



USER MANUAL

TempCentre Data Management Desktop Software

UM_TEMP CENTRE2_141010 REV. D

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Overview

TempCentre data management software is comprehensive desktop software designed for downloading configuring TempSen made data loggers and viewing, analyzing, storing, archiving data collected during cold chain logistics, which is also developed for helping users achieve FDA 21 CFR PART 11 compliance.

TempCentre software is characterized for its user-friendly interface and process oriented function modules, enabling quick access to data by flexible searching, analysis in depth with versatile analysis methods, and provide user with accurate and intuitive insight into the environmental conditions that your goods has been experienced throughout supply chain. Furthermore, database-based storage and retrieval system would offer a simple ways to pinpoint the data you need among the large amounts of data.

Minimum System Requirements

- Pentium 1 GHz or higher, 512 MB of RAM or higher
- A hard drive with 1GB available disk space
- Windows 7 or above
- A VGA monitor with display resolution of 1024 x 768px or better
- Administrator account of the computer.

Getting Started

TempCentre provides following basic functions for user to manage data and devices.

- [Downloading Device](#)
Download data from TempSen made data loggers to local machine.
- [Configuring Device](#)
Allows user to configure all compatible data logging devices with recording parameters.
- [Data Base](#)
The light rational data base installed in local machine to store all the data records users choose to save.
- [Viewing and Analyzing Data](#)
- [21 CFR 11 compliance module](#)
Allows to manage users accessing program, add and manage electronic signatures, assign system operation rights, and provides time stamped trails for audit.

Menu Bar

- **File** To Open, Save, Export, Delete, Import, Print, Email data records.
- **Options** Provides options to configure date/time, graph and report view settings..
- **Administration** Allows to add, edit user account, change security settings, and assign user rights and meanings for electronic signatures.
- **Devices** Calibration management and firmware update
- **Help** To look up Help file, check for Updates and learn about TempCentre software.

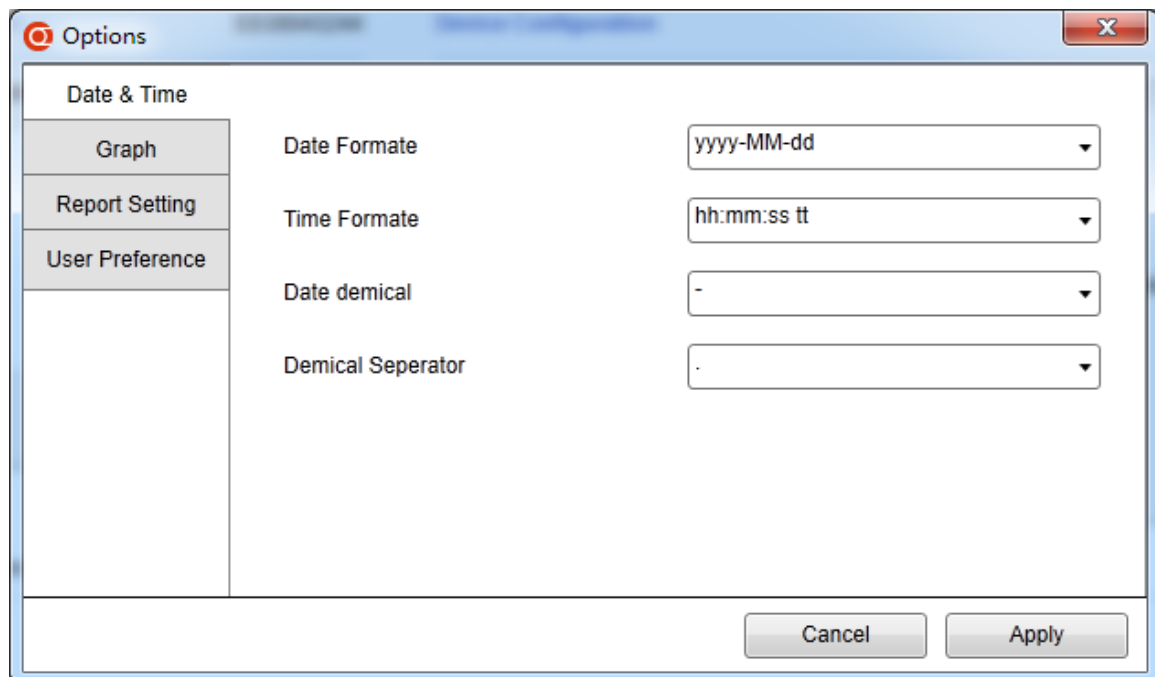
NOTE Administration only available after 21 CFR 11 compliance module is enabled.
Calibration is applicable to specific types only.

Options

Please click on **Options** in menu bar to change general options.

Date & Time

Select date, time format for system and date, decimal separators.



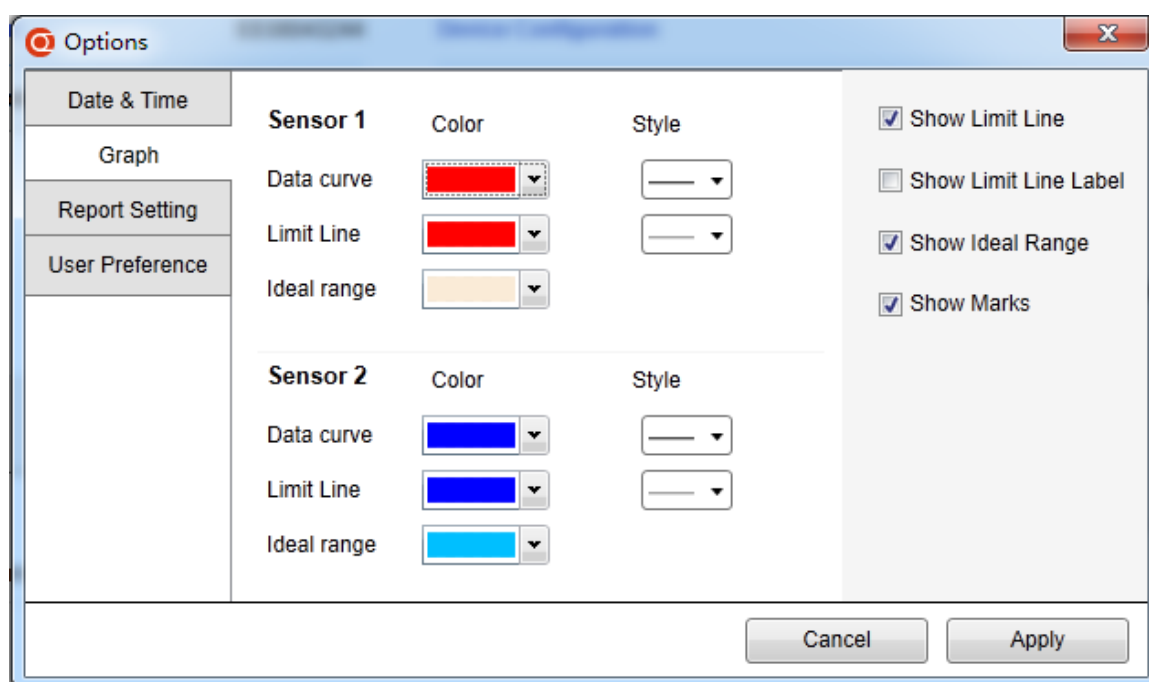
The screenshot shows the 'Options' dialog box with the 'Date & Time' tab selected. The dialog has a sidebar on the left with four tabs: 'Date & Time' (selected), 'Graph', 'Report Setting', and 'User Preference'. The main area contains four settings, each with a label and a dropdown menu:

Setting	Value
Date Formate	yyyy-MM-dd
Time Formate	hh:mm:ss tt
Date demical	-
Demical Seperator	.

At the bottom right of the dialog are two buttons: 'Cancel' and 'Apply'.

