

Software tempbase 2 User Manual



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I Introduction

11 Overview

The tempbase-2 data management software is a comprehensive desktop software designed for analyzing and managing the temperature and humidity data recorded by tempmate data loggers. The software integrates the most dependable temperature and humidity sensing technology and the most advanced system kernel to date. It is characterized by 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.

1.3 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 another pointing device

A VGA monitor with display resolution 1366 x 768 pixels or better

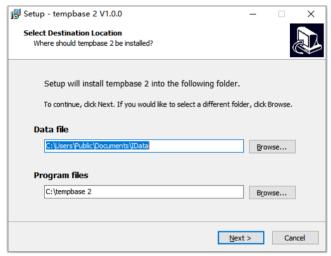
Computer administrator account



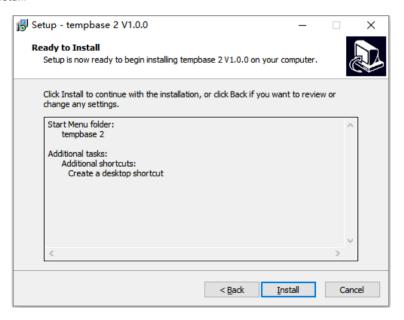
II Install & Start

2.1 Install

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

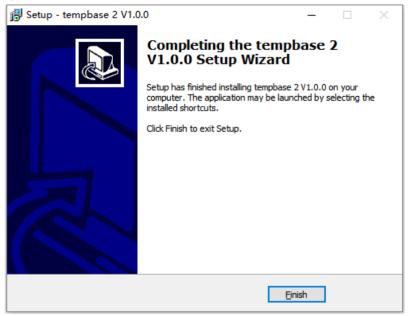


3) Click Install.





4) Click Finish to complete the installation.



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.



2.4 Update

If a new version of the tempbase-2 software is available, the user is notified of this at startup and an option for direct update is offered.

After confirmation, the software is automatically updated and is then immediately available to the user. Previously stored data will not be lost.

III Functions

3.1 Toolbar

Stop: Stopping of the logging operation is prevented and the logger can only be stopped by software.

Full Data: Even if the data logger is stopped, the logger is still recording until the memory is full, or battery is low ("Shadow Log"). This data can be downloaded here completely.

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

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.

Log: User's operation of the system

Export: Export data in the format of PDF, XLS or IME.

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

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



IV Download Data

4.1 Connect data logger

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

4.2 Read data

Click Download on the toolbar to read and download the data saved on 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 being downloaded, the data will be saved to the database automatically. The data can be viewed in the "Database" interface.



V Summary

5.1 Device Information

Serial Number: The unique ID of the data logger. It cannot be changed.

Logging Interval: The interval time between two successive points of recording.

Logging Status: The current working status of the logger. **Trip Number:** 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 can be started, including manual start, timed start, immediate

start.

Repeat Start: The logger can be started repeatedly, and the previously recorded data is cleared

after a new startup.

5.2 Statistical Information

Total Memory: Maximum amount of data points the logger can save.

Current Readings: The number of readings the software downloads from the logger.

Start Time: The time when the logger starts running.

First Reading: The time when the first data point is recorded. **Last Reading**: The time when the last point was recorded.

MKT: Mean kinetic temperature value.

Logging Duration: The total time that the logger kept recording.

Stop Mode (Actual): The logger's actual stop mode, including temporary stop, stop via software, manual stop.

Stop Mode (Set): The set stop mode, including stop via software, manual stop.

Temporary PDF: Whether the PDF report is allowed to be generated temporarily after the logger is plugged-in to the computer during recording.

Maximum: The maximum value among the recorded temperature and humidity readings.

Minimum: The minimum value among the recorded temperature and humidity readings.

Average: The average value of the recorded temperature and humidity readings.

First Alarm: The recorded time when the first out-of-limit alarm was triggered.



5.3 Alarm information

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

Alarm Delay: The time an alarm threshold breach needs to exceed before an alarm is 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

Serial Number: The unique code of the logger. It cannot be changed.

