

# StickLog Pro

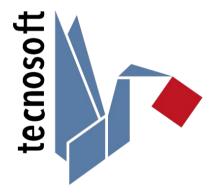
Management software for TempStick, HumiStick data loggers and TecnoStick Interface, SRI connection bays

**User's Manual** 

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# Introduction

StickLog Pro is the management software for different Tecnosoft data loggers: TempStick, TempStick Probe, TempStick Square and HumiStick through the TecnoStick Interface USB and SRI portable interface.

It allows to program the data loggers using different parameters such as sample rate, start delay, tracking of the items monitored, also using a bar codes (a bar code reader is necessary).

The temperature curve analysis is made using the MKT (Mean Kinetic Temperature) formula that allows to immediately know if the monitoring was within the set limits.

Each data logger has its own serial number; the logger can come with a calibration certificate lasting one year, to certify the accuracy of the sensor.

# System general features

Following, a list of the main features; to know all the features read the different sections of the user manual:

- non editable device data;
- non editable software data:
- analysis with pre set or customized parameters;
- MKT analysis, with customized validation criteria;
- pre start comments;
- data in graph mode, with zoom, and table;
- customized, with own logo, printed reports;
- creation of profiles to be recalled before programming the loggers, to avoid to re set the parameters each time;
- data sent via email;
- export in CSV format (MS Excel compatible).

#### Devices available

Following the list of loggers currently supported, with necessary accessories.

Data loggers	Communication bays
TempStick series (new version)	TecnoStick Interface USB
HumiStick ( new version)	SRI
Discontinued models still supported in StickLog Pro: TempStick series (old version), HumiStick (old version)	

#### How to read the manual

The manual is designed so to give immediate support for the actions required; it is not a simple list of the program's features and the chapters and paragraphs titles suggest immediately what is explained there. Chapters sequence follow standard use procedure of the system, from software installation to logger's programming and download, finishing with report printing. In brackets, near the title, you find the windows name to which the explanation is referring to.

# **System Requirements**

# Hardware

Description	Minimum Requirements
Operating System	Windows 10
Processor (CPU)	Core i3
RAM	4 GB
Free USB Ports	2
Hard disk free space	2 GB

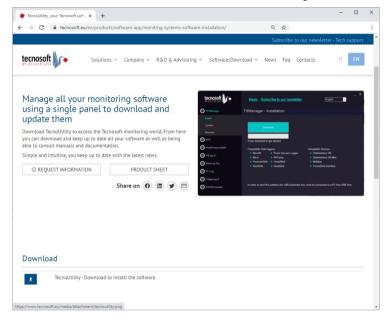
# Software

Item	Minimum version
.NET Framework	4.0

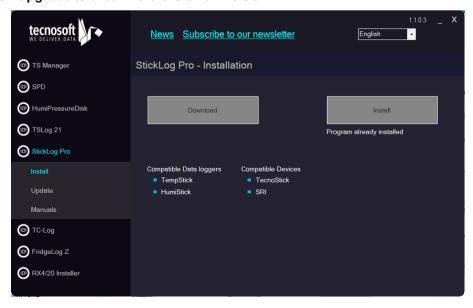
# **Installation**

# Where to get the software

All Tecnosoft software are available through the *TecnoUtility* Windows app from Tecnosoft. Just open your browser and digit <u>tecnosoft.eu</u> in the URL's bar. Once the website is open, choose **Software/Download** and then scroll down to select *TecnoUtility*. Click on it and download the software by clicking on the **Download to install the software** link under the *Download* section to start downloading the software.



Once download is complete just double click on the file to open *TecnoUtility*. Select **StickLog Pro** and then **Install** and click **Download** to start downloading and installing the software. If the software is already installed click on **Upgrade** to check if there is a new version.



Note: in case you have installed the software in a folder different from the default one, you have to indicate the installation folder in order to check for updates.

Follow below instructions according to the type of installation you wish to perform.

# Installation pre-requisites

The installation of StickLog Pro requires the installation of some additional components; if these are not already present on the system they will automatically be requested to be downloaded and installed before it actually installs StickLog Pro. The component pre-requisites are:

Microsoft .NET Framework

### Registration

The first time you install the program on a specific PC you will be asked to register it. Fill out the form and send the information: you will receive an immediate reply to the email address you just introduced. In the email there is the activation code you need to complete registration. Copy and paste it in the proper field in the registration window.

It is possible to view a video tutorial on how register correctly: <a href="https://www.youtube.com/watch?">https://www.youtube.com/watch?</a> v=pcO4u3O9IOE

Save the code as it might be still useful in the event of updates: you can reuse it as long as you are installing on the same PC.

Registration has no cost and the software can be installed on all PCs you need.

# **Devices and accessories**

The loggers managed by the StickLog Pro software are connected to the PC by means of a single interface, the TecnoStick Interface.

The TempStick series loggers can be managed also with the SRI portable interface.

# Connecting the TecnoStick Interface or the SRI

In the kit there is also a USB cable: connect the biggest flat end in the free USB port of your PC while the other smaller end in the USB connector on the device.

As soon as the device is connected to the PC, Windows will detect its presence and will begin the driver installation procedure. According to your operating system, proceed as follows.

#### **USB** driver installation

To install USB drivers follow instructions on our dedicated FAQ page: <a href="https://www.tecnosoft.eu/en/faqs/#faqcategory-usb-drivers">https://www.tecnosoft.eu/en/faqs/#faqcategory-usb-drivers</a>.

# Data loggers connection to interface devices

The devices must be inserted in the slot on each interface: you can insert the loggers on both sides since communication is available on both faces of the device.



# **QuickStart Guide**

To immediately use the system with the TecnoStick Interface, follow these steps (the software is meant to be already installed, p. 9); to use the SRI and the other functions of the software, please refer to proper chapter in the manual:

- 1. be sure that the TecnoStick Interface is connected to a USB port and that the USB drivers are correctly installed (p. 11). Start the software and see that in the centre, in the box *Connect via*, the is the option *TecnoStick Interface*;
- insert the logger you want to program in the interface and double click on TecnoStick Interface or click on Connect:
- 3. the software will show some details about the device: click on **Start**;
- 4. if Start is not enabled, click on Stop first;
- 5. in the *Start Mission* window, in the *Device Details* box on the left, type the name you want to give to your device in the field *Name* (you can set a generic name, a reminder of what you are monitoring or to the place where the logger is installed, like Laboratory, Fridge 1 etc.);
- 6. In the box *Mission Parameters* set the acquisition rhythm in the field *Sample Rate*, in *hours* and *minutes*) and the maximum and minimum limits (*Minimum* and *Maximum*) for the thermal analysis on the graph;
- 7. click on **Start** in the bottom right corner. When the message *Mission Started* shows up, click on **OK** and then on **Disconnect** in the top left corner of the window;
- 8. take the logger out from the interface and place it where you want to monitor temperature/humidity;
- 9. when the monitoring period ends, take back the logger and insert it again in the interface connected to the PC. Start the program, click on **Connect** and then on **Download**. The mission is automatically saved in the archive:
- 10. click on the different tabs to analyse the data in graph and tabular form;
- 11. to print data, click on **Report**, on the bottom; to include the table in the report, enable the option *Include Table with report*, in the bottom right corner;
- 12. click on Close to exit this window;
- 13. to look at previously downloaded missions, click on **Database** in the main window.

