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WE DELIVER DATA

TSLog21

User's Manual

Date 23/05/2019

Syrinx **System**
and TSLog21 management software
compatible with FDA 21 CFR Part 11 and GAMP 5

Software Version 1.0.0.0

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Introduction

TSLog21 is a data acquisition system based on wireless sensors.
The system has been developed to facilitate temperature and humidity monitoring of any environment: in different fields of application: pharmaceutical, medical, healthcare, food&beverages. The different sensors can cover monitoring of rooms, fridges, freezers, fridge cells, incubators, ovens, sterilised rooms and many more,
Note that for simplicity, throughout the user manual and any other documentation, fridges, freezers, rooms or any other ambient are referred to as a Monitoring Spot.

The devices based upon the ZED radio modules that can accept up to two sensors each. These are intelligent sensors, for a quick and easy recalibration: just replace the expiring sensor with a new calibrated one and the system will recognize it and will be automatically calibrated, updating the dates.

Intelligent sensors can be of temperature only or temperature and humidity. It is possible to buy ZED radio modules and chose any type of Intelligent sensor: if you chose to have just one sensor on your ZED you can add another sensor later, of another type also.

ZEDs transmit via radio data from the sensors to receivers called EAPL (Ethernet Access Point Lite) connected to the network; these send data to a collector called Syrinx. Data are shown on the FridgeLog Z software installed on one or more PCs.

Note: present manual describes operations on the TSLog21 software. It is not intended for installation and configuration of the system.

N.B.: the software must be installed and run for the first time by the Administrator, who will then create and assign permissions to the other users (see p. 29).

Definitions

Definition	Description
TSLog21 Software Suite Setup	The Installation files provided for installation of all software components needed to properly run TSLog21 program and Syrinx programs.
TSLog21 Program	Main program to handle operation (data view, settings configuration).
TsLog21 Manuals	PDF document containing information about the use of TSLog21 program (also called user's manual).
Hardware protection key	USB dongle for software license protection.
ZED Radio Node	Radio module to which up to two sensors of different type can be connected.
Intelligent Sensors	Pre calibrated sensors of temperature and temperature/humidity that must be connected to the ZEDs.
Cable extensions	Extensions that canbe used between ZED and sensors to extended their distance from the radio module and to monitor different locations.
EAPL	Gateway module that receives data from the ZED.
Syrinx	Data collector that receives data from the EAPLS via the local network.
EAPL power supply	Power supply for EAPL (included with the EAPL)..
Syrinx power supply	Power supply for Syrinx (included with the Syrinx).
Network cable	Ethernet cable for EAPL and Syrinx (included with the EAPL and the Syrinx).
USB modem	USB modem to connect to the Syrinx to get SMS alarms (SIM not included).
Group	A set of monitoring points defined in the software ideally all located in the same area.
Sensor	A monitoring point defined in the software where a physical sensor is actually placed.
Profiles	A profile is a set of parameters that define ways of analyzing data in a Sensor.
Users	A user is associated to a person who can execute selected actions based on his authorization level.
Workstations	A station is a computer running TSLog21.
Customer	A customer identifies a company or a person requesting the user intervention.
Monitoring point	A place where the measurements are needed.
Audit trail	Is a full list of executed software tasks.

Items
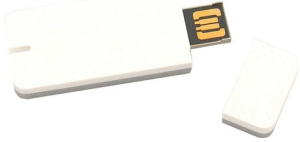
Image	Component
	ZED
	Temperature Intelligent Sensor
	Temperature Intelligent Sensor Thin Cable
	Temperature Intelligent Sensor 200

Image	Component
	Temperature Intelligent Sensor -80
	Temperature&Humidity Intelligent Sensor
	Hygroclip Intelligent Sensor
	Cable extension (different lengths)
	EAPL (with power supply and Ethernet cable)
	Syrinx (with power supply and Ethernet cable)

Image	Component
	USB modem
	Hardware protection key
	System Configuration Document

System Requirements

Hardware

Description	Minimum	Recommended
Processor	Core i3	Core i5
RAM	4 GB	8 GB
Display Resolution	1024x768	HD
HD free space	2 GB	3 GB
Free USB ports	1	1
Ethernet Connection		

Software

Description	Supported
Operating System	Windows 7 / 10 (32, 64 bit)

Main Functions

Premises

The following instructions are intended for a system already installed and configured, where users have already been created by an Administrator. For first start and main configuration, refer to the Administrator Manual at page 29.

Launching the Program

To launch the program double click the **TSLog21** icon on the desktop. Once the program is launched you will be presented with the login window: select your user name from the list in the *User* field and enter the corresponding password in the field below. Click on **Login** to proceed or **Quit** to close.
To start the software the USB hardware protection key must be connected to the PC.

Login Window

The top part of this page displays the software version. Towards the middle the User and Password fields are displayed. Once the software is launched a particular user may be selected from the *User* field and the corresponding password may be entered in the *Password* field. To access the program click on the **Login** button. Clicking on **Exit** will close the program.

If a user is already logged on, the *User* field will display the User name and the **Login** button is changed to **Logout**.

The Main Window

The *main window* will appear subdivided into a number of areas. The centre of the window displays the contents of the page that is currently selected: the pages (number of displayed pages depends upon the permissions of the user currently logged on) are selected by clicking on the tabs at the top of the program

