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# ECG Analysis Software

Version 1.2

# User Manual

CE 0123

EDAN

# About this Manual

P/N: 01.54.458733

MPN: 01.54.458733012

Release Date: December 2020

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# 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) can not be held liable.

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# 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

**1 Safety Guidance ..... 1**

1.1 Indications for Use/Intended Use ..... 1
1.2 Warnings and Cautions ..... 1
1.2.1 General Warnings ..... 1
1.2.2 General Cautions ..... 3
1.2.3 General Operation Tips ..... 3
1.2.4 Protecting Personal Information ..... 5
1.3 List of Symbols ..... 6

**2 Introduction ..... 8**

2.1 System Running Environment ..... 8
2.1.1 Basic Requirements on the Internet ..... 9
2.1.2 Compatibility of Server ..... 9
2.1.3 Compatibility of Client ..... 9
2.1.4 Performance of Client ..... 10
2.1.5 Cybersecurity Risk ..... 10
2.2 Installing/Uninstalling Server Software ..... 11
2.2.1 Installing Server Software ..... 11
2.2.2 Uninstalling Server Software ..... 15
2.3 Installing Client Software ..... 15
2.3.1 Installing Client Software ..... 15
2.3.2 Configuring Server Connection ..... 19
2.3.3 Uninstalling Client Software ..... 19
2.4 Product Models and Features ..... 19
2.5 Data Ports ..... 19
2.6 User Rights Management ..... 20

**3 Operation ..... 21**

3.1 Backend Management ..... 21
3.1.1 Hospitals ..... 21
3.1.2 Department ..... 22
3.1.3 Role ..... 22
3.1.4 User ..... 23
3.1.5 Equipment ..... 23
3.1.6 Package ..... 23
3.2 Creating an Application ..... 24
3.3 Resting ECG ..... 24

3.3.1 Resting ECG Data Retrieval ..... 24
3.3.2 Resting ECG Views ..... 25
3.4 Holter ..... 28
3.4.1 Holter Data Retrieval ..... 28
3.4.2 Holter Data Views ..... 29
3.5 Ambulatory Blood Pressure ..... 34
3.5.1 ABP Data Retrieval ..... 34
3.5.2 ABP Data Views ..... 34
3.5.3 Previewing and Printing BP Report ..... 35
3.6 Statistics ..... 35
3.7 Other ..... 36
3.7.1 Restrictions ..... 36
3.7.2 Warning Message and Operation Log ..... 36
3.7.3 System Message ..... 36
3.8 Data Backup and Recovery ..... 36
3.8.1 Data Backup ..... 36
3.8.2 Data Recovery ..... 38
3.9 Care and Maintenance ..... 39
3.9.1 Care and Maintenance ..... 39
3.9.2 Troubleshooting ..... 40
3.10 Warranty and Service ..... 40
3.10.1 Warranty ..... 40
3.10.2 Contact information ..... 40

**Appendix 1 Abbreviations ..... 41**

**Appendix 2 Technical Specifications ..... 42**

# 1 Safety Guidance

## 1.1 Indications for Use/Intended Use

The ECG Analysis Software is intended to receive, store, display and manage the data and/or report about resting ECG, ambulatory ECG and ambulatory blood pressure. The software is also capable of ECG test process management, workload statistics, and report printing.

The ECG Analysis Software provides automated measurements and interpretation including rhythms and morphological information for resting ECG. The ECG analysis Software is helpful for physicians in ambulatory ECG analysis including QRS detection and classification, arrhythmia and ST segment deviation. All the initial auto-analysis is provided to the clinicians on an advisory basis only and useful for enhancing the diagnostic process. The automated analysis cannot substitute for the final diagnosis of physicians but may be edited, deleted and confirmed by the physicians.

The ECG Analysis Software is intended for use in adult and pediatric population.

The ECG Analysis Software is intended to be used only in hospital and healthcare facilities by physicians or trained healthcare professionals.

**WARNING**

1. This system is not intended for home use.
2. This system is not intended for treatment or monitoring.
3. The results given by the system should be examined based on the overall clinical condition of the patient, and they cannot substitute for regular checking.

## 1.2 Warnings and Cautions

In order to use the software safely and effectively, and avoid the possibility of system failure, be familiar with the operation method of Windows, and read the user manual in detail to know how to properly operate the software. The following **WARNING** and **CAUTION** precautions during the operation of the system must be paid more attention to.

**NOTE:**

The pictures and interfaces in this manual are for reference only.

### 1.2.1 General Warnings

## WARNING

1. The system is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
2. Only qualified service engineers can install this equipment, and only service engineers authorized by the manufacturer can open the shell.
3. **EXPLOSION HAZARD** - Do not use the system in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
4. **SHOCK HAZARD** - - The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.
5. Only the patient cable and other accessories supplied by the manufacturer can be connected to this system. Or else, the performance and electric shock protection cannot be guaranteed. The system has been safety tested with the recommended accessories, peripherals, and leads, and no hazard is found when the system is operated with cardiac pacemakers or other stimulators.
6. This software should be installed and run in the environment as instructed.
7. The measurements and interpretation provided by the system are on advisory basis only.
8. Follow this user manual to operate the system. Avoid any potential risk caused by data error and confusion.
9. Pay attention to the security of system running environment and make a backup of data on a periodic basis.
10. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).
11. Do not exceed the maximum permitted load when using the multiple portable socket-outlet(s) to supply the system.
12. Multiple portable socket-outlets shall not be placed on the floor.
13. Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system, unless it's specified as part of the system by manufacturer. And the multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment which is intended to form part of the system.
14. All the accessories connected to system must be installed outside the patient vicinity if they do not meet the requirement of IEC/EN 60601-1.
15. You should purchase computer, printer, and bar code reader from the manufacturer. Otherwise, the manufacturer will not be held responsible for the maintenance of the PC hardware, operating system and other accessories.
16. Safety checks should be performed at least every 12 months.
17. Any serious incident that has occurred in relation to the device should be reported to

the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

18. Account and password need to be kept confidential. It is recommended to use a complex password.

## 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. Do not handle the CD while smoking or eating.
8. Do not get the CD wet.

## 1.2.3 General Operation Tips

**CAUTION**

1 The system may interfere with other devices during its operation. The data may possibly not be able to be analyzed as a result. In this case, contact the manufacturer.

2 In case of login failure due to incorrect entry of server IP in the initial installation, change the server IP in the “config” file in the root directory of client.

3 In case if any incident happens, such as power interruption or network disconnected, the system will automatically store the data and analytical results so as to provide maximum data protection.

4 Users will be disconnected from the system after a long idle period (24h by default). Log in again to the system. The data you handled before will be stored.

5 When you cannot retrieve patient information from HIS, you can manually enter a new order. The test data can be matched with the patient by the “Assign” button.

6 When data transmission fails, keep the data and contact the manufacturer for solution.

7 When data interpretation fails, the system will store the data. Users should contact the manufacturer timely.

8 To avoid data leakage, system vulnerability or attacks, disable the unnecessary ports and remote operation of the system. Disable the user accounts that are no longer used. Install the security and antivirus software such as McAfee and update periodically. Add the system to the whitelist.

9 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.

10 Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e. cannot remove without tools).

11 Ensure that the system is connected only to the device authorized/approved by EDAN. Users should operate all EDAN deployed and supported devices within EDAN authorized specifications, including EDAN approved software, software configuration, security configuration, etc.

12 Protect all the passwords to prevent unauthorized changes.

13 Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.

14 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.

15 Dos and DDos protection of the router or switch must be turned on for defensing against attacks.

16 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 PC with the system are into the same VLAN, and isolate it from other VLANs.

17 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. Refer to section 6.1.4 *Deleting Examination Records*.

18 Please protect the privacy of the information and data displayed on the screen, and those information and the data stored in the system.

19 It is recommended that you activate Windows password strategy.

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

21 Install security software, anti-virus software, and activate firewall and auto updates. Run the anti-virus software on a regular basis. Add the ECG Analysis Software to the whitelist.

22 Disable unnecessary services from the operating system and reduce vulnerabilities.

23 Close the default services of remote desktop, Telnet, file sharing of Windows.

24 It is recommended that you disable the Administrator and Guest accounts.

25 Destroy the sensitive information in the idle or scrapped device.

26 It is recommended that you change your password periodically.

### 1.2.4 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. EDAN 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 Ensure that the system is connected only to the device authorized/approved by EDAN. Users should operate all EDAN deployed and supported devices within EDAN authorized specifications, including EDAN approved software, software configuration, security configuration, etc.

4 Protect all the passwords to prevent unauthorized changes.

5 Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.

6 Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. 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.

7 Dos and DDos protection of the router or switch must be turned on for defensing against attacks.

8 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 PC with the system are into the same VLAN, and isolate it from other VLANs.

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 Please protect the privacy of the information and data displayed on the screen, and those information and the data stored in the system.

11 It is recommended that you activate Windows password strategy.

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

13 Install security software, anti-virus software, and activate firewall and auto updates. Run the anti-virus software on a regular basis. Add the ECG Analysis Software to the whitelist.

14 Failure of network security measures may lead to patient information leakage and data loss.

15 Disable unnecessary services from the operating system and reduce vulnerabilities.

16 Close the default services of remote desktop, Telnet, file sharing of Windows.

17 It is recommended that you disable the Administrator and Guest accounts.

18 Destroy the sensitive information in the idle or scrapped device.

19 It is recommended that you change your password periodically.

## 1.3 List of Symbols

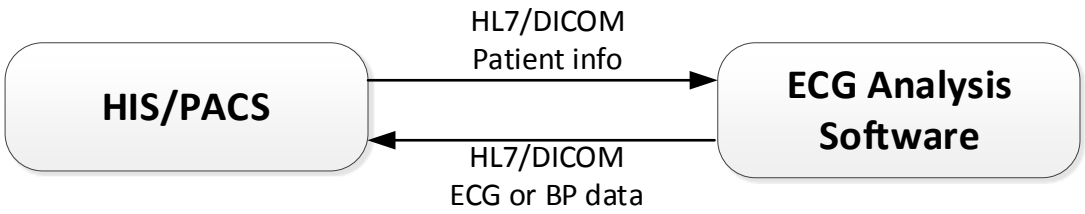
| | |
|---|---|
| SN | Serial Number |
|  | Caution |
|  | Consult operating instructions |
| P/N | Part Number |
|  | Date of manufacture |
|  | MANUFACTURER |
| EC REP | Authorized Representative in the European Community |
| CE 0123 | CE Mark |
| Rx Only | Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician. |
|  | Disposal method |
|  | Refer to instruction manual/booklet<br>(Background: Blue; Symbol: White) |
|  | General warning sign<br>(Background: Yellow; Symbol & Outline: Black) |
| MD | Medical device |
| UDI | Unique Device Identifier |

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

# 2 Introduction

The ECG Analysis Software is a network-based medical information system for ECG data management. It retrieves resting ECG data, Holter data, BP monitoring data, and the electrophysiology report. It also stores patient information and original waveforms. In addition, the software enables digital, automatic and standardized management of workflows from order, examination, diagnosis, report, browser, search, statistics, to administrator, so that teamwork is easy and efficiency is improved.

The ECG Analysis Software can be used independently or interactively with the HIS, PACS, and physical examination system. The information flow is shown in the figure below. ECG Analysis Software retrieves patient information from hospital's information system such as HIS and PACS. After processing the patient's ECG or BP data, the software returns the data to the hospital's information system. HL7 or DICOM is recommended for data transmission, but other data formats are supported as well.