# Tracking transports from the start to the end using bar codes

It is possible to track the items transported using the bar codes, if the items have one. To do this you will a bar code reader connect to the PC and programmed to read the bar codes of the items; alternatively, you will need to input the codes manually.

To test the reader, after installing the USB drivers if necessary (follow instructions manual of the device), use a program such as Note Pad of Windows: try to read one bar code of the items to transport and if it appears on screen , the reader is working properly. Be sure the reader is set to put an Enter command each time a bar code is read.

#### Insert the code at the start

After point 6 of the above steps, place the cursor in the field *Item* in the box *Items Monitored*. Read the first bar code and it will be added to the list below. Keep reading all the bar codes. Go to step 7 and finish programming operation. Even if the codes are all the same, you can read them all to track exact number of items transported.

#### Check codes at the end

After point 9 of the above steps, place the cursor on the field below the field *Operator*, at the top, in the centre, in the box *User Parameters*, above the list of bar codes inserted at the start. Read the codes of the received items: if the read code is in the list, this will turn green (if there are identical codes, the first one will turn green; if you read another identical code, the second one will turn green and so on), if the read code is n ot present in the list, it will be added and will turn red. If a code in the list is not read at the end, it will remains white.

# **Basic operations**

# Launching the Program

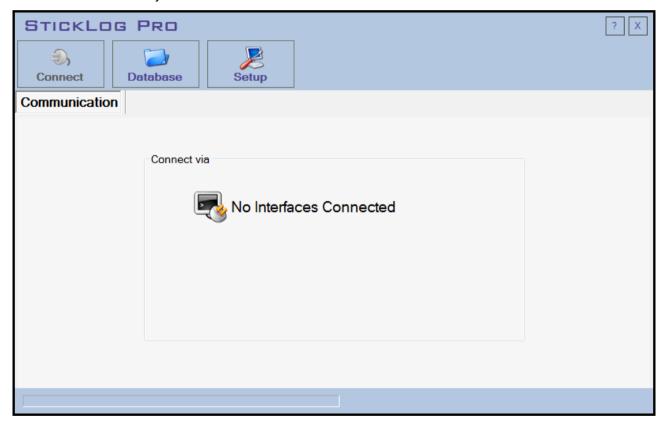
Once the installation is complete, double click on the **StickLog Pro** icon on the desktop to start the program, alternatively navigate to **Start – All Programs – Tecnosoft – StickLog Pro – StickLog Pro**.

#### The Main Window

The Main Window shows in the main area, called *Communication*, the interfaces connected, while above the functions buttons.

The blue bar below shows the progress of the programming and downloading operations

The Connect button may be disabled if there is no interface connected or selected.



# Online Help and Information

Click on ? on the top right corner to open the *Information* window with version number and software licence. Click on the logo to open the PDF manual. Browse the different chapters to know the program features in details.

# Program language change

To change the program language click on **Setup** and in the *General* tab select the proper language from the field on the left. Click on **Apply** or on **OK** to apply the changes. Close and restart the software.



# Configuration

The StickLog Pro doesn't require any particular configuration; you can start using it immediately. All the options and features that can be enabled in configuration allows a more simple and quick use of the software, and also more advanced analysis of the data.

Click on **Setup** to access the configuration window.

# Exit the program

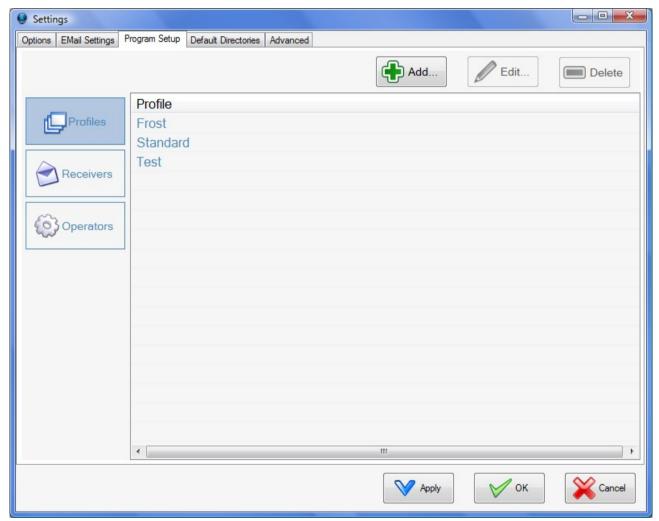
To exit the program just click on the **X** on the top right of the Main Window.

# **Profiles - Setup window Program Setup tab**

A Profile is defined as a set of pre-configured parameters that can be recalled when a mission is started on a logger. In this way, if we always use the same parameters (from acquisition step to start delay to temperature limits) we won't need to set them again every time.

Moreover, Profiles can be uploaded onto the SRI for TempStick programming.

To create new profiles, simply click on **Setup** and then select the tab *Program Setup*. You'll find on the left three buttons to access the three archives, above three buttons to manage them, in the centre space the list of items created for each archive.



For each profile and for each mission it is possible to identify a sender, a recipient and an operator, if it regards a transport. You can create two separate lists, for receivers and operators, from this tab.

#### Receivers

Create a list of possible recipients for your monitored shipments. Click on Receivers to access this list.

#### Adding a receiver

Click on **Add** to open the *Add...* window and type in the name of the receiver in the blank field. Click on **OK** to add the item.



#### Edit a receiver

To edit a receiver select it from the list and click on **Edit** or double click on it. After the changes click on **OK**. **Note:** editing a receiver will make it disappear from all profiles where it was selected.

#### Deleting a receiver

To delete a receiver select it from the list and click on **Delete**. You can delete multiple receivers by selecting them using CTRL and SHIFT keys on your keyboard.

Note: deleting a receiver will make it disappear from all profiles where it was selected.

### **Operators**

Create a list of operators that start the missions. Click on **Operators** to access this list.

#### Adding an operator

Click on **Add** to open the *Add...* window and type in the name of the operator in the blank field. Click on **OK** to confirm.



### Edit an operator

To edit an operator select it from the list and click on **Edit** or double click on it. After the changes click on **OK**. **Note:** editing an operator will make it disappear from all profiles where it was selected.

#### Delete an operator

To delete an operator select it from the list and click on **Delete**. You can delete multiple receivers by selecting them using CTRL and SHIFT keys on your keyboard.

