Ice Melting Point Validation Method for Digital Data Logging Thermometers

The cheaper, faster, easier way to establish and maintain thermometer traceability.

What is Traceability?

Measurement traceability is an ***unbroken chain*** of calibrations to a specified reference, where each link in the chain contributes to the total measurement uncertainty.

So why should we care?

Traceability is required to demonstrate that measurements are accurate, reliable, and meaningful, and that they fall within the users' uncertainty needs.

If your measurements (and measuring device) are NOT traceable to a reference or standard, then you have no way of knowing if your measurements are right!

Traceability makes measurements MEANINGFUL.

The Melting Point of Ice

When ice melts, the resulting mixture of ice and water has a temperature of exactly 0.00 °C under normal atmospheric pressure

This is a fundamental, physical property of water

We call the temperature equilibration of ice and water the *ice melting point*

The ice melting point is internationally recognized as a **specified reference measurement standard**

In other words, it's an *intrinsic standard*

How does this fit with my vaccine temperature monitoring needs?

We already know…

- Maintaining the right vaccine storage temperature is critical to ensuring that children receive effective vaccine.
- Continuous temperature monitoring is required to determine if vaccines are safe and effective.
- The only way to know if continuous monitoring measurements are accurate is by establishing traceability.

Users can pay a company to calibrate their thermometers, but without seeing full documentation of the unbroken chain of comparisons to a standard reference, it's hard to be sure that the calibration establishes traceability.

- It's not easy for the average user to determine whether laboratories and companies are meeting the requirements for establishing traceability
- Some companies compound the issue with misleading terminology and claims (e.g., "NIST – traceable")
- This process can ultimately be expensive and time-consuming

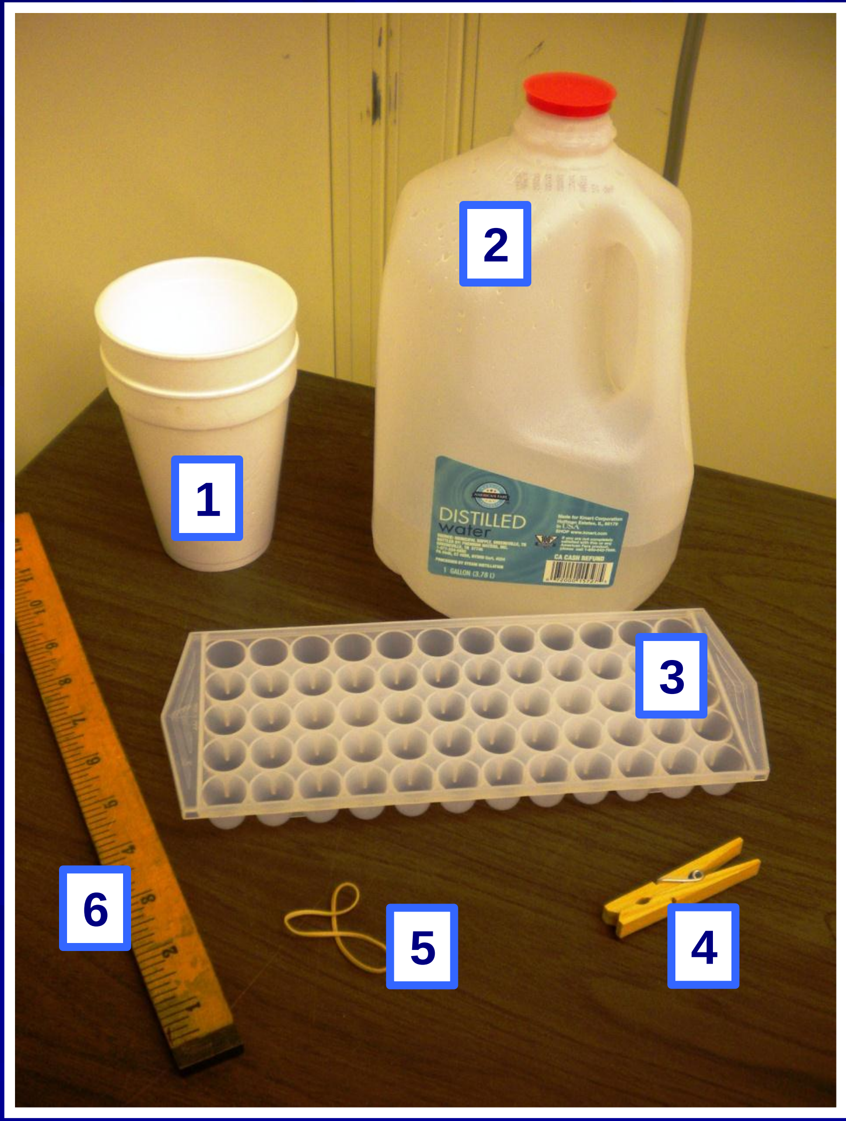
The cheaper, faster, and easier way to establish traceability is to DO IT YOURSELF with an ice point validation method that just about anyone can follow.

