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# 1 Basic Information

## 1.1 Manufacturer

Company: Shenzhen New Element Medical Equipment Technology Development Co., Ltd.

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Email: xys@szxys.cn

## 1.2 Product

Name: Remote & Mobile ECG Monitoring System (hereinafter referred to as the system)

Model: XYS.WRM-1E

File Name: Product Description

File Number: XYS-WRM-1E (E)-E-005

Version: C/1

Date: November 2010

Language: English

## 1.3 Revision History

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Table 1-1 shows the revision history.

**Table 1-1**

<b>Date</b>	<b>Version</b>	<b>Description</b>	<b>Remarks</b>
-------------	----------------	--------------------	----------------



<b>Date</b>	<b>Version</b>	<b>Description</b>	<b>Remarks</b>
04/2008	A/0	The first version.	Software version 1.0
06/2010	A/1	Features are added or revised.	Software version 1.1
07/2010	A/2	Problems in V1.1 are solved.	Software version 1.2
08/2010	C/0	Problems in V1.2 are solved; new features are added.	Software version 1.3
12/2010	C/1	New features are added.	Software version 1.4.3

## 1.4 Product Classification

ECG collectors are internal-powered general devices, type CF application instead of type AP or APG.

## 1.5 Application Standards

GB/T 191-2000, GB 9706.1-2007, GB 9706.25-2005, GB 9969.1-2008, YY 1139-2000

## 2 Overview

Remote & Mobile ECG Monitoring System, model XYS.WRM-1E (hereinafter referred to as the system), is developed and manufactured by Shenzhen New Element Medical Equipment Technology Development Co., Ltd.

Integrating advanced medical and information technologies, the system can monitor ECG anytime and anywhere by employing world wide network resources. Doctors can monitor, analyze and process ECG signals remotely, enabling remote diagnosis, home treatment, centralized patient management. This is essential network and digital monitoring.

The system enables patients to obtain doctors' diagnosis and suggestions in time. Thus, doctors can get ECG monitoring conveniently. For malignant cardiovascular disease patients, their relatives and doctors can be alarmed immediately in the case of emergency. Then, patients can be rescued and treated timely.

### 2.1 Components

The system consists of ECG collector, lead wires and software (health mobile phone and server). See Figure 2-1.



**Figure 2-1 ECG Monitoring System**



## 2.2 Work Flow

The system can collect ECG signals through ECG collectors and send the signals to health mobile phone via Bluetooth in real time for analysis. It will automatically send an alarm in case of abnormal ECG (or manual alarm by pressing the "Emergency" button), and upload ECG data to the remote server through GPRS/Internet. The server will send an alarm immediately after receiving abnormal ECG signals to the doctor for timely processing.

## 2.3 Application

Applicable to abnormal ECG and HR signals monitoring.

### 3 Central Service Website

Welcome to use Remote & Mobile Medical Monitoring System. You can type the server address (for example: <http://121.33.253.77/Wrm20091201/Default.aspx>) in the address bar of IE to access the homepage (as shown in Figure 3.1-1).

#### 3.1 Common Operations

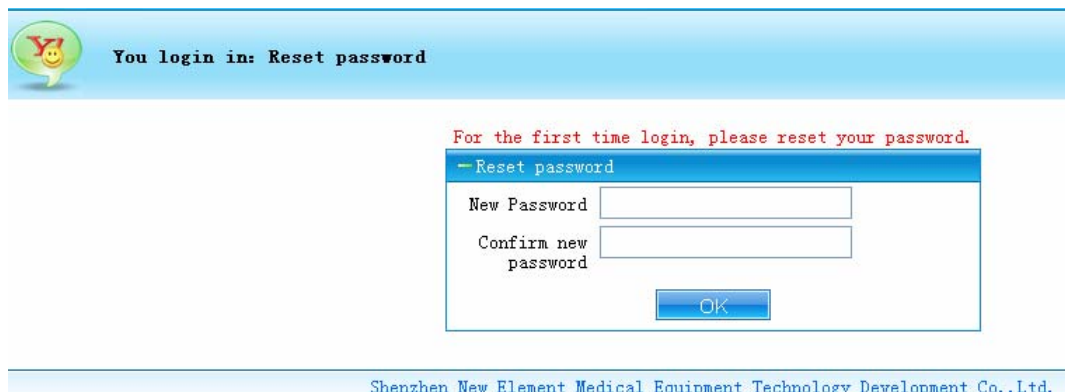
##### 3.1.1 Login and Logout

Access the system website. For a user who does not log in, the page will be redirected to <http://domain name/WrmWeb/Default.aspx>. See Figure 3.1-1.



