Non-Technical SOP

Title	**Blood Bank Refrigerators (Helmer iSeries with i.C^3)**	
Prepared by	Stephanie Codina	Date: 10.8.2012
Owner	Stephanie Codina	Date: 10.8.2012

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

12 month (or new) management review and approval: Signature acknowledges SOP version remains in effect with NO revisions.		
Print Name	**Signature**	**Date**

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1. PURPOSE

Red blood cells, whole blood, and thawed plasma products are stored at temperatures between 1-6°C. Reagents are stored at temperatures within the temperature range specified by the manufacturer. Blood product refrigerators must be equipped with a system for continuous temperature monitoring and an audible alarm. The alarm must activate at a temperature that will allow proper action to be taken before blood products reach unacceptable conditions. The temperature and alarms are frequently checked to ensure an appropriate temperature is maintained.

2. SCOPE

This procedure applies to all Helmer iSeries refrigerators with i.C^3 in the blood bank.

3. RESPONSIBILITY

All blood bank staff members must understand appropriate refrigerator temperatures, refrigerator maintenance, and the steps that must be taken when a refrigerator is out of the appropriate temperature range.

4. DEFINITIONS

i.C^3 – An intuitive user interface and icon-driven touchscreen.

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5. PROCEDURE

General Guidelines

Blood bank refrigerators:

1. Shall only contain blood products, reagents, and patient specimens. If the refrigerator contains reagents, the temperature and alarms will be adjusted to meet the manufacturer's storage recommendations (refrigerator range will be 2-6°C and the alarms will sound at 2.5°C and 5.5°C).
2. Shall be equipped with a fan for circulating air to ensure proper temperature is maintained throughout the refrigerator.
3. Shall be equipped with a visual and audible alarm system, and have continuous temperature monitoring device via a chart recorder. Alarm is set to activate at a temperature that will allow proper action to be taken before components reach unacceptable temperature. The audible alarm sounds within the blood bank where there is 24 hour coverage.
4. Shall be connected to an emergency power source, alarm system has a battery backup.
5. Shall have a calibrated thermometer placed on upper and lower shelves near the door.
6. Shall have clearly designated areas for:
   a. Unprocessed blood products
   b. Uncrossmatched blood products separated by blood group and Rh type
   c. Crossmatched blood products separated by the last name of the patient to whom they are crossmatched
   d. Rejected, outdated, and quarantined blood products
   e. Directed donor and autologous blood products

Daily Quality Control

Step	Action
1	Review the recording chart. A. Verify that the recording chart is positioned at the correct date and time. If not, re-adjust to the correct date and time and document the correction on **both** the front of the recording chart and the "Blood Bank Refrigerator Temperature Form." B. Ensure the temperature has been within the acceptable temperature range for the previous 24 hours.
2	Read and record the following temperatures on the "Blood Bank Refrigerator Temperature Form." The acceptable temperature range is 2-6°C. A. Chart recorder read to the nearest whole number (for example, 2 or 3) B. Thermometer read to the nearest 0.5 degree (for example, 2.5 or 3.0) C. Digital display read to the nearest 0.1 degree (for example, 2.6 or 2.7)
3	Visually inspect the appearance of blood products in inventory. A. Examine blood products for hemolysis, clots, change in color or unusual color, comparison of segments with bag. B. Quarantine any unacceptable blood products in inventory. C. Record findings on the QC form.

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Step	Action
4	Interpret the refrigerator's operation. A. S = satisfactory B. U = unsatisfactory. If unsatisfactory, a. Document corrective action on the reverse side of the "Blood Bank Refrigerator Temperature Form." b. Notify a supervisor if unable to resolve. c. If the temperature is out of range, move the contents of the refrigerator. Refer to section, "Blood Bank Refrigerator in Alarm."

