Operation Manual

Cardio SW-Holter

Version:1.0

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Notes on Reading

To operate the software safely and make complete usage of the functions, please read this instruction manual carefully before use.

We recommend keeping this manual in an appropriate location in order to refer when required during operation.

This operation manual is subject to change without prior notice.

This operation manual is a general-purpose manual for Cardio SW-Holter, the analysis software for Holter System: Cardio SW-Holter Not all the parts and functions involved in this operation manual are standard configurations, and some may require the support of the relevant equipment and software. Please read the list of the accessories attached to the device, and if there are any questions, please contact the dealer.

Warranty

MC Digital Solutions Inc. (hereinafter referred to as “MC” or “the company”) provides warranty for one (1) year or the period specified in the contract for any product defect arising from the quality of materials and workmanship.

Consumables are not covered by the warranty, which include but not limited to leads, batteries, electrodes, etc.

Damage arising from unauthorized disassembly or repair by the user, or any damage arising from negligence, accident, fire, flood, lightning stroke, misuse or even intentional act, as well as any of products without the original identification label shall not be covered by the warranty and the company shall not bear any warranty responsibility.

The company does not accept any warranty claim in any other form, including for any commercial or other applicable purpose. The company does not accept any liability for any loss arising from other special, indirect, inevitable, accidental, or damage of punitive nature.

Any expense for product repair beyond the warranty will be borne by the user.

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Safety Information

Applications

- The software for MC Cardio SW-Holter (hereinafter referred to as Cardio SW-Holter) is intended to be used only by trained operators;
- Cardio SW-Holter is intended to be used in hospitals but can also be used in clinics, physicians research centers, outreach centers or anywhere Holter examination is performed;
- Cardio SW-Holter provides users with an explanation in terms of morphology, rhythm and conduction rather than a diagnostic point of view, and the physician is advised to arrive at his / her own point of view based on such an explanation;
- Cardio SW-Holter is not intended for family use;
- Cardio SW-Holter is not intended to be used as a heart-implantable device;
- Cardio SW-Holter is to be applied clinically to:
  - ✧ assess the condition of arrhythmias and myocardial ischemia for patients;
  - ✧ assess patients' ST-segment changes;
  - ✧ assess patient’s reaction to anti-arrhythmic drugs;
  - ✧ assessthe condition of patients implanted with a pacemaker.

Warning Marks

Warning marks used in this manual include:

Warning: to alert the user that using the device in such a way or incorrect operations may result in death or serious injury.

Note: to alert the user that using the device in such a way or incorrect operations may lead to personal injury or other problems with devices, such as abnormal functioning, operational failures, device damage, or resulting in losses of other facilities and properties.

Tips: *to provide additional or specific information on advice, conditions and alternatives methods.*

Device symbols

Symbol	Description
	Indication of a requirement that the operation manual need to be consulted.
	CF type device
	Product serial number

1 About this manual

Purpose of this manual

This manual is mainly intended to introduce the functions and operations of "Cardio SW-Holter".

Scope **of application**

This manual is applicable for clinical professionals and other authorized users.

Abbreviations

In this manual:

- "Ambulatory ECG" is referred to as "Holter" for short.
- Computers that operate "Cardio SW-Holter" is called "analysis host".
- "MC Cardio SW-Holter" is referred to as "Cardio SW-Holter" for short.
- Ambulatory ECG recorder is referred to as "Holter recorder" or "recorder" for short.

Legends and names

All legends used in this manual are for illustrative purpose.

All names given in examples and legends in this manual are fictitious, any similarities are purely coincidence.

Version history

In the bottom of every page of this manual, there is the document version number. The version number is changed with the update of the document.

Version	Date	Remarks
A	May 12, 2014	The first version of this document

2 Foreword

General

Cardio SW-Holter scans and analyzes patient's recorded heart beats and provides an analysis report as a reference to the physician in a clinical diagnosis.

Cardio SW-Holter has the following functions:

- ✧ Patient file database management and rapid search by category selection.
- ✧ ECG data playback and auto analysis
- ✧ Detection of arrhythmias, such as ventricular and supraventricular types.
- ✧ Template editing, allowing for one-on-one verification and editing of heart beat morphology.
- ✧ Various histogram tools
- ✧ Several atrial fibrillation/atrial flutter analysis tools such as R-R interval dispersion chart, waterfall chart, and R-Rinterval trends..
- ✧ Saving and printing electrocardiogram episodes.
- ✧ Cardiac rhythm analysis and evaluation for patient implanted with a pacemaker
- ✧ ST and QT analysis
- ✧ Heart rate variability analysis
- ✧ Heart rate turbulence (HRT) analysis
- ✧ OSA analysis

Types of recorder

Cardio SW-Holter supports any of 12-lead and 3-channel recorders.

Preliminary checks:

Before using the Cardio SW-Holter, please check the date and ensure that the PC date is the current date.
Before using the Cardio SW-Holter, the encryption key must be inserted into the USB port of the analysis host.

Make sure that the USB port is configured correctly and that the key is illuminated.

Try different USB ports if the key is not being recognized by the software.

Main function interfaces

Following is the commonly used function interfaces:

Screen	Explanation
First interface	This interface appears as the Cardio SW-Holter is being initiated, and in this interface, all function designations are provided. Refer to **P4 and P15～P25**.
Patient data register interface	This provides for a new patient, and following the entry, an auto analysis for the patient will becommenced. Refer to **P7**.
Parameter setting interface	For setting the analysis parameters prior to auto analysis of the patient data. Refer to **P9 and P26～P40**.
Edit analysis interface	For editing, analyzing and reporting the analysis results after the auto analysis of the patient. Refer to **P41～P116**.
Report preview/print interface	This is the preview and print window for the patient report. Refer to **P117**.

Note: Before using the device, the operator should be familiar with the clinical operational procedures of Holter analysis/recording.

Note: Analysis results provided by Cardio SW-Holter are only for the physician's reference during clinical diagnosis and treatment, and it shall be the physician's responsibility to make a specific diagnostic conclusion and to propose a required treatment.

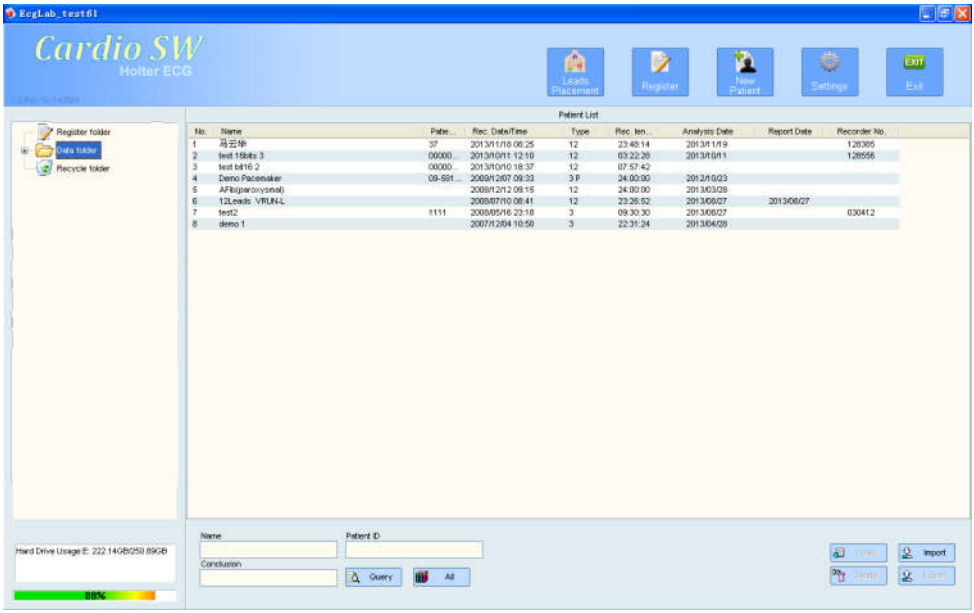
3 Start

This chapter describes how to perform a patient analysis.

- ✧ The processes for downloading data from a recorder and subsuquent analysis will be described in detail.
- ✧ For archived patients, please refer to the section "Accessing archived patients" on **P15**.

Step 1: Entering into the program - First interface

Double-click the "Cardio SW-Holter" icon on the desktop or use the program menu. The program starts to operateand enters into the first interface of Cardio SW-Holter.



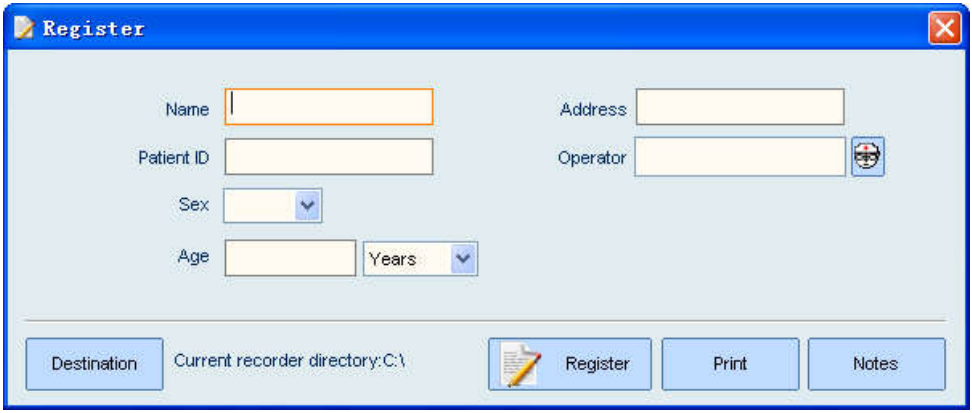
For detailed description of functions and operations of the first interface, please refer to the section "Accessing archived patients" on **P15**.

Note: If the progress bar indicating the usable space of hard drive has entered into the red zone, prepare a backup and secure the patient file appropriately.

Step 2: Registering patient data

Using the following steps to register the patient data into the recorder or the flash card：

1. Connect the recorder or insert the flash card.
2. Click the “Register” button, and the register window for patient data to the card will shown:



3. Enter the basic data of the patient, including:
   a) Name
   b) Patient ID number
4. Click “Destination” to choose the directory to which registration data is to be entered. The directory where the recorder or the flash card is located is advisable.
5. Click the "**Print**" button to print the “Ambulatory ECG activity record card”.
6. Click the “**Notes**" button to enter the “Notepad” tool of the operating system, where you can edit and modify the notes in the “Ambulatory ECG activity record card”.
7. Click the "**Register**" button.
8. If the registration record of the patient already exists, the following warning will be displayed: "**The**

patient was registered on yyyy-mm-dd! Do you want to overwrite the previous registration record? Yes or No?". If '**Yes**' selected, Cardio SW-Holter will use the current patient data to overwrite the previous registration record, and if '**No**' selected, directly exit the register window.

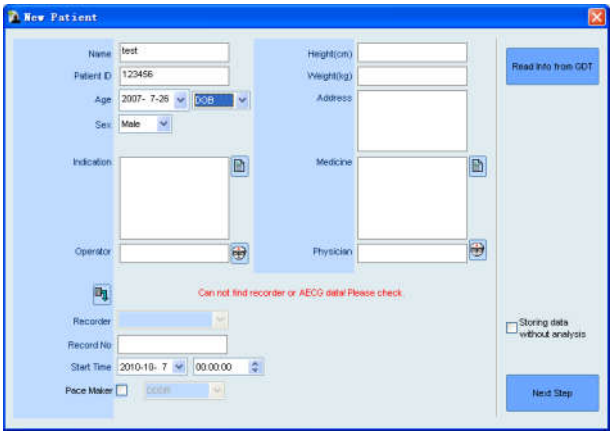
9. If the register is successful, a note of "**Register successfully**" will be displayed, and one registration record of the patient is added to the "**Patient registration" box**.
10. If the recorder has been connected or the flash card has been inserted into the card reader, the registration information of the patient will be written directly into the recorder or the flash card.

Note: The directory where the recorder or the flash card is located is automatically assigned by the operating system, and normally the directory is designated "Movable disk X: "

Step 3: Start a new patient

When a recording is completed, use the following steps to create a new patient and download the ECG data:

1. Connect the recorder with the optional USB cable, or insert the flash card recorded with the ECG data into the card reader.
2. Click the "New Patient" button to display the patient card window:



3. If the recorder (or flash card) is detected, the following message will shown:
   "The ECG data are found in the following directory: X:\" or
   "The ECG data for multiple days are found in the following directory: X:\"
   Where, X is the drive letter automatically assigned by the operating system to the recorder or the flash card.
4. If no recorder (or flash card) is detected, the following message will be shown:
   "ECG data cannot be found! Please check"
   Re-connect the recorder or re-insert the flash card, and then click the  button to detect again.

5. If the patient data has been registered in the connected recorder or flash card, the information of the patient will be automatically read and entered into the entry box.
6. Enter/modify the patient data, the necessary data including:
   a) Name
   b) Patient number
   c) Start date and start time

   The other additional data is optional, and can be modified during post editing.
7. If "Storing data without analysis" is enabled, the patient will not be analyzed after connection,
8. Click the next step.

   Cardio SW-Holter will use the patient data above to create the patient file, and start to transfer the data in the recorder or the flash card into the patient file, the data transferred including: ECG data, pacemaker pulse record, and patient event record.
9. After the transfer , the analysis of the ECG data begins.

Warning: When the free hard disk space in the application zone becomes insufficient, "New Patient" will not proceed. Make a backup and then continue with the operation.

Note: Normally the recorder type and start date / time will be automatically acquired from the recorded data. But for some recorder types, the start date / time will be required to enter manually.

Note: If the message of "ECG data cannot be found! Please check" is displayed, ensure connect the recorder or insert the flash card, and then click the button to detect again and acquire start date / time. Otherwise the time must be manually entered.

Note: If no data is detected, entering the next step will not be allowed.

Note: If the data is of multiple day recording, archives will be created for every 24 hour period.

Step 4: Data download and analysis

Cardio SW-Holter downloads the ECG data from the recorder or the flash card and automatically performs analysis. The process is as follows:

1. The ECG data is transferred from the flash card, and if the data is of multiple days, multiple archives with the same name but different starting time will be created automatically for every 24 hours after reading, and then the analysis of the data for the first 24 hours starts automatically.
2. Pre-analysis (also called “self-study”)
   The ECG data for the first 30 minutes is analyzed, and the features of the current ECG are acquired. After the pre-analysis, the process goes into the “Set ST” interface.

3. In this interface, the operator can browse 24 hour ECG, and set the ST and arrhythmia analysis

parameters based on the pre-analysis results.

Description of the interface:

✧ Zone 1: ST setting zone

The operator can check or set the ST measurement point location for each channel. Typically, 3 measurement points may be set for ST measurement: the reference point (also called the equipotential point), the J point and the ST measurement point. The reference point value, as the reference potential, is used to calculate the absolute value of the J point and the ST point; the J point is used to measure the value of the J point and the slope of the ST segment; and the ST point is typically used to measure the ST level.

The ST channel list is used to configure each channel to enable/disable ST analysis as determined by the operator.

The position of the measurement point can be adjusted by pressing the left mouse button and moving the mouse.

Move the cursor to the measurement point to be adjusted. The measurement point can be switched by double-clicking the left mouse button.

The arrow keys on the keyboard can also be used to move the current measurement points; and the “Tab” key can be used to switch the measurement points.

✧ Zone 2: the zone for setting key analysis

parameters .

Include:

■ **Primary analysis channel**

Setting the primary analysis channel.

Since the primary analysis channel will have significant influence on the automatic analysis results, select an ECG channel with better waveform and better specificity in the recording as the primary analysis channel.

■ **Secondary analysis channel**

Setting the secondary analysis channel.

The secondary analysis channel(s) can improve the analysis accuracy, and in patient where no analysis on the primary analysis channel can be performed due to for example, electrode detachment, effective supplementation the primary channel is available

It is recommended to select 1 ~ 2 secondary analysis channels.

Selecting further secondary analysis channels will not necessarily result in more accurate analysis, and occasionally additionalartifacts may be detected. More secondary analysis channels selected, the longer the analysis time.

■ **Pacemaker analysis parameters**

Such parameters used to enable the pacemaker analysis are set as follows:

Pacemaker pulse filtering: This parameter is used to filter out the disturbing(higher voltage)signals caused by the pacing pulse in the ECG, to remove the associated interference of pacemaker pulse with the detection of QRS complex.

Pacemaker type: This parameter is used to set the pacemaker type. If the pacemaker type cannot be identified, the type should be set to DDD or DDDR.

- **Artifact rejection switch**

When the "Artifacts rejection" is enabled, Cardio SW-Holter will automatically detect and remove the artifact that is not involved in the arrhythmia analysis, the heart beat statistics, the heart rate calculation, etc..

Enabling "Artifact rejection" can effectively reduce the workload of subsequent editing caused by the artifact.

Note: Enabling "Artifact rejection" may possibly suppress a few valid QRSs', in this recording,they can be retrieved with the editing tool; and if necessary, analysis can be performed again with the artifacts rejection switch disabled.

- **Analysis gain adjustment**

Adjusting the ECG gain during analysis.

When the amplitude of the ECG is especially small, adjust this parameter to effectively improve the detection rate of the QRSs and reduce potential missing QRS detection.

The optional gains settings are: 1/2, 1 (default), 2 and 4.

✧ Zone 3: ECG edit window

This window is used to browse the whole ECG waveform recording, and review the QRS detection analysis effects.

The operator is not required to edit here.

✧ Zone 4: Toolbar

The following common tools are provided:

■ **Cancel and return**

Cancel analysis and return to the first interface.

After selecting, Cardio SW-Holter will display the message: "**Data has not been saved and can be lost! Are you sure to cancel and return?**". Click to confirm and return to the first interface.

Note: If it is a newly created patient file, before selecting "Cancel and return", confirm that the patient data has been stored. Otherwise the data will not be saved.

■ **Start analysis**

Click to start automatic analysis.

If pacemaker pulse data has been detected by Cardio SW-Holter while the pacemaker analysis is not enabled,, the following message will be displayed: "**Pacemaker analysis is disabled! Are you sure you want to continue?**". This is because the recorder maymistakenly detect

pacemaker pulse, when loose electrode connection or other disturbances exist. If so, please click the "Confirm" button to directly start analysis.

Note: Before clicking the "Start analysis", onfirm that the primary analysis channel, the secondary analysis channel, the pacemaker analysis switch and the arrhythmia analysis parameters have been correctly set.

■ **Analysis parameters**

These parameters are used to set more detailed arrhythmia analysis.

Click to enter into the parameter setting window, and for more detailed operations, refer to the section "Parameter setting" on P28.

■ **Startpoint of analysis**

Set the start position (time) for ECG analysis.

It is commonly used to remove any artifact in theECG that may have occurred in the initial placement of the electrode, in order to reduce the workload of editing.

■ **Endpoint of analysis**

Setting the ECG end position (time) for analysis.

It is commonly used to remove the artifactin the ECG due to incorrect termination of the recording, in order to reduce the workload of editing.

■ **Reset**

Delete the setting of the start and end points of the analysis, reset to the start and end points for the whole data recording.

✧ Zone 5: Status display for the start and end points of the analysis

Display the status information about the start and end points of the current ECG data analysis.

4. Automatic detection of QRS
5. Sorting out of QRS waveforms
6. Creating of QRS indexes
7. Analysis of abnormal cardiac rhythm
8. QT analysis
9. Analysis of heart rate variability
10. Saving of analysis results

The operation from step 4 to 10 is automatic, and may take some time, so please wait patiently.

Step 5: Editing and analysis

After scanning, the automatic analysis results will be saved, and then can be edited and analyzed to ensure the accuracy of the analysis results.

Cardio SW-Holter has a set of editing tools that faciliate the analysis results to be conveniently edited and modified. The analysis report will be automatically updated according to the edited and modified results.

For detailed operations, please refer to the section “Editing and analysis” on P41.

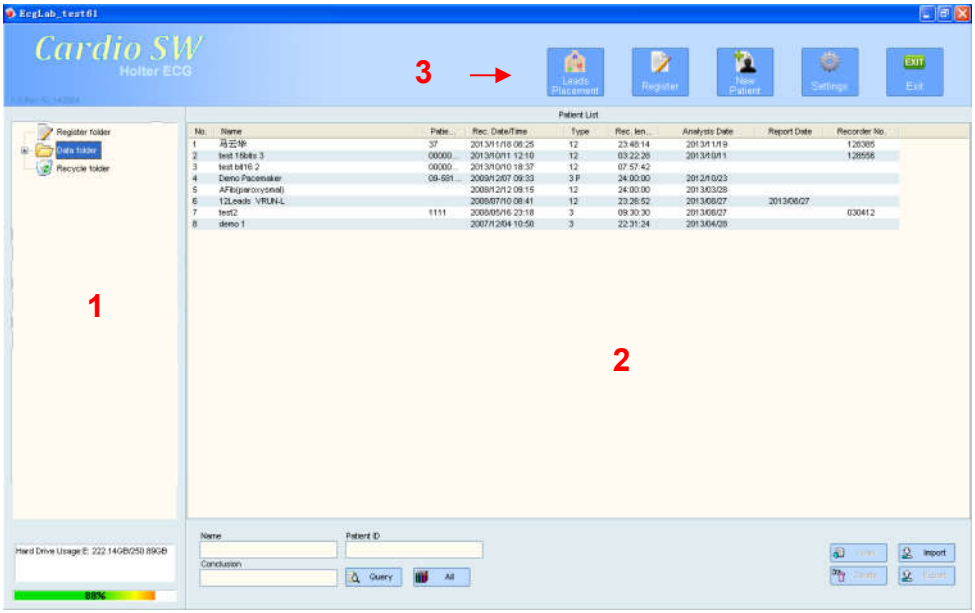
Step 6: Selecting, previewing and printing of report

On the report screen, the format of the printed report can be selected according to specific requirements,.Default options are also provided for the report processing.