**Figure 3.1-1 Login interface**

Password change is required by the system after the first login. The interface is as follows:





### Figure 3.1-2 Password reset interface

The homepage after login is shown in Figure 3.1-3.

Logout: to protect your privacy, click **EXIT** on the upper right to quit the system.



Figure 3.1-3 Homepage

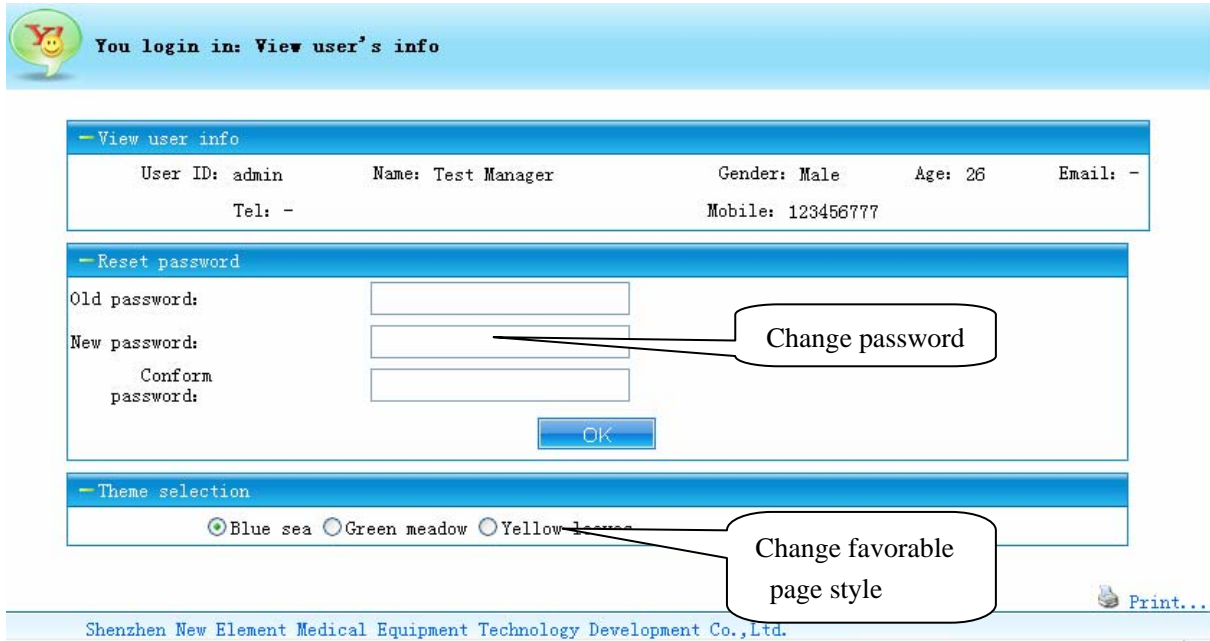
### 3.1.2 Language

The system supports multi-language. Select a language by clicking **English** or **Italian** on the upper right to switch working modes in different languages.

### 3.1.3 Personal Information

Click **MY INFO** on the upper right to view personal information (see Figure 3.1-4). The user can change password and set favorable page style on this page.





**Figure 3.1-4 Personal information**

### 3.1.4 Sorting and Searching

Sorting and searching functions are available in the system. You can click the name of a column to re-sort it.

For the following patient list, click **Age** to sort the column in ascending order (as shown in Figure 3.1-5).

