Bath Temperature Validation Methods for CLIA-Regulated Laboratories

Fill bath(s) to fill line.

Rotate temperature sensor(s) down.

Set temperature controller(s) to 65°C.

NIST-certified digital thermometer with cable and optional immersion probe

Stir bars

DI water
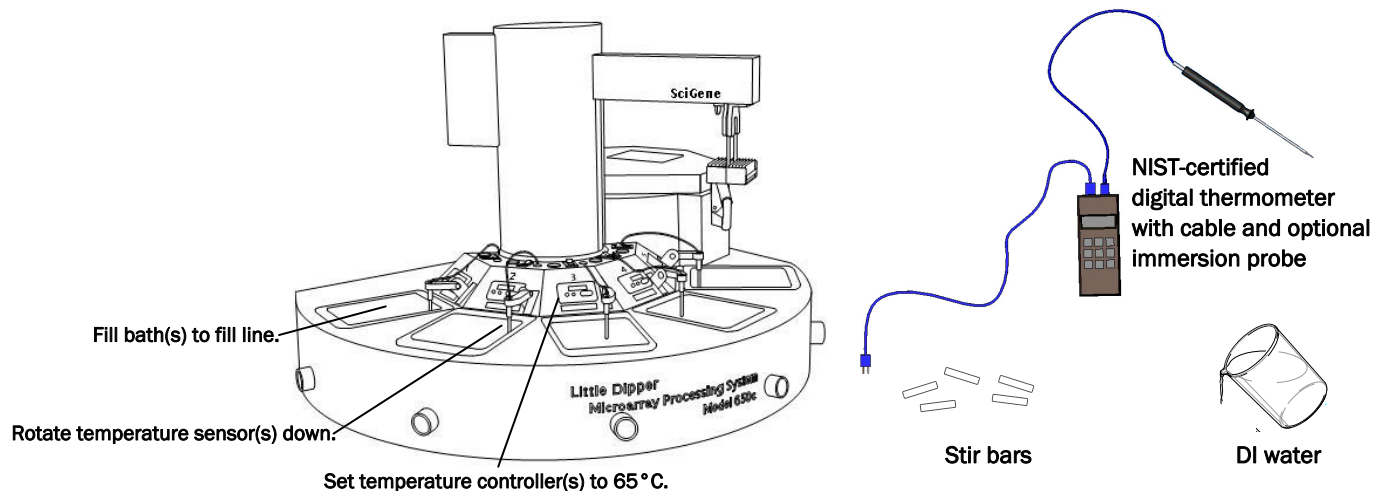
Introduction

The temperature controllers that regulate bath temperatures on the Little Dipper Processor are calibrated at the factory to ensure bath temperatures are accurate to within 0.5°C across its operating range. Periodic validation of the accuracy of the temperatures maintained by the baths is normally required in CLIA-regulated laboratories.

This document describes two alternate procedures to validate the temperatures maintained by the controllers on the instrument. It also provides a protocol for calibrating the controllers to achieve accurate temperatures using a NIST-calibrated digital thermometer.

Equipment and Supplies Needed

- Little Dipper Processor with standard baths (670 ml)
- De-ionized water
- Stir bars
- Digital thermometer and cable, NIST-certified (SciGene cat. #1051-52-0)

If using Method II:
- Immersion, T-type temperature probe for digital thermometer (SciGene Cat. #1051-52-1)

Instrument Setup

1. Fill all baths with de-ionized water. Fill to the indented '—' line on the sides of the baths, located 1/4" from the top. Failure to fill the bath to this level will give spurious results.

2. Rotate the temperature sensors to the down position.

3. Add a stir bar in each bath. Turn on main power to the instrument. Activate and set rotation speed of stir bars in all baths such that a vortex is formed without splashing.

4. Turn on power to the bath controllers. Set each to 65°C and allow the temperature to stabilize (~30 minutes).

Method I – Temperature Validation Using Built-in Temperature Probe

1. For *each* bath to be tested, ensure that:

   a. the bath is filled to the fill line, 1/4" from the top.
   b. the temperature sensor is rotated completely down.
   c. the temperature on the controller is set to 65°C.
   d. the temperature has stabilized.

   ⚠ The temperature probe will not accurately sense the temperature if the liquid level is below the fill line.

   ⚠ The digital thermometer will not report an accurate value if the bath temperature has not yet stabilized.

2. Using the cable provided with the digital thermometer, plug one end into the blue receptacle above the bath and the other into the thermometer.

3. Turn ON the thermometer and allow it to stabilize for one minute.

4. If the controller is calibrated correctly, the temperature displayed on the thermometer should be within ±0.5°C from that shown on the controller.

> Record the date, controller set temperature (65°C), digital thermometer temperature, and your initials in a temperature log book maintained in your lab. You have completed temperature validation for that bath.

5. Repeat steps 1 through 4 for the remaining controllers.

6. If the temperature difference between the controller and digital thermometer is more than 0.5°C, the controller requires calibration. Proceed to "**Calibrating the Temperature Controller**" section of this document.