window. The *Login, Data and View* tabs are available to all user types. An *Advanced* user may also access the *Archive* tab whilst the *Setup* tab is only available to users with *Administrator* permissions (see the section *Administrator* for more details).
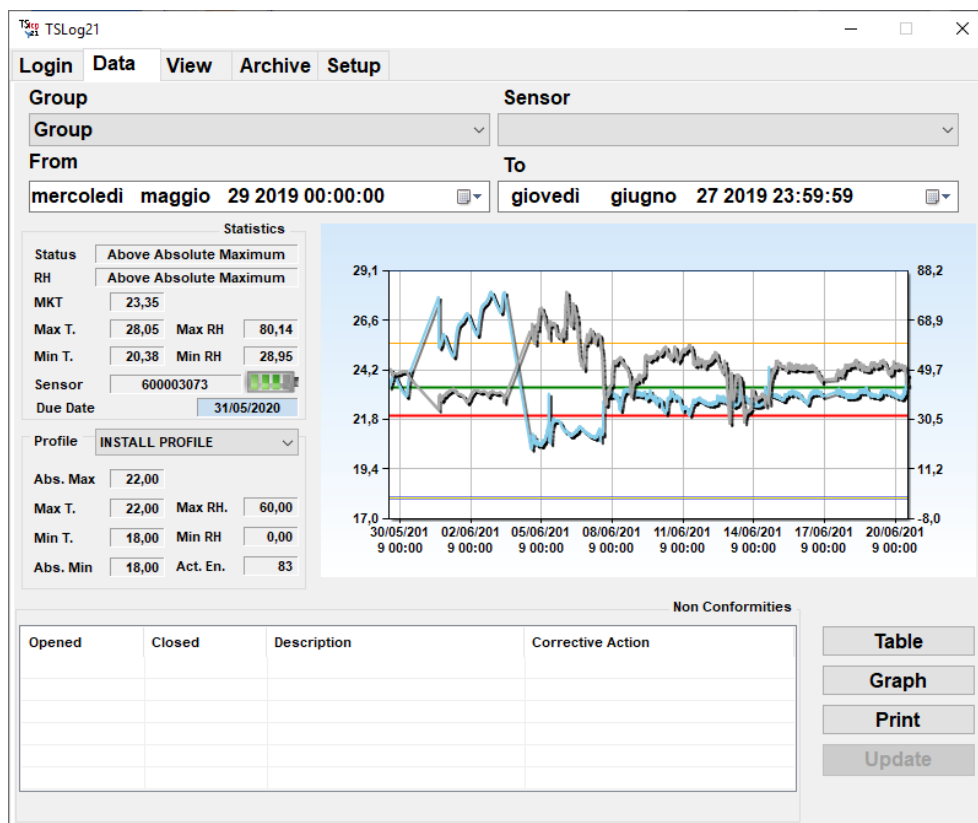
Closing the program

To close the program click on the **Exit** button in the *Login page*.

Data Analysis

Select *Data* tab to access the readings that have been stored on the PC, classified by *Group* and *Sensors*.

Selecting the data to be displayed

First of all one must select the *Group* and *Sensor* whose data will be displayed (you can customize Group and Sensor labels, refer to page 31). This tab will show all the data pertaining to the particular monitoring spot, starting from the first time a sensor has been assigned to that position.

Selecting the time window

Towards the top part of the tab you will find a date/time filter which enables you to select the date and time of the first and last samples to be shown in the graph and table of readings. The data displayed will be matched as closely as possible to the selected range; for example if you select 1st June as a starting date but the software only holds readings starting from the 5th June, the display will show data starting from the 5th June.

Statistics

Additional statistical information will be displayed adjacent to the graph/table. These are:
– *Status*: this field will display a result for the temperature generated according to the parameters set in the *Profile* currently set for that particular data logger (see p. 14);
– *RH*: this field will display a result for the humidity generated according to the parameters set in the *Profile* currently set for that particular data logger (see p. 14). It will be displayed only if humidity has been enabled (RH stands for Relative Humidity);
– *MKT*: the Mean Kinetic Temperature (see p.34), this is a single derived temperature that represents the equivalent effect of the temperature variations during storage; if this is within the thresholds for correct conservation the storage profile is accepted;
– *Max T.*: the highest temperature recorded;
– *Min T.*: the lowest temperature recorded;
– *Max RH.*: the highest humidity recorded;
– *Min RH.*: the lowest humidity recorded;
– *Sensor:* the serial number of the most recent sensor assigned to this *Fridge*;
– Battery status: only for wireless sensor a four state battery charge is displayed;
– *Due date:* the date at which the sensor is due for recalibration.

Profile

This section displays the settings in the profile with which the data logger was programmed when this data was downloaded. From the drop down list you may select from a list of *Profiles* used in the chosen time window. The parameters that determine the quality of the storage profile will change according to the selected *Profile*, and therefore the limits in the graph as well as the *Status* message in the *Statistics* area may change. The profile parameters are (see p. 33):
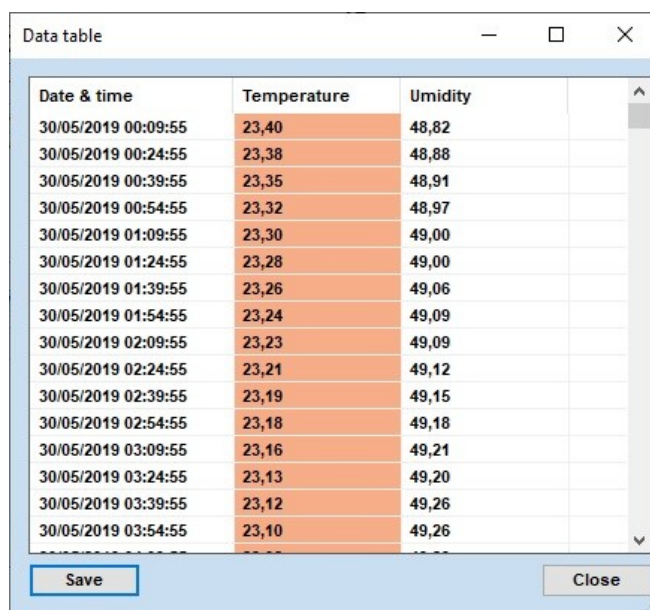– *Abs. Max.*: absolute maximum threshold (above this the entire storage is unacceptable);
– *Max T.*: maximum temperature threshold for correct conservation;
– *Min T.*: minimum temperature threshold for correct conservation;
– *Abs. Min.*: absolute minimum threshold (below this the entire storage is unacceptable);
– *Max RH.*: maximum humidity threshold for correct conservation.
– *Min RH*: minimum humidity threshold for correct conservation.
– *Act. En.*: The activation energy used for the MKT calculation

The middle part of the page shows a preview of the graph that gives an immediate general idea of how the storage temperature varied. At the bottom left of the page you will find these buttons (if no data is displayed all buttons will be disabled): **Table, Graph, Print, Update** (Update and View may be not enabled or not visible). At the bottom left you will see a list of non-conformities (if any) that have been raised due to events within the selected time window. The list displays:
– *Opened*: the date and time to which the NC refers;
– *Closed*: the date on which the NC was solved;
– *Description*: a description of the NC;
– *Corrective Action*: a description of the corrective action taken.

