TMI-Orion

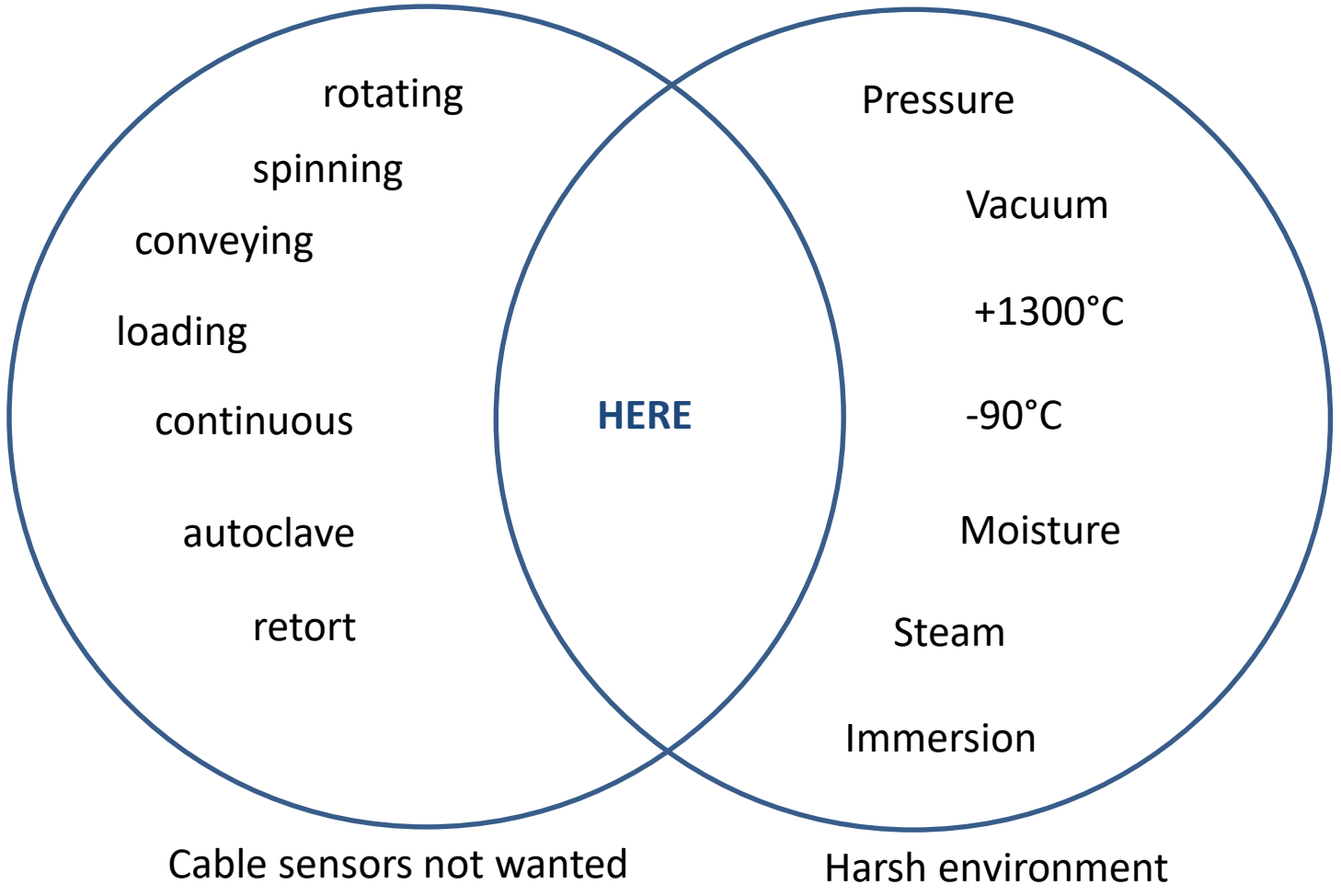
HIGH TECH DATA LOGGING SOLUTIONS FOR PHARMACEUTICAL PROCESSING

TMI-ORION

Our core business

- High tech embedded data logging solutions for validation and quality control of processes in extreme conditions.
- Wide range of miniature and embedded loggers/ real time transmitters
- High and low temperature acquisition electronics operating without thermal shield (-90°C to 140°C)

Where do we find TMI ORION wireless loggers



Measured parameters

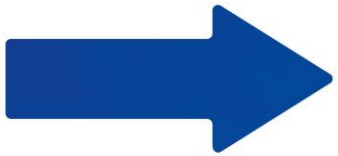
Parameters	Measuring range
Temperature	From -90°C to +1800°C
Pressure (absolute)	From 30mbar to 30 Bar
Relative humidity	From 2% to 98% HR
Air velocity	From 0 to 40m/s
Rotating (nb of laps)	From 0 to 150 laps/ min

And more upon request…

➔ Including data logger acquisition electronics exposed to the temperature range -90°C to +140°C without thermal shield

Applications

- Autoclave Sterilization
- H2O2 Sterilization
- EtO Sterilization
- Depyrogenation
- Lyophilization
- Environmental chamber
- Stability chamber
- Incubation
- Ovens
- Cold storage
- Aerosol
- Washer disinfector



- Heat penetration test
- Thermal distribution test
- Temperature mapping
- Humidity mapping
- Process closed loop control

Communication and operating modes

- Communication

Communication	Protocol	Communication Interface
Wired	Proprietary protocol	Single, 6 or 12 USB interface
Radio with wired start	2,4GHz	Single, 6 or 12 USB interface
FullRadio (without contact)	2,4GHz	Radio receiver/transmitter

- Operating

Operating
Recording
Recording + radio transmission

Wireless data logging systems: recording only

- NanoVACQ Flat

- PicoVACQ

- NanoVACQ

- VACQ Xflat

NanoVACQ Flat loggers (temperature)

NanoVACQ Flat
D.40mm
Length from 11mm
1 temperature channel

- Watertight under pressure
- Biocompatible
- 0 to 140°C, +/-0.1°C accuracy
- Available with a D.2mm (Needle probe) or a D.3mm probe (standard)
- RTD based (not thermocouple) – Calibration: once a year
- Applications = Autoclaves, Stability chamber, Incubators

PicoVACQ and NanoVACQ loggers (temperature, pressure, humidity)

PicoVACQ
D.15mm or 16mm
Length from 22mm
Up to 2 Channels

NanoVACQ
D.31mm
Length from 39mm
Up to 3 Channels

PicoVACQ & NanoVACQ

- Watertight under pressure (except humidity and Tdi loggers)
- Biocompatible
- 0 to 140°C, +/-0.1°C accuracy
- RTD based (not thermocouple) – Calibration: once a year
- -80 to 350°C = Cold storage, Lyophilization, Autoclaves, Depyrogenation
- 30mbar to 5 Bar = Steam autoclaves
- 2 to 98% RH = Stability chamber, EtO sterilization, Incubators…

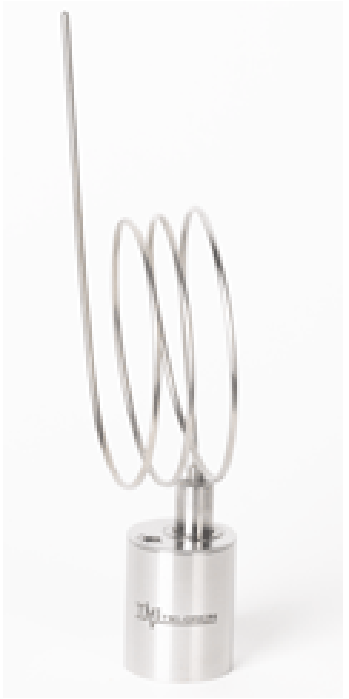
NanoVACQ

- Larger Battery for extended lifetime
- Available with 2.4 GHz FM and FullRadio for Real Time Data
- Recommended for Routine use
- Operating down to -90°C for low temperature freezers

PicoVACQ and NanoVACQ loggers (temperature)

PicoVACQ & NanoVACQ

- Available with different Pt100 rigid, flexible and semi rigid probes (SS316L, Viton, Teflon)
- Interchangeable probe on Tdi versions, non watertight
- Watertight under pressure (except Tdi versions)
- Biocompatible
- -80°C to 350°C depending on the versions
- Calibration: Once a Year