After selecting the report format, the preview and printing can be initiated.For details, refer to the sections “Report” on P87 and “Preview/printing of report” on P117.

4 Accessing archived patients

The first interface of Cardio SW-Holter provides various functions，which can be used to process the patient files



In the first interface, the following operations can be performed for the patient files: query, sorting, import/export, retrieval and editing, and deleting.

A detailed description of functions and operations are as follows:

Functions of the first interface

✧ Zone 1: Data and the default folders include:

■ **Patient register box**

This folder contains the registration record for a patient to receive a Holter recording and diagnosis.

When Holter informationfor the patient in the "**Patient register box**" is completed, the corresponding record can be selected, and then a "New Patient" record can now be started by double-clicking the left mouse. button.

- **Work folder**

This folder contains the formal patient file record for Holter recording. A complete patient file normally includes: patient information, long-term ECG data, and analysis results.

Under the "Work folder" there are two types of sub-folders: one is " data folder", used to archive the patient file in the work folder; and the other one is " search folder", used for fast retrieval of the patient file in the current work folder and setting the retrieval conditions.

These two sub-folders are characterized as follows:

- Patient file records can be moved between the "Data folders".
- Each "Data folder" can have a plurality of "Search folders".
- The "Search folder" searches the patient file records only in the data folder with which it associates andnot the patient file records in anyother "Data folder".

- **Recycling bin**

This folder contains the patient file records deleted from the work folder. The patient file records in the recycling bin can be returned to the work folder.

If a patient file in the recycling bin is deleted, that patient file will be permanently deleted, and cannot be restored.

✧ Zone 2: Patient list

This list includes the patient file records in the folder currently selected. Items displayed for each patient file record include:

- Name
- Patient ID number
- Recording date/time
- Type, possible types include: '3' – 3-channel patient data, '12' – 12-lead patient data, '3P' – 3-channel pacemaker patient, and '12P' – 12-lead pacemaker patient.
- Recording length
- Analysis date/time, and the date/time for the last analysis
- Report date, the preview or print date of the last report
- Recorder Serial number
- Name and directory of the archived file

The width of every column in the list can be adjusted, and the layout after adjustment will be automatically

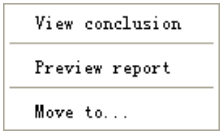
memorized as the layout displayed at a later time.

Click an option in the header of the list to sort the records. If “Type” is clicked, the patient records in the list can be sorted by “Type”.

The patient list supports leaving the operation menu by clicking the right mouse button, the menu includes:

- Conclusion review

  For a fast review of the patient conclusion.



- Report preview

  It appears only when the report file for the patient has been created.

- Move to...

  This function can move the selected patient to another data folder which includes the recycling bin.

To enter the patient in the check box, use the mouse to select the patient to be entered while pressing the “Shift” key or “Ctrl” key.

✧ Zone 3:
The following functions are provided:

- **New patient**

  To start creating a patient file, download ECG data from the recorder (or the flash card of the card reader).

The new patient datawill directly enter the work folder.

The new patient data can now be used to make an arrhythmia analysis and its report.

For a new patient operation, refer to the section "Starting a new patient" on P7.

- **Register**

This function is used to register information about a patient who requires a Holter scan. The patient information registered becomes a registration record to be saved in the "Patient register box".When the ECG monitoring is completed, it is used to create a new patient file.

If a recorder or flash card is connected, the register function can write the patient information into the recorder or the flash card.

For more detailed register operations, please refer to the section "Register patient data" on P5.

- **Setting**

Setting the system parameters, including the uniform arrhythmia analysis parameter, the language type, the hospital information (name and address), etc.

For more detailed operation of the setting function, please refer to the section "Parameter setting" on P26.

- **Leads layout**

Used to illustrate the 3 most common layouts of

electrode placement, and are used for reference only.

- **Exit**

  Exiting the Cardio SW-Holter.

✧ Zone 4: Status of used memory storage space
This zone covers the progress bar and the text information of the used memory storage space.

✧ Zone 5: Query function
This function uses the patient name and patient ID to place the patient in the current patient list.

✧ Zone 6: Other functions
Other functions include:

- **Retrieving patients**

  Using this function, you can retrieve the selected individual patientand load them into the edit analysis interface.

  You can also use the left mouse button to double-click the patient to retrieve the patient for edit and analysis.

- **Deleting patients**

  Using this function, selected patientscan be deleted(multiple patients can be checked), and the deleted patients can be found in the “Recycling bin ” and restored.

- **Importing patients**

  Use this function to import patient files from a storage device (such as movable hard disk, CD,

USB disk, etc.).

It can also be used to import patient files from other hospitals or previously backed-up patient files.

Patient files from other hospitals or any previously backed-up patient files cannot be analyzed and edited in this system until entered through the "Import patient" function.

■ **Exporting patients**

Using this function, he selected patient may be exported to storage devices, such as hard disk, U disk, movable hard disk, etc.

This function also provides for patient backup, academic exchange, etc.

Note: When the progress bar indicating the used space of the hard disk enters the red zone, make a backup file and process the patient files later.

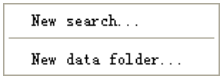
Note: Any of patient files in the recycling bin cannot be restored after being deleted.

Note: The electrode placement layout is for reference only. In actual cases, please follow physician's instructions and their specific requirements .

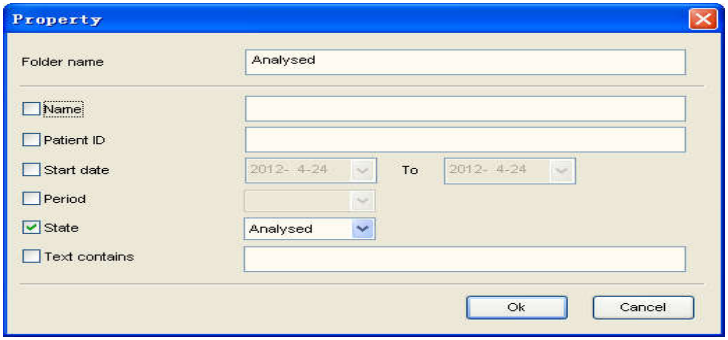
Creating search folder

"search folder" can be used to fast retrieve the case

file in the current work folder, and the retrieval conditions can be set.



Use the right mouse button to click any " data folder", and select the "New search folder" option in the pop-up menu. At this time the "Property" window of the new search folder will open:



Description of properties of the search folder:

- ✧ Folder name: This property is entered by the operator to display the name in the folder list. It is recommended to use a name relevant to retrieval conditions. The folder name is allowed to be duplicated.
- ✧ Patient name: This is one of the retrieval conditions. Cardio SW-Holter supports fuzzy retrieval. For instance, when "Zhang" is entered, all the patient files having names containing "Zhang" therein will be retrieved from the current data folder .
- ✧ Patient No.: This is one of retrieval conditions. In fuzzy retrieval, the search order is from left to right.
- ✧ Examination date: This is one of retrieval conditions, which is allowed to be selected only when the condition "Time period" has not been selected. The recording start date in the patient file is used as the

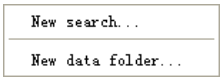
retrieval condition, and the range of the retrieval date can then be set.

- ✧ Time period: This is one of retrieval conditions, which is allowed to be selected only when the condition “Examination date” has not been selected. The recording start date in the patient file is used as the retrieval condition, and a plurality of fixed retrieval ranges can be chosen, such as: today, this week, month, year, past one week, past two weeks, past three weeks, past one month, past two months, past three months, past half a year and past one year.
- ✧ Status: This is one of retrieval conditions; and the options are: analyzed, unanalyzed, printed, and unprinted.
- ✧ Conclusion words: This is one of retrieval conditions, which supports fuzzy retrieval.

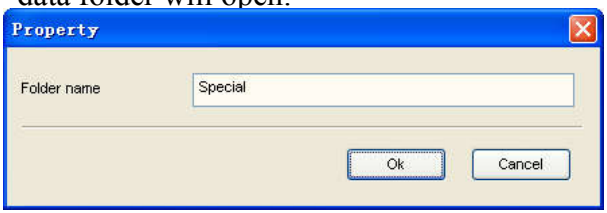
The retrieval conditions can be combined.
After clicking the "Confirm" button, the new search folder will appear under the selected data folder.

Creating data folder

“data folder” is used to sort and archive the patient file in the work folder to avoid too multiple patient files in the current work folder.



Use the right mouse button to click any “ data folder”, and choose “New data folder” in the options of the pop-up menu. At this time the “New” window of the data folder will open:



Description of properties of thedata folder:

✧ Folder name: This property is entered by the operator to display the namein the folder list. The folder name can be duplicated.

After clicking the “Confirm” button, the new data folder will appear under the “ work folder”.

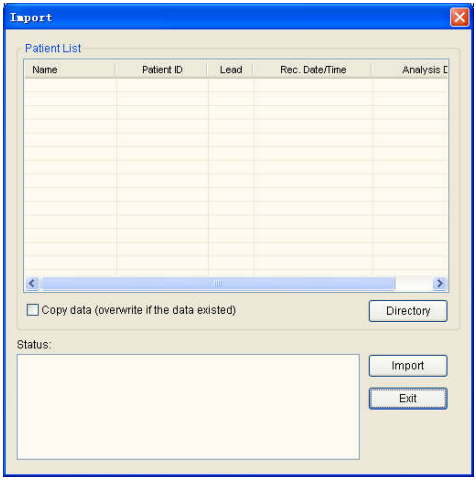
The patient files in other data folders can "Move to" the new data file.

In each data folder, respective search folders can be created.

Importing patient

The patient file previously backed-up and the patient file from other hospitals can be imported into the current patient database, and Cardio SW-Holter therefore can perform operation on these patient files, such as edit and analysis.

Click the "Importing patient” button in the lower right of the first interface to enter the “Importing patient” interface.



Description:

- ✧ “Selecting directory”: Select the directory towhich the patient is imported. “Copying data to work directory”: The setting is enabled by default. When it is enabled, the import program will first copy the patient file to the current data storage directory, and then register the copied patient file to the patient database. The original patient file will remain unchanged; and if it is not enabled, the original patient file will be registered to the database directly.

  If a patient is imported from the backup CD or movable disk, it enables the “Copy data to work directory”.
- ✧ “Status” list: This list shows the import progress log.
- ✧ “Import patient” button: Clicking this button pops up the select window of the data work folder:

Select one folder from the data folder list as the archived data folder for the imported patient.

Click the “New” button to create a new data folder.

Click the “OK” button to start the import operation.

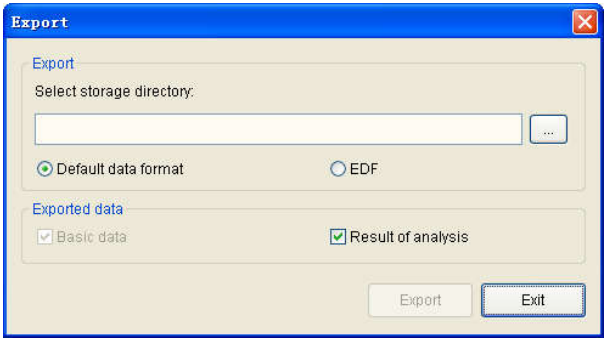
Click the “Cancel” button to cancel the import operation.

- ✧ “Return” button: This button is used to exit the import interface.

Exporting patient

Patients in the patient database can be exported to the other media, such as movable disk. . The exported patient data can be used for backups, academic exchanges, etc.

Click the “Export patient” button in the lower right of the first interface to enter the “Exporting patient” interface.



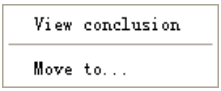
Description:

- ✧ “Select storage directory” is used for storing the exported patient, which can be stored in other directories of the movable storage device, hard disk, etc. The device having the storage directory must be re-writable.
- ✧ “Default data format”, it is used to export the system default formatted data.
- ✧ “EDF”, the abbreviation of Europe Data Format, is used for academic research. The data exported in this format includes only the basic information on the patient and the raw ECG data, the results of QRS detection and arrhythmia analysis are not included.
- ✧ “Basic data”, an options of the exporting operation and is always enabled.

- ✧ “Result of analysis” , an option of the exporting operation is enabled by default. When disabled, only the basic information on the patient, basic parameters and the raw ECG data is exported.The exported data is compatible with previous versions of software.
- ✧ “Export patient” button is used to initiate data exporting. When the export is complete, the “Export patient” window will be automatically disabled.
- ✧ “Exit” button is used to exit the “Export patient” window.

Recycling bin

The patients contained in the recycling bin are those deleted from the “Data folder” .



The patients in the recycling bin can be restored with “Move to...”.

The patients in the recycling bin can be retrieved for review, edited and deleted, .

After a patient is deleted in the data folder, it will enter into the recycling bin automatically, and it can then be restored again when needed.

The patients deleted in the recycling bin will not be restored.

Note: When deleting data in the recycling bin, ensure in advance that the data is to be deleted or has been backed up. Once the data is deleted, it cannot be restored.

5 Parameter setting

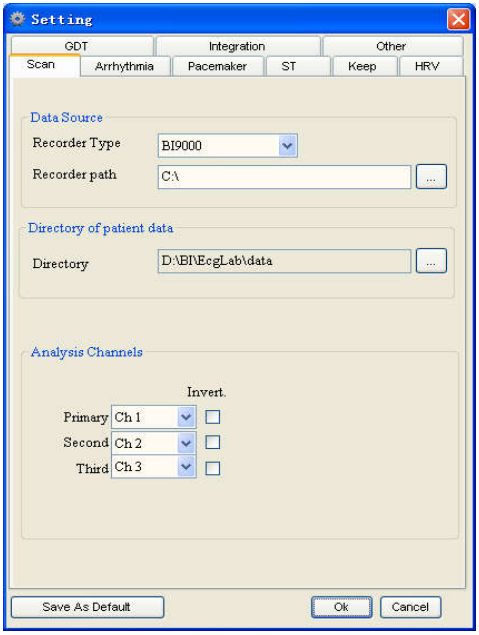
Entering the parameter setting interface:

- By clicking the “Setting” icon in the first interface,, refer to P4 and P15;
- By clicking the “Analysis parameter” icon in the pre-analysis interface,, refer to P9;
- By clicking the “Analysis parameter setting” in the patient data window for editing and analysis,;

The parameter setting window consists of a set of parameter pages. They are described individually as follows:

ECG data

Setting the location for saving ECG data source and patient data. During pre-analysis, this parameter page is not displayed.



The key parameters in this page are described as follows:

✧ Data source

- Recorder type: Set the default recorder type.
  Cardio SW-Holter automatically detects the recorder type.
- Driver: Set the default recorder directory.

  This parameter is primarily used in the "Register" function as the default directory for writing patient data.

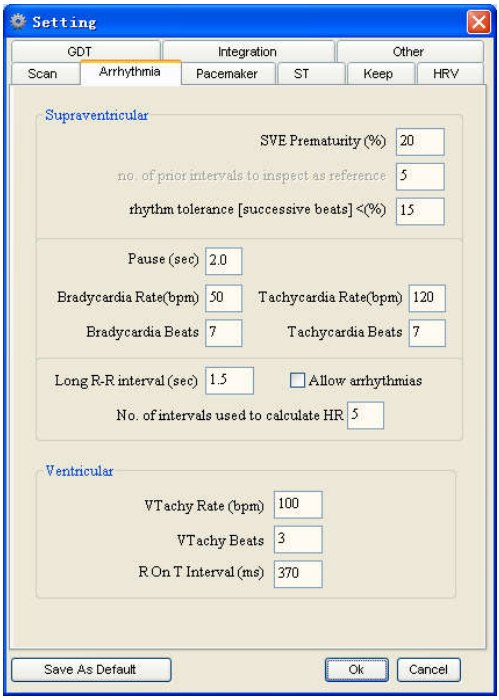
✧ Directory of patient data
This parameter sets the directory for storing the patient data file. It defaults as the data sub-directory under Cardio SW-Holter installation directory, for example: X:...\Cardio SW-Holter\data.

✧ Analysis channels
This parameter is used to set the default channel for the initial analysis. The setting of a 3-channel or 12-lead is automatically provided, depending on the recorder type.

Note:All of the analysis channels are not permitted to be NA (null).

Arrhythmia parameter

Setting the arrhythmia analysis parameters.



The key parameter instructions in this page are described as follows:

✧ Supraventricular rhythm parameter

- ■ "SVE Prematurity (%)": The range is 10~99, and the default value is 20.

  If the system defines too many heart beats as SVE, slightly increase the percentage. If no SVE can be found, slightly decrease the percentage. Inherent sinus arrhythmia may lead to the detection of false positive SVE . In this case, increasing the percentage gradually will achieve the desired result.
- ■ "Number of heart beats for calculating reference rhythm": The range is 1~16, and

the default value is 5.

- "In successive SVE, subsequent supraventricular premature RR interval change< (%)": The range is 1~99, and the default value is 15. This parameter is used to determine the successive SVEs beats.

✧ Arrhythmia

- "Bradycardia rate (bpm)": The input range is 20~120, and the default value is 50 bpm.
- "Number of Bradycardia beats": The input range is 1~16, and the default value is 7.
- "Pause (sec)": The input range is 0.5~10.0, and the default value is 2.0 seconds.
- "Tachycardia rate (bpm)": The input range is 50~250, and the default value is 120 bpm.
- "Number of Tachycardia beats": The input range is 1~16, and the default value is 7.
- "Long R-R interval (sec)": The input range is 0.5~10.0, and the default value is 1.5 sec.
- "Allow arrhythmias" switch: The default value is disabled. When enabled, the statistical calculation of pauses and long R-R interval events will allow for longer intervals of ventricular beats, supraventricular beats, etc.
- " Calculation of RR interval number": Used for calculating the number of beats for maximum heart rate and the minimum heart rate. The input range is 1~16, and the default value is 5.

✧ Ventricular rhythm parameters

- "VTachy rate (bpm)": The input range is

50~150, and the default value is 100 bpm.

- "Number of VTachy beats": The input range is 3~20, and the default value is 3.
- "R on T interval (ms)": The input range is 200~1000, and the default value is 370 ms.

✧ Heart rate

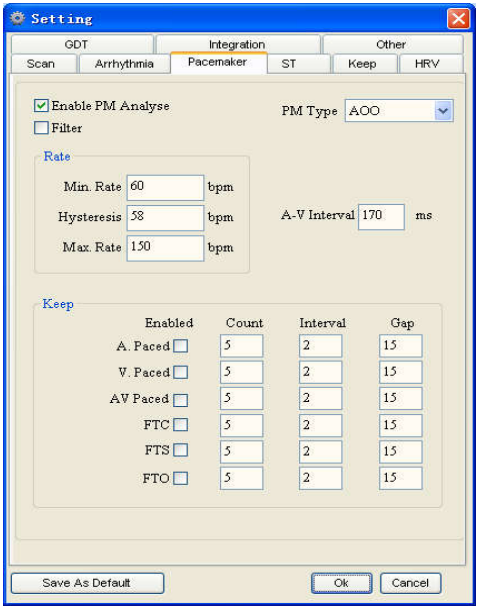
- The Holter algorithm calculates heart rate for a periodic zone (such as in a histogram) . The heart rate is the total number of valid R-R intervals divided by the total time span of the valid R-R intervals (ms), then multiplied by 60000. It is shown as beats/minute (BPM). The invalid R-R intervals (eg. those resulting from noise) are excluded.
- The number of RR intervals for calculating the maximum/minimum heart rate can be set.

✧ Pause

- "Pause" is defined as a fixed R-R interval that exceeds the criteria set for normal length (such as 2.5 seconds).
- If "Allow arrhythmia" switch is not enabled, the pause can only detect the N-N interval.

Pacemaker analysis

Setting the parameters for pacemaker analysis



The key parameters in this screen are described as follows:

- ✧ PM analysis

  This parameter is used for enabling or disabling the PM analysis and for analyzing smoothness and abnormal conditions of a pacemaker function.

- ✧ PM pulse filter

  This parameter is for enabling or disabling the filtering of PM pulses in the ECG data. When enabled, the effects of the PM pulse on ECG analysis can be significantly reduced.

- ✧ PM type

  This parameter is for setting the PM type, and

Cardio SW-Holter will use the type specified to analyze smoothness and abnormal conditions of pacemaker function.

✧ Rhythm setting

The parameters of pacemaker rhythm

The parameters include:

- Minimum rhythm: The input range is 30~150, and the default valueis 60 bpm.
- Hysteresis: The input range is 25~150, and the default valueis 58 bpm.
- Maximum rhythm: The input range is 50~250, and the default valueis 158 bpm.

✧ A-V interval

This parameter is applicable to the interval of the atrial and ventricular pacemaker pulse. The input range is 50~350 ms, and the default valueis 170 ms.

