GIMA

PROFESSIONAL MEDICAL PRODUCTS

ECG HOLTER WITH SOFTWARE

Use and maintenance book

REF **TLC5000 (GIMA 35130)**

CONTEC MEDICAL SYSTEMS CO., LTD
No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
Made in China

EC REP Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany

Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

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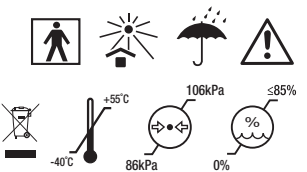


M35130-EN-Rev.2-01.24

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.

CONTENTS

Chapter 1 Introduction

1.1 Environment Condition

The environment requirement of operation, transport and storage for Dynamic ECG Systems:

Operation Environment:

Environment Temperature:	10 ℃~45 ℃
Relative Humidity:	≤85 %
Atmospheric Pressure:	86 kPa~106 kPa
Power Supply:	DC 3 V

Transport and Storage Environment:

Environment Temperature:	-40 ℃~+55 ℃
Relative Humidity:	≤85 %
Atmospheric Pressure:	86 kPa~106kPa

1.2 Product Feature

Dynamic ECG Systems contain recorder & analysis software. Recorder is an easy- to -use unit, which collects 12-lead ECG waveform synchronously and records continuously for 24 hours. In addition, it also reviews ECG waveform. It is easy for you to use analysis software which plays back ECG waveform stored in ambulatory recorder and achieves kinds of analysis functions, such as arrhythmia, HRVA, QTDA, TWA, etc.

1.3 Safety

The design of Dynamic ECG Systems accords with the international safety standard IEC60601-2-47.

⚠ Warning:

Arbitrary modification to the device is forbidden.

Avoid strong vibration and shock when using or moving the device. Doctor must tell the patient monitored by recorder not to do violent movement.

Turn off the device before cleaning and disinfection. Do not use sharp material to wipe the screen.

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.

Do not connect the device to both the human body and computer at the same time.

Do not remove the USB plug when the device is in turning on state.

The environment where the device to be used should be kept away from vibration, dust, corrosive or combustible matter, and avoid from extreme temperature and humidity, and

do not use the device in a humid environment.

Maintenance and repair are not allowed during using the device.

Other equipment or network is forbidden to connect with the system except the signal input/output part connected to the system accessories.

Materials of product accessories should comply with the biological compatibility requirements.

The materials selected for the design and manufacture of the device shall meet its excepted service life. Any corrosion, aging, mechanical wear or degradation of biological materials caused by bacteria, plants, animals, etc. will not degrade the mechanical properties of the device.

Avoid contact with water. Avoid using or storing the device in places where excessive air pressure, humidity or temperature exceeds the specified standard, poor ventilation or dusty.

NO modification of equipment.

Pay attention to battery's positive and negative anodes when replacing.

Please use LR6 AA alkaline battery to ensure the normal work of device.

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 ST algorithm has tested for accuary of the ST segment data.The significance of the ST segment changes needs to be determined by a clinician.

	Type BF applied part		
	USB interface		
	WEEE disposal		
	Covering Protection rate		
	Serial number		
	Follow instructions for use		Caution: read instructions (warnings) carefully

CE 0123	Medical Device compliant with Directive 93/42/EEC		
EC REP	Authorized representative in the European community		
	Manufacturer		
	Date of manufacture		
	Temperature limit		
	Humidity limit		
	Atmospheric pressure limit		
	Keep in a cool, dry place		Keep away from sunlight
	Fragile, handle with care		

	This side up		Imported by
	Product code		Lot number

1.4 Maintenance and Cleaning

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

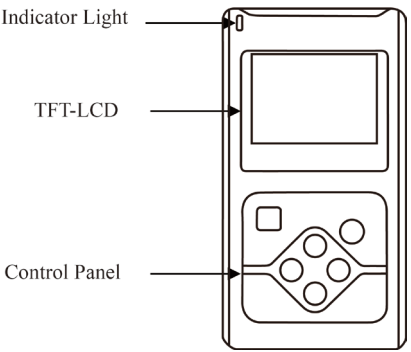


Fig.2-1 Front view

2.1.2 Side view

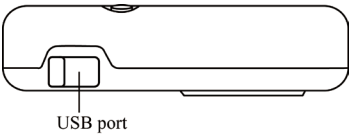


Fig.2-2 Side view

2.1.3 Bottom view

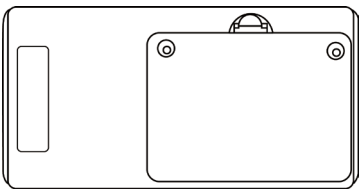


Fig.2-3 Bottom view

2.2 Definition of Keystoke, Interface and Indicator Light

 function key: marker/affirmance/choice

 function key: menu/cancel/turn on/off

 direction key: left

 direction key: right

 direction key: go up

 direction key: go down

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

Chapter 3 Preparing Work before Using

3.1 Electrode Placement

⚠ Notice:

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

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

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

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

Fig.3-1

◆ Deal with the skin

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

◆ Place the electrode

Use high-quality ECG electrode to attach the right place and connect with the correspond electrode. To prevent the electrode drop and the baseline excursion caused by pulling, use the medical adhesive belt or plaster to fix every electrode and cable properly. After the cables get together, use the adhesive belt to fix in the abdomen; the rest cables can be tucked into the recorder's waistband. 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.

3.2 Battery Installation and Notice

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

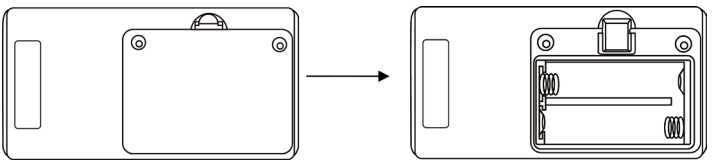


Fig.3-2

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

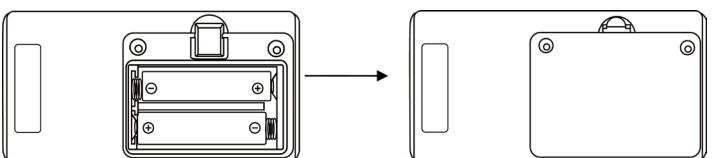


Fig.3-3

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

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

Table 3-a1

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

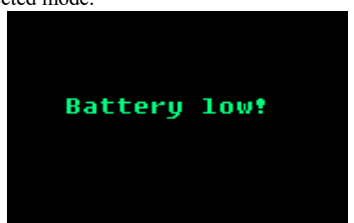


Fig.3-4

When the energy of battery is low, the recorder turn into protected mode in order to protect the

recorder from damaging. Under protected mode the device don't run until the device is electricized by USB or the batteries are full.

⚠ **Warning:**

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

⚠ **Notice:**

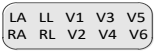
Please confirm all electrodes and lead wires are connected well to patient. Otherwise, interference in waveform at the beginning of record may lead to failure analysis.

⚠ **Notice:**

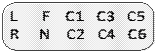
Please take off the battery after monitoring in order to protect the recorder from damaging because of battery leak.

Instructions:

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



3-5 usually American



3-6 usually European

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

usually American	usually European
LA	L
RA	R
LL	F
RL	N
V1	C1
V2	C2
V3	C3
V4	C4
V5	C5
V6	C6

Chapter 4 Recorder Operation Explanation

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

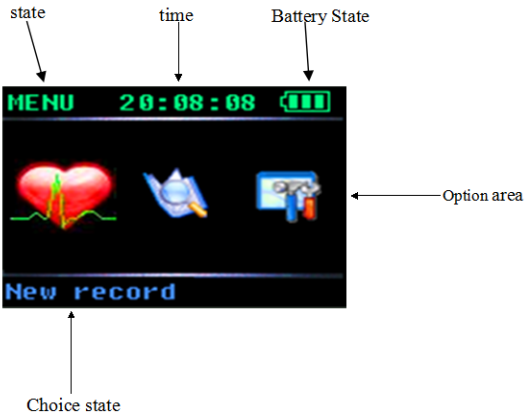


Fig.4-1 Main interface

4.1 New Record

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

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

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

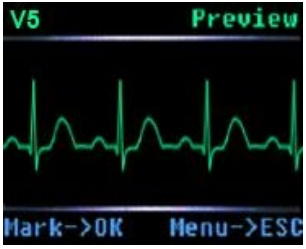


Fig.4-2

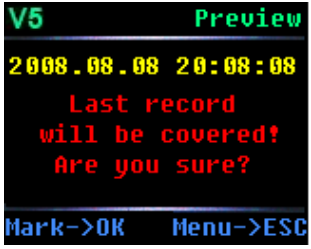


Fig.4-3

Press  to cancel recording and return to the main interface.

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

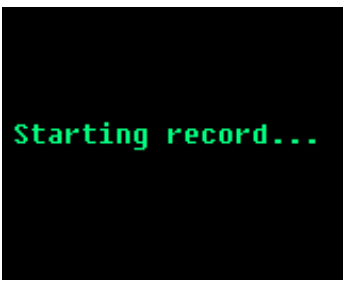


Fig.4-4

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

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

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

Fig.4-5

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

Fig.4-6

4.2 Review Record

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

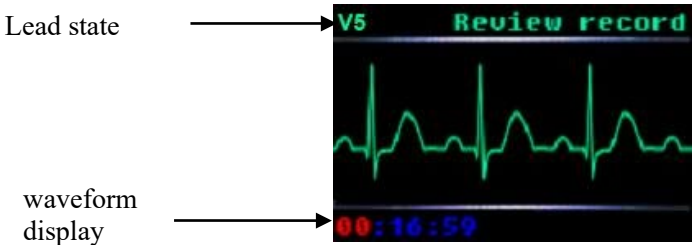


Fig.4-7

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

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

Fig.4-8

4.3 System Set

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

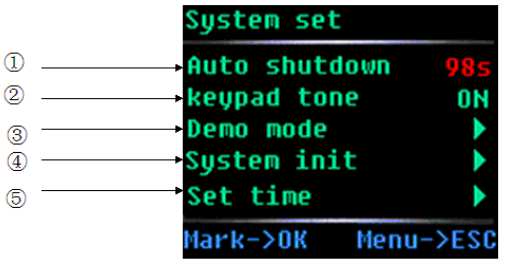


Fig.4-9

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

① Auto shutdown set

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

② Keypad tone set

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

③ Demo mode

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

Fig.4-10

Press ▶ to switch ECG lead waveform.