The ECG Analysis Software is installed by a CD. The software system consists of server and client. The server has several modules such as database service, storage manager, data ports, and AI analysis. The client has the following modules:

- Order: Enter the patient information and generate an order for examination
- Examination: Perform the resting ECG, ambulatory ECG, or blood pressure examination according to the order list. The test data is automatically uploaded to the medical information system.
- Diagnosis: Retrieve test data and make diagnosis and upload it to the system.
- Browser: Search patient data by departments, time, or patient ID. View the data.
- Statistics: Calculate the workload of departments and staff.
- Administrator: Configure the settings of institutions, departments, users, roles, rights, package, equipment and etc.

**NOTE**: The roles of nurse, technician, and physician can assign to one individual or several individuals.

## 2.1 System Running Environment

### 2.1.1 Basic Requirements on the Internet

LAN bandwidth ≥ 300Mbps

WAN bandwidth ≥ 5 Mbps

Client bandwidth ≥ 1 Mbps

**NOTE**:

ECG Analysis Software excluding the AI-SEMIP is unable to be used when it is disconnected to the network.

### 2.1.2 Compatibility of Server

Hardware

| **Component** | **Configuration recommended** |
|---|---|
| CPU | Intel Xeon(R) CPU E5410, @ 2.33GHZ |
| Memory | ≥8G |
| Hard disk | ≥500G |

Software

| | |
|---|---|
| Operating System | Windows Server 2008 R2 or higher or version compatible |
| Database | SQL Server 2012 R2 or higher |

### 2.1.3 Compatibility of Client

Hardware

| **Component** | **Configuration recommended** |
|---|---|
| CPU | Intel(R) Core(TM) i5-6300U CPU @ 2.40GHz. Same performance or better |
| Memory | ≥8G |
| Hard Disk | ≥500G |
| Browser | IE8 or above<br>IE9 or above is recommended. |
| Resolution | ≥1360*768 |

Software

| | |
|---|---|
| Operating system | Windows 7 Pro, 32bit / 64bit or version compatible |

**NOTE:**

- If the PC is not purchased from EDAN, we will not be held responsible for the maintenance of the PC hardware or the operating system.
- To ensure the system performance, the above running requirements should be met.
- Make sure that the PC with the system have installed the graphics driver. Otherwise the ECG waveforms may not be displayed properly.
- Holter Data Views is not supported by an IE8 browser. If you need such views, install an IE9 or above browser.

## 2.1.4 Performance of Client

**Maximum Concurrency**

Up to 50 users can log in to the system or use the system for order search at the same time.

**Efficiency**

Four seconds or less are required to establish an order.

## 2.1.5 Cybersecurity Risk

The following cybersecurity risks can be reduced to the acceptable level when the following risk controls are taken.

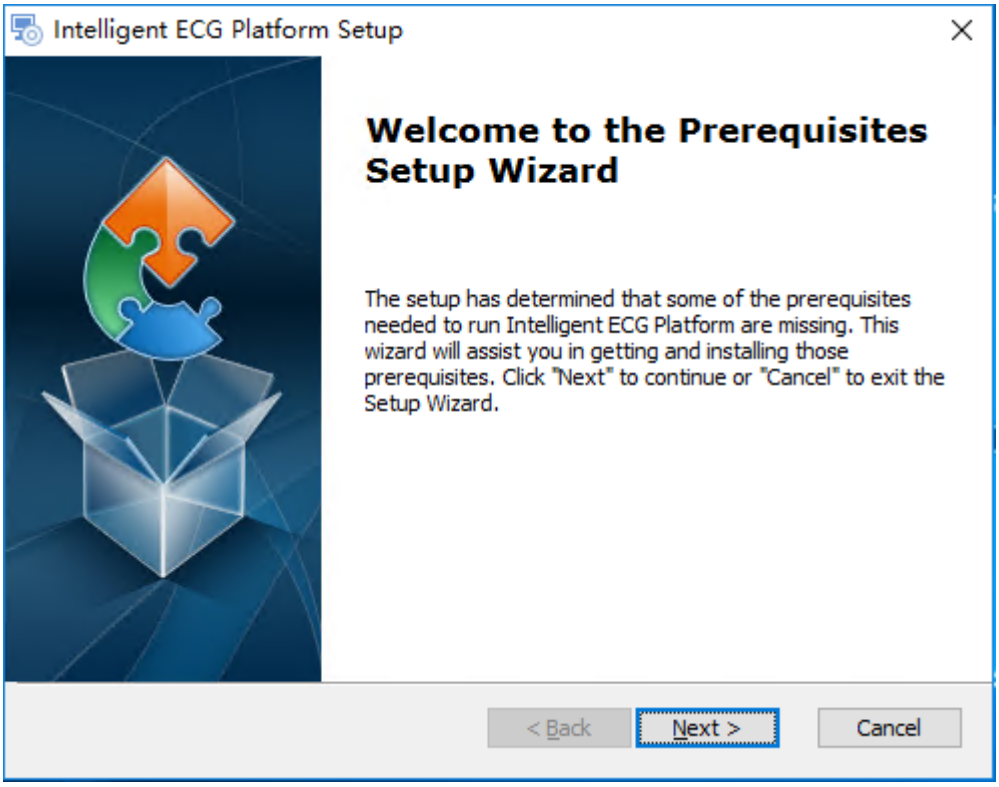
| Threat | Vulnerability | Impact | Risk Controls |
|---|---|---|---|
| The software cannot be started or data is modified or used without authorization. | Viruses invade the computers using this software. | 1 Patient data is lost.<br>2 Patient data is modified. | The computer where the software is installed needs to install anti-virus software. |
| When the software is running, viruses invade the computers that use this software. | Data is modified or transferred due to insecure network. | Patient data is leaked. | The software needs to be used in a network environment that security is ensured by the hospital. |
| The data is damaged and abnormal data is displayed when opening. | The data is altered maliciously due to insecure network. | Patient data is altered. | The software checks data integrity when the client software opens the downloaded file. |
| Data transmission failure | Data transmission fails due to network instability. | Data is lost. | The client software makes a local backup of the data it receives. |

## 2.2 Installing/Uninstalling Server Software

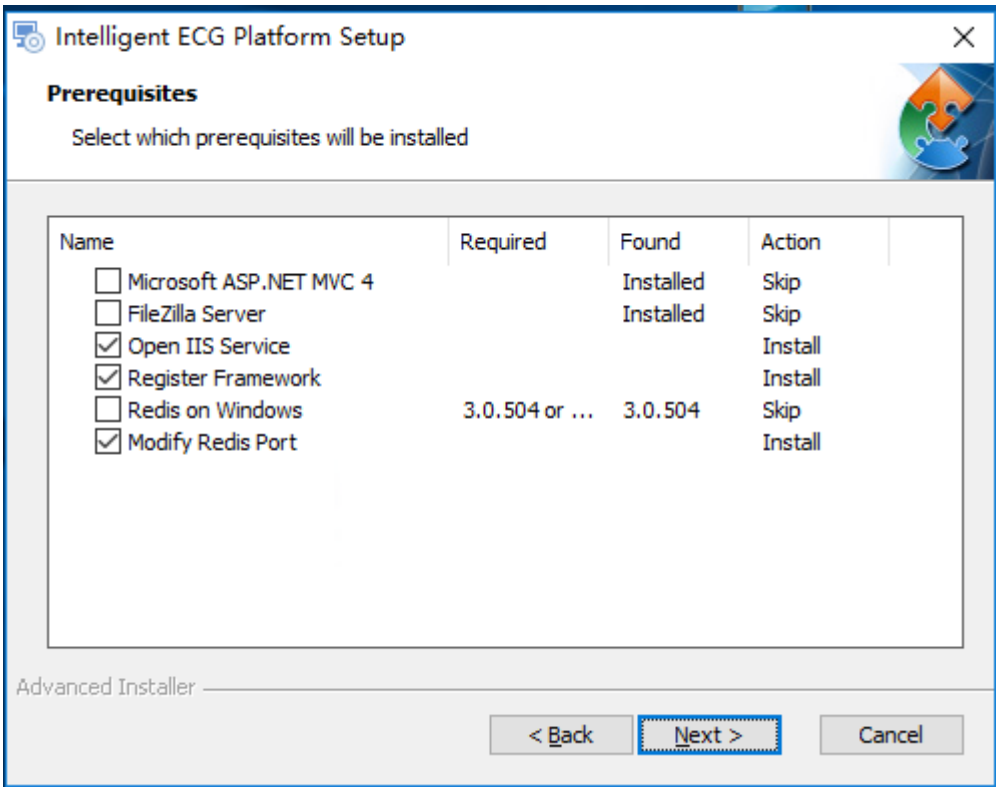
The server software should be installed or uninstalled by the engineer authorized by EDAN.

### 2.2.1 Installing Server Software

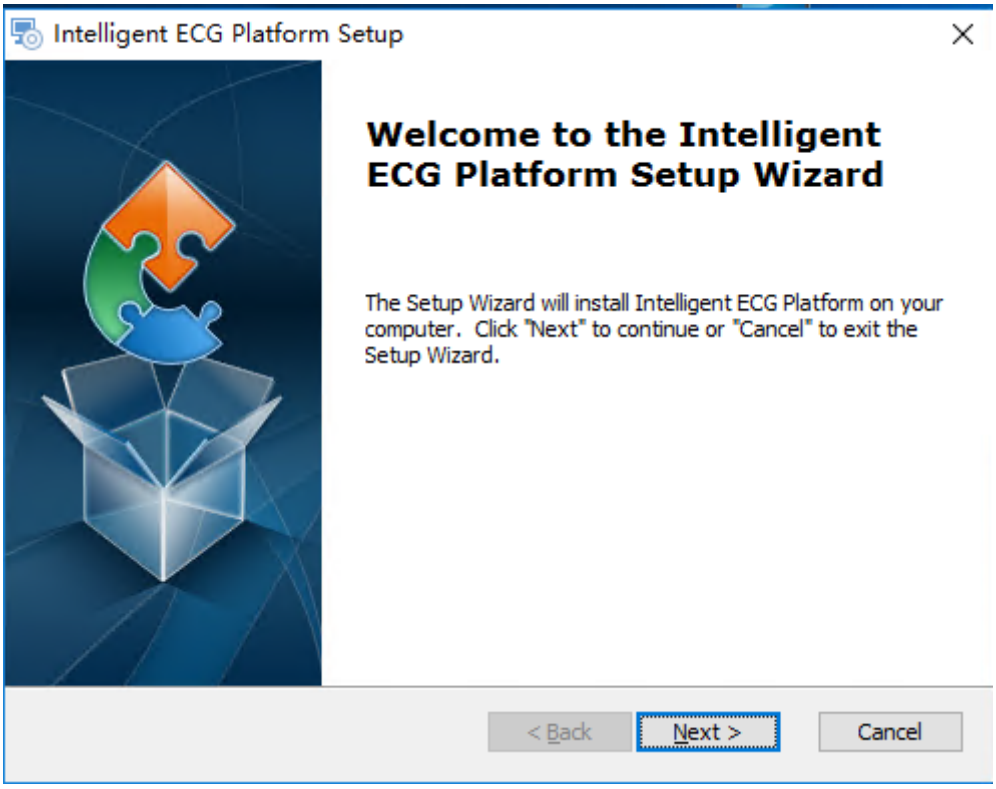
1. Double click  . The following window opens. Click **Next.**