- Measurement uncertainty for this method is ±0.01 °C

Ice Point Validation Method: Materials

To make an ice melting point for validating data logging thermometers, you will need to obtain a few simple materials

1. An insulated container: styrofoam cup (or 2 stacked together), coffee thermos, etc
2. Water: distilled, deionized, or reverse osmosis for uncertainty = ±0.01 °C. Tap water is OK too, and gives uncertainty = ±0.02 °C
3. Mini ice cube tray. It's critical that the tray make cubes no larger than the size of a gumdrop.
4. A clothespin
5. Rubber band
6. Ruler



All of these items can be purchased in major retail stores for under $20

Step 1: Preparing Your Materials

1. Wash your hands, or wear on powder-free gloves. This is to maintain water purity, as salts and oils from our hands can contaminate the ice point (and give you the wrong answer)

2. Rinse off the ice cube tray and then fill with the same water you will be using for the validation (e.g., distilled, deionized, etc). Freeze the tray.

3. Make sure you will have enough ice cubes before you start building the ice melting point – make more than you think you will need (we needed 3 trays full to fill a large styrofoam cup)

4. When you are ready to set up the ice melting point, connect the data logger you wish to validate to your computer and open the logger software to adjust the recording interval. Choose a much higher frequency interval than you would normally use, such as 1 reading / 10 s.

5. If the logger features a computer-only start, start the logger now. For a magnetic key or button push start, just initialize the logger in the software program, and wait to start the logger until after you have the ice melting point set up.

6. Rinse or wipe off your logger probe. This is especially important if it has glycol residue on it. Rinse out your insulated container, too.

7. Lay out your materials and data logger (with probe) on a clean work surface

Step 2: Marking Probe Immersion Depth

When the probe is immersed in the ice point, the probe tip should be at least 1 inch above the bottom of the cup

You can make sure you end up with the right immersion depth later by placing a ruler inside the cup, then lowering your probe to the correct depth

Mark the spot where the top of the probe just sticks above the rim of the cup by wrapping it with a rubber band

This doesn't need to be exact , and it's OK if the probe tip is more than one inch above the bottom of the cup. Just make sure to mark a spot that will give you AT LEAST one inch of clearance.

Step 3: Fill the cup with ice

Empty the ice cube trays into a clean bowl or container – make sure the cubes are no larger than a gumdrop!

Don't use any cubes that fall on the floor – they're dirty!

Wearing gloves (or using freshly washed hands), pack the insulated cup with ice cubes