④ System initialization

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

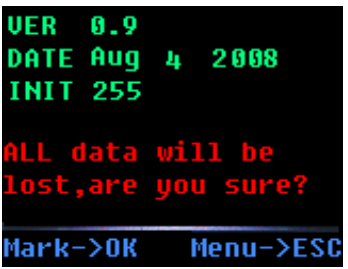


Fig.4-11

⚠ **Notice:**

Detailed edition information depends on current recorder.

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

⑤ Time set

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

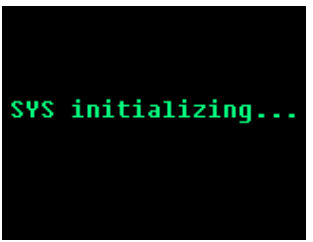


Fig.4-12

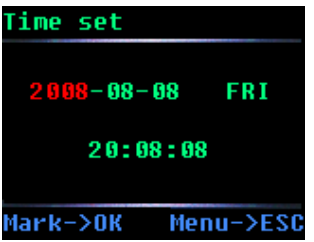


Fig.4-13

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

4.4 Replay Record

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

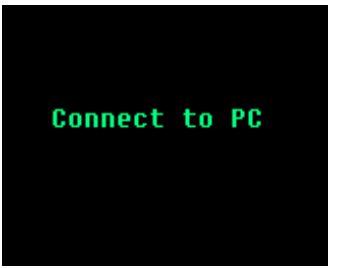


Fig.4-14

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

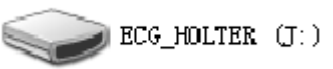


Fig.4-15

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

Fig.4-16

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

⚠ **Notice:**

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

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

Fig.4-17

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

⚠ **Notice:**

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

Chapter 5 Malfunction Analysis and Troubleshooting

5.1 Daily Maintenance

5.1.1 Maintenance after use

Long press  to turn off the device.

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

Clean the device and accessories.

Place the device in a cool and dry environment.

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

5.1.2 Inspection and Maintenance of Lead cables and Electrodes

Use a multimeter to detect the connectivity of the lead cable by checking whether each wire of the lead cable is in good contact. The resistance of each wire from the electrode plug to the corresponding pin in the lead cable plug should be less than 2Ω. The integrity of the lead cable must be checked regularly. Any lead wire damage will cause a false waveform of the corresponding lead or all leads on the ECG. The lead cable can be cleaned with water or neutral

solvent. Do not use the detergent or germicide containing alcohol (Please do not immerse the lead cables in liquid for disinfection).

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

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

5.2 The Problem Related to the Battery

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

The record time of the recorder can't reach 24 hours.	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. The characteristic and brand of the battery are different.	Change another new battery.
The data can't be cleared away.	1. If the voltage above 3.5V, which beyond the working voltage, part of the electron hard disk may be broken.	Please contact our company.
	2. Some part of the recorder may be damaged because the electrolyte in the battery flows out.	Please contact our company.

5.3 The Problem Related to the Skin and the Electrode

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

5.4 The Problem Related to the Cable and the Input Plug

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

5.5 Other Problems

Problem	Cause	Correction
The communication of data is failed.	There is something wrong with the USB cable.	Change another USB cable.
	The USB interface of computer don't match the USB interface of the recorder.	Use 2.0 interface.

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 (as **Fig.6-1**).

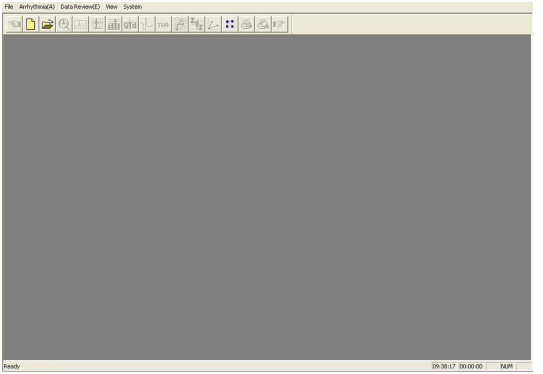


Fig.6-1

Replay HOLTER Recorder

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

If the recorder to be used TF memory, please choose the collection file ECG_WAVE.BIN (as **Fig.6-2**) first. Certainly you could also copy the case history to other place, then choose. If the recorder to be used Flash memory, please turn to **Fig.6-2**.

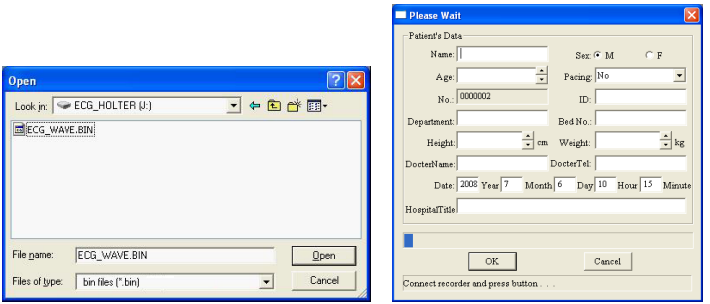
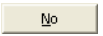


Fig.6-2

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

After inputting the patient's data, click 

, and the computer begins to read data from the recorder. The process will finish when prompt as **Fig.6-3** show up. Here click 

to enter the interface of arrhythmia analysis (as **Fig.6-5**), and click 

to enter the template replay interface (for the analyzed cases) or to the order replay interface (for the not analyzed cases).

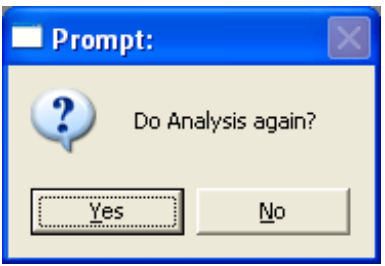


Fig.6-3

⚠ **Notice:**

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. There into 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".

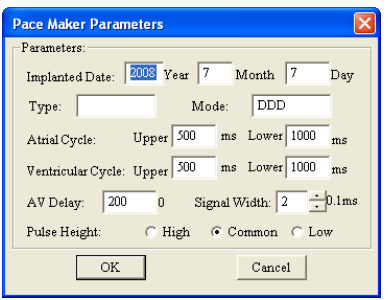


Fig.6-4

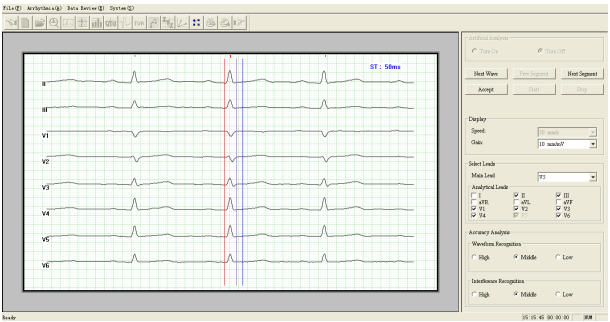


Fig.6-5

The left side of the interface (as **Fig.6-5**) is the waveform display window, showing the waves of all analyses leads. Here need operators 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 window, well 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 "Show Lead" to choose other leads as main analytical lead.

RR refractory period: This parameter is general 300ms, it means the shortest time between the two heart beats, the default value is 300ms, the user can adjust it according to the specific circumstance, if the patient's heart rate is too quick, it should be set as low as possible, in order to prevent losing the analysis for some heart beats.

Click the options under the "Leads Analyzed" could decide which leads to be analyzed, the default is 8 collected leads.

When the amplitude of the case's wave is too low, please choose "H" in the resolution option ("Height").

When the case meets much disturbance, please choose "H" in the "distinguish O" Option. The options "Height" and "distinguish O" don't need to adjust generally. The user can choose according to the actual circumstances.

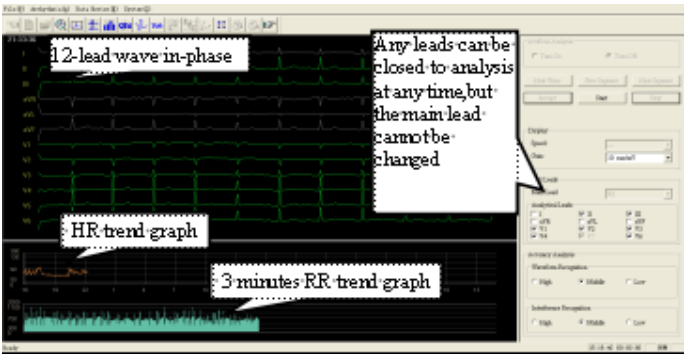


Fig.6-6

Click the "Stop" button, the system will stop temporarily. User can browse the 12 lead ECG through "←↑→↓" on the keyboard. In the HR trend graph, there is a green symbol line, which represents the place of the current wave. User can go back to a point, change condition ("Leads Analyzed", "Height", "distinguish O"), click "Start", the part starting at the green sign will be analyzed again. (as **Fig.6-7**).

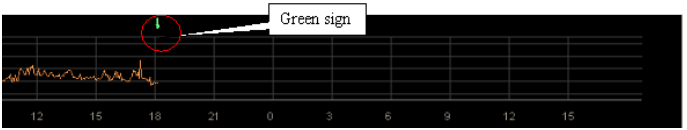


Fig.6-7

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

General 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.

