



TempTale® Ultra

Validated, Sleek, USB Temperature Datalogger with Advanced Functionality

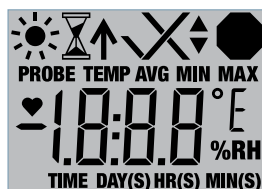
Introducing the TempTale® Ultra datalogger—a sleekly designed, USB temperature monitor that supports up to six temperature alarms, and is fully validated for the mission-critical Life Sciences market. This new monitor from Sensitech Inc. is easy-to-implement and will impress receivers with its intuitive LCD, fast download speeds, and automatic PDF generation without the need for additional software.

The TempTale Ultra datalogger is a thinner and more intuitive monitor than previous models, and is the next-generation of the world-class TempTale product line. It supports up to six programmable time and temperature alarms, including Mean Kinetic Temperature (MKT) and duration. The monitor's low thermal mass supports its compliance with USP <1118> response time standards. Moreover, **the device does not require labeling per IATA's Dangerous Goods Regulations.**

Receiver quality departments can be confident knowing that the TempTale Ultra datalogger automatically generates a secure PDF or a PDF/A, as well as an encrypted TTV data file when plugged into a USB port. The files can then be easily uploaded and archived in ColdStream® CCM 1.8A, built to comply with FDA 21 CFR Part 11 and EC Annex 11.

Key TempTale Ultra Features

- Thin 12.5mm housing—easily slips into standard packaging
- Large LCD screen with clear indication of alarm status and trip visibility
- Up to six programmable alarms, including MKT and Trip Duration
- Single or Multiple Use recording options
- Increased download performance—up to 5X faster download speeds
- USB interface enables direct download to software
- PDF configurable reports capable of supporting local time zones and five languages for receiving sites
- Shipment details can be written to the device and subsequently displayed on the PDF
- Option to Write Protect USB flash drive for virus protection



TempTale® Ultra 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	± 0.5°C from -10°C to 45°C ± 1.0°C from 45°C to 70°C ± 1.0°C from -30°C to -10°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, 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 8.0 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.

TempTale Manager® Desktop Software 8.0 Software

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 delivered through Sensitech's Professional Services team.