Date Format	Time Format	Date Separator	Decimal Separator
dd/MM/yyyy	HH:mm:ss	/	.
MM/dd/yyyy	H:m:s	-	,
yyyy/MM/dd	hh:mm:ss tt	.	
dd/MM/yy	h:m:s tt		
MM/dd/yy			
yy/MM/dd			

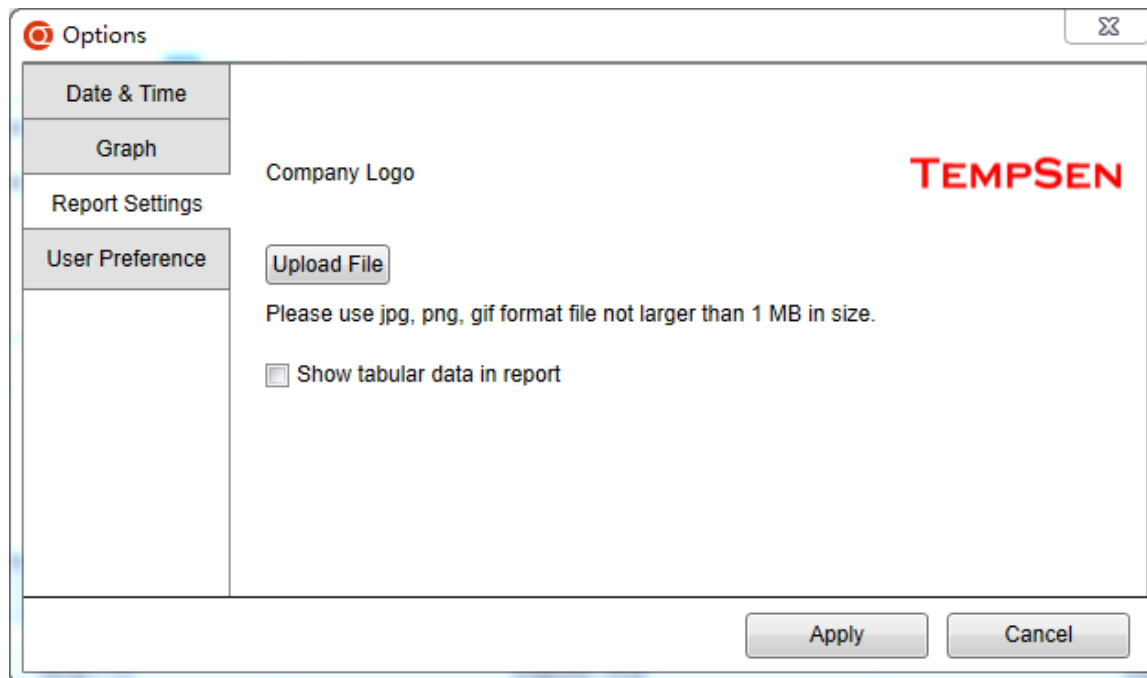
Graph



- Specify color and type for data curve and limit line display in graph view.
- Change default setting for graph view.
 - Show/hide limit line
 - Show/hide limit line label
 - Show/hide ideal range
 - Show/hide marks

Report Settings

Basic settings for PDF report exported from TempCentre.



- Company Logo
Upload an image file for the report header, please make sure use JPG, PNG or GIF format file which is not larger than 1MB in size.
- Show tabular data in report
- Show event list in report

User Preference

- Device Configuration
 - Select default Temperature Unit between Celsius and Fahrenheit for data logger configuration.
 - Auto PDF Report, default setting for auto PDF report created by device
 - Default report language
 - Default time zone
 - Default date format

NOTE • Date format settings only applicable to specific models supporting customizing time zone for auto PDF report.

Downloading Device



Click on (Download Device) in tool bar to enter downloading device mode, TempCentre starts to scan all USB ports of current machine to search for data logger to be downloaded, so please plug in USB data logger right now, download of data starts automatically once device is found.

Device capable of generating PDF report only begins to establish communication with TempCentre after PDF report generation completes, and generally you can see “PdF” on device LCD, indicating that device is generating PDF report right now, please wait for couple of se



Device connected



Downloading... 50%

Alpha TH30

SN:	0000000001
Firmware:	X2.1
Status:	Recording
Memory Available:	99.99%
Remaining Battery:	573 Day

Configuring Device

Click  (Configure Device) in tool bar to enter into configuration mode, TempCentre would begin to search and connect TempSen USB data logger automatically, and you are allowed to start configuration of device after device is connected.

Configure Device

Save Profile

Apply

Temperature Unit

☒ °C
 ☐ °F

Configuration Profile

Open

Trip Number:

GD20062810

Logging Mode

Start/Stop

☐ Repeat Start

Logging Interval

0

Hour

1

Minute

0

Second

Logging Cycle

10 Day

Please send this report to
jack@lollipopharma.com

Start Mode

Manual Start

☒ Start Delay
 ☐ Temperature Start

Start Delay

10

Minute

Alarms

PDF Options

Advanced Settings

☐ No Alarm Setting
 ☒ High & Low Alarm
 ☐ Multiple Alarms

Alarm Zones	Alarm Limit	Alarm Type	Alarm Delay	
↑ ☒ High	≥ 8 °C	Single Event	0 Hour 0 Minute 0 Second	Sensor 1
↓ ☒ Low	≤ 2 °C	Single Event	0 Hour 0 Minute 0 Second	T
↑ ☐ High	≥ %	Single Event	0 Hour 0 Minute 0 Second	Sensor 2
↓ ☐ Low	≤ %	Single Event	0 Hour 0 Minute 0 Second	RH

Configuration Options

▪ Trip Number

A unique 10 digits alphanumeric number automatically generated for identifying each monitoring task.

▪ Trip Description

A brief note entered by user for describing monitoring task and to be showed on data report.

NOTE Only ASCII characters are allowed for trip description.
() { } \ are illegal characters for trip description.

▪ Logging Mode

1. Standard (Start/Stop)

Logger stops recording until memory is used up.

2. Loop (Endless)

Recording continues even memory is full under this mode, new data overrides old data point in memory, logger provides monitoring and alarm statistics over entire monitoring course. Data points available will be the latest full memory readings.

▪ Logging Interval

Time interval for logger to sample and record one data point.

▪ Start Mode

1. Manual Start

Device needs to be started by pressing **Start/Stop** button, and 2 additional options are available under this mode, you need to select one between the two.

a) **Start Delay**, the time device needs to wait before starting recording after manually activated.

b) **Condition Start**, device starts recording when temperature meets the preset temperature condition, there are 3 types of temperature start mechanisms available.

- **Over**, device would start recording when temperature goes over the temperature value preset.
- **Under**, device would start recording when temperature goes the temperature value preset.
- **Between**, device would start recording when temperature falls in between the temperature range preset.

NOTE Condition Start applicable to specific models.

2. Auto Start

Allows device to start recording on pre-set specific date/time, logger starts recording automatically when time is up, no need to press **Start/Stop** button after configuration.

▪ Repeat Start

Repeat Start is an independent option under Startup, if enabled, you could restart Alpha data logger for next round of monitoring with the same recording parameters of previous recording by pressing Start/Stop button, no need to program the logger again.

NOTE Repeat Start is only effective after recording is stopped.

Repeat Start is only available for multi-use Alpha model.

▪ Disable Stop Button

This option is used to avoid mistaken Stop Button action, once enabled, device could not be stopped by pressing **Start/Stop** button on device, recording will stop when logging cycle ends up, however, you are still allowed to stop recording through TempCentre.

▪ Alarm Settings

1. Alarm Mode

- a) No alarm setting
- b) High & Low alarms, 2 alarm ranges determined by 2 alarm limits.
- c) Multiple Alarm ranges, 5 alarm ranges determined by 5 alarm limits.
 - High ranges: A1, A2, A3
 - Ideal range: A4 (No alarm will be triggered when data falls within this range)
 - Low ranges: A5, A6

2. Alarm Type

- a) Single Event

Alarm could only be triggered when data over/under alarm limit for a consecutive time not less than alarm delay.
- b) Cumulative Events

Alarm could be triggered once the cumulatively total time data within alarm range is not less than alarm delay.

▪ PDF Report Settings

The following settings are applied to PDF report generated by device automatically.

