**Purpose**

To describe the quality control and maintenance procedures performed to ensure acceptable storage temperatures are maintained within regulatory temperature guidelines and required documentation is available for review.

**Procedure: All Storage Devices**

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| **Step** | **Action** | **Related Documents** |
| **Temp Trak**  |
|  **Contact Information** | Contact Engineering * Temp Trak is not responding or temperature differences indicate the Temp Trak is incorrect
* Temp Trak needs calibration
* *Note: TempTrak can be reached at 1-888-533-6900 if so advised by Engineering*
 | Removing Equipment from Service |
| **Troubleshooting** |
| **Temperature readings** are not within the acceptable limits or do not agree within + 2˚C | Circle the unacceptable temperature reading(s) and begin corrective action.* Open and close door firmly, wait 10 minutes and repeat the maintenance steps.
* Record follow up temperature separated by forward slash and document the corrective action taken in the comments field.
* If maintenance parameters are still not met:
	+ Remove equipment from service.
	+ Continue problem solving steps:
		- Contact Engineering
		- Relocate contents
 | Removing Equipment From Service Responding to Temperature Alarms |
| **LED Status is flashing green** | * Check power source and replace the 9-volt battery if necessary.
 |  |
| **Additional Maintenance for all devices** |
| **Monthly: Temp Comparisons** | * Compare Temp Trak readings against manual temperature readings in each unit on the Manual Storage Unit Temperature Log:
	+ Record manual temperature reading top and bottom
	+ Record digital reading
	+ Record simultaneous Temp Trak reading
	+ Temperatures must agree within 2o degrees C.
	+ If greater than 2oC, go to section “Troubleshooting”.
 |  Using the Temp Trak System to Monitor Blood Storage Devices  |

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| **Step** | **Action** | **Related Documents** |
| **Annually:****Cleaning** | Annually perform interior and exterior cleaning* Relocate contents to acceptable storage units
* Wipe interior and exterior with disinfectant solution.
* Allow unit to return to temperature.
* Return contents.
* Document cleaning on Maintenance logs and Temp Trak.
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| **Specific Unit Requirements** | **Appendix A**: Platelet Incubators**Appendix B:** Ultra Low Freezers**Appendix C:** Blood and Reagent Storage Refrigerators and Freezers |  |

**Appendix A: Platelet Incubators**

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| **Step** | **Action** | **Related Documents** |
| **High/****Low Alarm Testing** | **Automatic high and low temperature alarm tests** are performed following installation, quarterly or if needed after repairs.* The Peltier based temperature probe can automatically heat and cool.
* Remove all platelet products from the platelet incubator during this period of varying temperatures.
* From the HOME page, press MAIN.
* Press DOWN to highlight System Alarm Test & STATUS page.
* Press SELECT to access the System Alarm Test & Status page.
* Press UP or DOWN to move the cursor to the desired test.
* Press ENTER to start the test. The HOME page appears, an alarm sounds, and the status is displayed on the HOME page during the test. Each test takes approximately 15 to 30 seconds to complete.
* **High Alarm Auto Test** – Physically heats the upper temperature probe to cause a high alarm condition. After the test alarm activates, the system returns to normal operating mode.
* **Low Alarm Auto Test** – Physically cools the upper temperature probe to cause a low alarm condition. After the test alarm activates, the system returns to normal operating mode.
* Document on the Platelet Incubator Maintenance Form (PIM) and in Temp Trak.
 | Platelet Incubator Maintenance Form |
| **Agitator****Motion****Alarm** | **Agitator Motion and Alarm check.** * Stop the Platelet Agitator and wait the designated time for the motion alarm to sound. The Programmed Time Delay is 1 minute.
* Record results on the PIM form.
* Turn the agitator back on.
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**Appendix A: Platelet Incubators (continued)**

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| **Step** | **Action** | **Related Documents** |
| **Door Open****Alarm** | **Door Open Alarm check.** * Open the door to disengage the door switch.
* Wait for the alarm to sound, the programmed time delay is 1 minute.
* Document results on the PIM form.

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| **Power Failure Alarm** | **Platelet Incubator Power Failure alarm check.** * With the platelet incubator turned ON, disconnect it from the power and wait for the alarm to sound. There is no programmed time delay for this alarm.
* Reconnect the instrument to the power source.
* Document results on the PIM form.

