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Work Instruction

Title:	**TC Alarm Check of Refrigerator Freezer and Platelet Incubator**	**WI Number** SFOWI-0033 **Revision:** 13
Department: Immunohematology **Area:** 2425 Geary Blvd SFO Hospital Lab	***Document is in the Final Approval Process. 2 - approvals are required***	
Type of Document: Work Instruction		**Review Period -** 340 **Days**

PURPOSE

It is critical that blood products and reagents are stored within the correct temperature range. Blood/blood component refrigerators, freezers and platelet incubator are equipped with local audible alarms. This ensures that blood bank personnel are alerted should any of the equipment malfunctions. The alarms are set to activate at a temperature still within range allowing adequate time for blood bank staff to take corrective action before situation turns critical. The temperature alarms activate when the chamber temperature reaches the low or high alarm setpoints. The Power Failure alarm activates when AC power is lost. The Door Open alarm activates when the door is left open for an extended period of time.

The alarm systems for storage equipment are checked at scheduled frequency to ensure they are working correctly. Alarm tests should also be performed after major repairs or calibration.

The temperature alarms for i Series Helmer refrigerators, freezers and platelet incubator can be tested using the built-in Peltier device which physically heats or cools the upper temperature probe making it unnecessary to immerse the probe in chilled or warm water. This automatic method does not affect the chamber temperature.

REAGENTS

A. 1 cup of tap water
B. Crushed ice

EQUIPMENT:

A. NIST certified thermometer
B. CheckPoint Wireless Temperature Monitoring System
C. Container of enough depth to accommodate the temperature probes
D. Squeeze bottle of warm water
E. Applicator sticks

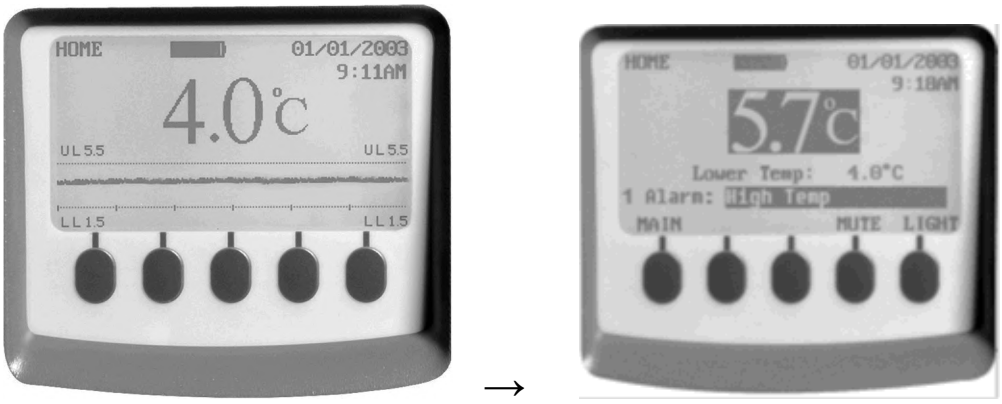
QUALITY CONTROL

A. Local alarms for refrigerators, freezers and the platelet incubator are checked **quarterly**.
B. Alarm Checks for OR refrigerators are performed quarterly by licensed contractors.
C. CheckPoint temperature probes are replaced annually with new calibrated probes.
D. Backup batteries for the i.Center monitoring system are replaced annually.
E. Blood Bank supervisor reviews the results for acceptability.
F. Alarms are set to go off before the refrigerators reach 1 or 6 °C for blood, 2 or 6 °C for reagents, before platelet incubator and RT reaches 20 or 24 °C, and before freezer becomes warmer than -18°C.

PROCEDURE:

Storage Temperature Range and Alarm Settings

Equipment	Temperature	Low Alarm	High Alarm
Refrigerator for blood	1°C to 6°C	1.5°C	5.5°C
Refrigerator for reagents	2°C to 6°C	2.5°C	5.5°C
Freezer	-18°C or less	NA	-20.0°C
Platelet Incubator	20°C to 24°C	20.5°C	23.5°C
Room Temperature	20°C to 24°C	20.5°C	23.5°C



i.Center HOME screen - Press the left most button to get to screen with MAIN option

EVENT LOG - An entire event line that is highlighted indicates that the alarm was caused by a system self-test initiated by an operator.