1. PDF Report Title

This report title would be used for PDF report created automatically by data logger.

2. Time Base

Select Time Zone and enable/disable Day Light Saving time (DST) for PDF report.

3. Date Format

- YYYY-MM-DD
- MM-DD-YYYY
- DD-MM-YYYY

4. Language

Select language for PDF report.

-
- NOTE**
- PDF reports settings only applicable to specific models.
 - Date formats settings only applicable to specific models.
 - It's only allowed to enter ASCII characters for report title.
 - `(){} \` are illegal characters for report title.
-

▪ Advanced Settings

1. Disable Stop Button

If enabled, device will be stopped manually by pressing Stop button.

2. AccessKey

AccessKey is used to protect the configuration attempts to device, if set, AccessKey will be written into device, and user will be prompted to enter AccessKey before next time configuring device.

AccessKey comprises of six numeric characters.

Apply Configuration

Click **Apply** button on status bar of workspace to write configuration parameters into device.



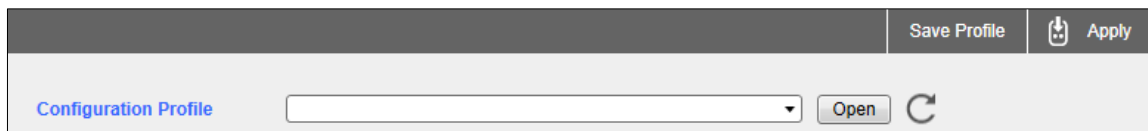
IMPORTANT

Please do not remove device from computer before you are prompted of configuration success to avoid configuration error.

Configuration Profile

▪ Saving Configuration Profile

Save current configuration parameters as configuration profile for future use by clicking **Save Profile** on status bar of workspace.



Configuration profile will be saved as .tpscfg format file, and it's a product model specific file, so it will cause configuration error if configuration profile is applied to different model of product.

-
- NOTE**
- All configuration parameters and options except Trip Number will be save as part of configuration profile.
 - Auto start time could not be saved into configuration profile.
-

▪ Loading Configuration Profile

You could simply load the recently used configuration profile from configuration profile drop list, or load new profile by clicking on **Open** to choose the configuration profile you need.

The screenshot shows the TEMPSSEN configuration interface. The 'Configuration Profile' dropdown menu is open, displaying a list of files: C:\Users\ASUS\Desktop\cfg\New_configAlpha TH30.tpscfcg, C:\Users\ASUS\Desktop\cfg\New_configAlpha TH30.tpscfcg, C:\Users\ASUS\Desktop\New_configAlpha TH30.tpscfcg, C:\Users\ASUS\Desktop\Vaccin_delivery_Alpha_TD80S.tpscfcg, C:\Users\ASUS\Desktop\Freezer_lab_Alpha_T50X.tpscfcg, and C:\Users\ASUS\Desktop\Transit_validation_Alpha_T30.tpscfcg. The 'Open' button is visible to the right of the dropdown. Other configuration options visible include 'Logging Mode', 'Logging Interval', 'Logging Cycle' (set to 10 Day), 'Start Mode' (set to Manual Start), and 'Start Delay' (set to 10 Minute).

▪ Restore Configuration to Default

Click  right to **Open** button to restore current configuration parameters to default parameters.



IMPORTANT

- Configuration profile only can be applied to the product of same model.
- Configuration profile may not be applied to product with significant change in firmware.

Viewing and Analyzing Data

Summary View

In summary view you could see all summarized monitoring information and statistics.

0000000001_GD20065636*

×

Operate ▾

Export ▾

Save

Summary

Graph

Report

View Options ▾

Device Information

Device: Alpha TH30
S/N: 0000000001
Firmware: X2.1
Current Status: Stopped[Manual]

Logging Interval: 1m
Logging Cycle: 10d
Logging Mode: Start/Stop

Start Mode: Manual Start
Start Delay: 10m

Logging Summary

T Temperature

RH Relative Humidity

Start Time: 2017.04.20 15:10:18
Stop Time: 2017.04.20 16:31:18
Data Points: 82
Trip Length: 1h21m

Max: 31.4°C@2017.04.20 16:21:18
Min: 28.7°C@2017.04.20 16:31:18
Avg: 30.4°C
MKT: 30.4°C