Name:  Gender:  Age:  -  Keyword:   unlimited  Activated  Inactive

Patient List											
User ID	Name	Gender	Age	Tel	Mobile					Status	
96	96	Female	0	41313131313	123586				Relative	Care relation	Activated
87	87	Female	0		123586				Relative	Care relation	Activated
76	76	Female	0		123323231332132				Relative	Care relation	Activated
60	59	Female	0		123586				Relative	Care relation	Activated
54	54	Male	0		985888867777				Relative	Care relation	Activated
46	46	Female	0		5222222222226				Relative	Care relation	Activated
36	36	Female	0		64541651				Relative	Care relation	Activated
34	34	Female	0		1111322				Relative	Care relation	Activated

Record Qty.: 140, Page 1/18     Go to:

**Figure 3.1-5 Sorting page (ascending order)**

Click **Age** again, the column will be listed in descending order (as shown in Figure 3.1-6).



User ID	Name	Gender	Age	Tel	Mobile			Status
30	30	Female	199	52222222222226				Activated
25	25	Female	199	1354654+65				Activated
7	7	Male	199	133333235				Activated
6	6	Female	199	123455				Activated
5	5	Female	150	1258663				Activated
66	66	Male	140	12345678925				Activated
2	2	Male	120	12345678925				Activated
100	100	Female	100	13131313				Activated

Record Qty.: 140, Page 1/18 First Back Next Last Go to:

**Figure 3.1-6 Sorting page (descending order)**

Enter relevant search criteria on top of the form to display matching information in the list (as shown in Figure 3.1-7)

User ID	Name	Gender	Age	Tel	Mobile			Status
30	30	Female	199	52222222222226				Activated
25	25	Female	199	1354654+65				Activated
6	6	Female	199	123455				Activated
5	5	Female	150	1258663				Activated
100	100	Female	100	13131313				Activated
65	65	Female	95	52222222222226				Activated
77	77	Female	71	123323231332132				Activated
68	68	Female	67	123455				Activated

Record Qty.: 77, Page 1/10 First Back Next Last Go to:

**Figure 3.1-7 Column search**

## 3.2 Operation Guide for Administrators

Enter correct administrator account and password on the login interface (as shown in Figure 3.1-1), and then click **Sign in** to access backstage management system homepage (see Figure 3.2-1).

The administrator can perform the following operations: doctor management and patient management.



Figure 3.2-1 Administrator interface

### 3.2.1 Doctor Management

Click [Doctor User Management](#) to access the doctor management interface. The homepage displays doctor list (see Figure 3.2-2). The administrator can manage basic information of doctors, monitoring relations and create new doctors.

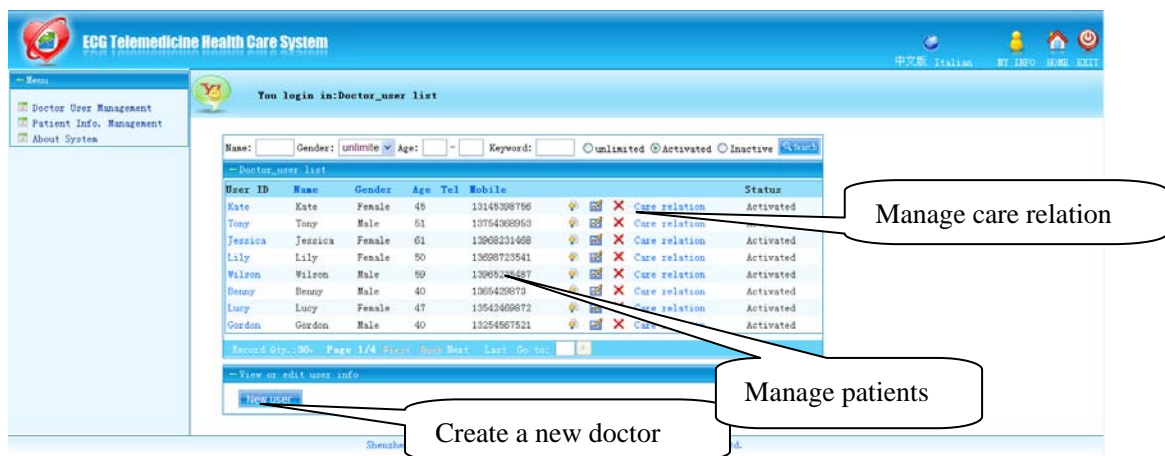


Figure 3.2-2 Doctor management

#### 3.2.1.1 Creating a New Doctor

Click [New user](#) on the above figure, a text box is displayed under the doctor list. Fill in relevant information and click **Save** to create a new doctor (see Figure 3.2-3).



