DATA SHEET

TMI-Orion

CalPower

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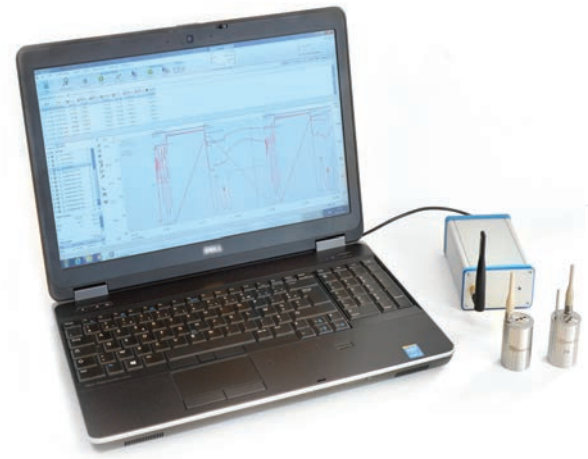
Qlever Software

Food processing
Pharmaceutical
Medical



Software solutions for TMI-Orion data loggers monitoring inside pharmaceutical, medical and food industries processes.

Qlever is a software solution for the acquisition, analysis and visualization of data measured by TMI-Orion data loggers. Qlever helps define the conditions of use of TMI-Orion and customer equipment, collect raw data, calculate and create industry oriented measurement and validation reports. It offers ease of use, flexibility, and customization.

TMI-Orion offers a wide range of industry oriented software modules which work in combination with Qlever software platform. A choice of Qlever Modules address the specific reporting needs of the pharmaceutical industry, laboratories, health centers, autoclave validation, medical device manufacturers, and the food processing industries.

Qlever is a highly reliable software solution used with TMI-Orion data loggers, including FullRadio loggers which allow monitoring and process control of industrial processes.

Qlever SOFTWARE PLATFORM

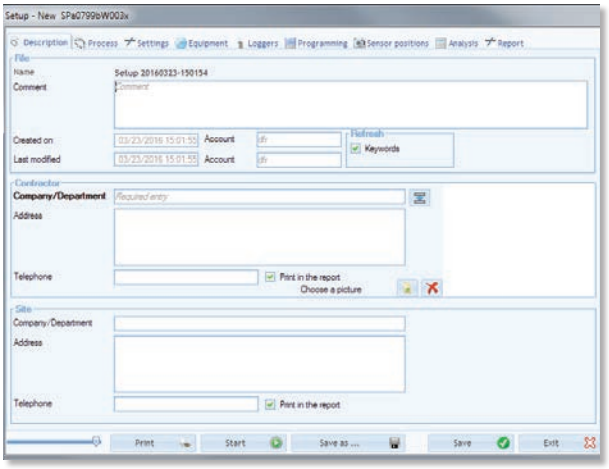
Qlever is the general platform of our software offering. It operates alone or in combination with one or several industry specific software modules.

• **Qlever:** Software platform dedicated to the management of one or several TMI-Orion data loggers.

Set up and programming of TMI-Orion equipment, collection of data, processing (lethality calculations F0 / A0 / Vp, saturated steam, ...), analysis and display of data.

• **Qlever Lite:** Simplified software solution intended for managing a single wired TMI-Orion data logger. Cannot be combined with any of the software modules.

Only for set up and programming as well as for processing and visualization of a selection of data (F0, A0, Vp, Regnault).



Example: Setup Window

Raw data from TMI-Orion data loggers cannot be modified. The entire database is secured by encryption.

Functions	Qlever	Qlever Lite
Set up and reading of the data loggers	•	•
Calculations: F0, A0, Vp, saturated steam	•	•
Data exportation to spreadsheet	•	•
Encrypted databases	•	•
Compatible with a USB mono logger communication interface	•	•
Compatible with a USB multi logger communication interface	•	
Data analysis and statistics: minimum, maximum, average, maximum spread, standard deviation, time above, time under, ramp time, equilibration time, MKT, calculation of slope...	•	
Library of calculations and automatic calculations upon reading the data	•	
Overlap and merging of curves (data files except set up)	•	
Manages TMI-Orion FullRadio data loggers	•	
Real time data collection (FullRadio/wired)	•	
Compatibility with the Authentication-tracking software module (compliant with FDA 21 CFR Part 11)	•	
Can be combined with all software modules	•	

SOFTWARE MODULES

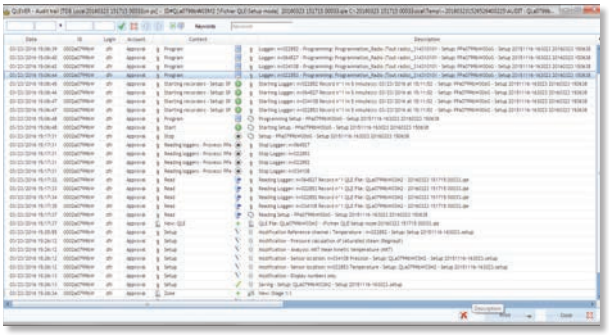
TMI-Orion offers a range of industry oriented software modules which can be combined to answer the specific reporting requirements and needs of pharmaceutical industry, medical sector and food processing industries. These modules operate together with Qlever software platform.