Table

Clicking on the **Table** button will bring up a window named *Data Table* that shows the time stamp and temperature reading for each acquisition taken. Values that have exceeded the maximum threshold are displayed in red, whereas those that are below the minimum threshold are shown in blue.

One may browse through the table using the scrollbar on the right. Clicking on the **Save** button will export the table in SYLK format (.slk) such that the data may be then imported into a spreadsheet program such as *Microsoft Excel.*
Click on the **Close** button to close the window.

Graph

Click on the **Graph** button to open a window that shows the readings taken in graphical format. This window may be maximised to cover the entire screen.
The graph displays several lines according to what is enabled for that sensor, temperature or humidity also:
– *cyan*: this plot shows the temperature profile. Positioning the mouse cursor on the curve will open a pop up box that displays the time stamp and temperature value at that point;
– *wide red line*: this indicates the absolute maximum temperature for quick comparison;
– *narrow red line*: maximum temperature threshold for correct conservation;
– *narrow blue line*: minimum temperature threshold for correct conservation;
– *wide blue line*: absolute minimum temperature threshold;
– *green*: the Mean kinetic temperature, calculated according to the profile selected in the *statistics* area of the *View Data* page;
– *grey*: humidity curve. Positioning the mouse cursor on the curve will open a pop up box that displays the time stamp and humidity value at that point;
– *orange*: maximum humidity threshold for correct conservation;
– *yellow*: minimum humidity threshold for correct conservation.
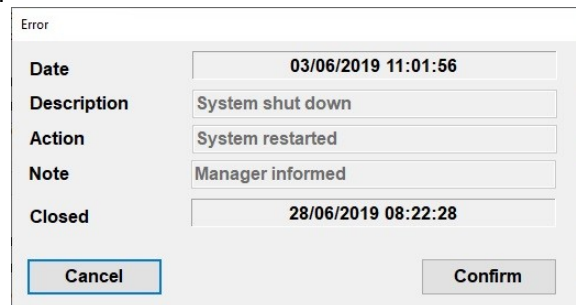
Zooming functions

You may zoom into an area of the graph by clicking and dragging the left mouse button; this will enclose the area you would like to zoom into with a shaded rectangle. Once the desired area is covered, release the mouse button to scale the graph such that only the selected area is displayed in the graph.

You may keep zooming into the graph by repeating the above procedure. The graph also holds a horizontal and vertical scrollbar using which you may scroll through the graph at the current zoom level. To return to the previous zoom level simply click on the small zoom-out buttons at the extremities of the scrollbars (these buttons enclose a small circle). Note that the zoom-out buttons for the horizontal and vertical axis are independent of each other so you will have to click both to scale both axis back to the previous zoom level. To return to the original zoom level, that is to display the entire graph, click on the **Unzoom** button at the bottom left.

Adding a Non Conformity

To add a non conformity and its corresponding corrective action simply double click the point on the graph at which the NC will be inserted.

This window holds four fields:
- *Date*: the date and time at which the NC will be inserted, taken from the point you just clicked on the graph;
- *Description*: the description of the NC. Once you click on **Confirm** this field cannot be changed.
- *Action*: a description of the solution you adopted..
- *Notes*: A free text field where you may insert additional notes or the name of the person inserting the NC.
- *Closed: t*he date when the NC was solved be resolved or open. Once you click on **Close** this field cannot be edited anymore.

To save the NC in the *Graph* click on the **Confirm** button, alternatively click on the **Cancel** button to cancel the adding. Once the NC has been attended to and resolved, you should click on the **Close** button.

The non conformities and alarm conditions are shown on the graph as small red stars. If you position and hold the cursor on these stars, the description will appear. The NC's are also reported in the *Data* tab according to the selected *Sensor*,

WARNING! In the interest of security and to preserve the integrity of the system it is not possible to edit or delete non conformities once these are added.

Printing a report of the data acquired

Click on the **Print** button to print a report containing the graph of readings as well as the statistics information: select the required printer from the list and click **OK** to proceed.

Before actually printing, the program will bring up a preview of the page to be printed: after that the sensor parameters will be printed.

Update

Wireless system add data in background. The **Update** button reload data added in background.

View tab

The view tab lets users define images where to put placeholder of sensors. If no views are defined a blank page will be displayed. If any view has been created a Thumbnail of image and a description for each view defined is present.
To add, remove or rename a view click right mouse button to display menu.
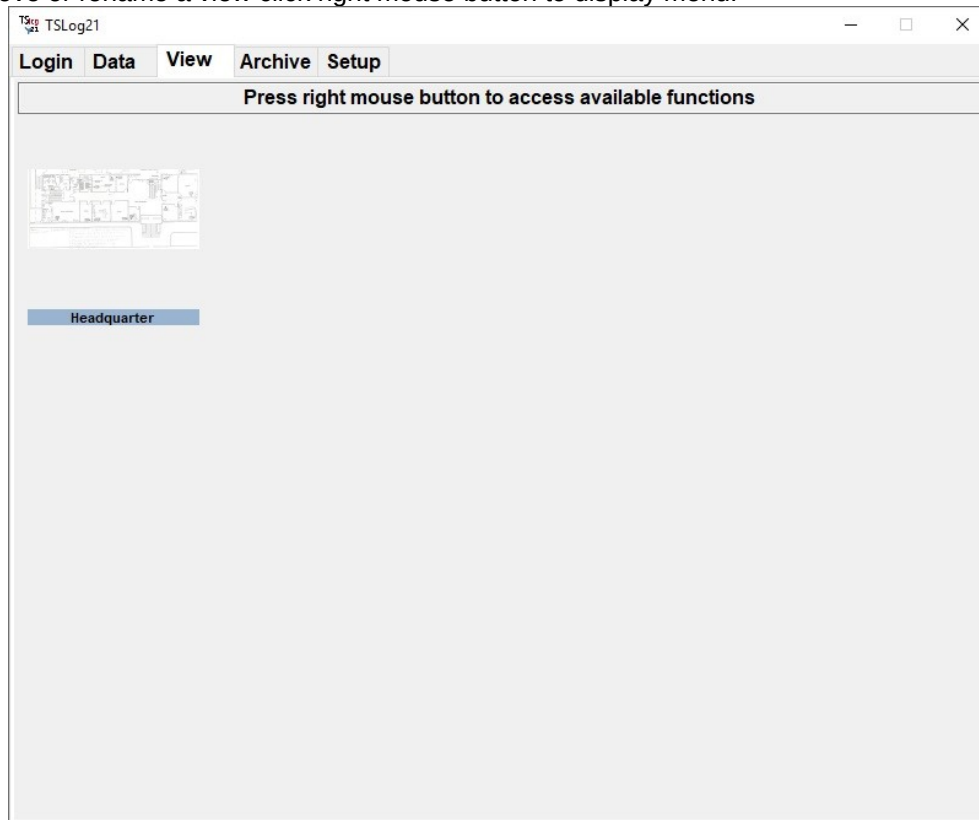
To fully display a view double click on it; the full view image will be displayed.

