TMI-Orion

Qlever Software

Industrial processes

Acquisition, analysis and visualization of data measured by TMI-Orion data loggers placed inside industrial processes.

Qlever is a software solution for the acquisition, analysis and visualization of data measured by TMI-Orion data loggers.

Qlever features:

*   Define the validation and qualification parameters of your processes (load plan, normative values...)
*   Generate, verify and approve industry specific reports.

Qlever software works in combination with specific software modules to answer the needs of the different industries.

Optional: Compliant with FDA 21 CFR Part 11 directives and FD X15-140/IEC 60068.3.11 norm.

Qlever software is easy to use, intuitive, and allows customization by the user.
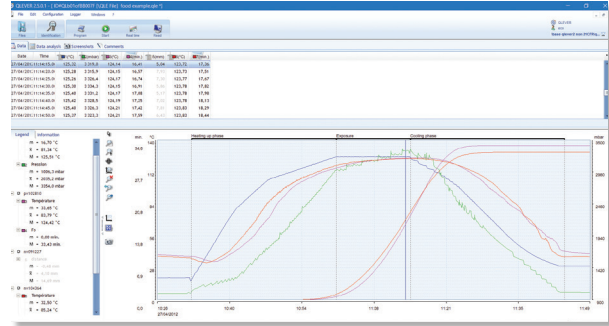
HIGHLIGHTS

*   **Data treatment and presentation in an extensive validation and qualification report compliant with applicable norms (optional).**

*   **Creation of setup library per application describing the configuration, the setup of TMI-Orion datalogger and customer equipment, as well as calculations to apply on collected data (optional).**

*   **Data and access tracking, modifications follow-up, for compliance with FDA 21CFR Part 11 directives (optional).**

*   **Real time supervision of industrial processes, with TMI-Orion FullRadio or radio data loggers placed inside the processes.**

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Qlever SOFTWARE

Two versions of Qlever Software are available:

- **Qlever Software:** Software platform dedicated to one or more TMI-Orion data loggers. Works in combination with one or more software modules.

- **Qlever Lite Software:** Simplified software solution for the management of a single wired TMI-Orion data logger. Cannot be combined with software modules. Environment limited to its setup and programming, treatment and display of a selection of data (F0, A0, Vp, saturated steam).

Functions	Qlever	Qlever Lite
Data collection and treatment		
Setup and programming of TMI-Orion equipment	•	•
Collection and recording of measured data	•	•
Compatible with universal thermocouple data loggers	Version 2.3.0.0 and above	Version 2.3.0.0 and above
Standard calculations: F0, A0, Vp, saturated steam, dew point, etc.	•	•
Possible export of raw data to a spreadsheet	•	•
Up to 30 crypted databases, local or on a server	•	•
Compatible with USB single data logger communication interface (Mono USB)	•	•
Compatible with USB multiple data logger communication interface (MOUSB, Multi USB)	•	
Creation of calculation libraries and automatic calculations upon data reading	•	
Curve overlay and fusion (data files except setup)	•	
Management of radio and FullRadio TMI-Orion data loggers	•	
Collection and visualization of real time data from TMI-Orion radio and FullRadio data loggers	•	
Can be combined with all Qlever software modules	•	
Data analysis and display		
Optional compliance with FDA 21 CFR Part 11	•	
Data analysis and statistics: minimum, maximum, average, maximum gap, type gap, time above, time under, ramp time, balance time, MKT, slope calculation...	•	
Creation of validation reports	•	

OPTIONAL SOFTWARE MODULES

• Authentication-tracking module – FDA 21 CFR Part 11 compliant:

- Secured management of user access, with creation of different accounts and access levels. (Administrator, approver, operator). Report verification and approval.

- Verbose audit trail with complete tracking of processes and data, including addition, deletion, modification operations.

Example of Audit trail

• LDAP module for user management

The Administrator may use the Microsoft Windows Active Directory LDAP to override Qlever user management. This optimizes consistency in user authorization management throughout the company information system.

This module requires the Authentication-tracking module.

• Mapping module

Data treatment and presentation in an extensive report compliant with **FDX 15-140 / IEC 60068.3.11**,

Intended for characterization and checking of temperature

and humidity in climatic and thermostatic chambers or other kinds of thermal regulation devices such as rooms, ovens, autoclaves.

Door opening and power cut tests with recovery time calculation.

Creation of relative humidity calculated channels with:
• data loggers placed in the chamber
+ 1 temperature data logger and 1 humidity data logger, OR
• data loggers placed in the chamber
+ 1 Optidew® hygrometer

Mapping module visualization example

• Autoclave validation module

Data treatment and presentation in an extensive validation report.
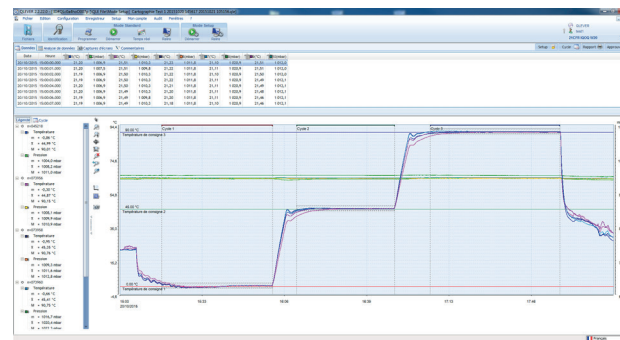
Intended for autoclave qualification and sterilization cycles validation.

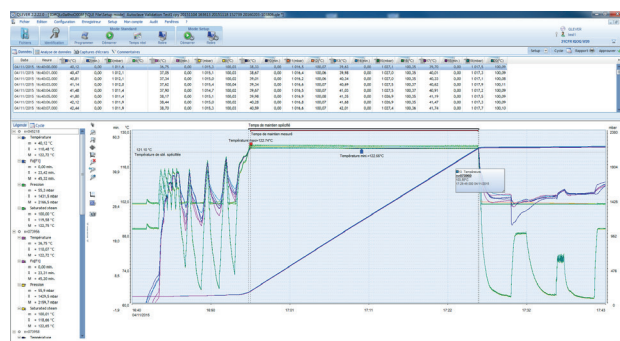Analysis of vacuum test, pre-treatment phases, plateau phases...

Calculation of saturated steam, calculation of F0 sterilization value, calculation of dynamic pressure, air evacuation calculations for heat penetration analysis in sterilization cycle pre-treatment.

Autoclave validation module visualization example

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SUPPORT

IQ/OQ validation protocol

TMI-Orion offers optional documentation support including the installation qualification protocol and the operational qualification protocol (IQ/OQ - Installation qualification and Operational Qualification) of each Qlever module. The validation protocols are usually integrated in the customer quality process.

Optional IQ/OQ protocol validation support.

Commissioning

Optional commissioning support for TMI-Orion system.

TECHNICAL SPECIFICATIONS

- Multilingual environment.
- Data files in TMI-Orion proprietary format.
- The database is encrypted and cannot be modified.
- Database administration services (user account and access management, restore and save, reindex...).
- Single station or multiple stations database use (user data sharing)
- Keyword search engine.

- Secured data file import or export.
- Multiple station Qlever licence.
- Compliant with Windows® 7/8/10/11.
- Minimum requirement for software installation:
  - RAM : 8 Go
  - Disk space: 200 MB (Not including data measured by the loggers)

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