



**INDIANA ACTSI**  
Clinical and Translational Sciences Institute

**STANDARD OPERATING PROCEDURE**  
**Indiana CTSI Specimen Storage Facility**

TITLE: STANDARD OPERATING PROCEDURE FOR WATER BATH MAINTENANCE

CHAPTER: 3-Equipment

SOP #: SF-3-12.02

SUPERSEDES SOP #: N/A

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Quality Compliance Specialist

## 1. REVISION

### 1.1. Significant changes in this revision include:

- 1.1.1. Section 5.4 edited to allow use of similar products to Kimwipes. Updated Section 6.4.1.1.3 accordingly.
- 1.1.2. Section 5.8 corrected to change NIST traceable timer to NIST traceable thermometer.
- 1.1.3. Section 6.1.2 edited for clarity.
- 1.1.4. Updated Section 6.4.2 to refer personnel to SF-1-10 in the event of equipment malfunction.
- 1.1.5. Updated Appendix A to remove the redundant documentation of cleaning date and improve formatting.

## 2. PURPOSE

- 2.1. This Standard Operating Procedure (SOP) defines the procedures used in the Indiana CTSI Specimen Storage Facility (SSF) for using water baths in a manner compliant with all appropriate regulatory and protocol specific requirements and to ensure that all personnel are consistently operating baths in a compliant matter.

## 3. PRINCIPLE

- 3.1. A water bath is a laboratory tool commonly used in chemistry, biology, and medicine to heat materials gently and gradually to fixed temperatures, or to keep materials warm over a period of time. The water bath used in the SSF is a reciprocal shaking water bath to provide more rapid temperature equilibration than a static water bath. It is used for DNA rehydration, manual DNA processing, and, if desired, for thawing frozen blood samples in preparation for DNA extraction. The temperature range is ~27°C to 55°C without the gable cover and to 99.9°C with use of the gable cover. Tray shaking speed is easily adjusted between 30 and 200 cycles per minute at 5cpm intervals. The tray stroke can be adjusted to three different lengths: 0.5", 1", and 1.5". Actual operation parameters are defined. Proper use and maintenance of the water bath will assure many years of service.

#### 4. SCOPE

- 4.1. The SOP applies to all SSF staff and is intended to outline maintenance, calibration, and documentation procedures used within the laboratory to ensure that water baths perform with reliable precision and accuracy. Actual operation parameters are defined in protocols and other documents, not this SOP.

#### 5. MATERIALS

- 5.1. Distilled Water or R/O water
- 5.2. Any commercial brand of quaternary ammonium germicide (e.g., Conflikt™ Detergent Disinfectant, Fisher Scientific cat# 04-355-33)
- 5.3. Paper Towels
- 5.4. Kimwipes® (or similar product)
- 5.5. Warm Soap solution (dilute mixture of general use soap and water)
- 5.6. Screwdriver (Phillips)
- 5.7. Allen Wrench, appropriately sized
- 5.8. NIST traceable thermometer

#### 6. PROCEDURE

##### 6.1. OPERATION

- 6.1.1. Ensure that the water level is at least 1” above the bottom of the base tray.
  - 6.1.1.1. If the water level is not at least 1” above the bottom of the base tray, use distilled water to bring bath media to the desired level.
- 6.1.2. If microorganisms form on the top of the bath media during use, add 6 to 8 drops quaternary ammonium germicide (any commercial brand). Document completion in comments section on Appendix A.
- 6.1.3. When placing flat bottom vessels in the bath, always use the base tray to avoid possible damage to the heater.
- 6.1.4. When using a temperature setting above 60°C, the use of the lid is recommended to optimize the temperature control.
- 6.1.5. Ensure that an NIST traceable thermometer (calibrated at the desired temperature range) is available for use. To ensure an accurate temperature measurement, ensure that the thermometer is not touching the sides or resting on the bottom of the water bath.
- 6.1.6. Power up: Depress the power switch located at the lower right hand corner of the bath. The unit is fully operational upon application of power. The display will show the actual bath temperature.
- 6.1.7. To set temperature control point:
  - 6.1.7.1. Press ENTER until set point temperature is displayed.
  - 6.1.7.2. Press UP or DOWN until desired set point is displayed.
  - 6.1.7.3. Press ENTER again to set the new value.
  - 6.1.7.4. Display will return to actual temperature.
  - 6.1.7.5. If ENTER is not pressed, new value will not be set and display will return to actual temperature.

