



QLEVER 2

User's manual

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Chapter - 1 INTRODUCTION

1 *Hardware configuration*

Work station	
<i>Operating system</i>	
	Windows Vista, 32 bits
	Windows 7, 32 bits
	Windows 7, 64 bits
	Windows 8, 32 bits
	Windows 8, 64 bits
	Windows 10, 32 bits
	Windows 10, 64 bits
<i>Minimal hardware configuration</i>	
	4 GB of RAM
	CD-ROM player (only if installation by CD)
	200 MB available to install QLEVER (excluding the data measured by the loggers)
	NTFS partition for the TDB QLEVER data management
	RS232 serial ports for old RS232 TMI-Orion interfaces
	USB ports for TMI-Orion USB interfaces
	Screen resolution: 1024 x 768
Server	
<i>Operating system</i>	
	Microsoft Windows server®
	If LDAP option then Microsoft Windows Active Directory®
<i>Minimal hardware configuration</i>	
	Free disk space: 40 GB (No cloud)



Work station

2 *Installation and update*

Prerequisites:

- Qlever must have the following access rights to all files located in the Qlever Database Files (TDB) folder (Qlever installation folder named Qlever files): read, write, modify and delete.
- The same access rights must be granted to the Microsoft Windows™ user's local temporary directory.

2.1 First installation

1. If you are using a USB type TMI-Orion Interface, you should install the drivers prior to using QLEVER software so the communication ports are later set up automatically.
2. Insert the supplied the USB drive (or the CD-ROM containing QLEVER software).
 - open the CD-ROM folder.
 - double click on the "setup – QLEVER x.x.x.x.exe" file ("x.x.x.x" the version number of the software). Same procedure in case you downloaded the software through the internet.
3. Select the language.
4. Click **"Next"**.
5. Read the software license contract. If you agree with the terms, check the box **"I understand and I accept the terms of the license contract"** then click **"Next"**.
6. If you want to change the folder where the software will be installed, click **"Browse"** and select the target folder then click **"Next"**.
7. Check the box to create a tab on your **"Desktop"** and/or in the **"Fast launching"** bar then click **"Next"**.
8. Click **"Install"** to start installing the software.
9. Click **"Finish"**, the software will run.
10. Set the directories used by the software (cf. 1.2 Directories Management).
11. For a first install, type your QLEVER license key and validate.
12. If your version of QLEVER includes the Secure mode (FDA 21CFR part 11 compliance), you should set the Administrator account and create at least one User account. Then log out from the Administrator account and log onto the newly created User account.



13. Add the configuration files of the loggers (*cf. 2.1 CET/CEX configurations files installation*).
14. Set the units (*cf. 1.5 Units*).
15. Set the communication ports (*cf. 1.3 Communication ports*).



2.2 Update

1. Double click on the "setup – QLEVER x.x.x.x.exe" file ("x.x.x.x" the version number of the software). Same procedure in case you downloaded the software through the internet.
2. Select the language.
3. Click "**Next**".
4. Read the software license contract. If you agree with the terms, check the box "**I understand and I accept the terms of the license contract**" then click "**Next**".
5. Do not change the folder where the software will be installed, click "**Next**".
6. Check the box to create a tab on your "**Desktop**" and/or in the "**Fast launching**" bar then click "**Next**".
7. Click "**Install**" to start installing the software.
8. Click "**Finish**", the software will run.

3 QLEVER and QLEVER Lite

There are two versions of QLEVER:

· **QLEVER Lite:**

o List of the functions that are not available with the QLEVER Lite version:

- Merge the open files
- Merge the table of the current file
- Data analysis (like Min. / Max. / Avg. & slope calculations)
- Library of calculations and automatic calculations
- From the reading loggers window, creating a single files and the merge of the tables of the current file.
- Use of the Multi-logger interface (only the MONO-USB is visible, no Radio, no FullRadio, no wired real time)
- 21CFR or other options.

· **QLEVER:**

- This version allows every functions and options according to the license you get.



4 Quick Start Guide

1. Connect the interface to the computer.
2. Connect a logger to the interface.
3. Select the **"Configuration > Communication ports configuration"** menu.
4. In the tab **"Wired communication"**, select the port where the interface has been installed.
5. Save to close the window.
6. Open the **"Configuration > Managing configuration file"** menu.
7. Insert the USB drive or the CD-ROM containing the logger configuration files.
8. Click on **"Install"**, click on **"Install from TMI-Orion USB drive"** or **"Install from CD"**.
9. Close the window.
10. Click on **"Identification"** from the tool bar.
11. This window displays information from the connected logger including status and the real time reading.
12. Close the window.
13. Click **"program"** from the tool bar.
14. A default programming will allow you to program the logger for one minute with one acquisition every second.
15. Click **"program"**, close the window giving you the programming status then close the window.
16. Click on **"Start"**.
17. Click **"Start all the loggers"**. Close the window giving the starting status then close the window.
18. By default, the logger would start recording straightaway.
19. Wait for at least one minute before the logger has finished recording.
20. Click on **"read again"** from the tool bar.
21. Make sure that **"save separately the data of each logger"** and **"automatically open the created files"** are checked then click on **"read the selection again"**.
22. Close the window giving the reading status.
23. The file containing all data is now automatically open.



Chapter - 2 Standard features

1 *Software configuration*

1.1 Languages

It is possible to change the language of the software in the menu “? > Languages” or by clicking on the language currently used in the software message bar.

Just click on the desired language from the list.

1.2 Directories Management

The software uses different directories to work. These directories can be set by clicking on “Configuration > directory management”.

The software would use two types of data systems:

1.2.1 ***QLEVER Data Management System: TMI Data Base (TDB)***

This is a secured database managed by the software called TMI Data Base (TDB). It is used by default when creating and opening recordings. It is possible to create up to 10 different TDB's.

1.2.2 ***TDB Directory***

The Directory management TDB tab allows you to set the directories where:

- Configuration files will be installed.
- Data from the loggers will be saved by default.
- The setup, process and report will be saved.
- User's accounts will be saved.

Remove a TDB:

- Exit Qlever
- Delete (or rename) the unwanted TDB directory by Microsoft Windows™
- Run Qlever

⇒ C:\ProgramData\tdb\ is the TDB default directory

⇒ The user must have Microsoft Windows rights on this folder

⇒ ***Please, don't synchronize the TDB directory!***



1.2.3 External files

It is also possible to save or read recorded data to or from files not belonging to the TDB. Meaning, save or read to or from a USB drive or any other drive.

The External file tab allows you to set the directories where:

- Configuration files will be installed or exported (cet, cetx files).
- Data from the loggers will be saved to external files (qle files).

⇒ The user must have Microsoft Windows rights on these folders.

1.2.4 TDB Administration

- See section 6 Administration, Backup and Restore of the entire TDB database.
- "Save the QLE file" for a compatibility with TMI Xvacq, Valivac Software

1.3 Communication ports

In order to communicate with the loggers, you should set the communication port where the communication interface is installed.

To access the settings, you should select "**Configuration > Communication ports configuration**":

- **Interface management**: the table from the first tab allows you to select the ports where the communication interfaces are connected.
- **Real time communication**: the table from the second tab allows you to select the ports where the radio receiver antennas are connected.
 - "Not configured": means that you must add and configure this radio receptor in "**Radio network configuration**" ("**Configuration**" menu and "**Radio Network**").

If you connect an interface on a USB port only after opening such window, you would need to click on "**Communication ports update**" to refresh the screen and see this interface in the list.

FullRadio:

- Before using FullRadio loggers, one radio receiver should be installed and selected as a communication interface in **Interface management** tab.
- Before using FullRadio loggers in real time communication, one radio receiver should be installed and selected as a real time communication interface and configure in "**Radio Network**" menu.

Display All: display all ports and calibration Jofra® equipment (display only)

⇒ The metrology equipment must not be checked because it's not TMI-ORION interface.



1.4 Radio network configuration (Fullradio)

1.4.1 Pre requisite

- Communication ports selection including at least one radio receiver selected as an interface
- FullRadio loggers configuration files installation

The installation generates an automatic configuration for your Radio Network, but some parameters can be changed by clicking on “Configuration” menu and “Radio Network”.

Radio network tab

A radio network includes several loggers with the same radio transmission settings for real time data reception.

- The left part of the screen shows the status of the configured items, each network is composed of:
 - An editable name, e.g. “Autoclave 1”
 - One or several Radio receiver(s) (one dedicated to each computer)
 - One or several FullRadio logger(s)
 - A configuration including a radio transmission channel, an address and a PanID, to avoid possible radio interference between various networks or radio devices in your premises.
- The right part of the screen shows the hardware to be configured.
- COM “Not used”: means that Port COM has not been checked in "Communication Port Management" / "Real Time Communication". In this case, go to this screen to check if you want to use it to receive the data in real time.

Add a receiver or a logger: click on the “<” button or drag-and-drop on the selected network.

Delete a network, a receiver or a logger: click on “-” in the first left column.

Create a new radio network: click on “New network” (you can create up to 100 different networks).

Configuration tab

- Automatic search of FullRadio loggers (**standard mode only**) (cf. 1.4.2 Fullradio logger menu).
- Automatic search of FullRadio loggers (**setup mode only**) (cf. 1.4.2 Fullradio logger menu).
- Read running loggers (cf. 2.5 Read the loggers).

Remove all FullRadio loggers: remove all current Fullradio loggers.



Save the modifications: click on **“Save”**.

⇒ *Do not mistake the radio network configuration for the list of the loggers you will use.*

1.4.2 Fullradio logger menu

FullRadio loggers are loggers designed with a “wireless” radio transmission and reception. As with *traditional* Radio loggers, real time data transmission may be activated according to the selected programming.

Some FullRadio logger setting menus can be found in every logger management screen (right click).

- **Configure a Radio Network for FullRadio loggers**
 - Network configuration [*cf. 1.4 Radio network configuration (Fullradio)*].
- **Configure the FullRadio loggers beep emission.**
 - The radio receiver will -or will not- beep during radio transmission.
- **Automatic search of FullRadio loggers**
 - The **automatic search mode** is the default mode. It enables the automatic communication with every selected logger.

⇒ Yet a non-automatic search mode may be recommended for numerous FullRadio loggers use: it would prevent you from waiting until all loggers are detected to add, delete or modify their configuration.

“+” and **“-”** columns are displayed on the right side of every FullRadio logger management list.

- Click on **“+”** button to reach the FullRadio loggers list (sorted by network name), add a FullRadio logger and start to communicate.
- Click on **“-”** button to delete a FullRadio logger from the list and stop the communication.

Those menus will not appear if neither Radio reception interface nor FullRadio logger has been installed.

1.5 Units

This software allows you to set the display of the physical parameters (temperature, pressure...) in terms of units.

To access the unit's settings, select the **“Configuration > Unit management”** menu.

A list would let you to select the right unit for each physical parameter.



1.6 Library of calculation

This software allows you to set automatic calculations (*cf. 3.3.4 Calculated columns*) that apply automatically when loggers are read (except in setup mode).

To reach the library of calculation settings, select the “**Configuration > Library of calculation**” menu.

In the calculation list:

- Check the box to apply the calculation to the next reading operation.
- Name and number of the calculation.
- Calculation type (Offset, F_0 ...).
- Calculation settings.
- Other fields: Created by, on, Modified by, on.

You can Delete, Add or modify a calculation, it's also possible to add a calculation from each calculated column.

1.7 User preferences

Files:

- **When an external file is opened, ask whether it should be imported:** each time an external file is opened (e.g. on `E:\mes_qlé`), QLEVER asks whether it should be imported (in TDB) or not.
- **Display the preview in the file manager:** if unchecked, the TDB response time is optimized because the graph previews are not loaded in QLEVER file manager.

Interface & loggers:

- **Display the interface serial number** (checked as default): uncheck this box if interface serial number display is not required. It will be removed from On-Screen Information.
- **Display: “Programming will erase the memory of the logger”** (checked as default): allow to display or not such message when programming loggers with the standard mode or starting (and programming) a setup with the setup mode).
- **Starting loggers:**
 - **Display the channel value** (checked as default): display the value of each connected loggers in the “Starting loggers” windows (also shows the type of thermocouple for the universal thermocouple logger).
 - **Battery status** (default is unchecked): The lowest battery voltage recorded when using the logger (and not only since the start of the last recording).



- **Memory status:**
 - Memory used: This window displays the memory level already used by the logger.
 - The memory level used for this programming.
- ⇒ Some options will not be possible if “Automatic search of FullRadio loggers” is deactivated.

Parameters:

- Date format (default is automatic):
 - Automatic: according to the language.
 - Day/month/year format.
 - Mouth/day/year format.
 - Year/day/month format.

2 *Logger management*

2.1 CET/CETX Configuration files installation

To be able to use a logger, the corresponding configuration file needs to be installed in the software. This installation is done by copying the corresponding **CET** or **CETX** extension file in the TDB directory.

To access the configuration files installation, select the “**Configuration > Configuration files management**” menu.

From the list, for every logger the following information would be displayed:

- The serial number
- The configuration CET or CETX file version
- If it's a **FullRadio** logger or not
- The configuration date (calibration date)
- An information symbol shows the validity of the date of every configuration file.
- The status of the configuration files as follows:
 - Imported: following installation of configuration files within the TDB
 - Restored: following the restore of configuration files within the TDB



- Adjusted: following the adjustment of logger using QLEVER with calibration mode (display in green)
- The user who and the date when one of the three above actions was performed.

Installation of configuration files:

If the CET / CETX configuration files are:

- On the TMI-Orion USB drive, click on **“Install”** button, choose the **“Install from TMI-Orion USB drive”** menu to directly install files contained on the drive.
- On the TMI-ORION CD, click on **“Install”** button, choose the **“Install from folder”** menu to select to the Window explorer any files located on the PC.
- On a folder, click **“Install from a folder”** button allow to select a directory located on the PC.

The **“Delete”** button allows you to delete files corresponding to the lines selected in the chart.

The **“Export”** button allows you to export the selected configuration files from the TDB to any directory of the PC or external drive.

Right click on one or more loggers to view the history of the logger recorded in the TBD database.

Once the **FullRadio** loggers are installed, the radio network configuration window is displayed to enable the network configuration for real time data reception.

⇒ The default directory can be specified by the **“Configuration, Directory management”** Menu.

⇒ *Note that with the Secure mode (21 CFR part 11), only an “Approval” account would be allowed to manage the configuration files.*

2.1.1 Updating a CET/CETX Configuration file in a logger

- Connect the logger (only this logger) to the interface
- Click on **“Configuration/managing configuration files”** menu
- Click on **“Install from a folder”** button, select the import directory, and select the cet file
- Select the cet line
- Click on **“Restore”** button
- Select the imported cet
- Click on **“Restore”** button
- Click on **“Apply”** button

⇒ *Note that with the Secure mode (21 CFR part 11), only an “Approval” account would be allowed to manage the configuration files.*



2.1.2 Installation of coefficients files for universal thermocouples

To access the configuration files installation, select the “**Configuration > Configuration files management**” menu.

- Click on “**Install from a folder**” button, select the import directory, and select the file .qcfgcoeff

2.1.3 Installation of cfgcet configuration files for the calibration expert mode

To access the configuration files installation, select the “**Configuration > Configuration files management**” menu.

- Click on “**Install from a folder**” button, select the import directory, and select the file .cfgcet

2.2 Hardware identification

2.2.1 Prerequisite

- Communication ports selection
- Configuration files installation

With the version QLEVER Lite only MONO-USB interfaces are visible.

2.2.2 Description

If you want to know the status of the loggers or interfaces connected to the PC, use the “**Identification**” window.

To access this screen, click on “**Identification**” button from the software tool bar

The “**Menu**” button allows you to access a menu to:

- See the logger history
- Change the used serial port
- Search the connected loggers
- Modify a Radio Network for FullRadio loggers
- Configure RF Receiver beep for FullRadio loggers



- For all selected loggers:
 - Erase memory
 - Battery replacement
- Select all logger (CTRL-A)

The upper part of the window displays the serial ports used, connected interfaces and loggers. By clicking on a logger from this list, the lower part of the window is refreshed with the following information:

1. **Identity:** This window gives information on the logger electronic part. The “**Stop**” button stops the logger if it was working.
2. **Channels (s):** This window gives real time values of the selected loggers. A visual indicator shows if the display is in real time or stopped.
3. **Memory status:** This window displays the memory level already used by the logger. The “**erase memory**” button erases all data stored in memory (or right click for all selected loggers).
4. **Battery status:** This window displays statistics on the battery:
 - Real time voltage
 - The lowest battery voltage recorded
 - The minimum voltage value where the battery stops working until we replace it
 - If the battery pack needs to be replaced, first replace the battery pack inside the logger then click on “**replace battery**” button to reset all information back to zero (or right click for all selected loggers).
 - The elapsed battery life time (since the last replace battery).
5. **Configuration:** This window shows the configuration file status. If the file is not installed, then just click on “**install file**” button to install it.

2.3 Program the loggers

2.3.1 Prerequisite

- Ports selection
- Configuration files installation

2.3.2 Description

To record data, the loggers need to be programmed first.



To access the programming screen, click on **“Program”** button from the tool bar.

The upper part displays the existing programs and allows you to create new ones or to modify them.

Once you have selected the right program for each logger click on **“Program”** button to program the loggers.

The lower part of the screen displays information about the connected logger:

- Check whether the logger configuration file was installed.
- Status of the logger, stop or recording.
- Battery status.
- The different options of the logger
- The selected program for the logger. This can be different for each logger.
- The memory level used for this programming.
- **“+”** and **“−”** allow to add or remove a Fullradio logger

Remarks:

- When programming a logger, all data previously recorded are erased from the memory. The display (or not) of the warning message can be configured from the user preferences.
- Programming a logger does not mean you have started it. This is an additional step.

2.3.3 Create a new programming

To create a new program, click **“Add programming”** button.

The open window shows two tabs

“Programming” tab

Type a name for the new program and check the options you would like to use for this program. Of course, such options are only possible when the logger includes them in the hardware.

Depending on your loggers you will be able to use the following options:

- **Start on threshold:** This option allows you to select a minimum temperature value before the recording starts. In this case the logger uses its first sampling rate to check if this temperature has been reached.
- **Stop on threshold:** This option allows you to select a temperature value before the recording starts. In this case the logger uses its first sampling rate to check if this temperature has been reached.
- **Radio mode** (only available for the radio loggers): The logger can emit



data through the radio, only record the data in the memory, or do both. It is also possible to select a temperature threshold. The logger would only emit above such temperature

- **Maximum acquisition frequency:** According to their feature, some loggers have a frequency feature up to 4, 10 or 64 acquisitions per second (default frequency: 1 acquisition per second). You may select this option by checking the required mode.
- **Rotating memory:** Some loggers can be programmed with a programming which requires more memory capacity than the one set in the logger. In this case, when the logger reaches the maximum capacity of its memory, it erases the first data and continues recording.
- **Rotation:** This option must be checked when using a rotation logger and doesn't take in consideration the other options.

"Description" tab

You can add a description and check the account(s) used for the creation or modification of the program including dates.

Then click on **"Validate"** button.

A new line appears in the programming table with the name you gave for this program. By clicking on the tab at the end of the line you can modify the parameters of the program. This can also be done by clicking on the **"Modify"** button on the right part of the window.

"Save as..." button save the selected programming to a copy.

Under the programming line, an extra line is automatically added. The figures with the light blue colored background show the required duration. The figures with the light yellow colored background show the acquisition rate. Just click on the line for modification.

By clicking on the **"+"** and **"-"** tabs at the end of the line, you can add and remove a sequence for the program. The number of sequences depends on the loggers and the selected options.

You can also set all the loggers with such program with a right click and selecting **"apply the programming to all the loggers"**.

Besides such program can be automatically set by default by opening this window, do a right click and select **"define as programming by default"**.

2.4 Start the loggers

2.4.1 Prerequisite

- Ports selection



- Files configuration installation
- Loggers programmed

2.4.2 Description

The logger must first be started to begin recording.

To access the window that allows you to start the loggers click on **“Start”** button from the tool bar.

The table shows the connected loggers and interfaces as well as the status of all the loggers.

It's possible to display (see **User preferences**):

- The channel values
- The thermocouple type (only if universal thermocouple)
- Battery information
- Memory information

In order to modify the time and date for a specific logger to start, click on the **“Start”** column in the corresponding line for the specific logger.

In order to modify the time and date for all loggers to start, use the box below.

Once the time and date for the logger(s) to start are set, click on **“Start all loggers”**. The loggers status is then modified from Stopped to Recording status.

Remark:

Some loggers can store several recordings in memory. To clear the memory, you have to program the logger and not only start it. You could also use the **“Erase Memory”** function from the **“Identification”** window or check **“Erase the memory before starting”**.

2.5 Read the loggers

2.5.1 Prerequisite

- Ports selection
- Configuration files installation
- Loggers starting

2.5.2 Description

To select the window for downloading the data recorded by the logger click on **“Read”** from the software tool bar.



The table shows the loggers and the interfaces connected to your computer. For each connected logger you see the list of the recordings.

You can modify the directory within the TDB and file name in which the recording will be saved, by clicking on the tab located at the end of the **“Save under...”** column on the line of a specific logger.

If more than one logger is connected and/or if the loggers contain more than one recording, you can decide to create a single file merging data of several recordings and/or several loggers. To do so you must select one or more recordings from the table, then do a right-click and choose **“add the selected recordings to the single file**. A small tab will appear at the beginning of the selected lines. You must then check **“create a single file with the recordings preceded by the symbol”**.

This feature is not available with the Version QLEVER Lite.

Only the selected lines will be read. To select more lines, just press the **“CTRL”** key from the keyboard then click on the required recordings.

If you wish to read everything, it is also possible to press the **“CTRL + A”** keys from the keyboard or right click, menu, **“Select all”**. All the recordings will then be selected.

If some **FullRadio** loggers are running, a selection window will open and allow you to load the available running loggers list. You can deactivate this functionality in **“Radio network”** windows. If you don't read some **FullRadio** loggers, they will automatically be excluded from the data file.

Apply automatic calculations: this software allows you to set automatic calculations (cf. 3.3.4 *Calculated columns*) that apply automatically when loggers are read (except in setup mode). To reach the library of calculation settings, click on **“Calculator”** button select the **“Configuration > Library of calculation”** menu.

⇒ *This function is not available in Setup mode and calibration mode.*

Once you have completed your selection, click the **“Read”** button.

2.6 Loggers History

QLEVER records the different operations performed on every logger.

This history is accessible by right clicking on the name of the logger from:

- a data file QLE (except on old QLEVER 1.x files)
- the identification screen of the material
- the installation screen of the configuration files.

The history of the loggers is shown as a chart with several columns:

- Command type: programmed, started, read, process...



- For the replace battery, the old values are displayed
- Date
- Performed by
- Command description
- Symbol
- Software Version

2.7 Universal thermocouples configuration

Prerequisites:

- Only universal thermocouple logger can be configured.

Description:

Each channel of a universal thermocouple logger can be configured with these types: B, E, J, K, N, R, T or S.

Thermocouples configuration are templates to be applied to configure the connection of the logger.

Click on **“Logger”** menu, **“Thermocouples configuration”**, or right click on a logger in **“Managing configuration files”** screen.

Displayed for each channel:

- Channel number and thermocouple.
- Min and max temperature: measurable temperature range by the chosen thermocouple.
- Gain and resistor values are logger technical information's.

Create a new thermocouple configuration:

- Select the logger.
- For each channel, choose the type of thermocouple.
- Click on **“Save as”** to record the configuration as a new configuration.
- The new configuration is displayed in the list of available configurations.

Modify an existing thermocouple configuration:

- Select the logger.
- Select a configuration in the list.




- Click on **“Apply”**.
- Modify the type of thermocouple of the logger channels
- Click on:
 - **“Save”** to record the configuration.
 - **“Save as”** to record the configuration as a new configuration
- Click on **“Configure”** of update the logger.

Choose the same thermocouple's type at all channels:

- Select **“Apply to all”** on a logger channel.

Modify the configuration name:

- Select a configuration in the list.
- Click on  to rename the configuration

Delete a configuration:

- Select a configuration in the list.
- Click on **“—”** to remove the selected configuration.

Configure the logger with a thermocouple configuration:

- Select the logger.
- Select a thermocouple configuration.
- Click on **“Configure”**.
- Connect the logger (except FullRadio logger).
- The Configuration screen will update the logger with a new cetx configuration files.
⇒ **The configuration date will be updated.**
- Click on **“Configure”**.
- You can connect the thermocouples

Important:

- ⇒ **“Configure”** reset only the adjustment of all THn channels, not the adjustment of the internal channels.
- ⇒ **“Configure”** replace the current cetx configuration file (date updated).
- ⇒ You can restore an old cetx configuration file, see **“Managing configuration files”**



installation” screen.

- ⇒ The thermocouple type is saved in the cetx configuration files on each universal thermocouple logger.
- ⇒ You can display the configured thermocouple type in the “**Starting logger**” screen (see **User preferences**”.
- ⇒ The displayed value is only valid if a thermocouple is not connected.
- ⇒ 21CFR: Approval and operator can use all functionalities.

2.8 Timestamp

This window, accessible from Qlever's "**Windows**" menu, "**Timestamp**", is used to record events that occurs while recording data. For example, the recording of the opening date of the door of an equipment in the calculation of the recovery time (see Mapping).

Advantages:

- Avoid having to write time on paper.
- Benefit from the accuracy and accuracy of the time (in relation to that of the recorders).
- Ability to retrieve these timestamps easily and without error from the QLE data file (after replay) by clicking on the "date selection" icon to the right of the date in the zone dates, dates of the cycles, dates in the setup, ...

These timestamps are recorded in a file common to all Qlever users:

- ID: unique identifier of the event.
- Date and time of the event.
- Description of the event.
- “-” : deleting the selected line in the table
- Right-click to access a menu of features:
 - Delete All: removes all timestamps from the list.
 - Add: add a new date and time
 - Refresh: refreshes the list of timestamps.

Entering a new timestamp:

1. If necessary, fill in the description.
 - o +1 is used to give a number that is incremented in the description.
 - o -1 the opposite.



2. Click this button to save a new timestamp (or Enter key).

Settings:

- Always visible: allows you to keep this window on top of others.
- Time: QLEVER timestamp measurement can be done:
 - o By reading the system clock of the PC.
 - o By reading a clock on USB (which brings a better accuracy and a better stability because the clock of some PC fluctuates or is resynchronize their clock by the network if they are on-line).



3 QLE data files

3.1 QLE Files Management

The data files created by the QLEVER software include a QLE extension name.

They are created when the memory of a logger is downloaded or when opening a file earlier created with xVACQ software.

In order to open one or more QLE file located in the TDB, go to “**File > open**” menu.

In order to open one or more external QLE file, go to “**File > open an external file**” menu.

Besides it is easy to open recent files, just go to “**File > Recent file**” menu.

3.2 Data display

3.2.1 Description

The window that shows the recorded data within a QLE file consist of three parts.

1. The top part with different tabs shows:

- Table with data.
- Data analysis.
- Screenshots.
- Also some specific tabs related to options of the software.

2. The lower left part with different tabs shows:

- The graph legend.
- Zones or cycles.

3. The lower right part shows the graph.

3.2.2 Numerical data, analysis...

3.2.2.1 Data

The top part shows the data within a table.

The first two columns show the acquisition date and time, while the next columns show the logger values. The title of the column shows the channel number together with the unit. To obtain more information just move the mouse over the title of one of the columns to obtain the logger serial number and the channel number. You can also find the channel number in



the legend and obtain the same information. It is possible to hide the column by clicking on the title of the associated column.

A click on the header of the column of the data would allow you to:


- **Thick:** get the line of the curve and the data column thicker
- **Hide:** hide the curve of the graph (the data are shaded but will still be used within the calculations)
- **Hide all but me:** Hide all curves but the selected curve (the data are shaded but will still be used within the calculations)
- **Exclude:** exclude the channel (the data will not be used in the calculations). Click the legend to include the channel again.
- **Modify the color of the curve**
- **Configuration:**
 - **Graphic:**
 - Set the gridlines for the X & Y axis as well as the color for the background of the graph.
 - **Personalize curves**, set quickly:
 - Color
 - Exclude/include
 - Hide quickly curves
 - Thick
 - **Data:**
 - Hide the Date column (for small screen)

When selecting a line form, the table, a vertical reference line mark will be displayed on the graph at the same exact sample date. You can then move this reference line mark by moving within the table pressing the “↑” and “↓” keys.

When using the scroll bars on every table, the following information displays:

- The number of the first visible line in the table.
- The number of the last visible line in the table.
- The total number of lines in the table.

When using right click on a date/hour:

- Adding a zone (see Zone)
-  Selection of a begin/end date for adding quickly a zone for a calculation (see Min/Max/Avg) or for defining quickly cycle of the setup mode.
 - **CTRL + Click:** select automatically the date + hour



- **CTRL + D:** deselect the two dates
- Zoom
- Configuration (see Configuration)

⇒ Values windows allow to show more information.

3.2.2.2 Data analysis

Within the main tab statistics, analysis and calculations can be displayed.

This feature is not available with the Version QLEVER Lite.

3.2.2.2.1 Min/Max/Avg

The first tab allows you to make “minimum, maximum and average” type statistics within a specific area of the graph.

A table will show for each selected channel (depending on the setting):

- The minimum value with the date/time when this was reached.
- The maximum value with the date/time when this was reached.
- The average value.
- The standard deviation.
- The maximum – minimum variation

For each unit (depending on the setting):

- Min. value
- Max. value
- The max. range
- The mean of mean
- The minimum of the maximum values with the date/time when this was reached.
- The homogeneity or Max. spread in setup mode only

For only one unit (depending on the setting):

Time above / Time Below:

- The time above a threshold with total time, min., max. time above and occurrence (number of times the threshold has been > threshold)
- The time below a threshold with total time, min., max. time below and



occurrence (number of times the threshold has been < threshold)

- Comparison operator used:
 - Time above > threshold
 - Time below < threshold
 - This calculation is with data linearization.

For F0/A0/C0/P0:

- Display or not the F0/A0/C0/P0 formula parameters (default=Yes)

Legend:

M = max. value, m = min. value for average.

Red = maxi value, blue = mini value.

When using the Setup mode, those results would be displayed for every stage of the cycles, if calculations or zones are displayed in blue, it means that the dates have been changed manually from setup "Cycles" windows.

This feature is not available with the Version QLEVER Lite.

3.2.2.2.2 Slope calculation

The second tab allows you to calculate the slope.

A table will show for each selected channel:

- The slope
- The squared correlation coefficient
- Slope duration
- Start and end of date/time for the slope

Other tabs can also appear according to the options installed with the software.

When using the Setup mode, the results will be displayed for every stage of cycle.

This feature is not available with the Version QLEVER Lite.

3.2.2.3 Screenshots

This tab allows you to manage the various screen shots made from the graph.

For each picture, it is possible to:

- Remove the picture
- Display and modify its name and add comment or print.



- **Export** as a JPG file.
- **Copy** to clipboard.
- Print this screen shot in the report or not in setup mode.

In reports, screenshots will be printed according to the capture date (only for new captures).

- The background color of the graph can be configured in the "**Configuration**" screen (right click on the graph).

3.2.3 *Legend, scales and zones/cycles*

The lower left part shows with two tabs the graph legend. The first tab with the description of the curves, and a second tab with the description of the zones or cycles.

3.2.3.1 Legend and scales

- **Graph legend.**

The Legend tab displays the curves legend.

The display is in the form of a hierarchical tree. The hierarchy starts with the logger serial number, the channel number and for every channel the minimum, the maximum and the average values within the current zoom of the graph.

F₀, A₀... don't display average.

A click on the specified number in the legend would allow you to:

- **Thick:** get the line of the curve and the data column thicker
- **Hide:** hide the curve of the graph (the data are shaded but will still be used within the calculations)
- **Hide all but me:** Hide all curves but the selected curve (the data are shaded but will still be used within the calculations)
- **Exclude:** exclude the channel (the data will not be used in the calculations). Click the legend to include the channel again.
- Modify the **color of the curve**
- **Configuration:**
 - **Graphic:**
 - Set the gridlines for the X & Y axis as well as the color for the background of the graph
 - **Personalize curves**, set quickly:
 - Color



- Exclude/include
- Hide quickly curves
- Thick
- **Data:**
 - Hide the Date column (for small screen)

Keyboard shortcuts in the configuration window:

Key	Action
F2	Keep temperature channels and hide other channels
F3	Keep pressure channels and hide other channels
F4	Hide all calculated channels to keep only the channels logger
F5	Do not hide curve
F6	Hide all curves
F7	Reverse selection curves hidden
F9	Keep calculated channels and hide the others
ENTER	Validate
ESC	Cancel

- **Logger History**

To check the history of the logger, right click on the name of the logger to obtain a complete description of the programming used to create the data and other information on the start, read... (*cf. 2.6 Loggers History*).

- **Graph scales**

Under the information tab (or Cycle tab when using the Setup mode), a table shows the current graph scales. It is possible to edit these values.

