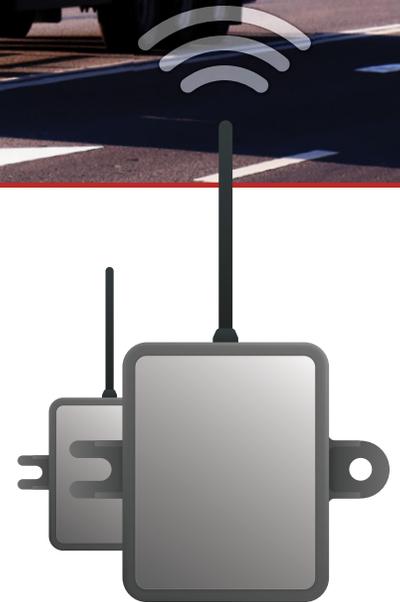


TEMPTRAC - Calibration of Sensors



Calibration of Temperature Control and Monitoring Devices

Technical Supplement to Valor Technical Report

Model guidance for the storage and transport of time
and temperature sensitive products.

July, 2016

Table of Contents

Declaration of Conformance	3
Glossary	4
Abbreviations	4
Part 1: Introduction	
1.1 Requirements	5
1.2 Objectives	6
1.3 Target Readership	6
Part 2: Guidance	
2.1 Associated Materials and Equipment	7
2.2 Procedure	8
2.2.1 Prerequisites	9
2.2.2 Establishing the Ice-Point Bath (<i>excerpt from ASTM E563-11</i>)	10
2.2.3 Placing the Device in the Bath	11
2.2.4 Carrying Out the Calibration, Step by Step	12
2.2.5 Maintaining the Bath Temperature	12
2.2.6 Actions to Take Following the Test	13
References	14
Annex 1 – Generic Temperature Calibration Check Form	15
Revision History	16

EN 12830 Declaration of Conformance

May 3, 2016

Declaration of Conformity to European Council Directives

Valor hereby declares that the following temperature monitoring and recording products:

Model - TempTrac Part # 110302040413

*Manufactured by Valor H.K.
4320 Harvester Rd
Burlington, Ont.
Canada,
L7L 5S4*

when integrated into Geotab telematics platform have been tested and found to comply with the essential requirements of the following European Standard:

Temperature Recorders EN 12830:1999 Class I S&T Group B

Provided that the Valor TempTrac product has been integrated with a Geotab GO6 or GO7 (FW version 107.9.3 or newer) telematics device and has not been modified in any way and is installed and maintained as per manufactures instructions.

The tests that verified that the Valor TempTrac Part # 110302040413 temperature monitor conform to these standards were performed by:

Shanghai Balong Automotive Corporation
*No. 5500, Shenzhuan Road, Dongjing Town,
Songjiang Distric, Shanghai, P.R. China
Post Code: 200131*

ISO/TS 16949-2009
Certification Registration No: **12 111 21859/01 TMS**
IATF Certificate No: **0124437**

Signed,



Valor H.K
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Abbreviations

- ▶ **SENSOR** – Sensor
 - ▶ **SOP** – Standard Operating Procedure
 - ▶ **TTSP** – Time and Temperature Sensitive Product
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Glossary

Standard Operating Procedure (SOP):

A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating policies and procedures can be effective catalysts to drive performance improvement and improve organizational results.

Temperature Control Device:

A device which actively controls the operation of cooling plant used to store or transport TTSPs.

Temperature Monitoring Device:

A device which monitors the temperature of spaces used to store or transport TTSPs.

Thermal Time Constant:

The most common definitions of the thermal reaction time are the so-called “Tau” (τ , the 19th letter of the Greek alphabet) and “T90”. “Tau” stands for the time a device needs to adapt to 63% of the end value of a temperature change whereas “T90” represents the time to adapt to 90% of the change. “T90” approximately equals to $2.5 * \text{“Tau”}$. These constants are commonly evaluated by experiment on the test device under well-defined conditions as described in EN12830.