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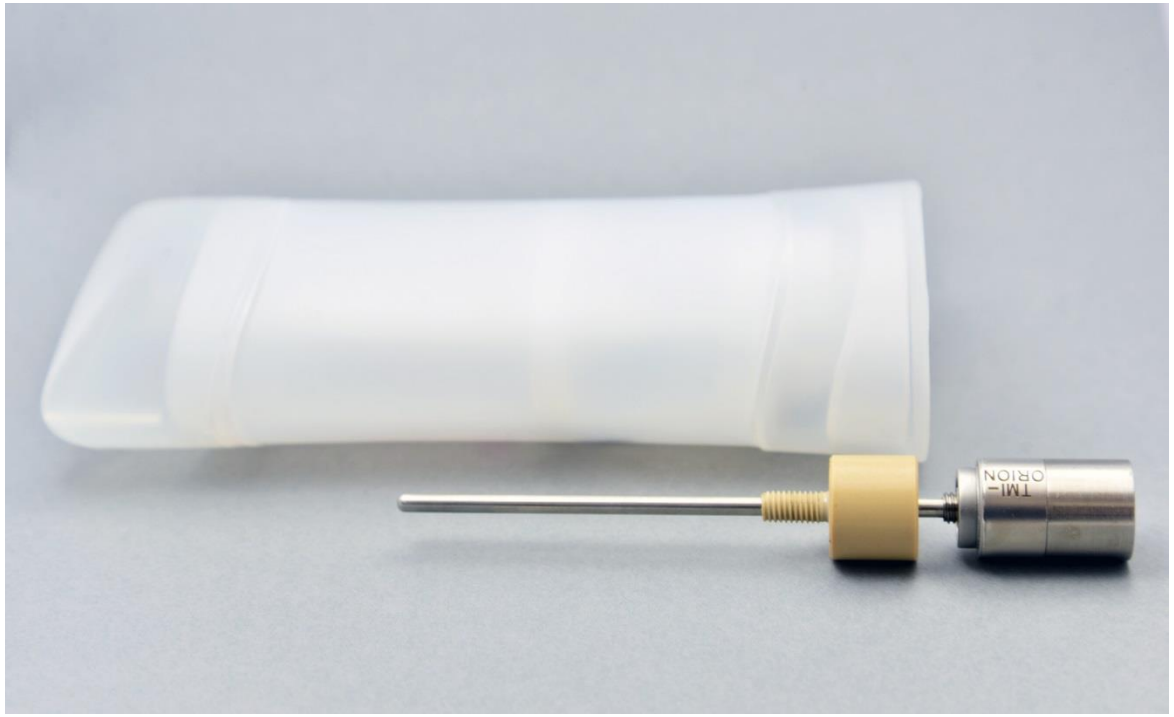
PicoVACQ Uturn (temperature)

- PicoVACQ with one channel
- Special design to fit in a pouch
- Limited headspace
- 76 loggers ordered by a pharma company, because of this customized design
- Watertight

➔ Measure temperature through the cap in a pouch during sterilization process in autoclaves

PicoVACQ and NanoVACQ Flat (temperature)



Measure temperature inside a stick with PicoVACQ

Measure temperature inside Vials with PicoVACQ or NanoVACQ Flat

PicoVACQ and NanoVACQ loggers (temperature, pressure)

PicoVACQ & NanoVACQ

- Operating from -30°C to 140°C, and from 30mbar to 15 Bar (30 Bar upon request)
- Watertight under pressure
- Biocompatible
- Calibration: Once a Year

PicoVACQ PT

D.16 or 17mm x L.35mm
2 Channels

Operating from -30 to140°C, Uncertainty +/-0,1°C
Operating from 30mbar to 15bar, Uncertainty +/- 30mbar
Operating from 30mbar to 30bar, Uncertainty +/- 100mbar

Up to 4Hz Sampling Rate

NanoVACQ PT-TC

D.31mm x L.39mm
3 Channels

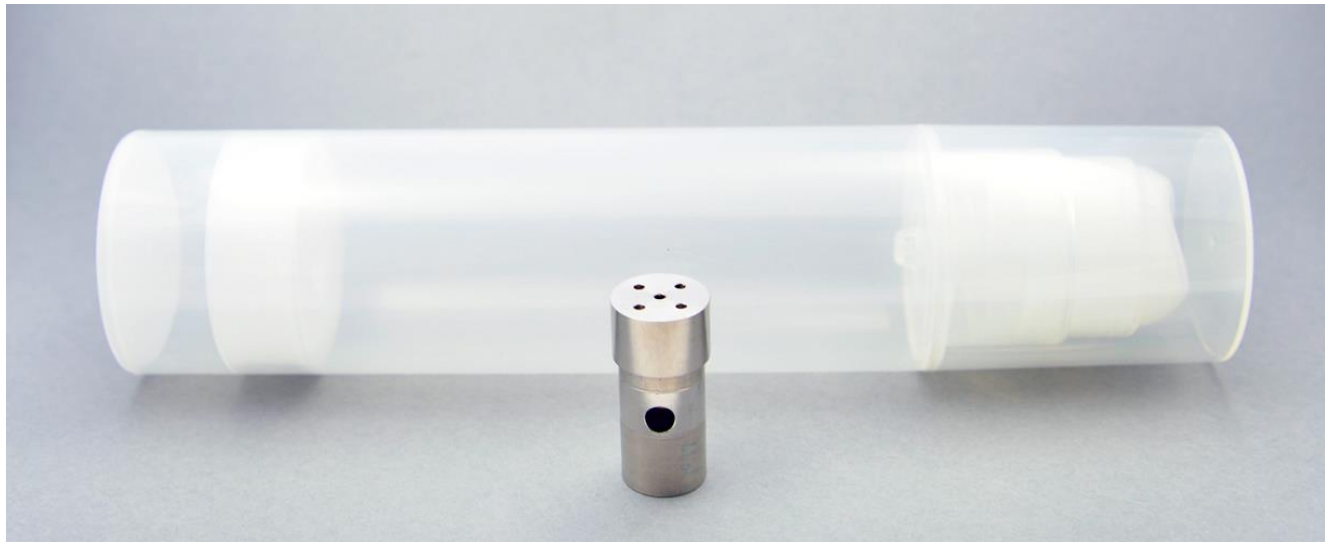
Operating from -30 to140°C, Uncertainty +/-0,1°C
Operating from 30mbar to 5bar, Uncertainty +/- 10mbar
Operating from 30mbar to 15bar, Uncertainty +/- 12mbar

Up to 10Hz Sampling Rate

Configurations

- PT
- PT-TC
- PT-Td

PicoVACQ PT (temperature, pressure)



- PicoVACQ with two channels
- Fit in a spray
- Limited space
- Available in ATEX compliant version

➔ Measure temperature and pressure until the spray blows up, destructive tests

PicoVACQ and NanoVACQ loggers (temperature, humidity)

PicoVACQ & NanoVACQ

- Operating from 0°C to 80°C or 140°C, and from 2 to 98% RH
- Non watertight under pressure
- Biocompatible
- Calibration: Once a Year

PicoVACQ HT

Operating from 0°C to 80°C, Uncertainty +/-0,1°C
Operating from -30°C to 0°C, Uncertainty +/-0,2°C

Operating from 2 to 98% RH, Uncertainty +/- 3,5% RH (2% RH as an option)

NanoVACQ HT

Operating from 0°C to 140°C, Uncertainty +/-0,1°C
Can operate down to -60°C if required

Operating from 2 to 98% RH, Uncertainty +/- 3,5% RH (2% RH as an option)

Configurations:
- HT
- HT-TC
- HT-Td

ATEX compliant: PicoVACQ and NanoVACQ loggers
(temperature, pressure, humidity)

PicoVACQ EX versions, ATEX marking II 1 G Ex ia IIC T6 Ga

- Available in temperature, temperature/pressure and temperature/humidity versions
- Operating from -30°C to 70°C, from 30mbar to 15 Bar and from 2% to 98% RH

➔ *Thus, PicoVACQ 1Tc Ex and PicoVACQ PT Ex used with 015P battery pack, can be used in non explosive environment up to 140°C*

NanoVACQ EX versions, ATEX marking II 1 G Ex ia IIC T3 Ga

- Available in temperature, temperature/pressure and temperature/humidity versions
- Operating from -30°C to 140°C, from 30mbar to 15 Bar and from 2% to 98% RH

NanoVACQ EX

Available versions :
1Tc
1Td
PT
PT-TC
HT

PicoVACQ EX

Available versions:
1Tc
PT
HT

VACQ XFlat loggers (temperature)

VACQ XFlat

Up to 16 thermocouple channels

Max dimensions:

L.150 mm x H.20 mm x W.80 mm

- **Non watertight** logger
- Available in 4, 8 and 16 thermocouple channels (type T or K)
- Operate up to 140°C without thermal shield
- Up to 400°C with special shields designed for depyrogenation processes
- Multichannel acquisition system outside an autoclave

VACQ XFlat loggers (temperature)- Thermal shield

Thermal shield S045160204

Dimensions:
45mm high
160mm wide
204mm long

- Up to 400°C with special shields designed for depyrogenation processes
- For 4 thermocouple VACQ Xflat for instance, thermal shield S045160204

Materials	Performances
PEEK, Microtherm, SS	60 mn @ 250°C 30 mn @ 350°C

Communication and operating modes

- Communication

Communication	Protocol
Wired	Proprietary protocol
Radio with wired start	2,4GHz
FullRadio (without contact)	2,4GHz

- Operating

Operating
Recording
Recording + radio transmission

Wireless data logging systems: recording and REAL TIME READING

- NanoVACQ Radio or FullRadio

- VACQ Xflat Radio or FullRadio

Wireless data logging systems: recording and REAL TIME READING

Radio & FullRadio

- Simultaneous recording and real time reading
- Radio receiver/transmitter required
- Similar operating ranges to standard loggers
- Longer metallic cover on NanoVACQ's compared to standard ones
- Qlever software **mandatory**

- Applications: similar to standard loggers but taking in account radio transmission limitations

Wireless data logging systems: Radio loggers

Radio

- Mandatory contact with the logger
- **USB communication interface** required to program, start/stop loggers and download data
- Radio receiver/transmitter required
- Similar operating ranges to standard loggers
- Longer metallic cover on NanoVACQ's compared to standard ones
- Qlever software mandatory
- Applications: similar to standard loggers but taking in account radio transmission limitations

Wireless data logging systems: FullRadio loggers

FullRadio

- No contact with the logger
- Communication done **through radio waves**
- Radio receiver/transmitter required as a communication interface
- Ethernet, USB, RS485 connections for the receiver

➔ No need to stand near the loggers to program/start/stop/read them

- Similar operating ranges to standard loggers
- Longer metallic cover on NanoVACQ's compared to standard ones
- Qlever software mandatory
- Applications: similar to standard loggers but taking in account radio transmission limitations

FullRadio loggers: Radio receiver/transmitter

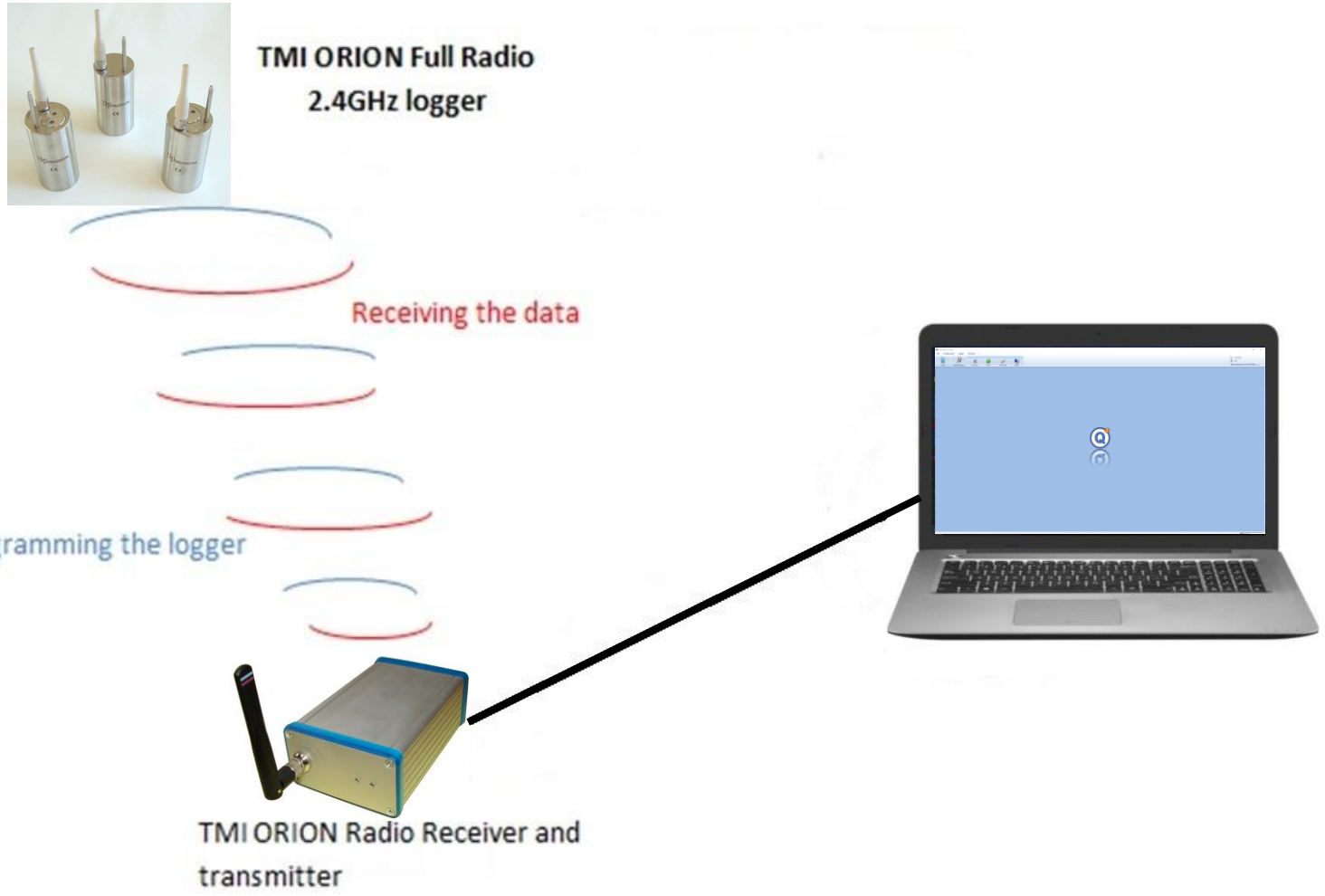
Features

- Communication done **through radio waves**
- Ethernet, USB, RS485 connections for the receiver

➔ No need to stand near the loggers to program/start/stop/read them

- No limitation of the number of the managed loggers

FullRadio loggers operating mode

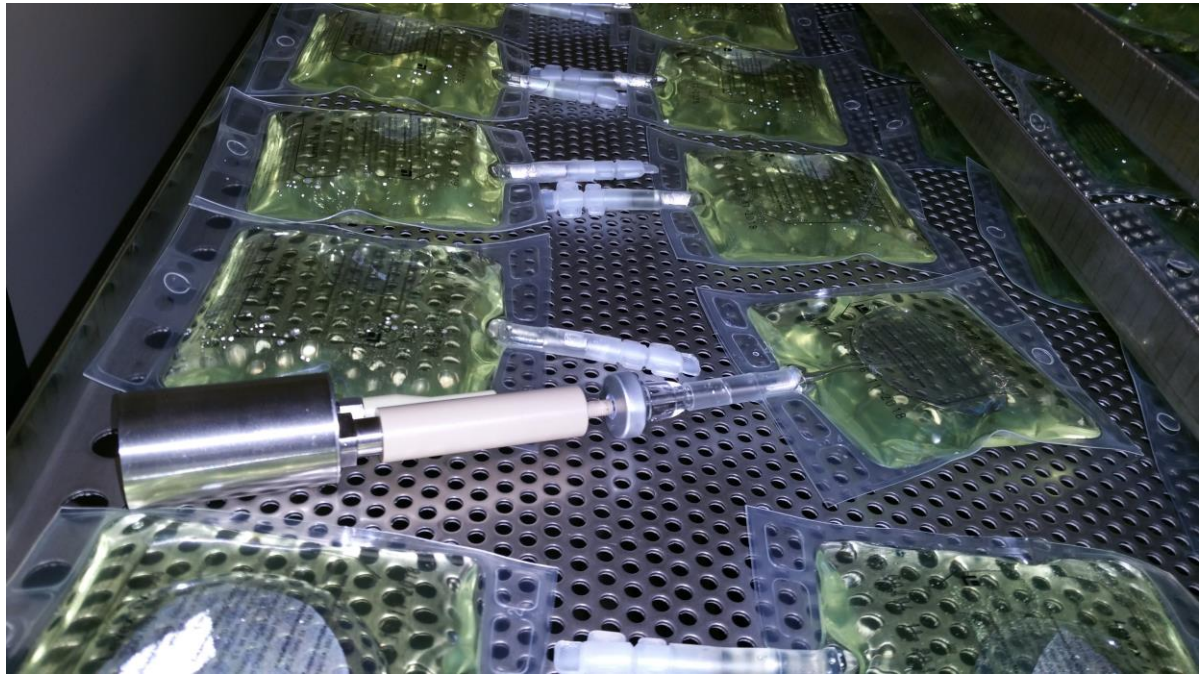


FullRadio loggers

Applications:

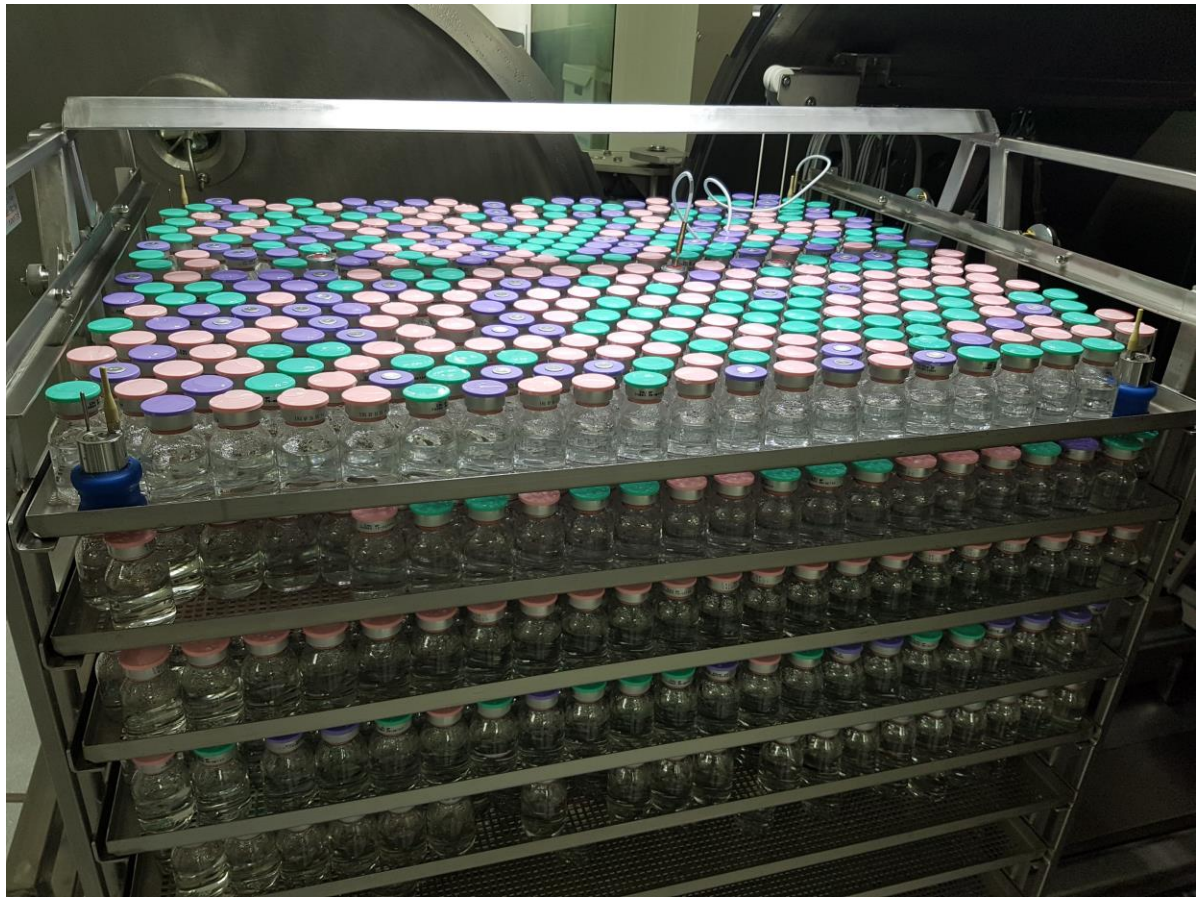
- Real time data from loggers inside autoclaves
- Program, start, stop, read loggers without touching them
- Great feature for limited access applications such as low temperature freezer where opening the door requires an 8 hour stabilization time afterwards

FullRadio loggers



FullRadio loggers

FullRadio loggers



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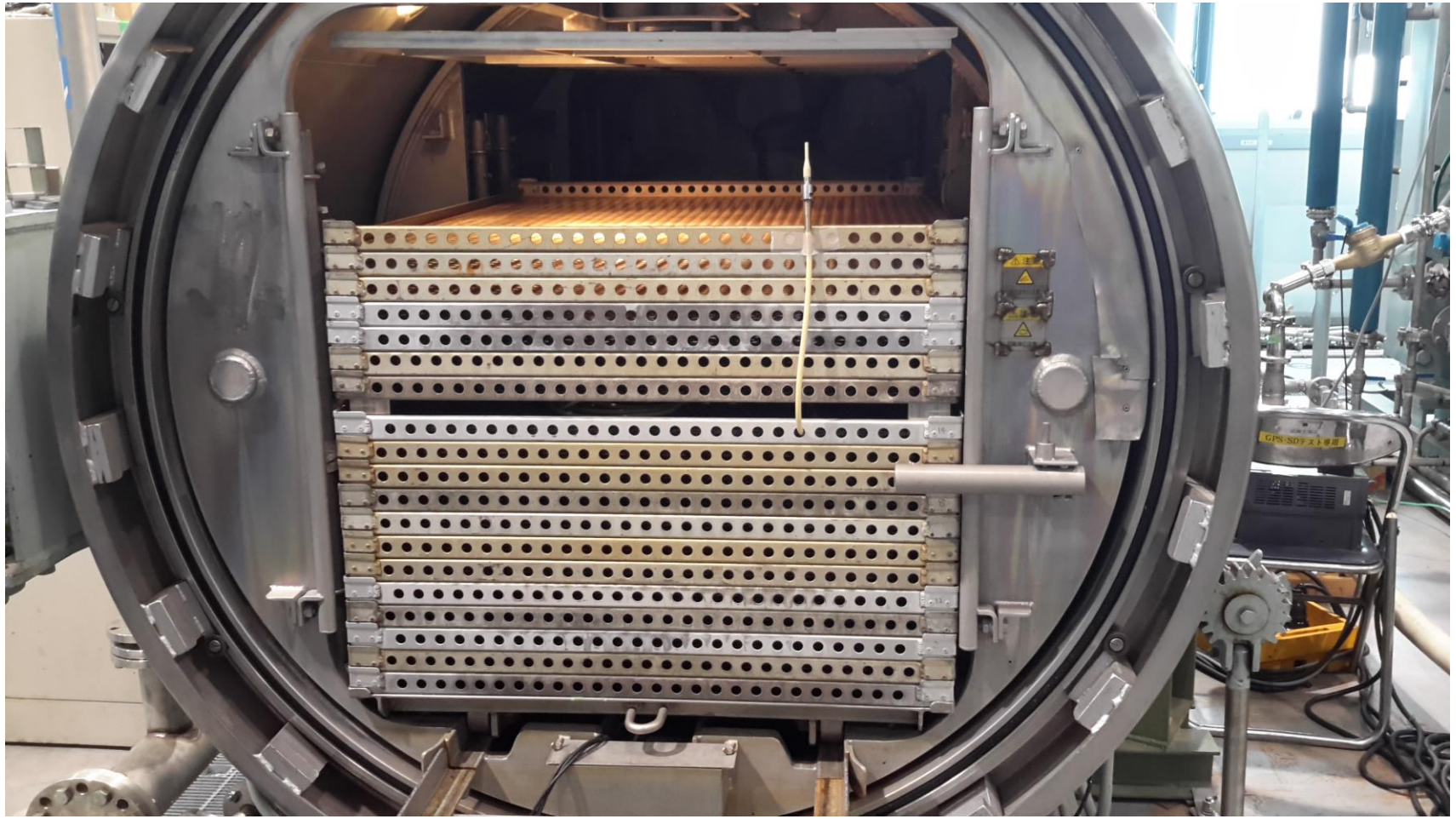
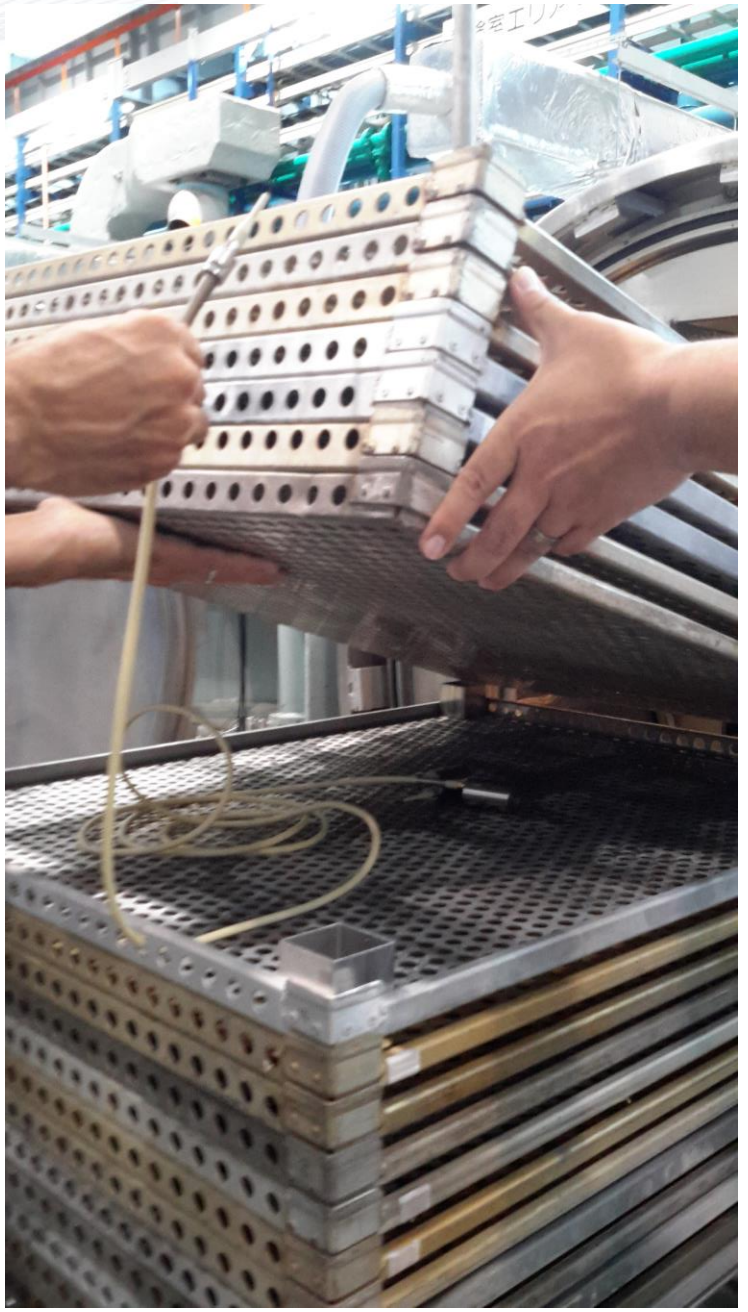
FullRadio loggers