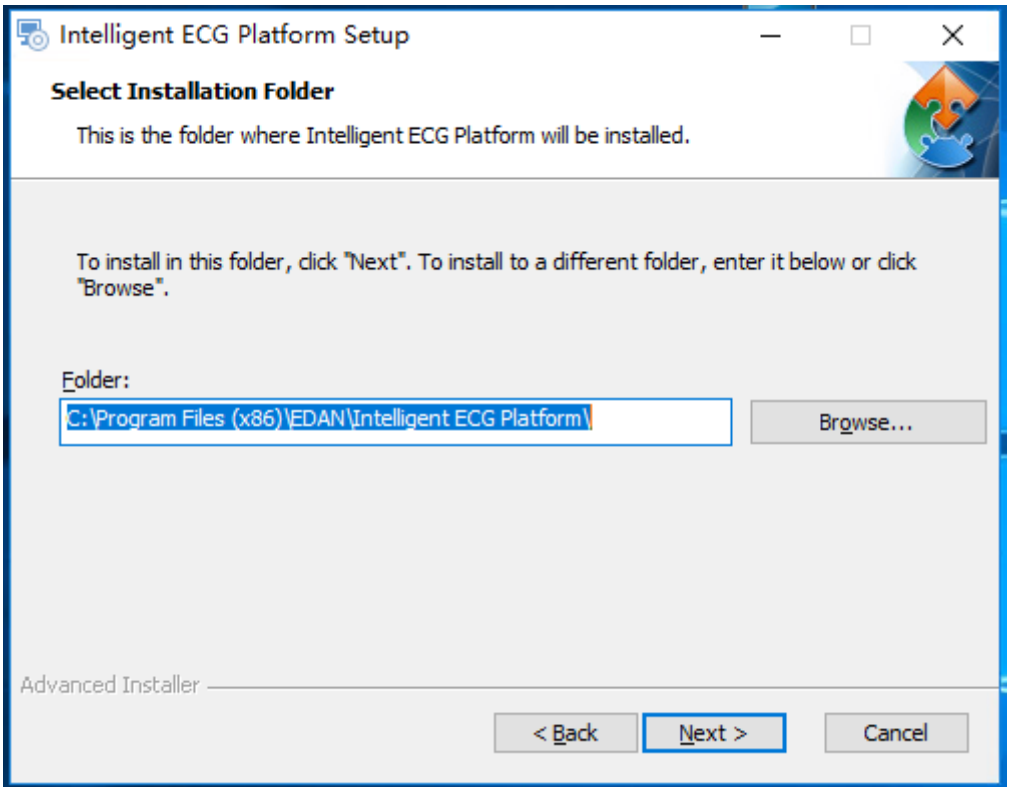

2. The system automatically identifies the prerequisites to install prior to the software. Or alternatively, you select the prerequisites to install. Click **Next**.



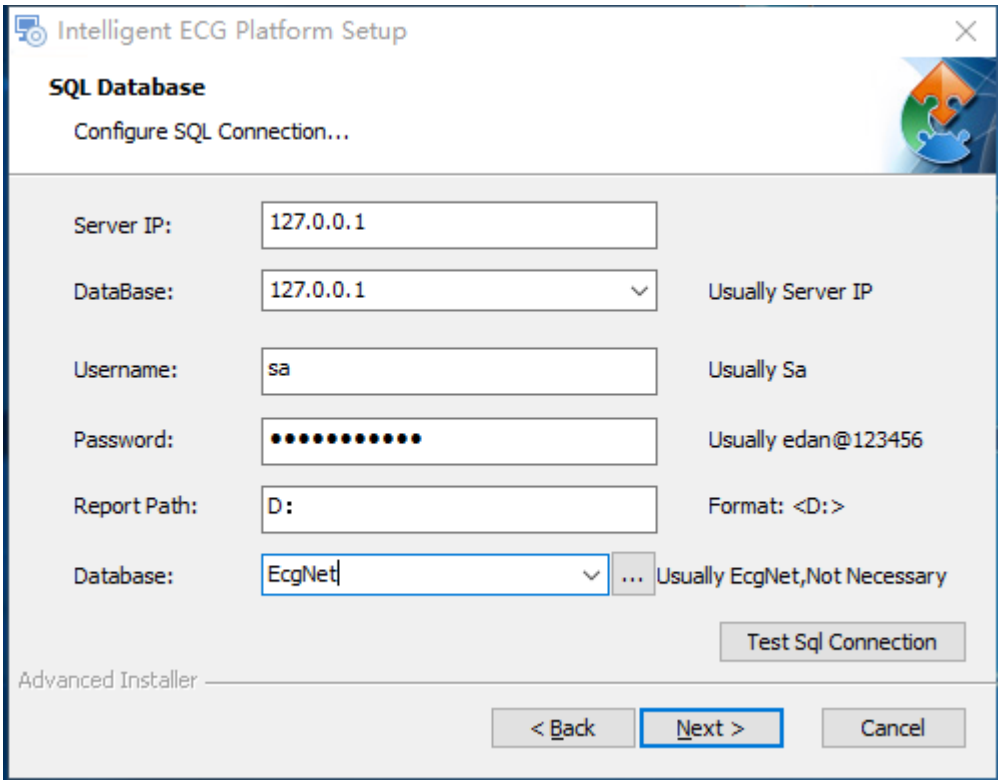

3. The system installs the prerequisites. Press any key as the message tells you to.
4. The prerequisites are installed. The following setup window opens. Click **Next**.




5. Click **Browse**. Select the installation folder. Click **Next**.




6. Fill in the text box for SQL connection. Click **Test Sql Connection**. When the test is passed, click **Next**.

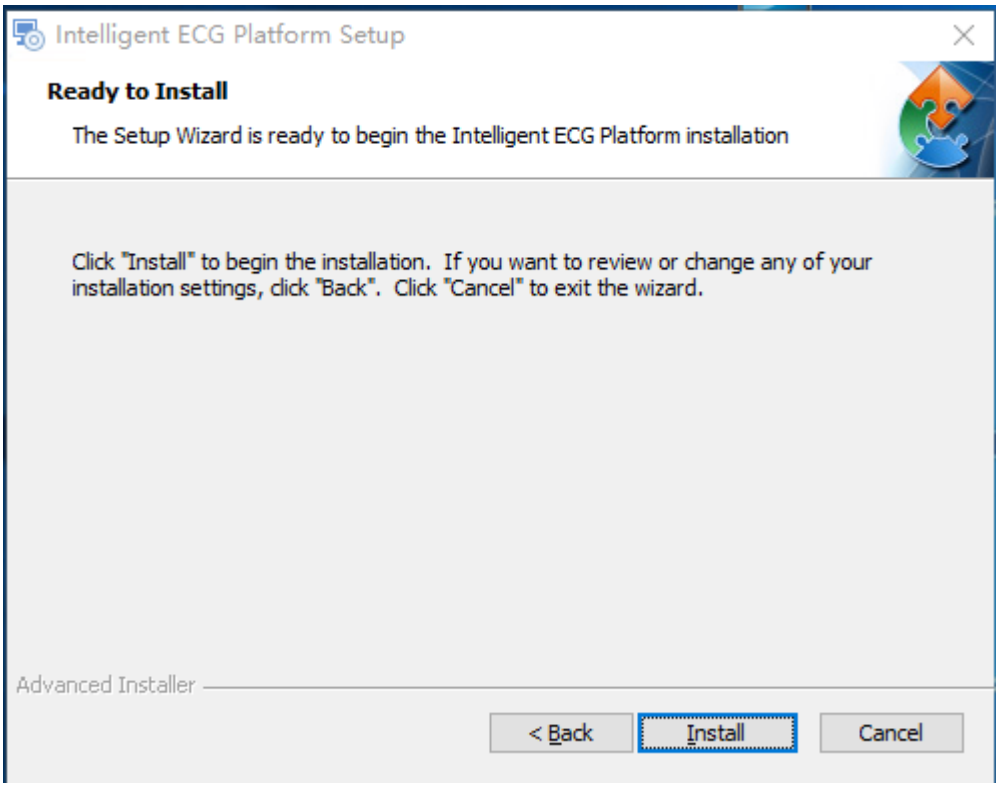


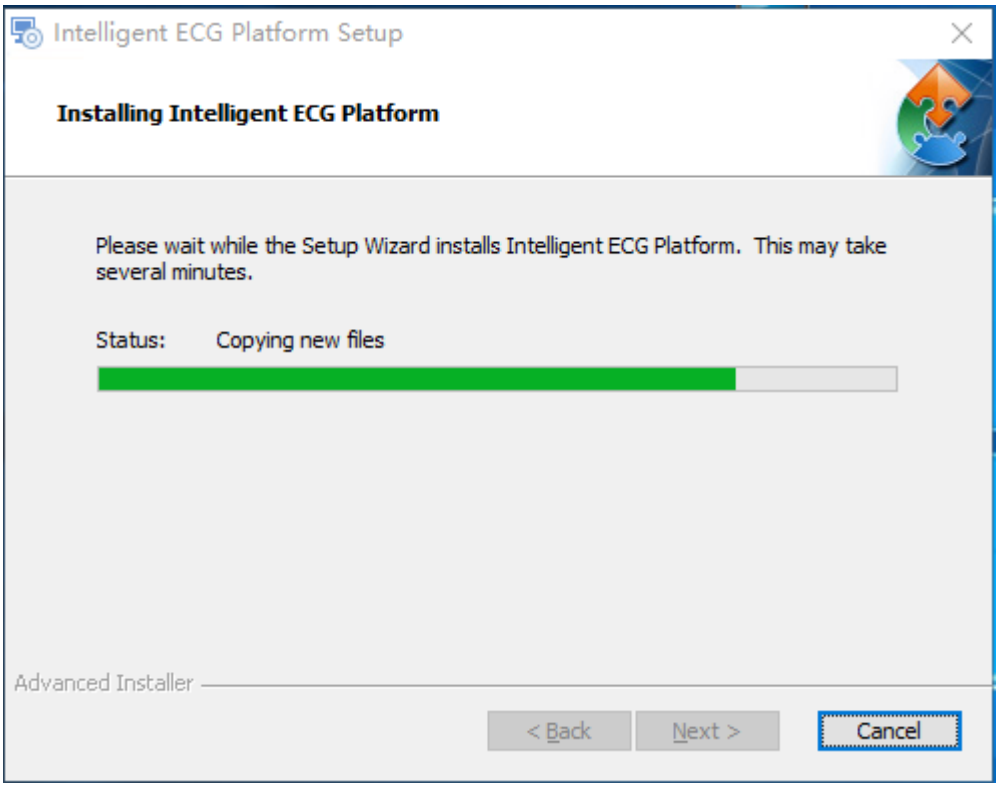

**NOTE**:

It is recommended to set a complex password that consists of numbers, letters, and special characters. The length is not less that 8 digits.