**NOTE**: In the event of a power interruption, the audible alarm sounds and the central alarm relay activates. To disable the audible portion of this alarm, use the Key Activated Switch located on the front control panel of the Platelet Incubator behind the swing out door in the upper right panel. Disabling the power failure alarm also disables the audible portion of the temperature alarm, but the central alarm output and the red temperature alarm light on the controller are still functional.  |
| **Quarterly Maintenance** |
| **Step** | **Action** | **Related Documents** |
| **Calibration of iSeries**  | **Calibrate the digital i.Center Temperature Monitor** quarterly, following programming changes, and as needed to verify the upper or lower temperature display on the HOME page is accurately calibrated. * Before attempting to calibrate the Temperature Monitor, verify that there is proper clearance around the device for ventilation (at least 4 inches of space top and back).
* Verify that the preventative maintenance schedule has been followed, including the quarterly cleaning of the condenser.
* Ensure that the storage chamber is empty of platelet products, and that the Platelet Agitator is turned ON.

 **Verify i.Center** temperature monitor readings: * Allow the chamber temperature to stabilize for approximately 30 minutes.
* Place a NIST Traceable Thermometer in the back, right, bottom corner.
* Allow the thermometer to accurately register the chamber air temperature for 30 minutes.
* Compare the NIST Thermometer reading to the displayed value on the Temperature Monitor.
* Record results on the PIM form.
* **Note:** Calibration is required only if there is a difference greater than 0.5°C between the Temperature Monitor and the NIST Thermometer reading.

(All readings must be between 20.5°C – 23.5°C.)  |  |
| **Appendix A: Platelet Incubators (continued)** **Quarterly Maintenance** |
| **Step** | **Action** | **Related Documents** |
|  | **To Calibrate the i.Center Temperature Monitor**:1. From the HOME page, press MAIN.
2. Press DOWN to highlight Edit Configuration
3. Press SELECT.
4. Enter the 4-digit password 1234. The CONFIGURATION page appears.
5. Press DOWN to highlight Temperature Calibration.
6. Press SELECT.
7. Press INC to select the Upper probe for calibration.
8. Press DOWN until Temperature is highlighted.Press INC or DEC to change the temperature to match the readout of the NIST Thermometer.
9. Press DOWN until STORE CALIBRATION is highlighted.
10. Press ENTER to save all changes.
11. Press HOME to return to the HOME page.
* **Document Calibration on the PIM form.**
 |  |
| **Condenser** | **Clean the Condenser** quarterly**,** or more frequently if excessive lint or dust is observed. * The air-cooled condenser is the finned surface located at the rear upper right corner of the Platelet Incubator.
* Clean using a soft brush and vacuum cleaner.
* Document on a PIM form.
 |  |
| **Calibrate the Temperature Controller** | **Calibrate the Temperature Controller** quarterly and as needed to ensure precise storage temperature. **Verify** the Temperature Controller Reading by following the steps outlined above for the **i.Center Temperature Monitor.** * Instead of using the digital display compare the NIST Thermometer reading to the Temperature Controller reading.
* Record results on the PIM form.
* **Note:** Calibration is required only if there is a difference greater than 0.5°C between the Temperature Monitor and the NIST Thermometer reading.

(All readings must be between 20.5°C – 23.5°C.)  |  |
| **Calibrate the Temperature Controller:**1. Press and hold the ▼ and ▲ buttons at the same time for 3 seconds. The display alternates between tunE and oFF. This indicates that the controller is in the program mode.
2. At the tune prompt press the ▼ button twice. The display alternates between LEUL and 1.
3. Press and hold the **\*** button and press the ▲ button to display 3. The display alternates between LEUL and 3 indicating that the controller is in the Level 3 program menu.
4. From the Level 3 program menu press the ▲ button repeatedly until the display alternates between 2Ero and the offset value set during factory calibration.
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| **Appendix A: Platelet Incubators (continued)** **Quarterly Maintenance** |
| **Step** | **Action** | **Related Documents** |
| **Calibrate the Temperature Controller**  | 1. Determine the amount of adjustment needed by comparing the difference between the temperature displayed on the Temperature Controller and NIST Thermometer reading.

**EXAMPLE:**  If the temperature controller reads 22.0, but the NIST Thermometer reads 22.3; a +0.3 adjustment is needed.**NOTE:** Pay close attention to the decimal place so that a whole value is not entered when a decimal value is required.1. To make the adjustment, hold the \* button when 2Ero is displayed and use the ▼ or ▲ buttons to lower or raise the difference.
2. Release the \* button and press and hold the ▼ and ▲ buttons simultaneously until the operating temperature appears on the display.
3. Allow the chamber temperature to stabilize for 30 minutes and re-verify the Temperature Controller reading.
4. Perform additional adjustments if necessary.
5. Document calibration on the Platelet Incubator Maintenance Form.
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| **Annual Maintenance** |
|  | **Performed by HMC Engineering Department*** Conduct a visual inspection of the internal components, and condition of the motor bearing assembly and wheels.
* Lubricate the 4 wheel bearings with a few drops of light weight oil. Do not use grease.
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**Appendix B: Ultralow Freezers**

