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## ECG HOLTER WITH SOFTWARE

#### **User Manual**



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





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#### **Foreword**

This user manual describes features and request of this product, main structure, function, specification, correct method for transportation, installation, usage, operation, repair, maintenance and storage, as well as the safety procedure to protect both the user and equipment. Refer to the respective chapters for details.

Please read this user manual before using the product, and operate according to this manual strictly. As for abnormality, human injury and equipment damages caused by wrong operation, which violates the rules in manual, our company without responsibility for this kind of danger and will not maintain free for this kind of malfunction.

The information contained in this document is subject to change without notice.



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## Chapter 1 INTRODUCTION

#### 1.1 Environment Condition

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

Operation Environment:

Environment Temperature: 10°C~45°C Relative Humidity: ≤85%

Atmospheric pressure: 86 kPa~106 kPa

Power Supply: DC 3V

Transport and Storage Environment:

Environment Temperature: -40°C~+55°C

Relative Humidity: ≤85%

Atmospheric pressure: 86 kPa~106kPa

#### 1.2 Product Feature

TLC5000 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 TLC5000 Dynamic ECG Systems accords with the international safety standard IEC60601-2-47.



#### Warning:

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

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

Please don't use this device when scanning MRI.

Please don't use device which has High level electromagnetic radiation in the vicinity of the recorder.

The device is not intended for synchronous gathering.



#### Note:

TLC5000 Dynamic ECG Systems must be operated by the personnel who has been trained and authorized. Person specially assigned for safekeeping.



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

The environment where the device will be used should be reasonably free from vibration, dust, corrosive or combustible matter, and shun extremes of temperature and humidity, and so on.

Doctor must tell patient monitored by recorder not to do much movement.

TLC5000 Dynamic ECG Systems is not useful for infants.

Please insert the batteries properly in the right direction for the improper insertion may damage the device and the TLC5000 Dynamic ECG Systems will be not working.

TLC5000 Dynamic ECG Systems is an independent equipment so impossible hazard caused by the summation of leakage currents because of several equipments interconnected.

For protecting environment, please deal with the batteries according to the local rule of law.



Refer to accompanying documents.



This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community



**EUROPEAN REPRESENTATIVE** 



The protection categories against electric shock of the patient connections are: this symbol indicates that the instrument is IEC 60601-1 Type B equipment.



Reclaimable icon.



USB interface.

### 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 Leads' port



Leads' port

fig. 2-2

Leads port



While connecting lead wires, please refer to lead wires indicator in figure 2-4



#### 2.1.3 Side view



fig. 2-3 Side view

#### 2.1.4 Bottom view



fig. 2-4 Bottom view

Lead wires indicator

## 2.2 Definition of keystroke, 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



#### Note

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.

Position of the electrode placement is shown as fig.3-1

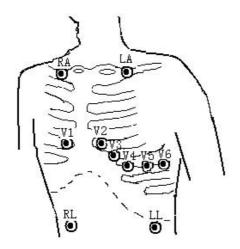


fig. 3-1

#### 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.



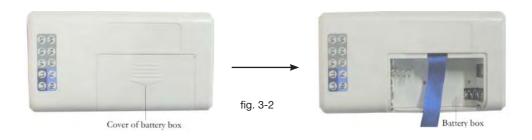
#### Place the electrode

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 coursed 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

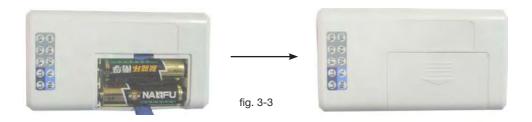
## 3.2.1 Open the battery cover according to the direction which the arrowhead on the cover indicates.

Follow as fig.3-2.



## 3.2.2 Please insert the batteries properly in the right direction, and then close the cover.

Follow as 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.

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 electrified 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.



#### Note

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.



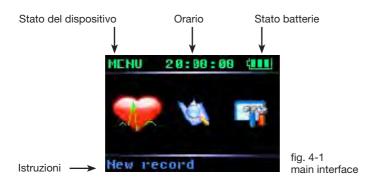
#### Note

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



## 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.



#### 4.1 New record





Use or to choose on main interface, press



to enter new record operation, display interface is as fig.4-2.

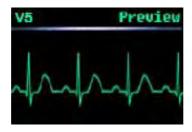


fig. 4-2

to switch lead status.



On the interface, press or to change the gain, press







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.



fia. 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 showed 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:

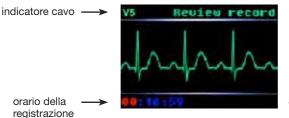


fig. 4-7

Under this interface, use or to change lead marker ( $\square$ ,  $\square$ , AVR, AVL, AVF, V1, V2, V3, V4, V5, V6)



to switch between hour, minute and second, the red one shows

the option which has been chosen, use (A) or (V) to change the value.





If the recorder doesn't have 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



"system set" interface as fig.4-9



fig. 4-9



Use \( \rightarrow \) or \( \rightarrow \) to choose the option use \( \rightarrow \) or \( \rightarrow \) 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 Language

Under this option, you can select a language "ENG/ITA".



#### 3 Demo mode

Under the item, the demonstration waveform is shown in figure 4-10

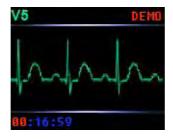


fig. 4-10

Press



to switch ECG lead waveform.

4 system initialization

Press



to enter the interface as shown in figure 4-11.



fig. 4-11



#### **Note**

Detailed edition information depends on recorder.

Press



to enter the initialization interface as shown in figure 4-12



fig. 4-12



#### 5 Time set



to enter the time set interface as fig.4-13



fig. 4-13







Use or to choose the option, use or to change the value,









to save the setting and return superior menu.



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



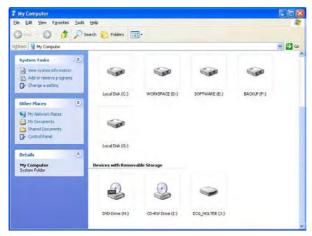


fig. 4-15

Open the disk, you can see a file named ECG\_WAVE.BIN, as fig.4-16



fig. 4-16

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



#### Note

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.





#### Note

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 The problem related to the battery

Problem	Cause	Correction
	1.The battery is used up.	Change another battery.
The recorder has no response and the indicator isn't light after the battery is put in.	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	1.The quality of the battery is poor. or the battery has been put for a long time.	Change another high-quality new battery.
can't reach 24 hours.	2.The battery can't be charged enough.	Recommend to use the battery whose capacity is over 1000mAh.
	3. 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.



## 5.2 The problem related to the skin and the electrode.

Problem	Cause	Correction
The wave is disturbed;	The skin can't be cleaned well, or the electrode isn't attached right.	Clean the skin and attach once more.
the quality of the ECG signal is poor.	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 server	Ask the patient to avoid server movement when monitoring.
The amplitude of some ECG wave is small, which is difficult for analysis.	The cable is broken.	Change a new cable.

## 5.3 The problem related to the cable and the input plug

Problem	Cause	Correction
The output wave of the recorder is a straight line.	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.
is a straight line.	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,	The cable isn't connected well	Connect the cable once again according to the operation manual.
and the quality of ECG signal is poor.	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.