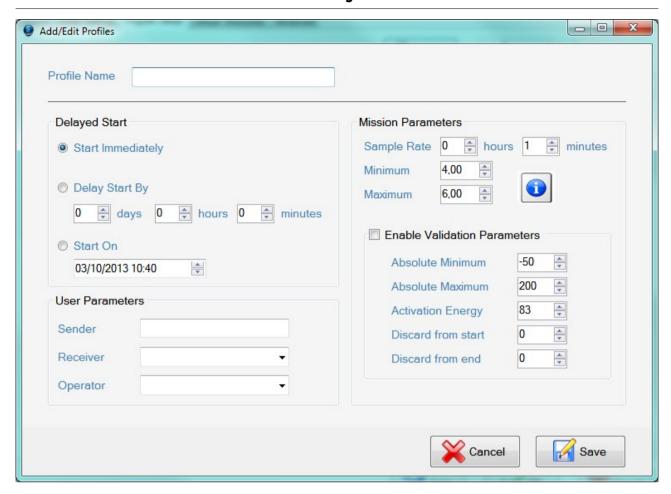
Note: deleting an operator will make it disappear from all profiles where it was selected.

#### **Profiles**

Create a list of profiles to be uploaded whenever you start a mission: all these parameters can be eventually changed before the mission is started. Click on **Profiles** to access this list.

#### Adding a profile

Click on **Add** to open the *Add/Edit Profiles* window and type the name of the profile in the *Profile Name* field. Fill in the other fields with the necessary parameters.



#### Set a start delay

In the *Delayed Start* box you can set a delay for the acquisition start from the programming time The options are 3:

- immediate start: select Start Immediately;
- start with delay: select *Delay Start By* and set the default delay, expressed in days, hours, minutes to start the acquisitions (maximum delay: 45 days, 12 hours and 15 minutes);
- start at a fixed time: select Start on and set the exact day and hour to start the acquisitions. If you set
  a past time the software will automatically set a delay of two minutes.

#### Set a Sender, Receiver and Operator

You can type in a sender for this profile and select a receiver and an operator from the created lists, or create new items directly in the fields here. In the *User Fields* box type in the *Sender* in the proper field, the *Receiver* in its field, or select it from the drop down list and the *Operator* in its field, or select it from the drop down list.

#### Set the acquisition rate

In the *Mission Parameters* box you can set the rate of acquisition in the *Sample Rate* field, in hours and minutes (minimum interval: 1 minute; maximum interval 4 hours and 15 minutes).

#### Set the temperature limits for analysis

In the *Mission Parameters* box you can set the standard *Maximum* and *Minimum* temperature limits, i.e. the correct conservation limits for your product, while in the *Enable Validation Parameters* box (to be enabled if you want to use them) the values for the validation criteria with which you might want to program each logger; the parameters are used partially for the MKT calculation and partially to make an automatic analysis of the MK itself by the software and the SRI.

The Validation Criteria uses both the standard limits and the values here set:

 Absolute Minimum and Absolute Maximum: minimum and maximum temperature that the curve mustn't never exceed, to be accepted. If those are exceeded once, the mission is considered failed;

- Activation Energy: a parameter used to calculate the MKT (p. 39). Each micro-organism has its own AE: if you need to monitor several of those, use the lowest value; if you don't know the exact value, just use the standard one (83,6);
- Discard from start / Discard from end: in minutes; to make a better analysis, you can discard some minutes at the curve extremes since they might give a false MKT result.

Note: to better understand MKT and these parameters, please refer to the chapter *Validation Criteria* at p. 38. In case of TempStick<sup>2</sup> the parameters are considered for the external sensor.

#### Edit a profile

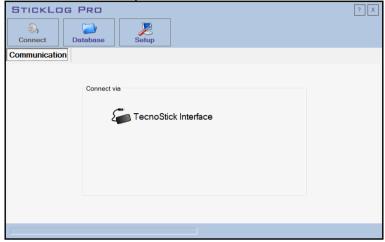
To edit a profile select it from the list and click on **Edit** or double click on it. After the changes click on **OK**.

#### Delete a profile

To delete a profile select it from the list and click on **Delete**. You can delete multiple receivers by selecting them using CTRL and SHIFT keys on your keyboard.

# Start a mission with the TecnoStick Interface

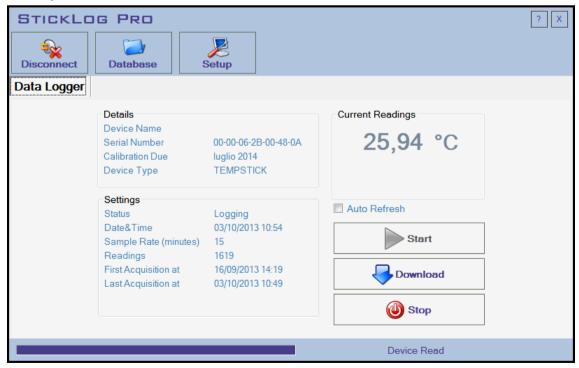
To start a mission using the TecnoStick Interface, be sure the interface is connected to the PC, that the drivers are correctly installed and that a TempStick or a HumiStick is inserted in the interface.



Select the interface from the *Communication* box in the main window and click on **Connect** or directly on **TecnoStick Interface**. In the main area the data of the device and the action buttons will appear.

# Data logger information

In the *Details* box you'll find the *Name* assigned to this logger, the *Serial Number*, the expiry date for calibration (*Calibration Due*) and the type of logger. If the calibration date flashes with red background it means it is expired.



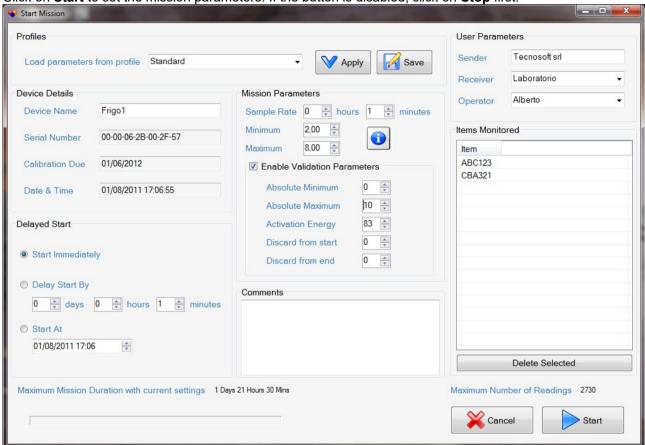
In the Settings box there are the current or last mission data. You'll see the Status which can be Stopped, In Acquisition or Waiting for delay if it has been programmed a delayed start. The time and date of the logger are shown: those are synchronized every time you program a new mission; then there is the programmed

Sample Rate, in minutes, together with the number of acquisitions (Readings). At the bottom there are the date and time of the first and last acquisition (First acquisition at e Last acquisition at).

In the *Current Readings* box there are the current values read from the logger. Enabling the *Auto Refresh* option this data, with some other details, will be updated automatically. During the refresh the buttons are disabled.

### Programming a mission

Click on Start to set the mission parameters. If the button is disabled, click on Stop first.