◆ Change window size

Move the mouse arrowhead to the side of box, when the arrowhead turn to "↔"or"↕", 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**)

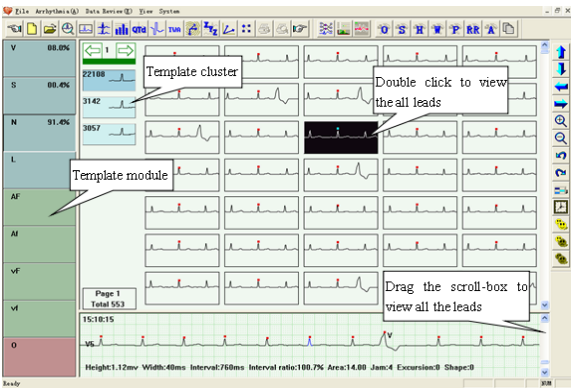


Fig.6-8

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 beat), 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.

classifying parameter adjustment function (as **Fig.6-9**).

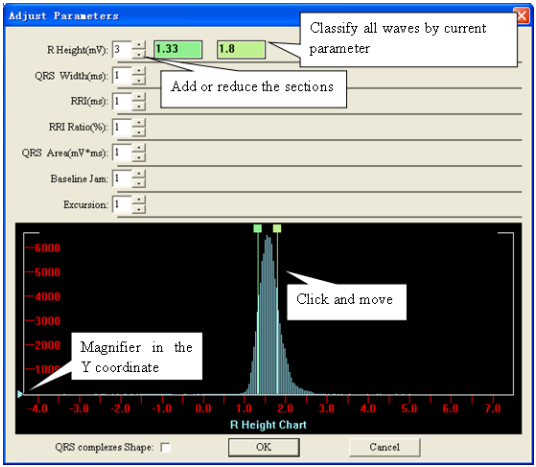


Fig.6-9

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.

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

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.

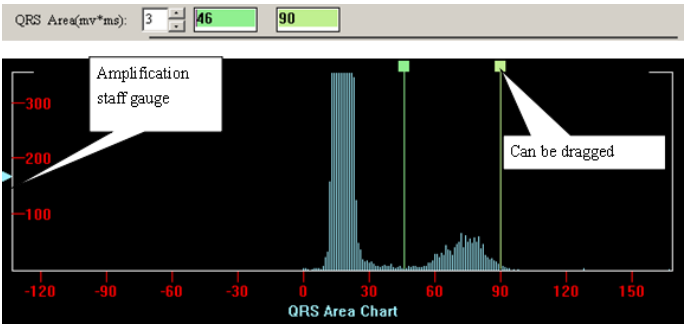
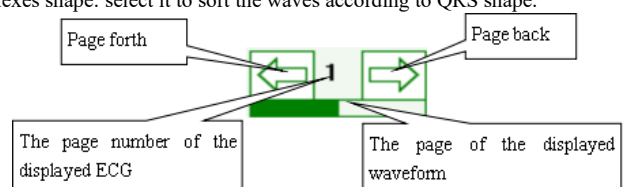
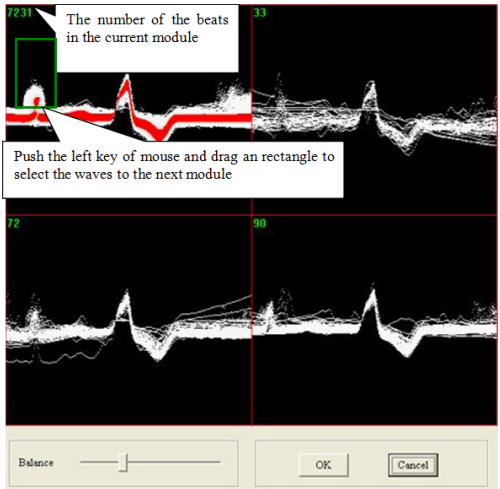


Fig.6-10

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 fist module, the density of the wave is more higher and the color is more ducker. 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;

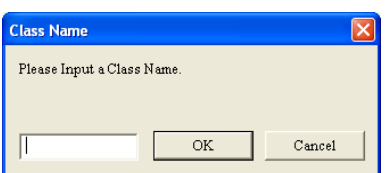
 Classify by the shape of the QRS width, click the button  to change the default parameters;

 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;

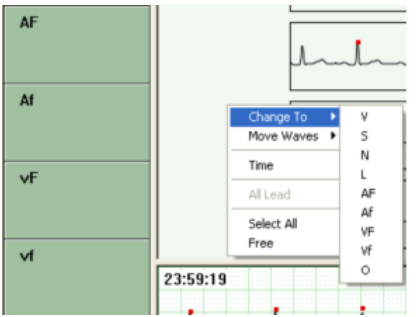
 Classify by the shape of the QRS's Area(mv*ms), click the button  to change the default parameters.

 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

Click the right button of mouse, and then an editor menu will be opened.



Change the class module; at the same time put the waveform, which is changed into the 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", "^", "v" 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 microimage

 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

Order replay module

Click the  button and enter order replay module.

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

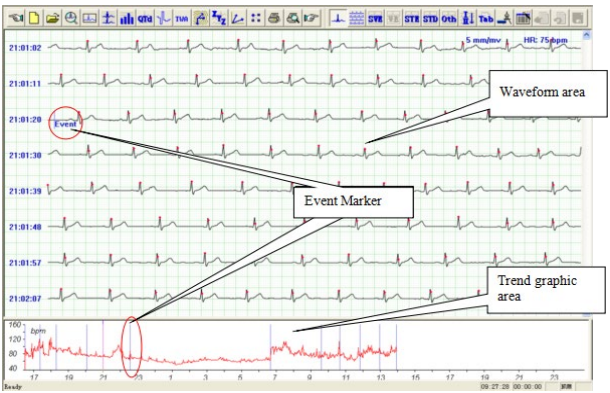


Fig.6-11

Event marker, including the blue lines and "Event" in the waveform area and the blue lines in the trend graphic area, shows the operator has press the event button on this position and recorded an event.

Put the arrowhead on the ECG and click the right key of the mouse, then appear the menu as **Fig.6-12**. The physician can examine and analyze the ECG according to what he needs.

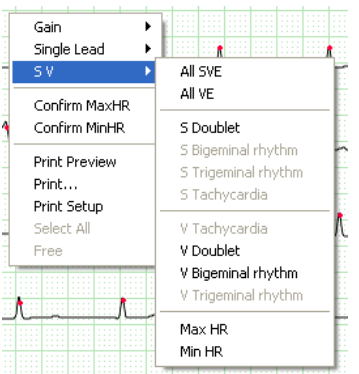


Fig.6-12

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.

Prompt:

The strip graph is 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 3.5s after the beginning time is the main wave.

Pressing "Ctrl" key on the keyboard and clicking the left key of mouse on one 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.6-12,** 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 leads according to the needs by  button (as **Fig.6-13**).

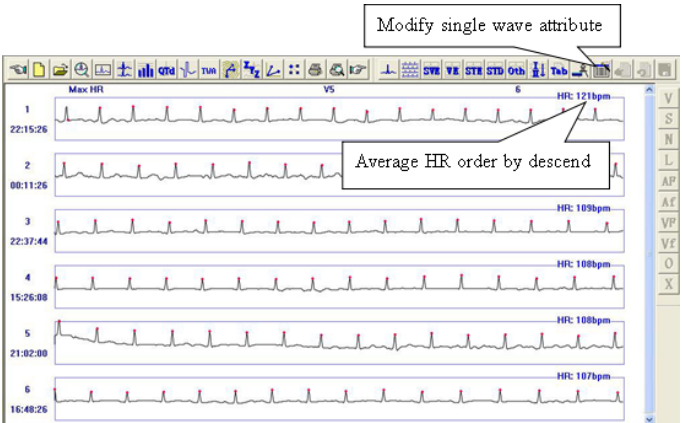

Modify single wave attribute
Average HR order by descend
Max HR
V5
6
HR: 121bpm
HR: 109bpm
HR: 108bpm
HR: 108bpm
HR: 107bpm
1
22:15:26
2
00:11:26
3
22:37:44
4
15:26:08
5
21:02:00
6
16:48:26
V
S
N
L
AP
Af
VP
Vf
O
X

Fig.6-13

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 NO.1 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 NO.1 graph, following that, Max HR in the main report will also change.

⚠ **Notice: 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.6-14.**

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

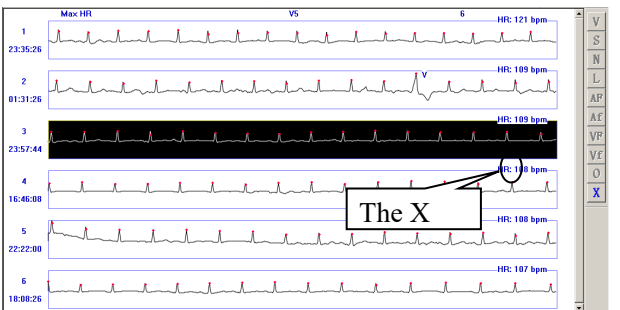


Fig.6-14

Click  button, show the multi-lead ECG from the starting time (as **Fig.6-15**).

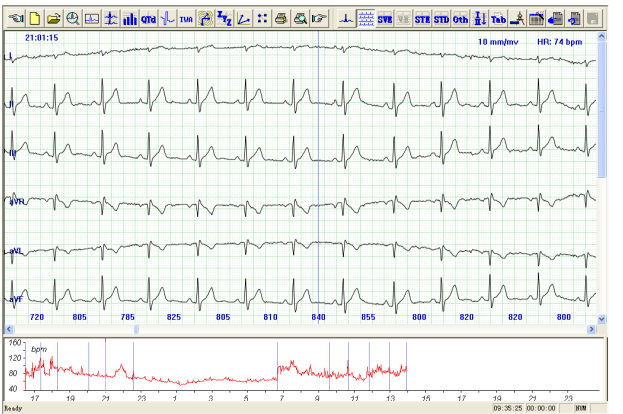


Fig.6-15

⚠ **Notice: 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.

