

# EDAN Agile PLM Electronic Signature Information

--Signatures related to this document and performed in EDAN Agile PLM.

文件名称(Document Name) : Holter分析软件说明书\_英文

文件编号(Number) : 01.54.456516

版本(Version) : 2.1

产品型号(Product Model) : SE-2003;SE-2003A;SE-2012;SE-2012A

项目编码(Project Code) : 2410C005

## 签批信息(Signature):

作者(Originator) : 张 妞 (zhangniu) 2023-12-12 16:28:52

审核人(Reviewers) : 魏 丹莉 (weidanli) 2023-12-12 18:44:51

审核人(Reviewers) : 黄 炜乐 (huangweile) 2023-12-13 14:50:38

批准人(Approvers) : 沈 东雪 (shendongxue) 2023-12-14 11:26:13

SE-2003&SE-2012 Series

Holter System

Analysis Software

Version 2.1

# User Manual



## **About this Manual**

P/N: 01.54.456516

MPN: 01.54.456516021

Release Date: Dec. 2023

© Copyright EDAN INSTRUMENTS, INC. 2014-2023. All rights reserved.

## **Statement**

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which Edan Instruments, Inc. (hereinafter called EDAN) cannot be held liable.

EDAN owns the copyrights of this manual. Without prior written consent of EDAN, any materials contained in this manual shall not be photocopied, reproduced or translated into other languages.

Materials protected by the copyright law, including but not limited to confidential information such as technical information and patent information are contained in this manual, the user shall not disclose such information to any irrelevant third party.

The user shall understand that nothing in this manual grants him, expressly or implicitly, any right or license to use any of the intellectual properties of EDAN.

EDAN holds the rights to modify, update, and ultimately explain this manual.

## **Responsibility of the Manufacturer**

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

## **Terms Used in this Manual**

This guide is designed to give key concepts on safety precautions.

### **WARNING**

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

### **CAUTION**

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

### **NOTE**

A **NOTE** provides useful information regarding a function or a procedure.

# Table of Contents

<b>Chapter 1 Safety Guidance</b> .....	<b>1</b>
1.1 Indications for Use/Intended Use .....	1
1.2 Warnings and Cautions .....	1
1.2.1 Safety Warnings .....	2
1.2.2 General Cautions .....	2
1.2.3 Protecting Personal Information .....	2
1.3 List of Symbols .....	4
<b>Chapter 2 About the Manual</b> .....	<b>7</b>
2.1 Application of the Manual .....	7
2.2 Applicable Object .....	7
2.3 Product Reference .....	7
2.4 Legend and Name .....	7
<b>Chapter 3 Introduction</b> .....	<b>8</b>
3.1 Components .....	8
3.2 Features .....	8
3.3 System Installation and Running Requirements .....	9
3.4 Software Installation .....	10
3.5 Main Screens .....	14
3.6 Basic Functions .....	14
3.7 Advanced Functions .....	15
<b>Chapter 4 Patient Record Management</b> .....	<b>16</b>
4.1 Main Menu .....	16
4.2 Registering Patient Information .....	19
4.3 Scanning ECG Data .....	19
4.3.1 Scan .....	20
4.3.2 Import .....	20
4.4 Archiving a Patient Record .....	20
4.5 Restoring a Patient Record .....	21
4.6 Exporting a Patient Record .....	21
<b>Chapter 5 ECG Data Analysis</b> .....	<b>22</b>
<b>Chapter 6 ECG Data Editing</b> .....	<b>26</b>
6.1 Editing Patient Information .....	26
6.2 Editing Template .....	26
6.2.1 Template Analysis .....	26
6.2.2 Editing Superimposed Graph .....	31
6.2.3 Editing Histogram .....	32
6.2.4 Editing RR Bird View .....	33
6.2.5 Editing Poincare Plot .....	34

6.2.6	Editing Poincare Plot and Superimposed Graph .....	35
6.2.7	Keyboard Operation and Other Useful Operations .....	36
6.3	General ECG View Window .....	40
6.3.1	Inserting Beats .....	41
6.3.2	Deleting Beats .....	42
6.3.3	Modifying Beats .....	42
6.3.4	Modifying Successive Beats .....	42
6.3.5	Inserting Beats in Batch .....	43
6.3.6	Measuring ECG .....	43
6.3.7	Quick Browse of ECG .....	44
6.3.8	Saving ECG Strip .....	44
6.3.9	Relocating R Waves .....	45
6.3.10	Printing ECG .....	45
6.3.11	Defining an Arrhythmia Event .....	45
6.3.12	Display Options .....	46
6.4	STe .....	47
6.4.1	ST Event List .....	48
6.4.2	HR Trend .....	49
6.4.3	ST Trend .....	49
6.4.4	ST Reanalysis .....	50
6.5	Events .....	51
6.6	Strips .....	54
6.7	Page Scan .....	55
6.8	Trend .....	56
6.9	Tabular .....	56
6.10	HRV .....	57
6.10.1	HRV Histogram .....	59
6.10.2	HRV Table .....	59
6.10.3	Power Spectrum Graph .....	61
6.11	QT .....	61
6.12	Pacing Electrophysiology .....	62
6.12.1	Pacing Event Definition .....	62
6.12.2	Pacing Histogram .....	63
6.12.3	Pacing Trend .....	64
6.12.4	Pacing Events .....	64
6.13	Statistic Information .....	65
6.14	Report .....	65
<b>Chapter 7 System Settings .....</b>		<b>67</b>
7.1	Common Setting .....	67
7.2	Workflow Setting .....	67

7.3	Analysis Setting.....	68
7.4	View.....	69
7.5	Maintenance.....	69
7.6	GDT.....	70
7.7	File Output Setting.....	71
<b>Chapter 8</b>	<b>System Tips.....</b>	<b>72</b>
<b>Chapter 9</b>	<b>Maintenance.....</b>	<b>73</b>
<b>Chapter 10</b>	<b>Accessories.....</b>	<b>74</b>
<b>Chapter 11</b>	<b>Warranty and Service.....</b>	<b>75</b>
11.1	Warranty.....	75
11.2	Contact Information.....	75
<b>Appendix 1</b>	<b>Abbreviations.....</b>	<b>76</b>

# Chapter 1 Safety Guidance

This chapter provides important safety information related to the use of SE-2003&SE-2012 Series Holter System analysis software.

## 1.1 Indications for Use/Intended Use

The SE-2003&SE-2012 Series Holter System (including recorder and analysis software) is intended to record, analyze, display, edit and generate report of ambulatory ECG. The Holter System is intended to be used by trained personnel under the direction of doctors. The analysis results are offered to doctors on an advisory basis only. The Holter System is intended for adult, pediatric patients including infants weighing less than 10 kg.

It can be used for the following indications:

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
2. Evaluation of patients for ST segment changes.
3. Evaluation of drug response in patients taking anti-arrhythmic medications.
4. Evaluation of patients with pacemakers.

## 1.2 Warnings and Cautions

In order to use the software safely and effectively, and avoid the possibility of system failure, firstly be familiar with the operation method of Windows, and read the user manual in detail and be sure to be familiar with the proper operation method of SE-2003&SE-2012 Series Holter System analysis software and Holter System Recorder. The following **WARNING** and **CAUTION** must be paid more attention to during the operation of the system.

### **NOTE:**

1. This system is not intended for home use.
2. The pictures and screens in this manual are for reference only.



## 1.2.1 Safety Warnings

---

---

### **WARNING**

1. Failure to follow the safety instructions for operating the instrument and system could endanger the patient. The manufacturer accepts no liability for damages resulting from improper use.
  2. The system should be installed by qualified service engineers. Do not switch on the power until all cables have been properly connected and verified.
  3. The user should get professional training and read this manual in detail before using the system.
  4. This system is not intended for treatment.
  5. Do not move the main unit or the monitor while working.
  6. Only accessories supplied or recommended by the manufacturer can be connected to the system.
- 
- 

## 1.2.2 General Cautions

---

---

### **CAUTION**

1. Federal (U.S.) law restricts this device to sale by or on the order of a physician.
  2. Do not bend or press the CD.
  3. Keep the CD away from direct sunlight and high temperature. Otherwise, the CD may become deformed.
  4. Do not touch the disk surface of the recorded side. If the surface becomes contaminated with any foreign substance such as fingerprints, reading data may be impossible.
  5. Clean the CD with a disk cleaner. Do not use organic solvents such as acetone.
  6. This CD-ROM disk is not an audio CD, and cannot be played with an audio CD player.
  7. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 °C and 45 °C during operation.
  8. Do not use the system in a dusty environment with bad ventilation or in the presence of corrosive. Avoid vibration.
  9. Do not handle the CD while smoking or eating.
  10. Do not get the CD wet.
- 
- 

## 1.2.3 Protecting Personal Information

Protecting personal health information is a major component of security strategy. To protect the personal information and ensure the proper device performance, the user should take necessary precautions in accordance with local laws and regulations and institution's policies. Manufacturer recommends health care organizations or medical institutions to implement a

comprehensive and multifaceted strategy to protect the information and systems from internal and external security threats.

To ensure the patients' safety and protect their personal health information, the user should implement practices or measures that include:

1. Physical safeguards - physical safety measures to ensure that unauthorized personnel do not have access to the system.
2. Operational safeguards - safety measures during operation.
3. Administrative safeguards - safety measures in management.
4. Technical safeguards - safety measures in technical field.

---




### **CAUTION**










- 1 The access/operation of the system is restricted to authorized personnel only. Assign only staff with a specific role the right to use the system.
- 2 Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e. cannot remove without tools).
- 3 Make a backup of data on a periodic basis.
- 4 Ensure that the system is connected only to the device authorized/approved by manufacturer. Users should operate all system deployed and supported by manufacturer within specifications authorized by manufacturer, including the software, software configuration, security configuration, etc. approved by manufacturer.
- 5 Protect all the passwords to prevent unauthorized changes. Only the manufacturer's service personnel are allowed to modify the Maintenance settings.
- 6 Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.
- 7 When connecting the system to a shared network, data security issues of the network topology and configuration must be considered. Since the patient sensitive data are not encrypted and might be transmitted from the system to the network, the medical institution should be responsible for the network security. Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It's recommended to use Windows defender firewall or any other firewall that can defend against Dos and DDos attacks, and keep it up to date.
- 8 Dos and DDos protection of the router or switch must be turned on for defending against attacks.
- 9 When the system is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are







removed from the system.

- 10 For security, disable all unused USB and network ports.
- 11 When deploying the network, it is recommended to isolate the network and the Intranet system of the hospital by using VLAN so as to ensure the network security. Only trusted devices are allowed to join the VLAN network.
- 12 Please protect the privacy for the information and the data displayed on the screen, and for the information and the data stored in the system.
- 13 When building the networking environment: 1) If a wireless router is used, please turn on the MAC address filtering function of the wireless router and add the MAC address of the system to the rule list. The wireless router only allows devices in the rule list to access the wireless network. 2) It is suggested to build a VLAN, assign the LAN ports where the approved switch port and the system are into the same VLAN, and isolate them from other VLANs.
- 14 It is advised not to establish administrator and guest accounts.
- 15 The system does not support file or file folder sharing which will cause irreversible data lost or damage.
- 16 Destroy the sensitive information in the idle or scrapped device.
- 17 It is recommended that you activate Windows password strategy.

### 1.3 List of Symbols

NO.	Symbol	Description
1		Caution
2		Consult operating instructions
3		General symbol for recovery/recyclable

4	P/N	Part Number
5		SERIAL NUMBER
6		Date of manufacture
7		MANUFACTURER
8		CE marking
9		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
10		Disposal method
11	<b>Rx Only</b>	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
12		This way up
13		Fragile, handle with care
14		Keep away from rain

15		Stacking limit by number
16		Handle with care
17		Do not step on
18		Front
19		Medical Device
20		Unique Device Identifier

**NOTE:** The user manual is printed in black and white.

# Chapter 2 About the Manual

## 2.1 Application of the Manual

The manual mainly introduces functions of analysis software and the way to operate it.

## 2.2 Applicable Object

The manual is applicable to clinical professionals and other authorized users.

## 2.3 Product Reference

In this manual:

- ◆ A computer running analysis software is called "Analysis Host".
- ◆ Holter System analysis software is shortened to "analysis software".
- ◆ Ambulatory ECG recorder is called "Holter System Recorder" or "Recorder".
- ◆ Menu options to start a new process, open window/menu or input information by clicking your mouse in the active windows called "Buttons".

## 2.4 Legend and Name

All legends provided in the manual are just for examples.

All names shown in examples and legends are imaginary. It is coincidence if somebody happens to have the same name with that in the manual.

## Chapter 3 Introduction

The SE-2003&SE-2012 Series Holter System is intended to be used in hospitals and clinics. It should be used by trained personnel under instructions of physician to evaluate long-term ambulatory ECG data. The analysis results generated by the system are only reference for physicians to make clinical diagnoses and treatment. The exact diagnosis decision and therapeutic procedures lie with the physician.

---

---

### **WARNING**

Operators should familiarize themselves with the clinical operating procedures of Holter prior to use.

---

---

### **3.1 Components**

The SE-2003&SE-2012 Series Holter System has the following components:

- ◆ Holter System Recorder that has four models: SE-2003, SE-2012, SE-2003A, and SE-2012A.

The analysis software is only intended to analyze ambulatory 3/12-channel ECG data from recorder manufactured by Edan Instruments, Inc.

To avoid errors, check and enter the patient data carefully. For details, please refer to *SE-2003&SE-2012 Series Holter System Recorder User Manual*.

- ◆ Patient Cables
- ◆ Holter System Analysis Software

### **3.2 Features**

- ◆ Supporting multi-channel beat detection
- ◆ Accurate classification of QRS morphology
- ◆ Supporting automatic detection of arrhythmia
- ◆ Supporting re-analysis
- ◆ Reviewing, editing, and saving strips
- ◆ Supporting full disclosure of ECG
- ◆ Template analysis, event analysis, ST analysis, pacing analysis, HRV time-domain/frequency-domain analysis, and QT analysis
- ◆ Customizing workflows

### 3.3 System Installation and Running Requirements

#### **CAUTION**

1. This system can only be operated at secure networks. Otherwise, patients' information and health conditions may leak.
2. Install anti-virus software in the PC that runs this system and update the software timely.
3. If the PC is not purchased from our company, we will not be held responsible for the maintenance of the PC hardware or the operating system.
4. Sharing of files or file storage folders on the network is not supported by the SE-2003&SE-2012 Series Holter System Analysis Software and may cause irreversible data lost or corruption.
5. Install the SE-2003&SE-2012 Series Holter System Analysis Software in dedicated PC to ensure the Holter System Analysis Software runs properly.

#### **NOTE:**

1. This system can only be operated at secure networks. Otherwise, patients' information and health conditions may leak.
2. Install anti-virus software in the PC that runs this system and update the software timely.
3. If the PC is not purchased from our company, we will not be held responsible for the maintenance of the PC hardware or the operating system.

System installation and running requirements are given in the table below.