Weekly Quality Control

Step	Action
1	Weekly QC is performed each Monday.
2	Obtain a new temperature chart. Be sure the new temperature chart is appropriate for the refrigerator and will record temperatures correctly. A. Stamp the back of the chart with the hospital address stamp. B. Stamp the back of the chart with the "date on" stamp. C. Record the refrigerator identification on the back of the chart to identify the storage container. D. Record the current date in the "date on" line. E. Initial the back of the chart next to the date.
3	On the chart recorder, press the "C" (chart change) button until the stylus begins to move to the left, then release the button. The LED will flash to indicate the current temperature range value.
4	When the stylus stops moving, remove the chart knob by turning it counter-clockwise, then swing it toward the top of the chart recorder.
5	Gently lift the stylus and remove the current temperature chart.
6	Press the new chart onto the chart recorder. Gently lift the stylus and turn the paper so the pen is on the correct day and time line groove.
7	Hold the chart paper to prevent it from turning while re-installing the chart knob. Turn the knob clockwise until snug.
8	Press and hold the "C" (chart change) button until the stylus starts to move to the right, then release the button.

Step	Action
9	Confirm the stylus is marking the correct temperature on the correct day/time. If not, repeat steps 3-9. Do not try to move or adjust the chart while it is on the recorder.
10	Record the following information on the removed chart and forward the chart to a supervisor or designee for review. A. Date removed B. Tech's initials

Quarterly Quality Control

Step	Action
1	Calibrate the temperature probes to ensure accuracy. Note: The chart and upper temperature probes are located at the top of the refrigerator. The lower temperature probe is located at the bottom, left-hand side of the refrigerator. A. Place a calibrated thermometer inside the refrigerator probe bottle along with the temperature probe(s). B. Allow the temperature to stabilize. . C. Read the temperature of the calibrated thermometer to the nearest 0.5°C and record on the QC form. D. Compare the reading of the thermometer to that of the digital reading on the refrigerator display. Record the reading of the digital display on the QC form. E. If the temperatures are ≥1°C different, determine how much to increase or decrease the offset value to make the monitor reading match the calibrated thermometer. For example, if the thermometer reads 3.0 and the digital display reads, 4.5, the offset will decrease by 1.5 so both temperatures match. F. Enter and save the temperature reading in the refrigerator configuration. a. Touch the i.C3 APPs button b. Touch the settings button i.C³ Settings c. Touch "Temperature Calibration" d. Touch the "+" plus or "-" minus buttons to increase or decrease the value to match the measured value. G. Remove the calibrated thermometer from the refrigerator. H. Document the temperature probe calibration on the maintenance form. I. Notify a supervisor or designee immediately if a problem exists.

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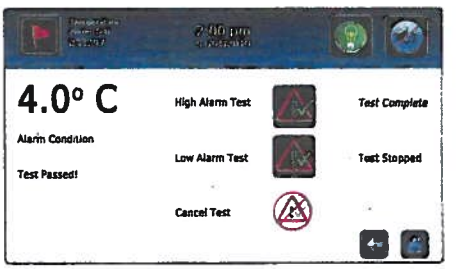
Step	Action
2	Calibrate the temperature chart. A. Place a calibrated thermometer inside the refrigerator probe bottle along with the temperature probe. B. Allow the temperature to stabilize. . C. Read the temperature of the calibrated thermometer to the nearest 0.5°C and record on the QC form. D. Compare the reading of the thermometer to that of the temperature chart. The chart and calibrated thermometer should agree within 1°C. E. Adjust the chart temperature as needed. a. Touch the left arrow "◀" to increase the temperature recorded on the chart. b. Touch the right arrow "▶" to decrease the temperature recorded on the chart.
3	Test the alarm quarterly. Helmer refrigerators electronically heat and cool the probe making manual alarm checks unnecessary. Calibrate the temperature probe prior to performing the alarm checks.  A. Low Alarm Test a. Identify the current setting for the low alarm setpoint. b. Touch the Click on the i.C3 APPs button  c. Touch "Temperature Alarm Test." d. The alarm screen shown above will display. e. Touch the "Low Alarm Test" button to start the low alarm test. The button will begin to flash and the message, "Peltier Test Probe Cooling" message will appear. f. Watch the temperature at which the probe triggers the alarm to sound. This should be ≥2.5°C. g. Document the alarm check on the "Refrigerator Temperature Form." h. Notify a supervisor or designee immediately if a problem exists

