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| **Plasma Thawer Function Verification and Maintenance** | | | | | |
| **Purpose** | This procedure provides instructions for periodic maintenance and verification of Helmer Plasma Thawer and DT1 thermometer. | | | | |
| **Policy Statements** | * Temperature of the plasma thawer shall be documented each day of use. * Each plasma thawer used for the preparation of blood components shall be verified as part of installation validation, after adjustments or repairs, and every 3 months (quarterly). * Quarterly verification shall be performed per posted Equipment Maintenance schedule. | | | | |
| **Related**  **Documents** | * [TSf 18.2.1 Mpls Daily QC Form](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/Mplsf/200112.pdf) * [TSf 18.2.2 STP Daily QC Form](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/STPf/200153.pdf) * [TSf 17.10.3 Equipment Maintenance](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/Sysf/199566.pdf) * [TSf 17.12.1 Plasma Thawer Alarm Test](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/Sysf/199567.pdf) | | | | |
| **Materials** | * DT1 Thermometer * NIST certified thermometer * 10% bleach * Distilled water * Drain hose for DH4 Plasma Thawer * Light oil | | | | |
| **Procedure** |  | | | | |
|  | **Step** | Action | | | |
| Daily Quality Control | 1 | Record DT1 thermometer temperature reading on the daily equipment quality control sheet.  Acceptable: 30-37ºC | | | |
|  | 2 | Record the Helmer digital control temperature reading on the daily equipment quality control sheet.  Acceptable 30-37ºC  Note: *If digital temperature does not match DT1 thermometer within 2ºC, see Annual Thermometer Calibration Check section.* | | | |
|  | 3 | Check water level. If low, add distilled water to upper fill line. | | | |
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|  | **Step** | **Action** | | | |
| Weekly Maintenance-Clean Plasma Thawer at least weekly | 1 | Turn the power switch OFF before draining the chamber bath. | | | |
| 2 | Place the open end of the drain hose securely into a drain or bucket. | | | |
| 3 | Push the other end of the drain hose with the coupling valve into the drain plug, located on the left side of the unit towards the back, until it “clicks” securely in place.  The chamber water will immediately begin to flow freely out of the chamber. If air pockets are seen in the tubing at the drain plug, which will slow the draining speed, simply squeeze the tubing and release to remove the air pockets. | | | |
|  | 4 | Remove the finger screw at the top of the basket assemblies and carefully lift if from the unit. | | | |
|  | 5 | Wipe bottom of bath with towel to remove any sediment. | | | |
|  | 6 | Using a soft cloth or sponge clean each basket assembly and the chamber bath walls with a disinfectant cleaning solution. | | | |
|  | 7 | Returning Basket Assembly to bath, make sure rollers are outside basket guards | | | |
|  | 8 | Disconnect the drain tub-coupling valve from the unit (by depressing dark gray button). | | | |
|  | 9 | Refill the chamber bath with distilled water to the fill line. | | | |
|  | 10 | Turn power switch ON. Do not use until temperature is above 30ºC. | | | |
|  | 11 | Record cleaning on Blood Bank Duties Chart. | | | |
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|  | **Step** | **Action** | | | |
| Quarterly Maintenance | 1 | Lubricate basket assembly lift-out rail with light oil   1. Raise the basket assemblies and remove them from the unit. 2. Place no more than 2-3 drops of light duty oil on your finger and rub oil along the length of the lift-out rail. 3. Reattach the basket assemblies. | | | |
|  | 2 | High Alarm Test.   1. Remove Chamber cover and any products from the unit. 2. Press the ∧ and ∨ keys at the same time for 3 seconds. The temperature controller display will alternate between **tunE** and **oFF** indicating you are in the program menu. 3. At the **tunE prompt**, press the ∧ key until the display reads **AL.Hi**. 4. Press the \* button to view the high alarm setting. This should set at be 37°C. If needing adjustment depress the \* button, and use the ∧ and ∨ keys to set the desired value of 37°C. 5. Exit back to the main menu by releasing the \* button, then press and hold the ∧ and ∨ keys simultaneously until the operating temperature appears on the digital display. 6. Hold the \* button and press the ∧ key to increase the set temperature value from 36.0°C to 37.5°C. Release the \* button. 7. Observe the temperature controller display noting the temperature at which the alarm sounds. Verify that the basket assemblies lift out of the chamber and the Cycle Time display blinks **E1**, **and the temperature controller displays a visual alarm-ALR.** 8. Record observation on the Plasma Thawer Alarm Test form. 9. Reset the set temperature to 36.0°C by depressing the \* button and using the ∨ key. 10. Allow the chamber temperature to stabilize before using. | | | |
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|  | **Step** | **Action** | | | |
| Annual Thermometer Calibration Check | 1 | Place a certified NIST thermometer inside the chamber bath. | | | |
| 2 | Allow the chamber temperature to stabilize for at least 30 minutes. | | | |