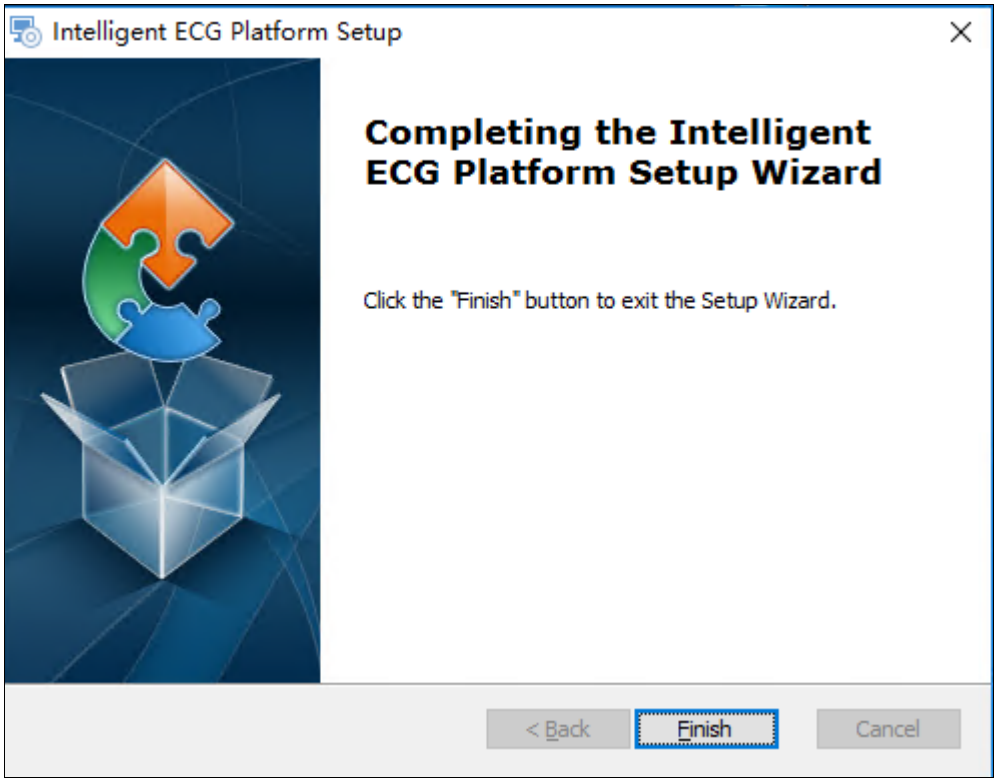
It is better to use Network Service to activate the SQL database. Grant the Write Only permission.

7. Click **Install**.




8. Wait till the installation is finished. Click **Finish.**




9. Check if the software is available in the installation folder. If available, the installation succeeds.

### 2.2.2 Uninstalling Server Software

In the server PC, select Start > Control Panel > Programs > Programs and Features. The "Uninstall or change a program" window opens. Right click **ECGServer** in the list. Select **Uninstall**. In the pop-up dialog box, select **Yes**. Wait till the software is uninstalled.

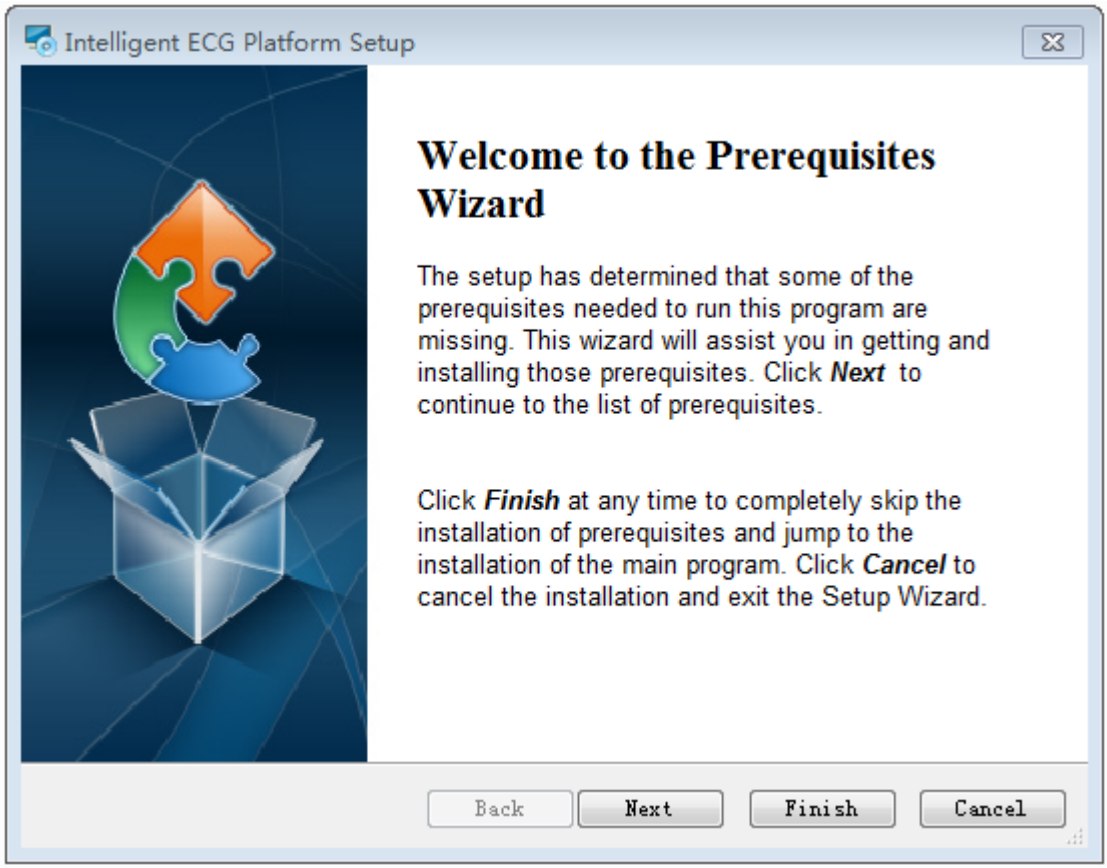
## 2.3 Installing Client Software

The following sections take the Intelligent ECG Platform for example.

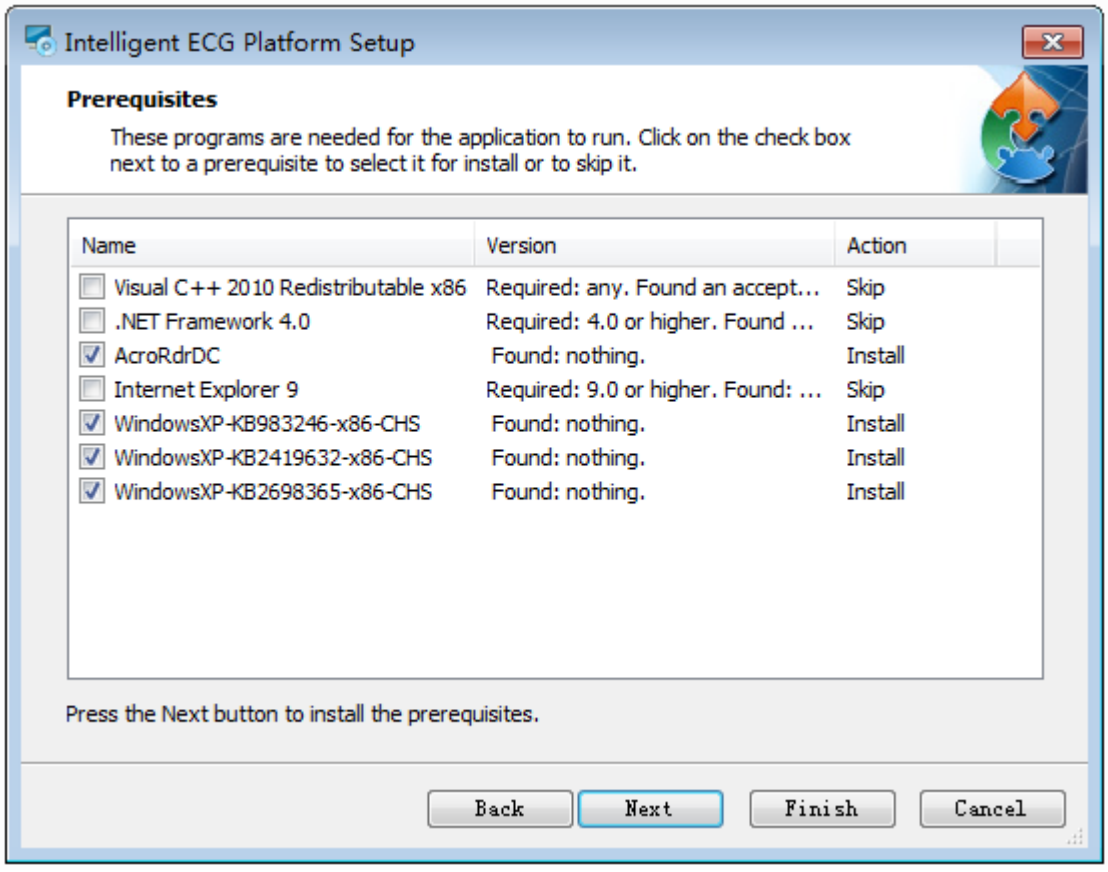
### 2.3.1 Installing Client Software

1. Double click 

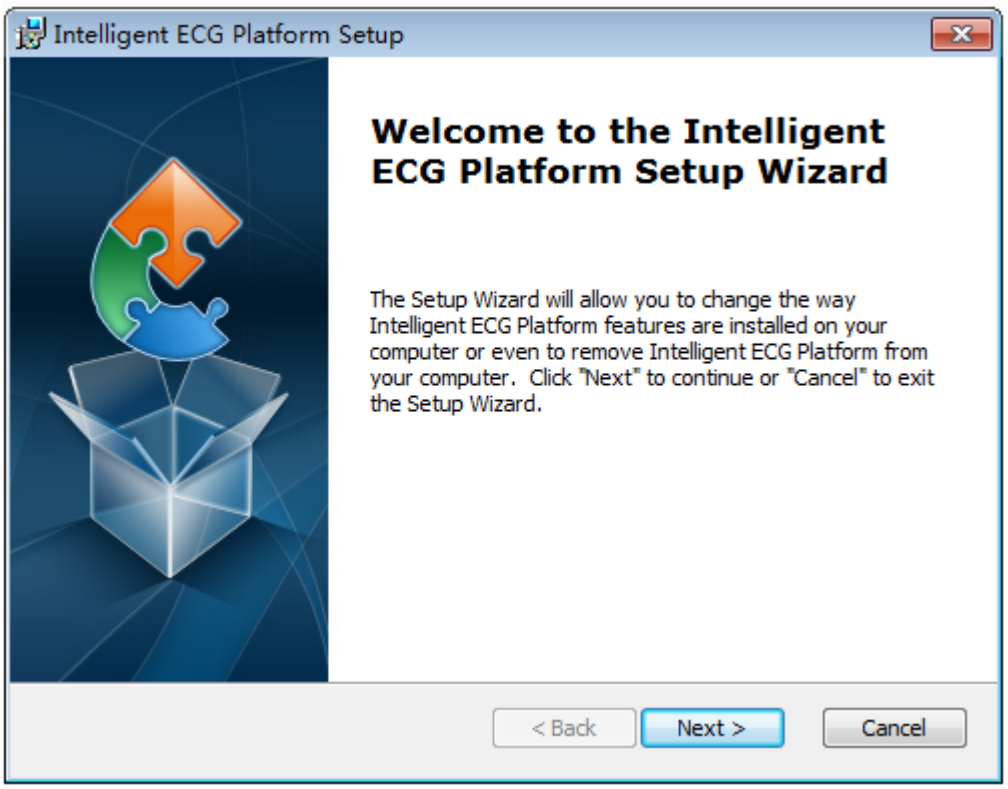
. The following window opens. Click **Next.**



