

Data Management Software

User Manual

Oct, 2021

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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

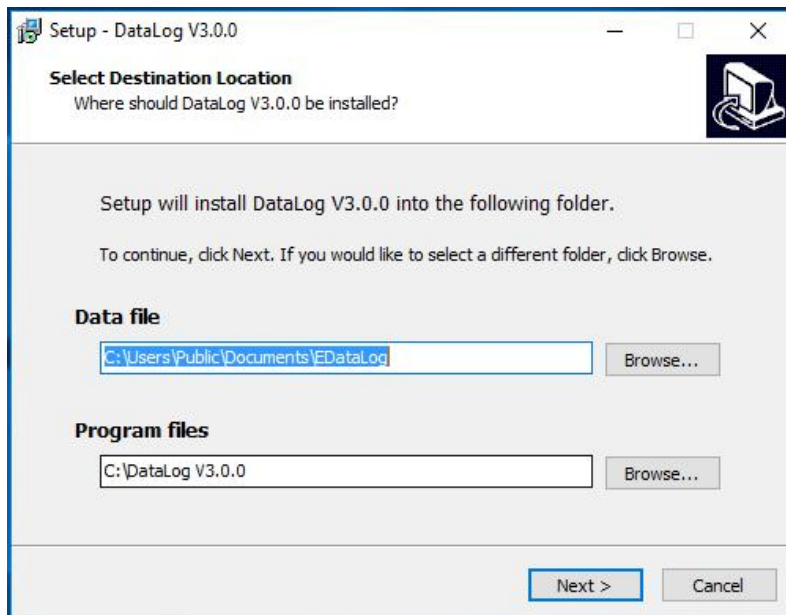
A VGA monitor with display resolution 1024 x 768 pixels or better

Computer administrator account

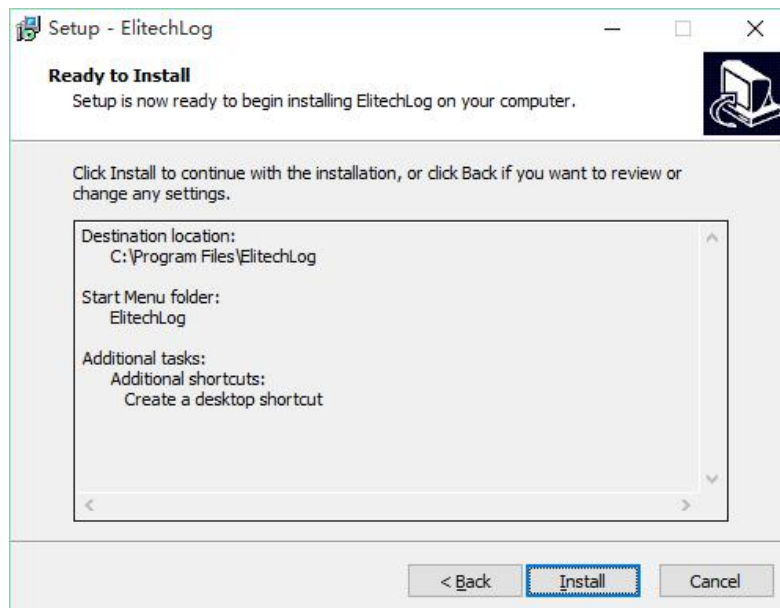
II Install & Start

2.1 Install

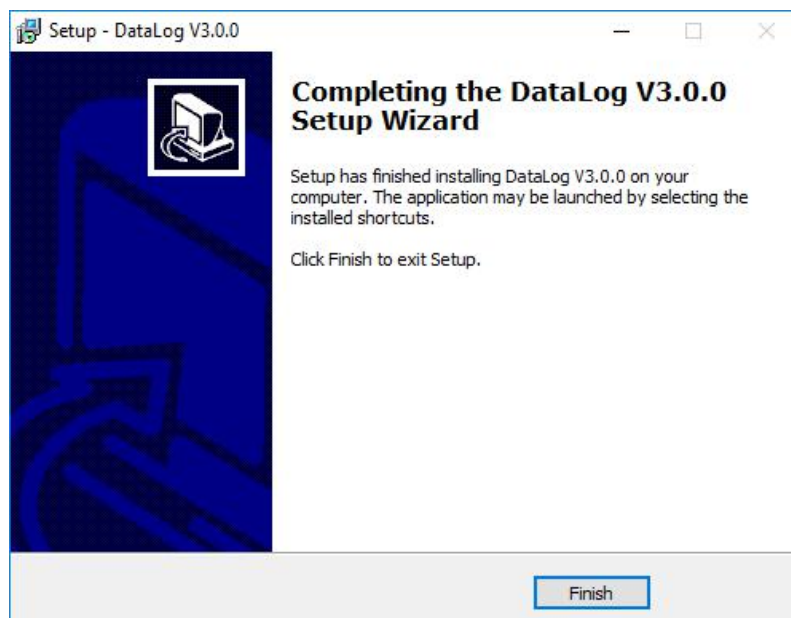
- 1) Double click installer to start installation.
- 2) Select destination location.



- 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



Not Connected

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: $-40^{\circ}\text{C} \sim 90^{\circ}\text{C}$; humidity range: $0\% \sim 100\%$.

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.

