

# Data Sheet

## TL-Sensors and Accessories

Temperature Measurement Sensors for Laboratory and  
Production Freeze Dryers



Doc. Nr.: 920006

## Change History

Version	Date	Change
V1	2020-07-30	Initial Creation
V2	2022-02-22	Change RFID Serial Nr., Update Sensor Selection Table
V3	2022-03-31	Update Centering Crosses for 10H,10R,15R
V4	2022-11-14	Update Sensor Selection Table
V5	2024-01-31	Update Sensor Design

## Abbreviations

Abbreviation	Description
ANT-PH1	Antenna type for fixed installation in a freeze dryer chamber
API	Active Pharmaceutical Ingredient or drug
CIP/SIP	Cleaning in Place / Sterilization in Place
FDA	U.S. Food and Drug Administration
ISM Band	ISM bands (Industrial, Scientific and Medical Band) are frequency ranges that can be used license-free by high-frequency devices in industry, science and medicine.
T.PRO	Tempris Model Series T.PRO is the abbreviated term for the application of the Tempris measuring system in the production freeze dryer.
TL10, TL20, etc.	TL is the abbreviation for <b>T</b> empris sensors for <b>L</b> yophilization and the index refers to a specific sensor size.
TL-ANT-xx	TL Antennas
TL-CC-xx	TL Centering Cross
TLM	TLM stands for Tempris Lyophilization Monitor and is a software license operating under Windows in real-time.
TL-PIT-xx	Stands for Tempris Piercing Tool and is an accessory for preparing the TL sensor with centering cross and stopper so that it can be positioned centrally on the vial bottom. The tool is used outside the sterile area.
T <sub>b</sub>	Product temperature at vial bottom
T <sub>p</sub>	Product temperature
T <sub>s</sub>	Temperature at shelf surface of the freeze dryer
TSH	Tempris Sensor Holder is an accessory in the form of an ISO-vial replica which is used in conjunction with the TL sensor in order to measure the T <sub>s</sub> .

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## 1 Tempris Introduction

The modular temperature measurement system consists of a **Temperature InterRogation Unit (TIRU)**, software for data visualization and evaluation, antennas and sensors. The passive sensor technology is activated by a radiated trigger signal via an interrogation antenna. The sensor measuring crystal oscillates at its characteristic frequency and the backscatter signal is converted into a temperature value by TIRU via an interrogation antenna. The measuring system uses the 2.4 GHz ISM (Industrial, Science, Medical) frequency band which is allocated worldwide.

Further information about this radio measuring device can be found in the TLM manual.

The Tempris products are divided into the following groups:

- (1) Software, e.g., TLM
- (2) Interrogation Unit, e.g., T.PRO
- (3) Antennas, e.g., ANT-PH1
- (4) Sensors, e.g., TL10

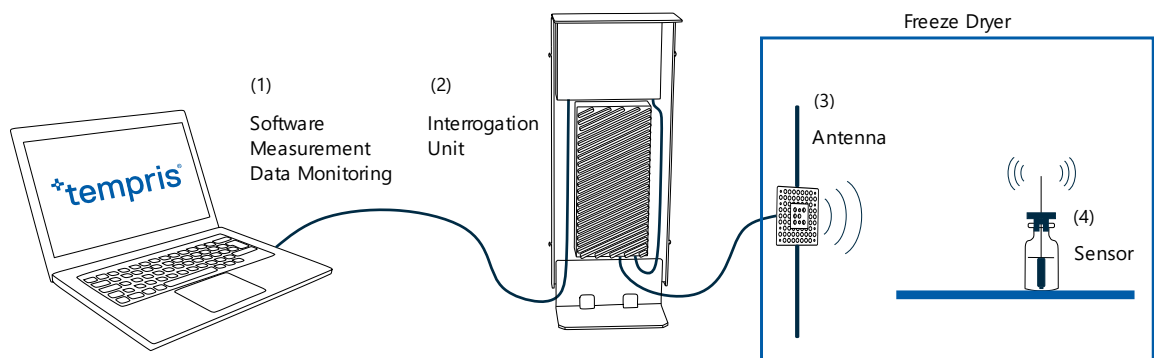


Figure 1-1: Tempris system components

## 2 Importance of Temperature Monitoring during Freeze Drying

For freeze drying process, the product temperature can be considered as the most critical product parameter that determines the quality of the final product. Each formulation composition has its own critical formulation temperature, which serves as the basis for the upper limit of the product temperature during primary drying in order to avoid product defects and to meet the critical quality characteristics. The representative determination of the product temperature during the different phases of the freeze-drying cycle is important to assess the suitability of the applied process conditions.

