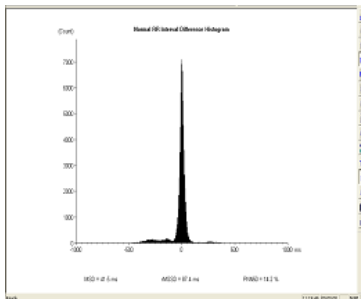


Fig.6-43

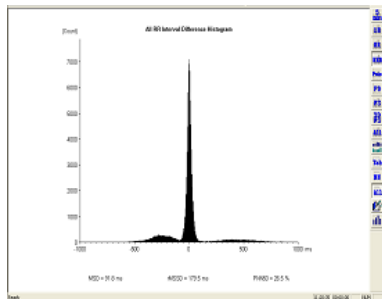




Fig.6-44

Click  button to display the whole process of the sinus beats RR interval poin care (as Fig.6-45).

Click  button to display the all beats RR interval poincare (as Fig.6-46).

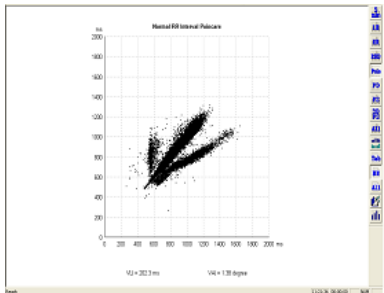


Fig.6-45

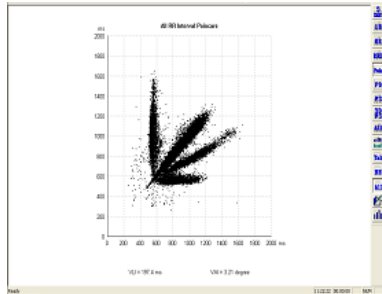



Fig.6-46

Click  button to display the whole process of the sinus beats RR interval dispersion poincare (as Fig.6-47).

Click  button to display the all beats RR interval dispersion poincare (as Fig.6-48).

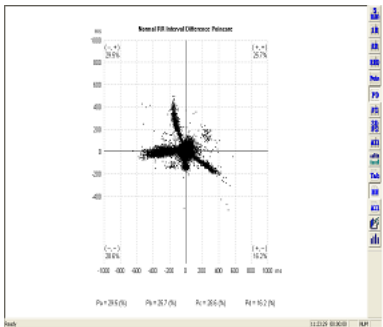


Fig.6-47

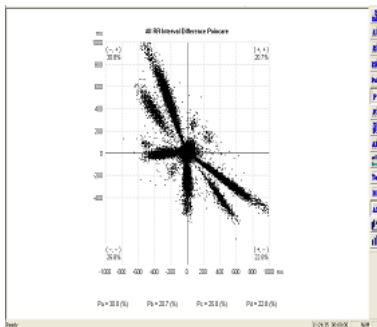




Fig.6-48

Click  button to display the whole process of the sinus beats frequency graph (as Fig.6-49).

Click  button to display the all beats frequency graph (as Fig.6-50).

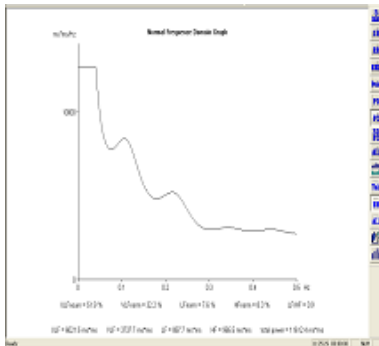


Fig.6-49

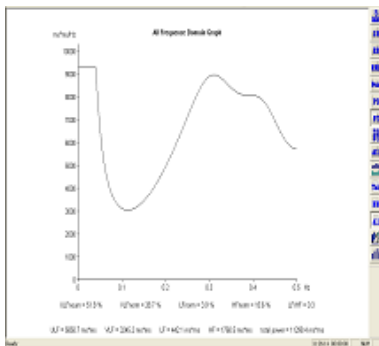




Fig.6-50

Click  button to display the whole process of the sinus beats frequency 3D graph (as Fig.6-51).

Click  button to display the all beats frequency graph (as Fig.6-52).