Max: 58.1% @2017.04.20 15:37:18
Min: 50.9% @2017.04.20 16:21:18
Avg: 53.3%

×

T/N: GD20065636

Please send this report to jack@lollipharma.com

Table

Alarms

Violation Events

Events

Comments

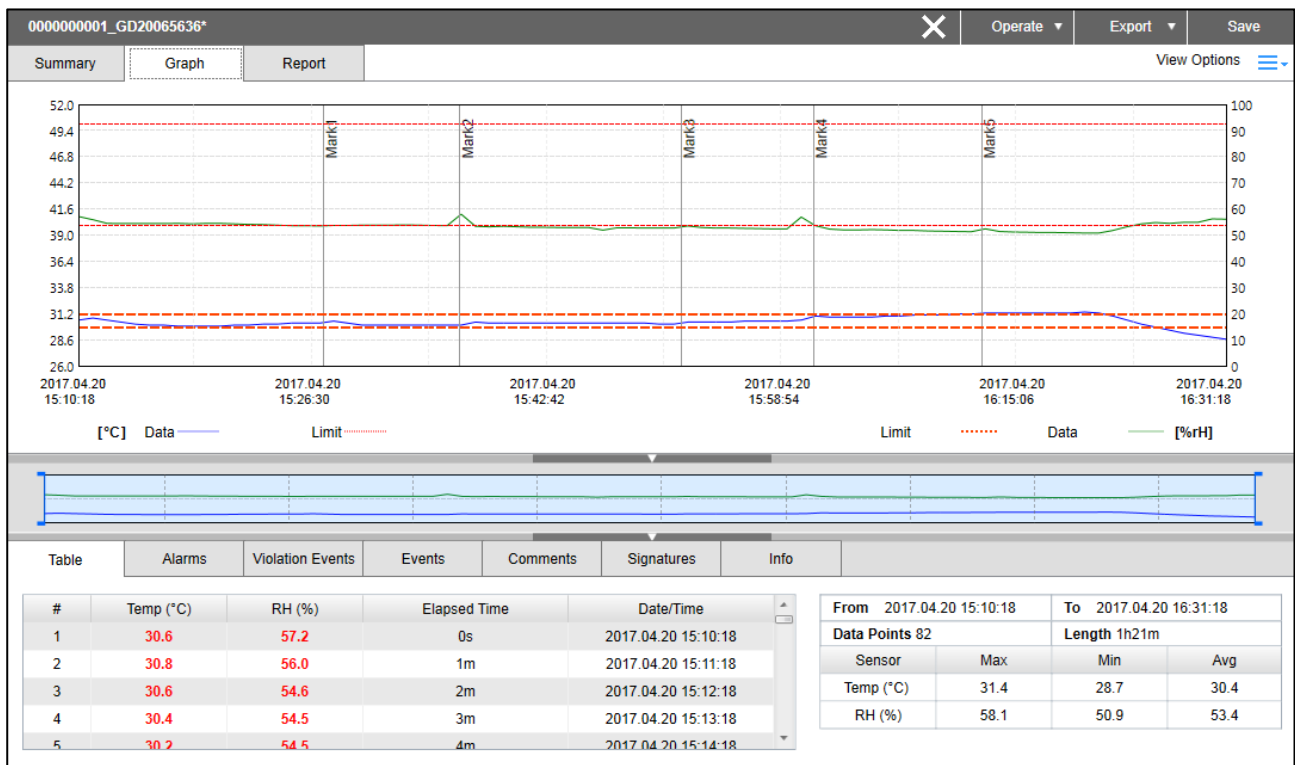
Signatures

Info

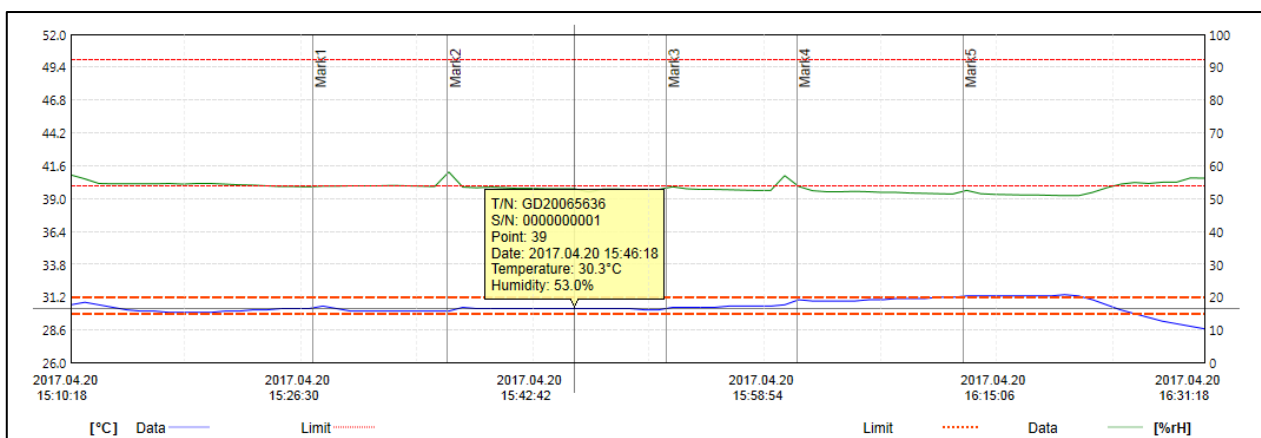
Alarm Zones	Alarm Delay(Type)	Violation Events	Total Violation Time	Alarm First Triggered@	Status
(T)High: ≥ 50.0°C	0s(Single)	0	0s		OK
(T)Low: ≤ 40.0°C	0s(Single)	1	1h21m	2017.04.20 15:10:18	Alarm
(RH)High: ≥ 20.0%	0s(Single)	1	1h21m	2017.04.20 15:10:18	Alarm
(RH)Low: ≤ 15.0%	0s(Single)	0	0s		OK

Graph View

Readouts are plotted as curve(s) in graph view, you could have intuitive understanding about temperature or humidity fluctuations throughout monitoring.



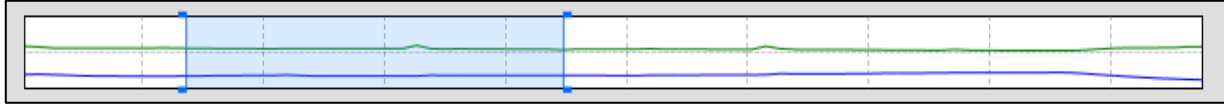
Move mouse over any data curve, a window carrying detailed formation of closest point appears.



Mini Graph

Mini graph presents complete data curve(s) throughout monitoring cycle, and you could specify a time

range on thumbnail graph by dragging the vertical bars on both left and right side of thumbnail graph to zoom in the data falling within the range selected on main graph, to enable precise partial analysis .



Report View

Combining summary, graph and tabular view into report view, which also constitutes the layout and contents of PDF report exported from TempCentre.

TEMPSEN
Record ID: 0000000001_GD20065636
X

0000000001_GD20065636

Please send this report to jack@lollipoppharma.com

Device Information

Device: Alpha TH30	Logging Interval: 1m	Start Mode: Manual Start	Current Status: Stopped[Manual]
S/N: 0000000001	Logging Cycle: 10d	Start Delay: 10m	
Firmware: X2.1	Logging Mode: Start/Stop		

Advanced Settings

Logging Summary	Temperature	Relative Humidity
Start Time: 2017.04.20 15:10:18	Max: 31.4°C@2017.04.20 16:21:18	Max: 58.1% @2017.04.20 15:37:18
Stop Time: 2017.04.20 16:31:18	Min: 28.7°C@2017.04.20 16:31:18	Min: 50.9% @2017.04.20 16:21:18
Data Points: 82	Avg: 30.4°C	Avg: 53.3%
Trip Length: 1h21m	MKT: 30.4°C	

NOTE • Report view is only able to display 25 pages of report, please browse the remaining pages in exported PDF report.

Extension Window

Extension window is located at the bottom of workspace, which includes several tabs to present a variety of information related to data record and device.

Table View

All data points present in table view

#	Temp (°C)	RH (%)	Elapsed Time	Date/Time
1	30.6	57.2	0s	2017.04.20 15:10:18
2	30.8	56.0	1m	2017.04.20 15:11:18
3	30.6	54.6	2m	2017.04.20 15:12:18
4	30.4	54.5	3m	2017.04.20 15:13:18
5	30.2	54.5	4m	2017.04.20 15:14:18
6	30.1	54.5	5m	2017.04.20 15:15:18
7	30.1	54.5	6m	2017.04.20 15:16:18
8	30.0	54.6	7m	2017.04.20 15:17:18
9	30.0	54.4	8m	2017.04.20 15:18:18
10	30.0	54.6	9m	2017.04.20 15:19:18
11	30.0	54.6	10m	2017.04.20 15:20:18
12	30.1	54.4	11m	2017.04.20 15:21:18
13	30.1	54.2	12m	2017.04.20 15:22:18
14	30.2	54.1	13m	2017.04.20 15:23:18
15	30.2	53.9	14m	2017.04.20 15:24:18
16	30.3	53.7	15m	2017.04.20 15:25:18
17	30.3	53.7	16m	2017.04.20 15:26:18
18	30.3	53.6	17m	2017.04.20 15:27:18
20	30.5	53.8	19m	2017.04.20 15:28:18

Any values violating alarm thresholds display in red, and time stamped marks display in blue.

Real-time Statistics

Statistics for data within time range specified on mini graph show in table of real-time statistics statistical values change as time range changes, statistics include:

From 2017.04.20 15:10:18		To 2017.04.20 16:31:18	
Data Points 82		Length 1h21m	
Sensor	Max	Min	Avg
Temp (°C)	31.4	28.7	30.4
RH (%)	58.1	50.9	53.4

1. **Data Points**, number of data points within selected time range.
2. **Length**, time length of the selected time range.
3. **Max**, maximum value of data within selected time range.
4. **Min**, minimum value of data within selected time range.
5. **Avg**, average value of data within selected time range.

■ Violation Events

Statistics for each alarm limit violation event would be displayed in date order, every individual event with duration time longer than preset alarm delay is highlighted in bold red.

#	Alarm Zone	From	To	Time Length	Data Points
1	(T)Low: <= 40.0 °C	2017.04.20 15:10:18	2017.04.20 16:31:18	1h21m	82
2	(RH)High: >= 20.0 %	2017.04.20 15:10:18	2017.04.20 16:31:18	1h21m	82

■ Comments

Enter comments for current data record, you are allowed to input up to 250 characters.

Table	Alarms	Violation Events	Events	Comments	Signatures	Info
Route_Q3_Shipping309_A						

■ Signatures

Review electronic signature history information of current data record.

Table	Alarms	Violation Events	Events	Comments	Signatures	Info										
<table><tr><th>User Name</th><th>Full Name</th><th>Meanings</th><th>Date/Time</th><th></th></tr><tr><td>TOKI</td><td>GIN TOKI</td><td>PASS</td><td>4/20/2017 4:58:23 PM</td><td></td></tr></table>							User Name	Full Name	Meanings	Date/Time		TOKI	GIN TOKI	PASS	4/20/2017 4:58:23 PM	
User Name	Full Name	Meanings	Date/Time													
TOKI	GIN TOKI	PASS	4/20/2017 4:58:23 PM													

■ Info

Display additional information of data record and device.

Table	Alarms	Violation Events	Events	Comments	Signatures	Info
- Record ID: 000000001_GD20065636						

View Options

Click **View Option** in right upper corner of workspace, a menu with options for setting up all views appears.

