## TempTale Ultra Probeless Dry Ice Monitor

# Introducing the TempTale<sub>®</sub> Ultra Probeless Dry Ice monitor—a compact USB temperature datalogger that can be placed directly into dry ice environments as low as -95°C.

This new datalogger can be programmed with up to six temperature alarms, including MKT and duration. The integrated USB connector provides fast and easy download of data, and automatically generates a secure PDF report and encrypted data file when connected to a USB port on a PC. These files can be subsequently downloaded, viewed and archived in Sensitech's TempTale Manager® Desktop (TTMD) software or ColdStream® Cold Chain Manager private cloud database application—built to comply with FDA 21 CFR Part 11 and EC Annex 11. Furthermore, the TempTale Ultra Probeless Dry Ice monitor meets IATA's 2018 Dangerous Goods Regulations 59th Edition and thus requires no additional shipment labeling.

#### TempTale<sub>®</sub> Ultra Probeless Dry Ice Features

- Monitor temperatures as low as -95°C
- Place directly into dry ice environment in contact with product
- 3-Point NIST traceable calibration certificate accessible in TTMD or ColdStream software
- Large LCD screen provides clear indication of alarm status and trip statistics
- Program up to six alarms, including MKT and Trip Duration
- Flashing LEDs clearly indicate Start/Stop modes and Alarm status inside and outside of dry ice environments
- Download directly to PC via integrated USB connector
- Configurable PDF options such as, time zone, language and PDF/A file format
- Add shipment information prior to shipping to display on PDF report and in software when monitor is downloaded
- Write-protected flash drive for virus protection

#### TempTale Manager® Desktop Software

TempTale Manager® Desktop (TTMD) is a robust, multi-lingual, Windows-based software application used for configuring, downloading and archiving time and temperature data collected from TempTale temperature monitors. The power of TTMD software lies in its intuitive user interface that allows users to effortlessly analyze trip data in order to make high-quality shipment disposition decisions, and ensure that Standard Operating Procedures (SOPs) are delivering acceptable results.



Sample running display Current temperature reading, no alarm



Sample stopped display Alarmed, total time above high limit



#### ColdStream<sub>®</sub> Cold Chain Manager Software

ColdStream<sup>®</sup> Cold Chain Manager (CCM) is a validated, hosted and secure relational database application that is easily accessible via the Internet for query, reporting and analysis of stored data. ColdStream CCM provides centralized storage for time and temperature records in a secure, 21 CFR Part 11 compliant repository. The hosted database application enables robust cold chain data analysis, reporting, and opportunities for process improvement.



### TempTale. Ultra Probeless Dry Ice Monitor

| Г                                | empTale₀ Ultra Probeless Dry Ice Specifications  |
|----------------------------------|--|
| Monitoring Recording Options     | Single Use, Single Use with User Programmable Overwrite  |
| Operating Range                  | -95°C to +30°C (-139°F to +86°F)   |
| Measurement Range                | -90°C to +30°C (-130°F to +86°F)   |
| Temperature Accuracy Range       | ±1.0°C from -90°C to +30°C (±1.8°F from -130°F to +86°F)   |
| Temperature Resolution           | 0.1°C over full temperature measurement range  |
| Data Storage Capacity            | 16,000 data points (16K)   |
| Operating Life / Battery Type    | <ul> <li>30 days of continuous exposure to dry ice temperatures at or below -80°C</li> </ul>   |
|                                  | Two (2) TL-2450 3.6v coin cell lithium batteries—non-replaceable   |
| Data Sampling Interval           | Programmable from 30 seconds up to a maximum of 15 minutes in 30 second increments   |
| Start Up Delay                   | 0 minutes to 24 hours in 30 second increments  |
| Programmable Alarms              | <ul> <li>Programmable high and low limits → alarm is triggered when temperature exceeds set limits</li> <li>Up to six alarms (single temperature limit, temperature range, dual temperature range, MKT, duration)</li> </ul> |
| Alarm Delay Time Thresholds      | Single event (continuous), cumulative  |
| LCD Indicators                   | Started, start-up delay, running, stopped  |
|                                  | <ul> <li>Alarm status: OK ( ✓ ), Alarmed (×)</li> </ul>  |
|                                  | Trip summary data (average, minimum, maximum)  |
|                                  | Current temperature reading  |
|                                  | Time remaining / time elapsed against alarm thresholds   |
|                                  | Total Time Above High/Low Alarm limits   |
| LED Indicators                   | Blinking Startup LED   |
|                                  | Blinking Stop LED  |
|                                  | File generation in process   |
|                                  | <ul> <li>Printer-ready mode activated for printing of PDF report to USB printer</li> </ul>   |
| Start Up Options                 | Manual push button or automatic launch option  |
| Typical Dimensions               | 108mm L x 50.2mm W x 15.2mm H  |
| Weight                           | Approximately 65 g (2.3 oz)  |
| PDF Languages                    | English, German, French, Spanish, Chinese  |
| PDF File Formats                 | PDF or PDF/A   |
| IP Rating                        | IP64 (with silicon cap on)   |
| Time Accuracy                    | $\pm$ 5 minutes per month when exposed to temperatures at or above -90°C   |
| Quality Assurance Certifications | <ul> <li>CE, RTCA – D016ØG compliant, RoHS compliant,<br/>Response time tested to U.S. Pharmacopeia (USP) &lt;1118&gt; and EN 12830 standards</li> </ul>   |
|                                  | <ul> <li>3-point NIST<sub>☉</sub> Traceable Certificate of Calibration</li> </ul>  |
|                                  | Validation Manual  |
| Data Analysis Software           | TempTale® Manager Desktop Software 8.3 or higher   |
|                                  | ColdStream <sub>®</sub> Cold Chain Manager Software 1.8B or higher   |
| Minimum System Requirements      | Windows PC w/ Windows 7 or higher; Adobe Reader 9.0 or higher  |
| Computer Interface               | USB 2.0, A-type plug   |
| Ship Air in Accordance With      | 2018 IATA Dangerous Goods Regulations 59th Edition   |

Sensitech has performed all necessary testing and can provide documentation supporting our compliance at your request.



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