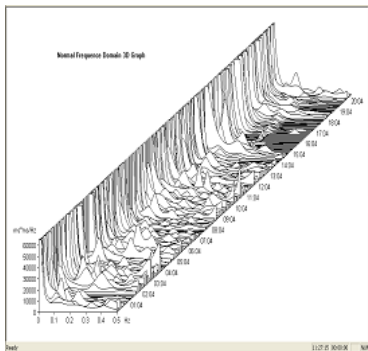


Fig.6-51

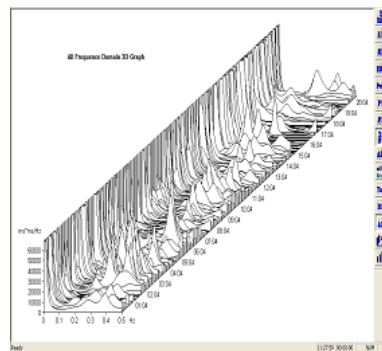




Fig.6-52

Click  button to display the whole process of the sinus beats analysis composite graphs (as Fig.6-53).

Click  button to display the all beats analysis composite graphs (as Fig.6-54).

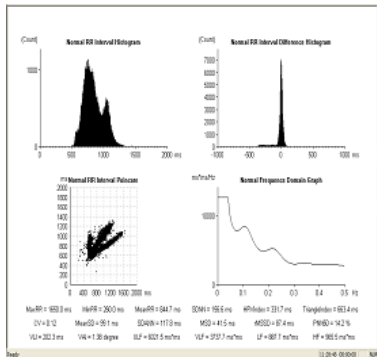


Fig.6-53

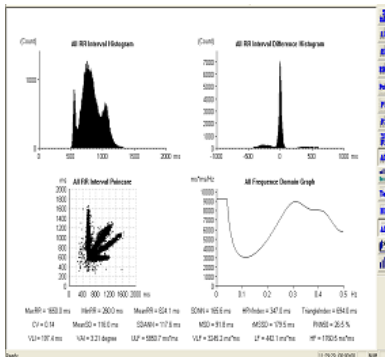




Fig.6-54

Click  button to display the whole process of the sinus beats HRD trend graph (as Fig.6-55).

Click  button to display the all beats arrhythmia trend graph (as Fig.6-56).

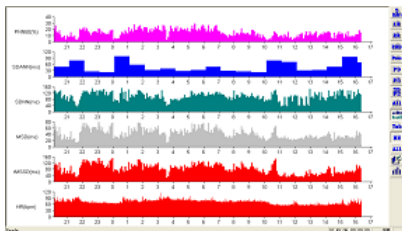


Fig.6-55

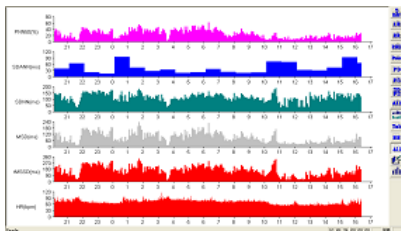




Fig.6-56

Click  button, display the whole process of the sinus beats HRV data table (as Fig.6-57)

Click  button to display the all beats HRV data table (as Fig.6-58)

Hour	HRmax	HRmin	HRavg	SDHR	HRVmax	CV	MSD	ARMSD	PMSD	VLI	VAm	Degree	VLF	VLF	LF	HF
22:50	180	260	774	118.4	2110	0.18	36	84	12.0	139	1.10	1986.6	2696.8	543.6	800.9	
23:50	130	305	728	118.7	1805	0.11	30	77	11.1	129	1.18	2174.4	2203.0	611.2	752.8	
00:50	100	365	883	138.2	106.1	0.14	62	120	16.6	110	1.63	324.8	1216.5	1431.3	2219.0	
01:50	100	393	826	129.6	1819	0.13	63	116	14.2	121	1.62	290.7	1478.9	1277.2	1616.1	
02:50	190	300	811	141.7	1875	0.12	36	81	12.1	179	1.24	4200.4	3294.2	620.5	890.2	
03:50	130	300	763	128.8	1546	0.14	67	113	24.0	123	1.64	1377.0	2638.8	1032.3	1720.5	
04:50	124	336	767	130.9	166.0	0.13	63	119	20.3	106	1.92	463.8	1488.6	883.2	1252.0	
05:50	100	300	877	85.5	1427	0.11	36	78	17.4	39	1.53	752.4	1283.9	470.5	540.7	
06:50	114	325	738	91.3	116.6	0.12	47	80	19.0	90	1.77	207.8	1115.3	630.0	875.5	
07:50	128	400	796	121.2	146.7	0.16	62	116	22.0	118	2.16	380.6	1172.4	1481.8	1546.3	
08:50	125	355	760	124.8	176.2	0.14	56	100	19.7	128	1.92	790.3	2239.4	1483.8	1475.0	
09:50	130	375	823	119.9	130.0	0.12	30	85	11.3	110	1.24	687.1	1673.0	861.0	809.4	
10:50	125	340	888	138.1	113.1	0.13	46	86	13.8	109	1.90	390.8	1612.4	1677.8	1130.6	
11:50	1425	380	814	103.3	151.1	0.11	36	78	11.2	105	1.23	309.3	1523.0	645.0	713.1	

