Data Management Software

User Manual

Mar, 2018

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I Introduction

1.1 Overview

Data Management Software is comprehensive desktop software designed for analyzing and managing the temperature and humidity data recorded by Elitech data loggers.

The software integrates the most dependable temperature and humidity sensing technology and the most advanced system kernel to date. It is characterized of reliable data, quick response, simple operation and other strong functions, enabling users to track and collect temperature and humidity data of sensitive products timely and accurately in their testing, production, transport and storage, so that the whole cold chain can be monitored and traced with product safety guaranteed.

1.2 Compatible logger models

1. USB data loggers:
LogEt 6、LogEt 8F/S、MSL-51/H、RC-18、RC-19、RC-51/H、RC-55、RC-5+、LogEt8TE、LogEt8TH、LogEt 8 PTE、LogEt 8 THE、LogEt 8 BLE、LogEt 8 UTE、GSP-8A、Tlog 100、Tlog 100H、Tlog 100E、Tlog 100EH、Tlog 100EC、Tlog 100EL、Tlog B100、Tlog B100H、Tlog B100E、Tlog B100EH、TemLog 20、TemLog 20H

2. Serial port data loggers:
EC4A/C, GSP-6, RC-4, RC-4HA/C/D/E, RC-5, RC-61、GSP-8

1.3 Installation environment requirements

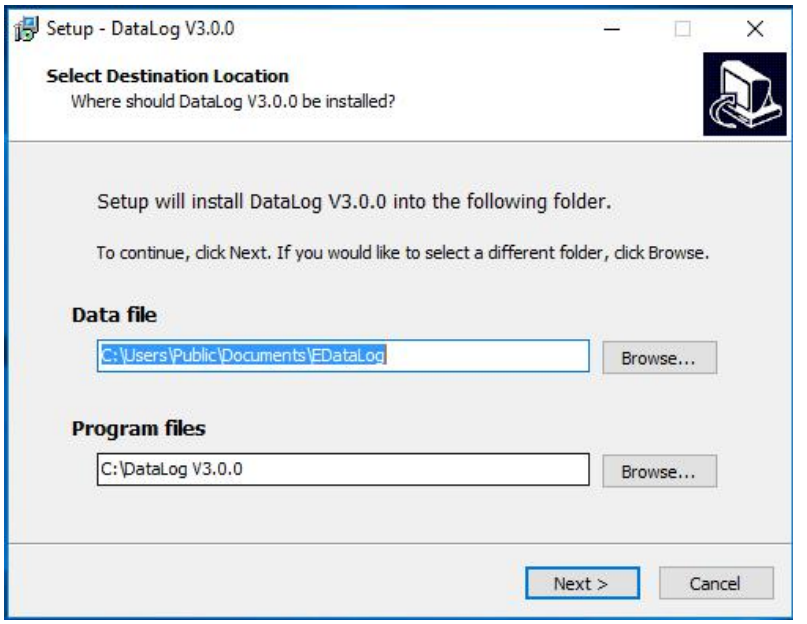
Pentium 1GHz or above, 2G or more
A hard drive with 1GB available disk space
Windows XP(32 bit), Windows 7 / 8 / 10
Mouse or other pointing device
A VGA monitor with display resolution 1024 x 768 pixels or better
Computer administrator account

II Install & Start

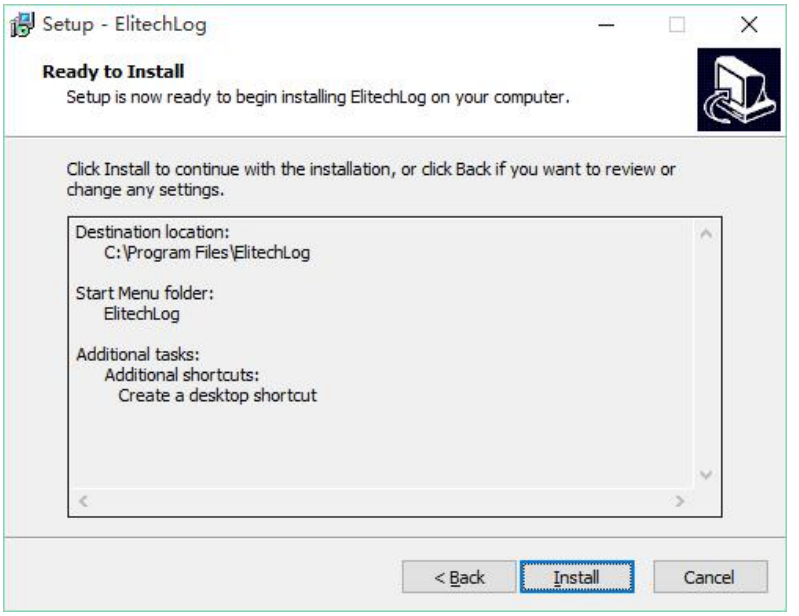
2.1 Install

1) Double click installer to start installation.

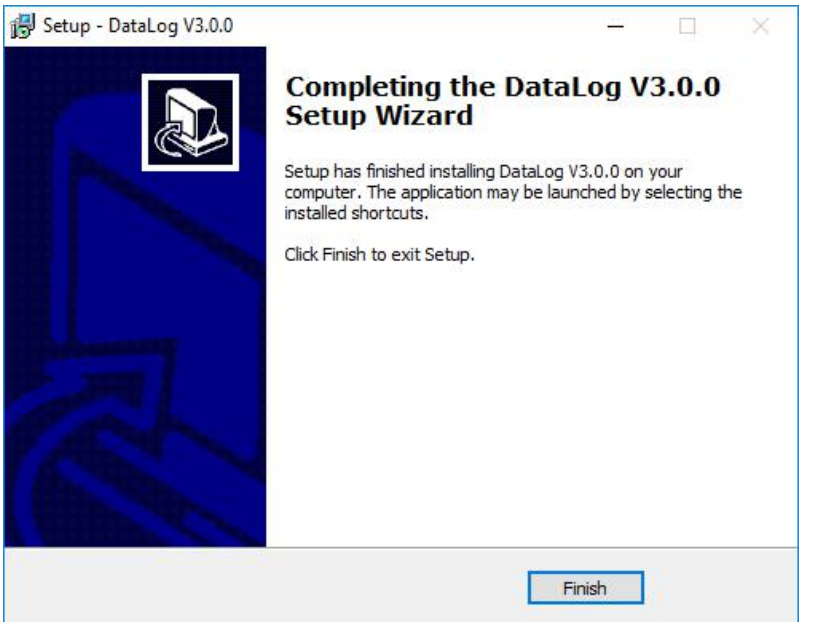
2) Select destination location.



3) Click Install.



4) Click Finish and installation completes.



2.2 Start

Double click  on your computer desktop to start the software.

2.3 Uninstall

1) Open Windows start menu, find this software.
2) Right click Uninstall to enter Add or Remove Programs.
3) click Uninstall.
4) Wait until uninstallation completes.

III Functions

3.1 Toolbar

Download: When the data logger is connected to a computer, the software will automatically read and download the data from the logger.

Summary: After successfully downloading the data, the software will show the logger's basic information, statistics and alarm status.

Parameter: Users can set the parameters of a connected data logger, including log interval, start delay, trip code, trip description and alarm settings.

Graph: Includes three tabs: graph, table and summary. The data downloaded from the logger will be shown here, so is historical data to be compared. Graph is drawn based on the data. The table will display all the data, including serial number, time, temperature or humidity. Summary presents parameters and data of one or more loggers in column, so data from different loggers can be listed visually here.

Database: The data downloaded from the logger is automatically saved to the database, so users can view the data anytime. Data can also be filtered as needed. Default display is latest one month's data. Users can also view data of a selected time range, filter alarm data, drag and select multiple lines of data. The data of multiple devices can be viewed and compared at the same time. It supports multi-graph drawing, parameter comparison and other functions.

Import: Custom format data files can be imported to facilitate multi-user data sharing and viewing.

Email: Data can be sent by email. This function allows the data in the currently displayed graph to be exported automatically to PDF and Excel format files, which can be sent to user specified mailbox.

System: Include three tabs: Option (to change date/time format and language), Email settings (to set email parameters) and FDA 21 CFR Part 11 Module (to enable and configure the module).

3.2 Status bar

Connection status: When connected to a computer, the logger will show in the status bar its model.

IV Download Data

4.1 Connect data logger

Connect the data logger to a computer for downloading data. Only one logger can be connected to the software at a time. It does not support simultaneous operation of multiple loggers.

4.2 Read data

Click Download on the toolbar to read and download the data in the logger. If the data logger is connected for the first time, the software will automatically read and download the data.

4.3 Store data

After downloaded, the data will be saved to the database automatically. The data can be viewed in "Database" interface.

V Summary

5.1 Device information

S/N: The unique ID of the data logger. It cannot be changed.
Log interval: The interval time between two successive points of data.
Device status: The current working status of the logger.
Trip code: User-created code, used to identify each task.
Trip description: A brief description of the task.
Start delay: The time from the logger started to the first point saved.
Start mode: The mode the logger to be started, including manual start, timing start, immediate start.
Software version number: The logger's internal program version number.
Repeated start: The logger is started repeatedly, and the previously recorded data is cleared after a new startup.
Allow pause: During recording, temperature/humidity collection and storage is suspended.
Temporary report: Whether the PDF report is allowed to be generated after the logger is inserted into the computer during recording.

5.2 Statistical information

Memory capacity: Maximum amount of data points the logger can save.
Data points: The amount of readings the software downloads from the logger.
Start time: The time when the logger starts running.
First record time: The time when the first point is recorded.
Last record time: The time when the last point is recorded.
MKT: Average kinetic temperature value.
Elapsed time: The total time that the logger keeps recording.
Stop mode: The logger's actual stop mode, including temporary stop, stop via software, manual stop.
Stop mode: The set stop mode, including stop via software, manual stop.
Max: The maximum value among the recorded temperature and humidity readings.
Min: The minimum value among the recorded temperature and humidity readings.
Avg: The average value of the recorded temperature and humidity readings.