In the new window, *Start Mission*, you can upload a profile previously saved from the *Profiles* box; from the *Load parameters from profile* field select the chosen profile and click **Apply**. You can also manually set all parameters and then save a new profile, clicking on **Save**: type in the name of the new profile to add it to the list

In this window the boxes *Delayed Start*, *Mission Parameters* and *User Fields* are exactly like the ones in the profile creation window (p. 16).

After setting all necessary parameters click on **Start** to program the logger. The window will close and the logger *Status* will be *In Acquisition*. Click on **Disconnect** and remove it from the interface to place it in the monitoring spot.

Note: when a logger is started, the data in its memory are wiped out. Be sure you have saved important data before programming a new mission.

#### Give the logger a name

In the *Device Details* box set a name for the logger in the Name field. The other fields are not editable: the *Serial Number*, the *Calibration Due* date and the *Date & Time* of the logger.

#### Adding comments

In the *Comments* box you can add free notes, up to a certain limit. If you exceed this limit, the maximum number of readings will be lower and you can see it in the *Maximum Number of Readings* field.

#### Calculate mission duration

Mission duration is automatically calculated in the *Maximum Mission Duration with current settings* field, according to the *Maximum Number of Readings* available and the *Sample Rate*.

### Adding a list of monitored items

In the *Items Monitored* field you can create a list of monitored items, for example during a transport. This list is useful to track from the beginning to the end all the items monitored. In the *Item* field type in the name or the code of the items to be monitored and then press Enter to add item to the list.

#### Deleting items from the list

To delete one or more items from the list, select them and click on **Delete Selected**.

### Track monitored items at start using a bar code reader

You can track the items using a bar code reader too, if the items have a bar code. You'll need a bar code connected to the PC via USB or serial port and programmed to read the bar codes of your items; if you don't have it, you'll need to input them manually.

To test the reader, after installing the drivers, use the Windows Note Pad: try to read a bar code and if it appears, it works. Be sure the reader is set to go "a capo" (like pressing the Enter key) each time it makes a reading.

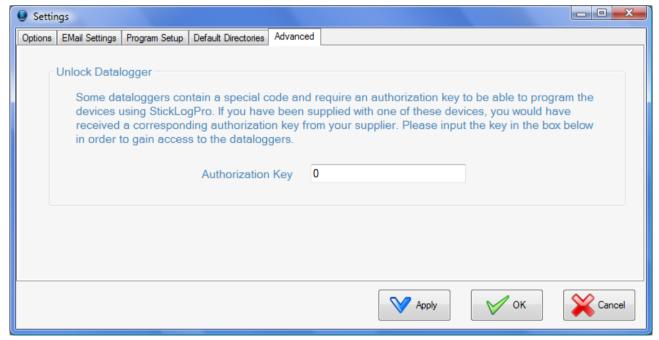
#### Insert the codes at start

Place the cursor in the Item field in the *Items Monitored* box. Read the first code that will be added to the list below. Keep reading the codes down to the last one. Even if the codes are all the same, you can use this function to track quantities.

### Start a logger with a particular code

Some loggers can be started only using a particular code. The loggers with a series of "0" (zero) or the code 62B at the centre of their serial number can be read without any code. The others, instead, will need this code to be inserted in the *Authorization Key* field in the *Advanced* tab in the *Setup* window. This code can be provided by Tecnosoft or the provider of the system.

This function can be used, for example, if you want to let a user to download data but not to reprogram the logger, erasing the data. If you want this function ask Tecnosoft to provide loggers with special serial number.



# Stand by function for TempSticks

If you start a TempStick without delay (so set to *Immediately* in the *Start Delay* field), you can put it in a stand by status using a metal clip on the reading strips, within a minute from programming. As soon as the clip is removed, the logger will start acquiring: putting on the clip again it won't go in the stand by status again.

Note: this function is available on TempStick and TempStick Probe only.





# Mission download with TecnoStick Interface and data analysis

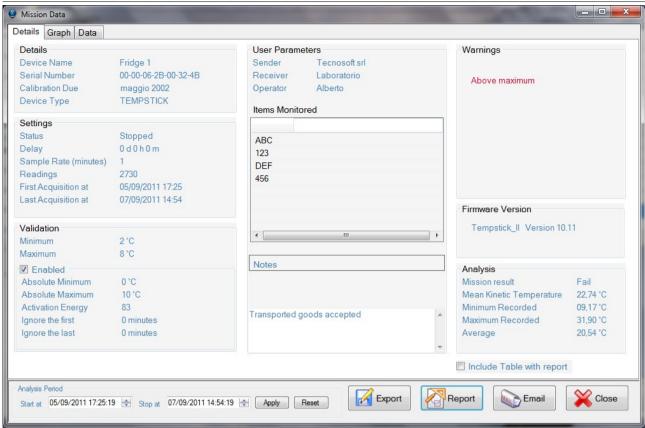
To download the data with a TecnoStick Interface be sure that the interface is connected, the drivers installed and that a TempStick is inserted in it. Select the interface from the *Communication* box in the main window and click on **Connect** or directly on **TecnoStick Interface**. In the main area the data of the device and the action buttons will appear.

Click on **Download** to start downloading data. It is possible to download missions that have at least one data, so not the ones waiting to start after a delay has been set.

Note: once downloaded, the data are automatically saved in the *Database* of the program.

# Data analysis - Details

After the download is complete the *Mission Data* window will open: here you can see all data and parameters of the mission.



#### Mission details

In the *Details* tab it is possible to see the settings used to start the mission and the results of the analysis based on the Validation Criteria (if enabled).

In the *Details* box you'll see the *Name* assigned to it, the *Serial Number*, the expiration date of the calibration (*Calibration Due*) and the type of logger. If the calibration date flashes with red background it means it is expired.

In the Settings box there are the mission data. You'll see the Status which can be Stopped or In Acquisition and also if a Delay has been programmed. The time and date of the logger are shown: those are synchronized every time you program a new mission; then there is the programmed Sample Rate, in minutes, together with the number of acquisitions (Readings). At the bottom there are the date and time of the first and last acquisition (First acquisition at e Last acquisition at).

#### Analysis through the limits

In the *Validation* box there are the limits for analysis, from the correct conservation limits (*Minimum* and *Maximum*) to the ones for the *Validation Criteria*, that can be *Enabled* or not. In the *Analysis* box there are some information from the acquired data:

- Mission Result: it shows if the recorded data are within the criteria set at the beginning. A mission is Failed when: an acquisition is out of the absolute limits; MKT is out of standard limits;
- Temperature Statistics
- Mean Kinetic Temperature: calculated MKT;
- Minimum Recorded: minimum recorded temperature;
- Maximum Recorded: maximum recorded temperature;
- Average: temperature average;
- Humidity Statistics (for HumiStick only);
- Minimum: minimum recorded humidity;
- Maximum: maximum recorded humidity;
- Average: humidity average.

In the Warnings box there is the comment regarding the mission based on the criteria.