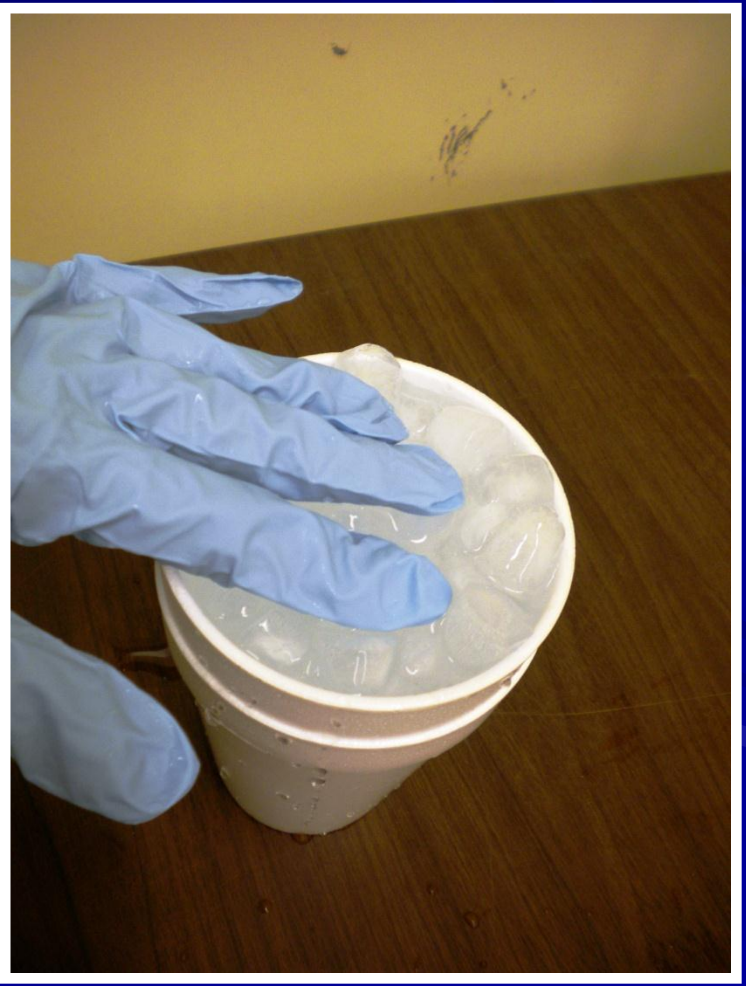
Step 4: Add water

Pour water over the ice in the cup, filling it almost all the way to the top

Wait about one minute before proceeding to the next step (some of the ice cubes will melt)

Step 5: Add more ice

Add more ice to fill the cup all the way to the top. Push down on the ice cubes to make sure the ice fills the entire cup all the way to the bottom – there should be not be any floating ice.



Step 6: Insert the data logger probe

Clip the clothespin around the logger probe in the spot that you previous marked with a rubber band

Carefully (gently) insert the probe into the center of the cup and push it straight down until the clothespin is level with the rim of the cup

Make sure the probe is going straight down and that it is NOT tilting or touching the cup

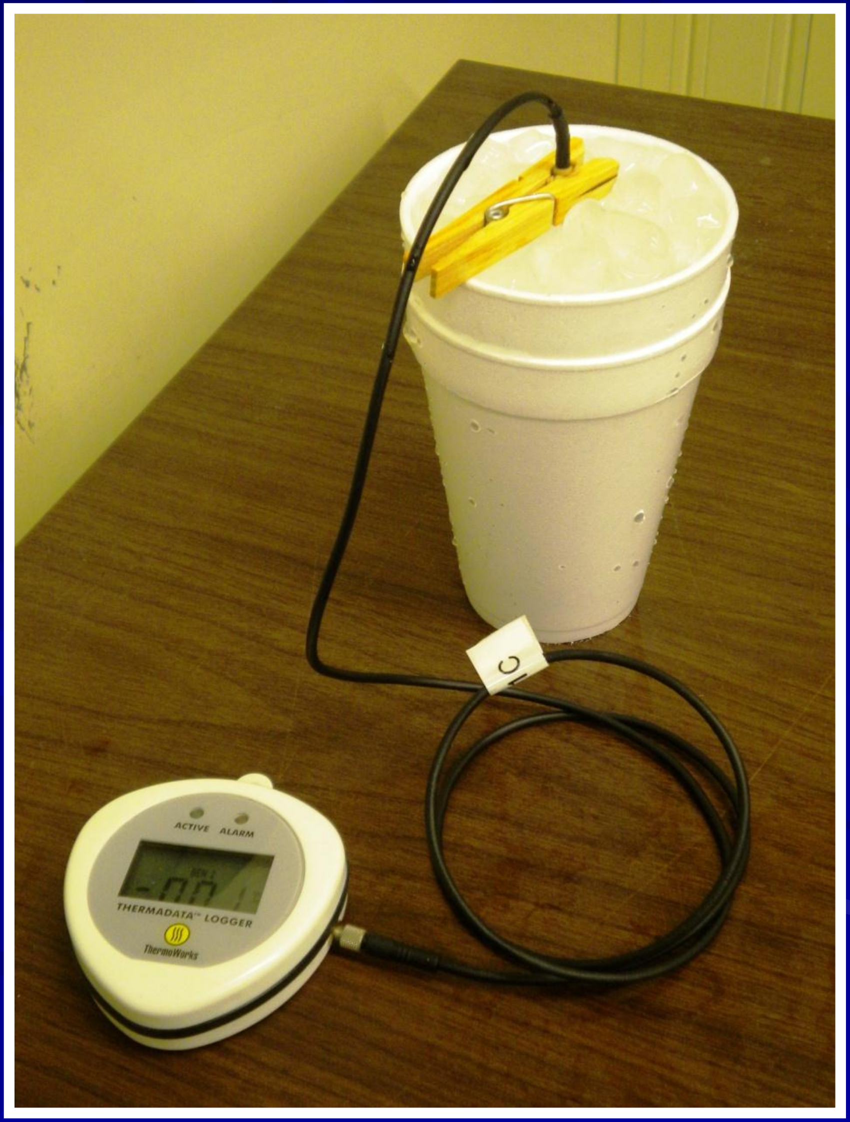
Step 7: Record temperature measurements

After inserting the logger probe, wait ~10 minutes for the device to equilibrate to the temperature of the ice and water, then start the logger using a key or button push

