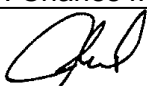




Document History:

Title: Alarm System Check: Blood, Blood Component, Derivative Storage Equipment and Plasma Thawer **Site(s):** All DSM sites

Document #:	160-QC-14	Version #:	02
Section:	Manitoba Transfusion Quality Manual for Blood Banks	Subsection:	QC Module

Approved by: Dr. Charles Musuka **Written By:** TM Discipline Team
Signature: 
Date: 28-OCT-2013 Date: March 2011

1. Annual Review:

#	Reviewed by:	Date:	Approval:	Date:
1				
2				
3				
4				
5				

2. Summary of Revisions:

#	Details of Revisions:	Date:	Approval:	Date:
1	New document		Dr. Kabani	
2	6.5 added temp must be set a minimum of 0.5 degrees. Added note, if equipment is to be used as back up.	Oct 25	C Musuka	28-OCT-2013
3				
4				
5				

3. Date Archived:

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1.0 Principle

To ensure the alarm system of the blood, blood component and derivative storage equipment or plasma thawer is functioning correctly

2.0 Scope and Related Policies

Refer to Policy Storage Equipment Standards: Blood, Blood Components and Derivatives.

3.0 Materials

- Calibrated reference thermometer
- Water
- Crushed ice
- Table salt
- Containers, suitable size
- QC Forms- Daily Temperature and Weekly/Monthly Maintenance Record: Fridge/Freezer/
Platelet Incubator/ Plasma Thawer
- QC Form- Daily/Weekly/Monthly Maintenance Checklist
- QC Forms- Alarm System Check Record: Fridge/ Freezer/ Platelet Incubator/ Plasma Thawer
- QC Form- Quarterly/Semi-annually/Annual Maintenance Checklist
- QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer
- QC Forms- Four Hour Manual Temperature Record: Fridge/Freezer/Platelet Incubator
- Calibration Label

4.0 Procedure

Alarm system checks include the following:

- Audible alarm test
- Platelet Agitator Motion alarm test
- Alarm system battery back-up test
- Refrigerator low and high temperature sensor activation
- Freezer high temperature sensor activation
- Platelet incubator low and high temperature sensor activation
- Plasma thawer high temperature activation

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4.0 Procedure Cont'd

4.1 Weekly Audible Alarm Test (Fridges /Freezers/ Platelet Incubators):

4.1.1 Press "alarm test" button:

- Disconnect power cord if there is no "alarm test" button
- Some models have an indicator light as well as an audible alarm

4.1.2 Verify that the audible alarm sounds and indicator light flashes, if applicable:

- Verify that the audible alarm is activated at the remote location if applicable
- Record "Pass" on appropriate QC Form- Daily Temperature and Weekly/Monthly Maintenance record

4.1.3 If the alarm does not sound:

- Notify the Charge Technologist
- Record the details on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer
- Record "Fail" on appropriate QC Form- Daily Temperature and Weekly/Monthly Maintenance Record
- Read and record the temperature of the equipment every 4 hours on appropriate QC Forms- Four Hour Manual Temperature Record until the alarm is repaired

4.1.4 If equipment was disconnected to perform test, reconnect the equipment.

4.1.5 Document testing on:

- QC Form- Daily/Weekly/Monthly Maintenance Checklist
- Appropriate QC Forms- Daily Temperature and Weekly/Monthly Maintenance Record

4.2 Weekly Platelet Agitator Motion Alarm Activation (Helmer Platelet Incubators)

4.2.1 Turn the agitator switch on and the alarm switch on.

Note: The remote alarm may activate so wait 10 minutes before proceeding

4.2.2 Turn the agitator switch off and after approximately 2- 3 minute delay verify:

- Audible alarm sounds
- Remote alarm activates
- Record "Pass" on QC Form- Daily Temperature and Weekly/Monthly Maintenance Record: Platelet Incubator

4.2.3 If the alarm does not sound:

- Notify the Charge Technologist
- Record the details on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer
- Record "Fail" on QC Form- Daily Temperature and Weekly/Monthly Maintenance Record: Platelet Incubator
- Determine if back-up agitator available. Refer to QC Procedure- Alarm Response Malfunction