Fig.6-57

Hour	HRmax	HRmin	HRavg	SDHR	HRVmax	CV	MSD	ARMSD	PMSD	VLI	VAm	Degree	VLF	VLF	LF	HF	VLF
22:50	1408	280	752	128.3	2278	0.10	62	168	22.0	140	2.02	299	1071.3	2140.1	4200	1607.9	
23:50	1218	306	726	116.4	202.8	0.12	69	168	21.4	131	2.12	1393.0	1197.1	836.6	1274.8		
00:50	1488	515	881	157.2	125.8	0.10	154	288	36.0	128	5.06	201.7	779.6	305.2	3916.7		
01:50	1088	310	881	151.2	102.8	0.11	126	238	26.6	126	4.00	207.8	1240.0	456.6	3385.4		
02:50	1668	300	798	148.1	288.7	0.14	75	162	21.6	174	2.64	1863.7	2196.4	138.4	1466.8		
03:50	1188	300	767	147.6	234.2	0.10	140	278	47.1	133	5.14	198.2	1492.0	1492.0	2489.0		
04:50	1245	450	745	126.3	173.8	0.10	115	184	36.6	121	4.20	215.6	344.0	300.0	181.5		
05:50	1188	340	676	97.7	163.9	0.13	75	143	26.9	90	3.04	184.4	162.2	222.9	185.6		
06:50	1148	315	718	108.7	101.6	0.16	112	181	38.8	89	4.18	171.4	621.9	291.6	1667.1		
07:50	1228	400	792	140.1	188.8	0.10	152	241.9	110	5.90	193.6	1651	421.2	2933.7			
08:50	1328	355	762	126.7	194.3	0.10	136	228	30.6	124	4.92	483.1	1391.6	280.0	2022.3		
09:50	1388	326	807	116.6	163.9	0.14	80	176	22.6	116	2.07	121.8	1388.9	362.7	1681.4		
10:50	1278	380	797	118.9	147.4	0.15	80	181	27.5	111	3.45	198.1	11700	400.5	1919.0		
11:50	1425	510	801	126.9	188.4	0.13	80	147	22.2	108	2.47	245.7	1400	400.1	1318.1		
12:50	1428	360	676	147.1	140.1	0.14	74	146	17.0	121	3.10	1421.6	1162.4	454.7	1181.0		

Fig.6-58



Click button to display the case report, sleeping time setting and additive analysis (as Fig.6-59).

Report editor

Main report | Additional report | Sleep studies

HR	77	Total Beats	27	Total Beats	73	Lead	Elevation	Dispersion
Min HR:	51	Coaglat	2	Coaglat	2	I	0	0
Max HR:	133	Short max	0	Short max	0	II	0	0
Total Beats	9040	Long max	0	Long max	0	III	0	0
Absorbed Beats	110	Prevalgep	0	Prevalgep	0	IVR	0	20
Absorbed Percentage	1	Signatur	0	Signatur	0	VL	0	0
Power	SSV[Law Demand]	Max V in a Min	4	Max V in a Min	4	VP	0	0
R.R. + 2000 ms	0	SENR	146	Power	11607.4	V1	0	16
Max R-Rint		SEANR	129.8	ULF	5390.4	V2	40	0
Time		MSGD	54.2	VLF	21546	V3	13	0
		FRHSO	11.2	LF	473.4	V4	74	0
		CV	0.08	HF	422.9	V5	1	0
						V6	0	0