Initial alarm: The recorded time when the first out-of-limit alarm is triggered.

5.3 Alarm information

Alarm value: The alarm set-point of the logger (temperature / humidity)

Alarm delay: If the specified time when the measured temperature exceeds the alarm set-point elapses, the alarm will be triggered.

Alarm type: The set alarm type of the logger (single / cumulative).

Overrun time: The cumulative time of out-of-limits readings.

Overrun times: The number of out-of-limits readings.

Status: The status of the logger in each alarm zone.

VI Parameter Settings

6.1 Device parameters

S/N: The unique code of the logger. It cannot be changed.
Log interval: The interval time between two successive points of data. It can be configured per day or time.
Trip code: User-created code, used to identify each task.
Trip description: A brief description of the task. 100 alphabetic and numeric characters.
Start mode: The mode the logger to be started, including manual start, timing start, immediate start. When timing start is set, start time choice box is available.
Start delay: The wait time from the logger started to the first reading saved. When manual start is selected, start delay choice box is available.
Timing start: The logger starts running at the specified time. When timing start is selected, timing start selection box is available.
Stop mode: The way that the logger is stopped: manually, or via software.
Repeated start: The logger is started repeatedly, and the previously recorded data is cleared after a new startup.
Allow pause: During recording, the temperature and humidity collection and storage are suspended.
Temporary report: Whether the PDF report is allowed to be generated after the logger is inserted into the computer during recording.
Cyclic Record: When the data memory is full new data automatically replaces the oldest readings.
PDF language: The PDF report generated is in English / Chinese.
Temperature unit: Celsius / Fahrenheit.

6.2 Alarm parameters

Alarm mode: No alarm, high / low limit alarm, more high / low limit alarm zones optional.
Alarm value: Alarm set-point; temperature range: -40℃~ 90℃; humidity range: 0% ~ 100%.
Alarm type: Single / cumulative.
Single type: Temperature/Humidity is above or below the alarm threshold and its duration is not less than the alarm delay, alarm will be triggered.

Cumulative type: Temperature/Humidity is above or below the alarm threshold and its cumulative time is not less than the alarm delay, alarm will be triggered.

Alarm delay: The time when temperature / humidity value exceeds the alarm set-point until the alarm event is triggered.

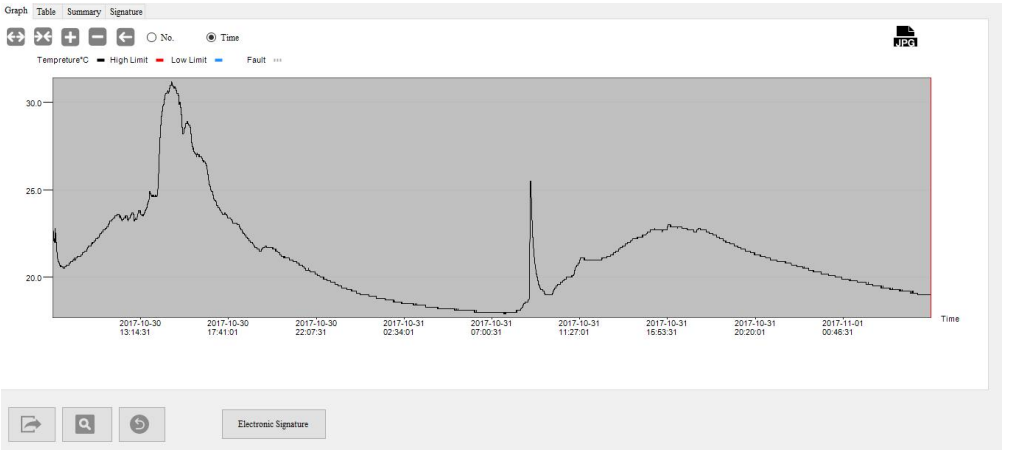
6.3 Parameter template

Export template: The parameter values in current page are saved as a file.

Import template: Reads the specified parameter template file and loads the parameter values in the file into the interface.

VII Graph

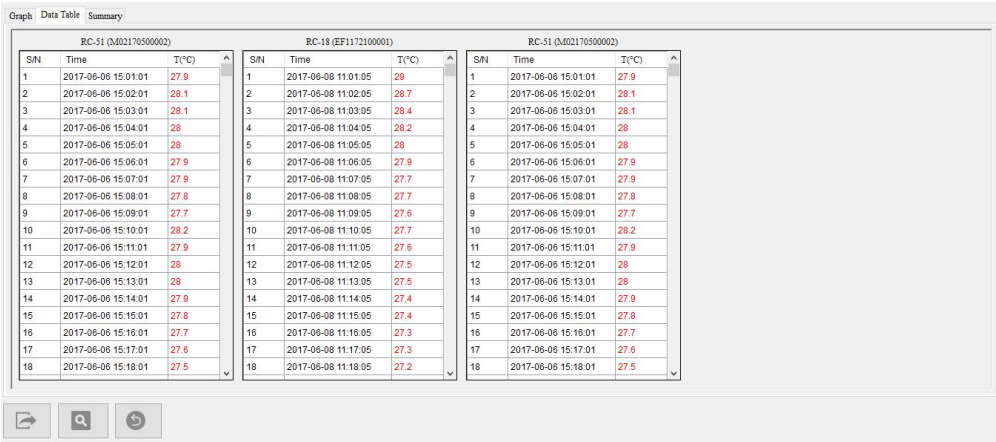
7.1 Graph



Click the "Graph" tab to display currently selected data of the logger. It can be the data of a currently connected logger or the historical data stored in the database. 10 data curves can be displayed at the same time for users to compare the temperature and humidity changes. The Y-axis on the left side of the graph shows the temperature scale value and the right Y-axis shows the humidity scale value. The X-axis shows the logger's time or reading's No.

Toolbar: The graph supports zoom and drag functions, allowing the user to zoom in, zoom out, and drag the curve by clicking the button in the upper left corner. The curve can be restored to its original state at any time after operation.

7.2 Table



S/N	Time	T(°C)
1	2017-06-06 15:01:01	27.9
2	2017-06-06 15:02:01	28.1
3	2017-06-06 15:03:01	28.1
4	2017-06-06 15:04:01	28
5	2017-06-06 15:05:01	28
6	2017-06-06 15:06:01	27.9
7	2017-06-06 15:07:01	27.9
8	2017-06-06 15:08:01	27.8
9	2017-06-06 15:09:01	27.7
10	2017-06-06 15:10:01	28.2
11	2017-06-06 15:11:01	27.9
12	2017-06-06 15:12:01	28
13	2017-06-06 15:13:01	28
14	2017-06-06 15:14:01	27.9
15	2017-06-06 15:15:01	27.8
16	2017-06-06 15:16:01	27.7
17	2017-06-06 15:17:01	27.6
18	2017-06-06 15:18:01	27.5

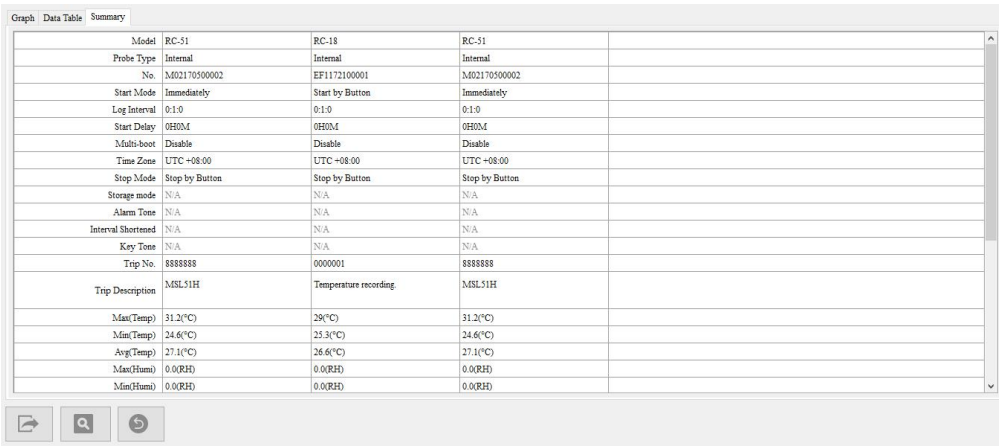
S/N	Time	T(°C)
1	2017-06-08 11:01:05	29
2	2017-06-08 11:02:05	28.7
3	2017-06-08 11:03:05	28.4
4	2017-06-08 11:04:05	28.2
5	2017-06-08 11:05:05	28
6	2017-06-08 11:06:05	27.9
7	2017-06-08 11:07:05	27.7
8	2017-06-08 11:08:05	27.7
9	2017-06-08 11:09:05	27.6
10	2017-06-08 11:10:05	27.7
11	2017-06-08 11:11:05	27.6
12	2017-06-08 11:12:05	27.5
13	2017-06-08 11:13:05	27.5
14	2017-06-08 11:14:05	27.4
15	2017-06-08 11:15:05	27.4
16	2017-06-08 11:16:05	27.3
17	2017-06-08 11:17:05	27.3
18	2017-06-08 11:18:05	27.2

S/N	Time	T(°C)
1	2017-06-06 15:01:01	27.9
2	2017-06-06 15:02:01	28.1
3	2017-06-06 15:03:01	28.1
4	2017-06-06 15:04:01	28
5	2017-06-06 15:05:01	28
6	2017-06-06 15:06:01	27.9
7	2017-06-06 15:07:01	27.9
8	2017-06-06 15:08:01	27.8
9	2017-06-06 15:09:01	27.7
10	2017-06-06 15:10:01	28.2
11	2017-06-06 15:11:01	27.9
12	2017-06-06 15:12:01	28
13	2017-06-06 15:13:01	28
14	2017-06-06 15:14:01	27.9
15	2017-06-06 15:15:01	27.8
16	2017-06-06 15:16:01	27.7
17	2017-06-06 15:17:01	27.6
18	2017-06-06 15:18:01	27.5

Click the "Table" tab to display currently selected data of the logger. It can be the data of a currently connected logger or the historical data stored in the database. Data from multiple devices can be viewed for comparison. Normal temperature and humidity data is marked in black, overrun value in red, and USB value in gray.