Item	Configuration	Requirements
PC hardware	CPU	Intel P4 2.6G Hz or above
	Memory	2G or above
	Hard Disk	100G or above
	Main Board	The main board of Intel chipset is recommended
	Display:	19" TFT or above, 16 bit actual color, regular icon and font setup Supported resolution: 1366×768, 1440×900, 1920×1080
	Printer	HP LaserJet printer (Resolution: 600 dpi or above)
	Others	FLASH card-reader using USB port At least 2 free USB ports 24x or above CD-ROM
PC software	PC system	Windows XP SP3 Windows 7, 32 bits/64 bits

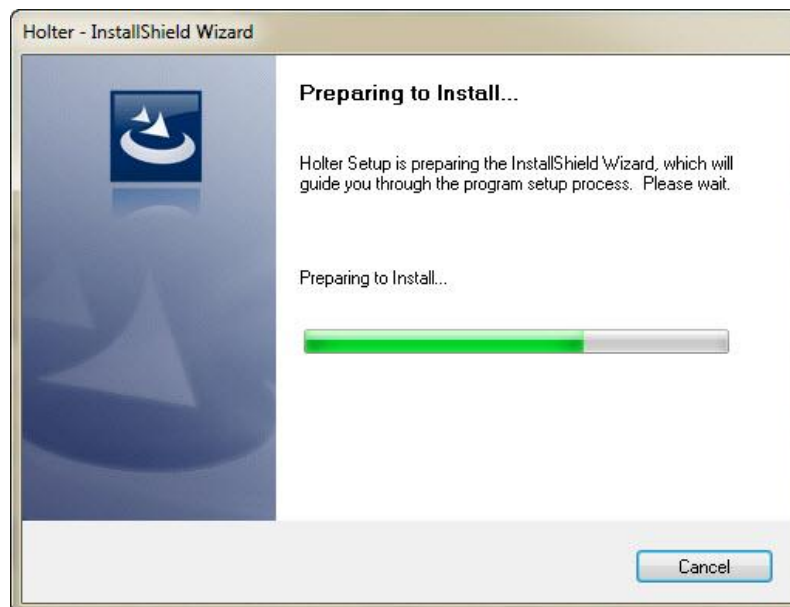


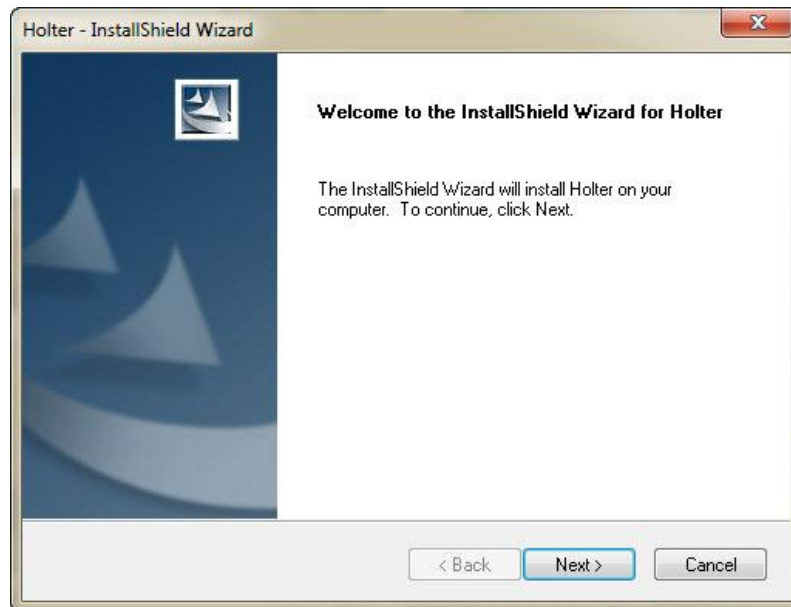
		Windows 8, 32 bits/64 bits Windows 10, 32 bits/64 bits
Power requirements	Operating voltage	220±22 V~
	Operating frequency	50±1 Hz
Working environment	Temperature	5°C to 45°C
	Relative humidity	10% RH to 95% RH (non-condensing)
	Atmospheric pressure	70 kPa to 106 kPa

### 3.4 Software Installation

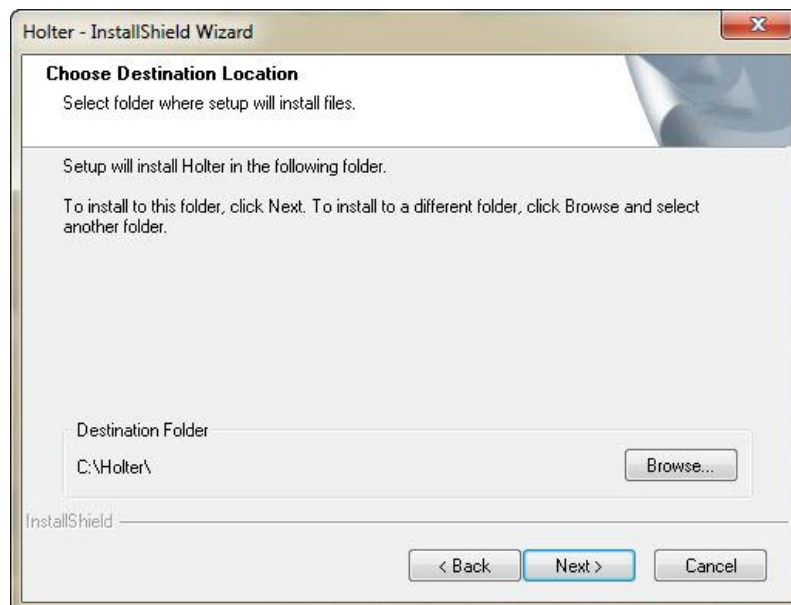
The procedure for installing the analysis software are as follows:

1. Insert the installation CD into CD-ROM, and double-click on **setup.exe** . The following windows will be displayed.

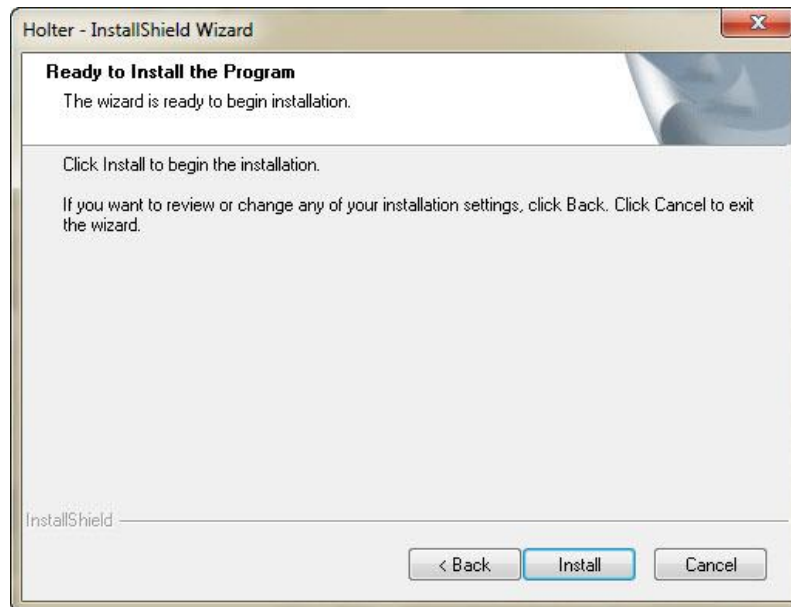




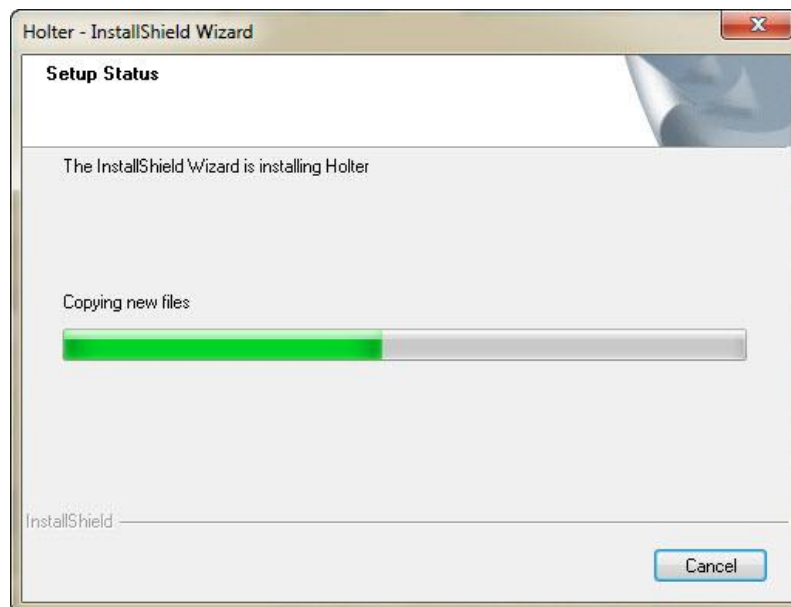
2. Click on the **Next >** button and the following window will be displayed.

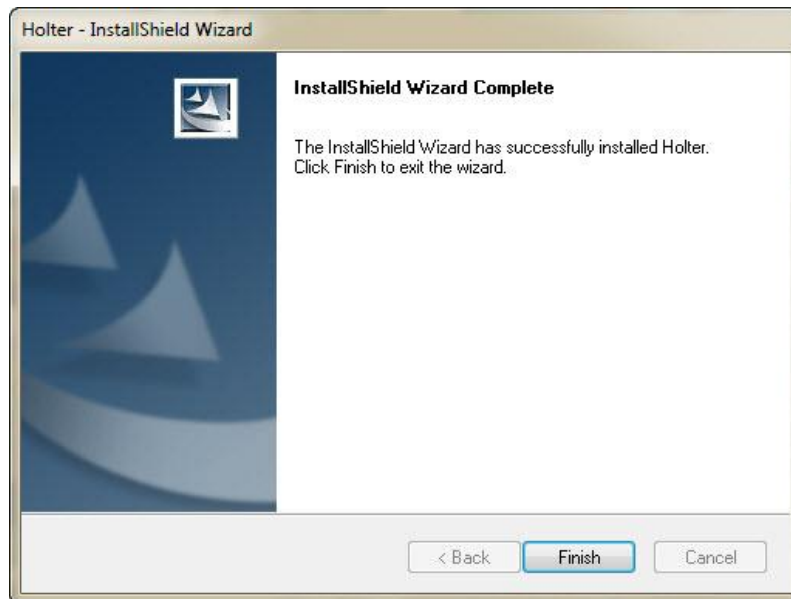


3. Click on the **Next >** button to install the analysis software to the default folder. Or click on the **Browse...** button to choose the installation path, and then click on the **Next >** button to continue. The following window will be displayed.



4. Click on the **Install** button to continue.





5. Click on the **Finish** button. The analysis software is installed successfully.

**NOTE:**

1. Insert the dongle before starting the analysis software.
2. It is recommended to shut down other applications before using the software.

### 3.5 Main Screens

To perform automatic analysis and create a report, you may enter the following screens in a workflow.

Screen	Description
Main menu	The main menu is displayed when you start the analysis software and it provides access to functions like Register Patient Info and Recorder DB.
Patient information input	Input patient information.
Analysis setting	Set analysis parameters before automatic analysis of a patient record.
Record editing and analyzing	Review, edit and report analysis results after completion of automatic analysis
Report preview/printing	Preview report before printing.

### 3.6 Basic Functions

- ◆ Patient Information Registration.

Input, modify, or delete the patient information, including name, age, gender, and record time etc.

- ◆ Archive, restore, import, and export patient records.

- ◆ Automatic analysis

1) The system uses three channels for analysis to ensure all the heartbeats are detected.

2) Arrhythmia analysis

Automatically analyzes ECG data, identifies and marks the beats as N (normal), V (ventricular), S (atrial), aP (atrial pacing), vP (ventricular pacing), and avP (AV dual pacing) etc.

Automatically identifies arrhythmia events such as isolated VE, VE couplet, VE runs, VE bigeminy, VE trigeminy, bradycardia, tachycardia, pause, isolated SVE, SVE couplet, SVE bigeminy, SVE trigeminy, atrial fibrillation/flutter, abnormal ST segment, pacing FTC/FTS/FTO, etc.

3) HRV analysis

Displays RR histogram, Poincare plot, power spectrum graph, and SDNN trend.

4) QT interval analysis

Displays the QT list, QT histogram, and QTc percentage.

### 5) ST analysis

Displays the ST trend of 12 leads.

After resetting the ST measurement points, you can refresh the results without reanalyzing.

Calculate myocardial ischemia load.

#### ◆ Replay

Replay ECG waveforms and HR trend throughout the record. Automatically read patient information from the Recorder.

#### ◆ Event

Identify the events marked by the patient.

Add, modify, and delete events, and display the ECG strip when an event occurs.

#### ◆ Statistics

Count the number of arrhythmia events, HR, and ST deviation and allow you to edit the value.

#### ◆ Beat editing

View, merge, and reclassify beats in the **Template** tab.

Insert, delete, and modify beats in the ECG view window, with event types and related statistical data synchronized automatically.

Edit beats by means of histograms. More than 20 types of histograms are available.

#### ◆ Allow you to define an ECG strip as an event. The ECG strip can be printed vertically or horizontally.

#### ◆ Report printing

Print diagnosis report, statistical charts, strips, trend charts, histograms, ECG full disclosure, and Poincare plot etc.

Provide various types of comment and select what you want to be shown in the diagnosis report.

## 3.7 Advanced Functions

The following advanced functions are configurable:

- ◆ T wave alternans analysis
- ◆ SAECG analysis
- ◆ VCG analysis
- ◆ Waterfall plot analysis

# Chapter 4 Patient Record Management

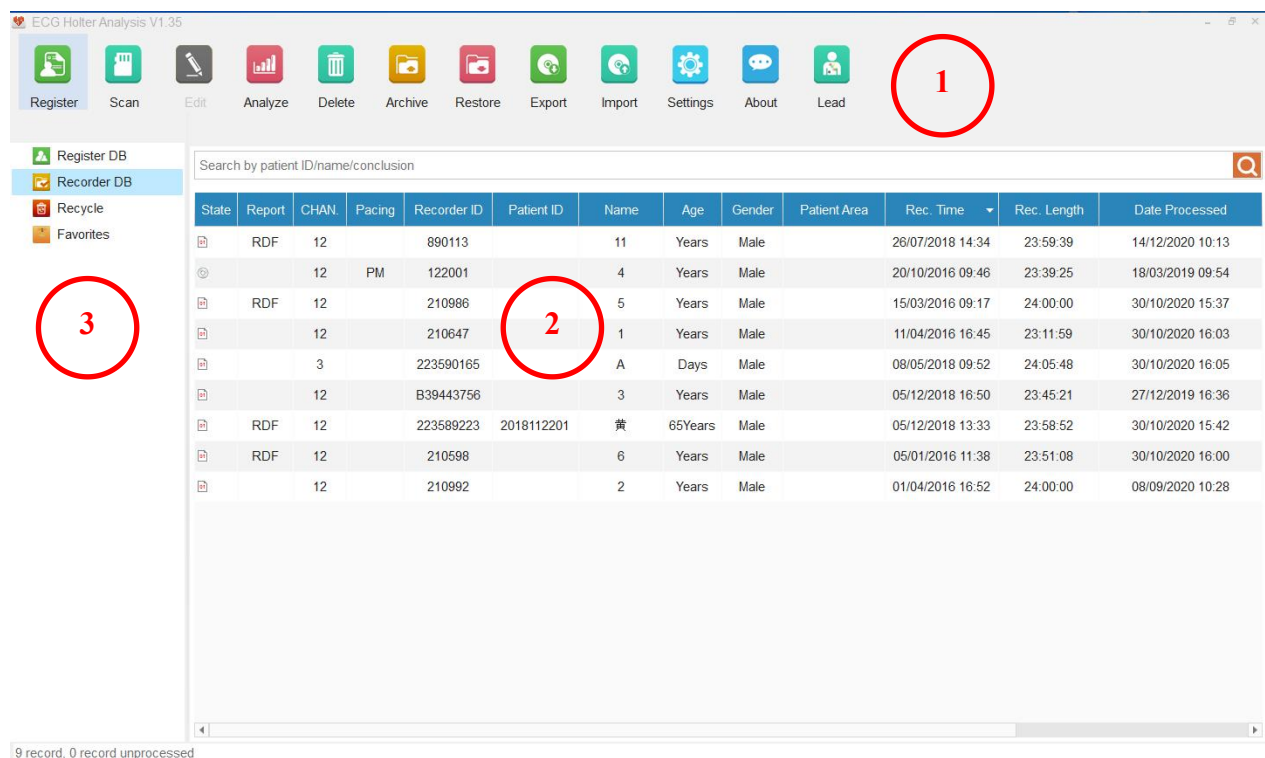
## CAUTION

Please ensure that patients' ECG data are completely imported to Holter analysis software before using this software.

### 4.1 Main Menu

Double click on the Holter icon on the desktop to start the program.

The main menu of Holter Analysis System is displayed as below:



#### ***Region 1 Main Toolbar***


The main toolbar contains the following options:

Option	Description
Search	Enter patient name, ID, and diagnostic conclusion to search for ECG data.


<b>About</b>	Obtain software information.
<b>Lead</b>	View lead placement.
<b>Register</b>	Register patient information.
<b>Scan</b>	Load data from the Recorder or other external memory.
<b>Edit</b>	Modify the patient information and ECG data of the selected record.
<b>Analyze</b>	Analyze the selected examination record.
<b>Delete</b>	Delete patient records. If the record is deleted from the <b>Recycle</b> folder, the data will be deleted permanently.
<b>Archive</b>	If a record is archived, only its diagnosis report remains. The original ECG data and analysis data will be stored in the specified memory. In this way, more system storage space will be available.
<b>Restore</b>	Recover the archived data.
<b>Export</b>	Export data to other memories.
<b>Import</b>	Import data from other memories.
<b>Settings</b>	Set system parameters.

### **Region 2 Patient Record List**

A patient record can be in the following status:

: Newly imported record

: Analyzed record

: Diagnosed record

: Archived record

You can only see the patient information and diagnosis report if a record has been archived.

If a record is marked with **RDF** in the **Report** column, it indicates that a report has been generated for the record.



If a record is marked with **PM** in the **Pacing** column, it indicates that pacemaker analysis has been performed for the record.

Right click on the patient record list, a menu will be displayed. The menu contains the following options.

Option	Description
<b>Select All</b>	Select all the records.
<b>Reset All</b>	Not Select any record.
<b>Cancel Task</b>	Cancel analysis task for the patient records that are waiting in line.
<b>Move to...</b>	Move the record(s) to another folder.
<b>Copy to...</b>	Copy the record(s) to another folder.
<b>View conclusion</b>	Display the manually input comment.
<b>Collection</b>	Add the record(s) to the <b>Favorites</b> folder.
<b>Report</b>	Review the report.