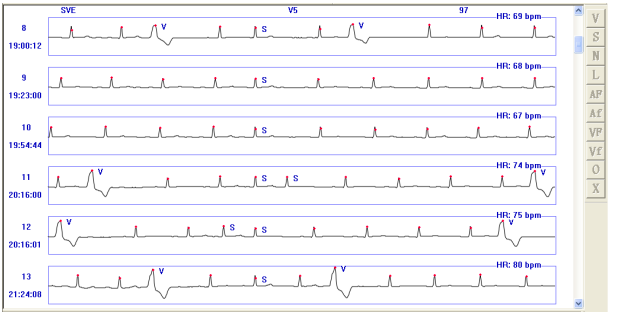


Fig.6-16

Click VE button, show the strip graph of ventricular electrocardiogram (as **Fig.6-17**).

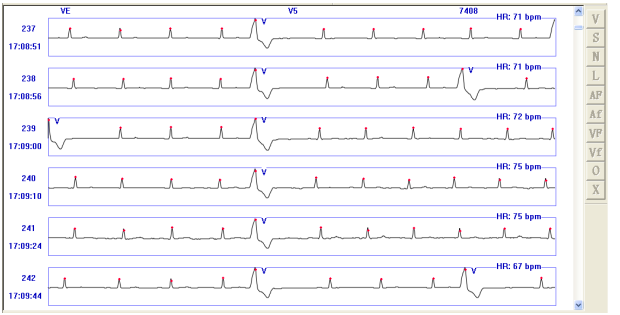
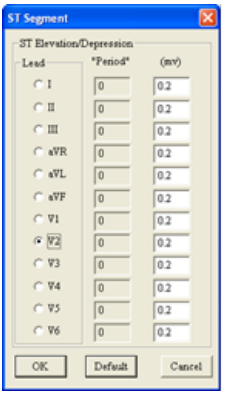


Fig.6-17

⚠ **Notice: the strip graph of SVE and VE can be modified on attribute in the selected state, while the strip graph of STE, STD and Oth can only be deleted.**

Click the 

button, enter ST elevation ECG analysis.



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.6-18**.

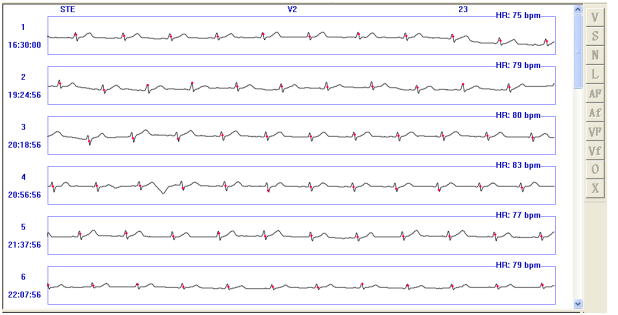
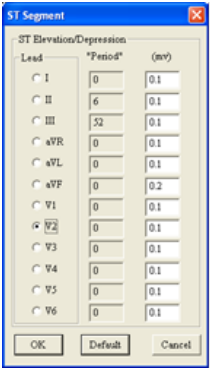


Fig.6-18

Click 

button, display ST depression electrocardiogram.



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 of all the STE strip graphs of this lead, as **Fig.6-19**.

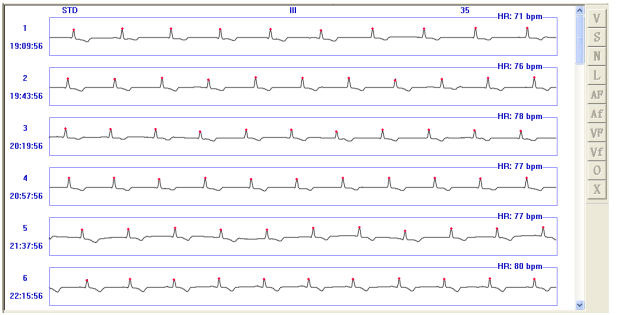


Fig.6-19

Note:

- **The ST segment analysis can be performed by the software when all leads are using any one of or all calibration signals.**
- **The parameters displayed in ST Segment interface are the analysis parameters used**

for "STE"(ST elevation) and "STD"(ST depression) analysis functions. Physician can modify the parameters and then repeat the ST segment analysis to this lead.

- **The software has myocardial ischemia analysis function, which can analyze the ST depression events, display the ST depression fragments of all leads in the myocardial ischemia data table (Figure 6-23), and provide a print report.**

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.

STLE analysis

Click "STLE" item inside of "Arrhythmia" item, show ST adjusting window as **Fig.6-20**.

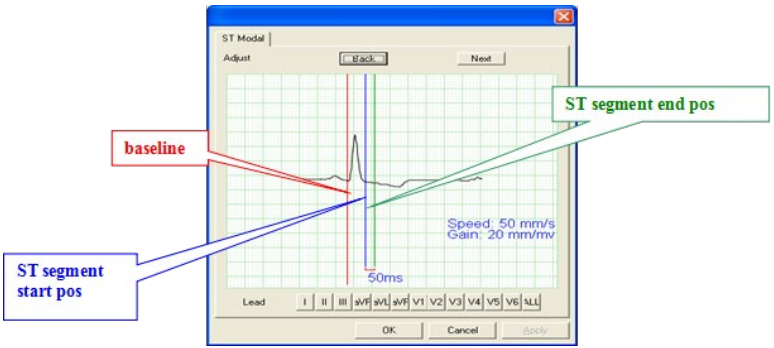


Fig.6-20

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 key 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 the Arrhythmia Table.

Arrhythmia Table: display the arrhythmia statistic for every hour, as **Fig.6-21**.

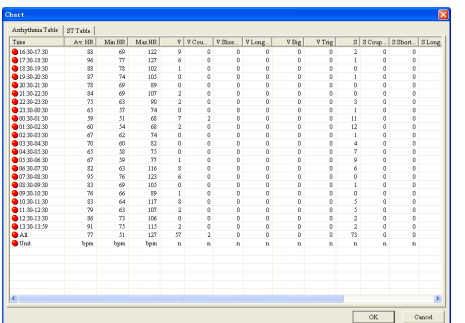


Fig.6-21

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.

ST Table : display the ST average voltage statistic of each lead for every hour, as **Fig.6-22**.

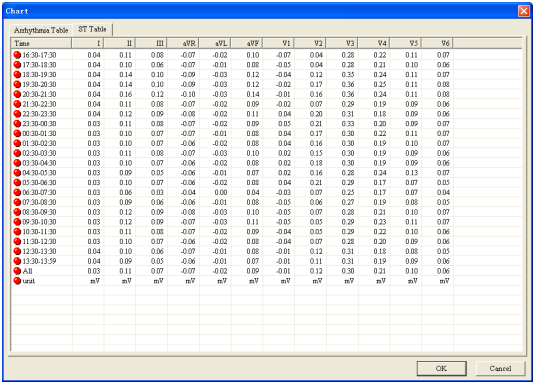


Fig.6-22

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 table as **Fig.6-23**.

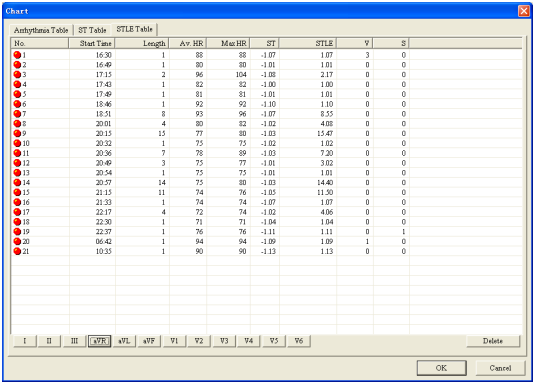


Fig.6-23

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-lead waveform, the beginning time of waveform is the same as "beginning time" of the row as Fig.6-24.

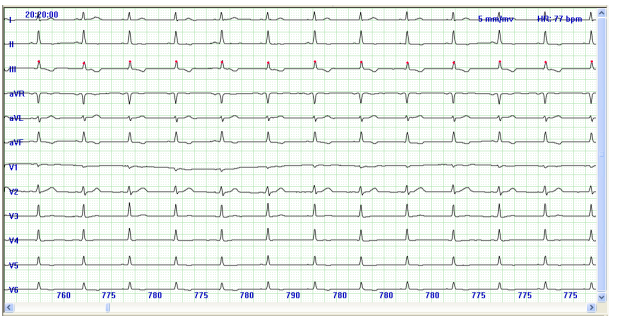
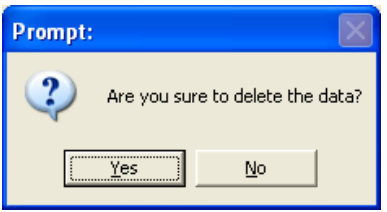


Fig.6-24

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.

QTD analysis

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. Its main function is reflecting Ventricle Repolarization inconsistency, and denote inconsistent

degree of Ventricular excitability resumptive time, or denote difference degree of Ventricular Refractory period.

QT dispersion graph is as Fig.6-25.

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 cycle. 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.

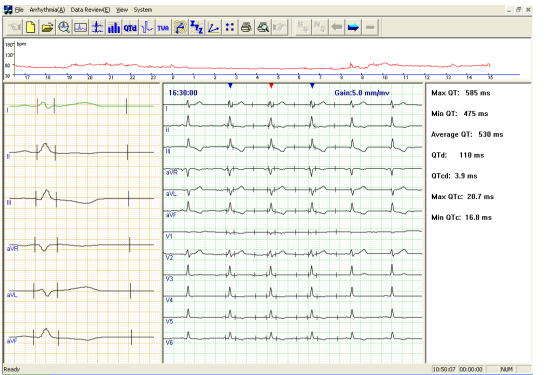


Fig.6-25

HRT analysis module.