4.2.4 Document testing on:

- QC Form- Daily/Weekly/Monthly Maintenance Checklist
- QC Form- Daily Temperature and Weekly/Monthly Maintenance Record Platelet Incubator

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4.3 Monthly Alarm System Battery Back-up Test (Fridges /Freezers /Platelet Incubators):

- 4.3.1** Disconnect the equipment from the main power supply and then disconnect the back-up power supply (if there is a separate one) connected to the alarm system.
- 4.3.2** Verify that the audible and/or visual alarm sounds.
- Verify that the audible alarm is activated at the remote location if applicable
 - Record "Pass" on appropriate QC Forms: Daily Temperature and Weekly/Monthly Maintenance Records
- 4.3.3** If the alarm does not sound:
- Replace the battery and repeat the test
- 4.3.4** If the test fails after the battery has been replaced:
- Notify the Charge Technologist
 - Record the details on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer
 - Record "Fail" on appropriate QC Forms-Daily Temperature and Weekly/Monthly Maintenance Records
 - Read and record the temperature of the equipment every 4 hours on appropriate QC Forms- Four Hour Manual Temperature Record until the alarm system is repaired
- 4.3.5** If equipment was disconnected to perform the test, reconnect the equipment.
Note: For fridges and freezers following disconnection from power supply wait 5 minutes prior to reconnecting.
- 4.3.6** Document testing on:
- QC Form- Daily/Weekly/Monthly Maintenance Checklist
 - Appropriate QC Forms- Daily Temperature and Weekly Monthly Maintenance Record

4.4 Quarterly Refrigerator Low and High Temperature Sensor Activation Test: (Refer to procedural note 6.5)

Note: The recommended low temperature set point should be no colder than 1.5°C for Blood and Thawed plasma and 2.5°C for Derivatives (dependent on manufacturer's instructions) and the recommended high temperature set point should be no warmer than 5.5°C. Refer to the manufacturer's stated specifications for alarm set points.

Note: Always perform low activation followed by high activation. Pre alarm temperatures only need to be documented prior to starting alarm activations.

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4.0 Procedure Cont'd

4.4.1 Test for low activation:

- 4.4.1.1** Place reference thermometer into the 10% glycerol container that stores the alarm temperature sensor.
- 4.4.1.2** Read and record on QC Form- Alarm System Check Record: Fridge the following pre-alarm temperatures:
- The Digital Controller (Internal Thermometer)
 - The Reference Thermometer
- Note:** The temperature readings should agree within 1°C.
- 4.4.1.3** Place the 10 % glycerol container with the alarm sensor and reference thermometer into a pan containing an ice and water slush at a temperature of -4°C or colder.
- Add several spoonfuls of salt to the slush to achieve this temperature, if necessary
- 4.4.1.4** Gently agitate the pan periodically until the alarm sounds.
- 4.4.1.5** Read and record the following temperatures at which the alarm sounds as the Low activation on QC Form- Alarm System Check Record: Fridge:
- The Digital Controller (Internal Thermometer)
 - The Reference Thermometer
- Note:** Temperature readings should agree within 1°C.
- 4.4.1.6** Verify that the alarm is activated on the equipment and remotely:
- Document on QC Form Alarm System Check Record: Fridge
- 4.4.1.7** Document alarm check as Pass or Fail on QC Form- Alarm System Check Record: Fridge.
- 4.4.1.8** Repeat the test if the alarm does not sound at the expected temperature.
- 4.4.1.9** Remove the sensor container from the ice slush.
- 4.4.1.10** Notify the Charge Technologist if repeated alarm testing fails:
- Contact the service company if necessary
 - Record details on QC Form - Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer

