TempTale®Ultra

TempTale® Ultra BIO Monitor

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 ±0.22°C from -10°C to +25°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.
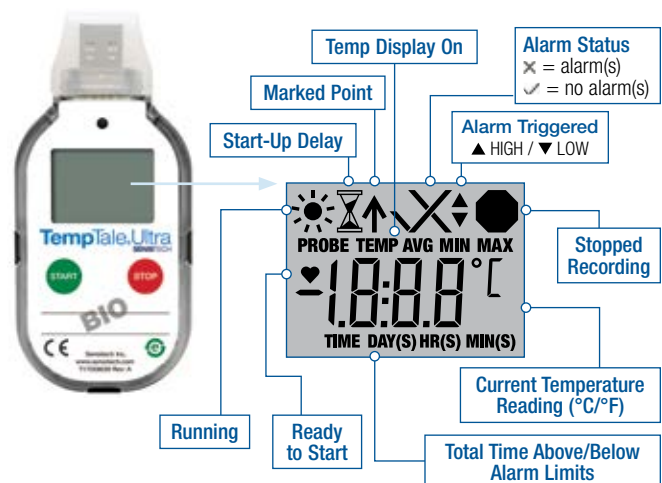
TempTale Manager® Desktop Software 8.0

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.

sensitech.com

TempTale Ultra BIO Specifications	
Monitoring Recording Options	Single Use, Single-Use with User Programmable Overwrite, or Multiple Use
Temperature Measurement Range	-30°C to + 70°C
Temperature Accuracy Range	±0.22°C from -10°C to +25°C ±0.5°C from -18°C to -10°C ±0.5°C from +25°C to +50°C ±1.0°C from -30°C to -18°C ±1.0°C from +50°C to +70°C
Temperature Resolution	0.1°C/F over full temperature measurement range
Data Memory Type	Non-volatile 16K Flash memory
Data Storage Capacity	16,000 data points (16K)
Battery Life / Type	12 months operating life / 3.0v coin cell lithium battery – non-replaceable
Data Sampling Interval	Programmable from 30 seconds up to a maximum of 120 minutes
Water Resistant Housing	IP64 (with protective cap over USB connector)
Start Up Delay	0 minutes to 24 hours
Programmable Alarms	Programmable high and low limits -> alarm is triggered when temperature exceeds set limits; Up to six alarm types (single temperature limit, temperature range, dual temperature range, MKT, duration)
Alarm Delay Time Thresholds	Single event (continuous) or cumulative
LCD Indicators	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
Start Up Options	Manual push button or automatic launch option
Dimensions	108mm L x 50.2mm W x 12.5mm H
Weight	51g (1.8 oz)
Quality Assurance Certifications	CE, EN/12830, RTCA – DO160G; 3-point NIST® traceable Certificate of Calibration
Minimum System Requirements	Windows® PC w/ Windows® 7 or higher; Adobe® Reader 9.0 or higher
Data Analysis and Cold Chain Continuous Improvement Software	TempTale Manager® Desktop 8.0 or higher; ColdStream® Cold Chain Manager 1.8A or higher
Computer Interface	USB 2.0, A-type plug
Ship air, ground, ocean in accordance with –	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.