

PoChain

Operation Instruction Manual

V1.1.2

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1. General Introduction

1.1 Introduction

This software is a recorder data management software specially developed for users, with various characteristic functions and simple operation. This software not only provides graphs, tables and other intuitive forms of data statistics, and can export a variety of format files for preservation, but also can record and screen data, it is very convenient for individuals to view the data of recorder device ,also for enterprise and department to manage all kinds of devices data.

1.2 Performance

This software has good security and confidentiality, and it is convenient to use.

1.3 Functions

Main functions:

- (1) Read data;
- (2) Upload data;
- (3) Query historical data;
- (4) Parameter configuration;
- (5) Graphs and tables;
- (6) Statistical device information;
- (7) Signature;
- (8) Import and export for data;
- (9) Email.

2. Installation and Startup

2.1 Operating Environment

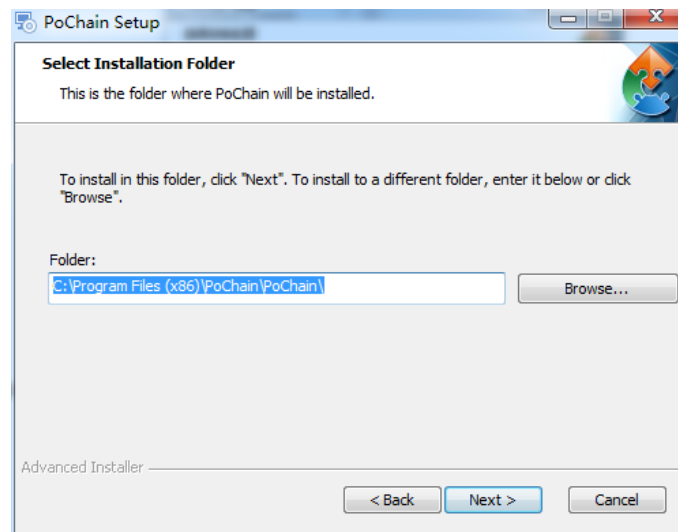
This software must run with Windows 7 or above version of the operating system, and the operating system must be installed.NET Framework 4.6 or above version of the operating environment.

2.2 Installation

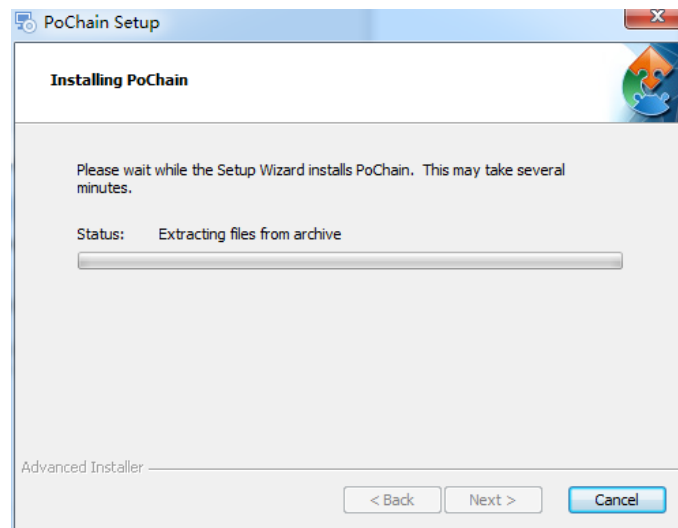
Double-click to open the software installation package, enter the installation wizard window, and click "Next", as shown below:



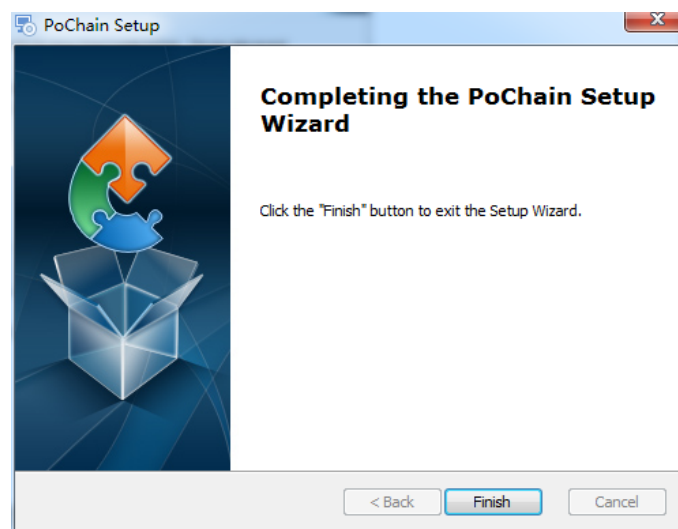
Select the installation path of the software in the window that appears, and click "Next", as shown below:



Click "Install" in the pop-up window to start installing the software, as shown below:



Click "Finish" after the installation, as shown below:



2.3 Startup

After the installation is finished, the default is the offline version (no login mode). FDA21 CFR Part 11 module needs to be enabled to use all functions of the software.

What is FDA 21 CFR Part 11 compliance?

The United States Food and Drug Administration (FDA) promulgated the federal regulatory code, chapter 21, Part 11 (21 CFR Part 11) in 1997, and issued industry guidelines in 2003 to refine the rules. In the 21 CFR Part 11 regulations, electronic records are considered to have the same effect as written records and handwritten signatures and are applicable to any records created, modified, maintained, archived, retrieved, transmitted or stored in a persistent storage medium governed by existing FDA rules.

21 CFR Part 11 is widely accepted and implemented by biomedical enterprises, hospitals, research institutes and laboratories in the United States. Since the promulgation has been promoted to the world, although not mandatory, but by Europe, Asia and other countries generally accepted and used. Any drug, biomedical device or information system exported to the United States shall comply with 21 CFR Part 11. In case of violation, the FDA will, in accordance with the regulations, deprive the export right to the United States.

Specific operations to enable 21 CFR Part 11 are as follows:

After the installation is finished, open the software, click the "System" button, and select "FDA21 CFR Part 11 module", and choose "Start FDA21 CFR Part 11 module", finally click "Yes" to restart the software in the pop-up window to unlock all functions of the software. The following is a full function model to describe the use of the software.

