

Document History:

Title: Alarm System Check: Blood, Blood Component, Plasma Protein Product Storage Equipment and Plasma Thawer
Site(s): All Shared Health TM Sites

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Details of Recent Revision

- Updated throughout with eTraceLine, standardized font and added SOP numbers
- Incorporated notes throughout into bullets
- 4.1 added to refer to Operator's Manual; 4.1.1 updated to "Access alarm test function" depending on make/model as not all equipment has "Alarm test button"
- 4.2 added to refer to Operator's Manual and added job aid reference for sites that have agitator set point programmed to Off
- 4.5 and 4.7 added to refer to Operator's Manual, revised and expanded set point for alarm activation

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**Alarm System Check:
Blood, Blood Component, Plasma Protein Product Storage Equipment
and Plasma Thawer**

1.0 Principle

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

2.0 Scope and Related Policies

2.1 Refer to policy *Storage Equipment Standards: Blood, Blood Components and Plasma Protein Product*, 160-QC-02

- 2.2** Alarm system checks include the following:
- Audible alarm test
 - Platelet agitator alarm test
 - Alarm system battery back-up test
 - Refrigerator high temperature sensor activation
 - Freezer high temperature sensor activation
 - Platelet incubator low and high temperature sensor activation
 - Plasma thawer high temperature activation

3.0 Materials

Calibrated reference thermometer

Water

Crushed ice

Table salt

Containers, suitable size

QC Forms:

Form	Equipment	Document ID #
Equipment labels – Alarms		F160-80-14
4 Hour Temperature Record	Freezer Form A	F160-QCFORM-16
	Freezer Form B	F160-QCFORM-17
	Fridge Form A	F160-QCFORM-18
	Fridge Form B	F160-QCFORM-19
	Platelet Incubator	F160-QCFORM-20
Alarm System Check Record	Freezer	F160-QCFORM-01
	Fridge	F160-QCFORM-02
	Plasma Thawer	F160-QCFORM-03
	Platelet Incubator	F160-QCFORM-04
Daily Temperature and Weekly/Monthly Maintenance Record	Ambient (Room Temp)	F160-QCFORM-35
	Freezer QC Form A	F160-QCFORM-06
	Freezer QC Form B	F160-QCFORM-07
	Fridge QC Form A	F160-QCFORM-08
	Fridge QC Form B	F160-QCFORM-09
	Fridge QC Form C	F160-QCFORM-40
	Plasma Thawer/Waterbath/Drybath	F160-QCFORM-10
	Platelet Incubator	F160-QCFORM-11
Daily/Weekly/Monthly Maintenance Checklist: Crossmatch		F160-QCFORM-13
Daily/Weekly/Monthly Maintenance Checklist: Non-Crossmatch		F160-QCFORM-14
Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer		F160-QCFORM-15
Quarterly/Semi-annually/Annual Maintenance Checklist		F160-QCFORM-21

4.0 Procedure

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

Refer to Operator's Manual instructions to activate alarm test for each make/model of fridge, freezer and/or platelet incubator

4.1.1 Access **Alarm Test** function:

- Disconnect power cord if there is no **Alarm Test** function
- Some models have an indicator light as well as an audible alarm

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

- Verify audible alarm is activated at 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 charge technologist
- Record the details on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer*, F160-QCFORM-15
- Record **Fail** on appropriate QC form *Daily Temperature and Weekly/Monthly Maintenance Record*
- Read and record the temperature of the equipment every four (4) hours using appropriate QC form *Four Hour Manual Temperature Record* until alarm is repaired

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

4.1.5 Document testing on appropriate QC form:

- *Daily/Weekly/Monthly Maintenance Checklist*
- *Daily Temperature and Weekly/Monthly Maintenance Record*

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

Refer to Operator's Manual instructions to activate agitator alarm for each make/model of platelet incubator

- For sites with Helmer PC 100 that have agitator alarm set point programmed to off, refer to Job Aid: *Helmer Platelet Agitator Audible Alarm Check*, JA160-QC-14B