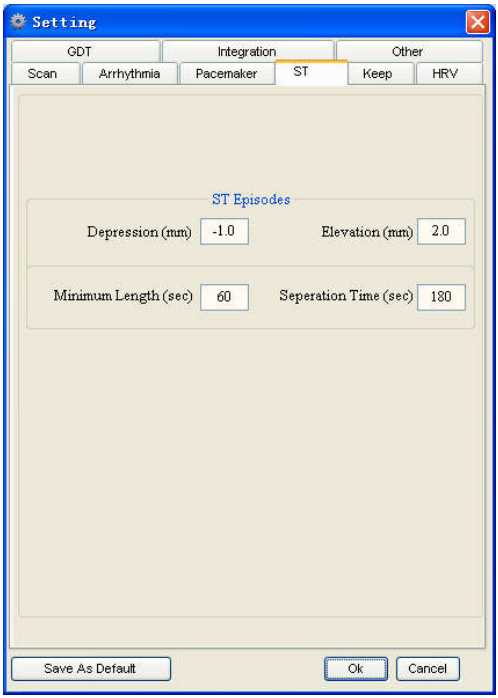
✧ Event retention

The settings for saving the pacemaker event episode.

- Keeping On/Off: Enable or disable the operation and indication of the event.
- Amount: The total number of the event episodes saved.
- Interval: For setting the minimum number of intervals of event episode, and the default value is 2.
- Gap: For setting the time span of the event episodes, and the default value is15 minutes.

ST analysis

Setting the criteria for determing the ST abnormal event.



The following describes how ST measurement operated by Cardio SW-Holter:

- Determine
- Detection and selection of the appropriate beats according that excludes: beats with noise, ventricular ectopy beats and “Special normal heart rate” (eg. pacemaker beats). Measuring and calculating ST value for each appropriate beat in each channel as follows: Calculates the ST value by averaging over the ST values of all the prior appropriate beats in a 6-second window.
- The ST value (average value) of every beat

in all channels will be determined.

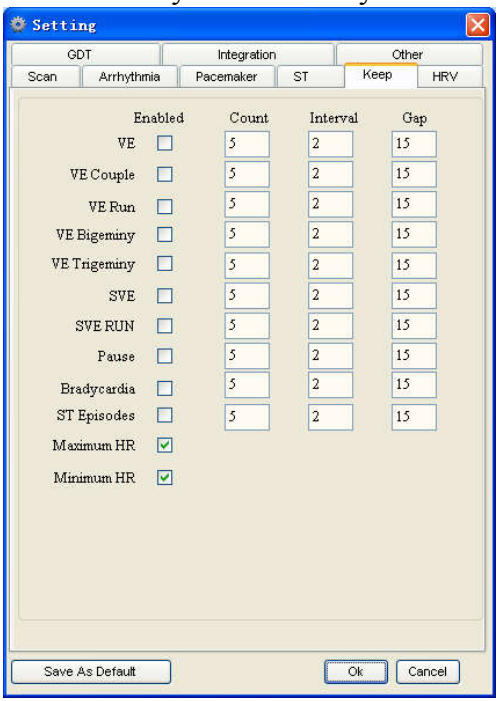
Note: ST measurements values are the absolute value. The measurement value of -1 mm means that the level value of ST is 1 mm lower than a predetermined isoelectric value.

The parameters in this screen are described as follows:

- ✧ Setting for ST abnormality
  - ■ ST abnormalities are always determined according to the ST level value.
  - ■ Depressed threshold: The range is -0.1~-100.0 mm, and the default valueis -1.0 mm (-0.1 mv).
  - ■ Elevated threshold: The range is 0.0~100.0 mm, and the default value is2.0 mm (0.2 mv).
  - ■ Minimum duration: The range is 30~120 seconds, and the default value is60 seconds.
  - ■ Interval between 2 successive ST abnormalities: The range is 0~300 seconds, and the default value is180 seconds.

Event retention

Setting the criteria for Cardio SW-Holter to automatically save the arrhythmia event episodes.



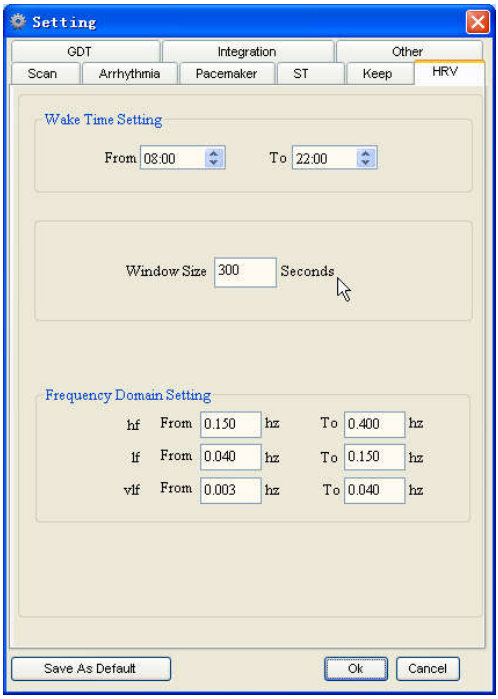
The criteria are described as follows:

- ✧ Option for retention or not.
- ✧ Amount: The total number of the event episodes saved.
- ✧ Interval: Set the minimum number of intervals between events, and the default value is 2.
- ✧ Gap: Set the time span between events, and the default value is 15 minutes.

For Maximum/Minimum heart rate, the default retention is enabled, and the other values are required to be checked..

Heart rate variability

Setting common parameters for analyzing the heart rate variability.



The parameters on this screen are described as follows:

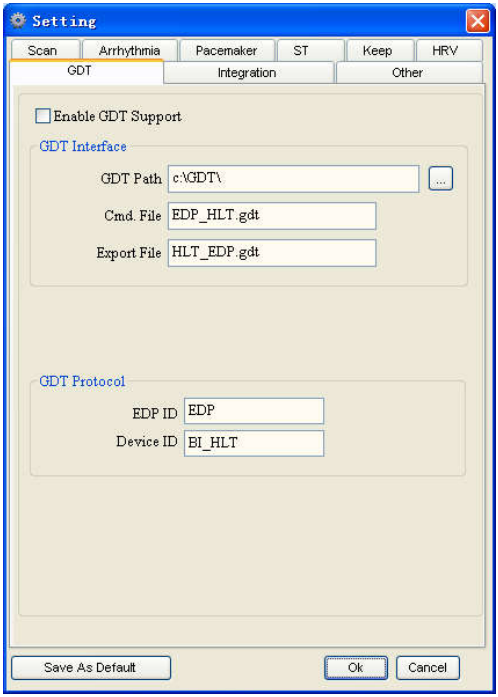
- ✧ Analysis interval: The range is 60~600 seconds, and the default value is300 seconds (5 minutes)
- ✧ Awake time setting : the default value is 08:00 ~ 22:00
- ✧ Frequency domain parameters
  - ■ High frequency (hf)：Default value is 0.15 ~ 0.40 Hz
  - ■ Low frequency (lf)：Default value is 0.04 ~ 0.15 Hz
  - ■ Ultra low frequency (vlf)：Default value is 0.003 ~ 0.04 Hz

- Input range: Lower limit of high frequency >/= Upper limit of low frequency; Lower limit of low frequency >/= Upper limit of ultra low frequency.

Note: It is not advisable to randomly adjust the parameters of the heart rate variability without specialized knowledge.

GDT setting

Setting the GDT interface and parameters.



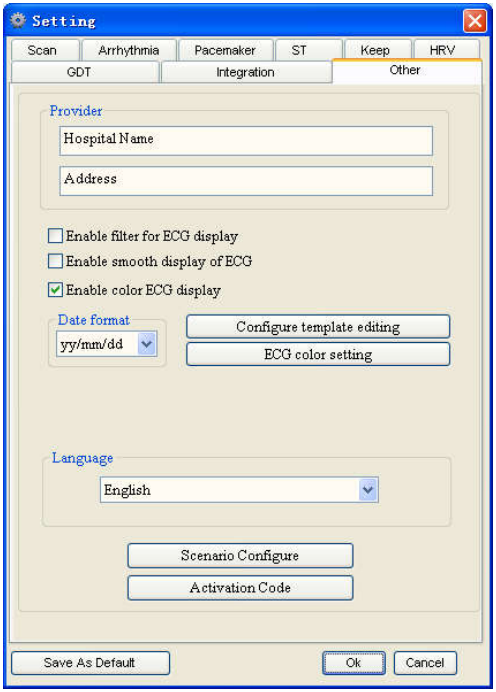
The parameters on this screen are described as follows:

- ✧ Enable GDT: Enabling the GDT interface.
- ✧ GDT interface
  - ■ GDT directory: Specifying the directory for exchanging the file with EDP. Default: C:\GDT\
  - ■ Command file: The command file name sent by EDP to Cardio SW-Holter
  - ■ Output file: The data file name sent by Cardio SW-Holter to EDP
- ✧ GDT protocol parameter
  - ■ EDP ID: This parameter is set as 8315 or 8316 in the GDT protocol, the default is

EDP

- Device ID: The ID assigned by the EDP to Cardio SW-Holter, the default ID is BI_HLT

Other



On this screen, the following parameters can be set:

- ✧ "Hospital name": The name will be printed in the report.
- ✧ "Language": For selecting a software interface language (to be supported by the operating system).
- ✧ Display switch for ECG filtering.
- ✧ Display switch for ECG smoothing.
- ✧ Switch for ECG color display.
- ✧ "Date format": The default format is yyyy/mm/dd.
- ✧ "Template editing mode": For setting different types of heart beat editing, two editing modes are available: the Single QRS mode and the ECG episode mode.

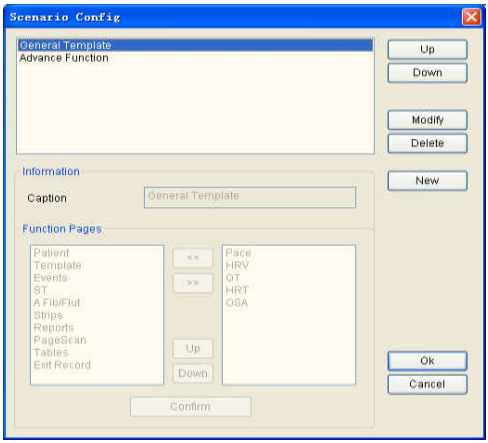
- ✧ “ECG color setting”: For setting colors of various types of ECGs. “Workflow configuration”: For arranging functions in the edit interface.
- ✧ “Activation code”: Activating advanced functions.

Note: After changing the language setting, restart Cardio SW-Holter to validate the change.

Workflow configuration - Arranging functions in the edit and analysis interface

The “Edit/analysis” interface consists of a set of functions that can be clipped and reordered as required. These functions are called”Workflow”. .

Click “Workflow configuration” to open “workflow configuration window":



Listed on the top of the window are the workflow functions currently available: General editing mode and Advance function. “Up” and “Down” can be used to change the order of the functions.

Clicking the “Modify” button, the workflow functions

can be adjusted and their order set.

“>>“ button: For removing a function from the workflow.

“<<“ button: For adding to the workflow a function selected from the list of available functions on the right.

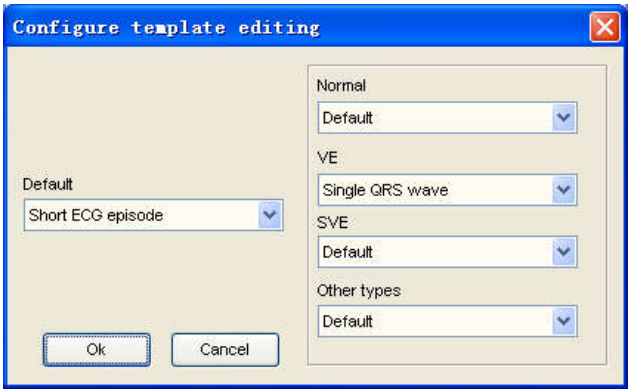
“Up” and “Down” buttons: For adjusting the order of the functions in the workflow.

After modifying the functions, click the “OK” button to exit the modification status.

If the workflow has been modified, click the “Save and return” button before exiting.

Template editing mode setting

Cardio SW-Holter provides two template editing modes: “ECG episode mode” and “Single QRS mode”. The operator can set the template editing mode by preference or in accordance with this template.



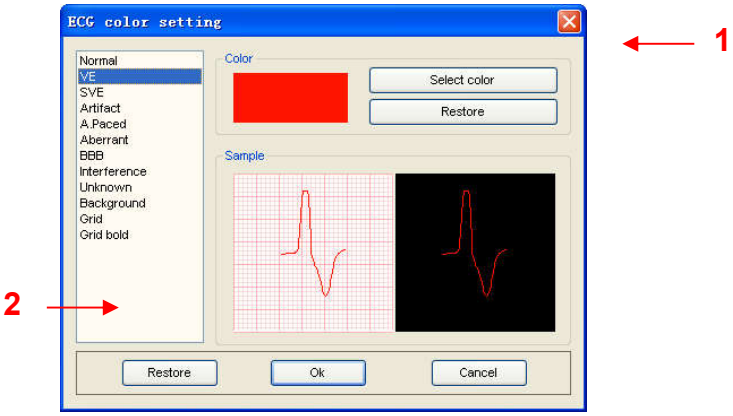
Description:

✧ “Default”: The editing mode as set to default values.

- ✧ “OK” button: For exiting with the setting saved.
- ✧ “Cancel” button: For exiting with the setting unchanged.

ECG color setting

Different types of ECGs being displayed in different colors, facilitates quick identification of abnormal ECGs.



Description:

- ✧ “Select color”: For opening the system palette to select color for the current item.
- ✧ “Restore” (1): For canceling the color modification for the current item, and restoring to the color before being modified.
- ✧ “Restore” (2): For canceling the color modification for all the items, and restoring to the color before being modified.
- ✧ “OK”: For saving the modified color. After saving, the color before being modified cannot be restored.
- ✧ “Cancel”: For canceling the modification, and exiting the “ECG color setting” window.

6 Edit analysis

The “Edit analysis” interface can be accessed by using two operations:

1. Creating a new patient
2. Loading an existing patient

The “Edit analysis”interface consists a a set of functions that can be used to edit,modify and print the analysis report of the patient analyzed and saved.

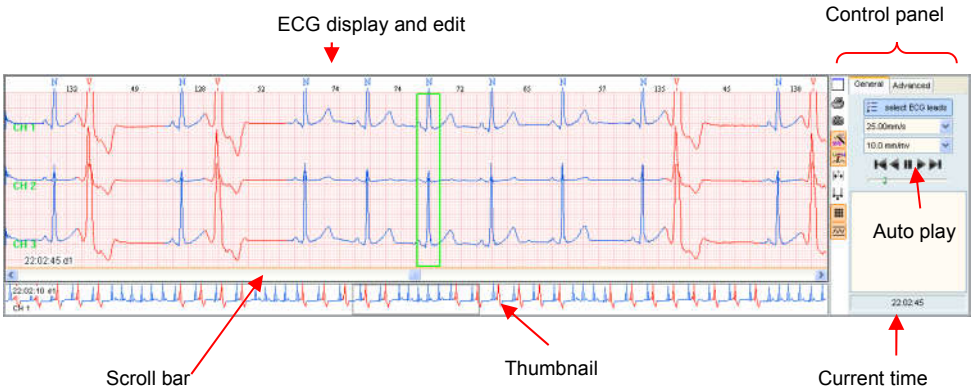
The operator can combine and arrange these functions to suit. Such a combined multiple functions work interface is called workflow. The operation to create a workflow is described in "**Parameter setting**"->"**Other**”->“**"Workflow configuration**. Refer to P38.

Workflows can be selected by clicking the  button on the right corner of the screen.

The following sections will describe the operation of these edit/analysis functions in detail.

General ECG edit window

In most functional interface of the “Edit analysis”, there is a common ECG edit window as follows.



The window provides the following functions:

- Browsing and editing the ECG of any time period.
- Automatically positioning to show the ECG complexes.
- Automatically fast playing a set of events or all the heart beats in a template.
- Modifying/inserting/deleting the QRS marks on the ECG.
- Measuring values of the RR interval and ST segment of ECG.
- Fast browsing the entire ECG recording.

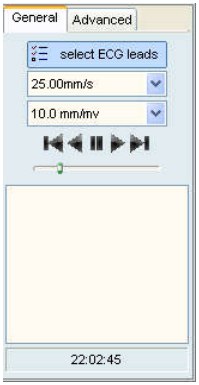
The ECG edit window consists of the ECG display edit window, thumbnail, general tool bar and control panel.

The shortcut keys of the general tool bar are described as follows:

✧ ☐: For opening the full ECG window, and

displaying all the 12-lead ECGs. Double click the left mouse button in the ECG display zone to open the full ECG window.

- ✧ button: For printing out at the current ECG .
- ✧ button: For saving the ECG episode. The saved ECG episode can be confirmed again in the "Episode" function screen, and this episode will appear in the report.
- ✧ : SVE intelligent edit switch. When enabled, after any heart beat that is edited in the ECGs, SVE analysis will be automatically performed for the subsequent heart beats after this heart beats.
- ✧ : For enabling shortcut keys operation for the keyboard. When disabled, mis-operation of the keyboard can be avoided.
- ✧ : Measurements start when this button is activated.
- ✧ : Switch for caliper measurement.
- ✧ : Switch for ECG background grid.



- ✧ : Switch displays thumbnails below the ECG window.

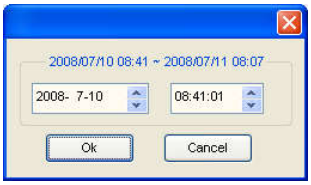
The function keys on the control panel are described as follows:

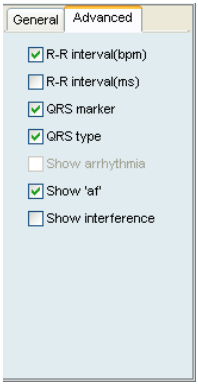
- ✧ Display channel: Select the channel to be displayed .
- ✧ Paper speed selection list: For horizontally

zooming in/ out on the ECG. Selectable speeds include: 6.25 mm /s, 12.5 mm /s, 25 mm /s and 50 mm /s.

- ✧ Gain selection list: For vertically zooming in/out
- ✧ Amplitude of ECG: Slectable amplitudes include: 5 mm/mv, 10 mm/mv, 20 mm/mv, 40 mm/mv and 80 mm/mv.
- ✧  Auto play button: Control auto play.
- ✧ Time display: Displays the corresponding time of the ECG (the time when the ECG was recorded).

  The time display window will pop up when clicking the time display box by the left mouse button. After entering the time and clicking the OK button in the window, the time of the ECG window will change to the time entered.





- ✧ Display information switch settings includes switches for displaying: " R-R interval (bpm)", "R-R interval (ms)", " heart beat position", "heart beat type", "arrhythmia", "af mark", and "interference".

  Where:

  The switch for displaying "arrhythmia" is only available in "Event", "ST", "Episode", and "Page scan".

  When the switch for displaying " af mark" is

enabled, the heart beat types of the normal/ atrial premature beat in all the atrial fibrillation/atrial flutter events are shown as “af”.

When the switch for displaying “interference” is enabled, the artifacts (ECG interference) automatically suppressed by the analysis algorithm will be displayed in order to facilitate editing the heart beats.

Scroll bar below the ECG edit window:For

Fast scrolling and browsing the ECG.

For frequently-used operations of the ECG edit window, refer to the description below.

Zooming in/out ECG

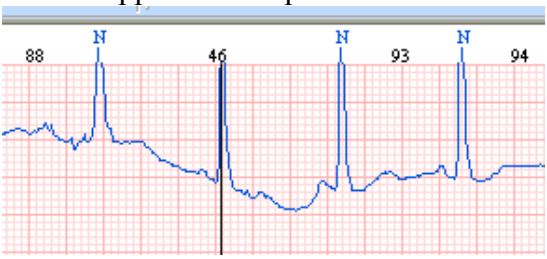
Select a paper speed from the "Paper speed" list to horizontally zoom in or zoom out the displayed ECG. Selectable speeds include: 6.25 mm /s, 12.5 mm /s, 25 mm /s and 50 mm /s.The default value is 25mm/s.

Select a gain setting from the "Gain" list to vertically zoom in or zoom out the ECG displayed. Selectable gains include: 5 mm/mv, 10 mm/mv, 20 mm/mv, 40 mm/mv and 80 mm/mv. The default value is 10mm/mV.

Inserting heart beat

A specific designated mark of heart beat can be inserted in any position of the ECG. The operation steps are as follows:

1. Click the left mouse button on the position of ECG to be inserted. At this time in the ECG, a cursor line will appear in this position:



2. Then click the right mouse button, and at this time the heart beat type list window will pop up.
3. Click the left mouse button to choose the heart beat type to be inserted .
4. The insert operation can also be done by directly pressing the corresponding shortcut keys.

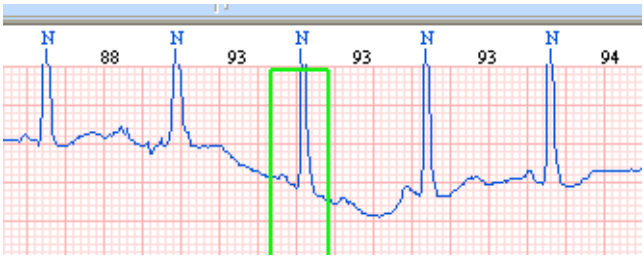
Note: The distance from the position where mark of heart beat inserted to the nearest heart beat should not be less than 200 ms.

Note: After performing the insert operation, Cardio SW-Holter will automatically re-analyze and collect the cardiac rhythm events.

Deleting heart beat

For deleting any marked heart beat in the ECG, steps are as follows:

1. Use the left mouse button to click the heart beat to be deleted. At this time the heart beat will be surrounded by a green box.



2. Click the right mouse button to open the operation menu, and select the operation of "Delete QRS mark" , which results in deletion of the designated heart beat .
3. Deletion can also be made by directly pressing the shortcut key '**X**' on the keyboard.

