

# TempTale<sup>®</sup>4

## Multi-Alarm Monitors

### Cold Chain Monitoring in a Changing Regulatory Environment

Driven by global regulatory and standards-based guidance documents, the Life Sciences industry is under greater scrutiny to document the storage, handling, and distribution of temperature-sensitive medicinal products to ensure product quality and patient safety. Sensitech's TempTale<sup>®</sup>4 Multi-Alarm monitors deliver extremely precise, targeted temperature monitoring to help ensure compliance with these growing global regulations.

#### Mitigate Risk with TempTale4 Multi-Alarm Monitors

TempTale4 (TT4) Multi-Alarm temperature monitors help to mitigate the overall risk associated with "alarmed" shipments by monitoring temperatures based on stability data. By monitoring for "allowable" temperature excursions, the related high costs of quarantining, investigating, and documenting shipments outside of label claim can be greatly reduced. Furthermore, the TempTale4 USB Multi-Alarm monitor is World Health Organization (WHO) pre-qualified as a user-programmable temperature datalogger (E006/028).

#### Highly Advanced and Flexible Alarm Design

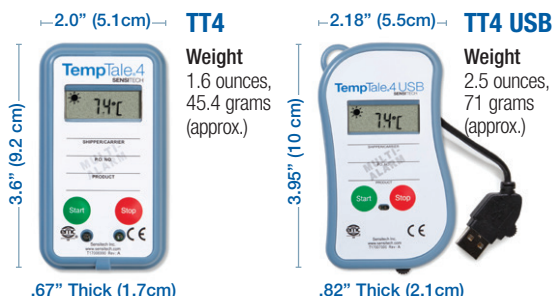
TT4 Multi-Alarm monitors provides users with up to six (6) individual programmable time-and-temperature alarms. Supported alarm types include:

- Single temperature limit (high or low) alarm
- Single and Dual temperature range alarms
- Mean Kinetic Temperature (MKT) alarm
- Duration/Time-only alarm

\*Time thresholds can be configured as continuous or cumulative time events

#### Choose the Model that Best Fits Your Application

Our advanced multi-alarm feature is available in both the TT4 and TT4 USB models.



TT4 Multi-Alarm Specifications	
<b>Single-Use Overwrite and Multiple-Use Options</b>	Overwrite/change pre-configured profile one or multiple times
<b>Temperature Measurement Range</b>	-30°C to 70°C
<b>Temperature Accuracy Range</b>	±1.0°C from -30°C to -10°C ±0.5°C from -10°C to 45°C ±1.0°C from 45°C to 70°C
<b>Optional Version</b>	±0.2°C at 0°C
<b>Temperature Resolution</b>	0.1°C over full temperature measurement range
<b>Memory Capacity</b>	16,000 data points
<b>Battery Life/Type</b>	1-year run life/3.6 V lithium battery
<b>Data Sampling Interval</b>	Programmable from 10 seconds up to a maximum of 2 hours
<b>Programmable Alarms</b>	Maximum of 6 alarms using any combination of 4 alarm types
<b>Alarm Types</b>	High/low temperature limit; Single temperature range; Dual temperature range; MKT; Time-only
<b>LCD Indicators</b>	OK and Alarm status; Trip summary (avg., min., max.); Time remaining/ time elapsed on threshold counter; Current temperature display (last temperature recorded)
<b>Quality Documentation and Validation Tools</b>	Integrated NIST <sup>®</sup> traceable 3-point Certificate of Validation; Validation Manual
<b>Data Analysis and Monitor Configuration Software</b>	TTMD 7.3 or ColdStream <sup>®</sup> CCM 1.8
<b>FAA Compliance</b>	RTCA/DO-160

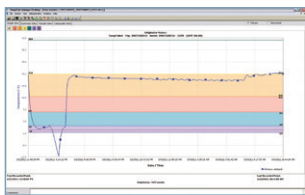
### TempTale Manager<sup>®</sup> Desktop 7.3 Software