View or edit user info

Affiliations: Shenzhen New Element | User ID:  \*

Password:  Use default system password

Name:  \* Gender:  Male  Female \*

DATA OF BATH:  \* Email:


Mobile:  \* TEL:

Department:  Position:

Active

Figure 3.2-3 Creating a new doctor

### 3.2.1.2 Managing Doctor Information

Click  to view basic information of a doctor (as shown in Figure 3.2-4). The administrator can edit the information.

Name:  Gender:  Age:  -  Keyword:   unlimited  Activated  Inactive

Doctor\_user list

User ID	Name	Gender	Age	Tel	Mobile	Status
Kate	Kate	Female	45	13145398756	Care relation	Activated
Tony	Tony	Male	51	13754368953	Care relation	Activated
Jessica	Jessica	Female	61	13968231468	Care relation	Activated
Lily	Lily	Female	50	13698723541	Care relation	Activated
Wilson	Wilson	Male	59	13965235487	Care relation	Activated
Benny	Benny	Male	40	1365429873	Care relation	Activated
Lucy	Lucy	Female	47	13542469872	Care relation	Activated
Gordon	Gordon	Male	40	13254567521	Care relation	Activated

Record Qty.: 30, Page 1/4     Go to:

View or edit user info

Affiliations: Shenzhen New Element | User ID: Tina \*

Password:  Use default system password

Name: Tina \* Gender:  Male  Female \*

DATA OF BATH: 1979-05-29 \* Email:

Mobile: 13568452368 \* TEL:

Department:  Position:

Active

Figure 3.2-4 Doctor information

### 3.2.1.3 Managing Care Relation

Click **Care relation** in Figure 3.2-2 to view care relation (as shown in Figure 3.2-5). The administrator can set the care relation.

Select the distributed patient and click **Save care relation** to finish patient distribution.

- Doctor info

User ID:Tony	Name:Tony	Gender:Male	Age:51	Email:-
Tel:-		Mobile:13754368953		
Hospital:Shenzhen New Element Medical Equipment Technology Development Co.,Ltd.				
Department:-		Position:-		

Name:  Gender: unlimite Age:  -  Keyword:  Search

- Patient List

	User ID	Name	Gender	Age	Tel	Mobile	Status
<input checked="" type="checkbox"/>	Ailsa	Ailsa	Female	38		13579632549	Activated
<input checked="" type="checkbox"/>	Mickey	Mickey	Male	41		1398632552	Activated
<input checked="" type="checkbox"/>	Hilton	Hilton	Female	35		13256987453	Activated
<input checked="" type="checkbox"/>	Carlos	Carlos	Male	43		13756893247	Activated
<input type="checkbox"/>	Carl	Carl	Male	38		13675126983	Activated
<input type="checkbox"/>	Billy	Billy	Male	29		13653236985	Activated
<input type="checkbox"/>	Bert	Bert	Male	36		13654236987	Activated
<input type="checkbox"/>	Aaron	Aaron	Female	23		1354236589	Activated

Record Qty.:156. Page 1/20 First Back Next Last Go to:  >

Select view:  
 All  To be arranged  Arranged

Save care re
Back

**Figure 3.2-5 Care relation management**

A patient can be distributed to several doctors at the same time. The guardianship of other doctors toward the patient can coexist. Please manage other doctors or patients to cancel the guardianship.