### Region 3 Storage Folders

The three storage folders are used to:

- ◆ **Register DB:** store registered patient information.
- ◆ **Recorder DB:** store data from the Recorder.
- ◆ **Recycle:** store data deleted from Recorder DB.
- ◆ **Favorites:** store the collection of data.

Right click on a storage folder, a menu will be displayed. The menu contains the following options.

Option	Description
<b>Default Folder</b>	Set the selected folder as the default folder. Imported data will be stored in this folder automatically.
<b>New Folder</b>	Create a new data folder. The name of the new folder cannot be the same as those of the existing folders.
<b>Rename</b>	Rename the selected folder. The name of the four folders provided by the system cannot be modified.
<b>Delete</b>	Delete the selected folder. Data in the deleted folder will be transferred to the <b>Recycle</b> folder automatically.

**CAUTION**

Data that are deleted are unable to be restored. Please make a backup before deleting the data.

Users should make a backup of historical data on a periodic basis.

## 4.2 Registering Patient Information

A patient can be registered before ECG recording. Click **Register** on the main toolbar, the following window will be displayed.

On this window, you can:

Input patient information and click **Save** to save the patient information to the **Register DB**, or click **Register** to save the patient information to the Recorder.

Click **Print** to print an Events Card for the patient to record daily activities and symptoms.

Click **Notes** to edit the notes to be printed on the Events Card.

## 4.3 Scanning ECG Data

After ECG recording, you have to import the data to the Holter Analysis Software. There are two ways of data import: scan and import.

### 4.3.1 Scan

To import a single record:

1. Click **Scan** on the main toolbar. The system automatically enters the Single Import window and scans the sampled data.
2. Click **Next Step**. The sampled data will be stored in the Recorder DB, and the system automatically enters the analysis setup screen.

To import records in batch:

1. Click **Scan > Batch Import**.
2. Set scan path.  
System will go through the chosen disk or given path for ECG data. If data are stored in the SD or CF card, click Removable Disk for search.
3. Click **Scan** to start data search.  
The search path will be remembered by the system. All found data will be listed in a window.
4. Select the data to be imported. Click **Import**.
5. When data is successfully imported, remove the external memory.

### 4.3.2 Import

Import records that have been exported from Holter analysis software before.

1. Click **Import** on the main toolbar.
2. Select records in **arc** and **zarc** format. Click **Open**. They will be listed in the import window.
3. Click the check box before records that you want to import and select the storage folder from the drop-down list.
4. Click **Import**. Records are successfully imported.

## 4.4 Archiving a Patient Record

To save system storage space, patient records are archived, which means you transfer ECG data in patient records to external memories (hard disk or compact disk), leaving only patient information and diagnosis report in the system.

To archive a patient record:

1. Click the check box before a record in the Recorder DB. Click **Archive** on the main toolbar.
2. Select the saving path and click **Archive**. System will transfer ECG data to the target memory.
3. Status of the record is changed to be archived.

**NOTE:** Please ensure the external memory is marked and stored for the possibility of future use.

## 4.5 Restoring a Patient Record

To restore a patient record:

1. Click the check box before an archived record. Click **Restore** on the main toolbar. The **Restore** window will be displayed.
2. Select the memory where the record has been archived and click **Restore**. The system automatically searches for and restores all ECG data of the record.

## 4.6 Exporting a Patient Record

Copy ECG data of a patient record to other memories. To export a patient record:

1. Click the check box before the patient record(s) to be exported. Click **Export** on the main toolbar. The **Export** window will be displayed.
2. Set the export path.
3. Exported record will be named by the system by default unless you change it.
4. Click **Export**. ECG data of the record are copied. The data file is in **arc** format. If **Compress data** is clicked, it will be **zarc** format.

# Chapter 5 ECG Data Analysis

System will automatically analyze the ECG data after they are scanned and enter the analysis screen below. In this screen, you can set the analysis parameters. If you need to reanalyze the ECG data, go to the **Pat. Info** tab, click **Reanalyze**.



This screen contains the following options.

Option	Description
Channel Setting	<p>Analysis channels include one important channel and two ancillary channels. Data analysis is based on the important channel. But if the signal of this channel is weak, ancillary channels will be used for analysis.</p> <ul style="list-style-type: none"> <li>◆ Important channel. We recommend that you pull the scroll bar to quickly browse the entire ECG, and select a channel with good signals, large QRS amplitude, and ectopic beat waveform as the important channel.</li> <li>◆ Ancillary channels. They are used only when multi-channel analysis is activated. Exclude channels with poor signal quality and small signal amplitude. Choose a channel with large T wave amplitude and good signal quality for QT analysis.</li> </ul>

ST Setting	<ul style="list-style-type: none"> <li>◆ Click &lt;&lt; and &gt;&gt; buttons to move E point (baseline), J point, and ST point.</li> <li>◆ To move the vertical indication line: place the cursor onto the line, and keep your left mouse button pressed to move the line.</li> </ul>	
Noise Level	See Chapter 7 System Settings.	
Child mode	Use pediatric algorithm to analyze ECG data.	
Auto remove interfer.	Enable the system to automatically remove ECG interference signals and not to analyze them.	
Multi CHAN analyze	To activate this function, see Chapter 7 System Settings.	
Pacing Setting	Click the check box before <b>Pacemaker analysis</b> . Select pacemaker type from the drop-down list. Choose to do pacing event analysis or not.	
Parameter setting	Set the following rhythm parameters.	
	Isolated VE	Early ventricular beat followed by a non-ventricular beat
	VE Couplet	Two consecutive ventricular beat
	VE Runs	Three or more consecutive ventricular beats
	VE Bigeminy	V-N occurs in couple for specified times
	VE Trigeminy	V-N-N occurs in couple for specified times
	Bradycardia	Number of heartbeats less than or equal to the predefined heart rate is continuously greater than the specified number
	Tachycardia	Number of heartbeats more than or equal to the predefined heart rate is continuously greater than the specified number
	Long RR interval(PAUSE)	Longer than the specified RR interval Note: The default value is 2000ms.
	Atrial	A premature or escape beat from an atrium or node (functional); or an abnormal atrial premature beat. Set the percentage of prematurity, number of beat as reference, compensatory pause, HR variation range, and RR interval.

	PAC Couplet	Two consecutive atrial cardiac beats
	Atrial Tachycardia	Three or more consecutive atrial cardiac beats
	Atrial Bigeminy	When SN occurs in couple for consecutive specified number of times
	Atrial Trigeminy	When SNN occurs in couple for consecutive specified number of times
	Max./Min. HR	Set the number of QRS to be involved in the mean value calculation. You can select whether to allow ectopic heartbeat (including pacing) to be involved in calculation of maximum and minimum heart rates.
	ST	In lowering events, ST depression is greater than the specified value and its duration longer than the specified time. In raising events, ST elevation is greater than the specified value and its duration longer than the specified time.
	Pacing	The pacing event analysis function is available only when <b>Pacemaker analysis</b> is enabled. <ul style="list-style-type: none"> <li>◆ FTS: When the spacing between the initial pacing value and former beat is less than the specified value.</li> <li>◆ FTC: when beat is not detected for more than a specified time after initial pacing value.</li> <li>◆ FTO: When RR interval or RP interval is greater than the specified value.</li> </ul>
	HRV	Set the length of analysis, high frequency range, low frequency range, and very low frequency range for HR variability.
Analysis start and end	Click some point on the ECG where the signal is good as the start of analysis. Click <b>Start</b> . And another good point behind as the end of analysis. Click <b>End</b> . ECG data between the start and end points will be analyzed while the other data out of this range are excluded. The length of time out of the range is also deducted from record duration in the report.	
Set to remove interference	Set ECG segments as interference and not to be analyzed.	

After setting the above parameters, click **Analyze** to conduct analysis. When analysis is done, the template editing screen is displayed.

### **Heart rate calculation**

- Heart rate of a single beat is calculated by the formula:  $HR = (60 * 1000 / RR + 0.5)$ , in which RR means the RR interval (in ms) of the beat.

#### Maximum and minimum heart rate

The maximum and minimum HR events are calculated every five minutes. The most appropriate events are selected by the software by default. You are also allowed to select from them. The events you selected will present the maximum and minimum HR and be displayed in the report.

### **Average heart rate calculation**

- Select the RR interval that meets the conditions: the type of the previous heartbeat and the next heartbeat are the same, this value is non-artifact and does not exceed 2500ms;
- Taking the average RR interval to calculate the average heart rate needs to meet two conditions: one is to select the number of RR intervals that meet the conditions to be greater than or equal to 10. Second, the value should be greater than or equal to 1/4 of the total number of heartbeats.
- If the above conditions are not met, then relax the conditions (i).
- If there is no RR interval that meets the conditions, the average heart rate is 0.

### **R-R interval (PAUSE) calculation**

R-R interval is the duration of two adjacent R waves. The criteria for judging a long R-R interval can be configured in the settings.



# Chapter 6 ECG Data Editing

## 6.1 Editing Patient Information

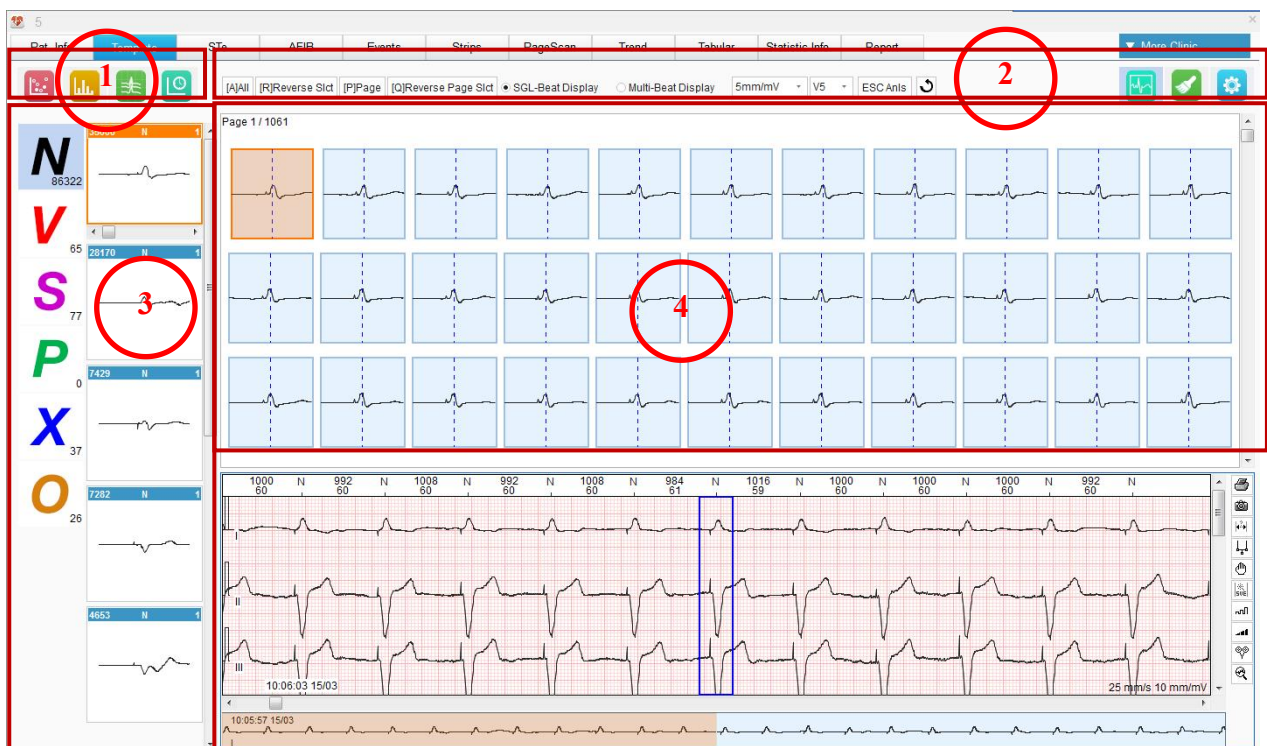
Click on the **Pat. Info** tab. The patient information page is displayed. On this page you can do the following:

- ◆ Input patient's basic information. Click **Save**.
- ◆ Click **Diary**. Input information about the patient's daily activities.

## 6.2 Editing Template

### 6.2.1 Template Analysis






Template analysis includes template review/edit and beat review/edit/modify. Click on the **Template** tab. Template analysis screen is displayed as below.




#### Region 1: Analysis Toolbar




The analysis tools are Poincare plot, RR histogram, focus (superimposed graph), and RR bird view.

Button	Description
--------	-------------



	Click this button to display the Poincare plot of all beats.
	Click this button to display RR histogram of all beats.
	<p>Click this button to display superimposed graph of beats of a type of templates.</p> <ul style="list-style-type: none"> <li>◆ If N is chosen, what is shown is the superimposed graph of N templates. But if there are templates are classified as non-N templates under the category of N type templates, the superimposed graph will not count in such templates.</li> <li>◆ If P is chosen, the superimposed graph will count in the templates which are the same type with the first template shown on the top.</li> <li>◆ If O is chosen,  will turn grey which indicates not functioning.</li> </ul>
	Click this button to display RR bird view.

### **Region 2: Common Toolbar**

<b>Option/Button</b>	<b>Description</b>
[A] Select All	Select all the beats of a group of marked templates. This can also be done by pressing Ctrl+A on your keyboard.
[R] Reverse Select	From a group of marked templates, select all the beats other than that selected before. This can also be done by pressing Ctrl+R on your keyboard.
[P] Select Page	Select all the beats on the present page. This can also be done by pressing Ctrl+P on your keyboard.
[Q] Reverse Page Select	From the present page, select the beat(s) other than that selected before. This can also be done by pressing Ctrl+Q on your keyboard.
Single-Beat Display	Display every single beat individually in Region 4.
Multi-Beat Display	Display strips of beat in Region 4.
Change gain setting	Click the arrow beside the gain to change its setting. When changed, the ECG waves will show this change in <i>Region 4 Beat View</i> .
Lead selection	Click on the arrow button to select a lead from the drop-down menu. The main lead is shown by default.
	Click this button to not to display the ECG view window. Click once more to display. When the window

	is open, ECG is displayed right below Region 4. When it is closed, ECG is not displayed and beats shown in Region 4 will extend to this area, so more beats are shown.
	Use this brush to mark beats with type. To mark beat types, click this button to display a menu, which lists types of beats as in Table 6-1. Select a type and a brush accompanied with the type mark is displayed. Use this brush to mark beats in region 4. Select <b>None</b> from the menu to stop brushing.
	With this option you can set the analysis parameters of atrial beats, especially premature beats.
	Cancel the last modification to beats.
ESC Anls	Configure the escape analysis setting. After configuration, click <b>OK</b> to start analysis.

### **Region 3: Template View**

1. Templates are classified as N (normal), V (ventricular), S (atrial), P (pacing), X (artifact), D (deleted), and O (others) types.
2. Click one of the above types. All the templates of this type can be viewed in the area right beside it.
3. In this area, press ↑ and ↓ to scroll up and down. Press → and ← to scroll through beats.
4. Press **Ctrl** and click your left mouse button to select multiple templates. After selection, click your right mouse button, a menu will pop up.
5. In this menu, the options are beat types, Poincare plot, focus, HIST., and Poincare plot + focus.
  - ◆ See Table 6-1 for specific types of beat.
  - ◆ Select a type of beat to mark the templates.
  - ◆ Select **Poincare Plot** to enter the Poincare plot (excluding 24-h and hourly plot) of templates.
  - ◆ Select **Focus** to enter the superimposed graph of templates.
  - ◆ Select **HIST.** to enter the histogram of templates.
  - ◆ Select **Poincare Plot + Focus** to enter the Poincare plot and superimposed graph of templates.
6. Keep **Alt** and your left mouse button pressed to move templates out from the right window to a new type on the left. When moving, the cursor is shaped like .
7. Keep your left mouse button pressed to drag templates with the same type mark so that they are put together. When dragging, the cursor is shaped like . Differently marked templates cannot be put together.

8. Use letter keys and number keys on the keyboard to modify beat type of a template.

#### **Region 4: Beat View**

In the beat view, all beats in the selected templates are displayed.


The first beat is by default focused. If beats covers more than one page, do the following to view them:

- ◆ Click on the arrow buttons on the scroll bar to switch from one page to another.
- ◆ Click scroll bar or the blank space to switch from one page to another.
- ◆ Press **Page Up** or **Page Down** on your keyboard to switch from one page to another.
- ◆ Scroll your mouse wheel to switch from one page to another.

To select a beat(s):

- ◆ Press the arrow keys on your keyboard to switch from one beat to another.
- ◆ Keep your left mouse button pressed to drag a beat(s).
- ◆ Press **Ctrl** and your left mouse button to select or not to select beats.
- ◆ Press **Shift** and your left mouse button to select two beats and the beats between them.