TempTale Manager<sup>®</sup> Desktop (TTMD) 7.3 is a robust, multi-lingual, Windows-based software application that is used for configuring, downloading, displaying, reporting and archiving time-and-temperature data collected from all TempTale4 temperature and humidity monitors. TTMD Software is compatible with Microsoft<sup>®</sup> Windows<sup>®</sup> 8.1 and Windows<sup>®</sup> 7 operating systems. The power of TTMD software lies in its extremely intuitive user interface that allows users to effortlessly

### Desktop Software

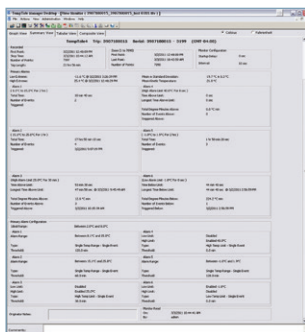
retrieve, display and analyze trip data in order to make higher quality shipment disposition decisions and ensure that Standard Operating Procedures (SOPs) are delivering acceptable results. TTMD's extensive multi-language support and powerful data export and transfer options greatly enhances our users' ability to share data globally with remote locations and business partners.

### Software Features



◀ **Graph View** implements graphing controls and tool tips to allow for easy viewing of alarm profiles

◀ **Tabular View** lists information for each data point, displaying the date, time and temperature; including secondary sensor data (e.g. humidity readings)



◀ **Summary View** is a concise display of the monitor's recorded data, temperature and time. It also displays statistical data, such as minimums and maximums, mean and standard deviation

### TTMD 7.3 Key Features

- Windows 8.1 and Windows 7 operating system support
- User programmable option to set the time zone used in the PDF report
- Multi-language support for 10 different languages including: US English, UK English, Spanish, Dutch, French, German, Portuguese, Chinese, Japanese and Russian
- Automatically export downloaded monitor data files to PDF and Microsoft<sup>®</sup> Excel
- Draw objects and add annotations to graphs to provide additional information about a trip or temperature excursion
- Overlay graphs from multiple monitors onto a single graph for simple, easy comparative analysis
- Summary View automatically calculates and displays key trip (min, max, mean, MKT) and alarm statistics in a simple report format
- Automatically add the raw data and PDF files as e-mail attachments to easily e-mail files to multiple recipients
- View and print NIST<sup>®</sup> traceable 3-Point Certificate of Validation

### ColdStream<sup>®</sup> Cold Chain Manager 1.8

### Web-Enabled Application

ColdStream<sup>®</sup> Cold Chain Manager (CCM) is a validated, hosted and secure relational database application easily accessible via the Internet for query, reporting, and analysis of stored data. ColdStream CCM enables users to share critical data quickly and efficiently through password protected, selective access—across their own organization as well as with business partners.

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 potential opportunities for process improvement. The reporting and analysis services are delivered through Sensitech's Professional Services team.

Sensitech Inc. is a leading provider of supply and cold chain visibility solutions that enable our customers – global leaders in the food, life sciences, and industrial markets – to track, monitor and protect the quality and integrity of their temperature-sensitive products across complex supply chains. Through its logistics security division, FreightWatch International, Sensitech also offers origin-to-destination services that provide customers with real-time cargo transparency, helping them to mitigate such risks as theft, diversion, counterfeiting, and chain of custody. Sensitech Inc. is an ISO 9001:2008 company based in Beverly, Mass., with more than 30 sales, service and distribution locations around the world. Sensitech is a part of UTC Building & Industrial Systems, a unit of United Technologies Corp., a leading provider to the aerospace and building systems industries worldwide. Visit [www.sensitech.com](http://www.sensitech.com) for additional information. © 2015. Sensitech Inc. All Rights Reserved. Unless otherwise indicated, all trademarks and service marks are the property of Sensitech Inc. NIST is a registered trademark of The National Institute of Standards and Technology Agency of the United States Government. Microsoft and Windows are registered trademarks of Microsoft Corporation in the United States and other countries.