#### Additional data and list of monitored items, also using a bar code reader

In the centre boxes the list of items and optional comments are shown. At the top there are the *User Parameters*, i.e. *Sender, Receiver* and *Operator*, at the centre the *Items Monitored*, i.e. the list of objects/sites created at the beginning, while at the bottom there are the *Notes*: you can read startin notes and type in new ones. It is possible to check the *Items* manually or with a bar code reader. Read a new code or type it in and press Enter: if the code is in the list, it will become green, if there isn't it will be added in red. If a code remains white, it means it was not received. If you have many identical codes, use this function to track quantities.

### Graph

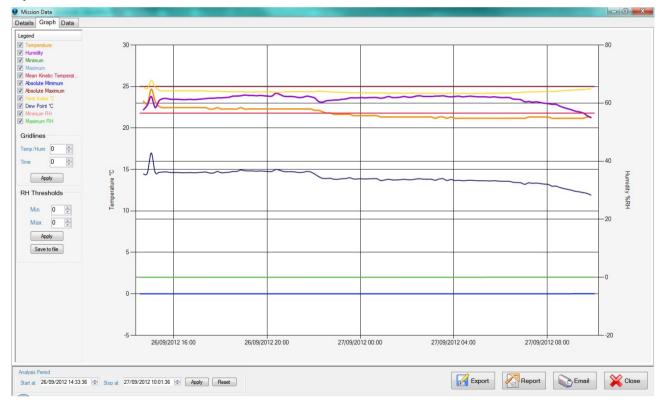
Selecting the *Graph* tab the curves of the data will be shown. In the main area there is the graph with the values and the limits and the calculated MKT. Vertically are shown the temperature or humidity values, horizontally there is the time line. On the left there is the temperature scale, on the right the humidity scale. This is the list of the available curves/lines:

- Temperature
- Humidity
- Minimum
- Maximum
- MKT
- Absolute Minimum
- Absolute Maximum
- Heat Index °C
- Dew Point °C
- Minimum RH
- Maximum RH

#### Setting Minimum and Maximum for humidity

If you have also humidity data, you can set also a minimum and maximum to show two lines on the graph. In the box *RH Thresholds* set in the proper field the value in % for both lines and then click on **Apply** to see them on the graph.

If you want to save these thresholds in the mission saved on the archive, click on Save to file.



#### Zoom function

To zoom an area of the graph select it by clicking in a spot, keep the mouse button pressed, drag the mouse to create a box to include the desired are and then release the button. You can apply different zoom levels. When a report is printed, all data will be printed regardless the zoom selected.

#### Unzoom

To go back to the normal graph, click **Reset**.

#### Gridlines

You change the grid of the graph on the left by indicating a value for the horizontal lines (*Temp/Humi*: set the interval for a vertical line, in °C; *Time*: set the interval for the vertical lines, in minutes). At the end click **Apply**.

Selecting a time range for the analysis

It is possible to select a time range to display and analyse the data. In the bottom box *Analysis Period* select in the first field, *Start at*, starting date and time for the analysis and in the second one, *Stop at*, select ending date and time. Click on **Apply** to zoom in the time range selected and on **Reset** to disable it. This selection will affect also the data shown in the table (p. 25).

The legend and the selection of the graph curves

On the left there is the legend. You can select and deselect all the curves by clicking on the small box on their left. Graph will be displayed accordingly. If you don't see any curve check that at least one is enabled.

#### The table - Data

Clicking on the *Data* tab you'll see the data table with a progressive number for each acquisition, date and time and the values.

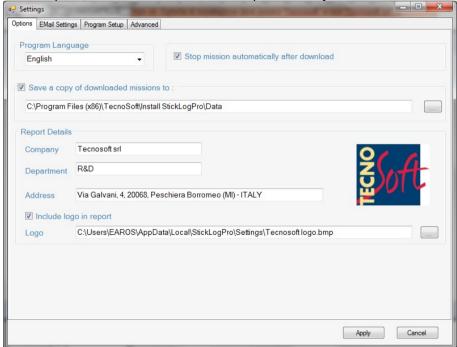
If you think there aren't all acquired data, check that a time range is not enabled and click on **Reset**. Data exceeding maximum limit are in red, the ones below minimum in blue (only for temperature).

#### Export the data table into Excel

To export the data table in excel format click in **Export**. A window where to choose the destination path and file name will open.

# Saving data in a backup folder

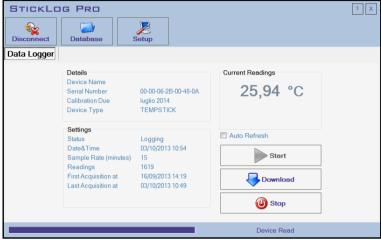
You can choose to automatically save the downloaded data also in a backup folder and not only in the default one (p. 37). Click on **Setup** in the main window and, from the *Options* tab, check the *Save a copy of downloaded mission to* option; in the field below select the path where you want to save this copy.



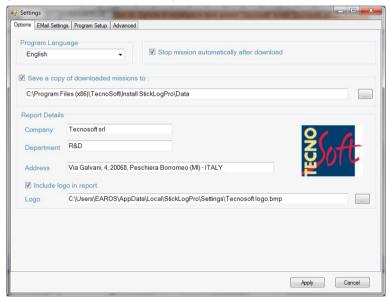
# **Stopping a mission**

The first are in to slight on Star when the learner is connected.

The first one is to click on **Stop** when the logger is connected.



The second one is to enable the option *Stop mission automatically after download* in the *Options* tab of the *Settings* window (**Setup** button in the main window).



# **Report printing**

To print a mission report you need to open it from the **Database** (p. 28) or download it directly from the logger (p. 22).

Click on the **Report** button in the *Mission data* window to open the print preview window. he report is made up by a header, the parameters and statistics, the graph and, optionally, the data table.

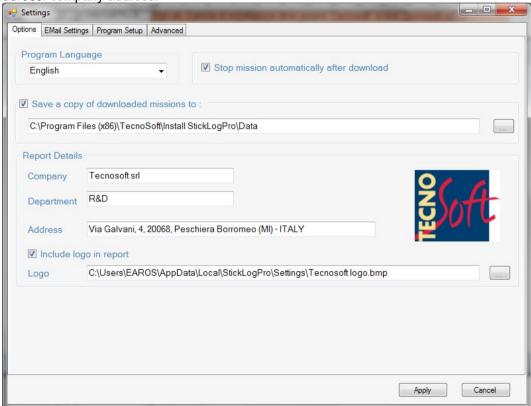
### Printing the data table

To include the data table in the report select the option *Include Table with report* in the *Mission data* window.

### Report customization

You can customize the header of the report. Open the *Settings* window (**Setup** button from the main window) and in the *Options* window fill the following fields in the *Report Details* box:

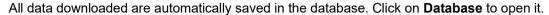
- Company: the name of the company;
- Department: name of department or area, if available;
- Address: company address.