4.2.1 Ensure both the agitator and alarm switches are on:

- The remote alarm may activate so wait 10 minutes before proceeding

4.2.2 Turn agitator switch off; after approximately a 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 is available. Refer to QC procedure *Alarm Response Malfunction*, 160-QC-13

4.2.4 Document testing on QC form:

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

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

- 4.3.1** Disconnect equipment from main power supply then disconnect back-up power supply (if there is a separate one) connected to the alarm system
- 4.3.2** Verify audible and/or visual alarm sounds:
 - Verify audible alarm is activated at the remote location, if applicable
 - Record **Pass** on appropriate QC form *Daily Temperature and Weekly/Monthly Maintenance Records*
- 4.3.3** If alarm does not sound, replace battery and repeat test
- 4.3.4** If test fails after battery has been replaced:
 - Notify charge technologist
 - Record 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 temperature of equipment every four (4) hours on appropriate QC form, *Four Hour Temperature Record*, until the alarm system is repaired
- 4.3.5** If equipment was disconnected to perform test, reconnect:
 - For fridges and freezers, following disconnection from power supply wait 5 minutes before reconnecting
- 4.3.6** Document testing on appropriate QC forms:
 - *Daily/Weekly/Monthly Maintenance Checklist*
 - *Daily Temperature and Weekly/Monthly Maintenance Record*

4.4 Refrigerator: Quarterly Low and High Temperature Sensor Activation Test:

(Refer to **Procedural Note 6.5**)

The recommended low temperature set point should be no colder than 1.5°C for blood and/or thawed plasma and 2.5°C for plasma protein products (PPP), dependent upon manufacturer's instructions. The recommended high temperature set point should be no warmer than 5.5°C for blood and/or thawed plasma and 7.5°C for PPP; refer to manufacturer's stated specifications for alarm set points.

- Always perform low activation followed by high activation. Pre-alarm temperatures are documented prior to starting alarm activations.
- For Sanyo fridge, see **Procedural Note 6.6**

4.4.1 Low Activation Test

- 4.4.1.1** Place reference thermometer into 10% glycerol container containing alarm temperature sensor
- 4.4.1.2** Pre-alarm: read and record the following temperatures on QC form *Alarm System Check Record: Fridge*:
 - Digital Controller (Internal Thermometer)
 - Reference Thermometer
 - The temperature readings should agree within 1°C
- 4.4.1.3** Place 10% glycerol container with alarm sensor and reference thermometer into pan containing an ice and water slush at a temperature of -4°C or colder:
 - Add several tablespoons of salt to slush to achieve temperature, if necessary
- 4.4.1.4** Gently agitate pan periodically until alarm sounds

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- 4.4.1.5 Read and record the following temperatures at which the alarm sounds for the low activation on QC form *Alarm System Check Record: Fridge*:
 - Digital Controller (Internal Thermometer)
 - Reference Thermometer
 - Temperature readings should agree within 1°C.
 - 4.4.1.6 Verify alarm is activated on equipment and remotely and 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 test if the alarm does not sound at expected temperature
 - 4.4.1.9 Remove sensor container from ice slush
 - 4.4.1.10 Notify charge technologist if repeated alarm testing fails:
 - Contact service company if necessary
 - Record details on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer*

4.4.2 High Activation Test

- 4.4.2.1 Place reference thermometer into 10% glycerol container containing alarm temperature sensor
- 4.4.2.2 Verify operating temperature is within acceptable range
- 4.4.2.3 Place 10% glycerol container with alarm sensor and reference thermometer into pan containing warm water at a temperature of 12 - 15°C
- 4.4.2.4 Allow the water 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*:
 - Digital Controller (Internal Thermometer)
 - Reference thermometer
 - Temperature readings should agree within 1°C
- 4.4.2.6 Verify alarm is activated on the equipment and remotely and 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*
- 4.4.2.8 Repeat test if the alarm does not sound at expected temperature
- 4.4.2.9 Remove sensor container from warm water
- 4.4.2.10 Notify charge technologist if repeated alarm testing fails:
 - Contact the service company if necessary
 - Record details on QC form *Equipment Malfunction and Correction Action Record: Storage Equipment and Plasma Thawer*

4.4.3 Temperature Sensor Calibration

The recommended set point is 0°C. Refer to manufacturer's stated specific specifications. Testing not applicable to all models of refrigerator; refer to Operator's 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
- Initials of technologist performing testing
- Next due date

4.5 Freezer: Quarterly High Temperature Sensor Activation Test

The recommended high temperature set point is -18.5°C. Refer to the manufacturer's stated specification for alarm set points.