### 5.4 Other problems

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

## Chapter 6 INSTRUCTIONS FOR ANALYSIS SOFTWARE

Turn on the computer and enter the WINDOWS98/2000/XP operation system. Double click the TLC5000 graph on the desktop, then enter the TLC5000 Dynamic ECG operation systems As fig.6-1.

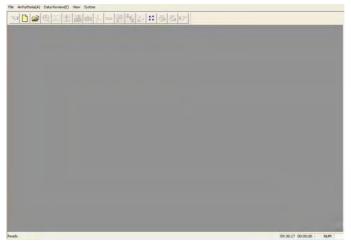


fig. 6-1

Replay HOLTER recorder

Click the "New" in the menu of "File" or click, information.



and input the new patient

If the recorder use SD 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 use Flash memory please turn to fig.6-2.





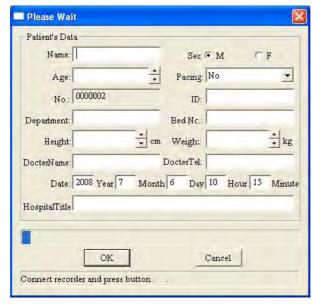


fig. 6-2

OK.

The doctor input the new information about the patient.

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

Connect the HOLTER recorder with the computer, and then click the the computer begins to read data from the recorder.

After the communication finished, enter the interface as fig.6-3.



#### Note:

Replay the same recorder, you must unplug the replaying cable and connect again, then begin to operate.



This menu is to ask whether to make the arrhythmia analysis.

Click <u>Yes</u> button as fig.6-3, and enter the analytical interface as fig.6-5.

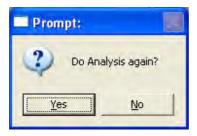


fig. 6-3



#### Attention

If the patient takes a pacemaker, first enter the dialog box as fig.6-4, the doctor modify the items on the dialog box according to the parameter of pacemaker. The accuracy of pacing pulse analysis relatives to the "high" or "low" of pacing pulse, usually choose "middle", if the pulse is very low, please choose the "high".

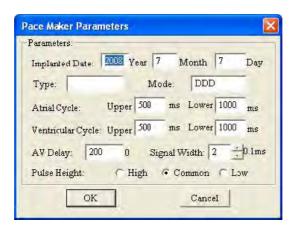
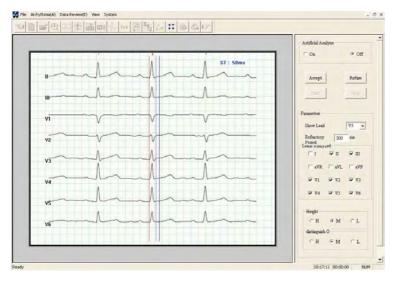


fig. 6-4

Click button, and enter the module compilation (have analyzed) or order replaying interface (have not analyzed).

Click Yes to enter the interface as shown in fig.6-5.





fia. 6-5

The interface as fig.6-5 is to ask the user to 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. When clicking, the line, which is near the clicking point, will be changed.

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

If the current wave is good, please knock the Accept

button, and then

the system enters the arrhythmia analysis as fig.6-6. If the user wants to stop arrhythmia analysis, please close direct. If the current wave is not good, please click the Refuse button.

then the system will show the waves constantly until you click Accept to enter the arrhythmia analysis.

Click the dialog box at the right of the main analytical lead to choose 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 concrete circumstance, if the patient's heart rate is very quick, it should be set lower, in order to prevent losing the analysis for some heart beats.

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

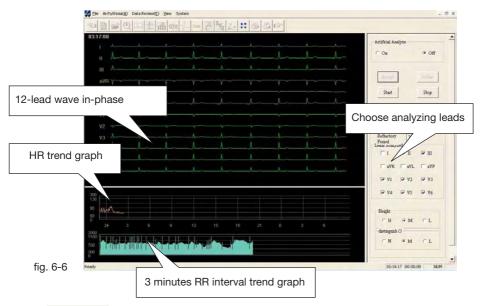
When the amplitude of the case's wave is too low, please choose "high" in the "resolution" option

When the case meets much disturbance, please choose "high" in the "preci-



sion of judging interfering" option Analysis precision and precision of judging interfering don't need to adjust generally. The user can choose according to the actual circumstances.

Click **Accept** and enter the picture as fig.6-6.



Click Stop , the system will stop temporarily. User can browse

the 12 lead ECG through " → † → † " on the keyboard. In the heart rate 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 (analytical leads, discernment, discernment in disturb), click the part behind the green sign will be analyzed again. (as fig.6-7).



Click **Stop** in the analytical process, the analysis will stop temporarily.

Or use "space" to switch "start/stop".



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

When the analysis finished, user can enter different module by choosing different options.

Function explanation of edit module



Represent: Arrhythmia analysis module, template replay, order replay module,

HRV analysis module, QTD analysis module, HRT module, TWA module, VCG module, VLP module and TVCG module.



Go to the previous operation F



go to the next operation

· scroll bar usage

Click the " **A** at the right side of the Window or scroll bar to change the content showed in the window.

Change window size

Move the mouse arrowhead to the side of box, when the arrowhead turn

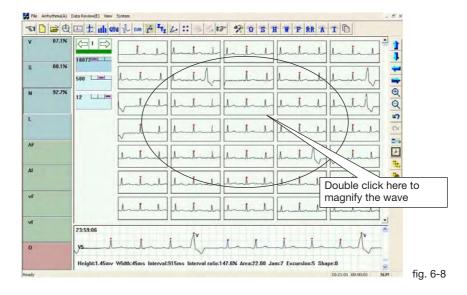
to " • " or " , press the left keypad of mouse and don't set free until drag to the wanted location.

Screen interface distributing.

Click



into the replay module.(as 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. The blank means no wave.

V: ventricular premature beat module

AF: atrial flutter module

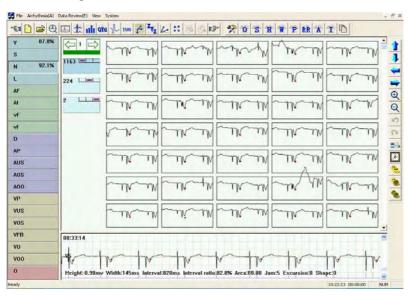
S: atrial premature beat module Af: atrial fibrillation module N: NN heart pacing module VF: ventricular flutter module L: long interval module

Vf: ventricular fibrillation module

vi. verificular fibrillation filot

O: interfering module

If it is pacing case, then the template will increase 11 classes automatically, shown as fig.6-9.



fia. 6-9

They are:

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

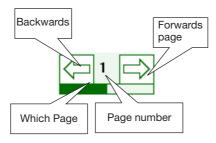


VOS: Ventricular Under Sense VFB: Ventricular fusion beat VO: Ventricular Pseudofusion

VOO: Ventricular asynchronous pacing

If it is pacing case, under the ECG showed, there will be marker with blue lines, the position on the ECG is pacing point.

The right window above is a display of the chosen module to display concrete wave. The right window below is the detail what the arrowhead points to at the right window above.



Press to enter the following interface to adjust classifying parameters. As fig.6-10.

