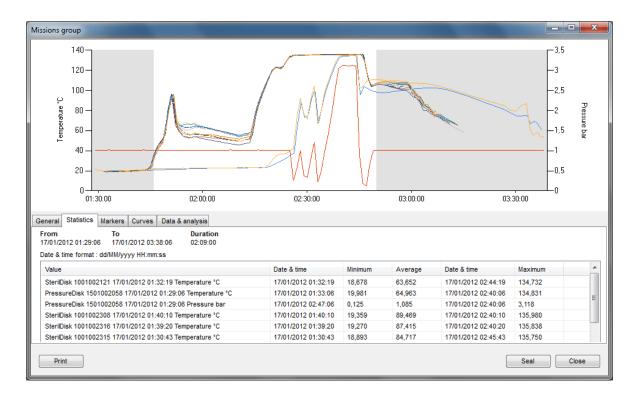
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TS MANAGER (Part # TS0165)

21 CFR Part 11, Annex 11, GAMP 5 compatible system
User's Manual
(Basic and Pro Versions)



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Introduction

TS Manager come in three different versions:

- Limited
- Basic
- Pro

Present manual covers just the last two version, indication where a feature is available for just the Pro version. Basic and Pro versions are an FDA 21 CFR part 11, Annex 11 and GAMP 5 complaint while Limited version has various limitations and not such compatibility.

The software manages a number of Tecnosoft data loggers and in the Basic and Pro versions is particularly suited for pharmaceutical, medical, healthcare and validation processes. By including this software and its compatible data loggers, for temperature, humidity and pressure monitoring, in your processes you will be able to implement operating procedures that are fully compliant with these guidelines.

The TS Manager system can be used in any stage of your process that involves monitoring and electronic recording of data: for example, in the validation of autoclave and sterilization processes or warehouses and stock houses, fridges, freezers validation and mapping.

By means of this software you are able to program the data loggers by applying various logging profiles, download data from the devices and analyze the recorded data, after which they may be printed by means of customized reports or exported in XML and Excel formats.

Main characteristics of the system

This software is fully compliant with the requirements of the aforementioned directives, and also contains other specific features that facilitate the implementation of the system for particular applications.

The non-exhaustive list below outlines some prominent features of the system; to learn about all the features of the program please refer to the specific sections of this manual:

- the data stored in the data loggers cannot be modified or edited
- the data stored by the software cannot be modified or edited and an integrity check both of the data and the database can be performed automatically or any time upon request
- every user must access the software by means of a username and password
- client/server installation and shared database
- multi-user access
- graded user access levels different permissions for each level
- all the operations carried out using the software are recorded in an Audit Trail that cannot be modified
- data are analysed by means of pre-set or customized parameters
- pre and post mission comments may be added to the logged data
- data is displayed in spreadsheet or graph format with zoom feature
- personalized reports may be printed
- data may be exported in XML and xls (MS Excel) format
- data can be encrypted (Pro version only)
- ban of Users who insert wrong password for a customizable amount of attempts
- multi-graph with Sections creation and analysis
- possibility to generate Groups from Sections for a more detailed analysis
- for system validators: a list of clients and the equipment they validate including associations with the data loggers used to validate the systems.

Compatible devices

TS Manager is a flexible software and system and more and more Tecnosoft devices are constantly added. At present the devices and their accessories outlined in the list below are compatible with the system.

Communication Bay	Loggers Supported
	TempStick, HumiStick
	SterilDisk, S-Micro

Contents

Communication Bay	Loggers Supported
	SterilDisk, S-Micro, S-Micro L, S-Micro XL, S-Radio, S-MicroW, RHTemp, PressureDisk, Pirani Vacuum Logger

The software supports also old and discontinued connection bays and old models. Discontinued Connection Base supports: DiskInterface USB with adapters.

Discontinued Data Loggers: PasteurDisk, SterilDisk Can, PasteurDisk Can, SterilDisk Jumbo, SterilCyl, PasteurCyl, PasteurCyl Jumbo, SterilCyl Jumbo, S-Disk J, L-Disk, PressureDisk V, SterilCyl Radio, PasteurCyl Radio, P-Radio.

IQ/OQ Protocols

The system can be provided with Installation and Qualification Protocols (IQ/OQ) for a complete validation of the whole solution.

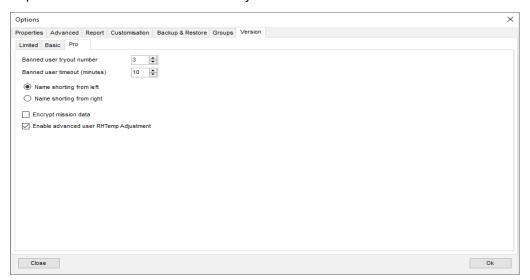
How to use this manual

This manual was designed to quickly give users the information needed to carry out specific tasks; it is therefore not merely a list of program functions, and furthermore, the titles of each chapter, section and paragraph have been chosen such that the user may immediately identify what is to be explained. The sequence in which the chapters are presented follow a hypothetical standard sequence that would normally be followed when using the software, from installation to configuration, to starting and downloading data from the devices, and ending with printing and managing reports. Next to the titles you will also see, within brackets, the name of the window or particular option that is being referred to.

Note: this software must be installed and started (for the first time) by an Administrator, possibly the person managing that particular PC or network (especially for client/server installations), who will then assign the passwords and permissions to the other users of the system.

Pro Version options List (Administrator only)

Following is a list of options available in the Pro version only.



Option	Description
Banned use tryout number	Number of times a user can digit wrong password before ban.
Banned user timeout (minutes)	Time of the ban for a user who missed too many times to type the correct password.
Name shorting from left	Names or serial numbers of the device shortened from left in the header columns for the synchronized data table of the groups in the printed report (only 8 characters are printed).
Name shorting from right	Names or serial numbers of the device shortened from right in the header columns for the synchronized data table of the groups in the printed report (only 8 characters are printed).
Encrypt mission data	The downloaded data will be written in an encrypted file

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	

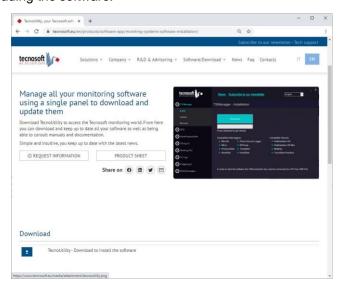
Software

Item	Minimum version
.NET Framework	4.0
Microsoft SQL Server Express	Express 2012
MSSQL Instance	
Server Instance Running	

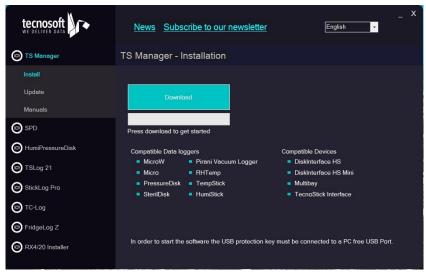
Installation and database setup

Where to get the software

All Tecnosoft software are available through the TecnoUtility Windows app from Tecnosoft. Just open your browser and digit tecnosoft.eu 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 **TS Manager** 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 TS Manager includes the installation of some additional required components; if these are not already present on the system they will automatically be installed before it actually installs TS Manager. The component pre- requisites are:

- Microsoft .NET Framework
- Microsoft SQL Server Express

Three possible installation scenarios

There are three possibles scenarios under which the program may be installed:

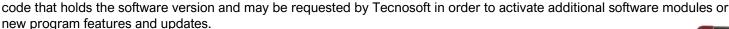
- client/server: the database (server) and the software program (client) are installed on the same PC, and no other PC's need to access the database
- client/server + client: one PC will have a client/server installation whilst one or more additional PC's will connect, as clients, to the client/server PC in order to access the database.
- server + client: the database is installed on a single PC, acting as a server, which is accessed by multiple client PC's
 acting as clients.

Note: to be able to install this software you must access your Windows operating system as a user that is able to install programs (generally an Administrator). When installing we recommend that you install the software for all users (Everyone) and not only for the active user.

Once the installation is complete, before starting the program on client machines, you will need to insert the USB hardware protection key.

USB protection key

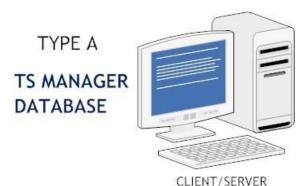
To be able to run TS Manager, you will need the USB protection key (there are two versions, the smaller one is the newest) supplied with the software, and insert it in a USB slot on the machine. This must be plugged from the moment the program is started. The USB protection key does not require any driver to be installed and also contains a



If you have the white bigger key readings from its internal barometer are displayed and updated in real time in the bottom right corner of the main window (p. 22).



Client/server installation - standalone PC (type A)

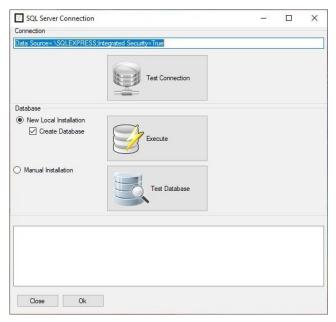


Once the installation starts, follow the on-screen prompts when they appear. The installation program will check whether all the pre-requisite components are installed. If not they will be automatically installed. This part of the installation may take a few minutes to complete. Once all the components are installed, the actual TS Manager software will install. Once this is complete the only remaining step will be to create the database on the same PC, since this is a standalone PC installation.

Creating the database (SQL Server Connection) - type A

Once the software has installed, double click on the **TSManager** icon on the desktop, or start the program from Start > **Tecnosoft > TSManager**.

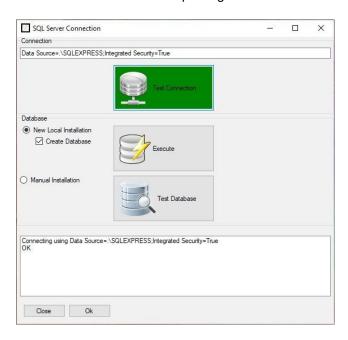
Upon the very first time the program is launched, you will be asked to create the database. The *SQL Server Connection* window will appear where one may choose the required options according to the type of installation required. If the window does not appear, manually open it by selecting **Start > Tecnosoft > TS Manager DB Creation**. For type A (client/server) installation, select the first option *New Local Installation*, then enable the Create Database option, making sure you do not change the default connection string (*Connection*).



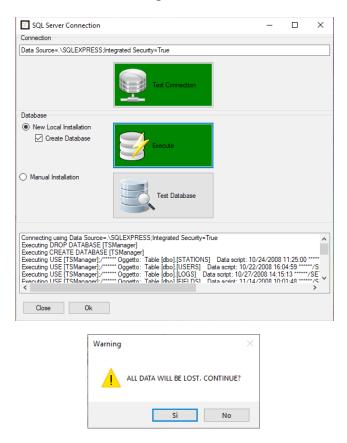
Note: if this window does not show up, close the Login window of the TS Manager and keep pressed SHIFT key on the keyboard and then right click on TS Manager icon and select Open. Alternatively select Start – Tecnosoft – TS Manager DB Creation.

To create the database, carry out the following steps:

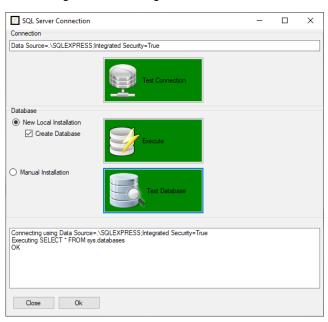
• click on **Test Connection** to verify that SQL is correctly installed and that it is able to connect to the database via the connection string. Once the test is complete, the button will turn green if the test is successful or red if SQL was not installed properly or if the user does not have sufficient privileges to access the database;



create the database by clicking Execute. If the operation is successful, the button will turn green. In most cases, if the
Test Connection was successful, this operation will succeed. A possible case for failure would be if the database has
already been created, and you are trying to recreate it or the user may not have enough privileges to delete the old
database. Note: creating a new database will delete all the data in the old database including the archives:
answer Yes to Proceed.



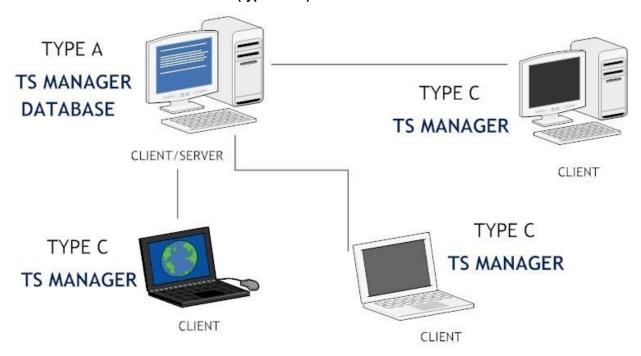
• finally, check that the database is functioning correctly by clicking on the **Test Database** button. If the first two tests were successful, this button will turn green, indicating that the test was OK.



Click on **OK** to run the program.

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Client/server + client installation - multi-user (type A + C)



In this type of installation, the setup will consist of a PC upon which both the database and the software will be installed, since the same PC will act as a database server and also as a client for one user, and another client PC's that will connect to the database on the client /server PC.

First and foremost, the installation should be run on the client/server PC, where a type A installation described above should be ran (p. <u>13</u>). Once complete, proceed to install the software on the other client PC's. You may follow the same procedure here, since in reality it is the type of database connection that changes (type C) not the actual installation.

Network administrator tasks

In this type of installation, the network administrator needs to carry out additional tasks, for two reasons:

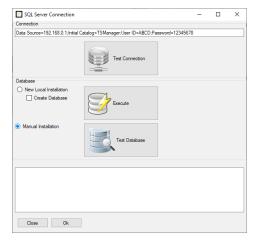
- each client PC needs to be given sufficient privileges to access the client/server PC and to read and write data to the TSManager database on the client server.;
- each client needs the correct connection string to access the database on the client/server PC.

Database Connection (SQL Server Connection) - type A

To create the database on the server PC, follow the instructions described above (p. 13).

Database connection (SQL Server Connection) – type C

After creating the database on the client/server PC, you may proceed to connect the clients to the client/server database. Your network administrator will provide you with the connection string, that needs to be entered in the appropriate field (Connection) in the SQL Server Connection window, as well as ensuring that you have been granted sufficient privileges to access the database.

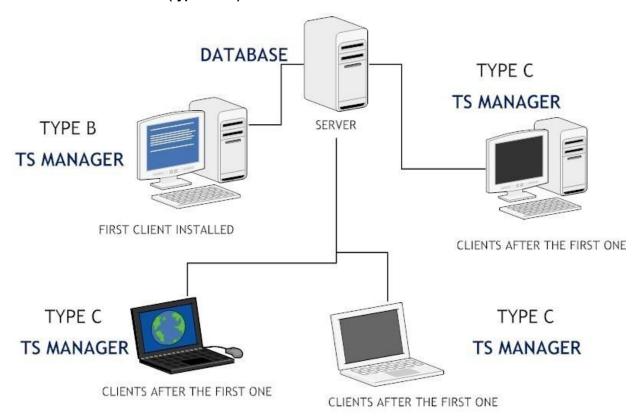


The steps to do this are:

- after inserting the correct connection string, select Manual Installation and disable the Create Database option;
- click on Test Connection and once this turns green, click on Test Database;
- if the procedure was successful, click on OK to run the program.

If this procedure fails, make sure the connection string is correct, and that the user of the particular client PC has sufficient rights to access the client/server PC.

Client+server installation - multi-user (type B + C)



This type of installation has the following setup: one PC will hold the database and will act as a server to the other client PC's. The client PC's, running TS Manager, will then connect to the server to access the database. First and foremost, the installation on the server needs to be carried out. The network administrator needs to to install SQL, unless already present, and needs to make note of the connection string that will be then passed on the client PC's to enable them to have read and write access to the database.

After that the software can be installed on the other PC's. The installation on the client machines can follow the instructions described for a Type A installation (p. <u>13</u>). The database creation, however, will be different: the first client PC will create the database directly on the server (Type B). The other clients will then connect to the database that has already been created by the first PC, and will therefore be a type C connection as described above (p. <u>16</u>).

Network administrator tasks

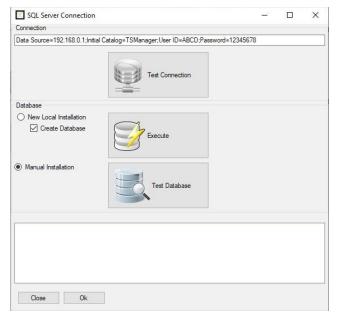
In this type of installation, the network administrator needs to carry out additional tasks, for two reasons:

- each client PC needs to be given sufficient privileges to access the client/server PC and to read and write data to the TS Manager database on the client server;
- each client PC needs to be given the correct connection string that will enable them to access the database on the client/server PC.

Creating the database (SQL Server Connection) - type B

After having installed the software on the first client PC, the database needs to be created directly on the server. It is very important that the correct connection string is used. Select Manual Installation and enable the Create Database option. Carry out the following tasks:

- click on Test Connection; if the operation fails (the button turns red instead of green) double check the connection string and that the user has sufficient privileges to access the server;
- click on Execute to create the database on the server; if the operation fails and the button does not turn green, one of the possibilities is that we are trying to recreate a TS Manager database that already exists, and it is not possible to delete the old one to create the new one. Reasons for this could be that the user does not have sufficient privileges to delete it or that another user is currently connected to the database. Note: re-creating a database will delete all the data and archives from the old database;
- click on Test Database to verify that it is up and running.



Once this procedure is complete, click on OK to launch the program.

Connecting to the database (SQL Server Connection) – type C

To connect to the database on the server, please follow the instructions described in the section above (p. $\underline{16}$).

Modifying the connection string (Administrator only)

If required, the connection string may be modified on each PC even after the database has been created. To do so you need to access TS Manager as an administrator (p. <u>28</u>). Select Options from the Tools menu at the top and open the Advanced window. In the database section locate the Connection String field and insert the new connection string. To test that the client is able to connect to the database, click on Test: it will turn green if the connection is functioning.

Note: default string for local installation should be Data Source=.\SQLEXPRESS;Integrated Security=True

Recreating the database - How to gain access to the SQL Server Connection window

If the database has already been created and the connection to the PC has already been made, there are three ways to re-gain access to the SQL Server Connection window.

The first method, only for Administrator users, is by accessing the Options window (click on Tools – Options) and click on the **Advanced** button in the Database area found in the Advanced tab.



The second method may be carried out by starting the program whilst keeping the SHIFT button on your keyboard pressed. The SQL Server Connection will this time appear in the program language you have selected (whereas when this window appears on the first program launch it is always in English).

The third method is to access the Start Menu of Windows, selecting the TS Manager DB Creation item.

Note: when recreating the database and erasing all the tables, the Comments (p. <u>69</u>) will be held as they are saved in a folder and not in the database. If you want to remove them you have to delete them from the software or delete the Comments.xml file (typically saved in the C:\Users\[User_Name]\AppData\Roaming\TecnoSoft\TSManager folder). Program update

When program is updated, the database structure may change. Be sure to updated it too by pressing the button **Force database check at program start**, in the Advanced tab in the Options window. Close and start the program again. Same procedure must be followed when restoring backups from older versions.

Software configuration and setup

After installing the program according to your preferred configuration, you need to follow the instructions below to configure and use the software. The following chapters describe the procedures that must be carried out for each program function, from managing the archives to analyzing the acquired data. Some functions are not enabled in some user privilege levels, and for each function the level of user that may access the particular function will be notified. We recommend that each user (regardless of privilege level) reads the Main Program Functions section (p. 22), where the main window, the program structure and the basic functions are described.