Time and Temperature Sensitive Product (TTSP):

Any good or product which, when not stored or transported within pre- defined environmental conditions and/ or within pre-defined time limits, is degraded to the extent that it no longer performs as originally intended.

Triple Point:

The temperature and pressure at which a substance can exist in equilibrium in the liquid, solid, and gaseous states. The triple point of pure water is at 0.01 degrees Celsius and 4.58 millimeters of mercury and is used to calibrate thermometers.

PART 1 : Introduction

1.0 Introduction

This technical supplement has been written to describe a way to calibrate temperature monitoring and temperature control devices, in the absence of a nationally or internationally accredited calibration laboratory, using the “ice-water” procedure.

1.1 Requirements

As a general rule, temperature measurement and control devices must periodically be calibrated in order to prove their accuracy over the full operating temperature range and according to the device’s data sheet definitions. Proven accuracy is mandatory because inaccurate readings can lead to a false sense of security and place TTSPs at risk.

The devices are covered by calibration certificates from the device manufacturer (Valor). These certificates are valid for a 24-month period of time and the associated devices may be used throughout this period without additional calibration.

However, there are circumstances under which proper device calibration or re-calibration is needed. The list below is not comprehensive but illustrates some of these circumstances:

- ▶ The device is used for longer than the period covered by the calibration certificate, either at the user’s risk or with the approval of the manufacturer.
- ▶ The device was used or treated beyond the manufacturer’s data sheet limitations (e.g. excessive temperature, shock, etc.).
- ▶ The device’s measurements are suspect.
- ▶ Regulatory bodies require regular proof of calibration - e.g. at 12 month intervals – and proof of calibration cannot be provided by the manufacturer’s certificate.

PART 1 : Introduction**1.2 Objectives**

Ideally, calibration should be carried out by a trained individual with the appropriate equipment. Wherever possible, calibration should be carried out in accordance with the device manufacturer’s instructions following a device-specific SOP.

This Technical Supplement gives generic advice on how to calibrate a Valor temperature measurement or control device.

The simple and accurate method described below can be used to prove the device’s functionality and accuracy at one single point of temperature using the so-called “ice-water procedure”.

1.3 Target Readership

This document is intended to be read by managers and technical staff that are responsible for the monitoring, installation and maintenance of temperature measurement and control equipment throughout the cold chain. Responsible managers must understand the necessity of calibration; technical personnel must be able to carry out and/or supervise the appropriate calibration procedures.



PART 2 : Guidance

2.0 Guidance

The calibration method described below is relatively simple to carry out but requires close attention to detail. The accuracy of the results also dependent upon the use of a high quality reference thermometer with a valid calibration certificate.

2.1 Associated Materials and Equipment

Reliable results will be achieved if the following equipment and materials are used:



- a. Wherever possible, use reference temperature measurement equipment regularly calibrated by an accredited laboratory, e.g. Fluke Hart Scientific precision equipment². The illustration below shows an example of this type of instrument.

Figure 1 – Example of a reference thermometer.

Source: Fluke Corporation

- b. Always use a temperature measurement reference instrument which is of higher accuracy than the device to be calibrated – for example, a thermometer with a rated accuracy of $\pm 0.2^{\circ}\text{C}$ should be used to calibrate a device with a rated accuracy of $\pm 0.3^{\circ}\text{C}$.

List Continued On Next Page>

² Fluke 1524 Reference Thermometer. Digital Image. Fluke Corporation. Accessed November 11, 2016. <http://us.flukecal.com>.

Please note: that the mention of this company does **not** imply any endorsement or recommendation by Valor H.K..