3.2.3.2 Zones

The same Information tab also displays the zones created from the graph. A table shows different columns:

- 1st column with a box to check to show or hide the zone.
- 2nd column with the zone color.



- 3rd column is a graphic icon.
- 4th column includes zone name and more information.
- 5th column where you click to edit the zone.
- 6th column allows an automatic zoom on the zone by left clicking for a 10 % wider zoom or right clicking for a normal zoom. Available statistics in "Legend" tab can be read very quickly. The zoom results are different according to the zone type (marker, straight line, etc...).

To create a zone, just click on the zone button or just click the "+" button. A menu will appear with different types of zone that can be created or right click on the graph

To remove a zone just select a zone from the table and click on "-" button.





When using the Setup mode, the stages of the cycles would be displayed in the same table.








3.2.4 The graph

The lower right part of the window shows the graph from the record.

Below the curve(s) you will find the horizontal time axis and on both vertical sides the physical measurement axis.

On the left graph a tool bar to browse the graph:

Icon	Action
	Cursor mode
	Displays information on the selected curves Allows to display a cursor and to select the corresponding line of the data table Allows to show a contextual menu to create zones on the graph
	Zoom by selection
	To zoom, it is necessary to do a hold on left click on the graph and to move the mouse. A selection box appears and it is then possible to make a zoom on the selected area. To cancel the zoom, do a right click on the graph.
	Progressive move
	Hold on left click on a specific location within the graph a zoom in. Hold on right click on a specific location within the graph and zoom out.
	Graph move

Icon	Action
	To move the graph just hold on the left click and move the mouse.
	Auto scaling
	By clicking on this button, the graph is displayed again but using the full scales for the showed physical parameters within the visible zone.
	Zoom reset
	Restore initial zoom
	Undo zoom
	Undo last change zoom
	Redo zoom
	Restore the previous zoom
	Zone button
	Add fixed marks on the graph
	Screenshot
	By clicking on this button you create a screenshot of the graph which will be saved in the "screenshots" tab.
	Fullscreen/windowed mode
	By clicking on this button, the software changes to full screen mode. Click again to come back to windowed mode.

Keyboard/mouse Short key	Action
Wheel mouse on the graph	Zoom
CTRL + Wheel mouse on the graph	Zoom
SHIFT + Wheel mouse on the graph	Horizontal Move
CTRL + SHIFT + Wheel mouse on the graph	Vertical Move
Press wheel mouse on the graph	Move
Space key	Graph move Mode
⇐ ⇨ ⇩ ⇪ Key	Move
Mouse Right click	Contextual menu



3.3 Data files managements

3.3.1 Zone creation

It is possible to create zones from the graph. The purpose is to highlight some areas of the graph. Zones are also used to show results of calculations and statistics made from specific areas of the graph.

To create a zone just click on the “zone” tab of the open file then clicks on “+” button under the tablet or do a right click on the graph. A contextual menu opens and allows selection of the type of zone type to be created.

Horizontal zone

This would be a zone parallel to the time axis and with two physical values as boundaries. It is defined by:

- A name.
- A physical parameter (Temperature, pressure, ...).
- A minimum and maximum value (as default corresponding to the min. and max. values from the current zoom).
- A color and a hatching style.

Vertical zone

This would be a zone perpendicular to the time axis with two dates as boundaries. It is defined by:

- A name.
- A start and end dates (as default corresponding to the min. and max. values from the current zoom).
- A color and a hatching style.

Rectangular zone

This would be a zone like a box with two physical values and two dates as boundaries. It is defined by:

- A name.
- A physical parameter (Temperature, pressure...).
- A minimum and maximum value (as default corresponding to the min. and max. values from the current zoom).
- A minimum and maximum date (as default corresponding to the min. and max. values from the current zoom).
- A color and a hatching style.

Vertical reference mark

This would be a vertical line plotted on a specific date. It is defined:

- A name.
- A date (as default the date under the mouse click).
- A color.

Horizontal reference mark on a physical value

This would be a horizontal line plotted on a specific physical value. It is defined by:

- A name.
- A physical parameter (Temperature, pressure...).
- A value (as default the value under the mouse click)

Marker on a physical value

This would be a maker on a specific physical value. It is defined by:


- A name.
- A location name from the icon
- A physical parameter (Temperature, pressure...).
- A value (as default the value under the mouse click)
- An Icon

If a channel is thickened, then this channel will be taken into account when later a marker will be created.

⇒ The date and time created from the “Timestamp” window are available by clicking on the "selection" icon to the right of the date.

3.3.2 Min./Max./Avg Calculation

To create or modify a calculation of “**Min./Max./Avg**” type select the “**Data Analysis**” tab from the open file, then select the “**Min./Max./Avg**” tab.

 : Click on button. A window will appear with a table showing existing calculations. Click on the “+” button to create and define a new calculation using three new tabs.

The lower part of the window gets larger, and allows to you to create the calculation with four icons:

General

Give a name and a description to this calculation.

Channel(s)



Select the channel(s) used for the calculation. Right Click to show the quick channel selection menu.

Zones

Define the zone on which the calculation will be done. The zone is defined by a start and end times.

The start time could be:

- The beginning of the all recording.
- A specific chosen date to be typed in the box.
- The start time of an existing zone to be selected in the combo box.

The end date could be:

- The end of the all recording.
- A specific chosen date to be typed in the box.
- The end date of an existing zone to be selected in the combo box

Parameters

- Display the time above and below a value

To add “calculate a time above and below a value”, check the box “time above” then indicate the threshold value and its unit.

- Display the Min. value
- Display the Max. value
- Display the max. range
- Display the mean of mean
- Display the minimum of the maximum values with the date/time when this was reached.
- Display the homogeneity or Max. spread in setup mode only
- Display the F0 parameters


Just click on “**validate**” to validate the creation.

This feature is not available with the Version QLEVER Lite.

3.3.3 Slope Calculation

To create or modify a slope calculation select the “**data analysis**” tab from the open file then select the “**Slopes**” tab.



 : Click on button. A window will appear with a table showing existing slope calculations. Click on the “+” button to create and define a new slope calculation using three new tabs.

General

Give a name and a description to this calculation.

Channels(s)

Select the physical parameter and the channel(s) used for the calculation.

Zones

Define the zone on which the slope calculation will be done. The zone is defined by a start and end times. However, there are two methods when using those two dates.

- The dates are used to bounder the area where the slopes will be searched. In this case the slopes will be found in this area anytime reaching the values defined in the **Settings** tab.
- The zone is defined by a start and end time.

The start time could be:

- The beginning of the all recording.
- A specific chosen date to be typed in the box.
- The start time of an existing zone to be selected in the combo box.

The end time can could be:

- The end of the all recording.
- A specific chosen date to be typed in the box.
- The end date of an existing zone to be selected in the combo box

Settings

If the dates are used to bounder the area where the slopes will be searched, it is necessary to also specify a frame between a minimum and maximum physical value inside which the slopes will have to be calculated. Also specify the direction of the searched slope.

The minimum value can be defined in two different ways:

- By a fixed value.
- By a zone. In this case, it is the minimum value of the zone that will be used.

The maximum value can be defined in two different ways:

- By a fixed value.
- By a zone. In this case, it is the maximum value of the zone that will be used.

To choose the direction of the slope check on of the dedicated boxes.

Just click on “**validate**” button to validate the calculation creation.



This feature is not available with the Version QLEVER Lite.

3.3.4 Calculated columns

It is possible to add columns to the data the file with results of a calculation for each sample. To do so, go to “**Edit > Calculated columns management**” menu.

A window will appear with a table showing existing calculated column.

- The 1st column is the name.
- The 2nd column is the type.
- The 3rd column shows the summary of the settings.

To edit or delete a calculated column just select the corresponding line and click on “**Edit**” or “**Delete**” button.

Click on the “+” button to create and define a new calculated column. A contextual menu will appear, then select the column type that you want to add. Once selecting one type of calculation from the menu, a window will appear where you need to type the parameters and settings for the calculation.

⇒ Setup type calculated columns are shaded. They can't be modified because they belong to the measurement report.

⇒ Not used and excluded channels are not available on the channels list.

⇒ **Caution:** in the case of channel exclusion, the calculated channels are recalculated only in “**setup**” mode, not in “**standard**” mode.

⇒ You must Save, close and open the current Qle file to update Excluded channels in the logger channel list.

⇒ **Caution:** in the 21CFR Secure Mode Audit, the channels carry their column number when entering the parameters of the new channel, but this column number may be shifted if you insert other types of calculated channels.

3.3.4.1 $F_0/A_0/C_0$... type column

The table on the right allows the selection of the columns on which you wish to make the calculation. For each selected column a new column will be created with the parameter setting defined on the left part.

The left part allows you to define such calculation in the following way:

- A list allows to choose the calculation type:
 - F_0 : for sterilization, expressed in minute.
 - A_0 : for disinfection, expressed in second.
 - C_0 : for cooking, expressed in minute.



- P_0 : for pasteurization, expressed in minute.
- *Define...*: allows to modify the label of this calculation type and to choose the unit it will have to be displayed.
- T_R : The reference temperature.
- Z_R : Bacterial reduction temperature $V = \int 10^{\frac{T(t)-T_r}{Z_r}}, \forall T(t) \geq T_i$
- T_i : Temperature threshold for the calculation.

3.3.4.2 Offset type column

Add a value to one or more columns to create offset(s).

Just specify:

- The name.
- The value for the subtraction (if this value is negative, it will be added).
- The physical parameter for the value.

The calculation will be: $X = Y - V$ with:

- X = new column value.
- Y = reference column value.
- V = value to be subtracted.

According to the specified physical parameter, only channels with the same physical parameter are displayed on the right end table. Check the box to add the calculated column on the desired channel(s).

3.3.4.3 Percentage type column

Add a column with a percentage results using a reference value.

Just specify:

- The name
- The reference value.
- The physical parameter for the value.

Calculation will be: $X = \frac{Y - V}{V} \times 100$ with:

- X = new column value.
- Y = Value from the channel
- V = reference value

According to the specified physical parameter, only channels with the same physical parameter are displayed on the right end table. Check the box to add the calculated column on the desired



channel(s).

3.3.4.4 Delta (Δ) type column

Add a column with Δ results, difference between two existing logger columns of the same physical parameter.

Just specify:

- The name.
- The physical parameter for the value.
- The formula $V_1 - V_2$ or $V_2 - V_1$ with:

X = value of the new column.

V_1 = the first value.

V_2 = the second value.

Depending on the physical parameter of the value, the table on the right hand side will only show the sensor with the same physical parameter. You only need to check the sensor(s) related to the calculated column. For every sensor channel a new calculated column will be added.

⇒ All selected channel must be in the same table (see "Edition", "Merge the table of the current file" or check "Merge the table" when you read the data loggers).

⇒ Not available in real time mode.

3.3.4.5 Saturated vapour temperature calculation (Regnault) type column

Add a column with temperature values calculated from the pressure of the saturated steam thanks to the Regnault table (100 °C à 150 °C).

Just specify:

- The name of the calculation.

Depending on the physical parameter of the value, the table on the right hand side will only show the sensor with the same physical parameter. You only need to check the sensor(s) related to the calculated column. For every sensor channel a new calculated column will be added.

3.3.4.6 Saturated vapour pressure calculation (Regnault) type column

Add a column with pressure values calculated from the temperature of the saturated steam thanks to the Regnault table (100 °C à 150 °C).

Ce type de colonne permet de réaliser un calcul de la valeur de la vapeur saturée, c'est-à-dire d'une pression en fonction d'une température selon la table de Regnault (100 °C à 150 °C).

Just specify:



- The name of the calculation.

Depending on the physical parameter of the value, the table on the right hand side will only show the sensor with the same physical parameter. You only need to check the sensor(s) related to the calculated column. For every sensor channel a new calculated column will be added.

3.3.4.7 Polynomial type column

Add a value to one or more columns to create polynomial calculation

Just specify:

- The name.
- The value a
- The value b
- The physical parameter for the value.

The calculation will be: $Y = aX + b$ with:

- Y = new column value (same physical parameter as b).
- X = reference column value.

Check the box to add the calculated column on the desired channel(s).

3.3.4.8 Apply the last calculation




This menu allows you to load the screens containing the parameters of the last calculation performed to save time if you use the same formula often.

3.3.5 Origin change

Select “**Edit > Modify the file’s beginning date**” menu.

It is possible to modify the date and time of origin of a recording by typing information in the table on the left part of the window.

The buttons on the tool bar of the graph also allow:

Icon	Action
	To shift the origin of the curves manually
	To make a zoom on the graph
	To move the graph



To finish just click on “**save**” button. A new file is then created.




3.3.6 File merging

To use this menu, it is necessary that more than one files are open at the same time. Note that all the open files would be used in this merging process.

Select “**Edit > Merge the open files**” menu.

The table on the left shows the files which are used for this merging process. The date and time of origin for each file is shown.

The buttons on the tool bar of the graph also allow:

Icon	Action
	To shift the origin of the curves manually
	To make a zoom on the graph
	To move the graph

It is possible to modify the date and time of origin just like explained in the earlier section

It is possible to merge those tables into one single table (*cf. 3.3.7 Table merging*).

Click on “**Save**” button. A new file is then created.

Note that the files created with the Setup mode cannot be merged.

This feature is not available with the Version QLEVER Lite.

3.3.7 Table merging

When a file includes more than one data table, after a file merging process for instance, it is possible to merge those tables into one single table. We would end up with only one time base for all the data. If there is no available data at a certain date and time, there would be empty boxes.

Select “**Edit > Merge the data of the current files**” menu.

Note that the data tables from files created with the Setup mode cannot be merged.

This feature is not available with the Version QLEVER Basic.

3.3.8 Create a new file from the current zoom

Select “**Edit > Create a new file from the current zoom**” menu.



⇒ Only user F0, A0, C0, ... calculated channels (not setup mode) are recalculated.

⇒ Only a data file created in standard mode.

This feature is not available with the Version QLEVER Basic.

3.3.9 Printing

Select **"File > Print"** menu to print the file.

By clicking on **"Print"** button the standard printing window of Windows opens allowing the choice of the printer and the printing format.

The printing parameter window allows:

To print the numerical data over a period. By default, the period represents the whole data.

- Print every lines or one line out of x.
- To print the graph with background color.
- To print the graph legend on a separate page.
- To print the Min./Max./Avg. calculation.
- To print the comment of the QLE file.

3.3.10 Export of file

Select **"File > Exporter"** menu to export the QLE file as external file.

3.3.11 Export of data loggers

Select the menu **"File > Export the data"** in order to export the data to a spreadsheet.

- Data file
 - Select the start and end dates. As default data from the entire recording will be exported.
- Min./Max./Avg. calculations

Configuration of the format of such exported data:

- Select the separator for the columns. ";" or TAB
- Select the type of file, CSV ou TXT
- Choose to separate the milliseconds into a new column (data only)
- Export to the ValiVacq format
- Choose to automatically open the file



The new created file will be compatible with any spreadsheets

⇒ Is the QLE file includes several tables, they will be written in a raw. If you want a single table, go to “Merge the table of the current file” in “**Edition**” menu.

4 Real time and Radio loggers use

Radio Channel	Frequencies (MHz)
11	2405
12	2410
13	2415
14	2420
15	2425
16	2430
17	2435
18	2440
19	2445
20	2450
21	2455
22	2460
23	2465
24	2470
25	2475

Channels Frequencies

4.1 Programming and starting

The radio loggers can be programmed (*cf. 2.3 Program the loggers*) and started (*cf. 2.4 Start the loggers*) as any logger.

However, if several radio loggers are used simultaneously, a window will pop up before the start of the loggers to specify for the offset to shift the start time between two loggers. You have to type in a value multiple of 100 milliseconds. The purpose of this time shift is to prevent the loggers from transmitting data simultaneously which could create data loss.

The number of recorders possible for radio reception depends on:

- The chosen rate of the programming divided by 100 milliseconds (for example: in 1 second it is possible to pass 10 in the best case).
- The number of loggers and not the number of channels (a 32-channel thermocouple



vacq counts as 1)

- The environmental conditions where the recorders and the radio receiver are located, which influence the quality of radio communication. For example, if the environment is disturbed in electrical equipment, or by metal walls, the radio waves will be more disturbed, and it will certainly require numerous transmission re-tests.
- The computer power required to process this data in the case of a large number of loggers (computing, displaying).

4.2 Real time file creation

After the radio loggers started, click on **“Real time”** or **“File > New... > Real time file”** menu.

A window opens and allows the selection of started radio loggers for a real-time monitoring.

- Select the loggers for the real-time monitoring
 - Right click menu:
 - Select all, select none
 - Select all loggers with the same radio channel
 - Delete radio status
 - Refresh the list
- Select a file in which the data will be saved.
- Click the “next” button.

The following window lets you add columns which will be calculated in real time at the time of the data reception.

- To add calculated columns, click on **“Calculated column management”**, the method is then the same as described in paragraph 3.3.4.
- Then click “Validating” to finish, the created file opens

4.3 Monitoring

You can monitor the radio loggers thanks to the real-time file created as above.

If you close the file, the data displayed so far will be lost. If you open the file again, the new data will be added.

When a radio loggers monitoring file is open, a window entitled “Radio” allows:


- To modify the serial ports connected to the radio receivers.
- To visualize the loggers which are currently monitored.
- To monitor the quality of the reception (only for Radio loggers).



- To activate/deactivate the sound emitted on every transmission on the USB receiver's data.

5 Data Files Management System: TDB

QLEVER uses a secured data file management called TMI Data Base (TDB). It is a secured data base used by the software when saving and reading any recordings (*cf. 1.2 Directories Management*).

IMPORTANT NOTE: the TDB must be installed on NTFS partition. To open a file, go to "File" and "Open" or click the  button from the tool bar.

5.1 Description of the functions of the files management system

This data management system is similar to the Windows Explorer.

The TDB and QLEVER can be used on a network meaning that the files could be accessed by multiple users. To do so, just specify a directory that can be accessed by every user when doing the setting of the directories (*cf. 1.2 Directories Management*).

Selecting a file or directory and by right-clicking, you can access various functions just like in the Windows Explorer. The same functions are also available from the "**Directory**" and "**File**" menu on the top.

According to the type of file (Setup, Process, QLE files, Reports), some specific functions will appear at the bottom part of the window.

Functions related to the directories on the left hand part are:

- New, Rename, Move or Delete.
- Properties directory, icon directory and check TDB index
- Search file
- Display of the recent files
- Some directories being part of the QLEVER system cannot be moved, renamed or deleted.

Functions related to the files on the right hand part:

- Display of the GUID (Globally Unique Identifier).
- Display the name of the file with Unicode.
- A file already opened by some other user shows red and it is not possible to open.
- Display of an icon showing the type of file.
- Display of an picture showing a curve for a QLE file or report or generally the equipment picture for a Setup.
- Display of some dates and user's names for creation and modification details.
- Usual functions with the right-click.
- Starting a Setup
- Read a process
- Approve a measuring report
- Force and close a file.

Also, for the QLE file, in the bottom part of the window you can:



By selecting a file, rename the file, modify the description and add key word to help the file research.

Click **“Save”** to record the change.

5.2 File research by date or keywords

Find a file becomes easy with the TDB. Type one or more keywords then click the magnifier icon.

For instance, if you need to find files related to the logger with serial number *NV034108*, type *NV034108* and click on the magnifier icon.

For example, if you need to find all the Setup files, type the word *“Setup”* and click on the magnifier icon.

Further, using the **“Recent Files”** button, you can list all the files by date of modification, or another method is **“File > Recent Files”** Menu

5.3 Globally Unique Identifier (GUID)

The TDB gives a unique identification to every file. This identification starts with QL for the QLE files, RP for the Reports, PP for the process, SP for Setup, etc.

The label of the column is ID# or GUID# depending on the screen display.

5.4 Export of file

5.4.1 Export of QLE file format

Export is the copy of file(s) from the TDB to the hard drive or external drive like an USB memory stick.

Right-click on one or several files than select **“Export”** from the menu list. Then choose the directory of destination.

When using the Security (*21CFR part 11*) mode, you have to create a password for the exported file.

⇒ *Brick file don't have an exportation password.*

5.4.2 Export of VCQ file format (for compatibility only)

Right-click on one or several QLE files than select **“Export VCQ file”** from the menu list. Then choose the directory of destination.

Such feature is only available in order to maintain some compatibility with XVacq or ValiVACQ.

Only VCQ files can be opened with Xvacq or ValiVacq software.

Only QLE files, that were created when reading loggers with the box "Create a file for each record" checked, include a VCQ file.



⇒ This function is available only if “Save the VCQ file” is checked in the TDB Administration.

5.5 Import of file

Import to copy from an external drive like the hard drive or USB file to the TDB.

From the TDB, go to “**File > Import**”. Select one or more files.

With the Security (21CFR part 11) mode, you need to type the necessary password to open imported files.

⇒ Brick file don't have an importation password.

6 Administration, Backup and Restore of the entire TDB database

6.1 General description

- When using the security mode, only the administrator use could use such functions. Therefore, login using your **Administrator** account.
- Not using the security mode every user is an Administrator.

Go to “**Configuration**” menu then click “**Directory Management**”, “**TDB Administration**”, “**Data**”.

During the database administration jobs such as backup, restore, compressing or reindexing, the TDB will be automatically locked during the time for the job to be completed. This in order to avoid other users to access the data base.

6.2 Backup the TDB database

- Login using your **Administrator** account
- Go to “**Configuration**” menu then click “**Directory Management**”, “**TDB Administration**”, “**Data**”.
- Click “**Backup**”
- Select a directory and a password.
- All data including (QLE files, user's account, etc.) will be saved.
- Depending on the size of your TDB, such job could take few minutes or more. During such time, other users could not access to any data.

⇒ Depending on the size of your TDB, such job could take few minutes or more. During such time, other users could not access to any data.

⇒ If one of the files in the TDB (TMI Data Base) is larger than 4GB then it will not be possible



to perform a backup by Qlever. This is not a limitation of Qlever but a limitation of the 32-bit backup system. Back up the database with another utility or with a copy-and-paste operation from Windows Explorer (but no user needs to work on it).

6.3 Restore the TDB database

- Login using your **Administrator** account
- Go to “**Configuration**” menu then click “**Directory Management**”, “**TDB Administration**”, “**Data**”.
- Click “**Restore**”.
- Select the directory chosen for the Backup.
- Type the password chosen for the Backup.

⇒ Depending on the size of your TDB, such job could take few minutes or more. During such time, other users could not access to any data.

⇒ **Important notice:** such restore replaces every data (QLE files, user's account, etc.) with the data included in the backup file.

6.4 Reindexing the TDB database

Such function allows you to compress the database after some time in order to improve access time and save some disc space.

- Login using your **Administrator** account
- Go to “**Configuration**” menu then click “**Directory Management**”, “**TDB Administration**”, “**Data**”.
- Click “**Reindexing**” for a fast process.
- Click “**Compression**” for a long process but with a more efficient compression of the files.
- Click “**Check**” for a TDB index files check.
- At the following date

Depending on the size of your TDB, such job could take few minutes or more. During such time, other users could not access to any data.

6.5 Lock the TDB database

- Login using your **Administrator** account
- Go to “**Configuration**” menu then click “**Directory Management**”, “**TDB Administration**”, “**Data**”.
- Click “**Lock**”



This allows you to manually lock the database access for administration maintenance reasons.

6.6 Unlock the TDB database

- Login using your **Administrator** account
- Go to “**Configuration**” menu then click “**Directory Management**”, “**TDB Administration**”, “**Data**”.
- Click “**Unlock**”

This allows you to manually unlock the database access for administration maintenance reasons.

During the database administration jobs such as backup, restore or reindexing, the TDB will be automatically locked during the time for the job to be completed. This in order to avoid other users to access the data base.

When using the secure mode, only the administrator could unlock the TDB.

6.7 Logout the users from the TDB database

- Click “**Logout all the users**”

In case, by mistaken one more computers are left connected to the TDB, the Administrator can log the users out from the TDB in order to proceed with a Backup or Restore job.



Chapter - 3 Options for QLEVER

This feature is not available with the Version QLEVER Lite.

1 *Brick option*

1.1 Prerequisites

- QLEVER license with:
 - Autoclave validation option included
- At least one temperature data logger

1.2 Description of the Brick option

The brick option would add functions to the software to help monitoring the curing process of ceramic products in kiln tunnels.

- As a first step, you need to create one or more reference describing the kiln tunnel, the kiln car and the position of the thermocouples.
- As a second step, you need to link a reference file with a data file.

1.3 Create or modify a reference Kiln file

To create a new “kiln” file click **“File > New... > Kiln file”**.

To modify a “kiln” file, open it.

Si the “kiln” file has been associated with a Qle file, click on **“Description”** button.

1.3.1 *Description of the oven [tab 1]*

In the first tab you would type the information related to the oven.

- Name, Site, Comment to be specified for the kiln, manufacturing site, process, etc.
- Picture: It is possible to add a graphic element like a photograph picture or a diagram to visualize the kiln.
 - ⇒ This picture will be used in the Tmi Data Base.
- Kiln parameters: to type the technical information for the kiln. When typing correct information, it becomes easy to link the temperature data to specific locations within the tunnel.
- Measurement report:
 - Header for the report



- Final evaluation and remarks

1.3.2 Load description and thermocouples description [tab 2]

In the second tab you would define the load as well as the thermocouple distribution layout.

1.3.2.1 Load description

From this section you would define the load type, the quantity, the unit weight and also to add a photograph. These elements are for information only and optional.

1.3.2.2 Load organization

From this section you would define the elements distribution in the kiln car. When one of the three values is modified, the 4 diagrams in the right-hand side would be automatically updated according to those modifications.

Caution: if the number of elements is important, it is preferable to separate the load into blocs made of several elements.

1.3.2.3 Thermocouples management

From this section you would define the number of thermocouples that would be used. It is possible to type this information later, for example after reading the memory of the logger.

To specify the number of thermocouples, simply enter the data. The table below will be updated. It is also possible to modify the description column and add a comment.

Then you can position the thermocouples on the 4 theoretical views and/or on the photographs.

1.3.2.3.1 Positioning on the drawing.

On each kiln car view, tags labeled with a number related to the thermocouple can be moved with the mouse except on the 3D view. Just click on the tag and move it to the required position. The 3 other views are then updated in real time.

1.3.2.3.2 Positioning on the photograph

From the "Positioning on photograph" tab it is possible to add up to two photograph pictures. On each of them it is possible to move the tags showing the thermocouples by using the mouse.

1.3.3 Setting up the oven / Kiln tunnel configuration [tab 3]

This tab allows to position the various elements inside the kiln and to divide the tunnel into



various zones.

In the top of the screen, a comment for the report.

The kiln is displayed in the upper part of the window. From the blue window you can define and move the kiln section.

1.3.3.1 Kiln elements positioning

1.3.3.1.1 Add new elements

To add elements inside the kiln tunnel just select the element from the list then drag and drop on the kiln diagram in the lower part. Then release the button to leave the element at the required place.

It is also possible to add several elements at the same time. You have to:

- Select from the combo box on the right the type and number of elements to be added.

- Define the distance from the first element to the kiln entrance.

- Define the elements position

- Define the distance between each element

- Then click on "add" button.

1.3.3.1.2 Elements modification

To modify elements already positioned, it is possible to:

- Click on a kiln element and move it with a click.

- Modify, using the table, the distance and the position from the element.

1.3.3.1.3 Delete Elements

To remove one or more elements just select them in the middle chart, then click on "**Delete**" button or press the "Delete" key from the keyboard.

1.3.3.1.4 Elements Icon customization

It is possible to personalize the icon for kiln elements.

To do so just:

- Go in the software installation directory software and find "kiln element"

- Create images files in PNG format of 26 pixels high by 26 pixels large and name them *1.png*, *2.png*, etc.

- Open the elements.ini file and modify it so there is one line per image:



[IMAGES]
1 = image 1 name
2 = image 2 name
...

1.3.3.2 Zones definition

To create a zone just click on “Zones” tab and fill the fields in and click the “add” button.

It is possible to modify them by publishing directly the values in the chart recapitulating the existing zones.

It is also possible to remove a zone by selecting it in the table and press the “Delete” key from the keyboard.

1.3.4 Pushes and incidents management [tab 4]

This tab allows modification of the push duration when the speed changes or incidents occurred during the process.

To modify only one push just edit the duration, the reason for change or any comment.

To modify several subsequent pushes just fill the lower part in:

New duration of each modified push.

he pushes that need modification by defining the first and the last push.

By modifying if necessary the reason of the duration change

By adding a comment

Then just click the “**Modify**” button and the changes are recorded.

In the bottom, a comment for le report.

1.4 Associate a Kiln file and a data file

To link a kiln file and a data file you should do as follows:

Open a QLE data file

Click on “**Edit > Process > Kiln file**” menu

Choose the kiln file corresponding to the process and validate

The two files are then associated.

The reference kiln file is copied inside the data file and is not modified. It could be used as many times as necessary with other data files.

Once the association is validated:

- New tab appears in the display window of a QLE file. It is the “**brick**” tab.
- The pushes, the kiln elements and the zones are displayed above the graph.



Under this tab, two other tabs.

- **“Description”** and **“Report”** button

1.4.1 Kiln description

The **“Description”** button displays the brick reference file parameters.

Using the table, you can associate the loggers thermocouples with those defined in the brick reference file.

The right-hand side part shows the temperature grade given by the various thermocouples at the specific location chosen on the graph or from the data table.

By clicking the **“Open”** button, it is possible to open a window showing the current selected view of the load.

1.4.2 Pushes management

This tab allows modification of the pushes duration using the graph.

The following steps should be followed:

Make a zoom on the required part of the graph

Click on the graph at the exact place where the required push must begin

Select the push form the table

Click the **“Apply”** button

All pushes are automatically shifted to take the modification into account.

1.5 Dissociate a kiln file from a data file

Simply open the QLE data file, then click **“Edit > Remove the process”** menu.

1.6 Display or print a measurement Report

Two possible scenarios:

- Existing Report: Use the **“File > Open”** menu and select a Report file from the TDB and double click or right-click and go to **“Open”**.
- The report is to be created.
Open a QLE data file associated with a kiln file.
Once you close the preview, you can type a name for the report and save.

Choose your print out mode:

- Save as: allow to save the report in the QLEVER TDB without preview and



print.

- Default printer: allow to print on the windows default printer without preview.
- PDF: allow to export the report to PDF format.
- Open the preview: allow to see the report before print.

You could choose to print one or every of the following:

- Parameters
 - Display signature or not
 - Display signature only on the first page
 - The legend
 - A summary table of zones manually added
 - The comment of the QLE file
- The graph
- Data of every column:
 - Default Data mode
 - Date and hour column
 - Logger column:
 - Channel colour, serial number, physical unit
 - Condensed data on 25 columns with calculation (min., max., avg., max-avg, avg-min...)
 - Choose a physical property for the statistics (temperature, ...)
 - Adding or not statistics (min., max., avg...)
 - Printed data description:
 - Stage start date and stage end date number are printed
 - Date and hour column
 - Logger column:
 - Channel colour, channel number, physical unit
 - Statistics for each line:
 - Min. value (optional)
 - Max. value (optional)
 - Average (optional)



- Max. – Min. (optional)
 - Avg. – Min. (optional)
 - Max. – Min. (optional)
 - Event e1 and e2
- Print all lines or one line out of x:
 - Hidden data channels are printed in the report.
 - Excluded data channels are not printer in the report.
- Loading plan
- Picture of the equipment
- Screen shots (if you do not wish to print a screen shot, go to the “Screen shot” tab and uncheck “Print in the report”).
- Min./Max./Avg. statistics of Data Analysis tab
 - User calculations: calculations manually added from “**Data analysis**” tab, button “**Modify**”. See “**Data analysis**” paragraph.
 - Page break between each table: if you want to get your report more readable, it is possible to separate each **Min./Max./Avg.** calculation with a page break.

2 Option Secure mode for QLEVER (21CFR)

2.1 Prerequisites

- QLEVER license with:
 - 21CFR secure mode option included
 - An “Administrator” Account.
 - Depending on the case, an LDAP license and a network connection.

2.2 Description of the option Secure mode (21CFR)

The secure mode for QLEVER is 21CFR part 11 compliant.

The secure mode features:

- User Account Management with access levels
- Data security and integrity
- Audit Trail reports
- Depending on the Qlever license content, reports approbation on the recorded data.



2.3 Installation and configuration in Secure Mode

2.3.1 Create the Administrator account

When installing the software, the Administrator account should be the first to be created.

Identification of the Administrator account is unique and cannot be modified: **admin**

- When installing, QLEVER starts login with an administrator account, you must fill the related information in.
- Then click the “**Password**” button. Choose and type a password for the Administrator account. Click “**OK**”.

Important notice:

You should remember your password.

- Login as the Administrator again (Login is : **admin**)
- Type the password you chose.
- Click OK.