Physiologic Interpretation:

Time

Ctrl Cancel

Report editor

Main report | Additional report | Sleep studies

Flatten & Filter Data:

AF	2	Beats	0	Period	AF	0	Beats	0	Period
VF	0	Beats	0	Period	VF	0	Beats	0	Period

Artificial parking

DDD: []

Arted Parking: []

Parking: []

Parking: []

Parall/Parallel: []

No Parking: []

Under Sense: []

Over Sense: []

Vectorize parking

Parking Polar: []

VE Parking: []

Parking: []

Parking: []

Parall/Parallel: []

No Parking: []

Under Sense: []

Over Sense: []

Ctrl Cancel

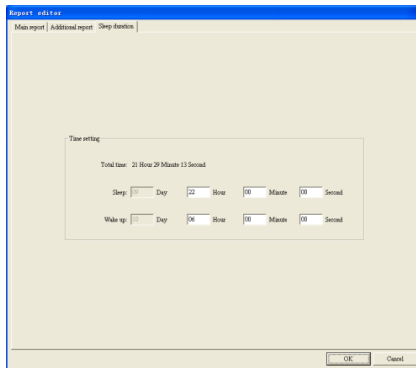


Fig.6-59

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

Physician: Click the blank under "Physician" to put in the diagnostic conclusion manually or add corresponding words from term library there.

Attention: The content under "Physician" will be printed in the report as diagnostic conclusion.

Term library: A professional term library as diagnostic conclusion, where the terms can be added and deleted.

Add: Click the input frame, put in the term there and click "Add", the term can be added to the list of term library.

Delete: Select a item in the list of term library and click "Delete" to delete it.

Copy: Select a item in the list of term library and click "Copy", the selected term will be added to the diagnostic conclusion.

Compute: The differences in statistic between report and fact may result from a lack of update for the latest modify. Click "Compute" and "OK" to solve it.

Print: Click "print" and "OK" to generate the report with PDF format.

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

Sleep time setting: Fill the factual time of sleep and wake to perform the dormancy asphyxia analyze.

Additive analysis edit window: edit the data in the Additive analysis report.

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



Click button to display the "Select Printing" window, where the physician can select the required report to print.(as Fig.6-60).

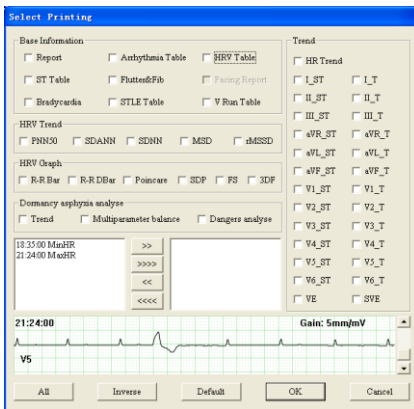


Fig.6-60

Report: select "main report" to report.

ST Table: select "ST Table" in "sequential replay" to print.

Arrhythmia Table: select "arrhythmia table" in "sequential replay" to print.

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

STLE Table: select "STLE Table" to print.

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

Bradycardia: select "Bradycardia Table" to print.

STLE Table: select "STLE table" of a single lead to print.

Lead: select the lead whose "STLE table" to be printed.

HRV Table: select "HRV Table" to print.

Pacing Report: select "Pacing Report" to print.

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

HRV graph: select various graphs in the HRV analysis to print.

RR Bar: RR interval histogram;

RR DBar: RR interval dispersion histogram;

Poincar: RR interval poincare;

SDP: RR interval dispersion poincare;


FS: frequency graph;


3DF: frequency 3D graph.


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


Trend: select various trend graphs to print, including: HR, ST of each lead, T of each lead, VE and SVE.

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 items.

Inverse: cancel all of the items you have selected, and select all of the items 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 is not selective to print if it has not been examined in HRV analyze.

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

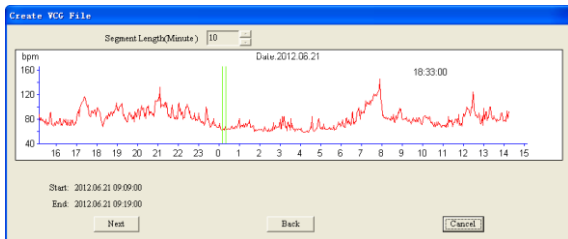


to preview it.