To modify type of a beat:

- ◆ Press **Alt** and your left mouse button to drag one beat to the target template type. When dragging, the cursor is shaped like .
- ◆ You can also use letter keys and number keys on the keyboard to modify beat type

Select a beat and click you right mouse button, a menu will pop up. The options available are beat types, match QRS by type, match QRS by premature, classify QRS by delay, classify ECG waves in low amplitude as artifacts, select all, reverse select, page select, reverse page select and so on.


- ◆ For specific beat types, see Table 6-1.
- ◆ The sub-menu of **Match QRS by Type** includes the above beat types.
- ◆ The sub-menu of **Match QRS by Premature** includes ventricular (V) and atrial (S).
- ◆ The sub-menu of Classify QRS by delay includes atrial escape (W), ventricular escape (E), and junctional escape (G).
- ◆ Classify ECG waves in low amplitude as artifacts: Beats that are less than or equal to the amplitude of the selected beat will be classified as artifacts. They will form a new X group and finally move to template X in the Template View.

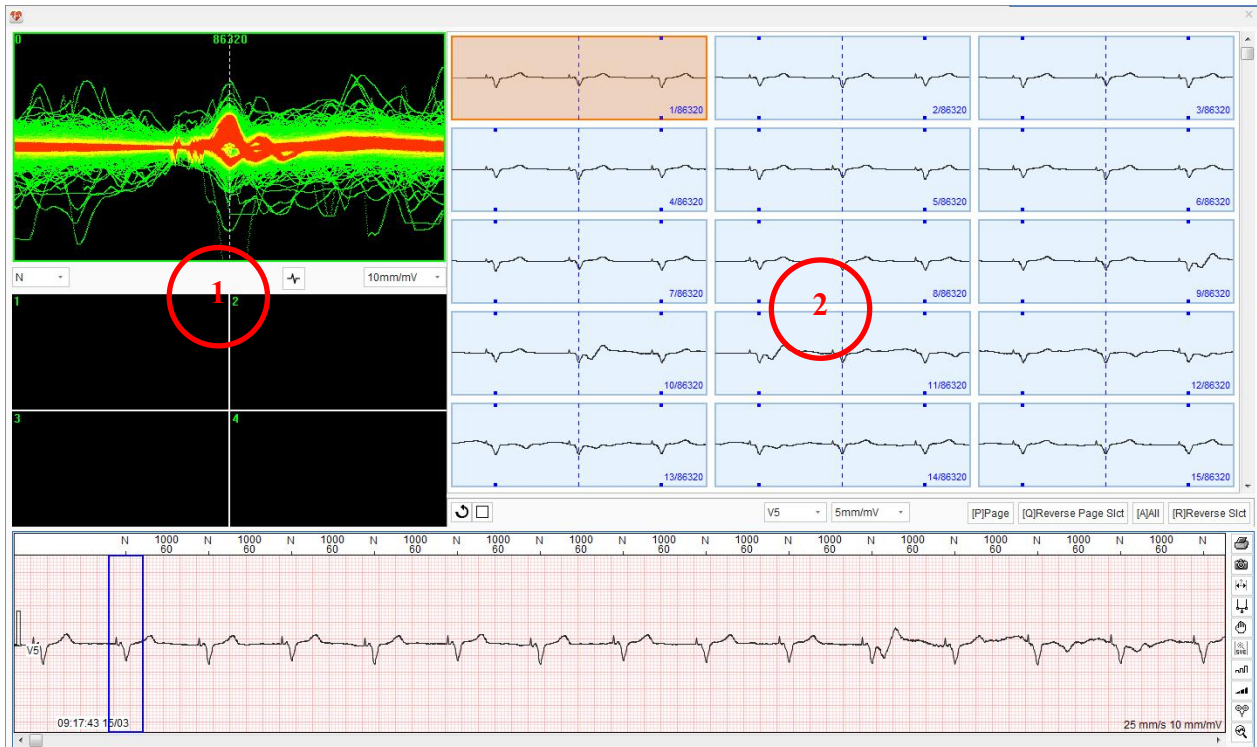
To display the full disclosure of ECG, double click on any beat or press **Enter**.

Table 6-1 Beat Types

Type	Description
N	Mark the current QRS wave as normal beat.
V	Mark the current QRS wave as ventricular ectopic beat.
S	Mark the current QRS wave as atrial ectopic beat.
J	Mark the current QRS wave as junctional premature beat.
A	Mark the selected QRS wave as aberrant conduction beat.
Af	Mark the current QRS wave as atrial fibrillation.
AF	Mark the current QRS wave as atrial flutter.
R	Mark the current QRS wave as R on T.
aP	Mark the selected QRS wave as atrial paced beat.
vP	Mark the selected QRS wave as ventricular paced beat.
avP	Mark the selected QRS wave as atrial-ventricular paced beat.
aE	Mark the selected QRS wave as atrial escape beat.
vE	Mark the current QRS wave as ventricular escape beat.
nE	Mark the selected QRS wave as nodal escape beat.
LB.	Mark the selected QRS wave as left bundle-branch block.
RB.	Mark the selected QRS wave as right bundle-branch block.
fP	Mark the selected QRS wave as pacing fusion beat.
F	Mark the selected QRS wave as ventricular fusion beat.
I	Mark the selected QRS wave as interpolated premature beat.
X	Mark the selected QRS wave as artifact beat.
D	Delete the selected QRS wave.

## 6.2.2 Editing Superimposed Graph

By superimposing heartbeats, you can check the analysis accuracy and sort again the beats by type. This will reduce detection mistakes and failures. To edit this graph, click  in the template analysis toolbar. See the following editing screen.





### Region 1: Superimposed Graph View

In this region, you can see superimposed heartbeats and separate beats into four areas coded 1, 2, 3, and 4.

- ◆ Scroll your mouse wheel to zoom in/out the whole superimposed graph. Keep your mouse wheel pressed to drag the graph.
- ◆ Click on the arrow button. A drop-down list is displayed. You can switch from one template type to another or one lead to another.
- ◆ Keep your left mouse button pressed to mark beats you want to separate with a white rectangle. Press a number key (1, 2, 3, and 4) to separate the beats to the corresponding coded area below. In the same way, you mark beats and press number key 0 to move beats back up.
- ◆ To relocate the QRS: mark beats in the way mentioned above. Click your right mouse button. Select **Relocate R waves**. The central lines of R waves will be aligned.




- ◆ To toggle between single-beat superimposition and multiple beats superimposition, click



- ◆ In the case of multiple beats superimposition, you can align the superimposition with the beat in the far left or right by clicking  or .

### **Region 2: Strip View**


Strips of heartbeats from a coded area of superimposed graph view are displayed in this region. To display single lead or three leads in each strip, select System Settings > View > Leads displayed in templates.

- ◆ To cancel the last modification to beats, click .
- ◆ To select the superimposed beats in a white square, click . To select the superimposed beats in curves, click .
- ◆ To change the gain of strips, click the drop-down arrow beside the gain. Select the gain you want.

## **6.2.3 Editing Histogram**


Use an RR histogram to edit heartbeats within a specified RR interval. The RR histogram is useful in the following cases.

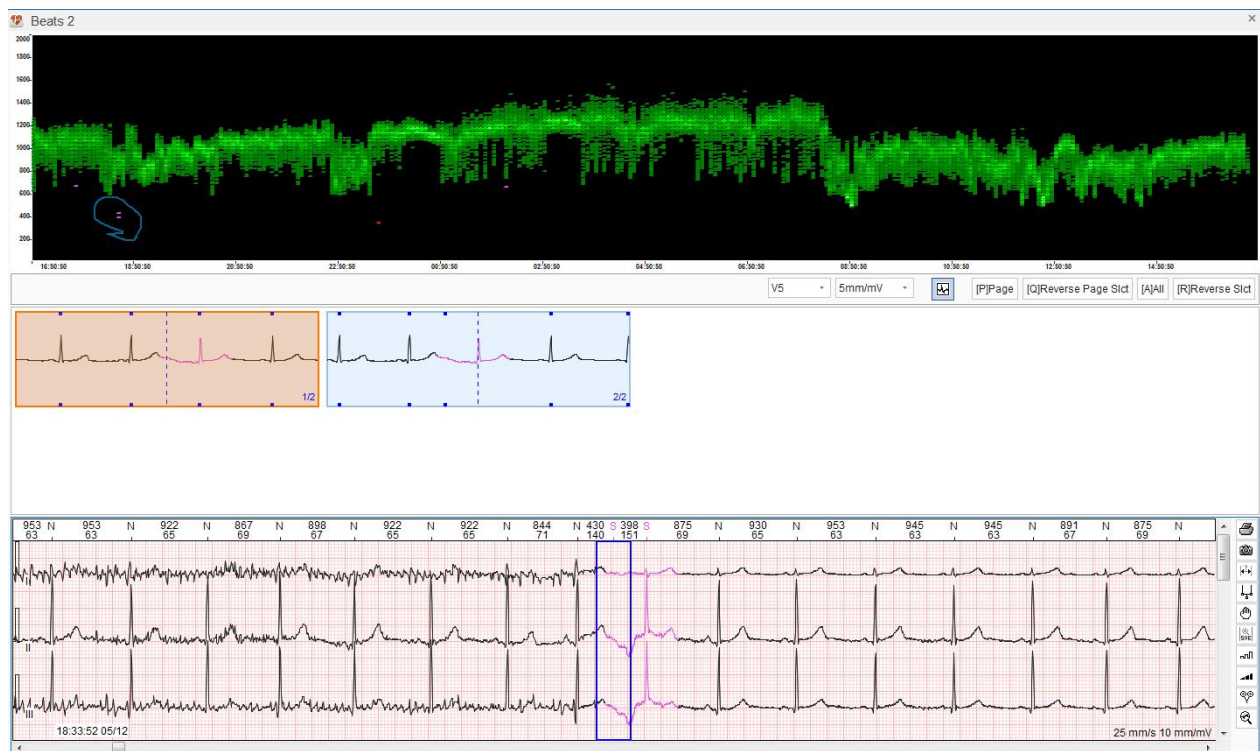
- ◆ Based on the feature that the RR interval of a supraventricular beat is short, use the histogram to search for unidentified atrial premature beats in N-type templates or search for normal beats in S-type templates.
- ◆ Based on the feature that the RR interval of an artifact beat is short, use the histogram to rule out artifact beats.

Click  in the template analysis toolbar to enter the histogram editing screen. This screen contains the following operations:

- ◆ Hold down the left-mouse button to select RR intervals within a certain range on the histogram. The beat strips just within the range will be displayed. To edit the beats, select a strip and then click your right mouse button. Select the option you want from the pop-up menu.
- ◆ Right click on a histogram column. Modify beat types by selecting the desired type from the pop-up menu. From this menu, you can also select where to insert the beat (before or after), what type of beat to insert, and insert in batch. If you want to insert beats in batch, from the sub-menu you can select the ways of inserting: by rescanning with a lead or by R-R guess.

## 6.2.4 Editing RR Bird View

RR bird view is a supplement to RR histogram which cannot be edited in time sequence. With a RR bird view you can quickly select over a period of 24 hours or longer the beats that are within abnormal RR intervals, such as atrial, ventricular, and long RR. Click  in the template analysis toolbar to enter the RR bird view editing screen below.



On the top is the RR bird view where the X-axis indicates time and Y-axis indicates RR interval. RR intervals are sorted by colors. Green indicates normal, red indicates VE, and purple indicates SVE. This histogram contains the following operations:

- ◆ Keep your left mouse button pressed to select QRS at any RR interval and any time with a blue rectangle. Then it will be displayed in the strip window. In this window, you can modify QRS type, use type brush and four selection options etc. After modification, click **Update** at the bottom of screen to update QRS.
- ◆ To display a specified type of RR intervals, right click the RR bird view and a menu will pop up. Select a type from the sub-menu of **View mode**. Then only this type of RR intervals is displayed in the histogram.
- ◆ To vertically zoom in/out on the histogram, hold down the **Ctrl** key and scroll the mouse wheel. Or right click the histogram, select **Zoom in** or **Zoom out** from the pop-up menu.




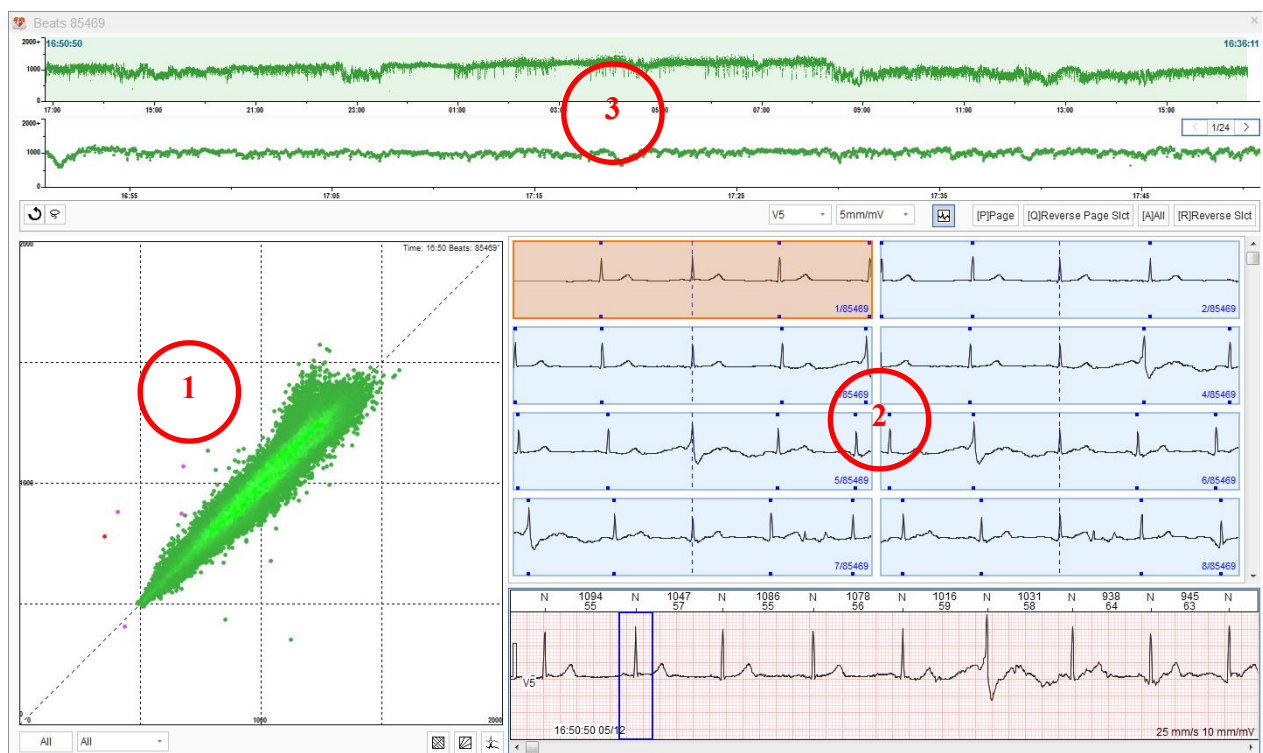
- ◆ After zooming in, if you want to vertically drag the histogram, hold down the mouse wheel to move the histogram up or down.
- ◆ Template synchronization. When QRS is modified to a type that is new to the previous classification, it will be placed separately in the template view.

## 6.2.5 Editing Poincare Plot

Poincare plot is R-R interval scatter plot, also called as Lorenz Plot. It is used to reflect adjacent R-R interval changes.







Poincare plot is created by plotting successive pairs of sinus R-R intervals as coupling point. Plot the  $RR_n$  interval (ms) as X value in the horizontal coordinate and the  $RR_{n+1}$  interval as Y value in the vertical coordinate. Then plot  $RR_{n+1}$  interval (ms) as X value and the  $RR_{n+2}$  interval (ms) as Y value. Repeat the operation to create a plot over a time period.

Click  in the template analysis toolbar to enter the Poincare plot editing screen below.



### **Region 1: Poincare Plot View**

- ◆ Click **All** to select the beat types to be displayed in the plot.
- ◆ Click the drop-down arrow beside **All** to display the Poincare plot over hours.

- ◆ Click  to close or open ECG view window and click again to cancel.
- ◆ Click  to determine how to select the plots. The default way of selection is random curve. You can click this button again to switch your option between random curve and rectangle.
- ◆ Click  to display the equal heart rate line. Click this button again to hide the line.
- ◆ Click  to display the heart rate differential line. Click this button again to hide the line.
- ◆ Click  to display the focus graph (superimposed graph). Click this button again to hide the graph
- ◆ Click  to cancel your last operation on beats. Such operations include modifying beats (by clicking your right mouse button), modifying beats (by pressing keys on your keyboard), matching QRS by type or by premature. This button is valid for operation on superimposed graph, Poincare plot, sequential Poincare plot, ECG strip, and ECG view window.
- ◆ If no area is selected by random curve or rectangle, or the selected area has no beats, when you click your right mouse button, you have two options: Lorenz plot, and Difference scatter plot. You can only select one of them to display.
- ◆ When you have selected beats in this plot, you can modify the selected beats to the desired type from the pop-up menu by clicking your right mouse button...
- ◆ Scroll your mouse wheel to zoom in/out the Poincare plot.
- ◆ After zooming in, hold down the mouse wheel to drag the plot.
- ◆ Place the cursor anywhere on the plot, values in horizontal coordinate and vertical coordinate at that point is displayed right below the cursor.