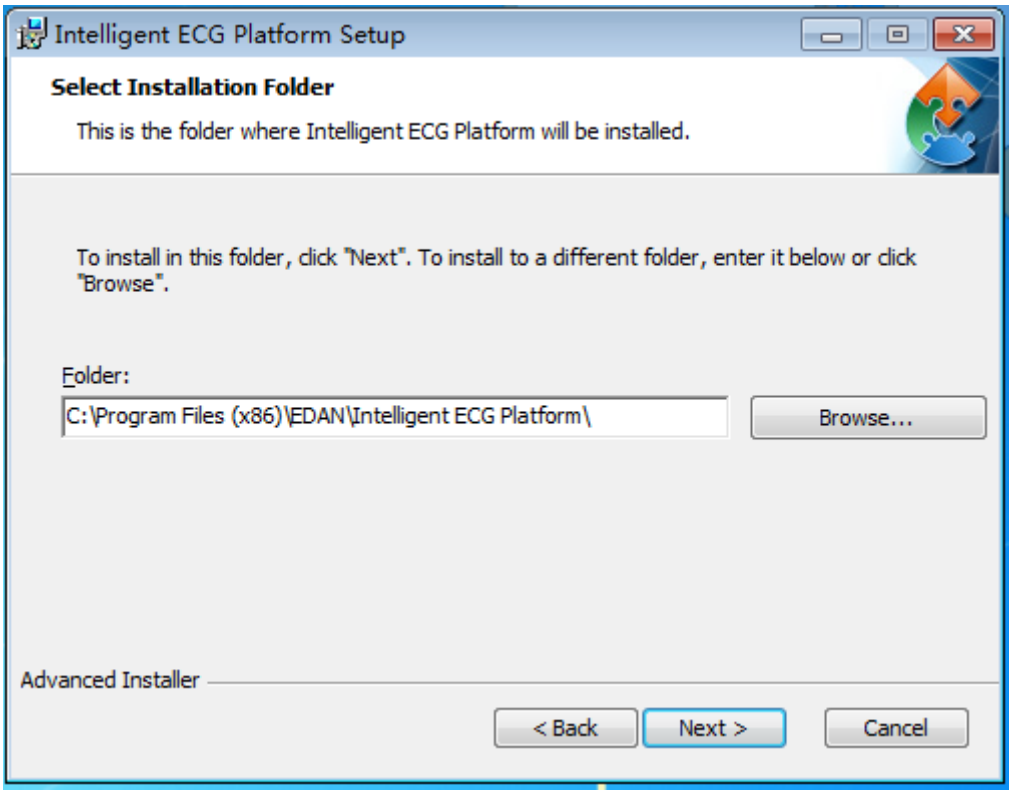

2. The system automatically identifies the prerequisites to install prior to the software. Or alternatively, you select the prerequisites to install. Click **Next**.



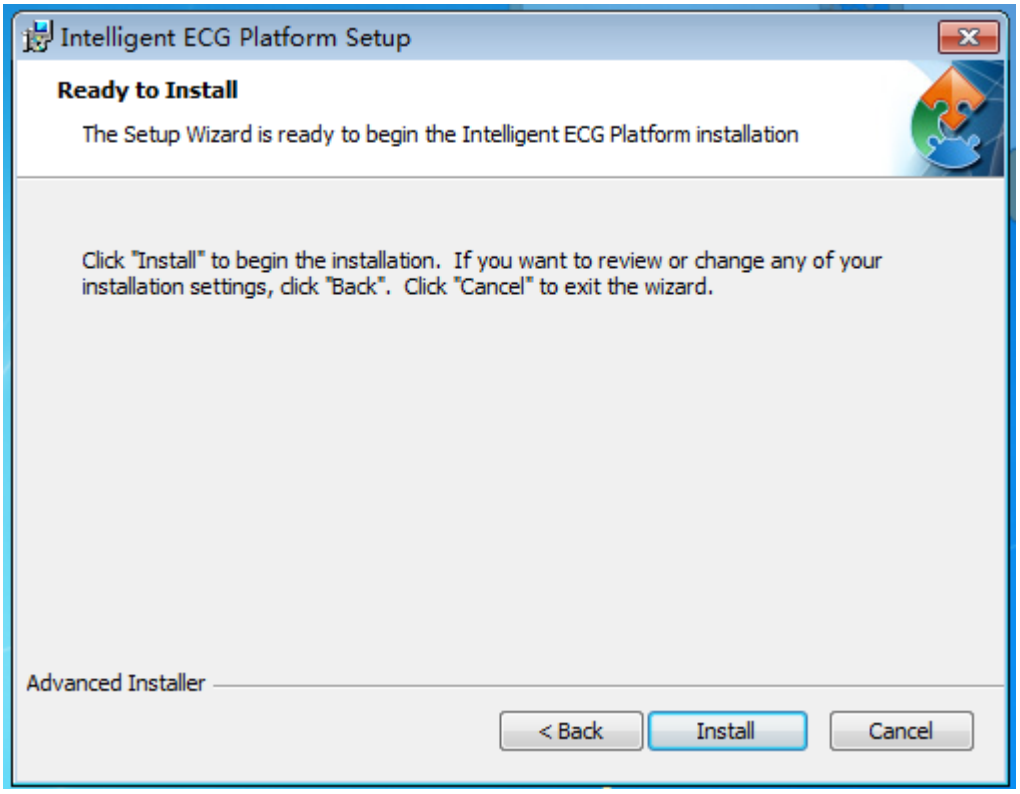
3. When the prerequisite programs are installed, the following window opens. Click **Next**.



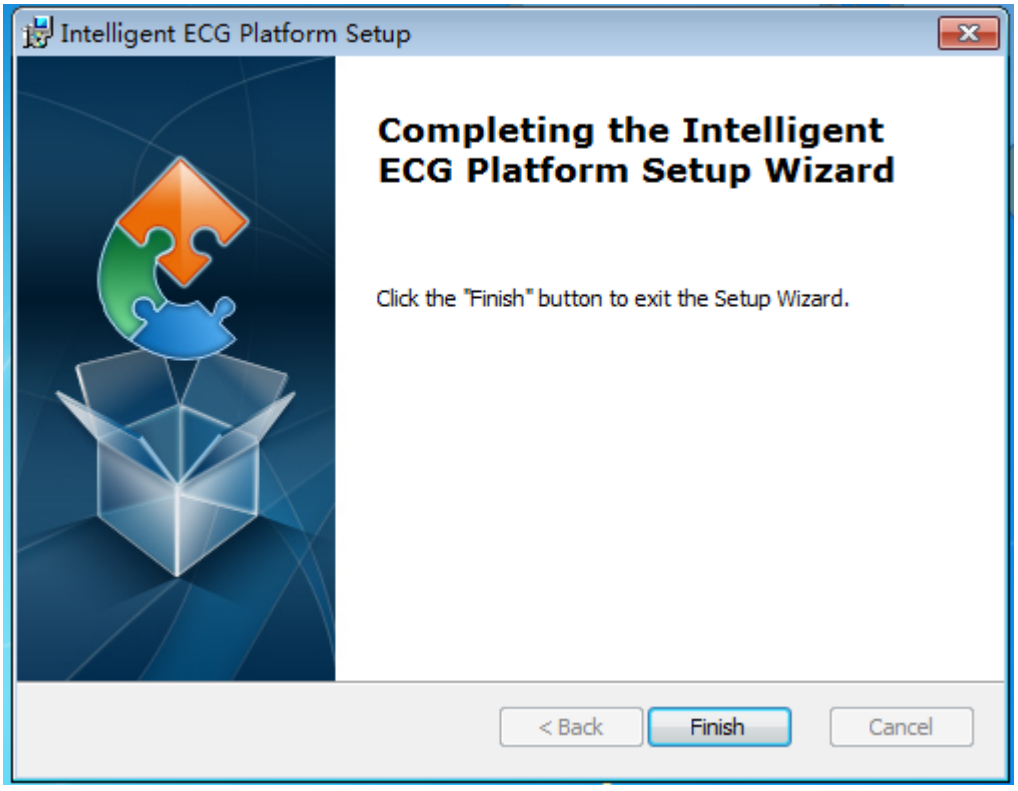

4. Click **Browse**. Select the installation folder. Click **Next**.




5. Click **Install**.




6. Wait till the following window opens. Click **Finish**. The installation of client software is finished now.




7. Check if the software is available in the installation folder. If available, the installation succeeds.

### 2.3.2 Configuring Server Connection

The client software is installed. Before login to the software, you need to configure the server connection as follows.

1. Double click 

. The server setup window opens.
2. Enter the Server IP. Click **Test**.
3. Enter the FTP IP. Click **Test**. If both the test results are passed, click **OK**.

### 2.3.3 Uninstalling Client Software

In the client PC, select Start > Control Panel > Programs > Programs and Features. The "Uninstall or change a program" window opens. Right click **Intelligent ECG Platform** in the list. Select **Uninstall**. In the pop-up dialog box, select **Yes**. Wait till the software is uninstalled.

## 2.4 Product Models and Features

The table below shows the configuration difference between models.

| Models | Features | | | |
|---|---|---|---|---|
| | **ECG data analysis** | **Resting ECG data management** | **Ambulatory BP data management** | **Holter data management** |
| Smart ECG Net | X | X | ● | X |
| Intelligent ECG Platform | X | X | X | X |
| SE-1818 | X | X | ● | ● |
| AI-SEMIP | X | ● | ● | ● |
| **NOTE**: X = Standard ● = Optional | | | | |

## 2.5 Data Ports

Serial port: USB 2.0/3.0 for data interaction.

LAN port: TCP/IP, HTTP for data interaction.

## 2.6 User Rights Management

The software provides such roles as nurse, technician, physician, director, and administrator. Different roles have different access. All needs user name and password to log in the software.

1. Nurse: access to Case Center, New Patient, and User Settings.
2. Technician: access to Case Center, New Patient, User Settings, and Data Retrieval.
3. Physician: access to Case Center, New Patient, User Settings, and Data Analysis.
4. Director: access to Case Center, New Patient, User Settings, Data Retrieval, Data Analysis, and Statistics.
5. Administrator: access to Department Management, Rights Configuration, User Management, Equipment Management, Roles Management.

# 3 Operation

This chapter describes how to operate the ECG analysis software using Intelligent ECG Platform for example.

To open the software, double click the icon 

.

To close the software, click  in the upper right corner.

To change to another user account, click **Cancellation**.

**NOTE**:

- The names of people in this user manual are fictitious.
- All illustrations in this manual are provided as examples only.

## 3.1 Backend Management

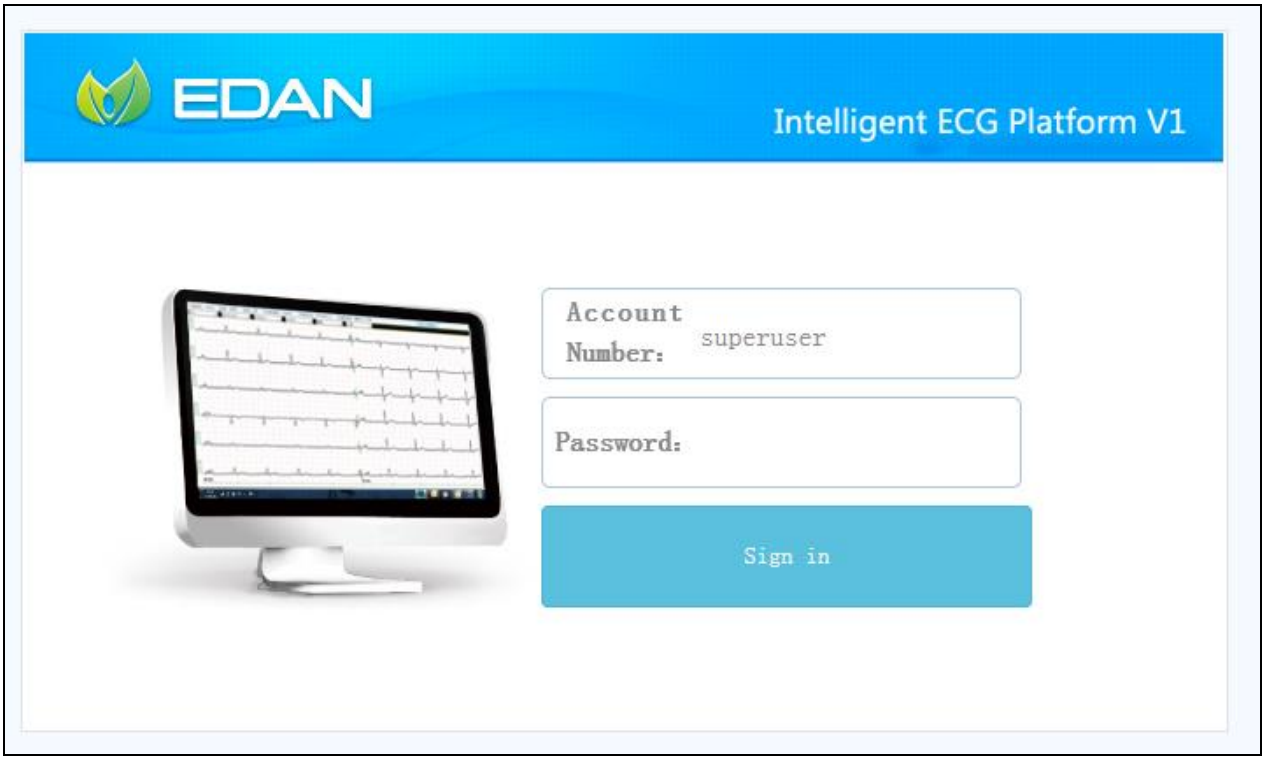
The backend management include medical institutions, departments, users, equipment, roles, rights (hospital registration), examination package, and system settings.