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| **Step** | **Action** | **Related Documents** |
| **Monthly Maintenance** |
| **Clean** | * Perform monthly at a minimum; more often as needed
* Clean door gaskets, hinges, inner doors
* Using a soft cloth, remove any frost build-up form the gasket and doors.
* Clean probe cover.
* Remove any ice build-up around sensor probe.
* Clean Vacuum Relief Port
* Observe the inner side of the port periodically for frost and ice build-up and remove any frost with a soft dry cloth.
* Clean Air Filter.
* Open the front lower door by grasping the bottom left corner.
* Locate the grille on the door. Grasp the middle of the grille material and gently pull out to remove.
* Wash the filter material using water and a mild detergent.
* Dry by pressing between two towels
* Install the filter back into the grille and attach the grille.
* Check System Battery
* Press the Mode key until Configuration indicator lights.
* Press and right arrow until SYS BAT TEST is displayed in the message center
* Press Enter to initiate the test.
* TESTING BATT will display during the testing period.
* At completion BATT GOOD or BATT FAIL will display. If test fails replace battery.
 | Refrigerator and Freezer Maintenance Form |
| **Quarterly Maintenance** |
| **Alarm****Testing** | **High Alarm Test*** Press the Mode key until Configuration indicator lights.
* Press the right arrow until HI ALRM TEST is displayed in the message center.
* Press Enter to initiate the test.
* The temperature on the display will begin to increase until the high alarm set point (-65°C) has been reached.
* The audible alarm will sound and the alarm indicator will flash.
* Press the Mute key to silence the alarm.

**Low Alarm test*** Press the Mode key until Configuration indicator lights.
* Press the right arrow until LO ALRM TEST is displayed in the message center.
* Press Enter to initiate the test.
* The temperature on the display will begin to decrease until the low alarm set point (-90°C) has been reached.
* The audible alarm will sound and the alarm indicator will flash.
* Press the Mute key to silence the alarm.
* If Alarm does not sound take equipment out of service
 | Refrigerator and Freezer Maintenance form |

**Appendix C: Refrigerator and Freezers**

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| **Step** | **Action** | **Related Documents** |
| **Quarterly Maintenance** |
| **HVAC** | **Schedule HMC HVAC** * Check door hinges
* Check door gaskets
* Vacuum condensing units
 | Daily Equipment, Temperature, and Inventory Duties Checklist |
| **High/****Low****Alarm Testing** | **High and low alarms are tested**. Newer refrigerator and freezer models can be done electronically; older models will be tested with a manual method described in detail in steps to follow. Temp Trak alarms will be verified quarterly.* Place the alarm probe and a NIST calibrated thermometer in a full container of glycerol or similar solution and verify the starting temperature is between 1-6°C.
* **Low alarm activation**
	+ Perform first. Place the container with the probe and thermometer in a pan containing ice/water slush -1°C or colder.
	+ Add several spoonfuls of table salt to help lower the temp.
	+ Close the refrigerator door.
	+ Agitate the container periodically until the alarm sounds.
	+ Record the temperatures as the low alarm (chart, digital, internal, Temp Trak).
	+ Silence the audible alarm.
* **High alarm activation**
	+ Place the container with the probe and thermometer in a pan of cool water that is a temperature of 12-15°C.
	+ Close the refrigerator door.
	+ Agitate the container periodically until the alarm sounds.
	+ Record the temperatures as the high alarm (chart, digital, internal, Temp Trak).
	+ Silence the audible alarm.
* **Respond to Temp Trak pager alarm: High and Low**
	+ If Temp Trak pager did not respond when audible alarm sounded, maintain probe and NIST in solution until the Temp Trak pager sounds.
* See Troubleshooting section if temperatures are not consistent with expected alarm settings
 | Refrigerator/Freezer Maintenance FormUsing the Temp Trak to System to Monitor Blood Storage Devices |
| **Alarm does not sound** | * Slide the digital monitor box up and release it from the anchor.
* Check the battery to ensure that the contact wires are snapped firmly into place.
* Try alarm again.
* If still it doesn’t sound, then replace the 9-volt battery.
* Try alarm again.
* If the alarm still will not sound, remove equipment from service.
 |  |

**References:**

* AABB Standards for Blood Banks and Transfusion Services, Current Edition.
* Helmer Platelet Incubator Operation Manual, Version A, Rev. 360093-1E
* Helmer Flatbed Agitator Operation Manual, Version A, Rev. 360092-1E
* Helmer Chart Recorder Operation Manual, Rev 360076-1EAABB
* Helmer *i* Series Refrigerator Service Manual
* Helmer *i* Series Freezer Service Manual
* Jewett Refrigerator Service Manual
* VWR Model 5600 Series -86 ULT Freezer Manual