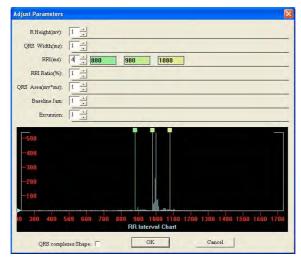


fig. 6-10

The left is the parameter name and unit. The middle is about how many kinds the parameter divided into. The right is the verge of the classification. The verge of the classification is in accordance with the lines in the distributing graph.



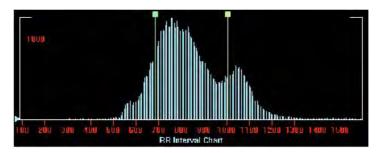


fig. 6-11

Picture 6-11 shows the distributing graph of the wave. The y-axis is the number of wave, the abscissa is attribute value of wave. The classified line corresponds to the editor box Press the square in the line to move the line to change the verge of the classification. The blue triangle on the left is the amplified staff gauge.

```
QRS complexes Shape:
```

This box decides whether to sort the waves according to shape. Wave display window. As fig.6-12

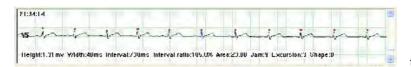
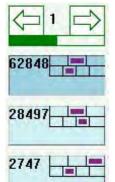


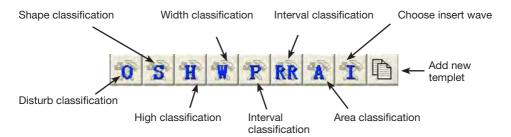
fig. 6-12



When the number of classification is large, it's used to turn the pages. The number in the middle means the current page.

The number in the square means the number of the waves. The two rectangles on the right mean there are two parameters to be classified, including height and interval. The number of diamonds in quadrate bar is the classified number according to the parameters. The purple square means the place of the wave. For example, the first kind in the above, the height of the R wave is between 0.64 and 1.22, and the RR interval is between 520 and 948. Keep the left button down, drag the wave into the classify molding board. It can change the class of these waves.





When knocking the correspond button, the system calculates the proper circumscription of the classification, and divides the parameter into some kinds automatically. For example, when knocking the "Disturb classification" button, the system calculates the proper circumscription of the classification, and divides the parameter into three kinds automatically. When knocking the "Shape classification " button, the system will divide into four kinds automatically. When knocking the "High classification " button, the system will divide into three kinds automatically.



is "choose insert wave" button. When knocking this button,

the system will choose the inserting wave out to make the user easy to edit.



Open dialog box to add classify.



Click the right button open the editor menu.



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 change the chosen wave to the corresponding sort.

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

#### Control graph display key



Remove the ECG in the left window up



Remove the ECG in the left window down



Remove the ECG in the left window left



Remove the ECG in the left window right



Amplify the ECG in the left window



Lessen the ECG in the left window



Cancel the edit operation



Recover the edit operation



Display or hide the statistics



Display or hide the time



Choose all the ECG in the left window



Reverse choice the wave in the left window



Cancel choice in the left window

click the 🔛 button and enter order replay module.

The picture is the order replay picture of main analysis lead. And the doctor can choose the wave of other leads. As fig.6-13



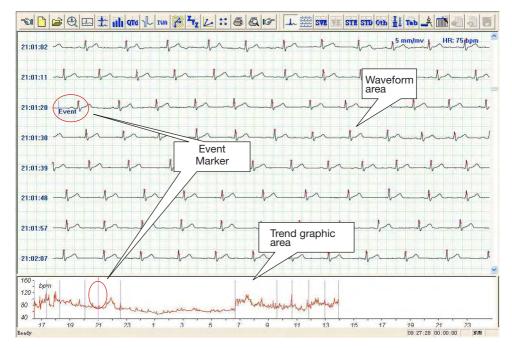


fig. 6-13



#### Note:

The calculate function of HR is as follows: HR = 60000 ms / Average R-R Interval Average R-R Interval is an average of R-R interval that is from all waves in the screen.

Put the arrowhead on the ECG and knock the right key of the mouse, then appear the menu as fig.6-14. The physician can examine and analyze the ECG according to what he needs.



fig. 6-14



For example, knock "the highest heart rate", and appear the highest heart rate ECG, which is for the main analytical lead. Of course, the physician can choose other lead according to what he needs. As fig.6-15.

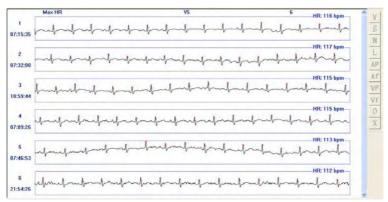


fig. 6-15

In this picture, knock the right key of the mouse, appear and choose "Confirm MaxHR", then show the highest heart rate. As fig.6-16.



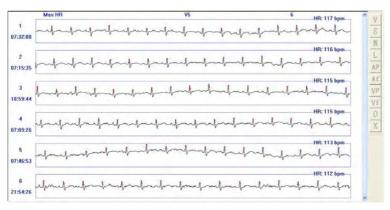


fig. 6-16



button, show the multi-lead ECG. As fig.6-17.



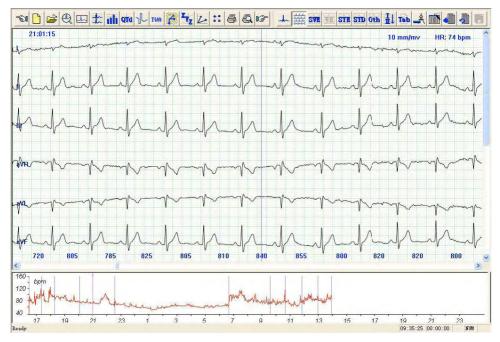


fig. 6-17

Knock buttor

button, show supra ventricular electrocardiogram.

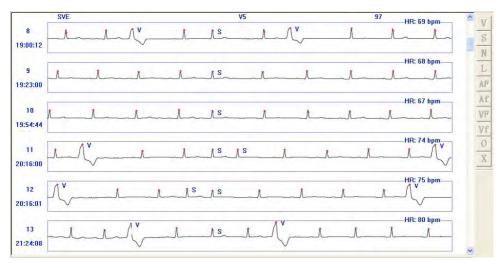


fig. 6-18



button, show ventricular electrocardiogram. As fig.6-19.



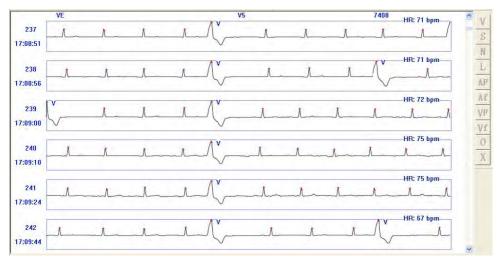


fig. 6-19

V Change type into ventricular premature beat

S Change type to atrial premature beat

N Change type to sinus pulsation

Change type to long intermission

AF Change type to atrial flutter

Af Change type to atrial fibrillation

Change type to ventricular flutter

vf Change type to ventricular fibrillation

Change type to disturb

X Delete

Press CTRL, and choose the bar picture by mouse at the same time,

are just used for deleting, not others.

Knocking the



button, enter ST elevation ECG.