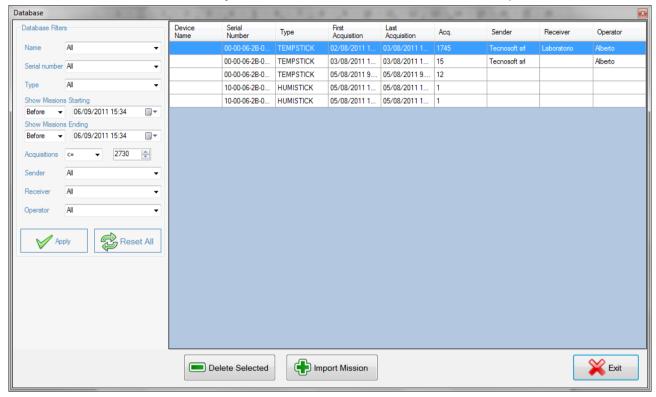


#### Printing a logo in the header

You can add the company logo to the header. Enable the option *Include logo in report* and set the path of the logo in the field below. Be sure it has the correct format.

# **Database**





In the main part there is the list of missions. Clicking on the titles of the columns you can sort them.

# Using the filters to find a mission - Database Filters

You can use filters to display the missions. On the left, in the *Database Filters* box, you can search for missions using:

- Name: name of the logger, if used, by selecting it from the drop down list;
- Serial number;
- Type: data logger kind;
- time range, selecting missions started in a certain date (Show Mission Starting) and ended before another date (Show Missions Ending);
- Acquisitions: number of maximum acquisitions;
- Receiver;
- Operator.

Click Apply to set the filters or Reset All to disable them.

# Deleting a mission

To delete a mission, select it and then click on **Delete Selected**. You can also delete multiple missions.

# Import a mission

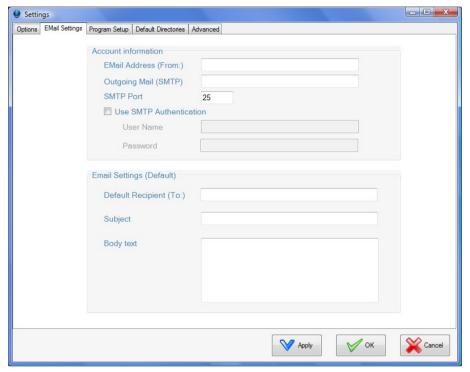
You can import a mission (XML file) that you might have received by email or a backed up mission, by clicking on **Import Mission**: select the path and the file to open itz.

# Send data via email

To be able to send data via email, set the account parameters in the configuration window. Data sent can be imported in the database.

# Configuration of the email account parameters

Click on **Setup** and open the *Email Settings* tab. You have to set the parameters for email account to be used to send the data of the missions.



In the Account Information box the parameters to set are the following:

- Email Address (From): the sender account;
- Outgoing Mail (SMTP): the outgoing server;
- SMTP Port: server port;
- Use SMTP Authentication: enable this if it is necessary to use password to send emails;
- User Name (only if Use SMTP Authentication is enabled): login for the email account;
- Password (only if Use SMTP Authentication is enabled): password for the email account.

In the *Email Settings (Default)* box the parameters are the following:

- Default Recipient (To): default email address for recipient;
- Subject;
- Body Text.

#### Send the data

After downloading a logger (p. 22) or having opened a mission from the archive (p. 28) click **Email**, to open the *Change Email Settings* window. Here there are the parameters set for the email account and that can still be changed. Filled all necessary fields, click on **Send Email** to send data your recipient.

# Import received data

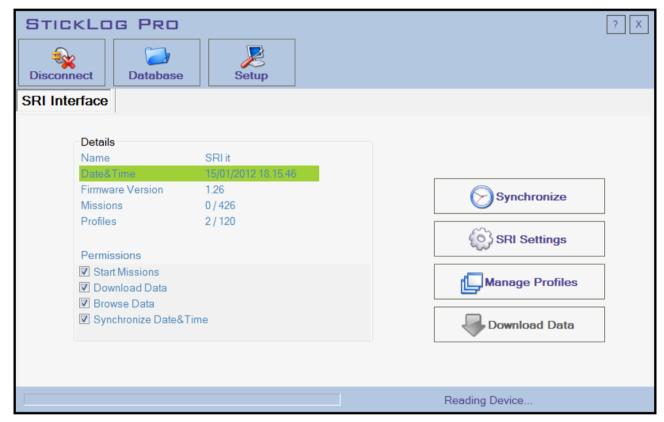
Read here on how to import data (p. 28).

### The SRI

The SRI is a portable device that works with replaceable batteries and that can program TempStick and TempStick Probe and download their data, saving them in its memory, without the use of a PC. In a second time, you can import all data from the SRI to the software. SRI can save up to 300 full missions (2730 acquisitions). SRI must first be programmed, with profiles (p. 16) in its memory; with those it is possible to start the TempSticks. When data are downloaded, it immediately calculates the MKT (p. 39) and gives a result of the mission.

Connect the SRI to the USB cable connected to the PC and be sure that drivers have been installed as shown before (p. 11). In the main window, in the *Connection* box, SRI will appear.

Click on **Connect**. Its information will be shown and all the function buttons.



#### Information on the SRI - Details

In the *Details* box you'll find the name of the SRI (*Name*), its *Date&Time* (if green, it is synchronized, if not is red), *Firmware Version*, number of saved *Missions* and the number of *Profiles* loaded.

Under *Permissions* there are the four functions of the SRI: the checking mark means they are enabled on this device.

- Start Missions: SRI can start loggers.
- Download Data: SRI can download data (it cannot stop acquisitions).
- Browse Data: downloaded missions can be browsed and reviewed.
- Synchronize Date&Time: manual setting of the clock enabled.

# **Clock synchronization**

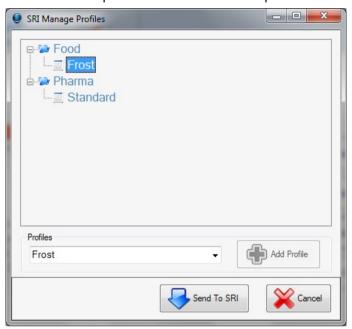
To synchronize the clock between SRI and PC, click on **Synchronize**.

# **Configuring the SRI**

Click on **SRI Settings** to open the panel for configuration. In the *Unit Name* field type in a name for the SRI while below enable or disable functions for the SRI itself (*Permit the user to*). For each function, see above, *Information on the SRI – Details*. Click on **Apply** to confirm.

# Managing profiles on the SRI

Click on **Manage Profiles** to open the window for profiles uploading to the SRI. In the main area there are the profiles currently uploaded while in the drop down list the list of all the profiles available.



#### Adding a profile

Select a profile and click on Add Profile.

#### Deleting a profile

Right on the profile to delete and select Delete Profile.

#### Creating folders for the profiles

You can create a tree view for the profiles, with two levels of folders. Right click in the main area and select **Create Folder**. In the new window type in the name of the folder and click on **OK**. If you want to create a sub folder, right click the main folder and proceed in the same way.

#### Deleting a folder

Right click on the folder to delete and click on Delete Folder. The profiles in it will be removed from the SRI.

#### Uploading profiles to the SRI

To upload the profiles and the folders to the SRI, click on **Send to SRI**.