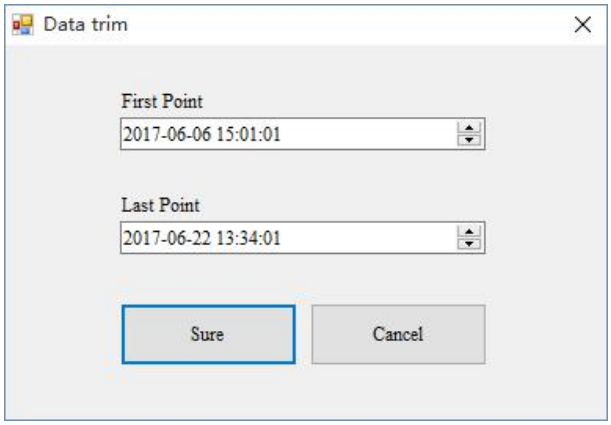
7.3 Summary

Click Summary tab to see the statistics, unavailable parameters displayed in gray.



Model	RC-51	RC-18	RC-51
Probe Type	Internal	Internal	Internal
No.	M02170500002	EF1172100001	M02170500002
Start Mode	Immediately	Start by Button	Immediately
Log Interval	0:1:0	0:1:0	0:1:0
Start Delay	0H0M	0H0M	0H0M
Multi-boot	Disable	Disable	Disable
Time Zone	UTC +08:00	UTC +08:00	UTC +08:00
Stop Mode	Stop by Button	Stop by Button	Stop by Button
Storage mode	N/A	N/A	N/A
Alarm Tone	N/A	N/A	N/A
Interval Shortened	N/A	N/A	N/A
Key Tone	N/A	N/A	N/A
Trip No.	8888888	0000001	8888888
Trip Description	MSL51H	Temperature recording.	MSL51H
Max(Temp)	31.2(°C)	29(°C)	31.2(°C)
Min(Temp)	24.6(°C)	25.3(°C)	24.6(°C)
Avg(Temp)	27.1(°C)	26.6(°C)	27.1(°C)
Max(Humi)	0.0(RH)	0.0(RH)	0.0(RH)
Min(Humi)	0.0(RH)	0.0(RH)	0.0(RH)

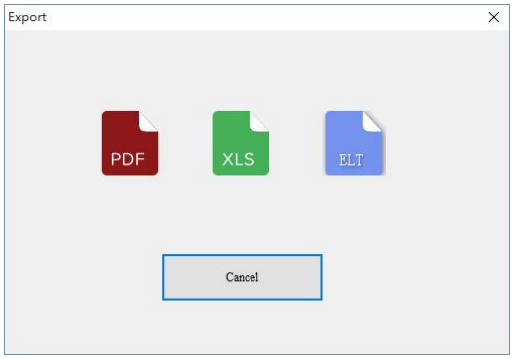
7.4 Data filtering



Click the "Filter Data" button at the bottom left. Select "Start time" and "End time", and click "OK", the software will automatically filter the data within specified time period. After data filtered, the software will automatically redraw the graph, table, and summary.

7.5 Export data

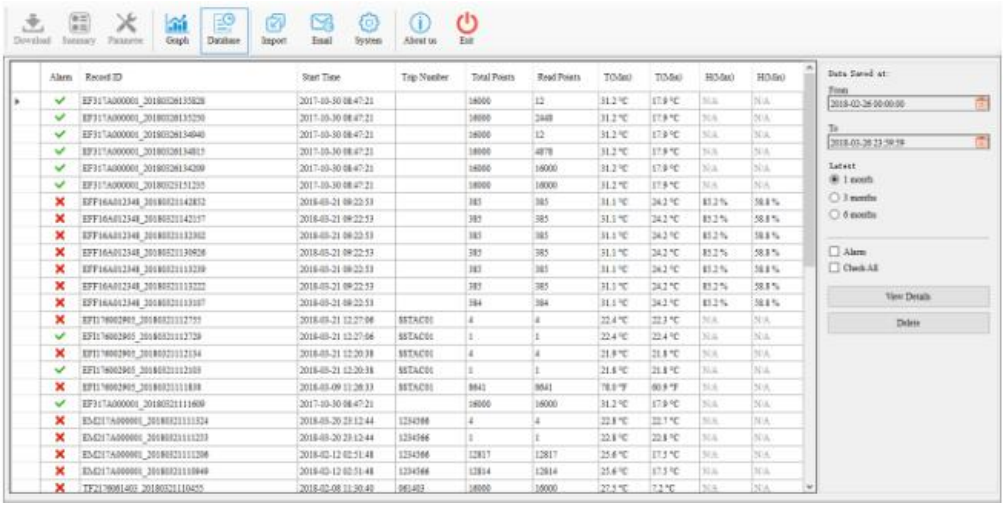
Click the "Export Data" button at the bottom left to export report to PDF, Excel and ELT (custom format) format.



VIII Database

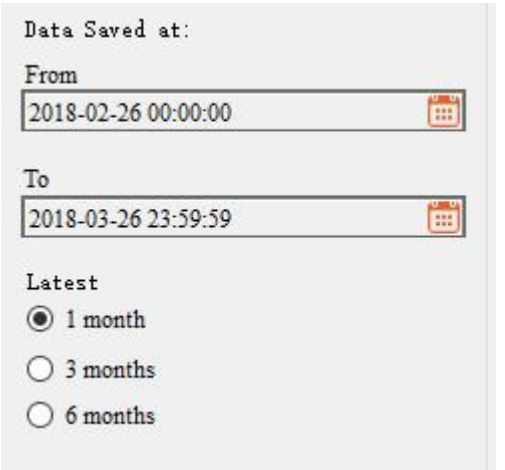
8.1 Historical data table

Click Database on the toolbar to query historical data. The data downloaded from the logger is automatically saved to the database and can be filtered as needed. Default display is the latest month's data. Users can also view data of a selected time range, filter alarm data, drag and select multiple lines of data. The data of multiple devices can be viewed and compared at the same time. It supports multi-graph drawing, parameter comparison and other functions.



8.2 Filter data

Select the time range in certain month(s), the software will automatically filters out the historical data for that time period and displays the data in the table.



8.3 Select data line

	Alarm	Record ID	Start Time	Trip Number	Total Points	Read Points	T(Max)	T(Min)	H(Max)	H(Min)
▸	✓	EF317A000001_20180326135828	2017-10-30 08:47:21		16000	12	31.2 °C	17.9 °C	N/A	N/A
	✓	EF317A000001_20180326135250	2017-10-30 08:47:21		16000	2448	31.2 °C	17.9 °C	N/A	N/A
	✓	EF317A000001_20180326134940	2017-10-30 08:47:21		16000	12	31.2 °C	17.9 °C	N/A	N/A
	✓	EF317A000001_20180326134815	2017-10-30 08:47:21		16000	4878	31.2 °C	17.9 °C	N/A	N/A
	✓	EF317A000001_20180326134209	2017-10-30 08:47:21		16000	16000	31.2 °C	17.9 °C	N/A	N/A
	✓	EF317A000001_20180323151235	2017-10-30 08:47:21		16000	16000	31.2 °C	17.9 °C	N/A	N/A
	✗	EFF16A012348_20180321142852	2018-03-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %
	✗	EFF16A012348_20180321142157	2018-03-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %

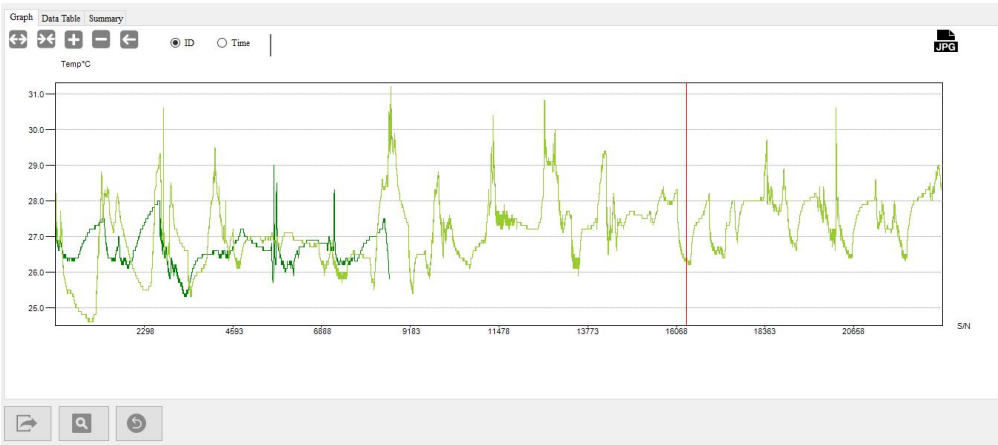
Click the first column on the left side of the data table to select the data line, or hold down the mouse to drag multiple lines of data.