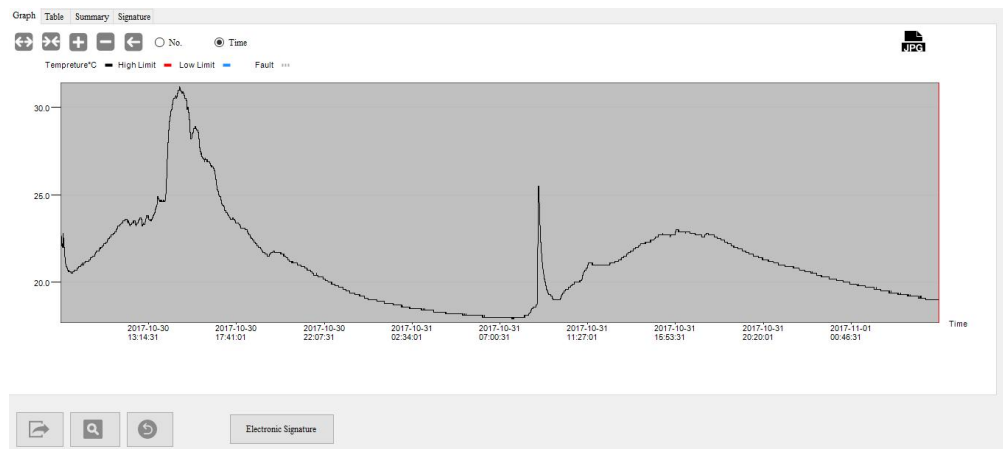
6.3 Parameter template

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

RC-51 (M0217050002)			RC-18 (EF1172100001)			RC-51 (M0217050002)		
SIN	Time	T(°C)	SIN	Time	T(°C)	SIN	Time	T(°C)
1	2017-06-06 15:01:01	27.9	1	2017-06-08 11:01:05	29	1	2017-06-06 15:01:01	27.9
2	2017-06-06 15:02:01	28.1	2	2017-06-08 11:02:05	28.7	2	2017-06-06 15:02:01	28.1
3	2017-06-06 15:03:01	28.1	3	2017-06-08 11:03:05	28.4	3	2017-06-06 15:03:01	28.1
4	2017-06-06 15:04:01	28	4	2017-06-08 11:04:05	28.2	4	2017-06-06 15:04:01	28
5	2017-06-06 15:05:01	28	5	2017-06-08 11:05:05	28	5	2017-06-06 15:05:01	28
6	2017-06-06 15:06:01	27.9	6	2017-06-08 11:06:05	27.9	6	2017-06-06 15:06:01	27.9
7	2017-06-06 15:07:01	27.9	7	2017-06-08 11:07:05	27.7	7	2017-06-06 15:07:01	27.9
8	2017-06-06 15:08:01	27.8	8	2017-06-08 11:08:05	27.7	8	2017-06-06 15:08:01	27.8
9	2017-06-06 15:09:01	27.7	9	2017-06-08 11:09:05	27.6	9	2017-06-06 15:09:01	27.7
10	2017-06-06 15:10:01	28.2	10	2017-06-08 11:10:05	27.7	10	2017-06-06 15:10:01	28.2
11	2017-06-06 15:11:01	27.9	11	2017-06-08 11:11:05	27.6	11	2017-06-06 15:11:01	27.9
12	2017-06-06 15:12:01	28	12	2017-06-08 11:12:05	27.5	12	2017-06-06 15:12:01	28
13	2017-06-06 15:13:01	28	13	2017-06-08 11:13:05	27.5	13	2017-06-06 15:13:01	28
14	2017-06-06 15:14:01	27.9	14	2017-06-08 11:14:05	27.4	14	2017-06-06 15:14:01	27.9
15	2017-06-06 15:15:01	27.8	15	2017-06-08 11:15:05	27.4	15	2017-06-06 15:15:01	27.8
16	2017-06-06 15:16:01	27.7	16	2017-06-08 11:16:05	27.3	16	2017-06-06 15:16:01	27.7
17	2017-06-06 15:17:01	27.6	17	2017-06-08 11:17:05	27.3	17	2017-06-06 15:17:01	27.6
18	2017-06-06 15:18:01	27.5	18	2017-06-08 11:18:05	27.2	18	2017-06-06 15:18:01	27.5

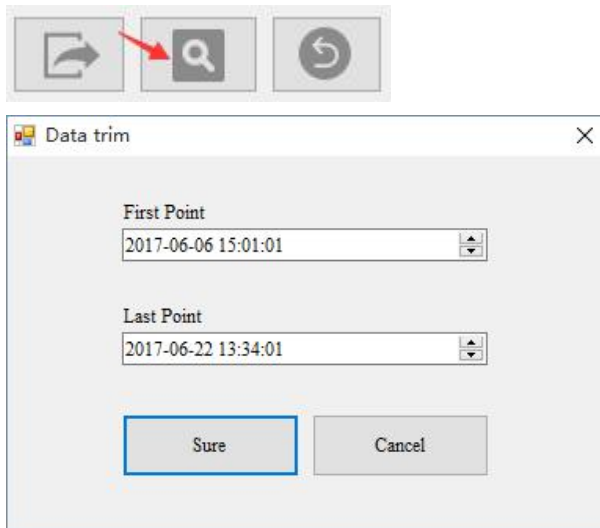
Click the "Table" tab to display currently selected data of the logger. It can be the data of a currently connected logger or the historical data stored in the database. Data from multiple devices can be viewed for comparison. Normal temperature and humidity data is marked in black, overrun value in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

7.3 Summary

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

Graph Data Table Summary				
Model	RC-51	RC-18	RC-51	
Probe Type	Internal	Internal	Internal	
No	M0217050002	EF1172100001	M0217050002	
Start Mode	Immediately	Start by Button	Immediately	
Log Interval	0:1:0	0:1:0	0:1:0	
Start Delay	00:00:0	00:00:0	00:00:0	
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(Hum)	0.0(RH)	0.0(RH)	0.0(RH)	
Min(Hum)	0.0(RH)	0.0(RH)	0.0(RH)	

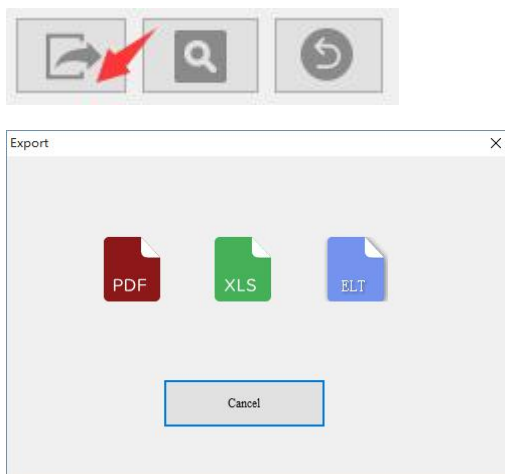
7.4 Data filtering



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.