If your logger features a computer start, it should have already been recording – no further action is required

Allow the system to collect data for 30 minutes following equilibration time

After 30 minutes, remove the logger from the ice point setup and download data



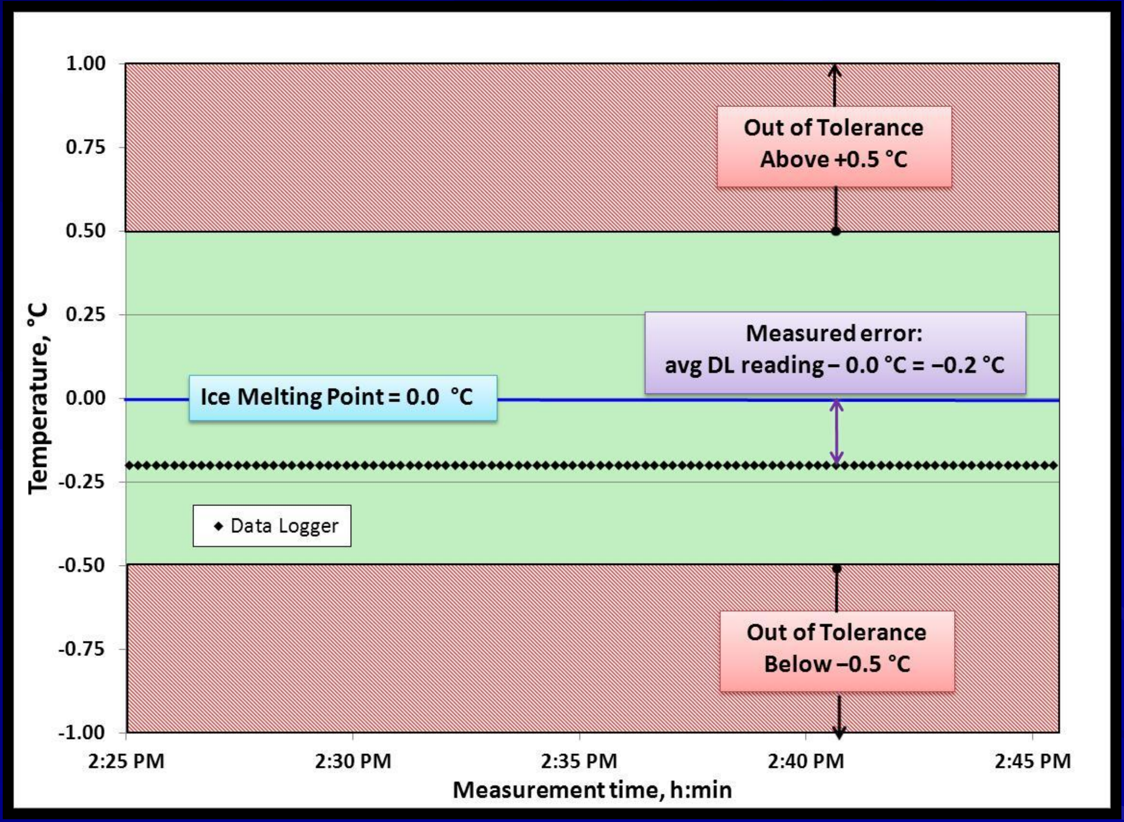
Step 8: Interpreting the results

Depending on when the logger was started and stopped, you may observe a cool-down or warm-up period (equilibration) following insertion into or removal from the ice point.

For validation purposes, we only need to look at the data from the 30 minutes with the probe in the ice point following the equilibration period

If the logger is functioning properly and the ice point was constructed correctly, this selection of data will likely fall in a straight or nearly straight line at a temperature close to 0 °C

The measured error is the difference between the reference ice point temperature (0 °C) and the average data logger temperature over the 30 minutes of post-equilibration measurements