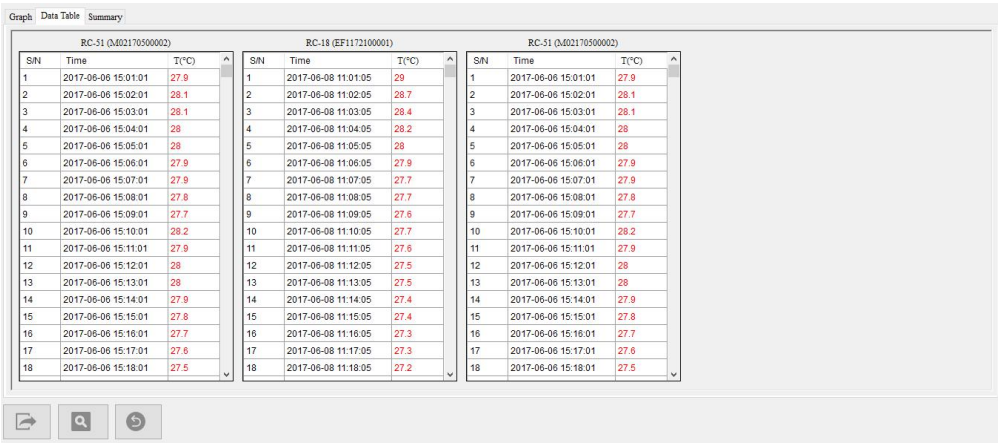
It is used to view the records of multiple devices, or delete the selected data line. Up to 10 records can be viewed and compared at the same time. There is no limit of the number of lines when deleting records.

8.4 View details

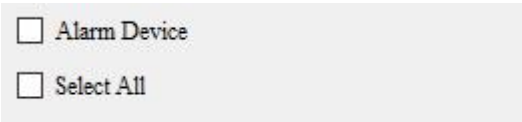
Click the "View details" button in the right sidebar to view the data details in graph,

table or summary.

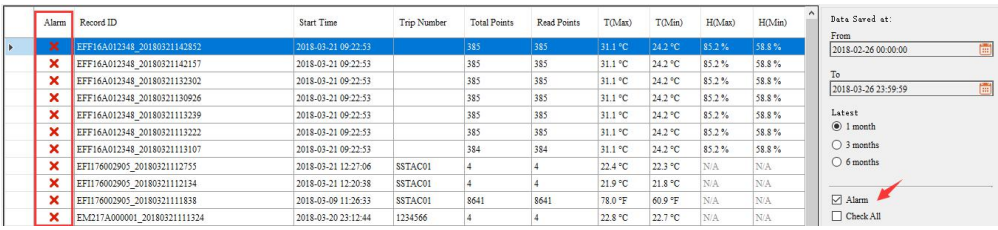




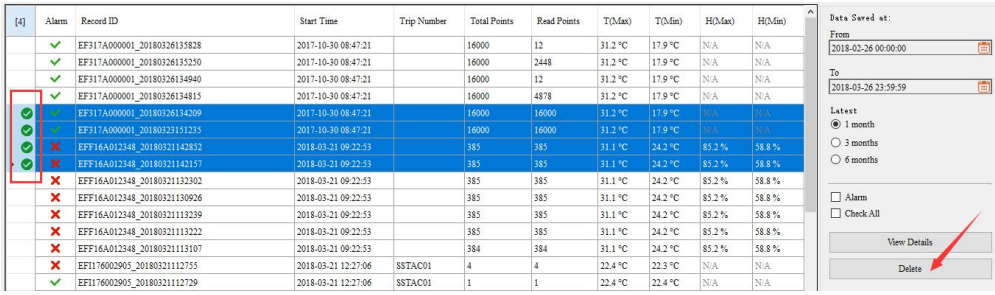
8.5 Display alarm data



Check “Alarm” in the right sidebar to view only the data of the alarmed device.



8.6 Delete data



First click on the blank in the first column on the left side of the data table to select the data to be deleted. Then click the "Delete" button on the right sidebar, the software will prompt the user "whether to delete the data." After confirmed, the data will be deleted and cannot be recovered.

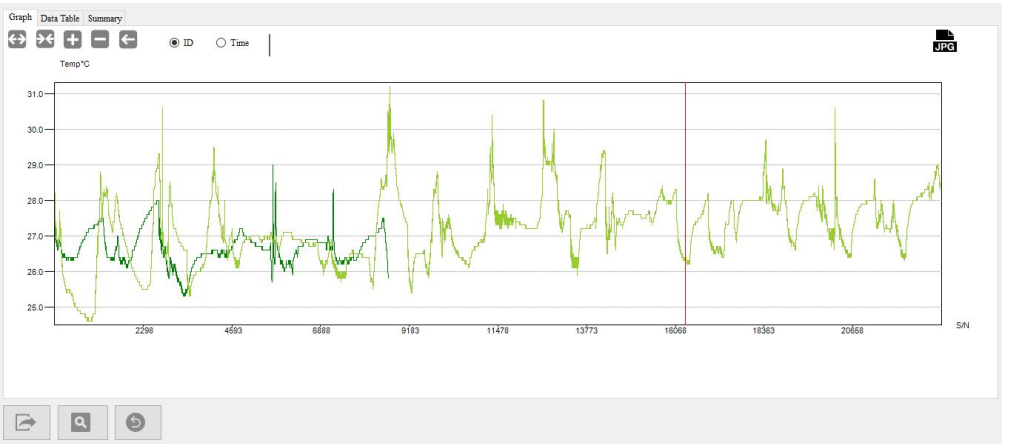
IX Import Data

9.1 How to import

Click Import on the toolbar and select the file to be imported for sharing data between multiple computers with "Data Management Software" installed. Users can import the previously exported ELT format data file into the software. The software will automatically analyze the imported data and display it in the "Summary" interface, drawing graphs, tables and showing summary.

9.2 View imported data

After imported, the data will automatically skip to the "Summary" interface.



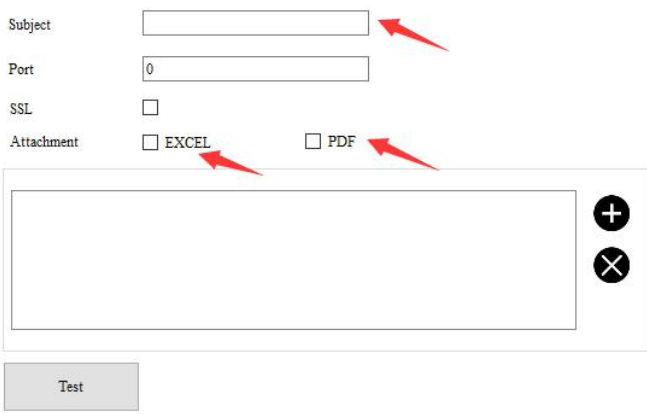
X Send E-mail

10.1 Function

Click Email on the toolbar to send the data by mail. This function allows the data in the currently displayed graph to be exported automatically to PDF and Excel format files, which can be sent to a user specified mailbox.

10.2 Mail information

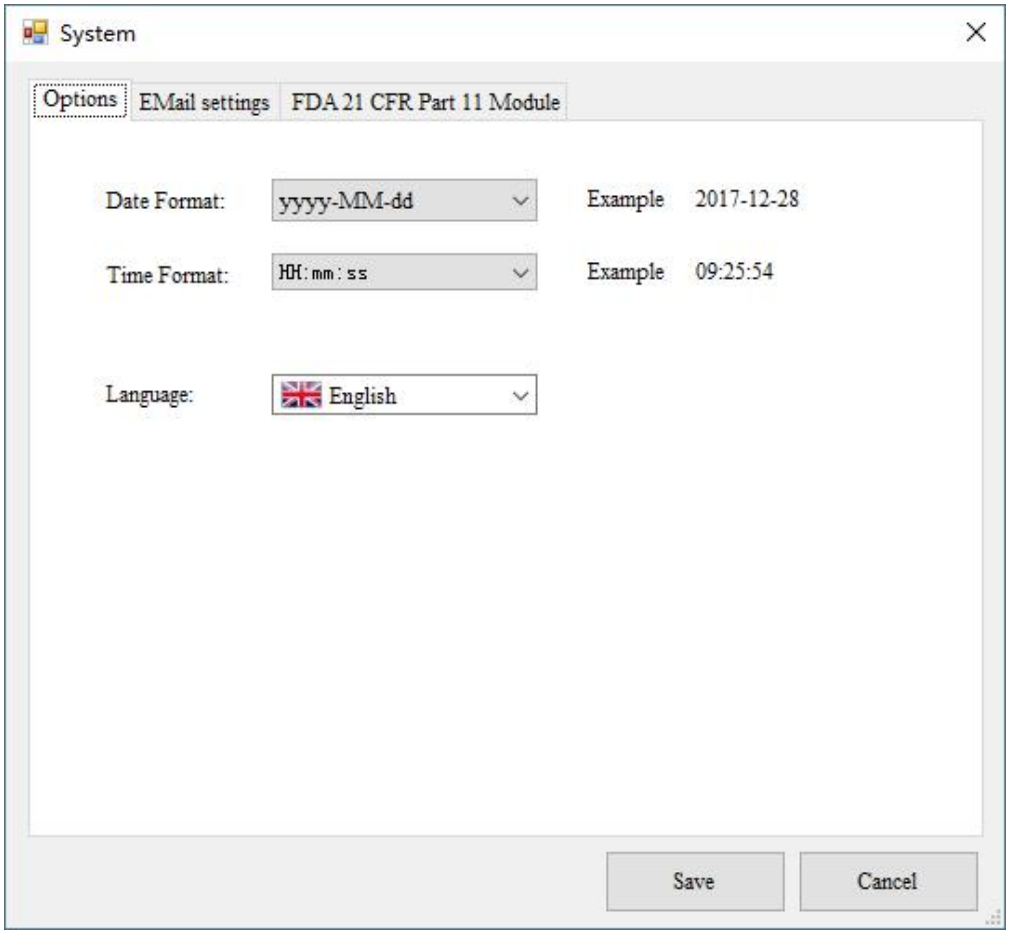
The contents of the email include subject, PDF, EXCEL, etc. It can be sent only when email parameters have been set in "System". If you do not want to send the PDF or EXCEL file, please do not check it.