# Connecting the data logger to the interface

To connect a *TempStick* data logger to a *SRI*, simply insert the flat end of the data logger in the appropriate slot (next to the USB connector) on the interface. The direction in which you insert the data logger is irrelevant. Once you have completed the setup or download operations, remove the data logger from the slot.



# Replacing the batteries

To replace the batteries, open the battery cover at the back of the interface by pressing on the arrow and sliding the door in the direction indicated by the arrow. Remove the existing batteries and replace them, taking care to use the correct polarity. Replace the cover. You will have to set the date and time on the unit again.



# Using the SRI

The Starter&Reader Interface is equipped with a display, three LEDs and 6 keys. The display shows information upon the device status or that of the mission being analysed, the graph or table of readings and the menu's for the unit functions. The green LED is activated, along with the buzzer, when a device has been correctly programmed. The red LED becomes active if a communication error occurs of if the batteries are low. In the latter case replace the batteries immediately.

The keys are used to browse the menu's (four direction keys), to select menu entries (**OK** button) or to abort operations or exit screens (**ESC** button).

Below is a detailed explanation of the various *SRI* functions. The images shown are for an *SRI* configured in the *Programmer/Reader* mode. If your *SRI* is not in this mode some features shown will not be available.

#### Setting the Date and Time

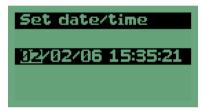
After replacing the batteries, you must set the time on the unit. The following window will appear:



Click **OK** to open the next window where the date and time are to be set. To change the date and time at any stage, with the display off click **OK** and in the following window select *Clock* and click **OK**.



In the *Date and Time* window, use the left and right keys to select the different parts of the date and time, the up and down keys to change the selected numbers and the **OK** button to enter the changes.



Click **OK** to confirm the change. Press **ESC** to exit the screen.

Starting a Mission (only for *Programmer mode*)

Insert the TempStick in the unit: the unit will detect this action and bring up the programming window. If this does not appear, remove and re-insert the data logger.

N.B: if the *SRI* is programmed as a simple *Programmer*, once the TempStick is inserted, the window where you may select the profile to be used will appear first.



The *Start* entry is already selected, however if this is not the case use the directional arrows to select it (see picture) and then press **OK**. A list of available profiles will appear and you may select one of these to be used to program the data logger. If there are no profiles available the *No Programs* message will appear. Use the directional arrows to select the profile and press **OK**.



The programming procedure will begin, this takes a few seconds after which a program success message will appear, along with the green LED and the beeper.



You may now remove the data logger and program another one.

Downloading data from a TempStick (Only for Reader mode)

Insert the TempStick in the unit and select the entry Read. The SRI will start downloading data from the device.

N.B: if the *SRI* is configured as a simple *Reader* only, once the TempStick is inserted the download of data will automatically begin.

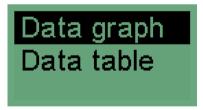


Once the data is downloaded, a window that evaluates the transport will appear. The centre of the screen will show the message *BAD* if the transport conditions where not optimal, alternatively *OK* will appear. In the former case the reason for the rejected transport will appear below the message (If there is more than one reason, the most significant reason will be shown) The data downloaded is automatically saved in the unit memory.



Click on **OK** to view some information relating to the mission, as well as the data that has been downloaded. There are four menu items: *Statistics*, *Information*, *Graph*, *Table*.





#### Statistics Window

This window will show the most important parameters of the profile with which the device has been programmed. You may scroll the window up and down using the directional keys.



The parameters show are:

- MKT: MKT calculated;
- Maximum Threshold: Maximum limit for correct conservation;
- Minimum Threshold: minimum limit for correct conservation;

- · Abs. Max Threshold: Absolute maximum limit that cannot be surpassed;
- Abs. Min Threshold: Absolute minimum limit that cannot be surpassed;
- Discard Start: minutes to be excluded from the start of the mission for score calculation;
- Discard End: minutes to be excluded from the end of the mission for score calculation;
- Activation energy: the AE set.

To exit the window press **ESC**.

#### Information Window

These entries are used to identify the mission being shown, based upon the data inserted when the mission was started.



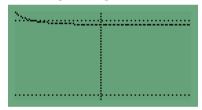
The information shown is:

- Sender: the firm that sends the items being monitored
- Address: the receiver of the goods
- Operator: the operator that started the mission
- · Notes: additional information
- Objects: objects or sites monitored

To exit the window press ESC.

#### **Graph Window**

This windows holds a simple but effective graphical representation of the data downloaded. The temperature thresholds are also shown to aid the analysis. You may zoom into the graph using the up and down buttons. Once the zoom is set, you may scroll left and right using the directional keys.



To exit the window press ESC.

#### **Table Window**

This window holds a table of all the data points taken by the data logger. The table holds the date and time and the corresponding temperature value. Use the up and down keys to scroll within the table. The black lines indicate a new day has started and the date is shown within the line.



To exit the window press ESC.

#### Viewing data off saved missions

In order to view the data stored in the *SRI*, you must first ensure that there is no data logger connected to the unit. Select the *Review* entry (press **ESC** to exit windows if you are not in the main menu; if the *SRI* is off, press **OK** and then select **Review**). A window will appear holding a list of saved missions identified by means of the date, time, serial number and other entries (*Sender* etc...).



To view all the parameters, select the required entry and use the left and right keys to scroll. Once you choose the mission, press **OK** to open the viewing page (p. 34).

### Turning the SRI off

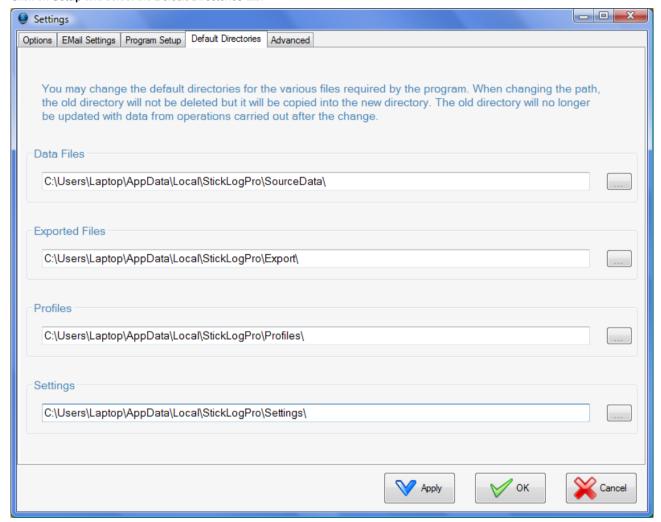
To switch off the *SRI*, press **ESC** until you have exited all the menus, and then press **ESC** again to turn the unit off.

# Resetting the device

The reset button is located at the back of the unit, and is only accessible once the battery cover is removed (p. 32). Using a thin object (such as a paper-clip) press the button that is located underneath the slot in the battery compartment. The device will be reset, however the items in memory are not deleted.