Note: After performing deletion, Cardio SW-Holter will automatically re-analyze and collect the cardiac rhythm events.

Modifying heart beat

To modify the types of any heart beat in the ECG, steps are as follows:

1. Use the left mouse button to click the heart beat to be modified. At this time the heart beat will be surrounded by a green box.

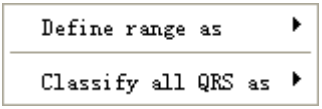
2. Click the right mouse button, and the window of heart beat type list will pop up.
3. Click the left mouse button to choose the type to be modified to complete the operation.
4. Modification can also be made by directly pressing the shortcut keys of the corresponding type on the keyboard.

Note: After the modification operation, Cardio SW-Holter will automatically re-analyze and collect the cardiac rhythm events.

Modifying multiple successive heart beats

If the successive heart beats that need to be modified are in the current ECG window, the modification can be quickly completed by the steps as follows:

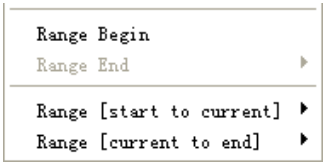
1. Press the SHIFT or CTRL key, and move the cursor to the start position of the heart beat to be modified Press the left mouse button and move the mouse, and a box will appear in the ECG window. Move the mouse, until all the heart beats to be modified are in the box, and then release the left mouse button, a pop up window will be shown as follows:



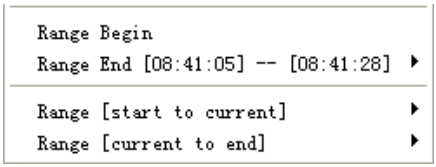
2. Select a new type in “Modify all heart beats selected as” to complete the modification.

If the successive heart beats go beyond the width of ECG window, perform the following steps:

1. Move the cursor to the start position , and then press the right mouse button, and select “Range begin” in the pop-up option list,:



2. Move the cursor to the end position, and then press the right mouse button, andselect “Range end” in the pop-up option list:



3. Select a new type in the “Range end”->“Modify all heart beats selected as” to complete the modification.

Note: After the modification, Cardio SW-Holter will automatically reanalyze and collect the cardiac rhythm events.

Measure ECG

In the ECG window, the RR interval and ST segment value can be measured. The operation steps are as follows:

1. Press the  button to ensure that the ECG window enters into the measurement status.

2. Move the cursor to the measurement start point;
3. Press the left mouse button; the cursor position will be automatically recorded as the start position of the measurement window,and it will also be regarded as the reference point of ECG amplitude measurement..
4. Drag the cursor to the end position to be measured; and while dragging a small tip window will appear in the status bar, displaying the interval (ms) and level difference (mv) from the current cursor position to the start position.
5. Release the left mouse button. At this time the value in the small tip window is the time interval (ms) of the measurement window and the electrical voltage level difference (mv) between the two points
6. At this time, the entire measurement window moves with the mouse.
7. Press the right or left mouse button to cancel the current measurement window.
8. Release the  button to exit the measurement status.

Auto play

The “ECG edit window” has auto play functions. Depending on the function to which the window belongs, it can automatically play the selected beats(template edit function) or the selected cardiac rhythms event (event edit function).

The operation steps are as follows:

1. Selecting the object to be played (which can be a template, or the cardiac rhythm event);
2. Press  or  to start auto play;

3. Adjust the slider bar to adjust the play speed;
4. The play direction can be changed by pressing  or  when playing;
5. The play can be paused by pressing  when playing;
6. When all the selected objects are played, the window will automatically exit the play state;
7. Auto play can also be stopped and exited by pressing  or  during playing.

Fast browse of ECG

.

At the bottom of the ECG edit window, there is a scroll bar and its length corresponds to that of the ECG. When clicking on or dragging the scroll bar, the ECG in the window will scroll. The minimum unit of scrolling is one page.

For 12-lead patient data, the scroll bar on the right of the window can be used to switch the leads displayed in the ECG. A full screen of ECG can be displayed by pressing  and for 12-lead patient, all the 12-lead ECG waveforms will be displayed.

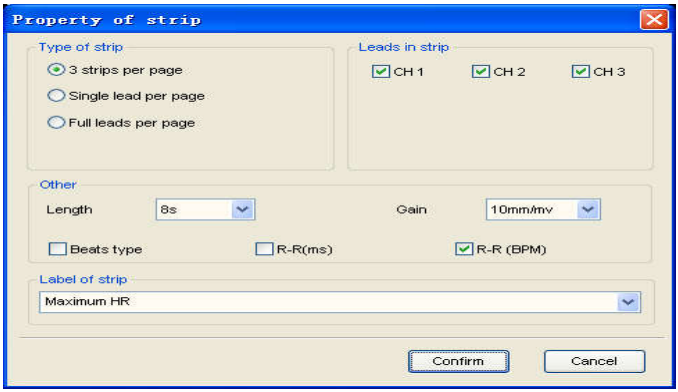
The leads of the ECG can be set by clicking on the “displaying leads” button in the control panel on the right side.

Saving ECG episodes

The ECGs in the ECG edit window can be saved as

episodes to be printed in a report. The operation steps are as follows:

1. After clicking the button, in the ECG edit window will pop up a solid line box for marking the saved ECG episode. You can move the ECG leftwards or rightwards to adjust the saved episodes.
2. Clicking the button again shows the following window:



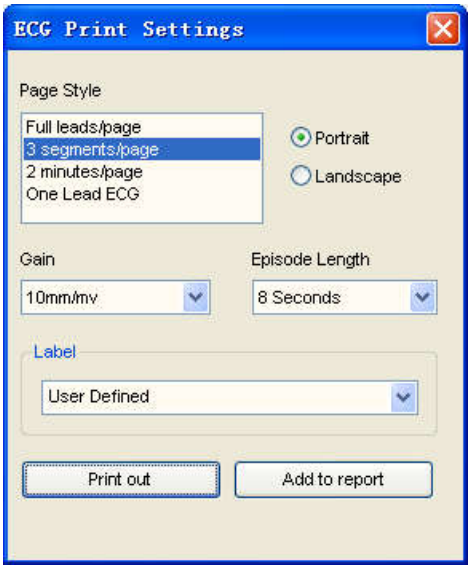
3. Select the type of ECG episode from :
   a) 3 episodes per page: 8-second, 3-channel ECG episode, and normally 3 ECG episodes of that type are printed in a report page.
   b) Single lead continuous ECG: 72-second, single lead continuous ECG, and one ECG of this type is printed in one report page.
   c) Full lead ECG: 8-second, full lead ECG, and one ECG episode of this type is printed in one report page.
4. Select leads for ECG episode;
5. Select gain for ECG episode;

6. Select to enable ECG episode: heart beat type, R-R interval (ms) and R-R interval (heart rate);
7. Set label for the ECG episode saved. Either select one directly from a list of existing labels, or directly enter one (newly entered label will be automatically added to the list of existing labels);
8. Click the "Confirm" button to save the ECG episode. All the saved ECG episodes can be viewed in the "Episode" function and printed out;
9. Saving can be canceled by clicking the "Cancel" button.

ECG instant print

Providing the instant print for ECG in the ECG window.

1. Select one episode of ECG to be printed. (as .).
2. Click the button to pop up the "Instant print settings" window:



3. Select an instant print style (4 styles are available for the portrait and landscape modes respectively).

4. Select the length of the ECG episode(continuous print is available).
5. Select the gain and label.
6. Click the "Instant print" button to enter the print preview interface or output the data to printer directly.
7. Click the "Add to report" button to add the ECG required to be printed as the report page to the report document.

Self-defining arrhythmia events

In the ECG edit window, arrhythmia events can be self-defined.

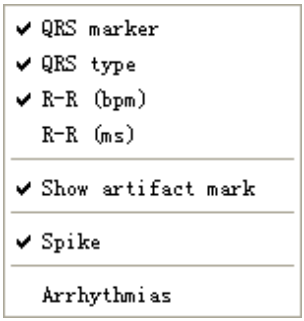
The operations are as follows:

1. Move the cursor to the start position of the event with the CTRL key pressed down. Press the left mouse button and move the cursor to the end position of the event. Release the left mouse button (at this time a menu will pop up). Select "Define event "-> Event type is in the pop-up menu,.
2. Alternatively, move the cursor to the heart beat position where the event starts, click the right mouse button, and in the pop-up menu, select "Range begin"; then move the ECG and the cursor to the heart beat position where the event ends, and click the right mouse button. At this time, select "Range end"-> Event type is in the pop-up menu.

Note: This operation can also be used to modify all the heart beat types in a selected range and also print the ECG in the selected range.

Displaying options

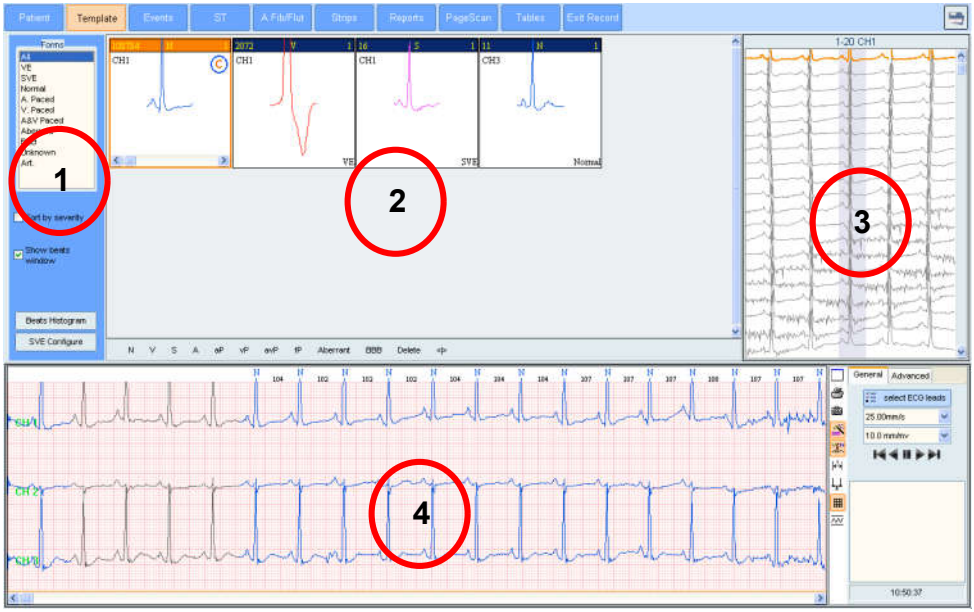
The information displayed in the ECG can be set by clicking the right mouse button on the heart beat marking range to pop up the option menu:,



And to click the option by left mouse button.

Note: The “Spike” option is used to enable the pacemaker pulse display, which appears only in a pacemaker patient.

Template edit



Beat detection and beat type identification are the most basic analysis for the ECG. In the heart beat detection , all of the heart beats with the same QRS feature will be assigned a type and form one template, so all the heart beats (QRS) of one patient can be entered into several or dozens of templates. In the template operation, all the heart beats can be browsed, edited and modified.

The template edit function interface consists of the following zones:

- ✧ Zone 1: Includes:
  - ■ Classified display list.
  - ■ Switch for sorting templates by severity.
  - ■ Switch for heart beat superimposition window.
  - ■ Button for heart beat histogram, used to

enter into the heart beat histogram editing process.

- Button for supraventricular setting, used to adjust the supraventricular analysis parameter and re-analyze.

✧ Zone 2: .

- Consisting of a set of independent small windows for template display.
- Each small window can be used to fast browse template heart beats, modify single heart beat, modify template type, and integrate templates. The heart beat edit window can be entered by double clicking the small window, please refer to detailed operation on Page 57-59.
- This zone supports drag/drop of the same template type(using the mouse to drag a small window to another window of the same type).
- This zone supports both the keyboard and mouse operations.
- Displaying in combination with the heart beat superimposition display window on the left of the screen and ECG edit window on the bottom of the screen.
- Providing fast operation toolbar .
- The "<|>" (split) key in the fast operation tool bar is used to divide the heart beat forms similar to the current heart beat form from the current template, so as to provide a new template.

✧ Zone 3: Heart beat superimposition display window

- All the heart beats in the selected template are displayed with R waves vertically aligned and superimposed .
- Single or multiple heart beats can be selected.
- Clicking the right mouse button can pop up the heart beat form list to perfom modification.
- Clicking the top of the window by using the left mouse button can set.
  displaying leads, gain, and number of heart beats, etc.

✧ Zone 4: ECG edit window

- The ECG including the current heart beat can be browsed and edited.

- All of the heart beats in the template can be automatically fast played.
- Modifying/inserting/deleting of heart beats is possible in the ECG.
- The RR interval and ST segment value of the ECG can be measured.
- Please refer to Section"General ECG edit window" on Page41.

For common operations, please refer to the following descriptions.

Keyboard and general information for the template edit

General information for keyboard and template edit is as follows:

Keyboard

The ↑ and ↓ keys: For selecting heart beat in the small template.

The → and ← keys:For selecting small template.

The Ctrl+ key: For modifying the type of the whole template.

Heart beat type

N: Normal beat, corresponding to **N** on the keyboard and **3** on the keypad

V: Ventricular beat, corresponding to **V** on the keyboard and **1** on the keypad

S: Supraventricular beat, corresponding to **S** on the keyboard and **2** on the keypad

A: Unknown or artifactual beat, corresponding to **A** on the keyboard and **0** on the keypad

aP: Heart beat of atrial pacing,, corresponding to **4** on the keypad

vP: Heart beat of ventricular pacing,, corresponding to **5** on the keypad

avP:Heart beat of atrioventricular (double-chamber pacing), corresponding to **6** on the keypad

fP: Fusion-paced beat, corresponding to **7** on the keypad

Aberrant: Heart beat of abnormal type, corresponding to **8** on the keypad

BBB: Bundle-branch block, corresponding to **9** on the keypad

Fast browsing all the heart beats within one template

All of the heart beats with the same QRS feature comprise one template, so you can, in the template edit function, conveniently fast browse all the heart beats in a template. Here are two methods :

The first method is to use the auto play function provided by the ECG edit window.

The second method is to use the scroll bar in the small window of the template to retrieve and browse.

A detailed description is given below.

Auto play

This method is to use the auto play function in the ECG edit window. The steps are as follows:

1. Select the template requiring to be played;
2. Press the  button in the ECG edit window;
3. Adjust the auto play speed till satisfactory;
4. Press the  button to pause playing;
5. Press the  button to review the heart beats played;
6. Click or drag the scroll bar in the ECG edit window to scroll the ECG back and forth.

QRSs in the small window of the template

These QRSs are browsed by using the function of scroll retrieval provided in the small window of template. The steps are as follows:

1. Select a template;
2. Use the mouse to click or drag the scroll bar below the small window of this template;

3. The small window of the template will display heart beats in time sequence;
4. Th ECG edit window will correspondingly display the ECG of this heart beat;
5. Click or drag the scroll bar in the ECG edit window to scroll the ECG back and forth.

Changing the template type

When changing the template type, all the heart beat types belonging to this template will also be modified at the same time.

This function is suitable to quickly modify large quantities of heart beat types that have previously assigned. The operation steps are as follows:

1. Select template;
2. Click the right mouse button, with the type list popping up;
3. Select a new type from the type list, to start modification;
4. Wait for the modification to finish (the modification time depends on the number of heart beats in the template);
5. The keyboard operation is an alternative way: CTRL+ the type key.

Integrating templates

Templates of the same type can be integrated, and the heart beats in all of the integrated templates will be combined into the target template.

This function is used to classify a large quantity of heart beats of the same type, so as to reduce the number of templates.

The operation steps are as follows:

1. Select a template by pressing and holding the left mouse button on the template, with the cursor in the "drag-drop" state  ;
2. Move the cursor to the target template (required to be of the same type), and then release the left mouse

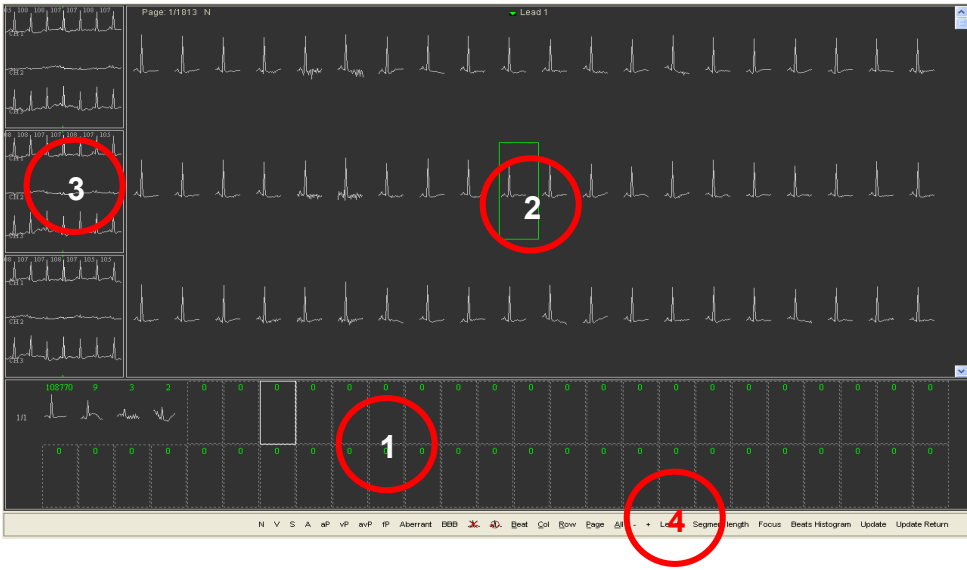
button, which is the so-called integrated “drag-drop” operation.

3. Wait for the integration operation to finish.
4. The cursor state  indicating that the integration is allowed, and  indicating “not allowed”.

Note: The dragged template will be integrated into the target template where the former was dropped.

Heart beat edit window – Single QRS mode

If it is required to perform detailed editing and correction for the heart beats in the template, the heart beat edit window can be entered. Double click the left mouse button on the selected template to open the heart beat edit window. When the type of template edit mode is set to “Single QRS mode”, the opened edit window is as follows:



The window interface is described as follows:

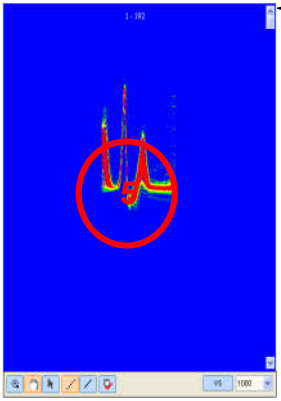
- ✧ Zone 1: Sub-template display zone
  - ■ Displaying all sub-templates by quantity.
  - ■ The sub-templates can be selected, modified, and deleted
  - ■ This zone supports keyboard operation: The ←, →, ↓ and ↑ keys are used to select sub-templates, , and the type keys can also be used to modify the type of sub-template. Refer to the description for heart beat type on P55.
  - ■ The Tab key can be used to choose the next sub-template. When pressing down the "Shift" key at the same time, the previous sub-template will be selected.
  - ■ Double-clicking the left mouse button on the sub-template display zone to make it active. When in the active state, the cursor's color is green.
  - ■ Clicking the right mouse button enables the modification for the types of sub-template.
  - ■ This zone also supports page scroll with the mouse wheel.
- ✧ Zone 2: Heart beat display zone
  - ■ This zone displays all the heart beats in the active sub-template in the form of an ECG episode.
  - ■ Single or multiple heart beats can be selected, modified, and deleted
  - ■ The ECG thumbnail of all the heart beats in the column in the cursor is correspondingly

displayed in Zone 3.

- This zone supports keyboard operation: ←, →, ↓ and ↑ keys are used to select the heart beat, Page Down/Page Up keys are used to scroll pages, and the type keys can also be used to modify types of heart beats. Refer to the description for heart beat type on P55.
- Clicking the left mouse button on the corresponding zone to make it active. When in the active state, the cursor's color is green.
- Clicking the right mouse button to modify the type of the selected heart beat.
- This zone supports page scroll with the mouse wheel.

✧ Zone 3: ECG thumbnail

- All the heart beat ECG thumbnails in the column in the "Heart beat display zone" where the cursor is in are correspondingly shown.



✧ Zone 4: Toolbar, including:

- "Type" button.
- "Delete/undelete" button.
- "Cursor type" button in the heart beat display zone.
- "Superimposition edit" button: For starting the anti-confusion window.
- "Update return" button: For updating and exiting the heart beat edit window.
- "Update" button: For updating but not exiting.
- "Heart beat histogram" button: For entering

the heart beat histogram window.

- ✧ Zone 5: Superimposition edit window
  - ■ The Superimposition edit window can be displayed by clicking “Superimposition edit” in the toolbar ..
  - ■ For detailed operation description, refer to “Superimposition edit window” on P63.