- The alarm set point must be set at a minimum of 0.5 degrees above the acceptable storage temperature for frozen blood components of colder than -18°C

4.5.1 Place reference thermometer into container with alarm temperature sensor

4.5.2 Pre-alarm: read and record the following alarm temperatures on QC form *Alarm System Check Record: Freezer*:

- Digital Controller (Internal Thermometer)
- Reference thermometer
- Temperature readings should agree within 1°C

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

4.5.4 Warm alarm probe and reference thermometer slowly with occasional agitation until alarm sounds:

- The specific temperature of activation cannot be determined accurately during rapid warming

4.5.5 Read and record following temperatures at which alarm sounds as the high activation on QC form *Alarm System Check Record: Freezer*:

- Digital Controller (Internal Thermometer)
- Reference thermometer
- Temperature readings should agree within 1°C.

4.5.6 Verify alarm is activated on the equipment and remotely and document on QC form *Alarm System Check Record: Freezer*

4.5.7 Document alarm check as **Pass** or **Fail** on QC form *Alarm System Check Record: Freezer*

4.5.8 Repeat test if alarm does not sound at expected temperature

4.5.9 Remove sensor container from cold water

4.5.10 Notify charge technologist if repeated alarm testing fails:

- Contact service company if necessary
- Document details on QC form *Equipment Malfunction and Corrective Action Record Storage Equipment and Plasma Thawer*

4.5.11 Document testing on QC form *Quarterly/Semi-annually/Annual Maintenance Checklist*

4.5.12 Place completed *Calibration Label* on front of equipment indicating:

- Date tested
- Initials of technologist performing testing
- Next due date

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

Refer to Operator's Manual instructions to activate agitator alarm for each make/model of platelet incubator.

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

4.6.1 Low Activation Test

4.6.1.1 Place reference thermometer into incubator near alarm sensor

4.6.1.2 Pre-alarm: read and record the following temperatures on QC form *Alarm System Check Record: Platelet Incubator*:

- Digital Controller (Internal Thermometer)
- Reference thermometer

4.6.1.3 Fill a small cup with water at least 1°C below 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 RTD sensor into the cup

4.6.1.6 Watch for alarm indicator light on temperature controller to flash **LO** when reading passes alarm set point:

- Audible alarm will enter delay mode and sound after delay period has cycled

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*:

- Digital Controller (internal thermometer)
- Reference thermometer
- Temperature readings should agree within 1°C

4.6.1.8 Immediately add ice or more cold water to container in order to maintain temperature below 20°C; wait for audible alarm to sound after delay period

4.6.1.9 Verify audible alarm is activated on equipment and remotely and document on QC form *Alarm System Check Record: Platelet Incubator*

4.6.1.10 Document alarm check as **Pass** or **Fail** on QC form *Alarm System Check Record: Platelet Incubator*

4.6.1.11 Repeat test if alarm does not sound at expected temperature

4.6.1.12 Remove sensor from cup

4.6.1.13 Notify the charge technologist if repeated alarm testing fails:

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

4.6.2 High Activation Test

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 at least 1°C above high alarm setting of 23.5°C

4.6.2.3 Place reference thermometer and the RTD sensor into cup

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

- Audible alarm will enter delay mode and sound after 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*:

- Digital Controller (Internal Thermometer)
- Reference thermometer
- Temperature readings should agree within 1°C

4.6.2.6 Immediately wrap a hot cloth around container to maintain temperature above 24°C and wait for audible alarm to sound after delay period

4.6.2.7 Verify audible alarm is activated on equipment and remotely and document on QC form *Alarm System Check Record: Platelet Incubator*

4.6.2.8 Document alarm checks as **Pass** or **Fail** on QC form *Alarm System Check Record: Platelet Incubator*

4.6.2.9 Repeat testing if alarm does not sound at expected temperature

4.6.2.10 Remove sensor from cup and return into RTD holding bracket and enclosure (if applicable)

4.6.2.11 Notify charge technologist if repeated alarm testing fails:

- Contact 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*

4.6.4 Place a completed *Calibration Label* on front of the equipment indicating:

- Date tested
- Initials of technologist performing test
- Next due date

4.7 Plasma Thawer: Quarterly High Temperature Sensor Activation Test

Refer to Operator's Manual instructions to activate high alarm for each make/model of plasma thawer.

