**Purpose:**

To detail the steps involved in the calibration, cleaning, maintenance and operation of the Helmer Platelet Incubator.

**Procedure:**

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| --- | --- | --- |
| **Step** | **Action** | **Related Documents** |
| **Procedure A: Quality Control and Maintenance – Daily QC** |  |
| **1** | * **Temperature Monitoring**
	+ The Platelet Incubator temperature is calibrated using a thermometer certified by the National Institute of Standards and Technology (NIST).
 |  |
| **2** | * **Take daily temperatures** of the followingand recordon the Helmer Platelet Incubator Daily QC and Maintenance Form
* Chart Recorder
* Digital Center Temperature Monitor
* Temperature Controller located behind the swing-out door in the upper right corner of the Platelet Incubator
* NIST verified thermometer taped to the inside of the glass door.
 | * Platelet Incubator Daily QC & Maintenance Form
 |
| **3** | * Temperatures must be between 20-24°C and agree within 2°C.
* For discrepancies >2°C, recheck temps in approximately 10 minutes and record new readings.
* If temperatures have not corrected, initiate appropriate calibration procedure(s).
 |  |
| **4** | * + **Calibrate the Chart Recorder** if the Chart Recorder temperature reading varies from the chamber temperature by > 2°C:
* Allow the chamber to stabilize at the set temperature.
* Adjust the Chart Recorder by pressing and holding the **Left** or **Right** **Arrow** button for 5 seconds. The arrows match the direction of adjustment for the stylus on the graph. Hold the appropriate button until the stylus moves to the correct temperature.
* The new temperature setting takes effect when neither arrow key is pressed seconds.
 |  |
| **Procedure B: Quality Control and Maintenance – Weekly QC** |
| **1** | **Change the chart recorder graph weekly.*** Press and hold the Chart Change button.
* When the stylus begins to move to the left, release the button.
* When the stylus has moved to the edge of the chart, remove the chart knob by unscrewing it in a counterclockwise direction.
 |  |
| **Step** | **Action** | **Related Documents** |
| **Procedure B: Quality Control and Maintenance – Weekly QC cont.** |
| **2** | * Remove the chart from the previous week and insert a new chart.
* Position the new chart so that the correct time line coincides with the time line groove.
 |  |
| **3** | * Reattach the chart knob and turn clockwise until it fits securely against the chart. Do not over tighten.
* Press and hold the Chart Change button until the stylus moves to the right, and release
 |  |
| **4** | * Confirm that the stylus is marking on the chart paper, if not refer to the Helmer Platelet Incubator Operation Manual, Troubleshooting.
 |  |
| **5** | * Chart recorder graph charts must be stamped with the following information:
* Start Date
* Stop Date
* Instrument number
* Tech ID.
 |  |
| **6** | * Check the “Chart Changed” box for that day on the Platelet Incubator Daily QC and Maintenance form.
 |  |
| **7** | * Any temperature recording out of normal range must be explained in writing on the chart beside the tracing, as well as documented in the “Comments” section of the Daily QC form, including date, time, and Tech ID .
 |  |
| **8** | * **Clean with a mild detergent and soft cloth** weekly or as needed
 |  |
| **Procedure C: Quality Control and Maintenance – Quarterly QC** |
| **1** | * **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 *Platelet Incubator Maintenance Log (PIML)*.
 | * Platelet Incubator Daily QC and Maintenance Form
 |
| **2** | * **Calibrate the digital i.Center Temperature Monitor** quarterly, following programming changes and as needed to verify that 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.
 |  |
| **Step** | **Action** | **Related Documents** |
| **Procedure C: Quality Control and Maintenance – Quarterly QC cont.** |
| **2 cont** | * 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 Platelet Incubator Maintenance Form.
* Calibration is required if there is a difference of 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.
* To calibrate the i.Center temperature monitor:
	+ From the HOME page, press MAIN.
	+ Press DOWN to highlight Edit Configuration.
	+ Press SELECT.
	+ Enter the 4-digit password 1234. The CONFIGURATION page appears.
	+ Press DOWN to highlight Temperature Calibration.
	+ Press SELECT.
	+ Press INC to select the Upper probe for calibration.
	+ Press DOWN until Temperature is highlighted.
	+ Press INC or DEC to change the temperature to match the readout of the NIST Thermometer.
	+ Press DOWN until STORE CALIBRATION is highlighted.
	+ Press ENTER to save all changes.
	+ Press HOME to return to the HOME page.
	+ Document calibration on the PIML.
 |  |
| **3** | * + **Calibrate the Temperature Controller** quarterly and as needed to ensure precise storage temperature.