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. As fig. 6-20.



fig. 6-20

Knocking

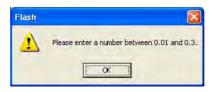


button, display ST depression electrocardiogram.





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. As fig. 6-21.

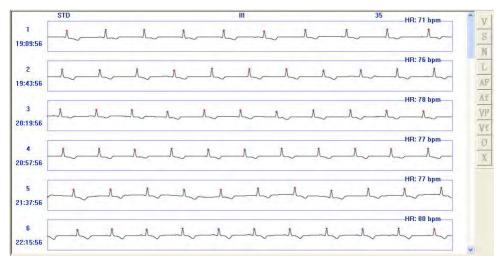


fig. 6-21

Click



button, display other classified ECG: couple S, S bigeminal

rhythm, S trigeminal rhythm, atrial tachycardia; ventricular tachycardia, couple V, V bigeminal rhythm, V trigeminal rhythm; long intermission, atrial flutter, atrial fibrillation, ventricular flutter, ventricular fibrillation; maximal heart rate, minimal heart rate.

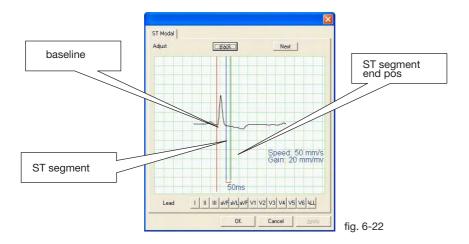
Before do the operations, which have been introduced, if refresh button (high bright) means the data need refresh, click this button to refresh data.





Click button to choose the number of lead to display the mono-lead ECG.

Click" STLE "item inside of" Arrhythmia "item, show fig.6-22.



Put the cursor near the line, which needs adjust, click the left button adjust the line's position.

The doctor can choose to lead and waveform according to the demand, adjust ST segment. Click "OK" button, show as following.



Click button, display the Arrhythmia Table.

Arrhythmia Table A as fig.6-23.



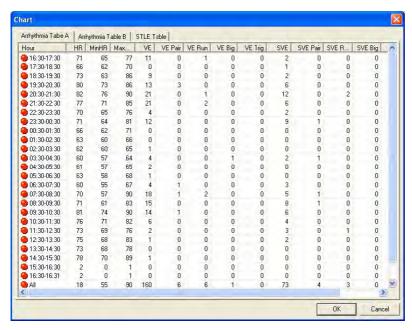


fig. 6-23

## Arrhythmia Table B as fig.6-24.

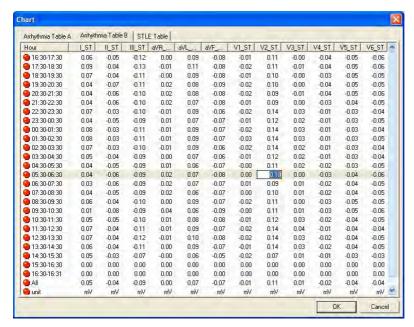


fig. 6-24



## STLE table as fig.6-25.

Arrhythmia Table A	Arrhythmia Table B	STLE Table						
Serial Number	Start Time	Length(min)	HR(bpm)	MaxHR(bpm)	ST(mm)	STLE(mm*min)	٧	S
<b>●</b> 1	16:30	2	77	77	-1.21	2.42	1	1
2	16:37	160	68	80	-1.22	195.04	12	2
3	19:19	5	80	81	-1.04	5.21	0	0
4	19:26	16	75	82	-1.08	17.25	3	0
<b>9</b> 5	19:45	1	76	76	-1.07	1.07	0	0
<b>6</b>	19:49	4	79	80	-1.14	4.56	0	0
7	19:55	1	80	80	-1.01	1.01	0	0
8	19:58	20	80	86	-1.20	23.97	4	3
9	20:22	3	80	80	-1.07	3.22	0	0
10	20:27	22	81	83	-1.12	24.67	4	1
11	20:58	18	77	80	-1.12	20.24	1	1
12	21:18	15	80	84	-1.16	17.45	8	0
13	21:38	15	76	79	-1.10	16.45	6	0
14	22:19	12	73	76	-1.14	13.71	0	0
15	22:38	12	69	72	-1.07	12.87	0	0
16	22:55	9	70	76	-1.05	9.49	1	2
<b>1</b> 7	23:06	1	68	68	-1,01	1.01	0	0
<b>3</b> 18	23:10	4	68	69	-1.06	4.23	1	0
19	23:21	1	68	68	-1.03	1.03	0	0
20	23:28	5	69	72	-1.08	5.38	1	2
21	00:07	14	67	72	-1.10	15.34	3	2
22	00:41	94	63	66	-1.18	110.55	0	0
23	02:27	5	62	62	-1.11	5.54	0	0
24	02:45	34	61	65	-1.03	35.18	1	0
25	03:21	17	61	63	-1.05	17.82	0	0
1 11	III aVR a	/L aVF	V1	V2 V3	V4	V5 V6		Delete

fig. 6-25



#### Nota:

HR is an average in the period of time. MaxHR is a maximum of HR per minute in the period of time.

Each row in the table stands for each period of time of ST depression of display lead. The data of table contains. beginning time, lasting time (min), HR (bpm), MaxHR (bpm),ST (mm), total burthen (mm\*min), ventricular premature beat in period of time and atrial premature beat in period of time. User could delete some periods of time in table directly, knock "ok", the changed file will be saved.

User could double click the row in the table, then the order review window will display multi-leads waveform, the beginning time of waveform is the same as "beginning time" of the row as fig.6-26.



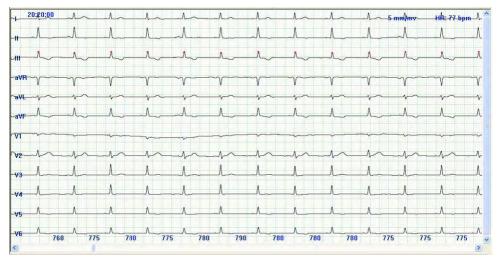


fig. 6-26

After deleting some periods of time, if user don't 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. ■

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 presumptive time, or denote difference degree of Ventricular Refractory period.

QT dispersion graph is as fig.6-27.

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 heartbeat. 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. 6-27

Click button, enter HRT analysis module.

HRT could be quantificationally 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.6-28:

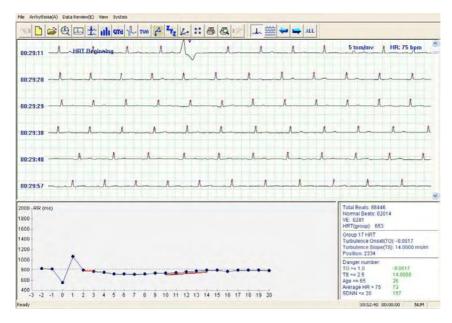


fig. 6-28

ALL

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 interphase 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.



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. 6-29:



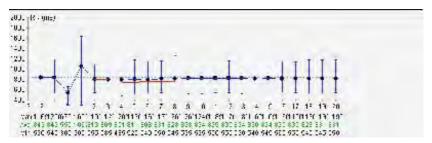


fig. 6-29

The erect line on the dot express RR interphase the maximal value and least value on different period of time.

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

The graph on the right below window is the conclusion as fig.6-30.