- 6.1.7.6. Once the temperature has stabilized, ensure that the NIST traceable thermometer displays the desired temperature; adjust the temperature control until the NIST thermometer displays the desired temperature.
  - 6.1.8. To set speed (set to 0 if you want it to be stationary):
    - 6.1.8.1. Press ENTER until set point speed is displayed.
    - 6.1.8.2. Press UP or DOWN until desired speed is displayed.
    - 6.1.8.3. Press ENTER again to set new speed.
    - 6.1.8.4. Display will show actual speed for 10 seconds, then return to actual temperature.
    - 6.1.8.5. If ENTER is not pressed, new value will not be set and display will return to actual temperature.
  - 6.1.9. To begin or end shaking motion, press START/STOP key.
  - 6.1.10. If the Water Bath fails to function as defined in section 6.1 above, record on Appendix A, Water Bath Maintenance & Service Log, Comments section, and notify SSF Management. Proceed per SF-1-10 SOP for Out of Specification Condition Notification and Management.
- ## 6.2. EXPLANATION OF CONTROLS
- 6.2.1. Power Switch - The power switch is located on the lower right hand side of the bath; it provides power for the entire unit.
  - 6.2.2. Hi-Limit Thermostat - is located immediately to the left of the power switch on the lower right corner of the bath. The high limit is an adjustable control used to prevent thermal runaway in the event that the primary control fails. After the bath temperature has stabilized, use a standard screwdriver to adjust the potentiometer. When delivered, the Hi-Limit is turned fully clockwise (highest setting). In this position, the Hi-Limit light will be OFF. Turn the potentiometer counter-clockwise until the Hi-Limit is ON, and then adjust clockwise 1/8 of a turn. Verify that the Hi-Limit light is OFF. Now if the bath temperature rises above the desired setting, the Hi-Limit protection will be activated.
    - 6.2.2.1. If the bath temperature rises above the desired setting and the Hi-Limit protection is activated, record on Appendix A in the "additional comments" section and notify SSF Management. Proceed per SF-1-10 SOP for Out of Specification Condition Notification and Management.
  - 6.2.3. Control Panel Components (located on top of the bath):
    - 6.2.3.1. LED Display - The three-digit LED display used to show both the actual and set point values for the temperature/shaking speed.
    - 6.2.3.2. Heater On Lamp - The "Heater ON" lamp is illuminated when power is applied to the heater.
    - 6.2.3.3. Indicator Lamps - These lamps indicate which of 4 parameters (Actual Temp, Actual Speed, Set point Temp and Set point Speed) is displayed in the LED window.
    - 6.2.3.4. Enter Key - The Enter Key is used to choose which parameter is displayed in the LED window, and is also used to store a new set point value.
    - 6.2.3.5. UP & DOWN Keys - are used to adjust temperature and speed set point values. Pressing & holding these keys will increase/decrease the display value slowly at first, and then rapidly.
    - 6.2.3.6. Offset Key- is used to adjust the temperature to match a calibrated reference thermometer.

- 6.2.3.7. Shaker Start/Stop Key - This key is used to toggle the tray shaking motion on or off.

### 6.3. CLEANING (monthly)

- 6.3.1.1. **Clarification:** Stainless steel will resist corrosion; however, it is not impervious to it. Proper maintenance of the stainless steel bath chamber is essential. It should be cleaned on a monthly basis.
  - 6.3.1.1.1. Wipe inside of water bath using mild soapy water
  - 6.3.1.1.2. Rinse with distilled water.
  - 6.3.1.1.3. Thoroughly dry the chamber after cleaning.
  - 6.3.1.1.4. Document completion on Appendix A.