The screenshot shows a 'View Options' menu with the following settings:

- Temperature Unit:** ☒ °C Celsius, ☐ °F Farenheit
- Sensors:** ☒ Sensor 1: Temp, ☒ Sensor 2: RH
- Edit Marks:** ☒ Show Limit Line, ☐ Show Limit Line Label, ☐ Show Ideal Range, ☒ Show Marks
- X Axis:** ☒ Date/Time, ☐ Elapsed Time, ☐ Data Points

1. **Temperature Unit**, convert temperature readings between Celsius and Fahrenheit.
2. **Show/hide measurement channel**, choose to turn on/off the display of one of the measurement channels if there is more than one channel available.
3. **Edit Marks**, edit alias of time marks placed during recording for better identification.
4. **Graph View Options**
 - a) Show Limit Line, check to show alarm limit line
 - b) Show Limit Line Label, check to show alarm limit line label
 - c) Show Ideal Range
 - d) Show Marks
 - e) X Axis, change X axis between different coordinate options.
 - Date/Time
 - Elapsed Time
 - Data/Points

NOTE Options in **View Option** menu will vary under different views.

Data Base

Data base is the where user could search, retrieve, analyze, comment and compare data stored in TempCentre data base.



Please click  on tool bar to enter data base mode.

Data Record List Pane

You could search data records in left pane, all data records stored in data base will be presented in pages, please navigate to certain page through page selector at the bottom of pane.

Click on  to extend data record list to data record table, more columns would appear.

Data Base					
0000000001_GC03082520					
From	2015-12-14 20:12:12	Current / All Data Records: 749/749			
To	2017-04-20 23:59:59	Status ☒ OK ☒ Alarm ☒ No Alarm Setting			
Search by record name, id, description		Latest 1 year			
Record Name	Record ID	Trip Description	Start Time	Save Time	Status
0000000001_GC03082520	0000000001_GC03082520		2017-03-03 19:00:01	2017-03-06 09:14:12	✗
0000000001_GC03082650	0000000001_GC03082650		2017-03-03 19:00:00	2017-03-06 09:14:12	✗
0000000001_GC03082828	0000000001_GC03082828		2017-03-03 19:00:00	2017-03-06 09:14:12	✗
0000000001_GC03083012	0000000001_GC03083012		2017-03-03 19:00:00	2017-03-06 09:14:12	✗
0000000001_GC03083314	0000000001_GC03083314		2017-03-03 19:00:00	2017-03-06 09:14:12	✗
0000000001_GC03083511	0000000001_GC03083511		2017-03-03 19:00:00	2017-03-06 09:14:12	✗
0000000001_GC03083632	0000000001_GC03083632		2017-03-03 19:00:00	2017-03-06 09:14:12	✗
0000000001_GC03083810	0000000001_GC03083810		2017-03-03 19:00:00	2017-03-06 09:14:12	✗
0000000001_GC03083938	0000000001_GC03083938		2017-03-03 19:00:00	2017-03-06 09:14:12	✗
0000000001_GC03084046	0000000001_GC03084046		2017-03-03 19:00:00	2017-03-06 09:14:12	✗
0000000001_GC03084158	0000000001_GC03084158		2017-03-03 19:00:00	2017-03-06 09:14:12	✗
0000000001_GC02060028	0000000001_GC02060028		2017-03-02 14:10:00	2017-03-03 13:45:21	✗
0000000002_GC02055940	0000000002_GC02055940		2017-03-02 14:10:00	2017-03-03 13:45:21	✗
0000000003_GC02060104	0000000003_GC02060104		2017-03-02 14:10:00	2017-03-03 13:45:21	✗
0000000004_GC02055914	0000000004_GC02055914		2017-03-02 14:10:00	2017-03-03 13:45:21	✗
0000000001_GC02072526	0000000001_GC02072526		2017-03-02 15:30:00	2017-03-02 16:49:35	✗
0000000002_GC02072508	0000000002_GC02072508		2017-03-02 15:30:00	2017-03-02 16:49:35	✗
0000000003_GC02072432	0000000003_GC02072432		2017-03-02 15:30:00	2017-03-02 16:49:35	✗
0000000004_GC02072356	0000000004_GC02072356		2017-03-02 15:30:00	2017-03-02 16:49:35	✗
3333333333_GB22083650	3333333333_GB22083650		2017-02-22 16:37:13	2017-03-01 09:05:43	

Select and View Operation

Single click on a data record in data record list pane to select a data record.

Double click a data record in data list pane to view a data record.

“” displays in column left to record name indicating this data record is currently presented in current views.

▪ Menu Options

After selection of data record in list pane, right click mouse you will have an operation menu for data records. Please find menu options as below.

- Rename Data
- View Selected Data
- Export Selected Data
- Delete Selected Data
- Compare Selected Data
 - Add to Data Comparison
 - Remove from Data Comparison
 - Exit from Data Comparison

▪ Data Record ID and Name

- Each Record ID is composed of device serial number and trip number.
- Data record name is the same with record ID by default, you are allowed to change record name by right clicking on data record list pane, select **Rename Data** to perform renaming, a maximum of 50 characters are allowed for a record name. Record name is used as data record identification and file name of data exported.

Filters and Searching

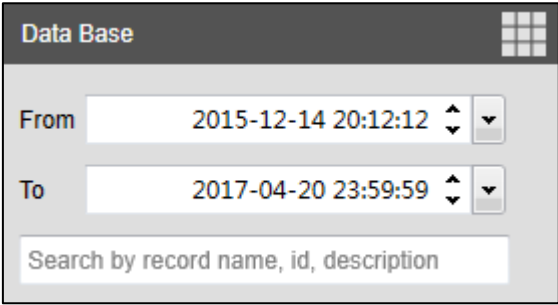
With the assistance of retrieve criteria and searching function, you could quickly locate the data record you need.

▪ Filter Criterias

1. **Date Range:** Define a data range by specifying start and end date.
2. **Status:** Filter data on different alarm status, including Alarm, OK, No Alarm Setting.
3. **Latest Time Period Selectors:** Quickly specify latest time period to narrow down search scale.

▪ Searching

You are allowed to search for specific data directly record by Record Name, and you could also search by Record ID or Trip Description through changing search options, click downward arrow left to search input box to expand search option menu.

A screenshot of a web application window titled "Data Base". The window has a dark grey header bar with the title and a small grid icon on the right. Below the header, there are two date-time selection fields. The first field is labeled "From" and contains the text "2015-12-14 20:12:12" with a small up/down arrow icon to its right. The second field is labeled "To" and contains the text "2017-04-20 23:59:59" with a similar up/down arrow icon. Below these fields is a search bar with the placeholder text "Search by record name, id, description".

Data Base	
From	2015-12-14 20:12:12
To	2017-04-20 23:59:59
Search by record name, id, description	

- **Restore to Default State**

Please click on  to clear all filters and restore to default state.

Data Comparison

Search for multiple data records and put them together into data comparison. A maximum of up to 50 data records could be put into data comparison.



How to compare different data records

1. Multi-select the data records you need to compare in data record list pane.
2. Right click mouse, select **Compare Selected Data**
3. Data comparison begins

You could also add data to or remove data from comparison, right click on mouse in data record list panel, select **Add Data to Comparison** or **Remove Data from Comparison**. To exit from data comparison, please right click mouse in data record list panel, select **Exit from Data Comparison**

Comparison Views

Summary View

In data comparison, summary view presents summarized information of all data into tabular views.

Graph view

In data comparison, curves representing every data record will be plotted into one graph. If there is more than one measurement channel (sensor) in records compared, then sensor 1 will be displayed as default view, please switch to "Sensor 2" in View Option menu.

- **List View**

In data comparison, readings from all data records display in tabular view in extension window.

Opening and Importing Data Files

Please open and import external file by clicking **File** in menu bar, and select **Open** to open single file, and select **Import** to import multiple files into TempCentre data base.

Compatible File Formats

1. .tps format file, please note TempCentre 2.0 or above could not open or import ,tps format file created by TempCentre 1.3.3 or lower.

Exporting Data Files

Please move to **File>Export** or click **Export** button on title bar of workspace, to export currently viewing data record. Or you could select data record(s) in data record list pane of data base, and right click mouse, choose **Export Selected Data Record** to export currently selected data records.

