KAISER PERMANENTE

Kaiser Permanente Medical Center, San Francisco
Northern California Region
********** **********

Work Instruction

Title:	**TC Platelet Incubator and Agitator**	**WI Number** SFOWI-0036 **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

The optimum storage temperature for platelet products is between 20°C to 24°C. The platelet incubator provides a stable and continuously monitored environment for storage of this product. In order to maintain the functionality of platelets by preventing the formation of aggregates, platelet products must be gently agitated during storage. The platelet incubator has recording thermometric probes, audible alarms and an emergency power source. Quality control checks are scheduled and performed. This procedure describes the steps for operation, quality control and preventive maintenance needed to ensure proper function.

EQUIPMENT

A. Helmer, Inc. i Series Platelet Incubator Model PC900i.
B. Helmer, Inc. i Series Platelet Agitator Model PF48i
C. NIST certified thermometer.

SUPPLIES

A. 6 non-rechargeable, 1.5V D Cell Alkaline for battery backup.
B. 1 9V battery for chart recorder backup.
C. Helmer Platelet Incubator Temperature Charts No. 220273.

QUALITY CONTROL

A. Daily temperature quality control
B. Temperature charts are replaced every Monday
C. Wireless Continuous Temperature Monitoring System
D. Quarterly maintenance and alarm checks
E. Quarterly clean and vacuum condenser and grill by BioMed
F. Quarterly electrical safety check by BioMed
G. Annual maintenance

PROCEDURE

NOTE: Refer to Equipment Manual for troubleshooting instructions.

A. Operation of the Platelet Incubator

1. Front Panel Features and Controls

a. Main Power Switch
b. Temperature Controller
c. Battery Backup Key Activation Switch
d. Chart Recorder
e. i.Center

2. Rear Panel

a. RS232 Communication Port
b. Flash Port
c. Alarm
d. Circuit Breaker
e. Power Entry Module
f. Central Alarm Terminals

3. Main Screen Features and Controls

a. Main temperature display
b. Date and time
c. Battery Charge Level
d. Function Keys
e. Alarms Status
f. Contrast Adjustment
g. 24-Hour Upper Probe Temperature Graph

h. **HOME Page**

Home page is the starting page for all interfaces with the i.Center. If no key is pressed for two minutes while viewing any other page (except the change password page), the screen automatically returns to the HOME page.

i. **Event Log**

From the HOME page, press MAIN.
Press SELECT to access a list of alarm events.
Press UP or DOWN to scroll through the events.
Press SELECT to display the details of the selected alarm.
Press BACK to return to the EVENT LOG or HOME to return to the HOME page.
Event log features:

- Temperature during event
- Time of event
- Date event occurred
- Alarm type:
  - DR = Door open
  - HI = High temperature
  - LO = Low temperature
  - CO = Compressor temperature
  - NB = No Battery
  - PO = Power Failure
- Alarm Status:
  - S = Start of alarm event
  - R = Alarm Reset (End of alarm event)
- Event Number

Number of door opening during a 48-hour period
Number of door openings today
Number of door openings from previous day

j. **Mute to silence the alarm**
Press the MUTE button (second button from the right) on HOME screen.
Press the MUTE button again to silence the alarm for 5 minutes.
Pressing the MUTE button again will add an additional 5 minutes up to a maximum of 60 minutes.
When the alarm event has ended, the remaining mute time will be automatically canceled and the mute time will return to its default value of 5 minutes.

4. **Continuous Temperature Monitoring**
The chamber temperature is monitored continuously by a wireless temperature monitoring system. Alert will be activated before the temperature is below 20 ^{o}C or above 24 ^{o}C.

B. Platelet Agitator

Store platelets at 20-24 ^{o}C on the platelet agitator.

1. Lay platelet bags flat on the drawer shelves.
2. Do not stack or overlap platelet bags to insure maximum air circulation, allowing CO_2 and O_2 to diffuse through the plastic bag.
3. Do not block the built-in fan (on the bottom of the unit) so that air can circulate to internally cool the agitator during storage, eliminating heat transfer to the platelet bags.
4. Turn on the agitator by flipping the switch located at the front of the unit.
5. Turn on the alarm by flipping the switch located at the bottom of the unit on the right side of the agitator.
   a. The audible alarm will sound in less than 2.5 minutes if the agitator does not move.
   b. The only time the alarm is turned off is when the platelet agitator is not being used. It should not be turned off when loading and unloading platelets.