Adding Sensors to a view

Once the full image is displayed using right mouse button a menu will be shown where *Add sensor* and *Remove sensor* choices are present. Adding a sensor will open a window where to select group and sensor to add. A pin will be placed at mouse position.
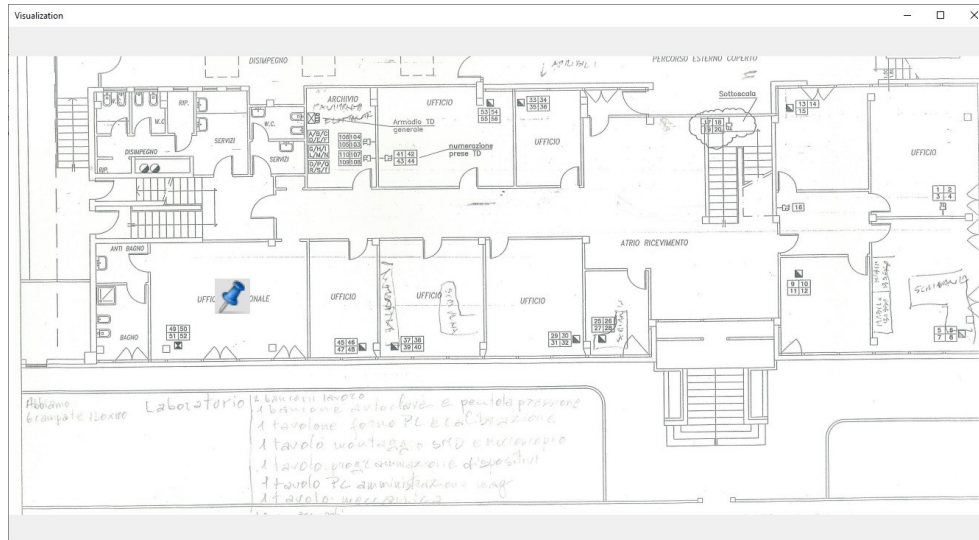
After a pin has been placed clicking on it will open the *Data* tab with data from the sensor displayed. To switch back to view use the new **View** button on on the bottom right corner of the tab.
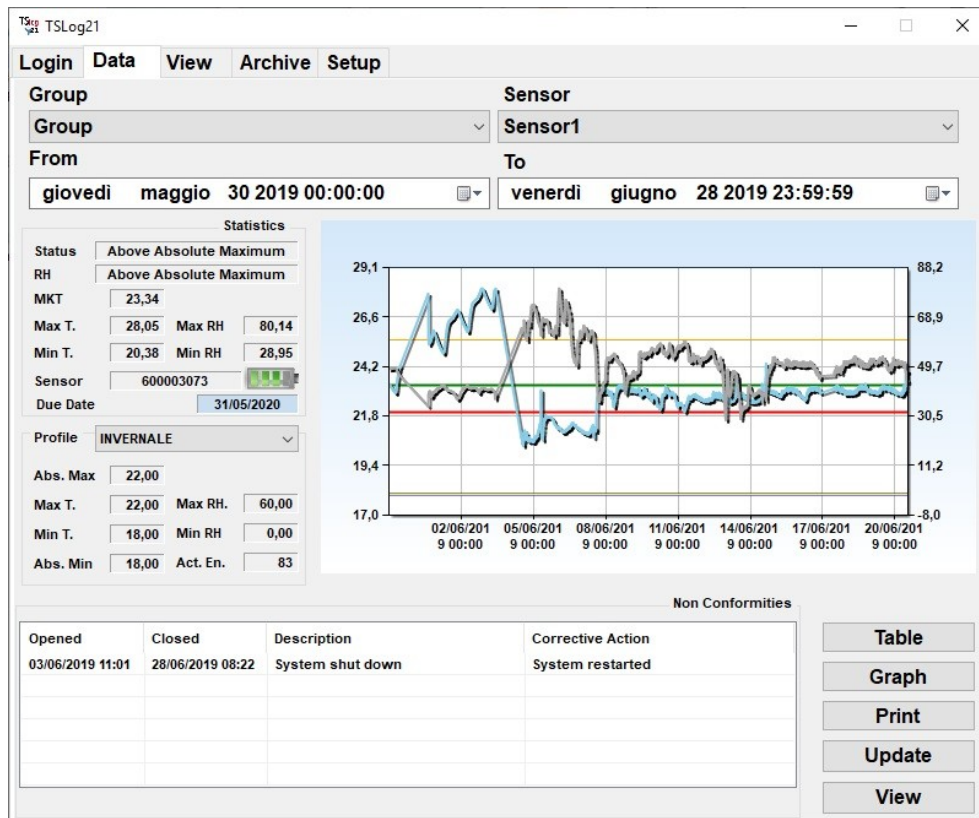
Archive (Advanced and Administrators Users only)

This tab displays the following tables*: Workstations, *Users, Profiles, Group | Sensor, Backup and Restore.*

An administrator may have already created entries in these lists; an *Advanced* user may add new elements to these lists, modify existing ones or delete entries if possible. This type of user cannot modify or delete users who have been assigned *Advanced* or *Administrator* rights.

