tempris® Easify Your Lyo Process

Pave your way to Pharma 4.0 with

Tempris – Easify Your Lyo Process

process control with wireless, battery-free
real-time temperature measurement

WHY USE TEMPRIS

as a PAT Tool for product temperature (Tp) measuring in process control?

Leading pharmaceutical companies have stated about PAT Tools[1]:

Cost savings

- batch failures have been reduced significantly
- saved API costs in technology transfer
- improved scale-up speed and efficiency
- fast tech transfer to manufacturing
- time line for approval much reduced

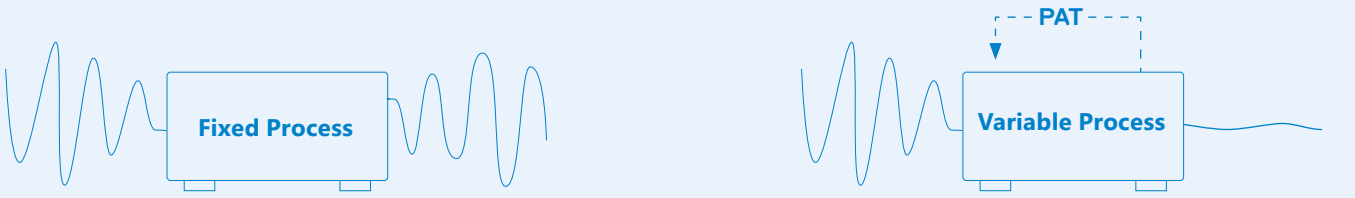
Increased product quality

- increased product robustness
- improved product reproducibility
- better product control
- comparable data from R&D and manufacturing

Better process understanding

- continuous process monitoring from lab- to production scale
- improved communication between R&D and manufacturing through understanding each other's parameters
- we do see improved process robustness and the potential for improved production
- helps trigger innovative and scientific ideas/solutions for process improvements

Impact of Active Control



Source: FDA

[1]Pharmaceutical Engineering, July/August 2012, Vol. 32. No.4 © ISPE.

Wireless Real-time Temperature Measurement System

Tempris paves the way for Pharma 4.0 for biotech and pharmaceutical companies in **lyophilization**, **sterilization** and **granulation**

Introduction

Tempris PAT Tool is
- a real-time product temperature measurement system
- a wireless and battery-free technology
- suitable for pharamceutical applications such as

→ lyophilization
→ sterilization
→ granulation

- cGMP, GAMP5 and 21 CFR Part 11 compliant as required by the United States Food and Drug Administration (FDA), the European Commission (CE) and other regulatory bodies in Asia and elsewhere.
- the only real-time product temperature measurement system used in laboratory, pilot and production freeze-dryers as well as for autoclaves and granulators.

Operating Principle

Quartz based sensor, operating on the principle of temperature dependent resonance: after excitation by a modulated microwave signal (2.4 GHz) the sensor continues oscillating at a temperature dependent frequency. Overlaying the sensor response with the carrier signal leads to a frequency shift from which the product temperature (Tp) can be derived.

Key Features

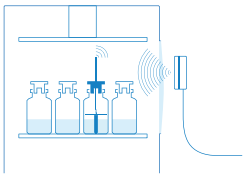
Sensors
- wireless, passive – no cable, no battery
- up to 40 per batch
- sterilizable and cleanable
- cGMP compliant
- accuracy: ±0.7K ...±0.3K
- calibration range: -70°C ... +130°C
- max. storage range: -200°C ... +140°C
- usable in all scales of FDs - easy data comparison
- for in-line Tp measuring
- suitable in lyophilization for vials, DC syringes, Lyoguard® trays, batch trays
- suitable in sterilization for LVP polymer infusion bags and bottles and SVP
- suitable for automatic loading / unloading with automatic sensor in vial positioning

Temperature Interrogation Unit
monitors and stores data of up to 40 sensors simultaneously
supports innovative antenna solutions
integrated antenna multiplexer
interface for PLC, SCADA, data recorder

Tempris Data Server Software
version available for lyophilization
supports new features like sensor loading plan, statistic support, etc.
GAMP 5 / 21 CFR Part 11 compliant