NOTE: 1. Refer to Equipment Manual for troubleshooting instructions. Refer to the respective equipment SOP for instructions on performing manual high and low alarm tests (for troubleshooting purposes).
2. Perform the Power Failure Alarm last; arrange for Facility Engineer to unplug each equipment from power.
3. Use BF0021 Quarterly Alarm Checks to record results.

A. Refrigerator Alarm Check

a. **Verify i.Center Temperature Monitor Reading**

i. Place a NIST certified thermometer inside the probe bottle and let it equilibrate for 30 minutes. To confirm that all thermometers and probes are reading correctly, record the temperatures from the NIST certified thermometer, refrigerator HOME display, temperature chart and CheckPoint. The acceptable difference in temperatures should be ± 1 °C

from the NIST thermometer. Proceed to calibrate the freezer probe and chart if necessary. Refer to ***Helmer Refrigerator SOP*** for instructions. If CheckPoint temperature is **more** than 1 °C from the NIST thermometer, write a Variance Log and notify supervisor.

b. **Automatic Low Temperature Alarm**

i. Identify the current setting for the low alarm setpoint. From the MAIN screen, navigate to and select View Configuration option. The setpoint should be +0.5 °C from the low temperature range, e.g. 1.5 °C for temperature range 1 – 6 °C. Go BACK when finished.

ii. From the MAIN screen, navigate to and select System Alarm Test & Status.

iii. Select 'Start Low Alarm Auto Test'. Press ENTER and return to HOME screen.

iv. A message, 'Low Alarm Test in Progress', should appear on screen. The message will clear when the test is completed.

v. View the Event Log to determine the temperature at the time the low temperature alarm event started (S). This value should match the low alarm setpoint.

c. **Automatic High Temperature Alarm**

i. Identify the current setting for the high alarm setpoint. From the MAIN screen, navigate to and select View Configuration option. The setpoint should be -0.5 °C from the high temperature range, e.g. 5.5 °C for temperature range 1 – 6 °C. Go BACK when finished.

ii. From the MAIN screen, navigate to and select System Alarm Test & Status.

iii. Select 'Start High Alarm Auto Test'. Press ENTER and return to HOME screen.

iv. A message, 'High Alarm Test in Progress', should appear on screen. The message will clear when the test is completed.

v. View the Event Log to determine the temperature at the time the high temperature alarm event started (S). This value should match the high alarm setpoint.

d. **Cancelling an Automatic Test in Progress**

i. From the MAIN screen, navigate to and select System Alarm Test & Status.

ii. Select 'Cancel High or Low Test'.

iii. Press ENTER and the test is cancelled.

e. **Power Failure Alarm**

The Power Failure alarm setpoint is 1 minute after the loss of AC power. During a power failure, the backup battery continues to provide power to the monitoring system.

i. Confirm the refrigerator is connected to AC power.

ii. Ensure the monitoring system backup battery is switched ON.

iii. Switch the AC ON/OFF switch OFF and start count-up timer simultaneously. Power failure alarm will activate within 1 minute. Note the elapsed time.

iv. Switch the AC ON/OFF switch ON. Power failure alarm will clear and audible alarm will cease.

f. Door Open Alarm

The Door Open alarm setpoint is 3 minutes of the door being continuously open.

i. Open the refrigerator door and note the time or start a count-up timer.
ii. When the Door Open alarm activates, the audible alarm sounds and the 'Door Open' message appears on the HOME screen.
iii. Stop the timer and note the time. It should be 3 minutes.
iv. Close the refrigerator door. The Door Open alarm should clear.

B. Freezer Alarm Check

a. **Verify i.Center Temperature Monitor Reading**

i. Place a NIST certified thermometer inside the probe bottle and let it equilibrate for 30 minutes. To confirm that all thermometers and probes are reading correctly, record the temperatures from the NIST certified thermometer, freezer HOME display, temperature chart and CheckPoint. The acceptable difference in temperatures should be ± 1 °C from the NIST thermometer. Proceed to calibrate the freezer probe and chart if necessary. Refer to ***Helmer Freezer SOP*** for instructions. If CheckPoint temperature is more than 1 °C from the NIST thermometer, write a Variance Log and notify supervisor.