C. DAILY Maintenance

Equipment	Temperature Range
Platelet Incubator	20^{o}C to 24^{o}C

1. Wireless Temperature Review

a. Every day, the previous 24 hours temperature recordings are reviewed to ensure that the temperature was continuously monitored and within range.

b. When the Wireless Temperature Monitoring System is not available, the temperature is manually recorded.
   i. Check both the HOME display temperature and the chart temperature. Ensure that the temperature is between 20-24^{o} C. The HOME display and chart temperatures should agree ±1 ^{o}C. Record the temperatures on the BF0017 BB Storage Temperature Log.
   ii. Check the chart for correct date and time and that the pen is recording. Write Y if the chart is accurate and functioning on the

BF0017 BB Storage Temperature Log.

iii. If the chart is functioning properly, there is no need to take manual temperature every 4 hours as the chart will record the temperature continuously.

2. **Maintenance Checks Failed**
   a. If checks reveal improper functioning of the platelet incubator or agitator, refer to manufacturer's manual for troubleshooting instructions.
   b. Call BioMed for service if unable to correct problem.
3. **Documentation**
   a. Record performance of daily tasks on the BF0029 CheckPoint Corrective Action Review form.
   b. Document corrective action performed on Variance Log. Notify Transfusion Service Supervisor or designee.

D. WEEKLY Maintenance

1. **Change Temperature Charts**

   Every Monday morning, the temperature recording charts on the platelet rotator are replaced. Platelet rotator temperature recording charts (No. 220273 sales@helmerinc.com) are located in the cabinet above the front desk of Transfusion Service.

   a. Open the chart recorder door. Press and hold the "chart change" button (C) for approximately one second until the pen begins to move to the far left of the chart. Release the button.
   b. Wait until the pen has moved to the edge of the chart, unscrew the center knob counter-clockwise and remove the old chart. Write your initials and the date removed.
   c. Write identity of the Platelet Incubator on the new chart, date, initial, and position chart so that the correct day/time line coincides with the time line groove.
   d. Re-attach the chart knob by turning it in a clockwise direction until it fits securely against the chart. (CAUTION: When the stylus is in the change position, pressing the Left or Right buttons changes the chart recorder temperature range).
   e. Press and hold the Chart Change (C) button again for approximately one second until the pen begins to move back onto the chart. Release the button.
   f. Confirm that the stylus is marking on the chart paper.
2. **Platelet Agitator Motion Alarm Check**
   a. Turn off the agitator and wait for the designated time for the alarm to sound.
   b. The acceptable range is < 2.5 minutes.
3. **Maintenance Checks Failed**
   a. If checks reveal improper functioning of the platelet incubator or agitator, refer to manufacturer's manual for troubleshooting instructions.
   b. Call BioMed (motion alarm) for service if unable to correct problem.
4. **Documentation**
   a. Record performance of tasks on the BF0002 Blood Bank Quality Control Checklist.
   b. Document any corrective action performed on Variance Log. Notify Transfusion Service Supervisor or designee.

E. QUARTERLY Maintenance

1. Refer to ***Quality Control-Weekly Monthly Quarterly Annually SOP*** for the maintenance schedule.
2. **Automatic Alarm Tests for High and Low Temperature**
   a. The temperature alarms for Helmer i Series 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.
   b. Refer to ***Alarm Check of Refrigerator Freezer and Platelet Incubator SOP*** for instructions.
3. **Manual High and Low Temperature Alarm Tests** can be performed for trouble shooting purpose. **NOTE: Remove platelets from the incubator before commencing MANUAL alarm tests.**
   a. **Low Alarm Activation**
      i. Fill an 8 ounce (0.2 liter) container half full of chilled water.
      ii. Immerse the NIST certified thermometer into the container.
      iii. Add crushed ice while stirring with an applicator stick until the thermometer reads about 21.5°C.
      iv. Remove the temperature probe from its mounted position.
      v. Insert the end of the platelet incubator probe into the container of water.
      vi. 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 (5ml) every 15 to 25 seconds should provide the desired temperature drop.
      vii. Stir the thermometer and probe constantly, keeping the ends in the liquid at the bottom of the container, not in the ice at the top.
      viii. The alarm should activate when the temperature exceeds the Low Temperature Alarm Setpoint value (20.5°C).
      ix. Record the temperature of the NIST thermometer, temperature chart and i.Center display when the alarm sounds.
   b. **High Alarm Activation**
      i. Fill an 8 ounce (0.2 liter) container half full of water.
      ii. Immerse the NIST certified thermometer in the container.
      iii. Remove the temperature probe from its mounted position.
      iv. Insert the end of the platelet incubator probe into the container of water.
      v. Slowly add hot water at a rate sufficient to provide a temperature increase of 0.5 °C per minute. The addition of approximately 1 teaspoon (5ml) every 15 to 25 seconds should provide the desired temperature increase.
      vi. Stir the thermometer and probe constantly keeping the ends in the liquid at the bottom of the container, not in the top.
      vii. The alarm should activate when the temperature exceeds the High Temperature Alarm Setpoint value (23.5°C).
      viii. Record the temperature of the NIST thermometer, temperature chart and i.Center display when the alarm sounds.