Post installation operations

Once the program is installed, we recommend you follow the procedures below:

1. change the program language if required. To do this click on Tools – Options and select the required language in the Language field. Click on Ok and then close and restart the software to apply the change;



- 2. create an administrator user (p. 20): this is a required operation and the program won't start until you have created one;
- 3. log in to the software as the newly created administrator (p. 28);
- 4. create the various users that will need to access the system (p. 27);
- 5. create the Stations (PC's that may connect to the shared database) if necessary (p. <u>33</u>). If you are going to use the software on a single PC, skip this operation;
- 6. create the Profiles (p. 42) and Customers (p. 41) archives.

Post configuration operations

Once you have configured the program and created the archives you require (the archives may also be accessed and created at a later stage), you are finally in a position to use the software and its basic functions: starting a data logger, downloading and analyzing the data. The main operations that need to be carried out are:

- 1. connecting to a device and starting a data-logging mission;
- 2. once the mission is complete, connecting to the device and downloading data;
- 3. analyzing the data according to the selected profiles and printing or exporting the data.

Running the program for the first time

Once you have installed the program on the computer or computers in your setup, and after creating the database and having connected all the machines running TS Manager software to the database, you may proceed to create the database tables. This operation can be carried out by any user with proper privileges on any PC, however, after the first access, when the tables are empty and there are no users present, you will need to create an administrator user.

<u>Creating the Administrator user – User window</u>

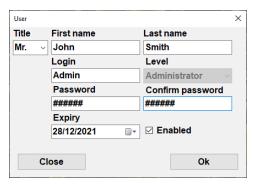
After the very first program start, when the archives are still blank, you'll be warned to create an Administrator user.



The *User* window will open and you can fill in the necessary information to add the first user to your database. At this stage you can add only an Administrator.



- Title: User's title. You may select one from the list or enter a new title manually;
- First Name: users first name;
- Last Name: users surname;
- Login: username used to access the program (along with the password);
- Level: Administrator is the only possible choice;
- Password: temporary password to be used to access the program. The software will require to change the password at
 first log in of this user. Input the password in this field: it must be 5 characters long. Retype the password in the Confirm
 Password field. Passwords can be changed any time by the single user. Note: 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. To access again as administrator
 once this is lost, you have to contact Tecnosoft;
- Expiry: the date after which the password will no longer be valid. Maximum period is 90 days. After this period expires, the software will ask to assign a new password. The new password cannot be identical to the previous one.
- Enabled: this option is used to enable or disable the user. Since we are creating the first Administrator user you
 must leave it enabled.



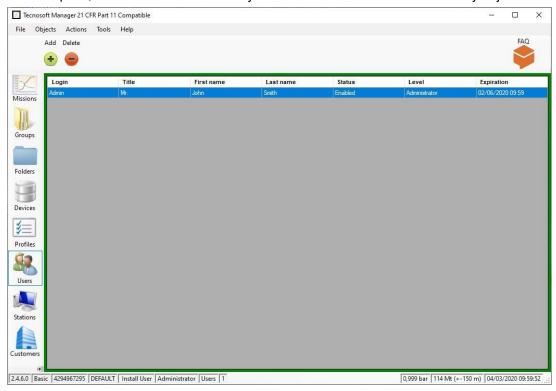
Click on **OK** to confirm the operation.

The login page

After the creation of the first user and whenever you start the program you will be presented with the login page. Select the user from the *Login* drop down list and digit the password in the proper field. Click on **Login** to access the program.



Once the main window opens, click on Users on the left: you will see there is the Administrator you just created in the list.



You will see that a new entry has been added to the Users list. Now close program by clicking on **File-Exit**. At this point, the Administrator user should create all the database tables or at least create the list of users for the software who will then create the tables, as long as they have sufficient privileges to do so. To create new users, access the program with as the Administrator user.

Main operations and basic configuration

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: https://www.youtube.com/watch?v=pcO4u3Q9IOE
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.

Retrieving the registration code (Administrator only)

If you need to retrieve the registration code you have to access the advanced tab of the Tools – Options window. There is a field named Registration code.



Starting the program

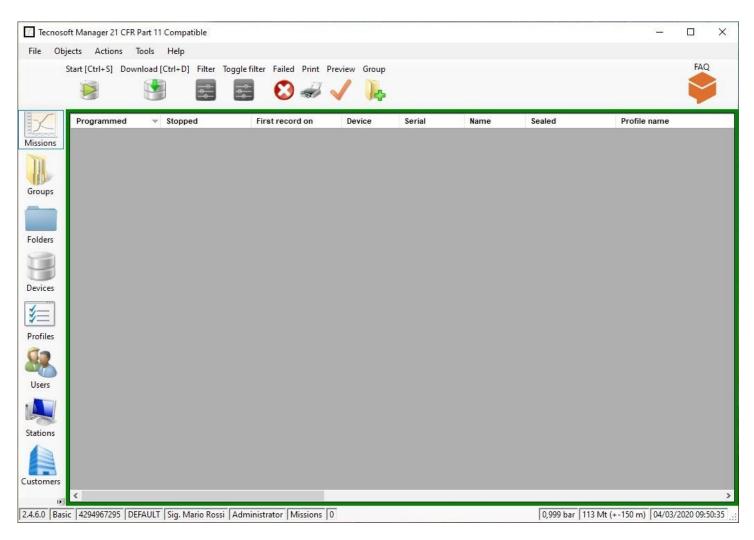
Once the PC has booted, double click the **TSManager** icon to run the program, or launch it from the Start menu. Once the program loads you will see the main login page: select the username from the drop-down list and enter the corresponding password in the Password field. Click on **Login** to proceed or **Quit** to exit the program.



Note: if it is the first time the selected user log in the program, you'll be asked to set a new password. See p. <u>28</u>. You can click on the eye icon to toggle between hidden and unhidden password.

The Main window

The main window will appear, which is divided into different sections. In the middle section you will see the details for the archive that is currently selected: the required archive, on the other hand, may be selected using the buttons on the left hand side or else from the Objects menu. The archives are: *Missions, Devices, Profiles, Users, Stations and Customers*. Each archive presents different options that may be accessed from the buttons above the main (details) pane or via the *Actions* menu item. To configure the program, on the other hand, you need to access the menu Tools – *Options*.



The Status Bar

The bottom part of the main window is used to display information related to the program as well as to the user currently accessing the program. Starting from the left hand side, each panel of the status bar holds:

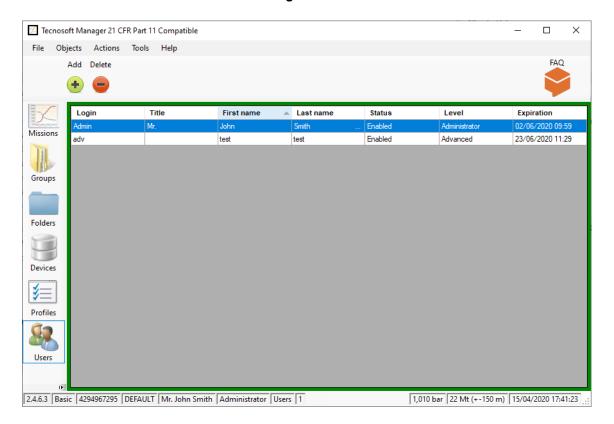
- the program version number and type (Limited, Basic, Pro). **Note**: if you have upgraded from a version previous than 2.4.6.0 your version will be Basic. If you want to upgrade to Pro contact Tecnosoft at sales@tecnosoft.eu;
- USB key code;
- Station name;
- name and surname of the current User;
- level of the current User:
- currently selected archive;
- number of records selected in current archive;
- barometric pressure reading taken from the sensor located in the hardware key and an approximation of the height above sea level (available with the white USB protection key only, p. 13);
- current date and time, taken from the PC.

Managing the archive tables

Once an archive is selected from the list, the details pane in the middle will display the details and elements for the particular archive. Depending upon the privilege level of the user, new entries may be added or removed from the archive. To add an entry, in general, you need to click on the **Add (+)** button, or select the menu item **Actions – Add**; to delete an entry, when it is possible, select it from the list and click on the **Delete (-)** button.

For each archive, the different columns will display details for each element in the list. Clicking on the column title will toggle the sorting of the elements by that column in ascending or descending order. For example, if you select **Users** and click once on **First Name**, the users in the list will be sorted in ascending alphabetical order, and an up arrow will appear close to the column name. If you click the title again, the arrow will change to a down arrow and the list will be sorted in descending order. This makes it simple to locate the items you are looking for.

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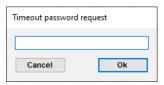
Editing and deleting entries

In TS Manager usually it is not possible to modify parts of an entry, to maintain conformance with the requirements of the regulations, since these may have been already tied to some program operations, such as starting a new mission. The administrator user, however, may delete an entry, where available, and create new ones (for example if an error was made when typing in some details). In any case the entry that has been deleted and the operations that were linked to such entries will remain traceable. Not all entries can be deleted.

Timeout – re-type password

To avoid the possibility that a third person uses TS Manager in the name of another user, for example if the legitimate user leaves the software idle, a timeout feature has been added. This means that if the software is not used and therefore the timeout period passes, the program will require the password for the logged user to be reinserted to continue. In the password window, that will remain on top of other windows, the user may then either insert the password and click **Ok** to keep working or choose **Quit** to close the program.

If the program is closed all analysis that have not been saved will be lost.



Setting the timeout period (Administrator only)

To change the timeout period, select *Options* from the *Tools* menu and *Advanced* tab. In the *Security box*, you will see the *Logout Timeout (Minutes)* option. The default value is 15 minutes: use the up and down arrows to change the value or enter it directly in the field. The minimum timeout is 3 minutes. Click **Ok** to confirm.

Security		
Require authentication to start mission	Logout timeout (minutes) 60	Only Administrators can add new Users
Require authentication to stop mission	Maximum days password expiry 90 💂	Integrity check on mission open

Changing the language (Administrator only)

The TS Manager installation program installs all the available languages. To change the language, access the *Properties* tab from the *Tools-Options* window.

Options			
Properties	Advanced	Report	Customisa
Language	English		~

Select the required language from the drop down list next to Language and click **Ok** to apply.

Changing the temperature measurement units (Administrator only)

Temperature may be displayed according to the Celsius or Fahrenheit scale. Access the Properties tab from the Tools – Options and select the scale from the Temperature mode section, then click **Ok** to apply changes.



Setting Users creation privileges (Administrator only)

It is possible to set that the Administrator only will have the rights to create new users. Just enable the option in the Advanced tab, Security box.

Security		
Require authentication to start mission	Logout timeout (minutes) 60	Only Administrators can add new Users
Require authentication to stop mission	Maximum days password expiry 90 🖨	Integrity check on mission open

Specifying the folder to which data logger missions are stored (Administrator only)

You can specify the folder in which missions will be saved. This data is stored in single files which are accessed by the database, and these may be stored in a different folder to that where the database is stored (even on a different PC), as long as the specified folder resides on a PC to which all the other PC's (including the database server PC) can connect with read and write access.

Open the *Advanced* tab from *Tools – Options* and in the *Mission Data Path* section, click on **Browse** and select the destination directory for the data. Once this is set, click on **Ok** to apply the changes.

Mission data path	
C:\ProgramData\TecnoSoft\TSManager\MissionData\	Browse
Calibration path	
C:\ProgramData\TecnoSoft\TSManager\Calibration\	Browse
Folders path	
C:\Users\AROS\Documents\TSManager Folders	Browse

Specifying the folder for calibration data (Administrator only)

Note: this option is not currently implemented, although present in the software. You can specify this folder, however the functions related to it will not become available until an update is released.

The calibration folder holds the files that contain the calibration data for each data logger being used by the software. The calibration data files are copied, manually, into this folder and will be supplied, if required, by Tecnosoft or downloaded via the web

Access the *Advanced* tab from *Tools – Options* and in the *Calibration Path* section click on **Browse** to specify the folder to which you will copy/have copied the calibration files. Once set, click on **Ok** to apply.

However, you can download calibration certificates from the Tecnosoft Support & Assistance website.

For certificates of data loggers and primary sensors, you can consult our support site where you can find the certificates of our instruments together with those of the references:

http://support.tecnosoft.eu/en

For registration instructions and more you can consult our FAQs: https://www.tecnosoft.eu/en/faqs/#faq-category-ts-manager-software

Applying changes to the configuration

In general, for the changes made to the configuration to take effect, you need to close and restart TS Manager.

Manual

To access the manual in PDF format, click on **Help – Manual**. You will need to have Adobe Acrobat Reader to be able to view the manual.

Closing the program

To exit the program, click on File - Exit. The program will be closed.

Managing the users

Once the program has been installed, and the database and the administrator user have been created, you may define the other users of the program and assign their privileges.

To be able to assign new users, you will need to access the program as an Administrator or Advanced user (if it has been enabled to do so, p. 25), although the Advanced user cannot add Administrator users or delete any entries from the lists.

Note: administrators may prevent Advanced users to create new users by selecting proper option. Check p. 25.

User privilege levels

TSManager caters for four levels of user, each with increasing privileges up to the Administrator who has full access to the program functions and features. The options and functions that are not available to the current user are hidden or grayed out. If you click on these functions, a message will appear informing you that you may not access the particular function due to restricted privileges.

Guest

A guest user can only view the content of the archives. This user may not carry out any of the program functions (e.g. start and download data loggers) and cannot manage the archives. When an audit is carried out (p. 93) the user should access the program as a Guest user.

Standard

Standard users have limited access to a number of functions, for example they can start data loggers but cannot create Groups.

<u>Advance</u>d

An Advanced user has access to most of the program functions, but does not have complete control over the archives, and furthermore cannot access the configuration page of the program.

Administrator

This is the highest user level and can access any program function or operation. It is the first user type that must be created, after which the others may follow. The password should be stored in a safe place since if you are unable to login as an administrator you will not be able to carry out all the program functions.

Should you forget he administrator password contact Tecnosoft at assistance@tecnosoft.eu.

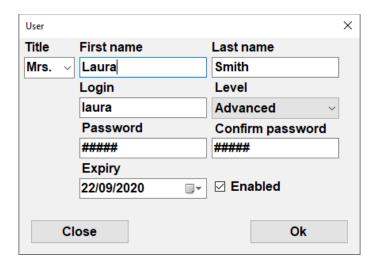
Adding a user (Administrator only, Advanced users may be eligible to crate Standard user – option depending)

To add a user, select the Users archive and click on Add. In the User window fill in the fields with the appropriate data (fields with an asterisk are required fields):

- *Title*: User's title. You may select one from the list or enter a new title manually; in this case, when you click OK to add the user, the program will ask whether you would like to add this title to the list. Choose Yes to add the title so that you can select it from the list for successive users, or No to leave the list as it is. See p. 28 for more information;
- First Name: first name for this user;
- Last Name: users surname;
- Login: username used to access the program:
- Password: password required to access the program with the above username. Input a temporary password in this field: the program will ask to input a different password at first access;
- Level: select the appropriate level for this user (default is Guest);
- Expiry: the expiration date of the password. Maximum duration is 90 days (default setting).

Once all the fields are complete, click on **Ok** to apply.

Note: apart from the password, it is not possible to modify any of the above fields not even by an Administrator. If you have made an error when adding the user, you will need to access the program as an Administrator, delete the entry and create a new user from scratch. Only users that have never logged in can be deleted.



Deleting a user (Administrator only)

You can delete users that have never logged in the program. To delete a user you simply select the entry from the list, and then click **Delete**. Confirm to proceed.

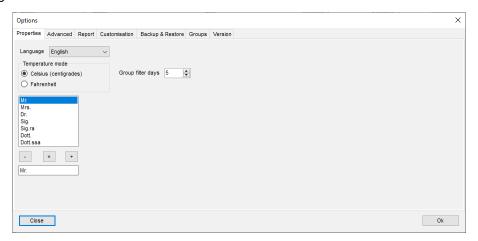
Note: you cannot undo this operation. You will have to create a new user if you inadvertently deleted one.

Enabling and disabling a user (Administrator only)

To change the state of a user, select the user from the list and then click on the **Status** button from the top row.

Managing the Titles (Administrator only)

Open the *Tools – Options* window: in the first tab, *Properties*, you can write new *Title* in the bottom left field and then click on + to add it to the list and select it next time. You can also delete a Title by selecting it and pressing the – button or change it, by selecting it and editing it and then click on =.



Logging into the program

The first time you access the software with a user, each user, apart from the first Administrator, you will be required to set a new password. This is requested because the users are created mainly by the Administrator and with proper option set, only by the Administrator, who knows the passwords for all users. To prevent this, the user who has never logged into the TS Manager and is trying to log in for the first time, will need to change the password. So, after selecting the user you want to log in with, the password field will disappear.



By clicking on **Login**, the software will require to enter current password and then type the new password and repeat it in the last field. Click **Ok** when finished to proceed to start the program.

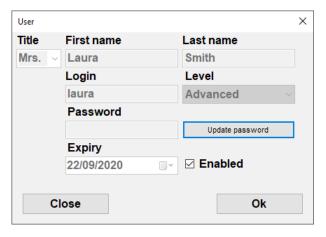


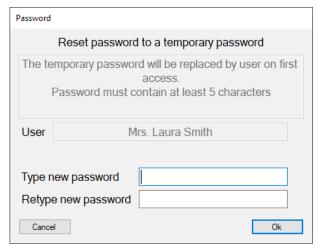
Note: when changing password you cannot use the previous password.

Once you have accessed as an administrator you can create as many users as you require, granting each one the appropriate privileges (p. <u>27</u>). Refer to the following chapters to find out the characteristics of each user privilege level and other program functions.

Changing the password (Administrator only and the user currently logged in for his/her own user)

To change a password double, click on the user you want to edit and click on the **Update password** button. In the new window type and retype the new password and click **Ok**.





Note: if you are not an Administrator you can change the password just for your user. In this case you will be required to type also the old password.

Password			
Change your password			
Password must be different from current password Password must contain at least 5 characters			
User Mrs. Laura Smith			
Type current password			
Type new password			
Retype new password			
Cancel			

Note: changing the password will update its expiration date.

Password expired

When password is expired software will prompt you and ask to choose a new password. The new password cannot be the same as the previous one.

Table of Privileges

Following is the table of accessible functions to all different levels with the possibility to see or act with that specific function.