	+ Verify the Temperature Controller Reading by following the steps outlined in **Procedure B.2.** for the i.Center Temperature Monitor.
* In this case, compare the NIST Thermometer reading to the Temperature Controller reading.
	+ Record results on the PIML.Calibration is required if there is a difference of greater than 0.5°C between the Temperature Controller and the NIST Thermometer reading. All readings must be between 20.5°C – 23.5°C.
* Calibrate the Temperature Controller, if needed:
	+ 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.
	+ At the tune prompt press the ▼ button twice. The display alternates between LEUL and 1.
	+ 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.
 |  |
| **Step** | **Action** | **Related Documents** |
| **Procedure C: Quality Control and Maintenance – Quarterly QC cont.** |
| **3 cont.** | * + From the Level 3 program menu press the ▲ button repeatedly until the display alternates between 2Ero and the offset value set during factory calibration.
	+ 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.* + To make the adjustment, hold the \* button when 2Ero is displayed and use the ▼ or ▲ buttons to lower or raise the difference.
	+ Release the \* button and press and hold the ▼ and ▲ buttons simultaneously until the operating temperature appears on the display.
	+ Allow the chamber temperature to stabilize for 30 minutes and re-verify the Temperature Controller reading (**Procedure B.3.A**.).
	+ Perform additional adjustments if necessary.
		- Document calibration on the Platelet Incubator Maintenance Form.
 |  |
| **4** | **Chart Recorder Battery Backup test.** * The 9V alkaline battery allows the Chart Recorder to continue functioning normally for approximately 2 hours.
* The light on the face of the Chart Recorder is a constant green color when the battery power is acceptable.
* The light flashes green when the battery needs to be replaced:
* Disconnect the battery in the Chart Recorder.
* Verify that the green LED on the Chart Recorder is flashing.
* Reconnect the battery.
* Verify that the green LED is no longer flashing, but consistently lit.
* If the green LED is still flashing, replace the battery.
* Document on the Platelet Incubator Maintenance Form.
 |  |
| **5** | * **Automatic high and low temperature alarm tests** are performed following installation, quarterly or more often, if needed (e.g. following repair).
* 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.
	+ **Start 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. View the test results on the Event Log.
 |  |
| **Step** | **Action** | **Related Documents** |
| **Procedure C: Quality Control and Maintenance – Quarterly QC cont.** |
| **5 cont** | * + **Start 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. View the test results on the event log.
* Document on the Platelet Incubator Maintenance Form.
 |  |
| **6** | * **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 PIML.
* Turn the agitator back on.
* Measure the number of agitations per minute by holding a ruler against the edge of the agitator, and counting how many times it hits the ruler in one minute, using a timing device.
	+ Record on the Platelet Incubator QC form
 |  |
| **7** | **Platelet incubator power failure alarm check.*** With the platelet incubator turned ON, disconnect it from power. Wait for the alarm to sound. There is no programmed time delay for this alarm.
* Reconnect the instrument to the power source.
* Record results on the PIML.

**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. |  |
| **8** | **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.
* Record results on the PIML.
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| **Procedure D: Quality Control and Maintenance – Annual Maintenance** |
| **1** | **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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| **Procedure E: Operation** |
| **1** | **Opening and closing a drawer**: * Lightly lift up on the drawer handle when sliding it in or out. The drawers slide easiest when pressure is applied evenly to the drawer handle.
* If a drawer is difficult to open, gently move the drawer back to the beginning position and start again.
 |  |
|  | **Action** | **Related Documents** |
| **Procedure E: Operation Cont.** |
| **2** | **Loading Platelets**: * Lay the platelet bags flat on the drawer shelves.
* Make sure that the tubing is placed neatly under or around the bag.
* **CAUTION:** Do not stack platelet bags on top of each other on the same shelf. If necessary, some drawers may be removed to provide extra space for thicker bags.
 |  |
| **3** | **Drawer Removal**: * Slide the drawer out until it stops.
* Press the two spring-loaded stops located in the plastic drawer guides on each side of the drawer.
* Pull the drawer out.
 |  |

**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