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Step	Action
3 Cont	B. High Alarm Test a. Identify the current setting for the high alarm setpoint. b. Touch the Click on the i.C3 APPs button  c. Touch "Temperature Alarm Test." d. The alarm screen shown above will display. e. Touch the "High Alarm Test" button to start the low alarm test. The button will begin to flash and the message, "Peltier Test Probe Warming" message will appear. f. Watch the temperature at which the probe triggers the alarm to sound. This should be $\leq 5.5^{o}C$. g. Document the alarm check on the "Refrigerator Temperature Form." h. Notify a supervisor or designee immediately if a problem exists
4	Test the Power Failure Alarm to ensure it activates in an appropriate amount of time. A. The power failure alarm is normally set at 3 minutes. B. Change the power failure alarm setting to zero minutes. a. Touch the i.C3 APPs button  b. Touch the settings button  c. Touch "Alarm Settings." Note, you will have to scroll down to see this option. Scroll by rubbing your finger up and down the side of the screen. d. Touch the "-" minus button to decrease the value to zero. C. Turn off the power to the refrigerator. During a power failure, the backup batteries continue to provide power to the monitoring system. D. The power failure alarm should activate immediately. a. An audible alarm will sound. b. The "Power Failure" message will appear on the screen. E. Turn the power back on. The power failure alarm should clear F. Change the power failure alarm setting to 3 minutes. a. Touch the i.C3 APPs button  b. Touch the settings button  c. Touch "Alarm Settings." Note, you will have to scroll down to see this option. Scroll by rubbing your finger up and down the side of the screen. d. Touch the "+" plus button to increase the value to three. G. Document the alarm failure check on the maintenance form. H. Notify a supervisor or designee immediately if a problem exists.

Step	Action
5	Test the door open alarm. A. The door open alarm is normally set at 3 minutes. B. Change the door open alarm setting to zero minutes. a. Touch the i.C3 APPs button  b. Touch the settings button  c. Touch "Alarm Settings." Note, you will have to scroll down to see this option. Scroll by rubbing your finger up and down the side of the screen. d. Touch the "-" minus button to decrease the value to zero. C. Open the refrigerator door. D. The door open alarm should activate immediately. a. An audible alarm will sound. b. The "Door Open" message will appear on the screen. E. Close the door. The power failure alarm should clear F. Change the door open alarm setting to 3 minutes. a. Touch the i.C3 APPs button  b. Touch the settings button  c. Touch "Alarm Settings." Note, you will have to scroll down to see this option. Scroll by rubbing your finger up and down the side of the screen. d. Touch the "+" plus button to increase the value to three. G. Document the Door Open Alarm check on the maintenance form. H. Notify a supervisor or designee immediately if a problem exists.
6	Check for the "No Battery" alarm message. A. On the "Home" screen, check if either the "Low Battery" or "No Battery" alarm is flashing. Change the batteries if either message is present. a. Avoid reusing batteries that may have some charge remaining. Install all fresh batteries. b. For iC[3] models, the biomedical engineering department will have to replace the battery. B. Test the battery backup. a. Disconnect the refrigerator from AC power. The display should continue to display information. Replace the batteries if the display is blank then repeat this test. b. Reconnect the refrigerator to AC power. C. Document the "No Battery" alarm check on the maintenance form. D. Notify a supervisor or designee immediately if a problem exists.

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Step	Action
7	Check batteries for the monitoring system. (This is the 9V battery located next to the temperature chart). A. Determine if the battery needs to be changed. a. Inspect the battery. A red light will flash if the battery is low on charge. b. Replace the battery if the light is flashing. B. Test the alarm. a. Disconnect the battery from the connection. The red light will flash to show low battery charge. b. Reconnect the battery to the connection. The red light will stop flashing. c. Notify a supervisor if the alarm is not functioning as expected. C. Document the battery check on the refrigerator temperature form.
8	Clean the condenser grill and external drain fan. A. Protect the items in the freezer from exposure to adverse temperatures. B. Unplug the refrigerator to eliminate the potential for electric shock. C. Clean the condenser grill and the drain fan using a soft brush and vacuum cleaner. a. The condenser grill is the finned surface on the rear of the refrigerator. b. The external drain fan is located on the rear of the freezer, directly above the water evaporation tray. D. Document the cleaning on the maintenance form. E. Notify a supervisor or designee immediately if a problem exists.
9	Examine the probe bottles. Clean and refill if necessary. The probe bottles are filled with 10% glycerol.
10	Wipe the interior, exterior, and gasket with a damp cloth and mild soap to clean.

