

# TempTale® Ultra Bio

## Maintain precise control of temperature-sensitive pharmaceuticals and biologics

The TempTale® Ultra BIO monitor is a leading solution for highly temperature-sensitive pharmaceuticals and biologics, including specialty and orphan drugs with no margin for error, whether in clinical trials or following the product's commercial launch. With the evolution of cell and gene therapy, at the front lines of personalized medicine, manufacturers face greater complexities in the supply chain. The need for more precise and accurate temperature monitoring has never been more critical.

The TempTale Ultra BIO monitor helps to assure the quality, safety, efficacy and potency of temperature-sensitive products in transit and storage with a **temperature accuracy range of  $\pm 0.22^{\circ}\text{C}$  from  $-10^{\circ}\text{C}$  to  $+25^{\circ}\text{C}$** . To further support precise temperature monitoring in the biologics market, the TempTale Ultra BIO supports up to six programmable alarms, including MKT and Trip Duration. This monitor contains a 3.0v coin cell battery, requiring no Lithium Handling Label, as outlined in IATA DG 2018, 59th Edition.

Sensitech Inc. is a leader in its due diligence and quality control methods throughout the design, testing, manufacturing and service of our monitors. Each TempTale Ultra BIO monitor is 3-Point NIST® traceable and comes with a Certificate of Calibration. Additionally, Sensitech can provide quick turnaround times for your order fulfillment needs around the globe.

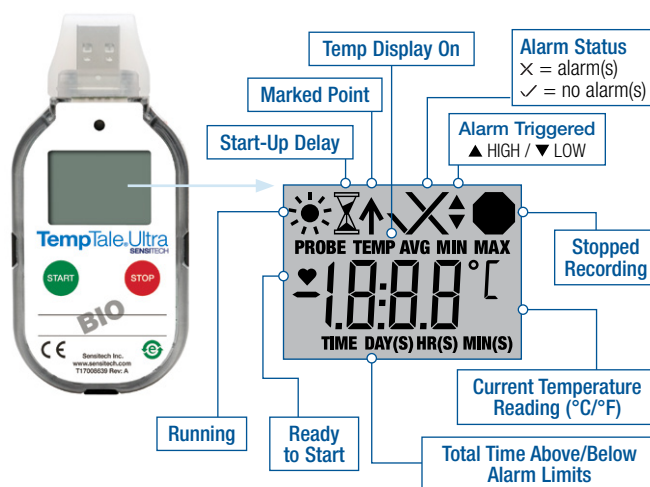
### TempTale Manager® Desktop Software 8.0

TempTale Manager® Desktop (TTMD) software 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 TempTale temperature monitors. The power of TTMD software lies in its intuitive user interface that allows users to effortlessly retrieve, display and analyze trip data in order to make high-quality shipment disposition decisions, and ensure that Standard Operating Procedures (SOPs) are delivering acceptable results. TTMD's language support and powerful data export options enhance the user's ability to share data globally with remote locations and business partners.

### ColdStream® Cold Chain Manager 1.8A

ColdStream® Cold Chain Manager (CCM) software is a validated, hosted and secure relational database application that is easily accessible via the Internet for query, reporting and analysis of archived 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 compliance repository. The hosted database application enables robust cold chain data analysis, reporting, and potential opportunities for process improvement. The reporting and analysis services are provided by Sensitech's Global Professional Services Team.



| TempTale Ultra BIO Specifications                                   |  |
|---|--|
| <b>Monitoring Recording Options</b>                                 | Single Use, Single-Use with User Programmable Overwrite, or Multiple Use   |
| <b>Temperature Measurement Range</b>                                | -30°C to + 70°C  |
| <b>Temperature Accuracy Range</b>                                   | ±0.22°C from -10°C to +25°C<br>±0.5°C from -18°C to -10°C<br>±0.5°C from +25°C to +50°C<br>±1.0°C from -30°C to -18°C<br>±1.0°C from +50°C to +70°C  |
| <b>Temperature Resolution</b>                                       | 0.1°C/F over full temperature measurement range  |
| <b>Data Memory Type</b>   | Non-volatile 16K Flash memory  |
| <b>Data Storage Capacity</b>  | 16,000 data points (16K)   |
| <b>Battery Life / Type</b>  | 12 months operating life / 3.0v coin cell lithium battery – non-replaceable  |
| <b>Data Sampling Interval</b>                                       | Programmable from 30 seconds up to a maximum of 120 minutes  |
| <b>Water Resistant Housing</b>                                      | IP64 (with protective cap over USB connector)  |
| <b>Start Up Delay</b>   | 0 minutes to 24 hours  |
| <b>Programmable Alarms</b>  | Programmable high and low limits -> alarm is triggered when temperature exceeds set limits;<br>Up to six alarm types (single temperature limit, temperature range, dual temperature range, MKT, duration)  |
| <b>Alarm Delay Time Thresholds</b>                                  | Single event (continuous) or cumulative  |
| <b>LCD Indicators</b>   | Started, start-up delay, running, stopped; Alarm status: OK (✓), Alarmed (✗); Trip summary data (average, minimum, maximum); Current temperature reading; Time remaining / time elapsed against alarm-time thresholds; Marked event  |
| <b>Start Up Options</b>   | Manual push button or automatic launch option  |
| <b>Dimensions</b>   | 108mm L x 50.2mm W x 12.5mm H  |
| <b>Weight</b>   | 51g (1.8 oz)   |
| <b>Quality Assurance Certifications</b>                             | CE, RTCA – D0160G compliant, RoHS compliant, Response time tested to U.S. Pharmacopeia (USP) <1118> and EN 12830 standards; 3-point NIST® Traceable Certificate of Calibration; Validation Manual  |
| <b>Minimum System Requirements</b>                                  | Windows® PC w/ Windows® 7 or higher; Adobe® Reader 9.0 or higher   |
| <b>Data Analysis and Cold Chain Continuous Improvement Software</b> | TempTale Manager® Desktop 8.0 or higher; ColdStream® Cold Chain Manager 1.8A or higher   |
| <b>Computer Interface</b>   | USB 2.0, A-type plug   |
| <b>Ship air, ground, ocean in accordance with –</b>                 | IATA 2017 IATA Dangerous Goods Regulations 58th Edition; UN 3091, Packing Instruction 970 Section II – Excepted Lithium Metal and Lithium Alloy Cells and Batteries; U.S. Department of Transportation Lithium Battery Hazardous Material Regulations 49 CFR Parts 171-180; 2016 International Maritime Dangerous Goods Regulations, Packing Instruction 903 |

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

Sensitech Inc. is focused on delivering supply chain visibility solutions that track, monitor and protect products for global leaders in the food, life sciences, consumer goods, and industrial markets. Our solutions are focused in three key areas: quality and compliance, supply chain security, and logistics performance management. Quality and compliance solutions address temperature-sensitive, complex supply chains focused on delivering the highest quality possible, while our supply chain security solutions help to mitigate risks associated with theft, diversion and chain of custody. Sensitech's logistics performance solutions deliver origin-to-destination, real-time transparency to any in-transit journey. Sensitech Inc. is an ISO 9001:2008 company, headquartered in Beverly, Mass., with more than 35 sales, service and distribution locations around the world. Sensitech is a part of UTC Climate, Controls & Security, 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. © 2019 Sensitech Inc. All Rights Reserved. Unless otherwise indicated, all trademarks and service marks are the property of Sensitech Inc. Microsoft, Windows, Windows XP, Windows Vista, and Internet Explorer are registered trademarks of Microsoft Corporation in the United States and other countries. NIST is a registered trademark of The National Institute of Standards and Technology Agency of the United States Government.