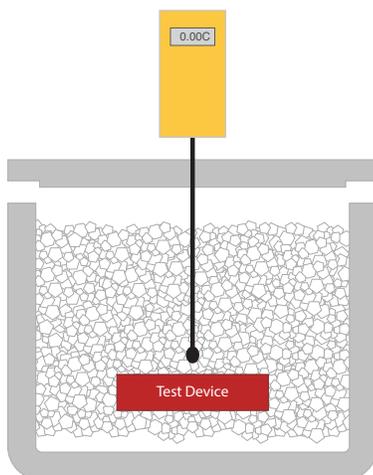
PART 2 : Guidance

2.1 Associated Materials and Equipment – Continued

- c. A thermally insulated container, tub open to the atmosphere, and large enough to contain enough melting ice-water in order to provide stable temperature conditions and allow full immersion of the device under test (SENSOR) as described in Section 3. In the cold chain operating environment, a vaccine carrier or small cold box with a hinged or separate lid would be a suitable choice. The required size depends on the dimensions of the SENSOR.
- d. Disposable latex gloves.
- e. Enough clean water must be available to make ice cubes and to set up a proper and stable ice-water triple-point mixture. **A transparent water-proof sealable pouch should be used to seal the SENSOR(s) before immersing it in the liquid in order to avoid water ingress and resulting damage.** As much air as possible should be extracted to ensure that the SENSOR is in good contact with the ice-water mixture. Sealing is always recommended, even for SENSOR(s) with a high IEC 60529 IP protection class rating because the protection might have been damaged – for example by dropping or battery replacement. Where the SENSOR has an external sensor, the sensor may be immersed directly in the bath, provided it has an IP7 or IP8 protection class rating. Otherwise it should be sealed in a pouch as described above, with the pouch tied tightly around the lead above the level of the ice-water.

2.2 Procedure

The ice-water bath provides an accurate reference temperature at 0°C if the melting ice-water mixture is properly set up, handled and maintained. An accurate temperature is achieved by this method because an ice-water mixture in a container which is open to the atmosphere will stabilize at its own “triple point”. At this point all three aggregate states of water coexist: liquid, solid and gaseous. For more physical details, refer to *ASTM E563-11*.



PART 2 : Guidance**2.2.1 Prerequisites**

- a. Only place clean equipment and distilled water inside the container. Use clean latex gloves to handle ice and equipment.
 - b. Although the temperature of the ice-water mixture stabilizes itself, its temperature must still be monitored before and during the calibration process using the calibrated reference thermometer. This is a mandatory requirement in order to prove the functionality and stability of the ice-water bath.
 - c. During extended testing periods enough ice must be added to the bath to maintain the water–ice equilibrium temperature and to prevent a possible temperature rise caused by excessive ice melting.
 - d. **Please note:** that only SENSORS which display a temperature reading can be calibrated by this method because the temperature indicated by the SENSOR must be compared to the ice-water bath temperature. Devices without a display need additional equipment to capture an immediate measurement read-out so that this can be compared with the reference temperature reading. This additional equipment is manufacturer-specific.
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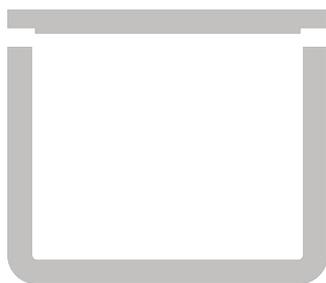


