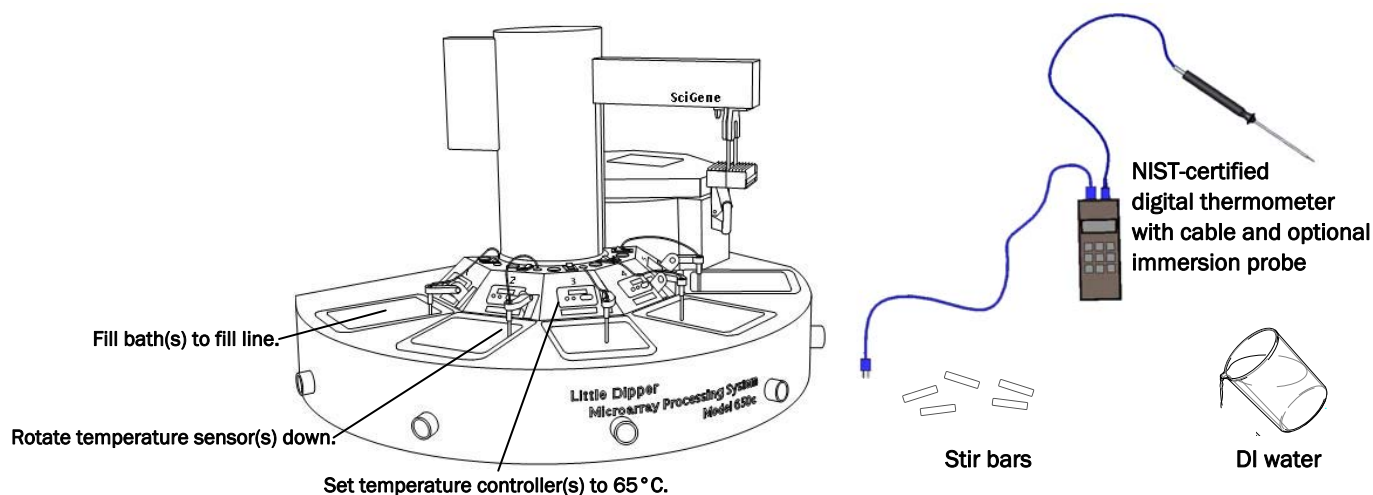


Bath Temperature Validation Methods for CLIA-Regulated Laboratories



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. SciGene recommends validating temperatures monthly.

This methods sheet describes two alternate procedures to validate the temperatures maintained by the temperature 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 individual powers to temperature controllers. Set the temperature on the controller to 65°C and allow the temperature to stabilize (approximately 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 to the down position.
 - c. the temperature on the controller has been set to 65°C.
 - d. the temperature has stabilized.



The temperature sensor will not accurately sense the temperature of the liquid in the bath if the water level is below the fill level.



The digital thermometer will not accurately report the temperature if the temperature in the bath has not stabilized.

2. Using the cable provided with the digital thermometer, plug one end into the blue receptacle found above the bath and the other into the digital thermometer.
3. Turn on the thermometer using the ON/OFF button. The temperature of the bath will be displayed.
4. If the controller is calibrated correctly, the temperature displayed on the digital thermometer should be within ±0.5°C from that shown on the controller.



Record the date, controller set temperature and digital thermometer temperature and your initials in a temperature log book maintained in your lab. You have completed the validation of temperature for that water bath.

Note: 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 methods sheet.

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

– End Method I –

Temperature Validation Methods for CLIA-Regulated Laboratories

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 to the down position.
 - c. the temperature on the controller has been set to 65 °C.
 - d. the temperature has stabilized.



The temperature sensor will not accurately sense the temperature of the liquid in the bath if the water level is below the fill level.



The digital thermometer will not accurately report the temperature if the temperature in the bath has not 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 not touching the bottom or sides of the bath.
4. Turn on the thermometer using the **ON/OFF** button. The temperature of the bath will be displayed. If the controller is calibrated correctly, the temperature displayed on the digital thermometer should be within ± 0.5 °C from that shown on the controller.

Record the date, controller set temperature and digital thermometer temperature and your initials in a temperature log book maintained in your lab. You have completed the validation of temperature for that water bath.

Note: 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 methods sheet.

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

– End Method II –

Calibrating the Temperature Controller

A temperature controller requires calibration only when the bath temperature shown on the controller display differs by more than 0.5 °C from the temperature shown on the NIST-certified digital thermometer. Follow these steps to adjust the controller to achieve accurate temperatures.

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 to the down position.
 - c. the temperature on the controller has been set to 65 °C.
 - d. the temperature has stabilized.



The temperature sensor will not accurately sense the temperature of the liquid in the bath if the water level is below the fill level.



The digital thermometer will not accurately report the temperature if the temperature in the bath has not stabilized.

2. Using the cable provided with the digital thermometer, plug one end into the blue receptacle found above the bath and the other into the digital thermometer.
3. Turn on the thermometer using the **ON/OFF** button. The temperature of the bath will be displayed.
4. On the temperature controller, press the **Infinity Key** (∞) for three seconds until “**OPEN**” appears.
5. Press the Down Arrow four times until “**Cal**” appears.
6. Press and hold the **SET** key. The existing offset value between the controller and digital thermometer is displayed.
7. Calculate the difference in the temperature shown on the controller and the digital thermometer; (e.g. the controller displays 52.5 °C and the digital thermometer displays 51.0 °C, the difference is 1.5 °C).
8. Press and hold the **SET** key and use the up and down arrows to enter the offset value calculated in Step 7. For example, if the controller displays a temperature that is 1.5 °C higher than the digital thermometer, adjust the offset value to minus 1.5 (-1.5) of the current offset.
9. Press the **Infinity Key** (∞) to exit calibration. The bath temperature is now calibrated for the set temperature you selected. Check and calibrate the controllers for the remaining baths, if necessary.

– End Calibration –