Heart beat edit window - ECG episode mode

When the template edit mode of this type is set to “ECG episode mode”, double click the left mouse button on the selected template to open the heart beat edit window, which is displayed as follows:

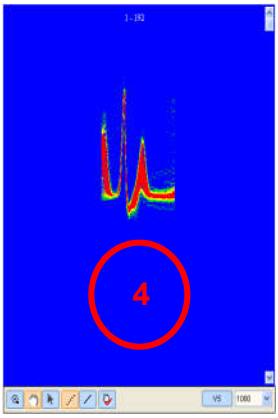
The window interface is described as follows:

- ✧ Zone 1: Sub-template display zone
  - ■ Sort by quantity and display all the sub-templates under the current template.
  - ■ The sub-template can be selected, modified, and deleted.
  - ■ This zone supports keyboard operation: The ←, →, ↓ and ↑ keys are used to select the sub-template, the Page Down/Page Up keys are used to scroll pages, and the type keys can also be used (refer to the description for heart beat type on P57).
  - ■ Tab key: For automatically moving to the next sub-template. The "Shift" key is for moving the sub-template in the reverse direction.
  - ■ Double-clicking the left mouse button on the corresponding zone to make it active. When in the active state the cursor's color is green.
  - ■ The mouse can be used to drag and select multiple sub-templates.
  - ■ Clicking the right mouse button can make the type list pop up. This type list is for modifying the types of sub-templates.
  - ■ This zone supports page scroll with the mouse wheel.
- ✧ Zone 2: ECG episode display zone
  - ■ Display the ECGs of all the heart beats included in the current sub-template.
  - ■ Every heart beat can be selected, modified, and deleted.

- The channel and time period of ECG can be set.
- This zone supports keyboard operation: The ←, →, ↓ and ↑ keys are used to select the heart beat, the Page Down/Page Up keys are used to scroll pages, and the type keys can also be used. (Refer to the description for heart beat type on P55).
- Tab key: For switching the activity status between Zone 2 and Zone 1, the keyboard is valid only when it is switched to the current active status zone. When in active status, the cursor's color is green.
- Clicking the corresponding zone with the left mouse button can make it active.
- The heart beat can be dragged and selected by moving the mouse while pressing and holding the left mouse button .
- Clicking the right mouse button can make the type list pop up, This type list is for modifying the type of the selected heart beat.
- This zone supports page scroll with the mouse wheel .

✧ Zone 3: Toolbar, including:

- "Heart beat type" shortcut key.
- Episode channel setting.
- Episode length setting.
- "Waveform amplitude zoom in/zoom out" button.
- "Heart beat histogram": For entering the heart beat histogram edit window.



- “Superimposition edit” button: For enabling the anti-confusion window.
- “Update/return” button: For updating and exiting the heart beat edit window.
- “Update” button: For updating but not exiting.

✧ Zone 4: Superimposition edit window

- The Superimposition edit window can be displayed by clicking the “Superimposition edit” in the toolbar .
- For more detailed operation descriptions, refer to “Superimposition edit window” on P63.

Modify heart beat type(s) in the heart beat display window

The operation steps are as follows:

1. Tab key or click the left mouse button on this zone to make the heart beat display window active.
2. Use the keyboard or the mouse to select the heart beat(s) to be modified.
3. Use the mouse to click the corresponding QRS type button on the toolbar.
4. Or press the letter keys or the number keys corresponding to the heart beat type on the keyboard. (Refer to the relevant description for the heart beat type on P57).
5. If the cursor (box) is on a selected range (row, column, page or all), the type of QRSs in the cursor selected range will be simultaneously modified.
6. Multiple heart beats can be flexibly selected by dragging and moving with the mouse.

Modifying the type of sub-template

Modifying the type of sub-template,will simultaneously modify the type of all the heart beats therein.

The operation steps are as follows:

1. Press the TAB key or double click the mouse button to enable the sub-template window to be active.
2. Use the mouse to select the sub-template(s) to be modified or use the keyboard to move the green cursor (box) to this sub-template.
3. Use the mouse to click on the button for the corresponding type on the toolbar.
4. Or press the corresponding key on the keyboard (keypad) for the type. (Refer to the relevant description for the heart beat type).
5. The type of all the heart beats in the sub-template will be modified simultaneously.
6. If multiple sub-templates are simultaneously selected, all the sub-templates selected will be modified.

Selecting multiple sub-templates

Two methods are available to simultaneously select multiple sub-templates.

The operation steps are as follows:

1. One method: Press the left mouse button and drag the mouse, with all the sub-templates between the pressing and the dragging position will be selected.
2. Another method: After confirming that the sub-template window is the currently active window (the cursor box's color is green), press the Ctrl key on the keyboard, and then use the mouse to click on the sub-template to be checked. Releasing the Ctrl

key will result in exiting the checked state.

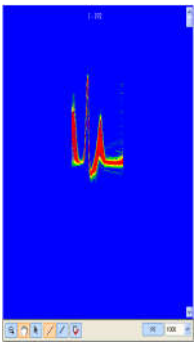
Examining zoomed in ECG

Open the ECG window to check selected heart beats. The operation steps are shown as follows:

1. Double click the mouse button on the heart beat in the heart beat display window to open the ECG window.
2. Or move the cursor to the heart beat to be viewed by using the keyboard and press the “Enter” key.

Superimposition edit window

Click the “Superimposition edit” on the toolbar to open the Superimposition edit window.



In the superimposition window, all the heart beats in the current sub-template are displayed with P-QRS-T superimposed, so as to either determine different types of heart beats in the pattern after superimposition: To find wide and abnormal QRS complexes in the normal QRS complexes (or vice versa); or to find SVE Prematurity with P wave changed from the normal QRS complexes (or vice versa). This function is typically called the “Anti-confusion” function.Function key and operation instructions:

-  : For zooming in/out superimposition ECG. Click the left mouse button to zoom in; and click the right mouse button to zoom out.
-  : For moving superimposed ECG. Press and hold the left mouse button and then move the mouse to move the superimposed

ECG to the display position.

-  : For selecting. When in the  state, the mouse can be used to drag and select a heart beat, and once selected the heart beat will be moved from the current superimposed ECG to the heart beat display zone (Zone 2) to be modified.
-  : For displaying superimposed with scattered color dots.
-  : For displaying superimposed with solid line
-  : Switch the unselected and selected heart beat superimposition ECGs.
-  : ECG channel setting.
- Superimposed heart beat count list: Set the number of superimposed heart beats, and when the number of heart beat superimposition is exceeded, another superimposition page will be added.
- The selection of heart beats can be canceled by pressing the  switch to display the selected heart beat superimposition ECG, and then using the mouse to drag and select the heart beat.

Re-classify

In the heart beat edit window, a re-classifying function is provided, and using the selected QRS as the sample, the heart beats in the sub-template similar to the sample will be sorted together and modified as the selected new type. The operation steps are as follows:

1. Select a heart beat as the sample;

2. Click the right mouse button, and in the pop up menu, select Re-classify and its new type;
3. In case of "ECG episode mode", in the pop up menu, the lead for processing can be selected;
4. In case of "Single QRS mode", before clicking the right mouse button, one blank sub-template (the count is 0) can be selected in the sub-template zone in advance;
5. After re-classifying, in the "ECG episode mode", the heart beats similar to the sample will be modified; and in the "Single QRS mode", a new sub-template will appear in the blank sub-template position. (If before sorting no sub-template is selected, the new sub-template will appear in the position of the last blank sub-template).

Integrating sub-templates

The sub-template integration function provided in the heart beat edit window of the "Single QRS mode" can integrate, the selected sub-templates,to reduce the number of sub-templates. It is also possible to integrate all the sub-templates.

The operation steps are as follows:

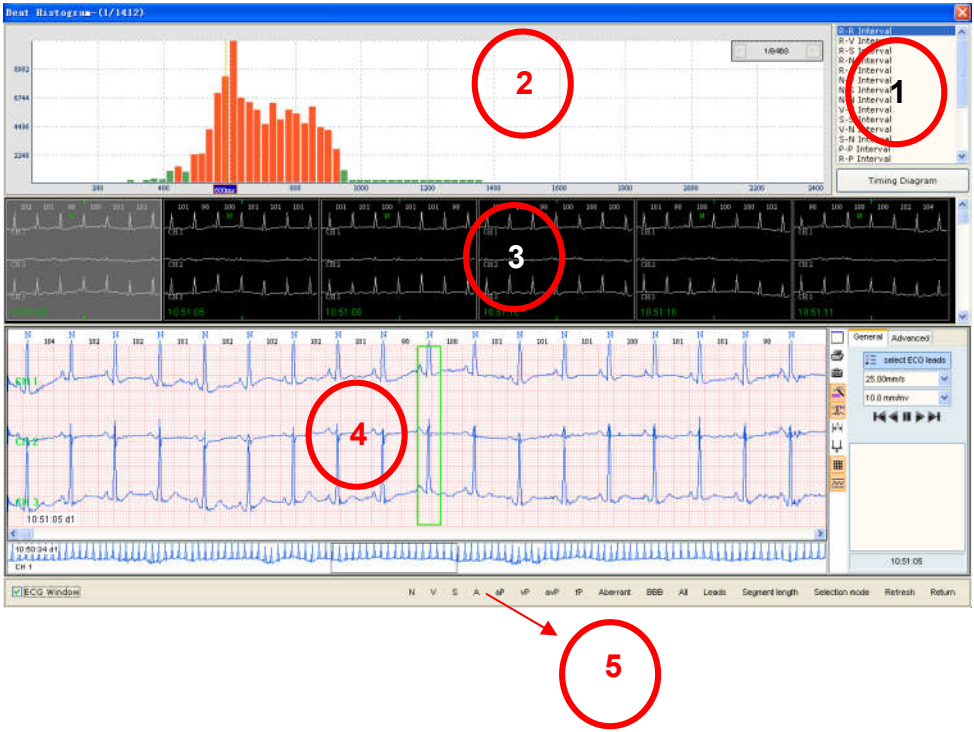
1. Select the sub-template(s) to be integrated either by pressing and holding the CTRL key and then clicking the left mouse button to select a single one, or by pressing and holding the left mouse button and then moving the mouse to select in the check box.
2. Click the right mouse button, and select "Integrate the selected templates" in the pop-up menu.
3. Directly click the right mouse button, and select "Integrate all the templates" in the pop up menu,

without selecting any sub-template.

4. If selecting “Automatically integrate templates by form”, the system will integrate the sub-templates in accordance with the form of the sub-template, with the sub-templates with similar form integrated.

Heart beat histogram/timing diagram

Click the "Heart beat histogram" to open the heart beat histogram window, displayed as below：



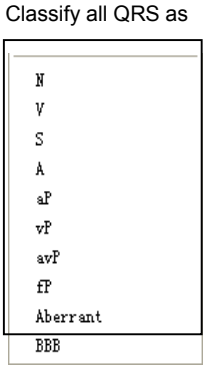
The window interface is described as follows:

- ✧ Zone 1: Type list
  - ■ In the histogram mode are provided over 20 heart beat histograms such as R-R, R-V, R-S, N-V, N-S, N-N, premature R-R interval, premature N-S interval, premature V-N interval.
  - ■ In the timing diagram mode are provided selections of "all", "normal", "ventricular", and "supraventricular" .
- ✧ Zone 2: Histogram or timing diagram

- There are two types of histogram, RR interval histogram, and premature interval histogram, the horizontal coordinate of the former is the RR interval; and the horizontal coordinate of the latter is the premature amount %.
- Use the mouse to directly click and select one or drag and select a zone.
- The selected heart beat will be displayed in Zone 3.
- The histogram in the selected zone can be zoomed in by pressing the CTRL key and the left mouse button and dragging.
- The histogram can be restored by double clicking the left mouse button.

✧ Zone 3: Heart beat edit zone

- The heart beat selected in the histogram will be displayed in the ECG episode mode.
- The keys of ←, →, ↑, ↓, Page Dn/Page Up on the keyboard are for moving and examining heart beat(s).
- The Enter key on the keyboard is for opening the ECG edit window.
- Click the right mouse button to open the edit operation menu (as displayed on the left).



✧ Zone 4: General ECG edit window

- For the detailed operations, please refer to Section “General ECG edit window” on P42.

✧ Zone 5: Toolbar

- The shortcut key for Heart beat type.
- The select key for Heart beat type.

- ECG episode length setting.
- The switch for ECG edit window display
- “Refresh” button: neither exiting nor updating the histogram (timing diagram).
- “Return” button: Exiting the window and updating.

Event edit

In this function page, you can review, modify, and delete all the abnormal events in the patient.

The event edit function interface consists of the following sections:

✧ Zone 1: List of available events

- List the types and quantity of all the arrhythmia event in the current patient.
- Double click the left mouse button on the events in the list to open the event edit

window.

- “Parameter setting” button: For setting parameters for arrhythmia analysis to re-analyze.

✧ Zone 2: Heart rate trend graph and time series histogram of events

- Heart rate trend graph: trend graph of average heart rate per minute.
- Time series event histogram is enabled to select arhythmia events.

✧ Zone 3: Event distribution histogram

- For individually displaying: Histogram based on RR interval, histogram based on geminal (successive) number and histogram based on ST value,in accordance with different arrhythmia types.

  Arhythmia events can be selected in the histogram

✧ Zone 4: Event episode edit window

- For displaying the episode of the currently selected event
- Sort the events by level of severity.
- Click the right mouse button to pop up the operation menu: as displayed on the left.
- “Delete” Operation: For deleting current event(s).
- “Delete all” Operation:For deleting all the currently selected events.
- “Save episode” Operation: For saving the current episode.
- “Select lead” Operation: For changing the current ECG display.
- –“Accept” Operation: For

"Maximum/Minimum heart rate" only, used to accept the current ECG episode as the maximum/minimum heart rate.

- This window supports keyboard operations, such as using the ↑ and ↓ key to select the event; and using the Page Down and Page Up key to scroll the page.

✧ Zone 5: ECG edit window

- For displaying the ECG of the selected event.
- For automatically fast playing all the selected events .
- For measuring the RR interval and ST segment value of the ECG.
- For modifying/inserting /deleting heart beats on the ECG, and automatically updating arrhythmia events after the ECG has been edited.
- For manually defining arrhythmia events.

For operations in common use, refer to the following description.

Select events occurring in a time interval

The operation steps are as follows:

1. Press the left mouse button on the time series histogram of events, and drag the mouse. In this trend graph, there is one small message window displaying the time interval and the number of events.
2. All the selected events in Zone 4interval will be displayed, and relevant edit operations can be performed.

Automatically playing events

The operation steps for automatically playing the event are as follows:

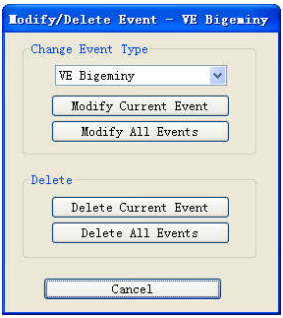
1. Select the event range to be played.
2. Press the  key in the ECG edit window to open the auto play function, and automatically fast play all the events.
3. Release the  key in the ECG edit window to pause play.
4. Press the  key in the ECG edit window to playback the events.

Modifying/deleting event

The type of some arrhythmia events can be modified.

The operation steps are as follows:

1. The selected events can be single events, some events or all the events.
2. Click the “Modify/Delete” button, and at this time the Modify/Delete Event window pops up a follows:



3. In the event type list, select the new type, and click the “Modify” button, and the event type will be modified, and the event content list will also be updated.
4. If the “Delete XXX” button is clicked, the event will be deleted.
5. Click the “Cancel” button to directly return.

Note: For the modification of a ventricular and supraventricular event, only the heart beat type in the ECG can be directly modified to correct such an event.

Fast saving the ECG episode

In the **event episode edit window**, click the right mouse button to pop up the operation menu. Select “Save episode” for operation, and at this time the episode of the

currently selected event will be kept.

If the zone to be kept needs adjusting, please use the  button in the ECG edit window (refer to "Save ECG episode" in the ECG edit window instructions on P49).

Accepting new maximum/minimum heart rate

Cardio SW-Holter is designed to automatically select the suitable sinus heart rate as the maximum/minimum heart rate, but sometimes, due to causes as artifacts, the automatically selected maximum/minimum heart rate may not be suitable. To deal with this patient, Cardio SW-Holter follows the heart rate distribution patient to automatically save up to 200 most appropriate ECG episodes. These available segments have been sorted in accordance with the heart rate, and the operator can select the suitable ECG episode from them as the maximum/minimum heart rate. When selecting the "Maximum/Minimum heart rate", the report statistics and episode will be simultaneously updated.

The operation steps are as follows:

1. In the event list, select the "Maximum heart rate"/"Minimum heart rate".
2. All the heart rate segments are displayed in Zone 4, and these segments have been sorted in accordance with the size of the heart rate. The current maximum/minimum heart rate segment will be shown in the first place, and at the same time this segment will also show word "Accept".
3. After selecting the segment, press the right mouse button to open the operation menu, and select the "Accept" for operation.

4. Or directly press ‘A’ on the keyboard.
5. At this time this segment will be accepted as the maximum/minimum heart rate, and will be placed in the first position and on the episode as well, the word “Accept” will be displayed.
6. **Note**: Operator-defined event functions are available in Zone 5 to define new maximum/minimum heart rate.

Event edit window

The "Event edit window function" is used to simultaneously edit large quantities of arrhythmia events. Use the left mouse button to double click the event in the event list to open the edit window of the event, as displayed in the following figure:

Interface and operation instructions:

- "Accept" button:for accepting the selected event.
- "Accept Page" button: for accepting all the events displayed in the current page.
- "Reject" button: for marking the selected event as reject.
- "Reject Page" button: for marking all the events displayed in the current page as reject.
- Select key: Click to select the type from the pop up list, the options are: Accept, Reject and None.
- "Save episode" button: for saving the current event

episode as the episode.

- "Update Return" button: for deleting the events marked as "Reject" and exit.

- Click the right mouse button to pop up the fast operation menu as displayed.

Note: Once updated and returned, all the events marked as 'Reject' will be deleted.

Atrial fibrillation /Atrial flutter

The Atrial fibrillation /Atrial flutter function interface consists of the following sections:

- ✧ Zone 1: Heart beat R-R interval dispersion trend graph
  - ■ Use 5 minutes as the step length to view the distribution of the heart beats in 5 minutes

in different R-R intervals, the horizontal coordinate is for time and the vertical coordinate is for RR interval. The color represents the quantity of the heart beats. The quantity of black heart beats is the lowest, the quantity of blue heart beats comes second and the quantity of red heart beats is the highest.

- If the heart beats are concentrated in some R-R intervals, the color in this position is bright (red), and on the contrary, the color is dim (blue or black).
- Through this R-R interval dispersion chart, patients of the atrial fibrillation/atrial flutter can be basically determined. Using the below tool, the start and end heart beat of the atrial fibrillation/atrial flutter episode can be accurately positioned.
- In the dispersion trend graph, double click the left mouse button to open the "Waterfall chart" window, for further analysis. For detailed operations, refer to Section "Waterfall chart" on P78.

✧ Zone 2: Atrial fibrillation event list

- Show the defined atrial fibrillation/atrial flutter events, including the starting time, the ending time and the duration of the atrial fibrillation/atrial flutter.
- "Delete" button: Delete event from the list.
- "Delete SVE" button: Delete all the SVEs in the atrial fibrillation/atrial flutter time (Change to Type N).
- "Detect AF." button: Automatically detect

and record the time period of the possible atrial fibrillation/atrial flutter.

- Select the events in the list, and the other windows will be displayed dynamically.

✧ Zone 3: 5-minute heart beat trend graph

- Show the heart beat trend graph as 5 minutes. The horizontal coordinate is for time, and the vertical coordinate is for RR interval (unit in ms).
- The trend graph of normal sinus rhythm is smooth, but the curve during atrial fibrillation/atrial flutter is variable.
- In the trend graph, every heart beat can be positioned.
- Click the heat beats in the trend graph, and the ECG below will be automatically positioned to the heart beat. On the contrary, scroll the ECG in the ECG edit window, and this trend graph is also positioned.
- When clicking the event list, the trend graph is automatically placed at the start position of the event.
- In the trend graph, double click the left mouse button to open "Whole course R-R interval trend graph". For the detailed operations, refer to Section "Whole course R-R interval trend graph" on P80.

✧ Zone 4: ECG edit window

- Follow the positioning in Zone 1, 2, and 3 to display the ECG.
- Accurately position the start heart beat and end heart beat of the atrial fibrillation/atrial flutter.

- Define the atrial fibrillation/atrial flutter event.
- The heart beat can be modified/inserted /deleted on the ECG, and when the ECG is edited, the arrhythmia event will be automatically updated.
- The ECG in all the 24 hours can be fast browsed.

Define the atrial fibrillation/atrial flutter event episode

1. Observe the heart beat energy distribution trend graph, and find a zone with low energy.
2. In the "5-minute heart beat trend graph", carefully observe whether this trend graph has successive serrated variable zone. If yes, place at the start position.
3. In the "ECG edit window", accurately position to the start heart beat, and click the right mouse button to open the self defined event menu, and select "Range begin".
4. Repeat 1 and 2 to find the end position with low energy.
5. In the "ECG edit window", accurately position to the end heart beat, and click the right button of the mouse to open the self defined event menu, and select "Range end"->"Define event" -> "Atrial fibrillation/atrial flutter".
6. At this time, in the event list, the event just defined appears.

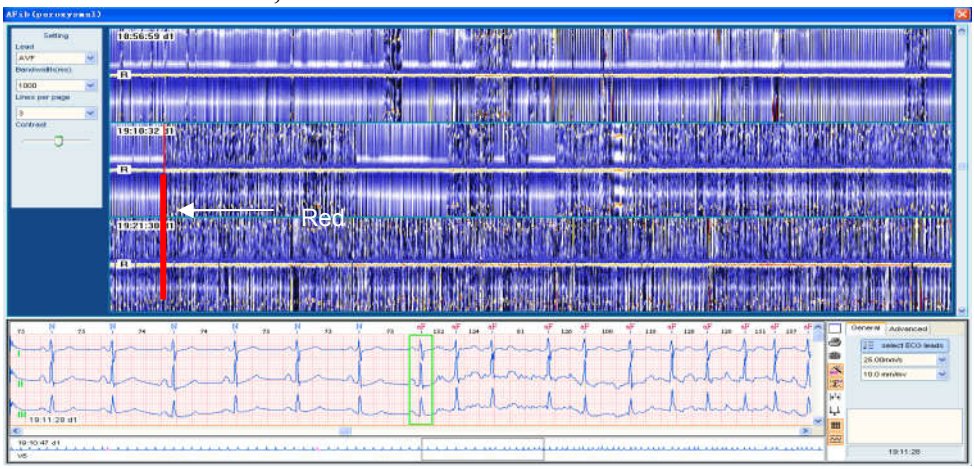
Delete atrial fibrillation/atrial flutter event

1. In the event list, select the atrial fibrillation/atrial flutter to be deleted, and then click the “Delete event” button.
2. You can also return to the “Event edit” function window, and use the event edit function provided by this window to delete.

