INDUSTRY FLYER

TMI-Orion

PHARMACEUTICAL
MEDICAL

HIGH TECH DATA LOGGING SOLUTIONS

TMI-ORION

www.tmi-orion.com

TMI-Orion

Pharmaceutical Medical

TMI-Orion presents a full range of high tech data loggers designed for medical and pharmaceutical industries, measuring temperature, pressure, humidity, in a variety of processes:

- **Steam sterilization**
- **Ethylene oxide sterilization**
- **Depyrogenation**
- **Freeze-drying**
- **Mapping of climatic and thermostatic chambers, freezers, cold rooms, etc...**
- **Spray**
- **Washing-disinfection**

TMI-Orion data loggers work with a dedicated software for visualization and data management in compliance with the regulations and norms:

FDA 21 CFR Part 11
EN 554
ISO 17665
EN 13060
EN 285
EN 868
EN ISO 15883
FD X15-140/IEC 60068.3.11
IQ/OQ protocol is available as an option.

TMI-Orion offers a high tech range of solutions for medical and pharmaceutical industries that combines performance, reliability and lasting quality.

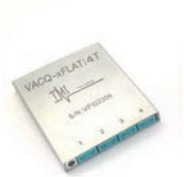
THE COMPANY

TMI-Orion has been a world leader in the design and manufacture of advanced solutions for measurement, validation, quality control and process control in harsh environments since 1994.

TMI-Orion offers a wide range of real time and wireless 2.4 GHz data loggers, and a software platform for the management and visualization of process data. Thanks to a 20-year strategy of scientific research and industrial development, the company is able to create sophisticated solutions to meet technological challenges and to answer the needs of its customers' demanding applications. Thanks to a high level of adaptability, TMI-Orion can also design customized solutions, in close cooperation with customers.







INDUSTRIAL PROCESSES OF MEDICAL AND PHARMACEUTICAL INDUSTRY

Steam sterilization validation

Steam autoclaves are used to sterilize products inside vials, bottles, pouches, and most pharmaceutical and medical equipment.

During the sterilization process, the temperature must reach a definite temperature for a determined period of time. TMI-Orion offers solutions to monitor temperature inside containers and temperature and pressure inside the autoclaves, with loggers of different sizes and various types of probes.

TMI-Orion solutions

- **Data loggers**
  PicoVACQ or NanoVACQ or VACQ xFlat
- **Software**
  Qlever software platform
  + Pharma Module (FDA 21 CFR Part 11)
  + Calibration Module
  + LDAP Module: optional
  OR
  Qlever software platform
  + Authentication-tracking Module (FDA 21 CFR Part 11)
  + Calibration Module
  + Autoclave validation Module (ISO 17665 / EN 13060 / EN 554 / EN 285 / EN 868): optional
  + LDAP Module: optional
- **Connectivity**
  2.4 GHz radio modem or wired interface for NanoVACQ and VACQ,
  Wired interface for PicoVACQ.

Ethylene oxide sterilization validation

Sterilizing with EtO implies low temperature long lasting cycles. Ethylene Oxide sterilization validation requires measuring relative humidity and temperature parameters inside the chambers wih ATEX compliant data loggers, such as the NanoVACQ HT Ex.
TMI-Orion has a range of **ATEX compliant data loggers** marked “II 1G Ex ia IIC T3 Ga” or “II 1G Ex ia IIC T6 Ga” and compliant with regulations **EN 60079-0 and EN 60079-11**.

TMI-Orion solutions

- **Data loggers**
  NanoVACQ Ex or PicoVACQ Ex
- **Software**
  Qlever software platform
  + Pharma Module (FDA 21 CFR Part 11)
  + Calibration Module
  + LDAP Module: optional
- **Connectivity**
  2.4 GHz radio transceiver or wired interface for NanoVACQ,
  Wired interface for PicoVACQ.

Depyrogenation

Depyrogenation, or dry heat sterilization process, uses hot air to reduce the level of pyrogens in static ovens or in tunnels.

In the process, temperature is measured with platinum or thermocouple sensors, protected by a thermal shield. Data loggers and thermal shields are selected according to the specific needs of the process and the characteristics of the oven or tunnel.