Tempris wireless temperature sensors provide the precise and accurate measurement of the product temperature throughout the freeze-drying cycle at critical positions.

The ultimate goal is to maintain the same product temperature versus time profile at all scales to ensure the same thermal conditions in the product and thus the desired product quality.

Tempris is the only sensor that (1) offers unbeatable performance in terms of measurement and handling and (2) can be used in all types of freeze dryers, all scales and all regulatory environments, i.e., from early development to routine production under sterile conditions. Tempris is thus a real PAT tool.

### 3 TL Sensor

The TL sensor is developed for real-time temperature measurements in the product in ISO-vials and bottles in conjunction with original stoppers. By using suitable accessories, sensors can be used for further formats such as bulk vials, sealable membrane bags or even double chamber cartridges. Another accessory is the Tempris sensor holder (TSH) which, in combination with a sensor, enables measurement of shelf temperature (T<sub>s</sub>). Please see chapter 6 for more information. Up to 40 sensors can be used simultaneously in each measurement cycle.

TL sensor models are available in five different sizes. The main distinguishing feature is the sensor length. The selection of sensor is based on vial type and filling volume. For optimum signal transmission, the sensor antenna must always be positioned outside the liquid. Sensor antennas and centering crosses are required for the measurement process in vials. Please see section 4.5 for further information about sensor selection.

Sensors	Sensor Length in mm w/o   w Antenna Pin	Sensor Volume in ml	maximum Filling Height in mm
TL10	13.5   17.5	0.19	8
TL20	21.0   25.0	0.30	16
TL30	31.0   35.0	0.48	25
TL60	62.0   67.0	1.42	50
TLxx	>40.0   >45	TBD	TBD

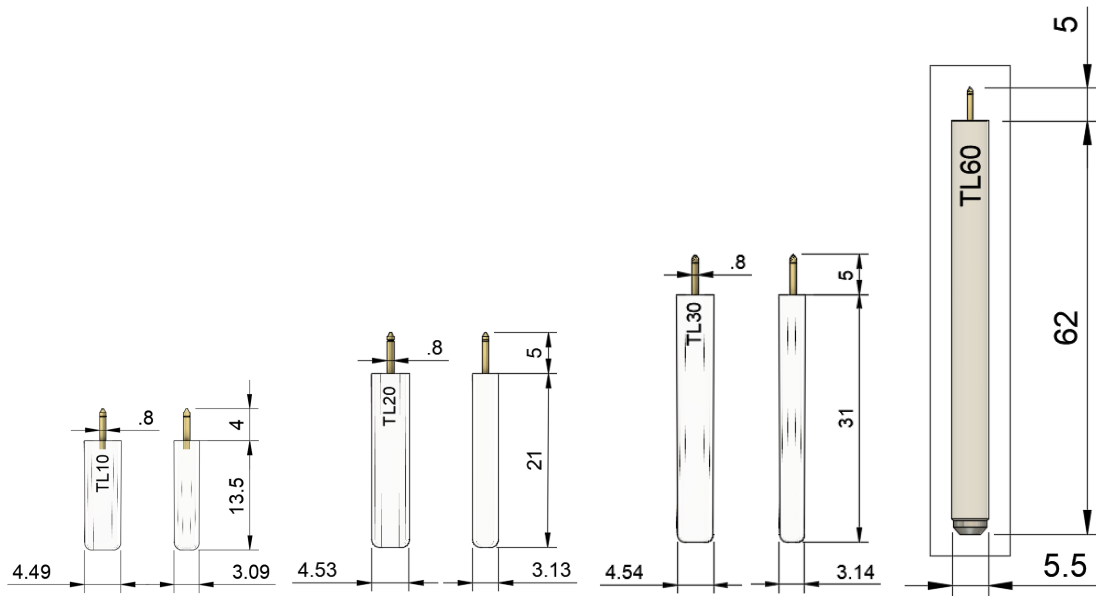


Figure 3-1: Sensors dimensions without sensor antennas - Drawing not to scale

### 3.1 Centering Cross and Sensor Antenna

The sensor antenna, held by the vial stopper, and the centering cross ensure the correct centric position and height of the sensor for measuring the product temperature at the vial bottom ( $T_b$ ). The sensor antenna and centering cross are disposable items because they can be deformed by stoppering process and correct positioning in the vial can no longer be ensured.