### 3.2.2 Patient Management

Click **Patient Info. Management** to access the patient management interface. The homepage displays patient list (see Figure 3.2-6). The administrator can manage basic information of patients, relative information, care relation and create new patients. (Log in as system administrator)

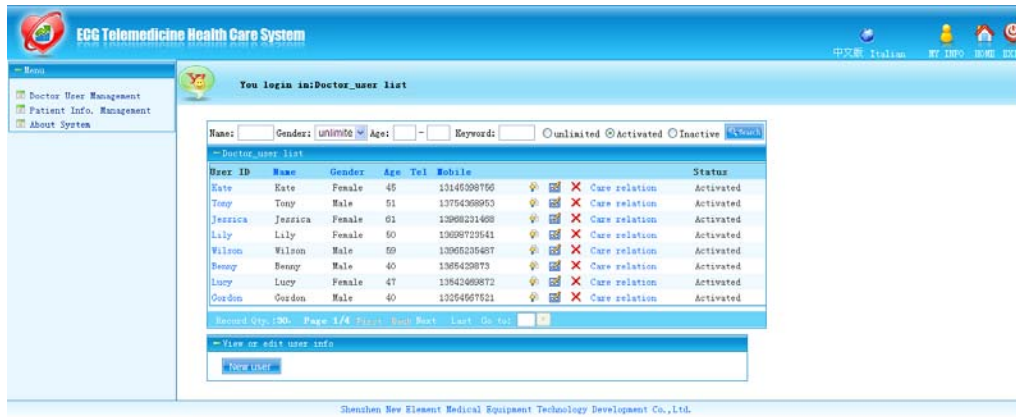



Figure 3.2-6 Patient management

### 3.2.2.1 Creating a New Patient

Click  on the above figure. Enter patient information under the patient list and click **Save** to create a new patient (see Figure 3.2-7).

View or edit user info

Affiliations: Shenzhen New Element | User ID: \*

Password:  Use default system password

Name: \* Gender:  Male  Female \*

DATA OF BIRTH: \* Email:

Mobile: \* TEL:

Medical record No.: Personal ID No.:

Height (cm): Weight (kg):

ADD:

Medical record:


Relative's info: View patient relatives' info

Active

Fill in patient information

Figure 3.2-7 Creating a new patient

### 3.2.2.2 Managing Patient Information

Click  to view basic information of a patient (as shown in Figure 3.2-8). The administrator can edit the information.

View or edit user info	
Affiliations: Shenzhen New Element	User ID: test1 *
Password: <input checked="" type="checkbox"/> Use original password	
Name: xiangting *	Gender: <input type="radio"/> Male <input checked="" type="radio"/> Female *
DATA OF BATH: 2010-11-10 *	Email: <input type="text"/>
Mobile: 123456 *	TEL: <input type="text"/>
Medical record No.: <input type="text"/>	Personal ID No.: <input type="text"/>
Height(cm): 0	Weight(kg): 0
ADD: <input type="text"/>	
Medical record: <input type="text"/>	
Relative's info: <a href="#">View patient relatives' s info</a>	
<input checked="" type="checkbox"/> Active <input type="button" value="Save"/> <input type="button" value="Cancel"/>	
<input type="button" value="New user"/>	

**Figure 3.2-8 Patient information**

### 3.2.2.3 Managing Care Relation

Click [Care relation](#) icon in Figure 3.2-6 to view care relation (as shown in Figure 3.2-9).

The administrator can set the care relation.

Select the distributed doctor and click **Save care relation** to finish doctor distribution.





**- Patient info**

User ID: Carl      Name: Carl      Gender: Male      Age: 38      Email: -  
 Tel: -      Mobile: 13675126983  
 Hospital: Shenzhen New Element Medical Equipment Technology Development Co.,Ltd.  
 Medical record No.: -      Personal ID No.: -  
 Height: Ocm      Weight: Okg  
 ADD: -  
 Medical history: -

Name:  Gender:  Age:  -  Keyword:

**- Doctor\_user list**

<input type="checkbox"/>	User ID	Name	Gender	Age	Tel	Mobile	Status
<input type="checkbox"/>	Kate	Kate	Female	45		13145398756	Activated
<input type="checkbox"/>	Tony	Tony	Male	51		13754368953	Activated
<input checked="" type="checkbox"/>	Jessica	Jessica	Female	61		13968231468	Activated
<input checked="" type="checkbox"/>	Lily	Lily	Female	50		13698723541	Activated
<input type="checkbox"/>	Wilson	Wilson	Male	59		13965235487	Activated
<input type="checkbox"/>	Benny	Benny	Male	40		1365429873	Activated
<input type="checkbox"/>	Lucy	Lucy	Female	47		13542469872	Activated
<input type="checkbox"/>	Gordon	Gordon	Male	40		13254567521	Activated

Record Qty.: 30. Page 1/4     Go to:

Select view:  
 All  To be arranged  Arranged

**Figure 3.2-9 Care relation management**

### 3.2.2.4 Managing Patient's Relative Information

Click [Relative](#) in Figure 3.2-6 to view patient's relatives (as shown in Figure 3.2-10).

Click to edit relatives' information, or click  to add relative information.

**- Patient info**

User ID: ww      Name: ww      Gender: Male      Age: 10      Email: -  
 Tel: -      Mobile: 000000  
 Hospital: Shenzhen New Element Medical Equipment Technology Development Co.,Ltd.  
 Medical record No.: -      Personal ID No.: -  
 Height: Ocm      Weight: Okg  
 ADD: -  
 Medical history: -

**- Relationship with patient**

No relationship information

**Figure 3.2-10 Patient's relative information**



About ECG System V1.4.3

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vn in


**Figure 3.3-1 About the ECG system**



## 4 Introduction to Silverlight

Silverlight is a browser-crossing and platform-crossing plug-in. It plays a role of analyzing ECG data in the remote & mobile ECG monitoring system. At the same time, Silverlight page can be installed to the desktop like a shortcut, making it more convenient for doctors when analyzing data.

### 4.1 Installation


Select **Silverlight Dynamic Analysis** in  on the main interface to access Silverlight page. Before using Silverlight function, some installations like Silverlight installation, client installation on PC and COM component installation are required.

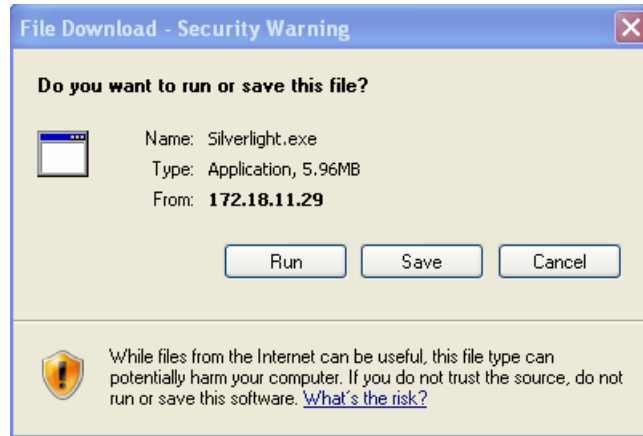
#### 4.1.1 Installing Silverlight

a) You need to install Silverlight components before using the software. Click Silverlight module, installation message is displayed as shown in Figure 4-1.



Figure 4-1

b) Click  in Figure 4-1, message box is displayed as shown in Figure 4-2.



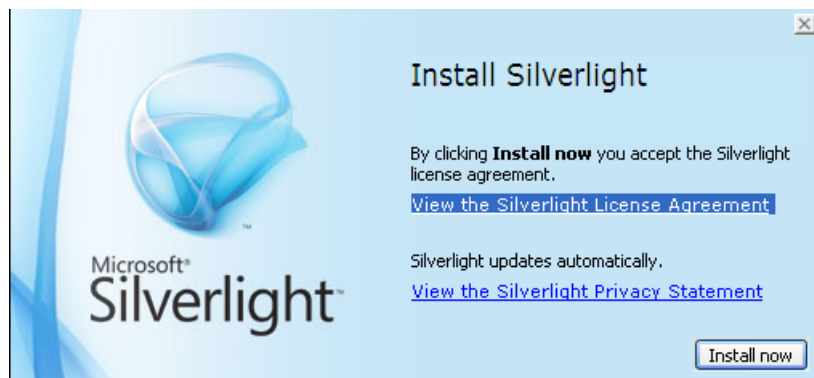
**Figure 4-2**

c) Click **Save** to save the downloaded file, or click **Cancel** to exit the installation. Save the downloaded file, as shown in Figure 4-3.



