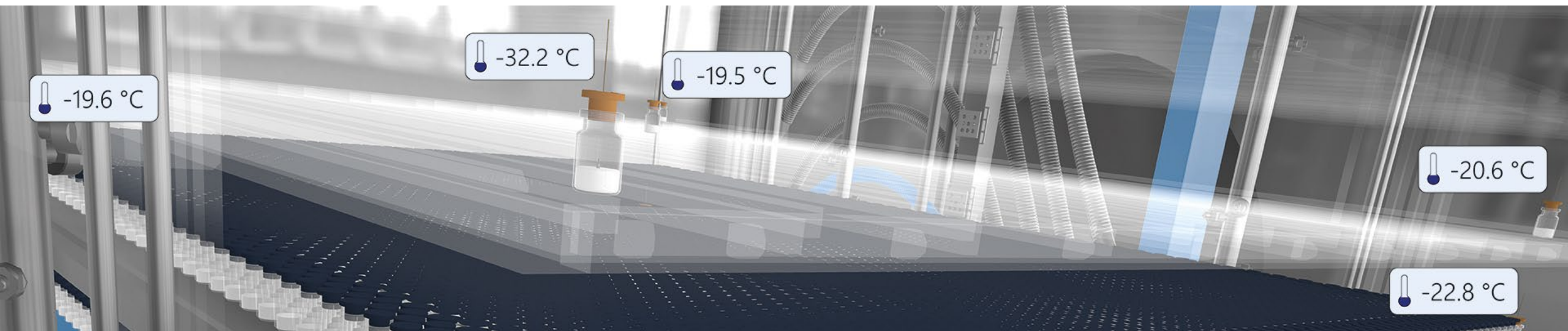


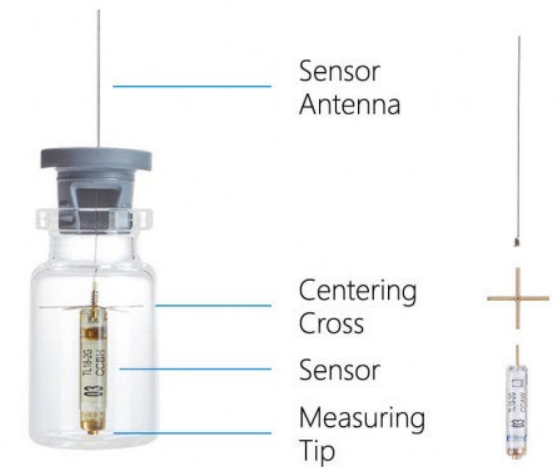
Tempris Solutions

Lyo Summit 2024

12.06.2024



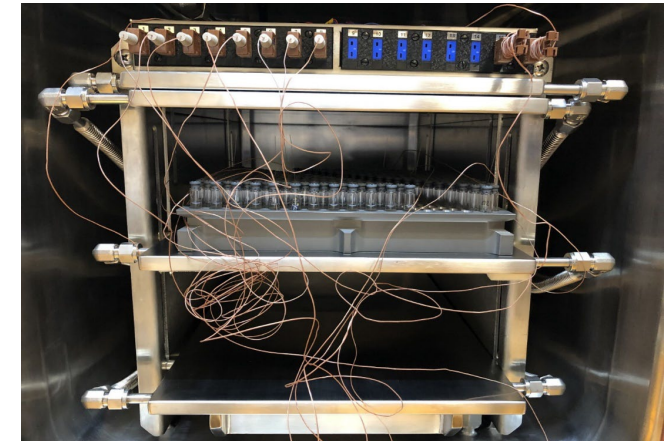
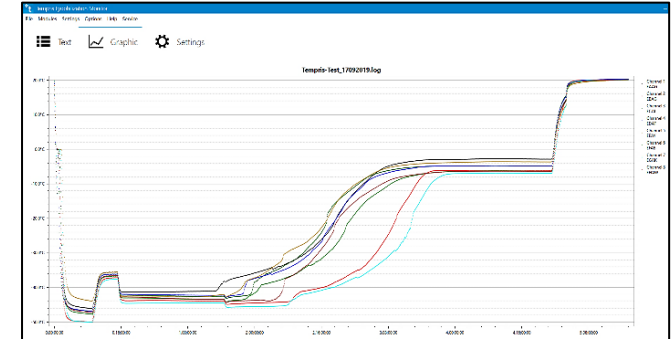
- ❖ Quick Recap
- ❖ Tempris Solution
- ❖ Summary: How Tempris adds value for FD Users
- ❖ Open Questions