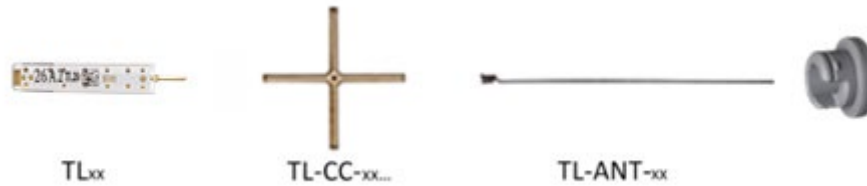


Figure 3.1-1: Sensor assembly (sensor, centering cross, sensor antenna, stopper)

### 3.2 Stoppering

The sensor antenna is designed in such a way that the flexible antenna is very easily deformed and pushed to the side when the plates are closed. The stopper closes the vial during the stopper process. The sensor is not damaged in the process and can be reused for the next application after replacing the sensor antenna and centering cross.



Figure 3.2-1: Sensor position in the vial before and after stoppering

### 3.3 Formulations containing Solvents

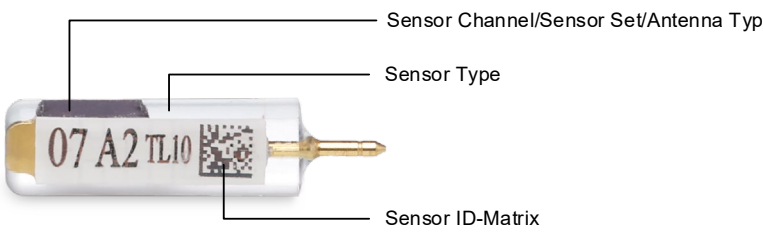
For use in solvent mixtures, a surface coating (USP Class VI polymer) is optionally offered for better protection of the sensor surface, which protects the sensor from aggressive media. The sensors are listed the corresponding documentation with the suffix "P" = Parylene coated.

### 3.4 Regulatory Requirements

The sensors with accessories that come into contact with the product meet the following regulatory requirements: GMP compliant, cGMP compliant or FDA compliant, GAMP 5, 2001/95/EC (RoHS).

## 4 Sensor Specifications

### 4.1 Sensor Identifications

	
Channel	Used for individual channel assignment, channel no. is referenced in the calibration certificate. Up to 40 different sensor channels can be used simultaneously per run.
Model	Application Lyophilization - See section 3
Identifier	Example: 07 A2 TL10 DataMatrix Code This means: Kanal 07; Sensor Set A; Lambda/2 Antenna; Design TL10 and Unique ID-Number Optically readable, unique sensor identification number, is referenced in the calibration certificate.
Serial Number 14x14 DataMatrixCode	Example: TL00004197 Unique serial number for electronic identification, appears in the calibration certificate and is kept together with the sensor coefficients in the measuring system, as well as in the measuring report.

### 4.2 Material Specifications

Sensor Color	Transparent, white primer
Sensor Housing	Polycarbonat Makrolon® 2458 shell on the outside, (Surface roughness $\leq 0.3 \mu\text{m}$ )
Sensor Pin for TL60	Stainless steel 1.4404
Sensor Filing	Internally potted with Epoxy resin for medical purposes, according to USP Class VI
Sensor Antenna Pin	Stainless steel 1.4404, gold plated
Sensor Antenna	Stainless steel 1.4401 / 316L
Sensor Centering Cross	PEEK - Polyether ether ketone
Sensor Antenna Extension	PEEK - Polyether ether ketone

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### 4.3 Environmental and Cleaning Conditions

Storage Temperature	Please always store TL sensors in a dry and clean place at room temperature when not in use.
Operating Temperature	Operating temperature depends on the calibration range, Please see section 4.4 for more information.
Humidity (max.)	100 % RH
Protection Class	IP 68
Pressure	10 <sup>-5</sup> ... 3 bar (1 ... 3 x 10 <sup>5</sup> Pa) Please note: The sensors withstand the typical FD pressure ranges during autoclaving. The autoclave temperature is typically 121.5°C, at 1.1 bar gauge pressure. Tempris sensor withstands approximately 2.1 bar (equivalent to approximately 133°C) due to the temperature range; pure atmospheric overpressure (i.e., without autoclaving) is specified as 5 bar.
Sterilization of TLxx Sensor	30 × saturated steam 3 min at +134°C or 50 × saturated steam 15 min at +121.5°C Please note: <ul style="list-style-type: none"> <li>• Frequent sterilization with saturated steam leads to sensor aging (increased color clouding or surface damage).</li> <li>• In case of clouding and/or damage, do not use the sensor any longer, as humidity intrusion leads to sensor defect. Sensors are checked during calibration.</li> <li>• TL-ANT and TL-CC: Only for single use</li> </ul>
Sterilization of Tempris Sensor Holder (TSH)	Since TSHs are always used with sensors, specified temperature ranges for "Sterilization of TLxx Sensor" must be observed. Due to the robust design of TSH, it is recommended to inspect it visually after each use in order to make sure it functions properly. Please see section 6 for more information about TSH.
Cleaning of Sensor and TSH	Clean contaminated sensors with alcohol (isopropanol) or distilled water. If other cleaning agents are to be used, please contact Tempris service before use: <a href="mailto:service@tempris.com">service@tempris.com</a> <b>Attention:</b> Please avoid ultrasonic cleaning absolutely because it causes sensor defect directly.