4.4.2 Test for high activation:

- 4.4.2.1** Place reference thermometer into the 10% glycerol container that stores the alarm temperature sensor.
- 4.4.2.2** Verify that the operating temperature is within acceptable range.
- 4.4.2.3** Place the 10 % glycerol container with the alarm sensor and reference thermometer into a pan containing warm water at a temperature of 12° to 15°C.
- 4.4.2.4** Allow the fluid in the container to warm slowly, with occasional agitation until the alarm sounds.
- 4.4.2.5** Read and record the following temperatures at which the alarm sounds as the high activation on QC Form- Alarm System Check Record: Fridge:
- The Digital Controller (Internal Thermometer)
 - The reference thermometer
- Note:** Temperature readings should agree within 1°C.
- 4.4.2.6** Verify that the alarm is activated on the equipment and remotely:
- Document on QC Form- Alarm System Check Record: Fridge
- 4.4.2.7** Document alarm check as Pass or Fail on QC Form- Alarm System check Record: Fridge.

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4.0 Procedure Cont'd

4.4.2.8 Repeat the test if the alarm does not sound at the expected temperature.

4.4.2.9 Remove the sensor container from the warm water.

4.4.2.10 Notify the Charge Technologist if repeated alarm testing fails:

- Contact the service company if necessary
- Record details on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer

4.4.3 Calibration of Temperature Sensor:

The recommended set point is 0°C. Refer to manufacturer's stated specific specifications.

Note: Testing not applicable to all models of refrigerator, refer to operators manual.

4.4.3.1 Place sensor in ice and water slush.

4.4.3.2 Gently agitate until temperature reaches and is maintained at 0°C.

4.4.3.3 Document temperature on QC Form- Alarm System Check Record: Fridge.

4.4.3.4 If sensor temperature of 0°C is not reached or maintained:

- Refer to operator's manual for calibration instructions
- Record details on QC Form-Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer

4.4.4 Document testing on QC Form- Quarterly/Semi-annually/Annual Maintenance Checklist.

4.4.5 Place completed "calibration label" on front of equipment indicating:

- Date tested
- Tech
- Next due date

4.5 Quarterly Freezer High Temperature Sensor Activation Test:

Note: The recommended high temperature set point is -20°C. Refer to the manufacture's stated specification for alarm set points.

4.5.1 Place reference thermometer in the container with the alarm temperature sensor.

4.5.2 Read and record on QC Form- Alarm System Check Record: Freezer the following pre-alarm temperatures:

- The Digital Controller (Internal Thermometer)
- The Reference Thermometer

Note: The temperature readings should agree within 1°C.

4.5.3 Place the container with the alarm sensor and reference thermometer into a container of cold water.

4.5.5 Warm the alarm probe and reference thermometer slowly with occasional agitation until alarm sounds.

Note: The specific temperature of activation cannot be determined accurately during rapid warming.

4.5.6 Read and record the following temperatures at which the alarm sounds as the high activation on QC Form- Alarm System Check Record: Freezer:

- The Digital Controller (Internal Thermometer)
- The Reference Thermometer

Note: Temperature readings should agree within 1°C.

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- 4.5.7 Verify that the alarm is activated on the equipment and remotely:
 - Document on QC Form- Alarm System Check Record: Freezer
- 4.5.8 Document alarm check as Pass or Fail on QC Form- Alarm System Check Record: Freezer.
- 4.5.9 Repeat the test if the alarm does not sound at the expected temperature.
- 4.5.10 Remove the sensor container from the cold water.
- 4.5.11 Notify the Charge Technologist if repeated alarm testing fails:
 - Contact the service company if necessary
 - Document details on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer
- 4.5.12 Document testing on QC Form-Quarterly/Semi-annually/Annual Maintenance Checklist.
- 4.5.13 Place completed "calibration label" on front of equipment indicating:
 - Date tested
 - Tech
 - Next due date

4.6 Quarterly Platelet Incubator Low and High Temperature Sensor Activation Tests:

Platelet incubator instructions are for Helmer PC900 and PC1200 models. Follow the manufacturers instructions for all other makes/models.

Note: The recommended low temperature set point is 20.5°C and the high temperature set point is 23.5°C. Refer to the manufacturer's stated specifications for alarm set points.

Note: Always perform low activation followed by high activation. Pre alarm temperatures only need to be documented prior to starting alarm activation.