Adding a User

Click on the **Add** button to create a new user. For each user you may set:
– *Login*: A name for this user. You cannot create two users with the same login;
– **Set Password** button: click here to open the password windows the password this user will use to access the program. Set here the following parameters:

– *Old password*: will be disabled when creating a new user;
– *New password*: set the new password, following indications on the right;

- – *Confirm new password*: type the password again;
- – *Expiry*: indicate a date for the password expiration. When this date comes the software will ask you to generate a new password. Maximum characters: 90.
- – *First name*: first name of the user;
- – *Last name*: last name of the user;
- – *Signature*: click on **Set** or double click in the box to upload an image of the user's signature. Click on **Clear** to remove it.
- – *Level*: set the level of the user such as *Advanced*, *Administrator* etc.
- – *Enabled*: check this option if the user is allowed to access (*Enabled*) or not;
- – *Permissions*: check this box if you want to set a list of groups/sesnors this user can view. He/she won't be able to view data from sensors not in the list. If the box is unchecked he/she will see all sensors from all groups.

Click **Ok** to confirm.

Editing a user

Click **Edit** button to change the password assigned to a user and edit other parameters, after selecting the user you want to edit.

Deleting a user

To remove a user select the user from the list and click on the **Delete** button. The software allows to delete users that have never accessed the software. In all other cases button will be disabled.

Adding a profile

Profiles contain the parameters used to program the data logger as well as to perform statistical analysis on the temperature readings according to the MKT and the validation parameters (see p. 33); they are used to analyse data and can be assigned to the sensors.
Click on the **Add** button in the *Profiles* tab. A window will appear where you may set these fields (refer to p. 33 for more details on each field):
- – *Name*: the profile name. Each profile must have a unique name;
- – *Label*: the printed label with which the profile will be shown in the data tab and reports;
- – *Abs. Max.*: absolute maximum threshold that should never be exceeded (default: 20)
- – *Abs. Min.*: absolute minimum threshold that should never be exceeded (default: -20);
- – *Max RH*: maximum threshold for humidity;
- – *Min RH*: minimum threshold for humidity;
- – in the *MKT* box you can set:
  - – *Max temperature*: maximum threshold for correct conservation (default: 15);
  - – *Min temperature*: minimum threshold for correct conservation (default: -15);
  - – *Activation energy*: this should match the value for the product being monitored. If this is not known it is recommended that the activation energy of water (83) be used as an approximation. (default: 83).

Editing a Profile

All the parameters of a profile, except the *Name*, may be changed as required. Select the profile to be monitored and click on the **Edit** button (you may also double click the entry name in the list). Make the necessary changes and click on **Ok** or **Cancel.**

Deleting a Profile

To delete a profile, select it from the list and then click on the **Delete** button; only profiles that have never been used can be deleted.

Adding a Group

In the *Group | Sensor* tab you may create a list *of Groups* (top list) and their associated *Sensors* (bottom list).

To add a new *Group* click on the **Add** button below the top list. Type:
– *Name*: the name of the *Group*. You cannot have two *Groups* with the same name;
– *Label*: the printed label with which the group will be shown in the data tab and reports;
– *Manager*: the name of the person in charge of the system for this group.
Click on **Ok** to effect changes or **Cancel** to discard.

Editing a Group

You may modify the parameters of each *Group,* except for the *Name* field, by selecting it from the list and clicking the **Edit** button (alternatively double click the entry). Click on **Ok** to effect changes or **Cancel** to discard.

Deleting a Group

To delete a *Group* from the list, select it and click on **Delete**.

Adding a Sensor

To add a *Sensor* to the list, first select a *Group* from the top list and click on the **Add** button under the bottom list and type:
– *Name*: the name assigned to the *Sensor*. You cannot create two *Sensors* with the same name under the same *Group*;
– *Label*: the printed label with which the sensor will be shown in the data tab and reports;
– *Unit*: the department in which the sensor is placed;

–   *Notes*: additional information pertaining to this *Sensor*;
–   *Profile*: you can assign one or more profiles to this spot as long as they have been created in the database. Click on the **+** button to display available profiles which you may use to analyse data. If you click on the **–** button you will remove the selected profile. Note that if there is only one profile in the list you cannot delete it.
–   *Sensor*: enable *Temperature* only or also *Humidity* according on the type of sensor associated to this monitoring spot.

History shows the list of sensors used through time for this monitoring spot.

Click on **Ok** to effect changes or **Cancel** to discard.

Printing all the data for all Sensors pertaining to a Store

After selecting the desired *Group* from the list, you can print all the data from all *Sensors* for that particular store by clicking on the **Print** button on the right.

Editing a Sensor

You can modify the parameters of each sensor, if required, except for the *Name*. Select it from the list and click the **Edit** button (alternatively double click the entry). Make the required changes, click on **Ok** to effect them or **Cancel** to discard.

Deleting a Sensor

To delete a sensor from the list, select it and click on **Delete**; confirm this operation in the next window.

Backup & Restore

This tab provides tools by which you may backup the data and settings such that if these get damaged in any way you may quickly and seamlessly restore the data.

Creating a backup

To create a backup of the database click on the **Backup** button. The backup folder can be indicated in this field by clicking on the browse button (**...**) next to the *Destination* field.