### 4.4 Calibration and Maintenance

Calibration Service	<b>Calibration Ranges</b>	<b>Accuracy</b>
	-60°C ... +40°C *	
	-60°C ... +60°C	± 0.7 K *   ± 0.5 K   ± 0.3 K
	-70°C ... +60°C	Resolution: 0.1°C   0.01°C
	-70°C ... +70°C	
	* Standard calibration range Data referring to the sensor accuracy	

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## 5 Sensor Components and Assembly

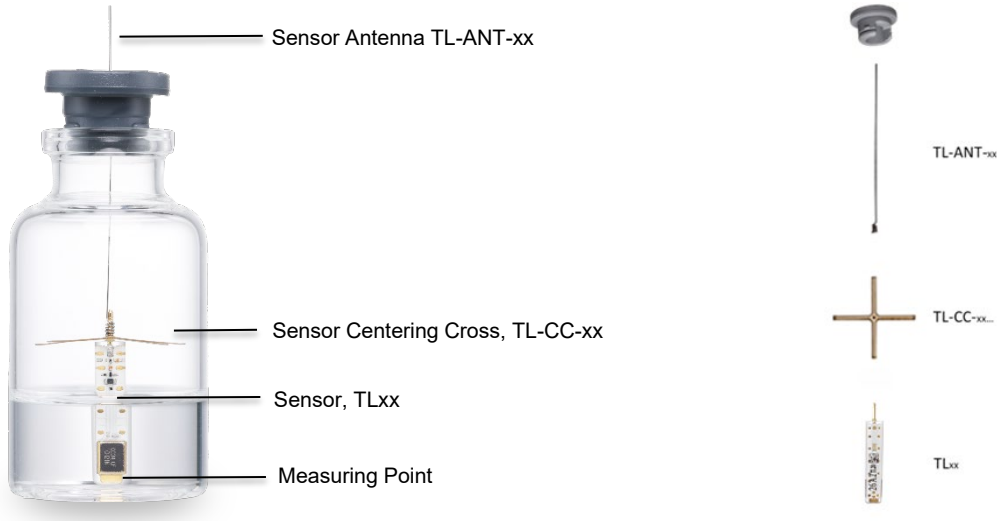


Figure 5-1: Sensor elements for vial insertion

In order to measure product temperature at the vial bottom ( $T_b$ ) centrally, a centering cross is used. This is preassembled together with antenna and stopper outside the sterile process. The Sensor incl. stopper can be sterilized in a Steri-Bag. The sterilized Steri-Bag is inserted into isolator via a Rapid Transfer Port (RTP). The Steri-Bag is positioned at a previously defined "station". Sensors are inserted into vials using Tempris Sensor Handling Tool.

### 5.1 Piercing Tool

Piercing tools are available for users in order to assemble sensor components together. For video instructions, please see: [www.tempris.com/tempris-video/tempris-piercing-tool-video.html](http://www.tempris.com/tempris-video/tempris-piercing-tool-video.html)



Figure 5.1-1: Components for a complete Piercing Tool

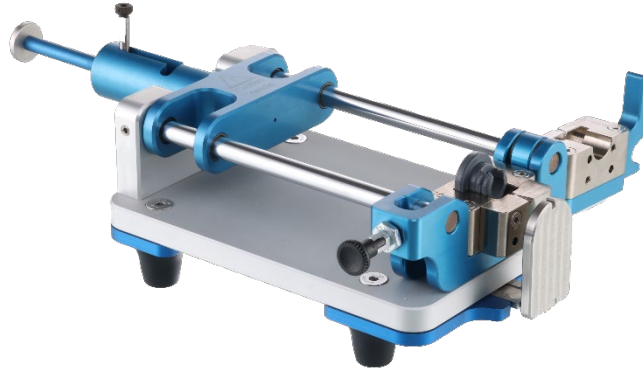


Figure 5.1-2 TL-PIT2-SET for Ø13 mm stoppers (2R / 4R vials)

There are stakes for Ø13 mm; Ø20 mm and Ø32 mm stoppers available.