Note: “Detect AF.” uses the analysis of abnormal R-R rhythm to detect atrial fibrillation/atrial flutter, and the detection results are only the supplementary measurements for editing, which should be confirmed by the physician.

Waterfall chart

"Waterfall chart" is an analyzing tool for charting P wave, atrial fibrillation/atrial flutter.



The interface consists of the following zones:

1. Waterfall chart display zone.
2. Waterfall chart parameter setting zone:
   - ✧ Lead selection list.
   - ✧ Waterfall chart bandwidth, the default value is 1000 ms.
   - ✧ Line number of the waterfall chart, the default value is 3.
   - ✧ Contrast slider of the waterfall chart.
3. ECG edit window.
   - ✧ Display the ECG of the waterfall cursor position.
   - ✧ Define and edit the atrial fibrillation/atrial flutter event.

Note: The "Waterfall chart" is an optional function, and for information on whether this function is enabled, please contact the supplier.

Instructions for observing the waterfall chart:

1. The position displayed by “R” in the waterfall chart is the R wave peak position of every heart beat, and in this position, normally there is a clear bright line (white in the sample figure).

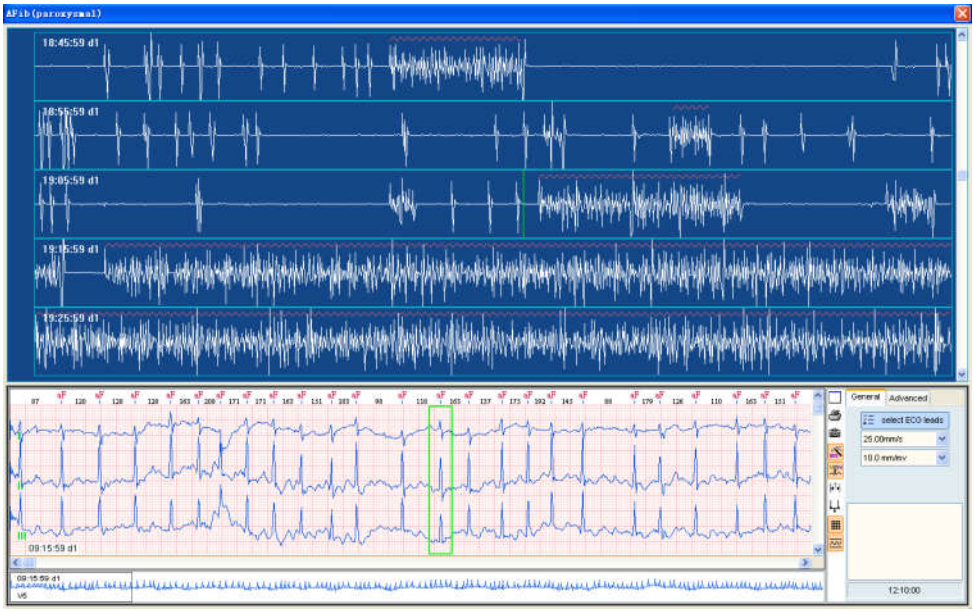
2. In case of a normal sinus ECG, in the area above the “R” position, normally there is one light white line, and this line is the P wave. Refer to the waterfall chart on the left of the red cursor position in the sample chart.

3. In the case of atrial fibrillation/atrial flutter ECG, in the area above the “R” position, no obvious line can be found. Refer to the waterfall chart on the right of the red cursor position in the sample chart.

4. ECG of types of atrial tachycardias, ventricular tachycardia, bigeminy, and trigeminy have characteristic waterfall chart.

Whole course R-R interval trend graph

The “Whole course R-R interval trend graph” is a trend connecting every heart beat, and this tool can be used for multiple types of arrhythmia analysis, such as atrial fibrillation/atrial flutter, pause, SVE etc.,.



The functional interface consists of the following zones:

1. R-R interval trend display zone.
2. ECG edit window.
   - ✧ Display the ECG of the selected cursor position.
   - ✧ Define and edit the atrial fibrillation/atrial flutter event.
   - ✧ Insert, modify, and delete heart beat.

Note: The "Whole course R-R interval trend graph" is an optional function, and for information on whether this function is enabled, please contact the supplier.

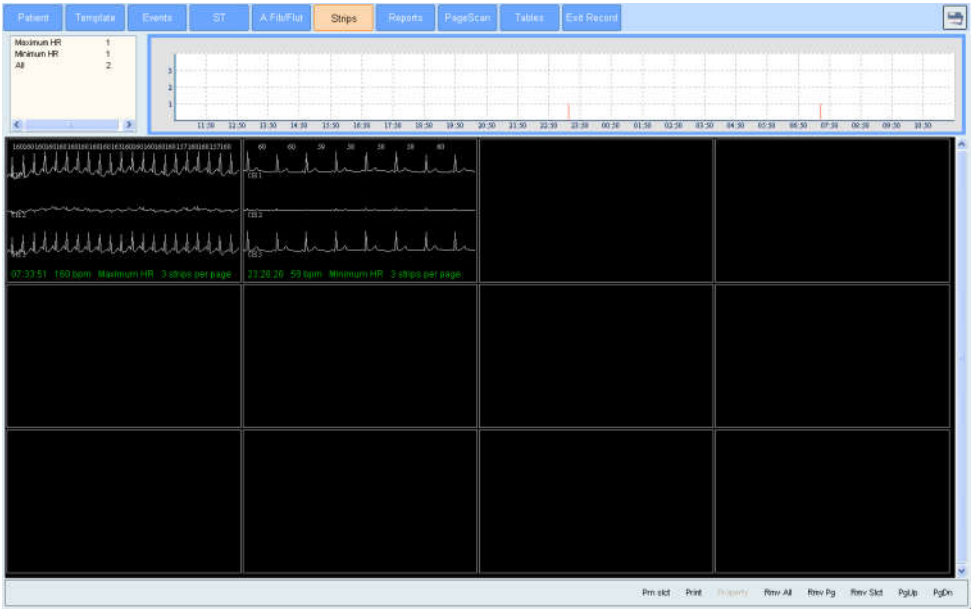
Observation and operation instructions for the R-R interval trend graph:

1. The horizontal coordinate of the trend graph is for heart beat, and the vertical coordinate is for R-R interval (ms), and every trend graph consists of 10-minute heart beat, and to highlight the variability in the R-R interval, the central line of the trend chart is the average R-R interval of the 10-minute period.
2. In the case of normal sinus ECG, the trend graph should be a smooth line near the central line. Please refer to the straight line in the sample chart.
3. In the case of atrial fibrillation/atrial flutter ECG, the trend graph is a segment of variable signal. Please refer to the variable signal segment in the sample chart.
4. The ECG of types shown as premature atrial beats, ventricular beats, escape beats, atrial tachycardias, ventricular tachycardia, bigeminy, and trigeminy have well definedcharacteristics in this trend graph.
5. Click the trend graph with the left mouse button to position the cursor and the ECG.
6. The arrow keys on the keyboard can be used to move the cursor.

7. The carriage return key can be used to define the start and end point of the atrial fibrillation/atrial flutter.

8. The DELETE key can be used to delete the atrial fibrillation/atrial flutter event where the cursor is positioned.

Saved episode



Saved ECG episodes during analysis are usually printed as strips.

The functional page is to re-confirm the strips that are to be printed.

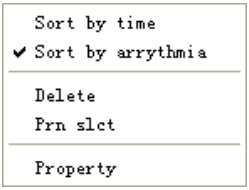
Two sources to save the episodes:

- One is automatically generated in accordance with the save setting in the parameter settings following the completion of automatic analysis;
- The other is generated when the operator selects the ECG with such functions as “Save episode” or image selection in the course of editing.

In this function page, all the saved episodes can be reconfirmed.

The episode function interface consists of the following sections:

- ✧ Episode list
  - ■ Show list by event type;
  - ■ Calculate the quantity of the episodes by the event type, and 0 means that there are no episodes of this type present.
- ✧ Episode distribution histogram window
  - ■ Display the episode distribution by time.
- ✧ Episode display zone
  - ■ Consisting of one set of small episode windows, these episodes can be selected individually and by multiple items.
  - ■ Click the right mouse button to open the fast operation menu (as displayed in the left figure).
  - ■ In the small episode window, o double click the mouse to open the ECG edit window.
  - ■ Scroll bar: Located on the rightmost of the episode display zone, it can be used to perform such operations as page scroll and dragging.
- ✧ Tool bar
  - ■ “Property”: Open the property setting window, and set the property of the selected episode. It can be used only when selecting a single episode.
  - ■ The “Delete selected”, “Delete page” and “Delete all” button can be used to delete the episode from the list.
  - ■ “Print”: Press the property setting of the episode to print all the episodes.
  - ■ “Print selected”: Follow the selected



sequence to print the selected episodes.

- ■ "Page Up" and "Page Down" button: Scroll page and view.

✧ ECG edit window

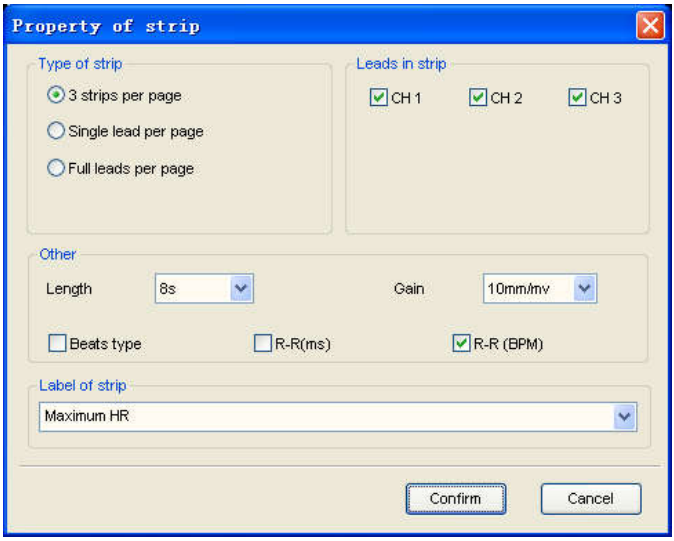
- ■ When double clicking the small episode window, the ECG edit window will open.
- ■ Click the "Return" button to close the ECG edit window and return to the episode display.

For the general operations, please refer to the following instructions.

Setting property of episode

The print property for every episode can be set.

Select one episode, and then click the "Property" button in the toolbar to open the "Episode property" window.



The property of the episode is described as follows:

1. For the type of episode, there are three options:

✧ "3 episodes per page": Print 3 episodes per page,

for every episode, at most 3-lead ECG is printed.

- ✧ "Single lead per page": Print single lead per page.
- ✧ "Full lead per page": Every page has one episode, and every episode has at most a 12-lead ECG.

2. Select channel that is related to the episode type.
   - ✧ "Single lead per page": Select only one lead.
   - ✧ "3 episodes per page": Select at most 3 leads.
   - ✧ "Full leads per page": Select all leads.
3. Other
   - ✧ Length, which is related to the episode type.
     - ■ "Single lead per page": Select only 72s.
     - ■ "3 episodes per page": Select at most 8s.
     - ■ "Full channel episode": Select 8s.
   - ✧ Gain, and the optional parameters are: 5 mm/mv, 10 mm/mv, and 20 mm/mv.
   - ✧ Heart beat type, R-R interval (ms) and R-R interval (heart rate) switch.
4. Episode Label: can be selected from the list, and may also be manually entered. The length of the label text shall not exceed 40 letter.

Browsing episode

The operation steps are as follows:

1. In the episode list, select the episode to be viewed.
2. When the number of episodes is over 9, the "Page Up" and "Page Down" button may be clicked to view by page. The scroll bar on the right can also be dragged to scroll the page.
3. Double click the small episode to load the ECG edit window to view this episode.

Resetting episode label

The episode label can also be reset. The labels of many episodes can be simultaneously modified.

The operation steps are as follows:

1. Select the episodes by which the label is to be modified.
2. In the label list, select the new label.
3. Or directly enter the new label in the label column.
4. Click the “Modify” button, and the selected episode label will be replaced by the new label.

Deleting episode

The saved episode can be deleted.

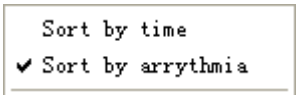
The operation steps are as follows:

1. From the episode list, select episode.
2. Select the episode to be deleted.
3. Click the “Delete” button to delete the selected episode.
4. Or click the “Delete page” button to delete all the episodes in the current page.
5. Or click the “Delete all” button to delete all the episodes on the current type.

Sorting by time or type

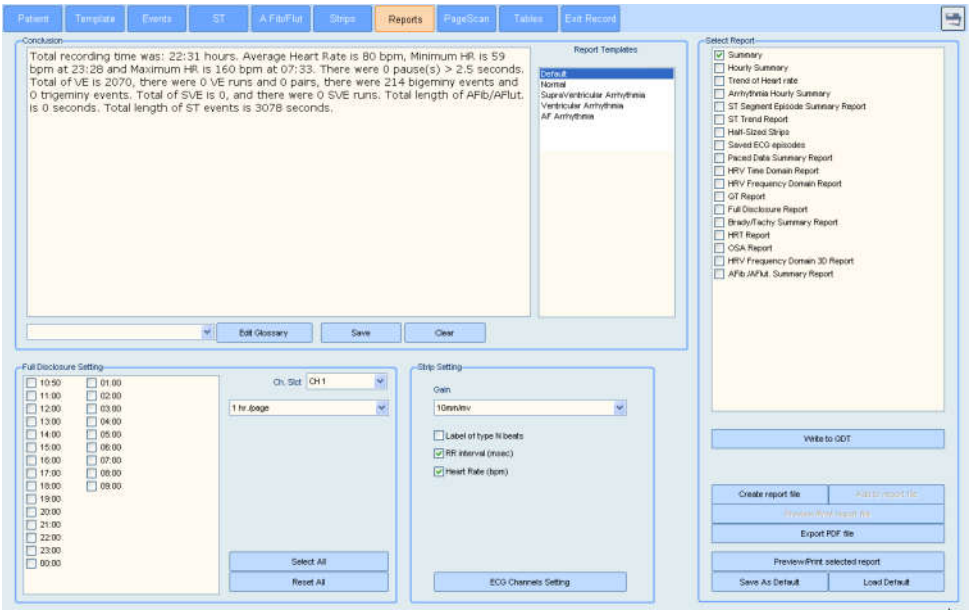
The operation steps are as follows:

1. In the episode, click the right mouse button, at this time the menu pops up:
   The saved episodes can be sorted by time,and sorted by type as well.



2. Select the type category.
3. The type category is also valid when the report is printed.

Report

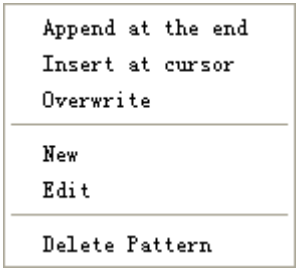


This function page provides the way to select, preview report and print report.

The functional interface consists of the following sections:

- ✧ Report list
  - ■ Display all the available reports. Before every report name, there is a check box, and the report is selected when marked with √.
- ✧ Conclusion edit window
  - ■ Directly enter the analysis conclusion in the conclusion edit window.
  - ■ Select the pre-defined glossary in the glossary list.
  - ■ Click the “Edit Glossary” button to enter into the glossary edit window.
  - ■ Select one Conclusion Template in the

"Report templates" to quickly create an analysis conclusion. The method is: Use the mouse to double click one template, and select an operation option from the "Append at the end", "Insert at cursor" and "Overwrite" in the pop up menu:



- Click the "Save" button to save the current conclusion.
- Click the "Clear" button to clear the content in the current conclusion window, and clear the saved conclusion.

✧ "Save as default": Save the checked report in the current report list as default report option.

✧ "Load default": Use the default report option to set the report list.

✧ Full disclosure setting
- Set the full disclosure report page type, there are two types for selection: 60 minutes/page and 30 minutes/page.
- Select the time of the full view to be printed, and the time in the list is set in accordance with the full disclosure report page type. Each time represents the starting time of the full disclosure ECGof every page.

✧ "Preview/Print selected report": Instant preview of the selected report.

- ✧ “Create report file”: Create new report file, and if the original report file exists, it will be overwritten.

  The report file is the file specifically used to store reports, which is separated from patient data and it can be individually saved, copied, previewed and printed.

  For patients with report files created, the report can be previewed and printed in the patient list without loading.

- ✧ “Add to report file”: Add the selected report to the created report file. Only when the report document is created, can this function be used.

  If the same report page already exists in the report file, the existing report page will be overwritten.

- ✧ “Preview report file”: Preview the created report file. Only when the report document is created, can this function be used.
- ✧ “Export PDF document”: Export the currently selected report as PDF file. This function works only when the valid PDF print facility is detected.
- ✧ “Write to GDT”: Export data file for the result of analysis and conclusion words in accordance with the GDT protocol. For more information on GDT, please refer to “GDT setting” in “Parameter setting”on P36.

Editing analysis conclusion

The conclusion text is entered into the conclusion edit window.

After completion of analysis, Cardio SW-Holter will automatically generate a “General report conclusion”.

The operator can also select one Conclusion Template in the “Report Templates” list to quickly create one conclusion. The method is: Use the mouse to double click one template, and select an operation option from the “Append at the end”, “Insert at cursor” and “Overwrite” in the pop up menu. The operator can create his/her own Conclusion Template, and for the details, please refer to Section “Conclusion Template” later.

The operator can insert the pre-defined glossary into the conclusion from the glossary list. Click the “Edit glossary” button to edit the glossary.

Click the “Save” button to save the conclusion text in the current edit window. After saving, the conclusion text will not be automatically replaced by the “General report conclusion” due to modification of the template and event. If the latest value is required, please load the “General report conclusion” from the “Report Templates”, or

Click the “Clear” button to clear the contents in the current conclusion window, and clear the saved conclusion and status.

Note: The conclusion text shall not exceed 500 letters.

Editing glossary

Click the “Edit Glossary” button to open the glossary

edit window, the edited glossary can be selected in the glossary list and appended to the conclusion edit window.

The selected glossary will be automatically inserted at the current cursor position in the conclusion edit window.

Saving default report setting/load default report setting

The required report can be set as default report, and in this way, it is not necessary to select reports repeatedly for every case.

The methods and steps to save default report are as follows:

1. Mark a √ in the checkbox in front of the name of every default report.
2. Click the "Save as default" button.

Click the "Load Default" button to restore the default report options.

Preview/Print report file

Click the "Preview/Print" button, and the system will automatically generate all the selected reports and open the preview/print report window.

For more detailed operations, refer to Section "Preview/Print Report" later.

Conclusion Template

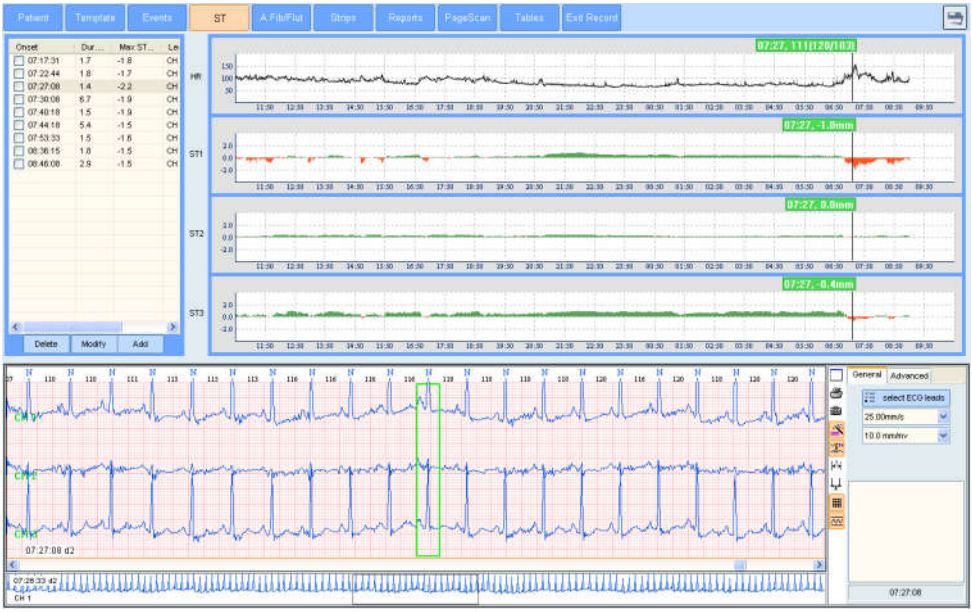
The general conclusions can be customized to templates, and the "Conclusion Template" can be used to quickly prepare conclusions:

1. Use the mouse to double click the options in the "Report Templates" list, and at this time the menu

pops up (as displayed in the left figure).