In the backend, you can add, delete, edit, or search for medical institutions, departments, users, departments, and etc.

### 3.1.1 Hospitals

To add a hospital:

1. Enter the administrator account and password. Click **Sign in**.




2. Click **Data**. The Data tab opens.
3. Click **Add**. A dialog box opens. Enter the hospital code (for registration), name and ESB address (http://127.0.0.1/esb/esb.asmx by default).
4. Click **Submit**.

### 3.1.2 Department

To add a department:

1. Click **Department**. The Department tab opens.
2. Click **Add**. Enter the department information.
3. Click **Submit**.

To modify department information, click **Update**.

Departments may be located in different regions. When you locate a region for a department, the region will be displayed in the frontend for institutional screening.

Mouse focus allows you to select an item to position the mouse pointer and type in the text box in the New Patient window.

Department authority means what data can be viewed by the department.

### 3.1.3 Role

In the Role tab, you can add roles to meet your needs. It is advised to assign a role a permission.

To change the name and permission of a role, click **Update**.

### 3.1.4 User

To add a user:

1. Click **User**. The User tab opens.
2. Click **Add.** Enter user information in the pop-up window.
3. Click **Submit**.

To restore the default password, click **Password Reset**. The user's password will be reset to default.

**NOTE**:

- To get the default user password, ask your administrator. To change the password, log in to the user account and change it in the user settings.
- In case if a user forgets the password, the administrator can reset it to default.
- Disable a user if necessary.

### 3.1.5 Equipment

To add equipment:

1. Click **Equipment**. The Equipment tab opens.
2. Click **Add.** Enter the necessary information such as equipment serial number and name in the pop-up window. Pay attention to the department and manufacturer model.
3. Click **Submit**.

To modify equipment information, click **Update**. All equipment information except its serial number can be modified.

### 3.1.6 Package

Please note that package is blank by default. To enable data retrieval, it is necessary to add packages.

| Serial number | Package number | Package name | Package Price | Package items | State | Sort number | Bedside or not | Report type | Operation |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 3 | Ambulatory blood pressure | 33 yuan | Ambulatory blood pressure | ✔ | 1 | ✖ | 1 | Update Disable |
| 2 | 2 | Holter | 22 yuan | Holter | ✔ | 1 | ✖ | 1 | Update Disable |
| 3 | 1 | Routine ECG (12 leads) | 11 yuan | Routine ECG (12 leads) | ✔ | 1 | ✖ | 1 | Update Disable |

## 3.2 Creating an Application

When you log in to the ECG analysis software, the client time will be synchronized with the server time.

To submit an application for test:

1. Click **New Patient** in the Case Center.
2. Enter the patient information and select a test.
3. Click **Save**.

All the on-line client software will update its list of applications. A window with the new application will pop up to prompt the user.

To modify an application, click **Edit**.

To search an application, select the search criteria on the left pane and click **Query**.

To delete an application, tick the check box before the application. Click **Delete**. A window will pop up. Click **Submit**.

## 3.3 Resting ECG

### 3.3.1 Resting ECG Data Retrieval

To retrieve ECG data, double click an application. The data is uploaded from the electrocardiograph to the ECG analysis software. The ECG analysis software can receive EDAN's DAT data and data of other formats such as SCP, FDA-XML, and DICOM. In the case of incompatible data, they will be stored in the "error" folder under the specified directory. When the ECG data is retrieved, the application is classified into the Diagnosed category. Other clients are synchronized.

To retrieve electrophysiology report, double click an electrophysiology application. A PDF report will be automatically retrieved from the electrophysiology workstation. After retrieval, the report will be archived. The application is classified into the Diagnosed category.

The communication between electrocardiograph and the ECG analysis software is as follows. The electrocardiograph downloads applications from the software via TLS protocol. When an ECG test is finished, the electrocardiograph uploads the test data to the software via SFTP. After the data is retrieved at the client, the application is classified into the Undiagnosed category. This is synchronized on other clients.

If the applications are not created at the client, you can upload them from the electrocardiograph. They will be placed in the Not Matched category. You can manually match the applications with

data or assign data to them.

## 3.3.2 Resting ECG Views

To view the ECG waveform and data, double click the undiagnosed application. Resting ECG views displays the resting ECG in various formats. These formats are displayed on a separate tab. The Resting ECG views is the place where you view, compare, and measure resting ECGs.

### Waveform analysis

In the Waveform Analysis tab, you can change the chart speed, gain, lead configuration, lead timing, reverse leads' location, zoom in or out on the waveform, and compare ECGs.

Glossary, measurement information, feature description, and diagnosis are displayed on the right pane.

- Measurement information: Values allow manual input. Favorable values are marked.
- Glossary: Add or edit the specified statements for easy selection.

Shortcut Menu

You can use a shortcut menu to access the most common tasks. You can access these tasks by clicking on the ECG traces with your right mouse button.

- R-R (bpm ) and R-R (ms): if selected, the values will be displayed on top of the ECG traces.
- Refilter: change the filter settings, including baseline filter, EMG filter, and lowpass filter.

Zoom in on a resting ECG

- To see a lead in more detail, double-click on the waveform.
- To switch to another lead for a closer look, click on the lead name such as I, II, and III in the upper left corner.
- To get R, QRS, PR, and QT/QTC values, click on a black inverted triangle. Five mark lines will appear. The values will be displayed.
- To measure ECG waveform, drag the mouse in the enlarged ECG screen. A pane with measurement results will be displayed. The pane consists of four lines. You can move each line by dragging. Moving up and down is to measure amplitude (in mV), left and right is to measure interval (in ms). Amplitude, interval, and heart rate are synchronous with line movement. You can also move the ECG waveform by clicking the yellow arrow keys.

To compare ECGs, click **Comparison**. You can select the ECGs for comparison.

AI-analysis

To analyze the ECG, click **AI-analysis**. The measurement and diagnosis by AI algorithm are displayed.

To modify diagnosis result, type in the Diagnosis text box. When you are done, click **OK**.

Creating ECG report

When you close the Waveform Analysis tab, ECG file in JPG, FDA-XML, or DICOM is generated as configured. An ECG report in PDF is created at the same time. In the report, you can see user's name or electronic signature, and product model.

## Using averaged template

In the **Average Template** tab, the 10s averaged complexes for ECG leads are displayed.
With averaged template you can perform the following operations.

- To compare the leads, select **Superposed Comparison**. Click the leads you want to compare. Their averaged templates are displayed in gray.
- To measure the complex, click **Ruler**. Drag the mouse from the onset to the offset. The duration, amplitude, and heart rate are displayed.

## Detailed measurements

The detailed measurement values are available on the right pane of the tabs such as Waveform analysis, Average template, and Rhythmic waveform.

## Rhythm analysis

To access the rhythm ECG analysis, click the **Rhythmic waveform**. In this tab, you can review rhythm ECG, arrhythmia, and other events you mark.

## Preview before print

You can preview the ECG report before print by the Preview tab.

In this tab, you can view the previous or next page, zoom in or out the report, and print the report.

To exit the preview, click **Close**.

## Printing ECG report

To print an ECG report, click the **Confirm and Print** tab or the **Print** button in the Preview tab.

Or alternatively, click the **Print** button in the Case Center. You can print multiple diagnosed reports at a time.

**NOTE:**

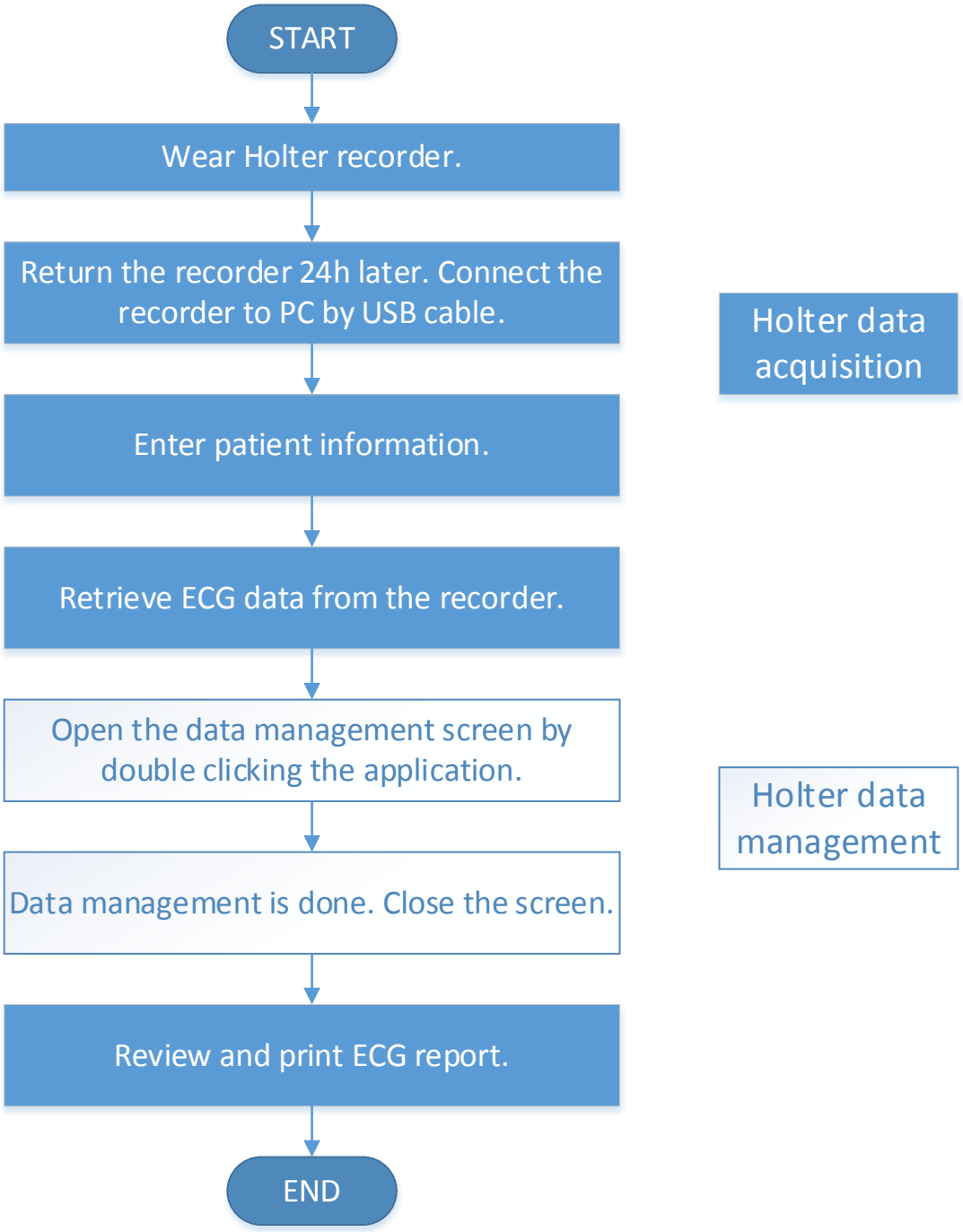
Printers should be configured in the Windows or other operating system. To install or add a color printer, check Microsoft's website to learn more. If a black and white printer is connected to your PC, you can print ECG reports in black and white only.