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.6-26**).

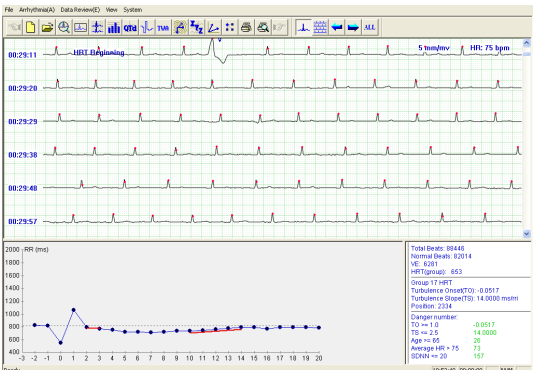


Fig.6-26

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.6-27**.

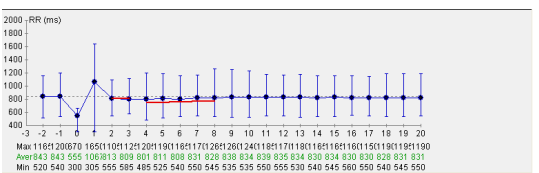


Fig.6-27

The erect line on the dot express RR interval 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.6-28**.

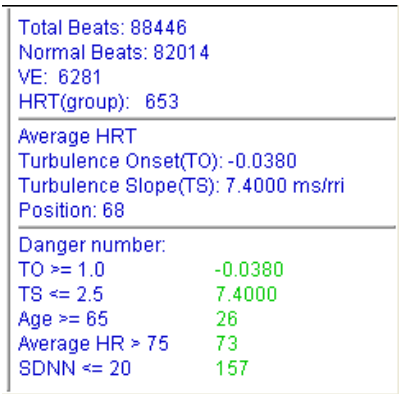


Fig.6-28

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.

T Wave alternation analysis module

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 ≥ 0.1mV. TWA is a important index on judging and preventing Arrhythmia.

The analysis adopts TWA measure basing on the maximum of T wave. The general method is: choose continuous 8 (16, 32 …128) waveforms, number QRS waveform from the first one, such as 1, 2, 3, ……, 8, then compare the maximum of T wave. If the difference of T wave is larger than the range that has preestablished, there is TWA phenomena. After comparing, carry out superposition of the singular number (1, 3, 5……) wave and superposition of dual number (2, 4, 6……) wave respectively, then draw the result after superposition, it will be more obvious as **Fig.6-29**:

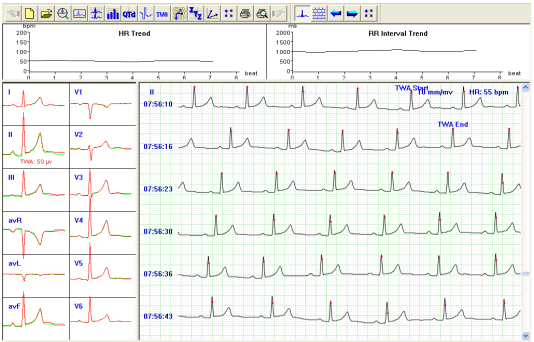


Fig.6-29

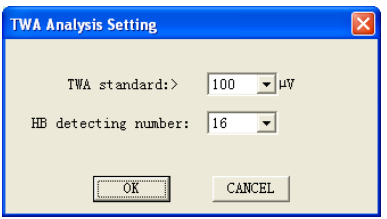
The position marked "TWA beginning", "TWA end" is the section of wave that satisfies TWA judged condition. On the left, it is the superposition graph of the singular number wave and dual number wave. The green line is the superposition wave of the singular number, the red line is the superposition wave 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 the 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.

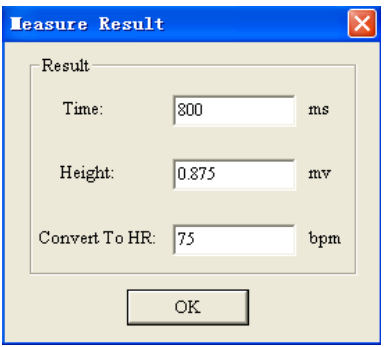
 and  express the switch between single lead and multi-lead for the current displaying waves.

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



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

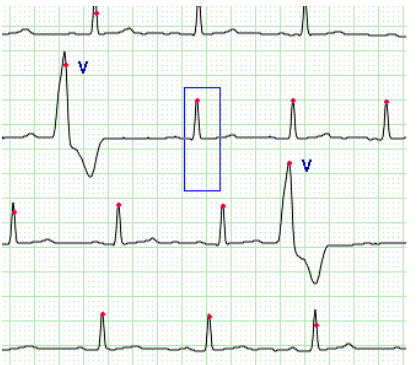
Click  button to measure RR and PR interval. Put the red point on the wave, pressing the left key and drag to draw an rectangle, then get the measure result;



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.

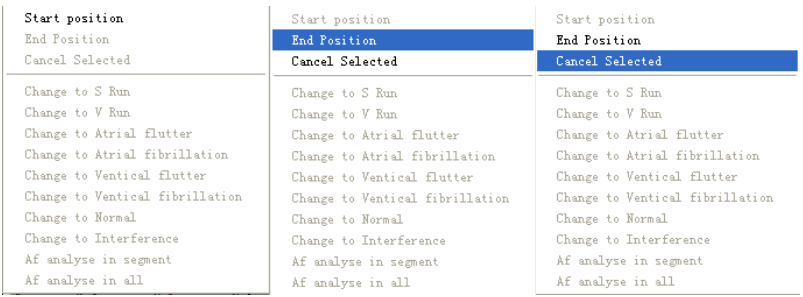
For example: put the blue rectangle on the S that need to modify, click the left button and the S will change to V, then continue click the left button, you will get the O.



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 V, 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.



Choose the start pos　　Choose the end pos　　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.6-32** automatically.

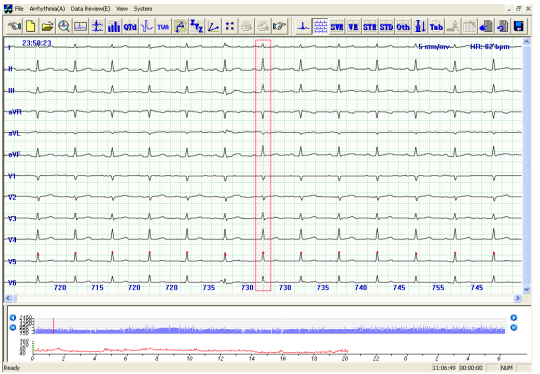


Fig.6-30

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 artifacts. 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. 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").

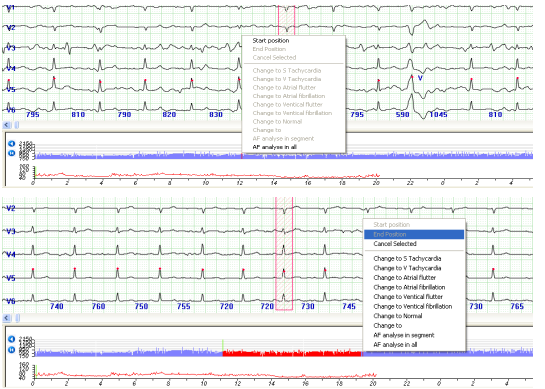


Fig.6-31

Click  button to store ECG of the current time in the print selective queue, as **Fig.6-55**

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, an change page by moving the scroll bar in the top right window (as **Fig.6-34**).

Click  button to display the all beats HRV analysis results in 5 minutes (as **Fig.6-33**).

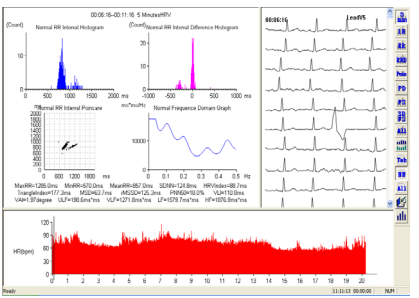


Fig.6-32

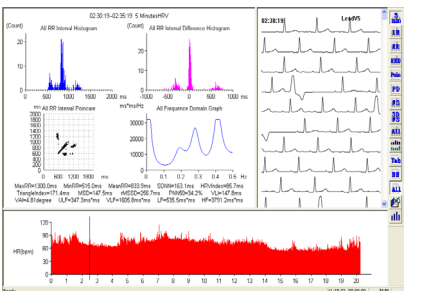


Fig.6-33

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, an change page by moving the scroll bar in the top right window (as **Fig.6-34**).

Click  button to display the all beats HRV analysis results in an hour (as **Fig.6-35**).

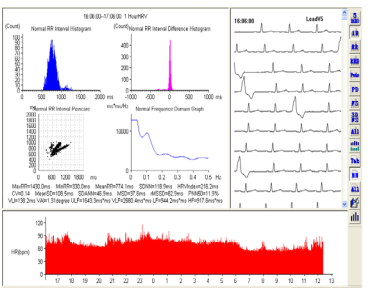


Fig.6-34

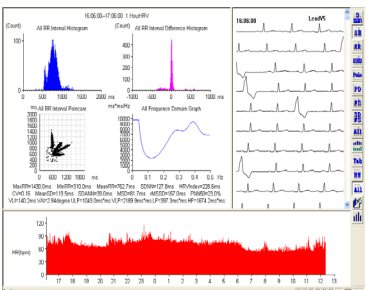


Fig.6-35

Click 

button to display the whole process of the sinus beats RR interval histogram (as **Fig.6-36**).

Click 

button to display the all beats RR interval histogram (as **Fig.6-37**).