Feature	Standard	Advanced	Administrator	Guest
Starting a logger		•	•	•
Downloading data	•	•	•	•
Open a Mission	•	•	•	•
Filter Missions archive	•	•	•	•
Preview a Mission	•	•	•	•
Mass Mission Printing	•	•	•	•
Set a Mission as failed	•	•	•	•
Print a Mission	•	•	•	•
Analyse a Mission	•	•	•	•
Exporting Mission data to excel	•	•	•	•
Saving a Mission Link for the Folders	•	•	•	•
Creating a Group	•	•	•	•
Opening a Group	•	•	•	•
Deleting a Group	•	•	•	•
Removing a Mission from a Group	•	•	•	•
Filter the Groups	•	•	•	•
Analyse a Group	•	•	•	•
Print a Group	•	•	•	•
Export data of a Group to excel	•	•	•	•

Feature	Standard	Advanced	Administrator	Guest
Saving a Group Link for the Folders	•	•	•	•
omrula expert	•	•	•	•
Manage the Folders	•	•	•	•
Delete a device	•	•	•	•
Check device Status	•	•	•	•
Change Name to a device	•	•	•	•
Create a profile	•	•	•	•
Delete a profile	•	•	•	•
Open a profile	•	•	•	•
User creation	•	(only if option is enabled and Standard users only)	•	•
Password change	(only for him/herself)	(only for him/herself)	•	(only for him/herself)
Delete a user	•	•	•	•
Open a user	•	•	•	•
Create a Station	•	•	•	•
Delete a Station	•	•	•	•
Open a Station	•	•	•	•
Create a Customer	•	•	•	•
Delete a Customer	•	•	•	•
Open a Customer	•	•	•	•
Create an Instrument	•	•	•	•
Delete an Instrument	•	•	•	•
Open an Instrument	•	•	•	•
Options window access	•	•	•	•
ntegrity Check	•	•	•	•
Audit Trail access	•	•	•	•
Audit Trail filter	•	•	•	•
Print Audit Trail	•	•	•	•
Export Audit Trail to excel	•	•	•	•
RHTemp adjustment	•	(if enabled)	•	•

<u>User ban (Pro Version – Administrator only)</u>

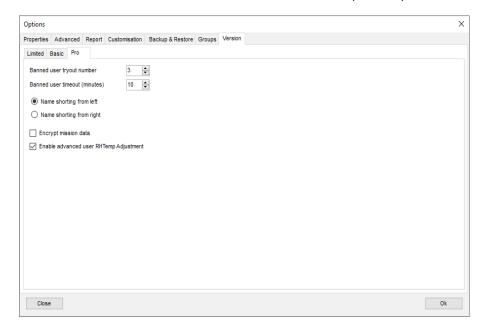
The Administrator can set a limit to the number of times a user can type a wrong password. When this number is reached, the user is banned for a period of time.

Setting the maximum number of wrong password typing (Pro Version - Administrator only)

To set the number of times a user can digit a mistyped password open the **Tools – Options** window and select *Version* tab. Select then *Pro* tab and set the number in the *Banned user tryout number* field.

Setting the period of ban

To set the period of ban for the user who mistype its password too many times, open the **Tools – Options** window and select *Version* tab. Select then *Pro* tab and set the number in the *Banned user timeout (minutes)* field.

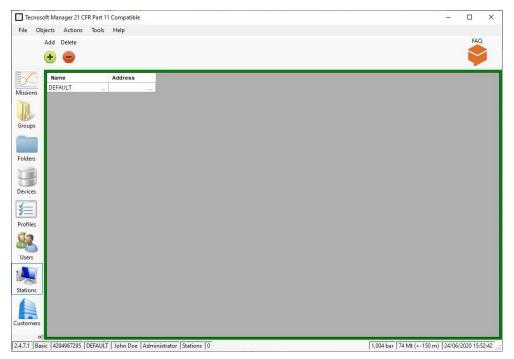


Managing the Stations (Stations)

A station is a terminal (PC) upon which TS Manager is installed. The Stations function allows you to give names to each computer running TS Manager. This will enable you to keep track of which computer started a specific mission. Once you have created a station for each PC, to actually assign the station to a specific PC you will need to set the configuration parameters (p. 34).

You can delete all the stations except for the station assigned to the PC from which the operation is being carried out. Furthermore, you can never delete the last station in the archive.

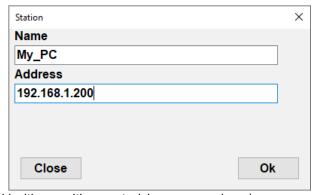
To access the stations archive, click on the Stations button from the left menu.



This archive is never empty, even right after program installation, since at least one station is required and can be shared by all the PC's running TS Manager. The default station is called DEFAULT and cannot be deleted unless you first create another station and associate it with the terminal you are using.

Adding a station (Administrator, Advanced only)

Click on **Add** to open the *Station* window and fill in the fields.



The following fields need to be filled in (those with an asterisk are compulsory):

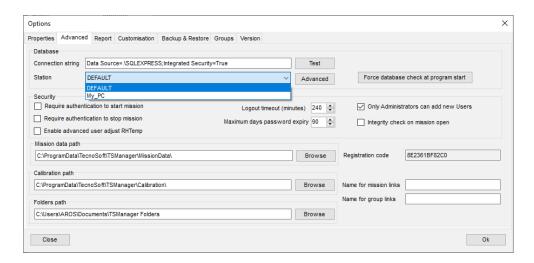
- Name: digit a name that will be used to identify the station;
- Address: an email or web or IP address linked to that terminal.

Note: it is not possible to modify any of the above fields, not even by an Administrator. If you have made an error when adding the station, you will need to access the program as an Administrator, delete the entry and create a new station from scratch.

Associating a station with a PC (Administrator only)

After creating all the stations required to identify all the computers that will access the TS Manager database, you may now link the station to the corresponding PC.

Select *Options* from the *Tools* menu and then open the *Advanced* tab. In the database section, next to the *Station* label select the station to which you want to assign the PC being used from the drop-down list. Click **Ok** to apply the change. Once you change the station assigned to the PC, TS Manager will ask you to close and restart the software.



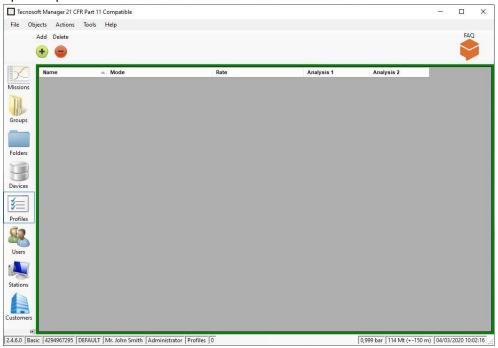
Deleting a station (Administrator only)

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

Note: you cannot undo this operation. You will have to create a new station if you inadvertently deleted one.

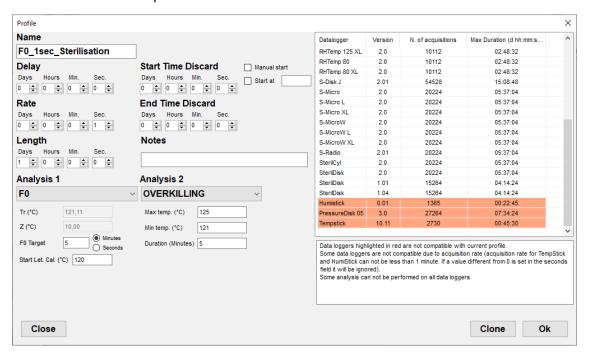
Managing the Profiles (Profiles)

To be able to launch a mission on a data logger, you will have to assign at least one profile by which data will be analyzed. The profiles are identified by their name, and hold a number of parameters that can be set by the user. You may access the profiles by clicking on the **Profiles** button from the left menu. The profiles are then selected when a mission is started, and therefore avoid you having to input the parameters each time a new mission is started.



Adding a profile (Administrator, Advanced only)

Click on the Add button to add a new profile and fill in the fields in the Profile window.



- Name: a name assigned to the profile;
- Mode: this field is displayed only for profiles created with versions previous than 1.4.7.1 and are grayed. New profiles, created with version 1.4.7.1 and above do not have this field. If present, it indicates the type of data loggers to which this profile is assigned. Old profiles cannot be used anymore but they can be copied using the Clone function to generate an identical profile. Just assign a new name to it;

- *Delay*: the delay, which applies from the instant the mission is programmed, after which the logger will start recording. This is expressed in Days, Hours, minutes (Min.) and seconds (Sec.);
- Rate: acquisition interval expressed in Days, Hours, minutes (Min.) and seconds (Sec.). It indicates how often a data is recorded;
- Length: mission duration, expressed in Days, Hours, minutes (Min.) and seconds (Sec.). When this time expires, the logger stops acquiring;
- Manual Start: select this option if you want the logger to start manually. When this option is selected and you start a logger that support this option, you will have to put a clip on the logger between the two metal ends within 60 seconds; the logger will check its presence every 60 seconds. When the clip is removed the acquisition will start according to the set Rate (this option is not supported by all loggers and all firmware versions). If you have set also a delay, it will be ignored;
- Start at: type in this field the temperature at which the logger must start its recordings. If the option is enabled, the device will check temperature every 60 seconds and start acquiring when that value is reached according to acquisition Rate (this option is not supported by all loggers and all firmware versions). If you have set also a delay, it will be ignored;
- Start Time Discard: this is the time, expressed in Days, Hours, minutes (Min.) and seconds (Sec.) that will be discarded from the Analysis from the start of the mission. The data is nevertheless recorded but the software will ignore them while checking the Analysis;
- End Time Discard: this is the time, expressed in Days, Hours, minutes (Min.) and seconds (Sec.) that will be discarded from the Analysis from the end of the mission. The data is nevertheless recorded but the software will ignore them while checking the Analysis;
- Notes: here you can type in some notes to help you to remind the use of the profile while starting a mission; these notes won't be printed in the report;
- Analysis 1 / 2: you may select standard formula from the drop down menus with which to perform additional analysis; some parameters cannot be modified by the user since fixed, specific values are required. The parameters shown may differ according to the logger type and the type of analysis chosen and will only be shown after a specific choice has been made. You may add profiles without including any predefined analysis.

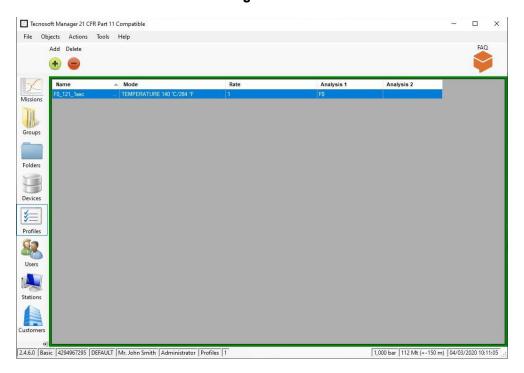
On the right part of the window a list of loggers is displayed: these are all loggers currently supported by TS Manager. Each logger has the following information:

- Version: the firmware version of the logger. Some loggers have different firmware version and so different features;
- Read: number of maximum acquisitions that can record before memory is full. If memory is full the logger will stop recording. Start a new mission to reset the memory:
- Duration: according to the set parameters (delay, rate, length) and the memory, here it is indicated the maximum duration of a mission before the logger will stop acquiring. For example, if you have set 1 second rate, it will show, in days, hours, minutes and seconds, the duration of the mission for each logger, according to the number of acquisitions in its memory. However, if the length set will stop the acquisitions before the memory is full, this duration will be shown.

When you set the different parameters for the profile some of the loggers will be highlighted in red meaning they cannot use this profile. Reasons may be vary: a function is not supported; *Rate or Analysis* are not compatible and so on.

Note: it is not possible to modify any of the above fields, not even by an Administrator. If you have made an error when adding the profile, you will need to access the program as an Administrator, delete the entry and create a new profile from scratch.

When finished, click **Ok** to save the new *Profile*.



Analysis types and Parameters

The Analysis is a set of values and parameters to be set so that the TS Manager will do automatic calculation and will provide an immediate result. The Analysis types that calculate Lethality share the same parameters. Here is the list of these common parameters:

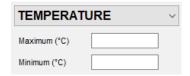
- Tr (°C): reference temperature of the process used in the Lethality formula;
- Z (°C): the value of Z used in the Lethality formula;
- F0 / FT / PU / A080 / A090 / A0T / Target (Min.): the target Lethality value that you want to reach during your process. Select if you want it to be expressed in Minutes or Seconds;
- Start Let. Calc. (°C): stands fro Start Lethality Calculation, the temperature value below which the recordings will not be considered when calculating Lethality.

Below is a list of all available analysis and the parameters that can be set for each of it.

TEMPERATURE

Here you can set a maximum and minimum value to check if temperature goes out of limits.

- Maximum (°C)
- Minimum (°C)



F0

Analysis to check Lethality. F0 is used for sterilization check.

- Tr (°C): fixed at 121,11;
- Z (°C): fixed at 10;
- F0 Target (Min.): free field;
- Start Let. Calc. (°C): free field.



FT

Analysis to check Lethality with all free fields.



PU

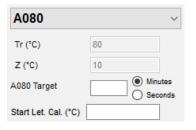
Analysis to check Lethality. PU means Pasteurization Units and is used especially in Pasteurization processes. All fields are free.



A080

Analysis to check Lethality. A0 is used especially for washer disinfectors check,

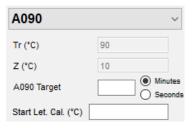
- Tr (°C): fixed at 80;
- Z (°C): fixed at 10;
- F0 Target (Min.): free field;
- Start Let. Calc. (°C): free field.



A090

Analysis to check Lethality. A0 is used especially for washer disinfectors check,

- Tr (°C): fixed at 90;
- Z (°C): fixed at 10;
- F0 Target (Min.): free field;
- Start Let. Calc. (°C): free field.



A0T

Analysis to check Lethality. A0 is used especially for washer disinfectors check, All fields are free.



OVERKILLING

Analysis to check stability of the autoclave but not only. It will check if the temperature is maintained within the two set limits for the indicated period.

- Max Temp. (°C): maximum temperature limit;
- *Min Temp.* (°C): minimum temperature limit;
- Duration (Minutes): duration (in minutes) of the stability period within limits set.



AIR LEAKAGE TEST

Analysis for pressure, to check if there are leaks during the vacuum period in an autoclave. The parameters are taken directly from the UNI EN ISO 13060.

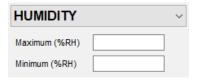
- Time t1-t2 (Sec 300/600): time in seconds between starting time and first step. Should be between 300 and 600 seconds;
- Time t2-t3 (Sec 600±10): time in seconds between first and second step. Must be 600±10 seconds;
- P. increase (mbar/min): increase of pressure during each period. It cannot exceed 1,3 mbar per minute, fixed value.



HUMIDITY

Here you can set a maximum and minimum value to check if humidity goes out of limits.

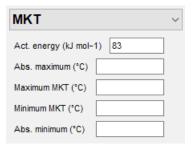
- Maximum (%RH)
- Minimum (%RH)



MKT

MKT is the calculation of the Mean Kinetic Temperature (read more in Addendum B, p. 96).

- Act. Energy (kJ mol-1): Activation Energy. By default, is set to 83 (leave this value if you don't know what to set);
- Abs. Maximum (°C): absolute temperature that must never be exceeded;
- Maximum MKT (°C): standard maximum conservation temperature that must not be exceeded by MKT;
- Minimum MKT (°C): standard minimum conservation temperature. MKT must never go below this;
- Abs. Minimum (°C): absolute temperature which MKT must never go below of.



Clone a profile (Administrator only)

It is possible to make an exact copy of a Profile simply opening it and clicking on Clone. A window will open where you have to assign a name to the new Profile.

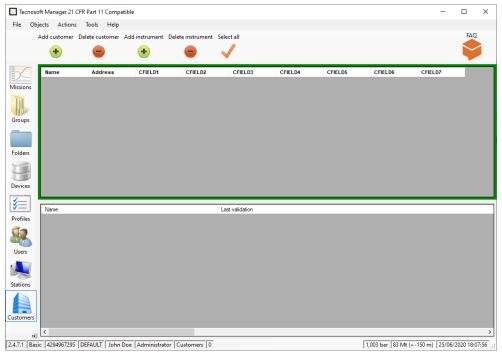
<u>Deleting a profile (Administrator only)</u>
To delete a profile, select it from the list and click Delete.

Note: you cannot undo this operation. You will have to create a new profile if you inadvertently deleted one.

Managing Customers and their Equipment (Customers)

This archive is especially suited for system validators, that is to those users who have a number of customers and possibly more than one piece of equipment, instrument, per client. In this manner, such users may keep track of their validation procedures, knowing which devices were used for each of their client's instruments. The top part of the middle pane holds the list of clients. The pane below holds the instrument (equipment) to be validated (autoclaves, incubators, disinfectors etc.): the pane enclosed in a green rectangle is the currently selected pane.

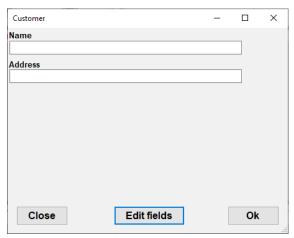
This part may also be used by normal users to keep track of their own missions, possibly also setting custom fields in the configuration section (p. 43).



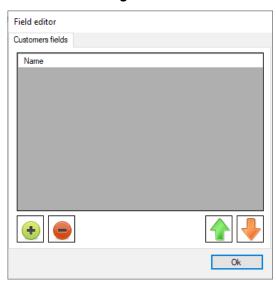
Adding a client (Administrator, Advanced only)

Click on **Add customer** to add a new client, and fill in the appropriate fields in the *Customer window*, which contains two fixed fields that cannot be changed:

- Name: the client's name or business name. We suggest to use different names to be able to find easily each
 Customer and to use the filters in the proper way;
- Address: the client's address.



You can add custom fields by clicking on **Edit fields**: for more information see p. 43.



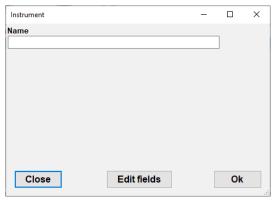
You may also select all the clients by clicking on the **Select All** button in the *Actions* menu, if the top part is highlighted in green.

Note: it is not possible to modify any of the above fields, not even by an Administrator. If you have made an error when adding the client, you will need to access the program as an Administrator, delete the entry and create a new client from scratch.

Adding an instrument (Administrator, Advanced only)

Select the client under which you would like to add an instrument, then click on the instrument pane and click **Add instrument** to add the new instrument. Fill in the fields in the *Instrument* window, that holds one standard and non-editable field name:

• Name: the name assigned to the instrument. We suggest to use different names to be able to find easily each Instruments and to use the filters in the proper way.



You can add custom fields by clicking on **Edit fields**: for more information see p. 43.



You may select all the instruments by clicking on the Select All button in the Actions menu, if the bottom part is highlighted in green.

Note: It is not possible to modify any of the above fields, not even by an Administrator. If you have made an error when adding an instrument, you will need to access the program as an Administrator, delete the entry and create a new instrument from scratch.

Using Customers and Instruments as Filters for the Missions

If you select one *Customer* and then one or more of its *Instruments* and then access the *Missions* archive you will only see those missions that have been performed on those specific instruments. You may enable or disable the filters by client and instrument by clicking on the **Toggle Filter** button in the *Actions* menu bar of the *Missions* archive.

User custom fields (Administrator only)

The user may add up to 16 custom fields for the clients and instruments and missions by means of the configuration window: these fields will appear in the Client or Instrument windows or when a mission is started (p. <u>46</u>) and the user can fill in those fields at that time.

We recommend, to those users who are using TS Manager to monitor their own plants and processes, to create a client entry for themselves so that they are able to keep a database of their own instruments and areas being monitored.

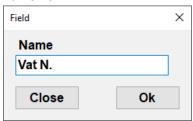
Adding custom fields

To add a new custom field, click on the **Edit fields** button in the window for *Customer or Instrument* creation: a list will open(at the beginning will be empty) where you can add items by clicking on the + and removing them be clicking on the -. You can access the same list select *Options* from the *Instruments* menu at the top and open the *Properties* tab. Three panes will appear: *Customers, Instruments and Missions*.