2. Select “Append at the end” for operation, so as to append the Conclusion Template to the end of the conclusion window.
3. Select “Insert at cursor” to append the Conclusion Template to the cursor position in the conclusion window.
4. Select the “Overwrite” to replace the Conclusion Template with the original words of the conclusion window.
5. Select “New” or “Edit” to open the Conclusion Templates Edit window, and the existing Conclusion Template can be created or modified:
6. The operations for the “Conclusion Templates Edit” are follows:
   - ✧ In the “Name” window, enter or modify the name of the Conclusion Template, and the name is then shown in the “Report Templates” list.
   - ✧ Enter the conclusion text in the “Content” window.
   - ✧ Select a data item in the “Data Items” list such as “Maximum heart rate”; and after a double-click, a data block ([#MAX_HR]) willl be inserted into the conclusion text. Cardio SW-Holter can automatically replace this data item with the data of the actual patient, for example, [#MAX_HR] is replaced with the maximum heart rate value.

ST Segment



The ST segment (from J point of QRS wave complex to the start point of T wave) is used to evaluate when the ST segment will be changed to one ST event. The ST event is judged in accordance with the measured ST segment shift, that is to say, 1 mm or more from the normal equipotential baseline (depending on the setting). To generate one ST event, the algorithm will detect the threshold of the ST event. (Refer to the instruction on P32) Every ST event will record the lead, time, duration, average value, maximum value and average heart rate.

This function page is used to:

- ✧ Validate the ST event generated by the algorithm.
- ✧ Remove false events (electrical interferences and artifacts can lead to an ST event).
- ✧ Generate and define a new ST event not

detected.

- ✧ View long-term ST change trend graph.

The validated ST events are listed in the "ST event list" report, and the total times of all the ST events are calculated in the total ST time (unit in second).

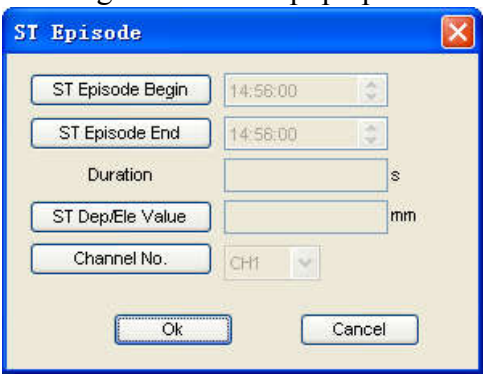
The functional interface consists of the following sections:

- ✧ ST event list
  - ■ Show the onset time of ST event, duration and ST depression/elevation amplitude.
  - ■ "Delete" button: Delete a selected ST event record.
  - ■ "Delete all": Delete all ST event records.
- ✧ "Delete" button: Delete the selected ST events
- ✧ "Modify" button: Modify the selected ST event message
- ✧ "Add" button: Add a new ST event
- ✧ Heart rate trend graph
  - ■ Show the average heart rate, maximum/minimum heart rate trend graph by minute increments.
- ✧ ST trend graph
  - ■ Display average ST trend graph per minute.
  - ■ View ST amplitude value at any time.
  - ■ Simultaneously the ECG edit window shows the ECG at this time (starting position per minute), and the measurement operation is performed on the ECG.
- ✧ Lead select buttons
  - ■ Consisting of the " ↑ " and " ↓ " button, the buttons can be used to select the trend lead.

- The data is valid only in the patient of 12-lead.

Modifying/adding ST event

After clicking the "Modify" or "Add" button, the following window will pop up:



1. Click the "ST segment begin" button to enable the starting time to set the ST event.
2. Click the "ST segment end" button to enable the ending time to set the ST event.
3. Click the "ST Dep/Ele Value" button to enable the entering of the ST value, and negative value represents depression.
4. Click the "Channel" button to enable the setting of ST channel.

Note: In the ECG Edit window, the ST event episode can also be added

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Pacing analysis

General

Cardio SW-Holter performs pacing analysis by studying the relationship between the heart beat and the pacemaker output signal (hereinafter called pulse). The key for correct analysis is the detection of a high quality output signal, and true pulse detection is performed in the Holter recorder which is required to enable the pacing pulse detection and separation. For more detailed operations, please refer to the operation manual of the Holter recorder.

Note: The operator should be advised that the pacing pulse detection can be subject to false positives and negatives. (Refer to the recorder operation manual).

Pacemaker code

The pacemaker codes define the working mode of the pacemaker. Please refer to the following table:

Type	Peacemaker cavity	Detecting cavity	Response	Programmable
Single	V	V	I	R
Double	D	D	D	R

The codes used are described as follows:

Code	Explanation
O	None
A	Atrial
D	Double
V	Ventricular
T	Trigger

I	Disabled
M	Multi programs
P	Single program

Pacemaker pulse analysis setting

To start pacemaker pulse analysis and detection in the Holter recorder must be enabled, the pacemaker parameters of Cardio SW-Holter must be set accordingly.The relevant parameters are as follows:

- ✧ Pacemaker pulse analysis on/off: enable or disable the pacemaker pulse analysis.
- ✧ Pacemaker pulse filter
  - ■ The ECG of patients implanted with a pacemaker can be effected by the pacemaker pulse to a degree, and the effected ECG influences the QRS detection and identification.
  - ■ Enable this switch to treat the ECG data when automatically performing analysis, and filter the pacemaker pulse.
  - ■ For some special patients treated with a pacemaker, the pacemaker pulse filtering can lead to the loss of QRS, requiring the filtering to be disabled.

Note: For every new patient treated with a pacemaker, the Pacemaker pulse filter switch is enabled by default.

- ✧ Rhythm setting
  - ■ The rhythm parameters of the pacemaker: These parameters are used to judge whether the pacemaker works normally.
  - ■ Minimum rhythm: The minimum start rhythm of trigger type pacemaker. It is the key parameter to identify whether the sensing of the pacemaker is failing.

- Hysteresis: It is a key parameter used to judge whether the pacemaker output is failing.
- Maximum rhythm: The maximum rhythm when the pacemaker is functioning.

✧ A-V interval: Set the minimum intervals for the atrial pacemaking and ventricular pacemakers. It is a key parameter for the dual chamber pacemaker.

✧ Pacemaker type selection. This parameter influences the detection of the paced beat type. If the pacemaker type is uncertain, it is recommended to set this parameter to DDD or DDDR type, and then Cardio SW-Holter will automatically perform the detection.

Pacemaker failure patients

The following general pacemaker failure patients exist:

✧ FTO (Failure to Output)
- Also called “Inhibition”
- When the pacemaker cannot output any pulse, FTO occurs, and on the ECG, extended R-R intervals can be observed.
- Normally, FTO is generated because the pacemaker cannot deliver an output pulse to trigger the heart. The possible causes may be pacemaker failure, incorrect pacemaker position or poor connection, and may also be a pathological change of the heart tissues in the electrode zone.
- Over sensitive pacemakers may incorrectly take the noise as one R wave so no output can be given.

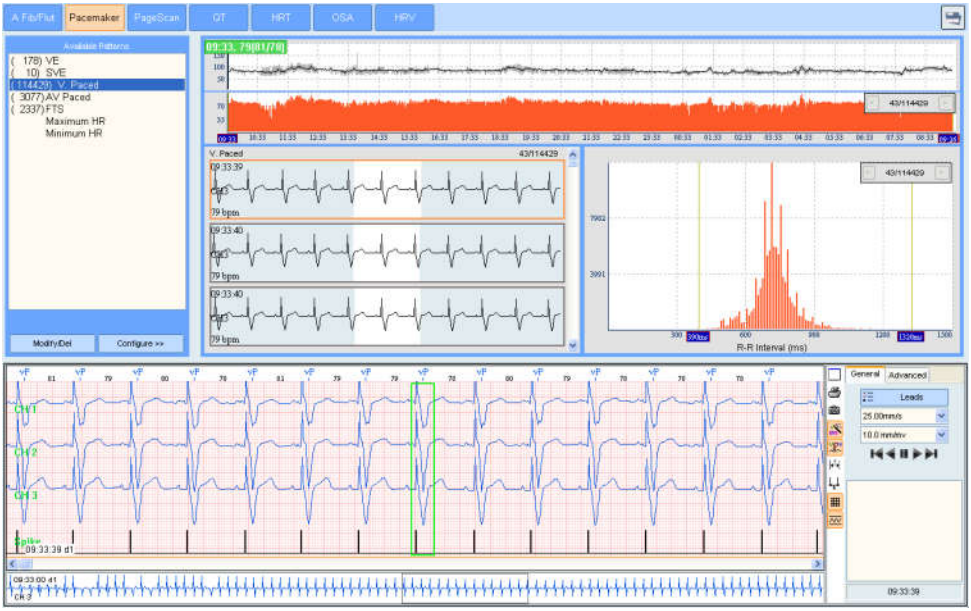
✧ FTS (Failure to Sense)

- When the pacemaker cannot correctly detect the ECG, FTS will be shown.
- The possible cause may be a problem with the pacemaker, poor electrode connection and may also be due to pathological change of the heart tissues in the electrode zone.

✧ FTC (Failure to Capture)

- The pacemaker is triggered, but FTC is generated when the heart beat cannot be triggered once.
- The cause may be due to the output being lower than the threshold required to trigger the heart beat once. This may be due to a loose electrode or incorrect position, damaged signal cable or low battery voltage.

Pacemaker analysis function window



This function page provides a statistical display and edit capability for the paced heart beat and possible pacing failure events.

The functional interface consists of the following sections:

- ✧ List and trend of paced heart beat and pacing failure event
  - ■ List statistics of various types of paced heart beat and pacing failure event.
  - ■ Heart rate trend graph, displaying the average heart rates per minute, and the maximum and minimum heart rate.
  - ■ Event trend distribution chart of RR interval.
  - ■ Event trend distribution chart by time.

- Modify and delete function button.

✧ ECG edit window

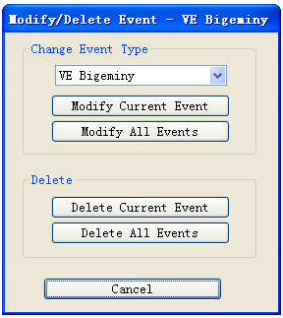
- Automatically position to show the current paced ECG.
- Automatically mark the pacing pulse.
- Will automatically fast play all the selected the pacing ECGs.
- Will measure the RR interval and pacing pulse front stage of ECG.
- The ECG in the entire 24 hours will be fast browsed.

For the normal operations, please refer to Section "Event edit" on P68.

Changing paced heart beat /pacemaker failure type

Perform corrections in this function page for errorst arising from paced heart beat or pacemaker failure type. The correction methods and steps are basically the same as those for the correction of the arrhythmia event. The specific steps are described as follows:

1. Select the object to be modified, which can be a single paced heart beat, some or all of the paced heart beats or pacemaker failure events.
2. Click the "Modify/Delete" button. At this time the "Modify Confirm" window pops up as follows:



3. In the type list, select the new type, and click the “Modify Current Event” or “Modify All Events” button, and the selected object type will be modified, and the list contents will be updated simultaneously.
4. Click the “Delete Current Event” or “Delete All Events” button to delete all the selected objects.
5. Click the “Cancel” button to directly return.

Page scan

The primary purposes of this function include:

1. Quickly browse the entire ECG
2. Quickly modify the heart beat type.
3. Add arrhythmia event.

The interface consists of the following sections:

- ✧ Zone 1: Long-term ECG display and edit window
  - ■ Display long-term ECG, and the optional terms are: 2 minutes, 4 minutes and 10 minutes.
  - ■ Display the ECG as a single lead, and each lead can be selected.
  - ■ Click the left mouse button to select the heart beat, and the ECG edit window below will correspondingly position to this heart beat.

- Press the left mouse button and move the mouse to select a segment of the ECG.
- Use the ← and → on the keyboard to move the heart beat, and the ECG window below will display accordingly.
- Click the right mouse button to open the operation menu, which provides operations such as modifying the heart beat type and the defined events.
- Use the scroll wheel of the mouse to fast scroll the page.
- On the scroll bar in the right side of the window, scrolling by one line/one page is provided.
- Keyboard: Modification key for heart beat type (refer to the heart beat type instructions on P55).

✧ Zone 2: trend graph

- Optional display: Heart rate trend graph or current valid event histogram.
- It Can also be used to select or position the ECG.
- Use the right mouse button to open the trend graph select list.

✧ Zone 3: ECG edit window

- Display zoomed in ECG.
- Provide edit functions.
- For details, refer to Section “General ECG edit window” on P42.

✧ Zone 4: Toolbar

- Set the ECG length displayed, the options are: 2 minutes, 4 minutes and 10 minutes.
- Select the display channel.

- Adjust the displayed amplitude of the ECG.
- "Page Up" and "Page Down" button: Display the ECG in the previous/next page.
-  Auto play button: Automatically play the ECG. During play, in the ECG zone, click the left mouse button to pause play.
- Enabling "Show arrhythmia" shows the arrhythmia mark.
- The time of ECG can be directly entered.

Modifying the heart beat type

Operation method:

1. First use the mouse to select the heart beat as a single heart beat, and also to select one segment of successive heart beats;
2. Click the right mouse button to open the operation menu;
3. Select the new type.

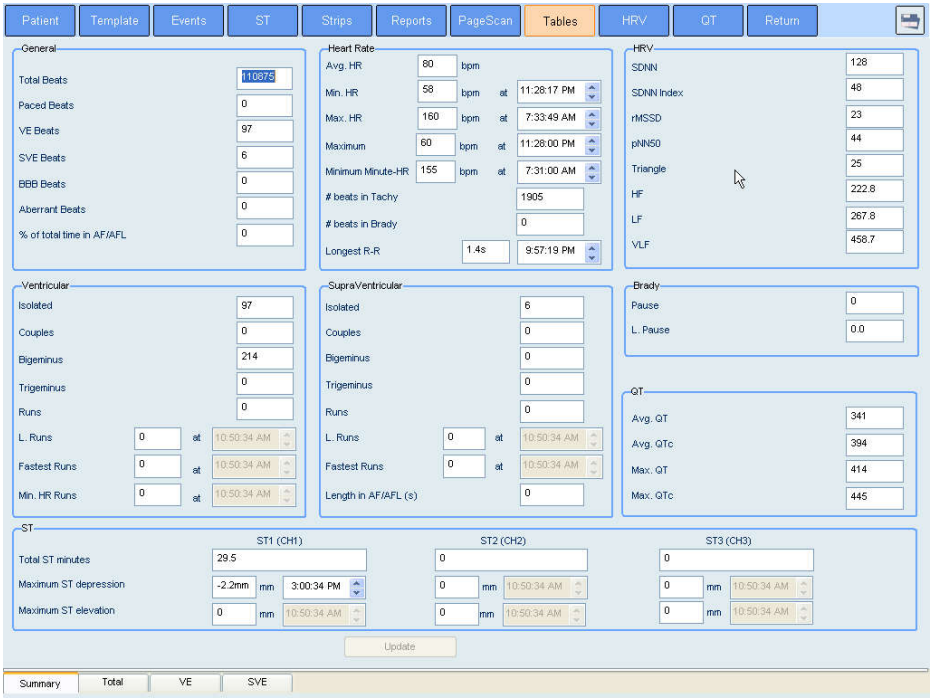
Defining the event

Operation method:

1. Firstly use the mouse to select the heart beat as a single heart beat, and also to select one segment of successive heart beats;
2. Click the right mouse button to open the operation menu;
3. Select the event type.

Note: Never use to define general arrhythmia events as ventricular premature and super-ventricular premature beats. Each arrhythmia patients can be automatically updated by Cardio SW-Holter by modifying the heart beat type.

Tables



"Tables" consists of several independent statistic data tables, which are: Summary, hourly summary, ventricular statistics and supraventricular statistics.

The function page button in the bottom of the screen can be used to select different lists.

The statistical data in the list can be modified and updated.

Heart rate variability

The "Heart rate variability" consists of the following function pages:

- ✧ RR interval dispersion graph
- ✧ Time domain trend graph
- ✧ Time domain trend list
- ✧ Frequency domain trend graph
- ✧ Frequency domain trend list
- ✧ 3-D chart of heart rate variability
- ✧ Long-term heart rate variability

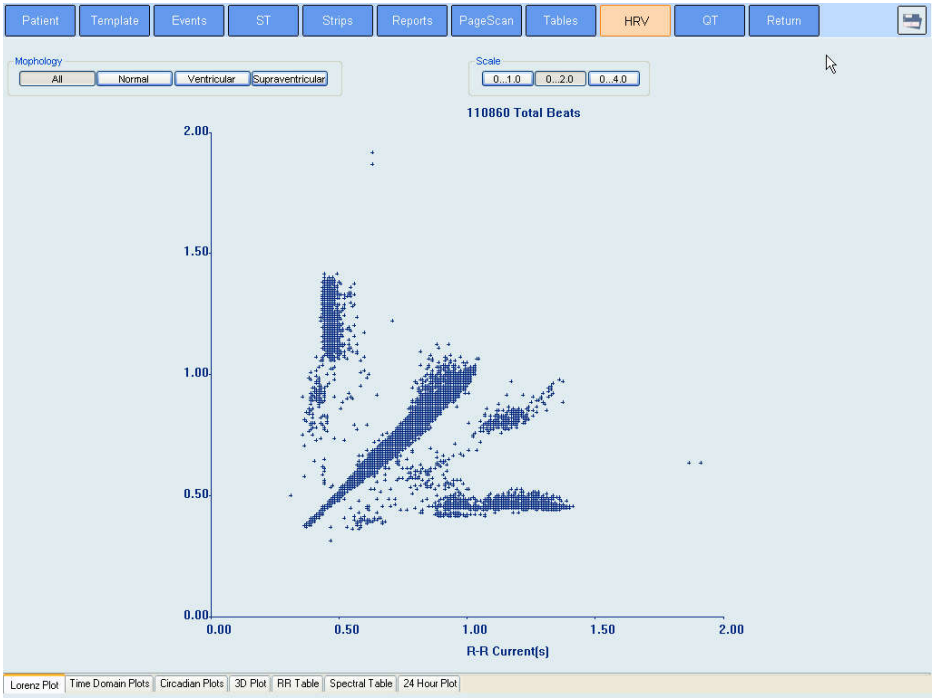
Note: As the method for calculation from various manufacturers is different, the frequency domain data from other manufacturers cannot be easily compared. In heart rate variability frequency analysis, patients with premature and missing beats should be avoided if possible, and the relevant module shall be used to edit the abnormal heart beat. For zones with large quantities of premature beats or missing beats, reference to the analysis data of the frequency domain in this zone will not be made.

RR interval dispersion graph

The RR interval dispersion graph is also called Lorenz Plot or Poincare Plot, which is used to reflect the changes of the adjacent RR interval.

In the preparation of the RR interval dispersion graph, the two adjacent sinus RR intervals are used as the coupling point, and the previous RR interval RRn (ms) is used for the horizontal coordinate. The later RR interval RRn+1 (ms) is for the vertical coordinate to determine one point; and then RRn+1 (ms) is used for the horizontal coordinate. The subsequent adjacent RRn+2(ms) is used for the vertical coordinate to determine a point, and so on. In a certain period of time, the distribution plot consisting of many dots is

established as below:.



The following operations can be performed for the RR interval:

- ✧ Type selection
  - ■ Dispersion chart of all the valid heart beats
  - ■ The dispersion chart of the normal heart beats
  - ■ The dispersion chart of the ventricular heart beats
  - ■ The dispersion chart of the supraventricular heart beats
- ✧ Zoom in or zoom out

  In accordance with the horizontal coordinate range, the following settings can be selected.
  - ■ 0 - 1.0(ms)
  - ■ 0 - 2.0(ms)
  - ■ 0 - 4.0(ms)

Time domain trend graph

The time domain trend graph includes the following parameters (the step length for the statistics is set in accordance with the short-term step length, and the default value is 5 minutes):

- ✧ SDNN (ms): Standard deviation of normal sinus R-R intervals
- ✧ SDSD (ms): Standard deviation of adjacent R-R interval difference
- ✧ rMSSD (ms): Root mean square value of adjacent normal sinus RR interval difference
- ✧ PNN5O(%): Percentage of total beats of adjacent R-R intervals > 50ms in the total RR intervals
- ✧ Tri. Index of HRV: Total of RR interval divided by height of RR interval histogram.
- ✧ MeanRR(ms): Average RR interval.

Time domain trend graph instructions:

- ✧ Two parameters produce a set of trend graph, and the horizontal coordinate is for time, the vertical coordinate is for parameters. The left and right scale, corresponds to the curve color and the coordinate color.
- ✧ Click any specified position in any trend graph to show the specific value of all the parameters at that moment.

Time domain trend list

Similar to "Time domain trend graph" parameters. There is an additional Beats data item, indicating the heart beats participating in the analysis.

Frequency domain trend graph

The frequency domain trend graph includes the following parameters (the statistical step length is set in accordance with the short-term step length, and the default value is 5 minutes):

- ✧ TP (ms^2): Total power, which is the total power of frequency less than or equal to 0.4Hz.
- ✧ VLF (ms^2): Extremely low frequency power, which is the total power of frequency less than or equal to 0.04Hz.
- ✧ LF (ms^2): Low frequency power, which is the total power of frequency between 0.04 and 0.15Hz.
- ✧ HF (ms^2): High frequency power, which is the total power of frequency between 0.15 and 0.4Hz.
- ✧ LFnorm: Low frequency normal power, of which the formula for calculation is LFnorm=LF*100/(TP-VLF).
- ✧ HFnorm: High frequency normal power, of which the formula for calculation is HFnorm=HF*100/(TP-VLF).