Total Beats: 88446 Normal Beats: 820 VE: 6281 HRT(group): 653	14
Average HRT Turbulence Onset( Turbulence Slope( Position: 68	•
Danger number: TO >= 1.0 TS <= 2.5 Age >= 65 Average HR > 75 SDNN <= 20	-0.0380 7.4000 26 73 157

fig. 6-30

Before seeing the whole case report, the option such as "normal heart pacing" will show the word "no judging". When the result is in the range that "the dangerous exponent" indicates, the corresponding result will turn to red to remind the user.

Click TWA button t enters the T Wave alternation analysis module. TWA express the alternate change of amplitude, form about T wave on the ECG.TWA have consanguineous relation with Arrhythmia. The amplitude, form and periodicity of T wave of the same lead change



alternately on the ECG, the wave that amplitude difference of near waves is same or larger than 1 mm is called TWA. 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) waveform, 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 pre-established, 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.6-31:

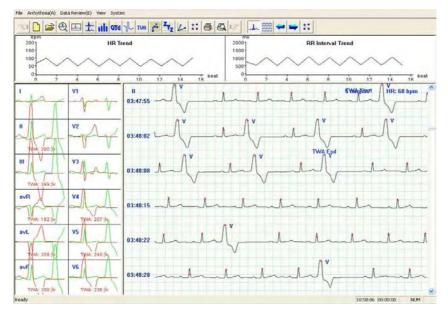


fig. 6-31

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 asV3-lead,V4-lead on above picture). The number express the height difference after superposition of the singular number wave and superposition of dual number wave. Click the rectangle where the wave is, the right wave graph will turn to single-lead wave of the appointed lead. "heart rate trend graph", "RR interphase trend graph"



above express the heart rate of TWA segment and the mutative trend of RR interphase.

Click

button in toolbar



the wave that satisfies last TWA analysis condition,

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

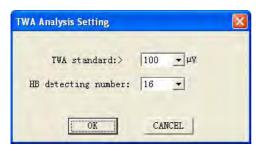


and

express the switch between single lead and multi-lead

for the current displaying waves.

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

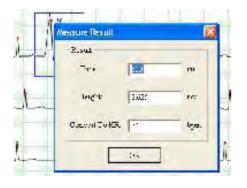


The user can set the TWA judging standard and the heart pacing longness for continuous measuring. The range for TWA judging standard is 40-100 mV, the heart pacing longness for continuous measuring is: 8–128. The purpose of enactment is analysis convenience and reducing mistake.

Click

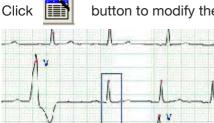


button to measure RR and PR interval.



Put the red target on the ECG, pressing the left button and dragging the red target, when there appears a blue rectangle, release the mouse, then the result of measure will turn on.

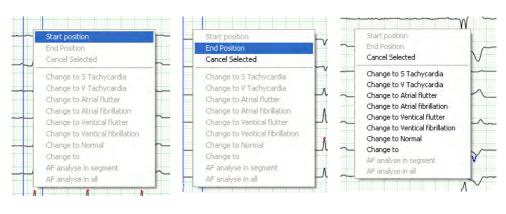




button to modify the type of QRS wave.

Put the mouse pointer which has the blue rectangle on the wave of QRS that need to modify, then you can click the left button to modify the wave. For example: put the blue rectangle on the S that need to modify in the left picture, click the left button and the S will change to V, then continue click the 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 po

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.6-32automatically.



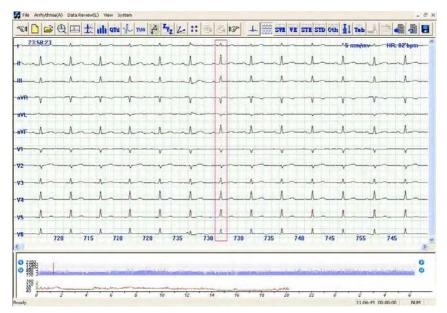


fig. 6-32

It is similar to the interface of order replay, but add the azury diagram at the top of 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 is the same as the waveform 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-channels graph and the green line on the HR trend will change at the same time. You will see that there are azury, navy blue, gray and some white lines on the RR interval graph. Their meaning is as follows:

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

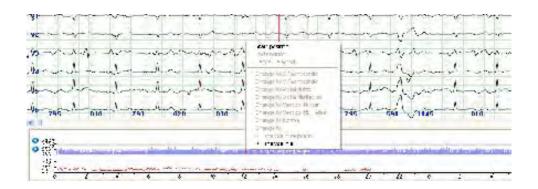
System support keyboard to view RR interval trend graph. Click the view

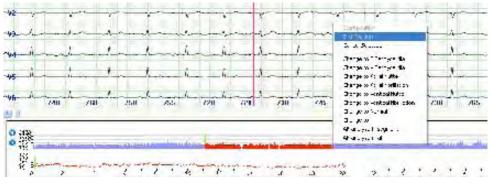
below, passing the " → " " ← " can view the RR interval forward or backward, passing the "Page Up", "Page Down", can turn over the page backward or forward, you can also pass the " \* " " \* " to play

the RR interval automatically, and press any key to stop playing.



The user can judge the atrial fibrillation occurrence time and length assumedly by using RR interval graph. Combining the multi-channel graph, if make sure that the segment is AF; pop up the menu as follows on the RR interval by clicking the right button: Choose a segment, when the segment turn red, its attribute can be modified to S Tachycardia, V Tachycardia, Atrial flutter, Atrial fibrillation, Ventricle flutter, Ventricle fibrillation, Normal, disturb. At the same time, user also can choose automatic atrial fibrillation analysis for this segment. You also can choose the whole automatic atrial fibrillation analysis at the beginning.





fia. 6-33

Click



button to print multi-channel ECG.

Click



button to cancel the print.

Click



button to fresh data.



Click



button, enter the arrhythmia analysis module.



Note

Click button, the system enters sinus mode arrhythmia analysis. Which is the default analysis.

Click



button, the system analyze all pulsation arrhythmia.

Click

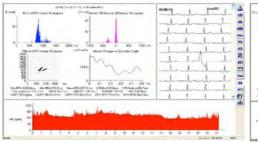


button, display 5minutes arrhythmia analysis graph.

The frequency domain, time domain and the integration electrocardiogram in 5 minutes. You can print them, can change the starting time by moving the y-axis line in the below trend graph, can change page by moving the scroll bar in the top right window. As fig.6-34.

Click (as fig.6-35)

button to display the all pulsation arrhythmia graph in 5 minutes.



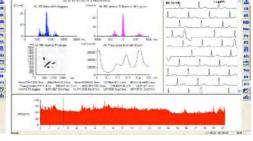


fig. 6-34

fig. 6-35

Click



button to display arrhythmia analysis graph 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 moving the y-axis line in the below trend graph, can change page by moving the scroll bar in the top right window. As fig.6-36.

Click button to display the whole pulsation arrhythmia graph in an hour. As fig.6-37.



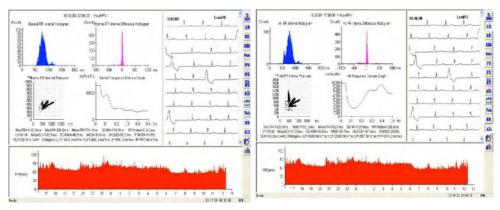


fig. 6-36 fig. 6-37

Click button to display the whole process RR interval histogram. As fig.6-38.