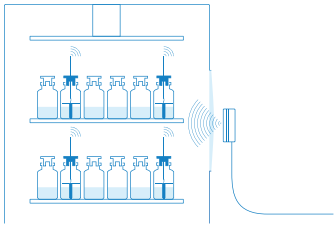
for further details see data sheets

Lyophilization Key Features and Benefits



Laboratory FD
Lab Scale Development

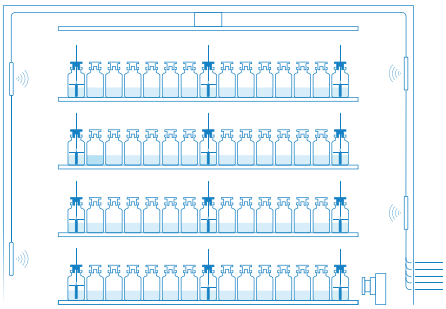
Lyo-cycle development in the laboratory establishes the base for the freeze drying cycle and its subsequent optimization. Tempris captures the product temperature (Tp) at the vial bottom (Tb), one of the most critical lyo-cycle parameters.



Pilot/Production FD
Scale-up, Transfer

Your product moves to a larger freeze-dryer, to a different type of freeze-dryer or simply to cGMP environment. These activities used to involve a change in Tp measurement technology (e.g., from TCs to RTDs, MTM cannot be used), causing problems or limitations with respect to the comparability of the obtained data (positioning of RTDs in sterile environment).

With Tempris, the same sensors which are used in lab scale development can also be used in pilot and production scale freeze-dryers at equivalent positions, thus providing directly comparable data.



Production FD
Process Monitoring/Control

Full production scale lyophilization under cGMP conditions places increased demands on the equipment used. The installation of wired temperature sensors is usually impossible where automatic loading- and unloading systems are in use. However, wireless Tempris sensors can be used in such environments, thus allowing you to capture valuable data in production, gain more insight and ensure more safety of your production process.

Sensors suitable for
vials, DC syringes, Lyoguard® trays, batch trays

Sensors
laboratory FD typically 8 per batch
production up to 40 per batch
sensors are sterilizable and cleanable

Installation
can be retrofitted to all freeze-dryers

PLC / SCADA
system software supports interfaces via Modbus/TCP IP, Profinet and Ethernet IP or via wired 4-20 mA.