Our common challenges:

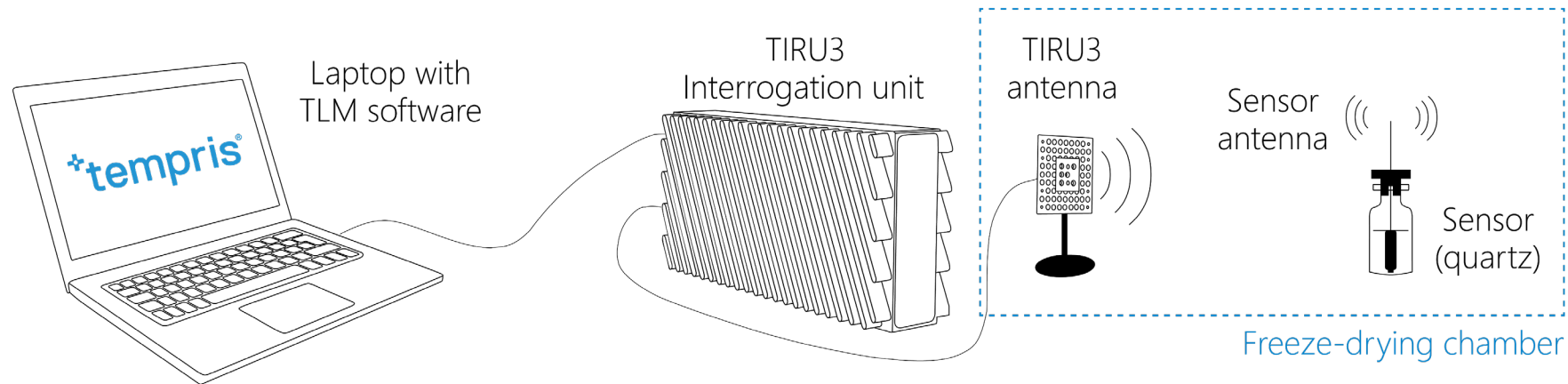
Quick Recap:

1. Product Temperature (T_p) is the most critical parameter in lyophilization
2. T_p used to be measured during production, but not any more
3. Not measuring T_p mainly driven by automatization left a gap
4. Is modelling the only sufficient tool for Lyo cycle optimization for all of FD types
5. Ideally T_p is measured using the same technology accros all scales and stages



Making it possible for you to measure T_p

Tempris - Temperature remote interrogation system



Product Temperature (T_p) Measurement for Lyophilization

Wireless & Battery-free & Real-time

Our Solution: Provide Tp data along the Process Chain w/o Technological Breaks



FORMULATION
DEVELOPMENT

PRECLINICAL
TESTING

CYCLE DEVELOPMENT AND
STABILITY STUDIES

PHASE 1

PHASE 2

CLINICAL TRIALS INTO COMMERCIAL PRODUCTION

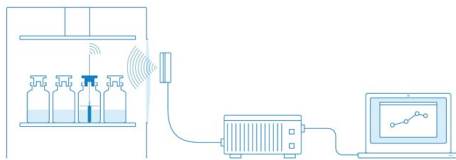
PHASE 3

FILE
NDA

T.LAB A1

LABORATORY FD

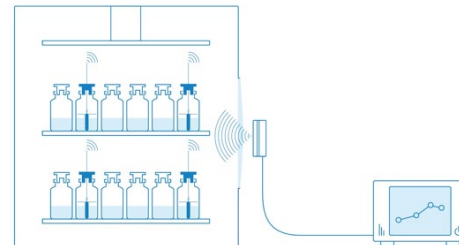
TYPICAL SHELF SIZE: 0.1 – 0.5 SQM
1-5 sq ft



T.LAB A2

PILOT FD

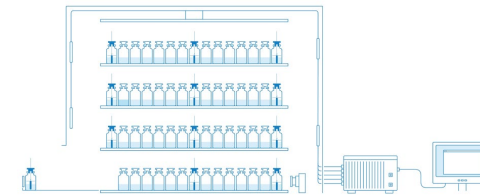
TYPICAL SHELF SIZE: 1 – 5 SQM
10-50 sq ft