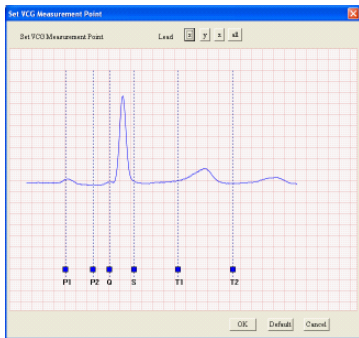


Choosing  button and enter the vector cardiogram module.

First the screen will appear dialog box about converting file.



Press SHIFT key and knock the ECG at the same time to choose the beginning time and end time, knock "continue "button, the QRS emendation graph about beginning and end positions will appear.



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.6-61.

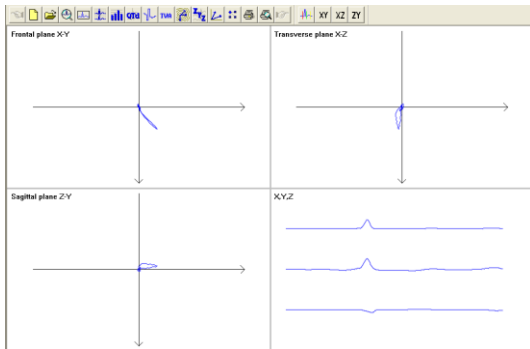



Fig.6-61

Click  button and enter Set VCG Measurement Point.

Click  button and enter Frontal plane X-Y graph (as Fig.6-62).

Click  button and enter Transverse plane X-Z graph (as Fig.6-62).

Click  button and enter Sagittal plane Z-Y graph (as Fig.6-62).

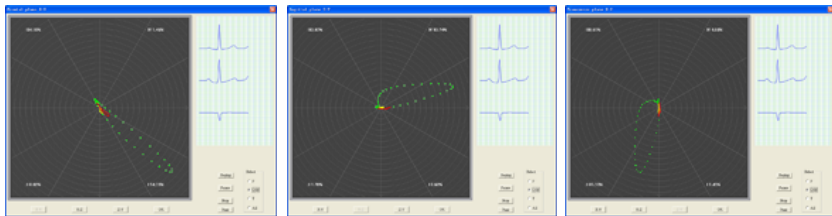


Fig.6-62

Click  button and enter VLP analytical module (as Fig.6-63).

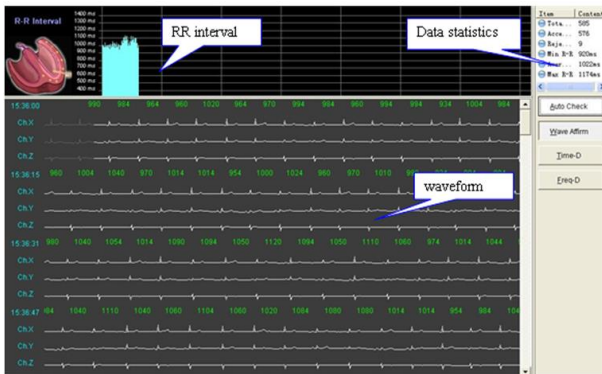


Fig.6-63

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;

Average R-R: Average R-R interval;

Max R-R: Maximal R-R interval.

Auto check

Auto filter ECG waves. Click the button to call up the "R-R Range" window (as Fig.6-64).



Fig.6-64

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

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

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

Wave affirm

Waves can be filtrated by "auto check" or manual (as Fig.6-63).

RR interval: display RR 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.

Time-D

Click this button to enter the time domain analysis interface (as Fig.6-65).

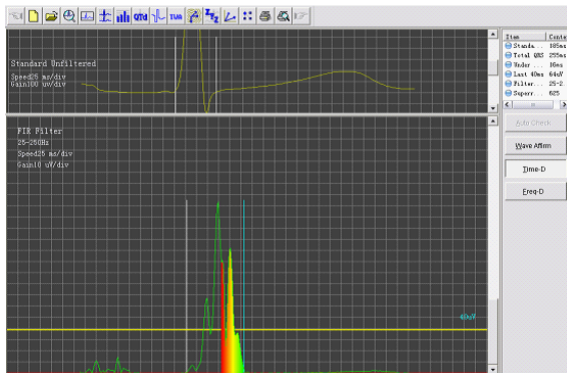


Fig.6-65

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 40 μV : 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 mean 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 adjust its position with " \leftarrow " and " \rightarrow " on keyboard, meanwhile the data of standard QRS will change, too.