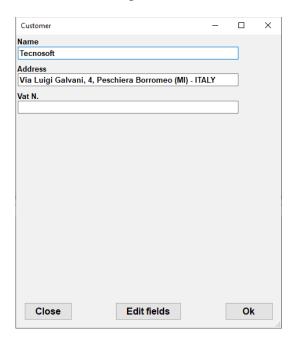
Click on the corresponding + button below the required pane to open the *Field* window. For Mission fields see p. <u>49</u>. A message will inform you of the number of fields you can still add.

Each custom field is identified by its *Name*. For example, for each instrument you may wish to specify to fields to hold the manufacturer and model or for the customer its Vat N. Once you have filled the Name field click Ok. Repeat the procedure to add all requested fields for *Customers and Instruments*.



You will see that the fields have been added to the proper list. From now on when a new *Customer or Instrument* window is called up these fields will appear in the window and they will of course also appear in the archive list.

You can move up and down the fields inside their own list by selecting them and clicking on the up and down arrows.



Deleting a custom field (Administrator only)

To delete a custom field select it from the list and the click on the - button.

Note: if you remove a field from the list, it will be removed from its customer or instrument too and all the related information will be lost. This operation is not reversible.

Deleting a customer (only Administrator users)

To delete a customer, select it from the list and then click **Delete**.

Note: this operation cannot be undone. You will have to recreate a client if you make an error.

Deleting an instrument (only Administrator users)

To delete an instrument, select the client to which the instrument belongs, and then select the instrument from the list, after which click on the **Delete** button.

Note: this operation cannot be undone. You will have to recreate the instrument if you make an error.

Devices and accessories

All the data loggers that are currently compatible with TS Manager connect to the PC by means of different connection bays that you can see at p. 9.

The first operation that needs to be done is to connect the interface to a free USB port. Drivers should have already been installed during software installation.

Connecting the interfaces

You may have received your interface with the loggers, with the TS Manager kit or separately. Each interface comes with a USB cable: connect the cable to the interface and then to a free USB port on the PC.

As soon as the device is connected to the PC, Windows will automatically detect it and will start installing the drivers, if not already installed.

Connecting the devices

The data loggers must be inserted in the interface in a particular manner, depending on the logger and the interface: if you connect the device incorrectly it will simply not be able to communicate with the PC, however there is no risk of damage to the device.

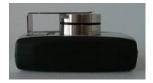
For loggers using the DiskInterface HS, DiskInterface HS Mini and Universal Multibay in general, the side of the data logger on which the serial number is engraved should face down and be placed on the base of the interface. In the case of cylindrical data loggers, where the laser marking I on the side, the probe tip should always be directed towards the top and be inserted in the fork.

See the images below to see how the data logger should be connected (not all loggers are shown) for correct communication with the software.











When using the TecnoStick Interface for TempStick and HumiStick, insert the flat part of the logger, with the three golden strips, in the narrow crack in the interface, opposite to the USB connector.



It is also possible to connect more than one interface simultaneously and start them and download data in sequence, one after the other.

Starting the data loggers (Missions)

After completing the stages described above, you may proceed to use the main functions of the program, that is the management of the data loggers and the analysis of the downloaded data. Make sure the interface is correctly connected to the PC, that the USB drivers are correctly installed and that the data logger is correctly connected to the interface.

The concept of a mission

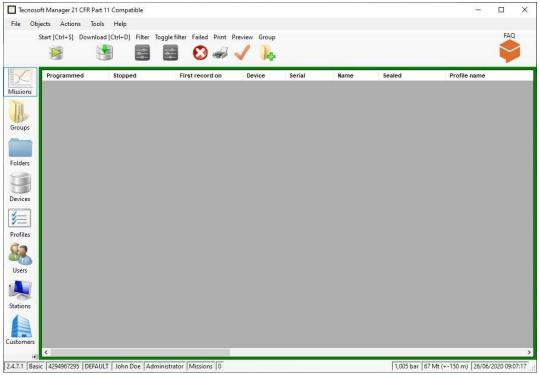
We can describe a mission as follows. Once a data logger is started we can say that it starts a data logging mission, that is a monitoring process that is well defined, with a start (normally the moment it is programmed) and an end, which could be the moment the data is downloaded, or a pre-programmed end date and time.

Each mission is therefore identified by means of two main parameters: the start date and time, and the serial number of the data logger. In fact, it is practically impossible that there exist two missions that start at exactly the same time, on the same day, on the same data logger (which holds a unique serial number).

Furthermore, TS Manager also adds other parameters that identify the mission in more details, and therefore makes it easier to identify, such as the station or user who started the data logger.

Starting a mission (Missions - Start)

Make sure the data logger is inserted in the interface connected to the PC, and from the *Missions* archive click on the **Start** button from the *Actions* menu. If the option that requires user authentication to launch a mission has been enabled, you will have to re-type your password to proceed (p. 49).



The *Mission Start* window will appear showing the list of interfaces connected to the PC and the port to which is connected as well as an image of the data logger that has been inserted, along with some additional information:

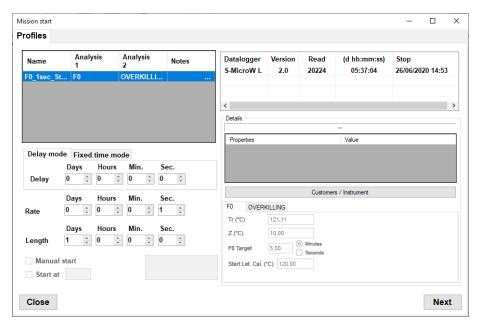
- the type of data logger and its firmware version;
- unique serial number that cannot be modified;
- suggested date for device recalibration. By default, is 12 months since last calibration. If it is highlighted in red it means that it expired;
- device status (Stopped if it is not acquiring, In Acquisition if a mission is in progress)
- acquisition interval, expressed in days, hours and minutes (if the device is stopped this value refers to the interval used in the previous mission);
- the current temperature being measured;
- the current pressure being measured (if available);
- the current humidity being measured (if available);
- battery voltage. If it is highlighted in red you should replace the battery. in the example below we see a connection with an S-MicroW L.

Click on **Next** to select the profile.

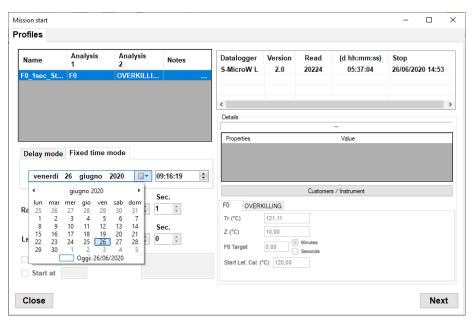


From the *Devices* tabs we move on to the *Profiles* tab, still within the *Mission Start* window. From the list at the top left of the form, select the profile you wish to use for this mission: only those profiles that are compatible with all connected loggers are shown (see p. <u>35</u>).

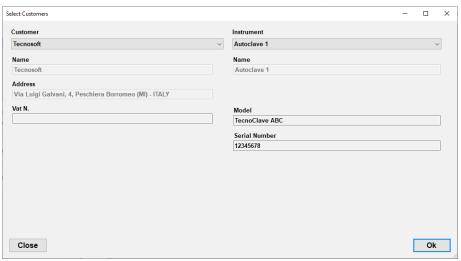
Note: if you try to start a logger that is acquiring, meaning it is currently recording a mission, the program will ask you if you want to download it first or you wish to proceed.



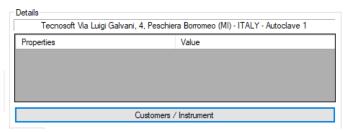
You cannot modify the parameters for the selected profile, not even those shown in the bottom left part of the form for the type of analysis selected. You can, however, select a different start delay: when creating a profile you can specify a delay in terms of days, hours, minutes and seconds only; however, when starting a new mission, you can instruct the logging to start at a specific date and time. By means of the *Fixed Time Mode* tab you can specify a fixed, precise date and time at which the mission will start. This is very helpful if you want to synchronize the acquisitions of all loggers in the Sync Data table in the *Groups* (p. <u>75</u>).



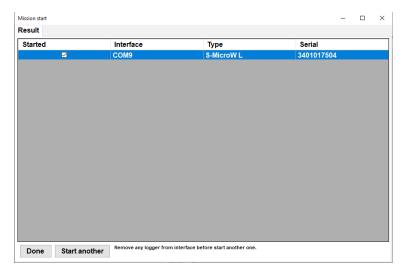
On the right hand side you may fill in the custom fields for the mission (see p. 49), or select a customer, by clicking on **Customer / Instrument**.



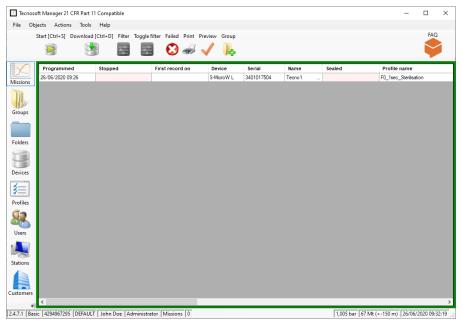
Select the Client and Instrument and these will appear at the top of the Details pane of the Mission Start window.



Click on **Next** to proceed. If you are starting the data logger for the first time with the current database, you will be asked to specify a name for the data logger. This operation is not mandatory but naming the loggers can be useful when performing analysis. For more information, please refer to the chapter *Setting the name of the datalogger (Devices – Name)* (p. <u>50</u>). TS Manager will program the data logger or data loggers and will show a window that holds a summary of the operation including some generic data as well as whether the mission was started correctly or not. Click on **Done** to exit or remove the logger in the interface, place a new one and click on **Start another** to start a mission on another data logger.



The *Missions* archive will show a new entry: the columns *Stopped* and *First record* on will be empty, indicating that the mission is still running and has not been stopped. If you start a new mission on a data logger that is acquiring, the current mission, which will be interrupted, will not be closed and will appear open in the database. There is no possibility to retrieve data of a previous mission on a restarted data logger.



Request user authentication when starting a mission (Options – Advanced – Security) (Administrator only)

The administrator may request that each user, whenever starting a new mission, reinserts his/her password. This additional option guarantees maximum security for the use of the system and its devices and reduces the risk of unauthorized operations. To enable this option, click on **Tools – Options**, access the *Advanced* tab and check on the *Require authentication* to *start mission* option.



Click Ok to apply the changes.

Mission customizable fields (Administrator only)

The user may add up to 16 custom fields for the missions: these fields will appear when a mission is started (p. $\underline{46}$) and the user can fill in those fields at that time.

Click on **Tools – Options** and open the *Customization* tab. The last list is the *Mission fields* list and works like the *Customers and Instruments* lists. You add fields by clicking on + and remove them by clicking on -. To move the fields in the list, use the **up** and **down** arrows.

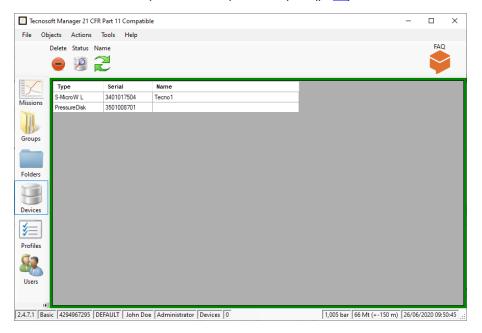
50/102 TS Manager Tecnosoft srl

When you add a filed the software will request to give it a name.

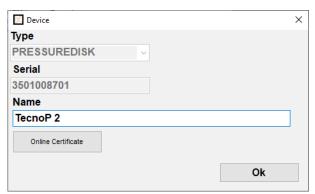


Setting the name of the data logger (Devices - Name)

When a data logger is started for the first time TS Manager will ask you to specify the name you wish to assign to the data logger. This operation is not mandatory. If you program a logger and don't assign a name to it, you can still do it be opening the *Devices* archive. The name is used in the Groups and in the printed report (p. <u>73</u>).



Select the logger you wish to change the name of and click on Name. Set the name you want to assign and click Ok to confirm.



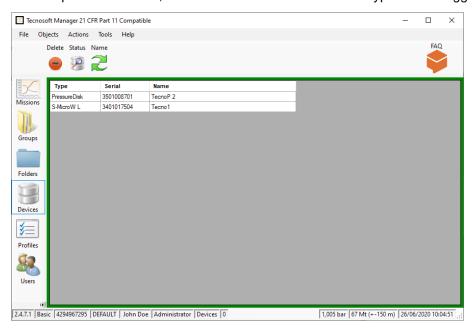
If you click on **Online Certificate** the Tecnosoft Support and Assistance website will open: here you can download the certificate of your logger and its related reference certificates.

The website link is: http://support.tecnosoft.eu/en

You have to register in order to be able to access the different area of the website. Instructions for registration are here: https://www.tecnosoft.eu/en/faqs/#faq-category-tecnosoft-service-and-support-website.

Checking the devices in use (Devices)

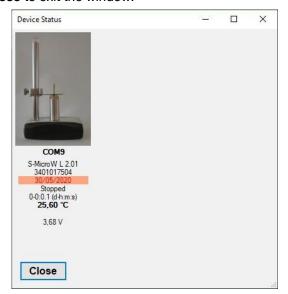
The *Devices* archive shows a list of all the devices that have been connected to the database. This list also displays some additional information about the particular device, such as the serial number and the type of data logger.



Checking the status of a device

If you would like to check the status of a device without starting it or downloading data, you can simply connect it to the interface (p. <u>45</u>) and click on the **Status** button in the *Actions* menu.

The *Device status* window will appear where device details will be displayed, among which the status of the device: *Stopped or In Acquisition*. Click on **Close** to exit the window.



Deleting a device (Administrator only)

You can delete a device by selecting it and clicking on **Delete**.

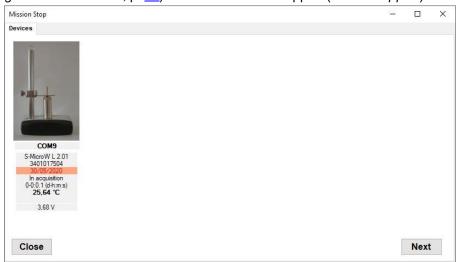
Stopping and downloading a mission (Missions)

After having started a data logger and used it to monitor your application, you may insert it into the interface and download the data for further analysis.

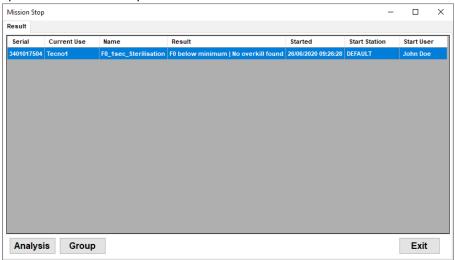
Downloading data from a device (Missions – Download)

Place the logger or loggers to download on the interface and click on the **Download** button to connect to the device; the *Mission Stop* window will appear, displaying some information about the connected unit. You may be asked to reinsert your password, if the Administrator has enabled this option (p. <u>53</u>).

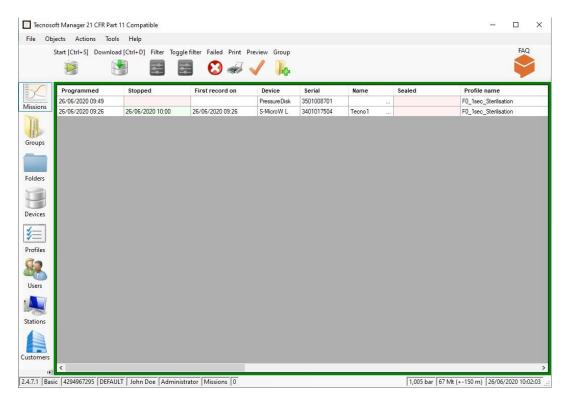
Click on **Next** to start downloading data. When you download data from a device that is currently acquiring (to check the status of a device see *Checking the devices in use*, p. <u>51</u>) this device will be stopped (status *Stopped*).



Once the download is complete, the *Result* window will appear, displaying the basic information related to the data that has just been downloaded, which are the name of the device, the profile used for the mission and, in the result column, the results of the analysis based upon the parameters set in the profile.



Click on **Analysis** to view the mission data. Click on **Exit** to close this window; you will be able to analyze the data later since the data that has been downloaded is accessible from the corresponding entry in the list displayed in the *Missions* archive. From the *Result* window you can also add the mission to a *Group*. For this see p.66.



User authentication request when downloading data (Options – Advanced – Security) (Administrator only)

The administrator may request that the user retypes the password each time a mission is to be downloaded. This additional security option guarantees maximum security for the use of the system and its devices and reduces the risk of unauthorized operations.

To enable this option, click on **Tools – Options**, access the *Advanced* tab and click on the *Require authentication* to stop *mission* option.

Security		
Require authentication to start mission	Logout timeout (minutes) 60	Only Administrators can add new Users
Require authentication to stop mission	Maximum days password expiry 90 👗	Integrity check on mission open

Click on **Ok** to apply the changes.

Files saved and data encryption (Pro Version - Administrator only)

When a logger is downloaded and a mission closed in the Mission archive of the database, two files are saved in the *Mission data folder set in the Options window* (p. <u>25</u>).

The two files are basically the same, one having the .XML extension and one having the .CXML. The latter is the one connected to the database while the XML is provided for general purposes to the user.

If no encryption option is enabled, the two files are exactly the same. If there is encryption enabled, the .CXML file will be encrypted.

Enable encryption (Pro Version – Administrator only)

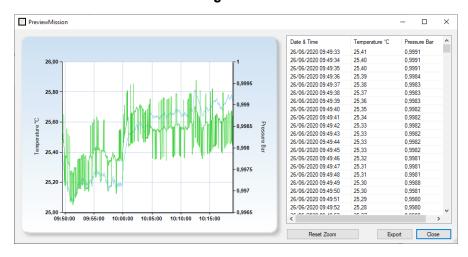
To enable encryption, open the *Pro* tab in the Version tab of the **Tools – Options** window. Check mark the *Encrypt mission data* option at the bottom.

Downloading a mission started using a different database

If you try to download the data from a data logger that has been started using a PC that is connected to a different database or using a different program (such as SPD or HumiPressureDisk), TS manager will notify you that the start mission record is not present and therefore you will not be able to view the recorded data.

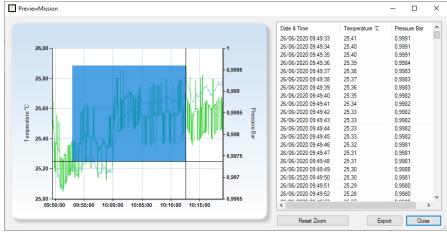
Checking a mission without stopping it or downloading data

You may check a mission in progress without having to stop it, simply insert the data logger in the interface and click on **Preview** in the *Missions* archive.

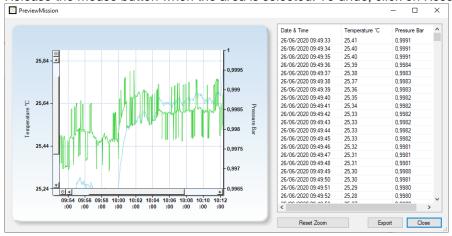


Zooming the graph in the Preview view

You can zoom in the graph of the preview mission view. Click on a spot inside the graph and, keeping pressed the mouse left button, drag the mouse to highlight in blue the area to be zoomed.



Release the mouse button when the area is selected. To undo, click on Reset Zoom.



Exporting Preview data

You can export the data in the preview data in a format that can be read by Excel. Just click on **Export** and select the folder where to save the file and its name.