### **Region 2: Strip View**

Strips of selected beats from the Poincare plot are displayed.

### **Region 3: Sequential Poincare Plot View**

- ◆ Both 24-hour and 1-hour sequential Poincare Plots are displayed.
- ◆ A green rectangle displayed on the 24-hour plot is 1-hour long. It is commensurate with the 1-hour sequential Poincare Plot.


## **6.2.6 Editing Poincare Plot and Superimposed Graph**

This is a combination of Poincare plot and superimposed graph. By such a combination heartbeat analysis becomes easier and faster.

Select templates from the template view window. Right click the templates. A menu will pop up. Select **Poincare Plot + Focus** to enter the editing screen shown below.



### Region 1: Superimposed Graph View

- ◆ Superimposed waveforms of one-hour scattering points are displayed by default. If specific scattering points are selected from the Poincare plot view, then superimposed waveforms of such points are displayed.
- ◆ There are two areas for waveform separation.
- ◆ Click the arrow . You can modify beat type from the drop-down list.

### Region 2: Poincare Plot View

- ◆ RR intervals of heartbeats from selected templates are displayed.
- ◆ Select a scattering point(s). Right click the mouse. Modify beat type with the pop-up menu.

### Region 3: Strip View

Strips of superimposed waveforms are displayed.

## 6.2.7 Keyboard Operation and Other Useful Operations

The following operations and information are helpful for template editing.

## Keyboard Operation

The following table lists the hot keys for modifying beats. This is applicable to template analysis screen, histogram editing screen, Poincare plot editing screen, RR bird view editing screen, Poincare plot + focus editing screen, and ECG view window.

**NOTE:** Hot keys of the numeric pad may not be available on your laptop.

Hot Key	Function
<b>N or 1</b>	Mark the current QRS wave as normal beat (N).
<b>V or 2</b>	Mark the current QRS wave as ventricular beat (V).
<b>S or 3</b>	Mark the current QRS wave as atrial beat (S).
<b>X or 0</b>	Mark the selected QRS wave as artifact beat (X).
<b>A or 7</b>	Mark the selected QRS wave as aberrant conduction beat (A).
<b>H or 6</b>	Mark the selected QRS wave as atrial-ventricular paced beat (avP).
<b>P or 5</b>	Mark the selected QRS wave as ventricular paced beat (vP).
<b>O or 4</b>	Mark the selected QRS wave as atrial paced beat (aP).
<b>W</b>	Mark the selected QRS wave as atrial escape beat (aE).
<b>G</b>	Mark the selected QRS wave as nodal escape beat (nE).
<b>E</b>	Mark the current QRS wave as ventricular escape beat (vE).
<b>L</b>	Mark the current QRS wave as left bundle branch block (LB.)
<b>B</b>	Mark the current QRS wave as right bundle branch block (RB.)
<b>R</b>	Mark the current QRS wave as R on T (R)
<b>K</b>	Mark the current QRS wave as atrial fibrillation (Af)
<b>M</b>	Mark the current QRS wave as atrial flutter (AF)
<b>Q</b>	Mark the current QRS wave as fused pacing (fP)

<b>J</b>	Mark the current QRS wave as junctional premature (J)
<b>F</b>	Mark the current QRS wave as ventricular fusion (F)
<b>I</b>	Mark the current QRS wave as interpolated premature (I)
<b>Delete or D</b>	Delete the selected QRS wave.

### QRS Type and Color Indication

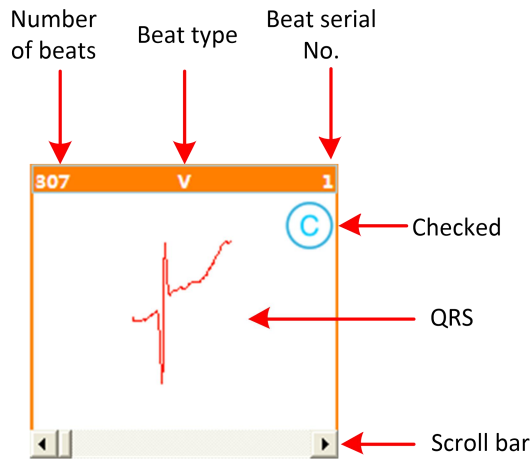
Color	Mark	QRS Type
■	N	Normal Sinus QRS
■	V	Premature ventricular contraction
■	S	Premature atrial contraction
■	J	Junctional premature beat
■	X	Artifact
■	LB./RB.	Left/right bundle branch block
■	A	Intra-ventricular aberrant conduction beat
■	aP	Atrial pacing
■	vP	Ventricular pacing
■	avP	AV dual pacing
■	fP	Fused pacing
■	aE	Atrial escape beat
■	nE	Nodoventricular escape beat
■	vE	Ventricular escape beat
■	R	R on T
■	Af	Atrial fibrillation
■	AF	Atrial flutter
■	F	Ventricular fusion
■	I	Interpolated premature beat
■	Del	Deleted beat

The difference between deleting a beat and defining a beat as an artifact is:

You delete a beat when the beat is misclassified. After deletion, beats are automatically connected, thereby forming new RR interval which will be included in arrhythmia analysis.

You define a beat as an artifact when the beat is poor in quality and its QRS cannot be identified. The artifact will be excluded from arrhythmia analysis.

#### 6.2.7.1. Quick Browse of All QRS in Template



Beats with the same QRS morphology make up a group of templates marked with the same beat type. You can use the scroll bar to quickly browse all QRS from the templates. Operation steps are as follows:

1. Select a template.
2. Click or drag the scroll bar at the bottom of the template pane.
3. QRS wave will be displayed in sequence in the template pane.
4. ECG view window will simultaneously respond and display ECG of this beat.
5. Click or drag scroll bar in the ECG view window to scroll ECG backward and forward.

### 6.2.7.2. Changing the Type of Template

If a template is changed to another type, then all beats bound to this template will be changed to that type too. This is used to quickly correct type of massive QRS. Operation steps are as follows:

1. Select one or more template(s) to be changed.
2. Right click on the template. A menu will pop up.
3. Select the target type from the menu. Type of QRS is changed.

### 6.2.7.3. Merging Templates

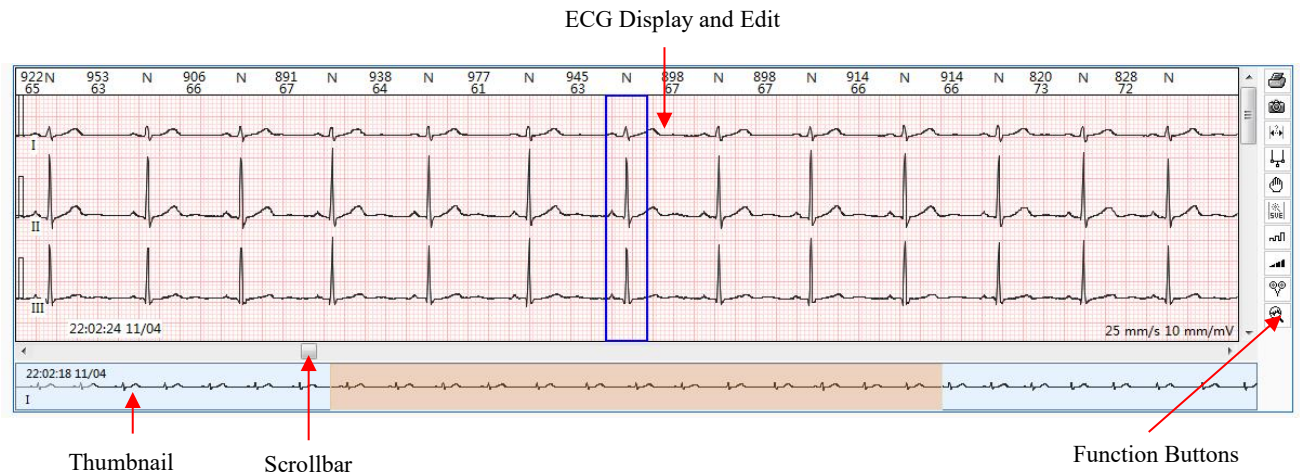
Beat(s) in several templates of the same type can be merged into one template. This is used to reduce the number of templates and ease the editing of patient data. Operation steps are as follows:

1. Select the template to be merged, press and keep your left mouse button pressed.
2. Move mouse (drag the template) onto the target template (must be of the same type). Release your left mouse button.

- Wait until merging is finished.

## 6.3 General ECG View Window

There is a general ECG view window in most tabs. The window is shown as below:













The ECG view window consists of the ECG display/edit area, thumbnail, and function buttons.

### Thumbnail

- ◆ To switch from one lead to another, right click on any point of thumbnail and select the target lead from the shortcut menu.
- ◆ The QRS thumbnails with a rectangle marker are shown in the ECG display area.
- ◆ Left click any point in the thumbnail, then its corresponding ECG will be marked with a rectangle and shown in the display area.

### Function Buttons

Button	Function
	Instantly print current ECG in the window, with the cursor-placed point as the start. You can select <b>Preview before printing</b> to preview the ECG to be printed.
	Save the selected strip. Click this button, a picture frame will be displayed. Move this frame to select a strip. Then select the label of strip and set the property of it. Click <b>OK</b> . The strip is saved. It can be found in the Strips tab. Strips shown in this tab will be included in the report.
	Turn on/off the measurement

	<p>Turn on/off the calipers.</p> <p>When turned on, boundary lines of the RR intervals will be displayed in the ECG display area. The RR interval and HR value of the selected beat will also be displayed on the right side of calipers. Move the cursor to the parallel jaws of calipers, an arrow will be displayed. Drag this arrow to change the width of calipers.</p>
	<p>Move the ECG waveforms of the selected lead longitudinally.</p>
	<p>SVE automatic edit.</p> <p>After marking a beat with S, click on this button to judge if the subsequent beats have equal RR intervals. If yes, they will be automatically marked with S too. And an atrial tachycardia event is created.</p>
	<p>Gain.</p> <p>This is to vertically scale up or down the ECG amplitude. The options are 5 mm/mV, 10 mm/mV, 20 mm/mV, 40 mm/mV, 80 mm/mV, and 160 mm/mV. The default value is 10 mm/mV.</p>
	<p>Speed.</p> <p>This is to horizontally scale up or down the ECG. The options are 6.25mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s, 100 mm/s, 200 mm/s, and 400 mm/s. The default value is 25 mm/s.</p>
	<p>Lead.</p> <p>Press this button to enter the <b>Lead Select</b> window. Select the lead(s) you want to display and the lead(s) to invert.</p> <p>Click the check box before <b>Lock</b> to synchronize ECG view with full disclosure view. The same leads will be displayed in both.</p> <p>Click the check box before <b>Tile in the window</b> to display the leads you have selected in the ECG view window.</p>
	<p>Zoom in on ECG waveform. Click this button, and select any lead in the view. You can get a closer look at the lead at most 10 times of the original size. To exit, click this button again.</p>

The following sections will describe regular operations in the ECG view window.

### 6.3.1 Inserting Beats

It is able to insert beat marked with designated type at any position of ECG. Operation steps are as follows:

1. Click on the position where a new beat is to be inserted, and then a cursor line will be displayed in the ECG view window.
2. Click your right mouse button, and then the beat type menu will pop up.
3. Select a type from the menu, and then a new beat of this type will be inserted.

#### NOTE:



1. The position to insert QRS has to be at least 200ms away from the nearest QRS.
2. After completion of inserting beats, the system will automatically recalculate rhythm events.

### 6.3.2 Deleting Beats

You can delete any marked beat. Operation steps are as follows:

1. Click on a marked beat to be deleted, and then a rectangle marker will appear in the ECG display area.
2. Click your right mouse button, and select **Delete the mark of QRS complex**. Or you can press **D** on the keyboard to delete the beat.

**NOTE:** After beats are deleted, the system will automatically recalculate rhythm events.

### 6.3.3 Modifying Beats

You can modify any marked beat on ECG. Operation steps are as follows:

1. Click on a marked beat to be modified, and then a rectangle marker will appear around the beat.
2. Click your right mouse button, and a menu will pop up.
3. Select the target type from the pop-up menu. Then the type of the selected beat will be modified.

Or you can use hot keys on the keyboard to modify beats. For information about the hot keys, please refer to section *6.2.7 Keyboard Operation and Other Useful Operations*.

**NOTE:** After beats are modified, the system will automatically recalculate rhythm events.

### 6.3.4 Modifying Successive Beats

If the successive beats to be modified are in the scope of current ECG window:

1. Place the cursor ahead of the first beat, then press and hold down left-mouse button. A blue rectangle will appear. Drag the mouse until the rectangle covers all beats to be modified, then release left-mouse button, a menu will pop up.
2. From the menu select **Classify all QRS as**. Select a beat type from the sub-menu. All beats will be modified.

If the successive beats to be modified are outside the scope of the ECG window:

1. Move the cursor to the first beat. Click your right mouse button and select **Select the start**.
2. Move the cursor to the last beat. Click your right mouse button and select **Select the end**.
3. In the pop-up menu, select **Classify all QRS as** from this menu. And in the sub-menu, select the beat type you want. All beats are modified.

**NOTE:** After beats are modified, the system will automatically recalculate rhythm events.

### 6.3.5 Inserting Beats in Batch

In the ECG view window:



Keep your left mouse button pressed to select a range, release your mouse button and a menu will be displayed. Select **Insert batch** and in the submenu you can choose to insert beats by rescanning with a lead or by R-R guess.

In the **Events** tab:

1. Click **Long R-R** from the available patterns. Select one or more ECG episodes displayed.
2. Right click on the mouse, and select **Insert batch**. In the submenu, you can choose to insert beats by rescanning with a lead or by R-R guess.

### 6.3.6 Measuring ECG

You can measure R-R interval and amplitude of ECG at any time in the ECG view window. Operation steps are as follows:


1. Click the  button.
2. Click your left mouse button, and the current position will be marked as the starting point of measurement.
3. Drag the mouse to the end point of measurement. Along with the movement of the mouse, there will be a small prompting window in the status bar to display the interval (ms) and the amplitude differential (mV) between the current mouse position and the starting point.
4. Release your left mouse button. The time interval (ms) and the amplitude differential (mv) between the starting and end points are displayed in the small prompting window.
5. Move your mouse to drag the whole window.
6. Click your left mouse button to exit the measurement window.
7. Click the  button again to exit measurement.

### 6.3.7 Quick Browse of ECG

You can use ECG view window to quickly display ECG.


Scroll your mouse wheel to scroll the ECG.

There is also a scroll bar at the bottom of ECG view window and its length is equivalent to the duration of ECG. The ECG will scroll along with clicking or dragging of scroll bar.

In the case of 12-lead ECG, you can use the scroll bar on the right side of this window to display the lead you want. Alternatively, you can click the button  to display or cancel the display of the ECG lead.

### 6.3.8 Saving ECG Strip

You save an episode of ECG wave as an ECG strip so that it will be part of the report. Operation steps are as follows:

1. Save an ECG strip in one of the following ways:
  - Click and move your left mouse button mouse to select the ECG waves you want. Select **Save ECG strip** from the pop-up menu.
  - Click your right mouse button on the ECG waves... Select **Mark Range** from the pop-up menu. Choose the start and end of the ECG. Select **Save ECG strip** from the pop-up menu.
  - Click your right mouse button on the ECG waves. Select **Save ECG strip** from the pop-up menu.
  - Click the function button  to save an ECG strip.
  
2. To set the type of the strip, the options are:
  - ◆ 3 strips per page: 3-lead ECG strip in optional length. The default length is 7s.
  - ◆ Single lead per page: single-lead ECG strip of 63s.
  - ◆ Full leads per page: Full leads ECG in optional length.
  
3. Select the leads you want to display.
4. Set the length of strip.
5. Set the gain and speed.
6. Choose whether to enable Beats type, R-R (ms), and R-R (bpm). They are enabled by default.
7. Set the label of the strip. You can select a label from the drop-down list or customize it. A customized label will be automatically added to the drop-down list.

8. Click **OK** to save the ECG strip. And this ECG strip can be found and printed out in the **Strips** tab.
9. Click **Cancel** to not to save the strip.

### 6.3.9 Relocating R Waves

Click the QRS marker or the beat type in the ECG View window. Hold and drag to the end. Select **Relocate R Waves** in the pop-up menu. When the R waves are relocated, the RR intervals and heart rate will be updated.


### 6.3.10 Printing ECG

In the ECG view window you can print out any episode of ECG. Operation steps are as follows:

1. Click your left mouse button and keep it pressed to drag along the ECG. Release your left mouse button. Select **Print** from the pop-up menu.