PART 2 : Guidance

2.2.2 Establishing The Ice-Point Bath (excerpt from ASTM E563-11)



Shaved / Fine Crushed Ice



Insulated Container



Reference Thermometer



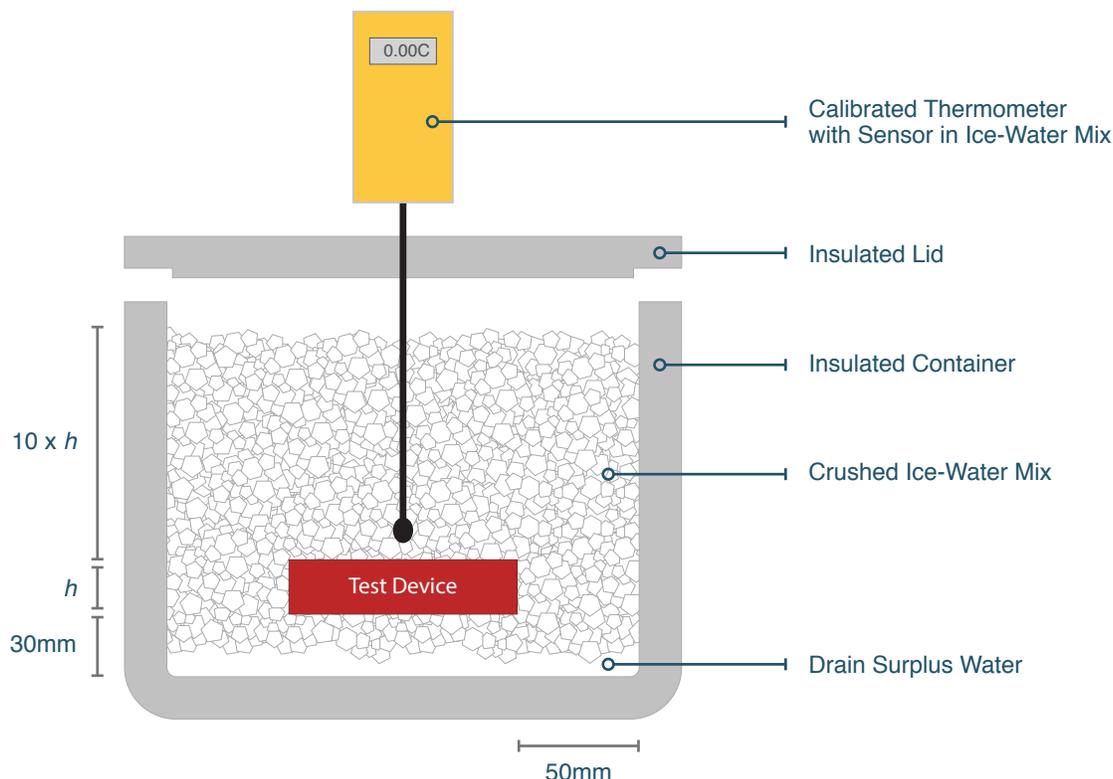
Test Device / Object

- a. Before using the bath, chill the required amount of distilled water close to 0°C.
- b. Freeze a suitable amount of the same water to produce ice-cubes, making sure that there is a sufficient quantity for the complete test run.
- c. Prepare shaved or fine crushed ice with a maximum 2mm to 3mm particle diameter; the finer the ice particles, the more accurate the ice-water temperature.
- d. Prepare the bath in the clean thermally insulated container. The container should be large enough not to affect the water-ice equilibrium temperature. The width, length or diameter and the overall depth must ensure that, when the thermal equilibrium state is reached, the test objects will not significantly modify the temperature of the bath over the region to which the ice point is to be applied. For normal applications, a width, length or diameter at least 100mm larger than the maximum SENSOR dimension size, and a depth of at least 300mm should be sufficient.
- e. Alternately add shaved ice and chilled water to the vessel, using just enough water to saturate the ice but not enough to float it. As the vessel fills, compress the ice- water mixture to force out excess water. The objective is to surround each particle of ice with water, filling all voids, but to keep the ice particles as close together as possible. Continue adding ice and water and compressing until the vessel is filled to the required level. Decant or siphon off excess water.
- f. Use the reference thermometer throughout the entire test period to confirm that a stable temperature is maintained.
- g. Cover the ice-point bath to protect it during the test period. Use an opaque and thermally insulating cover or stopper that is suitable for the application. This reduces heat transfer to the ambient environment through the surface of the bath. Allow the bath and vessel to equilibrate for at least 30 minutes before using.