Alarm	Record ID	Start Time	Trip Number	Total Points	Read Points	TO(5s)	TO(5s)	HO(5s)	HO(5s)
✓	EPF17A000001_2018020115028	2017-03-30 08:47:21		18000	12	31.2 °C	17.8 °C	NA	NA
✓	EPF17A000001_2018020115270	2017-03-30 08:47:21		18000	2488	31.2 °C	17.8 °C	NA	NA
✓	EPF17A000001_2018020115490	2017-03-30 08:47:21		18000	12	31.2 °C	17.8 °C	NA	NA
✓	EPF17A000001_20180201154817	2017-03-30 08:47:21		18000	4878	31.2 °C	17.8 °C	NA	NA
✓	EPF17A000001_20180201154209	2017-03-30 08:47:21		18000	16000	31.2 °C	17.8 °C	NA	NA
✓	EPF17A000001_20180201151255	2017-03-30 08:47:21		18000	16000	31.2 °C	17.8 °C	NA	NA
✗	EPF16A012348_20180521143852	2018-05-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %
✗	EPF16A012348_20180521142157	2018-05-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %
✗	EPF16A012348_20180521142362	2018-05-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %
✗	EPF16A012348_20180521139526	2018-05-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %
✗	EPF16A012348_20180521133299	2018-05-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %
✗	EPF16A012348_20180521133222	2018-05-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %
✗	EPF16A012348_20180521133387	2018-05-21 09:22:53		384	384	31.1 °C	24.2 °C	85.2 %	58.8 %
✗	EPF178062905_20180521127751	2018-05-21 12:27:06	85TAC01	4	4	22.4 °C	22.3 °C	NA	NA
✓	EPF178062905_20180521127728	2018-05-21 12:27:06	85TAC01	1	1	22.4 °C	22.4 °C	NA	NA
✗	EPF178062905_2018052112134	2018-05-21 12:20:38	85TAC01	4	4	21.8 °C	21.8 °C	NA	NA
✓	EPF178062905_20180521121308	2018-05-21 12:20:38	85TAC01	1	1	21.8 °C	21.8 °C	NA	NA
✗	EPF178062905_2018052111818	2018-05-09 11:28:33	85TAC01	8841	8841	78.8 °F	60.8 °F	NA	NA
✓	EPF17A000001_20180521114808	2017-03-30 08:47:21		18000	16000	31.2 °C	17.8 °C	NA	NA
✗	EN4217A000001_2018052111324	2018-05-20 23:12:44	1234566	4	4	22.8 °C	22.1 °C	NA	NA
✗	EN4217A000001_20180521113223	2018-05-20 23:12:44	1234566	1	1	22.8 °C	22.8 °C	NA	NA
✗	EN4217A000001_20180521113206	2018-05-12 02:51:48	1234566	12817	12817	25.6 °C	17.5 °C	NA	NA
✗	EN4217A000001_20180521113048	2018-05-12 02:51:48	1234566	12814	12814	25.6 °C	17.5 °C	NA	NA
✗	TF217091402_20180521110425	2018-02-09 11:30:49	061492	18000	18000	27.4 °C	7.2 °C	NA	NA

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.

Data Saved at:

From
2018-02-26 00:00:00

To
2018-03-26 23:59:59

Latest

☒ 1 month

☐ 3 months

☐ 6 months

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.

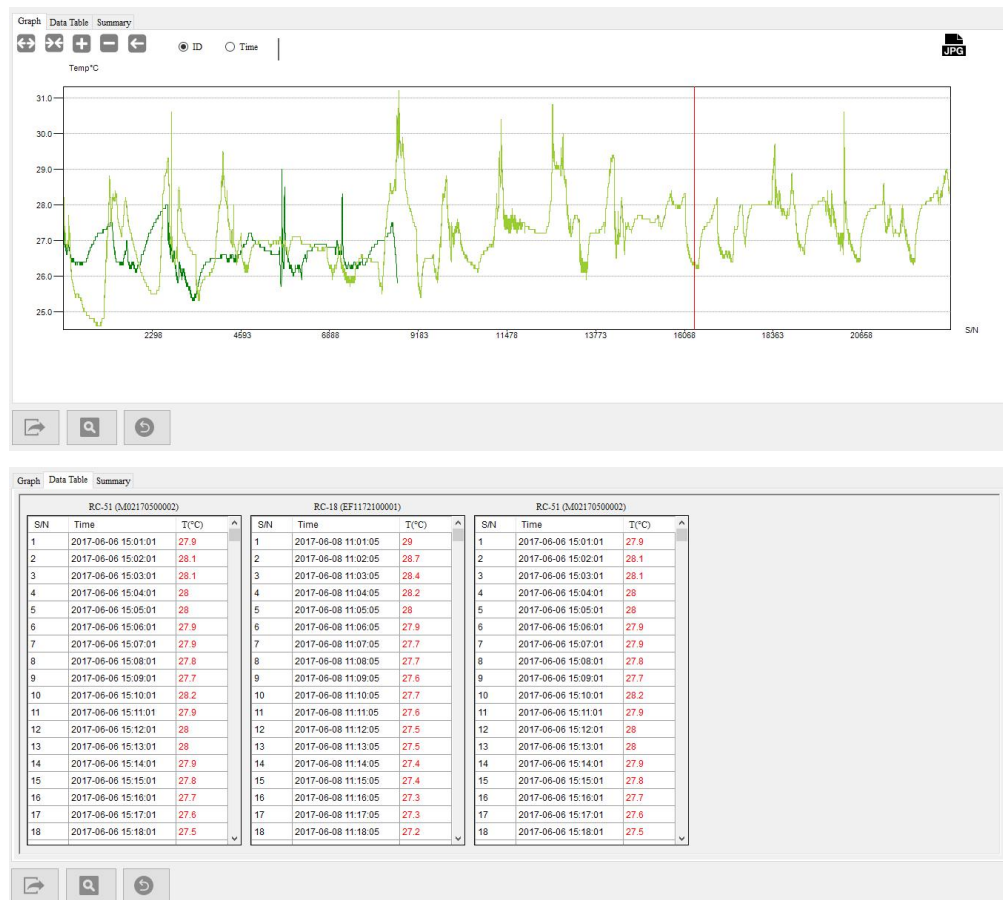
8.4 View details

Show

Delete

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

table or summary.