T.PRO

COMMERCIAL FD

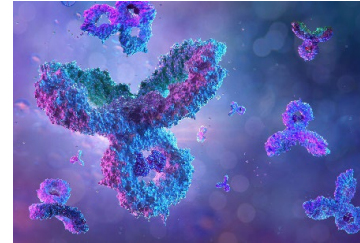
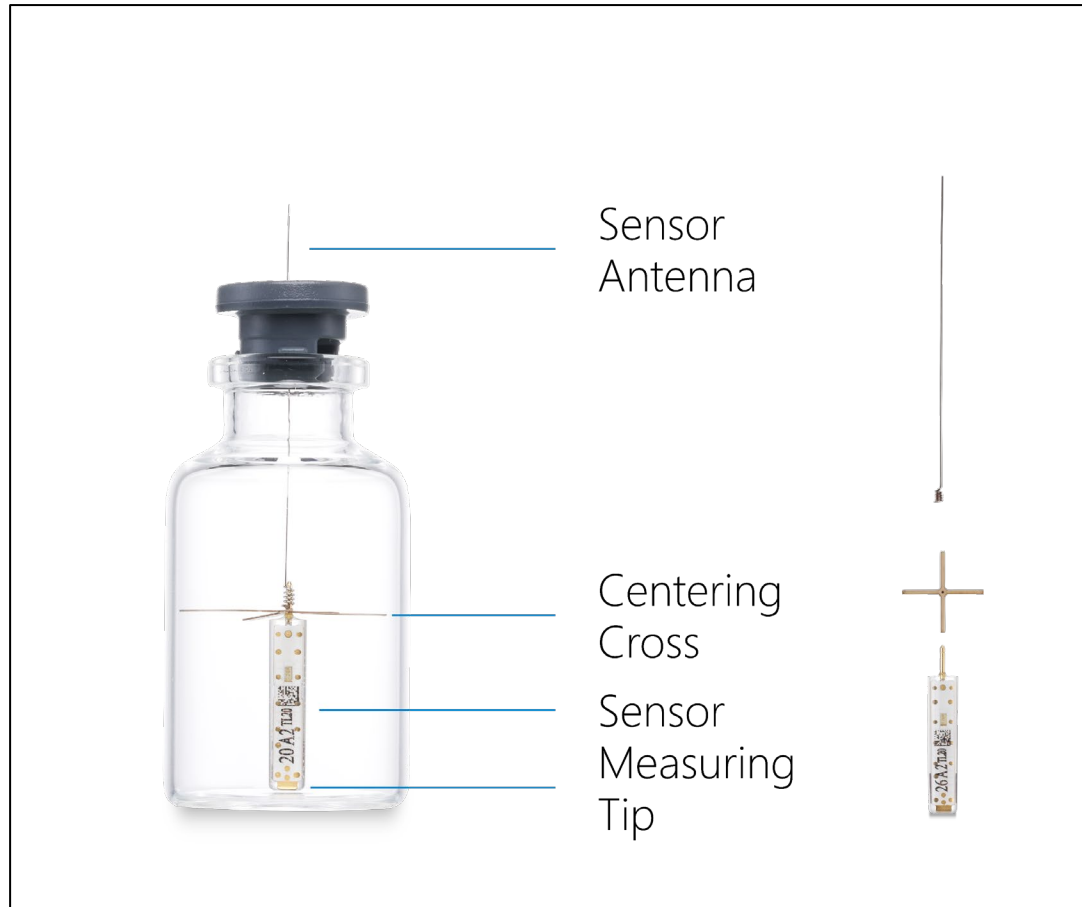
TYPICAL SHELF SIZE: 10 – 40 SQM
100 – 430 sq ft



**ONE SENSOR
TECHNOLOGY FITS
ALL SCALES**

The Smart Sensor
helps to
measure & monitor
the Product
Temperature in
Real Time.
*"The better the Data,
the safer the
Lyophilization
Process."*

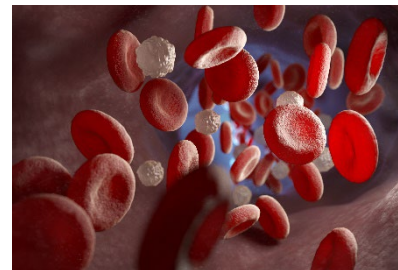
Our Sensor: The Gold Standard for all applications