   NOTE: If the NIST temperature is **more** than 1**°C** from the setpoint, refer to the troubleshooting section in the equipment manual and if necessary, proceed to calibrate the platelet incubator probe and chart.

4. **Power Failure Alarm**
   Refer to ***Alarm Check of Refrigerator Freezer and Platelet Incubator SOP*** for instructions.
5. **Door Open Alarm**
   Refer to ***Alarm Check of Refrigerator Freezer and Platelet Incubator SOP*** for instructions.
6. **Check Battery on Chart Recorder**
   a. Check chart recorder battery, which is mounted on the face of the recorder.
   b. The light on the face of the chart recorder remains a constant green color indicating that both the battery and the main power to the unit are good.
   c. If the AC power fails or the battery becomes weak, the light will begin "flashing". Replace with 1 non-rechargeable 9V Alkaline battery (date the battery).

   NOTE: Replace the battery after 1 year of use.
7. **Check Backup Batteries**
   a. BioMed will check the backup batteries (icon on electronic display) and change if needed.
8. **Check Condenser Grill & Clean if needed**
   a. The air-cooled condenser fins are located on the upper left side in the rear of the unit.
   b. Check and clean the condenser using a soft brush and vacuum cleaner.
   c. Task is performed by BioMed.
9. **Safety and Electrical Checks**
   a. Performed by BioMed.
10. **Check i.Series Temperature Monitor**
    a. BioMed will check the accuracy of the Temperature Monitor and calibrate if necessary.
11. **Check Temperature Controller**
    a. BioMed will check the accuracy of the Temperature Controller and calibrate if necessary.
12. **Check Moving Parts**
    a. BioMed will check all moving parts and lubricate them if necessary.
13. **Maintenance Checks Failed**
    a. If checks reveal improper functioning of the platelet incubator or agitator, refer to manufacturer's manual for troubleshooting instructions.
    b. Call BioMed for service if unable to correct problem.
14. **Documentation**
    a. Record performance of tasks on the BF0002 Blood Bank Quality Control Checklist.
    b. Document any corrective action performed on Variance Log. Notify Transfusion Service Supervisor or designee.

F. AS NEEDED Maintenance

1. **Calibrate i.Series Temperature Monitor**
   a. Allow the chamber temperature to stabilize by not opening the door for approximately 30 minutes.
   b. Place an independent, NIST certified thermometer in the chamber of the Platelet Incubator where the internal temperature sensor is located (back, right bottom corner). Allow 30 minutes for the independent thermometer to accurately register the chamber air temperature.

c. Compare the independent thermometer reading to the displayed value on the Temperature Monitor and chart recorder.

d. Change the temperature of the Temperature Monitor if there is > ± 1 °C difference between it and the independent NIST certified thermometer temperature reading.
   i. From MAIN screen, navigate to and select EDIT CONFIGURATION.
   ii. Enter 1234 for password. The CONFIGURATION page appears.
   iii. Navigate to and select TEMPERATURE CALIBRATION.
   iv. Press INC or DEC to change the temperature to match the readout of the NIST certified thermometer.
   v. Press DOWN until STORE CALIBRATION is highlighted.
   vi. Press ENTER to save changes and return to HOME page.

e. Record result on BF0011 Calibration of Thermometers QC form.

f. Calibrate the chart temperature also if it differs from the NIST certified thermometer reading.

2. **Calibrate Chart Temperature**

The chart temperature needs to be calibrated if it differs from the verified temperature above.

a. Press and hold 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.

b. The new temperature setting takes effect when neither arrow key is pressed for 5 seconds.

c. Record result on BF0011 Calibration of Thermometers QC form.

3. **Clean Interior**

a. Always turn the power switch off when cleaning the interior of the incubator and the flat-bed agitator shelves.

b. An all-purpose laboratory disinfectant cleaner may be used to wipe down the inside stainless steel walls, drawers and interior water drain tray when needed.

c. Painted interiors should be cleaned with a mild detergent.

4. **Clean Exterior**

a. Lightly wipe the roll-top door with a soft cotton cloth and non-abrasive liquid cleaner – do not push hard when cleaning and do not rub back and forth across the door. Lightly wipe in one direction.

b. If a cleaner must be used to clean debris off of the glass, then spray some window cleaner onto a soft cotton cloth and then wipe – do not spray the cleaner directly onto the clear part of the roll-top door.