# **Setting up folders database - Default Directories**

With StickLog Pro you can share your missions data and other configuration files with other user in your network or you can simply choose where to save your data rather than use default folders. Click on **Setup** and select the *Default Directories* tab.



There are four folders you can set. If you choose a shared folder, accessible by everyone, all users will see the same data.

# Choosing missions folder - Data Files

Type in or select the folder where to save all missions files in the Data Files field.

# Choosing export data folder - Export Files

Type in or select the folder where to save all Excel exported files in the Export Files field.

# Choosing profiles folder - Profiles

Type in or select the folder where to save all profiles in the *Profiles* field.

# Choosing settings folder - Settings

Type in or select the folder where to save all settings and options in the Settings field.

# **The Validation Criteria**

The *Validation Criteria* have been developed to provide the quality manager with a versatile tool that will automatically determine whether a specific product, that requires constant temperature control, has been shipped or stored correctly. The *Validation Criteria* provide for specific parameters and a simple algorithm (the MKT formula) that the software will use to determine whether a shipment or storage was detrimental to the product quality.

These parameters are derived from international reference standards: NCCLS H18-A3 Vo. 24 No. 38 "PROCEDURE FOR THE HANDLING AND PROCESSING OF BLOOD SPECIMENS"; Approved Guideline - 3<sup>rd</sup> Edition" and NCCLS GP16-A2 Vol. 21 No. 19 "URINALYSIS AND COLLECTION TRANSPORTATION, AND PRSERVATION OF URINE SPECIMENS"; Approved Guideline - 2<sup>nd</sup> Edition.

These parameters would then be set by the user according to the product being monitored.

# The temperature thresholds

StickLog Pro allows for four different temperature limits. The first two are the correct conservation temperature limits (max. and min.). Normally, these thresholds are very rigid, even if the product exhibits a degree of tolerance to higher or lower temperatures. The absolute min. and max. thresholds, on the other hand, are limits to which a product should never be subjected, otherwise the transport and the product itself will be refused since its integrity cannot be guaranteed. These latter limits normally cover a wider range than the first two, which allows for a tolerance margin.

### The transport graph

A typical product conservation graph is divided in three parts:

- Initial transitory: the time from when the mission has started to when it is actually monitoring a transport or storage of the product
- · Transport or storage
- · Final transitory, from the end of the mission to the moment data is downloaded

When analysing the graph we can nearly always discard the first and final part and use the central part of the mission to evaluate the transport.

For automatic analysis of the acquisitions it is necessary to exclude the two transitory periods. Knowledge of the process and procedures relating to the use of Tempstick within the company, it is usually quite easy to predict the duration of these transitory periods. For example, if we do not set a delay when programming a new mission, and we know that after a device is programmed it takes around 20 minutes until it is placed in the area to be monitored (for example the TempStick is put in the product's box, the box is put on the truck, etc.), the initial transitory can be set to 30-40 minutes. In this way we can be almost sure that all those acquisitions that are not related to the actual monitoring of the products will be excluded.

The final transitory duration can be determined in a similar manner.

# The activation energy

Activation energy of a given substance or product is a value that, when is reached, starts a given process. Usually it is a value between 60 and 100: it is recommended a standard value of 83.

# How to set the other mission parameters

The only other parameters related to the validation criteria are the delay and the acquisition interval.

The program calculates the scores starting from the first acquisition, and not from the time the device has been programmed. The delay period is therefore automatically ignored.

Since the data logger takes readings depending upon the value of the acquisition interval, it assumes a worst case condition and extends the duration of a recorded temperature for the duration of the whole interval until the next sample is taken. If, for example, we consider the product used in the examples above, if a sample taken at a certain time read 28 degrees, and the next sample, taken after 20 minutes, reads 4 degrees Celsius, the program will assume that the product was at 28 degrees for 20 minutes. It is most probable that it wasn't, however it has no means of knowing the value of samples in between readings and will therefore assume the worst case scenario.

### **MEAN KINETIC TEMPERATURE**

Mean kinetic temperature (MKT) is defined by the ICH as "A single derived temperature that, if maintained over a defined period of time, affords the same thermal challenge to a drug substance or drug product as would be experienced over a range of both higher and lower temperatures for an equivalent defined period. The mean kinetic temperature is higher than the arithmetic mean temperature and takes into account the Arrhenius equation."

Hence, the mean kinetic temperature may be considered as an isothermal storage temperature that simulates the non-isothermal effects of storage temperature variation. It is not a simple arithmetic mean but involves exponential and logarithmic relationships.

The Haynes formula can be used to calculate the MKT. It is higher than the arithmetic mean and takes into account the Arrhenius equation from which Haynes derived his formula. Thus, MKT is the single calculated temperature that stimulates the non-isothermal effects of storage temperature variations.

$$T_{k} = \frac{\Delta H/R}{-\ln \frac{e^{\frac{-\Delta H}{RT_{1}}} + e^{\frac{-\Delta H}{RT_{2}}} + \dots + e^{\frac{-\Delta H}{RT_{n}}}}{n}}$$

Tk = MKT in °K

 $\Delta H$  = Heat of activation / activation energy

R = Universal gas constant (8.3144 10-3 kJ.Mole-1 °K-1)

T<sub>i</sub> = temperature in °K

n = Total number of equal time periods over which data are collected

Mean kinetic temperature refers to a reference point, which can be calculated from a series of temperatures. It differs from other means in that higher temperatures are given greater weight in computing the average. This weighting is determined by a geometric transformation, the natural logarithm of the temperature number. Disproportionate weighting of higher temperatures in a temperature series according to the MKT recognises the accelerated rate of thermal degradation of materials at these higher temperatures. MKT accommodates this non-linear effect of temperature.

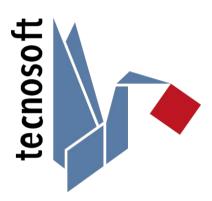
It is calculated from the average storage temperatures recorded over a time period and a running average calculated from the average of weekly high and low temperatures.

In order for MKT to be meaningful in anyway, an appropriate number of temperature / time sampling points should be used. MKT may only be applied in situations where temperature control of the storage area is good, but where occasional excursions do occur due to seasonal variation.

MKT may only be applied in cases where the scientific data regarding the thermal stability of the product in question, used to establish the original labelled storage conditions, permits limited excursions between 25°C to 30°C. The MA holder should be consulted as to whether these excursions affect the thermal stability of the products in question and hence whether or not the use of MKT is applicable.

Strict conditions should be applied to the use of MKT i.e.:

- It is only applicable to storage of products under controlled room temperature conditions (e.g. Those labelled "Do not store above 25°C")
- MKT is not appropriate for use for products requiring controlled low temperature storage.
- MKT cannot be used to compensate for poor temperature control of storage facilities due to e.g. poor design
- Excursions outside labelled storage requirements for products should be documented and investigated and reported to the MA holder
- Actual storage temperatures should not exceed 30°C at any point if MKT is to be applied. i.e. for an MKT of 25°C excursions between 15°C and 30°C are permitted.



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