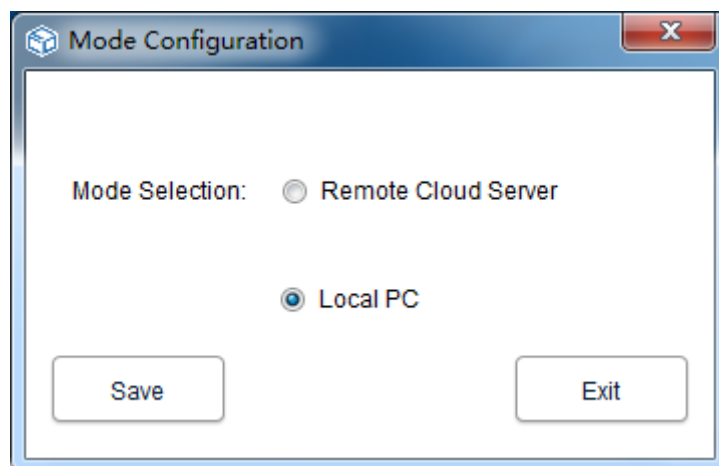
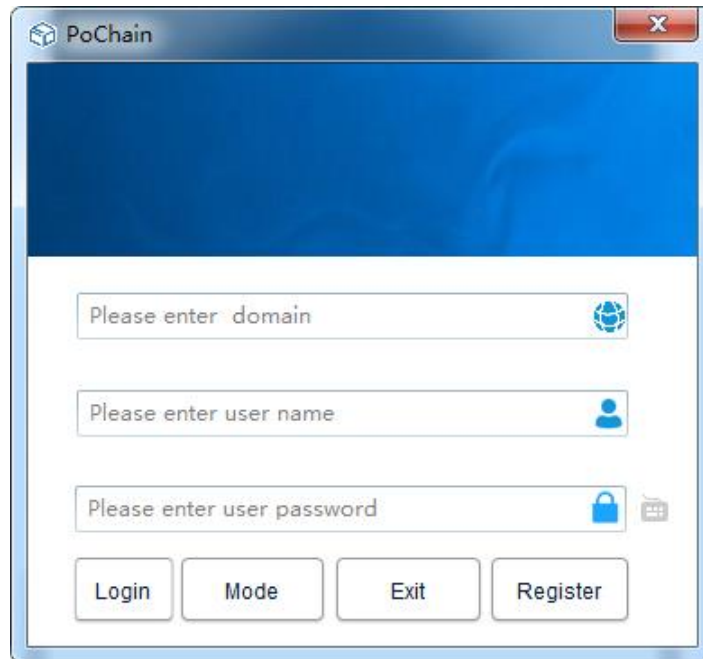
3. Login Modes

3.1 Local Computer

Click the "Mode" button in the login interface to enter the configuration interface of login modes. The system defaults to the local computer mode, after choosing this mode, all the user's data will be saved on the local computer and it can be operated by self.

3.2 Remote Cloud Server

Click the "Mode" button in the login interface to enter the configuration interface. Select the Remote Cloud Server Mode and click "Save" to enter it. If there is local user information, click "Save" to remind you whether to upload local user information and click "Yes". As shown below:



4. Registration

4.1 Administrator Registration

Click "Register" at the bottom right of the login interface, and then fill in the corresponding information. After finished, submit and save it. Finally, a pop-up shows that the registration has been successfully saved, as shown in the figure below:

The 'Register' window contains the following fields and controls:

- User Name:
- Real Name:
- Password:
- Confirm Password:
- Job Position:
- User Type: Administrator User
- Domain:
- Head Portrait:
- Submit:
- Exit:

4.2 Add User

Login administrator account, click "System ", choose "FDA21 CFR Part 11 module", then click "configure FDA21 CFR Part 11 module" in the lower left, and then, choose user account, click "Add User", fill in the corresponding information and click "Save" to add successfully. Therefore, regular users belonging to the same company need to be authorized by the administrator to log in. The operation interface is shown in the following figure:

The 'User Management' window displays the following table:

User Account	Security Strategy	User Rights	Signature Manager	
User Name	Real Name	Job Position	User Type	Status
Txw10086	Txw10086	Txw10086	Administrator	Enable

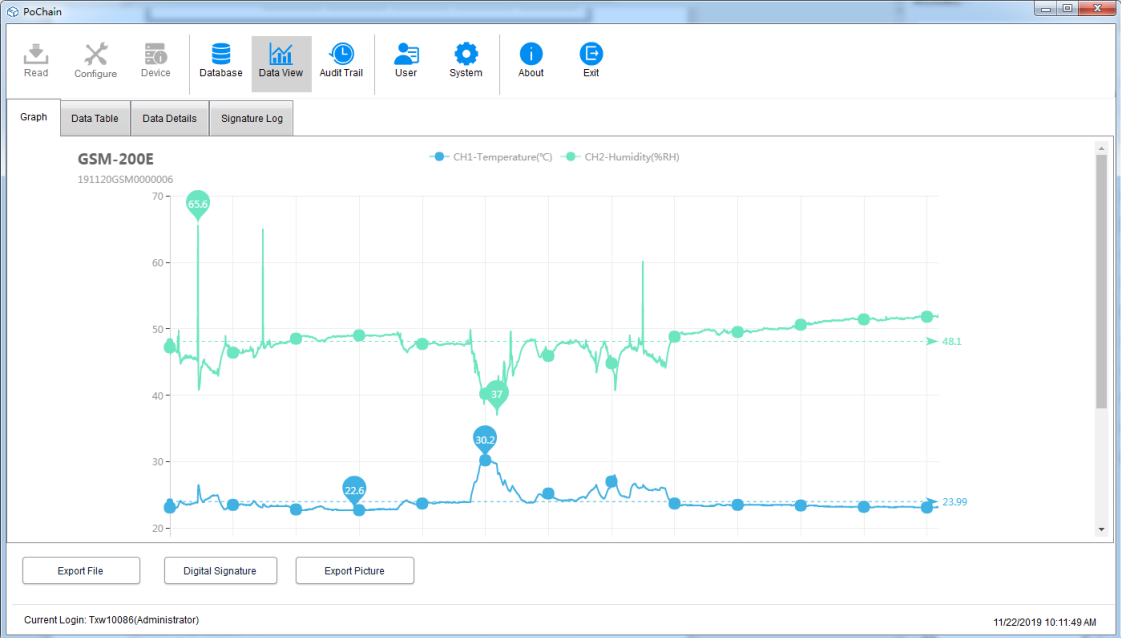
Below the table, the following buttons are available:

- Add User
- Revise User
- Lock User
- Unlock User
- Exit

5. Data Management

5.1 Reading Data

The software can obtain data from the recorder device in a very simple way. The software will automatically detect the device and read the data. All it needs is to connect the data recorder device to the computer, as shown below:



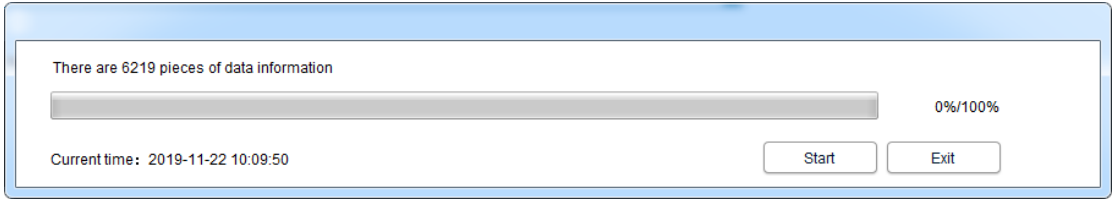
5.2 Upload Data

The function of uploading data only appears under Remote Cloud Server Mode, which is used for uploading data that is not synchronized to the cloud server by the local computer. The specific operation is as follows:

Click the "System " button, select "Yes" in the upload cloud server below, then click "Save", and click "Yes" in the pop-up window, as shown below:

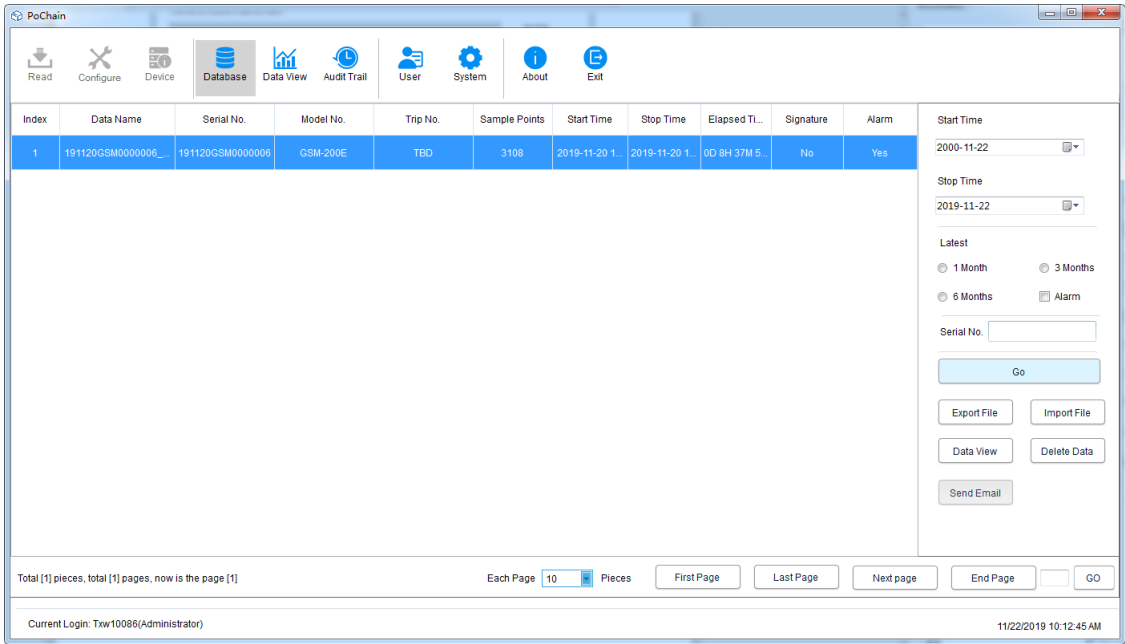
Setting	Value
Date Format	yyyy-MM-dd
Time Format	HH:mm:ss
Language	English
Upload to Cloud Server	Yes

Then jump to the interface of uploading, click "Start", wait for the uploading progress to be completed, click "Exit" and restart the software to take effect, as shown below:



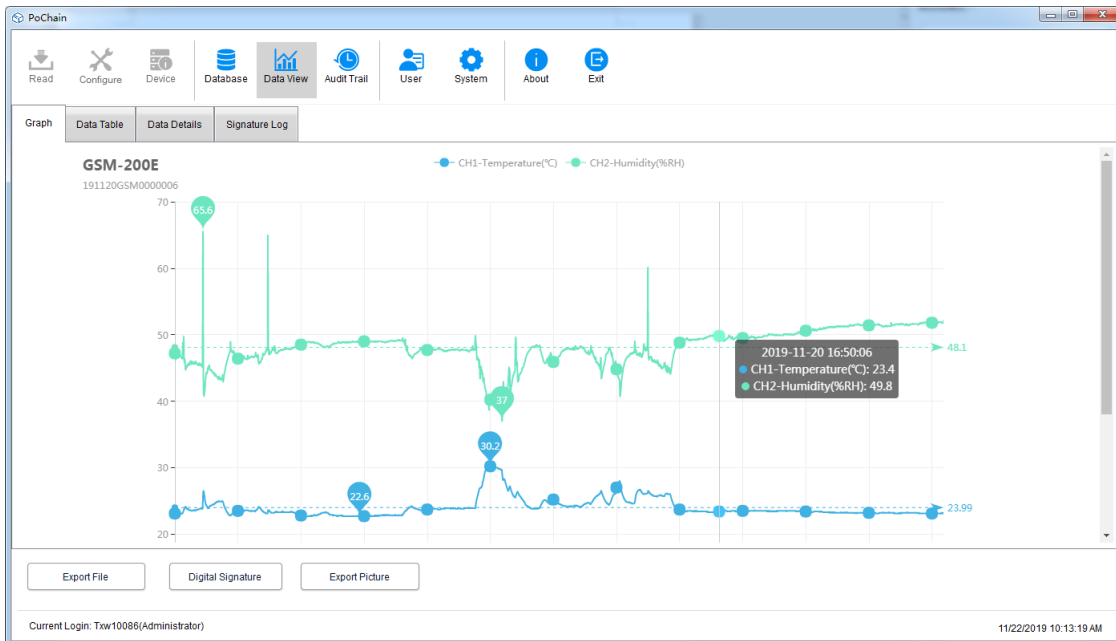
5.3 Data Query and Processing

Click the "Database" button in the main menu, and you can see that there are three options in the upper half of the right function bar: Start Time, Stop Time and Latest. Users can choose any query mode to find the required data. In the bottom half of the function bar is the option of data operation. If you select a data, you can view, delete, import and export it, as shown below:



5.4 Graphs and Tables

After click "Data View" button, you can see the data graph, the software provides the function of graph local zoom in and out, when the data volume is large, simply place the cursor position required to view the scroll wheel, and are looking at the lower left of the data graph, the software also provides export function with the documents and pictures, as shown in the figure below:



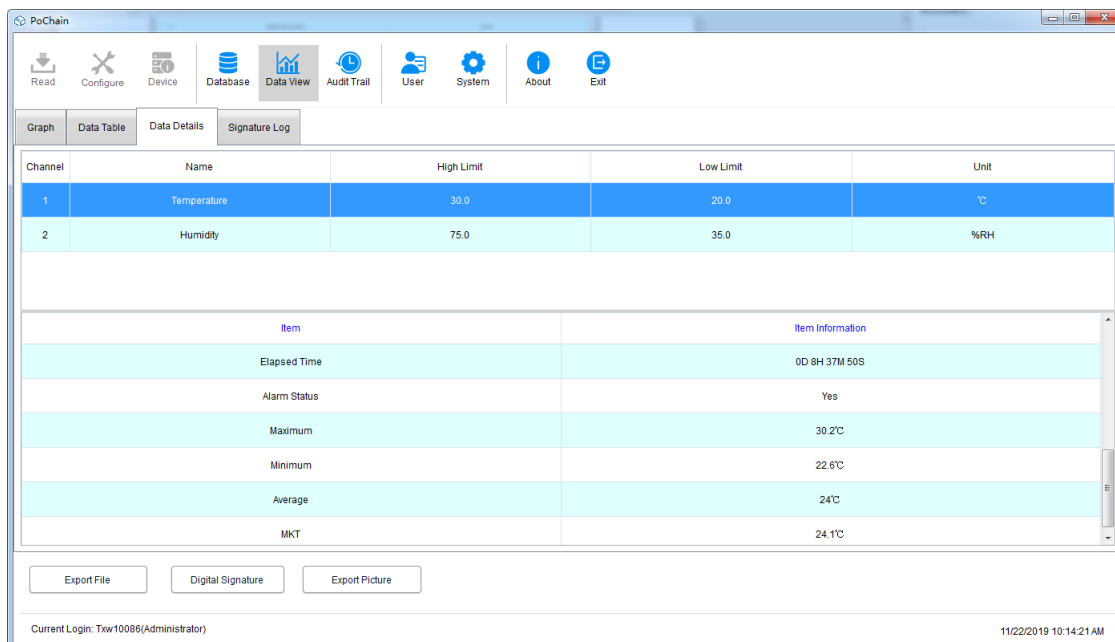
Click the "Data Table" option in "Data View" to view the data in the form of a table. The amount of data displayed on each page of the table can be changed, and the page jump is supported. That result in users can view the data flexibly. as shown in the following figure:

Chan.	Name	High Limit	Low Limit	Unit
1	Temperature	30.0	20.0	°C
2	Humidity	75.0	35.0	%RH

Index	Date and Time	Readings
1	2019-11-20 10:43:28	23.1°C
2	2019-11-20 10:43:36	23.1°C
3	2019-11-20 10:43:46	23.1°C
4	2019-11-20 10:43:56	23.1°C

5.5 Data Information Statistics

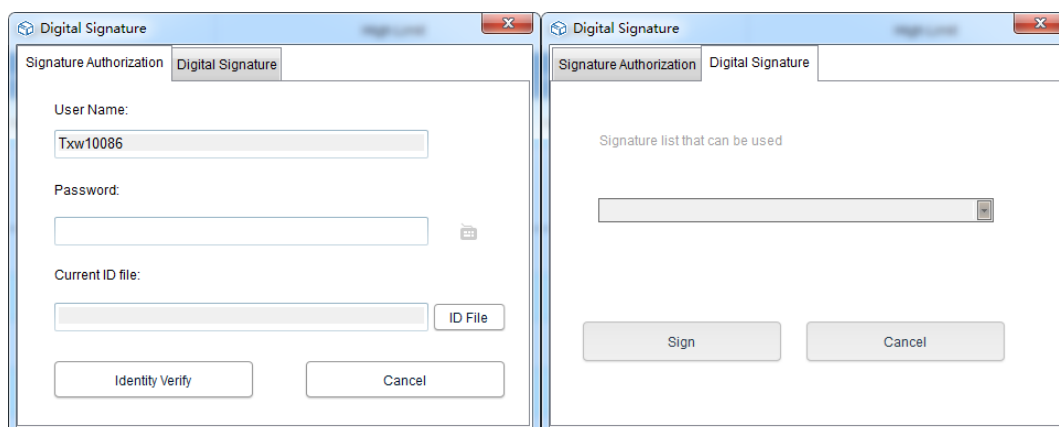
Click the "Data Details" option in "Data View", and you can see the statistics of the maximum value, minimum value, average value, record interval and other parameters in this piece of data, as shown in the figure below:



5.6 Digital Signature

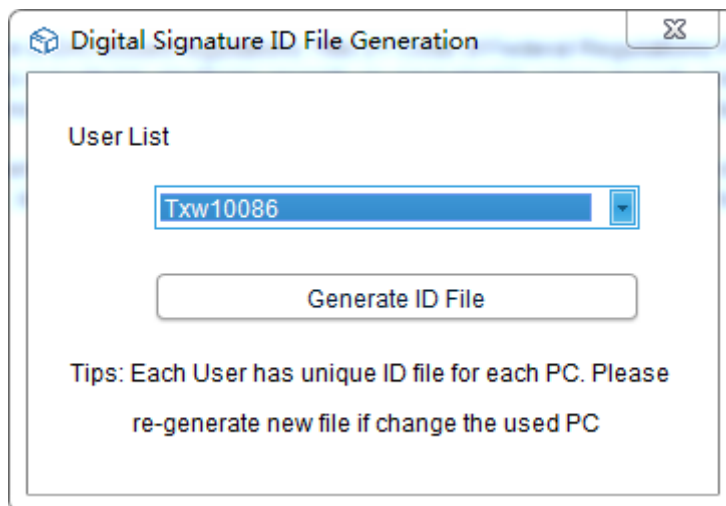
What's a signature? Signature is to mark, the object of signature is each piece of data, such as this data has qualified, the user can give this piece of data a signature with "Qualified", of course, the content of the signature is completely decided by the user, the specific operation is as follows:

In the main menu, click the "Database" button, and open a piece of data what you want from database, click on the lower left of the "Digital Signature" button, jump to the interface of digital signature at this time we need to fill in the login password, and choose ID file for authentication, and then it also need to select available signature, as shown in the figure below:

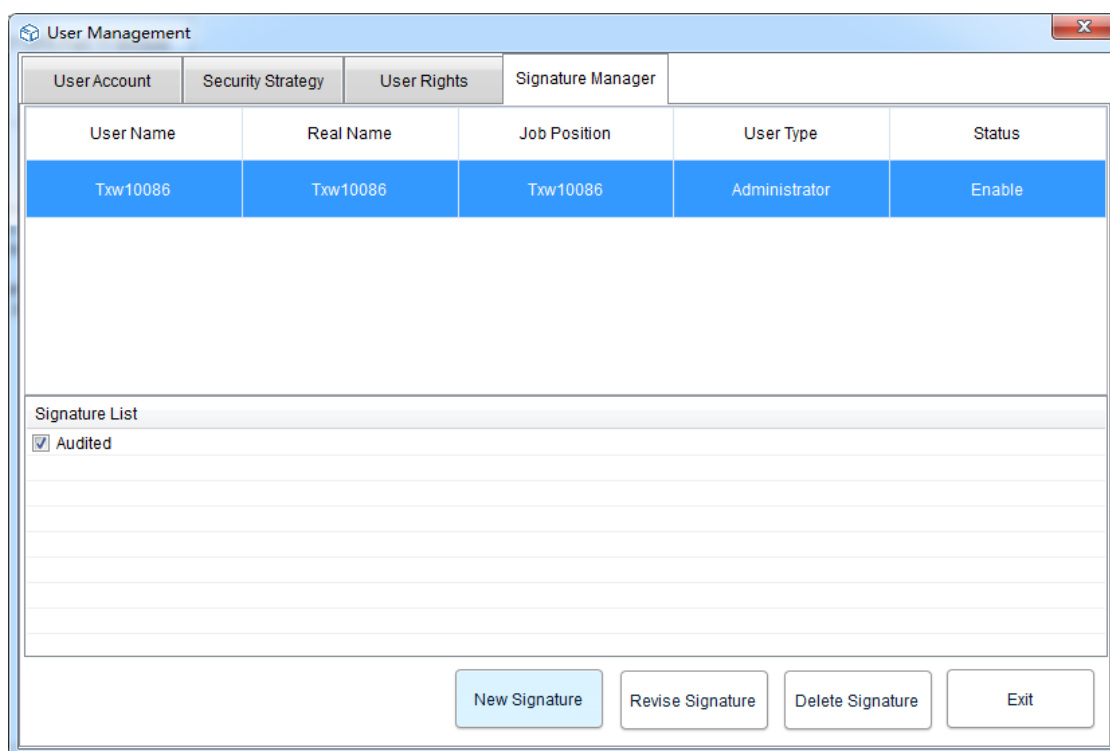


Firstly, the ID file is required. For the software itself, the ID file is unique and time-limited. The specific operation to obtain the ID file is as follows:

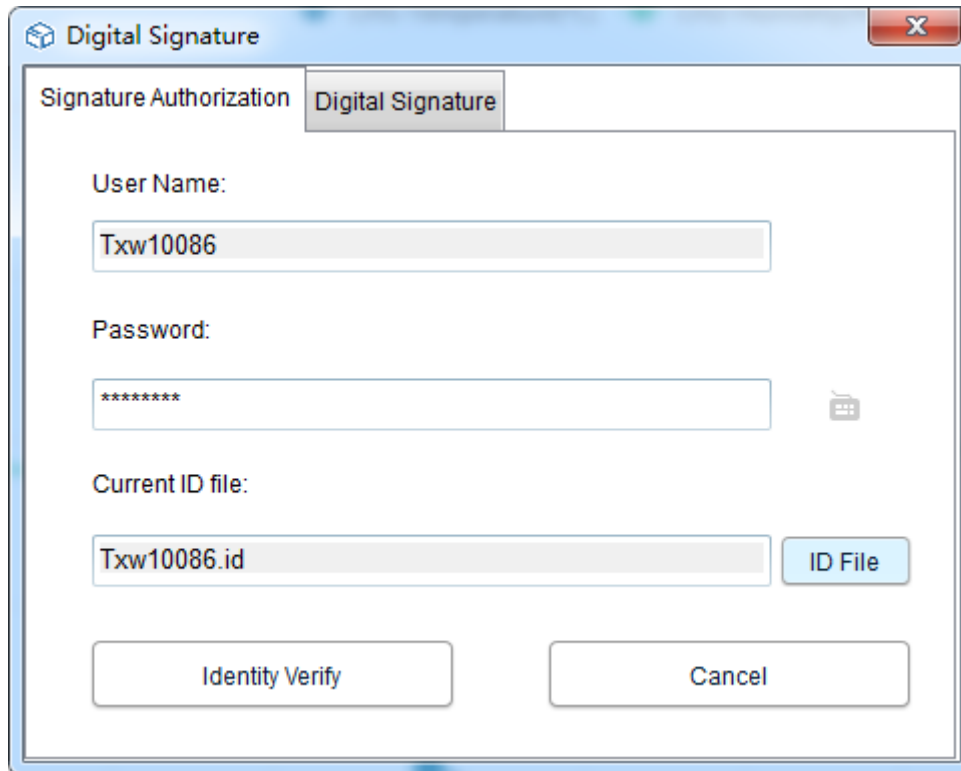
Click the "System " button in the main menu, select "FDA21 CFR Part 11 module", Click "FDA Digital Signature File Management", click "Generate ID File" in the pop-up window, and then name and save the file, as shown below:



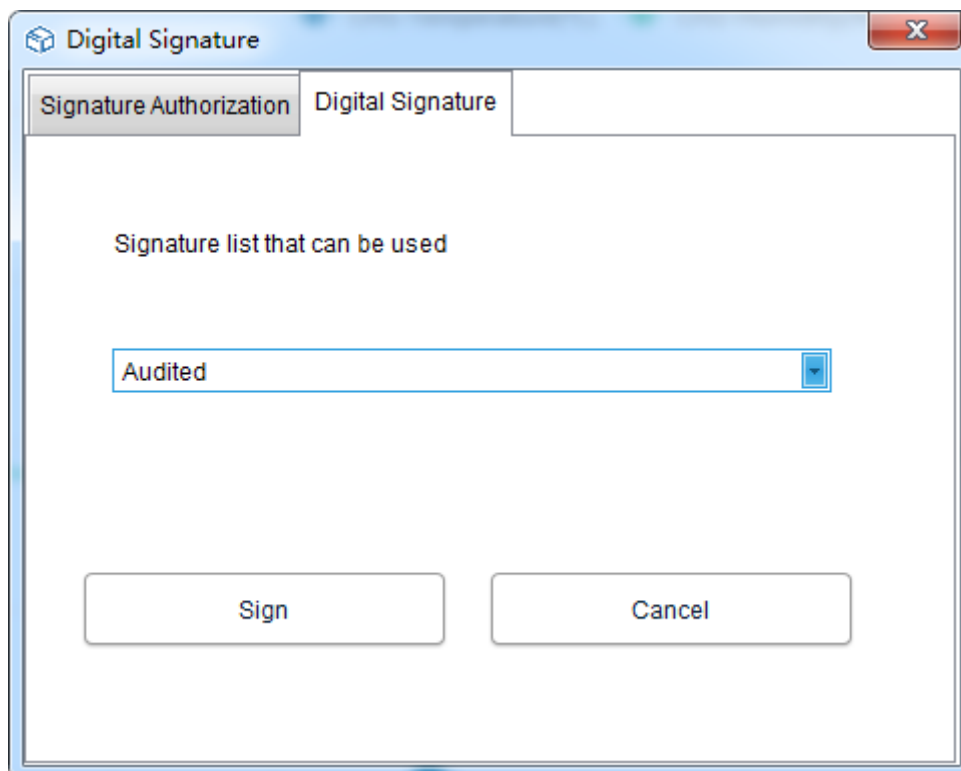
Then we need to create the available signature, after select "FDA21 CFR Part 11 module", click "configure FDA21 CFR Part 11" button and choose "Signature Manager" in the pop-up window, click on the "New Signature" below, then enter the signature name and click save to create successfully, after that, the signature will be displayed in the signature list, and the user can pick the needed signature, as shown in the figure below:



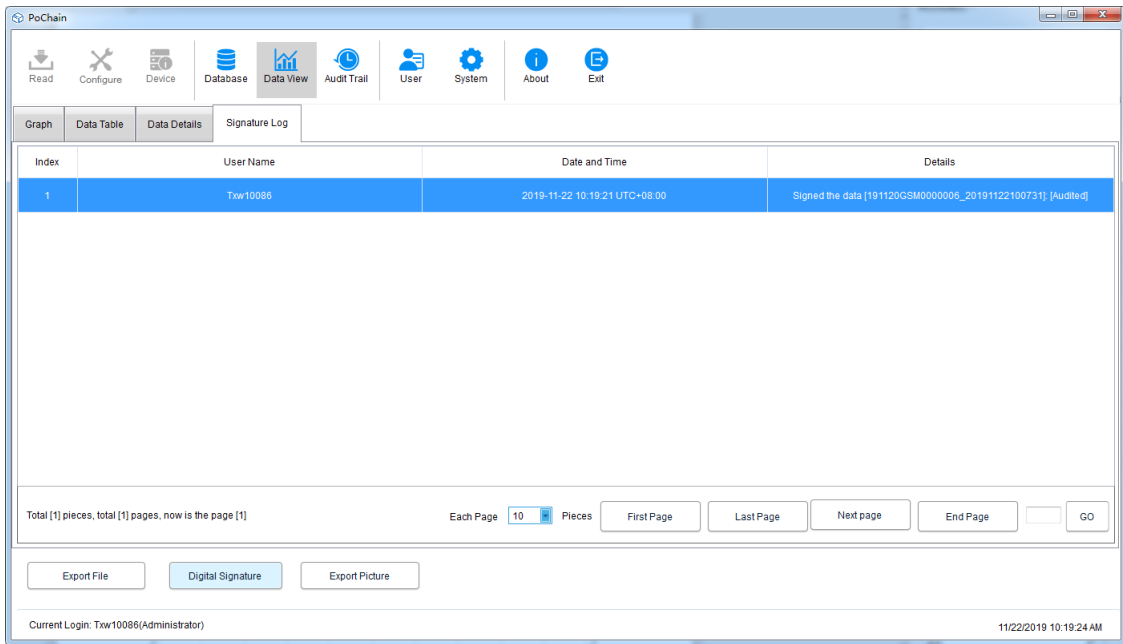
At this point, we can use the function, and repeat the previous operation back to the digital signature interface, enter the login password and the saved ID file, then click "Identity Verify", as shown in the figure below:



Then it will jump to retrieve the available signature, then select the signature we need and click "Sign" to finish it, as shown below:



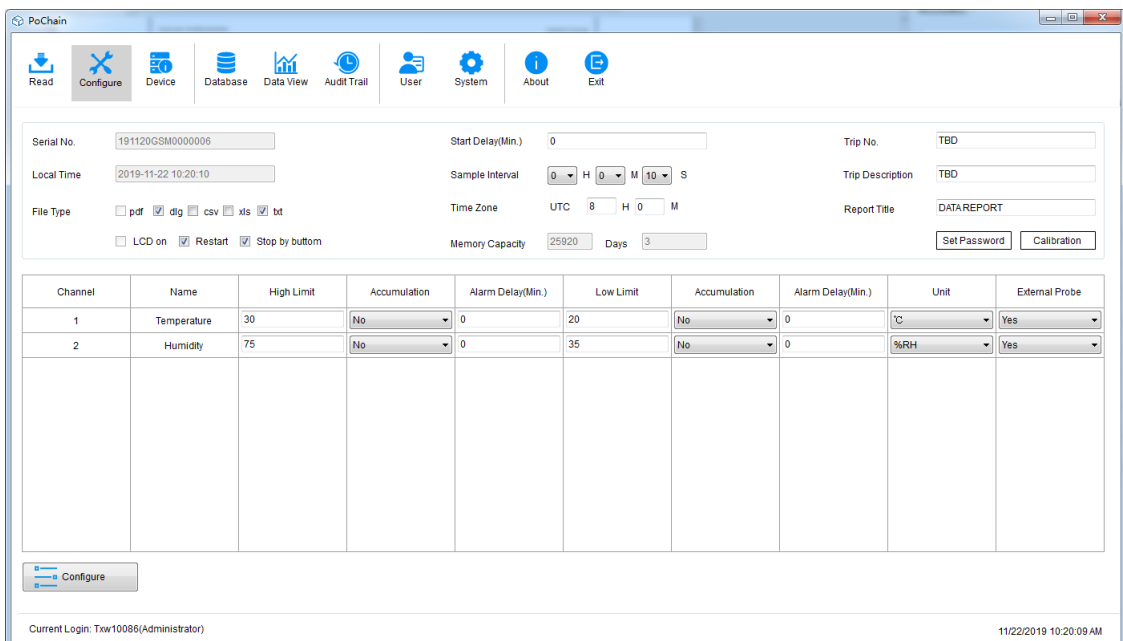
When you return to the database, you can see that the piece of data has been signed. Finally, click the "Data View" button and select "Signature Log", and you can see the details of the operating record, as shown in the figure below:



6. Equipment Operation

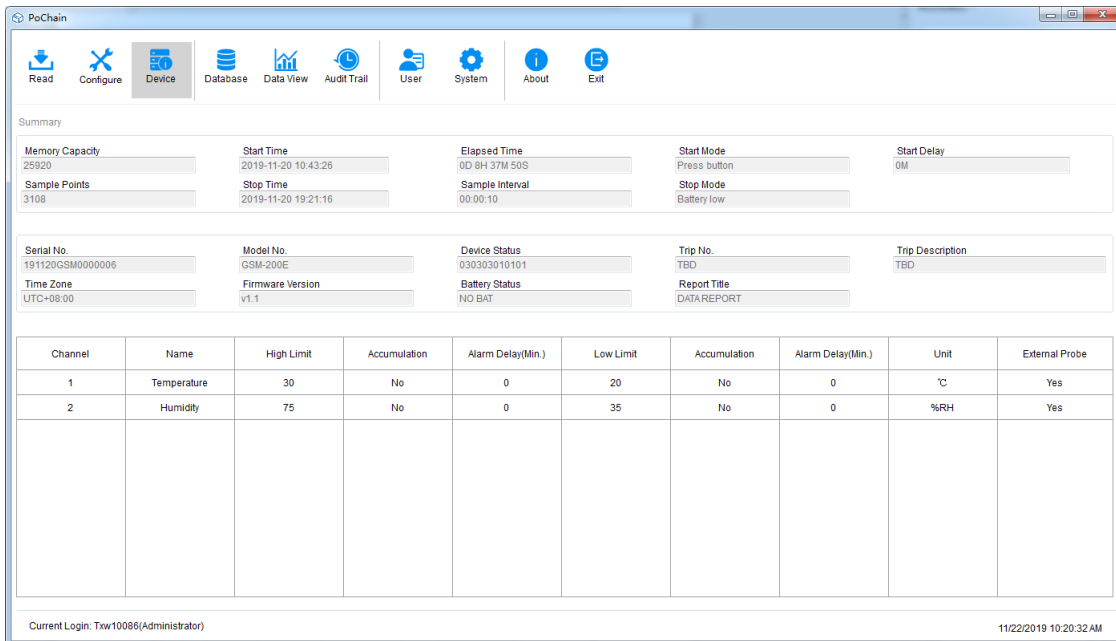
6.1 Parameter Configuration

Connect the recorder device, click the "Configure" button in the main menu, configure the device according to the required parameters, and click the "Configure" in the lower left to complete the configuration, as shown below:



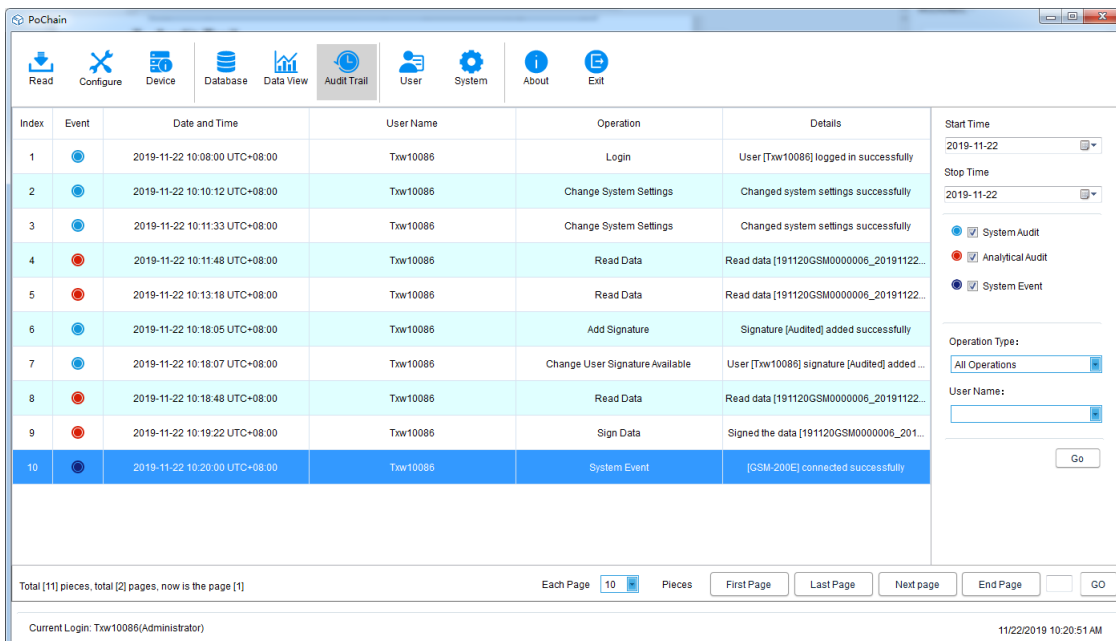
6.2 View Information

Connect the recorder device and click the "Device" button in the main menu to view all information of the device, as shown in the figure below:



7. Audit Trail

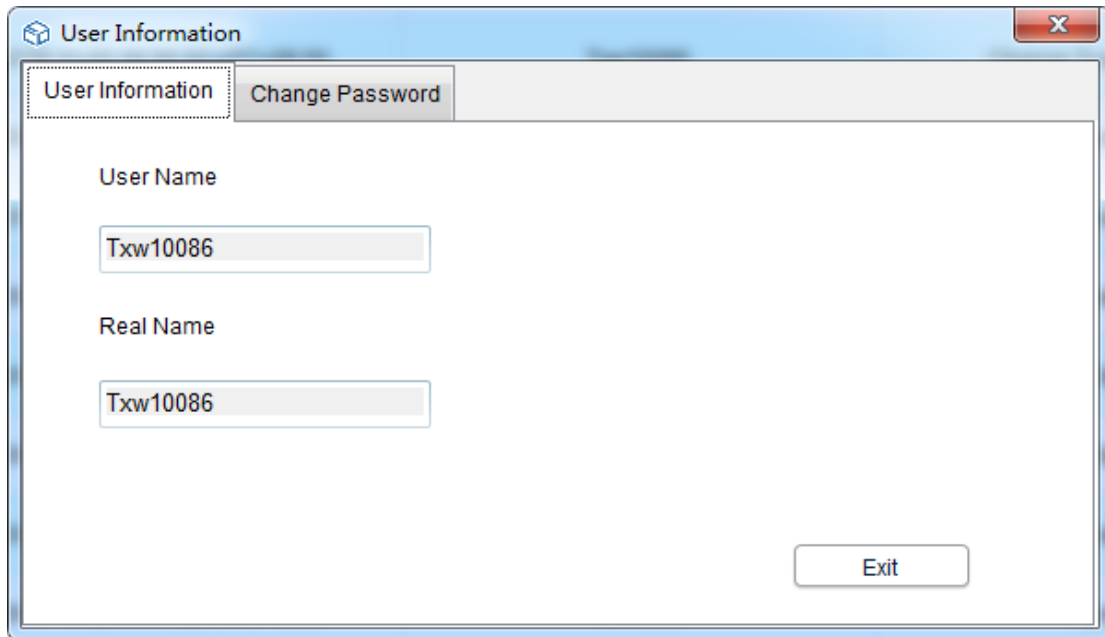
Click the "Audit Trail" button in the main menu to view the history records of all system operations, and the software provides time, operation type, user name and other tracking query methods, as shown in the figure below:



8. User Information

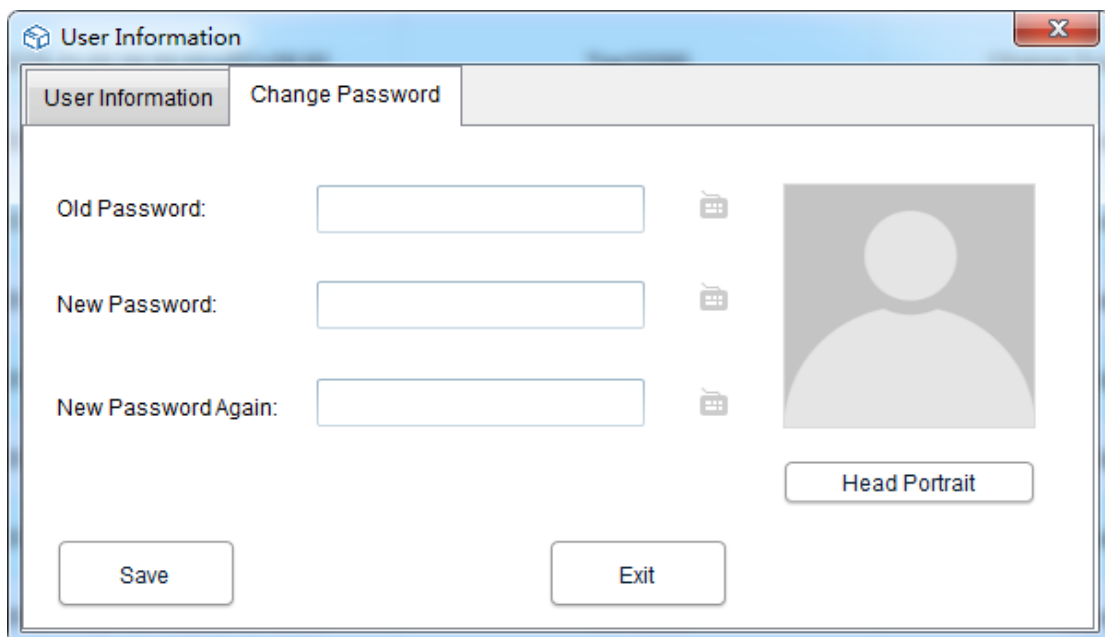
8.1 View User Information

Click the "User Information" button in the main menu to view the basic information of this user, as shown below:



8.2 Change the Password

Select "Change Password" from the user information option, enter the old password and the new password, then click "Save". Users can also modify their pictures here, as shown below:

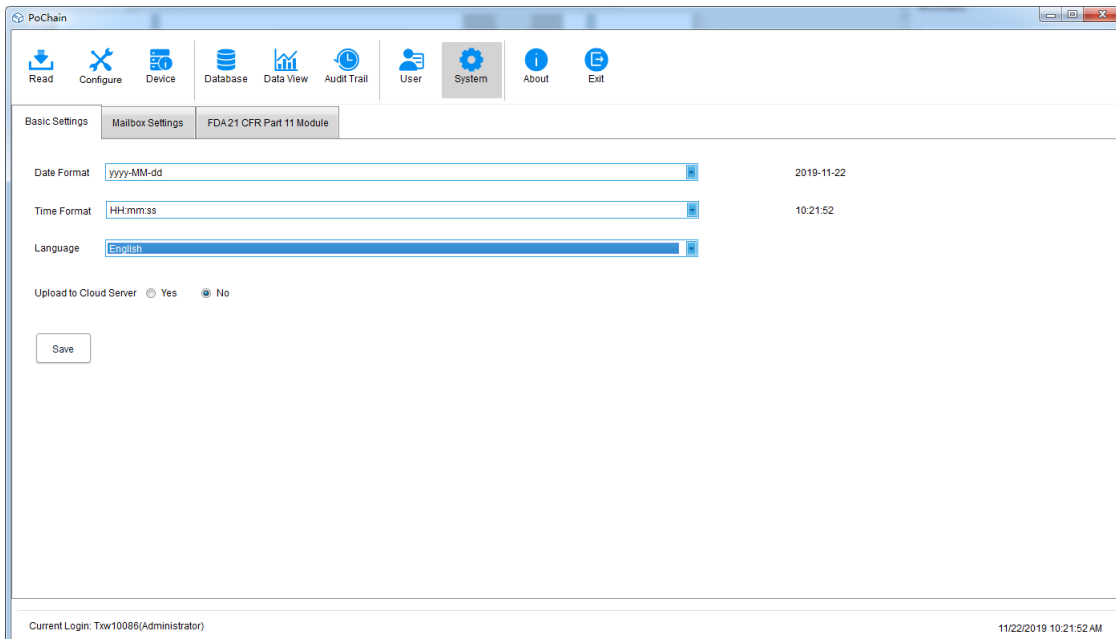


9. System Settings

9.1 Time and Language

The default language of this software is English. Certainly, users can switch the language freely through the following operations:

Click the "System " button in the main menu. In the basic setting, the user can set the display mode of time and date and languages. After setting, click "Save" and restart the software to take effect, as shown below:



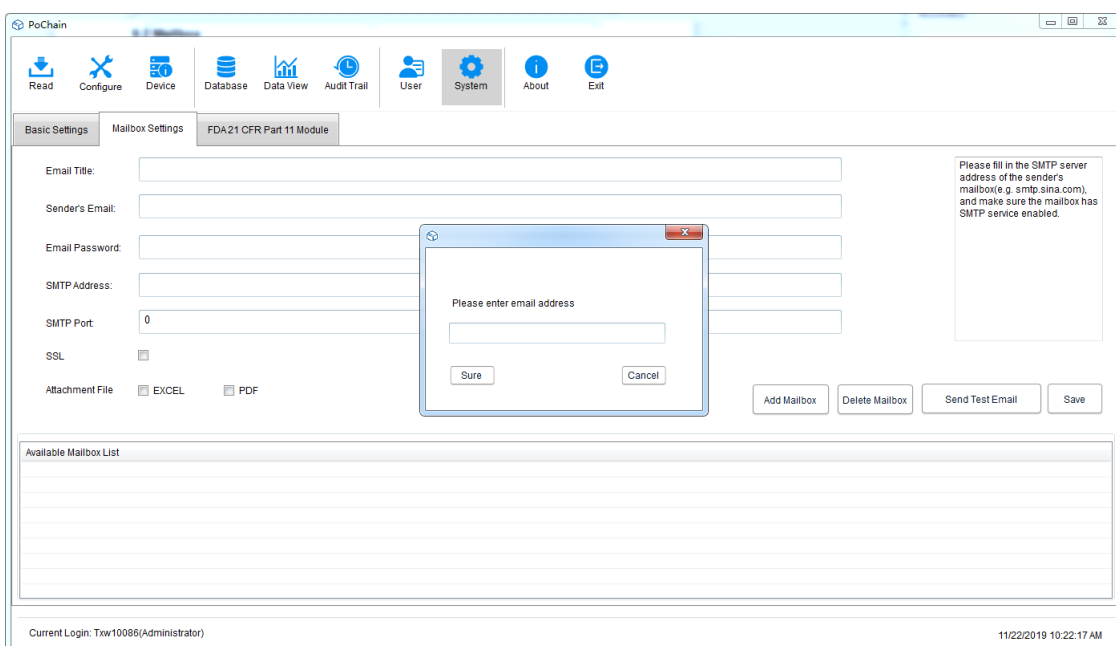
9.2 Mailbox

This software provides the function of sending email. The data recorded by the devices can be sent to the designated mailbox by email. Click the "System " button in the main menu and select "Mailbox Settings".

Setting sender's mailbox: fill in the subject, sender's mailbox, mailbox authorization password, SMTP address and SMTP port. The user can choose whether to use SSL or not, and the attachment file format of recorded data can be selected to send the mail.

Add recipient mailbox: click the "Add Mailbox" option on the right side to enter the recipient mailbox. The recipient mailbox can be added more than one, and the target recipient we can select from the list before sending email.

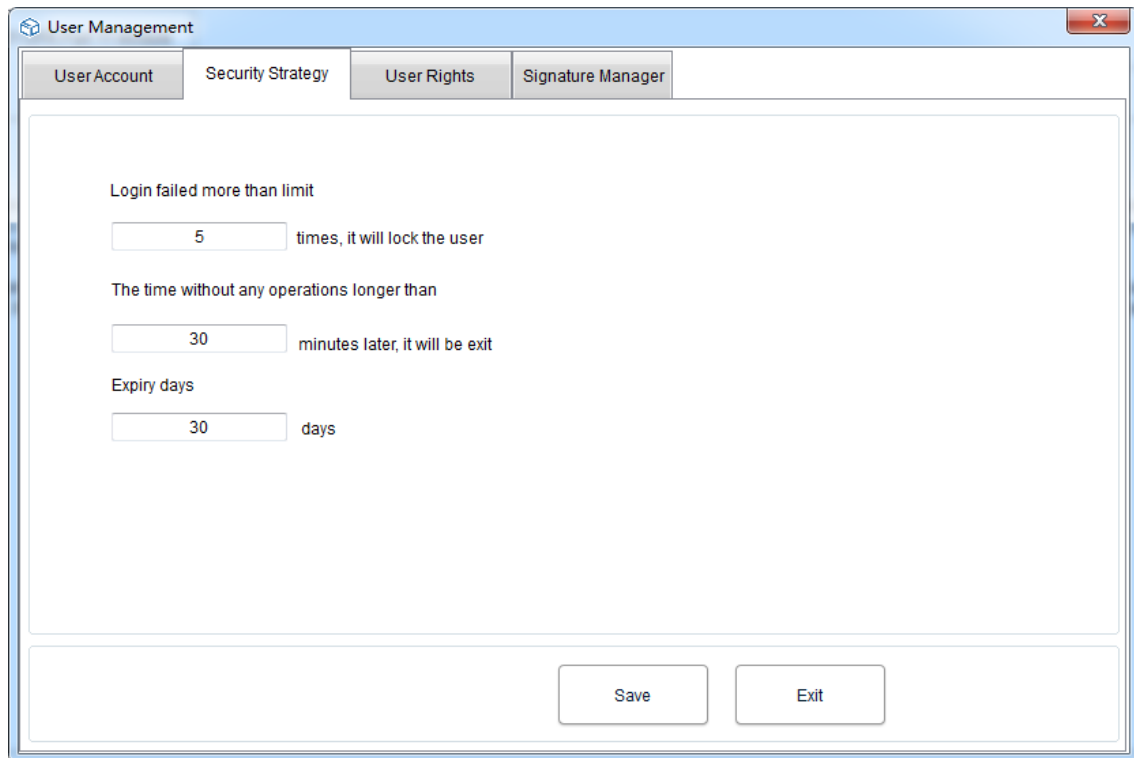
After all the above settings are finished, click "Save", and the software will restart automatically. As shown below:



Go back to the main menu and click the "Database" button to see the "Send Email" option in the lower right light up, and before setting the email, the option is grayed out and unselected. At this time, select a piece of data needed, click "Send Email", and the target recipient has been selected will receive the data file.

9.3 Account Security

In the main menu, click "System" button, select "FDA21 CFR Part 11 module", click "Configure FDA21 CFR Part 11 module", Choose the "Security Strategy" in the pop-up window, the user can set account lock, the logout time of account without operation and password expiration time, as shown in the figure below:



9.4 User Rights

Click the "System" button in the main menu, select "FDA21 CFR Part 11 module", and then click "Configure FDA21 CFR Part 11 module", and select "User Rights" in the pop-up window, where you can see the administrator rights and regular user rights.

Administrator rights: the administrator has all the rights to use the software functions, and can grant and revoke the rights of regular users;

Regular user rights: the regular user can only view and search data by default, if they want to access to audit trail records or delete data and so on, they need to be authorized by the administrator to use. As shown below:

User Management

User Account Security Strategy User Rights Signature Manager

User Name	Real Name	Job Position	User Type	Status
Txw10086	Txw10086	Txw10086	Administrator	Enable

- User Rights
 - Delete Data
 - View User Information
 - Change System Settings
 - Sign Data
 - Configure Device
 - View Audit Trail

Exit