8.5 Display alarm data

☐ Alarm Device

☐ Select All

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

Alarm	Record ID	Start Time	Trip Number	Total Points	Read Points	T0(max)	T0(min)	H0(max)	H0(min)
☒	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 %
☒	EFF16A012348_20180321132302	2018-03-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %
☒	EFF16A012348_20180321130926	2018-03-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %
☒	EFF16A012348_20180321132329	2018-03-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %
☒	EFF16A012348_20180321133222	2018-03-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %
☒	EFF16A012348_20180321133107	2018-03-21 09:22:53		384	384	31.1 °C	24.2 °C	85.2 %	58.8 %
☒	EF1176002905_2018032112755	2018-03-21 12:27:06	SSTAC01	4	4	22.4 °C	22.3 °C	N/A	N/A
☒	EF1176002905_2018032112134	2018-03-21 12:20:38	SSTAC01	4	4	21.9 °C	21.8 °C	N/A	N/A
☒	EF1176002905_2018032111838	2018-03-09 11:26:33	SSTAC01	8641	8641	78.0 °F	60.9 °F	N/A	N/A
☒	EM217A000001_20180321113324	2018-03-20 23:12:44	1234566	4	4	22.8 °C	22.7 °C	N/A	N/A

Data Saved at:

From: 2018-02-26 00:00:00

To: 2018-03-26 23:59:59

Latest

☒ 1 month

☐ 3 months

☐ 6 months

☒ Alarm

☐ Check All

8.6 Delete data

[4]	Alarm	Record ID	Start Time	Trip Number	Total Points	Read Points	T(Δmax)	T(Δmin)	H(Δmax)	H(Δmin)	
	✓	EF317A000001_20180326135828	2017-10-30 08:47:21		16000	12	31.2 °C	17.9 °C	N/A	N/A	
	✓	EF317A000001_20180326135220	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_20180323151225	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 %	
	✗	EFF16A012348_20180321132302	2018-03-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %	
	✗	EFF16A012348_20180321130926	2018-03-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %	
	✗	EFF16A012348_20180321132399	2018-03-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %	
	✗	EFF16A012348_20180321131222	2018-03-21 09:22:53		385	385	31.1 °C	24.2 °C	85.2 %	58.8 %	
	✗	EFF16A012348_20180321131107	2018-03-21 09:22:53		384	384	31.1 °C	24.2 °C	85.2 %	58.8 %	
	✗	EF1176002905_20180321112755	2018-03-21 12:27:06	SSTAC01	4	4	22.4 °C	22.3 °C	N/A	N/A	
	✓	EF1176002905_20180321112729	2018-03-21 12:27:06	SSTAC01	1	1	22.4 °C	22.4 °C	N/A	N/A	

Data Saved at:

From: 2018-02-26 00:00:00

To: 2018-03-26 23:59:59

Latest

☒ 1 month

☐ 3 months

☐ 6 months

☐ Alarm

☐ Check All

View Details

Delete

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.

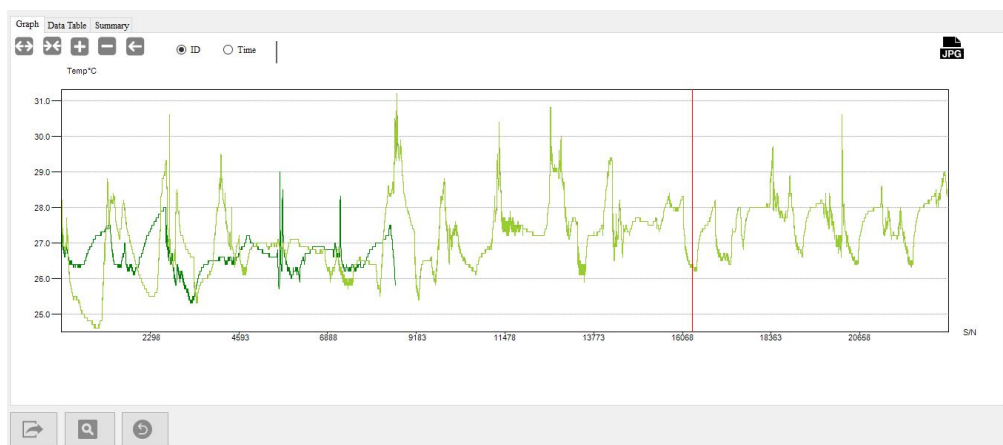
IX Import Data

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.



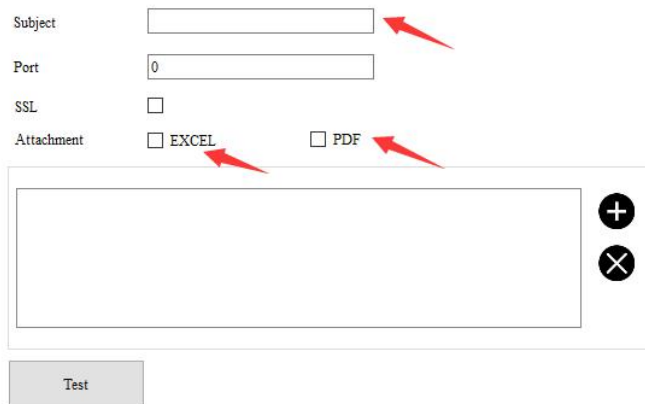
X Send E-mail

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.



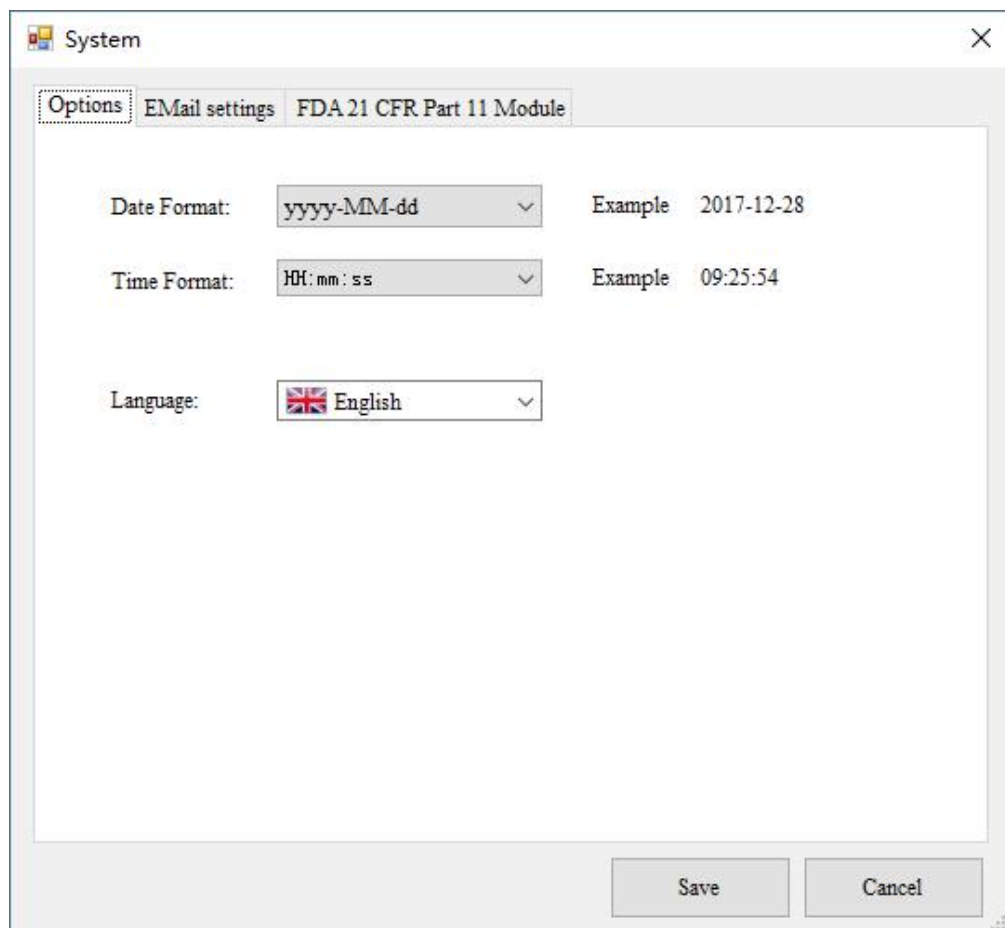
The screenshot shows a 'Send E-mail' dialog box. It contains the following fields and controls:

- Subject:** A text input field with a red arrow pointing to it.
- Port:** A text input field containing the value '0' with a red arrow pointing to it.
- SSL:** A checkbox that is currently unchecked.
- Attachment:** Two checkboxes, 'EXCEL' and 'PDF', both of which are unchecked. Red arrows point to each of these checkboxes.
- Content Area:** A large rectangular area for the email body, with a '+' icon for expanding and an 'X' icon for closing.
- Test:** A button located at the bottom left of the dialog.

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.



The screenshot shows a 'System' dialog box with a title bar containing a window icon and a close button. Inside the dialog, there are three tabs: 'Options' (selected), 'EMail settings', and 'FDA 21 CFR Part 11 Module'. The 'Options' tab contains three settings:

- Date Format:** A dropdown menu showing 'yyyy-MM-dd' with a downward arrow. To its right, the text 'Example' is followed by '2017-12-28'.
- Time Format:** A dropdown menu showing 'HH:mm:ss' with a downward arrow. To its right, the text 'Example' is followed by '09:25:54'.
- Language:** A dropdown menu showing a flag icon for English and the text 'English' with a downward arrow.

At the bottom right of the dialog, there are two buttons: 'Save' and 'Cancel'. A small version number 'v1.0.0.0' is visible in the bottom right corner of the dialog box.

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.

System

Options **Email Settings** FDA 21 CFR Part 11 Module

SMTP: smtp.163.com

Sender's address: vvklxz@163.com

Password: *****

Subject: test

Port: 25

SSL: ☐

Attachment: ☒ EXCEL ☒ PDF

Please fill in the SMTP server address of the sender's mailbox (e.g. Sina (smtp.sina.com)) and make sure your mailbox has SMTP service enabled.

☒ 57476662@qq.com

Test Email

Save Cancel

XII FDA 21 CFR Part 11 Module

12.1 What is FDA 21 CFR Part 11 compliance?

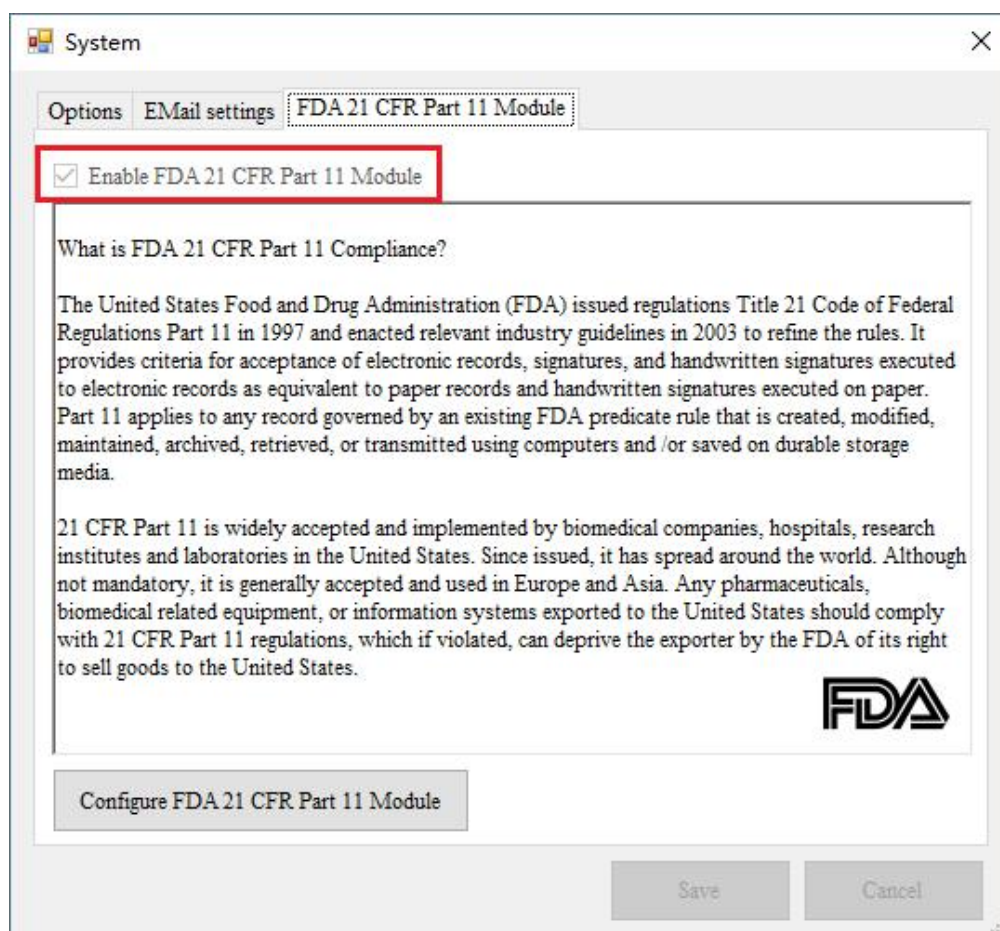
The United States Food and Drug Administration (FDA) issued regulations Title 21 Code of Federal Regulations Part 11 in 1997 and enacted relevant industry guidelines in 2003 to refine the rules. It provides criteria for acceptance of electronic records, signatures, and handwritten signatures executed 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.