Click the right mouse in the window to call up the menu (as Fig.6-66) where you can select the superposition wave you want to check. Multiply selection is supported.

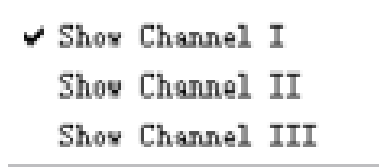


Fig.6-66

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 " \leftarrow " and " \rightarrow " 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 μ V" and "Last 40 ms" will also change.

Click the right key of mouse to call up the setting menu (as Fig.6-67).

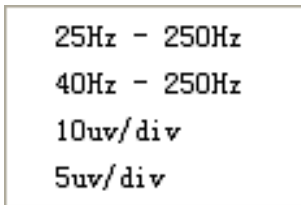


Fig.6-67

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.

Freq-D

Click this button to enter the interface of frequency domain analysis (as Fig.6-68).

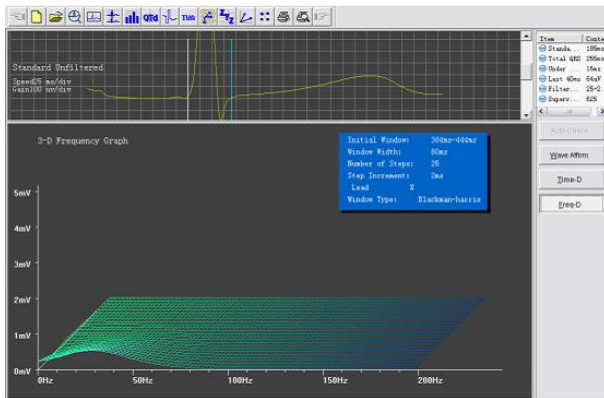





Fig.6-68

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.

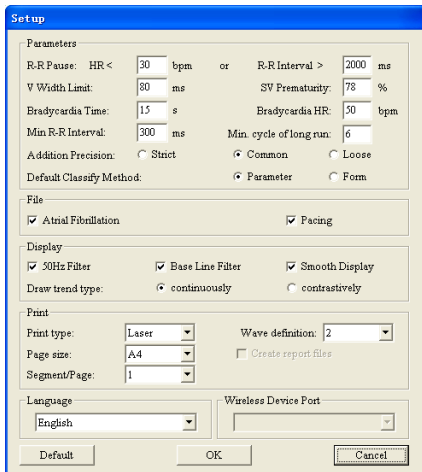
Click  button and enter TVCG analysis module.

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

Click  can measure RR or PR interval an so on;



Click  button and enter the parameter setting operation (as Fig.6-69).



The screenshot shows a 'Setup' dialog box with the following sections and settings:

- Parameters:**
 - R-R Pause: HR < 30 bpm or R-R Interval > 2000 ms
 - V Width Limit: 80 ms SV Prematurity: 78 %
 - Bradycardia Time: 15 s Bradycardia HR: 50 bpm
 - Min R-R Interval: 300 ms Min. cycle of long run: 6
 - Addition Precision: Strict Common Loose
 - Default Classify Method: Parameter Form
- File:**
 - Atrial Fibrillation Pacing
- Display:**
 - 50Hz Filter Base Line Filter Smooth Display
 - Draw trend type: continuously contrastively
- Print:**
 - Print type: Laser Wave definition: 2
 - Page size: A4 Create report files
 - Segment/Page: 1
- Language:** English
- Wireless Device Port:** (empty)

Buttons at the bottom: Default, OK, Cancel.

Fig.6-69

R-R Pause: A standard of judging pause module;

V Width Limit: A standard of judging ventricular premature beat module. A wave whose QRS complex time is longer than this parameter will be judged to V. The default is 80ms;

SV Prematurity: A parameter of judging V or S;

Bradycardia Time: the shortest time limit of bradycardia segment;

Bradycardia HR: the highest HR of bradycardia segment;

Min R-R Interval: 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. The default value is parameter method.

