

## Document History:

**Title:** Alarm Response Malfunction:  
Blood, Blood Component, Plasma Protein  
Product Storage Equipment and Plasma  
Thawer

**Site(s):** All Shared Health TM Sites

|                    |                                                      |                    |                  |
|--------------------|------------------------------------------------------|--------------------|------------------|
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| <b>Section:</b>    | <b>Shared Health Transfusion<br/>Medicine Manual</b> | <b>Subsection:</b> | <b>QC Module</b> |

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|------------------------------------------|-----------------------------------------------------------------------------------------------------|------------------------|-------------|
| <b>Approved by:</b><br><b>Signature:</b> | Charles Musuka<br> | <b>Date:</b>           | 05-FEB-2019 |
|                                          |                                                                                                     | <b>Effective Date:</b> | 14-MAR-2019 |

### Details of Recent Revision

- Update out of controlled environment from 30 to 60 minutes as per CSA/CSTM standards
- Replaced DSM with Shared Health
- 6.1: expanded criteria for alternate blood bank fridge
- 6.5: included statement to redistribute platelets, if applicable

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**Alarm Response Malfunction:  
Blood, Blood Component, Plasma Protein Product Storage Equipment  
and Plasma Thawer****1.0 Principle**

To outline the procedure used in the event of alarm activation or equipment malfunction

**2.0 Scope and Related Policies**

Refer to QC policy *Storage Equipment Standards: Blood, Blood Components and Derivatives*, 160-QC-02

**3.0 Materials**

QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer*, F160-QCFORM-15

QC form *Four Hour Manual Temperature Record: Fridge Form A/B*, F160-QCFORM-18/19

QC form *Four Hour Manual Temperature Record: Freezer Form A/B*, F160-QCFORM-16/17

QC form *Four Hour Manual Temperature Record: Platelet Incubator*, F160-QCFORM-20

Job Aid *Refrigerator Alarm Response*, JA160-QC-13A

Job Aid *Freezer Alarm Response*, JA160-QC-13B

Job Aid *Platelet Incubator Alarm Response*, JA160-QC-13C

Job Aid *Platelet Agitator Alarm Response*, JA160-QC-13D

**4.0 Procedure**

**Note:** All alarms on storage equipment shall be responded to immediately to ensure corrective action is taken before unacceptable temperatures are reached.

**4.1 Refrigerator Malfunction:****4.1.1** Silence the alarm**4.1.2** Read and record on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer*, F160-QCFORM-15, the following temperatures:

- Continuous Temperature Recording Device (i.e. chart recorder)
- Digital Controller (Internal Thermometer)
- Independent Thermometer

**4.1.3** Determine if temperatures are outside acceptable range:

- Blood and thawed plasma 1 – 6°C
- Derivatives 2 – 8°C (dependent upon manufacturer's instructions)

**Note:** if alarms are responded to immediately, the temperature should still be within the acceptable range

**4.1.4** Temperatures **within** the acceptable range and:

- High alarm was triggered, proceed to 4.1.6
- Low alarm was triggered, proceed to 4.1.7

**4.1.5** Temperatures **outside** acceptable range:

- Determine length of time temperature has been outside acceptable range
- Document on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer*, F160-QCFORM-15

- 4.1.5.1** Temperature outside acceptable range for **less than 60 minutes**:
- High alarm triggered, proceed to 4.1.6
  - Low alarm triggered, proceed to 4.1.7 and:
    - Quarantine all product affected
    - Consult charge/designate **or** BTS Medical Director/TM physician on-call to determine if product can be considered safe dependent upon time out of range and corresponding temperatures
- 4.1.5.2** Temperature outside acceptable range for **greater than 60 minutes**:
- Proceed to Procedural Note 6.2
  - Investigate cause and determine corrective action
- 4.1.6** Temperature indicates the **High Activation** alarm has been triggered, ensure:
- Doors are properly and securely closed
  - Temperature-sensing probe is properly seated in glycerol container
  - Power cord is plugged into the electrical outlet
- 4.1.6.1** Correct the problem and:
- Monitor temperature every 10-15 minutes
  - Record temperature of the refrigerator at 10, 20, 30 and 60 minutes, if necessary
  - If the temperature returns to acceptable limits within 60 minutes record the details on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*
- 4.1.6.2** If the temperature **does not** return to acceptable limits within 60 minutes or the refrigerator appears to be malfunctioning:
- Establish alternate blood bank refrigerator is functioning properly.
  - Remove all product and store in the alternate blood bank refrigerator; record details on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*
  - Refer to Procedural Note 6.1
  - Place sign on malfunctioning refrigerator clearly indicating it is not working and cannot be used to store product
- 4.1.7** Temperature indicates the **Low Activation** alarm has been triggered and the refrigerator appears to be malfunctioning:
- Establish the alternate blood bank refrigerator is functioning properly
  - Remove all products and store them in the alternate blood bank refrigerator; record details on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*
  - Refer to Procedural Note 6.1
  - Place a sign on malfunctioning refrigerator clearly indicating it is not working and cannot be used to store product
- 4.1.8** After the transfer of blood products has been completed, notify the charge technologist and/or maintenance/service.
- 4.1.9** Record the details of the malfunction and the correction action on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*
- 4.1.10** If an alarm sounds on a refrigerator located in a location outside of the blood bank, personnel from those areas shall assess the situation, as outlined above, and notify the blood bank as soon as possible.