Initializing administrator

User Name

Real Name

Password

Confirmed Password

Position

Save

Close

12.2.3 User Management

The screenshot shows the 'FDA 21 CFR Part 11 Module' window with the 'User Management' tab selected. The window contains a table with user information and a set of action buttons at the bottom.

	User Name	Real Name	Position	Type	Status
▶	admin	admin	dev	Administrator	Normal
	kevin	Kevin Li	test	User	Normal

Below the table, there are five buttons: 'Add', 'Change', 'Lock', 'Unlock', and 'Reset'. The 'Add' button is highlighted with a blue border.

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

The 'Add' dialog box is shown, which is used to create a new user account. It contains several input fields and radio buttons.

Fields:

- User Name:
- Real Name:
- Password:
- Confirmed Password:
- Position:

Type: ☐ Administrator ☒ User

Buttons: Save, Close

12.2.4 Rights Management

System Right

Administrator owns all system rights.

User right is granted or revoked by administrator.

The screenshot shows the 'FDA 21 CFR Part 11 Module' window with the 'Rights Management' tab selected. The interface includes a table of users, a 'System Right' list, and an 'Obtained Rights' list with navigation buttons.

User Name	Real Name	Position	Type	Status
admin	admin	dev	Administrator	Normal
kevin	Kevin Li	test	User	Normal

System Right

Obtained Rights
Configure Device
Sign Data
Change Options
Delete Data
View Audit Trail

Navigation buttons: >>, >, <, <<

12.2.5 Meaning Management

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

The screenshot shows a window titled "FDA 21 CFR Part 11 Module" with a close button (X) in the top right corner. Below the title bar is a tabbed interface with five tabs: "User Management", "Rights Management", "Meaning Management" (which is selected and highlighted with a dotted border), "Security Policy", and "Secure Mailbox".

Below the tabs is a table with the following columns: "User Name", "Real Name", "Position", "Type", and "Status". The table contains two rows of data:

User Name	Real Name	Position	Type	Status
admin	admin	dev	Administrator	Normal
kevin	Kevin Li	test	User	Normal

Below the table is a large gray rectangular area, likely a placeholder for a list or a detailed view. At the bottom of the window, there is a section labeled "Available meaning" with a table structure that is mostly empty. To the right of this section are three buttons: "Add", "Edit", and "Delete".

New Meaning:

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

The screenshot shows a dialog box titled "Meaning Name:". It contains a single text input field with a cursor inside. At the bottom right of the dialog box are two buttons: "Save" and "Cancel".

Available Meanings:

All meanings are listed.

Meanings:

User meanings are managed by Administrator.

12.2.6 Security Policy

The screenshot shows a web application window titled "FDA 21 CFR Part 11 Module". It has a tabbed interface with five tabs: "User Management", "Rights Management", "Meaning Management", "Security Policy" (which is the active tab), and "Secure Mailbox". The "Security Policy" tab contains three configuration sections:

- Login attempts:** A numeric input field with the value "0" and a "times" unit.
- Login protection:** A numeric input field with the value "0" and a "min" unit.
- Password expires on:** A numeric input field with the value "0" and a "day" unit.

Below these sections is a reminder text: "Reminder: 0 indicates that this setting is disabled." At the bottom of the configuration area is a "Save" button.

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.

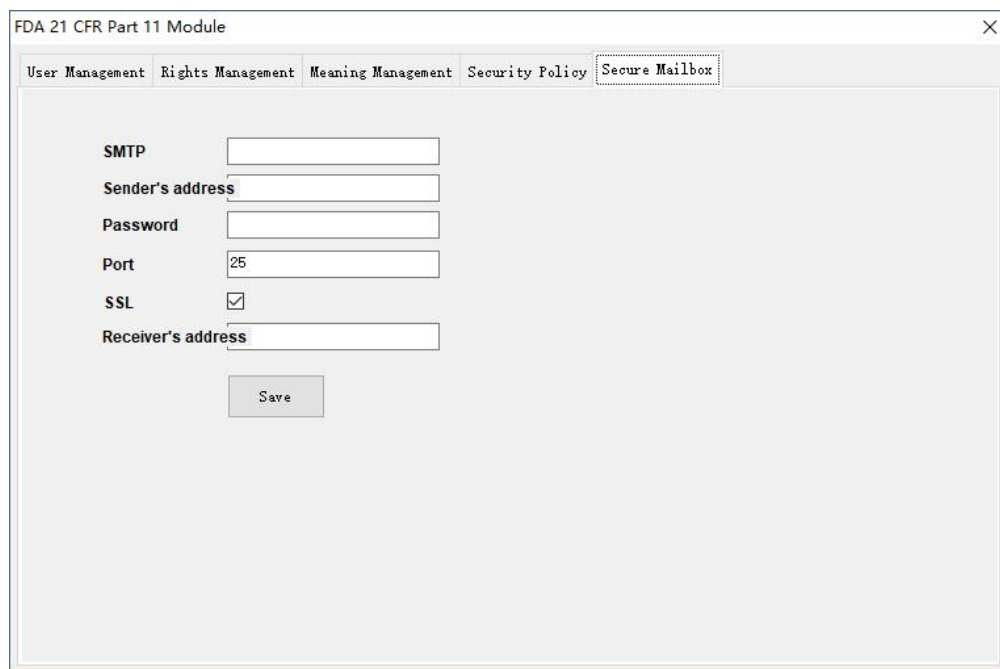
Password expiry date:

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.