Click button to display the whole pulsation RR interval histogram. As fig.6-39.

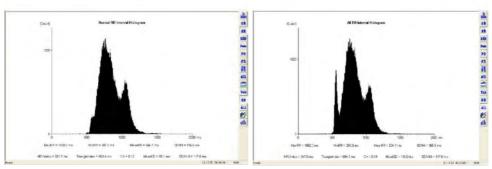
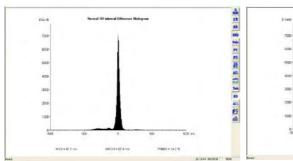


fig. 6-38 fig. 6-39

Click button to display the whole process RR interval dispersion histogram. (as fig.6-40)

Click button to display the whole pulsation RR interval dispersion histogram. (as fig.6-41)





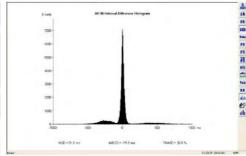
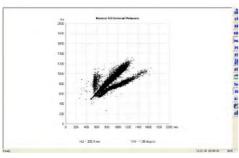


fig. 6-40

fig. 6-41

Click button to display the whole pulsation RR interval poincare. (as fig.6-42)

Click button to display all pulsation RR interval poincare. (as fig.6-43)



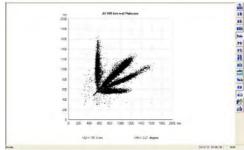


fig. 6-42

fig. 6-43

Click button to display sinus mode pulsation RR interval dispersion poincare. (fig.6-44)

Click button to display the whole pulsation RR interval dispersion poincare. (fig.6-45)



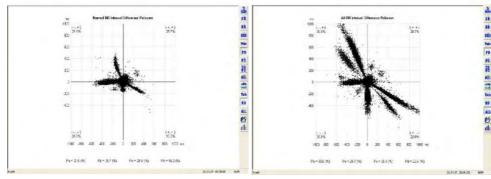
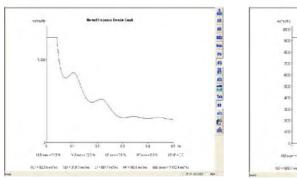


fig. 6-44 fig. 6-45

Click button to display sinus mode pulsation spectrum graph (fig.6-46).

Click button to display the whole pulsation spectrum graph (fig.6-47).



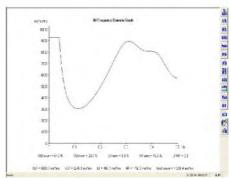
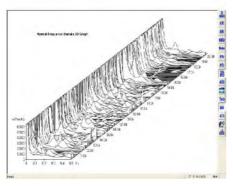


fig. 6-46 fig. 6-47

Click button to display 3D sinus mode pulsation spectrum graph (fig.6-48).

Click button to display the whole pulsation spectrum graph(fig.6-49).





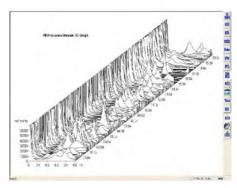
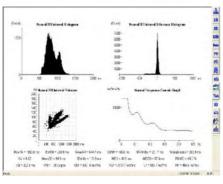


fig. 6-48

fig. 6-49

Click button to display all process analysis compositive graph (fig.6-50)

Click button to display the whole pulsation analysis compositive graph (fig.6-51)



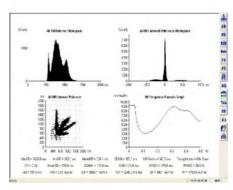


fig. 6-50

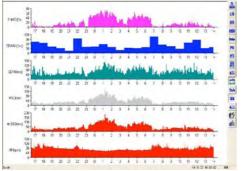
fig. 6-51

Click button to display all process heart rate aberrance trend graph (fig.6-52).

Click button to display heart rate aberrance trend graph of the whole pulsation (fig.6-53).

13





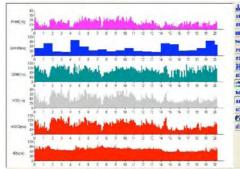


fig. 6-52

fig. 6-53





to display the whole heart rate variability data table (fig.6-54)





to display the heart rate variability data table of of the whole pulsation (fig.6-55)

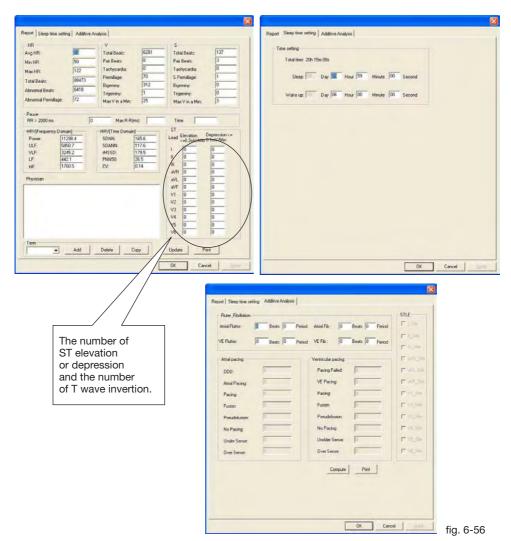
								Chef							
Hant	MaxPR	M-407	Medi PD MK	4 03 m	H7Mates PG	CA	VSD WK	MSSD ms	FNV&3	VU m	Teyre	U.F	VLF res'res	LF msters	HF HS'HS
2369 DD:00	1433	262	774	119.4	252.0	3.14	36	64	72.0	133	122	1886.5	2695 5	5435	5010
CD 69	1310	305	728	110.7	180.6	3.11	33	77	11.1	129	1.19	2174.4	2239.1	£122	7926
D1 59	1400	665	683	1302	10E1	2.11	0	128	*E6	119	183	3348	13/46	142:3	2021.8
(2.9) (3.9)	1500	310	525	1235	1929	2.13	-63	100	42	123	163	293 T	3575.0	127.2	NE:
CB 59 C4 59	1500	300	tti	(4:7	1073	3.12	30	0	1211	129	154	42X.1	3254.2	C20:5	600.2
CE 69	1300	300	703	126.0	1546	3.14	0	113	21.0	D	154	1377.0	2530 8	1050.3	122,6
(5.59 (5.59	1266	626	762	1129	166.9	113	62	121	20.7	105	152	43) 0	1006	8012	772.0
05:59 07:59	1153	397	677	165	161	3.11	18	78	7.1	¥	100	7104	12594	4335	5497
07.69	1115	55	730	91.0	183	3.12	\$	90	5.8	9)	1.77	2V 3	11:53	E338	8755
CD (0	1225	400	RIS	12:2	167	3:15	62	tis	22.3	118	2.6	363.5	1772 ±	1400.3	'52E.)
1019	1335	305	790	1240	176.2	3:11	66	138	19.7	128	1.52	790 0	29:3 /	1163.8	1/75.9
1059	1968	90	623	11:3	136.9	212	36	16	3.1	110	134	40.1	16/10	893	SHE
11 59 12 59	1275	50	806	(189	125.0	313	15	95	26	109	1.50	200 B	9532 E	1673	:des
1269	1425	660	114	00.0	12121	3.11	30	70	*12	105	123	202.3	1523 8	6400	7131
1359	100	417	001	1117	1347	3.70	×	69	27	160	nes	-244	Mine	1 101 E	-sec a