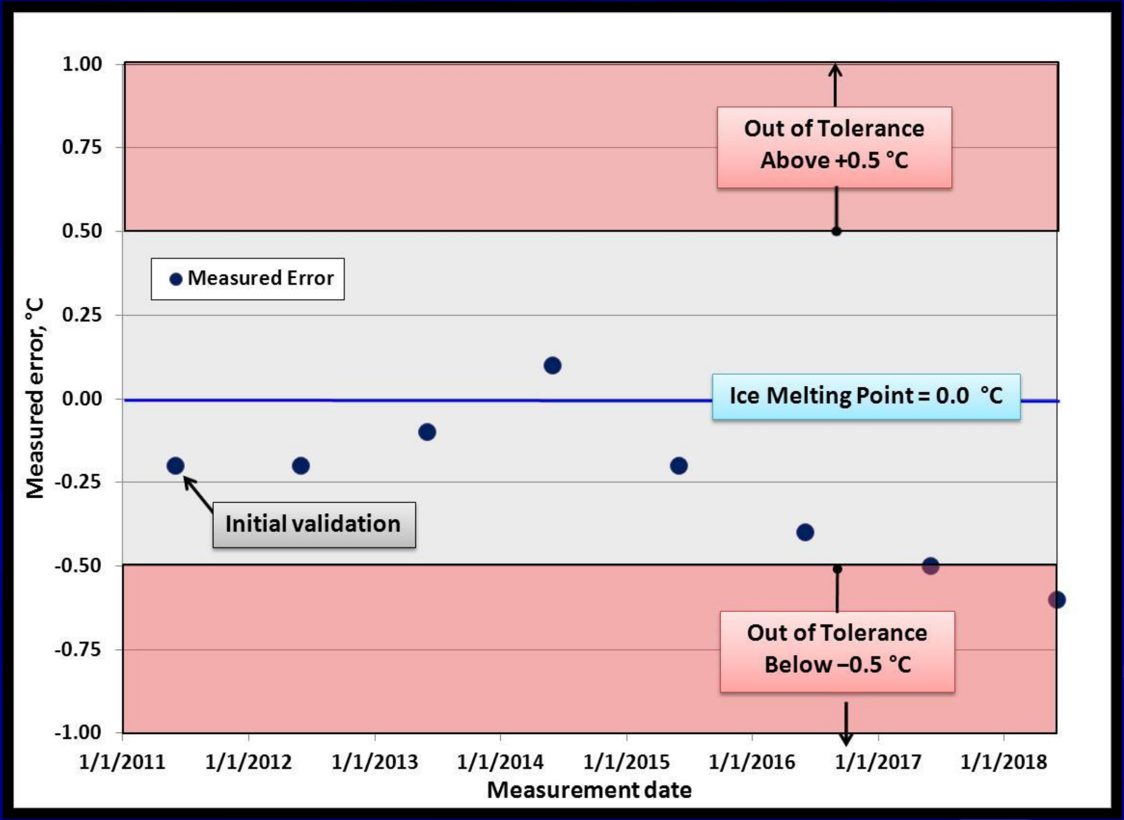
If the measured error falls within the specified accuracy (±0.5 °C), then the device is in tolerance and has been successfully validated at the ice melting point

A measured error > ±0.5 °C indicates that the device is out of tolerance and is NOT acceptable for vaccine temperature monitoring in its current condition

Step 9: Using ice melting point validation to maintain logger traceability

To maintain traceability, we need to keep documentation of logger validation:

THE CONTROL CHART →



Every time the logger undergoes an ice melting point validation, the measured error and measurement date are recorded on a control chart

Keeping an up-to-date control chart means that anyone can easily and quickly determine when the last validation occurred, and whether the device was **IN TOLERANCE** or **OUT OF TOLERANCE**

In the example control chart, we can see that a logger was validated at the ice point on an annual basis. From 2011-2017, the logger remained **in tolerance**, with a measured error ≤ ±0.5 °C

The 2018 validation check resulted in an error of 0.6 °C, which is > ±0.5 °C and is **out of tolerance**

How do I know when a data logger needs validation?

- Is the device brand new, or has it just been recalibrated or adjusted by the manufacturer?

Initial validation MUST be completed BEFORE the device is used to monitor vaccine temperature

- At a minimum, all data loggers used for vaccine temperature monitoring should be measured at the ice melting point on an ANNUAL BASIS, beginning from the initial validation date

- Any logger that produces questionable data or shows signs of measurement drift should also be measured at the ice melting point, REGARDLESS of whether it is due for annual validation

- Any logger that produces an OUT OF TOLERANCE measured error is no longer suitable for vaccine temperature monitoring – remove from service IMMEDIATELY!

- An out of tolerance logger may be returned to the manufacturer for recalibration or repair, or replaced with a new device. Either way, the process starts over from the beginning with a new initial validation.