XI System Settings

11.1 Options

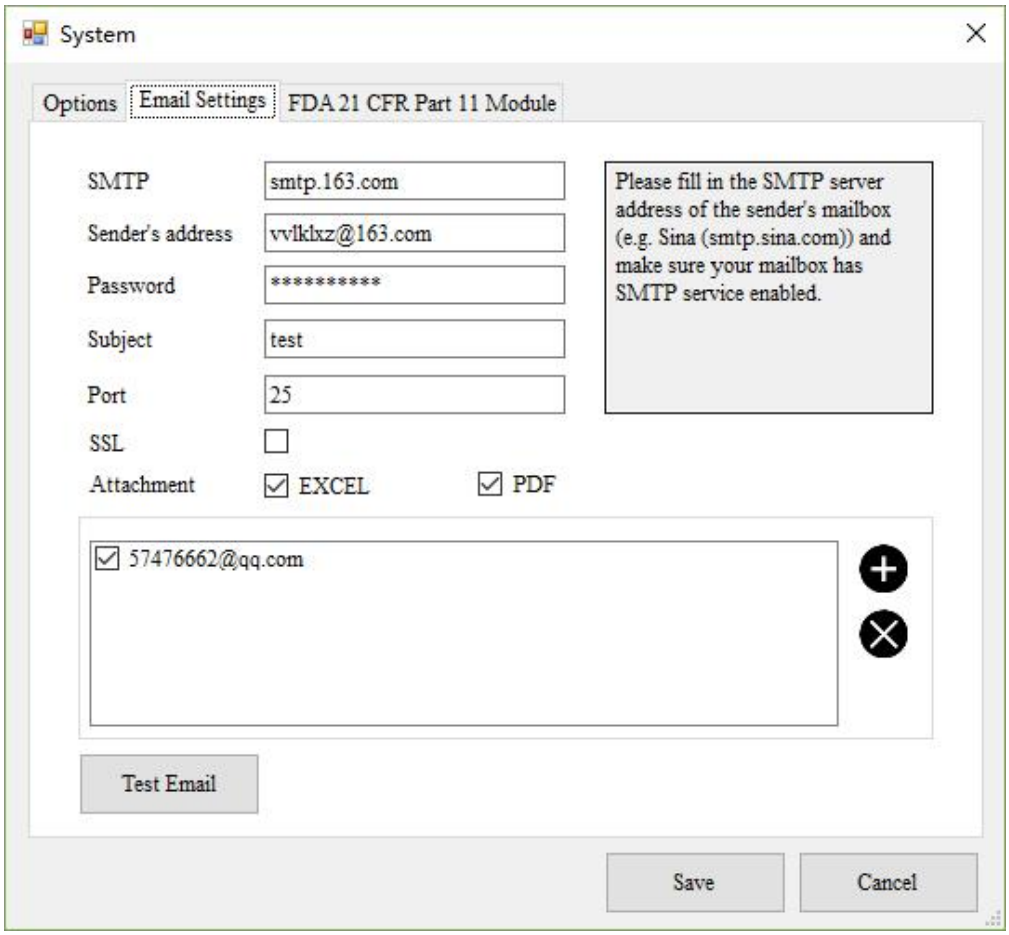
Click System on the toolbar to set the date/time format and language. Then click "Save", the latest date and time format will be automatically updated for your use next time.



11.2 Email settings

Click the "Email settings" tab.

Note: Before sending mail, users need to configure the mailbox parameters first. Click "Test Email" to check whether the parameters are correct and email can be sent.



XII FDA 21 CFR Part 11 Module

12.1 What is FDA 21 CFR Part 11 compliance?

The United States Food and Drug Administration (FDA) issued regulations Title 21 Code of Federal Regulations Part 11 in 1997 and enacted relevant industry guidelines in 2003 to refine the rules. It provides criteria for acceptance of electronic records, signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. Part 11 applies to any record governed by an existing FDA predicate rule that is created, modified, maintained, archived, retrieved, or transmitted using computers and /or saved on durable storage media.

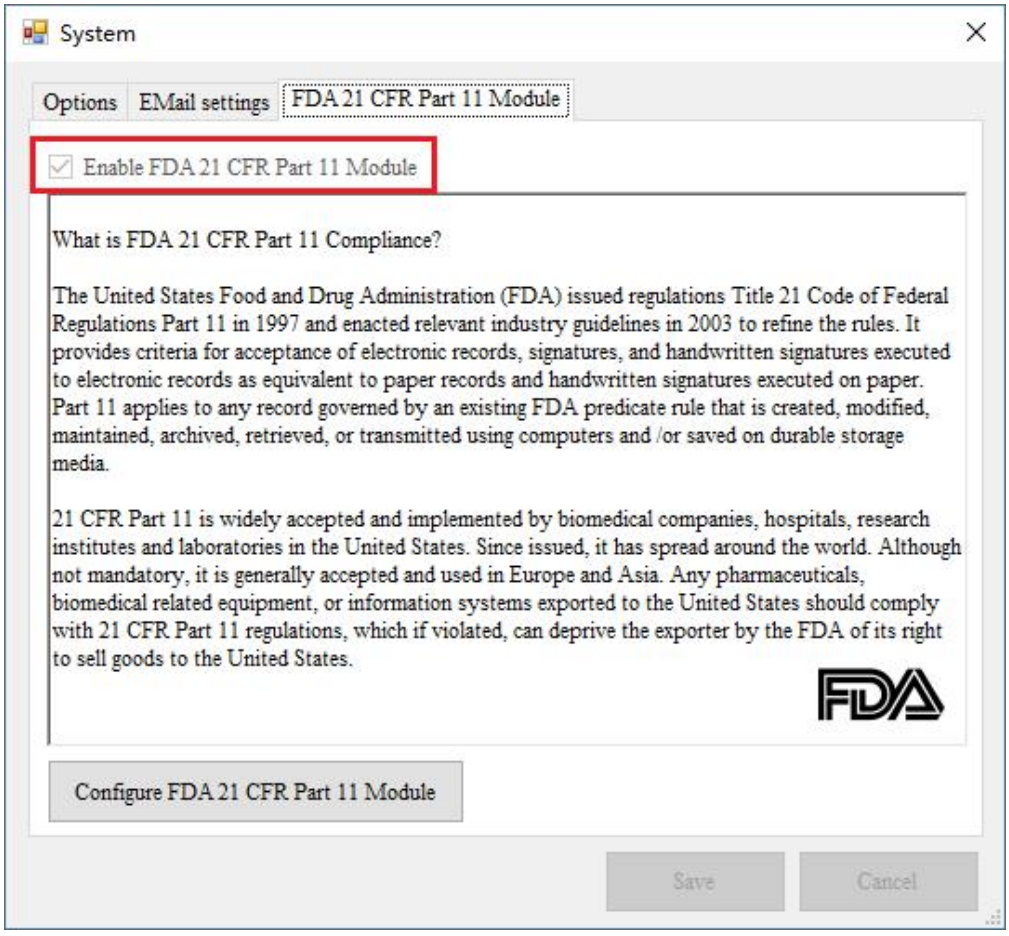
FDA 21 CFR Part 11 is widely accepted and implemented by biomedical companies, hospitals, research institutes and laboratories in the United States. Since issued, it has spread around the world. Although not mandatory, it is generally accepted and used in Europe and Asia. Any pharmaceuticals, biomedical related equipment, or information systems exported to the United States should comply with 21 CFR Part 11 regulations, which if violated, can deprive the exporter by the FDA of its right to sell goods to the United States.

12.2 Access to the Module

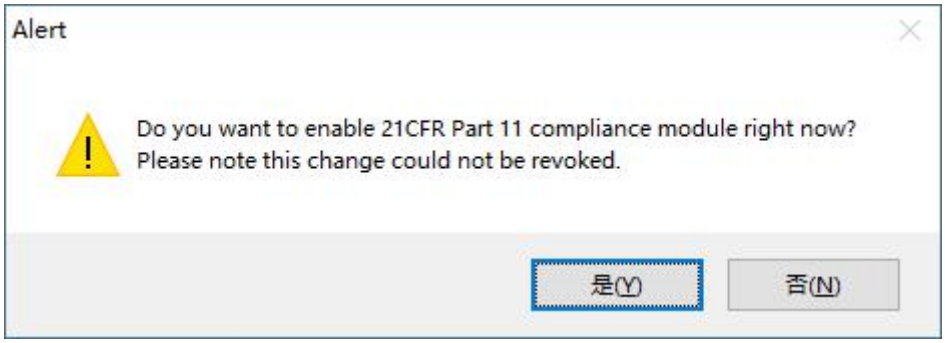
Click "System" on the toolbar and then click the tab FDA 21 CFR Part 11 Module.

Note: 21 CFR Part 11 module is not a default function ready for use after software installation. You need to enable this module by going to System > FDA 21 CFR Part 11 Module. The interface gives a brief introduction to the module.