• Authentication-tracking Module – Compliant with FDA 21 CFR Part 11

Dedicated to secure management of user access, with creation of different accounts and access levels (Administrator, approval, operator).

Complete tracking of processes and data including any addition, deletion or modification operation (Audit Trail).

This module is also included in the Pharma module.



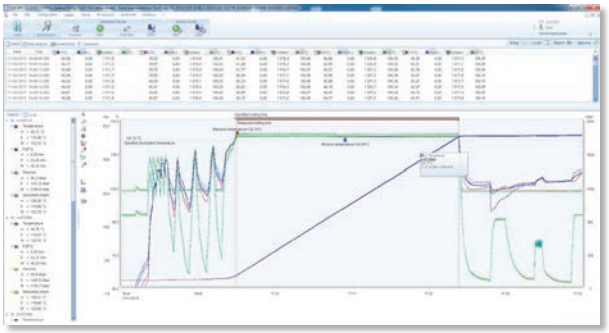
Example of audit trail

• Pharma Module - Compliant with FDA 21 CFR Part 11

Meets the requirements of the pharmaceutical industry.

Dedicated to all thermal cycle analysis.

An extensive measurement report with statistical calculations detailed by cycles and steps.

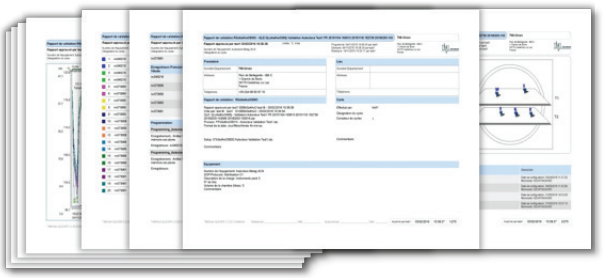


Example of graphic visualization

• Autoclave validation module

Intended for analysis and validation of humid heat sterilization cycles and vacuum test.

Data treatment and presentation in an extensive validation report in compliance with **ISO 17665 / EN 13060 / EN 554 / EN 285.**

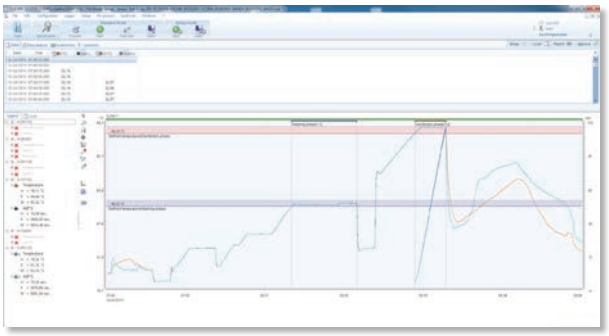


Example of validation report

• Washing-disinfection module

Meets the requirements of the industry. Intended for analysis and validation of washing and disinfection cycles.

Data treatment and presentation in an extensive validation report in compliance with **ISO 15883**.

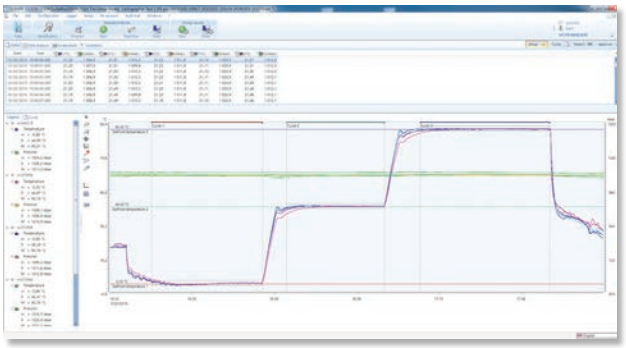


Example of graphic visualization

• Mapping module

Intended for climatic and thermostatic chambers – or any kind of thermal regulation devices such as rooms, ovens, autoclaves - characterization and checking of temperature and humidity.