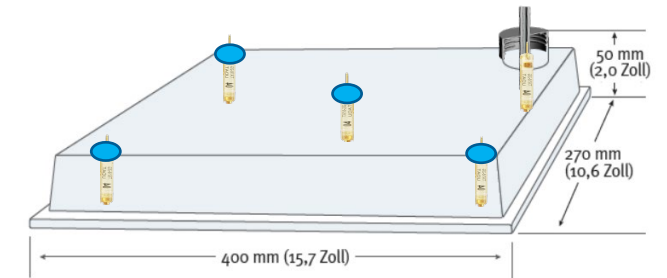
**Proteins and
monoclonal antibodies**



xRNA products

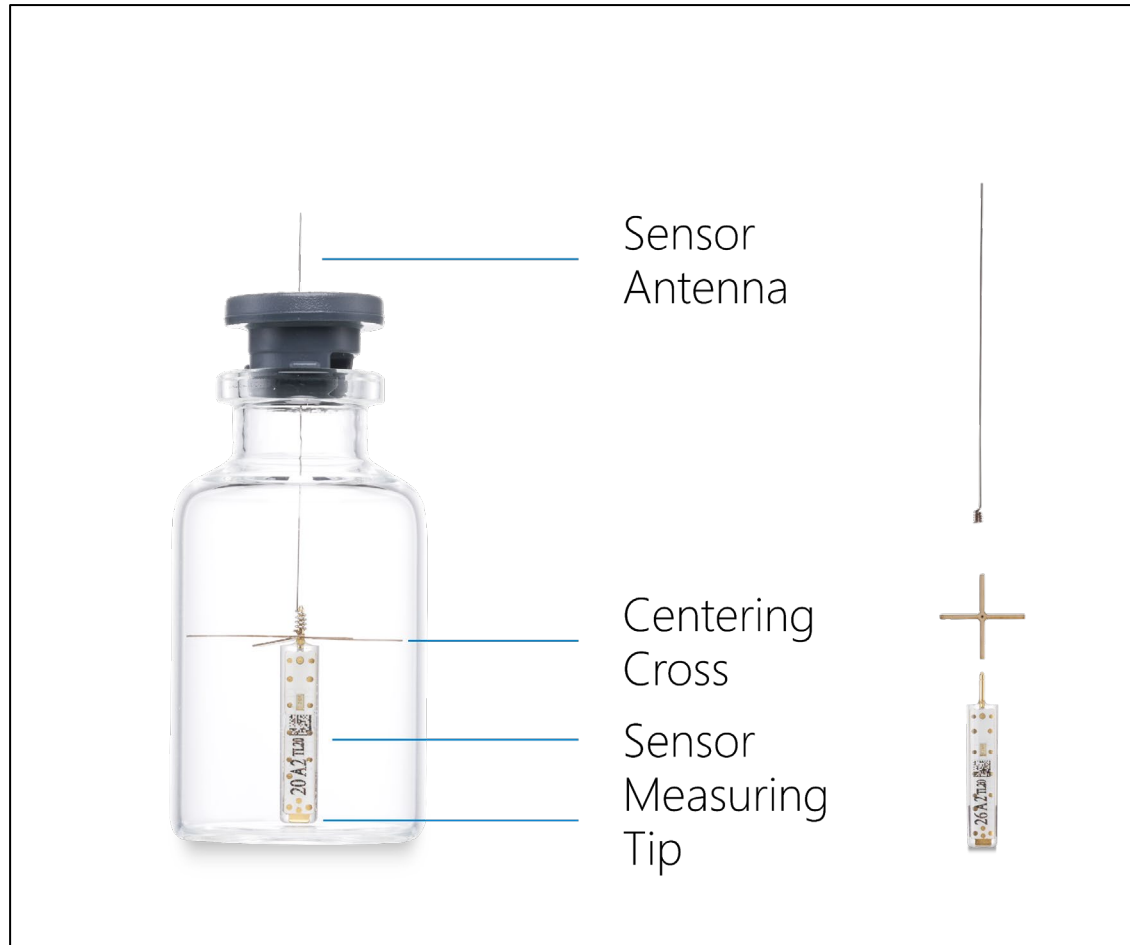


Blood Plasma



**Applicable for vials, infusion bottles,
cartridges, trays...**

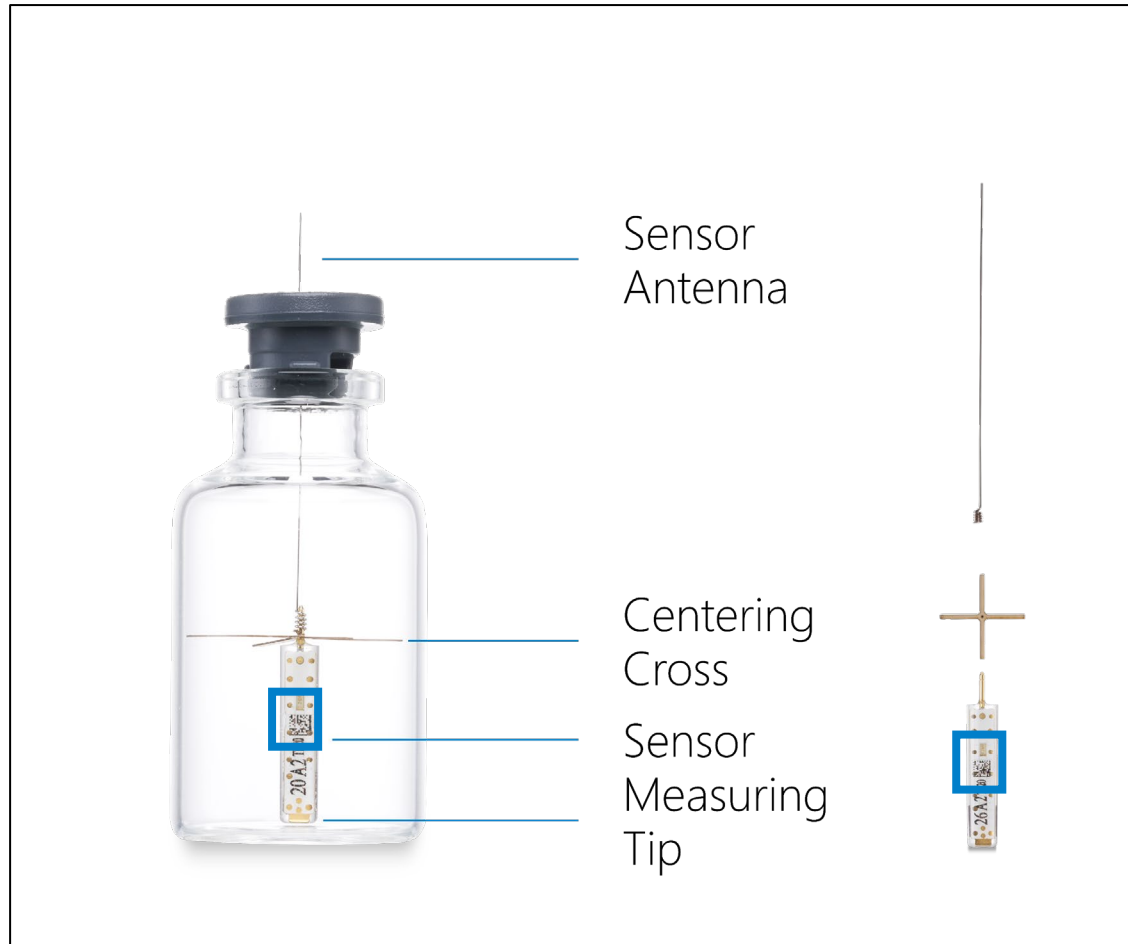
NEW Sensor: The Gold Standard for Tp Measurement



Key Advantages of the NEW Tempris Sensors

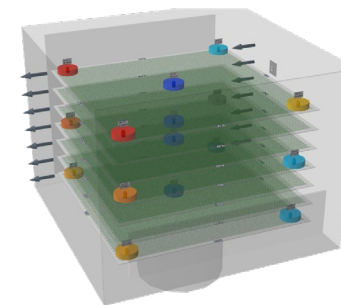
1. **Wireless, battery-free, real-time**
2. **No heat** input into product
3. **Up to 40** Sensors per batch
4. **Same sensor** technology in **all Lyo-scales**