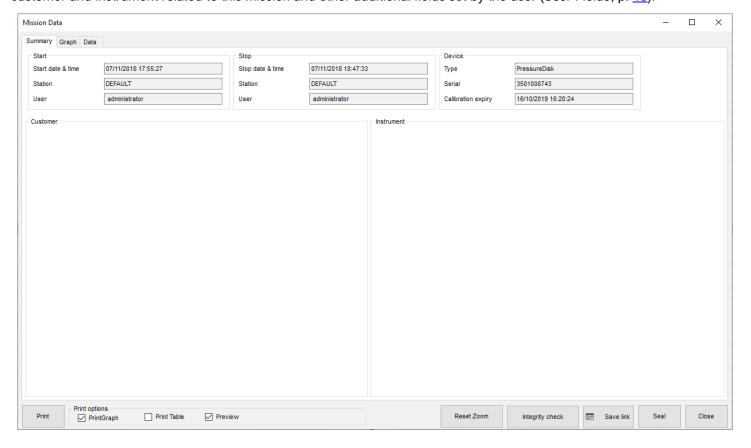
Analyzing single missions (Missions)

To view and analyze the data of a particular mission, click on the **Analysis** button after downloading the data (p. <u>52</u>) or alternatively double-click on the required mission in the *Missions* archive as long as the mission has been stopped (in which case the end date and time will be shown in the *Stopped* column and highlighted in green). You cannot access a mission that has not been stopped.

Once a saved mission is opened, the Mission Data window will appear, divided into three tab sheets: Summary, Graph and Data.

The Summary tab

The Summary displays all the information related to the mission: basic information such as the data logger serial number and model, up to information related to the traceability of the mission, which user started the mission and from which station, the customer and instrument related to this mission and other additional fields set by the user (*User Fields*, p. 43).

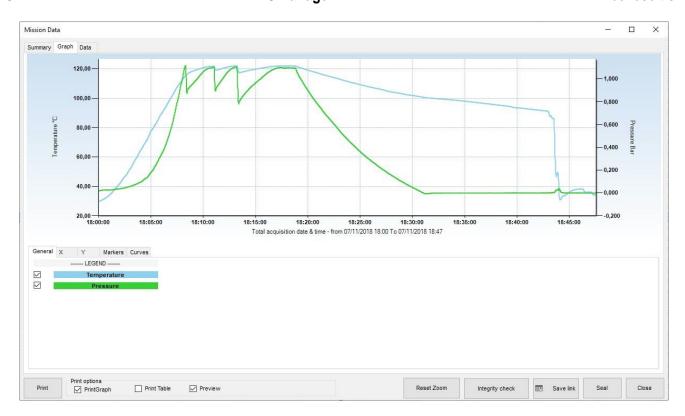


Analyzing data using the Graph

The graph is displayed by clicking on the Graph tab. In the main area you will see the plot, or plots if more than one channel is being measured, of the recorded data: on the left hand side you will see the temperature scale, whereas on the other end the scale for the second channel (pressure or humidity). The blue plot refers to the temperature readings, whereas the other channel is shown in green. The horizontal axis displays the time at which the measurements were taken: below this the global start and end date and time will be displayed. This global time means that it does not include the time to discard from the start and end of the mission, as set in the corresponding profile (p. 36) and neither the markers that you can set on the graph (p. 57). Below their different tabs that will help in analyzing data of the graph itself.

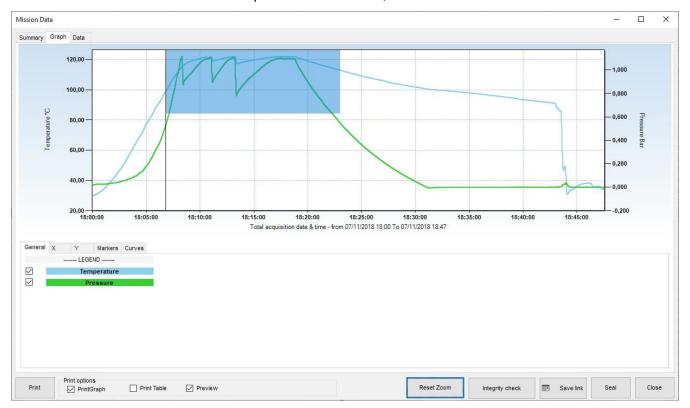
Selecting curves

From the General tab you can enable or disable each available curve on the graph, below the LEGEND title.



The Zoom function of the graph

You can zoom into an area of the graph by clicking on it with the left mouse button and dragging it: a blue area will appear that will enclose the area to be zoomed. Once the required area is selected, release the button.



Zoom out the Group graph

Once zoomed, vertical and horizontal scroll bars will appear so you can move through the graph at the selected zoom level. You can also re-zoom into a graph that has already been zoomed by following the same procedure described above.

To revert to the original graph, use the **Reset Zoom** button.

Setting grid-lines and scale

The graph is automatically generated once you open the mission but there are still some options you can set in order to customize its view. These options are setting the grid-lines, the thin grid inside the graph area, and the scale, the numbers at the right and at the left of the graph, for the vertical (Y) axis.

Setting the grid-lines for the time axis (X)

Click on the *X* tab and type the value you want to set in the field *Time Seconds*, then click on **Set**. For example, if you want to have a vertical line for the grid every 10 seconds type in 10 and click **Set**.



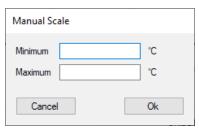
Setting the grid-lines for the values axis (Y)

Click on the Y tab and decide whether you want to set a grid for the first or second channel under GRIDLINES, if there is more than one. Then type in the proper field the desired value. For example, if you want a horizontal line every degree, type 1 in the *Temperature* °C and click on **Set**. If you want to set, for example, a line every 10 mbar, type 0,01 in the *Pressure Bar* field and click on **Set**. Setting a grid will automatically disable the other one.



Setting the Scale

Click on the Y tab and select **Manual** under *SCALE* (left or right) to set the scale of the graph. With this option you can change the scale of the values written on the left and right Y axis. For example, after you click on the left **Manual** set as the *Minimum* and *Maximum* values of °C for the scale 0°C and 100°C in the *Manual Scale* window: the graph will be redrawn only in the area from 0°C to 100°C. If there are values outside this range they won't be shown. Click **Ok** to confirm. From the Y tab you can select **Auto** to go back to default scale.



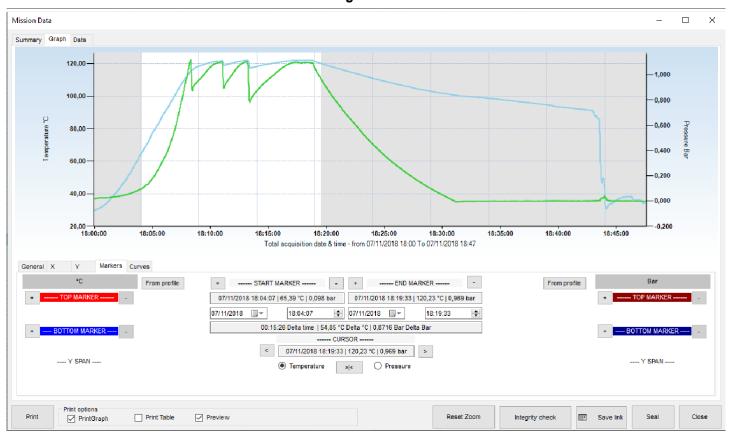
Setting the markers

Markers are horizontal or vertical lines that can be set directly on the graph. From the Markers tab you can set both vertical markers, from the central settings, and horizontal markers (two for each channel) on the left and right of the tab.

Setting vertical markers

You can set two vertical markers, one for the start and the other for the end of the process. These markers are used to exclude two portions, at the beginning and at the end of the graph, from the analysis. The excluded area will be grayed. This means that you can only exclude two portions of the graph; from the first acquisition to the first marker, and from the second marker to the last acquisition of the mission. You cannot perform an analysis on non-contiguous portions of the graph.

By positioning the cursor on the graph and clicking with the mouse, you will see two perpendicular lines that indicate the position of the marker on the graph. The marker can be aligned to the closest acquisition. To set the first marker click on the graph where you want to position it and then click on the + button to the left of *START MARKER*. Repeat the same for the *END MARKER*. The two extremities of the graph will be grayed while the central part, which is considered for that analysis, will remain white.



Below the START MARKER and END MARKER you will find: date and time of the marker with temperature and second channel value, where the marker meets the curves. Below there are two fields to set exact date and time for the marker, instead of moving it (see below) and a final bigger field with the difference (*Delta*) between the starting and ending time and values of the channels.

Note: if you select a date and time outside of the graph area the date and time will be automatically set at the beginning of the graph for the START MARKER and at the end of the graph for the END MARKER.

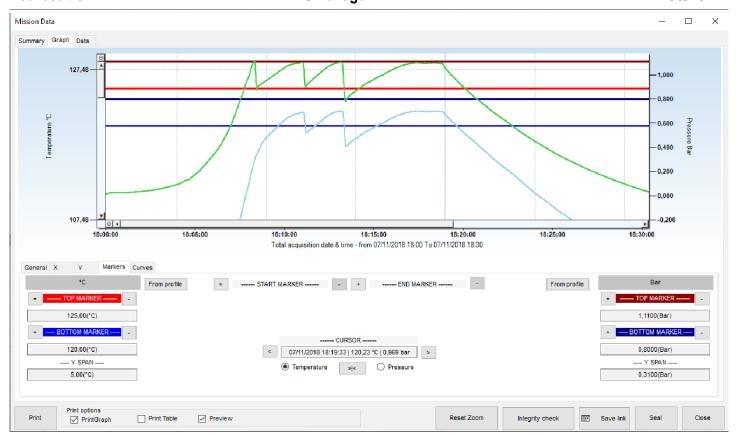
Aligning the cursor on the X axis

When you click on the graph to set a marker you hardly hit the right moment you want to set the marker on, even if you make use of the tooltip that is shown while you move the cursor on a curve in the graph. To place the cursor and therefore the marker on the exact desired moment, i.e. acquisition, use the buttons below the *CURSOR* writing. When you click somewhere in the graph the field below *CURSOR* will contain exact position of it: date, time, temperature and the second channel value (where the vertical line of the cursor meets the curves). If you want to place the cursor on an exact acquisition, select if you want an acquisition on the temperature or the second channel curve and click the >|< button. Then you can move from one acquisition to the other on that curve using the left and right arrows: < and >.



Setting Horizontal markers

There are also four horizontal markers in the Markers tab, two for each channel, identified on the left and right of the tab as *TOP MARKER and BOTTOM MARKER*. As for the vertical marker, click on the graph where you want to place the first top marker and then click on the + next to the left *TOP MARKER* field. Repeat for the other markers if required. When you set a marker a field below it will show the value at which it was set. For example, 124,25°C. You can change this value and set one manually, for example 123,00°C and press Enter on the keyboard: the marker will be moved to that value. The field under the two markers of the same channel *Y SPAN* will show the difference between the two limits.



Remove markers

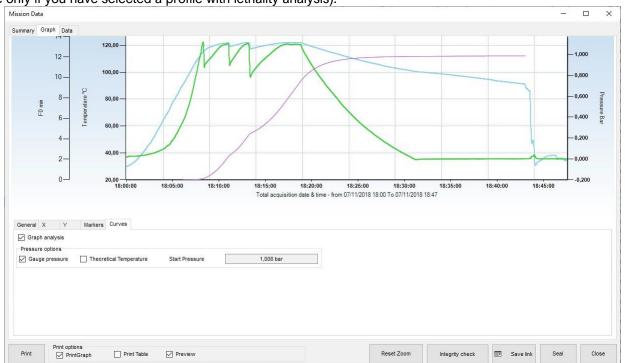
To remove a marker just click on the – on the right of its name.

Showing the Analysis curves and other curves

In the *Graph* tab there are available other curves to be shown. For example, if you have selected a Lethality analysis in the *Profile*, you can enable the view of the analysis curve.

Lethality Analysis curve

Select the *Curves* tab in the *Graph* tab to display new options. Select **Graph analysis** to draw the curve for the lethality (available only if you have selected a profile with lethality analysis).



Pressure curve options: gauge pressure and theoretical temperature

In the same *Curves* tab there are also options for the pressure curve. The first one lets you switch between absolute and *Gauge pressure* values. The logger register pressure in absolute pressure but you might want to compare it with the values coming from the autoclave, which are usually in gauge pressure.

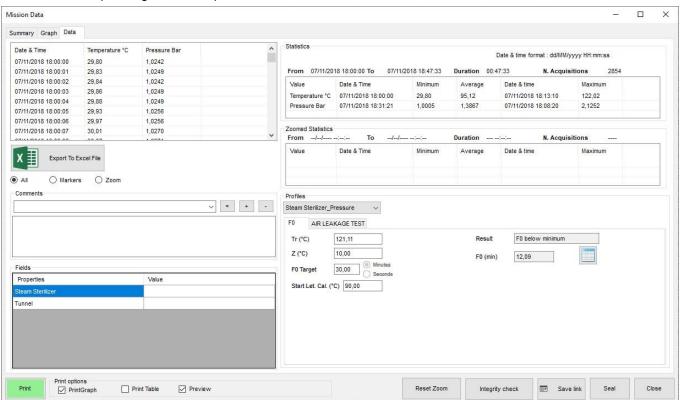
You can also display the *Theoretical Temperature*, a temperature curve calculated on pressure in saturated steam, since there is a unique correlation between temperature and pressure on those conditions.



Analyzing data using the table (Data)

Click on the *Data* tab to access the table of acquired values, the report of the mission statistics as well as the results of the analysis performed on the mission from the selected profile parameters.

On the left you will see the table of values with date, time, temperature and the second channel readings, if present. There might be other columns, depending on some options.



Mission Statistics (Data - Statistics)

On the right hand side the *Statistics* box shows the date and time for the start and end of the mission, the duration and the total number of acquisitions made. Further down, for each channel you will see the maximum, minimum and the average values. *Date & Time format* on the top right corner indicates the format used to display date and time which is that selected in the regional settings in the Windows control panel.

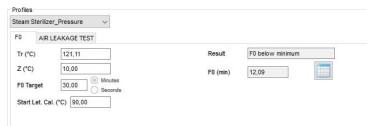


If you zoomed in the graph some additional statistics will be displayed below, in the Zoomed Statistics box.



Analyzing data using the profiles (Data - Profiles)

In the box below, labeled *Profiles*, the profiles you configured when starting the mission is selected in the drop down list and the results obtained from the analysis (*Result* field). Are shown In this area you can also select, from the drop down list, a different profile to that you generated earlier, to be used to analyze the data. If you analyze data with a different profile to that programmed when starting the logger, you will be able to view the results, however these will not be saved in the database. There are two tabs in the *Profiles* box, one for each available Profile.



If it has been selected a Lethality analysis (F0, FT etc.) then there will be an extra field below the Result field. It indicates the calculated value for the lethality and if you click on the button on the right you will be able to export the progressive lethality value into excel.

Additional post-mission notes

The user may also insert additional notes or comments related to the mission in the *Comments* field: this is a free-text area where the user may include notes or opinions on the data or analysis results that might be useful to a third person viewing the data at a later stage. You may also add preset comments from the drop down list. To add preset comments, give a name to the comment by writing it in the drop down list field, then type your comments in the text area and click on the + button to add it to the list of preset comments. To delete a preset comment select it and click on the – button. If you modify a preset comment and would like to change the comment to include the changes, click on the = button. Click **Close** to save the comments automatically, which can then be modified every time you reopen them.



To summarize:

+ to add a comment

to remove a comment

= to save changes to a comment

The Comments are not removed when recreating the database (p. 41).

Mission customized fields

At page 49 it was described the use of the customized fields for the Missions. When opening the Mission Data window, you

have the possibility to update or complete them through the *Fields* box in the bottom left corner of the *Data* tab. Just double click on the proper *Value* cell and type in the content you want.



Closing a mission permanently (Seal)

After analyzing the data for a mission, setting markers and adding comments as required, you can close the mission permanently by clicking on the **Seal** button. A confirmation message will appear and, if you accept, the mission can still be viewed, printed or exported, however you will not be able to perform further analysis using markers and comments. After closing a mission in this manner, you will note that the *Sealed* field for the corresponding mission in the *Missions* archive will be marked *YES*, indicating the mission has been permanently closed.

07/11/2018 11:41	07/11/2018 13:06	07/11/2018 11:50	S-MicroW XL	3401028861		Steam Sterilizer	
04/11/2018 17:22	04/11/2018 18:13	04/11/2018 17:25	Pressure Disk	3501008743	YES	Steam Sterilizer_Pre	
07/11/2018 17:56	07/11/2018 18:59	07/11/2018 18:00	S-MicroW XL	3401028861		Steam Sterilizer	

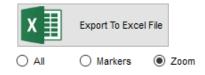
Exporting data in Excel

To export data in excel format, open the Data tab and click on the **Export to Excel File** option: a standard Windows dialogue will appear. Select the destination folder and type a name for the file. By default the file name will consist of the data logger serial number, and the start date and time in ISO format (YYYYMMDD) and (HhmmSS).

Export All data or only part of them

You can choose to export all data or only a portion by selecting the option below the export button:

- All: will export all data
- Markers: will export data between Markers only
- Zoom: will export zoomed data only



Mark a mission as failed

If, for any reason, you cannot download data from a started missions or a mission is for test only and you don't want to see it in the missions list any more, just select it from the *Missions* archive and click on **Failed** button above.

It won't be shown any more since Failed mission are hidden by default. To see them again use filters (p. 65).

Single Mission Report printing

To print a hard-copy of the report for a single mission, open it and select the *Data* tab and click on **Print**. If the *Preview* option is enabled a preview window will appear from which you could then proceed to print the report. The user can personalize the report in three ways:

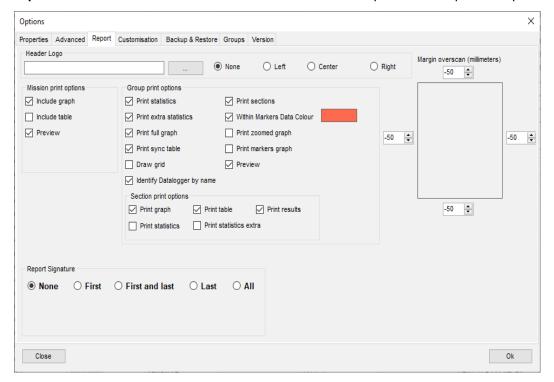
- adding a top header image
- include the graph
- include the table. Once the report is printed, the print button will appear green and similarly, in the *Missions* archive, the *Printed* column will also appear green.

Before sending the data to the printer, you can select the above options using the *Print Graph and Print Table* options. These options are by default enabled or disabled according to the settings chosen by the Administrator (p. <u>64</u>).



Report Printing Options (Administrator only)

From the Tools - Options window the Administrator can set different default options for the printed reports.



Changing the header image of the report

Click on **Tools – Options** and open the *Report* tab. In the *Header Logo* field you will see the path to the image file. You can change this file path to point to the file you require, which will appear on top of the report, by clicking on the **Browse** (...) button. Alternatively, you could also replace the existing file in the current folder, by overwriting it using the same name. Then you can decide if the header must be placed on the *Left*, on the *Right* or at the *Center* of the page. If you select None it won't be displayed, even if there is an image selected in the field.