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FullRadio loggers

FullRadio loggers

Typical Application:

- Program and set up **standard or radio data loggers** inside packagings on a basket takes a long time. When the sterilization cycle is about to start, if a problem occurs with the steam generator, then the cycle start is delayed for 3 hours. All loggers have to be retrieved, stopped and reprogrammed, which means: take all baskets out, open all packagings, remove and set the loggers back in place, close the packagings and push the baskets inside the autoclave… ➔ **Wasted time and money**
- With the **FullRadio data loggers**, all you need is to click on the Qlever software to stop the loggers and come back when the cycle is ready to start, then click on start button. It only takes a few minutes to restart the system and adapt your loggers to the new cycle parameters. ➔ **Save time and money**

FullRadio loggers

Radio standards

- R&TTE Directive 1999/5/CE (EU)
- FCC Part 15.247 (US)
- RSS-210 (Canada)
- ARIB TELEC (Japan)
- KCC RWA 58-2 (Korea)

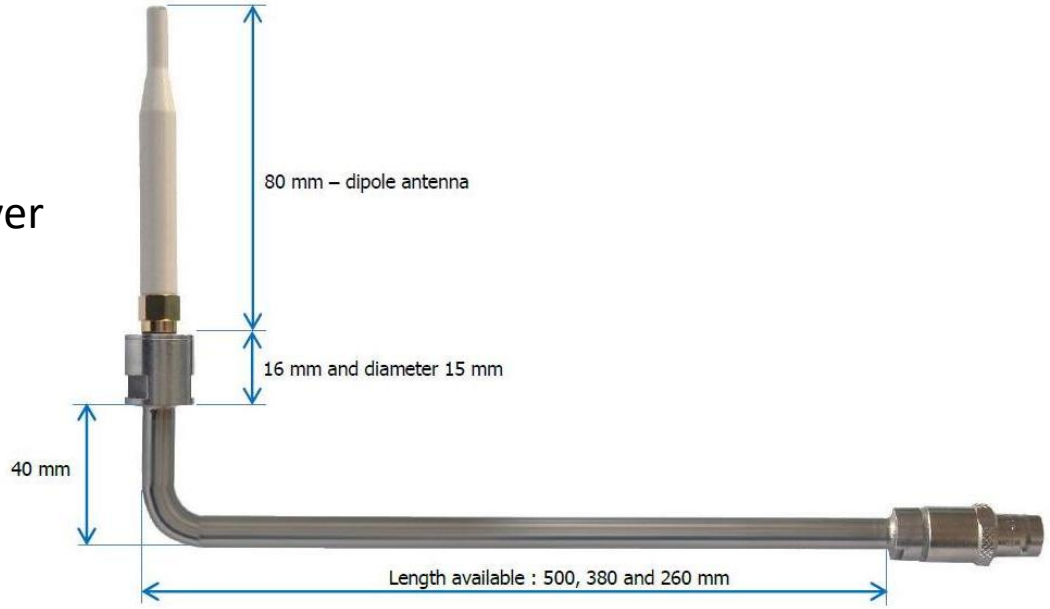
FullRadio loggers

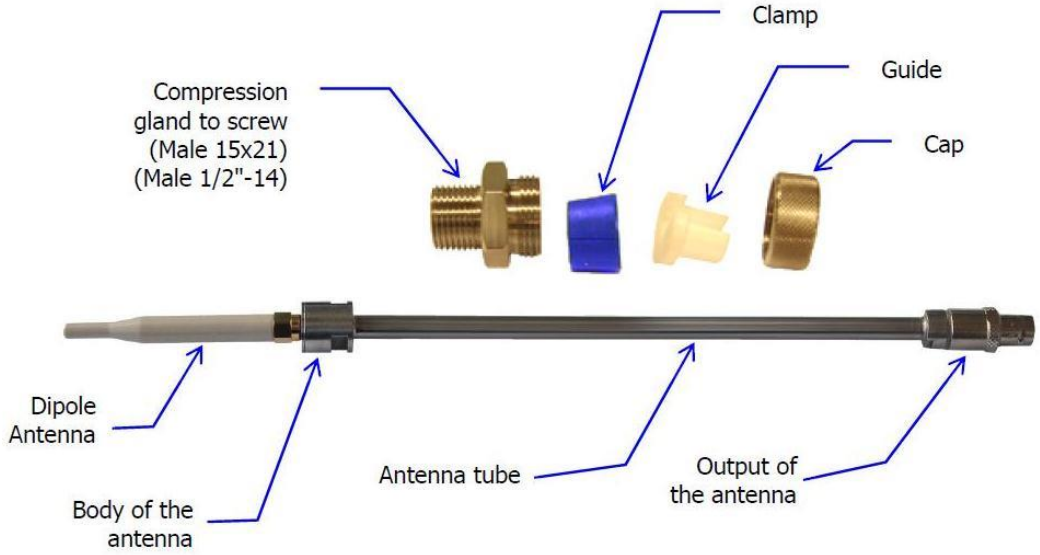
- Frequency Band: 2.4GHz ISM band (2.405 GHz to 2.480 GHz with 16 channels available for worldwide).
- Communication protocol : IEEE 802.15.4
- Frequency Band : 2.405 GHz to 2.475 GHz with 14 channels.
- Output power: Maximum 5 dBm (3.2mW).