5. **Documentation**

Indicate on BF0007 Daily Equipment Quality Control form after performing the 'as needed' maintenance tasks. Write as Comments if task(s) is not on form.

Platelet Incubator/Agitator MAINTENANCE FREQUENCY Table

TASK	Frequency			
	Weekly	Quarterly	Annually	As Needed

Change Temperature Chart	√			
Platelet Agitator Motion Alarm Check	√			
Automatic Alarm Tests for High and Low Temperature		√		
Power Failure Alarm		√		
Door Open Alarm		√		
Check Battery on Chart Recorder (replace if light is red or 1 year)		√		
Check Backup Batteries		√ (BioMed)		
Safety and Electrical Checks		√ (BioMed)		
Check i.Series Temperature Monitor & Calibrate if needed		√ (BioMed)		
Check Temperature Controller & Calibrate if needed		√ (BioMed)		
Check Moving Parts & Lubricate if needed		√ (BioMed)		
Check Condenser Grill & Clean if needed		√ (BioMed)		
Calibrate Chart Temperature				√
Clean Interior & Exterior				√
Clean Door Gaskets				√

PROCEDURE NOTE(S)

In Platelet Incubator/Agitator becomes non-operational, platelets can be stored at room temperature 20 - 24^{0}C (RT) without agitation up to 30 hours as long as the RT is continuously monitored or recorded every 4 hours. After 30 hours, return all platelets to blood supplier and order replacement units.

REFERENCES

A. AABB, Technical Manual, current edition, Bethesda, MD.

B. AABB, Standards for Blood Banks & Transfusion Services, current edition, Bethesda, MD.

C. Helmer Platelet Incubator Operation Manual, i.Series, Noblesville, IN 46060.

Associated Documents:

External Documents

SFOWI-0032 Quality Control-Weekly Monthly Quarterly Annually
SFOWI-0033 Alarm Check of Refrigerator Freezer and Platelet Incubator
SFOWI-0055 CheckPoint Temperature System
BF0002 Blood Bank Quality Control Checklist
BF0029 CheckPoint Corrective Action Review
BF0017 BB Storage Temperature Log
BF0011 Calibration of Thermometers QC
BF0021 Quarterly Alarm Checks
Associated Quality System Documents - None

Documents Generated:

Document Revision History:

Revision: 13	**Date Created:** 09/12/2005 **Date of Last Revision:** 01/31/2019	**Last Approval Date:** 08/24/2016

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	Approver	New Lab Director	12/3/06
2	Hi/Lo alarm check	Automatic alarm test	12/3/06
3	Approver	New Lab Director	1/7/07
4	Approver	New Lab Director	7/29/07
5	Procedure	Daily Maintenance - Review Check Point Temperature	4/24/10
6	Approver	Change Lab Director	6/1/11
7	Approver	New Lab Director	1/17/13
8	Approver	New BB Medical Director.	11/11/13
9	Whole document Procedure Procedure A.4. Procedure E. Procedure E.6. Procedure E.7. Procedure E.9. Procedure F. Procedure G. Associated Documents	Reformatted. Added instructions to troubleshoot when maintenance checks failed. Added maintenance frequency table. New. Added Checkpoint reference. Revised to align with new alarm check SOP and clarify documentation. Added Note to replace chart battery after 2 years. Added check backup batteries of monitoring system. Added safety and electrical checks. New. Added replace backup batteries for monitoring system annually. Added grease agitator drive shaft and calibrate chart temperature. New.	3/11/14
10	Whole document Procedure F.	Changed Engineering to BioMed. Deleted annual replacement of backup batteries as the charge is already checked quarterly and batteries will be replaced if needed at the time.	12/23/14
11	Procedure E.8.c.	Revised. Request BioMed to clean inside condenser if needed.	7/17/15
12	Approver	New CLIA Director.	8/23/16
13	Whole document	Changed 'As Needed' maintenance (Check/Calibrate Temp Monitor, Check/Lubricate parts, Check/Replace Backup	1/23/19

	Procedure Note(s)	batteries) to quarterly as per current BioMed practice. Changed from 24 hrs to 30 hrs for maximum time allowed for platelets storage without agitation per the 31st edition of AABB Reference Std 5.1.8A.	

Notification List:

Approvals:

First Approver's Signature

Name: Maria F Serrano/CA/KAIPERM
Title: Transfusion Service Medical Director

Second Approver's Signature

Name: Eric Suba/CA/KAIPERM
Title: Chief of Pathology; CLIA Director

Document History Section