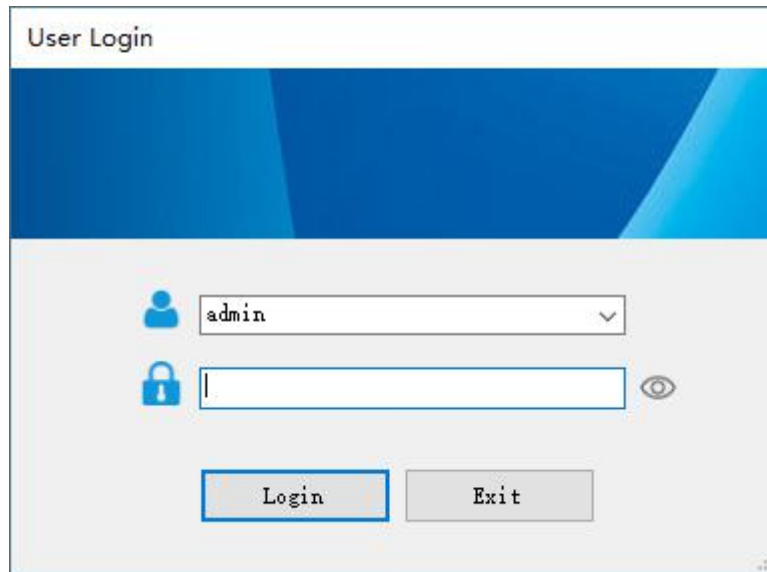


The screenshot shows a web application window titled "FDA 21 CFR Part 11 Module" with a close button (X) in the top right corner. Below the title bar is a navigation menu with five tabs: "User Management", "Rights Management", "Meaning Management", "Security Policy", and "Secure Mailbox". The "Secure Mailbox" tab is currently selected and highlighted with a dashed border. The main content area of the window contains a form with the following fields and controls:

- SMTP**: A text input field.
- Sender's address**: A text input field.
- Password**: A text input field.
- Port**: A text input field containing the value "25".
- SSL**: A checkbox that is currently checked.
- Receiver's address**: A text input field.
- Save**: A button located below the "Receiver's address" field.

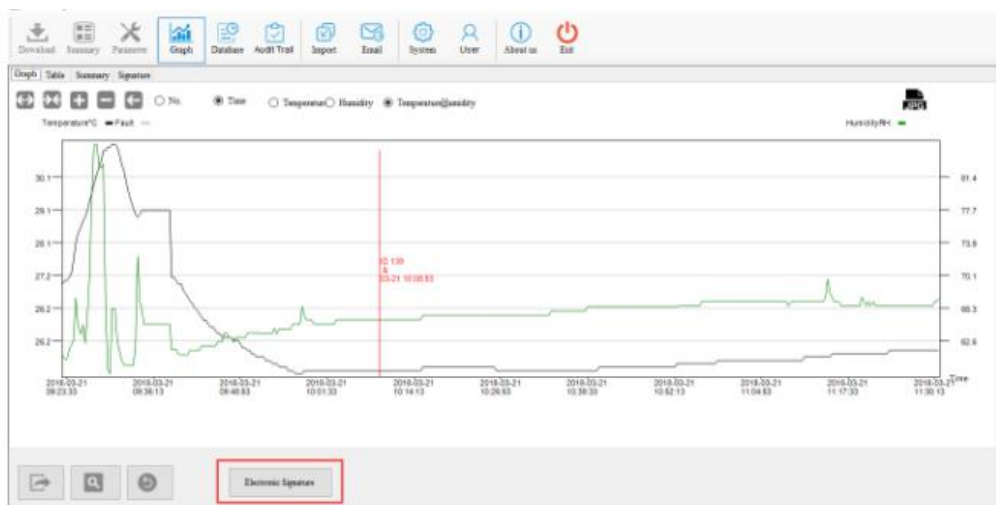
12.2.8 User Login

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



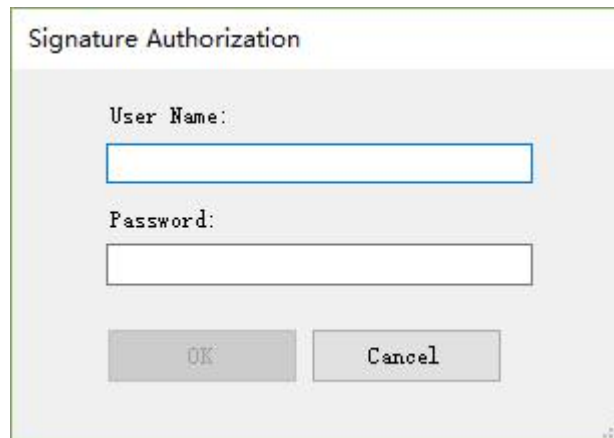
The User Login screen features a title bar with the text "User Login". Below the title bar is a blue decorative header. The main area is light gray and contains a user selection dropdown menu with a blue person icon and the text "admin". Below this is a password input field with a blue padlock icon on the left and a blue eye icon on the right. At the bottom, there are two buttons: "Login" (highlighted with a blue border) and "Exit".

12.2.9 Electronic Signature



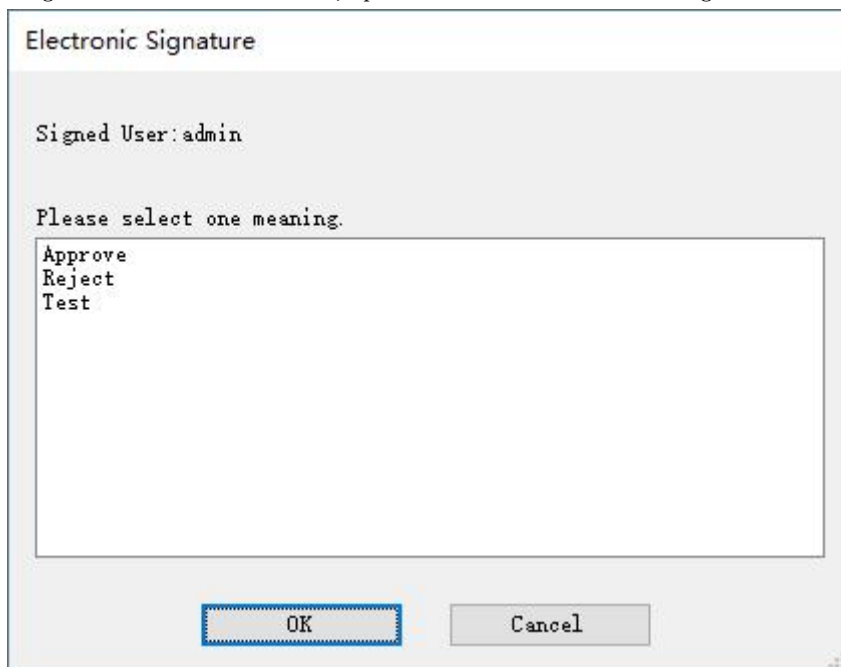
After the data logger is connected to a computer and its data is downloaded

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:



A dialog box titled "Signature Authorization" with a light gray background. It contains two text input fields: "User Name:" and "Password:". Below the fields are two buttons: "OK" and "Cancel". The "OK" button is highlighted with a blue border.