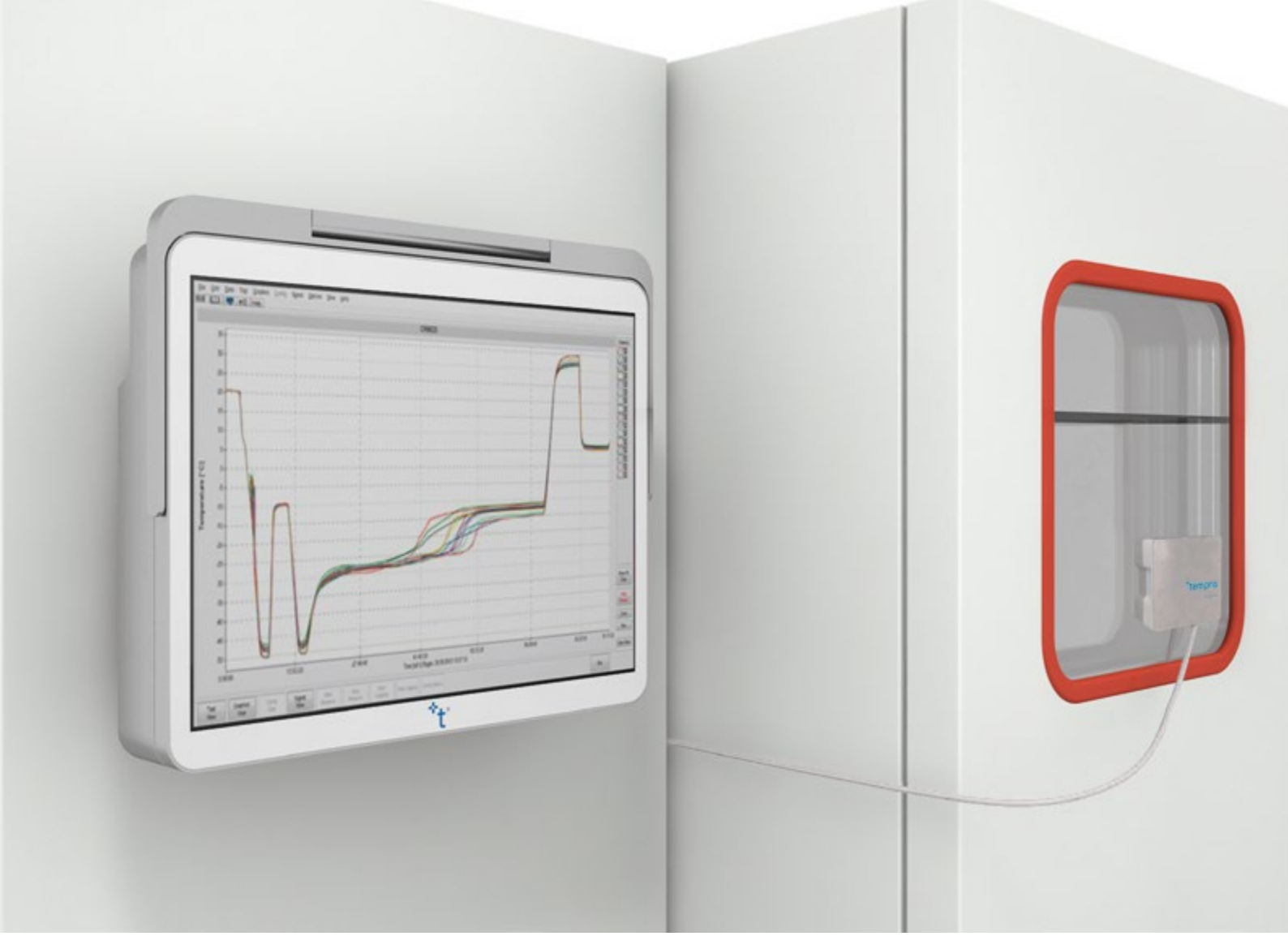
GMP Compliant
GAMP 5 – 21 CFR Part 11

Production Feature
for Pilot/Production FD

- supports auto loading system
- sensor function test for robot-assisted loading
- sensor positioning plan (loading plan)

Pave your way to Pharma 4.0 with **Tempris – A powerful PAT-Tool** process control with wireless, battery-free real-time temperature sensors.

Image: Introduction of Hof Sonderanlagenbau – fully automatic loading and unloading system with robot for inserting Tempris wireless temperature sensors into vials for process control at hot and cold spots.



Tempris Interrogation Unit TIRU3

The Tempris provides wireless- and battery-free, long term- and real-time measurement of product temperature. The key component of our new measurement system is the control unit, which principally allows for an unlimited number of Tempris sensors.

The main features of our new product generation are:

- substantially higher data throughput with improved signal analysis and optional extended data analysis in the lyophilization process.
- spectral analysis for continuous monitoring of interfering frequencies - such as WiFi and Bluetooth - and automatic switching to alternative frequencies.
- integrated multiplexer for controlling innovative antenna systems.
- simplified cabling through Power over Ethernet (PoE).
- suitable for complete automation in the SCADA / PLC with sensor identification for loading and unloading.
- digital identification of sensors via radio signal in combination with the proven quartz sensor technology (pat. pend.) for up to 40 sensors with digital calibration.
- support of additional frequency bands.
- designed for ATEX application.
- new TLM software generation with new features to assist the operator.

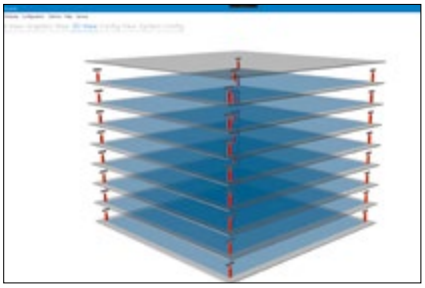
Software TLM

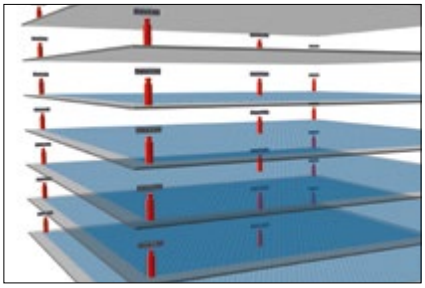
The new software version TLM 10.1 Lyophilization Monitoring. The Tempris Lyophilization Monitoring Software TLM is used to control the measuring unit, record data, set all parameters, visualize and export data. TLM complies with GAMP 5 / 21CFR Part 11.