4.6.1 Test for low activation:

- 4.6.1.1 Place reference thermometer into incubator near the alarm sensor.
- 4.6.1.2 Read and record on QC Form- Alarm System Check Record: Platelet Incubator the following pre- alarm temperatures:
 - The Digital Controller (Internal Thermometer)
 - The Reference Thermometer
- 4.6.1.3 Fill a small cup with water that is at least 1°C below the low alarm setting of 20.5°C.
- 4.6.1.4 Open the RTD sensor enclosure and carefully pull the RTD sensor out of the holding bracket (if applicable). The temperature sensitive portion of the sensor is located within 1 cm from the tip of the sensor.
- 4.6.1.5 Place reference thermometer and the RTD sensor in the cup.
- 4.6.1.6 Watch for the alarm indicator light on the temperature controller to flash "**LO**" when the reading passes the alarm set point.
 - The audible alarm will enter the delay mode and sound after the delay period has cycled

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4.6.1.7 Read and record the following temperatures at which the alarm indicator light first flashes "**LO**" as the low activation on QC Form- Alarm System Check Record:
Platelet Incubator:

- The Digital Controller (internal Thermometer)
- The Reference Thermometer

Note: Temperature readings should agree within 1°C.

4.6.1.8 Verify that the audible alarm is activated on the equipment and remotely:

- Document on QC Form- Alarm System Check Record: Platelet Incubator

4.6.1.9 Document alarm check as Pass or Fail on QC Form Alarm System Check Record: Platelet Incubator.

4.6.1.10 Repeat the test if the alarm does not sound at the expected temperature.

4.6.1.11 Remove the sensor from the cup.

4.6.1.12 Notify the Charge Technologist if repeated alarm testing fails:

- Contact the service company if necessary
- Record details on QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer

4.6.2 Test for high activation:

4.6.2.1 Place reference thermometer into incubator near sensor and verify operating temperature is within acceptable range.

4.6.2.2 Fill a small cup with water that is at least 1°C above the high alarm setting of 23.5°C.

4.6.2.3 Place reference thermometer and the RTD sensor in the cup.

4.6.2.4 Watch for the alarm indicator light on the temperature controller to flash "**HI**" when the reading passes the alarm set point:

- The audible alarm will enter the delay mode and sound after the delay period has cycled

4.6.2.5 Read and record the following temperatures at which the alarm indicator light first flashes "**HI**" as the high activation on QC Form- Alarm System Check Record:
Platelet Incubator:

- The Digital Controller (Internal Thermometer)
- The Reference Thermometer

Note: Temperature readings should agree within 1°C.

4.6.2.6 Verify that the audible alarm is activated on the equipment and remotely:

- Document on QC Form-Alarm System Check Record: Platelet Incubator

4.6.2.7 Document alarm checks as Pass or Fail on QC Form-Alarm System Check Record: Platelet Incubator.

4.6.2.8 Repeat testing if alarm does not sound at the expected temperature.

4.6.2.9 Remove the sensor from the cup and return into RTD holding bracket and enclosure (if applicable).

4.6.2.10 Notify Charge Technologist if repeated alarm testing fails:

- Contact the service company if necessary
- Document details on QC Form-Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer

4.6.3 Document testing on QC Form Quarterly/Semi-annually/Annual Maintenance Checklist.

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4.0 Procedure Cont'd

4.6.4 Place a completed calibration label on the front of the equipment indicating:

- Date tested
- Tech
- Next due date

4.7 Quarterly Plasma Thawer High Temperature Sensor Activation test:

Note: The recommended high temperature activation is a temperature greater than 37°C. Refer to the manufacturer's stated specification for alarm set points.

4.7.1 Place reference thermometer in the centre of the plasma thawer.

4.7.2 Allow temperature to stabilise for 5 minutes. Read and record on QC Form- Alarm System Check Record: Plasma Thawer the following pre- alarm temperatures:

- The Digital Controller
- The Reference Thermometer

Note: The temperatures should agree within 1°C.