12.2.1 Activate the Module

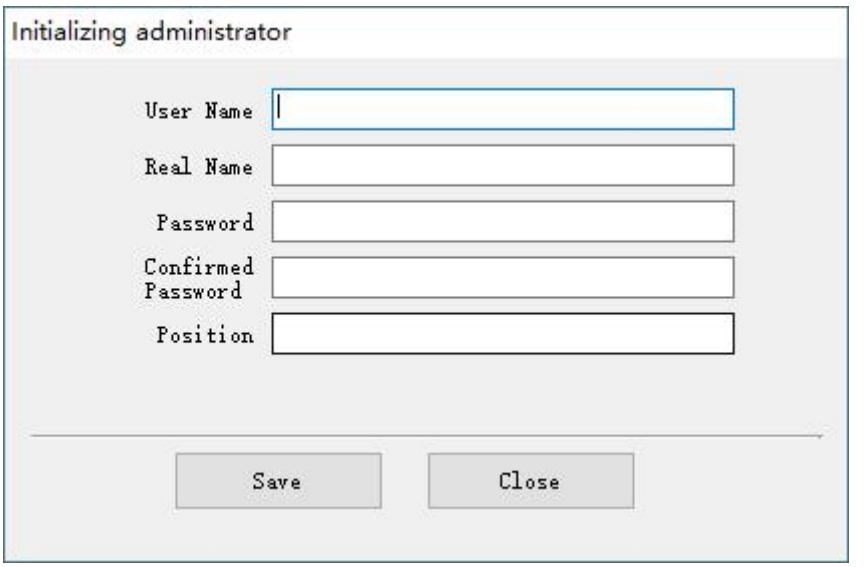


Check “FDA 21 CFR 11 Module” to activate the module. After FDA 21 CFR 11 module is enabled, program will restart for the changes to take effect. Click Yes.

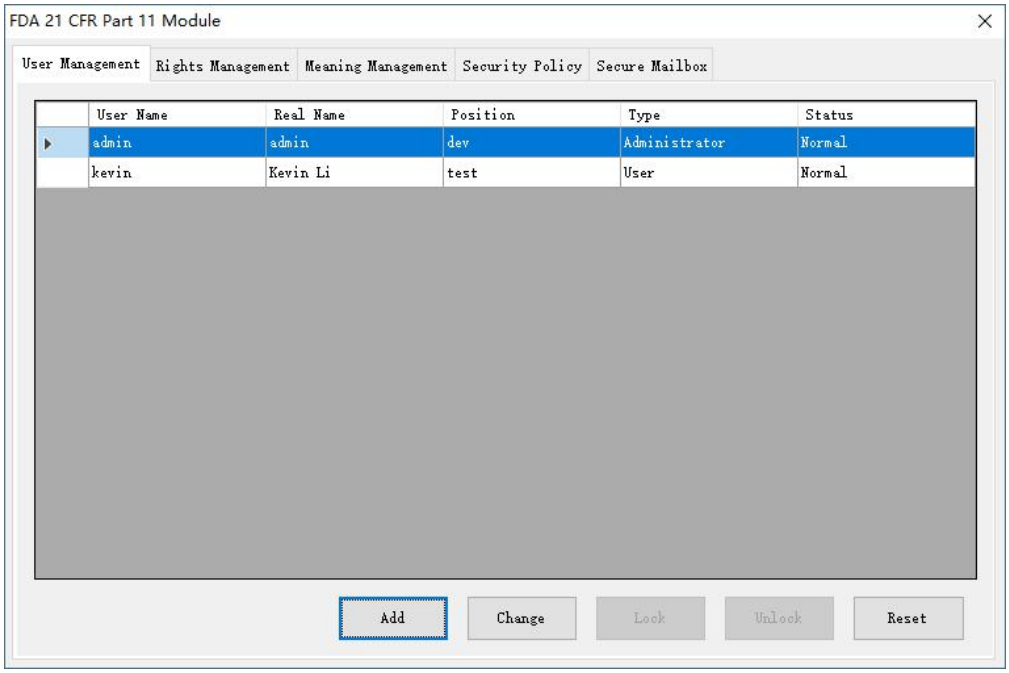


12.2.2 Initializing Administrator

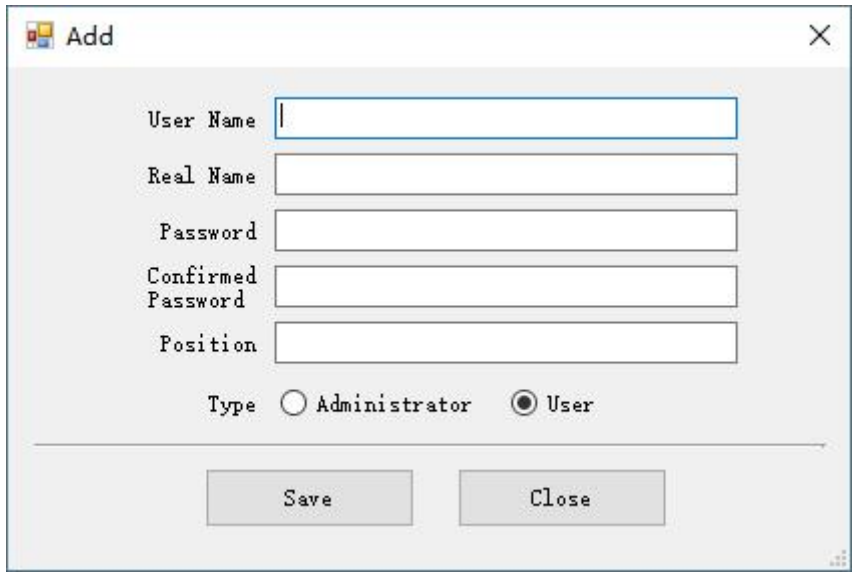
After FDA 21 CFR Part 11 module enabled, you are required to create an administrator account for login.



12.2.3 User Management



Administrator account can be used to create user accounts, change user info, lock/unlock user and reset passwords.

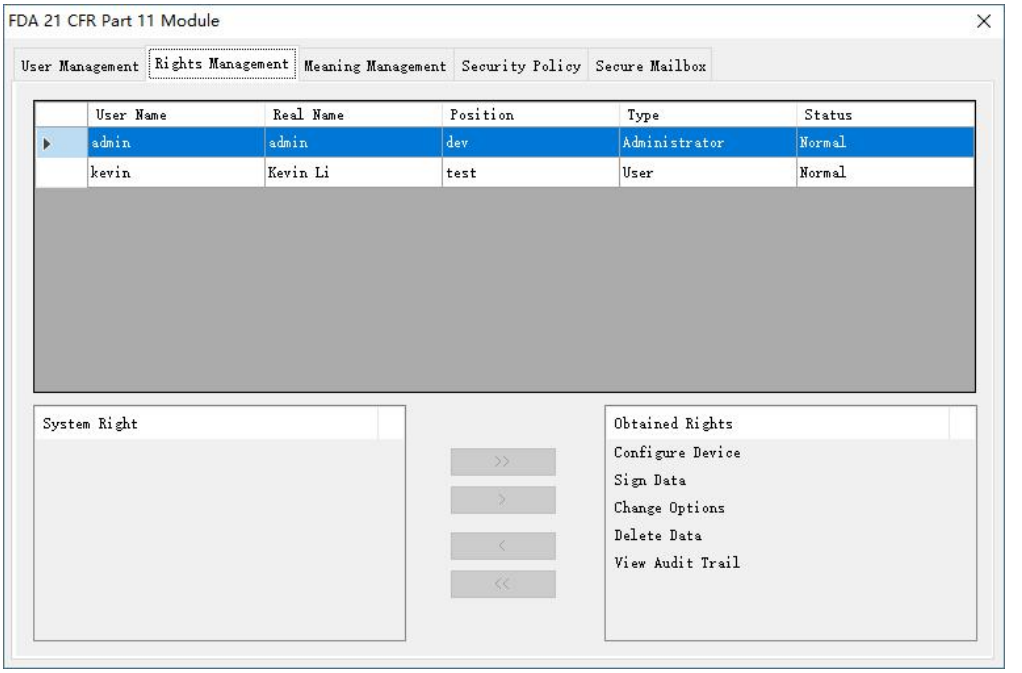


12.2.4 Rights Management

System Right

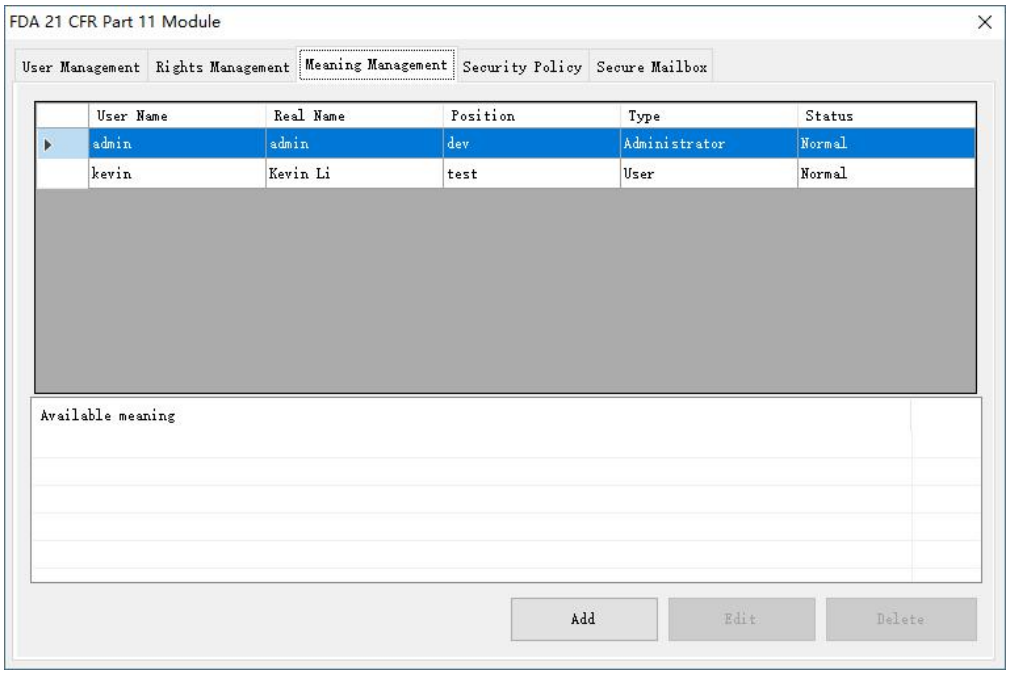
Administrator owns all system rights.