- The recommended high temperature activation is a temperature greater than 36.5 °C. Refer to manufacturer's stated specification for alarm set points.
- The alarm must be set at minimum of 0.5 degrees below the high plasma thawing range of 37°C.

4.7.1 Place reference thermometer in centre of 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:

- Digital Controller
- Reference thermometer
- The temperatures should agree within 1°C

4.7.3 Confirm **High Alarm** setting; refer to Operator's Manual

4.7.4 Change operating temperature to 0.5°C above **High Alarm** setting (e.g. if **High Alarm** setting is 36.5°C, change operating temperature to 37.0°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*:

- Digital Controller (Internal Thermometer)
- Reference thermometer
- Temperature readings should agree within 1°C

4.7.6 Verify audible alarm sounds and 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 QC form *Alarm System Check Record: Plasma Thawer*

4.7.8 Repeat test if alarm does not sound at expected temperature

4.7.9 Notify charge technologist if repeated alarm testing fails:

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

4.7.10 Change operating temperature of plasma thawer back to 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 front of the equipment indicating:

- Date tested
- Initials of technologist performing testing
- Next due date

5.0 Reporting

- 5.1** Ensure required documentation is complete on the following QC forms:
- *Daily/Weekly/Monthly Maintenance Checklist: Crossmatch/Non-crossmatch, F160-QCFORM-13/ F160-QCFORM-14*
 - *Quarterly/Semi-annually/ Annual Maintenance Checklist, F160-QCFORM-21*
 - *Daily Temperature and Weekly/Monthly Maintenance Record: Fridge/Freezer/Platelet Incubator/Plasma Thawer*
 - *Alarm System Check Record: Fridge/Freezer/Platelet Incubator/ Plasma Thawer*
 - *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15, if applicable*
 - *Four Hour 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 the following QC forms:
- *Daily Temperature and Weekly/Monthly Maintenance Record: Fridge/Freezer/Platelet Incubator/Plasma Thawer*
 - *Alarm System Check Record: Fridge/Freezer/Platelet Incubator/ Plasma Thawer*
 - *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15, if applicable*
 - *Four Hour Temperature Record: Fridge/Freezer/Platelet Incubator, if applicable*
- 5.3** Retain all completed QC records according to Record Retention Policy. Refer to *Appendix 8 Record Retention, 160-APP-07*.
- 5.4** Retain all completed equipment malfunction and corrective action records according to Record Retention Policy. Refer to *Appendix 8 Record Retention, 160-APP-07*.

6.0 Procedural Notes:

- 6.1** If storage equipment has a mechanism to electronically test 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, temperature change should occur slowly enough so measurements and recording are accurate. Too rapid a change in temperature may give false impression alarm does not sound until an inappropriate temperature is registered.
- 6.3** Alarms should sound simultaneously at site of refrigerator or freezer and at location of remote alarms. If remote alarms are used, alarm check should include a verification alarm sounded at 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:
- If equipment is to be used as backup for another type of product e.g. plasma protein product fridge to be used for backup of blood, ensure alarm will activate at required time for both products.

6.6 Sanyo blood bank fridges

- 6.6.1** If the internal temperature alarm is used, the lower and upper limits are set at 2°C and 6°C, respectively. When testing low and high alarm set points, read and record the temperature from the Reference Thermometer to a whole number.
- 6.6.2** If a separate alarm module is mounted onto the fridge and used as the audible alarm, record the Reference Thermometer to align with the decimal place the temperature of the alarm module is recorded to, i.e. if the separate alarm module reads 1.0°C, record the temperature from the Reference Thermometer to the tenth degree.