Figure 5.1-3: Centering cross holder TL-CC-HD for TL-PIT2-SET



Figure 5.1-4: TL-PIT-N1– not illustrated: TL-PIT-N2

PU: 1 set

N1: smaller needle for antennas without TL-Sensor antenna extension

N2: thicker needle for antennas with TL-Sensor antenna extension

Type	Suitable for Stopper Ø in mm	Usable for
TL-PIT-N1-SET	Ø 13, Ø 20	TL-ANT-50
TL-PIT-N2-SET	Ø 13, Ø 20	TL-ANT-60, TL-ANT-70, TL-ANT-90
TL-PIT2-SET	Ø13, Ø20, Ø32	TL-ANT-50, TL-ANT-60, TL-ANT-70, TL-ANT-90
TL-CC-HD	Ø13, Ø20, Ø32	TL-ANT-50, TL-ANT-60, TL-ANT-70, TL-ANT-90

This Piercing set allows safe and centered positioning of the sensor antenna in the stopper as well assembling the sensor components for each operation. Please see the data sheet of Semiautomatic Piercing Tool with document nr. 9200xx for more information.

## 6 Validation Tools for Freeze Drying Characterization

In addition to product temperature measurement ( $T_p$ ), the sensor can measure the shelf temperature at defined positions ( $T_s$ ) in conjunction with the TSH sensor holder. Through this sophisticated TSH solution, temperature profile data can be obtained during a validation process to evaluate potential issues related to occurring product irregularities (meltback, shrinking, etc.). The insertion of the TSH incl. sensor is intended for aseptic conditions.

Application examples during process validation:

- Troubleshooting for product irregularities,
- Temperature variability of the shelf in the inlet and outlet area,
- Temperature variability (dynamic) over the entire shelf stack under full load,
- Identification of critical positions (Hot and Cold Spots = HCS),
- Characterization of identical freeze dryers,
- Applicable for PQ runs, scale-up resp. transfer runs

### 6.1 Handling of Tempris Sensor Holder (TSH)

The shape of the TSH sensor holder is a replica of ISO vials with a flat bottom which provides a thermal contact surface to the shelf. The sensor is inserted into the TSH holder; a centering cross and stopper are not needed. (Please see Figure 6.1). All materials can be autoclaved and are GMP compliant.

TSH can be selected via the selection table in section 6.3.

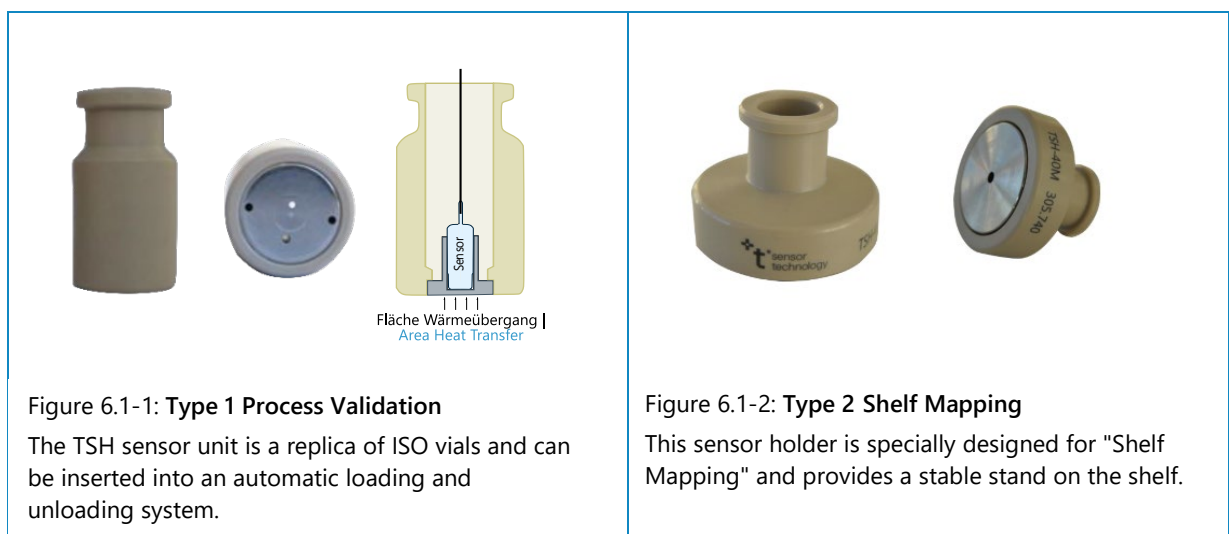


Figure 6.1-1: Type 1 Process Validation

The TSH sensor unit is a replica of ISO vials and can be inserted into an automatic loading and unloading system.