TMI-Orion solutions

- **Data loggers**
  PicoVACQ 1Td or VACQ xFlat with thermal shield
- **Software**
  Qlever software platform
  + Pharma Module (FDA 21 CFR Part 11)
  + Calibration Module
  + LDAP Module : optional
- **Connectivity**
  2.4 GHz radio transceiver or wired interface for VACQ xFlat,
  Wired interface for PicoVACQ.

Freeze-drying processes validation

Taking the water out of a product is a way to obtain a more stable product, smaller in volume and weight. This process freezes the product at low temperature, applying vacuum and heat so the ice can evaporate.

This process requires measuring the temperature of the chamber and the product.

TMI-Orion provides solutions based on platinum sensors at the end of flexible or semi-rigid probes that can easily fit into small vials through the rubber cap.

TMI-Orion solutions

- **Data loggers**
  NanoVACQ 1Tc-2Td or NanoVACQ 1Tc-2Tdi or PicoVACQ 1Td or PicoVACQ 1Tdi
- **Software**
  Qlever software platform
  + Pharma Module (FDA 21 CFR Part 11)
  + Calibration Module
  + LDAP Module : optional
- **Connectivity**
  2.4 GHz radio transceiver or wired interface for NanoVACQ,
  Wired interface for PicoVACQ.

Mapping of climatic and thermostatic chambers, freezers, cold rooms, etc...

Mapping is necessary to ensure all points of the chamber are at the required temperature.

A data logger operating for days at low temperature is recommended.

TMI-Orion solutions

- **Data loggers**
  NanoVACQ Temperature or PicoVACQ or MiniVACQ or VACQ xFlat
- **Software**
  Qlever software platform
  + Pharma Module (FDA 21 CFR Part 11)
  + Calibration Module
  + LDAP Module : optional

  OR

  Qlever software platform
  + Authentication-tracking Module (FDA 21 CFR Part 11)
  + Mapping module (FD X15-140 /IEC 60068.3.11)
  + Calibration Module
  + LDAP Module : optional
- **Connectivity**
  2.4 GHz radio transceiver or wired interface for NanoVACQ and VACQ xFlat,
  Wired interface for PicoVACQ and MiniVACQ.

Aerosol spray

In order to acquire process information during hot filling, crimping, water bath leakage test and transportation of products in aerosol spray containers, it is possible to insert a very small data logger directly inside the spray can.

TMI-Orion solutions

- **Data loggers**
  PicoVACQ PT Ex
- **Software**
  Qlever software platform
  + Pharma Module (FDA 21 CFR Part 11)
  + Calibration Module
  + LDAP Module : optional
  OR
  Qlever software platform
  + Authentication-tracking Module (FDA 21 CFR Part 11)
  + Calibration Module
  + LDAP Module : optional
- **Connectivity**
  Wired interface.

Washing-disinfection

Washing-disinfection cycles are performed for disinfection purposes or for cleaning loads prior to steam sterilization as this sterilization process is only efficient on clean surfaces.

After the washing-disinfection cycle, the load is inspected and readied for steam sterilization.

Washer-disinfector machines usually use hot sprayed water.

TMI-Orion offers solutions for setup and detailed analysis of washing and disinfection cycles. Validation reports are compliant with the **ISO 15883** norm.

TMI-Orion solutions

- **Data loggers**
  NanoVACQ or NanoVACQ Flat or PicoVACQ or MiniVACQ
- **Software**
  Qlever software platform
  + Pharma Module (FDA 21 CFR Part 11)
  + Calibration Module
  + LDAP Module : optional
  OR
  Qlever software platform
  + Authentication-tracking Module (FDA 21 CFR Part 11)
  + Calibration Module
  + Washing-disinfection Module (ISO 15883)
  + LDAP Module : optional
- **Connectivity**
  2.4 GHz radio transceiver or wired interface for NanoVACQ,
  Wired interface for NanoVACQ Flat, PicoVACQ and MiniVACQ.

Additional tip

Limited access containers

Thanks to its small size, the PicoVACQ easily fits inside bottles through standard bottle-necks or flexible packaging. It is designed to provide information during filling, sealing and transport.

For temperature measurement inside small vials, the logger stays outside the container; the probe is inserted through the wall and maintained at the cold point.