Or after marking range (for operations, see section 6.3.4 *Modifying Consecutive Beats*), select **Print** from the pop-up menu.

Or right click on the ECG view window. Select **Print** from the pop-up menu.

Or click on  button on the right side of the window (to print out the episode only shown in the window).

2. A print setting window will pop up. Select page style, lead, gain, and speed etc.
3. Click **Print** to print out the episode.

### 6.3.11 Defining an Arrhythmia Event

In the ECG view window you can define any episode of ECG waves as an arrhythmia event. Operations are as follows:

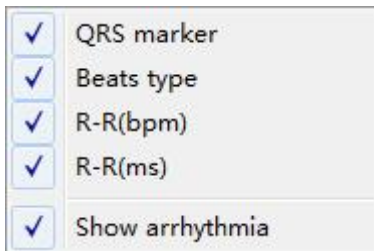
- ◆ Click your left mouse button and keep it pressed to drag along the ECG. Release your left mouse button. Select **Define Event** from the pop-up menu. Select an arrhythmia type from sub-menu to define an arrhythmia event.
- ◆ You can also mark range (for operations, see section 6.3.4 *Modifying Successive Beats*). Select **Define Event** from the pop-up menu. And then select an arrhythmia type from the sub-menu to define an arrhythmia event.

**NOTE:** In addition to defining an arrhythmia event, you can also modify beats or print out

ECG in an episode.

## 6.3.12 Display Options

You can decide what to be displayed on the bar at the top of ECG view window. Right click on the bar, the options are as follows:

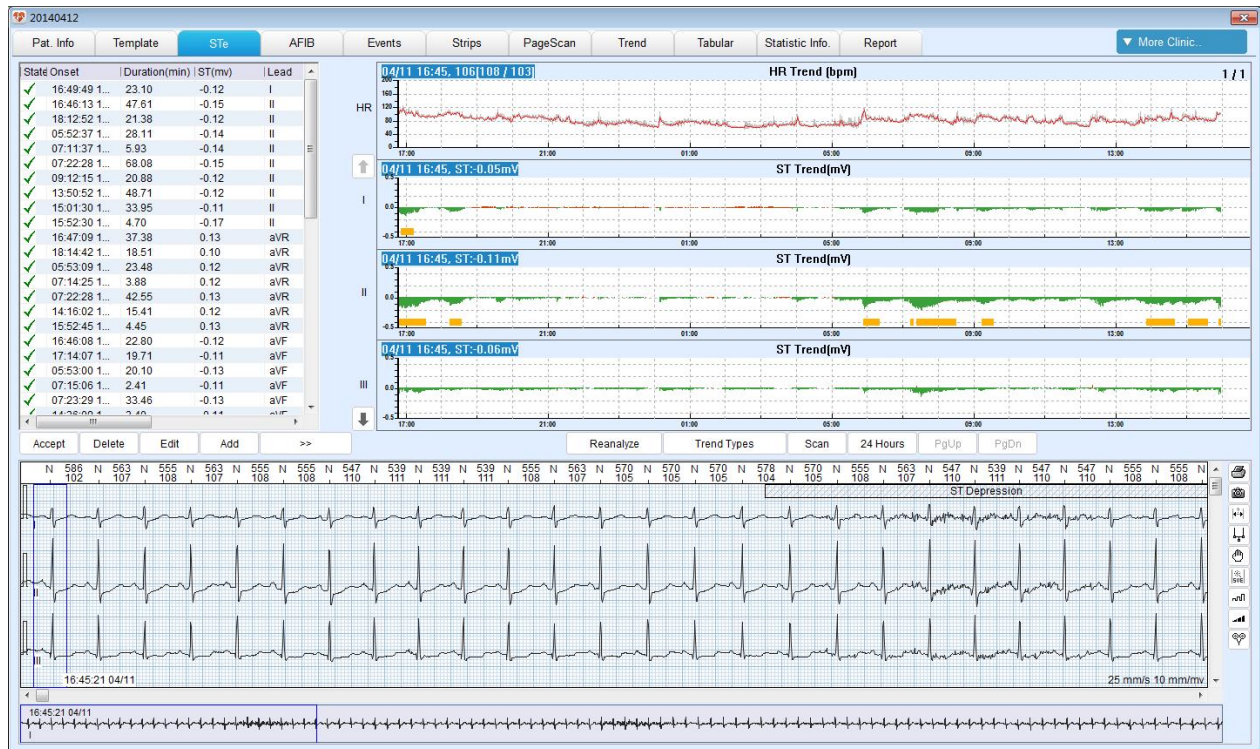


Click the checkbox before an option to display it on the bar. Click once more to hide on the bar.

## 6.4 STe

In this tab you can:

- ◆ Review the ST events automatically identified by the system.
- ◆ Remove the ST events misidentified due to interference or artifacts.
- ◆ View the ST trend.
- ◆ Define new ST events.



The above STe tab contains the following options:

- ◆ Switch leads to view the ST trends of all leads.
- ◆ Switch the trend types to be displayed. Trend types available are ST, T wave peak, and J.
- ◆ Accept, delete, edit, and add ST event.
- ◆ Full disclosure view of ECG.
- ◆ Automatically scan to display the synchronicity between trend charts and ECG.
- ◆ Select duration of the trend charts shown in horizontal coordinate. There are 6 hours, 12 hours, and 24 hours duration.

All leads will be subject to ST analysis.

Threshold can be reset to measure ST segment changes.

In the report, ST depression and elevation with their occurring time are described one by one.

Both HR and ST segment change of every single heart beat are displayed.

### 6.4.1 ST Event List

In the ST event list, you can see the starting time, duration, ST elevation or depression.

Click to view in ascending or descending order

Drag to adjust column width

Double click to edit a value

Click to display complete list and all function buttons

State	Onset	Duration(min)	ST(mv)	Lead
✓	07:11:37 1...	5.93	-0.14	II
✓	07:14:25 1...	3.88	0.12	aVR
✓	07:15:06 1...	2.41	-0.11	aVF
✓	07:21:16 1...	1.21	-0.23	V6
✓	07:22:28 1...	68.08	-0.15	II
✓	07:22:28 1...	42.55	0.13	aVR
✓	07:22:30 1...	34.45	-0.12	V5
✓	07:22:57 1...	16.11	-0.12	V6
✓	07:23:29 1...	33.46	-0.13	aVF
✓	07:29:35 1...	9.48	-0.13	V4
📄	08:07:00 1...	22.65	0.12	V2
✓	08:40:42 1...	23.31	0.13	V2
✓	09:07:40 1...	1.48	0.12	V2
✓	09:12:15 1...	20.88	-0.12	II
✓	09:37:53 1...	34.29	0.12	V2
✓	10:12:37 1...	19.38	0.12	V2
✓	10:41:05 1...	96.88	0.13	V2
✓	12:56:13 1...	42.13	0.12	V2
✗	13:50:52 1...	48.71	-0.12	II
✓	14:16:02 1...	15.41	0.12	aVR
✓	14:36:09 1...	3.40	-0.11	aVF
✓	15:01:30 1...	33.95	-0.11	II
✓	15:24:20 1...	24.54	0.12	V2

✓ Normal ST event  
 ✗ Deleted event  
 📄 Saved as strip

Accept Delete Edit Add >>

Function buttons and their descriptions are as follows:

Button	Function
View	To display ST events, you can select to either show all or hide deleted events. If <b>Hide Deleted</b> is selected, the deleted event will not be displayed in the event list.
Accept	Set a deleted ST event as normal.

<b>Delete</b>	Delete the selected ST event.
<b>Edit</b>	Edit the selected ST event. If multiple ST events are selected, the last selected event will be edited.
<b>Add</b>	Add a new ST event manually.
<b>Reanalyze</b>	Reanalyze the ECG record.
<b>All CH.</b>	Select one lead or all leads (channels) to be analyzed. The default setting is <b>All CH.</b>
<<	Return to the original size of event list.

You can press **Ctrl/Shift** + left mouse button to select multiple ST events.

Right click on any event, the options available are: delete, delete all, modify, add, accept, accept all, save strip, unsave, select all, and unselect all.

## 6.4.2 HR Trend

In the HR trend chart, you can do the following operations:

- ◆ Click your right mouse button to display grids.
- ◆ Double click your left mouse button to display ECG of all leads, and then double click again or press **Esc** to return to HR trend screen.
- ◆ Press the left or right arrow keys on your keyboard to move the mark line by minute.

## 6.4.3 ST Trend

In the ST trend charts, you can do the following operations:

- ◆ Switch leads: right click on the chart, select the lead you want to see from the pop-up menu.
- ◆ Delete event: Keep you left mouse button pressed and drag along the chart. Right click on the chart, select **Delete Event** from the pop-up menu.
- ◆ Add event: Keep you left mouse button pressed and drag along the chart. Right click on the chart, select **Add event** from the pop-up menu. The Add ST Event window is displayed. Enter ST elevation/depression in mV. Select slope (from J point to ST point) as horizontal (0), downsloping (-), or upsloping (+). An event will be added.
- ◆ Delete an area: Keep you left mouse button pressed and drag along the chart to select an area. Right click on the chart, select **Reject selected area** from the pop-up menu. ST elevation/depression of this deleted area will be 0 mV as shown in the report.
- ◆ Restore the deleted area: Keep you left mouse button pressed and drag along the deleted area. Right click on the chart, select **Accept drag area** from the pop-up menu.
- ◆ Event mark: ST events are marked with orange blocks in the horizontal coordinate. Double click on the mark to edit the ST event.



## 6.4.4 ST Reanalysis

If the ST measurement points are incorrect, you have to reanalyze. Click **Reanalyze** in the center of **STe** tab and the ST Reanalyze screen will be displayed as below.



### **Region 1: Measurement Point Adjustment**

To adjust the ST measurement points:

1. Right click on the region and select a lead from the pop-up menu.
2. Move the cursor to the beat display area. Press **Tab** and use the arrow keys on your keyboard to change the position of ISO. Press **Tab** again. Use the arrow keys on your keyboard to change the position of J point. And in the same way to change the position of ST point.
3. Scroll your mouse wheel or drag the scroll bar to switch from one beat to another. ST differential of the present beat is shown on the left side.
4. Reset the following threshold values to reanalyze.



ISO: baseline indicator which is between P and R. Suggest to position it in the middle of P-R interval.

JP: J point indicator which is behind R wave.

J+80 (60): ST point indicator which is varied depending on heart rate.

- ◆ J+80 msec, if heart rate < 100 bpm
- ◆ J+72 msec, if  $100 \text{ bpm} \leq \text{heart rate} < 110 \text{ bpm}$
- ◆ J+64 msec, if  $110 \text{ bpm} \leq \text{heart rate} < 120 \text{ bpm}$
- ◆ J+60 msec, if heart rate  $\geq 120 \text{ bpm}$

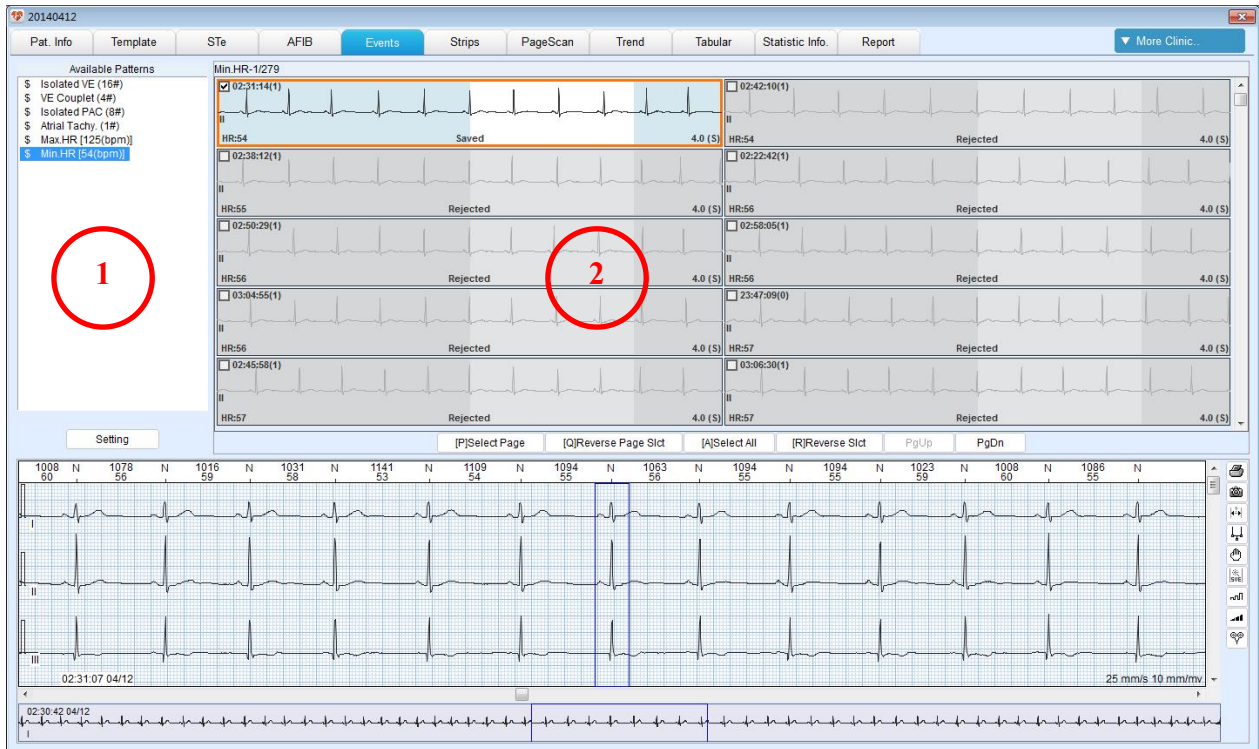
T wave offset: the end of T wave, used to calculate the magnitude of T wave.

### **Region 2: ST Trend**

After the measurement points are adjusted, ST trend will be updated automatically.

## **6.5 Events**

After editing the templates and updating events, you need to confirm the identified events and select the strips to be printed.



### Region 1 Event List

Number in "(" is the number of events.

Number in "[" is the parameter value of the event. Take Max. HR for example. The number in [ ] indicates the highest heart rate in the unit of *bpm*.

You can do the following operations:

- ◆ Click on an event type from the list. The related strips will be displayed in region 2. The "\$" sign indicates that the event has been viewed.
- ◆ Parameter setting. Events will be automatically updated after parameters are modified.

### Region 2 Strip View

Strips of an event type are displayed.

An event can be accepted or deleted. A deleted event will not be counted in the event list. Its strips can be saved or not.

To select a strip, you have the following options:

Button/Key	Function
<b>PgUp</b> or <b>PgDn</b> buttons	Turn pages up or down.
<b>Page Up</b> or <b>Page Down</b> keys on	Turn pages up or down.

the keyboard	
Mouse wheel (scrolling up/down)	
← or → keys on the keyboard	Select a single strip horizontally.
↑ or ↓ keys on the keyboard	Select a single strip vertically.
Left mouse button	Select a single strip.
<b>Ctrl</b> + left mouse button	Select multiple strips.
<b>Ctrl+A</b> or <b>Select All</b>	Select all the strips of the event type.
<b>Ctrl+P</b> or <b>Select Page</b>	Select all the strips displayed on the current page.

Click your right mouse button, the options are:

<b>Option</b>	<b>Description</b>
Delete	Delete the current strip.
Delete All	Delete all strips of the event type.
Accept	Accept an event strip that have been rejected.
Accept All	Accept all the strips that have been rejected.
Save Strip	Save the selected strip to the Strips screen
Unsave	Delete the selected strip from the Strips screen
Sort	Set the sort conditions for the events.
Leads	Select the leads to be displayed.
Insert batch	Insert beats in batch by rescanning with a channel or by RR guess.
Modify beat	Change the strip to a new type.

To operate with special events:

There is only one Max. HR event and one Min. HR event. Each of them has 200 strips but only one is selected. The first strip is selected by default, but you can select another strip to be calculated.