Restoring data from a backup file

If a backup was created at least once, you may restore the files from the backup by clicking on the **Restore** button: the data from the backup files found in the directory specified in the *Source (ZIP)* field will be restored into the software.
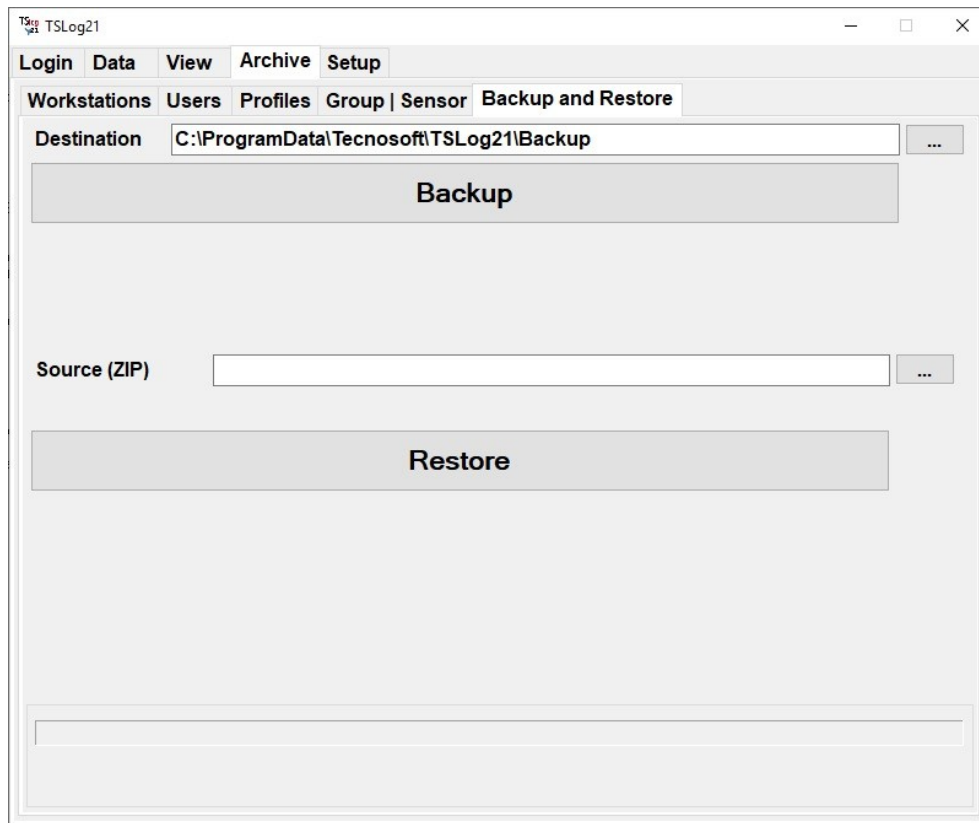
WARNING! If you restore files from a backup you will lose all the saved data and changes to the program settings since the last backup was made.

Signing the reports

Printed reports can be signed by the operator by hand, applying a signature image and with electronic signature. When the operator send a print command the software will ask which signatures he/she wishes to use.

First of he/she can chose whether to have or not a signature and on which pages to place it.

If an option different than None is enabled the operator can chose to include image signature, set in the user (see p. 21), the handwritten signature (a blank space will be left for the operator to sign it by hand) and the electronic signature (the password will be asked again and the First and Last name of the operator will be printed on the report).

Auditing and Audit Trail

The software includes the possibility to audit the whole database through the Audit Trail option. This option is available for Auditor users only.

Creating an Auditor user

Follow the instructions on how to create a user to create a new user with AUDITOR level.

The Audit Trail

Login as an *Auditor*. This user will have only one tab available, the audit trail.
Select a time range you want to audit, select *Workstations* and *Users* and the type of records you want to check (*All*, *Audited*, *Not audited*).

If a record has been audited, select it and click on **Mark records as audited**.
Clicking on **Verify** you can check database integrity.
Click on **Print** to print the records displayed.

Administrator Manual

TSLog21 software is a multi user program and the different users and their privileges are set up by an *Administrator:* a special user who is granted full access to the program features as well as to another set of additional functions. The installation and configuration of this software should be carried out by an *Administrator*, since it is this user who will need to configure the program and create additional users such that they can use the hardware and software of the *TSLog21* system.

Setting up the TSLog21 system

The steps presented below should be ideally followed in sequence in order to set up and start using the system:
1. system A*dministrator* must install the software (p. 29);
2. *Administrator* access the program using the credentials of the INSTALL USER:
   ◦ *Workstation*: INSTALL WORKSTATION
   ◦ *User*: INSTALL USER
   ◦ *Password*: Tecnosoft2019
3. The *Administrator* must now create a user for him/herself, obviously with *Administrator* privileges (p. 30);
4. the *Administrator* should now logout and login using the user name and password of the account he or she has just created;
5. next, all needed users will be created and assigned to all operators who will have access to the system;
6. next, the *Administrator* should configure the system: specify the mode of the database, the folder where database is saved, and other parameters in the *Setup* tab;
7. the A*dministrator* may now disconnect, and the *Advanced* user may login;
8. if the *Administrator* has not set up the entire system (*Groups*, *Sensors*, *Profiles* etc..), the *Advanced* operator can create them.

Installation

To install the software you need to have the installation files on a support (on a USB key or onto your hard drive). These instructions are not for complete installation of the system, its database and its hardware configuration. These instructions are just for local, client, installation. Run setup.exe file to start installation and chose Install now from the Installation menu.
Chose default options and click on **Finish** when installation is complete. For Database configuration refer to proper documentation.
NOTE: to install the software you must log into Windows as a user with sufficient rights to install software (normally an Administrator). During the installation, when prompted, install the software for all users of that PC and not only for the user who is currently logged in.

The hardware protection key

In order to use the *TSLog21* software you need to insert the USB hardware key that is supplied with the software. USB drivers will be installed automatically

Once this installation is complete you can run the *TSLog21* software.

First Access

The first time the software is run on the whole system (meaning no user has ever connected to the database and no user has been created in the database) you must log in as the INSTALL USER. Password for this user is Tecnosoft2019. Software will ask to change the password: type in old password, new password and confirm it. Click on OK. Workstation, which is the local PC connecting to the database, is INSTALL WORKSTATION. You can change it later. Once you have typed in correct password you can click on Login.

NOTE: remember to change the password of the INSTALL USER once configuration is completed!

Creating the Administrator and other users

In the main window (p.12), as INSTALL USER you will have access to all the program functions. The very first operation you should carry out is the creation of an *Administrator*. After this you should logout from the and login as the fixed *Administrator* you have just created. To do this select the *Archive* tab and then select *Users* and click on the **Add** button.