### 6.4. MAINTENANCE

#### 6.4.1. Routine (to be performed annually)

##### 6.4.1.1. Optical disc care

- 6.4.1.1.1. Remove the top/side panel located on the right side of the water bath by removing the four screws.
- 6.4.1.1.2. Locate the optical disc, which is a circular flat disc located on the left-hand side.
- 6.4.1.1.3. Wipe optical disc clean with a Kimwipe® (or similar product) to remove any debris.
- 6.4.1.1.4. Verify that the disc is aligned properly and does not rub against the optical sensor. Do this by rotating the disc by hand one turn clockwise.
  - 6.4.1.1.4.1. If the disc does make contact with the sensor, loosen the 2 set screws on eccentric with an appropriately sized Allen wrench. Reposition the disc and tighten the set screws. Note that this was performed in the comments section on Appendix A.

##### 6.4.1.2. Temperature safety check

- 6.4.1.2.1. Test operation of the Hi-Limit thermostat as described in 6.2.2.
- 6.4.1.2.2. Notify SSF Management if Hi-Limit thermostat is not functioning properly. Proceed per SF-1-10 for Out of Specification Condition Notification and Management.

#### 6.4.2. Non-Routine

- 6.4.2.1. If the equipment is not functioning or functioning improperly, consult the operation manual. If unable to resolve, notify SSF Management. Proceed per SF-1-10 for Out of Specification Condition Notification and Management.. Service should be performed by a qualified technician. If any service is performed, note on Appendix A and reserve a copy of the work order.

### 6.5. CALIBRATION AND FUNCTION VERIFICATION

- 6.5.1. The SSF does not conduct temperature checks and calibrations on the water bath. Staff has equipped the unit with an NIST traceable thermometer at all times during use. Accurate temperature will be noted from these readouts.

7. REFERENCES

- 7.1. Installation/Service Manual, Reciprocal Shaking Water Baths - Models 2870/2871 & 2872/2873 (located on share drive)

8. DOCUMENTATION

- 8.1. Maintenance logs are submitted for review by SSF Management and maintained per SF-1-6 Controlled Document Management SOP.
- 8.2. OOS results are documented as defined in SF-1-10 SOP for OOS Response and Management.
- 8.3. All Deviations are managed per the SF-1-9 Deviation Management SOP.

9. APPENDICES

- 9.1. The current version of each of the following appendices is used to guide and/or implement this SOP:

APPENDIX A – Water Bath Maintenance and Service Log (1 Page)

### SSF Water Bath Maintenance and Service Log

<b>Serial Number:</b> _____		<b>Year:</b> _____	
<b>CLEANING LOG (to be performed monthly)</b>			
Month	Date	Tech	Comments / Corrective Actions (Required if not acceptable)
January			
February			
March			
April			
May			
June			
July			
August			
September			
October			
November			
December			
<b>ANNUAL MAINTENANCE</b>			
<b>Optical Disc Care</b>	<b>Optical disc cleaned</b> <input type="checkbox"/>	<b>Initials/Date</b> _____	<b>Comments:</b>
	<b>Aligned properly</b> <input type="checkbox"/> Yes  No <input type="checkbox"/>	<b>Initials/Date</b> _____	<b>Comments:</b>
<b>Temperature Safety Check</b>	<b>Hi-Limit thermostat functional?</b> <input type="checkbox"/> yes <input type="checkbox"/> no	<b>Initials/Date</b> _____	<b>Comments:</b>
<b>SERVICE RECORD</b>			
<b>Activity</b>	<b>Date</b>	<b>Initials</b>	<b>Comments / Corrective Actions</b>
Out of Service			
Returned to Service (if applicable)			
<b>Additional Comments</b>			
Reviewed by Initials / Date:			