The header image file will be shown with the following criteria:

- the area for the header is a defined area on top of the page
- the height of the header will be resized according to the space reserved for the image header

• the length of the image will be resized accordingly

Some suggestions:

- avoid the use of logos that are taller than larger
- in case you have a vertical logo, meaning is taller than larger, create a blank horizontal image and place the logo where you want in it (in the center, on the left or on the right)

Adjusting the margins of the printed report

If the printed report seems to be out of the margins of your printer, you can adjust them by changing the values, expressed in mm, on the right of the *Report* tab of the <u>Options</u> window. Just type in the value desired, placing a – in front of it if you want to move the printed area in the opposite direction.

Default report printing options

To include or exclude the graph and/or the table from the report hard-copy enable or disable the *Include Graph* and *Include table* options. Select also *Preview* if you want to have the preview window opened by default.



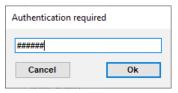
Signature on the Report

There are different ways the report can be signed. TS Manager can print proper spaces where the signature appears or can be written. First of all, decide if you don't want any signature (None), or if you want it on the First page, on the First and last, on the Last or All pages.



If you choose any option but *None* two more options will be shown. You can ask to print a space for the handwritten signature (*Include handwritten signature option*) and to add the electronic signature (*Include electronic signature option*). This means that it will be printed the user's name and last name.

If you request the electronic signature, you'll be asked to authenticate the user by typing the password, before printing.



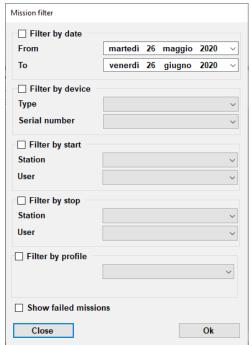
Filtering the Missions (Missions – Filter)

To locate a particular mission, you can sort the list of missions from the *Missions* archive by clicking on the column headers (p. 23); you can also select the client and instrument from the *Clients* archive (p. 42) and also filter the list by clicking on the **Filter** button.

In the resulting window you can select from various filter types, enabling them by clicking on the corresponding name of the particular pane and then selecting the various options within that pane.

For example, if you would like to locate a mission started within a certain time frame, you can enable the first filter, *Filter By date*, and set the start and end of the required period in the two fields occupying this pane. To apply the filter click **OK**. To go back to the original view, that displays all the missions, click **Filter** again; all the options will be disabled - simply click on **OK** to return to the Missions archive will all filters disabled.

You can enable or disable the clients and instruments filter by clicking on the **Toggle Filter** button in the Actions menu of the *Missions* archive. Below is a description of the various filter options.



Filtering missions by mission start date (Filter By Date)

Enable the *Filter By Date* checkbox, input the start date (*From*) and the end date (*To*) of the required period and click **OK** to view a list of missions whose, start date fall within that period.

Filtering missions by device type (Filter By Device)

Enable the *Filter By Device* checkbox and select the required data logger type (*Type*) or the *Serial Number* and click on **OK** to view the missions matching these two parameters.

Filtering missions by user (Filter By Start e Filter By Stop)

Enable the *Filter By Start* checkbox or the *Filter By Stop* checkbox to filter missions that have been started or stopped by a particular user. Use the *Station* drop-down list to choose the station on which the mission was started or stopped. Use the *User* drop-down list to select the surname of the user who started or stopped the mission. Click **OK** to view those missions that match these settings.

Filtering by Profile (Filter by Profile)

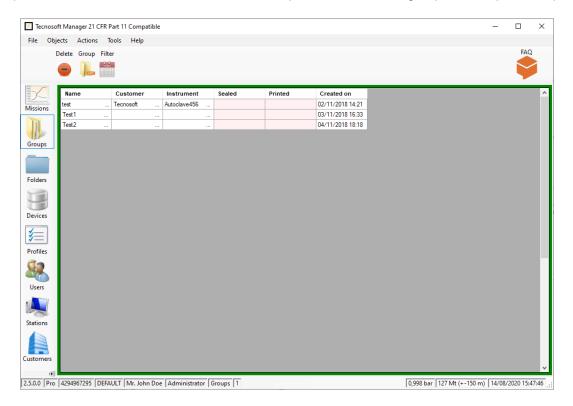
Enable the Filter by Profile option and select a filter from the drop down menu to display all the missions using that kind of profile.

How to show failed missions (Show Failed Missions)

To view failed marked some missions (p. 62) enable the Show Failed Missions filter.

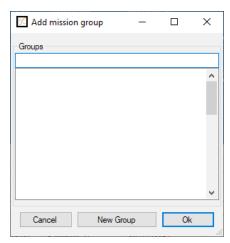
Grouping missions: multiple analysis and graph

Along with analyzing the single missions, it is also possible to select two or more and compare them on a single graph. It is possible to group a maximum of 2 channels: therefore, it is not possible to create a group with temperature, pressure, humidity.



Creation of a group

To create a group, select the *Missions* archive and select all the Missions you want to include in your Group. To select multiple missions just use the SHIFT and CTRL keys as you would multi select files in a folder. Keep pressed the Control key on the keyboard while you click on the missions to group or select the first mission and then the last mission while SHIFT key is pressed, to highlight all missions between those. Then, click on **Group**.



If the list is empty the only choice is to click on **New Group**, otherwise you can select one of the existing groups and click on **Ok** to add the selected missions to that group.

If you chose to create a new group, a new window will open.

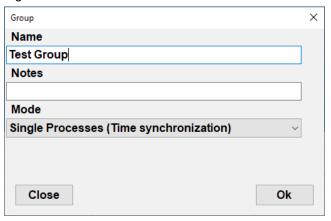
In the *Group* window, type in the *Name* of the group, additional *Notes* and then choose the *Mode*.

Group modes

A group can have two modes, depending on the nature of the selected missions to be compared.

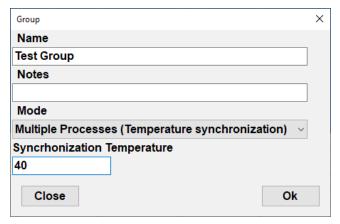
Single process

If the missions come all from the same process and made with different loggers, the mode is called *Single Process*. In this case them missions are synchronized using the time line.



Multiple Processes

If the selected missions refer to different processes made in different periods, even with the same loggers, select *Multiple Processes:* you'll be asked to set a temperature to be used to synchronize the curves, starting from the first time that temperature is recorded on each curve (*Synchronization Temperature*).

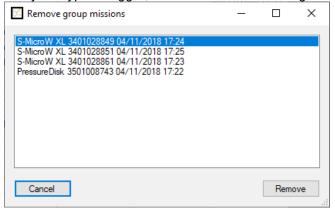


Adding missions to a group

Once a group is created and you want to add more missions to it, just follow the indication at page 66.

Remove a mission from a group

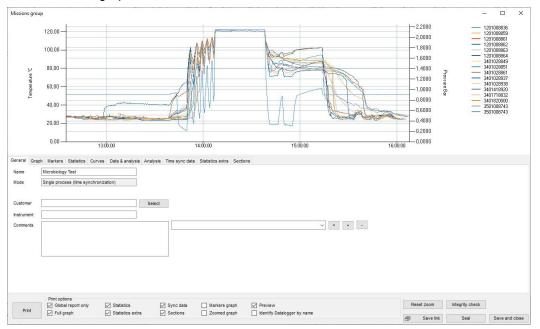
To remove a mission from a group, select the *Groups* archive, select the desired group and click on **Group** in the top bar. Select the mission to be removed, identified by the type of logger, serial number and starting date & time, and click on **Remove**.



Multigraph analysis

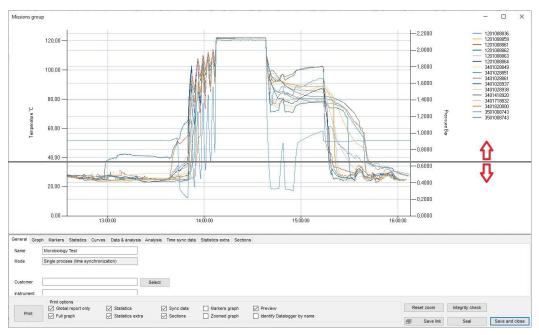
To open a Group analyze it, double click on it.

On top there is the area with the graph, below the tabs with data and statistics and other information.



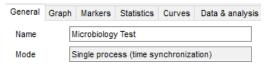
Adjusting graph area size

It is possible to change proportions between the area of the graphs and the tabs by placing the cursor on the limit line between the two areas (see the grey colour of the tab area) and keep pressed the left mouse button. Drag the mouse up and down to change size.



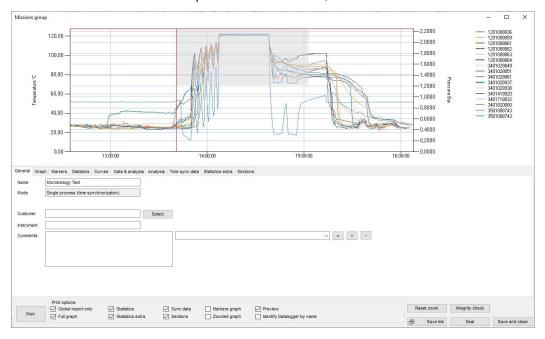
Rename the Group

Although you already have given the Group a name, you can still rename it by changing it in the *Name* field of the *General* tab.



Zooming the Group graph

You can zoom into an area of the graph by clicking on it with the left mouse button and dragging it: a gray area will appear that will enclose the area to be zoomed. Once the required area is selected, release the button.



Once zoomed, vertical and horizontal scroll bars will appear so you can move through the graph at the selected zoom level. You can also re-zoom into a graph that has already been zoomed by following the same procedure described above.

Zoom out the Group graph

To revert to the original graph, use the **Reset zoom** button.

Enable/Disable the Group legend

Open the *Graph* tab and enable the *Show Legend* option to display the legend on the right of the graph. To select what to show in the legend check p. 41.



Assign a group to a Customer/Instrument to a group

In the *General* tab there are additional information that you can fill in like assigning the group to a *Customer* and an *Instrument*.

Just click on **Select** to the right of the *Customer* field and choose the desired customer and instrument. Click **Ok** and they will appear in their own fields in the **General** tab.



Group Comments

The user may also insert additional comments related to the group in the *Comments* field: this is a free-text area where the user may include notes or opinions on the data or analysis results that might be useful to a third person viewing the data at a later stage. You may also add preset comments from the drop down list: this list is in common with the missions list (p. 61). To add preset comments, give a name to the comment by writing it in the drop down list field, then type your comments in the text area and click on the + button to add it to the list of preset comments. To delete a preset comment select it and click on the – button. If you modify a preset comment and would like to change the comment to include the changes, click on the = button.

To summarize:

+ to add a comment

- to remove a comment
- = to save changes to a comment

Comments		+	-

The Comments are not removed when recreating the database (p. 41).

Setting grid-lines and scale

The graph is automatically generated once you open the group but there are still some options you can set in order to customize its view. These options are setting the grid-lines, the thin grid inside the graph area, and the scale, the numbers at the right and at the left of the graph, for the vertical (Y) axis.

Setting the grid-lines for the time axis in a group

Click on the *Graph* tab and type the value you want to set in the field *Time* seconds under *GRIDLINES*, then click on **Set grid**. For example, if you want to have a vertical line for the grid every 10 seconds type in 10 and click **Set grid**.

Here you can also set every whence you want the time labels to be shown. For example, let's say you want a time tick with its label showing the time, every 30 minutes. Then type 1800 (seconds in 30 minutes) in the Time seconds field next to the **Set labels** button and then click the button itself.



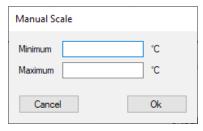
Setting the grid-lines for the values axis in a group

In the same tab you can set the grid for the Y axis and decide whether you want to set a grid for the first or second channel under *GRIDLINES*, if there is more than one. Type in the proper field, left or right, the desired value. For example, if you want a horizontal line every temperature degree, type 1 in the field under *Temperature* °C and click on **Set** to its left. If you want to set, for example, a line every 10 mbar (if there is the pressure channel in the graph), type 0,01 in the field under *Pressure Bar*. Once you set a value for the grid that value will correspond also to the labels for that axis.

Setting a grid for a channel will automatically disable the other one.

Setting the Scale in a group

From the same *Graph* tab select **Set** next to *Manual* under *Y SCALE* (left or right) to set the scale of the graph. With this option you can change the scale of the values written on the left and right Y axis. After you click on the left **Set** button next to *Manual* you can digit the *Minimum and Maximum* values of °C for the scale, for example, 0°C and 100°C, in the *Manual Scale* window: the graph will be redrawn only in the area from 0°C to 100°C. If there are values outside this range they won't be shown. Click **Ok** to confirm. From the same tab you can select **Auto** to go back to default scale. The same will happen with the right Y axis scale.



Setting the markers

Markers are horizontal or vertical lines that can be set directly on the graph. From the Markers tab you can set both vertical markers, from the central settings, and horizontal markers (two for each channel) on the left and right of the tab.

Setting vertical markers

You can set two vertical markers, one for the start and the other for the end of the process. These markers are used to exclude two portions, at the beginning and at the end of the graph, from the analysis. The excluded area will be grayed. This means that you can only exclude two portions of the graph; from the first acquisition to the first marker, and from the second marker to the last acquisition of the group. You cannot perform an analysis on non-contiguous portions of the

graph. This can be done using the Sections (p. 78).

By positioning the cursor on the graph and clicking with the mouse, you will see two perpendicular lines that indicate the position of the marker on the graph. The marker can be aligned to the closest acquisition. To set the first marker click on the graph where you want to position it and then click on the + button to the left of *START MARKER*. Repeat the same for the *END MARKER*. The two extremes of the graph will be grayed while the central part, which is considered for that analysis, will remain white.

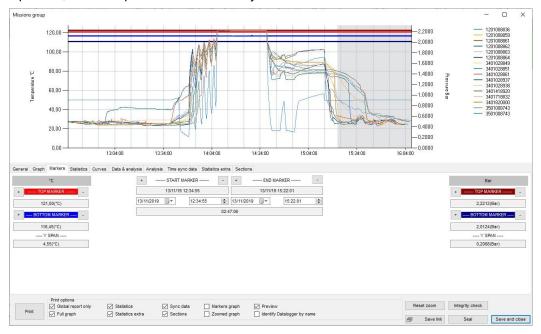


Below the START MARKER and END MARKER you will find the date and time of the marker with temperature and second channel value, where the marker meets the curves. Below there are two fields to set exact date and time for the marker, instead of moving it (see below) and a final bigger field with the difference (*Delta*) between the starting and ending time and values of the channels.

Note: if you select a date and time outside of the graph area the date and time will be automatically set at the beginning of the graph for the START MARKER and at the end of the graph for the END MARKER.

Setting horizontal markers

There are also four horizontal markers in the *Markers* tab, two for each channel, identified on the left and right of the tab as *TOP MARKER* and *BOTTOM MARKER*. As for the vertical marker, click on the graph where you want to place the first top marker and then click on the + next to the left *TOP MARKER* field. Repeat for the other markers if required. When you set a marker a field below it will show the value at which it was set. For example, 124,25°C. You can change this value by clicking on it and setting it manually, for example 123,00°C and press Enter on the keyboard: the marker will be moved to that value. The field under the



two markers of the same channel $\it YSPAN$ will show the difference between the two limits.

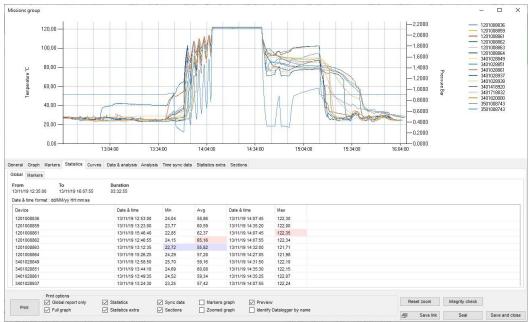
Remove markers

To remove a marker just click on the – on the right of its name.

Group Statistics

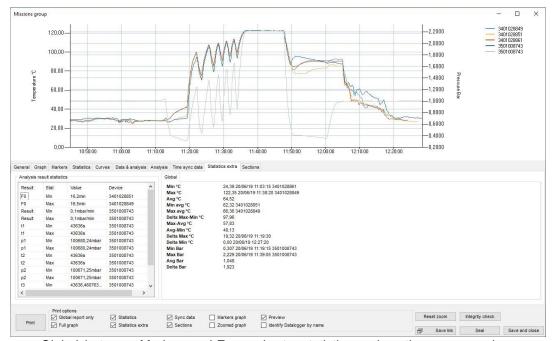
Open the *Statistics* tab and, apart from seeing the group *Duration*, you can see some statistics such as maximum, minimum and average for each curve. *Maximum and Minimum* are preceded by the *Date & Time* when they were recorded and the maximum and minimum values for each column are highlighted in red and blue.

Statistics are calculated on the *Global* data (all data shown in this group), between *Markers* and for the *Zoomed* portion of the graph, if you have set markers or zoomed in.



Extra Statistics

The tab Statistics extra will show you more statistics. On the left there is the box with the *Analysis result statistics*, listing for each *Device* the values calculated or recorded for each different parameter of the analysis set during the programming of the device. You can resize the columns by moving the separator in the header of the table.



On the right there are *Global*, between *Markers* and *Zoomed* extra statistics such as the average values among all curves, the minimum and maximum average, the difference (*Delta*) between minimum and maximum values and so on.

Managing the Curves and the Legend

Open the Curves tab: here all devices are listed and for each device all its channels.

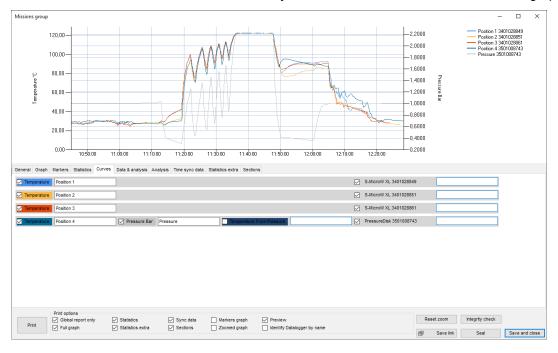
Names settings

If you have set a *Name* for the device (p. <u>42</u>), it will be shown in the rightmost field for each device: you can still change it by typing a new name in that field. If you delete the new name the default name, set in the *Devices* archive will be shown (p. <u>50</u>). If you want the field to be blank you have to remove the Name from the *Devices* list. The same name will be shown next to each channel, on the left, followed by a number indicating the channel's number. You can edit this name as well.

This very channel's Name will be shown in the legend in the top tight corner. If you disable the serial number on the right of each device line, it will be removed from the legend and only the Name will be shown. If you disable the serial number and the Name's field is blank, the model, serial number, date and time of the first acquisition will be shown in the legend.

Selecting the Curves

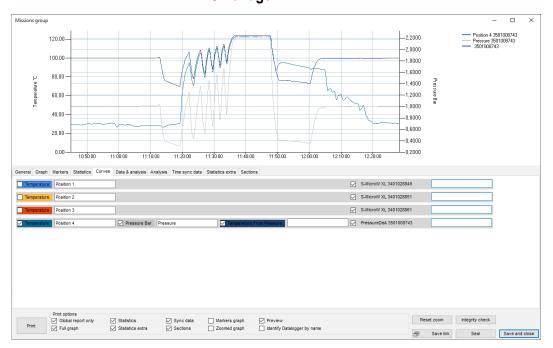
By clicking on the checkboxes on the leftmost of each channel you can disable or enable its curve on the graph.