## Storing ECG report

To store an ECG report, click **OK** under the diagnosis text box. Click **Browse**. Select the directory for storage. The file format can be configured in the backend. PDF and JPG formats are available.

ECG reports generated from other devices are stored in the specified directory. They can be archived and reviewed.

## 3.4 Holter




### 3.4.1 Holter Data Retrieval

To retrieve Holter data from EDAN's SE-2003&SE-2012 series Holter recorder:

- Connect the recorder to your PC by an USB 2.0 cable. Open the ECG analysis software. Double click the application that is not checked in the case center. The software

automatically retrieves Holter data from the recorder. The data is now matched to the application.

- Connect the recorder to your PC by a USB 2.0 cable. Store the Holter data to your PC. Open the ECG analysis software. Double click the application that is not checked in the case center. Click **Browse** to locate the data you store in the PC. Click **OK**. The data is now retrieved by the software.
- In the case of Holter electrophysiology, double click the electrophysiology application that is not checked in the case center. A PDF report is retrieved from the workstation. The application is now classified into the category of diagnosed.

A message is displayed when data retrieval is done. The application is classified into the category of Undiagnosed. And its status is synchronized on other clients.

## 3.4.2 Holter Data Views

To access the Holter views, double click the application. The data is automatically downloaded, decompressed, and displayed in the Case Center.

To create a Holter report, enter your diagnosis in the box and click **OK**. A PDF report is created. The report may include: Interpretative summary, statistics per hour, strips graph, ST event list, atrial fibrillation list, ST trending chart, HRV time-domain report, HRV power spectrum, QT analysis report, pacing analysis report, full enclosure report.

To print a Holter report, click **Preview** or **Printing**. Or alternatively, select diagnosed applications in the Case Center and click the **Print** button. You can print multiple reports at a time.

To delete an application, tick the check box before it, and click **Delete**. A message is displayed. Click **OK**. The application is deleted.

### 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

  The software uses algorithm to calculate the average heart rate.

### R-R interval 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.

## STe

With STe 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 and HR trend.
- Define new ST events.
- Review and measure ECG.

The **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.

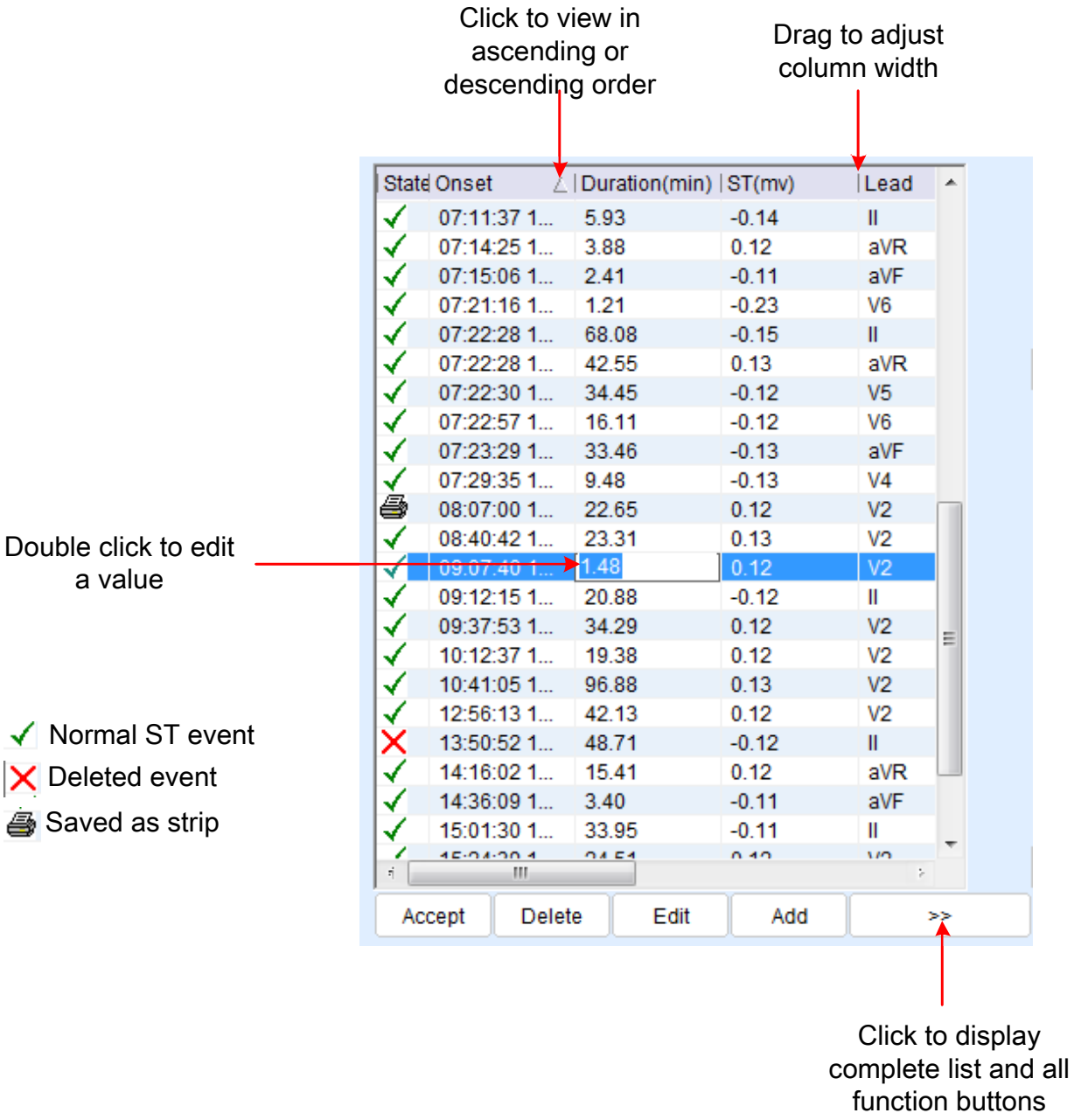
Threshold can be reset to measure ST segment changes.

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.

## ST event list

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




Function buttons and their descriptions are as follows:

| Button | Description |
|---|---|
| **View** | To display ST events, you can select to either show all or hide deleted events. If **Hide Deleted** is selected, the deleted event will not be displayed in the event list. |
| **Accept** | Set a deleted ST event as normal. |
| **Delete** | Delete the selected ST event. |
| **Edit** | Edit the selected ST event.<br>If multiple ST events are selected, the last selected event will be edited. |
| **Add** | Add a new ST event manually. |
| **Reanalyze** | Reanalyze the ECG record. |

| | |
|---|---|
| **All CH.** | Select one lead or all leads (channels) to be analyzed. The default setting is **All CH.**. |
| << | 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: save strip, unsave, select all.

Trend charts

To display another type of trend chart, click **Trend Types**.

## 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.

## 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.


Reset the following threshold values to reanalyze the ST trend.


- 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 as follows:

J+80 msec, if heart rate < 100 bpm

J+72 msec, if 100 bpm ≤ heart rate < 110 bpm

J+64 msec, if 110 bpm ≤ heart rate < 120 bpm

J+60 msec, if heart rate ≥ 120 bpm

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

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

# 3.5 Ambulatory Blood Pressure

## 3.5.1 ABP Data Retrieval

To retrieve ABP data:

- When the patient return the ABP monitor, connect the ABP monitor to your PC by a USB 2.0 cable. Log in to the ECG analysis software. Double click the application in the category of "Not checked". ABP data is retrieved and stored in the server. The application is now classified to the category of Undiagnosed. This status is synchronized on the other clients.
- To retrieve electrophysiology report, double click an electrophysiology application. A PDF report will be automatically retrieved from the specified directory. After retrieval, the application is classified into the Diagnosed category, which is told by a pop-up window and voice prompt.
- To match ABP data to an application, select the undiagnosed data. Click **Assign**. Select the application from the category of "Not checked". The ABP data is now combined with the application.

  If a message tells you that the device is disconnected, check if the ABP monitor works properly and if its connection with the PC is good.

## 3.5.2 ABP Data Views

To access the ABP data views, double click the application. The data is automatically downloaded and displayed. The ABP data views display ABP data table, 24-hour BP profile, and statistics.

To change the status of ABP data, double click the data in the BP data table. Data excluded will not be counted among the BP statistics. In the statistics tab, each table includes systolic BP pressure, diastolic BP pressure, mean arterial pressure (MAP), the maximum, minimum, and mean of BP pressure, standard deviation, and coefficient of variation (CV).

In addition to BP statistics, the 24-hour profile, histogram, correlation, and pie chart are available to display the ABP data.

To create a BP report, click **OK** when diagnosis is done. A PDF report with product model is generated. The report will be stored in the server when you exit the ABP data views. The application is classified to the diagnosed category.

### 3.5.3 Previewing and Printing BP Report

To preview the BP report, click the **Preview** button in the upper right corner of the ABP Data Views.

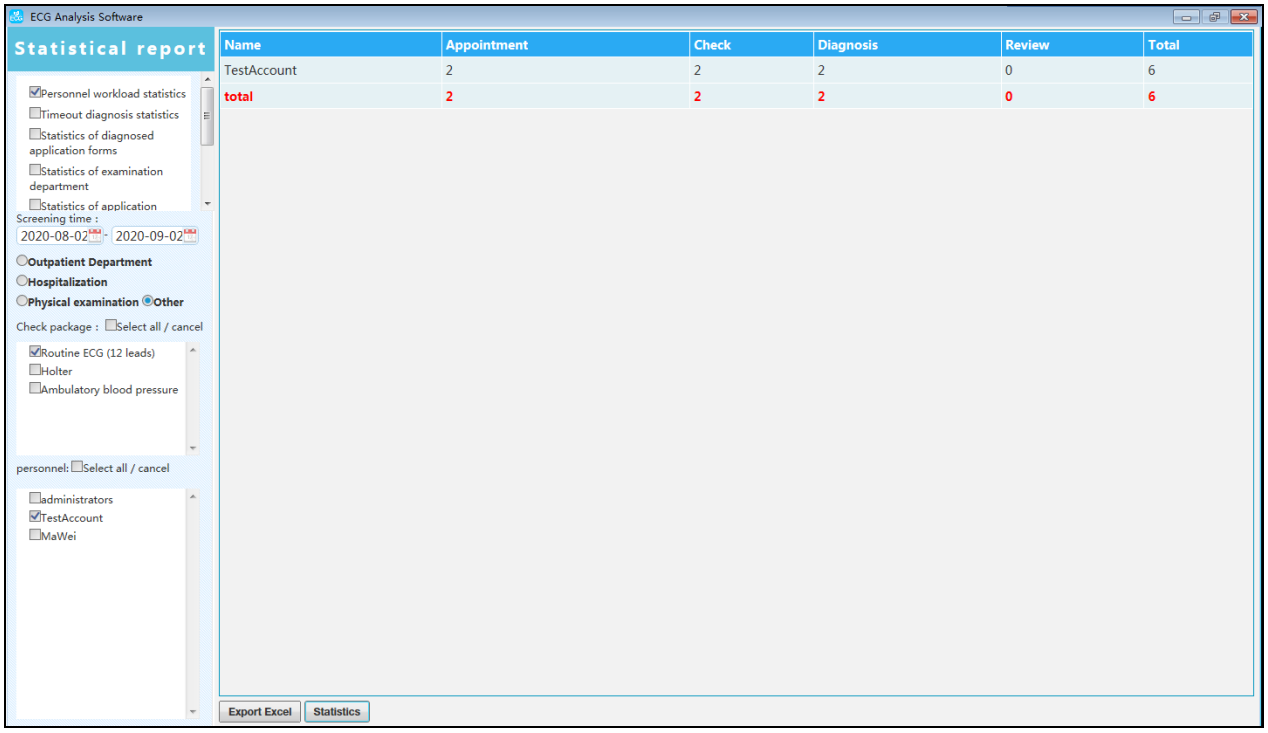
To print a BP report, select the application in the Case Center. Click **Print**. You can select multiple applications to print at a time.