2.3.2 Parameters for user accounts management

2.3.2.1 Parameters for user rights and accounts management by QLEVER

Configuration for all “approval” and “operator” accounts (and “administrators” depending on the case):

- **Minimum number characters** for the password
- **Enable the duration of the password validity (in days)**. For instance, you may want the users to change password every 30 days.

Changing a setting affects all users (including Administrators).

The validation period is equal to the last password change date + the duration of the password validity in days. This is why activating this function will require a password change as soon as a user logs in the next time.

Please note that the duration is calculated in days and not in hours, and in date UTC format (Universal Time Coordinated). This may introduce time differences from your local time but the duration is always correct.

*When password is replaced, the new password cannot be the same as the former one
The modification of a parameter takes effect as soon as the Administrator clicks on “**Save**”.*

- **Maximum number of retries for identification**. You may want to limit the number of retries when attempting to login. After x number of tries, the account would be



deactivated. Only the Administrator could activate the Account again.

- **Unique password.** You may want to prevent one single password to be chosen by two or more accounts.
- **Reset password after reactivation of an account:** check the box to activate this option. The password is automatically reset and will have to be changed by the user when next login.
- **Change of password by the user when first login:** check the box to activate this option. The user will have to change the password when first login.
The change of password when first login only applies to the accounts created after this option is activated.

⇒ The modification of a parameter takes effect as soon as the Administrator clicks on "Save".

2.3.2.2 Parameters for user rights and accounts management by LDAP

Prerequisites:

- A Qlever LDAP license.
- An "Administrator" account of Qlever.
- A **Microsoft Windows Active Directory** with LDAP server.
- A network connection to connect to LDAP.
- An LDAP server already installed, accessible and functional, as well as as appropriate (mandatory to perform test of IQOQ protocol and, in any case, to use Qlever in LDAP mode):
 - A "Approval" group.
 - A "Operator" group.
 - A "Administrator" group (to create if necessary).
 - The name of the groups can be chosen at your convenience, it will suffice to enter it in the parameter screens (value of the attribute).
 - One or more approvers in an "Approval" security group (see below).
 - One or more operators in the "Operator" security group (see below).
 - One or more administrators in the "Administrator" security group (see below).
- The client must ensure that they have a department (internal or external) that has the required knowledge to configure and manage LDAP user accounts.
- The "admin" login is assigned to the Qlever administrator account and should not be used for administrator-type accounts managed by LDAP.

The LDAP (Lightweight Directory Access Protocol) in **Microsoft Windows Active**



Directory is a directory access protocol. If this option is enabled under Qlever, it means that:

- Account management settings such as "password validity period activation", "maximum number of attempts to login", "password uniqueness", etc ... are managed by LDAP.
- Account management (creation, deletion, modification, activation, deactivation, password reset, etc ...) is managed by LDAP.
- The assignment of account types (Approval and Operator and Administrator) is managed by assigning to a "security group" of the LDAP.
- Qlever's first "**Administrator**" account is not managed by LDAP and must be created under Qlever before configuring Qlever in LDAP mode.
- Under Qlever, authentication of each user's access by username and password is validated by an LDAP connection (except Qlever administrator).
- **LDAP account authentication "Unicode" is not supported by QLEVER.**
- **A mode other than Microsoft Windows Active Directory is not supported by QLEVER.**

LDAP settings under Qlever:

- LDAP: Enable LDAP mode under Qlever (Default = no).
 - It is recommended to enable LDAP mode on a new TDB because the matching of the account ID names between Qlever and LDAP can lead to confusion of people names in the Audit (however, the GUID will not be the same).
 - **Caution: for account security reasons, once LDAP mode is activated:**
 - The database is migrated into LDAP mode.
 - It is not possible to disable the LDAP mode afterwards.
 - **Attention: in the case of an already existing TDB, Qlever user accounts with the same identifying the LDAP will be associated in the audit trail. If you do not want this to happen, then you need to create a new TDB.**
- Domain: The LDAP domain name. User Authentication will be in the form Identifier@domainname
- Server (LDAP): Name or Ip address of the LDAP server to contact during login.
- Port: LDAP server port (389 by default).
- Version: version of the contacted LDAP server value 2 or 3 (3 by default).
- SSL: SSL secure connection management (default = no).



- **auNegotiate:** connection via "Generic security service" GSS (default = no).
- **Base DN:** dn of the base object for search "sAMAccountName =".
For example: dc = tmiorion, dc = local.

"cn" is used to obtain the surname and first name, in addition to "givenname" and "sn".

"telephonenumber" is used to obtain the telephone number.

"mail" is used to get the email address.

- **Approval:** The value of the attribute for the Approver account type of the "Approval" security group.

For example: CN = QLEVER_TDB_PROD_APPROVAL

- **Operator:** The value of the attribute for the Operator account type of the "Operator" security group.

For example: CN = QLEVER_TDB_PROD_OPERATOR

- **Administrator:** The value of the attribute for the Administrator account type of the "Administrator" security group.

For example: CN = QLEVER_TDB_PROD_ADMINISTRATOR



2.3.2.3 Parameters for user rights and functionalities by QLEVER

Audit Configuration

- Entering the reason for the actions: if checked then the user will be asked to enter a comment on the reason for an action (modification, deletion, ...).

Checking the version of Qlever on the current TDB:

Optional option that can not be activated to ensure that all workstations are up to date and that a forgotten old workstation does not connect.
Only concerns the current TDB.

- **Installed version:** current version of Qlever equal to or greater than the minimum required version.
- **Minimum version required:** minimum version of Qlever mandatory if this version is entered.
- **Apply:** allows you to apply the current version number as the minimum required Qlever version.
- **Test:** allows you to test before saving
- **Cancel:** allows you to cancel the mandatory minimum version of Qlever.

⇒ Important: this option can only be activated for installed versions equal to or greater than version Qlever 2.4.8.0 because older versions do not have the verification procedure and therefore can connect to the database.

Setup: rights on the Setup for the operator (Setup to be started to create process)

- **Create:** if checked, the operator can create a Setup file (Setup menu, new)
- **Delete:** if checked, the operator can delete a Setup file from the file management of QLEVER
- **Modify:** if checked, the operator can modify the content of a Setup file

However, it is also possible to allow the operator to only modify some items of the Setup:

- **Description:** if checked the operator can modify the content of the "Description" tab.
- **Parameters:** if checked the operator can modify the content of the "Parameters" tab.
 - **Values of the parameters:** if checked the operator can modify the values of the parameters in the "Parameters" tab.
- **Equipment:** if checked the operator can modify the content of the "Equipment" tab.
- **Loggers:** if checked the operator can modify the content of the "Logger" tab.
- **Programming:** if checked the operator can modify the content of the "Programming" tab. if not checked the operator can't create a new setup.
- **Analysis:** if checked the operator can modify the content of the "Analysis" tab.
 - **Calculations:** if checked the operator can modify the calculations and formulas within the "Analysis" tab.

Functionalities and display would differ depending on the QLEVER version and



your licence (pharma, autoclave validation, washer-disinfectors, mapping, etc.) See below Analysis / F0,A0,C0,P0 only for Pharma.

- **Sensor positions:** if checked the operator can modify the content of the “Sensor positions” tab.
- **Report:** if checked the operator can modify the content of the “Report” tab.
- **Process:** if checked the operator can modify the content of the “Process” tab.

Setup: rights on the Setup for the operator (Setup in QLE after read)

- **Modify:** if checked, the operator can modify the content of a Setup file or use “Save as”.

However, it is also possible to allow the operator to only modify some items of the Setup:

- **Description:** if checked the operator can modify the content of the “Description” tab.
- **Parameters:** if checked the operator can modify the content of the “Parameters” tab.
 - **Values of the parameters:** if checked the operator can modify the values of the parameters in the “Parameters” tab.
- **Equipment:** if checked the operator can modify the content of the “Equipment” tab.
- **Loggers:** if checked the operator can modify the content of the “Logger” tab and exclude a logger in the QLE graph.
- **Analysis:** if checked the operator can modify the content of the “Analysis” tab.
 - **Calculations:** if checked the operator can modify the calculations and formulas within the “Analysis” tab.
Functionalities and display would differ depending on the QLEVER version and your licence (pharma, autoclave validation, washer-disinfectors, mapping, etc.) See below Analysis / F0,A0,C0,P0 only for Pharma.
- **Sensor positions:** if checked the operator can modify the content of the “Sensor positions” tab.
- **Report:** if checked the operator can modify the content of the “Report” tab.

Setup: rights on functionalities for all accounts:

For all Setup:

- **Analysis / Humidity calculation:** if unchecked, then the humidity calculation parameters are not displayed (default is checked).
 - Parameters / Hygrometer tab too.
- **Analysis / MKT calculation:** if unchecked, then this calculation parameters are not displayed (default is checked).
- **Analysis / Time above - time below:** if unchecked, then this calculation parameters are not displayed (default is checked).
- **Analysis / saturated steam:** if unchecked, then this calculation parameters are not displayed (default is checked).

Only for Pharma setup:

- **Process tab:** if unchecked, then the process tab is not displayed (default is checked).



- **Analysis / F0,A0,C0,P0:** if unchecked, then this formula and calculation parameters are not displayed (default is checked).
- **Analysis / events:** if unchecked, then this calculation parameters are not displayed (default is checked).
- **Analysis / Print in the report:** if unchecked, then min, max, avg,... calculation parameters are not displayed (default is checked).

***Note:** Numbers of tabs and display would differ depending on the QLEVER version and your licence (pharma, autoclave validation, washer-disinfectors, mapping, etc.)*

Calibration: rights on Adjustment for operator:

- **Adjustment:** if checked the operator can adjust a logger (default is unchecked)

Calibration: rights on Calibration for the approval and operator:

- **Degree of polynomial:** if checked the approval and operator can modify the content of the degree of polynomial in the step analysis windows (Only in expert mode calibration, default is checked).
- **Max spread:** if checked the operator can adjust a logger (default is unchecked) a max spread calculation is available (only temperature) in the report of the step analysis (Only in expert mode calibration, default is unchecked).

Calibration: rights on step setting for operator:

- **New:** if checked the operator can create a “step settings” file (default is unchecked)
- **Modification:** if checked the operator can modify a “step settings” file (default is unchecked)
- **Deleting:** if checked the operator can erase a “step settings” file (default is unchecked). Identical for the restore functionality.

Files: rights on files and directory management for the operator:

- **Directory**
 - **New:** if checked the operator can create a new directory (default is checked)
 - **Deleting:** if checked the operator can delete a directory (default is checked)
 - **Rename:** if checked the operator can modify the directory name (default is checked)
 - **Move:** if checked the operator can move a directory (default is



checked)

⇒ An approval has all rights to the files.

⇒ For operator, see also setup rights and cet rights.

▪ **QLE Files**

▪ **Deleting:** if checked the operator can delete a QLE file (default is checked)

▪ **Rename:** if checked the operator can modify the QLE file name (default is checked)

▪ **Move:** if checked the operator can move a QLE file (default is checked)

⇒ An approval has all rights to the files

CET: rights on CET configuration files for the operator:

▪ **Install:** if checked the operator can install a new CET file (default is unchecked)

▪ **Delete:** if checked the operator can delete a CET file (default is unchecked)

▪ **Export:** if checked the operator can export a CET file (default is unchecked)

▪ **Restore:** if checked the operator can restore an old CET file (default is unchecked)

Configuration Date and alarm of the CET/CETX

These parameters allow to configure information symbol to shows the validity of the date of every configuration file (for all accounts).

- Enable (default: unchecked):

Unchecked: any information symbol, any logger locked

Checked:

- If Configuration date > x days, then ⚠ is displayed (default is 180 days)
- If Configuration date > x days, then 🔴 is displayed (default is 356 days)

- Lock the logger (default: unchecked) : it's possible to lock a logger, only in setup mode and only at the process start, if the 🔴 date is over.

⇒ If the end of the recording is greater than the configuration date + number of days, then the logger will not be locked.



- ⇒ If a logger is locked, then all operations are possible except the start (eg stop, replay are allowed)
- ⇒ In standard mode, there is no locking of the logger.
- ⇒ To unlock a logger, it must update its configuration date (adjustment).

Report: rights on report for the approval and operator:

- **“Report approved by/Report not approved”**: if the box is unchecked, the approval mechanism will be disabled. In other words, the buttons “Approve” will not be displayed. Moreover, the reports will not show the ‘approved by’ or “not approved” (default setting is checked).

Report: rights on report for the operator:

- **“Type of Report”**: if the box is checked, the operator can change the type of the report. Only for Autoclave validation and Washer disinfectant (default setting is unchecked).

QLEVER: rights on functionalities for the approval and operator:

- **“Programming” in standard mode**: if checked it's possible to program loggers in standard mode (default is checked).
- **“Start” in standard mode**: if checked it's possible to start loggers in standard mode (default is checked).
- **“Read” in standard mode**: if checked it's possible to read loggers in standard mode (default is checked).
- **“Real time”**: if checked it's possible to run a real time with loggers (default is checked).

QLEVER: rights on functionalities for the operator only:

- **“Loggers”, “Erase memory”**: if checked the operator can erase the logger memory (default is checked).
- **“Loggers”, “Thermocouple configuration”**: if checked the operator can configure a universal thermocouple logger (default is checked).
- **“Directory Management”**: if checked the operator can modify the directory management (default is checked).



2.3.3 Account types

3 types of accounts with QLEVER:

- Administration
- Approval
- Operator

2.3.3.1 Administrator account

Once the software is installed, Administrator account would be the very first account created.

The identification of the Administrator cannot be changed: **admin**

Functions available for the Administrator account are:

- Manage the option for the account creation (except in LDAP mode).
- Create accounts (except in LDAP mode).
- Delete accounts (except in LDAP mode).
- Activate or disable accounts (except in LDAP mode).
- Modify information for the accounts (except in LDAP mode).
- Reset the password of accounts (except in LDAP mode).
- Print the list of users.
- Export the users file.
- Import the users file.
- View the software audit trail. Other audit trails related to the loggers would be displayed with faint font only.
- Print the software audit trail.
- Modify the QLEVER license.

However, no access to the following functions:

- Calibration file installation, programming, start, create setup file, read, open files, reports.

2.3.3.2 Approval Account

Functions available for the Approval accounts:

- Modify information for own account (except in LDAP mode).
- Calibration files installation, open files.



- Programming, start, read loggers in setup mode.
- Create, modify, delete a Setup file.
- Start a Process.
- View, print or delete reports.
- View Audit trails.
- Depending of the configuration by the Administrator
 - Programming, start, read loggers in standard mode.
 - Approve reports.

2.3.3.3 Operator Account

Functions available or limitation for the Operator accounts are:

- Modify information for own account (except in LDAP mode).
- Programming, start, read loggers in setup mode.
- Open files.
- Create a Process.
- View and print setup Reports.
- Cannot delete or approve setup reports.
- Can delete calibration report.
- No access to audit trails.
- Depending on the rights granted by the Administrator:
 - Programming, start, read loggers in standard mode.
 - Create, modify, delete Setup files.
 - New, modify, delete, move directory.
 - Install, delete, export, restore calibration files CET.
 - Delete, rename, move a QLE file.

2.4 Account Management with the Administrator

2.4.1 Create accounts

Accounts management with Qlever

Only the administrator account can create or delete other accounts.

At least one Approval account should be created when using QLEVER.



- Login with the Administrator account.
- Go to menu “**Administrator**” and “**Users accounts**”.
- Click “**New**”.
- Fill the necessary information in.

Approval level is the default value.

Both identification and password are the requested information when login.

- Click “**Save**”.

LDAP mode

Function not applicable in LDAP mode for the all accounts.

Account management (creation, deletion, modification, activation, deactivation, password reset,...) are managed by LDAP:

Just add the Microsoft user account in the "Approval" or "Operator" or "Administrator" security group of your LDAP.

Maximum number of accounts:

Maximum number of accounts is 65535 (sum of active, deactivated and delete accounts).

2.4.2 Modify accounts

Accounts management with Qlever

- Login with the Administrator account.
- Go to menu “**Administrator**” and “**Users accounts**”.
- Select an account from the list and click “**Modify**”.
- “**Activate**” allows the Administrator to activate an account that was previously disabled.
- “**Disable**” allows the Administrator to deactivate an account.
- “**Delete**” allows the Administrator to delete an account.
- “**Reset Password**” allows the Administered the reset the password of an account.
For instance, a user would forget password, by resetting the password, a new password would “calculated” by the system to be given to the user.

Click “**Save**” to record the change.



LDAP mode

Function not applicable in LDAP mode for the all accounts.

Account management (creation, deletion, modification, activation, deactivation, password reset, etc ...) are managed by LDAP:

Just modify the Microsoft user account in the "Approval" or "Operator" or "Administrator" security group of your LDAP.

2.4.3 Delete accounts

Accounts management with Qlever

- Login with the Administrator account.
- Go to menu **“Administrator”** and **“Users accounts”**.
- Select an account from the list and click **“Delete”**. Then confirm.

Delete is irreversible and the related identification will be no longer available for another account to be created (the account is grayed).

It's possible to delete:

- Administrator (but it's not possible to delete the default admin)
- Approval
- Operator

LDAP mode

Function not applicable in LDAP mode for the all accounts.

Account management (creation, deletion, modification, activation, deactivation, password reset, etc ...) are managed by LDAP:

Just remove the Microsoft user account in the "Approval" or "Operator" or "Administrator" security group of your LDAP (or erase or deactivate the Microsoft user account).

2.4.4 Print the list with users

- Login with the Administrator account.
- Go to menu **“Administrator”** and **“Users accounts”**.
- Click **“Print”**.
⇒ In LDAP mode, the list of accounts is grayed out on the screen because the accounts are not managed by Qlever



2.4.5 See the list of users that are logged into the TDB

- Log in with an Administrator account.
- Go to menu “**Administrator**” then “**User Account**”.
- From the »Connected » column, a green signal shows whether a user is currently connected onto the TDB.
- Click the Refresh button or press the F5 key in order to refresh the list.

⇒ In LDAP mode, the list of accounts is grayed out on the screen because the accounts are not managed by Qlever

2.4.6 Export and import of the user accounts

2.4.6.1 General remarks

- Only the Users file can be imported and exported.
- Only the Administrator can use the import/export function.
- “**Directory management**” menu, “**TDB Administration**” and “**Account**”.

2.4.6.2 Export

- The export function would create a file with a name as follows: “QLEVER_users_year-month-day_hour-minute-seconde.zip”
- The file is exported to a directory selected by the Administrator (local, network, USB drive, ...)

2.4.6.3 Import

- The Users file to be imported is located in the directory defined above.
- A warning would inform the Administrator that all the user accounts including the Administrator account would be overwritten with such import process. The Administrator password of the imported Users file will be needed.
- The imported users file would replace the current users file.

2.5 Login into QLEVER

- If you already logged as the Administrator, just logout from the menu “**Administrator** > **Logout**”.
- If you are already logged as an Operator or Approval, just log out from the menu “**My Account** > **Logout**”.



- Type the identification and password in and click OK for login to the actual TDB
- If you want to log in some other TDB, click the TDB icon to display the available TDB and just select the desired TDB.

When logging out and logging in, the open files would be closed.

The key symbol icon on the top right of the windows will give access to the same login function.


2.6 Audit trail

The system can track the actions by recording the following information:

- Date and time with UTC (Universal Time Code) format.
- The unique identification of the user.
- The login of the user.
- The account type of the user (Administrator, Approval or User).
- An icon to have a quick view of the type of action (action on the software, the logger or a file).
- Context of the action.
- An icon for the command type (Modify, Create, Login, Start, Read, etc.).
- An icon for the object related to the command (User, Logger, Setup file, etc.).
- Detailed description of the action.
- The reason for the action when available.
- The initial value.
- The value after modification.
- The computer name.

The color changes are shown in HTML format.

There are three types of Audit trails:

- Software Audit trail available to the Administrator account, from the **"Administrator > Audit"** menu (what is software is marked by  symbol and what is not software is displayed in gray).
- Global Audit trail, related to every action, available to the Approval account from the **"Audit Trail"** menu. Only some specific actions related to the qle file would not be included and could be found in the QLE file Audit Trail.
- QLE file Audit trail describing every action on a specific QLE data file, available to the Approval account from the **"Audit Trail > Audi Trail – QLE file"** menu.



In order to **view** or **print** one part of the Audit trail, you should type a start and end date and validate.

⇒ At each audit trail impression, a notification is added in the audit trail but will be printed only if it is between the start date and the end date.



3 Setup mode (Pharma 21CFR)

3.1 Prerequisites

- QLEVER license with:
 - Pharma 21CFR secure mode option included
- At least one temperature data logger

3.2 Description of the setup option

- The standard mode is the default and basic method for programming, starting and reading the loggers.
- The Setup mode is a QLEVER option. With this option, the loggers programming, starting and reading method would follow a specific protocol and would lead to the edition of report. Such protocol is described in a secured Setup file.
- In 21CFR mode (secure mode), the rights of the accounts of "operator" type can be changed by the Administrator.

3.3 Create or modify a Setup File

To create a new Setup file just click “**Setup > New – Pharma**”.

- A setup is a description of a test that will be done with logger(s) in order to create a test report.
- A setup file does not include the recorded data from the loggers.

3.3.1 Description tab

A Setup file will include general information to be specified in the description tab:

- A name of the file.
- A description of the file (do not print in the report if empty)
- Details about the contractor who will handle the validation tests. The name of the contractor will be displayed in the header of the report.
 - Print in the report.
- Details about the location of the test.
 - Print in the report.

⇒ If contractor and location are not printed, then the section is not printed.

- Check the “keywords” box if you wish to update the serial number and the type of channel (temperature, pressure) used by the search engine (*cf. 5.2 File research by*

date or keywords)

3.3.2 Process tab

During the Process when the loggers are recording in a Setup Mode, it is possible to type the starting and end dates for the Stages.



- **Time Stamp:**
 - Enable this function by checking the “Time Stamp” box.
- **Time:**

The time measurement base for such Time Stamp function could use either:


 - The PC clock.
 - The RTC USB dongle (for better accuracy and stability compared with the PC clock since some PC clocks could drift and get synchronized by the server).

⇒ **Important note:** when starting a process, the USB clock will be synchronized with the PC clock. In case you intend to start more than one processes, the Time Stamp function will use the last synchronization job.
- **Stages 1, 2, 3:**
 - Enable or disable Stages 1, 2, or 3 according to the profile of the cycle.


Icon :

- Click the Icon:
 -  in case the end date of a Stage is also the start date of the following Stage.
 -  in case the end date of a Stage is separated by data acquisitions from the start date of the following Stage.


Icon : To erase all dates.

During a Process, (available from the Read button or the Setup/Process menu),  button allows to manually time stamp the current ongoing Stage:

- **Start Date of the process (no obligatory entry):**

When the Process starts, click  or type a start date (corresponding to the start date for the printing of the data and graph in the “Print: Report” window).

If empty, then this date is the start measurement date.
- **Stages date:**

During the Process, click  or type the start date and end date of a Stage.


⇒ **Note that the start and end dates will be adjusted to the nearest logger**



sample (no linearization).

⇒ In case a date is prior to the first data or greater the last one, the software will adjust the best.

▪ **End date of the process (no obligatory entry):**

At the end of the process, click  or type the end date of the Stage (corresponding to the end date of the data and graph in the "Print: Report" window)

⇒ To modify a started process, click "**Read**" in setup mode or click "**Setup > Process**", and "**Modify**" button.

⇒ Once the data are later read with a QLE file, this section will not be available since the Process is finished. In case those dates need to be modified, it should be from the "Cycle » window.

⇒ **21CFR**: This tab can be hidden by the 21CFR Administrator.

3.3.3 Parameters tab

In this section, you will define the settings used for the report analysis.

Ramp and/or equilibration time calculation/elapsed time:

V_1 and V_2 are in the stage 1

V_3 and V_4 are in the stage 2

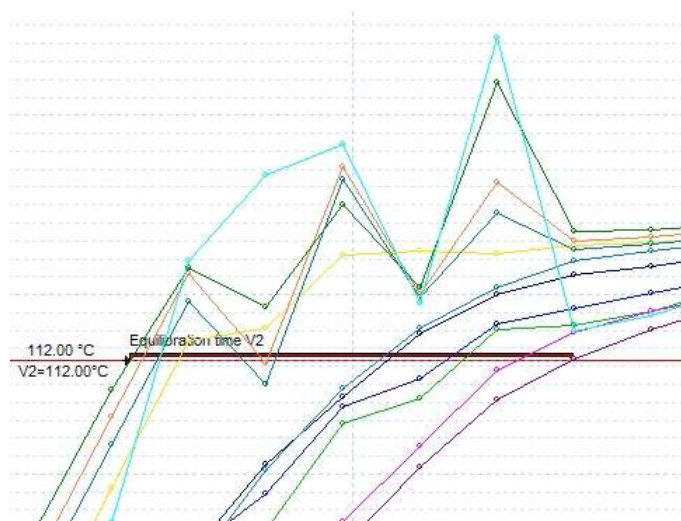
V_5 and V_6 are in the stage 3

with $V_n = V_1, V_2, V_3, V_4, V_5, V_6$, for example $V_n = V_1$ and $V_{n+1} = V_2$.

- **Ramp time ($V_1, V_2; V_3, V_4; V_5, V_6$):** check the box to calculate the time difference between the moments when all the sensors reached the V_n and the V_{n+1} values (except if "All sensors" unchecked for V_2, V_4, V_6).
 - V_n and V_{n+1} boxes must be previously checked to allow this calculation.
 - The calculation zone is included between the stage limits (start and end).
Si V_n or the V_{n+1} values are out of the stage limit, the calculation cannot be calculated.
 - If at least one of the sensors has not reached one of these values, the ramp time will not be calculated in the report
 - The reference sensor doesn't affect the ramp time calculation
 - Such calculation is done in a linearization mode.
- **Equilibration time ($V_1, V_2, V_3, V_4, V_5, V_6$):** check the box to calculate the period

between the moment when the temperature value V_n is first reached (first sensor to reach V_n value) and the moment V_n value is reached in all the load parts (last sensor to reach V_n value, except if "All sensors" unchecked for V_2, V_4, V_6). $V_n = V_1, V_2, V_3, V_4, V_5, V_6$

- **Print in the report:** The equilibration time can be calculated and display on the graph but it's possible not to print equilibration time in the report.
- **Reference sensor:** If a reference sensor is given, then it will be taken into account to determine the calculation of the start of the balancing time.
 - Only applies to V_1, V_3, V_5 for the start of the equilibration time.
 - The end of the equilibration time V_2, V_4, V_6 does not take into account the reference probe.
- The calculation zone is included between the stage limits (start and end).
- If at least one of the sensors has not reached this value, the equilibration time will not be calculated in the report, except if "**All sensors**" unchecked for V_2, V_4, V_6 .
- The equilibration time can be calculated on V_1 to V_6 values.
- The **reference sensor** doesn't affect the equilibration time calculation (except the start of the balancing time if "**Reference sensor**" is checked).
- This calculation is done in a linearization mode.
- This calculation is made with temperature values rounded to two decimal places (while depending on the case, the graph may show more precision).



Example of equilibration time in linearization mode.

- **Elapsed time (V_2, V_4, V_6):** check the box in order to calculate the various durations between the date when a first sensor reaches a temperature value V_2, V_4 or V_6 and when the other sensors reach the same temperature value (except if "All sensors" unchecked for V_2, V_4, V_6). $V_n = V_2, V_4$ or V_6 .
 - Equilibration time must be checked for the elapsed time calculation (you can

uncheck "Print in the report" if you don't want print the equilibration time).

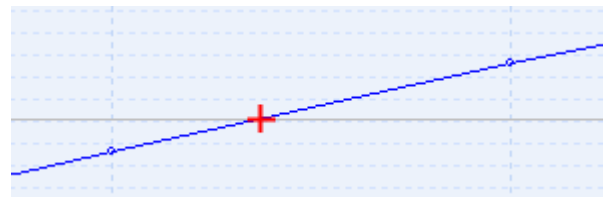
- In order to enable such calculation, the equilibration time box should be also checked.
- The calculation zone is included between the stage limits (start and end).
- If a sensor reaches the V_n value before the start date of the stage, its status will be "Value not reached". The V_n time stamp cannot be defined because the dating is out of the calculation zone.
- In case a reference channel is selected, durations will be calculated based on this specific sensor reaching V_n . The reference sensor will show an elapsed time = 0, those reaching V_n before will show negative duration values and those reaching V_n after will show positive duration values.
 - If a **reference channel** is selected, elapsed time will be automatically displayed, because the elapsed time duration may be different to the equilibration time duration.



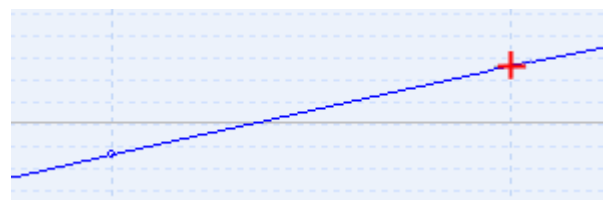
- Such calculation is done in a linearization mode.

■ **Calculations (ramp time, equilibration time, elapsed time):**

- **All sensors** ($> V_2, V_4, V_6$):
 - Only V_2, V_4, V_6
 - Checked (default value): In case one sensor did not reach such V_n temperature value, the elapsed time would not be calculated nor displayed in the report.
 - Unchecked: the elapsed time would be calculated.
- **Calculations without linearization:** if this box is unchecked, the calculation will be based on the linearization of two values, as shown below:



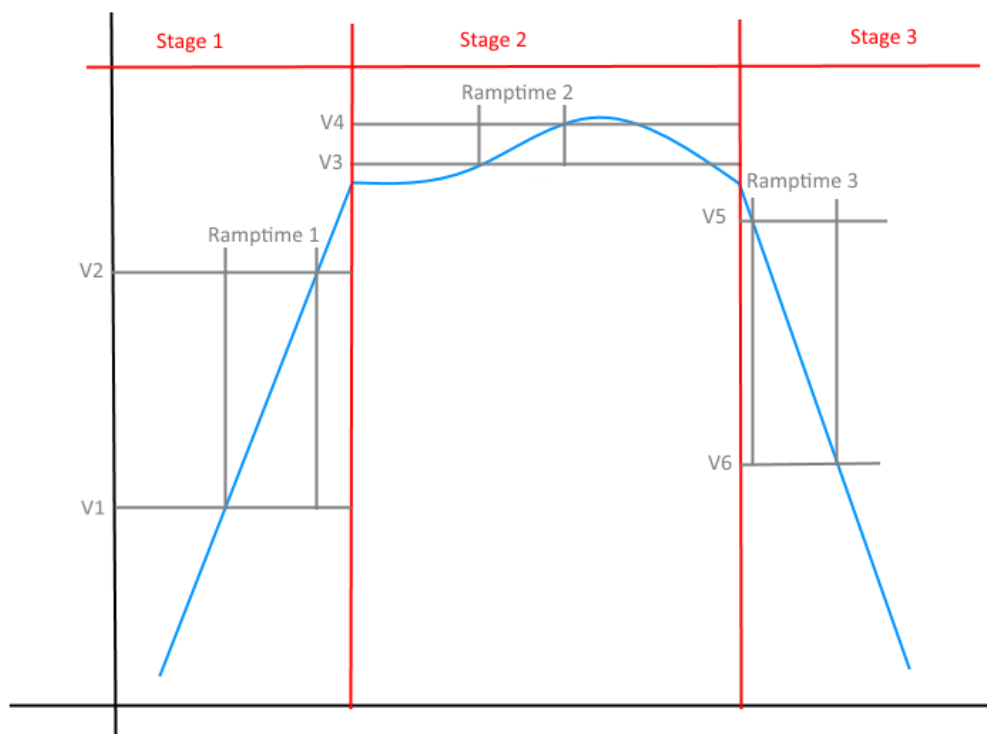
If this box is checked, as shown below:



Default is unchecked.

Define for each cycle:

- Stage 1:
 - Temperature V_1 value and the color of the related horizontal line
 - Temperature V_2 value and the color of the related horizontal line
- Stage 2:
 - Temperature V_3 value and the color of the related horizontal line
 - Temperature V_4 value and the color of the related horizontal line
- Stage 3:
 - Temperature V_5 value and the color of the related horizontal line
 - Temperature V_6 value and the color of the related horizontal line



Within this window, the parameters for the analysis of the final report can be typed.

Type the names for the Cycles and Stages in advance:

- It is possible to type both the names for the Cycles and Stages in advance. Those names will later be found in the "Cycle" window of the QLE file. Otherwise default names will be created.
- The various Cycles or Stages could not have the same name in order to avoid any confusion in the final report. For instance, numbers could be added to the name.



- Automatically define the Cycle1 Stage1 with the start and end date of the file.
 - If checked, then the following will happen (without the need to the “Define Cycle” windows):
 - The start date of Stage 1 will be the start date of the recording and the end date of Stage 1 will be the end date of the recording.
 - The other cycles and stages will turn grey
- ⇒ Once the data are downloaded, from the QLE file, this Parameter window will not be displayed. The information will be found on the “Cycle” window of the QLE file.

