Ultra Low Freezer Temperature Validation System with 21 CFR Part 11 Secure Software

OM-CP-ULT90 Series

- NIST Traceable Calibration Certificates
- FDA 21 CFR Part 11 Compliant
- IQ/OQ/PQ Validation Protocols
- Splash Proof OM-CP-CRYO-TEMP Logger
- -86 to 35°C (-122 to 95°F) Temperature Range
- 0.1°C Resolution and ±1.0°C Accuracy
- 1 Year Battery Life at -80°C (-112°F)
- User-Programmable Temperature Alarms with LED’s (OK, Warn, and Alarm)
- Hardware and Software Password Protection
- Simultaneous Starts, Memory Wrap
- User-Programmable Start Times, Sample Intervals, Logger Descriptions, Unique IDs

The OM-CP-ULT90 ultra low temperature freezer validation system can measure and log data as low as -86°C (-122°F). It can be placed in small and large freezers of varying configurations.

The system provides a complete stand-alone temperature mapping and validation solution for freezers to ensure uniform storage and testing conditions.

The OM-CP-ULT90 includes a USB docking station with 1.8 m (6') of cable (OM-CP-IFC300), the OM-CP-CRYO-TEMP data logger, and FDA 21 CFR Part 11 Secure Software and IQ/OQ/PQ validation protocols. For larger freezers, loggers can be plotted in one graph to show variances in different parts of the freezer.

Finally, as failure to monitor external freezer temperatures may invalidate internal freezer temperatures, an additional OM-CP-CRYO-TEMP can be included for placement outside of the freezer.

All models shown smaller than actual size.

NIST traceable calibration certificates included.
Specifications

TEMPERATURE

Sensor: NTC thermistor
Measurement Range: -86 to 35°C (-112 to 95°F) recommended, may be used up to 55°C (131°F)
Resolution: 0.1°C
Calibrated Accuracy: ±1.0°C
Specified Accuracy Range: -80 to 0°C (-62 to 32°F)
Memory: 32,767 readings; software configurable memory wrap
Reading Rate: 5 seconds to 30 minutes, selectable in software
Start Modes: Software programmable immediate start, delay start up to 30 days in advance or manual start with magnetic switch

Temperature Alarm: Software programmable high and low alarm limits and high and low warn limits, each setpoint may be individually enabled or disabled

Alarm Delay: Software programmable time delay for warn/alarm limits; logger will not indicate out of range status until the temperature has been out of range for a set period of time

Status Indicators:
- Green: (OK) indicates safe conditions during logging
- Yellow: (Warn) indicates warn limits have been exceeded
- Red: (Alarm) indicates alarm criteria (limits/delay) have been exceeded

Password Protection: An optional password may be programmed into the device to restrict access to configuration options; data may be read out without the password

Calibration: Digital calibration is available to the user through software

Calibration Date: Automatically recorded within device

Battery Type: 3.6V lithium battery, factory replaceable only (included)

Battery Life: 2 years typical @ 25°C, 1 min. reading intervals; 1 year typical @-80°C, 1 min reading intervals

Time Accuracy: ±2 minutes/month max at 20 to 30°C ±5 minutes/month max at -80°C (-112°F)

Data Format: Date and time stamped °C, °F, K, °R

Computer Interface: USB docking station to PC (OM-CP-IFC300)

Software: Windows XP SP3/Vista/7 and 8 (32- and 64-bit)

Operating Environment: -86 to 35°C (-123 to 95°F) (may be used up to 55°C); 0 to 100% RH

Dimensions: 83 H x 54 W x 11 mm D (3.3 x 2.1 x 0.4")

Ingress Protection/IP Rating: IP64 (splash resistant, not submersible)

Enclosure: ABS plastic, white, polycarbonate labeling

Weight: 40 g (1.4 oz) each

Total Weight for Packages:
- OM-CP-ULT90-9:
  1443 g (50.9 oz)
- OM-CP-ULT90-15:
  1681 g (59.3 oz)

Windows software (included) shows data in graphical format.

To Order

<table>
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<tr>
<th>Model No.</th>
<th>Description</th>
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Comes complete with data loggers, NIST calibration certificates, USB docking station, batteries and Secure Software. For more information on the OM-CP-CRYO-TEMP, please visit us online.