User right is granted or revoked by administrator.



12.2.5 Meaning Management

To sign electronically, user must select a meaning, which will be linked to the data record.



New Meaning:

Enter meaning name, click Save or Enter, the meaning will be saved to database.

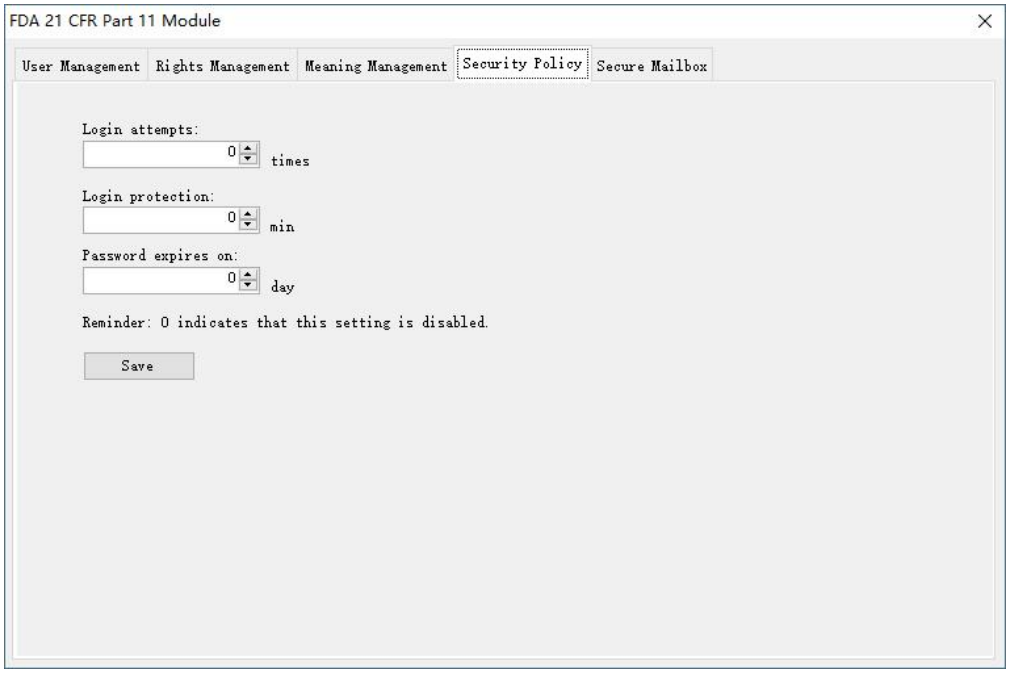
Available Meanings:

All meanings are listed.

Meanings:

User meanings are managed by Administrator.

12.2.6 Security Policy



Login attempts:

If login attempts exceeds the set times, the account will be locked. Please contact administrator to unlock the account.

Login protection:

If the system stays inactive after login for a period that exceeds the set time, it will be locked. User must log in again to operate the system.

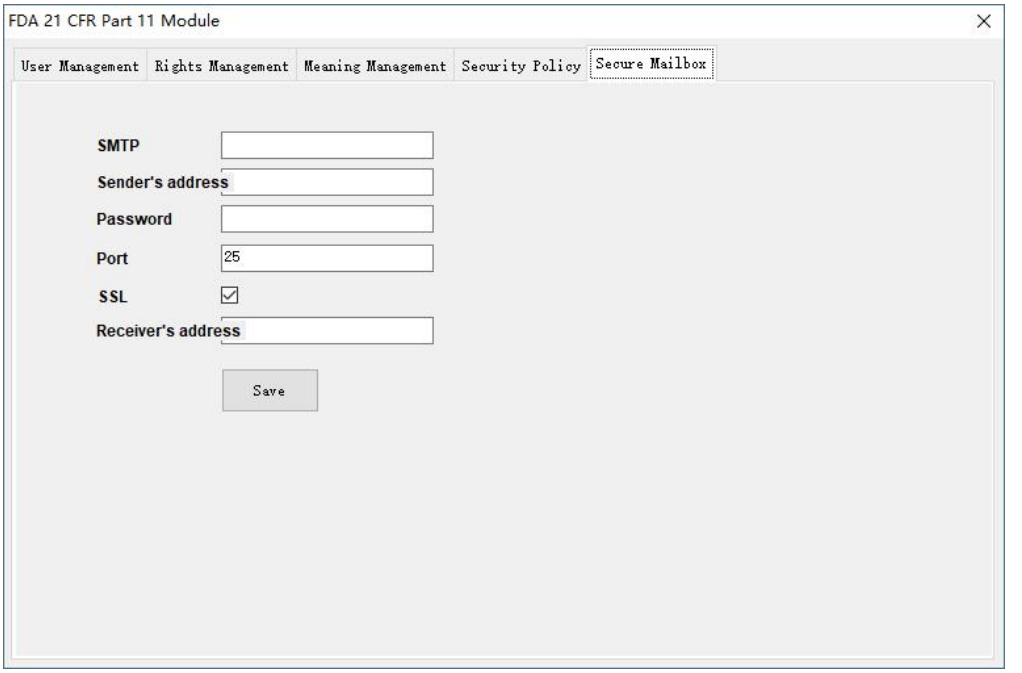
Password expiry date:

This setting indicates the password is valid before a certain period of time. If the password expires, the system will remind the user of changing it 3 days earlier.

Reminder: 0 indicates that this setting is disabled.

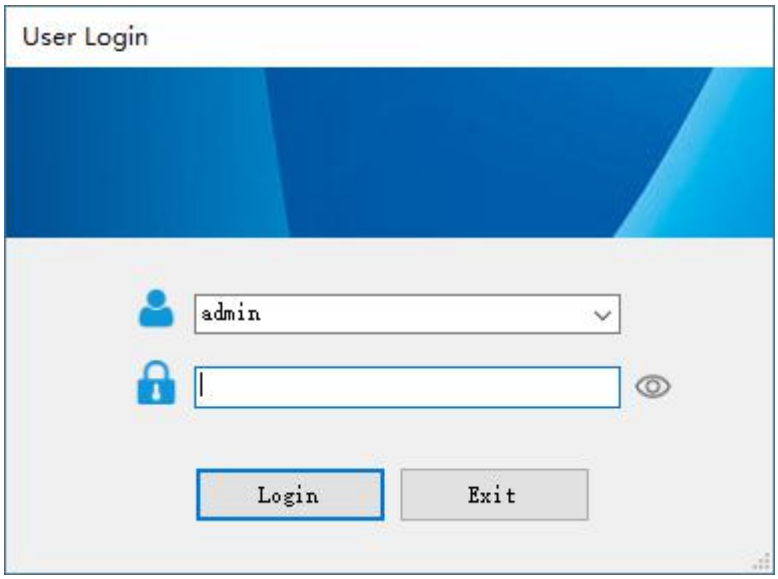
12.2.7 Secure Mailbox

Secure mailbox is used to send invalid login attempts to a user-specified email address.

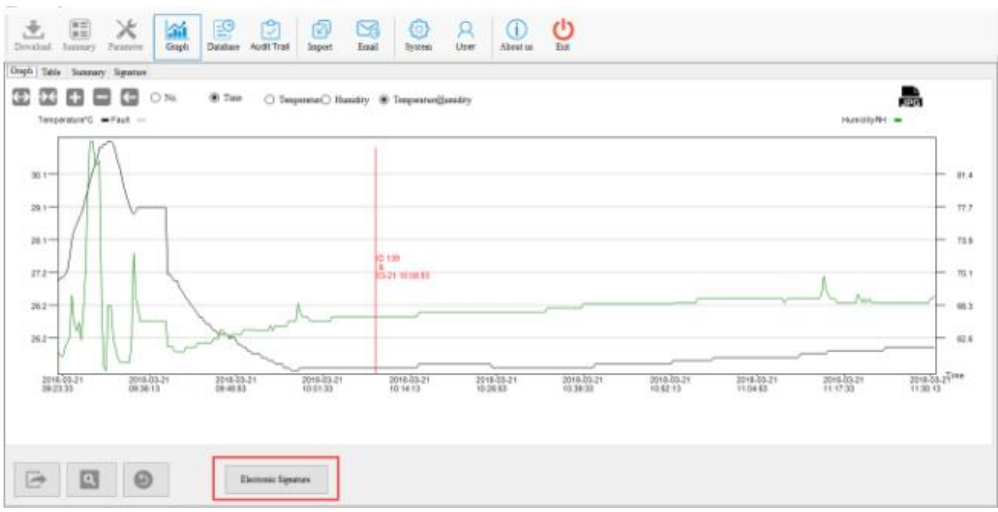


12.2.8 User Login

If FDA 21 CFR Part 11 module is enabled, user must log in to enter the system.