Figure 6.1-2: Type 2 Shelf Mapping

This sensor holder is specially designed for "Shelf Mapping" and provides a stable stand on the shelf.

## 6.2 Material Specifications of Tempris Sensor Holder

Type 1 Process Validation	Housing: Polyether ether ketone (PEEK), Insert (metallic ferrule): Stainless steel 1.4401
Type 2 Shelf Mapping	Housing: Polyether ether ketone (PEEK), Insert (metallic ferrule): Stainless steel 1.4401, O-Ring: Colored silicone

## 6.3 Selection Table of Tempris Sensor Holder (TSH)

Type 1 Process Validation	Outer Diameter (da) mm	Height mm
TSH-2R	16	35
TSH-3ml	16	31
TSH-6R	22	40
TSH-10R	24	45
TSH-20R	30	55
TSH-30R	30	75

Type 2 Shelf Mapping	Outer Diameter (da) mm	Height mm
TSH-40mm	40	30

PU: 10 pcs



Other TSH sizes are available on request.

## 7 List of Articles

Sensors	Article Number
TL10/2	351200
TL10/4	351400
TL20/2	352200
TL20/4	352400
TL30/2	353200
TL30/4	353400
TL60/2	356200
TL60/4	356400
TLxx	35xxxx
Centering Crosses	Article Number
TL-CC-16.0-13.8	305211
TL-CC-22.0-19.8	305212
TL-CC-24.0-21.8	305215
TL-CC-30.0-27.3	305219
TL-CC-42.5-36.8	305221
TL-CC-47.0-43.6	305240
TL-CC-20.5-18.0	305228
TL-CC-23.5-21.3	305214
TL-CC-26.5-23.8	305217
TL-CC-32.0-29.0	305220
TL-CC-36.0-31.7	305218
TL-CC-42.5-36.8	305221
TL-CC-51.6-45.8	305239
TL-CC-47.0-43.6	305240
TL-CC-66.0-62.0	305243
Sensor Antennas	Article Number
TL-ANT-25	300102
TL-ANT-50	300107
TL-ANT-60	300108
TL-ANT-70	300109
TL-ANT-90	300110
Piercing Tools	Article Number
TL-PIT-N1-SET	340131
TL-PIT-N2-SET	340132
TL-PIT-SA	340200
Tempris Sensor Holders	Article Number
TSH-2R	341702
TSH-3ml	341703
TSH-6R	341706
TSH-10R	341710
TSH-20R	341720
TSH-30R	341730
TSH-40mm (Type 2)	341740

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## 8 Safety Instructions

TL-Sensors must always be stored in a dry and clean environment when not in use.
Cleaning and sterilization instructions must be observed.
The sensor antenna pin must be outside the liquid during the temperature measurement. Otherwise, a sufficient signal for data transmission cannot be guaranteed. Please observe the instructions in the TLM manual.
When selecting sensors, the selection table in section 4.5 must be observed to avoid damage to the vial or sensor when closing the vials (stoppering). Before use, the user must check and approve the device. In case of deviating vial geometries please contact: <a href="mailto:service@tempris.com">service@tempris.com</a>
Centering crosses and sensor antennas are designed for single use, since the material properties are no longer guaranteed by the intended handling processes. Possible errors are such as poor sensor centering, loosening of the sensor antenna at the connection points with the consequence of signal failures.
Corresponding instructions of the manual and the training documents must be observed. The temperature measuring system may only be operated by trained personnel. Information on staff training is available at <a href="mailto:service@tempris.com">service@tempris.com</a>
For correct temperature measurement, the specified calibration and maintenance intervals must be observed. Individual service offers are available at <a href="mailto:service@tempris.com">service@tempris.com</a>

## 9 Approval

Customer Documentation number (if applicable)	950006	
Created by (Date, Signature)	Reviewed by (Date, Signature)	Approved by (Date, Signature)

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