Logging Interval: The interval time between two successive points of data. It can be configured per day or time.

Trip Number: 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 can be started, including manual start, timed start, immediate start. When timed start is set, the start time choice box becomes available.

Start Delay: The wait time from the start of the unit to the first reading saved. When manual start is selected, the start delay choice box becomes available.

Timing Start Time: The logger starts running at the specified time. When timed start is selected, the timed start selection box becomes available.

Stop Mode: The way that the logger is stopped; manually, or via software.

Temporary PDF: Whether the PDF report is allowed to be generated temporarily after the logger is plugged-in to the computer during recording.

Cyclic Logging: When the data memory is full, new data automatically replaces the oldest readings.

PDF Language: The language of the PDF report generated.

Temperature Unit: Celsius / Fahrenheit.

Set Password: Optional password, must be 6 digits long.

Calibration: If an analog sensor is used (like the tempmate-M1), the user can set an offset to increase the accuracy of recorded temperatures. The use of this function is at the user's own responsibility.

Multi-Configuration: if "Configure multiple devices with this setting" is activated, the user can configure more devices with the same settings page consecutively.



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°C - 90°C; humidity range: 0% - 100%.

Alarm Type: Single / cumulative.

Single Type: If the temperature/humidity is above or below the alarm threshold and its duration is not less than the alarm delay, an alarm will be triggered.

Cumulative Type: If the temperature/humidity is above or below the alarm threshold and its cumulated time is not less than the alarm delay, an alarm will be triggered.

Alarm Delay: The time an alarm threshold breach needs to exceed before an alarm 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



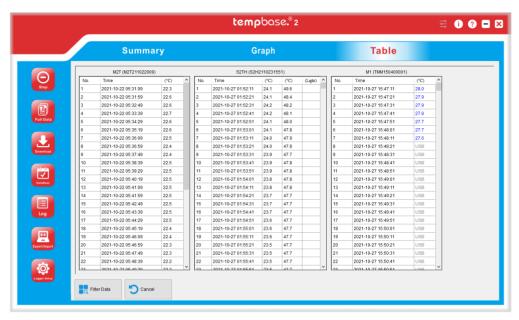
Click the "Graph" tab to display currently selected data of the logger. It can be the data of a currently connected logger, or the historical data stored in the database. 10 data curves can be displayed at the same time for users to compare the temperature and humidity changes. The Y-axis on the left 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 number.



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



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.

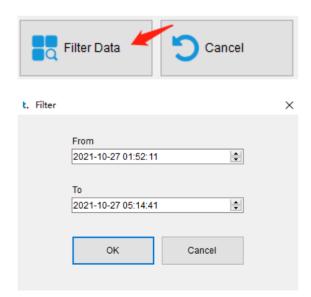


7.3 Summary

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



7.4 Data filtering

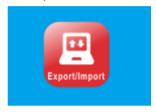




Click the "Filter Data" button at the bottom left. Select "Start time" and "End time", and click "OK", the software will automatically filter the data within the specified time period. After the data is filtered, the software will automatically redraw the graph, table, and summary.

7.5 Export data

Click the "Export/Import" button at the bottom left to export report to PDF, XLS and IME (custom format) format.



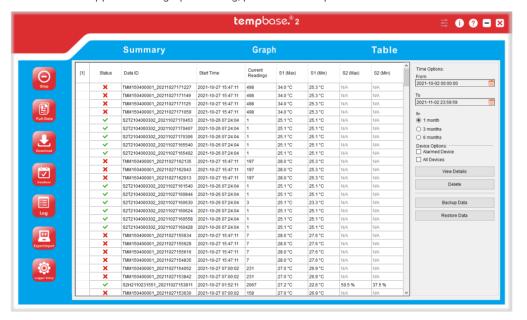




VIII Database

8.1 Historical data table

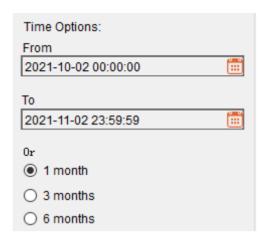
Click Database on the toolbar to query historical data. The data downloaded from the logger is automatically saved to the database and can be filtered as needed. Default display is the latest month's data. Users can also view data of a selected time range, filter alarm data, drag and select multiple 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.