After signature authorization, please select one meaning as follows:



A dialog box titled "Electronic Signature" with a light gray background. It displays "Signed User: admin". Below this, it says "Please select one meaning." and lists three options: "Approve", "Reject", and "Test". At the bottom are two buttons: "OK" and "Cancel". The "OK" button is highlighted with a blue border.

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.

Download

History

Favorite

Graph

Database

Audit Trail

Report

Email

System

User

About us

Exit

[D]	Alarm	Signature	Record ID	Start Time	Trip Number	Total Points	Read Points	TD(Sec)	TD(Sec)	RS(Sec)	RS(Sec)
*			EF117A000001_20180326110628	2017-03-30 08:47:21	18000	12	11.2 °C	17.9 °C	NA	NA	
			EF117A000001_20180326110720	2017-03-30 08:47:21	18000	12	11.2 °C	17.9 °C	NA	NA	
			EF117A000001_20180326110840	2017-03-30 08:47:21	18000	12	11.2 °C	17.9 °C	NA	NA	
			EF117A000001_20180326110815	2017-03-30 08:47:21	18000	4878	11.2 °C	17.9 °C	NA	NA	
			EF117A000001_20180326110409	2017-03-30 08:47:21	18000	18000	11.2 °C	17.9 °C	NA	NA	
			EF117A000001_20180325112125	2017-03-30 08:47:21	18000	10000	11.2 °C	17.9 °C	NA	NA	
			EF117A0012348_20180321142852	2018-03-21 09:22:53	385	385	11.1 °C	24.2 °C	83.2 %	58.8 %	
			EF117A0012348_20180321142157	2018-03-21 09:22:53	385	385	11.1 °C	24.2 °C	83.2 %	58.8 %	
			EF117A0012348_20180321133202	2018-03-21 09:22:53	385	385	11.1 °C	24.2 °C	83.2 %	58.8 %	
			EF117A0012348_20180321130926	2018-03-21 09:22:53	385	385	11.1 °C	24.2 °C	83.2 %	58.8 %	
			EF117A0012348_20180321133236	2018-03-21 09:22:53	385	385	11.1 °C	24.2 °C	83.2 %	58.8 %	
			EF117A0012348_20180321133222	2018-03-21 09:22:53	385	385	11.1 °C	24.2 °C	83.2 %	58.8 %	
			EF117A0012348_20180321133107	2018-03-21 09:22:53	384	384	11.1 °C	24.2 °C	83.2 %	58.8 %	
			EF1176002901_20180321127755	2018-03-21 12:27:06	85TAC01	4	22.4 °C	22.3 °C	NA	NA	
			EF1176002901_20180321127728	2018-03-21 12:27:06	85TAC01	1	22.4 °C	22.4 °C	NA	NA	
			EF1176002901_20180321125134	2018-03-21 12:20:38	85TAC01	4	21.8 °C	21.8 °C	NA	NA	
			EF1176002901_20180321125033	2018-03-21 12:20:38	85TAC01	1	21.8 °C	21.8 °C	NA	NA	
			EF1176002901_20180321113818	2018-03-09 11:28:33	86A1	86A1	18.8 °F	40.9 °F	NA	NA	
			EF117A000001_20180321111609	2017-03-30 08:47:21	18000	18000	11.2 °C	17.9 °C	NA	NA	
			EF117A000001_20180321110134	2018-03-20 23:12:44	1234566	4	22.8 °C	22.7 °C	NA	NA	
			EF117A000001_20180321110123	2018-03-20 23:12:44	1234566	1	22.8 °C	22.8 °C	NA	NA	
			EF117A000001_20180321110124	2018-03-12 02:51:48	1234566	12817	25.8 °C	17.3 °C	NA	NA	
			EF117A000001_20180321110149	2018-03-12 02:51:48	1234566	12814	25.8 °C	17.3 °C	NA	NA	
			EF1176001402_20180321110455	2018-02-08 11:20:40	861402	18000	17.2 °C	17.2 °C	NA	NA	

Data Export at:

From

2018-02-28 00:00:00

To

2018-03-28 21:59:59

Latest

☒ 1 month

☐ 3 months

☐ 6 months

☐ Alarm

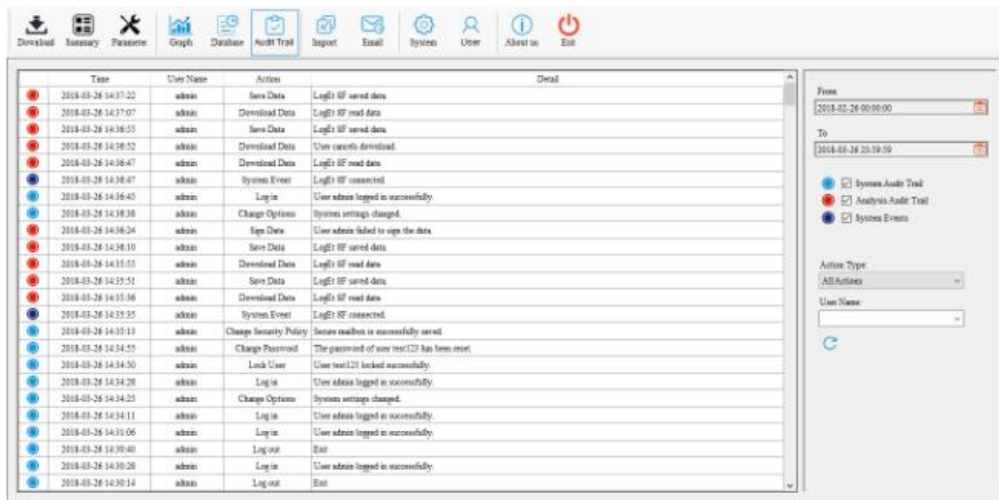
☐ Check All

View Details

Print

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
V5. 0. 0	2020-09-30	Add automatic update function
V6. 0. 0	2021-02-22	1.Add Spanish and Portuguese 2.Fixed some bugs
V6. 0. 1	2021-03-12	Fixed some bugs
V6. 0. 2	2021-04-16	1. Support RC-17 Series Recorder 2. Support RC-17N Series Recorder 3. Fixed some bugs
V6. 0. 3	2021-04-26	1. GSP-6 and GSP-6G increase display minimum and maximum function 2. Fixed some bugs
V6. 1. 0	2021-08-16	1. Added LogEt6 PTE product support 2. Support simple model customized products
V6. 2. 0	2021-10-28	1. Added Tlog 10 product support 2. Added Chinese traditional language 3. Fixed some bugs