Our NEW Sensor: The Gold Standard for Tp Measurement



Key Advantages of the NEW Tempris Sensors

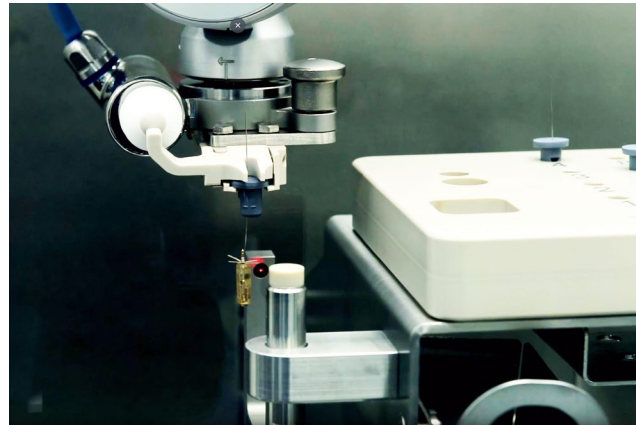
1. **Wireless, battery-free, real-time**
2. **No heat** input into product
3. **Up to 40** Sensors per batch
4. **Same sensor** technology in **all Lyo-scales**
5. Automatic recognition via **Matrix Code**
6. **Traceability for sensor positioning on shelf**
7. **Tp visualization in Digital 3D Twin**



Fully Automated Aseptic Sensor Placement and recognition by Robot

Sterilized sensor magazine placed in the isolator

The automation control system and the robot will handle all remaining sensor positioning steps.



Video: Easify Your Lyo Process



https://www.tempris.com/tempris-video/Tempris--Easify-Your-Lyo-Process-003_en_1920x1080.mp4

Semi-Automated Control of Sensor Insertion

Step 1 Sterilized sensor magazine placed in the isolator

Step 2: User manipulates the vial by removing the stopper

Step 3: Removal of the stoppers prepared with the sensor from the sensor magazine

Step 4. placing the stopper-sensor combination with tweezers on the intended vial

Step 5: Operator confirms the input via HMI, the sensor is guided to the target position of the respective shelf via the computer control.

Steps 2-5 are repeated by the user until all sensors are loaded in the FD.



T.PRO System for Commercial application

TLM - Software



TLM – Measuring Software
GAMP 5/ 21 CFR Part 11
Compliance

Interrogation Unit (TIRU)



T.PRO-A8 Measuring device
Transmitter with Backscatter
Receiver – POE+ LAN-Interface for
Laptop and Antenna Ports