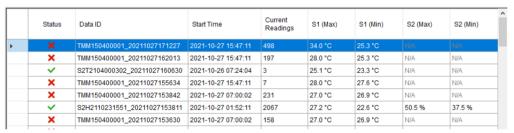
8.2 Filter data

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





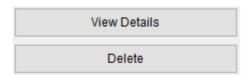
8.3 Select data line



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.

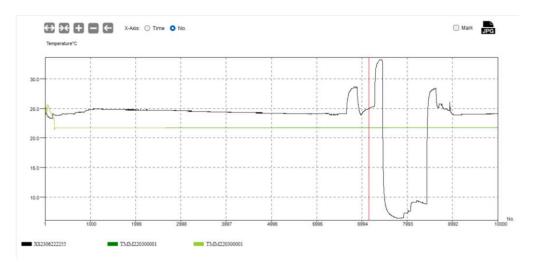
It is used to view the records of multiple devices or delete the selected data line. Up to 10 records can be viewed and compared at the same time. There is no limit of the number of lines when deleting records.

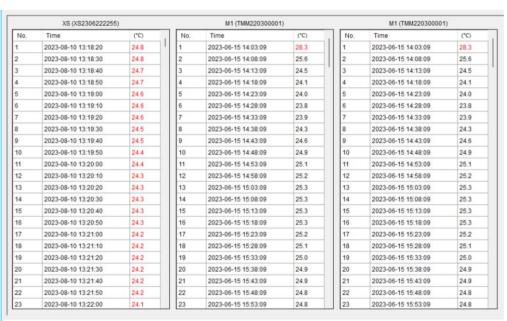
8.4 View details



Click the "View details" button in the right sidebar to view the data details in graph, table or summary.





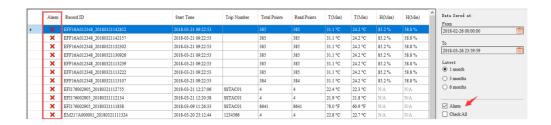


8.5 Display alarm data

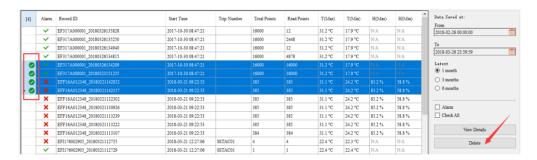


Check "Alarm Device" in the right sidebar to view only the data of the alarmed device.





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 ask the user to confirm this action, and once confirmed, the data will be deleted and cannot be recovered.



IX Import Data

9.1 How to import

Click "Export/Import" on the toolbar to export or import recordings. 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 the import, the software will automatically switch to the "Summary" interface.



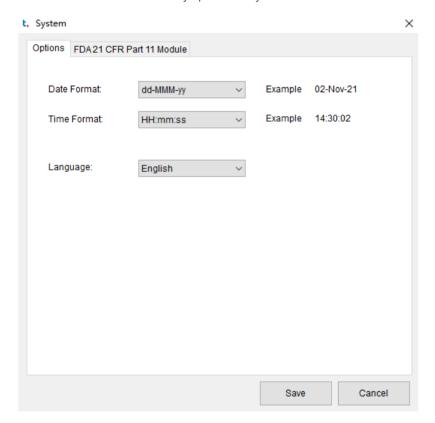


XI System Settings

11.1 Options



Click 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.