| 3 | Record the temperature readings of the digital display and DT1 thermometer on the Thermometer QC form.  Acceptable:  Display pr DT! Reading within ±1°C of the NIST certified thermometer  The digital display and DT1 reading must be within 1°C of each other.  See below if Temperature Controller or DT1 re-calibration is required  Note: Done yearly or if discrepancy noted between digital and DT1 thermometer. | | | |
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|  | **Step** | Action | | | |
| To Calibrate the Digital Display Temperature controller to the NIST thermometer | 1 | Press the ∧ and ∨ keys at the same time for 3 seconds. The display will alternate between **tune** and **oFF** indicating you are in the program menu. | | | |
| 2 | At the **tune** prompt, press the ∨ key twice. The display should alternate between **LEUL** and **1.** | | | |
| 3 | Press and hold \* and press the ∧ to display 3. The display should alternate between **LEUL** and **3**. | | | |
| 4 | Press the ∧ key repeatedly until the display alternates between **2Ero** and a decimal number that is the factory set calibration offset value. To make an adjustment, hold the \* at the **2Ero** prompt and use the ∧ and ∨ keys to raise or lower the calibration offset number. (For example, if the Set Temperature is 36.5°C, then a +0.5 adjustment is needed.) | | | |
|  | 5 | Exit back to the normal mode by holding the ∧ and ∨ keys for 3 seconds. | | | |
|  | 6 | Verify that the digital reading matches the NIST reading. | | | |
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|  | **Step** | **Action** | | | |
| To calibrate the DT1 Thermometer to the NIST thermometer | 1 | Remove the back cover on the Digital Thermometer by pulling the back plate away from the housing. | | | |
| 2 | Insert a Philips-type screwdriver into the calibration trim pot. | | | |
| 3 | Turn it clockwise to increase the temperature readout and counter-clockwise to decrease the temperature readout. Refer to the drawing in manual. | | | |
|  | 4 | When making calibration adjustments make very small movements on the calibration trim pot. Allow 15-30 seconds for the readout to stabilize before making any further adjustments (calibration changes are delayed on the readout due to the solar powered electronics system.) | | | |
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|  | **Step** | **Action** | | | |
| Malfunctions and Repairs | 1 | Remove equipment from service. | | | |
| 2 | Contact Biomed. | | | |
|  | 3 | Notify Technical Specialist. | | | |
|  | 4 | Document issue, actions and outcome on equipment service record form. | | | |
|  | 5 | Re-qualify according to above prior to returning equipment to use. | | | |
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| **Alternate Procedure** | A back-up plasma thawer is available in St. Paul and Mpls. Alternately, and clean container of warm (30-37ºC) tap water may be used. Monitor water temperature with a calibrated BB thermometer. Protect products during thawing using the Helmer product overwraps.   |  |  | | --- | --- | | **Step** | **Action** | | 1 | Make sure the plasma thawer is clean before adding water. | | 2 | Add DI water to the plasma thawer to the fill line. | | 3 | Plug the plasma thawer into red power outlet turn power switch ON. Do not use until temperature is above 30°C | | 4 | Record temperature on the daily QC sheet under plasma thawer. If two plasma thawers are being used write the BioMed number of second thawer and record temperature.  Acceptable 30-37°C | | 5 | Perform High Alarm Test and record on form TSf. 17.12.1   1. Remove Chamber cover and any products from the unit. 2. Press the ∧ and ∨ keys at the same time for 3 seconds. The temperature controller display will alternate between **tunE** and **oFF** indicating you are in the program menu. 3. At the **tunE prompt**, press the ∧ key until the display reads **AL.Hi**. 4. Press the \* button to view the high alarm setting. This should set at be 37°C. If needing adjustment depress the \* button, and use the ∧ and ∨ keys to set the desired value of 37°C. 5. Exit back to the main menu by releasing the \* button, then press and hold the ∧ and ∨ keys simultaneously until the operating temperature appears on the digital display. 6. Hold the \* button and press the ∧ key to increase the set temperature value from 36.0°C to 37.5°C. Release the \* button. 7. Observe the temperature controller display noting the temperature at which the alarm sounds. Verify that the basket assemblies lift out of the chamber and the Cycle Time display blinks **E1**, **and the temperature controller displays a visual alarm-ALR.** 8. Record observation on the Plasma Thawer Alarm Test form. 9. Reset the set temperature to 36.0°C by depressing the \* button and using the ∨ key.   Allow the chamber temperature to stabilize before using. | | 6 | If the temperature is in range and the high alarm is activated the plasma thawer is ready to use. | | | | | |
| **References** | Helmer Plasma Thawer users manual, current edition  DTI Thermometer users manual, current edition | | | | |
| **Approval**  **Workflow** | Transfusion Service/Technical Specialist | | | | |
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| **Historical Record** | **Version** | | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | | J. Wenzel | 08/29/06 | Initial Version |
|  | 2 | | J. Wenzel | 2/5/2010 | New format. Replaces TS 16.7.1 |
|  | 3 | | S. Cassidy | 04/10/2012 | Added Alternate Procedure. |
|  | 4. | | S. Cassidy | 12/15/2022 | Added steps to verify back-up equipment for use. |