TempCentre provides the following three formats that data record could be exported as:

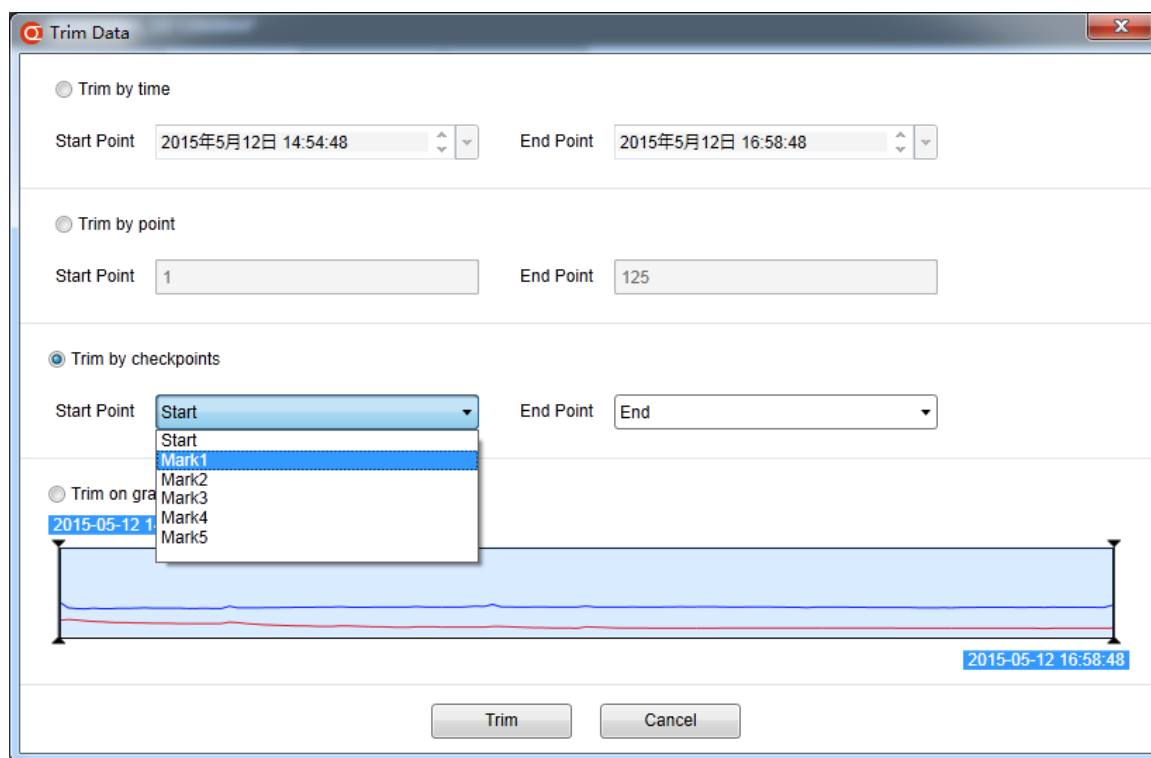
- a) **Export to TPS:** TPS(.tps) is a self-defined encrypted format developed by TempSen for exchanging data in between TempCentre software.
- b) **Export to PDF:** Data report will be saved as an Adobe® PDF format file.
- c) **Export to Excel:** Data report will be saved as spreadsheet format (.xlsx). Data records in comparison would be exported in batch to one spreadsheet file.

Handling Data Records

Trimming Data

Trimming data is a way to re-define the time range of a data record, to create a new data record based on the time range user actually needs, trim for data will not affect the original data record, the trimmed data record will be saved to data base (if user selects to do so) as a new data record, with a new trip number (the original trip number ended with _X1,2,3...). Mathematic statistics like maximum, minimum, average, MKT values will be re-calculated within the new time range.

Please click on **Operate** button in workspace status bar, see as below



Trim a data record in following 4 ways.

Trim by time	Trim data with the new start and stop time specified.
Trim by data points	Trim data with the new start and stop points specified.
Trim by checkpoints	Trim data with the new start and check points (start, time marks, stop) selected.
Trim on mini graph	Trim data based on the time range selected on mini graph.

Resetting Alarm Settings

This functionality allows you to reset alarm settings of existing data record, which is very useful in scenario like no alarm setting was set to loggers already deployed in shipment, but QA needs to analyze the data with alarm thresholds specified in quality manual after goods arrived.

Data record with alarm settings changed would be saved into data base as a new data record.

Data record with alarm settings reset will be saved into database as a new data record.

21 CFR 11 Compliance Module

What's 21 CFR 11 Compliance?

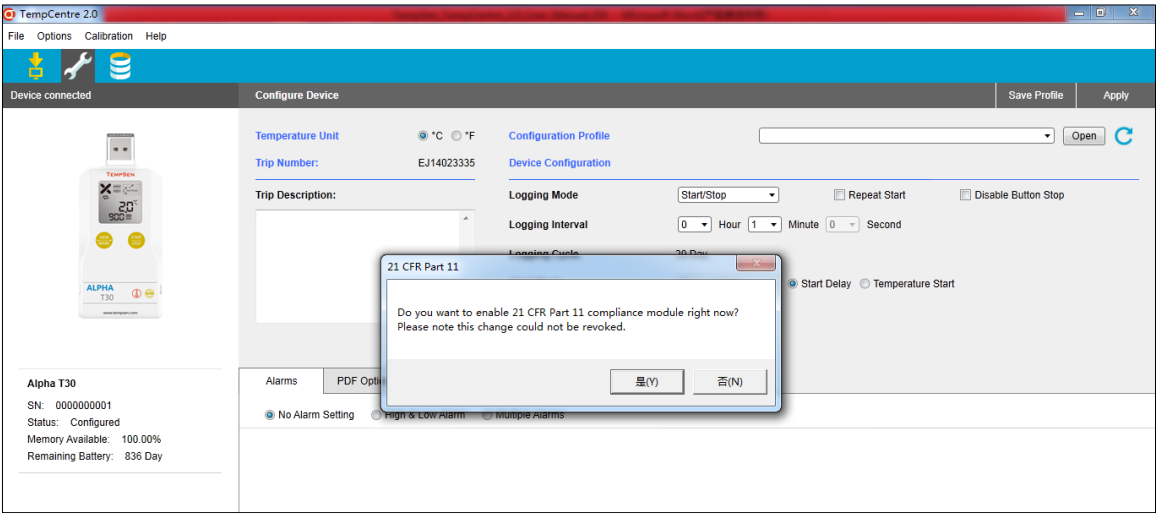
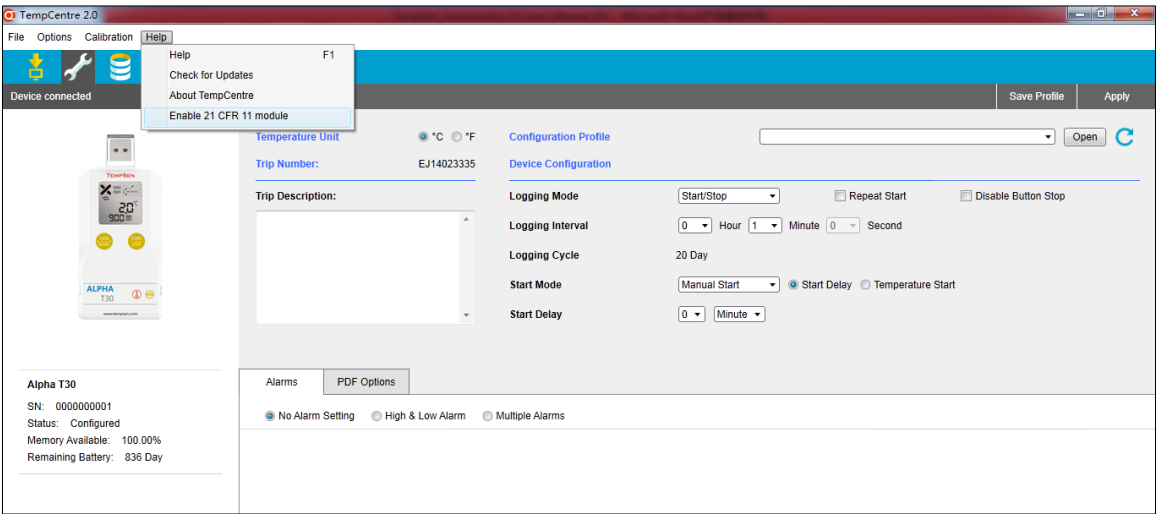
The Food and Drug Administration (FDA) issued regulations Title 21 Code of Federal Regulations Part 11 that provide criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. These regulations, which apply to all FDA program areas, are intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to promote and protect public health. 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.