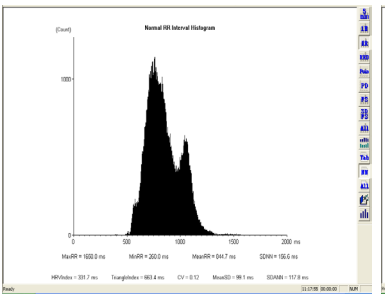


Fig.6-36

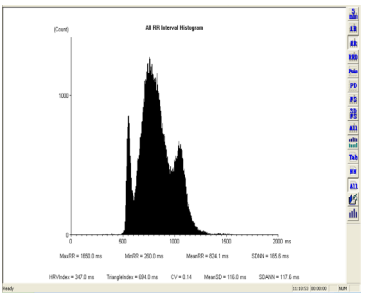


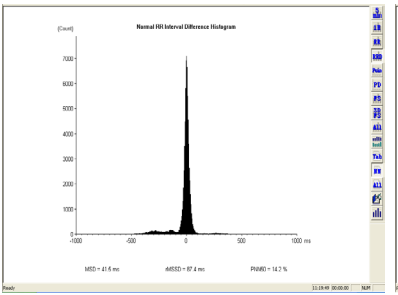
Fig.6-37

Click 

button to display the whole process of the sinus beats RR interval dispersion histogram (as **Fig.6-38**).

Click 

button to display the all beats RR interval dispersion histogram (as **Fig.6-39**).



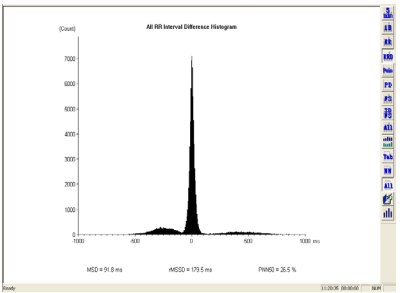


Fig.6-38 **Fig.6-39**

Click 

button to display the whole process of the sinus beats RR Interval Poincare (as **Fig.6-40**).

Click 

button to display the all beats RR Interval Poincare (as **Fig.6-41**).

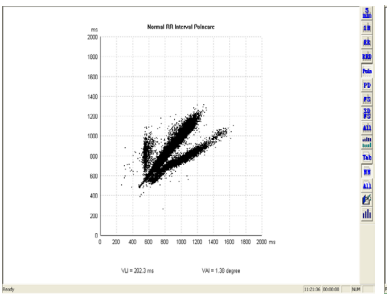


Fig.6-40

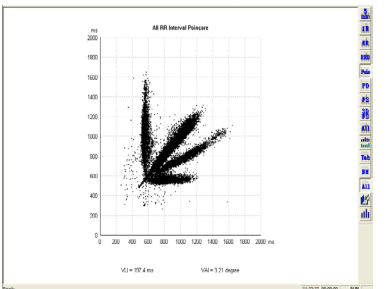


Fig.6-41

Click 

button to display the whole process of the sinus beats RR Interval Dispersion Poincare (as **Fig.6-42**).

Click 

button to display the all beats RR Interval Dispersion Poincare (as **Fig.6-43**).

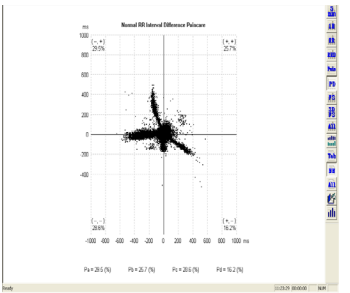


Fig.6-42

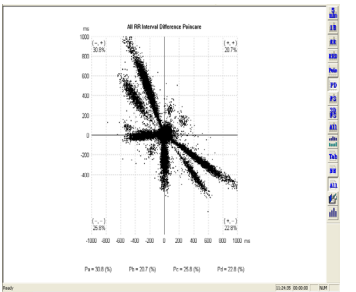


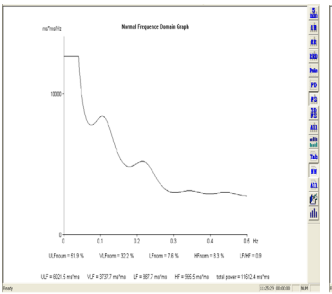
Fig.6-43

Click 

button to display the whole process of the sinus beats frequence graph (as **Fig.6-44**).

Click 

button to display the all beats frequence graph (as **Fig.6-45**).



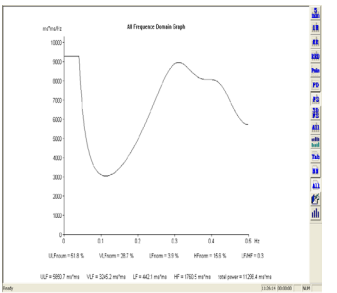


Fig.6-44 **Fig.6-45**

Click  button to display the whole process of the sinus beats frequence 3D graph (as **Fig.6-46**).

Click  button to display the all beats frequence graph (as **Fig.6-47**).

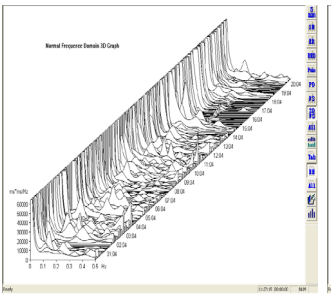


Fig.6-46

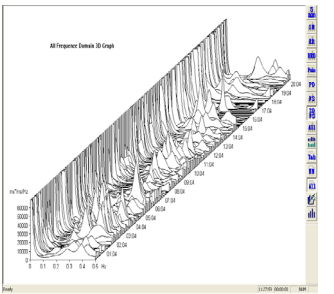


Fig.6-47

Click  button to display the whole process of the sinus beats analysis compositive graphs (as F**ig.6-48**).

Click  button to display the all beats analysis compositive graphs (as **Fig.6-49**).

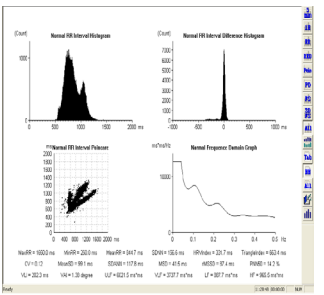


Fig.6-48

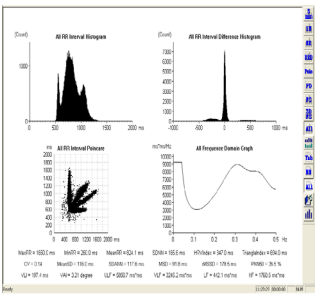


Fig.6-49

Click  button to display the whole process of the sinus beats HRD trend graph (as **Fig.6-50**).

Click  button to display the all beats arrhythmia trend graph (as **Fig.6-51**).

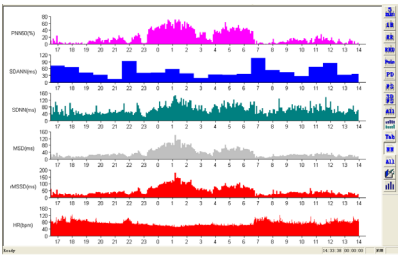


Fig.6-50

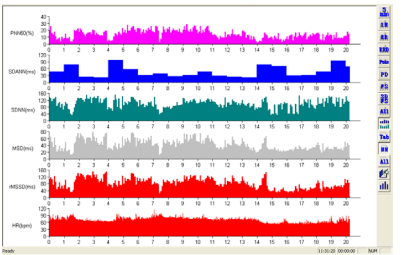


Fig.6-51

Click  button, display the whole process of the sinus beats HRV data table (as **Fig.6-52**).

Click  button to display the all beats HRV data table(as **Fig.6-53**).

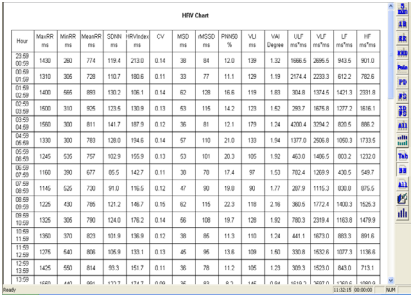


Fig.6-52

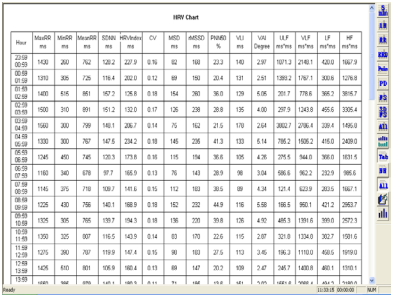
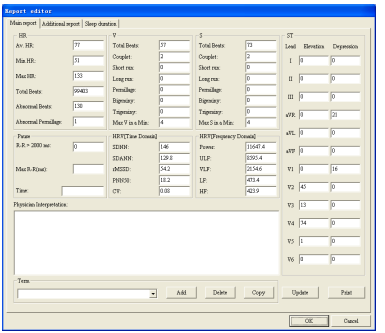
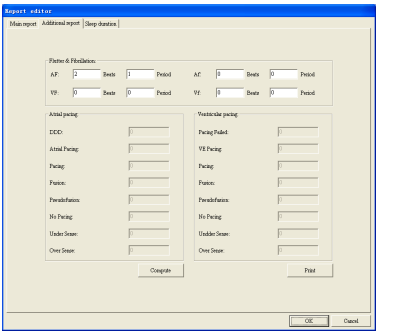


Fig.6-53

Click  button to display the case report, sleeping time setting and additive analysis(as **Fig.6-54**).





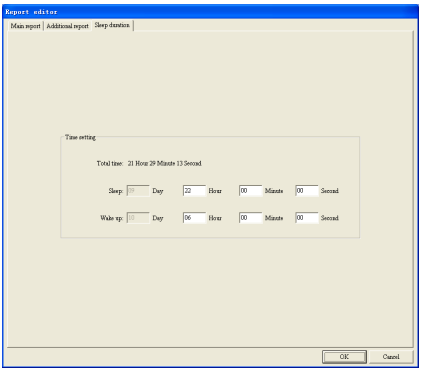


Fig.6-54

Report edit window: 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.