toy:	Model	EWEN.	Marks	THE	PET-SEASON PRIS	24	MSD	MED	POLE	(A.	Degree	ULF (b) In	10,000 A3	ar mains	115.03
23 59 00 99	1400	230	70	100.7	2073	6.96	×	163	733	145	257	1371.3	290.1	430.0	100.5
01 69	120	106	728	116.4	323	0.12	Z	153	20.1	131	25	1393.2	1207.1	300.5	12% 2
01 59 02 69	1100	136	X1	157.5	1263	C.18	154	363	350	120	606	22t7	7716	3662	3057
02:59 02:59	1600	110	301	1512	(353)	CTF	136	-39	29.9	136	400	2975	gai	166.6	333.4
03.59	168	530	7,9	140.1	236.7	Li	a	162	25	176	264	18627	236.4	200.1	1661
04-99	1330	330	192	147.6	254.2	6.38	16	235	21.3	137	64	783	1555.2	4:53	2830
05 59 06 59	126	40	76	120.5	173.5	E36	15	194	35.5	136	436	770.0	9840	361	1621.5
06.99 07.09	11 W	500	226	97	1989	ć13	76	143	75.9	30	354	SEE	9622	232.9	MEX
9 59 18 59	116	35	he	128.7	141.3	(1)	12	103	333	00	434	1254	6239	203.5	100.1
08 99 09 99	1225	400	ME	140.1	130.9	C.10	152	232	11.9	116	5.50	ixe	953.1	421.2	29(3.7
09-99 0-99	1325	26	75	129.7	1343	C.10	130	223	33.0	×	400	ız:	1701.6	299.0	2971
1.59	13%	28	XI	116.6	163	C.11	x	th	22.5	115	207	301.0	10048	3027	1216
199	12%	330	N7	281	147,4	11.3	×	103	27.5	15	34	1907	11100	4013	ciesc
299 389	1136	110	X1	136.6	130.4	C.12	×	147	23.2	130	2.0	262	1600.0	HC0.1	1312.1
3.59	100	THE	3%	18/1	18.3	rie.	71	16.	186	188	362	MALE E	236.4	M12	268.0

fig. 6-54 fig. 6-55



Click button to display the case report, sleeping time and additional analysis. (fig.6-56)





### Attention:

If it is pacing case, the main analysis result is in the additional analysis. Attention: If the report stat. data is not match before, the reason may be that your report have not updated the latest modification result, you need click" calculation", then click" OK"



# Attention:

The data about sleeping time must be filled in according to fact.

Click button to display the print graph. The physician could choose what kind graph to print. (fig.6-57)

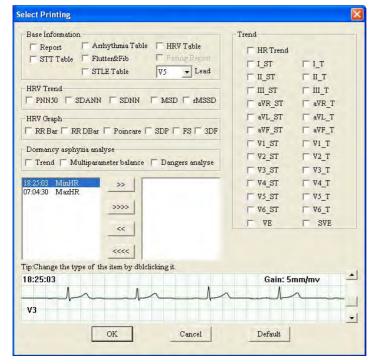


fig. 6-57

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.

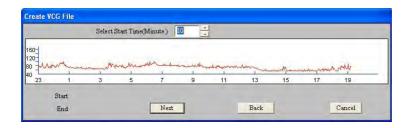
Click button to remove the single time in the right frame into the left and cancel the print.

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

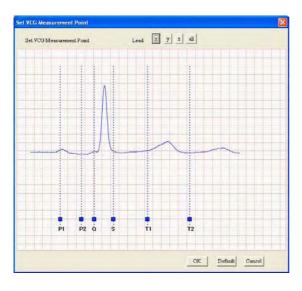
Choosing button and enter the vector cardiogram module.



Click button and the screen will appear t 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 yellow 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.6-58.



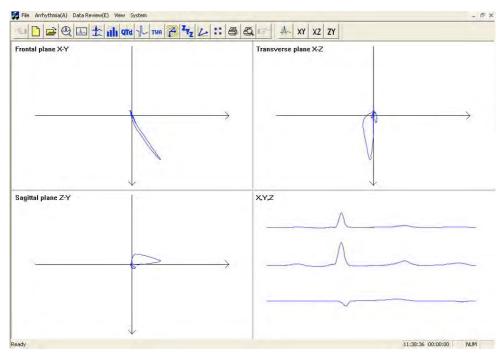


fig. 6-58

Click X-Y button and enter X-Y amplified graph. (fig.6-59)

Click X-Z button and enter X-Z amplified graph. (fig.6-59)

Click Z-Y button and enter Z-Y amplified graph (fig.6-59)

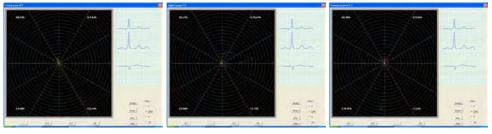


fig. 6-59



button and enter VLP analytical module. (fig.6-60)



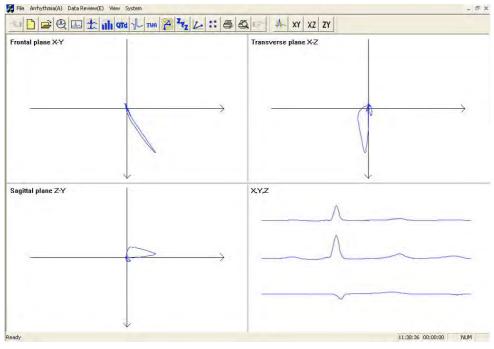
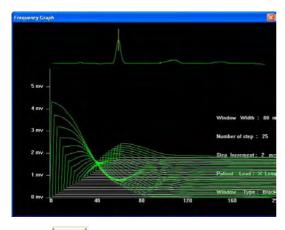


fig. 6-60

Click button to display ST segment spectrum graph after ECG superposition.



The yellow line in the picture is the end position of the QRS wave, you can use Page Up, Page Down to adjust by hand.

Click

button means the current wave can be chosen.



Click button means the current wave can't be chosen.

Click | ST | button can cancel all the waves, and adjust chosen

standard by hand.

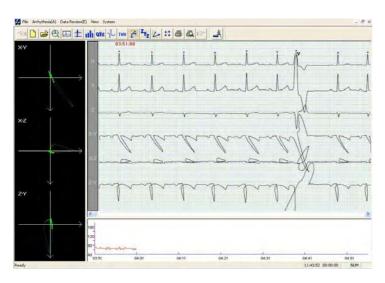
"move a waveform backwards", "page up ","page down".

Click button means the lowest and the highest waveform of heart rate.

Click button, display the statistic result.

Click button and enter TVCG analysis module.

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



Click



button and enter the parameter definition operation. As fig.6-61.