Receiving antenna

Transmission efficiency

- To optimize data transmission between loggers and radio receiver
- Inserted inside vessels such as autoclaves
- Mounted on the vessel feed through devices
- Different adaptors available for the feed through devices
- Different shapes, straight or right angled
- Different lengths, up to 500mm





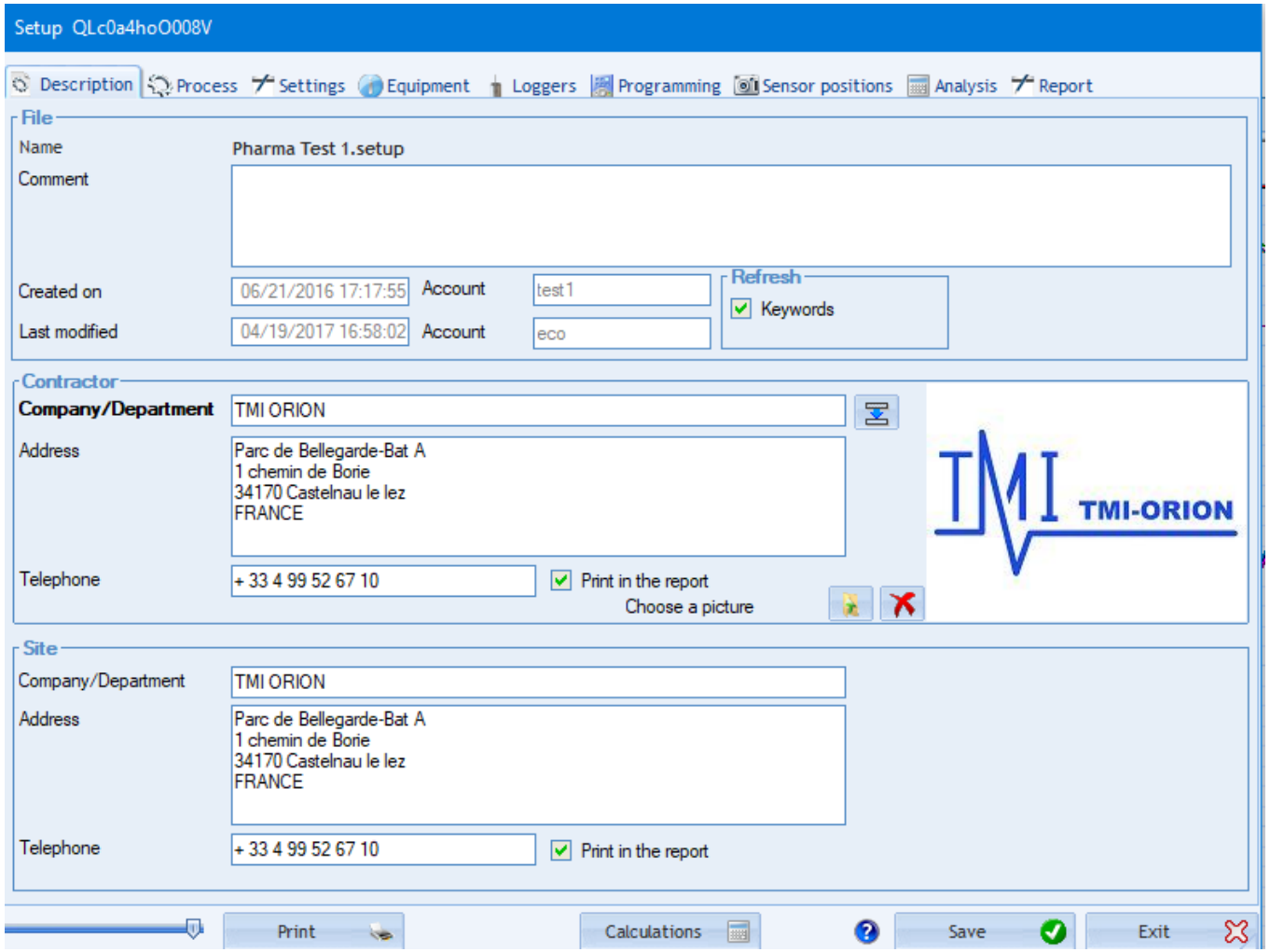
Wireless data logging solutions: QLEVER Pharma Software

- Manage all TMI ORION loggers
- **FDA 21 CFR Part 11 compliant**
- User friendly
- Specific reports
- IQ/OQ validation protocols
- Calibration/adjustment module as an option
- ISO 17665 and ISO 15883 modules as options
- FDX 15140 module as an option
- Specific reports compliant with these ISO requirements

Wireless data logging solutions: QLEVER Pharma Software

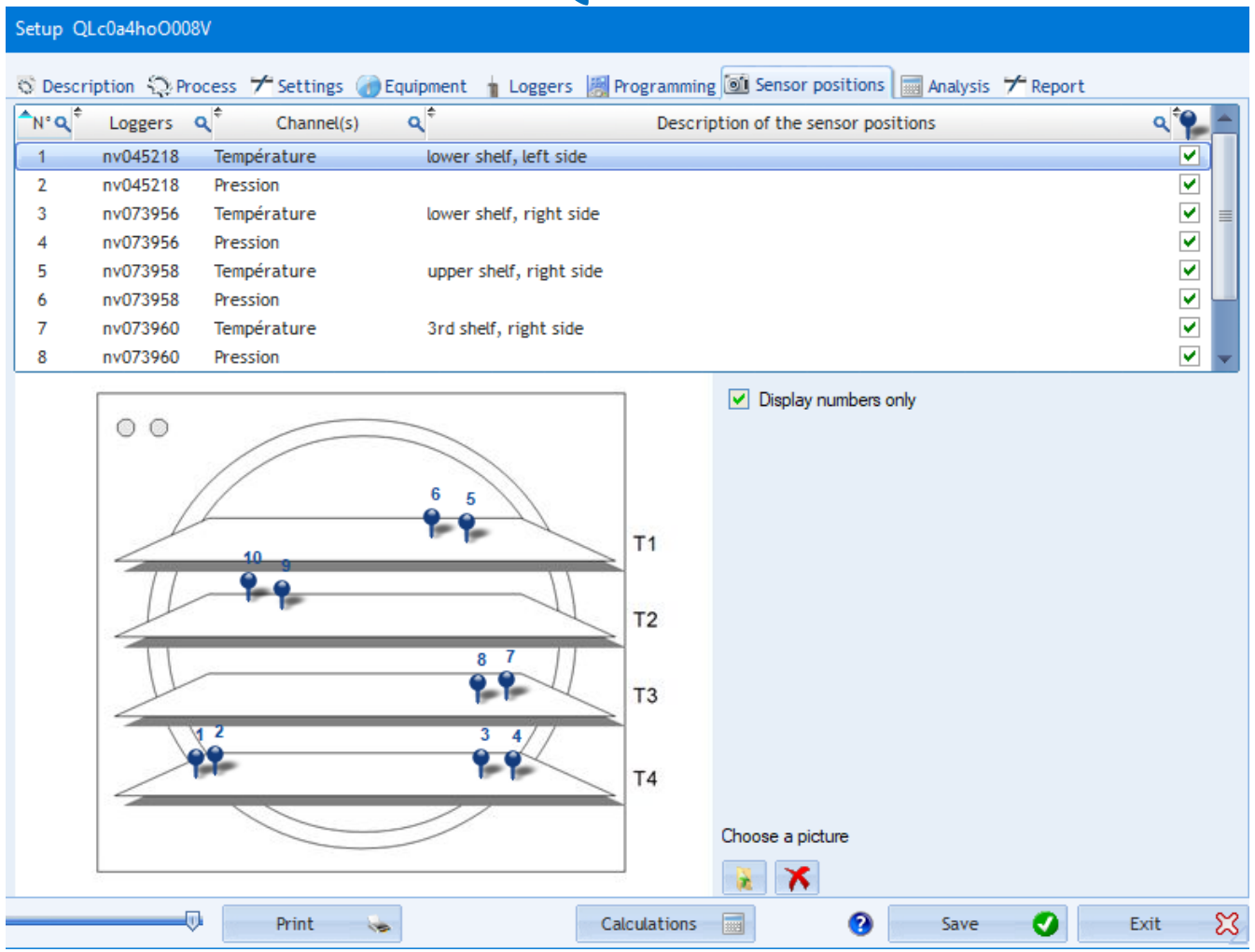
- Audit trails
- Different access levels and rights (administrator, approval, operator)
- Encrypted database management
- Setup library
- Multi users with one license per plant
- Operating on Windows 7, 8 and 10
- Specific reports including up to 3 different cycles in a row