How to achieve compliance with TempCentre?

With help of 21 CFR 11 Compliance module, TempCentre would assist regulated companies to meet compliance by implements user administration, access control, and electronics signatures and records retention.

Activating 21 CFR 11 Module

21 CFR 11 compliance module is not a default function ready for use after software installation, you need to active this module by going to **Help>Enable 21 CFR 11 Module**.



After 21 CFR 11 compliance module is enabled, program will restart for the changes to take effect.

Electronic Signature

Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Once you decide an electronic signature, there will be user authentication as first step, the process of signing consists of:

- User authentication
- Checking permission of adding an electronic signature
- Selection of a meaning from a pre-assigned meanings list.

Electronic signature generates printed name of signer, date and time of execution, history of all signatures related to this electronic record.

Please check out signature history tab in the extension window in workspace.

User Name	Full Name	Meanings	Date/Time	
David	David He	Approved	10/14/2015 17:25:33	✓
Lisa	Lisa May	Reviewed	10/14/2015 17:26:55	✓

NOTE You are allowed to add up to **200** electronic signatures to one data record.

User Accounts

After 21 CFR 11 compliance module first enabled during installation, you will be asked to setup the first admin account, user account comprise of following information.

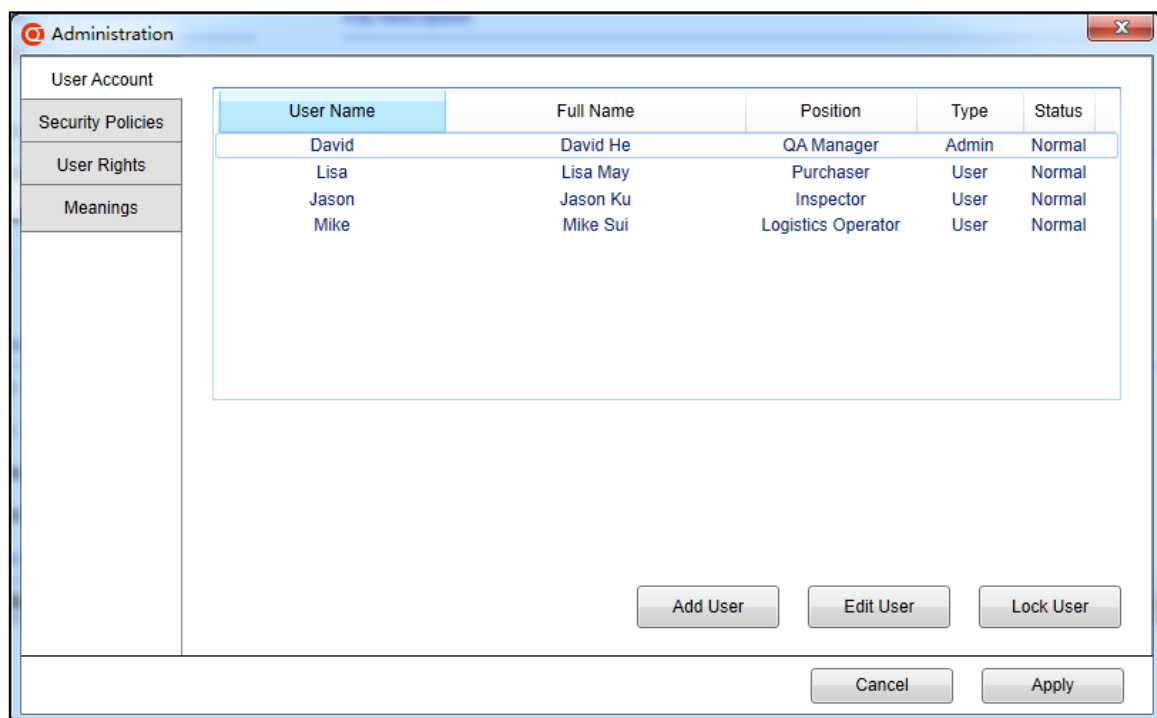
Account Information

User Name	Unique login name, up to 30 alphanumeric characters
Full Name	Full name, up to 50 alphanumeric characters
Password	6 to 24 ASCII characters
Role	Defines your role in your organization, up to 50 alphanumeric characters
Type	Select between User Account and Administrator Account

Difference between User Account and Administrator Account

1. Administrator account could create, edit, lock and manage other accounts, including administrator accounts.
2. Administrator account

Please go to **Menu bar > Administration > User Account** to add, edit, lock or unlock users in system.



Security Policies

To control visit to system, protect important information and prevent hostile access, you could enable and change the following security policies.

1. **Lock user after [] consecutive failed logon attempts.** User account will be locked if he/she login to system with incorrect user name or password for certain number of times in a row. Please ask admin account to unlock the locked account, max 9 attempt failures.
2. **Force logout if inactive time over [] minutes.** Specifies user session expiry time, max 999 minutes.
3. **Password expires after [] days(s).** Defines password expiry time, max 999 days.

Please leave input box empty or input zero (0) to disable any policy.

User Rights

TempCentre offers a series of system rights for controlling users' access to specific functions, rights available are shown below:

- Configure device
- Sign data (sign electronic signature for data record)
- Edit data (add comments, marks, change record name, report title)
- Change options (change system options)
- Delete data
- View audit trail

Admin account has all of the above rights by default.

Meanings

Allows admin account to add, edit, delete and assign meanings for user who will and has the right to sign electronic signature.



Administration

User Account

Security Policies

User Rights

Meanings

User Name	Full Name	Position	Type	Status
David	David He	QA Manager	Admin	Normal
Lisa	Lisa May	Purchaser	User	Normal
Jason	Jason Ku	Inspector	User	Normal
Mike	Mike Sui	Logistics Operator	User	Normal

Meanings Available

☐ Approved

☐ Reviewed

☐ Rejected

☐ Check

Add Meanings

Edit Meanings

Delete Meanings

Cancel

Apply

NOTE You are allowed to add up to 100 meanings in TempCentre program.

Audit Trail

Audit trails record all critical actions, including changes made to system or data records, to enable users, reviewers and inspectors to be aware that what, who, when about the changes made.

- What changes have been made
- Who made the changes
- When the changes are made

TempCentre provides two types of audit trails, system audit trail and analysis audit trail.

Audit Trails				Print	Export
Type	Action	User	Details	Date/Time	
	Login	David	Successful	2015-10-26 23:06	
	Log out	David	Successful	2015-10-26 23:05	
	Trim data	David	EA08A50026_EA28141306.EA08A50026_EA28141306_X1	2015-10-26 23:03	
	Import data	David	EA08A50032_EB02083352	2015-10-26 23:03	
	Import data	David	EA08A50026_EA28141306	2015-10-26 23:03	
	Import data	David	0000000001_EB06091754	2015-10-26 23:03	
	Login	David	Successful	2015-10-26 23:03	
	Log out	Mike	Successful	2015-10-26 23:02	
	Save data	Mike	0000000001_EJ26014818	2015-10-26 23:02	
	Configure device	Mike	0000000001,Alpha T30	2015-10-26 23:02	
	Login	Mike	Successful	2015-10-26 23:02	
	Log out	David	Successful	2015-10-26 23:02	
	Change rights	David	Mike: Added "Sign Record"	2015-10-26 23:02	
	Change rights	David	Mike: Added "Config Device"	2015-10-26 23:01	
	Change rights	David	Mike: Added "Change Options"	2015-10-26 23:01	
	Add user	David	Mike:User:Logistics Operator	2015-10-26 23:01	
	Change rights	David	Jason: Added "Config Device"	2015-10-26 22:58	
	Change rights	David	Jason: Added "Change Options"	2015-10-26 22:58	
	Add user	David	Jason:User:Inspector	2015-10-26 22:58	
	Change rights	David	Lisa: Added "Config Device"	2015-10-26 22:57	
	Change rights	David	Lisa: Added "Change Options"	2015-10-26 22:57	
	Add user	David	Lisa:User:Purchaser	2015-10-26 22:57	

< > Page 1 / 2 Go > >

78 Trails

NOTE Please click on  in pane left to refresh trails.