## 4.2 Freezer Malfunction

4.2.1 Silence the alarm

4.2.2 Read and record on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*, the following temperatures:

- Continuous Temperature Recording Device (i.e. chart recorder)
- Digital Controller (Internal Thermometer)
- Independent Thermometer

4.2.3 Determine if temperatures are outside of the acceptable range:

- Colder than -18°C

**Note:** If alarms are responded to immediately the temperature should still be within acceptable range.

4.2.4 Temperatures **within** the acceptable range proceed to 4.2.6

4.2.5 Temperatures **outside** the acceptable range:

- Determine length of time temperature has been outside acceptable range
- Document on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*

4.2.5.1 If outside acceptable range for **less than 60 minutes** proceed to 4.2.6.

4.2.5.2 If outside acceptable range for **greater than 60 minutes**:

- Proceed to Procedural Note 6.4
- Investigate cause and determine corrective action

4.2.6 If the temperature indicates the **High Activation** Alarm has been triggered ensure:

- Doors are properly and securely closed
- Temperature-sensing probe is properly seated in the glycerol container (if applicable)
- Power cord is plugged into the electrical outlet

**Note:** Ensure all products are still entirely frozen; if not, proceed to Procedural Note 6.4

4.2.6.1 Correct the problem and:

- Monitor temperature every 10-15 minutes
- Record temperatures on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*
- If the temperature returns to acceptable limits within 60 minutes, record the details on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*

4.2.6.2 If temperature **does not** return to acceptable limits within 60 minutes and freezer appears to be malfunctioning:

- Establish alternate freezer is functioning properly
- Remove all product and store in the alternate freezer; record details on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*
- Refer to Procedural Note 6.3
- Place sign on malfunctioning freezer clearly indicating it is not working and cannot be used to store product

4.2.7 After the transfer of blood products is complete, notify the charge technologist and/or maintenance/service

4.2.8 Record details of the malfunction and the correction action on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*

#### **4.3 Platelet Agitator Malfunction**

- 4.3.1 Silence the alarm
- 4.3.2 Establish the back-up platelet agitator is functioning properly:
  - If no back-up platelet agitator available, refer to Procedural Note 6.5
- 4.3.3 Remove malfunctioning agitator from the platelet incubator and replace with back-up agitator, if applicable
- 4.3.4 Notify the charge technologist and/or maintenance/service
- 4.3.5 Record the details of the malfunction and the correction action on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*

#### **4.4 Platelet Incubator Malfunction**

- 4.4.1 Silence the alarm
- 4.4.2 Read and record on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*, the following temperatures:
  - Continuous Recording Device (i.e. chart recorder),
  - Digital Controller (Internal Thermometer)
  - Independent Thermometer
- 4.4.3 Determine if temperature is outside the acceptable range of 20 - 24°C  
**Note:** If alarms are responded to immediately the temperature should still be within acceptable range
- 4.4.4 Temperature **within** acceptable range, proceed to 4.4.6
- 4.4.5 Temperature **outside** acceptable range:
  - Determine length of time temperature has been outside of acceptable range
  - Document on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*
- 4.4.5.1 If temperature is outside acceptable range for **less than 60 minutes**, proceed to 4.4.6
- 4.4.5.2 If temperature is outside acceptable range for **greater than 60 minutes**:
  - Proceed to Procedural Note 6.6
  - Investigate cause and determine corrective action
- 4.4.6 Temperature indicates high or low alarm has been activated, ensure:
  - Door is properly and securely closed
  - Power switch is turned on
  - Power cord is plugged into the electrical outlet
- 4.4.6.1 Correct the problem and:
  - Monitor the temperature every 10 minutes
  - Record the temperatures on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*
  - If the temperature returns to acceptable limits within 60 minutes record the details on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*
- 4.4.6.2 If the temperature does not return to acceptable limits within 60 minutes and the platelet incubator appears to be malfunctioning:

- Remove the platelets and platelet agitator from the incubator and place on an available counter
- If the room temperature is not monitored with a continuous recording device, record the ambient room temperature every 4 hours on QC form *Four Hour Manual Temperature Record: Platelet Incubator, F160-QCFORM-20*
- Place a sign on the malfunctioning platelet incubator clearly indicating it is not working and cannot be used to store platelets

**4.4.7** After the transfer of platelets has been completed, notify the charge technologist and/or maintenance/service

**4.4.8** Record the details of the malfunction and the correction action on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*

#### **4.5 Plasma Thawer Malfunction:**

**4.5.1** Turn off and unplug the malfunctioning equipment:

- Place a sign on the malfunctioning plasma thawer clearly indicating it is not working and cannot be used to thaw blood components

**4.5.2** Establish an alternate plasma thawer is functioning properly, if available:

- If alternative not available, refer to TL procedure *Thawing and Preparing Frozen Plasma Components for Issue in Trace Line, 160-TL-05*

**4.5.3** Record details of the malfunction and the corrective action on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*

### **5.0 Reporting**

**5.1** Ensure all equipment malfunctions and corrective actions have been:

- Documented on QC form *Equipment Malfunction and Corrective Action Record: Storage Equipment and Plasma Thawer, F160-QCFORM-15*
- Reviewed by the charge technologist/ designate

**5.2** Retain all completed equipment malfunction and correction records according to Record Retention Policy, refer to Appendix 8

### **6.0 Procedural Notes**

**6.1** Alternate blood bank refrigerator is:

**6.1.1 Not equipped with a continuous temperature-recording device:**

- Temperature must be recorded every 4 hours on QC form *Four Hour Manual Temperature Record: Fridge QC Form A/B, F160-QCFORM-18/19*, using a verified thermometer.

**6.1.2 Not available at site:**

- Blood, thawed plasma and plasma protein products (PPP) can be:
  - Packed as per INV procedure *Inter-facility Shipping of Blood, Blood Components and Plasma Protein Products, 160-INV-18*, and stored in validated shipping boxes for up to 24 hours
  - Transported to an alternate Shared Health site
- Notify charge technologist/ designate, BTS Medical Director or designate/TM physician on-call and required site Clinical Practitioner.

- Refer to Shared Health policy *Unscheduled Equipment Downtime Checklist, F100-10-26A*.

**Note:** A domestic or commercial refrigerator may not be used for interim storage.

**Note:** To be used as an interim back-up blood bank fridge to store blood components and blood products, the following must be available:

- Connection to an emergency power supply
- Ability to maintain the appropriate temperature
- Clearly labeled segregated area **or** designated storage container available within the fridge

**6.2** All blood, thawed plasma and PPPs stored in a blood bank refrigerator which has exceeded the acceptable temperature range for more than 60 minutes shall be discarded:

- Document in appropriate blood bank log
- Order replacement product as soon as possible
- Notify the charge technologist /designate and the BTS medical director or designate/TM physician on-call
- Refer to Shared Health policy *Unscheduled Equipment Downtime Checklist, F100-10-26A*
- Investigate cause and determine corrective action

**6.3** An alternate freezer is a laboratory freezer which can maintain a temperature of -18°C or colder

- **If it is not equipped with a continuous temperature recording device:**
  - The temperature must be recorded every 4 hours on QC form *Four Hour Manual Temperature Record: Freezer QC Form A/B, F160-QCFORM-17/18*, using a verified thermometer

**6.4** All frozen blood components stored in a blood bank freezer which has exceeded acceptable temperature range for greater than 60 minutes and been partially or entirely thawed shall be discarded:

- Document in appropriate blood bank log
- Order replacement product as soon as possible
- Notify the charge technologist/ designate and the BTS medical director or designate/TM physician on-call
- Refer to Shared Health policy *Unscheduled Equipment Downtime Checklist, F100-10-26A*
- Investigate cause and determine corrective action

**6.5** Back-up platelet agitator not available:

- Contact clinical unit to determine if platelets can be transfused immediately
- Contact appropriate Shared Health site for redistribution, if applicable
- If unable to transfuse, platelets must be discarded

**6.6** All platelets stored in an area (incubator/bench top) which has exceeded the acceptable temperature range for greater than 60 minutes shall be discarded:

- Document in appropriate blood bank log
- Order replacement product as soon as possible
- Notify the charge technologist/designate and the BTS medical Director or designate/TM physician on-call
- Refer to Shared Health policy *Unscheduled Equipment Downtime Checklist, F100-10-26A*
- Investigate cause and determine corrective action