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

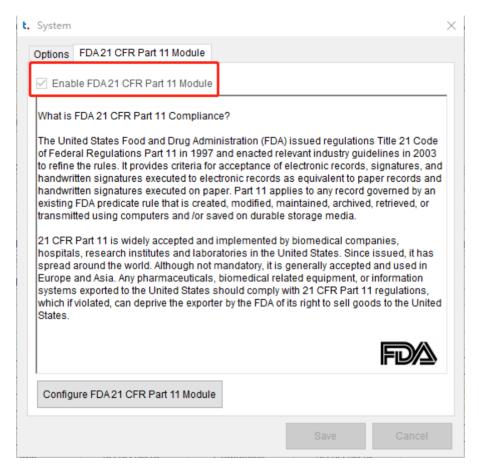
Click "System" on the toolbar and then click the tab FDA 21 CFR Part 11 Module.

Note: 21 CFR Part 11 module is not a default function ready for use after software installation.

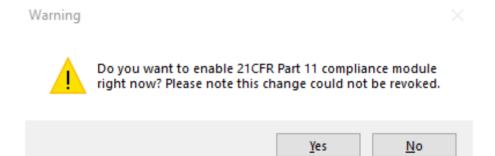
You need to enable this module by going to System > FDA 21 CFR Part 11 Module. The interface gives a brief introduction to the module.



12.2.1 Activate the module



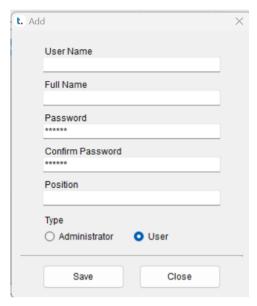
Check "FDA 21 CFR 11 Module" to activate the module. After the FDA 21 CFR 11 module is enabled, the program will restart for the changes to take effect. Click Yes.





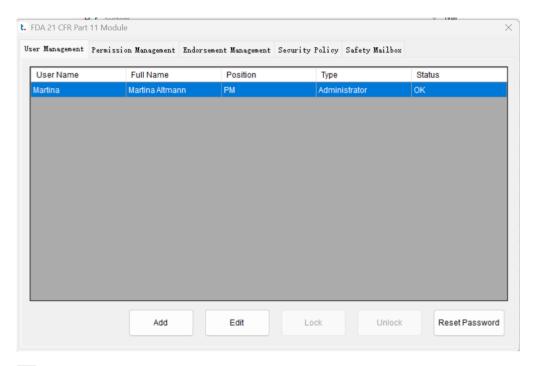
12.2.2 Initializing Administrator

After the FDA 21 CFR Part 11 module is enabled, the user is required to create an administrator account:

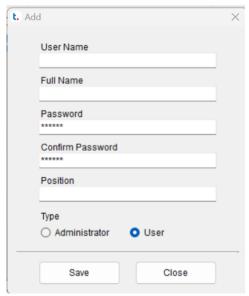




12.2.3 User Management



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



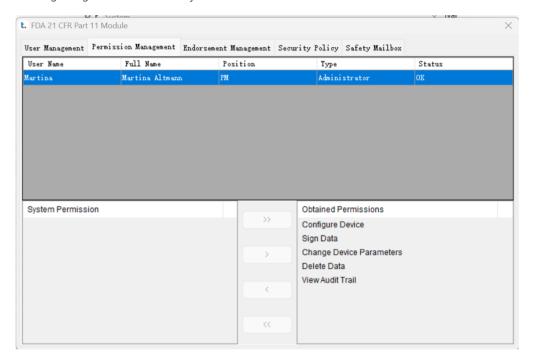


12.2.4 Permission Management

System Right

Administrator owns all system rights.

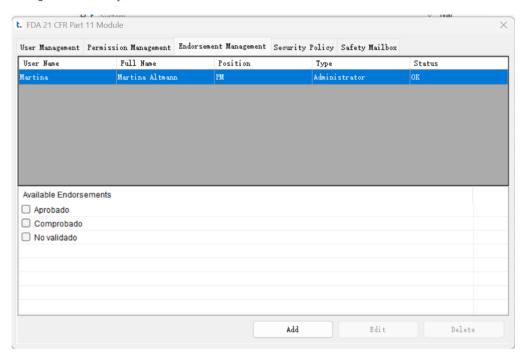
User right is granted or revoked by administrator.