3.3.4 *Equipment tab*


A Setup file includes information related to the Equipment (typically Autoclave) under test to be specified in the Equipment tab:

- Equipment ID
- SOP/Protocol (do not print in the report if empty)
- Description of the load (do not print in the report if empty)
- Comment (do not print in the report if empty)
- Picture of the equipment can be added

3.3.5 *Logger tab*

A Setup file includes information related to the TMI dataloggers used for the test.

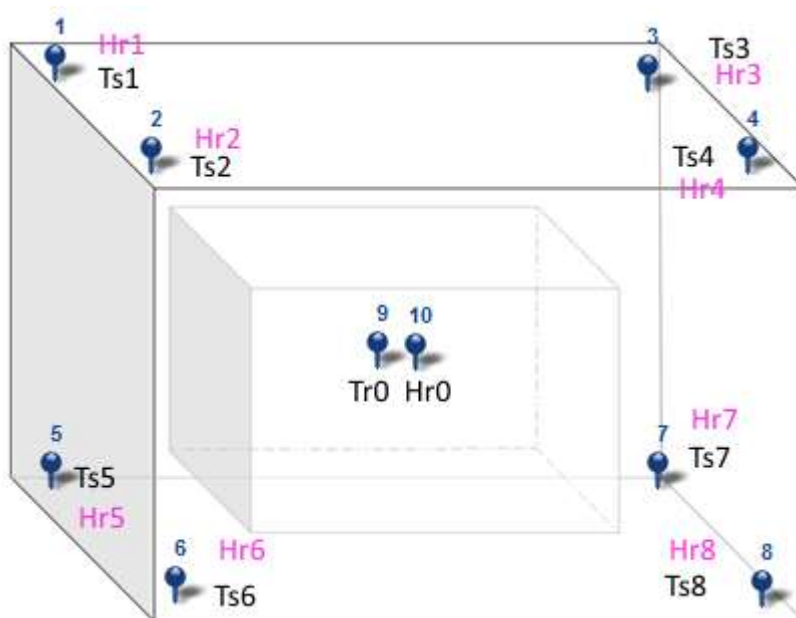
Add or remove serial numbers for the loggers to be used for the Setup. This can be using an automatic scan of logger(s) connected to the interface or selecting manually specific loggers with their calibration files stored in the TDB.

 **Used sensor for humidity calculation.** To calculate the dew point, and generate the calculated humidity channels, you must use:


- **One temperature sensor**
- **One humidity sensor**

⇒ See **Analysis / Humidity calculation / Include in calculations**


⇒ Warning, if “**Humidity calculation**” is not checked in **Analysis** tab, this setup column is grayed in the data qle file.



For example, for a base pair Tr0 Temperature and humidity Hr0, often at the center of the room, it is possible to generate the dew temperature and generate the relative humidity calculated channels Hr1 to Hr8 for all other temperature sensors Ts1 to Ts8.

 **Reference sensor:** it's possible to select a reference sensor by checking the box. This reference sensor will be used for various calculations for the test:

- Min. and max. Spread
 - Elapsed time (parameters tab)
- ⇒ *This reference sensor can't be used for the humidity calculation.*

 **Not used:** option not to use this sensor, ie:

- The sensor will not appear in the data columns or curves QLE
- The sensor will not be taken into account in the calculation of setup
- The sensor will not generate computed columns (unless used in the calculation of humidity)
- The sensor will not be notified in the excluded channel list report
- The sensor will not be visible on the loading plan
- The internal channel is automatically unused with a Vacq
- This feature can be activated before starting the setup (if you do not want to use a route once the data read back then since QLE data file, it must be excluded)

⇒ Beyond 70 sensors, the new will be added not visible by default to reduce the graphic processing time and not to obstruct the visibility of the loading plan.




Enable loggers to be excluded during startup (no checked as default): in the “Starting loggers” windows:

- Display an “Exclude” menu.
 - Enable Qlever to exclude the missing loggers.
- ⇒ Excluded loggers will be written in the 21CFR audit trail and the report.

3.3.6 Programming tab

A program is part of the Setup file.

- Add one or more programs clicking “**Programming**” (cf. 2.3 How to program the loggers)
- Delete a program using the “-” button.
- Edit a program using the  button.
- Link a program to logger(s) using the “+” button.
- Unlink a program from logger(s) using the “-” button.

A message would warn you whether a logger is not linked to any program.

3.3.7 Sensor positions view tab

From this tab, you can describe the position of the sensors inside the chamber using either a picture or the 3D view:

- For every sensor you can give a description of the position.
 - Check or uncheck the box from the blue tag column to show or hide the sensor in the picture or 3D View (a menu by right clicking on the column allows for additional options for selection).
 - You can click and drag the blue tag showing a sensor within the picture or the 3D view.
 - Possibility to display only the number of the logger in the loading plans (when the quantity of loggers used is large it's very difficult to identify a specific logger's position on the diagram).
- ⇒ If any sensor is visible, then the loading plan will not be printed in the report.

You may add 9 additional pictures of the cycle parameters.



3.3.8 Analysis tab

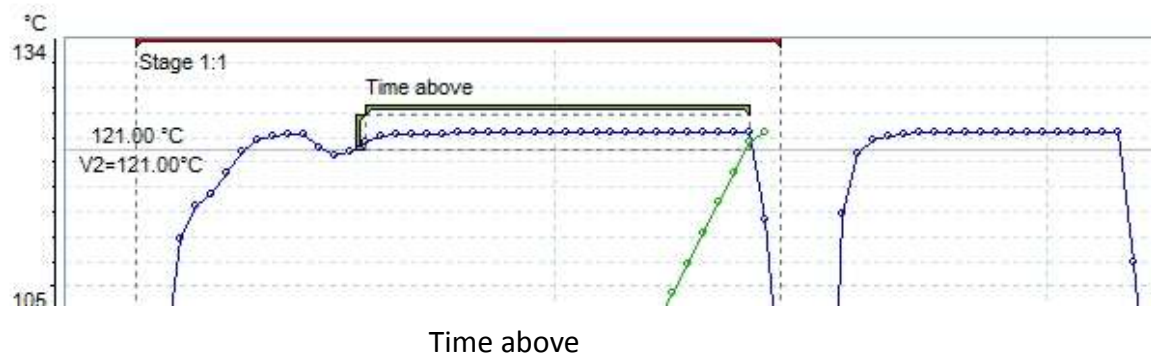
The Analysis tab allows you to define both the lethality calculations parameters and the conditions for triggered events.

Results will be displayed both in the report and the data file.

Two calculations possible:

- **Lethality type calculations** are available.
 - **F0/A0/C0... type of calculation:** enable or disable this calculation (default value = yes).
 - For each calculation, you can set a triggered event.
 - This calculation is done on the whole cycle (not for each stage).
 - Reset value for each cycle
 - Channel name is F0[F1] for the formula #1 and F0[F2] for the formula #2
- Or a **Mean Kinetic Temperature (MKT)** calculation
 - Check the box to perform MKT calculation.
 - Enter Δ_H value.
 - Choose MKT unit temperature.
- Two other **temperature triggered events** possible.
 - In the report:
 - In the data, e1/e2 will be displayed when the event occurs.
 - In the Event summary, the value of occurrence in the total number of times the event occurs.
- **Temperature calculation** of saturated steam (Regnault)
- **Pressure calculation** of saturated steam (Regnault)
- **Time above or time below:** duration above or below a value of temperature. Choose don't display in case it should not be in the report.
 - Comparison operator used:
 - Time above > threshold.
 - Time below < threshold.
 - For temperature channels, only.
 - This calculation is made **without linearization**, so make sure the sample rate you select for the programming of the loggers is relevant when it comes to validate your equipment and/or your process cycles.

- The displayed result is the longest duration only (smaller durations or overshoots/undershoots would be excluded). Thus, such calculation is specific to the **Pharma Setup** and different from “Time above” or “Time below” calculations found elsewhere in the software.
- Such calculation is made within each step only. Meaning it is not made between two steps or outside steps.
- In the report, in the “Total” column, we display the sum of every “Time above” or “Time below” durations of every defined step. Not the total “Time above” or “Time below” of the entire cycle.



- **Humidity calculation** (a temperature channel and a humidity channel used as a reference for calculated humidity channel, specified on “loggers” tab).
 - **Temperature: include in calculations or not**
 - **Humidity: include in calculations or not**
- Include in report calculations:**
- If checked, temperature and/or humidity channel is used for the setup calculations (Min, Max, Avg and others)
 - If not checked, the temperature and/or humidity channel is not used for the setup calculations, and the associated column is grayed out in the qle data file.

⇒ This calculation generates humidity calculated channels.

- Possibility to print or not in the report:
 - Min. and max. of each stage
 - Average of each stage
 - Max average – Min average of each stage
 - Max. range of each stage
 - Max. spread of each stage
 - Min. spread compared with the reference channel of each stage (printed out if a channel was selected)



- Max. spread compared with the reference channel of each stage (printed out if a channel was selected)
 - F_0 or MKT min and max of each stage
 - F_0 or MKT average of each stage
 - **Do not display the calculated columns until the cycles are defined** (not checked by default): to avoid calculated columns creation before the cycles are defined.
 - ⇒ Reduce the computation time
- ⇒ **21CFR**: Some settings can be hidden by the 21CFR Administrator.

3.3.9 Report tab

Top right part of the report can be chosen to be either:

- Contractor details (logo and address)
- Comment (a text zone for comments or a specific document reference)

3.3.10 Print a Setup

Click “**Print**” to print a description of the Setup.

3.3.11 Save a Setup

Click “**Save**”

When creating a Setup:

- Specify a directory inside the TDB for saving the Setup file.
- Name the file.
- Click “Ok”.

3.3.12 Save as...

Click “**Save as**” save a copy to a new setup

- Specify a directory inside the TDB for saving the Setup file.
- Name the file.
- Click “Ok”.



3.3.13 How restart the calculations of the report results from a QLE file

In the Setup windows, click on **"Calculations"** to restart the calculations of all the results of the report.

3.4 Open a setup file

To open a setup file, click **"Setup > Open"**.

In case you would like to open and/or edit a Setup file that was previously used to create a QLE data file, you should open the QLE data file itself then click the **"Setup"** button.

3.5 Start a Setup


In order to start a Setup, click **"Setup > Start"**. Select a Setup file from the list and click **"Start"**.

Starting the logger(s) in a Setup mode is the same process as the Standard mode (*cf. 2.4 Start the loggers*)

The loggers serial numbers defined in the Setup will need to be connected to the interface when starting. The system will scan and check.

To exclude a logger, select this logger and click right, choose **"Exclude"**.

Exclusion of a logger from the study

To exclude a logger from the study, select this logger and click on the **"Exclude"** button  or click on the right button, then select **"Exclude"**. You can select more than one. The exclusion will be reported in the report and the audit trail.

⇒ Only if **"Enable loggers to be excluded during startup"** in the Loggers tab of the Pharma setup is checked.

Start date

To avoid interpolation of the data, it is not possible to start "Now" with several loggers.

Options

Some options such as message display or value display are configurable in user preferences.

Hygrometer

If a hygrometer is used as a reference for calculated humidity channel a specific window will be open to control this equipment.

Quit allow to stop the hygrometer data acquisition and close the windows.



After starting, the Setup file is copied in a Process file.

The Process file is independent from the earlier Setup file.

3.6 Read a Process

In order to read recorded data from the logger(s) on a Setup mode, click **“Setup > Read”**.

Reading the logger(s) on a Setup mode is the same process as the Standard mode (*cf. 2.5 Read the loggers*).

The loggers serial numbers defined in the Setup will need to be connected to the interface when reading. The system will scan and check.

In case one logger could not be read for instance because of low battery, it will be possible to exclude this specific logger from the data file.

Exclude a logger

To exclude a logger, select this logger and click right, choose **“Exclude”** or clic on **“Exclude”** button.

With FullRadio loggers, it is possible to read running loggers (non-read loggers will be automatically excluded from the study).

If a hygrometer is used as a reference for calculated humidity channel a specific the hygrometer data are automatically saved.

3.7 Delete a Process file

In order to delete a Process file, click **“Setup > Delete Process”**.

From the TDB, select the Process file, do a right click and go to **“Delete”**.

Deleting a Process file is irreversable (the file won't be found in the recycle bin).

3.8 Cycles definition for the Report

Open a QLE data file (*cf. 3 QLE data files*) and select a QLE data file created with the Setup mode.

3.8.1 Add a Cycle

For every stage of every cycle, select the start and end times.

Click the **“Cycle”** button or do a right-click from the graph and go to **“Define Cycles”**.

- Type the name of Cycles, the start and end time and color for every stage.
- **Print the graph column:** if checked the graph of the **stage** will be printed (default value=yes). Saved only if the stage dates are defined.



Then click **“Validate”**.

⇒ Cycles and stages **calculations are without linearization**: it's not possible to set a date between two measurement points.

⇒ If the end time of a stage = the start time of the next stage:

- The data will be common to both stage
- The data will be taken into account for each calculation of the two stages.

The following will appear:

- On the top of the graph, the stages for every cycle are displayed.
 - In the **Cycle** tab, the stages of every cycle are displayed.
 - In the **Min/Max/Avg** tab, the results of various calculations for each stage such as:
 - Minimum, maximum, average and standard deviation calculated on one sensor.
(Note that “m” stands for minimum average and “M” stands for maximum)
 - Minimum value of every above minimum values (min. of min.).
 - Maximum value of every above maximum values (max. of max.).
 - Maximum range between the min. of min. and max. of max.
 - Maximum spread with a reference sensor at a specific time
(calculated if reference sensor is selected).
 - Minimum spread with a reference sensor at a specific time
(calculated if reference sensor is selected).
 - Maximum spread between any sensors at a specific time.
- ⇒ According to “Print in the report” to the Analysis Setup tab.

3.8.2 Delete a Cycle

Go to the Cycle tab, select a cycle and click the “” button.

3.8.3 Modify a Cycle

To modify a cycle or a stage, go to the Cycle tab, select a cycle and click on the edit column or click the “Cycle” button.

3.9 Exclude a sensor from the calculations and analysis

To exclude a sensor, click on the column header of the data table.



3.10 Display or print a measurement Report

Two possible scenarios:

- Existing Report: Use the “**File > Open**” menu and select a Report file from the TDB and double click or right-click and go to “**Open**”.
- The report is to be created.

Open a QLE data file created with the Setup mode.

If cycles and stages are already defined, click the “**Report**” button to preview the report.

Once you close the preview, you can type a name for the report and save.

Choose your print out mode:

- Save as: allow to save the report in the QLEVER TDB without preview and print.
- Default printer: allow to print on the windows default printer without preview.
- PDF: allow to export the report to PDF format.
- Open the preview: allow to see the report before print.

You could choose to print one or every of the following:

- Parameters
 - Display signature or not
 - Display signature only on the first page
 - The graph with background color, and:
 - Large: large size on a whole page only
 - Small + large: small preview in first page + large size on a while page
 - The graph of each stage selected in Cycle window
 - The legend
 - Zones: summarizing table including manually added zones. You can print details of every zone manually added by the user (“Cycle” tab on the left of the graph). Cycles/zones automatically created by the setup are not printed out in “Zones”, as they already appear in other report sections.
- Options
 - Page break between each section of the report
- The comment of the QLE file



- Data of every column:
 - 2 forms of table are available:
 - One table: like as the “Data” table in the QLE windows. The measured data channels and the calculated channels are in a single table.
 - Multiple tables:
 - First, the measured channels table (loggers)
 - And, as many table as calculated channel types.
 - ⇒ For example: the loggers channels, the F0 channels, the Saturated steam channels
 - Default Data mode
 - Printed data description:
 - Only cycles and stages are printed
 - The data between two steps are not printed
 - Stage start date and stage end date number are printed
 - Event column:
 - S = Stage start date (cycle:stage)
 - E = Stage end date (cycle:stage)
 - e1 = event #1 (see setup)
 - e2 = event #2 (see setup)
 - Date and hour column
 - Logger column
 - Channel colour, serial number, physical unit, channel name
 - Condensed data on 25 columns with calculation (min., max., avg., max-avg, avg-min...)
 - Choose a physical property for the statistics (temperature, ...)
 - Adding or not statistics (min., max., avg...)
 - Printed data description:
 - Stage start date and stage end date number are printed
 - Date and hour column
 - Logger column:
 - Channel colour, channel number, physical unit
 - Statistics for each line:



- Min. value (optional)
 - Max. value (optional)
 - Average (optional)
 - Max. – Min. (optional)
 - Avg. – Min. (optional)
 - Max. – Min. (optional)
 - Event e1 and e2
- Print all lines or one line out of x:
 - Hidden data channels are printed in the report.
 - Excluded data channels are not printed in the report.
- Print data:
 - Cycle/stage
 - Only cycles and stages are printed
 - The data between two steps are not printed
 - Start date to End date
 - Not possible to “cut” a cycle/stage
 - The data between two steps are printed
- The detailed report (average calculation, standard deviation calculation, minimum and maximum value calculation for every sample).
 - Printed data description:
 - Only cycles and stages are printed
 - The data between two stages are not printed
 - A table for each physical unit
 - Calculation of $\overline{F_0} - 3\sigma_{F_0}$ is displayed in the summary report.
- Loading plan in small and/or large size on a whole page.
- Picture of the equipment
- Screen shots (if you do not wish to print a screen shot, go to the “Screen shot” tab and uncheck “Print in the report”).
- Min./Max./Avg. statistics of Data Analysis tab
 - Setup calculations automatically generated by the setup.
 - User calculations: calculations manually added from “**Data analysis**” tab, button “**Modify**”. See “**Data analysis**” paragraph.



- Page break between each table: if you want to get your report more readable, it is possible to separate each **Min./Max./Avg.** calculation with a page break.
- Logger included in the study:
 - Loggers configuration date
 - Loggers firmware version

Only the Approval users can save reports.

3.11 Approve a Report

Two possible scenarios:

- Existing Report: Use the **"File > Open"** menu and select a Report file from the TDB. Then click **"Approve"** button.
- The report is to be created.

Open a QLE data file created with the Setup mode.

If cycles and stages are already defined, click **"Approval"** button. A preview of the report will show up.

Once you close the preview, you can type a name for the report and save. You can then confirm the approval of the report.

Approved reports show a V sign on the icon for **"Validated"**.

Only the Approval users can approve reports.



4 Calibration/Adjustment Temperature Mode

4.1 Prerequisites

- For the automated mode, in order to run the calibration hardware with RS232 interface, the PC should include a minimum number of one or two serial RS232 ports with SubD 9 or USB/RS232 convertors.
- **A crossed RS232 cable if the hardware is RS232**
- Microsoft® .NET Framework 3.5 installed
- QLEVER License key:
 - With manual only calibration option
 - With automated & manual calibration mode
- **For the automated mode, the automatic send of data should be disabled.**
- **Only use temperature loggers (don't use humidity or pressure or another logger)**
- **The Internal channels of the TMI loggers (T internal) can't be adjusted, only "as found" and "as left" (but possible in Expert Mode)**

4.2 Description of the Calibration/adjustment option

With the QLEVER Calibration option, it is possible to automatically generate temperature step points with direct communication with the calibration equipment. The values of the reference probe for each calibration step would be read for a specified duration through direct communication with the calibration instrument (temperature reference probe). The temperature values of the reference probe and every starting time and dates for every temperature steps are recorded in different files. Typing the data manually by the operator is also available in case the calibration hardware equipment is not compatible with direct communication.

With the QLEVER Calibration option, it is also possible to calibrate and adjust the loggers.

The **adjustment** applies a transfer function between raw values given by a logger (values I bit from the converter) and the measured values in temperature.

The **calibration** indicates the gap between the reference values within a comparison environment like a calibration bath or drywell and the values given by the logger within the same comparison environment.

When used with the Secure Mode option, a calibration audit trail is created.

4.3 How to install when using the automated mode

Connect the equipment (bath or drywell) to one of the serial ports of the PC. Connect the reference probe to the other serial port of the PC. Special serial cables must be used. Follow the instructions given by the manufacturer when installing the equipment or reference probe.



4.4 Type of equipment and instruments

- Bath® from Hart: 7321, 7381 and 73xx, 633x, Micro-Bath 6102, 7102, 7103.
 - Bath® from Lauda: RC20, RC25 and Proline series.
 - Hart® Scientific (Fluke) 9172, 917x and Fluke 914x
 - Hart® Micro-bath 6102 (Fluke)
 - Hart® Dry well temperature calibrator 9127 (Fluke).
 - Fluke® 9190A (ultra-cool dry-block calibrator)
 - Jofra® (Bath Mode et Dry-Block Mode) RTC-158, RTC-159
 - Votsch® VT serie (adress 1)
 - Sika® TP Solid, TP premium (micro-bath TPM255S, TP37166E.2, TP17650,...)
 - Wika® (micro-bath CTB9100) (Choose Sika in the Qlever list)
-
- Readout from Hart®: 1502A, 1529 and Black Stack 1560 (with the 2560 module).
 - Readout from AOIP®: PHP601 and PHP602 (reference probe on the channel 1/A).
 - Readout from Fluke®: 1521, 1523 and 1524.
 - Jofra® probes.

For Climatic Test Cabinets, Calibration/Adjustment in expert mode is mandatory (*cf. 9.3.1Type of equipment and instruments*).

If you want to communicate with an equipment via a RS232 serial port, you have to configure communication with suitable options described in section *Hardware configuration of supported calibration* .

Important notice:

- Only turn the calibration bath on when it contains the heat transfer fluid.
- For Hart® baths with refrigeration group, properly commute both switches (on/off switch and the Cooling switch).
- The calibration instrument must set with no auto power off (auto shutdown OFF) and without stamp data (no automatic data transfer via RS232).
- For Jofra®, select the type of the set point probe.
- For Votsch®, the adress is 1 (OP3 = 1 in menu)
- For SIKA®, use the cable provided by SIKA®.

4.5 Description of the calibration/adjustment process

- **Temperature Step Setting:**
 - Description of the hardware that would be used for the calibration/adjustment
 - Selection of the automated mode for the hardware
 - Define the temperature setpoint and the measurement duration
 - Create the DEFPAL file
- **Programming and starting** of the dataloggers under test.
- **Temperature Step Generating:**



- When in the automated mode, the sequence of setpoints would be generated automatically.
- When in the manual mode, the operator would need to type the values displayed by the temperature calibration instrument.
- Create a GENPAL file.
- **Stop and read** recordings from the dataloggers.
- **The Step analysis:**
 - Analyze the results from the temperature steps
 - Print a calibration report before adjustment
 - Adjust the logger(s) if necessary and print a calibration and adjustment report.

4.6 Step Settings

Click “**Logger > Calibration > Step Settings**” or open or create a new DEFPAL file from the Directory Management (TDB).

Description

- Shows the name of the file DEFPAL
- Shows the comments like description of the file or the protocol

Hardware

Calibration equipment:

- Type the model name of the calibration equipment (could be a calibration bath, drywell, climatic chamber, oven, etc.). Such information will be displayed in the calibration report.
- Type the serial number of the calibration equipment. Such information will be displayed in the calibration report.
- Type a description allows to record any information that the operator would like to flag.
- If automated mode is checked, select the model from the list. This checkbox allows to choose between the automated and manual mode.
- Select the COM port number: drop-down menu allows to select the serial port the device is connected to.
 - ***Important: Don't select this port (or another calibration probe or equipment) as interfaces in the “Configuration, Communication port configuration” menu.***
 - Attention the communication ports used by the TMI-ORION interfaces are grayed out.

The Cooling mode checkbox is used to optimize the cold unit management for FLUKE® or HART SCIENTIFIC® baths.

When on automated mode, the cold unit of these baths is not triggered above a certain threshold.

If the setpoint temperature of the step to be performed is higher than that of the previous step, and the setpoint temperature is very close to the default trigger



threshold of the bath cold unit, it may take a very long time for the bath to reach its setpoint temperature. To solve this problem, a new trigger threshold may be set for the cold unit in the Seuil (Threshold) text field.

Calibration standard probe:

- Type the model name of the calibration instrument (reference probe).
- Type the serial number for the instrument
- Type some description
- If automated mode is checked, select the model from the list.
- Select the COM port number.
 - **Important: Don't select this port (or another calibration probe or equipment) as interfaces in the "Configuration, Communication port configuration" menu.**
 - Attention the communication ports used by the TMI-ORION interfaces are grayed out.
- Select the channel number if more than one
- Offset \pm : Correction value for the standard probe with automated mode only.

Test

Click **Test** to test the communication with the equipment and instrument (automated mode only).

Steps

From the **Step** sheet of the **Step Settings** Windows, select the number of Steps and type the details for each step:

- Step Numbers is displayed in the list
- Type the temperature set point
- Type the duration for the stability
- Type the duration for the measurement

The unit for the duration for the stability is minutes. It is the elapsed time before any measurement on the temperature step. Once the temperature of the bath or any other equipment equals the setpoint, the measurement will start after the stability duration. This duration allows perfect stability and homogeneity before measurement. Default duration is set to 30 minutes

The unit for the duration of the measurement is minutes. It is the duration for which the calibration instrument like the reference probe will be recorded (after stability). Default value is 3 minutes.

When no automated standard probe mode, in case you prefer one single reading of the standard probe at one chosen moment, select Measurement date from the list.

"When the process is over, reset the equipment to" text field allows to define the temperature at which the calibration bath or oven should be reset at the end of the calibration cycle.

To add or remove steps, modify the number of steps from the list using the selection box on the top of the window.



Example of a Step Setting:

#	Step (°C)	Stability duration (min)	Measurement duration (min)
1	0	30	3
2	30	30	3
3	60	30	3
4	90	30	3
5	120	30	3
6	140	30	3

Configuration

Beginning of the stabilization time

Once the setpoint temperature is reached, you may wait for the temperature to be stable within a defined tolerance band before the stabilization time can start.

Such process guarantees the measurement reliability (since the **equipment** temperature probe is read, this process is activated in **equipment** automated mode only).

e.g.: If an overshoot occurs at a 50 °C plateau, the temperature will slowly decrease in case the cooling mode is not activated. If such duration (when temperature is decreasing) is longer than the stabilization time, measurements will be made although the temperature is not fully stable. This stability test is performed only before the stabilization time.

Parameters:

- "After" n seconds: time delay before the software starts and checks the temperature value is included in the tolerance band. This parameter must be set according to the equipment performances.
- Tolerance \pm : after such time delay, the software checks and waits for the equipment temperature to be within this tolerance band.

To disable this checking process, type "0" second in the "After" field.



Polynomial

- A table allows the creation of a polynomial correction for the standard probe. Such table applies to every Step Settings files (.delpal).

In case no polynomial correction is needed, do not type in anything.

- "Serial number" column: type in the serial number of the standard probe. It should be the exact same as typed in the "serial number" field for the Standard probe in the "Hardware" tab.



- “Name » column: type in a name for the polynomial.
 - “Polynomial” column: type in a name for the file that includes such polynomial.
 - Modification button : will open the window where the values are typed in for the polynomials creation and edition (see further down for details).
 - “Certificate” column: type in the calibration certificate number for the standard probe.
 - “Configuration date” is the date of the certificate of the standard probe including the “warning” icon.
 - “Description” icon: type in a text for description.
 - “By” column will display the user name
 - “Last modified” column will display the date of the last modification.
 - “+” or “-” buttons would add or delete rows within the table.
 - “Save” button will save the typed in data.
 - Click the Modification button  within the “Polynomial” column in order to create and edit Polynomials.
 - The “New” button created a new table.
 - The top table is for typing in the data given by the calibration certificate of the standard probe.
 - Press the “+” button to add a calibration step point.
 - Uncheck the box if the value is positive (true temperature above zero)
 - Type in the true value.
 - Type in the read value.
 - The error is calculated = True value - Read Value (for compatibility with XETAL software).
 - The “+” or “-” buttons add or delete a row from the table.
 - You must enter 3 lines with negatives values and 3 lines with positives values.
 - The “Polynomial function calculation” button calculates the polynomial based on the above data.
 - The first line is the creation date.
 - The 3 following lines are the coefficients for the first polynomial (for the negative values).
 - Line #1 = c
 - Line #2 = b
 - Line #3 = a in $y = ax^2 + bx + c$
 - The 3 others are the coefficients for the second polynomial (for the positive values).
- ⇒ There must be 6 lines, the first 3 are checked (any other combination is not possible).
- The “**Import**” button would import a TXT file that includes both polynomials in an ETA format for compatibility with XETAL software.
 - The “**Save**” button saves all the typed data within this window.
 - The “**Exit**” button closes the window.



For example:

≤ 0	Read value (°C)	True value (°C)	Error (°C)
X	-79.998	-80.000	-0.002
X	-54.995	-55.000	-0.005
X	0.000	0.000	0.000
	-0.001	0.000	0.001
	70.006	70.000	-0.006
	139.976	140.000	0.024

Click **Save** to save the DEFPAL file.

4.7 Step Generating

Prerequisites:

- A Step Setting DEFPAL file should exist.
- The dataloggers should be programmed and already started (*cf. 2.3 Program the loggers*).
 - The rate is generally between 5 and 10 seconds.
- The dataloggers should be placed inside the calibration equipment.
- Switch the calibration equipment on. If this is a calibration bath, it should only be switched on when filled with calibration fluid. Commute the cooling mode switch. Switch the temperature instrument on and put it inside the calibration equipment.
- Make sure the computer is NOT synchronized with an external clock (network, internet time server...) during the calibration process.
- With an automated standard probe, the loggers MUST be started on the computer which runs the step generation (otherwise the measurement start dates of the loggers and the standard probe will be out-of-sync).
-

Automated equipment and the standard probe mode:

- The QLEVER software can automatically generate the calibration steps.
- Once the hardware is ready, confirm the start of Step Generation.
- For every step, the QLEVER Software communicates with both the equipment and instrument to generate step, and reach the setpoint temperature. Measurement starts when the equipment temperature is stable.
- The measurement frequency of the standard the standard probe varies from 3 seconds to 9 seconds depending on the brand and model of connected standard probe connected.
- Every step for such process is displayed real time on the screen.
- Values measured by the standard probe are displayed real time in the "Standard probe" tab.



- Description of stages :
 - Click on “Logger/Calibration/Step generation” menu, open the step settings file DEFPAL and confirm by clicking “Yes”.
 - QLEVER configures the standard probe in automated mode.
 - QLEVER configures the equipment in automated mode.
 - For each step:
 - QLEVER sets the equipment to setpoint temperature.
 - QLEVER starts the stabilization time countdown.
 - QLEVER records values from the automated standard probe during the measurement period.
 - Once the measurement period is completed, QLEVER calculates the mean, min., max. and standard deviation.
 - End of step generation.

Note: When the stabilization time ends, the measurement starts, so both dates must be equal.

Automated equipment and manual standard probe mode:

- For every step, the operator should type the exact start date for the first temperature readout together with the average temperature value given from all the values taken during the measuring duration.
- Min., max. and standard deviation values entry is optional.
- Click “**Save**” for recording.
- Description of stages:
 - Click on “Logger/Calibration/Step generation” menu, open the step settings file DEFPAL and confirm by clicking “Yes”.
 - QLEVER configures the equipment in automated mode.
 - For each step:
 - QLEVER sets the equipment to setpoint temperature.
 - QLEVER starts the stabilization time countdown.
 - Wait until the stabilization period ends.
 - QLEVER displays “Reading in progress”.
 - Click “OK” and note the values measured by the manual standard probe.
 - QLEVER starts the measurement period countdown.
 - Once the measurement period is completed, calculate the mean of your measured values. Place it in the appropriate step line in QLEVER “Standard Probe” tab.
 - Min., max. and standard deviation values entry is optional.
 - End of step generation.
 - Click on “Save”.

Manual equipment and automated standard probe:

- The operator should synchronize the software with the equipment to get the same stabilization time.
- Description of stages :



- Click on “Logger/Calibration/Step generation” menu, open the step settings file DEFPAL and confirm by clicking “Yes”.
- QLEVER configures the standard probe in automated mode.
- For each step :
 - QLEVER displays the message “Put the set point of the equipment to x °C”
 - Set your equipment to the requested set point temperature.
 - Go back to QLEVER, then click “Yes”.
 - QLEVER starts the stabilization time countdown.
 - Once the stabilization period is completed, QLEVER starts recording values from the automated standard probe.
 - QLEVER records the values during the measurement period.
 - Once the measurement period is completed, QLEVER calculates the mean, min., max. and standard deviation.
- End of step generation.