Calculating theoretical temperature from pressure

If you have a pressure curve an extra channel will be added for that device called *Theoretical Temperature* and is the temperature calculated from pressure in saturated steam environment (so it can be used when temperature goes above 100°C). Since there is a univocal correlation between pressure in saturated steam and temperature, this option is very useful to check the good working of the autoclave.

If this curve is enabled the corresponding column will be shown in the synchronized data table (p. 75).

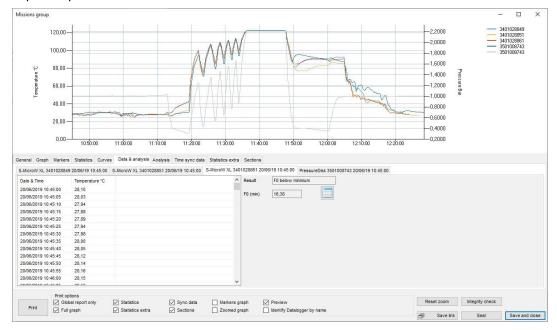


Checking Analysis

The Data & analysis tab holds many different tab, one for each mission and each has all the data in table format and the result of each single analysis (F0, Overkilling etc.).

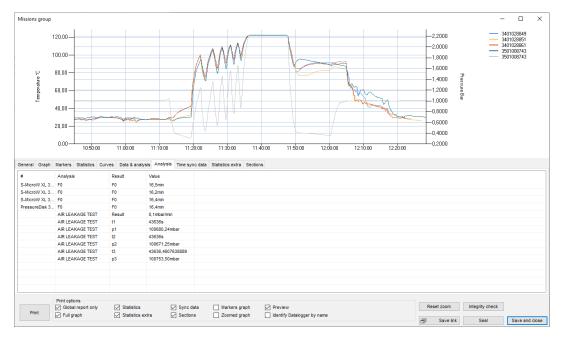
Progressive Lethality acquisition per acquisition

If you have set a Lethality analysis for that specific mission included in the current group, you will find a button next to the lethality calculated value. Click on it to export an Excel file that will present all the data plus the column for the progressive lethality acquisition per acquisition.



Analysis tab

In the *Analysis* tab there is the summary of all the analysis set for each single mission and their parameters, listed device per device.

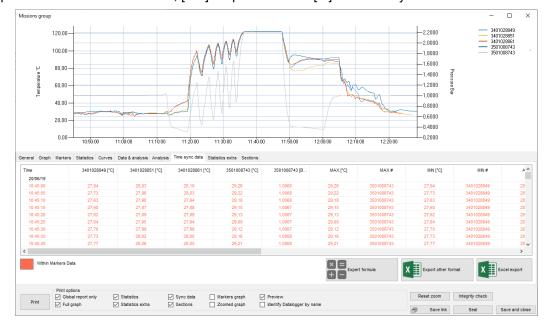


Synchronized data table

In the *Time sync* data tab there are all the data from all the channels of all loggers in the *Group*. In the first column, the time, there is the date at the beginning and then the time, acquisition per acquisition. If you have synchronized the start of the loggers using the *Fixed Time Mode* option (p. <u>47</u>) you will see an acquisition per device for each single moment listed in the first column. In the columns header there are the serial numbers of the loggers and the channel type (temperature, pressure, humidity). Scrolling on the table to the right more columns will be shown:

- MAX [°C]/[°F]: maximum temperature value recorded for that specific time
- MAX #: serial number of the logger that recorded the maximum value for that specific time
- MIN [°C]/[°F]: minimum temperature value recorded for that specific time
- MIN #: serial number of the logger that recorded the number value for that specific time
- AVG [°C]/[°F]: average temperature for that specific time
- MAX-MIN [°C]/[°F]: difference between the maximum and the minimum temperatures recorded in that specific moment
- MAX-AVG [°C]/[°F]: difference between the maximum and the average temperatures recorded in that specific moment
- AVG-MIN [°C]/[°F]: difference between the average and the minimum temperatures recorded in that specific moment

The same is repeated for the other channels, [Bar] for pressure and [%] for humidity.



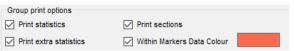
Markers and synchronized data

You will see that the values in the table of the *Time sync* data tab are all coloured (the colour may be different from the one in the image). This is because all data between time markers (vertical markers, p. <u>70</u>) are coloured differently than the ones outside the markers, which are black. Since there are no markers selected, all data are coloured. Set a couple of markers (p. <u>70</u>) and you will see that the data outside of them, in the table will in black.



Changing the colour of the data within markers in the Time sync table (Administrator only)

You can set a different colour for the values of the table within the set markers. Click on **Tools – Options** and open the *Report* tab. In the *Group* print options box double click in the coloured box next to *Within Markers Data Colour*: you can select the colour you like and then click **OK** to confirm.



If you disable this option all data will be black.

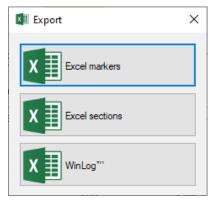
Exporting Group data to excel

From the *Time sync data* tab, you can click on the **Excel export** button to save an Excel file with all acquisition and other information from the *Group*. All data will be exported.

Exporting data between markers and sections

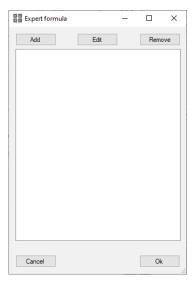
From the same tab you can click on the *Export other format* button to open a window with three choices:

- Excel markers: export the data between markers;
- Excel sections: export Sections data (p.);
- WinLog: export group data in WinLog Excel format.



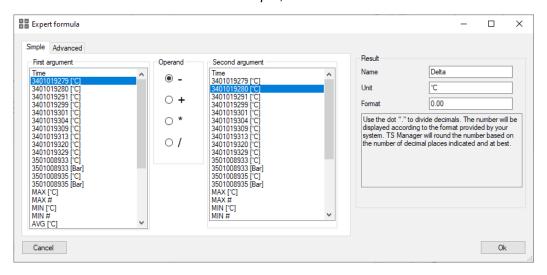
Use of formulas (Pro version only)

the columns available in the table. The new statistics will be presented in the same synchronized table. Press the button to open the window of the same name.



Generate simple statistics with formulas

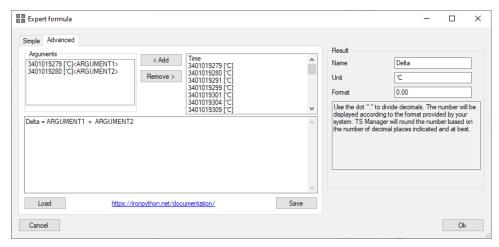
To create a formula click **Add**: in the new window select *Simple*, the first tab.



In this tab you can create simple formulas using standard mathematical operators. On the left you can choose the *First* and *Second* argument of the formula and the *Operator* that joins them. The arguments are nothing more than the columns of the synchronized data table. On the right, in the *Result* box, you can set a *Name* for the formula, the *Unit* of measure and the *Format*, or how the number must be expressed (how many decimal places are required. The value is rounded off as best as possible). The Unit field is textual, if you create a formula with two temperature arguments, the software will not automatically assign the unit of measure in degrees but will only show what is entered here.

Advanced formula generation

Select the *Advanced* tab to access the complex formula generation tool.



In the right column there are all the available *Arguments* that can be moved using the **< Add** and **Remove >** buttons in the left column, that of the *Arguments* selected for the formula.

In the larger box below you can compose your own complex formula using the Python programming language. Below is a link to access the documentation of this language.

The Group Sections

The Sections, the last tab of the Group, are used to divide the graph in different sectors and calculate some statistics and analysis on the portion only. They pretty work much like markers but have more features and can be multiple.

On the right there is a set of actions, in the Manage sections box: click on Add section to start.

A new tab will be added in the main area of the *Sections* tab and the central portion of the graph will be coloured. This is the first section. In the left part of the tab there are some configuration option for it, such as time range, *Name*, *Colour etc*. Below there are as many tabs as the curves included in the section, with the device serial number and analysis result.



Assigning a name and changing the colour to a section

Each section can be identified with a name. It is highly suggested to give the section a name. Type the name in the *Name* field. The name will appear on the graph, inside the section, You can even choose where to place the name within the section by clicking on the different radio buttons around the *Name* field: top left, top right, bottom right, bottom left.

The *Name* will be set also as the tab title.

To change the colour double click in the *Colour* field and select the desired colour and click **OK**.

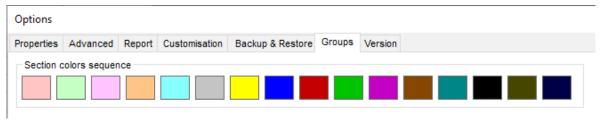
If you click on the *Show* option checkbox, disabling it, the section will be removed from the graph but not deleted. You can write some notes in the Note field. These won't printed in the report.

Changing Sections colour palette (Administrator only)

It is possible to set a standard palette for the *Sections*, so that they when they are added a default series of colours, in a precise order, will be given.

To do so click on **Tools – Options** and select the *Groups* tab.

In the Section colors sequence, double click on each colour to set the order of colours you wish to use when you create your Sections.



Setting the Section's area

You can choose the time range of the Section from the options at the top of the tab. The *Start and End* fields show the date and time that will include the section: you can edit them directly from here. In the middle, the Length field will show the duration of the section.

Below each group of fields (*Start, Length, End*) there are two arrow buttons, left and right. These are used to move the starting and ending point (*move start and move end*), for the *Start* and *End*, and to move the whole section shifting (*shift*) left and right, under the *Length* field.

Sections can be overlapping. The most recent one will cover the older one on the graph.



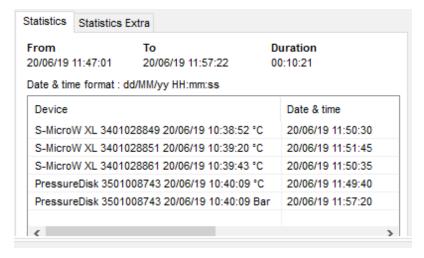
Section Analysis

Below the left are of the Section tab the list of tabs for each device is present: here you can scroll among all analysis results which are recalculated on the data of the Section only. By clicking on the button with the table, next to the Lethality value (the button is available on for Lethality analysis) you can export the data of the section and the progressive Lethality value for each acquisition included in the Section itself.



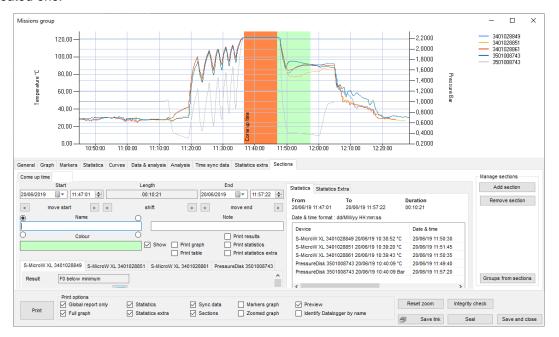
Section Statistics

In the right part of the *Section* tab you can see the tab for the *Statistics* and the *Statistics Extra*: they contain the same information provided by the tabs for the whole *Group* (p. 72 and p. 72) but this time related to the *Section* data only.



Adding a second Sections

If you click on **Add section**, on the right, to add the second or other sections after the first one, the new sections will be added after the last created one.



Creating Groups from Sections

It is possible to create *Groups* from *Sections* by simply clicking on the button on the bottom right of the *Sections* tab, **Groups from sections**.

This will generate as many groups as the *Sections* created for the open *Group*. The newly created *Groups* name will be the source *Group* name and the *Section* name.

This option is particularly helpful when you have recorded more than one process without stopping the loggers. In this way you can divide the processes into single *Groups* and analyze them separately.

Seal a Group

You can seal a group just like how you would do that with single missions and the concept of this operation is the same (p. <u>62</u>). Just click the **Seal** button in the *Mission Group window* to proceed.

Note: sealed group cannot be deleted.

Saving Group changes

To save all the analysis made and Sections created do NOT close the *Group* by clicking on the **X** on top right corner. Use the **Save and close** button in the bottom right corner instead.

Group report printing

To print a *Group* report just click on the **Print** button in the *Mission* group window. The report will include a first page with the group information followed by the selected information that can be chosen from the *Group* window, in the *Print* options box at the bottom.

	Print options				
Print	Global report only Full graph	✓ Statistics✓ Statistics extra	Sync data Sections	☐ Markers graph ☐ Zoomed graph	✓ Preview☐ Identify Datalogger by name

List of options for the Group report

Following is the list of options in the *Print* options box, with their explanation.

Option	Description (if enabled)
Global report only	Will print only the Group report. When disabled, the single Mission reports for each device will be added at the end of the Group report.
Full graph	Print the whole Group graph (note: the graph is printed with landscape orientation).
Statistics	Print the Statistics of the Group. Will add Global, Markers and Zoomed according to what is shown in the Statistics tab.
Statistics extra	Print the Statistics extra of the Group. Will add Global, Markers and Zoomed according to what is shown in the Statistics tab.
Sync data	Print the synchronized data table.
Sections	Print a list of Sections (for options about printing Sections check p. 81).
Markers graph	Print the graph between markers (note: the graph is printed with landscape orientation).
Zoomed graph	Print the graph in the zoomed area (note: the graph is printed with landscape orientation).
Preview	Will open a preview of the report before printing.
Identify datalogger by name	The Name will replace the serial number in most of the pages of the Group printed report, from the header of the columns of the data table to the lists for the statistics.

Sections Printing options

Each Section can be printed with a different set of parameters. The options are listed inside each single Section tab: here is the list of options.

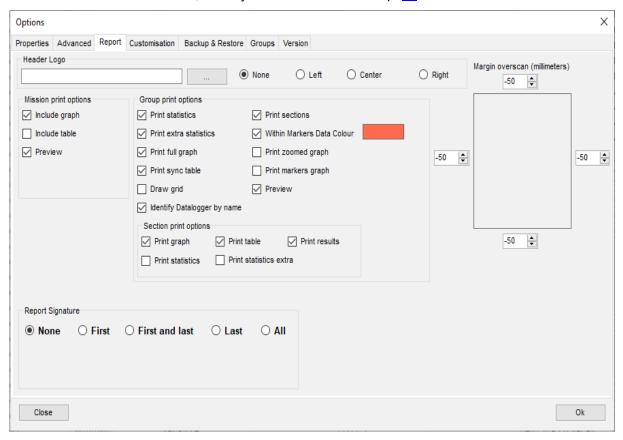
Option	Description (if enabled)			
Print graph	Print the Section graph (note: the graph is printed with landscape orientation).			
Print table	Print the Section synchronized data table			
Print results	Print the analysis results for each curve of the Section (only if an analysis has been set when programming the loggers.			
Print statistics	Print the Statistics of the Section.			
Print statistics extra	Print the Statistics extra of the Section.			

	Print results
Print graph	Print statistics
Print table	Print statistics extra

Setting default options for the Group report

From the **Tools** – **Options** window, *Report* tab, it is possible to set the default options for the report printing of the *Groups*.

Select the options you want to set as default: you will be able to change them from the *Group* window before printing the report, anyway. These are the same as the ones explained above but the *Draw grid* option, that will print the grid of the graph in the report and the *Within Markers Data Colour*, which you can find details of at p. 42.



For the other options, such as header, margins and signature, check the Single Mission Report Printing chapter at p. 63.

Shortening the columns headers in the reported (Pro version – Administrator only)

The printed columns header of the tables in the *Group* report can be of 8 characters maximum. The header will show the name of the device or the serial number, if no name is set or the option is disabled. Serial number have a variable number of characters while the name can be of 12 characters. By default the columns' header is shorted from the left, showing the last 8 characters on the right.

By accessing the *Pro* tab in the *Version* tab of the **Tools – Options** window it is possible to select if the header is shortened from the left or from the right by selecting proper option: *Name shorting from left, Name shorting from right*.

Filtering the Groups

You can filter the *Groups* per date. Open the **Tools – Options** window (Administrator only) and select the *Properties* tab. Set the number of days in the *Group filter days* field: only the groups of the last number of days set here will be shown. For example, if you set 30 only the groups created in the last 30 days will be displayed. To enable/disable the filter of the *Groups* click on **Filter** in the *Groups Archive*.



RHTemp Calibration Adjustment

When using RHTemp temperature and humidity data loggers, especially at their extreme in high temperature and high humidity, it is possible to have the necessity to make an adjustment of the readings.

With TS Manager it is available an internal adjustment feature: this option won't write a new calibration in the RHTemp but will save a correction profile that the TS Manager will use to show corrected values. To use the same profile on another PC with the TS Manager, you can export a profile from the first PC and import it on a second PC.

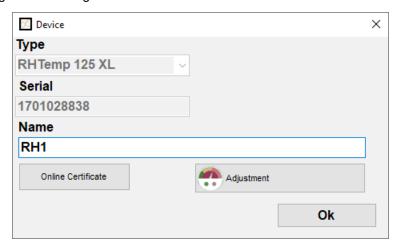
Enabling the Adjustment (Administrator, Advanced, Pro only)

Access the *Version - Pro* tab in the *Tools – Options* window and enable the option *Enable advanced user RHTemp Adjustment* to give the Advanced Users the possibility to perform RHTemp adjustment.

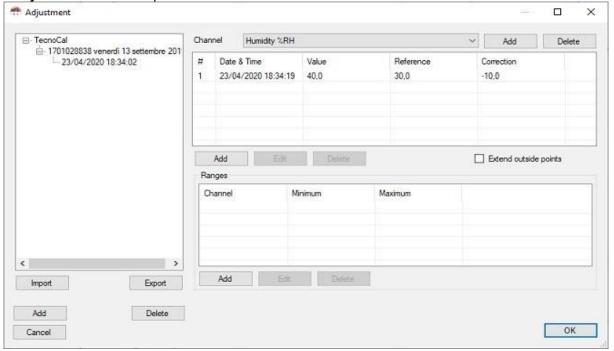
Enable advanced user RHTemp Adjustment

Adding a correction (Administrator, Advanced if enabled only)

Corrections can be added from the *Device* window that can be accessed the first time you start that specific logger or from the *Devices* archive, by selecting it and clicking on **Name**.

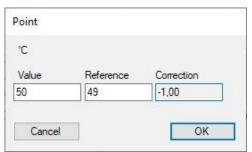


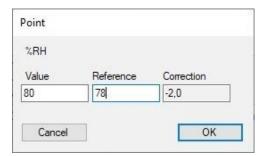
Click on the **Adjustment** button to open the window with the same name.



To add a correction, click on the **Add** button on the bottom left corner. Click on **Add** on the top right corner, near the *Channel* drop down list and select the *Channel* you wish to add a correction to: you can add as many channels as you want. One *Temperature* and one *Humidity* channel are already present in the drop down list. Typically, you will add one *Temperature Channel* and one or more *Humidity Channels*, referred to different temperatures.

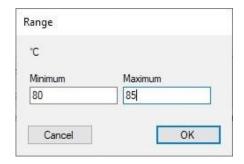
Once the requested channel is selected from the drop down list click on **Add** button below the top right list. Input the correction values in the new window.





Add as many points you want to each channel. To edit a point double click on it.