▪ System Audit Trail

The system audit trails record all critical system changes, and followings are sample system change actions.

Action	User Name (Operator)	Details	Action Detail Explanation
Add user	Jack	Lilly: User, "Lilly Yen"	Object user: account type, "full name"
Edit user	Jack	Lilly: Position "QM"	Object user: position detail
Edit user	Jack	Lilly: Full Name "Alex Ariston"	Object user: edit detail
Change Group	Jack	Lilly: Old "User", new "Admin"	Object user: Old account type, new account type.
Lock user	Martin	Jack	Object user
Lock user	System	Jack	User locked by system
Unlock user	Martin	Lilly	Object user
Change password	Jack	Lilly	Object user
Log on	Anderson	Failed	Login result
Log off	Anderson	Successful	Logout result
Add meaning	Lisa	"Released"	Meaning name
Delete meaning	Lisa	"Tested"	Meaning name
Assign meaning	Lisa	Macus: Added "Release"	Object user: Meaning added
Assign meaning	Lisa	Jackson: Removed "Rejected"	Object user: Meaning removed
Edit meaning	Macus	Old "Release", new "Released"	Old meaning, new meaning
Change rights	Max	Lilly: Added "Sign record"	Object user: right added
Change rights	Julian	Sarah: Removed "Delete Record"	Object user: right removed
Change security policies	Miya	Password validity: Old "30 days", new "10 days"	
Change security policies	Miya	Force logout inactive time: Old N/A, new "30 minutes"	

Change security policies	Miya	Failed login attempts restriction: Old N/A, new “6”	
System Event	Max	21 CFR 11 Compliance Module Deployed	

▪ Analysis Audit Trail

The analysis audit trail keeps significant changes to electronic records and devices, followings are the actions deemed as changes to data.

Action	User Name	Details	Action Detail Explanation
Configure device	Jack	DE12345678, ITAG3 Pro	Configured device serial number, device model.
Save record	Jack	DE12345678_DE12345678	Record ID of data saved
Import record	Maria	DE12345678_DE12345678	Record ID of data imported
Edit comment	Jack	DE12345678_DE12345678: “Thermal research_2015_09_logistics”	Record ID: “Comment after edit”
Edit record name	Ema	DE12345678_DE12345678: “a new data report”	Record ID: “Record name”
Edit mark	Lisa	DE12345678_DE12345678: Mark 1 “Open door”	Record ID: Mark number “Mark Name”
Edit report title	Elva	DE12345678_DE12345678: “New Vaccine Delivery”	Record ID: “Report Title”
Sign data	Anderson	DE12345678_DE12345678: “Approval”	Record ID: “Meaning”
Trim data	Anderson	DE12345678_DE12345678: DE12345678_DE12345678_X1	Record ID: Record ID of data after trimmed and saved
Reset Alarm Settings	Nicole	DE12345678_DE12345678: DE12345678_DE12345678_X1	Record ID: Record ID of data after alarm reset and saved
Delete record	Anderson	DE12345678_DE12345678_22	Record ID of data record deleted
Delete record	Anderson	All data deleted	
Renew calibration	Mike	DE12345678	Serial number of logger with calibration renewed

▪ Filter

Filter allows you to quickly find the audit trails you need, to facilitate accurate review or inspection.

Following filter options are available.

- Item
- Action
- User
- Date/Time

▪ Export and Print Audit Trail

To export or print the current audit trail, please go to menu bar, **File>Export** or **Print** to export or print audit trail under current filter criteria.

Devices

Calibration

Calibration validity period management is now available from TempCentre 2, to enable user to properly maintain calibration validity throughout device life cycle with periodical reminder, you will be prompted if calibration of current connected device will be due within 30 days.

You could go to **Menu bar>Devices>Calibration** to renew calibration information after receipt of this information, or you could turn off calibration notification on currently connected logger if you don't need it.

Calibration

Current calibration expires at : 2016-10-12

Renew Calibration

Calibration Date: 2015-10-14

Calibration valid period: 1 year (365 days)

Renew

☐ Enable calibration notification on current device.

Apply

NOTE Only part of Alpha logger models support calibration validity management,

Downloading TempCentre

Please download and install the latest version of TempCentre software from www.tempsen.com

How to download TempCentre software?

- If it's your first time to download software from www.tempsen.com, please sign up with the information required prior to downloading, then an email containing download link would be sent to the mail address you left in couple of minutes.
- If you want to download the software from again after your successful registration last time, please click "**I already signed up, download now**" button in dialogue box, then software would begin to download in couple of minutes.

Update

Please go to **Help>Check for Updates** to start TempCentre updater, then updater would start searching for available updates for current version online. If update is available, please download the update and then perform update.

TempCentre updater program also checks the availability of new update automatically every TempCentre starts running, and you will be prompted to download and perform update when update is available.

Auto update defaults to enabled, and you are allowed disable auto Update by going to **Help>About TempCentre**, click on **Disable Auto Update**.

NOTE Only could operation system administrator account perform update.

Installation and Uninstallation

Installation

1. Double click on TempCentre_2.0_Setup.exe to start installation
2. Click on **Next** in Welcome page
3. Select "I accept the terms in the License Agreement" to proceed.
4. Select language versions for program to be installed
5. Select or specify destination for program and data file (Data Base file)
6. Click **Install**

7. Click **Finish**
8. Installation completes.

NOTE Please DO NOT place Data File folder under any of the following folders in system disk, otherwise TempCentre will prompt Error while program runs.

- C:\Program Files
 - C:\Program Files(x86)
 - C:\Program Data
-

Uninstallation

1. Select **Start**, go to **Control Panel**
2. Navigate to **Add or Remove Programs**
3. Select TempCentre in list, click on **Uninstall/Change**
4. Uninstallation completes

Data Base Backup

Backup

Please backup the database file tempsen.db in data file folder.

Restore

Please replace the tempsen.db in data file folder with your backup tempsen.db file.

MKT

MKT (Mean Kinetic Temperature) is a simplified way of expressing the overall effect of temperature fluctuations during storage or transit of perishable goods.

Calculation:

$$T_{mkt} = \frac{\Delta E/R}{-\ln\left(\frac{e^{-\frac{\Delta E}{RT1}} + e^{-\frac{\Delta E}{RT2}} + \dots + e^{-\frac{\Delta E}{RTn}}}{n}\right)}$$

ΔE = activation energy (standard value: 83.144 kJ/mol)

R = 8.314472 J/mol-K (universal gas constant)

T = temperature in degrees K

n = the number of sample periods over which data is collected

Note: ln is the natural log and e^x is the natural log base.

NOTE Device does not provide MKT value under loop recording mode.

Why is MKT important in the life of pharmaceuticals and perishable goods?

The pharmaceutical and food industries are two closely regulated markets. The FDA provides regulations that require warehouse and shipment temperatures to be closely controlled and monitored. In addition, the FDA requires well-documented verification of these storage environments and any corrective actions taken if temperatures exceed specified storage conditions.

Revision History

Version	Date	Description
A	May 8, 2015	First Edition
B	June 26, 2015	1. Added threshold violation event statistics table. 2. Added resetting alarm settings
C	December. 2015	1. Added 21 CFR 11 Compliance Module
D	March 15, 2017	1. A series of changes including interface optimization and functionality improvements.

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