Addition Precision: The precision of atrial fibrillation analyze;

Atrial Fibrillation: The report of atrial fibrillation analyze could be saved when this item has been set;

Pacing: The report of pacing analyze could be saved when this item has been set;

50Hz Filter: Using 50Hz Filter;

Base Line Filter: Using this function when analyzing and display the electrocardiogram, filtering the baseline interference;

Smooth Display: Using Smooth Display;

Print type: Select a type for printing ECG waves;

Wave definition: Select a definition for printing ECG waves;

Page size: Select a paper size for printing;


Create report interface files: Create an electro-report after print;

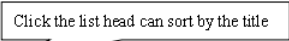
Language: Setting the interface's language of the software;

Wireless Device Port: Select a wireless device port;

Notice: "Create report files" is unenabled in default of "Bullzip PDF Printer".

Case Manage

Open the "Maintain" item in the "File", or click  button on main toolbar, enter the Case Manage (as **Fig.6-70**).




Number	Name	Sex	Age	Date	Time	Section	BedNum	ReportNum	Height (cm)	Weight (kg)	DoctorName	DoctorTel
0000087	Smith	Male	83	2000.09.14	08:09:00							
0000006	Jack	Male	70	2013.01.23	08:36:00	Heart	C07					
0000004	Joe	Male	73	2000.08.28	10:27:00	Heart						
0000003	Linda	Male	26	2000.08.24	16:47:00	Heart						
0000002	Johab	Male	36	2011.01.14	16:30:00		B01	001	170	70		

Fig.6-70


Show the deleted case

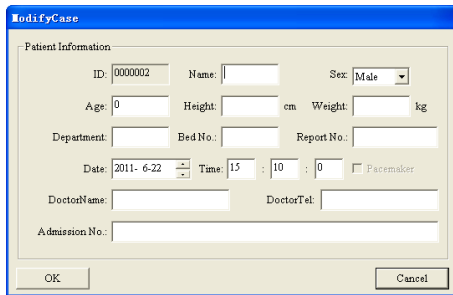


Click  button to display the existed cases and all the cases which include the existed and deleted in turn.

Modify Case



Select an item in the list, and click the  button to modify the information(as **Fig.6-71**).



The image shows a software dialog box titled "ModifyCase". It contains a "Patient Information" section with the following fields:

- ID: 0000002
- Name: [Empty text box]
- Sex: Male (dropdown menu)
- Age: 0
- Height: [Empty text box] cm
- Weight: [Empty text box] kg
- Department: [Empty text box]
- Bed No.: [Empty text box]
- Report No.: [Empty text box]
- Date: 2011- 6-22 (calendar icon)
- Time: 15 : 10 : 0 (time selection icons)
- Pacemaker
- DoctorName: [Empty text box]
- DoctorTel: [Empty text box]
- Admission No.: [Empty text box]

At the bottom of the dialog box are two buttons: "OK" and "Cancel".

Fig.6-71

Delete Case




Select an item in the list, and click the  button to delete the selected case. Before deleting the case, the software can give the user the tip to avoid misoperation. If the user clicks the "OK" button, then the selected case will be deleted. (as **Fig.6-72**)



Fig.6-72

Attention: Make sure you need to delete the case. If the case was deleted, it will not be come back.

View Report





Select one case in the list, click the button  to open the folder of the report. The user can view the report file. If the system appears the window as **Fig.6-73**, the selected case have not the report file.



Fig.6-73

Export Case

Select one or more cases in the list, and click the button  to choose the position of the export file.(as Fig.6-74)

Export case can save the space of the storage. If it's necessary for the user to import the exported file to the software.

then the system will appear the window.(as **Fig.6-75**)

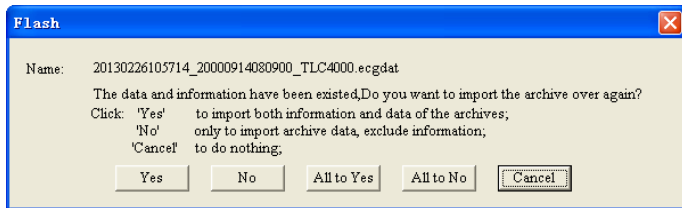


Fig.6-75

"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.

click the button  to page down.

Select case

Click the button  to select the case.

