



TempTale® Ultra

TempTale® Ultra 64K Monitor

The ideal temperature monitoring solution for extended ocean shipments and stationary applications (i.e., refrigerators and freezers) requiring frequent temperature sampling intervals.

Temperature-sensitive pharmaceuticals and biologics have no margin for error. Shipping via ocean containers only adds complexity to an already volatile supply chain, particularly at port changeovers. The TempTale® Ultra 64K monitor is an ideal solution for lengthy ocean shipments requiring frequent temperature sampling intervals.

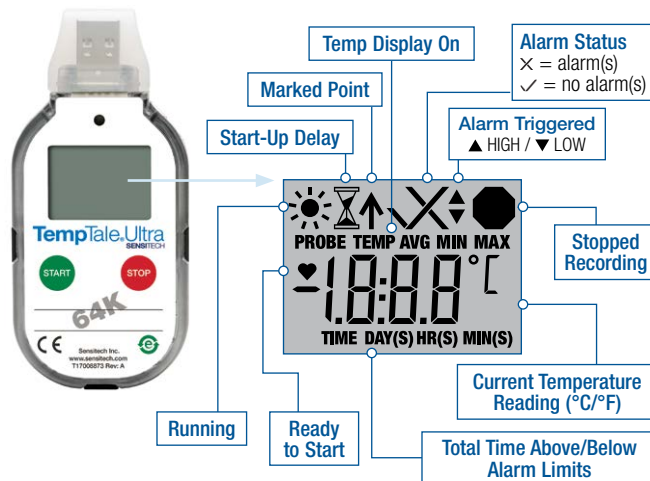
Sea freight is attractive to many pharmaceutical manufacturers for particular products given the lower shipping costs as compared to air freight. However, regulatory guidance—e.g., EU Good Distribution Practice Guidelines (GDP) - requires that temperatures be monitored to label claim during transportation and storage. Further, China's FDA regulations state that pharmaceutical imports and exports now require monitoring temperature-sensitive shipments in two- and five-minute data sampling intervals.

Further, the TempTale Ultra 64K monitor is also ideal for stationary applications where extended and unattended temperature monitoring is required to effectively monitor storage at remote sites. **The new TempTale Ultra 64K with expanded memory capacity will support two-minute temperature sampling for up to 88 days.**

Key TempTale Ultra 64K Features

- The expanded 64,000 data points of data storage capacity allows for extended stationary temperature monitoring of remote sites, as well as temperature measurements every two minutes for lengthy ocean shipments; i.e., ocean imports and exports to and from China.
- Contains a 3.6v coin cell battery, requiring no Lithium Handling Label, as specified in International Maritime Dangerous Goods Codes (IMDG) Special Provision 188.1 and IATA DG current edition
- Large LCD screen with clear indication of alarm status and trip visibility
- Automatic generation of secure PDF reports, configurable to support local time zones and five languages for receiving sites, including Simplified Chinese
- Up to six programmable alarms, including MKT and Trip Duration
- Quick file generation of both the raw data and PDF files increasing receiver efficiency.

- USB interface enables direct download to software
- Write Protected USB flash drive for virus protection
- Three-point NIST® traceable Certificate of Calibration



TempTale Ultra 64K 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	± 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
Temperature Resolution	0.1°C/F over full temperature measurement range
Data Memory Type	Non-volatile 64K Flash memory
Data Storage Capacity	64,000 data points (64K)
Battery Life / Type	12 months operating life / 3.6v 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 15.2mm H
Weight	60g (2.1 oz)
Quality Assurance Certifications	CE, UKCA, 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
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 8.2 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 Dangerous Good Regulations; 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; International Maritime Dangerous Goods Regulations, 38-16 Packing Instruction 903

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

TempTale Manager® Desktop Software 8.2

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 Inc. is a global leader in delivering supply chain visibility solutions. Our innovative monitoring products and services help to maintain the quality and integrity of our customers' valuable products at every step in their journey, all around the world. For 30 years, leading companies in the food, pharmaceutical, industrial, consumer goods and other industries have relied on Sensitech to help protect their products—and EO: sales@eofirm.com | www.eofirm.com | 0755-84200058

EO: sales@eofirm.com | www.eofirm.com | 0755-84200058
EO: sales@eofirm.com | www.eofirm.com | 0755-84200058