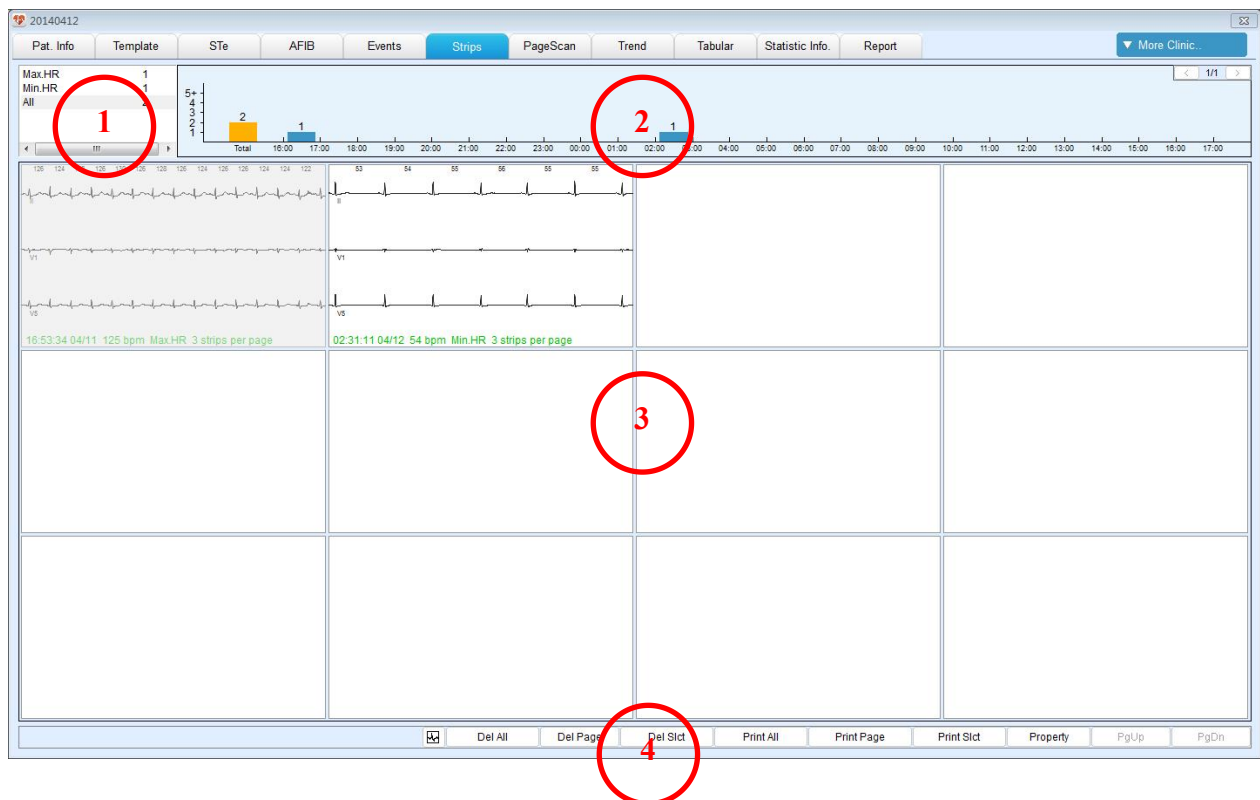
**NOTE:** Calculation will be automatically synchronized with modification on events.

## 6.6 Strips

In the **Strips** tab you can confirm again the strips to be printed.

The strips in this tab are created in the following ways:

- ◆ Automatically created at the end of automatic analysis based on the parameter setting.
- ◆ Manually selected and saved with the **Save ECG strip** option in the general ECG view window.
- ◆ Manually selected and saved with the **Save Strip** option in the **Events** tab.



### **Region 1: Strip List**

- ◆ The type and the number of strips are displayed.
- ◆ Click on a strip type and its distribution histogram will be displayed in Region 2.

### **Region 2: Strip Distribution Histogram**


- ◆ Display strips in time sequence.

- ◆ To select multiple histograms, press **Ctrl** + left mouse button, or keep your left mouse button pressed to drag along the histograms.
- ◆ Click on a histogram, the corresponding strips will be displayed in Region 3.

### Region 3: Strip View

- ◆ This strip view consists of a group of small strip windows, which can be selected multiply by dragging the mouse or pressing **Ctrl** + left mouse button.
- ◆ To move strips, hold down your left mouse button on the strip and move it to the desired position in this region.
- ◆ Double click on a small strip window to display ECG full disclosure view.
- ◆ Right click on a strip, a menu will be displayed. Select operations from the pop-up menu. With the **Property** option you can set the name and other parameters of the strip.






### Region 4: Toolbar

Button	Description
	Click this button to display the ECG view below the strip view.
<b>Property</b>	Click this button to enter the strip property configuration window.
<b>Del All, Del Page, Del Slet</b>	Delete all strips, one page of strips, or selected strips.
<b>Print All</b>	Print all the strips.
<b>Print Page</b>	Print all the strips displayed on the current page.
<b>Print Slet</b>	Print the selected strips.
<b>PgUp, PgDn</b>	Turn pages.

## 6.7 Page Scan



**Region 1: Thumbnail**

- ◆ Set time to start scanning: enter starting time to the input box or click on the start point on the thumbnail.
- ◆ CHAN: select the lead to scan.
- ◆ Gain: click + or – to set the gain of thumbnail.
- ◆ Scan and pause: click on  button to scan the thumbnail. Click on  button to stop scanning or when the predefined conditions are met it stop scanning automatically. Click on  button to scan from the beginning of thumbnail.
- ◆ Scanning speed: use  bar to control the scanning speed.
- ◆ Display: click on  button to select the displaying rate of beats per page. It is to display 4 min per page by default.
- ◆ Print: print out 15-min thumbnail on present channel.

**Region 2: Pause Scan Condition**

- ◆ Set the conditions of pause: heart rate, ventricular, and supraventricular are available for setting.
- ◆ When the above conditions are met, the system will stop scanning automatically.
- ◆ The reason of stop will be displayed at the top right corner. The event will be marked with a small rectangle in the thumbnail and displayed in the middle of ECG view window.

**Region 3: HR Trend View**

The HR trend is displayed by default to help you find out where the atrial fibrillation occurs.

**Region 4: Superimposed Graph View**

- ◆ On the left is two superimposed normal waveforms over 5 minutes.
- ◆ On the right is two superimposed ventricular waveforms over 5 minutes. If there are not ventricular waveforms, it is blank on the right.

**6.8 Trend**

In the **Trend** tab, trends of heart rate, ST, ventricular beat (number calculation per hour), atrial beat (number calculation per hour), and SDNN are displayed. In the ST trend view, right click your mouse button to switch from one lead to another.

**6.9 Tabular**

The **Tabular** tab displays parameters and the number of events per hour.

## 6.10 HRV

Cardiac rhythm varies according to time and body condition. The physiological phenomenon of variation in the time interval between heartbeats is called heart rate variability (HRV). To detect HRV, time-domain and frequency-domain methods are commonly used.

### Time-domain methods

Use time as independent variable to measure the change in N-N interval. There are long-period and short-period analysis. In the case of long period, we recommend 24 hours. And for short period, it should be at least 5 min. The following variables are used.

- ◆ SDNN, standard deviation of N-N intervals calculated over a period, in the unit of ms. The calculation formula is:

$$SDNN = \sqrt{\frac{\sum_{i=1}^N (RR_i - \text{meanRR})^2}{N}}$$

- ◆ SDANN, the standard deviation of the average N-N intervals calculated over 5 min, in the unit of ms. The calculation formula is:

$$SDANN = \sqrt{\frac{\sum_{i=1}^M (\overline{RR}_i - \text{mean}\overline{RR})^2}{M}}$$

- ◆ RMSSD, the square root of the mean of the squares of the successive differences between adjacent N-Ns, in the unit of ms. The calculation formula is:

$$rMSSD = \sqrt{\frac{\sum_{i=1}^{N-1} (RR_{i+1} - RR_i)^2}{N-1}}$$

- ◆ SDNN index, the mean of standard deviation of N-N intervals calculated over every 5 min, in the unit of ms. The calculation formula is:

$$SDNN_{\text{index}} = \frac{\sum_{i=1}^N SD_i}{N}$$

- ◆ NN50, the number of pairs of successive NNs that differ by more than 50 ms.



- ◆ TINN triangular index, the number of maximum N-N interval divided by the total number of N-N intervals.

### Frequency-domain methods

A complicated curve can be divided into sine curves of different frequency, of different amplitude, and of different phases. These curves are converted to spectrums for analysis.

Power spectral density (PSD) as an analysis method provides basic information on the power distribution across frequencies in N-N intervals. The algorithm used is FFT (fast Fourier transform).

Bands of frequency used in 24-hour recording are:

Total power (TP): variation in all R-R intervals,  $\leq 0.4$  Hz

Ultra low frequency (ULF):  $\leq 0.003$  Hz

Very low frequency (VLF): 0.003 Hz to 0.04 Hz

Low frequency (LF): 0.04 Hz to 0.15 Hz

High frequency (HF): 0.15 Hz to 0.4 Hz

Bands of frequency used in 5-min recording are:

Very low frequency (VLF):  $\leq 0.04$  Hz

Low frequency (LF): 0.04 Hz to 0.15 Hz

High frequency (HF): 0.15 Hz to 0.4 Hz

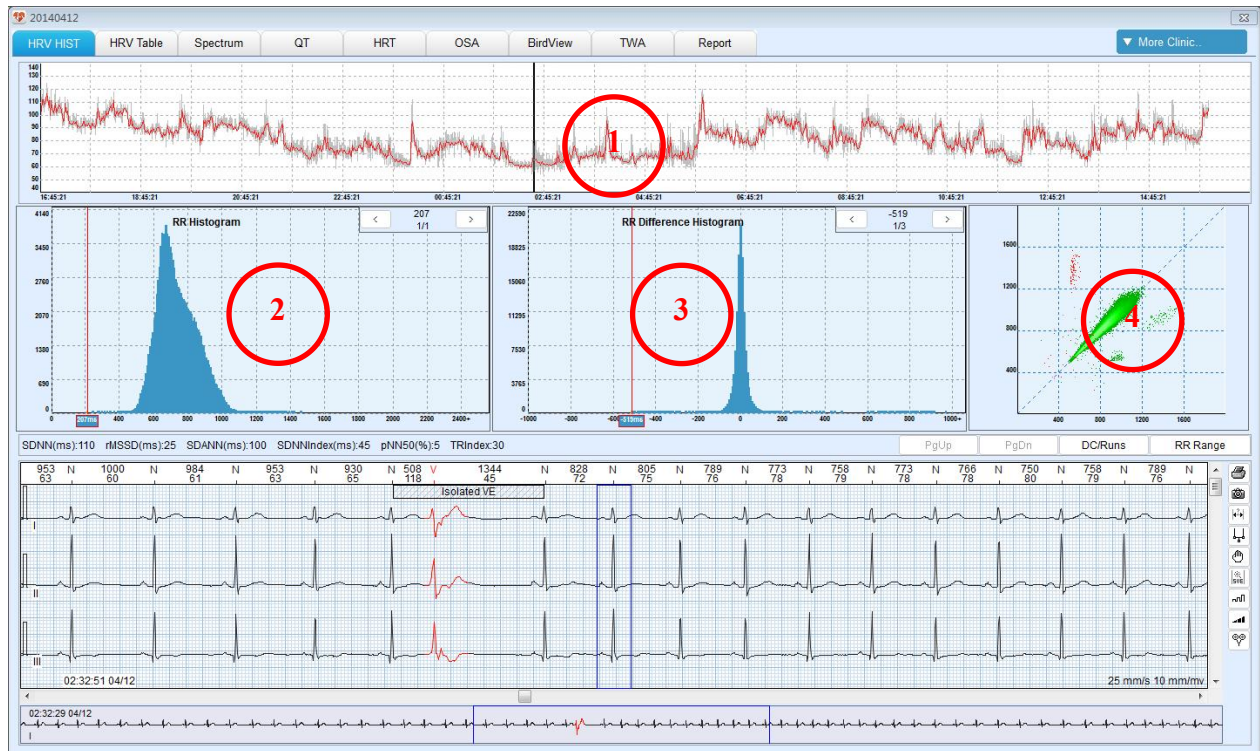
(The above parameters are expressed in the unit of  $ms^2$ .)

LF normalization (Lfnorm):  $LF \times 100 / TP$

HF normalization (Hfnorm):  $HF \times 100 / TP$

The power spectrum of HRV over a short period is very sensitive to ectopic beat, undetected beat, and artifact beat. So prior to PSD analysis, check carefully the recording data over 5 min to obtain useful data on N-N interval for 5-min analysis.

## 6.10.1 HRV Histogram



Click on [More Clinic...](#) button to switch from General Tools to Complex Tools. The first tab shown is **HRV HIST** as above.

### **Region 1: HR trend view**

### **Region 2: RR interval histogram**

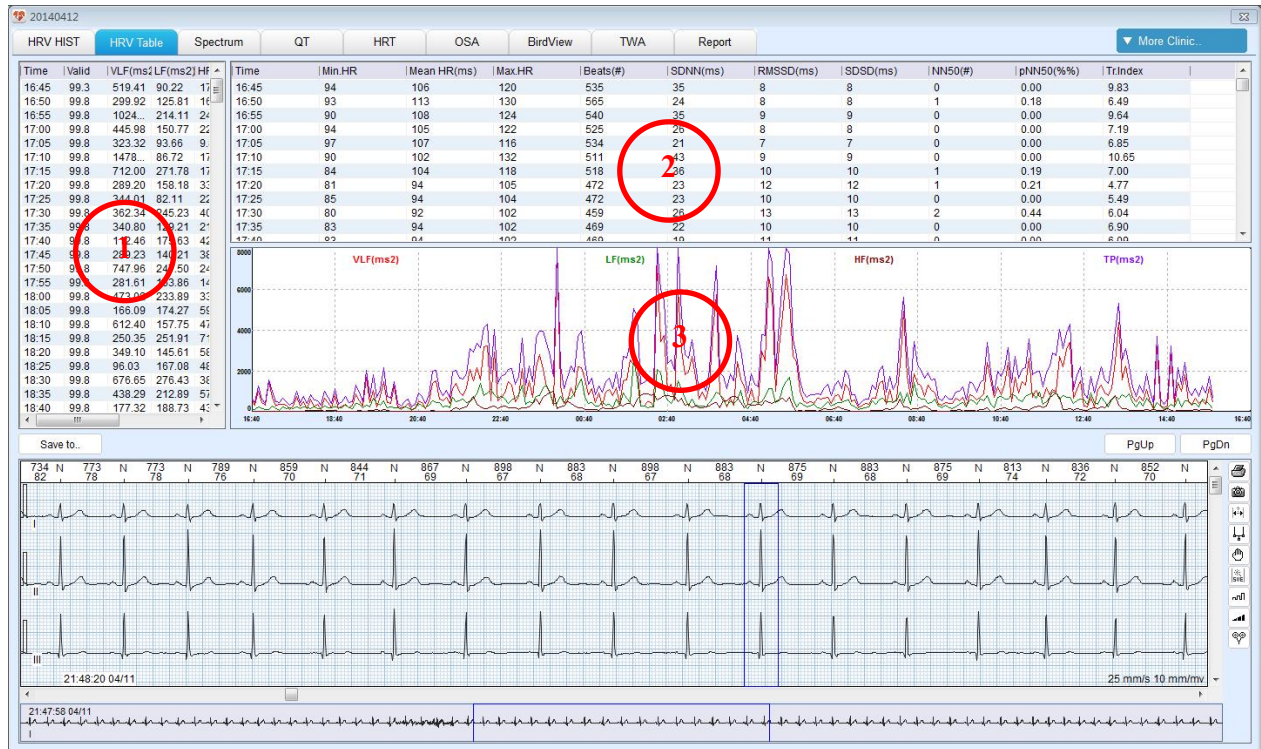
Left click on the histogram. Click < or > buttons to display the ECG of all selected beats.

### **Region 3: RR difference histogram**

### **Region 4: Poincare plot**

## 6.10.2 HRV Table

Use the **HRV Table** tab to view HRV analysis result. The tab is displayed as below.



### **Region 1: List of Frequency-Domain Analysis in 5-minute Length**

The bands of frequency are as follows:

Very low frequency (VLF):  $\leq 0.04$  Hz

Low frequency (LF): 0.04 Hz to 0.15 Hz

High frequency (HF): 0.15 Hz to 0.4 Hz

(The above parameters are expressed in the unit of ms<sup>2</sup>.)