4.7.3 Confirm the High Alarm setting (refer to operator's manual).

4.7.4 Change the operating temperature by 0.5°C over the High Alarm setting (e.g. if High Alarm setting is 37°C, then change the operating temperature to 37.5°C).

4.7.5 Read and record the following temperatures at which the alarm sounds as the high activation on QC Form- Alarm System Check Record: Plasma Thawer:

- The Digital Controller (Internal Thermometer)
- The Reference Thermometer

Note: Temperature readings should agree within 1°C.

4.7.6 Verify that the audible alarm sounds and that the basket assembly lifts out of the bath (if applicable):

- Document on QC Form- Alarm System Check Record: Plasma Thawer

4.7.7 Document alarm check as Pass or Fail on Form- QC Alarm System Check Record: Plasma Thawer.

4.7.8 Repeat the test if the alarm does not sound at the expected temperature.

4.7.9 Notify the Charge Technologist if repeated alarm testing fails:

- Contact the service company if necessary
- Record details on QC Form-Equipment Malfunction and Corrective Action Record: Storage equipment and Plasma Thawer

4.7.10 Change the operating temperature of the plasma thawer back to the original setting.

4.7.11 Document testing on QC Form-Quarterly/Semi-annually/Annual Maintenance Checklist.

4.7.12 Place a completed calibration label on the front of the equipment indicating:

- Date tested
- Tech
- Next due date

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5.0 Reporting

- 5.1** Ensure required documentation complete on:
- QC Form- Daily/Weekly/Monthly Maintenance Checklist
 - QC Form- Quarterly/Semi-annually/ Annual Maintenance Checklist
 - QC Forms- Daily Temperature and Weekly/ Monthly Maintenance Record: Fridge/Freezer/Platelet Incubator/Plasma Thawer
 - QC Forms- Alarm System Check Record: Fridge/Freezer/Platelet Incubator/ Plasma Thawer
 - QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer (if applicable)
 - QC Form- Four Hour Manual Temperature Record: Fridge/Freezer/Platelet Incubator (if applicable)
 - Calibration Label (if applicable)
- 5.2** The Charge Technologist or designate shall review the QC records and document on:
- QC Forms- Daily/Weekly/Monthly Cell Washer Maintenance Record: Fridge/Freezer/Platelet Incubator
 - QC Forms- Alarm System Check Record: Fridge/Freezer/Platelet Incubator/ Plasma Thawer
 - QC Form- Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer (if applicable)
 - QC Form- Four Hour Manual Temperature Record: Fridge/Freezer/Platelet Incubator (if applicable)
- 5.3** Retain all completed QC records according to Record Retention Policy. (Refer to Appendix 8).
- 5.4** Retain all completed equipment malfunction and corrective action records according to Record Retention Policy. (Refer to Appendix 8).

6.0 Procedural Notes:

- 6.1** If the storage equipment has a mechanism to electronically test the high and low temperature sensor activation, follow the manufacturer's instructions to determine the activation temperature. This should be part of weekly testing and cannot be used in place of the monthly or quarterly alarm system check.
- 6.2** When temperatures of alarm activation are checked, the temperature change should occur slowly enough so that the measurements and recording are accurate. Too rapid a change in temperature may give the false impression that the alarm does not sound until an inappropriate temperature is registered.
- 6.3** Alarms should sound simultaneously at the site of the refrigerator or freezer and at the location of remote alarms. If remote alarms are used, the alarm check should include a verification that the alarm sounded at the remote location.
- 6.4** The amount of 10% glycerol in which the refrigerator alarm temperature sensor is immersed must be no larger than the smallest volume red cell component stored in the refrigerator. (Approximately 200 ml)
- 6.5** For refrigerators and freezers with upper and lower temperature monitors, the low and high temperature sensor activation test must be performed on both. (If alarm activated from both - refer to operator's manual). The alarm must be set at a minimum of 0.5 degrees above the low storage temperature to allow sufficient time to react to the alarm and a minimum of 0.5 degrees below the high storage temperature. Note: if equipment is to be used as backup for another type

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of product e.g. derivative fridge to be used for backup of blood, then ensure that the alarm will activate at the required time for both products.