As Needed Maintenance

Step	Action
1	Notify the Biomedical Engineering department to replace burned out light bulbs in the refrigerator.

Refrigerator in Alarm

Step	Action
1	If the refrigerator alarm activates, push the alarm silence button to temporarily stop the audible alarm.

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Step	Action
2	Determine whether there is an obvious cause for alarm activation and correct. If corrected, make a note on the temperature chart indicating alarm activation and reason. A. Refrigerator door ajar B. Outlet power failure / unit unplugged C. Refrigerator failure D. The probe solution is empty or low
3	If the cause of alarm is not identified or if the problem is not immediately correctable, A. Monitor the internal thermometer temperature of the refrigerator every **15 minutes** until the alarm stops **or** until all blood products have been removed. Document the temperature on the "Manual Product Storage Temperature" form. B. If the temperature reaches a low of 1.5°C or high of 5.5°C, all blood products must be relocated to another storage container that will maintain temperatures between 2-6°C. Reagents must be moved when the low temperature reaches 2.5°C. Blood products can be moved to: a. Another blood product refrigerator. Be sure to temporarily label the shelves so incorrect blood products are not inadvertently issued. b. ARC shipping boxes containing wet ice. Refer to procedure, "Shipping Boxes Packing and Quality Control." Be sure to label the boxes with the contents. c. A refrigerator in core lab, if available. However, blood products should not be stored with patient specimens or reagents. d. Transfer to a sister hospital (WAH, SGAH, GEC) e. Contact the blood supplier to attempt to ship products to another hospital. C. Document movement of the blood products on the temperature chart. Include the exact time and tech's initials. D. Place a calibrated thermometer in the temporary storage container with the blood products. E. Monitor the temperature at least every 4 hours. Document the temperature of the temporary storage container on the "Manual Product Storage Temperature" form.
4	A. Notify a supervisor or designee as soon as possible but definitely within 1 business day. B. Notify Quest biomedical engineering if the problem persists or if repairs are needed. C. Notify plant operations if there is a problem with the power supply.

Step	Action
5	When the problem is resolved **and** the refrigerator temperature returns to the acceptable range, A. Re-activate the alarm B. Return the blood products to the refrigerator C. Document replacement of blood products on the temperature chart with exact time and initials D. Continue to monitor and document manual temperatures every 4 hours for a minimum of 12 hours.

6. RELATED DOCUMENTS

Blood Bank Refrigerator Temperature Form
Manual Downtime Temperature Form
Blood Bank Equipment and Maintenance
Blood Bank Equipment Record and Repair Instructions
Procedure: Thermometer Calibration and Installation

7. REFERENCES

1. Roback, J.D., Combs, M.R., Grossman, B.J., Hillyer, C.D. 2008. Technical Manual of the AABB, 16th ed. AABB Publishing, Bethesda, Maryland.
2. Standards for Blood Banks and Transfusion Services, 2012. AABB, 28th ed. AABB Publishing, Bethesda, Maryland.
3. Barry of Helmer Inc., Freezer Operation Manual, Helmer Freezer, 360086-1 Rev H; issued April 2009.
4. Barry of Helmer Inc., Temperature Chart Recorder Operation and Service Manual,360076-1 Rev H; issued April 2009
5. Barry of Helmer Inc., Freezer Service Manual 360087-1 Rev K; issued April 2009
6. Helmer i.C3 User Guide, 360129-1/C.
7. Helmer Refrigerator Operation Manual, i.Series and Horizon Series, 360127-1/A.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

9. ADDENDA AND APPENDICES

N/A