What is new?

- 40 sensors simultaneously
- sensor function test for robot-assisted loading
- visualization of the measured data
- sensor positioning plan (loading plan)
- 3D representation of the sensor positions
- input primary packaging - size, capacity, type, etc.
- modern Windows 10 design
- selection of different languages

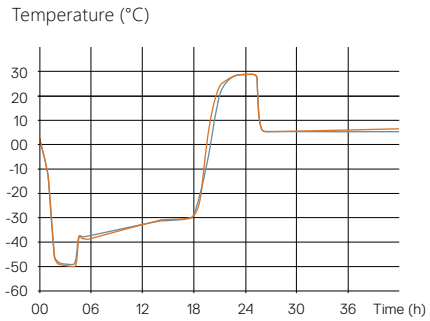
Data can optionally be analysed with the Tempris Data Analysis Software (TDA).





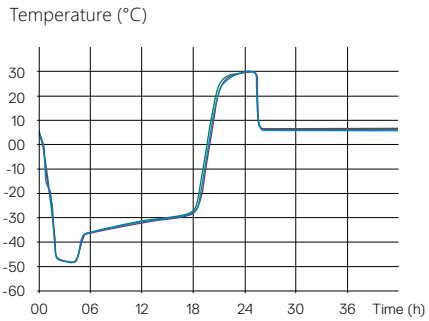
Lyo-Cycle Transfer with Tempris

Freeze dryer A



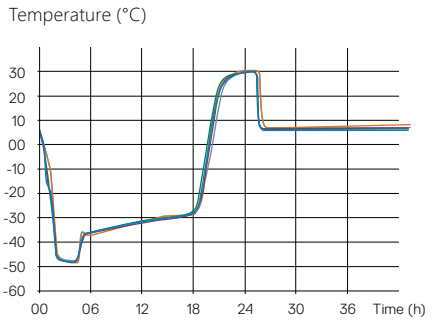
Example: Transfer of lyo-cycle from freeze-dryer A (24 m^2 / 258 sqft) to freeze-dryer B (33 m^2 / 355 sqft)

Freeze dryer B



Lyo-cycle temperature profiles from different runs on both freeze-dryers are superimposed to demonstrate that the lyo-cycles are equivalent.

Overlay Freeze dryer A+B



No further assessment of upper and lower temperature limits is required.

Sterilization with Tempris Sensors

Terminal sterilization of parenteral drugs and products such as

- liquid adjuvants for vaccines
- oncology drugs
- albumin and plasma proteins derived from blood
- immunoglobulins
- thrombolytics
- parenteral nutrition products such as lipid emulsions

The introduction of Tempris wireless sensors for real-time Tp monitoring in sterilization will overcome limitations so far posed by wired sensors and reference bottles.

Using Tempris allows for:

- temperature monitoring of actual product without reference bottles
- temperature monitoring at identified hot & cold spots (HCS)
- use of auto loading systems

Our Tempris solution for sterilization has been developed in cooperation with our customers. Based on their feedback, our wireless technology can:

- reduce risk of batch rejects
- reduce risk of equipment downtime
- increase overall productivity and quality assurance (QA)/risk assessment (RA) compliance of batch releases

Applications

- saturated steam process
- steam air mixture process
- hot water shower process

Granulation with Tempris Sensors

This is another example for our cooperation with customers.

We have been asked to find a solution for product temperature measurement without interruption of the granulation process while providing our key benefits such as

- reduce risk of batch rejects
- reduce risk of equipment downtime
- increase overall productivity and quality
  assurance (QA)/risk assessment (RA)
  compliance of batch releases

We prefer to work with our customers and find new solutions.

Should you have an application which Tempris is not used for yet, we would like to rise to the challenge.

Tempris - Easify Your Lyo Process

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DIN EN ISO 14001:2015
DIN EN ISO 9001:2015

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