Antenna Option



Radio Frequency Antennas
CIP/SIP compatible

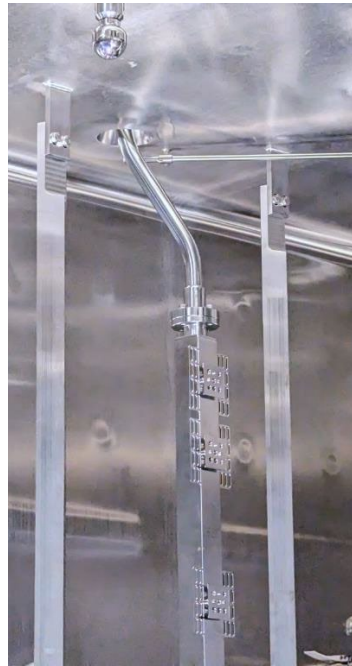
Sensor Options



**Wireless, Battery-Free
Temperature Sensor** with
flexible disposable Antenna
designed for Shelf Stopping

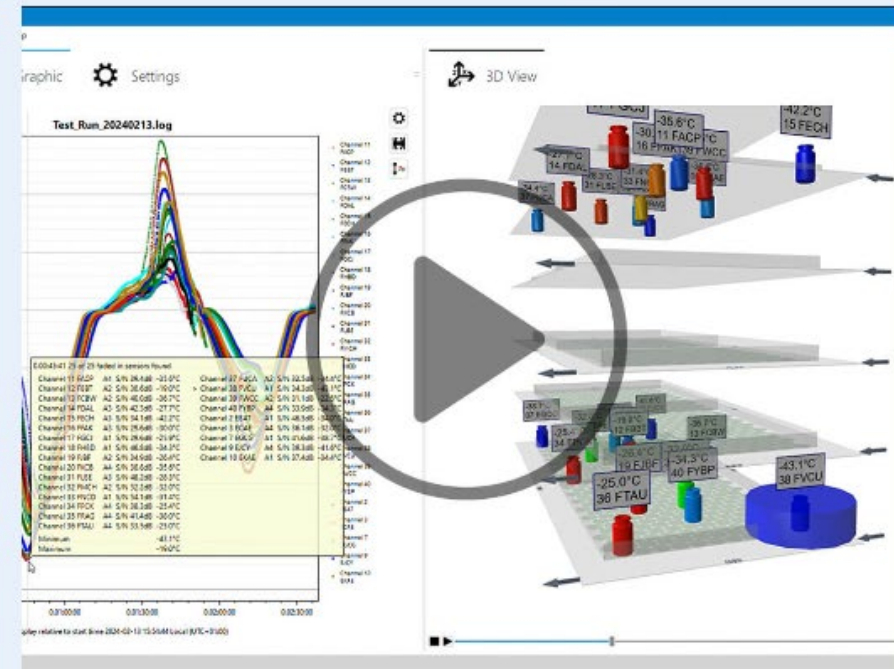
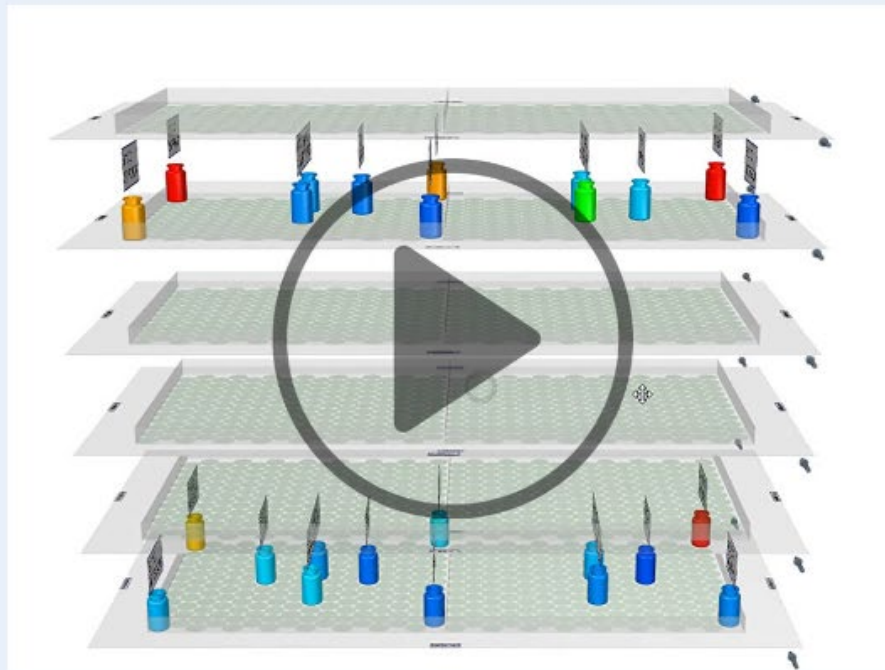
Our Antenna Solutions