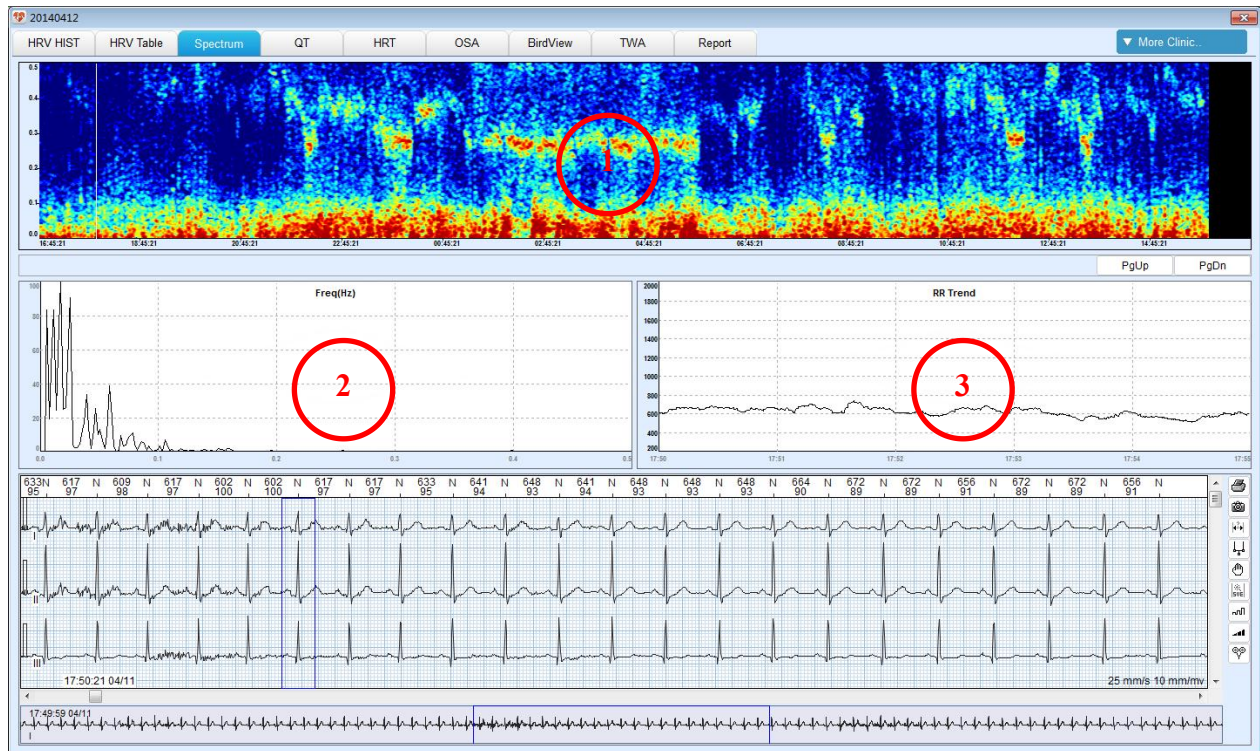
LF normalization (Lfnorm):  $LF \times 100 / TP$

HF normalization (Hfnorm):  $HF \times 100 / TP$

### **Region 2: List of Time-Domain Analysis in 5-minute Length**

### **Region 3: Trend of Frequency-Domain Analysis in 5-minute Length**

## 6.10.3 Power Spectrum Graph



### **Region 1: Power Spectrum Trend View**

Use FFT to calculate 5-minute HRV to obtain its power spectrum. Superimpose all such power spectrums over 24 hours and use colors to indicate power levels in a graph. With this graph, you can easily observe power distribution across frequencies.



In the above color card, 0 indicates the lowest power and 60 indicates the highest power.

Click on a specific time in the trend view to display power spectrum at that time in region 2 and RR trend in region 3.

## 6.11 QT



In the QT tab, you can see:

### **Region 1: QT List**

### **Region 2: QT Histogram**

Left click on a beginning position of the histogram. Click on  or  buttons to display ECG at QT intervals.

### **Region 3: QTc Percentage**

## 6.12 Pacing Electrophysiology

Click **More Clinic...** and select **Pacemaker Tools** from the drop-down list to enter the analysis screen of pacing electrophysiology.

### 6.12.1 Pacing Event Definition

- ◆ FTO (Fail to output)  
Pacemaker does not deliver electrical impulses at the time it ought to no matter what the problem is. This is expressed on the ECG that all of the P-P, R-P, and R-R intervals are greater than the predefined value.
- ◆ FTC (Fail to capture)

After electrical impulses are delivered, there is no electrocardial reaction. This is expressed on the ECG that P-R interval is greater than the predefined value.

◆ FTS (Fail to sense)

Pacemaker cannot sense normal P waves or QRS complexes and still delivers electrical impulses at its regular interval. This is expressed on the ECG that R-P interval is smaller than the predefined value. A sensing failure is caused by poor sensing or excessive sensing while FTS is mainly caused by poor sensing. And excessive sensing leads to FTO. Both excessive sensing and FTO have the same expression on ECG.

## 6.12.2 Pacing Histogram

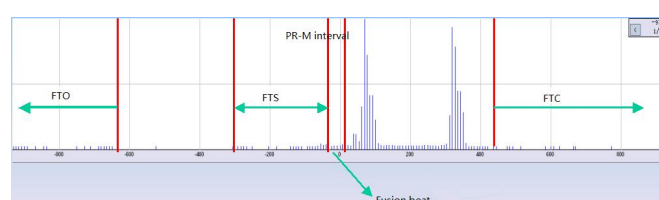


### **Region 1: PM-PM Interval Histogram**

Histogram of intervals between two successive adjacent pacing spikes (no beats in between)

### **Region 2: PM-R Interval Histogram**

Histogram of interval between a pacing spike and its nearest beat



To set the FTO, FTS, FTC, and fusion beat distribution can help evaluate the performance of pacemaker.

### 6.12.3 Pacing Trend



In the **Pacing Trend** tab, you can see:

- ① Atrial pacing trend,
- ② Ventricular pacing trend, and
- ③ Atrial-ventricular pacing trend.

### 6.12.4 Pacing Events

In the **Pacing Events** tab, you can see the number of pacing events as classified and strips of each event.

## 6.13 Statistic Information




In the **Statistic Info.** tab, you can see statistics for HR, VE, atrial, junctional, HRV, atrial fibrillation/flutter, ST segment, and pacing. You can edit such statistics and click **Save** to save your modification.

## 6.14 Report

After data editing, you will need to print a report. Use the **Report** tab to edit and print the report. The **Report** tab contains the following options:

Option	Description
Comment Automatically	<p>To add a comment, double click a type of comment you want from the list on the right. Then the comment will be added.</p> <p>To delete a comment, keep your left mouse button pressed to select the comment you want to delete. Press <b>Backspace</b> or <b>Delete</b> buttons on your keyboard.</p> <p>First letter associating input is supported.</p>
Comment Style	<p>Click <b>Edit</b> to display types of comment. You can modify the content of comment by direct input. Double click a field on the right to add statistics to the comment. The statistics is represented by &lt;\$field\$&gt;. After modification, click <b>OK</b> to save your modification.</p>
Comment Manually	<p>To edit glossary, click <b>Edit</b> on the right of Glossary. A txt file will be displayed. Edit the file and save it. Close the file. Click <b>Update</b> on the right of Glossary. The glossary will be updated.</p> <p>To add glossary to comment, double click the glossary you want. Then the glossary will be displayed in the manual comment.</p> <p>After manually editing the comment, click <b>Save</b>.</p>
Full Disclosure	<p>Click the check box before Full Disclosure to activate this function.</p> <p>Click the check box before the time to select at which one-hour interval the ECG is shown in the report.</p> <p>Click the box before the lead to select in which lead the</p>



	<p>ECG is shown in the report.</p> <p>Choose the print mode between 60s per line and 30s per line.</p>
Print/Preview	<p>To preview a report before printing, click <b>Print/Preview</b>. The report is displayed. Press <b>Ctrl</b> and scroll your mouse wheel to zoom in/out. Or click on  or  buttons to zoom in/out. Press the arrow keys on your keyboard or click on the arrow buttons to quickly turn pages.</p> <p>Click on  button to print a report. The system will print all pages of the report by default. You can also set the page scope to print.</p> <p>In addition to black and white, reports allow color printing by selecting <b>Color</b>.</p>

The comment generated automatically and manually will be both shown in the report.

## Chapter 7 System Settings

You can customize Holter analysis software to your own preference. To open the settings, click **Settings** on the main toolbar in the main menu.

### 7.1 Common Setting

The **Options** tab contains the following options.

Option	Description
Hospital name, address, telephone, and website	If you have entered these information, they will be shown in the printed report.
Set Hospital Logo	With this option, you can add the hospital logo to the report and determine where to be shown (limited to the top of report).
System Language	With this option, you can select the language in which the system is displayed.
Date Format	With this option, you can determine how the date is displayed. You can choose between yy/mm/dd, dd/mm/yy, and mm/dd/yy.
Height/Weight unit	With this option, you can select the unit in which patient's height and weight are expressed. You can choose between cm and inch for height, and kg and lb. for weight.
ECG Color Setting	With this option, you can change the color of the beats to display and preview the result.

### 7.2 Workflow Setting

The **Workflow** tab contains the following options.

Option	Description
General Tools, Complex Tools, Pacemaker Tools, and Resting ECG	The workflow of these four modules cannot be modified.
Customize 1, 2, 3 and 4	You can customize the workflow of these modules. The functions available to select are patient information, template, ST evaluation, events, strips, page scan, trend,

	<p>tabular, HRV histogram, HRV table, spectrum, QT, pacing histogram, pacing trend, pacing table, pacing events, average ECG, time ECG, report, and etc.</p> <p>You can set a customized workflow as default.</p> <p>You can select a customized workflow to edit ECG data.</p>
--	---

## 7.3 Analysis Setting

The **Analysis** tab contains the following options.

Option	Description
Multi CHAN Analyze	<p>With this option, the system uses ancillary channels to help detect heart beat without omissions.</p> <p>If this option is not selected, system will only analyze data from the important channel.</p>
Noise Level	<p>You can choose between high, medium, low or none.</p> <p>With this option, the system will automatically delete the ECG with bad signal. The heart beats in the deleted ECG will not be counted. The higher the noise level, the more ECG will be deleted. None means not to automatically delete artifact beats.</p> <p><b>Note:</b> Noise level setting is valid only when Multi CHAN analysis is activated.</p>
Child Mode	Use pediatric algorithm to analyze ECG data.
Notch Filter	<p>You can choose between 50Hz, 60Hz, or off.</p> <p>If AC interference is strong, it is recommended that you activate this function and select a value and reanalyze ECG data.</p>
DFT Filter	<p>With this option, you can filter out baseline wander and guarantee that the ECG is on the baseline.</p> <p><b>Note:</b> Please set off DFT filter when evaluating ST segment changes.</p>
Lowpass Filter	<p>Lowpass Filter restricts the bandwidth of input signals.</p> <p>Not selected by default.</p>
ECG Waveform Smoothing	<p>Make the ECG waveforms look smooth. Not selected by default.</p>

OSA Analysis	<p>Obstructive sleep apnea (OSA) screening based on the ECG recording during sleep.</p> <p><b>NOTE:</b> This function only applies to CE Area. This analysis takes a long time, so needs your patience.</p>
Print Setting	<p>You can choose between black and white, and color. With this option, you can select a way appropriate for your printer to print the report. Improper selection may affect the printing effect.</p>

## 7.4 View

Option	Description
Comment area is visible	<p>Comment of a report is divided into automatically generated and manually generated. You can determine whether the manually input comment is visible or not in the report. If this option is selected, the manually input comment and the automatic one will be put together in the printed report.</p>
Separate manual conclusion	<p>This option can be selected only when <b>Comment area is visible</b> is selected.</p> <p>With this option, the manually input comment will be displayed in an individual page, following the first page of the report.</p>
Grid	<p>With this option you can enable or disable the displaying of grid in the ECG View window.</p>
Style of ECG View Window	<p>You can choose between <b>Displayed on one line</b> and <b>Displayed on multiple lines</b>. The default setting is <b>Displayed on one line</b>.</p>
Leads displayed in templates	<p>You can choose between <b>Single Lead</b> and <b>Three leads</b>. The default setting is <b>Single Lead</b>.</p> <p>Only one lead is displayed in the Beat View for template analysis if <b>Single Lead</b> is selected. But three leads are displayed in the Beat View with multi-beat display if <b>Three Leads</b> is selected.</p>

## 7.5 Maintenance

Use the **Maintenance** tab to set the ECG storage path, passwords, and reconstruct database.

Option	Description
Choose ECG storing path	Choose the location to store ECG data.
Reconstruct database	Create a database that contains all files of the storage location.
Set system password	Enter the password before you access the settings.
Set login password	Enter the password before you start this analysis software.
Set analysis password	Enter the password before you access the analysis screen.

## 7.6 GDT

Option	Description
Enable GDT	This option is disabled by default. Once it is selected, the system can read information from GDT in the case of registering patient information or scanning a single record.
GDT Path	The default GDT path is C:\gdt. You can enter the path or click <b>Browse</b> to set the path.
Suffix	GDT is the default suffix. With this option, you can select the suffix of files to be searched in the GDT path. You can choose between .GDT and .001.
Input File Name	With this option, you can specify the name of files sent from the GDT server. The file name is “Holter_EKG” by default.
Output File Name	With this option, you can specify the name of files exported from Holter system. The file name is “Holter_EDP” by default.
ECG ID	With this option, you can specify the name of local port. “EKG” is the default name.
EDP ID	With this option, you can specify the name of GDT server. “EDP” is the default name.
Output when making diagnosis	With this option, you can enable or disable the output of GDT file after you click <b>Confirm Diagnosis</b> in the <b>Report</b> tab.

**NOTE:** To use GDT protocol for communications, you need to make sure that the Holter system is operated at secure networks. Otherwise, patients' information and health conditions may leak.

## 7.7 File Output Setting

Option	Description
File Name Setting	With this option, you can specify how to name a patient record. A record name consists of first name and last name of the patient by default.
PDF Setting	With this option, you can enable or disable the output of PDF report after confirming diagnosis. This option is disabled by default.
Output Path	With this option, you can set the path of exporting patient records.

## Chapter 8 System Tips

This system will provide you with helpful tips during operation. Please see the table below.

Tips	Probable Cause
“No sentinel detected.”	Dongle is removed during system operation.
“No correct sentinel have been detected. Do you want to enter DEMO mode?”	Dongle is not inserted or wrong dongle is inserted into the PC.
“Incorrect password!”	Incorrect password is typed in when entering the DEMO mode or logging in to system setting.
“No file is found under the GDT path!”	GDT file is unavailable under the GDT path.
“Different template can’t be combined.”	You try to put differently marked templates together.
“The length must be larger than 5 seconds.”	You select a segment of ECG which is less than 5s and define it as an ST episode.
“Less than two beats are found in the designated areas.”	You select a segment of ECG which contains less than two beats and define it as maximum or minimum heart rate.

## Chapter 9 Maintenance

You should be familiar with all the operation methods of this system. Read this user manual in detail, and don't use this system before understanding the whole operation process.

Holter System analysis software just needs simple maintenance during the operation process. But only the right operation method can guarantee the system's long-time and steady working. So you must strictly comply with the notice and maintenance presented by the manufacturer.

---

---

### **WARNING**

Turn off the power before cleaning.

---

---

---

---

### **CAUTION**

Avoid pouring liquid on the equipment while cleaning, and do not immerse any parts of the equipment into any liquid.

---

---

#### **Maintenance of the Main Unit and the Monitor**

- 1) Keep the main unit and the monitor clean. The main unit case can be cleaned with a soft cloth dampened with water. If necessary, use a mild detergent but carefully remove any residue. Use water very sparingly to prevent liquid from seeping into the equipment.
- 2) The main unit and the monitor should be placed in a dry and well-ventilated place. Avoid placing them in a dusty and humid environment. The air path for cooling the system should be kept well ventilated.

#### **Maintenance of the CD**

- 1) Do not bend or press the CD. Do not put heavy substances onto the CD. Protect it against crushing.
- 2) Keep the CD away from high temperature and humidity, direct sunlight, and dust.
- 3) Do not touch the disk surface on the recording side. Avoid fingerprints or scratch.
- 4) Clean the CD with a disk cleaner. Do not use organic solvents such as acetone.



## Chapter 10 Accessories

We recommend you use the following accessories to help operation of the Holter system analysis software.

Accessory	Part Number
USB Cable	01.57.471456
Installation CD	02.01.211447
Dongle	02.01.211263

The following printers are recommended.

Model Number	Manufacturer
HP P2035, HP P2010	Hewlett Packard Enterprise in USA
CANON iP1980	Canon Inc. in Japan

---

---

### **WARNING**

Only accessories or spare parts supplied by the manufacturer can be used. The use of third-party products may compromise system performance and safety.

---

---

The Holter System analysis software and accessories are available by contacting the manufacturer or your local distributor.

**NOTE:** The part name may vary depending on context, but the part number is unchanged.

# Chapter 11 Warranty and Service

## 11.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

- a) Damage caused by mishandling during shipping.
- b) Subsequent damage caused by improper use or maintenance.
- c) Damage caused by alteration or repair by anyone not authorized by EDAN.
- d) Damage caused by accidents.
- e) Replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

## 11.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: [support@edan.com](mailto:support@edan.com).

## Appendix 1 Abbreviations

<b>Abbreviation</b>	<b>Full Description</b>
LCD	Liquid Crystal Display
ECG	Electrocardiogram/Electrocardiograph
HR	Heart Rate
AC	Alternating Current
USB	Universal Serial Bus

P/N: 01.54.456516

MPN: 01.54.456516021



**EC REPRESENTATIVE**

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg Germany

TEL: +49-40-2513175 FAX: +49-40-255726

E-mail: shholding@hotmail.com

**EDAN INSTRUMENTS, INC.**

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District

Pingshan District, 518122 Shenzhen, P.R.China

Email: info@edan.com

TEL: +86-755-2689 8326 FAX: +86-755-2689 8330

[www.edan.com](http://www.edan.com)