If you use a browser to log in to the ECG Analysis Software, double click the application. You can review the application and its PDF report.

## 3.6 Statistics

1. Click **Statistics** in the Case Center. The Statistical Report screen is displayed.
2. Select the item from the left pane to calculate.
3. Click Statistics. The statistical table is displayed on the right pane.

With Statistics, you can calculate personnel workload, timeout diagnosis, and etc. You can also export the statistical table to an excel file by clicking **Export Excel**.



## 3.7 Other

### 3.7.1 Restrictions

User name and passwords consist of 2-20 letters and numbers. In the New Patient window, user name should be 0-30 Chinese or English characters. Special characters are allowed. Once the length is exceeded, a window will pop up to prompt you.

### 3.7.2 Warning Message and Operation Log

The software monitors the server for its storage space. Once the storage space reaches the warning limit, a warning message will be displayed to prompt you.

The software keeps track of user operation in the operation log. So the operation of software is traceable.

### 3.7.3 System Message

System messages and the corresponding causes are listed as follows:

| System Messages | Causes | Actions Taken |
|---|---|---|
| Please select an institution. | You log in to the client software right after a department is established or changed. | Select the institution as appropriate. |
| Wrong user name or password | The user name or password you enter is incorrect. | Enter the correct user name or password. |
| This user is not found. Please enter the correct user name and password. | The user name you enter is unavailable. | Create the account before login. |
| Data loading…please wait. | The waveforms are being loaded in the Waveform Analysis tab. | Wait till the waveforms are displayed. |

## 3.8 Data Backup and Recovery

### 3.8.1 Data Backup

The database of ECG Analysis Software can be backed up manually or automatically. The backup

needs to store in an external storage device. If server malfunction causes data loss or database corruption, you can use the backup to restore the data or database.

The Network Service is adopted for services. You need to activate the service yourself. With an account, you can access the directory and have the write permission only.

To back up the database:

1. Open the SQL Server. Enter the predefined user name and password for login.

   **NOTE**: SQL Server is not provided by EDAN. You need to purchase prior to use.

2. Expand the SQL server where you want to create your backup plan. Expand the **Management** folder. Right-click the **Maintenance Plans** folder and select the **Maintenance Plan Wizard**.
3. On the **SQL Server Maintenance Plan Wizar**d page, click **Next**.
4. On the **Select Plan Properties** page:
   a. In the **Name** box, enter the name of the maintenance plan you are creating.
   b. In the **Description** box, briefly describe your maintenance plan.
   c. In the **Run as** list, specify the credential that Microsoft SQL Server Agent uses when executing the maintenance plan.
   d. Select **Single schedule for the entire plan or no schedule** to specify the recurring schedule of the maintenance plan.
   e. Under Schedule, click **Change**. Specify the frequency of occurrence. Click **Next**.
5. On the **Select Target Servers** page, select the servers where you want to run the maintenance plan. This page is only visible on SQL Server instances that are configured as master servers.
6. On the **Select Maintenance Tasks** page, select **Backup Database (Full)**. Click **Next**.
7. On the **Select Maintenance Task Order** page, click **Next**.
8. On the **Define Backup Database (Full)** page, select the database or databases on which to run a full backup.

   Select the following options that are available on this page:

   **Database** list

   Specify Specific database.

   **Backup component**

   Select **Database** to back up the entire database.

   **Backup set will expire**

   Select **After** and enter a number of days to expiration, or select **On** and enter a data of expiration. This option is disabled if **URL** is selected as the backup destination.

   **Back up to**

   Select **Disk**.

   **Create a backup file for every database**

Create a backup file in the location specified in the folder box.

**Set backup compression** list

Select **Use the default server setting**.

When finished, click **Next**.

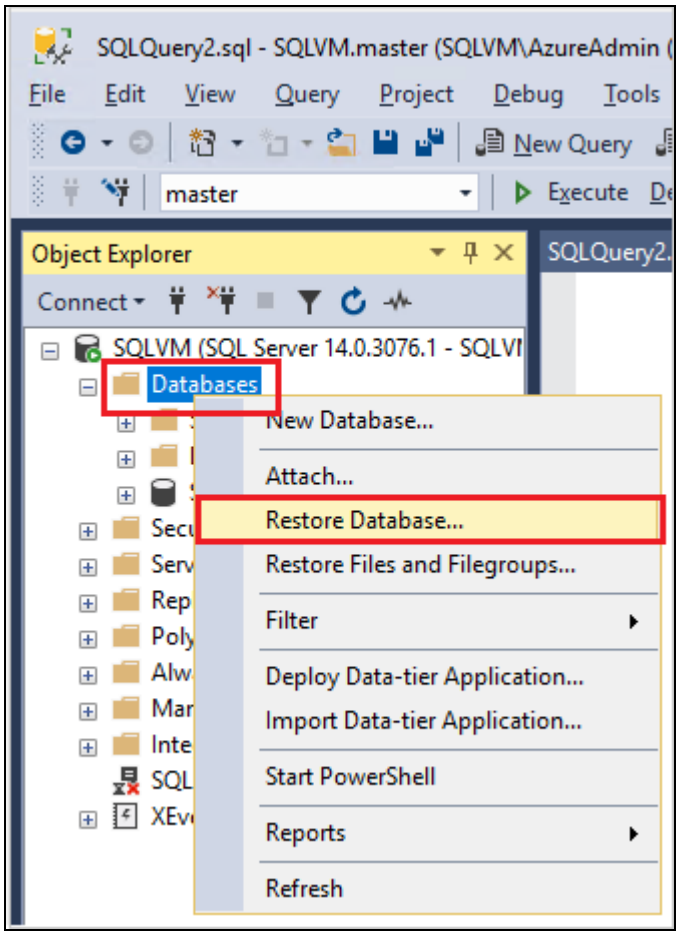
9. On the **Select Report Options** page, select **Write a report to a text file**. In the **Folder Location** box, specify the location of the file that will contain the report. Click **Next**.
10. On the **Complete the Wizard** page, verify the choices made on the previous pages, and click **Finish**.

When finished, the database (with .bak as file extension) will be automatically backed up to the specified location as scheduled.

### 3.8.2 Data Recovery

To restore your database:

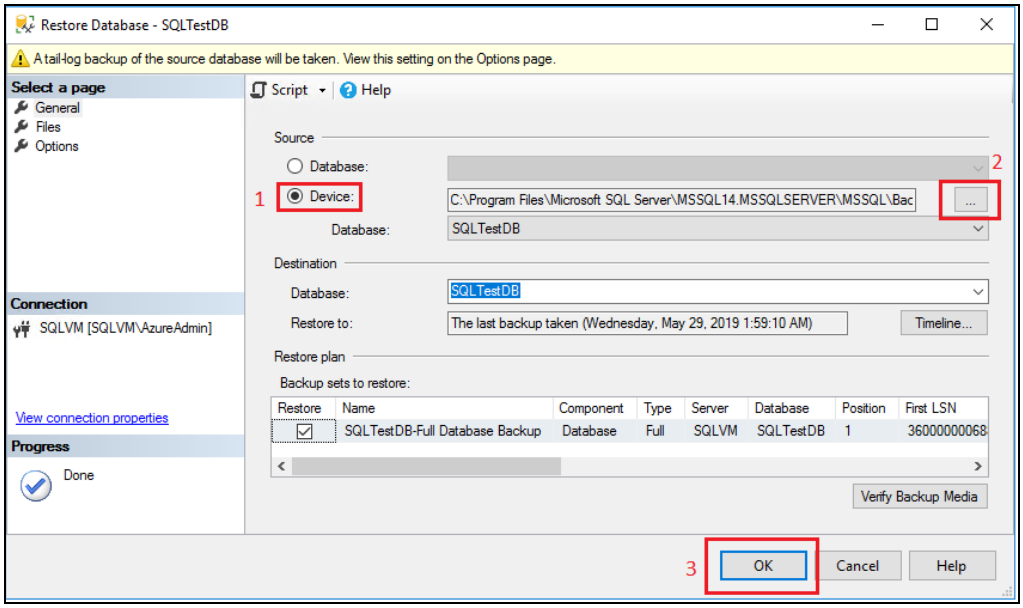
1. Launch SQL Server Management Studio (SSMS) and connect to your SQL Server instance.
2. Right-click the **Databases** node in **Object Explorer** and select **Restore Database…**.




3. Select **Device:** and then select the ellipses (…) to locate your backup file.
4. Select **Add** and navigate to where your .bak file is located. Select the .bak file and then select

**OK**.

5. Select **OK** to close the **Select backup devices** dialog box.
6. Select **OK** to restore the backup of your database.




## 3.9 Care and Maintenance

### 3.9.1 Care and Maintenance

**WARNING**

1. If the software is not in use for a long time, please log out as instructed. Avoid improper shutdown operations.
2. Use security software to scan the software on a periodic basis. Protect the software against virus infection.
3. Clean the software cache periodically. Avoid program running stuck.
4. The maintenance operations like software upgrade can only be completed by EDAN-qualified service personnel.
5. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

For the manufacture date, see the product label. There is no limit to the service life of the software.

### 3.9.2 Troubleshooting

| Trouble | Cause | Action | Remarks |
|---|---|---|---|
| Software login failure | OCX is not registered. | Register OCX at the root directory of client. | Only the administrator has such a permission. |

## 3.10 Warranty and Service

### 3.10.1 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.

### 3.10.2 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.

# Appendix 1 Abbreviations

| Abbreviation | Full Description |
|---|---|
| BP | Blood Pressure |
| ECG | Electrocardiogram/Electrocardiograph |
| HR | Heart Rate |
| USB | Universal Serial Bus |
| AGC | Auto Gain Control |
| HIS | Hospital Information System |
| PACS | Picture Archiving and Communication System |

# Appendix 2 Technical Specifications

The ECG Analysis Software complies with the following technical specifications:

EN 62304:2006 +A1: 2015
EN 60601-1-6: 2010+A1: 2015
EN 60601-2-47: 2015
EN 60601-2-25: 2015
EN 82304-1: 2017
EN 62366 -1: 2015

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