b. **Automatic High Alarm Test**

i. Identify the current setting for the high alarm setpoint. From the MAIN screen, navigate to and select View Configuration option. The setpoint should be -20 °C. Go BACK when finished.
ii. From the MAIN screen, navigate to and select System Alarm Test & Status.
iii. Select 'Start High Alarm Auto Test'. Press ENTER and return to HOME screen.
iv. A message, 'High Alarm Test in Progress', should appear on screen. The message will clear when the test is completed.
v. View the Event Log to determine the temperature at the time the high temperature alarm event started (S). This value should match the high alarm setpoint.

c. **Cancelling an Automatic Test in Progress**

i. From the MAIN screen, navigate to and select System Alarm Test & Status.
ii. Select 'Cancel High Test'.
iii. Press ENTER and the test is cancelled.

d. **Power Failure Alarm**

The Power Failure alarm setpoint is 1 minute after the loss of AC power. During a power failure, the backup battery continues to provide power to the monitoring system.

i. Confirm the freezer is connected to AC power.
ii. Ensure the monitoring system backup battery is switched ON.
iii. Switch the AC ON/OFF switch OFF and start count-up timer simultaneously. Power failure alarm will activate within 1 minute. Note the elapsed time.
iv. Switch the AC ON/OFF switch ON. Power failure alarm will clear and audible alarm will cease.

e. **The Door Open Alarm**

The Door Open Alarm setpoint is 3 minutes of the door being continuously open.

i. Open the refrigerator door and note the time or start a count-up timer.
ii. When the Door Open alarm activates, the audible alarm sounds and the 'Door Open' message appears on the HOME screen.

iii. Stop the timer and note the time. It should be 3 minutes.
iv. Close the refrigerator door. The Door Open alarm should clear.

C. Platelet Incubator Alarm Check

NOTE: Remove platelets from the incubator before commencing MANUAL alarm tests.

a. **Verify i.Center Temperature Monitor Reading**

i. Place a NIST certified thermometer inside the platelet incubator and let it equilibrate for 30 minutes. To confirm that all thermometers and probes are reading correctly, record the temperatures from the NIST certified thermometer, platelet incubator HOME display, temperature chart and CheckPoint. The acceptable difference in temperatures should be ± 1 °C from the NIST thermometer. Proceed to calibrate the freezer probe and chart if necessary. Refer to ***Platelet Incubator and Agitator SOP*** for instructions. If CheckPoint temperature is **more** than 1 °C from the NIST thermometer, write a Variance Log and notify supervisor.

b. **Automatic Low Temperature Alarm**

i. Identify the current setting for the low alarm setpoint. From the MAIN screen, navigate to and select View Configuration option. The setpoint should be 20.5 °C. Go BACK when finished.
ii. From the MAIN screen, navigate to and select System Alarm Test & Status.
iii. Select 'Start Low Alarm Auto Test'. Press ENTER and return to HOME screen.
iv. A message, 'Low Alarm Test in Progress', should appear on screen. The message will clear when the test is completed.
v. View the Event Log to determine the temperature at the time the low temperature alarm event started (S). This value should match the low alarm setpoint.

c. **Automatic High Temperature Alarm**

i. Identify the current setting for the high alarm setpoint. From the MAIN screen, navigate to and select View Configuration option. The setpoint should be 23.5 °C. Go BACK when finished.
ii. From the MAIN screen, navigate to and select System Alarm Test & Status.
iii. Select 'Start High Alarm Auto Test'. Press ENTER and return to HOME screen.
iv. A message, 'High Alarm Test in Progress', should appear on screen. The message will clear when the test is completed.
v. View the Event Log to determine the temperature at the time the high temperature alarm event started (S). This value should match the high alarm setpoint.

d. **Power Failure Alarm (performed by BioMed)**

The Power Failure alarm setpoint is 1 minute after the loss of AC power. During a power failure, the backup battery continues to provide power to the monitoring system.

i. Confirm the platelet incubator is connected to AC power.
i. Ensure the monitoring system backup battery is switched ON.
ii. Switch the AC ON/OFF switch OFF and start count-up timer simultaneously. Power failure alarm will activate within 1 minute. Note the elapsed time.

iii. Switch the AC ON/OFF switch ON. Power failure alarm will clear and audible alarm will cease.

e. **Door Open Alarm**

The Door Open Alarm setpoint is 2 minutes of the door being continuously open.

i. Open the door to disengage the door switch and note the time or start a count-up timer.
ii. When the Door Open alarm activates, the audible alarm sounds and the 'Door Open' message appears on the HOME screen.
iii. Stop the timer and note the time. It should be 2 minutes.
iv. Close the door. The Door Open alarm should clear.