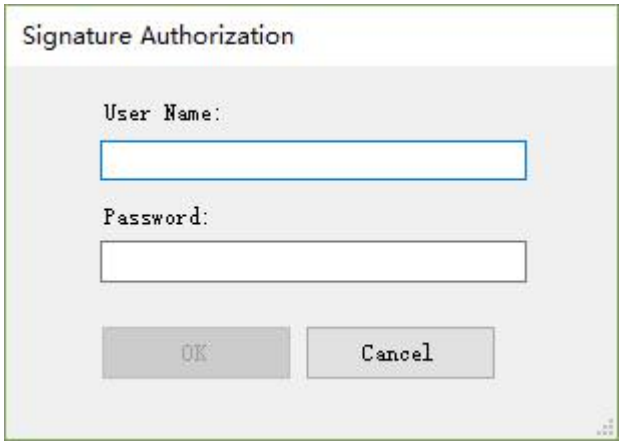


12.2.9 Electronic Signature

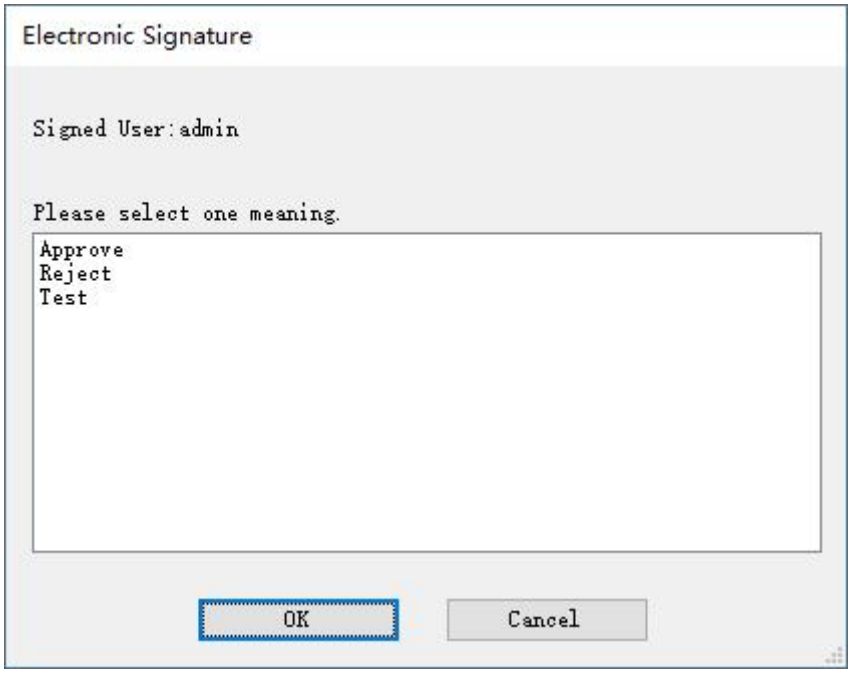


After the data logger is connected to a computer and its data is downloaded

to the database successfully, you may click "Graph" icon in the toolbar and then "Electronic Signature" to sign. Enter the user name and password in the popup interface as follows:



After signature authorization, please select one meaning as follows:



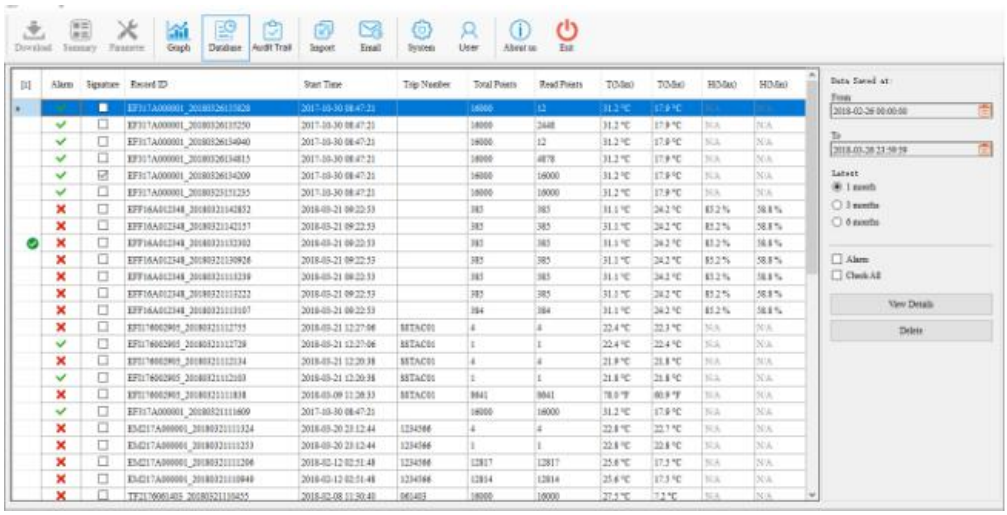
Then click OK. The system will sign and pop up "Signature success". Then you may click the tab "Signature" under "Graph" to view signature information.

Graph | Table | Summary | Signature

No.	User Name	Real Name	Meaning	Time
1	kevin	Kevin Li	Test	2017/12/28 9:35:59
2	kevin	Kevin Li	Reject	2017/12/28 9:35:49
3	admin	admin	Approve	2017/12/28 9:35:24

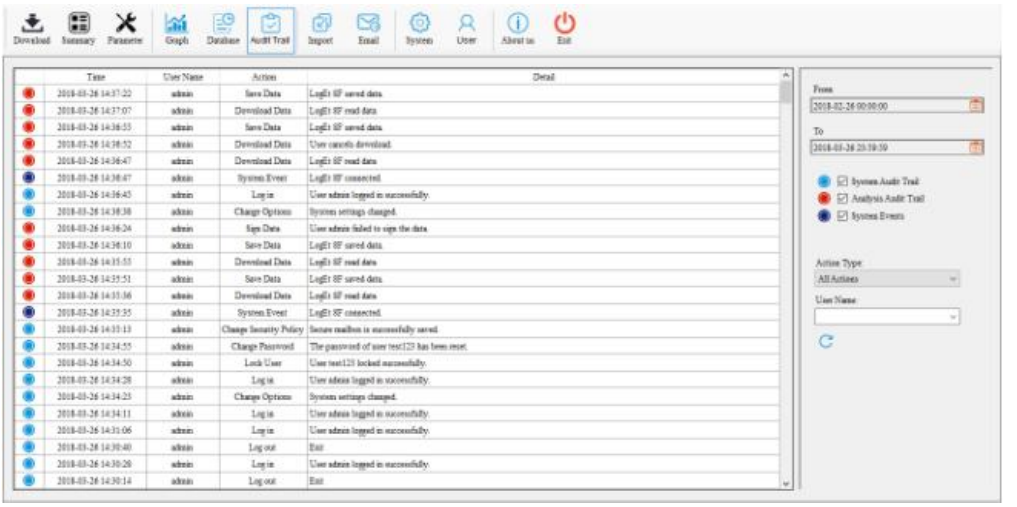
12.2.10 Historical Signature

After signed, the signature will show before the Record ID.
If you want to sign the data again, please double click the record and repeat the operation above.



12.2.11 Audit Trail

Audit trail records user's operations of the system, including time, actions, etc. The data can be filtered per time, audit type, action type and user name.



	Time	User Name	Action	
	2017-12-28 09:38:03	admin	Save Data	RC-5+ saved data.
	2017-12-28 09:37:58	admin	Download Data	RC-5+ read data
	2017-12-28 09:37:57	admin	System Event	RC-5+ connected.
	2017-12-28 09:37:55	System	Log in	User admin logged in successfully.
	2017-12-28 09:37:29	admin	Log out	Exit
	2017-12-28 09:36:00	admin	Sign Data	User kevin signed the data.
	2017-12-28 09:36:00	admin	Sign Data	Signature success
	2017-12-28 09:35:50	admin	Sign Data	User kevin signed the data.
	2017-12-28 09:35:50	admin	Sign Data	Signature success
	2017-12-28 09:35:38	admin	Change Meaning	User and meaning updated successfully kevin:.

XIII Q & A

1. The data logger cannot be connected?
Check if the computer USB port is available. If you are using a USB extension cable to connect the logger, make sure that USB can be read. If the cable is too long, the logger may not be connected successfully.

2. After the logger inserted, the software will pop up a prompt to enter password?
After the logger is connected to the computer, the software will automatically read the data of the logger. If the password is configured before the logger is started, the software will pop up a prompt to enter the password. If the password is forgotten, please check with the administrator who configured the logger.

3. It always prompts error when saving the data?
Check if the computer's disk space where the software is installed runs out.

4. Mail is not sent successfully when mailbox parameters have been set?
a) Please open the "System" interface, double check if the mail parameters are set correctly, including whether the SMTP address and port is consistent with that of the mailbox service provider. Please open your mail to check whether the mailbox service provider opened the SMTP service. If not, please contact your mail service provider to make sure you can use the SMTP service. If the SMTP configuration is incorrect, the mail cannot be sent.

b) Please check whether you entered a correct mail account and password. The mail cannot be sent from a wrong account.

c) If the mail parameters are confirmed correct, click "test mailbox" to make sure the mail can be sent.

5. The data cannot be read after the logger connected?
The logger is connected, but the software cannot read the data. Please check whether the status bar shows the logger model. If not, the logger is connected incorrectly. Please check whether the USB port is available or the cable is available. If OK, please check if the logger is damaged.

6. The software cannot be installed normally?
Please check whether the disk space where the software is installed runs out.

7. Errors always occur when the data is being read?
Please check if the USB port is loose and the cable is too long.

Version Log

Version	Date	Description
V1.0	2017-06-19	The first version.
V1.1	2017-07-31	Add LogEt, RC-5+.
V2.0	2017-12-12	Add FDA function.
V3.0	2018-03-26	FDA audit passed.
V3.3.0	2018-09-28	Increase GSP8, LogEt8TE and LogEt8TH support.
V3.3.1	2018-10-26	Modify humidity data to display wrong BUG. Replace LOG pictures.
V3.3.2	2018-12-25	Modify RC4HC humidity data unit to display no temperature error
V4.0.0	2019-03-01	Support LogET1 Series Recorder Support LogET8 Series Recorder Automatic update of new programs

V4.3.0	2019-11-05	1.Tlog adds repeat start and stop function 2.Enhance GSP-8A functionality 3.Fixed some bugs
V4.4.0	2020-01-19	Fixed some bugs
V4.5.0	2020-02-26	Modify the low voltage display range, modify the actual points and read points of the COM port