In the lower list, *Ranges*, you can add a temperature range where the above corrections are valid. For example, if you add different points on the humidity channel, these points might be valid in a specific temperature range. So, select the humidity channel you want to add a range to and then click on the lower *Add* button. You now can type in the range of validity of the above corrections.



So, you can create a full set of corrections:

- several points for temperature correction
- several pints for humidity correction on several different temperatures.

For example, you can add 20°C, 50°C, 80°C temperature points correction and then 40%, 70%, 80% humidity correction on two different ranges, at 25°C and at 80°C.

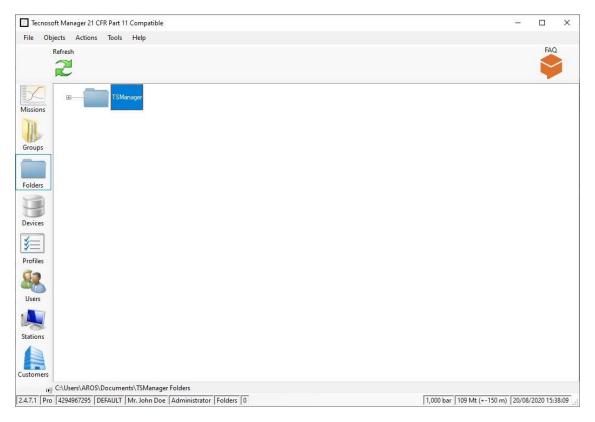
Exporting and importing RHTemp corrections between PCs (Administrator, Advanced if enabled only)

On the left the list of saved correction is shown. By selecting one and clicking on **Export** button below a file will be saved that can be imported on another PC. In fact, corrections are saved locally and not in the logger so if you are suing multiple PCs you have to export and import the necessary corrections between them. To import a correction, click on the **Import** button.

You can save more than one correction per day and per logger, identified by its serial number.

The Folders

One of the archives is called Folders: click on it.

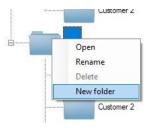


In this archive you can manage all of your records from the *Missions* to the *Groups* and also other documents. This archive will show a tree structure of folders connected to real folders on your hard drive. In each folder you can save documents (images, word and excel documents, PDF files etc.) that can be directly opened from the TS Manager. Moreover, you can save a link to a mission or to a group.

The root folder is called *TSManager* and shows the content of the folder set in the *Mission* data path in the **Tools – Options** window, *Advanced* tab.

Adding and renaming a folder

To add a new folder simply right click on the folder you want to create the new one into and select New folder. You will have the possibility to type in the name of the new folder.



If this does not happen because the main folder is closed (there is a + next to it, on the left), open it, by clicking on the +, and right click on the **New folder** and select *Rename*. Type the name of the folder.



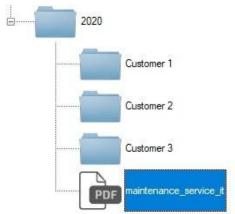
Opening a folder

You can open from the TS Manager *Folders* archive a folder on your computer. Just right click on the folder you want to open and select *Open*.



In the opened folder you can save any file you wish to add, including: Word, Excel, PowerPoint documents, images, PDF files etc.

If you double click on it from the TS Manager, that file will open.



Opening, Renaming and deleting a file

By right clicking on a file in the *Folders* view you will be able to select **Open** to open it, **Rename** to give a new name or **Delete** to cancel it.

Delete a folder

You cannot remove a folder from the Folders archive. You have to reach that folder on your hard drive and delete it from there.

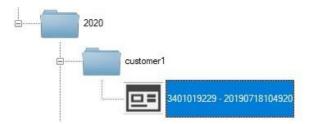
Refreshing the Folders

On top of the Folders section there is the **Refresh** button that is used to refresh the view when, for example, you change something directly from the folders in the hard drive.

Adding a Mission to a folder

To add a mission to a folder, open the *Mission* in question and click on **Save link** at the bottom right corner. You'll be asked to choose the path of the link: once the correct folder is open click on **Save**.

If you open now that folder from the *Folders* archive, you will see a new item: if you double click on it the linked *Mission* will open.



Adding a Group to a folder

To add a *Group* to a folder, open the *Group* and click on **Save link** at the bottom right corner. You'll be asked to choose the path of the link: once the correct folder is open click on **Save**.

If you open now that folder from the Folders archive, you will see a new item: if you double click on it the linked Group will open.



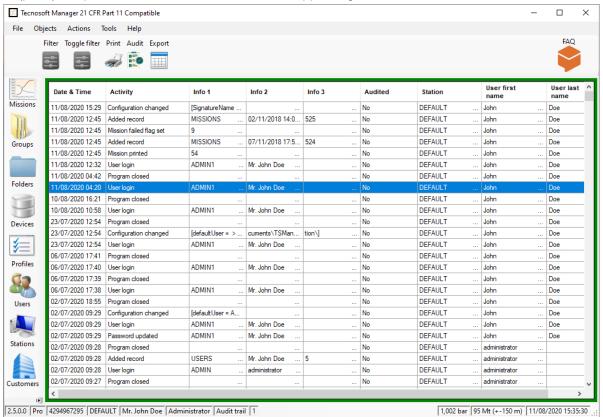
Audit Trail

The FDA 21 CFR Part 11, EU Annex 11 and GAMP 5 guidelines require that a log of every action carried out as part of the operating procedures should be maintained: this is called *Audit trail* TS Manager complies with this requirement by keeping a log of all the operations carried out by the program: from access of the database by a particular user, to starting missions, to analyzing data.

Click on the Audit trail archive to view the history of these operations.

After the *Date&Time* and *Activity* columns you will see an additional three columns, Info (1, 2 and 3) where the details on the particular operation are shown. According to the particular operation (*Activity*) the information displayed will change. For example, if the *Activity* is *Added Record*, in Info 1 we will see the name of the archive in which the record was added. If *Activity* is *Device Started*, Info 1 will show the type of data logger, and Info 2 will show the serial number of the device.

The *Audited* column will show whether that particular operation was audited, whether by an internal or external auditor. In the *Addendum A* (p. 95) it is possible to check all the indications appearing here.



On top of the window there are different actions buttons.

Mark a record as Audited

If you select a record and click on **Audit**, on top, it will be marked as audited: its status under the *Audited* column will change from *No to True* and will be highlighted in green.

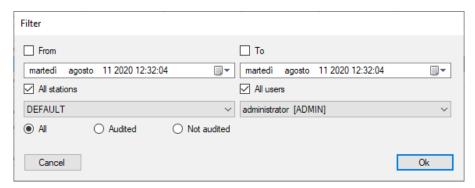
Date & Time	Activity	Info 1	Info 2	Info 3	Audited	Station	User first name	User last name
08/09/2020 18:09	User login	ADMIN	administrator		No	DEFAULT	administrator	
08/09/2020 18:05	Program closed				No	DEFAULT	administrator	
08/09/2020 18:04	Changed user sta	ADMIN	administrator		True	DEFAULT	John	Doe
08/09/2020 18:04	Password updated	ADMIN1	Mr. John Doe		True	DEFAULT	John	Doe
08/09/2020 18:04	Changed user sta	ADMIN	administrator		No	DEFAULT	John	Doe

Filtering the Audit Trail

Click on **Filter** to open the filters window. You can filter by a time range by enabling the *From* and *To* options and setting date and time for starting and ending extremes of the range.

You can also filter by *Stations* and *Users* by enabling proper options and selecting the *Station* and or the *User* from the drop down list.

Finally, you can choose to view All records, the Audited or Not audited ones only.



Once a filter is applied the **Toggle filter** button is framed by a square, meaning there is an active filter. Click on it to enable/disable it.

Exporting the Audit Trail

To export in Excel the Audit trail click on the **Export** button and choose the destination folder and the file name, if you want to change the default one.

Printing the Audit Trail

Click on **Print** to open the printing dialogue. Choose your printer and send the file to be printed.



Data Backup and Restore (Options – Backup & Restore)

You may carry out a backup of the database and all the corresponding data: we recommend that you carry out this operation periodically to secure a safe copy of the data to safeguard against PC failures, database corruption or accidental erasing.

Backup (Administrator only)

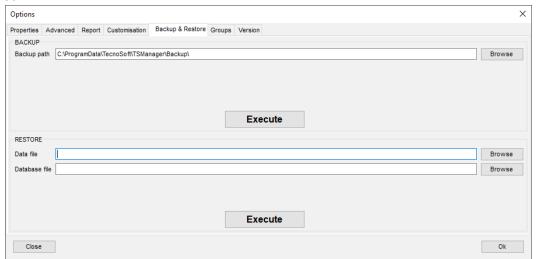
To carry out a backup, click on **Tools - Options** and select the *Backup & Restore* tab.

From the *Backup* box select the folder in which you would like to save the backup file and click **Execute**. Two files will be created in the selected folder: a zip file that holds all the data (*TSManager_Data*) and a .BAK file that holds a backup of the database (*TSManager_Database*). Both file-names also include the creation date (year, month and day). Keep a copy of both files.

Restore (Administrator only)

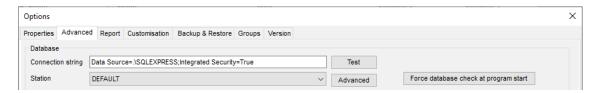
To restore the data from a backup, click on **Tools – Options** and select the *Backup* and *Restore* tab.

From the *Restore* box select the folder holding the data backup files and the one holding the database backup file and click on **Execute**. Answer the following questions by confirming your choice. You will be asked to restart the program so that the backup set can be restored.



Restoring a backup from an older version

When restoring a backup created with an older version of the program be sure to update the database by enabling the option *Force database check at program start*, in the *Advanced* tab in the *Options* window. Close and start the program again.



Transfer a database

You might need to transfer the backup from one computer to the other.

Backup in a Client/Server installation

If the database is shared on a server, the backup and restore operation should be performed by the network administrator directly on the server database.

Updating the program

To update the program, simply check TecnoUtility and the software Upgrade page. Before installing it, however, we suggest to perform a backup of your database. To know how to perform a backup see p. <u>91</u>.

Updating a Client / Server installation

Before updating TS Manager in a client / server installation, ask the IT manager to perform a backup of your database on the server. Then proceed updating TS Manager on all client PCs.

Running an Audit (Login – Audit)

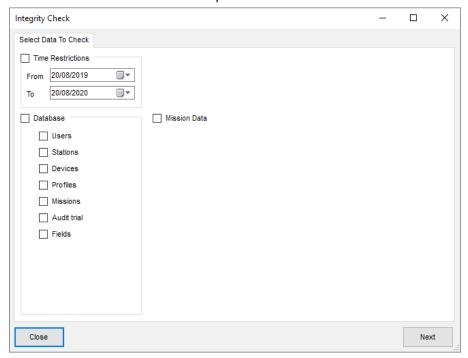
If your system is subject to internal or external audits, TS Manager is equipped with an *Audit* feature by which you can create a *Guest* user with a three day validity who is able to view the archives but cannot make any changes.

Database integrity test (Integrity Check)

The auditor, like any other user of the software, can, at any time, check the integrity of the archives and missions data and check whether they have been tampered with.

Click **Tools – Integrity Check** and select the archives (*Database*) and the missions (*Mission Data*) that you would like to test. You may also check a given time period to be tested (*Time Restrictions*).

After having selected what to test, click **Next** to start the test procedure. The program will instantly display the result indicating, if applicable, the archives and missions that have been tampered with.



Checking integrity of a single Mission

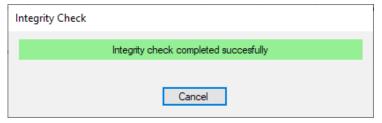
It is possible to check the integrity of single *Mission* by opening them and clicking **Checking integrity** button on the bottom right corner.

This will start the Integrity check process on the data of this *Mission*. Once it is complete it will be highlighted in green if everything's all right or in red if the data have been hacked.



Checking integrity of a Group

Open the *Group* you want to control and click on **Integrity check**. The process will run through all *Missions* included in the *Group* so it might take some time to complete.



Performing automatic check (Administrator only)

It is possible to require an integrity check even before opening a *Mission* or a *Group*, when you double click on them to open. Go to the *Advanced* tab in the **Tools – Options** window and enable the *Integrity check* on mission open. If a *Mission* or a *Group* will result to be hacked, the program won't open it.

Only Administrators can add new Users	
Integrity check on mission open	

Addendum A – Audit Trail Legend

Following there is the table with all the indications appearing in the Audit Trail.

Description	Info1	Info2	Info3	Note
Program started	N/A	N/A	N/A	
Program closed	N/A	N/A	N/A	
User Access	N/A	N/A	N/A	
User Log out	N/A	N/A	N/A	
Device started	Device type	Device serial number		
Device stopped	Device type	Device serial number		
Reading	N/A	N/A	N/A	
Record added	Table name	Record description	ID Record	
Record deleted	Table name	Record description	ID Record	
Record edited	N/A	N/A	N/A	
Backup	N/A	N/A	N/A	
Restore	N/A	N/A	N/A	
Configuration changed	Changed option 1	Changed option 2	Changed option 3	max change 3 options
Clock error occurred	N/A	Last valid time and date	N/A	·
Login failed	Access tried by UserLOGIN	N/A	N/A	UserLOGIN is the login used to try to access the software
SEALED	Sealed mission	ID sealed mission	N/A	N/A
FAILED	Failed mission	ID failed mission	N/A	N/A
CHANGEUSE	Device use changed	Device serial number	N/A	N/A
CHANGEUSERSTAT U S	User status changed	User Name	ID user changed	N/A
PRINTED	Mission printed	ID printed mission	N/A	N/A

Addendum B - MKT

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

 ΔH = Heat of activation / activation energy

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

Ti = 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 recognizes 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.

Addendum C – Lethality

Lethality is a time and its value is used to evaluate a thermal process such as sterilisation or pasteurisation. The variables that have to be set in the formula are:

- Reference temperature: the theoretical temperature at which the process should stay constantly. Usually the given information are: "I sterilize at 121°C for 10 minutes". 121°C is the reference temperature.
- **Z**: this is also a temperature, indicating the increase of temperature to be applied to the Reference temperature to reduce the time to a tenth. This parameter is connected to a specific microorganism. For example, if it takes 10 minutes at 121°C to have a specific reduction of a specific microorganism and the Z value is 10°C for that specific microorganisms, it will take 1 minute at 131°C to obtain the same reduction.

Depending on the parameters used in the formula and the purpose of the thermal process it may have different names:

- **F0**: standard sterilisation, when the Reference temperature is 121,11°C (250°F) and the Z value is 10 (botulinum)
- FT: where T stand for a Reference temperature different from 121°C. It might be F134, F110 and so on. Z value might also be different from 10
- PU: Pasteurisation Units, indicating a process with a Reference temperature usually below 100°C.
- A080: used for washer disinfectors with a Reference temperature of 80°C
- A090: used for washer disinfectors with a Reference temperature of 90°C
- A0T: used for washer disinfectors with a Reference temperature that can be set by the user

Addendum D - Overkilling

Overkilling is a method to check autoclaves.

It consists in setting two limits and a duration and check if the temperature stays within these two limits for the indicated period. These values are sometimes indicated by the manufacturer.

Addendum E – Vacuum Leak Test

Vacuum Leak Test is a test for autoclave requested by the UNI EN ISO 13060 standard. It consists in checking if a fixed increase of pressure is present between two specific periods of the process. The purpose is to check that there is no leakage in the machinery.

FAQ

1. What if I forget the password?

If you are not an Administrator user you can ask an Administrator to access TS Manager and change your password. When you will log in again the software will ask you to change your password again.

If you are an Administrator user and don't have other Administrators available, you have to contact Tecnosoft who will provide you a temporary password, valid for a limited time (few minutes). You can log in and change your password or create a new user.

2. I am banned but I must log in urgently.

You have to contact Tecnosoft who will provide you a temporary password, valid for a limited time (few minutes). You can log in and change your password or create a new user.

3. Can I create a Group with a Single Mission?

Yes, it is possible.

4. What is MKT?

Check the addendum at p. 96.

5. What is Lethality?

Check the addendum at p. 97.

6. What is Overkilling?

Check the addendum at p. 98.

7. What is the Vacuum Leak test?

Check the addendum at p. 99.

8. Can I delete a Mission?

No, it is not possible to delete a Mission, only to mark it as Failed (p. 62).

9. How many Missions can I group together?

There is no limit in the missions you can add to a Group.

10. What does it mean the data are encrypted?

It means that if you open that file with an editor or some other software, you won't be able to understand its content as it would be written with a special encoding format. The content might be edited but it will result in a hacked and damaged file that won't be opened anymore.

11. Can I add to a Group Missions from different device models?

Yes vou can.

12. Can I create a Group with temperature, pressure and humidity?

No, it is not possible: a Group can hold only two physical quantities.

13. Can I create a Group with two pressure curves?

Yes, you can.

14. I need to generate a backup but I don't have the Administrator rights.

It is still possible to generate a backup of the database, but nor restore it, even if you don't have Administrator rights. From the login window you can create a Guest user and guest users can generate a backup. To know how to create a new user check page <u>27</u>. To know how to generate a backup see page <u>27</u>.

The most common problems and their solutions are described below.

Unable to load DLL "FTD2XX.dll"

This error may appear when trying to connect to an interface. This message indicates that the drivers have not installed correctly. Try unplugging the USB cable and connect it to a different USB port to restart the driver installation.

SQL Installation issues

If you are working with a 64 bit operating system, SQL is probably already installed. If this is not the case and the installation proceeds to install SQL Express, if you occur in an installation error you need to manually install it: we suggest to install SQL Express 2017 (p.11).

If, on the other hand, you encounter problems after the installation, this could be caused by a change in the installation procedure on behalf of Microsoft.

To install SQL correctly, you will have to remove all components that use SQL on that PC. This procedure must be carried out by your internal IT support personnel or the owner of the PC on which you are trying to install TS Manager.

The steps to be carried out are the following (The files required can be found on the CD, in Program\Sqlfix):

- 1. install Microsoft Windows Install Cleanup (msicuu2.exe);
- 2. once the installation is complete run the program from **Start All Programs Windows Install Cleanup**;
- 3. scroll through the list that appears and select the MSXML x.x entries (where x.x is the installed version) and then click on **Remove**;
- 4. reinstall SQL:
- 5. if you are asked to install msxml6 core, you will have to install it (msxml6_x86.exe).

At times I am not able to communicate with the data loggers

When a communication error is encountered, the reason could be one or more of many (interface not found, TecnoCOM Port TimeOut, etc..)

Ensure that the interface is correctly connected to the PC, and that the data logger is inserted the right way in the interface cradle or adapter (if required). Check that the data logger is clean and dry, especially near the isolating washers, and that there are no labels or stickers on the device surface.

Check that the drivers have been correctly installed, by accessing Windows **Control Panel – System – Hardware – Device Manager**: if you see a warning icon next to the device name, it means the drivers have not installed correctly.

If you change the USB port to which the interface is connected, you have to reinstall the drivers. The USB drivers could be conflicting with other drivers or programs on the PC.

When a communication error occurs, try disconnecting the interface and reconnecting it to the USB port. If the problem persists contact Tecnosoft technical support.

I cannot see some of the missions

If you cannot see all the missions you expect to see, make sure that there are no filters enabled. Remember that there could be filters applied in the *Filter* window but also in the *Clients/Instruments* archive.

I get an error after update or restore

Be sure to follow procedure at p. 18.



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