Frequency domain trend graph operation:

- ✧ The horizontal coordinate of the trend graph is for time, and the vertical coordinate is for parameters. There is a left and right coordinate scale. TP, VLF, LF and HF correspond to the left coordinate scale, and Lfnorm and Hfnorm correspond to the right coordinate scale. Different colors are used to distinguish various parameters.
- ✧ Whether the curve of the specified parameter is displayed can be selected in accordance with the requirements.
- ✧ The time range of the horizontal coordinate can be set, and the options are:
  - ■ 1 hour
  - ■ 2 hours

- 4 hours
- 8 hours
- 16 hours
- 24 hours

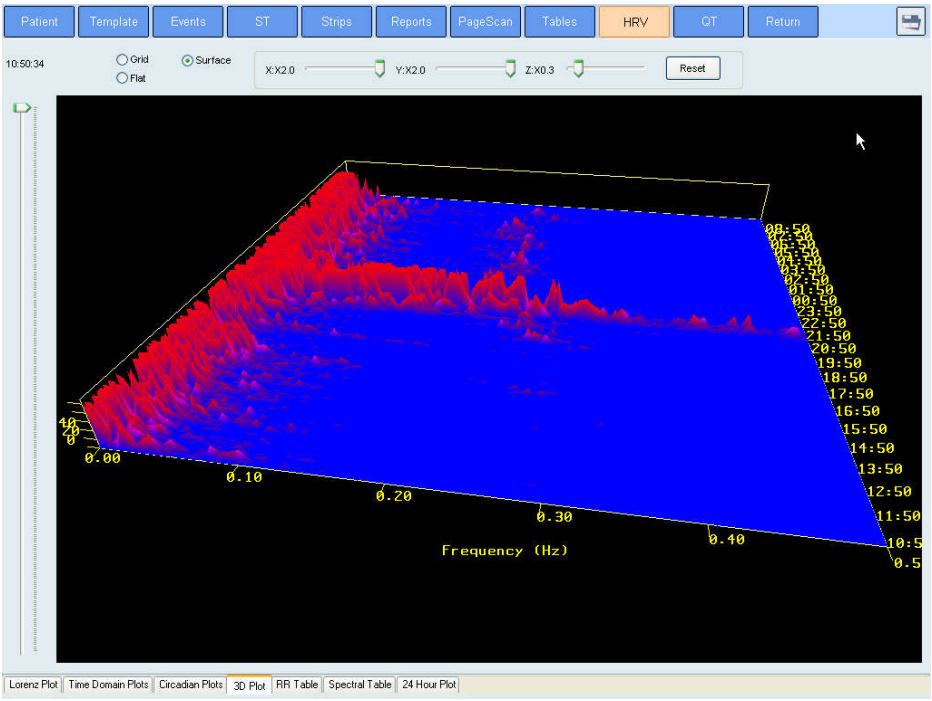
✧ The slider on the left can be used to control the start time displayed.

✧ Click the specified time in the trend graph to show the relevant parameter message at that moment.

Frequency domain trend list

The parameters in the list are basically the same as those in the "Frequency domain trend graph", except an additional normal beats parameter, which indicates the proportion of the normal heart beats at that time.

3D plot of heart rate variability



Operation instructions for a 3D plot:

- ✧ The 3D plot includes the X, Y, and Z coordinate, the X coordinate corresponds to the frequency, the range is 0 - 0.5 Hz, and the Y coordinate is for power, the unit is ms^2, and the Z coordinate is for the time coordinate, and every time range corresponds to one power spectra curve.
- ✧ Select the display mode:
  - ■ Grid
  - ■ Flat
  - ■ Texture
- ✧ Adjust the X, Y and Z slider to zoom in or zoom out the 3D plot in the X, Y and Z planes.
- ✧ Rotation: In the image display zone, press the left

mouse button and move the mouse to the left, and the image will revolve around the Y axis counterclockwise. Press to move the mouse to the right and the image will revolve around the Y axis clockwise. Moving the mouse up or down, the image will revolve around the X axle.

✧ By moving the left slider, the start time of the Z axis will be changed.

Long-term heart rate variability

The long term heart rate variability shows the frequency domain data and the time domain data, includes:

- ✧ Whole course long term heart rate variability
- ✧ Sleeping long term heart rate variability
- ✧ Waking long term heart rate variability

Operations for long time heart rate variability:

- ✧ Set waking time: By changing the setting of the wake time, the difference of the heart rate variability between the sleeping and waking time can be accurately confirmed.
- ✧ Power spectra trend graph: The horizontal coordinate is for the frequency, and the unit is Hz, and the vertical coordinate is for the power, and the unit is ms^2.
- ✧ RR interval histogram: The horizontal coordinate is

for the R-R interval, and the unit is ms, and the vertical coordinate is for the heart beats.

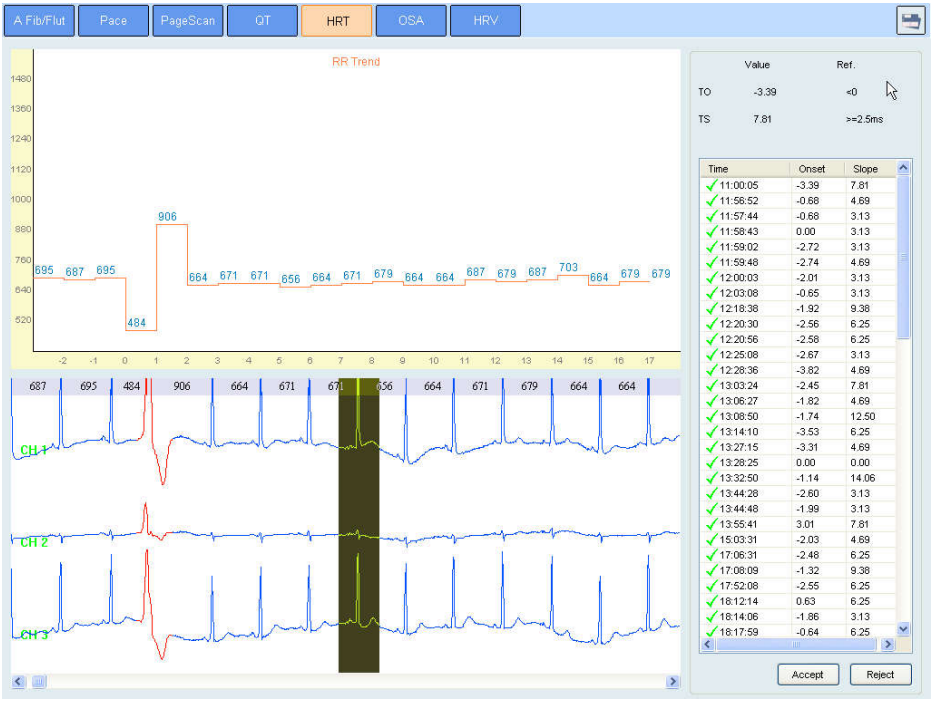
Heart rate turbulence

Heart Rate Turbulence (HRT) is the physiological response of the sinus node to premature ventricular contractions characterized by a short acceleration followed by a deceleration of the heart rate. That is the sensitivity of sinus node to a change of premature ventricular contraction. It has the following main parameters:

- ✧ Turbulence start (T0)
  - ■ Difference between the sum of the two normal RR intervals following and the sum of the two normal RR intervals preceding the premature ventricular contraction, which is divided by the latter, reflecting the acceleration of the heart rate after a premature ventricular contraction.
  - ■ Formula for calculation

  TO = ((RR1 + RR2) - (RR-2 + RR-1)) / (RR-2 + RR-1) * 100
- ✧ Turbulence slope (TS)
  - ■ It describes whether the phenomenon of deceleration after premature ventricular contractions exists. The steepest slope of the linear regression line for each sequence of five consecutive normal intervals following the premature ventricular contraction in the local averaged heart rate measurement.

The sinus heart rate is characterized by a short acceleration followed by a deceleration after premature ventricular contractions, and this phenomenon is often seen in normal subjects or low-risk patients.



In this function page, review, accept, and reject the selected heart rate turbulence event.

The functional interface consists of the following sections:

- ✧ RR interval plot
  - ■ Display RR interval of the sinus cardiac rhythm preceding and following the ventricular premature beat.
- ✧ ECG display window
  - ■ Automatically position and display the ECG of the current event.
- ✧ Heart rate turbulence event list
  - ■ Display the turbulence event of all the valid heart rates.
  - ■ The contents displayed include: time, onset, and slope.

- ✧ “Reject” button: Reject the current selected event as non-valid heart rate turbulence event. The reject event will not participate in the calculation of the final average value.
- ✧ “Accept” button: Accept the selected event.

For the general operations, please refer to the following instructions.

View the heart rate turbulence event

1. Select any record in the right list.
2. The RR interval plot shows the RR interval plot of the selected event.
3. The ECG window displays the ECG when the heart rate turbulence occurs.

Reject heart rate turbulence event

Reject non-valid heart rate turbulence events.

1. Select any record in the right list.
2. The ECG window displays the ECG when the heart rate turbulence occurs.
3. Click the “Reject” button
4. A “X” mark appears before the selected event,.

OSA

Obstructive sleep apnea (OSA) is a regular apnea caused by intermittent blockage of the respiratory duct during sleep. Around the world, millions of people are influenced by this symptom, and OSA is frequently related to diseases and death. Currently few medical measures can be used for detection and diagnosis.

OSA can frequently change the dynamic variability of the normal heart rate. In normal breathing, the dynamic change of the heart rate is displayed as broad-band reversed power law spectrum distribution. On the contrary, in the period of sleep apnea, the heart rate is typically shown to correspondingly increase and decrease with the obstructive breathing blockage and the breathing restoration cycle. These cycles are normally frequency turbulences between 0.01 and 0.04Hz, which is the feature of OSA to be distinguished from normal breath. By automatically identifying the dynamic change of the heart rate of the RR interval turbulence, Cardio SW-Holter detects and quantifies the frequent OSAs.

Hilbert algorithm is an analyzing technology which changes one set of time sequence to the corresponding transient amplitude value and frequency. With this algorithm, the time sequence of the RR interval is changed to the transient amplitude value and frequency unit, and the average value of these units are quantified for calculation and the stability of these values in terms of time, and thus the periodic heart ratevariability time of long term apnea is distinguished from normal breathing characteristics.

The following are the six experimental value ranges of the distribution parameter for detection:

AVAMP (Average Amplitude)	0.65 ~ 2.5
SDAMP (Standard Deviation of Amplitude)	0 ~ 0.6
AVFREQ (Average Frequency (Hz))	0.01 ~ 0.055
SDFREQ (Standard Deviation of Frequency)	0 ~ 0.01
AMPTime (Time above amplitude threshold)	0.006 ~ 1.0
FREQTime (Time within frequency thresholds)	0.7 ~ 1.0

Function window:

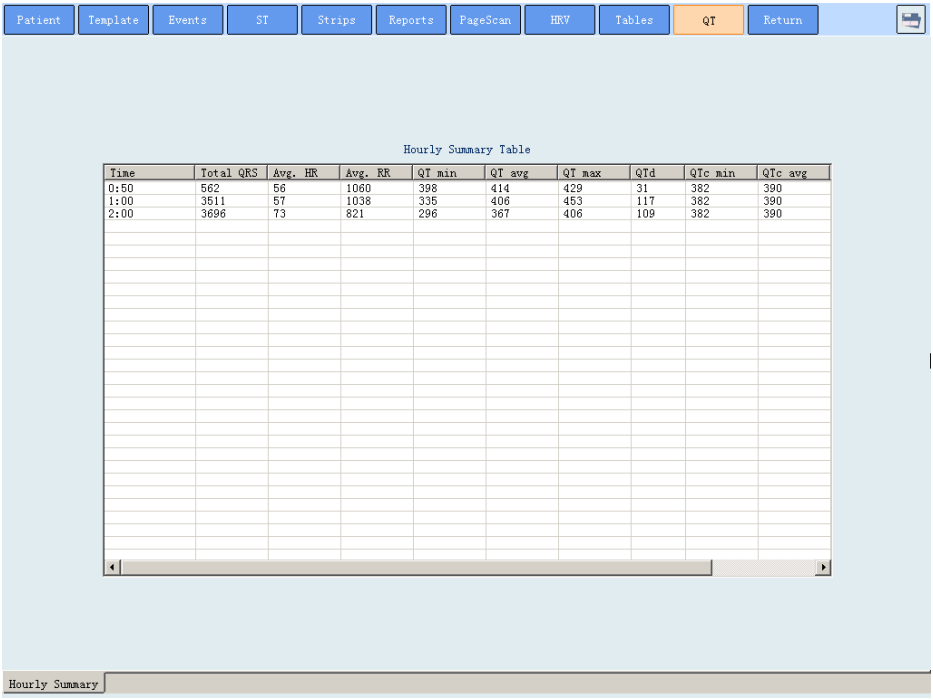
Operation instructions:

1. Click the “Recal.” button: Calculate and analyze the OSA event.
2. In the upper left edit window is the threshold for OSA to determine the parameters. After adjustment and modification, the “Recal.” button should be

clicked to enable validation.

3. Click the “Reject” button: Delete the selected events in the OSA event list.
4. Click the “Accept” button: Accept the deleted OSA event.

QT



Hourly Summary Table

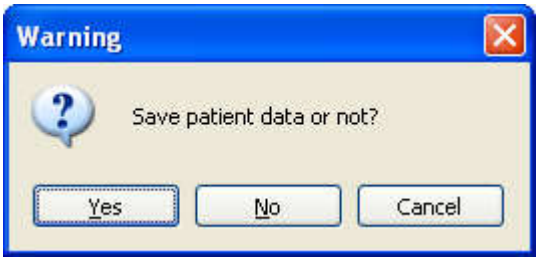
Time	Total QRS	Avg. HR	Avg. RR	QT min	QT avg	QT max	QTd	QTc min	QTc avg
0:50	562	56	1060	398	414	429	31	382	390
1:00	3511	57	1038	335	406	453	117	382	390
2:00	3696	73	821	296	367	406	109	382	390

Show hourly summary of QT data. The data include:

- Time
- Heart beat
- Hourly average heart rate
- Hourly average RR interval
- Minimum QT
- Average QT
- Maximum QT
- QTd
- Minimum QTc
- Average QTc
- Maximum QTc
- QTcd

Exit edit

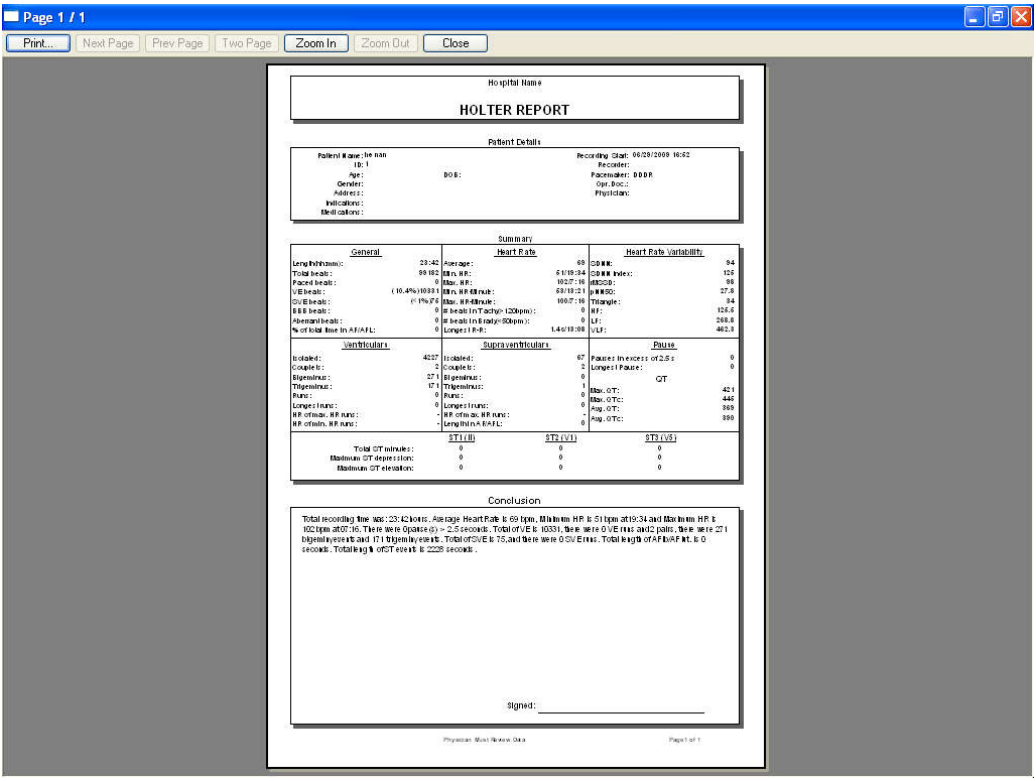
Click the page button to “Exit”, the pop up window prompts:



- Select “Yes”: Save the patient and return to the first interface;
- Select “No”: Do not save the patient and return to the first interface;
- Select “Cancel”: Cancel the exit operation.

7 Preview/Print Report

In the “Report” function page, select the report to be printed/previewed, and click the “Print /Preview” button, and an independent “Preview/Print Report” window will open:



The “Preview/print report” window consists of the following sections:

- Title bar of the window, which can show the current page number and the total number of pages.
- The report function buttons include:
  - “Print” button, which is used to output all the previewed report pages to the printer.
  - “Next page” and “Prev page” button, which can

be used to load any previewed report pages.

- "Two page", which is used to show two report pages on one screen.
- The "Zoom in" and "Zoom out" button can be used to zoom in/zoom out the report page.

– The report page is easy to view. When the mouse is moved to the report page, the cursor will show as the  icon. At this time, when the left mouse button is clicked, zooming in/zooming out the current report page is possible.

Attachment 1 Operating requirements for Cardio SW-Holter

Minimum configuration requirements of PC

Item	Requirement
CPU	Intel P4 2.6G Hz or above
Memory	1GB or above
Hard disk	160GB
Others	FLASH card reader with an USB interface At least 2 USB interfaces
Printer	HP or HP compatible laser printer

Requirements of the operating system

Cardio SW-Holter has been tested and operated in the following operating systems:

1. Windows 2000 Professional version
2. Windows 2000 Server version
3. Windows XP SP2
4. Windows 2003
5. Windows Vista
6. Windows 7

Attachment 2 Troubleshooting

In the case of a problem during use, the following table can be referenced for solutions. In the case of any damage or problem, stop using the equipment immediately, and contact the dealer or the manufacturer, but never make any repair without authorization.

Problem	Possible cause	Solution
The program is stopped, with no symptom.	The USB-Key is removed.	Re-insert the USB-Key.
Note: *Hardware key not found*	The USB-Key is removed. Or USB port not set.	Re-insert the USB-Key or reconfigure USB port.
The print preview is abnormal, but actually the printing is normal.	Possibly a virtual printer is installed (including the virtual printing of Office), and the default printer is not a local external printer.	1. Set the local external printer as the default printer. 2. If allowed, delete the other virtual printer(s). 3. If the problem still cannot be solved, download a new printer driver and reinstall the printer drive program.
It is required to print on B5 paper.	The default output of Cardio SW-Holter is print report on A4 paper.	Adjust the "Print preference" of the printer: 1. Paper size: A4 2. Scale output: B5 **Note**: For different printer models, the scale output setting positions are different.
Click the "New Patient" and the following message	The free disk space in the current work directory is	Please delete the patients and ensure that there is

is displayed: *"New Patient" function is unusable!* *The free space in the current directory is insufficient. Please backup and delete the patient data!*	not sufficient.	sufficient space in the work directory.
In the new patient window, the following message is displayed: *AECG data cannot be found! Please check.*	1. The recorder is not well connected or the flash card is not inserted. 2. The recorder or the card reader is connected, but the contact is poor. 3. The AECG data type is incorrect.	1. Reconnect the recorder or the card reader, until the correct connection message is displayed. 2. The same as Item 1. 3. Contact the technical support personnel.
When clicking the next step in “New Patient”, the following message is displayed: *Patient number cannot be null!*	No patient number is entered.	Enter the patient number. It can be the patient number and also the serial number can be entered.
When clicking the “Export patient” or “Delete patient” button, the following message is displayed: *Please select patient first!*	No patient to be exported or deleted is selected.	Tick the patient to be exported or deleted. **Note**: **The deleted patient cannot be restored.**
Click the “Start analyze” button, and the following message is displayed:	Cardio SW-Holter detected that there is pacemaker recorded data.	Confirm whether the patient is implanted with a pacemaker.

Pacemaking analysis disabled! Are you sure you want to continue?	When the electrode drops off or the interference is very high, the pacemaker recorded data generated in pacemaker pulse detection can be triggered.	1. If a pacemaker is implanted, please cancel and start the pacemaking analysis switch to start analysis again. 2. If no pacemaker is implanted, please confirm to continue.
When clicking "Cancel and return", the following message is displayed: *Data were not saved and can be lost! Are you sure you want to cancel and return?*	Cancel creating a new patient. If the new patient is canceled, the archive will be deleted.	1. Please confirm whether to cancel the patient. **Note**: **After cancelling, the patient data will not be saved.** 2. If you do not want to cancel, but do not want to continue analysis, please click the "Start analyze" button, and after completing the automatic analysis, click the "Return" button in the edit interface.
Note: *Any previous modification of the arrhythmia event will be updated. Are you sure you want to carry out analysis again?*	In the event edit, when modifying the event rule parameters, the user will be informed of the precautions.	Confirm to continue or cancel the update.

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