Pacing analysis

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

After recorder replay, the pace maker parameters setting window will appear, about its function, please refer to "replay HOLTHER recorder".

There are 11 templates windows in the template replay function (as Fig.6-77). One button is for a template. The letters on the button is 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.

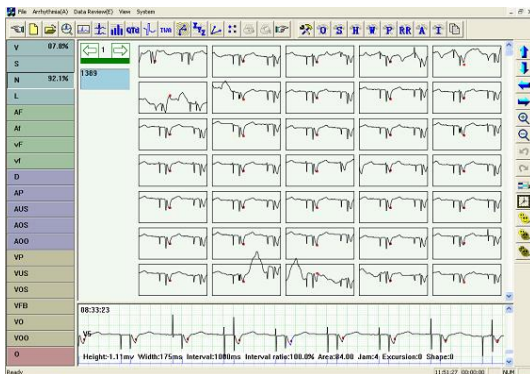


Fig.6-77



Enter the order replay, click the **Tab** button and appear the "Chart" dialog box which added the "Pacemaker Table" (as Fig.6-78).

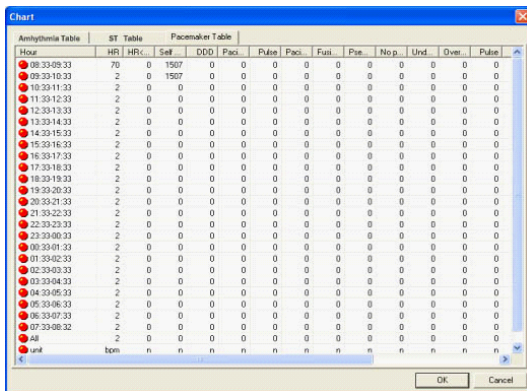


Fig.6-78

Sleep breath pause syndrome analysis



In case report please fill the correct sleep time and wake time about sleeping time segment (as Fig.6-79).

The screenshot shows a software window titled "Report editor" with a menu bar containing "Main report", "Additional report", and "Sleep duration". The main area contains a "Time setting" dialog box. Inside the dialog, it displays "Total time: 21 Hour 29 Minute 13 Second". Below this, there are two rows of input fields. The first row is labeled "Sleep:" and has fields for "Day" (value 07), "Hour" (value 22), "Minute" (value 00), and "Second" (value 00). The second row is labeled "Wake up:" and has fields for "Day" (value 07), "Hour" (value 06), "Minute" (value 00), and "Second" (value 00). At the bottom right of the dialog are "OK" and "Cancel" buttons.

Fig.6-79

Appendix I

When the device is shipped from the factory, the intact packaging should contain the following content, as shown below:

Name	Quantity
Host	1 pc
Electrodes	1 box
Leads	1 set
USB2.0 cable	1 pc
PC software	1 pc
Backpack	1 pc
User manual	1 pc

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.

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

$$HR = 60000 / \text{Sum of R-R interval of N heartbeats} / N)$$

Arrest recognition method: According to the pause maximum heart rate or minimum R-R 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


Guidance and manufacturer's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
The TLC6000 is intended for use in the electromagnetic environment specified below. The customer of the user of the TLC6000 should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The TLC6000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The TLC6000 is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

**Guidance and manufacturer's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS**

Guidance and manufacturer's declaration – electromagnetic immunity			
The TLC6000 is intended for use in the electromagnetic environment specified below. The customer or the user of TLC6000 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable	Not applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

**Guidance and manufacturer's declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

Guidance and manufacturer's declaration – electromagnetic immunity			
The TLC6000 is intended for use in the electromagnetic environment specified below. The customer or the user of TLC6000 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	1 V _{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the TLC6000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	1 V/m	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TLC6000 is used exceeds the applicable RF compliance level above, the TLC6000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TLC6000.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

**Recommended separation distances between portable and mobile
RF communications equipment and the EQUIPMENT or SYSTEM –
for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING**

Recommended separation distances between portable and mobile RF communications equipment and the TLC6000			
The TLC6000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TLC6000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TLC6000 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.35	0.35	0.70
0.1	1.11	1.11	2.21
1	3.50	3.50	7.00
10	11.06	11.06	22.13
100	35.00	35.00	70.00
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1	At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

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.