Wireless data logging solutions: QLEVER Pharma Software, setup



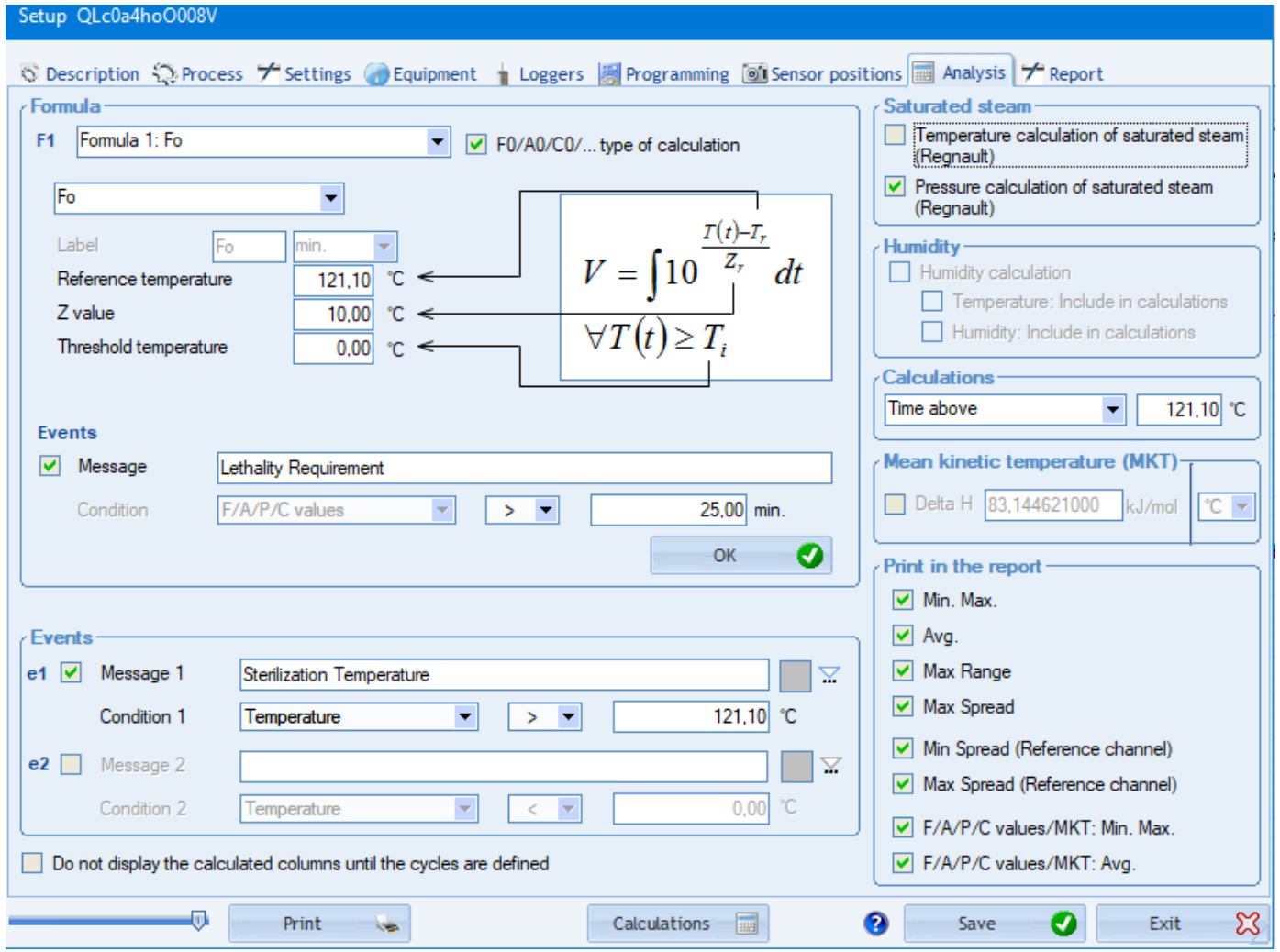
- Description of the process and location
- Process
- Settings
- Equipment to be validated
- Loggers to be used
- Programming to apply
- Sensor positions in the chamber
- Analysis: calculations to perform
- Report: report title and form

Wireless data logging solutions: QLEVER Pharma Software, setup



- Sensor location with description and loading map

Wireless data logging solutions: QLEVER Pharma Software, setup



- Calculations to be done and printed in the report
- Customized report

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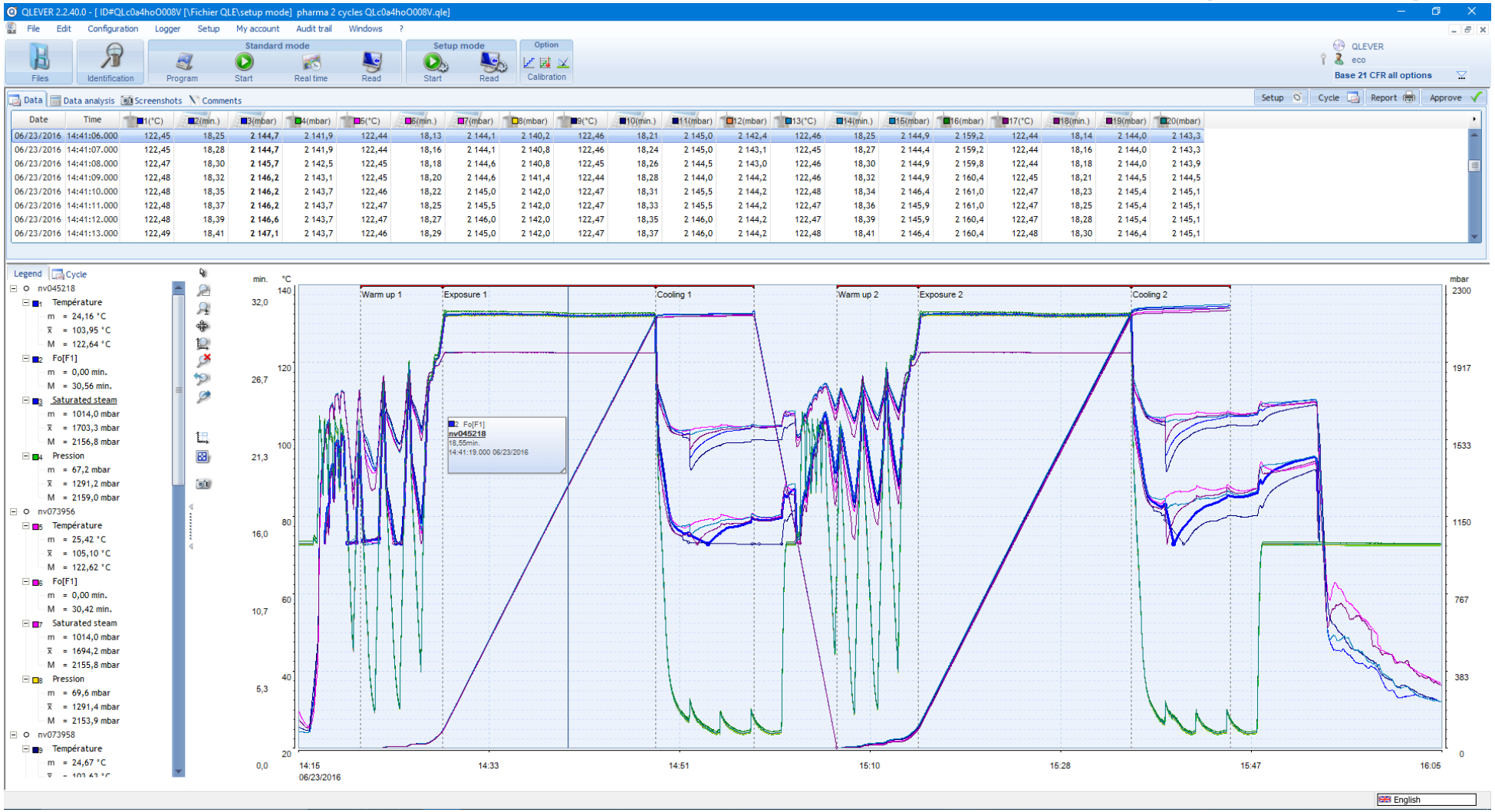
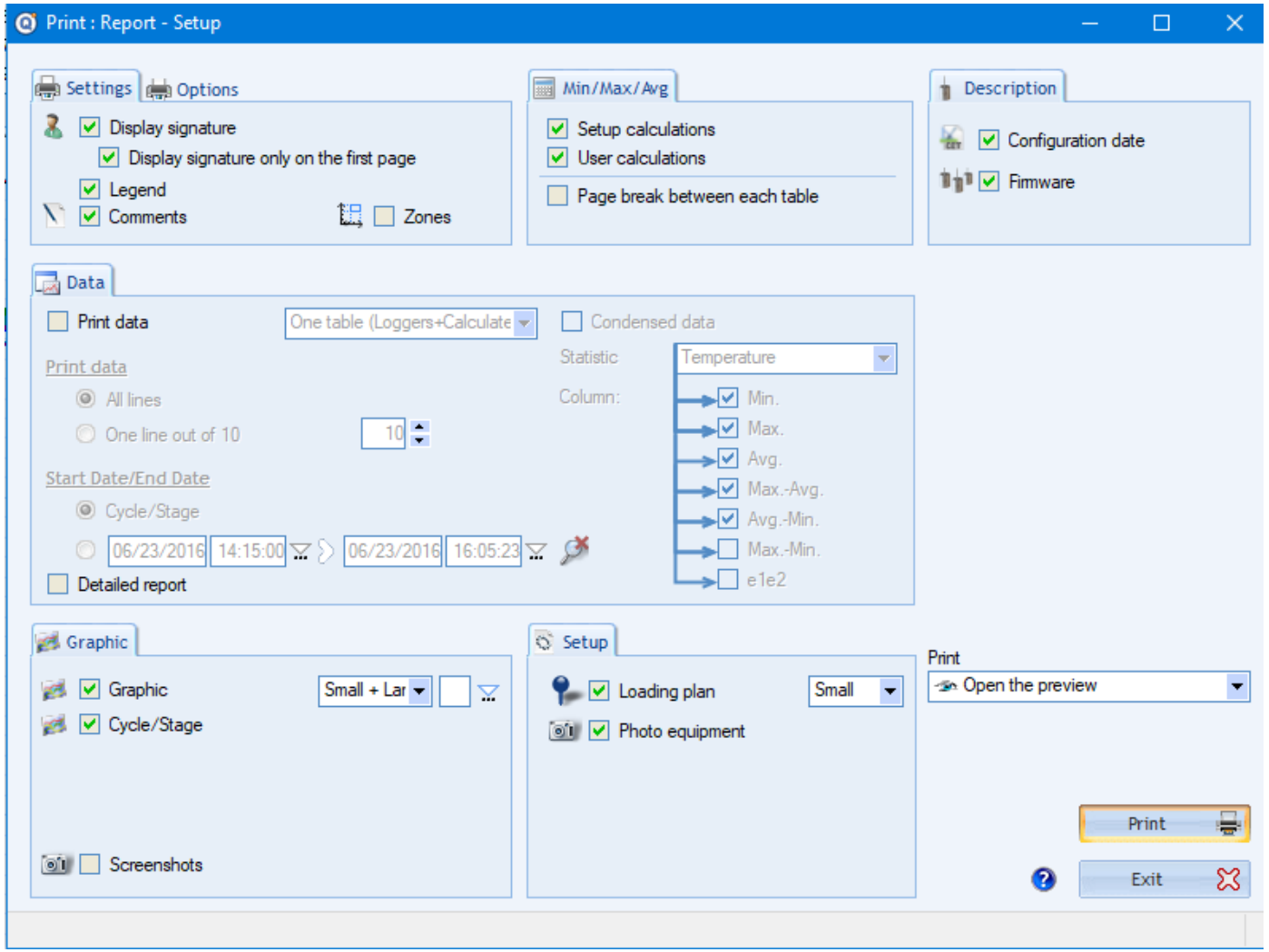
Wireless data logging solutions: QLEVER Pharma Software, Graphic display