TMI-ORION PORTFOLIO FOR MEDICAL AND PHARMACEUTICAL INDUSTRY

You will find a choice of loggers covering **temperatures from -90°C to 140°C**. A thermal shield is necessary to measure **temperatures up to +1200°C**.

Sensors are Pt100, Pt1000 or thermocouples. The probes have various forms and dimensions. Sensors can be internal to the logger, placed at the end of a rigid probe 10 to 100 mm long, or at the end of a flexible or semi-rigid probe, up to 1 meter long.

Depending on the models, you can chose loggers with **1 to 32 measurement channels**.

Data loggers

- **PicoVACQ Temperature:** 1 or 2 temperature sensors.



- **NanoVACQ Temperature, NanoVACQ Temperature Ex, NanoVACQ Temperature FullRadio, NanoVACQ Temperature radio:** 1, 2 or 3 temperature sensors.


- **NanoVACQ Flat:** 1 temperature sensor.

- **PicoVACQ HT (Humidity and Temperature)**

- **NanoVACQ HT (Humidity and Temperature), NanoVACQ HT FullRadio, NanoVACQ HT radio**


- **PicoVACQ PT (Pressure and Temperature)**

- **NanoVACQ PT (Pressure and Temperature) NanoVACQ PT FullRadio, NanoVACQ PT radio**

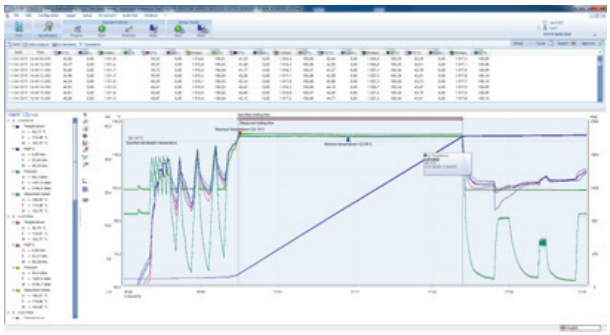

- **MiniVACQ:** 1 temperature sensor.

- **VACQ xFlat, VACQ xFlat radio, VACQ xFlat FullRadio:** 4, 8 or 16 thermocouple channels.



Software

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

- **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.

- **LDAP Module**
  The Administrator may now 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 or the Pharma module.

- **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.
  Complete tracking of processes and data including any addition, deletion or modification operation (Audit Trail).
  The functions of this module are also included in the Pharma module.

- **Autoclave validation module**
  Intended for analysis and validation of humid heat sterilization cycles and vacuum test.
  Calculation of saturated steam, calculation of dynamic pressure, air evacuation calculations for heat penetration analysis in sterilization cycle pre-treatment (Helix, BD, Prions).
  Data treatment and presentation in an extensive validation report in compliance with **ISO 17665 / EN 13060 / EN 554 / EN 285 / EN 868**.

- **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**.

- **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.
  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.

  Data treatment and presentation in an extensive compliance report with **FD X15-140 / IEC 60068.3.11**.

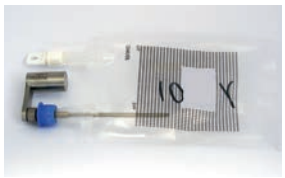
- **Calibration module**
  Dedicated to TMI-Orion temperature and humidity loggers calibration process: calibration, adjustment, checking and editing of a report. Available with a library of drivers, to communicate with a variety of calibration equipment: baths, ovens, reference probes. Delivers a calibration and adjustment report. Expert mode, Automatic mode and Manual mode available.

Connectivity and batteries

- Mono-USB interface (connection cable between loggers and the PC)
- 2.4 GHz radio gateway connected to the PC
- User replaceable batteries or battery packs.

Accessories

The positioning kits help maintain the logger sensor at the cold point inside the process. Depending on the applications, the logger will be placed inside or outside the container. Usual devices are available, and customization can be studied upon request.



Services

- Calibration and adjustment of sensors: every year
- After-sales services: metrology, repair, assistance, hotline
- Design of custom solutions (products and software)

Visit www.tmi-orion.com for information on all TMI-Orion products and list of business partners.

TMI TMI-ORION

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