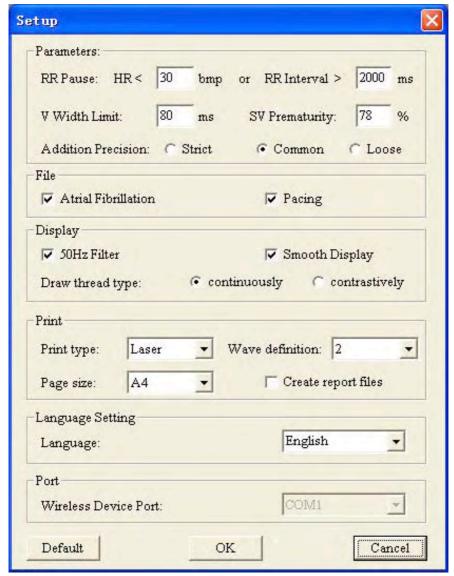


fig. 6-61

RR Pause: A standard of judging long interval module;

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

**SV Prematurity:** A parameter of judging V or S;

Addition Precision: The precision of atrial fibrillation analyse;



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

Pacing: The report of pacing analyse could be saved when this item

has been set;

50Hz Filter: Using 50Hz Filter;

Smooth Display: Using Smooth Display;

**Draw thread type:** Select a type for drawing threads; **Print type:** Select a type for printing ECG waves;

Wave definition: Select a definition for printing ECG waves;

Page size: Select a size for printing;

Create report files: Create an electronic report after print;

Language: Select a language for software. If the language has been chan-

ged, you should re-start the software.

Wireless Device Port: Select a wireless device port;

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

If the physician wants to analyze the case again, he can open the following dialog box as fig.6-62.

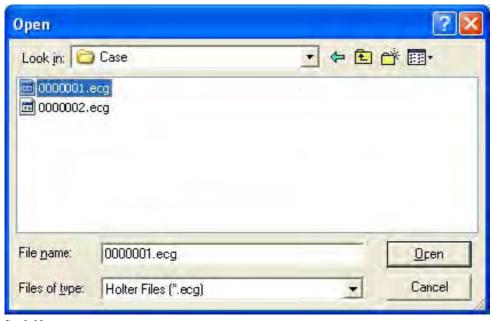


fig. 6-62



Open the "Maintain" item in the "File", the physician can operate the case by "delete", "open", "modify" and so on. Double click the item to open

the case. Select the item which to be deleted, click to delete the case.



Click the head of table, then the information of this list will be arranged again.



to display the information in turn. Select item and click



to modify the information. The item which has an icon indicates that this item has case, contrarily, has no case.

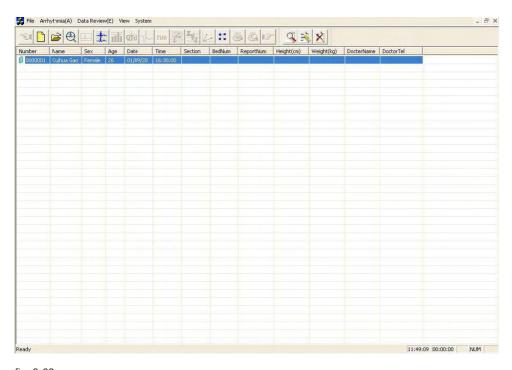


fig. 6-63



## Pacing analysis

When the data contain pacing signal, the system can identify it automatically and add the pacing analytical function. As fig.6-64.

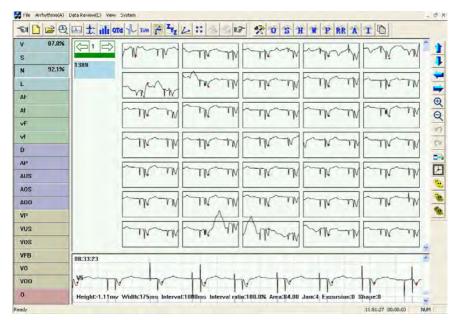


fig. 6-64

There are 11 button. Every button represents a module. The letter in the button means the name of the kind. (For example, D means dual chamber pacing). The percentage in the button means what percentage the wave is in the amount.

D: dual chamber pacing

AP: atrial pacing

AUS: atrial less sense

AOS: atrial over sense

AOO: atrial no pacing VP: ventricle pacing

VUS: ventricle less sense

VOS: ventricle over sense

VFB: ventricular fusion beat

VO: ventricle pseudofusion

VOO: ventricle no pacing

Enter the order replay, click the button and appear the "Data Table" dialog box which added the "Pacing Analysis Data Table" as fig.6-65.

All kinds of data Start. can be gotten from it.



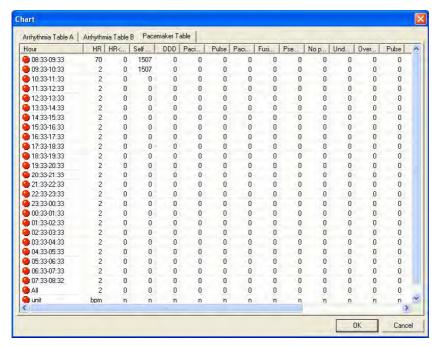


fig. 6-65

# Sleep breath pause syndrome analysis

First, make sure that the time when the patient begins to use recorder is correct, as fig.6-66.

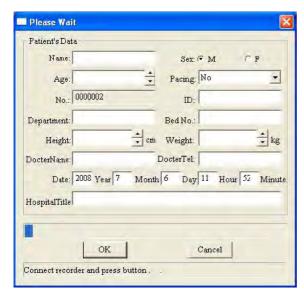


fig. 6-66



In case report please fill the correct sleep time and wake time about sleeping time segment as fig.6-67

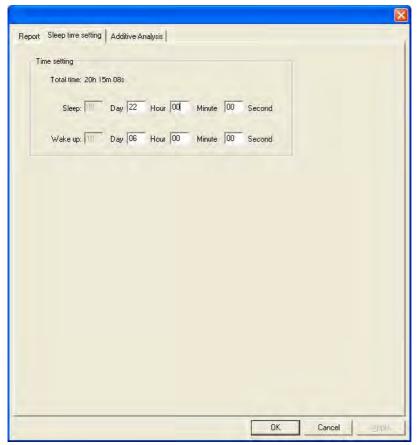


fig. 6-67

Last, in printing function dialog box please choose "trend graph", "multi-parameter contrast", "danger analysis" about the option of sleep asphyxia analysis graph, as fig.6-68.



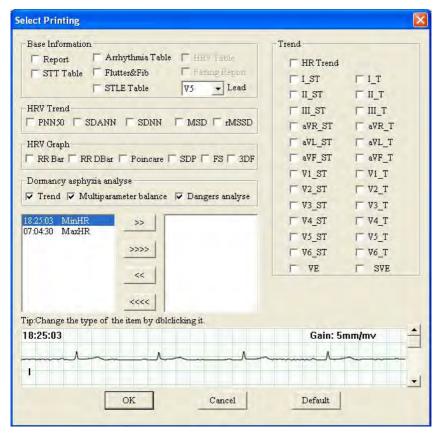


fig. 6-68

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



Notes	



Votes	



Notes	
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**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. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.

### **GIMA WARRANTY CONDITIONS**

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production. The warranty is valid for 12 months from the date of supply of GIMA. During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel traveling expenses and packaging not included. All components subject to wear are not included in the warranty. The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devicesor software due to outside agents such as: voltage changes, electro-magnetic elds, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.

The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.