Manual Equipment and Standard Probe mode:

- The operator should monitor the setpoint temperatures and stabilization times of his equipment.
- The user MUST note the first measurement exact start date from the computer clock, or synchronize the probe time with the computer clock (otherwise the measurement start dates of the loggers and the standard probe will be out-of-sync).
- For every step, the operator should type the exact start date for the first temperature readout together with the average temperature value given from all the values taken during the measuring duration.
- Min., max. and standard deviation values entry is optional.
- Click “Save” for recording.
- Description of stages:
 - Click on “Logger/Calibration/Step generation” menu, open the step settings file DEFPAL.
 - QLEVER displays the steps table
 - For each step:
 - Set your equipment to the requested setpoint temperature.
 - Wait until the stabilization period ends.
 - From then and during the measurement period, note the values measured by the manual standard probe.
 - Once the measurement period is completed, calculate the mean of your measured values. Place it in the appropriate step line in QLEVER “Standard Probe” tab.
 - Min., max. and standard deviation values entry is optional.
 - End of step generation.
 - Click on “Save”.

Save:

The data is recorded in a Step Generating GENPAL file. The name of the file is just the same



as the Steps Setting DEFPAL file that was previously selected.
The default directory is \Calibration.

4.8 Steps Analysis

Calibration and/or Adjustment can be done using the window based on the earlier GENPAL Step Generating file.

Prerequisites:

- One or more existing GENPAL Step Generating files.
- When in the automated mode, the dataloggers should have been stopped and with data downloaded within a QLE file(s).

Click **“Logger > Calibration > Steps Analysis”**.

For each step:

- The value for the calibration instrument is the reference value.
- The value from the channel f the data logger to be calibrated/adjusted is the readout value.
- The error is the difference between both the above values.

4.8.1 Files

Open a Step Generating file.

- Select one or more GENPAL Step Generating files
- For every file, the table will show the name of the file and the GUID, the name of the equipment, the name of the instrument and for every step, the date of the measurement, the duration of the measurement as well as the readout.
- Click “-” to remove a step from the list

Open a QLE data file

- Select one file with recordings from datalogger(s), or merge all qle files (before the “Steps Analysis” screen, open all QLE files and “Edit” menu, “Merge the open files” menu, close all files if opened).
- For every file, the table will show the name of the datalogger, the name of the file and the GUID, the start and end date for recording as well as the date for the configuration file for the specific logger.
- Click “-” to remove a logger from the list.

⇒ Don't use qle setup file for the calibration.

Open a CET/CETX configuration file

It is possible for the operator to type the values from the channels of the datalogger rather than using QLE file.

- Select one or more CET configuration files.
- For each file, the table will display the name of the datalogger, the name of the file and the date of the configuration file for this datalogger.
- Click “-” to remove a datalogger from the list.



Check the box **“Report: Creating a single file containing all the data loggers”** to create a calibration/adjustment report including:

- a max. deviation calculation (max Δ between each channel value and the standard probe value).
- An acceptance criteria before adjustment.
- An acceptance criteria after adjustment.
- All loggers data and standard probe values recorded during the measurement time of each step.

Checking the **“Report: Components of uncertainty”** check box will lead to a detailed calculation of the expanded calibration uncertainty (U) (only available with the automated calibration mode).

Validate and check the files selection when clicking **“Next”**.

4.8.2 Steps Analysis table

For every datalogger, the table will display:

- The serial number for the datalogger.
- The names of the temperature channels.
- The values of the temperature steps.
- The date of the readout from the reference sensor.
- The average value from the readout of the reference sensor.
 - The average is calculated with unrounded values of the reference sensor while the measurement time.
- The average value from the readout of the temperature channel of the datalogger.
 - The average is calculated with unrounded values of the datalogger channel while the measurement time.
- The error that would be the difference between both above values.
- The minimum, the maximum, the max-min and the standard deviation of the reference sensor.
- The minimum, the maximum, the max-min the standard deviation and the number of acquisitions of the temperature channel of the datalogger.
- If the **“Report: Creating a single file containing all the data loggers”** box was checked:
 - A max deviation calculation (between each channel value and the standard probe average value).
 - The max deviation date (logger date).
- The number of acquisitions during the measurement time.
- If the **“components of uncertainty”** box was checked, then:

(Components of uncertainty for a detailed calculation of the calibration expanded uncertainty (U))

 - Type in the value of uncertainty related to the logger (u_e).
 - Type in the value of uncertainty related to the standard probe (u_s).
 - Display a column calculates the standard deviation of the error (u_i).



- Display the result: the expanded (calibration) uncertainty (U) calculated as follows:

$$U = k \times \sqrt{(u_e)^2 + (u_s)^2 + (u_j)^2}$$

With $k = 2$; u_e = uncertainty related to the logger; u_s = uncertainty related to the standard probe; u_j = standard deviation of the error (for each acquisition, standard deviation of [probe value – channel value]).

- If the “**components of uncertainty**” box was not checked, then an icon “**Apply to all**” will appear next to the uncertainty (see the bottom of the windows). Such button icon will duplicate the value of uncertainty into the entire column “Uncertainty °C”.
⇒ In this case, this value is the expanded uncertainty (U) of the logger.

From the left:

- It is **possible to select the dataloggers or channels** using the box. At this stage, it is not possible to remove a temperature step.
For example: uncheck all not used channels for a thermocouple.

From the bottom part of the window, it is possible to:

- Type the uncertainty of the dataloggers.
- Check the box so the software selects the channels of the dataloggers related to the chosen value in \pm °C.
- Check the box to allow export of the data to a text file.

4.8.3 Edit the calibration values

Click on the column to type or edit the calibration values:

- Date and time of measurements.
- Values of the reference sensor readout.
- Values of the channel of the logger.

4.8.4 Export the results of the calibration or adjustment

In order to export the results to a text file when calibration or adjustment, the “**Export Data**” box should be ticked.

The files will be exported to the directory that can be configured from the menu “**Configuration > Directory Management > External file**”.

The export format is TXT file. For every step:

When calibration:

Logger Name *SPACE* Channel Name *HT HT HT CRLF*

And for each step

Reference Value *HT* Channel Value *HT* Error *HT* Uncertainty *CRLF*

When adjustment:



Logger Name *SPACE* Channel Name *HT HT HT CRLF*
And for each step
Reference Value *HT* Channel Value *HT* Error *HT* Channel Value after adjustment *HT*
Error after Adjustment *HT* Uncertainty *CRLF*

4.8.5 Generating calibration report

- Select the datalogger(s) and channel(s) needed for such calibration report.
- Click “Create the report”
- Type or edit the various texts for the header of the reports in the Report Settings window (cf. 4.8.5.3 *Settings for the calibration report*).
- Click “Next”.
- Select the folder within the TDB where the reports will be saved. Default folder will be “**Report\Calibration**”.
- If the “Detail Report” box was checked, the preview of every calibration report will be displayed. Every report can be then printed.
- A new window will appear.
- If the dataloggers need adjustment, then click “Step Analysis” otherwise, click “Exit”.

4.8.5.1 Requested step number for adjustment

To adjust a thermocouple, the requested step number is at least 1 and no more than 3. Regarding other type of loggers, the requested step number is at least 4 and no more than 8.

4.8.5.2 Start the adjustment and create a calibration/adjustment report

Prerequisites:

- The dataloggers to be adjusted should be connected to the interface.

In order to adjust:

- Select the dataloggers that need adjustment (the other dataloggers won't be display anymore).
- Click “**Start Adjustment**” in order to calculate the transfer function and display two new columns “Adjustment” that include:
 - The new value given from the adjusted channel.
 - The bias (error) after the transfer function is applied.
- Click “**Continue Adjustment**” to confirm the adjustment of the checked dataloggers.
- Type or edit the various texts for the header of the reports in the Report Settings window (cf. 4.8.5.3 *Settings for the calibration report*).
- Click “**Next**”.
- The Adjustment window will appear.

New configuration files CET can be created so the new transfer function can be calculated within every connected datalogger.

The CET configuration files can be exported. To do so, check the “**CET Export**” box before



clicking **“Complete the Adjustment”**. The files will be exported to the directory that can be configured from the menu **“Configuration > Directory Management > External file”**. They can be later exported from **“Configuration > Managing Configuration files”**.

In order to complete the adjustment for every datalogger:

- Connect the datalogger(s) to the interface.
- Click **“Complete Adjustment”**.
- The calibration/adjustment report will be automatically saved within the **“Report\Calibration”** folder from the TDB or any other chosen directory.
- Repeat according to the number of loggers and interfaces that you use.

In order to restore a previous adjustment (*cf. 2.1 CET/CETX Configuration files installation*).

4.8.5.3 Settings for the calibration report

From such window, information for the calibration/adjustment report can be typed for every logger.

- **Detailed Report:** if checked then an additional page will be printed showing each step, the date, the name of the operator and the GUID of the used files.
- **Open Preview:** if checked then the preview of the report will be displayed on the screen and printing will be possible by clicking on the Printer icon.

Title:

- Sub-title always printed except in adjustment.

Delivered to:

- Name, address and phone number of the company to whom the report is to be delivered.
- If the operator and service company details are the same, click the arrow button to copy the information.

Operator/Place of Calibration:

- Name, address and phone number of the service company that performed the calibration operation.
- Picture: logo of the company to displayed on the top of the report next to the name and address.
- Place: name or place of the calibration lab.
- Room Temperature.
- Calibration conditions: this is a text describing the conditions of the datalogger immersed in the bath.
- Calibration procedure.
- Adjustment procedure.
- Calibration method and comments.

Click **“Next”** to continue and save the changes for the following reports.

4.8.5.4 Printing a calibration/adjustment from a saved report

- Open the Directory Management
- Go to the directory **“Report\Calibration”** or any other folder chosen for saving the reports.



- Open a report.
- Click the Printer icon to print the report.

4.8.5.5 Change the text from a saved report

- Open the Directory Management
- Go to the directory "**Report\Calibration**" or any other folder chosen for saving the reports.
- Select a report.
- Click the "**Modify**" button.
- Make the changes and click "**Save**".
- Click "**Print**" to preview the report.
- Click the Printer icon to print the report.



5 Autoclave validation (setup) option

This function is not included in QLEVER Lite.

5.1 Prerequisites

- QLEVER license with:
 - Autoclave validation option included
 - 21CFR secure mode option included or not included
- At least one temperature data logger

5.2 Description of the autoclave validation setup option

- The Autoclave validation mode is a QLEVER option in which the starting and reading of the data loggers follow a specific protocol that is necessary for the production of a validation report. Such report will then be described in an autoclave validation setup file.
- **Available Analysis:**
 - Vacuum test (must be first in the data file)
 - Holding time
 - Rate of the pressure
 - Vacuum (pressure)
 - Air evacuation
 - Drying duration
 - Heating duration
- In 21CFR mode (secure mode), the rights of the accounts of "operator" type can be changed by the Administrator.

5.3 Steps for obtaining an autoclave validation report

- Creation of an autoclave validation setup file
- Starting of the autoclave validation process
- Programming and starting of the data loggers
- Data acquisition inside the equipment
- Reading of the loggers in Process mode
- Printing off of the validation report from the QLE data file



5.4 Create or modify an autoclave validation setup file

- To create a new setup, click on “**Setup > New – Autoclave validation**”.
- A setup is a description of the measurement to be made by the data loggers in order to create a validation report.
- It does not incorporate the data recorded by the loggers.

5.4.1 Description tab

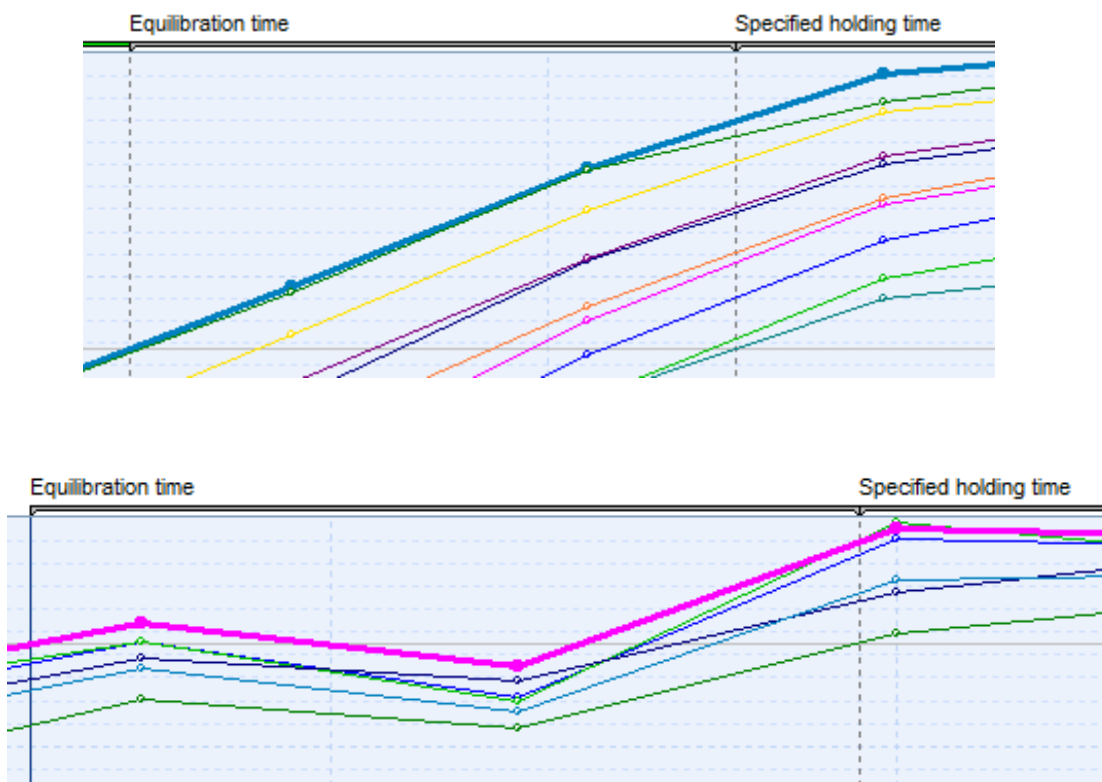
- This section displays the general Setup information:
- File name and description
- Name of the entity that will perform the measurements (displayed on top of the report)
 - Print in the report.
- Place where measurements are performed
 - Print in the report.
- Check the “**keywords**” box if you want keywords to be automatically updated if the data loggers, channel names, etc. are changed (*cf. 5.2 File research by date or keywords*)

5.4.2 Settings tab

The “Setting” tab enables you to describe:

5.4.2.1 Holding time

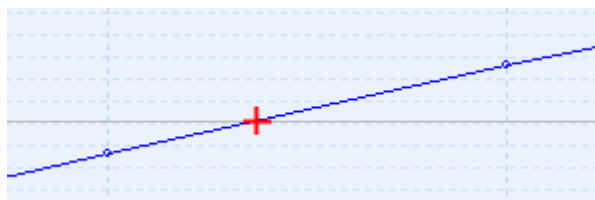
- **Cycle-specific reference values:**
 - **Holding time:** check this box to calculate the specified and measured holding time. You may uncheck this box if, for example, you wish to perform a vacuum test only.
 - **Sterilization temperature band:** the sterilization temperatures must stand within the specified temperature value (e.g. 121.10 °C) and the sum of the specified temperature value and sterilization temperature band value (e.g. $121.10 + 3 = 124.10$ °C).
 - **Equilibration time:** maximum time (in seconds) between the moment when the specified sterilization temperature is reached in the sterilizer chamber and the moment when it is reached throughout the load (when the last sensor reaches the specified temperature). E.g. 15 seconds. *See also reference sensor.*
Example (calculations with linearization):



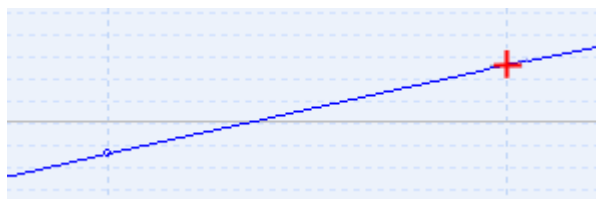
Non-conformity warning display: highlight the equilibration time in red, in the report, if the result value exceeds the above reference value.

- **Specified holding time:** time between the moment when a sensor is the last to measure a temperature equal to the specified sterilization temperature value and the moment when a sensor is the first to measure a temperature falling below this value.
- **Specified sterilization temperature:** sterilization temperature value to be reached during the specified holding time (e.g. 121.10 °C).
- **Stability:** maximum temperature difference recorded by a sensor during the measured holding time.
- **Homogeneity:** maximum temperature difference between the values recorded by the sensors, that is continuously calculated during the measured holding time.
- **Difference (average temperature):** check the box if you want to calculate a deviation between average loggers temperature and average Regnault temperature (Default value =0.5°C).
- **Do not notify when the measured holding time < to the specified holding time:** if not checked then when the measured holding time is strictly less than the specified holding time then the cell turns red in the report. Default = unchecked.

- **Do not display the measured holding time:** check the box if you do not want the measured holding time to be displayed on the graph and in the validation report. Yet it will be calculated. This option is incompatible with "Calculation Zone" window "Setting cycles." Default is unchecked.
- **Calculations without linearization:** if this box is unchecked, the equilibration and holding times calculation will be based on the linearization of two values, as shown below:



If this box is checked, as shown below:



Default is unchecked.

- **Detailed equilibration time:** if checked display equilibration time values for every sensor compared with the very first sensor that reaches the sterilization temperature or compared with a reference sensor (chosen in the logger tab) that reaches the sterilization temperature. Default is unchecked.
- **Cycle - Qualification values:**
 - **Qualification values:** to activate the following fields:
 - **Minimum temperature:** minimum temperature value reported by all the sensors during the measured holding time. This value must be equal to or exceed the specified sterilization temperature.
 - **Maximum temperature:** maximum temperature value reported by all the sensors during the **measured holding time**. This value must stand within the specified temperature value (e.g. 121.10 °C) and the sum of the specified temperature value and sterilization temperature band value (e.g. 121.10 + 3 = 124.10 °C).
 - **Stability**
 - **Homogeneity**



- **Holding time:** see **Specified holding time**.
- **Average temperature:** average of all the temperature values reported by the sensors during the measured holding time.
- **Minimum saturated vapor temperature:** minimum temperature value calculated from Regnault's table based on the pressure values obtained during the measured holding time.
- **Maximum saturated vapor temperature:** maximum temperature value calculated from Regnault's table based on the pressure values obtained during the measured holding time.

5.4.2.2 Evacuation / HELIX

- **Evacuation:** allows to activate an air evacuation test of the autoclave located before the heating phase (default value = no).
- **Color:** color of the evacuation phase in the graphic.
- **Parameters:**
- **Min delta:** value in pressure between the min and the max to detect and analyze each evacuation pulse, below this value the impulse is ignored. This allows to filter some irregularities in pressure, especially at the beginning of cycle (default value is 300 mBar).
- **Display:**
 - For the EMax marker:
Display the maximum marker of each evacuation (default value = yes).
 - For the EMin and EMax markers:
Display the minimum and maximum values of each evacuation (default value = yes).
- **Report:**
 - **Print in report:** allows you to show the calculation on the screen but not to print it in the report (default value = yes).
- **Evacuation table:**
 - Evacuation number from E1 to E10 (default = 4)
 - Reference value: this is the minimum value to reach for this pulse (default = 300 mBar).
 - Tolerance + : tolerance value above the reference value (default = 50 mBar)
 - Tolerance - : tolerance value below the reference value (default = 50 mBar)
 - Example: Reference value = 150 mBar, tolerance + = 50 mBar and tolerance - = 10 mBar then :



the acceptable tolerance band is $150 + 50 = 200$ mBar to $150 - 10 = 140$ mBar, values included.

- "+" button: allows you to add a new number after the selected line.
- "-" button: deletes the selected line.

⇒ On the graph:

- The evacuation phase and its duration are displayed.
- Pressure maximums marked "E Max" appear with a blue marker.
- The pressure minimums marked "E Min" appear with a green marker if the min value is within acceptable the tolerance band, otherwise with a red marker if not.
- The minimum pressure reference values to be reached can be viewed but by default, they are not visible so as not to overload the graph.

⇒ In the "Min / Max / Avg" tab of the "data analysis", a detailed analysis is displayed for each air evacuation:

- Evacuation number from E1 to the evacuation's number of the evacuation table.
- Value of the minimum pressure with measurement date.
- Maximum pressure value with measurement date.
- Pressure difference between the max and min values.
- Rate of variation of the pressure per second = $(\text{max} - \text{min}) / (\text{date of the max} - \text{date of the min})$.
- Duration: difference in seconds between the max value and the min value.
- If not found, then "not found" is displayed.
- The EMin Logger with each interval duration EMin.
- The EMax Logger with each interval duration EMax.

5.4.2.3 Pressure change

- **Rate of pressure change [Average]:**
 - Determine whether the average pressure change for any 3 seconds interval during the sterilization cycle (not only measured holding time) exceeds a rate of 1 000 KPa/min (10 bar/min). So, the logger record rate must be 1 second or 3 second (2 second is impossible).
 - The calculation stops when the first value exceeds the max rate of 1 000 KPa/min (10 bar/min) **in absolute value**.



- Only for the pressure channels (not calculated pressure channel).
- Calculations without linearization.
- The variation in the rate of pressure can be increasing or decreasing (i.e. positive if it increases or negative if it decreases).
- Calculated on the cycle (maybe modified by the Cycle windows).
- **Max:** Rate of pressure change [Max]:
 - Search the maximal rate of pressure change in the programming rate.
 - Display:
 - The maximal rate: **red** symbol if absolute value > 1 000 KPa/min (10 bar/min) else green symbol.
 - Maximal pressure and minimum pressure values.
 - Only for the pressure channels (not calculated pressure channel).
 - Calculations without linearization.
 - The variation in the rate of pressure can be increasing or decreasing (i.e. positive if it increases or negative if it decreases).
 - Calculated on the cycle (maybe modified by the cycle windows).

5.4.2.4 Vacuum

- **Vacuum (under pressure)**
 - Vacuum search area:
 - On the whole cycle (by default).
 - Exclusively after the holding time.
 - Display on the graphic: a marker will be positioned to indicate where is the value of the vacuum found.
 - Display the value of the channel: The value in pressure will be indicated or not.
 - Tolerance band: a tolerance band can be defined
 - Color of the tolerance band.
 - Reference value: this is the minimum value to reach for this pulse (default = 70 mBar).
 - Tolerance + : tolerance value above the reference value (default = 30 mBar)
 - Tolerance - : tolerance value below the reference value (default



= 30 mBar)

On the graphic, the vacuum is displayed with a green marker if the value is in the tolerance band, otherwise with a red marker if the value is out of tolerance.

5.4.2.5 Vacuum test

- **Vacuum test:** enables to activate the following fields.
- **S₁ Threshold:** minimum acceptable pressure value that the autoclave must reach to start the vacuum test (the default value is 70 mBar).
 - ⇒ Do not mistake S₁ for P₁ (P₁ is the minimal measured pressure value, so P₁ < S₁ is mandatory).
- **t₁ t₂ time:** number of seconds after the minimum pressure is reached. The default value is 300 seconds ± 10 s (this value must be a multiple of the recording rate).
- **t₂ t₃ time:** vacuum test time (in seconds) after the t₁t₂ time. The default value is 600 seconds ± 10 s (this value must be a multiple of the recording rate).

In t₀, ambient pressure (P₀) is measured.

In t₁, minimum pressure value (P₁) is reached.

In t₂, the vacuum test starts with the initial pressure value (P₂).

In t₃, the test ends with the final pressure value (P₃).

The rate of pressure increases in t₂ - t₃ interval shall not exceed 1.3 mbar/min.

⇒ The chosen pressure sensor for the vacuum test (for P₀, P₁, P₂...) is the one that measured the lower pressure value P₁ (and not the reference sensor in the setup).

⇒ Calculation without linearization.

5.4.2.6 Uncertainty values

- **Uncertainty values:** enables to activate the following fields:
 - Temperature
 - Pressure
 - Time

5.4.2.7 Graphic

Allow to display on the data logger curve graphic:

- **0 Bar** (depend of the current pressure unit): display a horizontal reference mark to



the graphic for the zero pressure.

- **Heating duration:** display the heating zone on the graphic (by default: heating begin estimated to the begin of equilibration time, but id “Evacuation” is activated then end of the evacuation to begin of equilibration time).
- **Drying duration:** display the drying (or cooling) zone on the graphic (end of the holding time to the ambient pressure).
- **Duration:** display the duration in the title of the zone (heating duration, holding time...) Default value=yes.

5.4.2.8 Cycle designation

- **Cycle designation:** to be entered by the user.
- **Cycle counter:** cycle number. Which does not increment each time a new autoclave validation process is started.
- **Comment:** remark entered by the user.

5.4.3 Equipment tab


This section enables you to enter the details of the equipment that will be used:


- Equipment name or number
- SOP protocol
- Load description
- Comment, batch number, chamber volume (in liters)
- Picture of the equipment

5.4.4 Logger tab

This section enables you to describe the data loggers that you will be using.

Add or remove the available data loggers. This can be done either automatically by browsing the plugged data loggers, or manually by designating each desired data logger.

 **Reference sensor:** It is possible to select a reference channel by checking the box. This reference sensor will be used for determining the starting point of equilibration time calculation.

 **Not used:** option not to use this sensor, ie:

- The sensor will not appear in the data columns or curves QLE




- The sensor will not be taken into account in the calculation of setup
- The sensor will not generate computed columns
- The sensor will not be notified in the excluded channel list report
- The sensor will not be visible on the loading plan
- The internal channel is automatically unused with a Vacq
- This feature can be activated before starting the setup (if you do not want to use a route once the data read back then since QLE data file, it must be excluded)

⇒ Beyond 70 sensors, the new will be added not visible by default to reduce the graphic processing time and not to obstruct the visibility of the loading plan.

5.4.5 Programming tab

This section enables you to describe the programs that you will be using.

- Click on **"Program"** to add one or several programs (*cf. 2.3 Program the loggers*)
- Click on **"-"** to remove a program
- Click on  for quick program change
- Click on **"+"** to assign the desired loggers to each program
- Click on **"-"** to remove a logger from a program

A message at the bottom of the screen will inform you in case loggers have not been assigned to any program.

5.4.6 Sensor positions view tab

This section enables you to indicate where the sensors will be placed inside the equipment:

- You may describe the position for each sensor of the list
- Check or uncheck the box located below the column with a pin in the header, to display the sensor on the loading plan (a menu by right clicking on the column allows for additional options for selection).
- Open and choose a loading plan proposed by QLEVER and open a picture that you have taken.
- You may move the pins (that represent the sensors) on the loading plan by left-clicking and sliding them.
- Click on the **"Printer"** button on the loading plan picture to print the loading plan.

⇒ If any sensor is visible, then the loading plan will not be printed in the report.

You may add 6 additional pictures of the cycle parameters, plus an additional one in



calculator tape format.

5.4.7 Analysis tab

This section enables you to describe the calculations that will be used in the report.

The results of these calculations (on the measured holding time) depend on the type of cycles defined. They will be displayed in the data analysis, in the window of the data file QLE and in the printed report.

- **F0/A0/C0... type of calculation:** enable or disable this calculation (default value = yes).
 - Two **F0 calculation formulas** are available (*cf. 3.3.4.1 F0/A0/C0... type column and Information related to autoclave validation report*).
- **Calculation of the water vapor temperature** (Regnault)/Sterilizing agent
 - Include saturated steam temperature channels (Regnault) in the calculations:
 - Minimum temperature, maximum temperature, chamber temperature, homogeneity, stability.

⇒ **21CFR:** Some settings can be hidden by the 21CFR Administrator.

5.4.8 Report

Type of report: depending on the procedure you use, it is possible to choose the type of report:

- Validation of autoclaves (full report)
 - Routine control (fast and condensed report)
- ⇒ **Available only in 21CFR (authorized for approvers by default and operators according to granted administrator rights).**

Conformity: Type whether the report is valid or not. The box “do not display” only appears after loggers data are read. It will prevent you from displaying the conformity indication in the report.

Top right part of the report can be chosen to be either:

- **Contractor** details (logo and address)
- **Comment** (a text zone for comments or a specific document reference)

Free text field:

- **Title:** Add a title to this text field.
- **Print in the report:** check the box to get the text printed before the loggers data in



the report.

- **Text field:** add a text or a results table (e.g. : of chemical indicators).

⇒ This field may be printed differently in the report if the content was copied and pasted from an external file (Word, Excel, ...)

5.4.9 Save an autoclave validation setup file

Click on **"Save"**.

For newly created validation setup files:

- Select the TDB in which you wish to save the setup file.
- Name the file.

Click **"OK"**

5.4.10 Save as...

Click on **"Save as"** to save a copy of the setup file under a new name.

- Select the TDB in which you wish to save the setup file.
- Rename the file.

Click **"OK"**

⇒ *This operation cannot be performed with setup files that were opened from a QLE file.*

5.4.11 How to restart the calculations of the validation report results from a QLE file

In the Setup windows, click on **"Calculations"** to restart the calculations of the holding time and all the results of the autoclave validation report.

5.5 Open an autoclave validation setup file

To modify a setup file, click on **"Setup > Open"**.

If you wish to review or modify a setup file that was used to generate a QLE data file, open a data file (*cf. 3 QLE data files*), select a file that was created in Setup mode, then click on **"Setup"** (on the upper right corner).

⇒ Warning: some modifications will restart the calculations.



5.6 Start an autoclave validation setup

To start a setup, click on **“Setup > Start”**.

Select a setup, then click on the **“Start”** button at the bottom of the Setup window.

Starting the loggers in Setup mode is the same process as in standard mode (*cf. 2.4 Start the loggers*)

The presence of the loggers required in the Setup is verified.

Start date

To avoid interpolation of the data, it is not possible to start "Now" with several loggers.

Options

Some options such as message display or value display are configurable in user preferences.

⇒ **After starting, the Setup file is copied in a Process file.**

⇒ **The Process file becomes independent from the Setup file that was used to create it.**

5.7 Read an autoclave validation process

To read the data recorded by the logger in setup mode, click on **“Setup > Read”**, and select the process that you have started.

Reading the data in Setup mode is the same process as in standard mode (*cf. 2.5 Read the loggers*)

The presence of the loggers connected, missing and required in the Process is verified.

If a logger was unable to record data (e.g. due to low battery), you will be proposed to exclude it from the data file.

✖ Exclude a logger

To exclude a logger, select this logger and click right, choose **“Exclude”** or clic on **“Exclude”** button.

Data File

As soon as the data file opens, the calculations specific to the report are launched.

A quick overview of the results is displayed in the Min/Max/Avg tab.

The specified sterilization temperature, holding time and measured holding time are displayed on the graph.

5.8 Delete an autoclave validation process file

To delete a process file, click on “**Setup > Delete process**”.

Select the Process file in the TDB, right click and select “**Delete**”.

Deleting a Process file is irreversible (the file cannot be found in the recycle bin).

5.9 Define cycles for the autoclave validation report

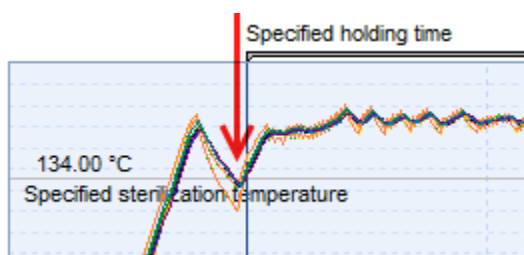
Open a data file (*cf. 3 QLE data files*) and select a file that was created in the autoclave validation setup mode.

Click on “**Cycle**”.

- **Cycle start and end dates**

- You may enter the start and end dates of the recorded data for the report (both starting and ending dates are included).

For example, if you want to start later to avoid an overshoot under the specified sterilization temperature, the start date will be here:



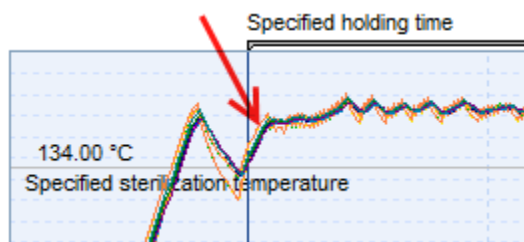
- **F₀/A₀... calculation start and end dates**

- Enter start and end dates to perform the F₀/A₀ calculations over the selected period of time (both starting and ending dates are included).

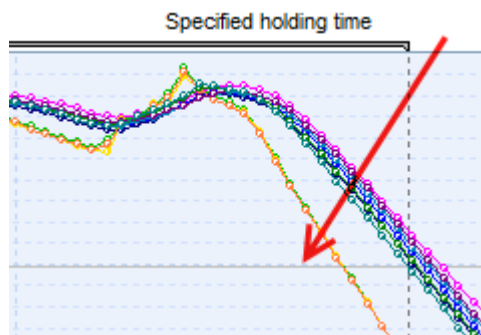
- **Calculation zone start and end dates**

- Enter start and end dates to replace those of the measured holding time that were automatically calculated.

For example, set the start date



Then, set the end date before the threshold:



If checked, the measured holding time will be renamed by "Holding time".