Fill in the fields as appropriate:
- *Login*: username used to access the program (along with the password). Login must be unique;
- **Set Password**: click this button to open the *Password Change* window. Being a new user you won't be required to type the **Old password** but just the *New password* and *Confirm* it. *Expiry* is the date after which the program will ask the user to enter a new password (90 days maximum). Click **Ok**;
  N.B.: take note of the administrator password and store it in a safe place. If you forget this password you will not be able to access the program as an administrator and will therefore not be able to use all the program features. It is impossible to retrieve the password once this is lost, not even by Tecnosoft.
- *First Name*: user's first name. It will be used for electronic signature;
- *Last Name*: user's surname. It will be used for electronic signature;
  - *Signature*: user's signature image. Click on Set or double click inside the box to open a window where you can select an image as the user's signature;
- *Level*: select Administrator;
  N.B.: if you select a different level of user, and close the program, on the next login you will no longer be able to access the software as an administrator, and therefore you will not be able to create another user with Administrator privileges and therefore you will not be able to make use of all the program features. If this occurs you will have to recreate the database (and lose all the data up to then) and repeat the operation to create an administrator user.
- *Enabled*: check this option;
- *Permissions*: check this option. If groups and monitoring points have already been created, click on **+** and select all the groups and monitoring points this user has permission to view.

Click on the **Ok** button to create the user. You will note that the new user has been added to the list of users.
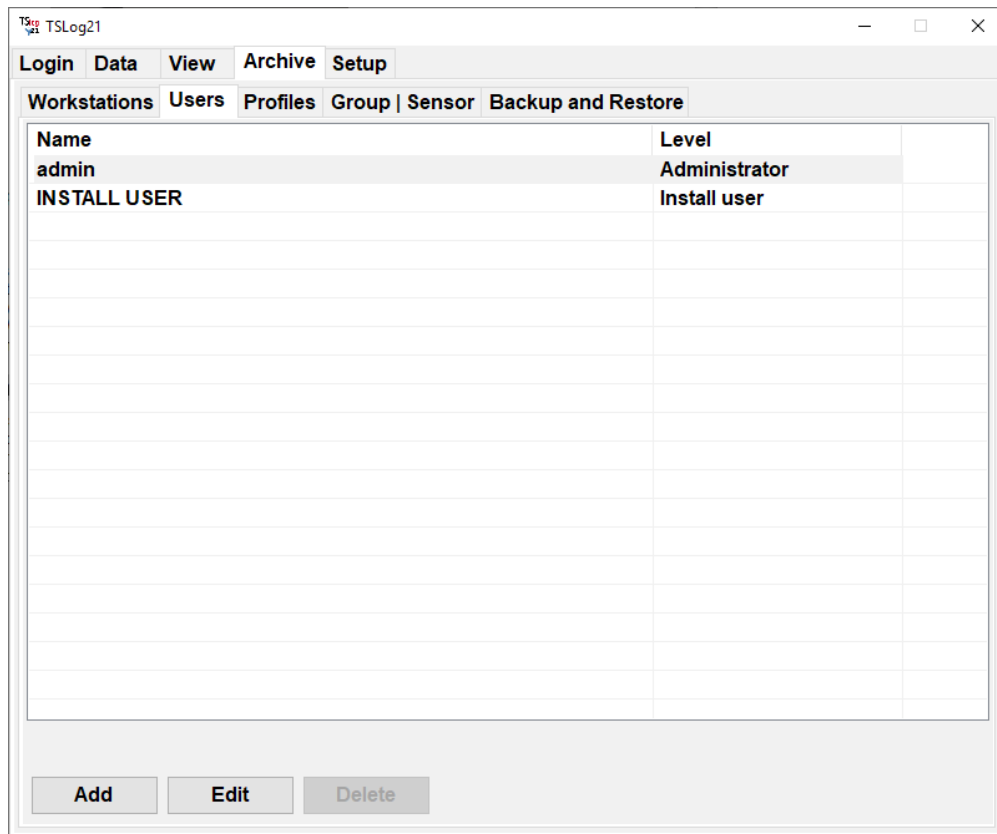
Click on the *Login* tab and then on the **Logout** button: this is the normal way of logging out in order to change user without having to restart the software. From the drop down list next to the *User* label select the user you have just created; type in the password in the field below and click on **Login**.
You may now carry out the program configuration according to your needs.

Configuring the software

Database settings

In the *Database* tab set if the database is Local or Remote. For correct configuration refer to proper documentation provided separately.

General settings

Click on the *Setup -General* tab to set the following parameters:
− *Root folder*: the path in which the database is stored. If you wish to change this folder click on the **Browse** button to select an alternate location;
− *Language*: select the language of the software (note: you must close and re-open the program for this change to take effect);
− *Group label*: indicate it the label to print for the groups;
− *Sensor label*: indicate here the label to print for the sensors;
− Workstation: set here the workstation for current PC (click on **Change** to select another workstation);
− *Logout timeout (minutes)*: set here after how many minutes of no activity the system will request the password;
− *Enable Z2L:* check this box to allow *Z2L* to run each time *TSLog21* starts, unless it is already running, this will allow data to be received from wireless sensors (note: do not enable it if *Z2L* is running elsewhere, for example on the *Syrinx*);
− *Battery check*: enable this if you want to have a warning when battery is low and set the levels of voltage for empty and full battery.
− *Run On Exit*: it is possible to request that certain tasks be carried out automatically when the program is closed. The basic operation carried out is the creation of a backup file in the folder specified in the *Backup And Restore* page. In this field you may specify a particular executable file that will be launched, upon closing the program, as soon as the backup is completed. The file must be located in the main

program directory; if this field is empty only the backup procedure will be carried out. You can select from three options found below this field:
- – *Prompt*: every time the program is closed, a window will appear asking whether the operation should be carried out (backup + executable file specified in the field);
- – *Run*: every time the program is closed the specified tasks will be automatically carried out;
- – *Ignore*: no automatic operation is carried out by the program when closed;
- – *Backup filename:* type here a name for the backup file if you wish it to be named always with the same name.