⚠ **Notice: 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.

⚠ **Notice: 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.

⚠ **Notice: 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.6-55**).

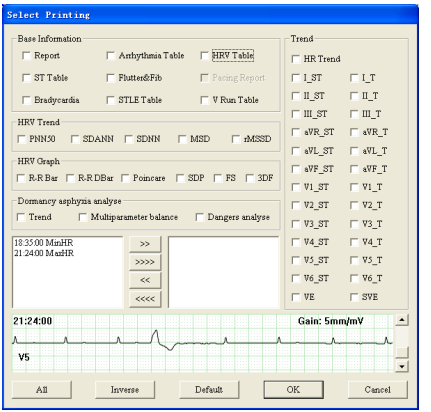


Fig.6-55

Report: Select "main report" to report.

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

Arrhythmia Table: select "Arrhythmia table" in "Order replay" to print.

Flutter & Fib: select "Atrial Fibrillation" report 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;

Poincare: RR Interval Poincare;

SDP:RR Interval Dispersion Poincare;

FS: frequence graph;

3DF:frequence 3D graph.

Dormancy asphyxia analyze: select dormancy asphyxia analyze report to print, including: the reports of Trend, Multiparameter 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.

⚠ **Notice:**

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.

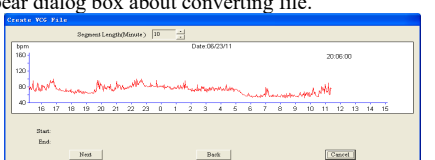
Modify the name of the ECG segment in the selective print queue by double click it.

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

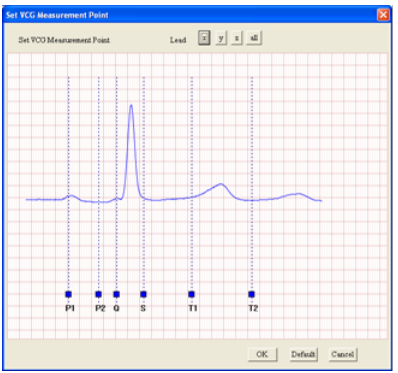
Vector cardiogram module

Choosing  button and enter the vectorcardiogram 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-leads VCG graph As **Fig.6-56**.

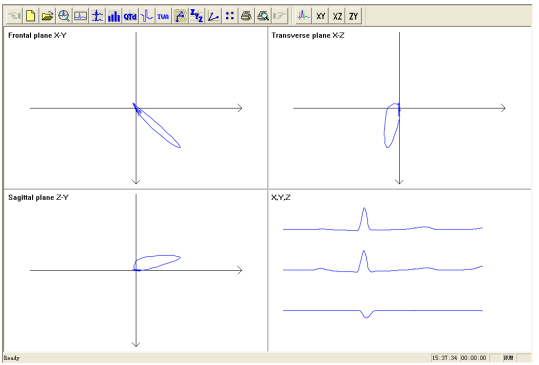


Fig.6-56

Click  button and enter Set VCG Measurement Point.

Click  button and enter Frontal plane X-Y graph (as **Fig.6-57**).

Click  button and enter Transverse plane X-Z graph (as **Fig.6-57**).

Click  button and enter Sagittal plane Z-Y graph (as **Fig.6-57**).

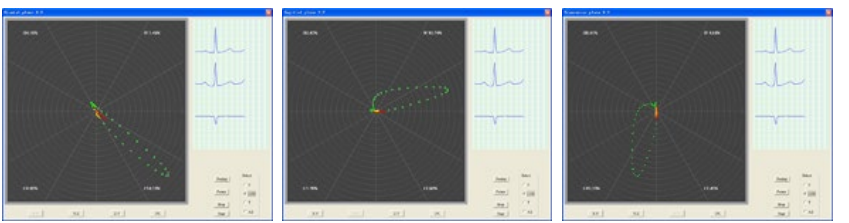


Fig.6-57

VLP analytical module

Click  button and enter VLP analytical module (as **Fig.6-58**).

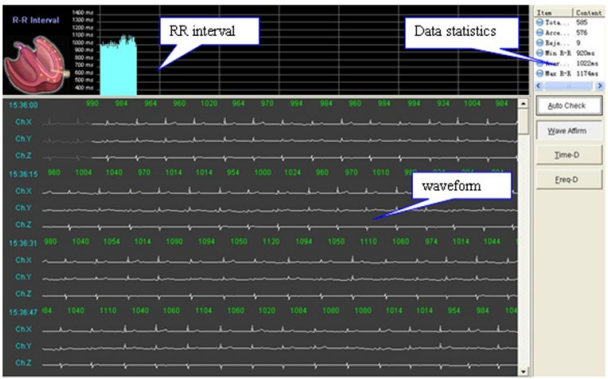


Fig.6-58

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";

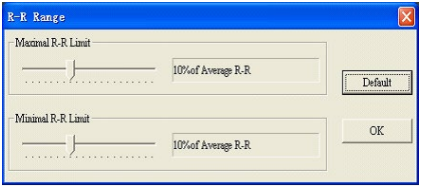
Min R-R: Minimal R-R interval;

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.



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

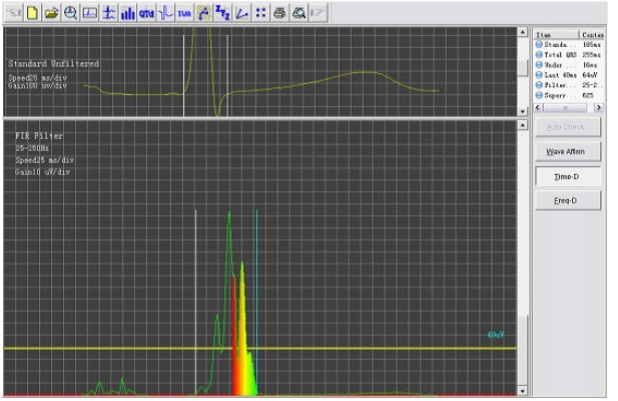
Waves can be filtrated by "auto check" or manual (as Fig.6-58).

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

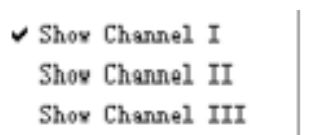
Click this button to enter the time domain analysis interface.



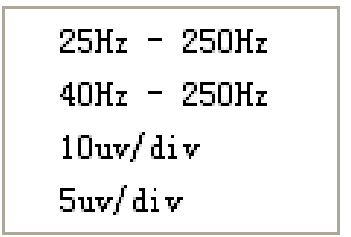
The content of "Statistics data" in this interface is as following:

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 meat square of the amplitude in the last 40 ms of QRS waves after filtering and Superposition.
Filter frequency: transmission bands of filter;
Superrimposition 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 "←" and "→" on keyboard, meanwhile the data of standard QRS will change, too.
Click the right mouse in the window to call up the menu where you can select the superposition wave you want to check. Multiply selection is supported.



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

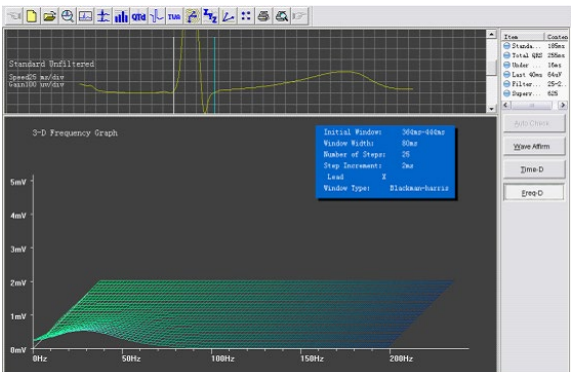


25 Hz~250 Hz: select the transmission band 25 Hz~250 Hz;
40 Hz~250 Hz: select the transmission band 40 Hz~250 Hz;
10 uv/div: select the gain 10 uv/div;

5 uv/div: select the gain 5 uv/div.

Freq-D

Click this button to enter the interface of frequency domain analysis.



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.

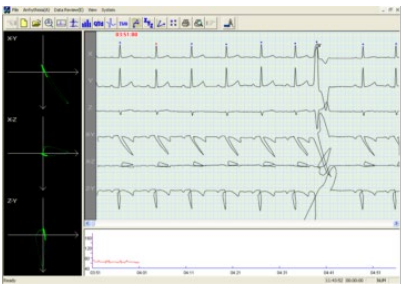
3-D frequency graph: display 3-D frequency graph of the single-lead superposed wave.

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

TVCG analysis module

Click  button and enter TVCG analysis module.

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



Click  button can measure RR or PR interval and so on.

Click  button and enter the parameter setting operation (as **Fig.6-59**).

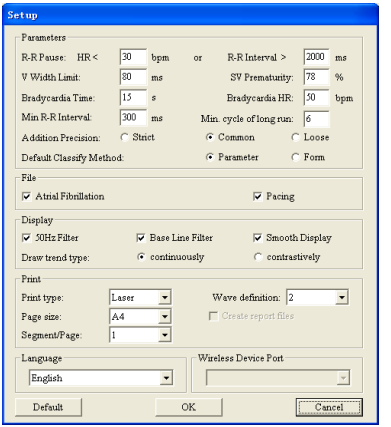


Fig.6-59

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

V Width Limit: A stander 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;

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 files: Create an electro-report after print;

Wireless Device Port: Select a wireless device port;

⚠ **Notice:** "Create report files" is un-enabled in default of "Bullzip PDF Printer".

If the physician wants to analyze the case again, he can click the "Open Old Case" in the menu of "File" to open the following dialog box (as **Fig.6-60**).