**Figure 4-3**

d) Click **Run** to install the software, or click **Cancel** to exit the installation. A dialog box will be displayed when clicking **Run**, as shown in Figure 4-4.



**Figure 4-4**

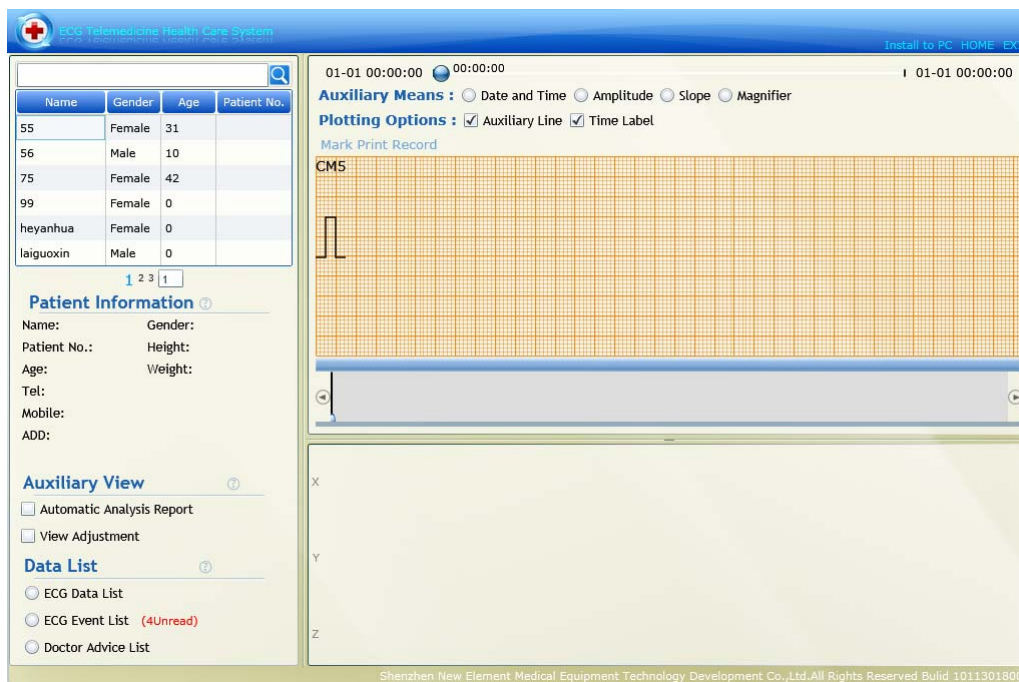


e) Click **Install now**, the installation progress is displayed until the installation is completed. Click [View the Silverlight License Agreement](#) to view Silverlight license agreement, or click [View the Silverlight Privacy Statement](#) to view Silverlight privacy statement.

f) Restart the browser after Silverlight is installed.

#### 4.1.2 Installing Client on PC

a) The doctor can access Silverlight page through the client. A dialog box is displayed when right clicking in the page, as shown in Figure 4-5.




**Figure 4-5 Silverlight client installation reminding**

b) Select **Install Remote & Mobile Real-Time Monitoring System to the Computer**, or click **Install to PC**. A dialogue box shown in Figure 4-6 is displayed.



Figure 4-6

c) Click **Install**. The shortcut icon  is displayed on the desktop. Click the icon to display the login interface, as shown in Figure 4-7, and enter doctor account and password to quickly access Remote & Mobile ECG Monitoring System V1.4.3.