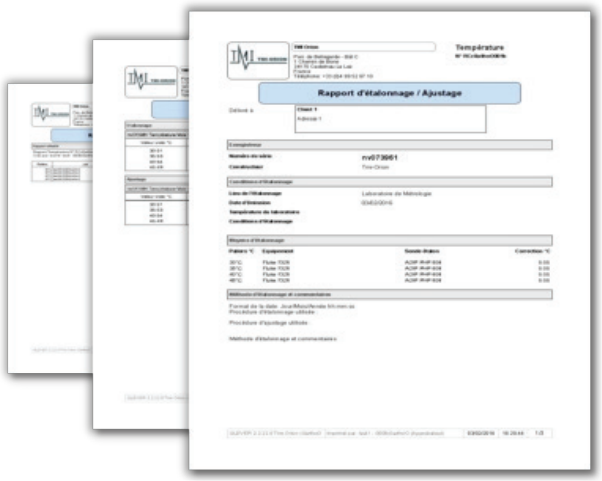
Data treatment and presentation in an extensive compliance report with **FDX 15-140 / IEC 60068.3.11**.



Example of graphic visualization

• Calibration module

Dedicated to TMI-Orion temperature and humidity loggers calibration process: calibration, adjustment, checking and editing of a report. Available with a library of drivers, to communicate with a wide variety of calibration equipment: baths, ovens, reference probes. Delivers a calibration and adjustment report. manual mode, automatic mode and expert mode available.



Example of calibration report

Calibration mode

Functions	Expert mode	Automatic mode	Manual mode
TMI-Orion temperature sensors calibration	•	•	•
TMI-Orion humidity sensors calibration	•		
FDA 21 CFR Part 21 option / Secure mode	•	•	•
Library of drivers for calibration devices	•	•	
Programming of Full-Automation scenarios	•		
Synchronization on external clock	•		
Mono and multi logger report	•		
Advanced control of calibration processes	• • •	• •	•
Advanced set up and display	• • •	• •	•

SOLUTIONS Qlever

		Pharmaceutical industry	Medical sector	Food processing industry	
Software		Qlever	Qlever	Qlever	Qlever Lite*
Software modules	**Pharma** (FDA 21 CFR Part 11)	●			
	Authentication-tracking (FDA 21 CFR Part 11)	*Included in the Pharma module*	■	■	
	Autoclave validation (ISO 17665 / EN 13060 / EN 554 / EN 285)	■	●		
	Washing-Disinfection (ISO 15 883)	■	●		
	Calibration	●	■	■	
	Mapping (FDX 15-140 / IEC 60068.3.11)	■	●	■	
Service	IQ/OQ protocol	●			

● recommended ■ optional

**Qlever Lite cannot be combined with software modules.*

IQ/OQ validation protocol:

TMI-Orion offers an optional document including the installation qualification protocol and the operational qualification protocol of each Qlever software module. The validation protocols generally integrate in the customer quality process.

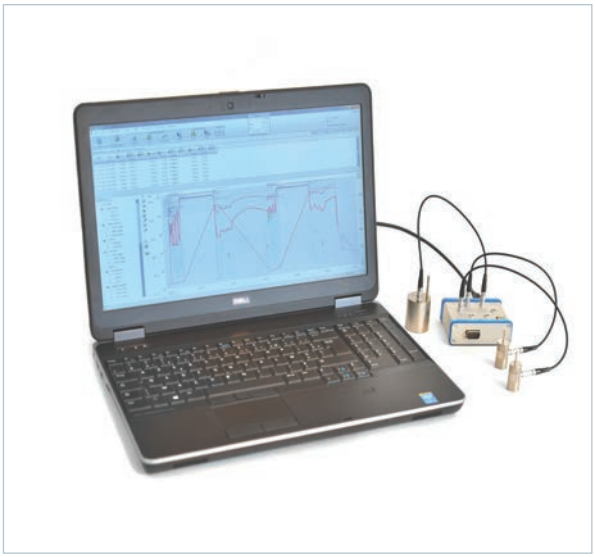
TECHNICAL SPECIFICATIONS

- Multi-lingual environment.
- Compatible with Windows® Vista / 7 / 8 / 10.
- Intuitive interface and file management.
- TMI-Orion format data files.
- Raw data cannot be modified, and the entire database is highly secured by encryption.
- Database management services (rights management…)
- Mono or multi workstations (sharing of data with network users).
- Search engine by key words.
- Import and export of data files.
- Database backup and restore.
- Minimum environment for the software:
  - RAM: 4 GB
  - Disk space: 200 MB (not including the data measured by the loggers)

USER BENEFITS

- Real time supervision of industrial processes with TMI-Orion FullRadio data loggers placed inside the processes.
- Creation of industry/application file libraries describing TMI-Orion data loggers and customer equipment configuration and programming, as well as the calculations performed on collected data.
- **FDA 21CFR Part 11** compliant with an encrypted database, secure access, audit trail and data modification prevention.

Qlever operating with FullRadio loggers



Qlever operating with loggers connected to a Multi USB interface

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