Start settings

In this tab you can set some default options to be used at startup.
- – *Group*: in this field you may select the default *Group* that will be used in the *Data* page (users may then select a different *Group* if required) from the drop down list. The list will hold the *Groups* that an *Administrator* or *Advanced* user have created (see p.14);
- – *Start view* activate the view selected in the next list when user login;
- – *Show Alarmd Sensors*: enabling this option the pop-up window with the list of fridges in alarm, when downloading data from a *FLI*, will be displayed.
- – *Default Days For Data Analisys*: set here the time range for the *View Data* tab; you'll be always able to change this range in the tab itself;
- – *Alarm Messages Time Window*: this indicates a time window, set as the number of days from the current date, from which alarm and NC messages will be loaded and displayed in the list on the *Login* page. If, for example, you set 15 (days) all alarm and NC messages from the last two weeks will appear in the list. The other alarms and NC's will not be deleted, they will simply not appear in the list. This feature enables the users to view, at a glance, the most recent NC's or alarms without having to browse through the data for each fridge;
- – *Hours for no data alarm (0=disable)*: set the number of hours without data to display a warning in login page. This is function is useful for wireless sensors.

Print settings

In this tab you can set some default options for the report printing.
- – *Group Print Days:* in this field you may set the number of days that will be considered once the print all data for a particular Group is clicked. The default value is 30, which means that, when this option is run, all the data from the last 30 days, for all fridges within that store will be printed;
- – *Enable Table Printing:* if this option is enabled, a table with all the readings for the selected period will be printed each time you print a report;
- – *Signature*: refer to instructions at p. 27 for these settings;
- – *Margins*: set here the margins for your printed report. If you set a value with "-" before it the margin will be moved externally, otherwise internally.

View Settings

In this tab you can set some default options for the *View* tab.
- – *Slideshow mode:* if this option is enabled clicking on a View will open it at full window and all Views will switch one after the other and current values will be displayed on the View;
- – *View switch interval (seconds):* set number of seconds for switching from a view to the following one;
- – *Unit switch interval (seconds)*: seconds to switch from one channel to the other (temperature/humidity) within the same view;
- – *Max delay (minutes)*: maximum delay in data display (won't be shown data older than this period).

Storage Acceptance Criteria

The *Storage Acceptance Criteria* adopted by the *TSLog21* system are specifically intended for the temperature monitoring of perishable goods during shipments, however these may also be used to analyse the conservation of foodstuffs in static locations such as fridges, freezers and so on. The parameters used by the software in order to produce a final result on whether storage was correctly carried out or not have been adapted from recommended procedures issued by the following international reference standards:
NCCLS H18-A3 Vol. 24 No. 38 "PROCEDURE FOR THE HANDLING AND PROCESSING OF BLOOD SPECIMENS"; Approved Guideline - 3rd Edition" and *NCCLS GP16-A2 Vol. 21 No. 19 "URINALYSIS AND COLLECTION TRANSPORTATION, AND PRSERVATION OF URINE SPECIMENS"; Approved Guideline - 2nd Edition.*

The temperature thresholds

TSLog21 makes use of 4 distinct thresholds. The first two represent the standard minimum and maximum temperatures that should not be exceeded in order to guarantee correct storage of the goods. These limits are normally quite tight, however in many cases some tolerance is accepted when the ambient temperature of the goods rises above or below the limits, since it is not said that the goods have actually reached the ambient temperature yet. The software caters for another two thresholds, the absolute minimum and maximum temperatures; these thresholds must never be exceeded and therefore normally specify a wider temperature window to guarantee a certain degree of tolerance.

The Activation energy

In chemistry, this is defined as the minimum energy necessary for a given chemical reaction to occur. It is therefore a measure of the temperature sensitivity of a product. This parameter forms part of the equation used to calculate the Mean Kinetic Temperature of a given storage temperature profile. For solids and liquids this parameter is typically within 60 – 100KJ/mol. Unless the specific value is known for a given substance, it is widely recommended that the value 83 is used which is the activation energy of water.

Default acceptance criteria parameters:

Minimum threshold: -15°C
Maximum threshold: 15°C
Absolute minimum threshold: -20°C
Absolute maximum threshold: 20°C
Activation energy: 83

MEAN KINETIC TEMPERATURE

The Mean Kinetic Temperature (MKT) is defined by the ICH (International Conference on Harmonization) as "a single derived temperature, which, if maintained over a defined period, would afford the same thermal challenge to a pharmaceutical product (or other perishable product) as would have been experienced over a range of both higher and lower temperatures for an equivalent defined period". The MKT yields a higher temperature than a simple arithmetic mean and may be calculated using the Arrhenius equation.

The mean kinetic temperature quantifies the cumulative thermal stress to which a product has been subjected when placed at varying temperatures during transport or storage. The MKT gives the higher temperatures a greater weight by computing the natural logarithm of the absolute temperature.

Haynes' formula may be used to calculate the MKT. This yields higher temperatures than the arithmetic mean and takes into account the Arrhenius equation from which Haynes derived his formula:

$$T_k = \frac{\Delta H / R}{-\ln \dfrac{e^{\frac{-\Delta H}{RT_1}} + e^{\frac{-\Delta H}{RT_2}} + \ldots + e^{\frac{-\Delta H}{RT_n}}}{n}}$$

T_k	=	MKT in ºK
ΔH	=	Heat of activation or activation energy
R	=	The universal gas constant (8.3144 ·10-3 kJ.mole-1 · ºK-1)
T_i	=	Temperature in ºK
n	=	The total number of equal time periods over which data has been collected.

The practical use of this equation is less complex than it seems. Most pharmaceutical or biological products have an activation energy (ΔH) in the range 42 – 125 kJ/mole. A value of around 83 (water) is considered typical for pharmaceuticals or foodstuffs.

The MKT is only valid under strict control conditions, that are:
- it is only applicable to products that need to be stored under controlled ambient temperature conditions (eg. Products that indicate "Do not store above 25ºC)
- the MKT is not recommended for products that need to be stored at extremely low temperatures
- the MKT cannot be used as a means to justify shortcomings in devices used to maintain ambient at a controlled temperature (e.g. manufacturing defects in fridges)

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