Note: This option is incompatible with "Do not display the measured holding time" (Setup window)

- **Color**
 - Select a color to modify the color of the holding time displayed on the graph.
- **Stability calculation start and end dates**
 - Enter start and end dates to calculate stability over the selected period of time (both starting and ending dates are included).
- **Homogeneity calculation start and end dates**
 - Enter start and end dates to calculate homogeneity over the selected period of time (both starting and ending dates are included).
- **Sterilizing steam calculation start and end dates (Sterilizing agent)**
 - Enter start and end dates to perform sterilizing stream calculations over the selected period of time (both starting and ending dates are included).
- **t_0 of the vacuum test**
 - Enter a date for measuring the ambient pressure (P_0).
⇒ t_0 must be on an acquisition measured by a pressure logger.
- **t_1 of the vacuum test**
 - Enter a date for measuring the minimum pressure (p_1).
⇒ t_1 must be on an acquisition measured by a pressure logger.
- **Start and end date of the air evacuation search area**
 - By default, the software searches for evacuations between the beginning of the file and the beginning of the equilibration time, but you want to restrict this



search area then specify a start and end date. The software will find evacuations according to your indications. Start and end date may be out of the cycle's date.

⇒ Icons "zoom" lets you view the start and end of the graph

5.10 Exclude a sensor from the calculations and analysis

To exclude a sensor, click on the column header of the data table.

5.11 Preview or print an autoclave validation report

There are two possible scenarios:

- The report file already exists: open the file in **"File > Open"**, then select and open the file in the Report/Autoclave validation directory.
- The report file is to be created:

Open a data file (*cf. 3 QLE data files*) and select a file that was created in setup mode.

Click on **"Report"**.

Choose your print out mode:

- Save as: allow to save the report in the QLEVER TDB without preview and print.
- Default printer: allow to print on the windows default printer without preview.
- PDF: allow to export the report to PDF format.
- Open the preview: allow to see the report before print.

You may print the following:

- Parameters
 - Signature
 - Display signature on the first page only
 - The legend
 - Comment on the QLE file
- Graph with background color
 - Equilibration time graph
 - Specified holding time graph
 - Measured holding time graph
 - Vacuum test graph



- Pictures
- Data of every column:
 - Default Data mode
 - Printed data description:
 - All data in the file are printed unless a cycle was defined.
 - Date and hour column
 - Logger column:
 - Channel colour, serial number, physical unit, channel name
 - Condensed data on 25 columns with calculation (min., max., avg., max-average, average-min...)
 - Choose a physical property for the statistics (temperature...)
 - Adding or not statistics (min., max., avg...)
 - Printed data description:
 - All data in the file are printed unless a cycle was defined.
 - Date and hour column
 - Logger column:
 - Channel colour, channel number, physical unit
 - Statistics for each line:
 - Min. value (optional)
 - Max. value (optional)
 - Average (optional)
 - Max. – Min. (optional)
 - Average – Min. (optional)
 - Max. – Min. (optional)
 - Print all lines or one line out of x (except equilibration time and holding time)
 - Hidden data channels are printed in the report.
 - Excluded data channels are not printed in the report.
- The loading plan in small and/or large size on a whole page
- Picture of the equipment
- Program descriptions



- List of excluded data loggers (typically the user would use more loggers than required to run a validation test just in case some fail or stand out of the metrological specifications. Additional loggers would be then excluded from the test to avoid any later questions)
- Screen shots (if you do not wish to print a screen shot, go to the “Screen shot” tab and uncheck “Print in the report”).
- Min/Max/Avg statistics of Data Analysis tab
 - Setup calculations automatically generated by the setup.
 - User calculations: calculations manually added from “**Data analysis**” tab, button “**Modify**”. See “**Data analysis**” paragraph.
 - Page break between each table: if you want to get your report more readable, it is possible to separate each **Min./Max./Avg.** calculation with a page break.
- Logger included in the study:
 - Loggers configuration date
 - Loggers firmware version

Click on “**Print**”.

If you wish to save the report when closing the preview, name the file and click “**OK**”.

5.12 Information related to autoclave validation report

Colors in the report:

- Important values are displayed with a gray background.
- If a value is out of its reference specification it will be displayed with a red background as:
 - Vacuum Test.
 - Mini and maxi temperature.
 - Stability and homogeneity.
 - Holding time duration
 - Measured holding time duration (if “Do not notify when” is unchecked in the setup)
 - Equilibration time (if “Non-conformity warning display” is checked in the setup).
 - Mini and maxi temperature (Regnault).



- Average temperature.
- Deviation between average loggers temperature and average Regnault temperature.
- Rate of pressure change.
- Evacuations.

Calculation of F0 in the report:

- Depending on the formula entered in the setup.
 - Calculated over the entire cycle time (by default, except for manual modification in the "Cycle" window) and therefore NOT ON the hold time.
- At the end of the F0 calculation time:
 - o F0 Max: is the largest value of F0 among all F0.
 - o F0 Min: is the smallest value of F0 among all F0.

Chamber temperature: lowest value among the average values calculated for each sensor (displayed as "m" in the Min/Max/Avg tab) during the measured holding time.

If pressure loggers were used and if "Calculation of the water vapor temperature (Regnault)" was checked in the setup appears the following values in the report:

- **Mini. temperature (Regnault):** Minimum temperature value among all temperature values given from the pressure values converted with the Regnault table during the measured holding time.
The result will in red if "Include in calculation the saturated steam" is checked and if < at the specified sterilization temperature.
- **Maxi. temperature (Regnault):** maximum value among all temperature values given from the pressure values converted with the Regnault table, during the measured holding time based on the pressure values. The result will in red if "Include in calculation the saturated steam" is checked and if > at the specified sterilization temperature + sterilization temperature band.
- **Average temperature (Regnault):** average of each temperature value given from a pressure value converted with the Regnault table, during the measured holding time.
- **Average temperature (loggers):** average of the temperature values recorded by all the loggers during the measured holding time.
- **Homogeneity:** max. spread between reference sensor and temperature value given from a pressure value converted with the Regnault table. Displayed only if a reference sensor is checked.

If pressure loggers were used appears the following values in the report:

- **Minimal pressure:** minimum value among all temperature values recorded by all the loggers during the measured holding time.



- **Maximal pressure:** maximum value among all temperature values recorded by all the loggers during the measured holding time.
- **Average pressure:** average of the pressure values recorded by all the loggers during the measured holding time.
- **Vacuum:** minimum pressure value recorded by all the sensors over the entire cycle.
- **Vacuum test:**
 - Difference (P3-P2): is the difference in pressure value measured between P3 and P2.
 - The leak rate must be less than 1.3mBar / min over a period of 10 minutes.
 - In description column:
 - The 1st line gives the result of the pressure leak rate analysis over a 10 minutes time interval.
 - The 2nd line appears when the result of the pressure leak rate analysis over a time interval of 1 minute is > 1.3mBar / min indicating the time of the violation.

For more definitions, go to “**Creation of an autoclave validation setup > Settings**”.

5.13 Approve an autoclave validation report

This function is available in the secure mode option only and only the Approval users can approve reports.

There are two possible scenarios:

- The report file already exists: open the file in “**File > Open**”, select the file in the Report directory and click on “**Approve**”.
- The report file is to be created:

Open a data file (*cf. 3 QLE data files*) and select a file that was created in setup mode.

As the cycles have already been defined (*cf. 5.9 Define cycles for the autoclave validation report*), you just need to click on “**Approve**”. A preview of the report will show up to be reviewed or printed off (*cf. 3.3.9 Printing*).

If you wish to approve the report when closing the preview, name the file and click “**OK**”.

Confirm approval of the measurement report.

Approved reports are represented by an icon with a V.



6 Washer-disinfector validation (setup) option

This function is not included in QLEVER Lite.

6.1 Prerequisites

- QLEVER license with
 - Washer-disinfector validation option included
 - 21CFR secure mode option included or not included
- At least one temperature data logger

6.2 Description of the washer-disinfector validation setup option

- The washer-disinfector validation mode is a QLEVER option in which the starting and reading of the data loggers follow a specific protocol that is necessary for the production of a validation report. Such report will be described in a washer-disinfector validation setup file.
- In 21CFR mode (secure mode), the rights of the accounts of "operator" type can be changed by the Administrator.

6.3 Generation process for a washer-disinfector validation report

- Creation of a new washer-disinfector validation setup
- Starting of the washer-disinfector validation process
- Programming and starting of the data loggers
- Data acquisition inside the equipment
- Reading of the loggers in Process mode
- Printing off of the validation report from the QLE data file

6.4 Create or modify a washer-disinfector validation setup file

To create a new setup, click on **“Setup > New – Washer-disinfector validation”**.

- A setup is a description of the measurement to be made by the data loggers in order to create a validation report.
- It does not incorporate the data recorded by the loggers.

6.4.1 Description tab

This section displays the general Setup information:



- File name and description.
- Name of the entity that will perform the measurements (displayed on top of the report).
 - Print in the report.
- Place where measurements are performed.
 - Print in the report.
- Check the “**keywords**” box if you want keywords to be automatically updated if the data loggers, channel names, etc. are changed (*cf. 5.2 File research by date or keywords*).

6.4.2 Settings tab

The “Setting” tab enables you to describe:

- The number of cycles to be analyzed (up to 3)
- The number of washing phases (up to 3) The presence of at least one washing phase.
- Washing phase reference values:
 - **Setpoint temperature:** setpoint value in temperature to be reached during the holding time.
 - **Holding time:** time between the moment when a sensor is the last to measure a temperature exceeding the setpoint temperature and the moment when a sensor is the first to measure a temperature falling below this value.
 - **Washing temperature band:** temperatures must stand within washing temperature band. Default value = 0°C to 5 °C.

For example:

- If the washing temperature band= 54 °C to 58 °C and the setpoint temperature = 53 °C then
 - Washing temperature band: 1°C to 5 °C
 - **Washing pressure band:** during a washing phase, the tolerance (min and max pressure values) on the measured pressures must be $\pm x \%$ of the average pressure value. 0% for deactivate the comparison. Default value = 20%.
 - **Stability:** maximum temperature difference recorded by a logger during the holding time.
 - **Homogeneity:** maximum temperature difference between the values recorded by the loggers, that is continuously calculated during the holding time.
- Disinfection phase reference values:
 - **Setpoint temperature:** setpoint value in temperature to be reached during



the holding time.

- **Holding time:** time between the moment when a sensor is the last to measure a temperature equal to the setpoint temperature and the moment when a sensor is the first to measure a temperature falling below this value.
- **Disinfection temperature band:** temperatures must stand within the disinfection temperature band. Default value = 0°C to 5 °C.

For example:

- Si disinfection temperature band: 91 °C to 95 °C and the setpoint temperature = 90 °C then
- Disinfection temperature band: 1°C to 5 °C
- **Stability:** maximum temperature difference recorded by a logger during the holding time.
- **Homogeneity:** maximum temperature difference between the values recorded by the loggers, that is continuously calculated during the holding time.
- Other cycle parameters:
 - **Cycle designation:** to be entered by the user.
 - **Cycle counter:** cycle number. Which does not increment each time a new autoclave validation process is started.
 - **Comment:** remark entered by the user.
- Washing phase qualification values:
 - **Qualification values:** to activate the following fields:
 - **Minimum temperature:** minimum temperature value reported by all the loggers during the holding time. This value must be equal to or exceed the setpoint temperature.
 - **Maximum temperature:** maximum temperature value reported by all the loggers during the holding time. This value must stand within the setpoint temperature value and the sum of the setpoint temperature value and the washing band value.
 - **Average temperature:** average of all the temperature values reported by the loggers during the holding time.
 - **Holding time:** see **Washing phase holding time**
 - **Stability:** see **Washing phase stability**
 - **Homogeneity:** see **Washing phase homogeneity**
- Disinfection phase qualification values:



- **Minimum temperature:** minimum temperature value reported by all the loggers during the holding time. This value must be equal to or exceed the setpoint temperature.
- **Maximum temperature:** maximum temperature value reported by all the loggers during the holding time. This value must stand within the setpoint temperature value and the sum of the setpoint temperature value and the disinfection band value.
- **Average temperature:** average of all the temperature values reported by the loggers during the holding time.
- **Holding time:** see **Disinfection phase holding time**
- **Stability:** see **Disinfection phase stability**
- **Homogeneity:** see **Disinfection phase homogeneity**

⇒ Qualification values = 0 are not printed in the report.

- Uncertainty values
 - **Uncertainty values:** enables to activate the following fields:
 - Temperature
 - Pressure
 - Time

6.4.3 Equipment tab

This section enables you to enter the details of the equipment that will be used:

- Equipment name or number
- SOP protocol
- Load description
- Comment, batch number, chamber volume in liters
- Picture of the equipment

6.4.4 Logger tab

This section enables you to describe the data loggers that you will be using.

Add or remove the available data loggers. This can be done either automatically by browsing the plugged data loggers, or manually by designating each desired data logger.

✗ **Not used:** option not to use this sensor, ie:

- The sensor will not appear in the data columns or curves QLE




- The sensor will not be taken into account in the calculation of setup
- The sensor will not generate computed columns
- The sensor will not be notified in the excluded channel list report
- The sensor will not be visible on the loading plan
- The internal channel is automatically unused with a Vacq
- This feature can be activated before starting the setup (if you do not want to use a route once the data read back then since QLE data file, it must be excluded)

⇒ Beyond 70 sensors, the new will be added not visible by default to reduce the graphic processing time and not to obstruct the visibility of the loading plan.

6.4.5 Programming tab

This section enables you to describe the programs that you will be using.

- Click on **"Program"** to add one or several programs (*cf. 2.3 Program the loggers*)
- Click on **"-"** to remove a program
- Click on  for quick program change
- Click on **"+"** to assign the desired loggers to each program
- Click on **"-"** to remove a logger from a program

A message at the bottom of the screen will inform you in case loggers have not been assigned to any program.

6.4.6 Sensor positions view tab

This section enables you to indicate where the sensors will be placed inside the equipment:

- You may describe the position for each sensor of the list.
- To display the sensor on the loading plan, check or uncheck the box located below the column represented by a pin (a menu by right clicking on the column allows for additional options for selection).
- Open and choose a loading plan proposed by QLEVER and open a picture that you have taken.
- You may move the pins (that represent the sensors) on the loading plan by left-clicking and moving them.
- Click on the **"Printer"** button on the loading plan picture to print the loading plan.
⇒ If no sensor is visible, then the loading plan will not be printed in the report.



You may add 6 additional pictures of the cycle parameters, plus an additional one in calculator tape format.

6.4.7 Analysis tab

This section enables you to describe the calculations that will be used in the report.

The results of these calculations depend on the type of cycles defined. They will be displayed in the data analysis, in the window of the data file QLE and in the printed report.

- **F0/A0/C0... type of calculation:** enable or disable this calculation (default value = yes).
 - Up to two A_0 calculation formulas are available (calculated on the disinfection phase) (cf. 3.3.4.1 *F0/A0/C0... type column*)
- **Do not display the calculated columns until the cycles are defined** (not checked by default): to avoid calculated columns creation before the cycles are defined.
 - ⇒ Reduce the computation time

6.4.8 Report

Type of report: depending on the procedure you use, it is possible to choose the title of the report:

- Validation report
 - Measurement report
- ⇒ In 21CFR (authorized for approvers by default and operators according to granted administrator rights).

Conformity: Type whether the report is valid or not. The box “do not display” only appears after loggers data are read. It will prevent you from displaying the conformity indication in the report.

Top right part of the report can be chosen to be either:

- **Contractor details** (logo and address)
- **Comment** (a text zone for comments or a specific document reference)

Free text field:

- **Title:** Add a title to this text field.
- **Print in the report:** check the box to get the text printed before the loggers data in the report.



- **Text field:** add a text or a results table (e.g. : of chemical indicators).
- ⇒ This field may be printed differently in the report if the content was copied and pasted from an external file (Word, Excel, ...)

6.4.9 Save a washer-disinfector validation setup file

Click on **“Save”**.

For newly created validation setup files:

- Select the TDB in which you wish to save the setup file.
- Name the file.

Click **“OK”**

6.4.10 Save as...

Click on **“Save as”** to save a copy of the setup file under a new name.

- Select the TDB in which you wish to save the setup file.
- Rename the file.

Click **“OK”**

This operation cannot be performed with setup files that were opened from a QLE file.

6.4.11 How to restart the calculations of the validation report results from a QLE file

Click on **“Calculations”** to restart the calculations of the holding time and all the results of the washer-disinfector validation report.

6.5 Open a washer-disinfector validation setup file

To modify a setup file, click on **“Setup > Open”**.

If you wish to review or modify a setup file that was used to generate a QLE data file, open a data file (*cf. 3 QLE data files*), select a file that was created in Setup mode, then click on **“Setup”** (on the upper right corner).

Warning: some modifications will restart the calculations.

6.6 Start a washer-disinfector validation setup file

To start a setup, click on **“Setup > Start”**.



Select a setup, then click on the **“Start”** button at the bottom of the Setup window.

Starting the loggers in Setup mode is the same process as in standard mode (*cf. 2.4 Start the loggers*)

The presence of the loggers required in the Setup is verified.

Start date

To avoid interpolation of the data, it is not possible to start "Now" with several loggers.

Options

Some options such as message display or value display are configurable in user preferences.

After starting, the Setup file is copied in a Process file.

The Process file becomes independent from the Setup file that was used to create it.

6.7 Read a washer-disinfector validation process

To read the data recorded by the logger in setup mode, click on **“Setup > Read”**, and select the process that you have started.

Reading the data in Setup mode is the same process as in standard mode (*cf. 2.5 Read the loggers*)

The presence of the loggers connected, missing and required in the Process is verified.

If a logger was unable to record data (e.g. due to low battery), you will be proposed to exclude it from the data file.

Exclude a logger

To exclude a logger, select this logger and click right, choose **“Exclude”** or clic on **“Exclude”** button.

Data file

As soon as the data file opens, the calculations specific to the report are launched.

A quick overview of the results is displayed in the Min/Max/Avg tab.

The setpoint temperatures and washing and disinfection phases are displayed on the graph.

6.8 Delete a washer-disinfector validation process

To delete a process file, click on **“Setup > Delete process”**.

Select the Process file in the TDB, right click and select **“Delete”**.

Deleting a Process file is irreversible (the file cannot be found in the recycle bin)



6.9 Define cycles for the washer-disinfector validation report

Open a data file (*cf. 3 QLE data files*) and select a file that was created in the washer-disinfector validation setup mode.

Click on **“Cycle”**.

- **Choose a cycle**
- **Cycle start and end dates**
 - You may enter the start and end dates of the recorded data for the report (both starting and ending dates are included).
- **Select a washing or disinfection phase**
- **Calculation zone start and end dates**
 - Enter start and end dates to replace those of the measured holding time that were automatically calculated (both starting and ending dates are included).
- **Stability calculation start and end dates**
 - Enter start and end dates to calculate stability over the selected period of time (both starting and ending dates are included).
- **Homogeneity calculation start and end dates**
 - Enter start and end dates to calculate homogeneity over the selected period of time (both starting and ending dates are included).

Icons "zoom" lets you view the start and end of the graph.

6.10 Exclude a sensor from the calculations and analysis

To exclude a sensor, click on the column header of the data table.

6.11 Preview or print a washer-disinfector validation report

There are two possible scenarios:

- The report file already exists: open the file in **“File > Open”**, then select and open the file in the Report/Washer-disinfector validation directory.
- The report file is to be created:
Open a data file (*cf. 3 QLE data files*) and select a file that was created in setup mode.
Click on **“Report”**.

Choose your print out mode:



- Save as: allow to save the report in the QLEVER TDB without preview and print.
- Default printer: allow to print on the windows default printer without preview.
- PDF: allow to export the report to PDF format.
- Open the preview: allow to see the report before print.

You may print the following:

- Parameters
 - Signature
 - Display signature on the first page only
 - The legend
 - Comment on the QLE file
- Graph (current view) with background color
 - Holding time (of the washing and disinfection phases)
- Pictures
- Data of every column:
 - Default Data mode
 - Printed data description:
 - All data in the file are printed unless a cycle was defined.
 - Date and hour column
 - Logger column:
 - Channel color, serial number, physical unit, channel name
 - Condensed data on 25 columns with calculation (min., max., avg., max-avg, avg-min...)
 - Choose a Physical property for the statistics (temperature, ...)
 - Adding or not statistics (min., max., avg...)
 - Printed data description:
 - All data in the file are printed
 - Phase name, start date, end date and duration
 - Date and hour column
 - Logger column:



- Channel color, channel number, physical unit
- Statistics for each line:
 - Min. value (optional)
 - Max. value (optional)
 - Average (optional)
 - Max. – Min. (optional)
 - Avg. – Min. (optional)
 - Max. – Min. (optional)
- Print all lines or one line out of x :
 - Hidden data channels are printed in the report.
 - Excluded data channels are not printer in the report.
- Loading plan in small and/or large size on a whole page
- Picture of the equipment
- Program descriptions
- List of excluded data loggers (typically the user would use more loggers than required to run a validation test just in case some fail or stand out of the metrological specifications. Additional loggers would be then excluded from the test to avoid any later questions).
- Screen shots (if you do not wish to print a screen shot, go to the “Screen shot” tab and uncheck “Print in the report”).
- Min. / Max. / Avg. statistics of Data Analysis tab
 - Setup calculations automatically generated by the setup.
 - User calculations: calculations manually added from “**Data analysis**” tab, button “**Modify**”. See “**Data analysis**” paragraph.
 - Page break between each table: if you want to get your report more readable, it is possible to separate each **Min./Max./Avg.** calculation with a page break.
- Logger included in the study:
 - Loggers configuration date
 - Loggers firmware version

Click on “**Print**”.

If you wish to save the report when closing the preview, name the file and click “**OK**”.



6.12 Information related to washer-disinfector report

Colors in the report:

- Important values are displayed with a gray background.
- If a value is out of its reference specification it will be displayed with a red background as:
 - Mini and maxi temperature
 - Average temperature
 - Stability and homogeneity
 - Holding time
 - Average pressure (if not deactivated)

Glossary:

Average pressure: average of the pressure values recorded by all the loggers during the measured holding time.

For more definitions, go to “**Creation of a washer-disinfector validation setup > Settings**”.

6.13 How to approve a washer-disinfector validation report

*This function enables you to approve a washer-disinfector validation report. It is available in the **secure mode** option only and only the Approval users can approve reports.*

There are two possible scenarios:

- The report file already exists: open the file in “**File > Open**”, select the file in the Report directory and click on “**Approve**”.
- The report file is to be created:

Open a data file (*cf. 3 QLE data files*) and select a file that was created in setup mode.

As the cycles have already been defined (*cf. 6.9 Define cycles for the washer-disinfector validation report*), you just need to click on “**Approve**”. A preview of the report will show up to be reviewed or printed off (*cf. 3.3.9 Printing*).

If you wish to approve the report when closing the preview, name the file and click “**OK**”.

Confirm approval of the measurement report.

Approved reports are represented by an icon with a V.



7 Rotation Setup Option (setup)

This function is not included in QLEVER Lite.

7.1 Prerequisites

- QLEVER license with:
 - Rotation mode option included.
 - 21CFR secure mode option included or not included.
- At least one "rotation" logger.

7.2 Description of the Rotation Setup option

- The Setup Rotation mode is a QLEVER option in which the starting and reading of the data loggers follow a specific protocol that is necessary for the production of a test report. Such report will then be described in a Rotation Setup file.
- In 21CFR mode (secure mode), the rights of the accounts of "operator" type can be changed by the Administrator.

7.3 Steps for obtaining a Rotation test report

- Creation of a rotation setup file
- Starting of the rotation process
- Programming and starting of the data loggers
- Data acquisition inside the equipment
- Reading of loggers in Process mode
- Printing out of the measurement report from the QLE data file

7.4 Create or modify a Rotation setup file

To create a new setup, click on **"Setup > New – Rotation"**.

- A setup is a description of a test that will be done with logger(s) in order to create a test report.
- A setup file does not include the recorded data from the loggers.

7.4.1 Description tab

This section displays the general Setup information:

- File name and description.



- Name of the entity that will perform the measurements (displayed on top of the report).
 - Print in the report.
- Place where measurements are performed.
 - Print in the report.
- Check the “keywords” box if you want keywords to be automatically updated if the data loggers, channel names, etc. are changed (*cf. 5.2 File research by date or keywords*).

7.4.2 Settings tab

The “Setting” tab enables you to describe:

- **Rotation speed:** type the rotation speed of your equipment
- **Cycle designation:** to be entered by the user
- **Comment:** remarks typed by the user

7.4.3 Equipment tab

This section enables you to enter the details of the equipment used for the test:

- Equipment name or number
- SOP protocol
- Load description
- Comment, batch number
- Picture of the equipment

7.4.4 Logger tab

This section enables you to describe the data loggers used for the test.

Add or remove the available data loggers. This can be done either by automatically browsing the plugged data loggers, or by manually designating each desired data logger.

✗ **Not used:** option not to use this sensor, ie:

- The sensor will not appear in the data columns or curves QLE
- The sensor will not be taken into account in the calculation of setup
- The sensor will not generate computed columns
- The sensor will not be notified in the excluded channel list report
- The sensor will not be visible on the loading plan




- The internal channel is automatically unused with a Vacq
- This feature can be activated before starting the setup (if you do not want to use a route once the data read back then since QLE data file, it must be excluded)

⇒ Beyond 70 sensors, the new will be added not visible by default to reduce the graphic processing time and not to obstruct the visibility of the loading plan.

7.4.5 Programming tab

This section enables you to describe the programs used for the test:

- Click on **"Programming"** to add one or several programs (*cf. 2.3 Program the loggers*)
- Click on **"–"** to delete a program
- Click on  for a quick program change
- Click on **"+"** to assign the desired loggers to a program
- Click on **"–"** to delete a logger from a program

A message at the bottom of the screen will inform you whether a logger is not linked to any program.

7.4.6 Sensor position view tab

This section enables you to indicate the location of the sensors inside the equipment:

- You can describe the position for each sensor of the list.
 - Check or uncheck the box located below the column with a pin in the header, to display the sensor on the loading plan.
 - Open and choose a loading plan proposed by QLEVER an open a picture you have taken.
 - You can move the pins (that represent the sensors) on the loading plan by left-clicking and sliding them.
 - Click on the **"Printer"** button on the loading plan picture to print the loading plan.
- ⇒ If any sensor is visible, then the loading plan will not be printed in the report.

You may add 6 additional pictures of the cycle parameters, plus an additional one in calculator tape format.



7.4.7 Analysis tab

This section enables you to describe the calculations that will be used in the report.

The results of those calculations depend on the type of cycles defined. They will be displayed in the data analysis, in the window of the data file QLE and in the printed report.

- Up to two calculation formulas are available (*cf. 3.3.4.1 F0/A0/C0... type column*)
- Calculation of the water vapor temperature (Regnault)

⇒ **21CFR**: Some settings can be hidden by the 21CFR Administrator.

7.4.8 Report tab

Top right part of the report can be chosen to be either:

- Contractor details (logo and address)
- Comment (a text zone for comments or a specific document reference)

7.4.9 Save a Rotation setup file

Click on “**Save**”.

For newly created validation setup files:

- Select the TDB in which you want to save the setup file.
- Name the file.

Click on “**Ok**”.

7.4.10 Save as...

Click on “**Save as...**” to save a copy of the setup file under a new name.

- Select the TDB in which you want to save the setup file.
- Rename the file.

Click on “**Ok**”.

This operation cannot be performed with setup files that were opened from a QLE file.

7.4.11 How to restart the calculations of the measurement report results

Click on “**Calculations**” to restart the calculations of each spiral and all the results of the measurement report.



7.5 Open a Rotation setup file

To open a setup file, click on **“Setup > Open”**.

If you wish to review or modify a setup file that was used to generate a QLE data file, open a data file (*cf. 3 QLE data files*), select a file that was created in Setup mode, then click on **“Setup”** (on the upper right corner).

Warning: some modifications will restart the calculations.

7.6 Start a Rotation setup

To start a setup, click on **“Setup > Start”**.

Select a setup, then click on the **“Start”** button at the bottom of the Setup window.

Starting the loggers in Setup mode is the same process as in standard mode (*cf. 2.4 Start the loggers*)

The presence of the loggers required in the Setup is verified.

Start date

To avoid interpolation of the data, it is not possible to start "Now" with several loggers.

Options

Some options such as message display or value display are configurable in user preferences.

After starting, the Setup file is saved as a Process file.

The Process file becomes independent from the Setup file that was used to create it.

7.7 Read a Rotation Process

To read the data recorded by the logger in setup mode, click on **“Setup > Read”**, and select the process that you have started.

Reading the data in Setup mode is the same process as in standard mode (*cf. 2.5 Read the loggers*)

The presence of the loggers connected, missing and required in the Process is verified.

If a logger was unable to record data (e.g. due to low battery), you will be proposed to exclude it from the data file.

✗ Exclude a logger

To exclude a logger, select this logger and click right, choose **“Exclude”** or clic on **“Exclude”** button.



7.8 Delete a Rotation Process file

To delete a process file, click on **“Setup > Delete process”**.

Select the Process file in the TDB, right click and select **“Delete”**.

Deleting a Process file is irreversible (the file cannot be found in the recycle bin).

7.9 Cycles definition for the Rotation test report

Open a data file (*cf. 3 QLE data files*) and select a file that was created with the Rotation Setup mode.

Click on **“Cycle”**.

For every rotation logger, both dates when entering and leaving every shell must be defined.

Every rotation logger has a channel **“Turn +”** and a channel **“Turn -”** that will differ according to how the logger is placed into the equipment.

To find out which channel counted the turns in the right way, select a logger from the list, then click on one of the two buttons for the channels **“Turn +”** and **“Turn -”**, and look at the graph.

Mark the start and end dates by using the icons to zoom in the graph. Each shell you print is displayed as a yellow hatched area defined by the start and end dates.

7.10 Exclude a sensor from the calculations and analysis

To exclude a sensor, click on the column header of the data table.

7.11 Preview or print a rotation measurement report

There are two possible scenarios:

- The report file already exists: open the file in **“File > Open”**, then select and open the file in the Report/Rotation directory.
- The report file is to be created:

Open a data file (*cf. 3 QLE data files*) and select a file that was created in setup mode.

Click on **“Report”**.

Choose your print out mode:

- Save as: allow to save the report in the QLEVER TDB without preview and print.
- Default printer: allow to print on the windows default printer without preview.



- PDF: allow to export the report to PDF format.
- Open the preview: allow to see the report before print.

You may print the following:

- Parameters
 - Signature
 - Display signature on the first page only
 - The legend
 - Comment on the QLE file
- Graph with background color
- Pictures
- Data displayed in each column
- Loading plan in small and/or large size on a whole page
- Picture of the equipment
- Program descriptions
- List of excluded data loggers (typically the user would use more loggers than required to run a validation test just in case some fail or stand out of the metrological specifications. Additional loggers would be then excluded from the test to avoid any later questions)
- Screen shots (if you do not wish to print a screen shot, go to the "Screen shot" tab and uncheck "Print in the report").
- Logger included in the study:
 - Loggers configuration date
 - Loggers firmware version

Click on "**Print**".

If you wish to save the report when closing the preview, name the file and click "**OK**".



8 Mapping Option (setup)

This function is not included in QLEVER Lite.

8.1 Prerequisites

- QLEVER license with:
 - Mapping mode option included.
 - 21CFR secure mode option included or not included.
- At least one temperature logger.
- In the case of using a hygrometer, you must:
 - That the workstation is powerful enough to ensure the acquisition of hygrometer data reliably and regularly.
 - That the workstation be dedicated to the acquisition of hygrometer data during the mapping process.
 - The workstation is on the inverter or the battery is sufficiently charged to go to the end of the process.

8.2 Description of the Mapping setup option

- The Mapping Setup mode is a QLEVER option in which the starting and reading of the data loggers follow a specific protocol that is necessary for the production of a test report. Such report will then be described in a Mapping Setup file.
- In 21CFR mode (secure mode), the rights of the accounts of "operator" type can be changed by the Administrator.

8.3 Steps of Mapping report generation

- Create a Mapping setup
- Start the Mapping Process
- Program and start the loggers
- Data acquisition inside the equipment
- Read the loggers in Process mode
- Print off the Mapping Report from the QLE file.

8.4 Create or modify a Mapping setup

- Click on **"Setup > New - Mapping"**.
- A setup is a description of a test that will be done with logger(s) in order to create a



mapping report.

- A setup file does not include the recorded data from the loggers.

8.4.1 Description tab

This section displays the general Setup information:

- File name and description
- Details about the contractor who will handle the validation tests. The name of the contractor will be displayed in the header of the report.
- Details about the location of the test.
- Check the “**keywords**” box if you want keywords to be automatically updated if the data loggers, channel names, etc. are changed (*cf. 5.2 File research by date or keywords*)

8.4.2 Settings tab

This section allows you to describe parameters such as:

8.4.2.1 Temperature Settings

- **Cycles:** for every cycle from 1 to 3 (Temperature and humidity)
 - Check or uncheck the box to allow the cycle analysis.
 - Write the cycle name in the field beside the box.
 - **Measurement period:** cycle minimum measurement period.
- **Temperature settings**
 - **Setpoint Temperature:** temperature value set to the controller (equipment) in order to obtain the specified temperature during the holding time.
 - **Specified temperature:** temperature value that should be obtained (desired temperature). Used for the conformity column in the report.