PART 2 : Guidance

2.2.3 Placing The Device In The Bath

- a. Seal the SENSOR in a clean plastic bag. Make sure that as little air as possible is trapped inside the bag in order to avoid false results by floating and/or lack of contact between the SENSOR and the ice-water.
- b. Pre-cool the SENSOR in water at less than +3°C before immersing it in the bath. Pre-cooling the SENSOR reduces the time to reach equilibrium at the ice point; it also helps to preserve the bath at the ice point for a prolonged time. Additionally, it ensures that the water-ice interface will be in close contact with the SENSOR; negligible melting is important, otherwise the water film thickness between the SENSOR and the ice-water will increase and distort the test results.
- c. Form a well in the ice-water bath that has the dimensions and intended immersion depth of the SENSOR.
- d. Insert the sealed SENSOR to a depth of at least ten object diameters or heights respectively below the surface. Keep the SENSOR a minimum of 30mm above the bottom of the container in order to avoid the zone at the bottom where denser melt water tends to accumulate.
- e. Replace the lid. For devices with an external sensor, make sure that the lid seals well around the sensor lead.
- f. Allow the bath and SENSOR to come to thermal equilibrium. Allow for the thermal time constant of the SENSOR.



PART 2 : Guidance**2.2.4 Carrying-Out The Calibration, Step-By-Step**

- a. Establish and maintain the ice-water bath, prove its temperature with the reference thermometer.
 - b. Ensure that the SENSOR remains immersed in the ice-water bath as described in point 3.3d above.
 - c. Directly read the SENSOR temperature display while it is still immersed in the bath. If this is not possible, remove the SENSOR and immediately read its temperature indicator; prompt action avoids false readings due to exposure to the ambient temperature.
 - d. Record the readings on a calibration reference data chart as per sample taken from EVM-SOP-E2-2. Store the chart at least until the next calibration takes place and preferably for a minimum of three years.
-

2.2.5 Maintaining The Bath Temperature

- a. As ice particles in the bath melt, excess water begins to accumulate. This melt water has a temperature slightly above 0 °C. Since the density of water is at its maximum at +4°C, the slightly warm melt water will collect at the bottom of the bath and, hence, around the SENSOR. Under these conditions, the bath will no longer be at 0°C and cannot serve as an ice-point bath. For this reason, surplus water should be removed, as it accumulates, from the bottom of the bath by decanting or siphoning. The presence of excess water can be detected if water overspill occurs when the ice is depressed. Add ice particles, and chilled water, as necessary so that the ice slush column always extends to at least 30mm below the lowest point of the test object.
- b. In order to sustain the ice point over prolonged periods, the ice-point bath can be immersed in another larger insulated bath that is kept near to 0°C.

PART 2 : Guidance**2.2.6 Actions To Take Following The Test**

There are two possible test outcomes: **pass** or **fail**.

1. The SENSOR passes the test:

A pass is achieved if the SENSOR temperature indication deviates from the reference thermometer reading³ by less than the tolerance allowed in the data sheet. In this case the SENSOR should be physically labelled as follows:

Calibration valid until: <enter the date one year after the calibration test>.

Note: If the manufacturer or the regulatory authority stipulates a shorter or longer period of validity, enter the appropriate date to take account of this.

After this period expires the calibration must be repeated, as described in this document.

2. The SENSOR fails the test:

If the SENSOR temperature indication deviates from the reference thermometer reading⁴ by more than the tolerance allowed in the data sheet.

In this case, take one of the following actions:

1. Return sensor to manufacture if sensor is within the warranty period for replacement sensor.
2. Replace sensor with either a new or calibrated sensor.

³ For example, if the reference instrument has an accuracy of $\pm 0.5^{\circ}\text{C}$ and the SENSOR deviates 0.3°C from the reference instrument reading, this is a pass.

⁴ For example, if the reference instrument has an accuracy of $\pm 0.5^{\circ}\text{C}$ and the SENSOR deviates 0.6°C from the reference instrument reading, this is a failure.

References

1. ASTM E563-11 *Standard Practice for Preparation and Use of an Ice-Point Bath as a Reference Temperature*
2. EN 12830:1999 *Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice cream. Tests, performance and suitability.*
3. IEC 60529: *Consolidated Edition 2.1 (incl. am1): Degrees of protection provided by enclosures (IP Code).*
4. VALOR. EVM-SOP-E2-2. *Checking the accuracy of temperature monitoring devices.*