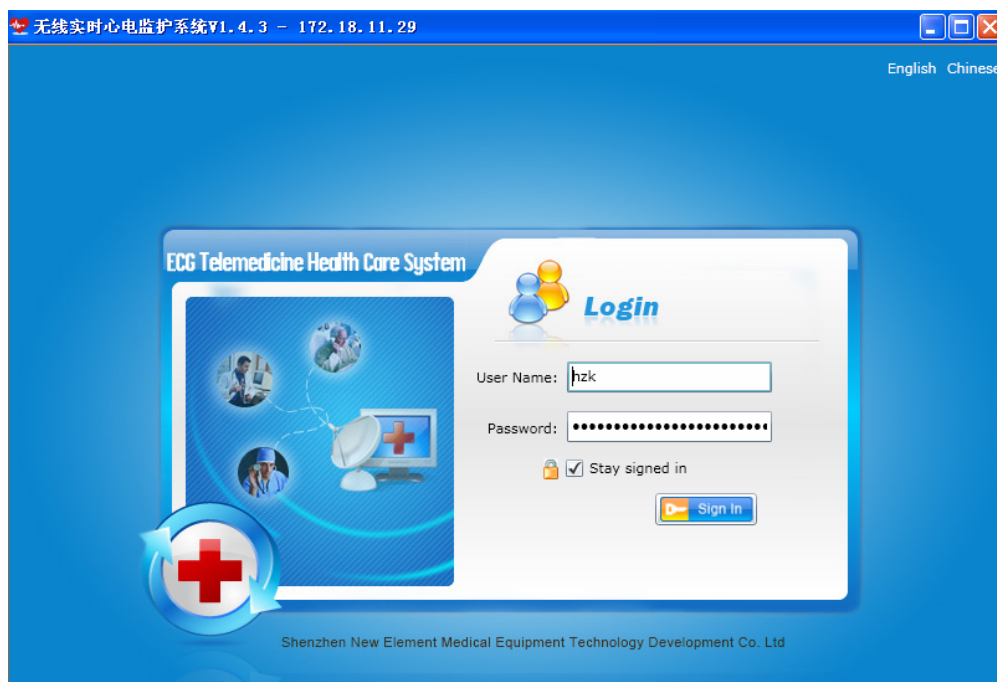


Figure 4-7

### 4.1.3 Registering COM Components

- a) Copy the **Y5WRM** folder to the home directory of Drive C.
- b) Double click **Register.bat**. A dialog box is displayed, as shown in Figure 4-8.



Figure 4-8

c) Click **OK**.

d) Double click **EcgDataSync.exe**. Components registration of Remote & Mobile ECG Monitoring System V1.4.3 is completed.

 **Caution:**

1. **Synchronization software needs to be installed before running Register.bat.**

2. **Make sure Drive D of the client computer is distributed to store data.**

3. Edit the target of attribute of shortcut icon  before performing synchronization on PC client.

**Steps: right click the shortcut icon on desktop -> Attribute -> add space+debug after the target, as shown in the following figure:**

Target (T): her.exe" 3122658911.172.18.11.100 debug

Add **Space+debug**  
after the attribute

## 5 ECG Collector Features

### 5.1 Parameters

ECG record channel: One channel (lead)

A/D shift accuracy: 12 bits

Sampling rate: 300 times/s

Dynamic range: 5.0 mVp-p

Amplitude-frequency: Meeting requirement of (0.05~60) Hz  $\frac{+0.4dB}{-3.0dB}$

Motion sensor: 3-axis

Record resolution: 8 bits

Record sampling rate: 75 times/s

Bandwidth: 0.05-60 Hz

Storage medium: SD card (1 GB / 2 GB)

### 5.2 Normal Working Conditions

Temperature: 0°C-40°C

Relative humidity: 10%-95% (no condensation)

Atmospheric pressure: 700 hPa to 1060 hPa

### 5.3 Dimension & Weight

Size: 90 mm (L) x 40 mm (W) x 16 mm (H)

Weight: 55 g (battery loaded)

### 5.4 Power

Battery: 3.7 V lithium-ion rechargeable battery

Running: 24-hour continuous wireless transmission

### 5.5 Bluetooth

Version: Version 1.2

Classification: Class 2 (max. transmission range: 10 m)

Protocol: SPP Protocol

Running type: slave PTP



Antenna type: Built-in

## 5.6 Transportation & Storage Conditions

Temperature: 0°C-40°C

Relative humidity: 5%-85%, frostless

## 5.7 FCC NOTE:

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:(1)this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.