In the case of a setup saved with an older version of Qlever <2.2.3.0, the specified temperature will be equal to the setpoint temperature.
 - **Maximum permissible error \pm :** given with +/- values of limits of the max permissible error of specifications.
 - +: upper limit to the specified temperature.
 - -: lower limit to the specified temperature.
 - E.g. +5 °C above and -1 °C below.
 - 999.99 value for disable.



- **Environmental Indicator:** equipment related to the control system that displays the chamber internal parameters.
- **Max. spread:** this value will be compared to the measured max. spread.
- **Stability:** this value will be compared to the maximum measured stability.
- **Homogeneity:** this value will be compared to the measured homogeneity.
- **Maxi temperature:** if enable then this value will be compared to the measured maximal temperature.
- **Temperature indicator:** allows you to indicate the position of the equipment temperature set point.
- **Clean air/Recycled air (rate)**

8.4.2.2 Humidity settings

- **Humidity:** enable or disable the study.
- **Setpoint Humidity:** humidity value set to the controller (equipment) in order to obtain the specified humidity during the holding time.
- **Specified humidity:** humidity value that should be obtained (desired humidity). Used for the conformity column in the report.

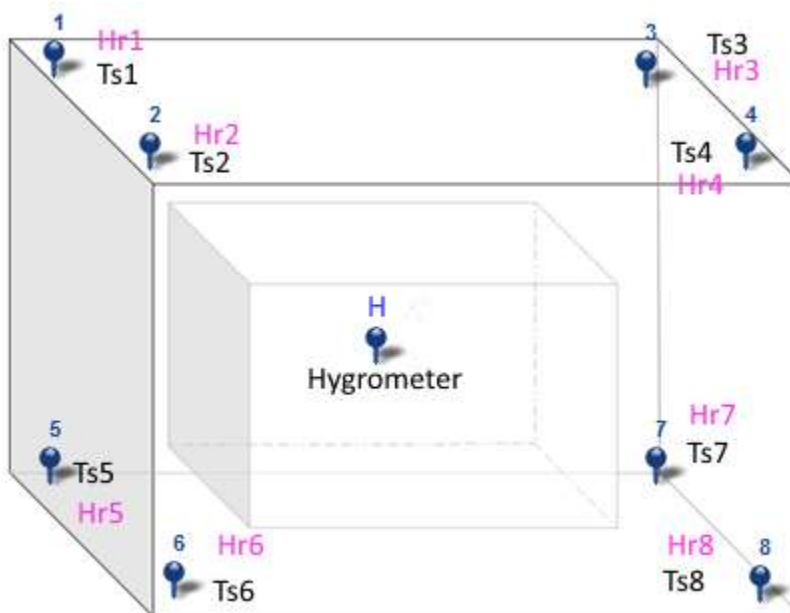
In the case of a setup saved with an older version of Qlever <2.2.3.0, the specified humidity will be equal to the setpoint humidity.

- **Maximum permissible error \pm :** given with +/- values of limits of the max permissible error of specifications.
 - +: upper limit to the specified humidity.
 - -: lower limit to the specified humidity.
 - E.g. +1 %HR above and -1 %HR below.
 - 999.99 value for disable.
- **Environmental Indicator:** equipment related to the control system that displays the chamber internal parameters.
- **Max. spread:** this value will be compared to the measured max. spread.
- **Stability:** this value will be compared to the maximum measured stability.
- **Homogeneity:** this value will be compared to the measured homogeneity.

For other definitions, go to “**Preview a mapping setup**”.

8.4.2.3 Hygrometer

H symbol in the loading plan:



With an hygrometer, often at the center of the room, it is possible to generate the dew temperature and generate the relative humidity calculated channels Hr1 to Hr8 for all other temperature sensors Ts1 to TS8.

- Used as reference for the calculated humidity channels:
 - Hygrometer channel are not included in the report calculation.
 - The recording time of the hygrometer will be equal to the duration of the logger programming.
 - The recording rate of the hygrometer will be synchronized as best as possible depending on the reaction of the device (mirror) and therefore be greater or equal to the default value of 5 second.
- Type the model name of the hygrometer
- Type the serial number for the instrument
- Type some description
- Value for U_{cj} : calibration expanded uncertainty with k=2
- “Optidew” is the default model for this Qlever version
- Select the COM port number.
 - **Important: Don't select this port (or another calibration probe**



or equipment) as interfaces in the “Configuration, Communication port configuration” menu.

- Attention the communication ports used by the TMI-ORION interfaces are grayed out.
- Test: allow testing connection with the hygrometer
- Mirror condition of the Hygrometer
 - Enable: if checked then the mirror condition percentage will be compared to the Maximum acceptable at each acquisition.
 - % Maximum acceptable : default value 10%
 - Don't start if out of the tolerance: if at the start of the process the % maximum acceptable is exceeded then the process will not start.

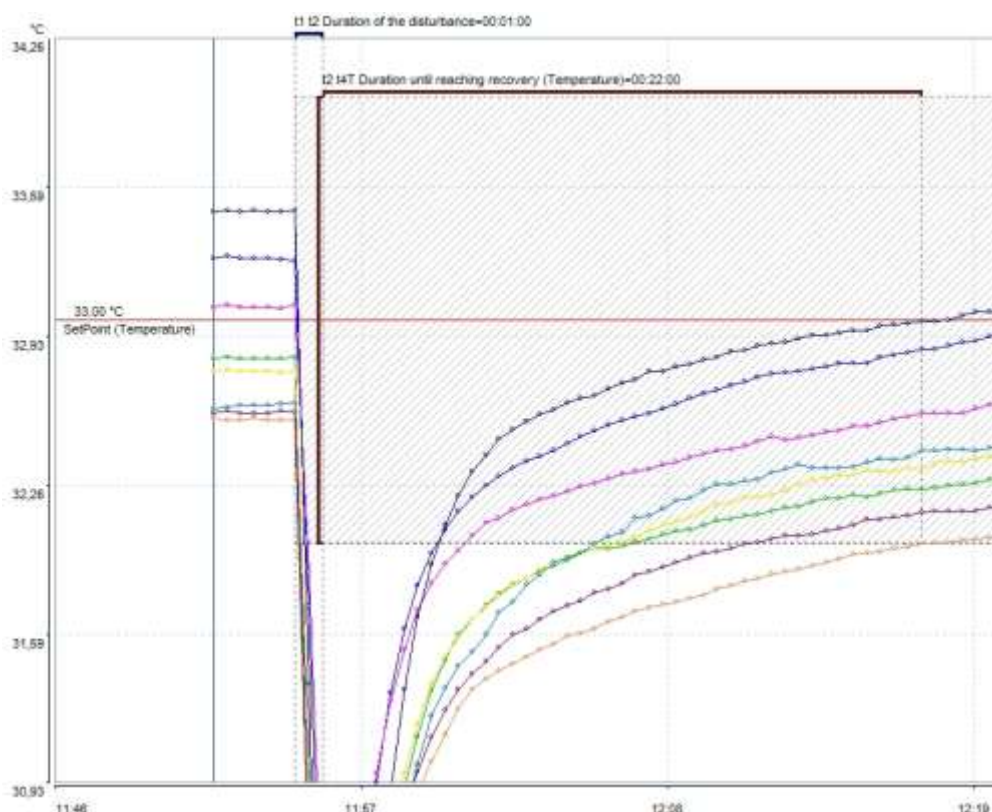
8.4.2.4 Duration until reaching recovery

The mapping module includes:

- An “Equipment door opening” test to define the recovery time. This test applies to temperature (T) and / or hygrometry (H) measurements.
- A “Power failure” test applied to temperature (T) and / or hygrometry (H) measurements.

⇒ It's advisable to record the dates and times of the events during the recording of the data from the window "**Timestamp**" accessible from the general menu "Windows" of Qlever.

⇒ Calculation with logger channels and humidity calculated channels.



⇒ This calculation cannot be combined with the temperature and / or humidity mapping cycle study, so fill in the **“Temperature”** and **“Humidity”** tab.

- **Elements defined manually by the operator:**

- Activation or not of the calculation in temperature and / or humidity.
- Value of the setpoint of the equipment in temperature and / or humidity.
- Minimum and maximum tolerance values in temperature and / or humidity. For example, min = 30 ° C and max = 40 ° C
- Description of the type of disturbance (title of the test in the report).
- Beginning date of the test.
 - The date of the beginning's file is the default value
- End date of the test
 - The date of the end file is the default value.
- t1: start time of the disturbance: enter the date or use a date that you have located from the graph or the data by a marker or other.
- t2: end of disturbance time:
- Calculation option with linearization or not.



- Percentage of the state of occupancy of the equipment.
- **Results:**
 - Maximum duration of the recovery time: if activated then the measured duration will be compared to this qualification value. If larger then it will be reported in red in the report, else in green. If not activated in blue.
 - Comparison activated or not (no bydefault).
 - Maximum duration until reaching recovery t2 t4T in HH: MM: SS in temperature.
 - Maximum duration until reaching recovery t2 t4H in HH: MM: SS in humidity.
 - t1 t3: possibility of displaying the duration "t1 t3T" and/or "t1 t3H" in the report (disable by default).
 - Ability to customize the text associated with the duration "t1 t3T" and/or "t1 t3H" in the report.

⇒ The date and time created from the **"Timestamp"** window are available by clicking on the "selection" icon to the right of the date.

Automatic elements defined by the software:

- t3T: time of the first probe "out of tolerance" in temperature.
 - First logger name in the report
- t4T: return time within the tolerances of all humidity probes.
- t3H: time of the first probe "out of tolerance" in temperature.
 - First logger name in the report
- t4H: hour of return in the tolerances of all the probes in humidity.

⇒ The steady state is determined when all probes are in the range of tolerance values.

⇒ t3 or t4 can be manually set or modified by the operator, and for t3, the first logger name can be named.

Results in the report and plots on the graph after reading the data:

- The period t1 t2, named "duration of disturbance".



- The period t_2 t_4 , called "duration until reaching recovery".
- The recovery time is counted from the end of the voluntary disturbance.
- The recovery time is expressed in minutes.

Logger programming

- The time interval between two measurements must be adapted to the observed phenomenon.

⇒ If no probe is out of tolerance, the duration until reaching recovery is = 00:00:00.

8.4.3 Equipment

This section enables you to enter the details of the equipment used for the test:


- Equipment ID
- SOP Protocol
- Load description
- Comment
- Chamber volume
- Picture of the equipment

8.4.4 Loggers

This section enables you to describe the data loggers used for the test.

- Add or remove the available data loggers. This can be done either automatically by browsing the plugged data loggers, or manually by designating each desired data logger.
- Homogeneity calculation requires calibration expanded uncertainty to be mentioned for every logger.
- **Calibration expanded uncertainties values U_{cj} with $k=2$ (default value: any modification applies to all loggers in the list):**
 - Time
 - Temperature
 - Pressure
 - Relative Humidity

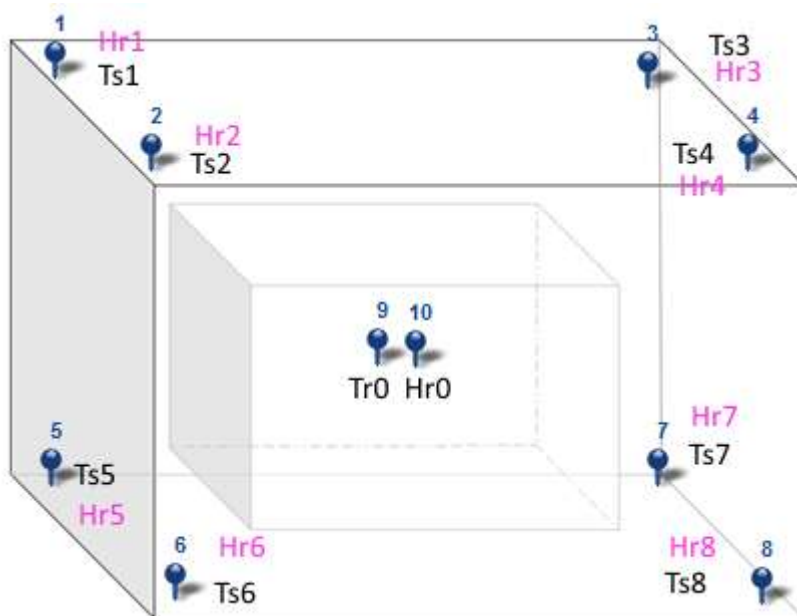
⇒ See “**Information related to Mapping report**” chapter.

 **Used sensor for humidity calculation.** To calculate the dew point, and generate the calculated humidity channels, you must use:

- **One temperature sensor**
- **One humidity sensor**

⇒ See **Analysis / Humidity calculation / Include in calculations**

⇒ Warning, if “**Humidity calculation**” is not checked in **Analysis** tab, this setup column is grayed.



For example, for a base pair Tr0 Temperature and humidity Hr0, often at the center of the room, it is possible to generate the dew temperature and generate the relative humidity calculated channels Hr1 to Hr8 for all other temperature sensors Ts1 to TS8.

✗ **Not used:** option not to use this sensor, ie:

- The sensor will not appear in the data columns or curves QLE
- The sensor will not be taken into account in the calculation of setup
- The sensor will not generate computed columns (unless used in the calculation of humidity)
- The sensor will not be notified in the excluded channel list report
- The sensor will not be visible on the loading plan
- The internal channel is automatically unused with a Vacq
- This feature can be activated before starting the setup (if you do not want to use a route once the data read back then since QLE data file, it must be excluded)


⇒ Beyond 70 sensors, the new will be added not visible by default to reduce the graphic



processing time and not to obstruct the visibility of the loading plan.

8.4.5 Programming

This section enables you to describe the programs that you will be using:

- Click on **“Program”** to add one or several programs (*cf. 2.3 Program the loggers*)
- Click on **“-**” to remove a program
- Click on  for quick program change
- Click on **“+”** to assign the desired loggers to each program
- Click on **“-”** to remove a logger from a program

A message at the bottom of the screen will inform you whether a logger is not linked to any program.

8.4.6 Sensor position view tab

This section enables you to indicate the location of the sensors inside the equipment:

- You can describe the position for each sensor of the list.
- Check or uncheck the box located below the column with a pin in the header, to display the sensor on the loading plan.
- Open and choose a loading plan proposed by QLEVER and open a picture you have taken.
- You can move the pins (that represent the sensors) on the loading plan by left-clicking and sliding them.
- Click on the **“Printer”** button on the loading plan picture to print the loading plan.
⇒ If any sensor is visible, then the loading plan will not be printed in the report.

You may add 6 additional pictures of the cycle parameters, plus an additional one in calculator tape format.

8.4.7 Analysis tab

This section enables you to describe the calculations that will be used in the report.

The results of these calculations depend on the type of cycles. They will be displayed in the data analysis, in the window of the data file QLE and in the printed report.

- **Mean Kinetic Temperature (MKT)** calculation
 - Check the box to perform MKT calculation



- Enter Δ_H value
- Choose MKT unit temperature
- **“Time above” and “time below” calculation in temperature for each cycle:**
 - Check the box to perform calculation
 - Enter the threshold value
 - Check the box if you want to check that the total time is between the minimum and maximum acceptable time (notified in red in the report):
 - Enter the minimal acceptable duration
 - Enter the maximal acceptable duration

⇒ This calculation is with data linearization and is similar to the calculation in “Analysis” “Min/Max/Avg”.
- **Humidity calculation** (a temperature channel and a humidity channel used as a reference for calculated humidity channel, specified on “loggers” tab).
 - **Temperature: include in calculations or not**
 - **Humidity: include in calculations or not**

Include in report calculations:

 - If checked, temperature and/or humidity channel is used for the setup calculations (Min, Max, Avg and others)
 - If not checked, the the temperature and/or humidity channel is not used for the setup calculations, and the associated column is grayed out in the qle data file.
 - If you use a hygrometer: not included in calculations.
- **Do not display the calculated columns until the cycles are defined** (not checked by default): to avoid calculated columns creation before the cycles are defined.

⇒ Reduce the computation time

⇒ This option will be deactivated if **“Duration until reaching recovery”** calculation is enabled.

⇒ **21CFR:** Some settings can be hidden by the 21CFR Administrator.

8.4.8 Report

- **Cycle designation:** cycles name
- **Cycle counter:** cycle number. Which does not increment each time a new autoclave validation process is started.
- **Conformity:** Type whether the report is valid or not. The box “do not display”



only appears after loggers data are read. It will prevent you from displaying the conformity indication in the report.

- Top right part of the report can be chosen to be either:
 - Contractor details (logo and address)
 - Comment (a text zone for comments or a specific document reference)
- **Comment:** entered by the user.
- **For every cycle from 1 to 3:**
 - **Comment:** remark entered by the user. To be printed in the report for each cycle.

8.4.9 Save a Mapping setup file

Click on **“Save”**.

For new setup file:

- Select the TDB folder where you want to save the setup file.
- Name the file.

Click on **“Ok”**.

8.4.10 Save as... a Mapping setup

Click on **“Save as...”** to save a copy of the setup file under a new name.

- Select the TDB in which you want to save the setup file.
- Rename the file.

Click on **“Ok”**.

This operation cannot be performed with setup files that were opened from a QLE file.

8.4.11 How to restart the calculations of the measurement report results

Click on **“Calculations”** to restart the calculations of the measurement report.

8.5 Open a Mapping setup file

Click on **“Setup > Open”** to open a setup file.

If you wish to review or modify a setup file that was used to generate a QLE data file, open a data file (*cf. 3 QLE data files*), select a file that was created in Setup mode, then click on **“Setup”**



(on the upper right corner).

Warning: some modifications will restart the calculations.

8.6 Start a Mapping Setup

To start a setup, click on **“Setup > Start”**.

Select a setup, then click on the **“Start”** button at the bottom of the Setup window.

Starting the loggers in Setup mode is the same process as in standard mode (*cf. 2.4 Start the loggers*)

The presence of the loggers required in the Setup is verified.

Start date

To avoid interpolation of the data, it is not possible to start "Now" with several loggers.

If the acquisition of the data with the hygrometer is activated then the data synchronization between the hygrometer and the loggers will only be possible if the operator chooses a sufficiently wide start time otherwise the start time will be exceeded.

Options

Some options such as message display or value display are configurable in user preferences.

After starting, the Setup file is copied in a Process file.

The Process file becomes independent from the Setup file that was used to create it.

8.7 Read a Mapping Process

To read the data recorded by the logger in setup mode, click on **“Setup > Read”**, and select the process that you have started.

Reading the data in Setup mode is the same process as in standard mode (*cf. 2.5 Read the loggers*)

The presence of the loggers connected, missing and required in the Process is verified.

If a logger was unable to record data (e.g. due to low battery), you will be proposed to exclude it from the data file.

✖ Exclude a logger

To exclude a logger, select this logger and click right, choose **“Exclude”** or clic on **“Exclude”** button.

Data file



Calculations dedicated to the report issue start as soon as the data file is opened.

Results can be previewed in the Min/Max/Avg tab.

The setpoint deviation, the setpoint temperature and the cycle are displayed in the graph.

8.8 Delete a Mapping Process file

To delete a process file, click on **“Setup > Delete process”**.

Select the Process file in the TDB, right click and select **“Delete”**.

Deleting a Process file is irreversible (the file cannot be found in the recycle bin).

8.9 Cycles definition for the Mapping test report

Open a data file (*cf. 3 QLE data files*) and select a file that was created with the Mapping Setup mode.

Click on **“Cycle”**.

For every selected cycle in the setup:

- **Check the box to allow the cycle analysis.**
- **Cycle start and end dates**
 - Enter the start and end dates of the recorded data (both starting and ending dates are included). By default, the duration is equal to the setup specified duration.
- **Color**
 - Select a color for cycle zone boundaries on the graph.

Icons "zoom" lets you view the start and end of the graph.

8.10 Exclude a sensor from the calculations and analysis

To exclude a sensor, click on the column header of the data table.

8.11 Preview or print a Mapping report

There are two possible scenarios:

- The report file already exists: open the file in **“File > Open”**, then select and open the file in the Report/Mapping directory.
- The report file is to be created:

Open a data file (*cf. 3 QLE data files*) and select a file that was created in setup mode.

Click on **“Report”**.



Choose your print out mode:

- Save as: allow to save the report in the QLEVER TDB without preview and print.
- Default printer: allow to print on the windows default printer without preview.
- PDF: allow to export the report to PDF format.
- Open the preview: allow to see the report before print.

You may print the following:

- Parameters
 - Signature
 - Display signature on the first page only
 - Comment on the QLE file
 - The legend
- Graph with background color
 - Full graph (+10% around the cycles)
 - Graph for each cycle (+10% around each cycles)
- Pictures
- Data of every column:
 - Default Data mode
 - Printed data description:
 - Only data cycles are printed
 - The data between two cycles are not printed
 - Date and hour column
 - Logger column:
 - Channel color, serial number, physical unit, channel name
 - Condensed data on 25 columns with calculation (min., max., avg., max-avg, avg-min...)
 - Choose a Physical property for the statistics (temperature...)
 - Adding or not statistics (min., max., avg...)
 - Printed data description:
 - Only data cycles are printed
 - The data between two cycles are not printed
 - Title cycle, start date, end date and duration are printed



- Date and hour column
- Logger column:
 - Channel color, channel number, physical unit
 - Statistics for each line:
 - Min. value (optional)
 - Max. value (optional)
 - Average (optional)
 - Max. – Min. (optional)
 - Avg. – Min. (optional)
 - Max. – Min. (optional)
 - The hygrometer columns are not taken into account in the statistics.
 - “H” = Hygrometer
 - Print all lines or one line out of x:
 - Hidden data channels are printed in the report.
 - Excluded data channels are not printed in the report.
 - “H” Hygrometers data channels are printed in the report.
- Loading plan in small and/or large size on a whole page
- Picture of the equipment
- Program descriptions
- List of excluded data loggers (typically the user would use more loggers than required to run a validation test just in case some fail or stand out of the metrological specifications. Additional loggers would be then excluded from the test to avoid any later questions)
- Screen shots (if you do not wish to print a screen shot, go to the “Screen shot” tab and uncheck “Print in the report”).
- Min. / Max. / Avg. statistics of Data Analysis tab
 - Setup calculations automatically generated by the setup.
 - User calculations: calculations manually added from “**Data analysis**” tab, button “**Modify**”. See “**Data analysis**” paragraph.
 - Page break between each table: if you want to get your report more readable, it is possible to separate each **Min./Max./Avg.** calculation with a page break.
- Logger included in the study:
 - Loggers configuration date



- Loggers firmware version

Click on “**Print**”.

If you wish to save the report when closing the preview, name the file and click “**OK**”.

8.12 Information related to Mapping report

Colors in the report:

- Important values are displayed with a gray background.
- If a value is out of its reference specification it will be displayed with a red background as:
 - Measured time
 - Set point deviation
 - Stability and homogeneity
 - Time above and time below (temperature only)
 - Average column (see conformity below)
 - Max temperature if is enable (and see below)
 - Maximum duration until reaching recovery if is enable (and see below)

For each cycle:

- **Measurement date:** date when measurement was performed.
- **Temperature**
 - **Specified temperature:** humidity value that should be obtained (desired temperature). Used for the conformity column in the report.
 - **Air Temperature:** mean of means that are calculated for each temperature sensor.
 - **Set point deviation** = mean of means (air Temperature) – set point temperature
 - **Indication error:** difference between the environment indicator value and the mean of means (air Temperature).
 - **Mini. Temperature:** minimum value of all temperature values.
 - **Maxi. Temperature:** maximum value of all temperature values.
 - **Max. range:** Max. of max. – Min. of Min. of the temperature values.
 - **Max. spread:** maximum temperature difference between the values recorded by the loggers, that is continuously calculated during the holding time.



- **Maximum stability:** greater value among stabilities values of each loggers.
- **Stability:** maximum temperature difference recorded by a logger during the holding time.
- **Homogeneity:** difference between the max of means + expanded uncertainty U_{mj} and min of mean - expanded uncertainty U_{mj} .
- **Max homogeneity:** difference between the max of measured values + expanded uncertainty U_{cj} and min of measured - expanded uncertainty U_{cj} .
- **s:** standard deviation.
- **MKT:** Mean Kinetic Temperature calculation.

▪ **Humidity**

- **Specified Humidity:** humidity value that should be obtained (desired humidity). Used for the conformity column in the report.
- **Air Humidity:** mean of means that are calculated for each humidity sensor.
- **Set point deviation** = mean of means (air humidity) – set point humidity
- **Indication error:** difference between the environment indicator value and the mean of means (air humidity).
- **Mini. Temperature:** minimum value of all humidity values.
- **Maxi. Temperature:** maximum value of all humidity values.
- **Max. range:** Max. of max. – Min. of Min. of the humidity values.
- **Max. spread:** maximum humidity difference between the values recorded by the loggers, that is continuously calculated during the holding time.
- **Maximum stability:** greater value among stabilities values of each loggers.
- **Stability:** maximum humidity difference recorded by a logger during the holding time.
- **Homogeneity:** difference between the max of means + expanded uncertainty U_{mj} and min of mean - expanded uncertainty U_{mj}
- **Max homogeneity:** difference between the max of measured values + expanded uncertainty U_{cj} and min of measured - expanded uncertainty U_{cj}
- **s:** standard deviation.

▪ For each measurement unit and logger:

- A summary including min., max., stability (max-min), mean, standard deviation, MKT (Mean Kinetic Temperature), min. and max. dates.
- Max temperature column in red background if enable and measured



temperature is > to the max temperature setup value.

○ Conformity:

- $\text{Min} \leq \text{Average} - \text{Expanded uncertainty } U_{mj} \leq \text{Min}$
- $\text{Min} \leq \text{Average} + \text{Expanded uncertainty } U_{mj} \leq \text{Min}$

With:

- Min. = Specified temperature or humidity – Max. Maximal permissible error.
- Max. = Specified temperature or humidity + Min. Maximal permissible error.
- Specified temperature/humidity: see setup value.
- Maximum permissible error (MPE): Min. / max. setup values.
- Expanded uncertainty with a “non-calculated column” channel of a temperature or humidity logger:

$$U_{mj} = k \times \sqrt{s_j^2 + u_{cj}^2}$$

With $k = 2$; s_j = standard deviation; $u_{cj} = U_{cj} / k$

- Expanded uncertainty of a humidity channel calculated from a temperature and humidity logger with impedance variation: see current mapping standard.
- Expanded uncertainty of a humidity channel calculated from a condensation hygrometer: see current mapping standard.

U_{cj} : calibration expanded uncertainty with $k=2$ (see Setup, logger tab).

- Average column in red background if:
 - Avg. - Expanded uncertainty $U_{mj} < \text{Specified temperature or humidity} - \text{Min MPE}$
 - Avg. + Expanded uncertainty $U_{mj} > \text{Specified temperature or humidity} + \text{Max. MPE}$

- For other definitions, go to “**Creation of a mapping setup > Settings**”.

8.13 Approve a Mapping report

This function is available in the secure mode option only and only the Approval users can



approve reports.

There are two possible scenarios:

- The report file already exists: open the file in “**File > Open**”, select the file in the Report directory and click on “**Approve**”.
- The report file is to be created:

Open a data file (*cf. 3 QLE data files*) and select a file that was created in setup mode.

As the cycles have already been defined (*cf. 8.9 Cycles definition for the Mapping test report*), you just need to click on “**Approve**”. A preview of the report will show up to be reviewed or printed off (*cf. 3.3.9 Printing*).

If you wish to approve the report when closing the preview, name the file and click “**OK**”. Confirm approval of the measurement report.

Approved reports are represented by an icon with a “V”.



9 Calibration/Adjustment in expert mode

9.1 Prerequisites

- For the automated mode, in order to run the calibration hardware with RS232 interface, the PC should include a minimum number of one or two serial RS232 ports with SubD 9 or USB/RS232 converters.
- **A crossed RS232 cable if the hardware is RS232**
- Microsoft® .NET Framework 3.5 installed or more
- Command line QLEVER icon: /metrology=1 and /metrology=1 /caldir=C:\nvacq on the workstation that will read the data files.
- QLEVER License key:
 - With **Expert Mode calibration** option
 - TMI-Orion Dongle
- **For the automated mode, the equipment automatic send of data should be disabled.**
- **Important: If you use temperature and humidity logger, you don't only adjust the temperature!**
- The .cfgcet file corresponding to your logger family.

9.2 Description of the Calibration/adjustment option

Calibration/Adjustment:

- Temperature
- Humidity

With the QLEVER Calibration Expert Mode, it is possible to automatically generate **temperature or humidity** step points with direct communication with the calibration equipment. The values of the reference probe for each calibration step would be read for a specified duration through direct communication with the calibration instrument (temperature reference probe). The **humidity** or **temperature** values of the reference probe and every starting time and dates for every temperature steps are recorded in different files. Typing the data manually by the operator is also available in case the calibration hardware equipment is not compatible with direct communication.

With the QLEVER Calibration option, it is also possible to calibrate and adjust the loggers. The **adjustment** applies a transfer function between raw values given by a logger (values I bit from the converter) and the measured values in temperature.

The **calibration** indicates the gap between the reference values within a comparison environment like a calibration bath or drywell and the values given by the logger within the same comparison environment.

When used with the Secure Mode option, a calibration audit trail is created.

In order to communicate with the QLEVER Software, the calibration must be set to Serial



RS232 mode with a suitable communication speed (*cf. 1 Hardware configuration of supported calibration*).

9.3 Installation in Expert Mode

9.3.1 Type of equipment and instruments

- Bath from Hart®: 7321, 7381 and 73xx, 633x, Micro-Bath 6102, 7102, 7103.
 - Bath from Lauda®: RC20, RC25 and Proline series.
 - Hart® Scientific (Fluke) 9172, 917x and Fluke 914x
 - Hart® Micro-bath 6102 (Fluke)
 - Hart® Dry well temperature calibrator 9127 (Fluke).
 - Fluke® 9190A (ultra-cool dry-block calibrator)
 - Jofra® (Bath Mode et Dry-Block Mode) RTC-158, RTC-159
 - CTS®
 - Votsch® VT serie (address 1)
 - THUNDER SCIENTIFIC® 2500 et 2900 (equipment and probe)
 - Optical Mitchell® (equipment and probe)
 - Votsch® VC serie (address 1)
 - Envirotronics® LH serie (address 1)
 - Cabinet/Optical Mitchell® S904 (Optical in probe and equipment must be selected)
 - Sika® TP Solid, TP premium (micro-bath TPM255S, TP37166E.2, TP17650,...)
 - Wika® (micro-bath CTB9100) (Choose Sika in the Qlever list)
-
- Readout from Hart®: 1502A, 1529 and Black Stack 1560 (with the 2560 module).
 - Readout from AOIP®: PHP601 and PHP602 (reference probe on the channel 1/A).
 - Readout from Fluke®: 1521, 1523 and 1524
 - Jofra® probes
 - Optidew Mitchell® Series 97430 and Modbus Series 401,501,...
 - Rotronic® et RotronicNT® Hydrolog probes
 - RH Systems® Dew point mirror 473 probe

If you want to communicate with an equipment via a RS232 serial port, you have to configure communication with suitable options described in section *Hardware configuration of supported calibration* .

Important notice:

- Only turn the calibration bath on when it contains the heat transfer fluid.
- For Hart baths with refrigeration group, properly commute both switches (on/off switch and the Cooling switch).
- The calibration instrument must set with no auto power off (auto shutdown OFF) and without stamp data (no automatic data transfer via RS232).
- For Jofra®, select the type of the set point probe.
- For Votsch® or Envirotronic®, the adresse is 1 (OP3 = 1 in menu)



- For OPTIDEW® Series 97430 in automated mode:
 - Display *REMOTE MODE*
- For OPTICAL® (old series) in automated mode:
 - Optical in probe and equipment must be selected with the same port
 - Display *REMOTE MODE*
 - REMOTE COMMS ON
- For SIKA®, use the cable provided by SIKA®.

9.3.2 Description of the calibration/adjustment process

- **Temperature Step Setting:**
 - Description of the hardware that would be used for the calibration/adjustment
 - Selection of the automated mode for the hardware
 - Define the temperature/humidity setpoint and the measurement duration
 - Create the DEFPAL+ file
- **Programming and starting of the dataloggers under test.**
- **Temperature Step Generating:**
 - When in the automated mode, the sequence of setpoints would be generated automatically.
 - When in the manual mode, the operator would need to type the values displayed by the temperature/humidity calibration instrument.
 - Create a GENPAL+ file.
- **Stop and read recordings from the dataloggers:**
 - **As found** for the calibration before adjustment
 - **Adjustment** for the adjustment
 - **As left** for the calibration after the adjustment
- **The Step analysis:**
 - Analyze the results from the temperature/humidity steps
 - Print a calibration report before adjustment
 - Adjust the logger(s) if necessary and print a calibration and adjustment report.