The MFA antenna is an ideal for continuous use

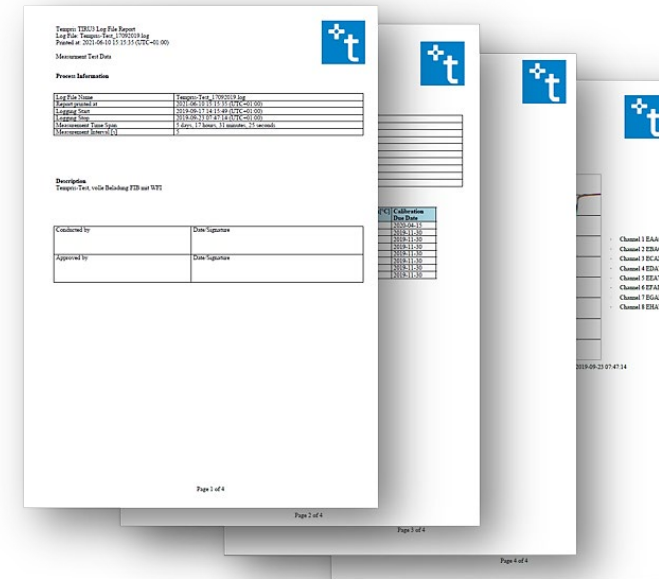
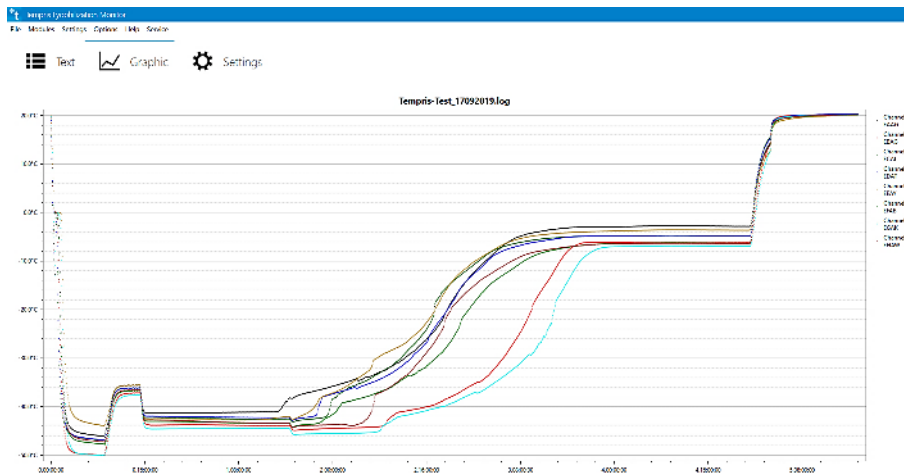
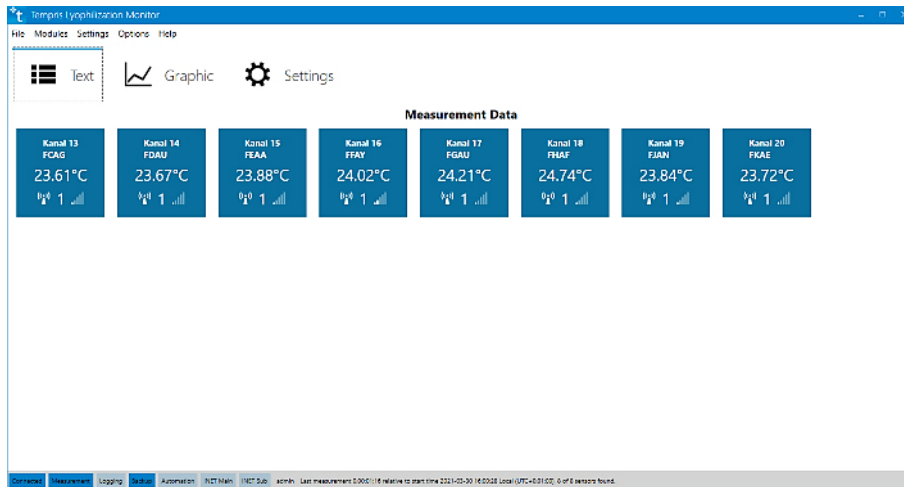


The ANT-PH1 antenna solution prioritizes easy retrofitting and installation.

Take a Look into the Software



<https://www.tempris.com/products/technology#video-software>

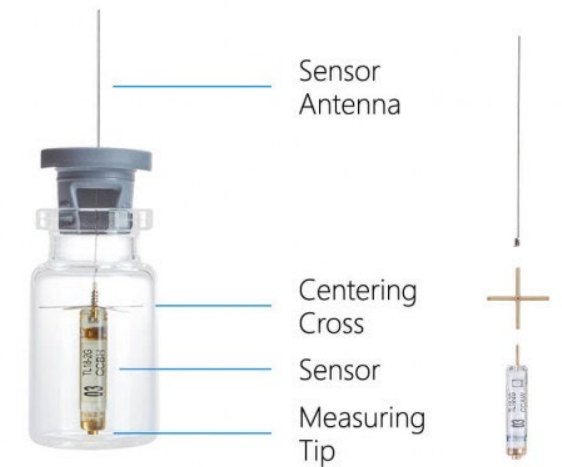


**Easy REPORT
Generation**

- 21CFR Part 11 / GAMP 5
- SCADA/PLC Interface
- Documentation of Sensor Position and more
- Language Settings

1. Precise Tp Measurement in real time
2. Measurement at all positions within FD possible via automatic loading
3. Data from all 3 phases of Freeze Drying (freezing, primary/secondary drying)
4. Sensors are applicable for highly potent drugs via automated processing
5. Applicable to all FDs sizes (lab, production)
6. Applicable for vials as primary packaging and bulk solutions
7. Digital Twin supports scalability and tech transfer

Questions ?



Thank You

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