— End Method I —

SciGene

Method II – Temperature Validation Using an Immersion Temperature Probe

1. For *each* bath to be tested, ensure that:

   a. the bath is filled to the fill line, 1/4" from the top.
   b. the temperature sensor is rotated completely down.
   c. the temperature on the controller is set to 65°C.
   d. the temperature has stabilized.

   ⚠️ **The temperature probe will not accurately sense the temperature if the liquid level is below the fill line.**

   ⚠️ **The digital thermometer will not report an accurate value if the bath temperature has not yet stabilized.**

2. Plug the cable of the immersion probe into the digital thermometer.

3. Immerse the probe ≥ 1 inch into the water bath so that the transition point of the probe is below the water but the tip of the probe is <u>not</u> touching the bottom or sides of the bath.

4. Turn on the thermometer and allow one minute to stabilize. If the controller is calibrated correctly, the temperature displayed on the thermometer should be within ±0.5°C from that shown on the controller.

   > Record the date, controller set temperature (65°C), digital thermometer temperature, and your initials in a temperature log book maintained in your lab. You have completed temperature validation for that bath.

5. Repeat steps 1 through 4 for the remaining controllers.

6. If the temperature difference between the controller and digital thermometer is more than 0.5°C, the controller requires calibration. Proceed to "**Calibrating the Temperature Controller**" section of this document.

<p align="center">— End Method II —</p>

Calibrating the Temperature Controller

Re-calibrating the temperature controller is recommended only if the display varies by more than 0.5°C to a connected NIST-certified digital thermometer (SciGene cat. #1051-52-0).

For Instruments Equipped with Watlow SD31 Controllers:

To adjust a controller to achieve accurate temperatures:

1. Turn ON the instrument and set the controller to 65°C. Allow 30 minutes for the temperature to stabilize.

2. Using the cable provided with the digital thermometer, plug one end into the blue receptacle found above the controller.

3. Turn on the thermometer. Allow 1 minute to stabilize. The actual temperature of the block will be displayed.

4. Calculate the difference in the temperature shown on the controller and the digital thermometer. For example, if the controller displays 65.0°C and the digital thermometer displays 66.5°C, the difference (offset) is 1.5°C.
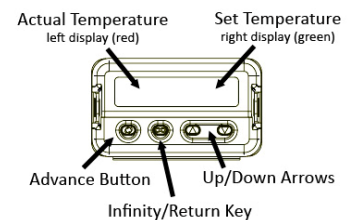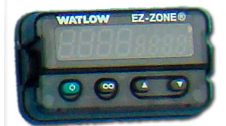
Actual Temperature

Set Button   Up/Down Arrows
Infinity/Return Key
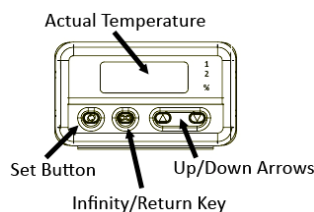
Calibrating the Temperature Controller (continued)

5. On the temperature controller, press the Infinity Key (∞) for three seconds until "OPEN" appears.

6. Press the down arrow four times until "Cal" appears.

7. Press and hold the SET key. The existing offset value between the controller and digital thermometer is displayed.

8. Press and hold the SET key and use the up/down arrows to adjust the offset value to the temperature difference calculated in Step 4. For example, if the controller shows a temperature 1.5°C lower than the thermometer, adjust the offset by adding 1.5 to the value shown.

9. Press the Infinity Key (∞) to exit calibration and return to the operation display. Verify that the temperature on the thermometer matches the display. the controller is now calibrated to provide accurate temperatures from 35 to 90°C.

For Instruments Equipped with EZ-Zone Controllers:

To adjust a controller to achieve accurate temperatures:

1. Turn ON the instrument and set the controller to 65°C. Allow 30 minutes for temperature to stabilize.

2. Using the cable provided with the digital thermometer, plug one end into the blue receptacle found above the controller.

3. Turn on the thermometer. Allow 1 minute for thermometer to stabilize. The actual temperature of the block will be displayed.

4. Calculate the difference between the temperature shown on the controller and on the digital thermometer. For example, if the controller displays 65.0°C and the thermometer displays 66.5°C, the difference (offset) is 1.5°C.

5. On the controller, press the up and down arrows simultaneously for 3 seconds. The left display shows "**A1**" and the right display shows "open".

Actual Temperature
left display (red)   Set Temperature
right display (green)

Advance Button   Up/Down Arrows
Infinity/Return Key

6. Press the Advance Button (green circle) 3 times until the right display shows "**i.CA**". The left display shows the offset value between the controller and thermometer when the unit was last calibrated.

7. Use the up or down arrow to adjust the offset value to the temperature difference calculated in Step 4. For example, if the controller shows a temperature 1.5°C lower than the thermometer, adjust the offset by adding 1.5 to the value shown.

8. Press the Infinity Key (∞) twice to exit calibration and return to the operation display. Verify that the temperature on the thermometer matches the display. The controller is now calibrated to provide accurate temperatures from 35 to 90°C.

<p align="center">— End Calibration —</p>

SciGene