12.2.5 Endorsement Management

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



New Endorsement: Enter endorsement name, click Save or Enter, it will then be saved to the database.

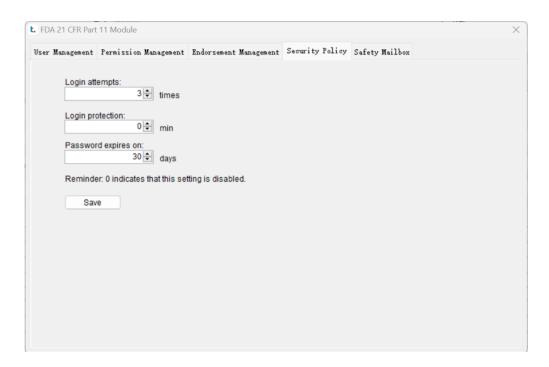


Available endorsement: All endorsements are listed.

Endorsements: User endorsements are managed by an administrator.



12.2.6 Security Policy



Login attempts: If multiple login attempts exceed the set times, the account will be locked. Only an 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.

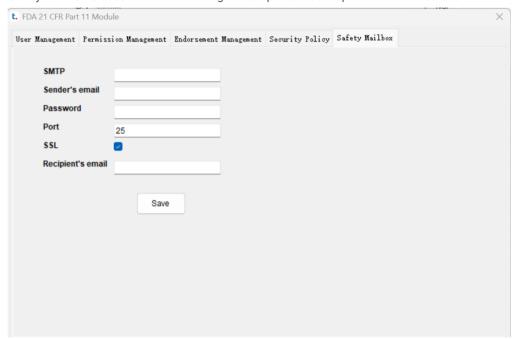
Password expiry date: This setting indicates the password is valid before a certain period. If the password expires, the system will remind the user to change it 3 days earlier.

Reminder: 0 indicates that this setting is disabled.



12.2.7 Safety Mailbox

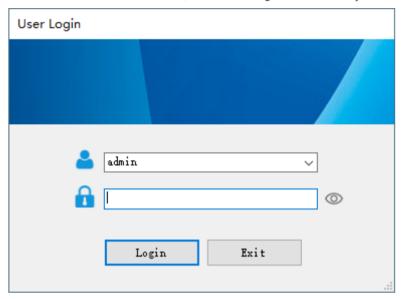
Safety mailbox is used to send invalid login attempts to a user-specified email address.





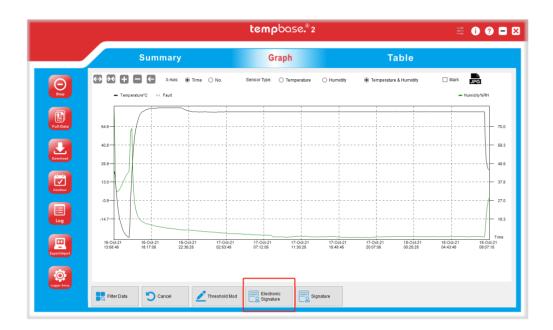
12.2.8 User Login

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

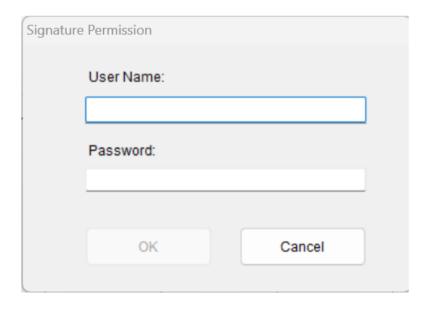




12.2.9 Electronic Signature

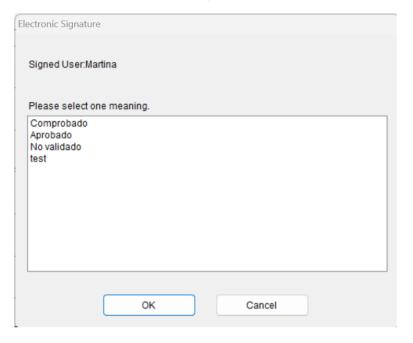


After the data logger is connected to a computer and its data is downloaded to the database successfully, click the "Graph" icon in the toolbar and then "Electronic Signature" to sign. Enter the username and password in the popup interface:

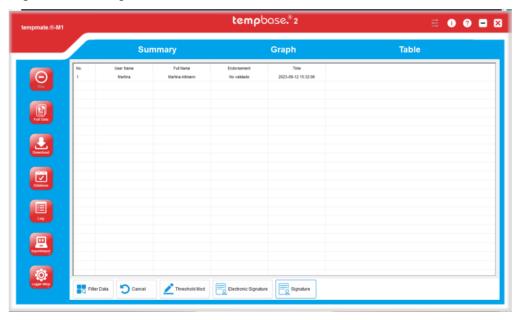




After signature authorization, select one meaning:



Then click OK. The system will sign and confirm with "Signature success". Then you may click the "Signature" to view signature information.

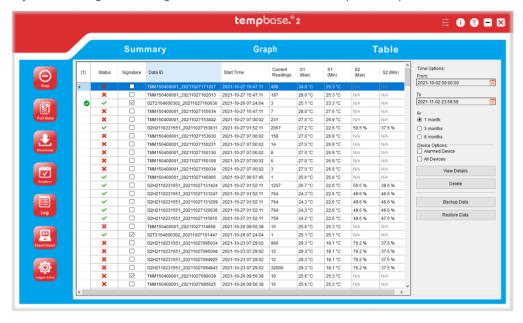




12.2.10 Historical Signature

After being signed, the signature will show up next to the Record ID.

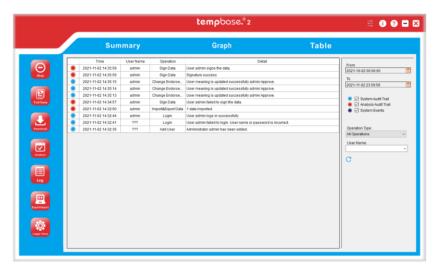
If you want to sign the data again, double click the record and repeat the operation above.

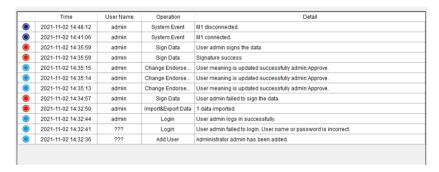




12.2.11 Audit Trail

Audit trail records user's operations of the system, including time, actions, etc., and can be viewed under *Log*, if the FDA 21 CFR part 11 module is activated and configured. The data can be filtered per time, audit type, action type and username.







Version Log

Version	Date	Description
V1.0.0	2021-06-10	The first version.
V2.0.0	2021-11-02	Change the program interface style; Added S1 and M1 product support; Some new features
V2.0.1	2022-01-27	1. "Full Data" function works with tempmate-S1;
V2.0.2	2022-02-17	1. Optimized the alarm setting function of M2;
V2.0.3	2022-03-11	Fixed an issue where the alarm threshold in the S2 report showed -400(Firmware version number: V1.4)
V2.0.4	2022-04-18	Modify some file information If M2 firmware version number between v1.6 to v1.9 so need the firmware version upgraded to 1.9 and then do the parameter setting
V3.0.0	2022-09-03	Added automatic update function
V3.0.1	2022-12-21	Add group configuration function
V3.0.2	2023-01-31	 Add calibration function Enhance the security of serial number configuration Optimize some functions
V3.0.3	2023-03-17	 Optimization of product configuration parameters under different power states Optimize temperature calibration function Synchronization time button optimization



V3.0.4 2023-09-19	 Automatic firmware update for tempmate-S1V2 data loggers (PDF-Symbol Fix). Added multi-lingual software settings and manuals Fixed a deviation where PDF-reports of the tempmate-M2 data loggers show a wrong measurement interval
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