9.4 Step Settings in expert mode

Click “**Logger > Calibration > Step Settings (Expert Mode)**” or open or create a new DEFPAL+ file from the Directory Management (TDB).

Select the calibration Mode:

- Temperature
- Humidity

Description tab

- Shows the name of the DEFPAL+ file
- Shows the comments like description of the file or the protocol

Configuration tab



Settings:

- Minimum temperature, maximum temperature, Standard deviation (max.):
 - These values are the range of the set points.
 - These values would be controlled while step generation process to ensure the measurement validity.
- Relative Humidity (min.), Relative Humidity (max.), Standard deviation (max.): same

Time:

- Choose the QLEVER measurement time:
 - System clock
 - External USB clock (better precision)

Beginning of the stabilization time

Once the setpoint temperature is reached, you may wait for the temperature to be stable within a defined tolerance band before the stabilization time can start.

Such process guarantees the measurement reliability (since the **equipment** temperature probe is read, this process is activated in **equipment** automated mode only).

e.g.: If an overshoot occurs at a 50 °C plateau, the temperature will slowly decrease in case the cooling mode is not activated. If such duration (when temperature is decreasing) is longer than the stabilization time, measurements will be made although the temperature is not fully stable.

Parameters:

- **“After” n seconds:** time delay before the software starts and checks the temperature value is included in the tolerance band. This parameter must be set according to the equipment performances.
- **Tolerance ±:** after such time delay, the software checks and waits for the equipment temperature to be within this tolerance band.
- **Stabilization time phase**
 - ⇒ When it comes to automated calibration equipment, when activated, a test is performed during the stabilization time phase. Such test verifies that the temperature of the calibration equipment stays within the tolerance. In case the value would be outside the tolerance.
- **Start over if out of the tolerance:** if checked the software would start the Beginning of the stabilization time procedure as well as the stabilization time that follows.

⇒ To disable this checking process, type “0” second in the “After” field.



It is not advisable to use this checking process in Humidity because a climatic chamber takes a long time to stabilize in temperature.

Humidity stability control during the measurement time

The purpose of this parameter is to ensure that the **steps analysis** found a measuring time to comply with a tolerance parameter. If the read value is out of tolerance, then the software will repeat at the beginning of the measurement time.

Parameters:

- **Enable / Disable** (disable by default): enable or not this control.
- **Start over if out of the tolerance**: if checked, when a value is out of tolerance range, then the software will restart the measurement time.
- **Tolerance**: maximum tolerance value of the standard probe.
- **Waiting time if out of tolerance (sec)**: wait time before restart the measurement time.
- **Time out (sec)**: this parameter avoids staying in loop if “the start over if out the tolerance” is activated.

Hardware tab

Calibration equipment:

- Type the model name of the calibration equipment (could be a calibration bath, drywell, climatic chamber, oven, etc.). Such information will be displayed in the calibration report.
- Type the serial number of the calibration equipment. Such information will be displayed in the calibration report.
- Type a description : allows to record any information that the operator would like to flag.
- If automated mode is checked, select the model from the list.
- Select the COM port number: drop-down menu allows to select the serial port the device is connected to.
 - **Important: Don't select this port (or another calibration probe or equipment) as interfaces in the “Configuration, Communication port configuration” menu.**
 - Attention the communication ports used by the TMI-ORION interfaces are grayed out.
- The Cooling mode checkbox is used to optimize the cold unit management for FLUKE or HART SCIENTIFIC baths.
 - **Threshold**: determines the “cooling mode”. If the Threshold value is lower than the value of the setpoint, then the “cooling mode” is “Auto” else “On”. Default value = 50°C.

When on automated mode, the cold unit of these baths is not triggered above a certain threshold.

If the setpoint temperature of the step to be performed is higher than that of the previous step, and the setpoint temperature is very close to the default trigger threshold of the bath cold unit, it may take a very long time for the bath to reach



its setpoint temperature. To solve this problem, a new trigger threshold may be set for the cold unit in the Threshold text field.

Standard probe tab

Calibration standard probe:

- Type the model name of the calibration instrument (reference probe).
- Type the serial number for the instrument
- Type some description
- If automated mode is checked, select the model from the list.
- Select the COM port number.
 - **Important: Don't select this port (or another calibration probe or equipment) as interfaces in the "Configuration, Communication port configuration" menu.**
 - Attention the communication ports used by the TMI-ORION interfaces are grayed out
- Select the channel number if more than one
- Select the protocol of communication.

Test button

Click **Test** to test the communication with the equipment and instrument (automated mode only).

Steps

From the **Step** sheet of the **Step Settings** Windows, select the number of Steps and type the details for each step:

Temperature tab

- Step Numbers is displayed in the list
- Type the temperature set point
- Type the duration for the stability
- Type the duration for the measurement
- The Type column allows to set the step type. This can be:
 - A calibration before adjustment step: As found
 - An adjustment step: Adjustment
 - A calibration before adjustment step that will also be used for adjustment: As found + Adjustment
 - A calibration after adjustment step: As left;
 - A step that allows to reach a lower temperature than that of the first calibration after adjustment step, between the adjustment step and the calibration after adjustment step: Hysteresis. Note: No measurement will be taken with this type of step.



The Hysteresis free step number (no sampling) text field is used to define the hysteresis step.

The First verification step text field is used to define the number of the first calibration after adjustment step.

Note: The only possible steps before the hysteresis step are "As found", "Adjustment" and "As found + Adjustment" steps. The only possible steps after the hysteresis step are "As left" steps.

“When the process is over, reset the equipment to” text field allows to define the temperature at which the calibration bath or oven should be reset at the end of the calibration cycle.

Humidity tab

- Step Numbers is displayed in the list
- Type the temperature setpoint
- Type the duration for the stabilization time in temperature
- Type the humidity setpoint
- Type the duration for the stabilization time in humidity
 - The stabilization time total= stabilization time in temperature + the stabilization time in humidity.
- Type the duration for the measurement
- The Type column allows to set the step type. This can be:
 - A calibration before adjustment step: As found
 - An adjustment step: Adjustment
 - Waiting the stability step: to avoid saturation in humidity
 - A calibration after adjustment step: As left

⇒ The total stabilization time = temperature stabilization time + humidity stabilization time.

- **“When the process is over, reset the equipment to”** text field allows to define the temperature and humidity at which the calibration bath or oven should be reset at the end of the calibration cycle.
- **Stop allows to** stop the humidity equipment when the process is over. Except in special cases, it is advisable to leave this value unchecked to avoid damaging the sensors of the recorders if the door of the equipment remains closed at



the end of the process for a long time (Default value = no).

The unit for the duration for the stability is minutes. It is the elapsed time before any measurement on the temperature step. Once the temperature of the bath or any other equipment equals the set point, the measurement will start after the stability duration. This duration allows perfect stability and homogeneity before measurement. Default duration is set to 30 minutes

The unit for the duration of the measurement is minutes. It is the duration for which the calibration instrument like the reference probe will be recorded (after stability). Default value is 3 minutes.

When no automated standard probe mode, in case you prefer one single reading of the standard probe at one chosen moment, select Measurement date from the list.

To add or remove steps, modify the number of steps from the list using the selection box on the top of the window.

Example of a Step Setting temperature:

#	Step (°C)	Stability duration (min)	Measurement duration (min)	Type
1	0	30	3	As found + Adjustment
2	30	30	3	As found + Adjustment
3	60	30	3	As found + Adjustment
4	90	30	3	As found + Adjustment
5	120	30	3	As found + Adjustment
6	140	30	3	As found + Adjustment

General (TDB) Settings

This tab contains "safety" parameters that allow to stop the calibration cycle.

- The Time out after (seconds) text field is used to enter the time after which the calibration process will stop if the calibration bath or oven cannot reach its set point temperature, if the Fin process Time out (Temperature) [End process if Time out (Temperature)] checkbox is checked.



Configuration CFGCET tab

The CFGCET files contain the parameters required by QLEVER to run the calibration and adjustment processes, update the configuration CET files and create the calibration certificates in automated mode.

They are specific to each type of logger.

They contain the following information:

- **Uncertainty** by quantity (e.g. 0.10 °C, 3.5 % RH...).
- **Maximum acceptable error** by quantity.

$$= \text{True value (standard probe)} - \text{Read value (logger)}$$
 - Note: A warning appears in the result tables if the logger's error exceeds the maximum acceptable error. This warning will not appear on the calibration certificate. **In setup mode, if error > this value then adjusts the logger.**
- **Maximum acceptable deviation** (max-min) on a measurement step (in units and points).

$$= \text{Max. read value} - \text{min. read value}$$
 - Note: if the measurement performed by the logger exceeds the maximum acceptable variation, the line corresponding to this measurement is highlighted in red in the result table.
- **Thermocouple** (or not). Don't check if it's the thermocouple internal channel.

A table with all the data required by QLEVER to adjust a logger (and update its CET file accordingly):

- The 1st column indicates the CET file method number.
- The 2nd column indicates its method name. Warning: the name is for information only, as when a logger is adjusted, no new CET file is created by the old file is amended. This means that the method coefficients only are changed. The original method name is retained.



- The 3rd column indicates which methods are displayed and their display order (-1 (for a cetx) ou 254 (for a cet) = non-displayed channel).
- The 4th column is used to indicate which channels are to be calibrated. Numbering starts from 0 (-1 (for a cetx) or 254 (for a cet) = ignore channel).
- The 5th column is used to indicate which channels are to be adjusted. Numbering starts from 0 (-1 (for a cetx) or 254 (for a cet) = ignore channel).
- The 6th column is used to indicate the channels that will be found by QLEVER in the QLE data file. Numbering channel starts with 1, not 0.
- The 7th column allows to enter the sensor name.
⇒ This is displaying is the report.

Loggers tab (calibration setup mode)

The loggers tab is used for enabling the “Calibration Setup”.

⇒ **Temperature Only.**

⇒ **Particularly intended for FullRadio recorders.**

⇒ **Do not add loggers from different families, for example, picovacqs with nanovacqs, or classic FullRadios with “temperature compensated” FullRadios.**

The “Calibration Setup” mode is a QLEVER option that features an automated flow of tasks including step settings, starting of the loggers, reading of the loggers. All tasks leading to calibration and adjustment jobs.

The tasks of such Setup mode are:

➔ **Step Settings**

➔ **Process creation**

➔ **Start of the loggers**

➔ **Step Generation “As found/Adjustment”**

➔ **Stop de loggers**

➔ **Reading the loggers**

➔ **Saving the data QLE file**

➔ **Step analysis for calibration and adjustment if necessary (< Maximum acceptable error)**

➔ **Report**

➔ **Start of the loggers**

➔ **Step Generation “As left”**

➔ **Reading the loggers**

➔ **Saving the data QLE file**



- Step analysis for “As left”
- Report
- End of Step Generation

Check “Activate” box so such function can be used.

Setup Mode Settings

- **Start the loggers** box checked means that the start of the loggers will be performed automatically with the Step Generation.

- **Wait the logger start date**

If checked (by default):

- Start the loggers
- Wait for the logger start time
- Equipment configuration
- Send the first Set point
- Wait the stabilization time of the equipment

If not checked:

- Start the loggers
- **No Wait** for the logger start time
- Equipment configuration
- Send the first Set point
- Wait the stabilization time of the equipment **and the loggers start time**

- **Reading of the loggers** box checked means that the reading of the loggers will be performed automatically with the Step Generation.

- **Step analysis** box checked means that the Setup will include the Step analysis.

- **As found:** means that the Setup will perform calibration with the edition of a report.
- **Adjustment:** means that the Setup will adjust the logger with error greater than the max (in the As found). Error set in the CFGCET file downloaded from the field located further down.

- **Degree of the polynomial (temperature):** in case you would like to use a specific degree of polynomial, then you should type a value between 2 and 4. Otherwise leave the 0 default value and the software will use the degree from the previous adjustment job. If is thermocouple, then the value must be = 0.
- **Always adjust:** adjustment whatever error.



- **Incident if > "value"**: used to determine the case of a "badly inserted probe" incident during calibration.
If the result of the calculation of the error is greater than this "value", then the software will notify this anomaly by a message.
(Default value = 0.5 ° C).
- **Probe defective if > "value"**: used to determine the case of a faulty probe or a sensor problem.
If one of the values of the channel of the logger is > at this "value" then the software will notify this anomaly by a message.
This mechanism will not work with a thermocouple.
(Default value = 200 ° C).
- **As left**: means that the Setup will keep the step generation for As Left job with edition of a report.
- **Print**: allows to set the type of printout for the reports.
 - **None**: no report will be print out (not recommended)
 - **Default printer**: reports will be printed on the default printer.
 - **Pdf**: reports will no printed on pdf format in an external file in QLEVER data files directory
 - **Open preview**: reports will be first displayed on a preview window.
- Check the box **"Report: Creating a single file containing all the data loggers"** to create a calibration/adjustment report including all loggers data and standard probe values. And some summary if a detailed report is chosen.
⇒ ***This option is only compatible in temperature.***

The table with the list of loggers shows the loggers used for such calibration job.

- Add or remove the available loggers. This could be automatically searching all connected loggers or manually by selecting individual loggers.


Configuration CFGCET

- Type the name of the CFGCET file corresponding to the family of chosen loggers (se General, Configuration CFGCET)

Programming tab (calibration setup mode)

This section enables you to describe the programs that you will be using:



- Click on “**Program**” to add one or several programs (*cf. 2.3 Program the loggers*)
- Click on “**–**” to remove a program
- Click on  for quick program change
- Click on “**+**” to assign the desired loggers to each program
- Click on “**–**” to remove a logger from a program

A message at the bottom of the screen will inform you whether a logger is not linked to any program.

Save

Click **Save** to save the DEFPAL+ file.

9.5 Step Generating in expert mode

Prerequisites:

- A Step Setting .DEFPAL+ file should exist.
- If no setup mode, the dataloggers should be programmed and already started (*cf. 2.3 Program the loggers*).
 - The rate is generally between 5 and 10 seconds.
- The dataloggers should be placed inside the calibration equipment.
- Switch the calibration equipment on. If this is a calibration bath, it should only be switched on when filled with calibration fluid. Commute the cooling mode switch. Switch the temperature instrument on and put it inside the calibration equipment.
- Make sure the computer is NOT synchronized with an external clock (network, internet time server...) during the calibration process.
- With an automated standard probe, the loggers MUST be started on the computer which runs the step generation (otherwise the measurement start dates of the loggers and the standard probe will be out-of-sync).

In setup mode, you should type the settings report (*Steps analysis, Settings tab, Report tab*)

Automated equipment and the standard probe mode:

- The QLEVER software can automatically generate the calibration steps.
- Once the hardware is ready, confirm the start of Step Generation.
- For every step, the QLEVER Software communicates with both the equipment and instrument to generate step, and reach the set point temperature. Measurement starts when the equipment temperature is stable.
- The measurement frequency of the standard the standard probe varies from 3 seconds to 9 seconds depending on the brand and model of connected standard probe connected.
- Every step for such process is displayed real time on the screen.
- Values measured by the standard probe are displayed real time in the “Standard probe” tab.



- Description of stages:
 - Click on “Logger/Calibration/Step generation” menu, open the step settings DEFPAL+ file and confirm by clicking “Yes”.
 - QLEVER configures the standard probe in automated mode.
 - QLEVER configures the equipment in automated mode.
 - For each step :
 - QLEVER sets the equipment to set point temperature.
 - QLEVER starts the stabilization time countdown.
 - QLEVER records values from the automated standard probe during the measurement period.
 - Once the measurement period is completed, QLEVER calculates the mean, min., max. and standard deviation.
 - End of step generation.

Note: When the stabilization time ends, the measurement starts, so both dates must be equal.

Automated equipment and manual standard probe mode:

- For every step, the operator should type the exact start date for the first temperature readout together with the average temperature value given from all the values taken during the measuring duration.
- Min., max. and standard deviation values entry is optional.
- Click “**Save**” for recording.
- Description of stages:
 - Click on “Logger/Calibration/Step generation” menu, open the step settings DEFPAL+ file and confirm by clicking “Yes”.
 - QLEVER configures the equipment in automated mode.
 - For each step :
 - QLEVER sets the equipment to setpoint temperature.
 - QLEVER starts the stabilization time countdown.
 - Wait until the stabilization period ends.
 - QLEVER displays “Reading in progress”.
 - Click “OK” and note the values measured by the manual standard probe.
 - QLEVER starts the measurement period countdown.
 - Once the measurement period is completed, calculate the mean of your measured values. Place it in the appropriate step line in QLEVER “Standard Probe” tab.
 - Min., max. and standard deviation values entry is optional.
 - End of step generation.
 - Click on “Save”.

Manual equipment and automated standard probe:

- The operator should synchronize the software with the equipment to get the same stabilization time.
- Description of stages :



- Click on “Logger/Calibration/Step generation” menu, open the step settings DEFPAL+ file and confirm by clicking “Yes”.
- QLEVER configures the standard probe in automated mode.
- For each step :
 - QLEVER displays the message “Put the set point of the equipment to x °C”
 - Set your equipment to the requested set point temperature.
 - Go back to QLEVER, then click “Yes”.
 - QLEVER starts the stabilization time countdown.
 - Once the stabilization period is completed, QLEVER starts recording values from the automated standard probe.
 - QLEVER records the values during the measurement period.
 - Once the measurement period is completed, QLEVER calculates the mean, min., max. and standard deviation.
- End of step generation.

Manual Equipment and Standard Probe mode:

- The operator should monitor the set point temperatures and stabilization times of his equipment.
- The user MUST note the first measurement exact start date from the computer clock, or synchronize the probe time with the computer clock (otherwise the measurement starts dates of the loggers and the standard probe will be out-of-sync).
- For every step, the operator should type the exact start date for the first temperature readout together with the average temperature value given from all the values taken during the measuring duration.
- Min., max. and standard deviation values entry is optional.
- Click “Save” for recording.
- Description of stages:
 - Click on “Logger/Calibration/Step generation” menu, open the step settings DEFPAL+ file.
 - QLEVER displays the steps table
 - For each step:
 - Set your equipment to the requested set point temperature.
 - Wait until the stabilization period ends.
 - From then and during the measurement period, note the values measured by the manual standard probe.
 - Once the measurement period is completed, calculate the mean of your measured values. Place it in the appropriate step line in QLEVER “Standard Probe” tab.
 - Min., max. and standard deviation values entry is optional.
 - End of step generation.
 - Click on “Save”.

The data is recorded in a Step Generating GENPAL+ file. The name of the file is just the same as the Steps Setting DEFPAL+ file that was previously selected.



9.6 Steps Analysis in expert mode

Calibration and/or Adjustment can be done using the window based on the earlier GENPAL+ Step Generating file.

Prerequisites:

- One or more existing GENPAL+ Step Generating files.
- When in the automated mode, the dataloggers should have been stopped and with data downloaded within a QLE file in as found mode, adjust mode or as left mode.
- **Is not possible to calibrate or adjust different type of loggers in the same time because only one CFGCET can be loaded.**
- Excluded QLE channels are not used.
- **Important: If you use temperature and humidity logger, you don't only adjust the temperature!**
- Remote compensated temperature recorders must be read again in "Adjustment (thermocouple)" mode (to have the temperatures in values).

Click "**Logger > Calibration > Steps Analysis (expert mode)**".

For each step:

- The value for the calibration instrument is the reference value.
- The value from the channel f the data logger to be calibrated/adjusted is the readout value.
- The error is the difference between both the above values.

9.6.1 Files

1 Choose a type:

"As found", "Adjustment" or "As left".
("All" is only for all preview type)

2 Open a Step Generating file.

- Select one or more GENPAL+ Step Generating files
- For every file, the table will show the name of the file and the GUID, the name of the equipment, the name of the instrument and for every step, the date of the measurement, the duration of the measurement as well as the readout.
- Click "**—**" to remove a step from the list

3 Select the CFGCET file corresponding to the logger(s) to be calibrated.


If missing, ask to TMI.

4 Open a QLE data file

- Select one or more QLE file with recordings from datalogger(s) (Right click on the QLE button, open the QLE file in the same directory than the GENPAL+ file).
- For every file, the table will show the name of the datalogger, the name of the file



and the GUID, the start and end date for recording as well as the date for the configuration file for the specific logger.

- Click “” to remove a logger from the list.
⇒ In Adjustment, the logger data (pt100,pt1000) are in points (pt).

5 Report

- Check the box “**Report: Creating a single file containing all the data loggers**” to create a calibration/adjustment report including all loggers data and standard probe values. And some summary if a detailed report is chosen.
 - ⇒ This option is only compatible in temperature.
 - ⇒ The default report is only a logger per report.

Validate and check the files selection when clicking “**Next**”.

9.6.2 Steps Analysis table in expert mode

For every datalogger, the table will display:

- The serial number for the datalogger.
- The names of the temperature channels.
- The values of the temperature steps.
- The date of the readout from the reference sensor.
- The average value from the readout of the reference sensor.
 - The average is calculated with unrounded values of the reference sensor while the measurement time.
- The average value from the readout of the temperature channel of the datalogger.
 - The average is calculated with unrounded values of the datalogger channel while the measurement time.
- The error that would be the difference between both above values.
- The minimum, the maximum, the max-min and the standard deviation of the reference sensor.
- The minimum, the maximum, the max-min the standard deviation and the number of acquisitions of the temperature channel of the datalogger.
- The max spread in temperature (maximum deviation at a given date between the value of the channel and the corresponding value of the standard probe).
 - The value of the channel when this deviation is maximum.
 - The value of the probe when this deviation is maximum.
 - Date of the instantaneous difference.
 ⇒ In the case where there is no acquisition of the standard probe on the same date as that of the channel, the date and the value of the standard probe will be interpolated between the value of the previous and next acquisition of the logger.
 ⇒ Therefore, if you care about this notion of interpolation (or linearization), it is preferable that:
 - The recording rate of the loggers is 1 second per acquisition to reduce the risk of interpolation.
 - The calibration probe must be able to record at a rate of 1 second per



acquisition.

- ⇒ Only if “**Report: Creating a single file containing all the data loggers**” is checked.
- ⇒ Only in temperature.
- ⇒ Only if “Max Spread” is checked in 21CFR secure mode (see Administrator operator/approval rights).
- Polynomial degree. If thermocouple the value is not editable.
 - ⇒ Only if checked is checked in 21CFR secure mode (see Administrator operator/approval rights).

It is possible to select the dataloggers or channels using the box. At this stage, it is not possible to remove a temperature step.

From the bottom part of the window, it is possible to:

- Type the uncertainty of the dataloggers.
- Check the box so the software selects the channels of the dataloggers related to the chosen value in \pm °C. This ⚠ icon will displayed when the difference between the average channel – average probe is greater than the threshold.
- Check the box to allow export of the data to a text file.
- Max error is calculated and displayed.

9.6.3 Edit manually the calibration values

Click on the column to type or edit the calibration values (not in secure mode):

- Date and time of measurements.
- Values of the reference sensor readout.
- Values of the channel of the logger.
- Polynomial degree (if thermocouple the value is not editable).

9.6.4 Probe data exportation

It's possible to export the standard probe raw data in a file:

- Select probe tab
- Right click on the table
- Export data menu
- Excel parameters:
 - ; as separator
 - .csv for the extension file
 - Open after saving
- Click on “**Export**” button



9.7 Generating calibration report

- Select the datalogger(s) and channel(s) needed for such calibration report.
- Click “Create the report”
- Type or edit the various texts for the header of the reports in the Report Settings window (*cf. 9.9 Settings for the calibration report*).
- Click “**Next**”
- Select the folder within the TDB where the reports will be saved. Default folder will be “**Report\Calibration**”.
- If the “**Preview**” box was checked, the preview of every calibration report will be displayed. Every report can be then printed.
- If “**Detailed Report**” box was checked, you can check some parameters (see settings for the report” for more explanations).
- A new window will appear.
- If the dataloggers need adjustment, then click “Step Analysis” otherwise, click “Exit”.

9.8 Start the adjustment and create a calibration/adjustment report

Prerequisites:

- The dataloggers to be adjusted should be connected to the interface.
- By default, the requested step number for adjustment is equal to the step number.
- In secure mode, the operator account does not have the rights to adjust.

In order to adjust:

- Select the dataloggers that need adjustment (the other dataloggers won't be display anymore).
- Click “**Adjustment**” in order to calculate the transfer function and display two new columns “Adjustment” that include:
 - The new value given from the adjusted channel.
 - The bias (error) after the transfer function is applied.
- Click “**Continue Adjustment**” to confirm the adjustment of the checked dataloggers.
- Type or edit the various texts for the header of the reports in the Report Settings window (*cf. 9.9 Settings for the calibration report*).
- Click “**Next**”.
- The Adjustment window will appear.
⇒ A no adjustment report will be printed if a logger could not be adjusted for a technical raison (eg, low battery, not connected,...)

New configuration files CET can be created so the new transfer function can be calculated within every connected datalogger.

The CET configuration files can be exported. To do so, check the “**CET Export**” box before



clicking **“Complete the Adjustment”**. The files will be exported to the directory that can be configured from the menu **“Configuration > Directory Management > External file”**. They can be later exported from **“Configuration > Managing Configuration files”**.

In order to complete the adjustment for every datalogger:

- Connect the datalogger(s) to the interface.
- Click **“Complete Adjustment”**.
- The calibration/adjustment report will be automatically saved within the **“Report\Calibration”** folder from the TDB or any other chosen directory.
- Repeat according to the number of loggers and interfaces that you use.

In order to restore a previous adjustment (*cf. 2.1 CET/CETX Configuration files installation*).

9.9 Settings for the calibration report

Steps analysis, Settings tab, Report tab

From such window, information for the calibration/adjustment report can be typed for every logger.

- Open Preview: if checked then the preview of the report will be displayed on the screen and printing will be possible by clicking on the Printer icon.
- Detailed Report: if checked then an additional page will be printed showing
 - Each step, the date, the name of the operator and the GUID of the used files.
 - Last adjustment date in the first page
- For each selected logger:
 - Table of average.
 - Table of Min. and max.
 - ⇒ Only if **“Report: Creating a single file containing all the data loggers”** is checked.
 - Table of max spread.
 - ⇒ Only if **“Report: Creating a single file containing all the data loggers”** is checked.
 - ⇒ Only in temperature.
 - ⇒ Only if **“Max Spread”** is checked in 21CFR secure mode.

Comment	Display order	Explanation of the comment column of the table of temperature max spread
Faulty probe	1	This error message appears in the report when the value of the channel of the logger is > to the value of the field "Faulty probe" (entered in the "Step settings" screen, "Logger" tab). Displayed only if Setup mode is enabled.
Incident	2	This error message appears in the As Found, As Left report when the error is > to the value of the "Incident" field (entered in the "Step settings" screen, "Logger" tab). Displayed only if Setup mode is enabled.
Error > +value of	3	This error message appears in the report where the error is found. Same error as in the table of average: the error exceeded the



temperatur e		adjustment criterion.
Error > - value of temperatur e	4	This error message appears in the report where the error is found. Same error as in the table of average: the error exceeded the adjustment criterion.

⇒ In the case of a thermocouple, case 1 can not be dissociated from case 2 because if a thermocouple probe is poorly connected or defective, it will be the ambient temperature inside the case that will be measured.

Summary table:

- Table of max of max spread.
 - ⇒ Only if “**Report: Creating a single file containing all the data loggers**” is checked.
- Table of max spread.
 - ⇒ Only if “**Report: Creating a single file containing all the data loggers**” is checked.
 - ⇒ Only in temperature.
 - ⇒ Only if “Max Spread” is checked in 21CFR secure mode.

Switch Contractor or Comment

Contractor/Place of Calibration:

- Name, address and phone number of the service company that performed the calibration operation.

Comment:

- Text of comment

Logo:

- Picture: logo of the company to displayed on the top of the report next to the name and address.


Delivered to:

- Company/Department: Name, address and phone number of the company to whom the report is to be delivered.
- If the operator and service company details are the same, click the arrow button to copy the information.
 - ⇒ If you do not want to print block in the report then do not enter anything in "Company/Department"
- Place: name or place of the calibration lab.
- Calibration conditions: this is a text describing the conditions of the datalogger immersed in the bath.
- Calibration procedure.
- Adjustment procedure.
- Calibration method and comments.

Empty fields are not printed

Click “**Next**” to continue and save the changes for the following reports.



⇒ In the **Error** columns, “E” will displayed if the Error is greater than the threshold (see )

9.10 Printing a calibration/adjustment from a saved report

- Open the Directory Management
- Go to the directory “**Report\Calibration**” or any other folder chosen for saving the reports.
- Open a report.
- Click the Printer icon to print the report.

9.11 Change the text from a saved report

- Open the Directory Management
- Go to the directory “**Report\Calibration**” or any other folder chosen for saving the reports.
- Select a report.
- Click the “**Modify**” button.
- Make the changes and click “**Save**”.
- Click “**Print**” to preview the report.
- Click the Printer icon to print the report.

9.12 Difference between calibration and calibration expert mode

Functionalities	QLEVER modules		
	Expert Mode	Automated Mode	Manual Mode
Calibration of TMI ORION Temperature loggers	X	X	X
Calibration of TMI ORION Humidity loggers	X		
Calibration equipment	X	X	



drivers library			
Fully Automated programming and reading processes	X		
Synchronization based on external clock	X		
Single and multi-loggers report	X	X	X
FDA 21 CFR Part 21 option (secured mode)	X	X	X






























Chapter - 4 Appendix

1 Hardware configuration of supported calibration equipment




Hardware configuration	Baud rate	Stop bit	Data bit	Parity
AOIP® (standard probe)	9600	1	8	No
Fluke® 1502A (standard probe)	2400	1	8	No
HART® Black Stack 1560 + 2560 (standard probe)	2400	1	8	No
FLUKE® 1521	2400	1	8	No
FLUKE® 152x - 1523 and 1524 (Thermometer readout)	9600	1	8	No
HART® Deep-Well Calibration Bath model 7341, 7321 and 7381 (Calibration Bath), 9127	2400	1	8	No
LAUDA® (bath)	9600	2	8	No
LAUDA® (bath), TYPE RP3530 (PROLINE)	9600	1	8	No
HART/FLUKE® Micro-Bath model 6102, 7102 and 7103 (bath)	2400	1	8	No
FLUKE® Well Calibration Bath model 917x (bath)	9600	1	8	No
Fluke® 9190A (ultra-cool dry-block calibrator)	9600	1	8	No
CTS® Clima temperature system (Adress= 1, CID /ASCII)	19200	0	8	Odd parity Parity bit = thru
Optidew Mitchell® (Series 97430 et Modbus rtu Series 401,501,...)	9600	1	8	Parity none without flow control
VOTSCH® and ENVIROTRONICS®	9600	1	8	Parity none, without flow control
THUNDER SCIENTIFIC 2500	9600	0	8	Parity none, without flow control
THUNDER SCIENTIFIC 2900	57600	0	8	Parity none, without flow control

2 Explanation of symbols

Icon	Explanation
	QLE data file (logger data)
	Setup Pharma
	Setup Autoclave validation
	Setup Washer disinfectant validation
	Setup Mapping
	Setup Rotation
	Kiln
	CET / CETX configuration file or loggers configuration panel
	Error related to a CET / CETX configuration file
	Icon for either a start of the recorders (recording) or a "Process" being recorded.
	Icon for either a Read of the recorders or read a process.
	If it's a file of the type "Process": indicates that the data of the recorders of this process file were re-read in a data file QLE) or a "Process" being recorded.
	File opened and locked in reading / writing mode by a user
	Unlock file
	RS232 Serial port
	Serial port (COM / RS232)
	Serial port (COM / RS232) in error or already used
	Mono-USB interface, 1 logger
	Multi-USB interface, up to 6 loggers
	Multi-USB interface, up to 12 loggers
	Radio-Frequency interface, wireless
	Logger / Logger column
	FullRadio logger
	Rotation logger
	FullRadio network
	Erase memory of selected loggers
	Full load battery

Icon	Explanation
	Low battery
	User management
	Audit file of the software or a QLE data file (21 CFR Part 11)
	Units management
	Calibration step settings
	Calibration step generation
	Calibration step analysis
	Locked resource or action
	Computed column / Calculation library
	Report
	Approved report
	Update status of connected loggers
	Update status of all loggers
	Stopped logger
	Stop selected loggers
	Stop all loggers
	Start selected loggers
	Start all loggers
	Add a logger, a programming, a zone, a file...
	Remove a logger, a programming, a zone, a file...
	Error
	Error
	In setup mode, exclude a logger
	Not in use logger's channel
	Excluded logger's channel
	Information symbol on the logger configuration date
	Information symbol on the logger configuration date (may be locked in 21CFR)
	In Calibration Step Analysis, this symbol is displayed when the error is greater than the threshold
m	Minimum (min)
M	Maximum (max)



Icon	Explanation
\bar{x}	Average (agv) arithmetic is the "simply" mean. Agv = the sum of the numerical values divided by the number of these numerical values.
s	Standard deviation (s or std)
	Zoom
	Hygrometer channel
+++	Indicate that the value is too big
	Microsoft Windows™