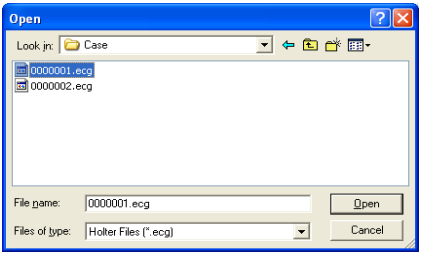


Fig.6-60

Open the "Maintain" item in the "File", or click  button on main toolbar, enter Case Manage as **Fig.6-61**.

Click  button to display the information in turn;

Click  button to modify information that has been selected in case list;

Click  button to delete the case which has been selected in case list;

Click  button to review report files;

Double click the item to open the case.

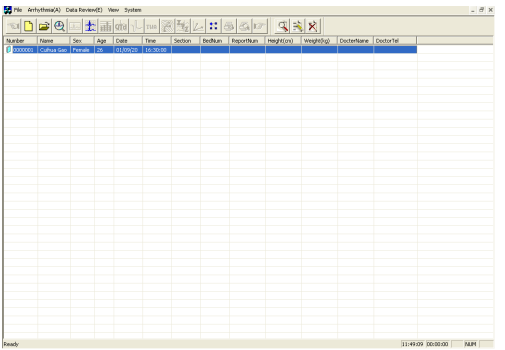


Fig.6-61

Pacing analysis

When the data contain pacing signal, the system can identify it automatically and add the pacing analyze function (as **Fig.6-64**).

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

There are 11 templates windows in the template replay function, as **Fig.6-62**. 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 where is pacing**

signal on the ECG wave.

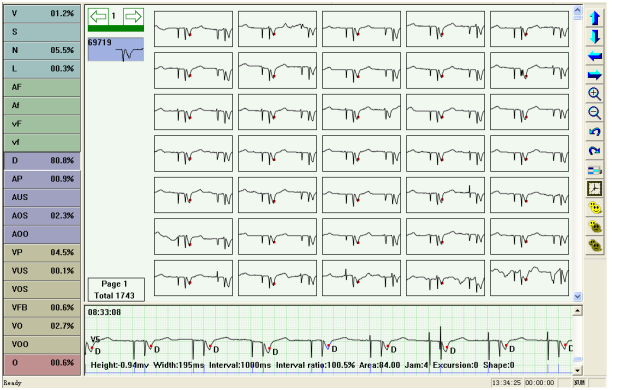


Fig.6-62

⚠ **Notice: The blue line under the ECG wave is marker for pacing, enter that it is pacing signal on the ECG wave.**

Enter the order replay, click the 

button and appear the "Chart" dialog box which added the "Pacemaker Table" (as **Fig.6-63**).

Arrhythmia Table | ST Table | Pacemaker Table

Hour	MR	MR/CSO	Self beat	DDD	Pacing Fail	Pulse	Pacing Wave	Fusion beat	P..	No..	U
08:33-09:33	54	16	200	2800	0	2830	30	0	0	0	
09:33-10:33	60	3	436	2695	0	2701	6	0	0	0	
10:33-11:33	64	6	586	2455	0	2478	23	0	0	0	
11:33-12:33	58	5	220	3128	0	3146	18	0	0	0	
12:33-13:33	18	13	139	2900	0	2926	26	0	0	0	
13:33-14:33	38	17	70	2846	0	2914	68	0	0	0	
14:33-15:33	50	12	29	3290	0	3304	14	0	0	0	
15:33-16:33	43	17	66	3211	0	3253	42	0	0	0	
16:33-17:33	58	4	199	3225	0	3244	19	0	0	0	
17:33-18:33	41	27	141	2504	0	2709	105	0	0	0	
18:33-19:33	31	33	150	2414	0	2521	107	0	0	0	
19:33-20:33	49	20	123	3143	0	3196	53	0	0	0	
20:33-21:33	54	15	255	2869	0	3014	145	0	0	0	
21:33-22:33	51	6	198	3112	0	3126	14	0	0	0	
22:33-23:33	64	1	386	2775	0	2776	1	0	0	0	
23:33-00:33	55	5	262	2969	0	2974	5	0	0	0	
00:33-01:33	57	6	167	3226	0	3232	6	0	0	0	
01:33-02:33	57	1	359	2930	0	2932	2	0	0	0	
02:33-03:33	58	4	93	3403	0	3409	6	0	0	0	
03:33-04:33	63	5	961	1684	0	1694	10	0	0	0	
04:33-05:33	61	0	414	2840	0	2840	0	0	0	0	
05:33-06:33	59	6	287	2961	0	2974	13	0	0	0	
06:33-07:33	49	13	59	3233	0	3262	29	0	0	0	
07:33-08:32	56	26	96	3006	0	3040	34	0	0	0	

Fig.6-63

Sleep breath pause syndrome analysis

First, make sure that the time when the patient begins to use recorder is correct (as **Fig.6-64**).

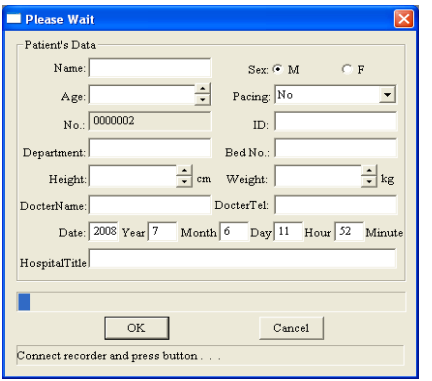


Fig.6-64

In case report  please fill the correct sleep time and wake time about sleeping time segment (as **Fig.6-65**).

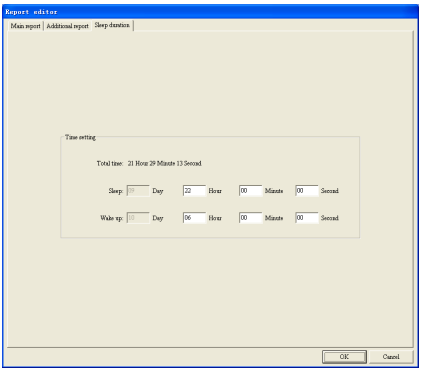


Fig.6-65

Last, in printing function dialog box  , "Trend", "Multiparameter balance", "Dangers analyse" about the option of "Dormancy asphyxia analyze" (as **Fig.6-66**).

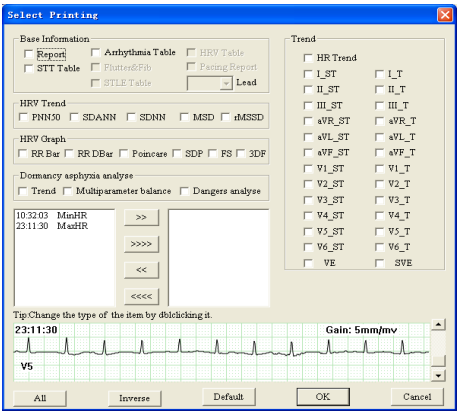


Fig.6-66

After confirming, the physician could print dormancy asphyxia analysis report and diagnose.

Appendix I

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

Name	Quality
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 / Sum of R-R interval of N heartbeats / N)

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

Supplementary explanation of ST segment analysis;

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

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

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

The user can view the number of ST-segment elevation and depression in each lead in the

"Report", that is, the number of fragments that occurred in each lead segment of the mouth.

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

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

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

Appendix III Guidance and Manufacture's Declaration

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

Guidance and manufacture's declaration – electromagnetic emission		
The *TLC5000 Dynamic ECG System* is intended for use in the electromagnetic environment specified below. The customer of the user of the *TLC5000 Dynamic ECG System* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *TLC5000 Dynamic ECG System* 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 *TLC5000 Dynamic ECG System* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that 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 manufacture's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *TLC5000 Dynamic ECG System* is intended for use in the electromagnetic environment specified below. The customer or the user of *TLC5000 Dynamic ECG System* 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%.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and manufacture's declaration – electromagnetic immunity			
The *TLC5000 Dynamic ECG System* is intended for use in the electromagnetic environment specified below. The customer or the user of *TLC5000 Dynamic ECG System* 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	3 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the *TLC5000 Dynamic ECG System*, 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	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz 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:

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 *TLC5000 Dynamic ECG System* is used exceeds the applicable RF compliance level above, the *TLC5000 Dynamic ECG System* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *TLC5000 Dynamic ECG System*. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 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 *TLC5000 Dynamic ECG System*			
The *TLC5000 Dynamic ECG System* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *TLC5000 Dynamic ECG System* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *TLC5000 Dynamic ECG System* 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 $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.37**	**0.37**	**0.74**
1	**1.17**	**1.17**	**2.33**
10	**3.69**	**3.69**	**7.38**
100	**11.67**	**11.67**	**23.33**
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 Accuracy of Operating Data

The systems having automated ECG analysis is required to fulfill of this table

Gross statistics	AHA DB		MIT DB		NST DB		CU DB	
	The assessment criteria required (%)	The actual test results (%)	The assessment criteria required (%)	The actual test results (%)	The assessment criteria required (%)	The actual test result (%)	The assessment criteria required (%)	The actual test results (%)
QRS Se (G)	98	98.91	98	98.79	83	83.44	--	--
QRS +P (G)	98	98.70	99	99.70	94	94.57	--	--
VEB Se (G)	83	83.45	83	83.82	79	79.82	--	--
VEB +P (G)	89	89.86	84	84.31	68	68.14	--	--
SVEB Se (G)	--	--	18	18.90	37	37.33	--	--
SVEB +P (G)	--	--	10	10.37	29	29.94	--	--

VEB Couplets Se (G)	63	63.19	57	57.73	--	--	/	/
VEB Couplets +P (G)	82	82.66	80	80.57	--	--	/	/
VEB Short Runs Se (G)	40	40.20	19	19.85	--	--	/	/
VEB Short Runs +P (G)	77	77.34	18	18.56	--	--	/	/
VEB Long Runs Se (G)	10	10.30	14	14.79	--	--	/	/
VEB Long Runs +P (G)	53	53.44	7	7.64	--	--	/	/

Appendix V Warranty

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.

Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.