- Setup management
- Cycle management
- Report printing
- Report approbation

Wireless data logging solutions: QLEVER Pharma Software, Printing options



Choose to print:

- Settings
- Min/max/Avg
- Description
- Data
- Graphic
- Setup

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Wireless data logging solutions: QLEVER Pharma Software, Report

Measurement Report:RPh01veHs000i - QLE:QLc0a4hoO008V pharma 2 cycles QLc0a4hoO008V.qle Process: PPc0a4hoO001X

TMI ORION

Report not approved

Units: °C, mbar

Programmed: 06/23/2016 14:13:53 by test1
Started: 06/23/2016 14:13:53 by test1
Reading: 06/23/2016 17:58:51 by test1

Equipment ID: Production autoclave
SOP/Protocol: 1

Parc de Bellegarde-Bat A
1 chemin de Borie
34170 Castelnau le lez
FRANCE

Cycle #1 - Start														
Description:	Stage 1 Warm up 1				Stage 2 Exposure 1				Stage 3 Cooling 1				Totals	
Stage Start	06/23/2016 14:21:00				06/23/2016 14:28:55				06/23/2016 14:49:31				06/23/2016 14:21:00	
Stage End	06/23/2016 14:28:55				06/23/2016 14:49:31				06/23/2016 14:59:00				06/23/2016 14:59:00	
Stage Duration	00:07:55				00:20:36				00:09:29				00:38:00	
Data: Temperature (°C)	Stage 1 Warm up 1				Stage 2 Exposure 1				Stage 3 Cooling 1				Totals	
Loggers	Min.	Max.	Avg.	Fo	Min.	Max.	Avg.	Fo	Min.	Max.	Avg.	Fo	Fo	Time>121.10°C
nv045218 Température	91,86	121,29	106,66	1,22	121,29	122,63	122,52M	28,60	95,39	121,42	102,36	0,26	30,08	00:20:37
nv073956 Température	91,25	121,16	105,79	1,16	121,16	122,61	122,51m	28,49	102,17	121,76	103,96M	0,29	29,95	00:20:37
nv073958 Température	92,40	121,19	107,09M	1,21	121,19	122,62	122,51	28,54	92,09	121,76	100,18m	0,24	29,99	00:20:37
nv073960 Température	92,21	121,31	106,80	1,22	121,31	122,65	122,52	28,57	101,27	121,40	103,68	0,28	30,07	00:20:38
nv073961 Température	86,81	121,23	105,26m	1,18	121,23	122,61	122,51	28,49	97,54	121,41	102,66	0,24	29,90	00:20:37
Min.	86,81 on nv073961 Température at 06/23/2016 14:22:08				121,16 on nv073956 Température at 06/23/2016 14:28:55				92,09 on nv073958 Température at 06/23/2016 14:52:54				Min time above 121.10°C 00:20:37	
Max.	121,31 on nv073960 Température at 06/23/2016 14:28:55				122,65 on nv073960 Température at 06/23/2016 14:29:13				121,76 on nv073956 Température at 06/23/2016 14:49:31				Max time above 121.10°C 00:20:38	
Avg.	106,32				122,51				102,57					
Max Range	34,50 (nv073960 nv073961)				1,49 (nv073960 nv073956)				29,67 (nv073956 nv073958)					
Max Spread	9,69 at 06/23/2016 14:21:57 (87,87 on nv073961 Température / 97,56 on nv073960 Température)				0,36 at 06/23/2016 14:49:31 (121,40 on nv073960 Température / 121,76 on nv073958 Température)				10,48 at 06/23/2016 14:52:55 (92,09 on nv073958 Température / 102,58 on nv073956 Température)					
Min. Fo	1,16 on nv073956 Fo[F1]				28,49 on nv073956 Fo[F1]				0,24 on nv073958 Fo[F1]				29,90 on nv073961 Fo[F1]	
Max. Fo	1,22 on nv045218 Fo[F1]				28,60 on nv045218 Fo[F1]				0,29 on nv073956 Fo[F1]				30,08 on nv045218 Fo[F1]	
Avg. Fo	1,20				28,54				0,26				30,00	
Data: Pressure (mbar)	Stage 1 Warm up 1				Stage 2 Exposure 1				Stage 3 Cooling 1				Totals	
Loggers	Min.	Max.	Avg.		Min.	Max.	Avg.		Min.	Max.	Avg.			
nv045218 Pression	175,2	2084,6	1102,6		1953,8	2159,0	2146,4		67,2	1953,8	245,8m			

- Report per cycle
- Divided into stages

Wireless data logging solutions: QLEVER Pharma Software, report

- Create as many temperature, pressure reports as you want
- Exclude some loggers from new reports
- Save reports inside the data base for fast access
- Print out as pdf files