D. Room Temperature - ice and water alarm check

a. Fill an 8 ounce (0.2 liter) container half full of room temperature water.
b. Insert a NIST certified thermometer into the container of water.
c. Insert the Check Point air probe into the water.
d. While constantly stirring with the thermometer and probe, slowly add crushed ice at a rate sufficient to provide a temperature drop of 0.5 °C per minute. The addition of crushed ice at a rate of approximately 1 teaspoon (5 ml) every 15 to 25 seconds should provide the desired temperature drop.
e. Record the time when the temperature of the NIST certified thermometer reaches the low alarm setpoint of 20.5 °C.
f. Record the time and temperature from the CheckPoint Numeric Table when the Red Alert Screen appears and red light starts flashing.
g. Remove the CheckPoint probe from the chilled water.
h. Slowly add warm water at a rate sufficient to provide a temperature increase of 0.5 °C per minute.
i. Stir with applicator sticks, keeping the NIST certified thermometer submerged in the liquid at the bottom of the container and not in the ice until it reaches 24 °C.
j. Insert the CheckPoint air probe into the bottom of the container.
k. Record the time when the temperature of the NIST certified thermometer reaches the high alarm setpoint 23.5 °C. Maintain temperature of water at 23.5 °C until the CheckPoint alert appears.
l. Record the time and temperature from the CheckPoint Numeric Table when the Red Alert Screen appears and red light starts flashing.
m. The acceptable difference in temperatures between the thermometers should be ± 1 °C.

PROCEDURE NOTES

None

REFERENCE

A. AABB, Standards for Blood Banks and Transfusion Services, current edition, Bethesda, MD.
B. AABB, Technical Manual, current edition, Bethesda, MD.
C. Helmer i.Series Refrigerators, Freezers and Platelet Incubators Operation and Service Manuals.

Associated Documents:

External Documents

Associated Documents:

SFOWI-0035 -- TC Helmer Freezer
SFOWI-0073 -- TC-Helmer Refrigerator
SFOWI-0036 -- TC Platelet Incubator and Agitator
SFOWI-0032 -- TC Quality Control-Weekly Monthly Quarterly Annually
SFOFCD-0224 -- BF0021 Quarterly Alarm Checks
SFOFCD-0225 -- BF0011 Calibration of Thermometers QC Form

Click to Open an Associated Document

Documents Generated:

Document Revision History:

Revision: 13	**Date Created:** 09/12/2005 **Date of Last Revision:** 01/31/2019	**Last Approval Date:** 07/02/2018

Document Author: Cara H Lim/CA/KAIPERM	**Document Manager:** Richard Chui/CA/KAIPERM

Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	
2	Freezer high alarm check	Helmer i series Hi alarm test can be done using the digital control panel.	12/3/06
2	Approver	New Lab Director	12/3/06
3	Procedure 3	Add platelet incubator alarm check and freezer automatic alarm check	1/7/07
3	Approver	New Lab Director	1/7/07
4	Approver	New Lab Director	7/29/07
5	Procedure	Change to alarm check of wireless temperature monitor system.	7/13/08
6	Procedure	Change back to equipment alarm check.	3/14/10
7	Procedure	Change Lab Director.	1/6/11
8	Approver	New Lab Director	1/17/13
9	Approver	New BB Medical Director.	12/19/13
10	Whole document	Revised and reformatted. Procedure for high and low temperature alarm checks for Helmer i.series freezers, refrigerators and platelet incubator changed from manual to automatic methods. Added automatic alarm checks for power failure and door open.	3/1/14
11	Procedure C.d. Platelet Incubator Alarm Check	Revised instructions for Power Failure Alarm Check and added that BioMed performs the task.	1/19/17
12	Purpose	Added reagents as per long standing practice, storage temperature of reagents is monitored the same as blood products.	6/28/18
13	Power Failure Alarm	Instructions revised from disconnecting power supply to switching off AC Power.	1/30/19

Notification List:

Approvals:

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Document History Section