PROCEDURE
Corewell Health East - Plasma Bath Maintenance and Operation - Blood Bank - Taylor, Trenton, Wayne

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital

Applicability Limited to: N/A

Reference #: 33955

Version #: 2

Effective Date: 12/08/2025

Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

1. **Principle**
   This document will provide instructions on performing the Quality Control (QC) and preventative maintenance of the Helmer DH8 and DH4 Plasma Thawing System.

2. **Responsibility**
   Personnel who have completed the competency requirements will perform these tasks.

3. **Definitions**
   A. **Daily:** on a given calendar date
   B. **Monthly:** within 30 days + 2 days
   C. **Quarterly:** within 3 calendar months + 2 days

4. **Reagent/Equipment Needed**
   A. Helmer DH8 Plasma Thawing System
   B. Helmer DH4 Plasma Thawing System
   C. National Institute Standards and Technology (NIST) Certified Thermometer
   D. Helmer Cleanbath (plasma bath additive)
   E. Cleaning/Sanitizing Product
   F. Distilled or Tap Water
   G. Plastic tubing
   H. Soft brush or vacuum cleaner

5. **Policies**
   A. To keep the Helmer Plasma Thawing systems in optimum performance, preventative maintenance has been developed based on the recommendations found in the Helmer Plasma Thawing System Operation-Service-Maintenance Manual.
   B. The Helmer Plasma Thawing system always remains on and the water at the appropriate temperature to be available for emergency situations when thawed plasma is needed rapidly.

C. Thawing times vary by product type and how the bags are manipulated when frozen (flat or folded). Refer to Operator Manual for more details on specific tawing times.
D. All preventative maintenance shall be documented on site-specific forms.
   1. Trenton campus: *Preventative Maintenance of the Plasma Bath-Trenton, Quarterly Maintenance of the Plasma Bath- Trenton* forms attached to this policy and *Blood Bank Temp Chart* located in the Transfusion Medicine policy, Corewell Health East - Blood Bank Quality Activities - Trenton.
   2. Taylor campus: *Plasma Bath Maintenance- Taylor, Wayne* attached to this policy and the Taylor specific *Temperature Log.*
   3. Wayne campus: *Plasma Bath Maintenance- Taylor, Wayne* form attached to this policy and *34004-02 Temperature Log* form located in the Transfusion Medicine policy, Corewell Health East - Shift Responsibilities in the Blood Bank - Wayne.
E. The Helmer DH8 Plasma Thawing System is the primary unit at Trenton campus and the Helmer DH4 Plasma Thawing System should only be in use in the event Helmer DH8 unit is taken out of service.
F. In the event of a plasma bath that needs to be taken out of service:
   1. Attach *Equipment Out of Service* form to the bath and complete a variance form. Both forms can be found in Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals.
   2. Place a service ticket to the Biomedical Department if a repair/service is required.

6. Procedure

A. Plasma Bath Operation
   1. When thawing plasma or cryoprecipitate of any size, a plasma overwrap bag must be used. The product is placed inside the overwrap bag.
   2. Press the LIFT OUT button to raise the baskets.
      a. Do not manually lift the baskets out of the chamber. Manually lifting baskets will damage the system.
   3. Secure the plasma bag to the basket. When loading multiple bags at once load plasma or cryoprecipitate bags together that require the same thaw time. Place thicker bags in the front-most compartment.
   4. Press the CYCLE TIME button to select a pre-programmed timing system.
   5. Press the CYCLE START button to lower the baskets and stat the thaw cycle.
   6. If at any point you need to pause the thawing process, press the LIFT OUT button to raise the baskets and temporarily pause the thawing cycle. When ready to resume thawing, press the LIFT OUT button to lower into the chamber and the agitation motion will resume.
   7. When the thaw cycle has reached the end of its programmed time, the baskets will stop agitating, lift out, and open. An audible alert sounds to indicate that the thaw cycle has completed and the cycle timer indicator resets to the previously selected time setting.
   8. Unhook the slot at the top of the overwrap bag from the tab on the basket.
   9. Remove the overwrap bag from the basket.
   10. Remove the product from the overwrap bag and discard the overwrap bag.
   11. **Emergency Shutdown**: All plasma bath thawing systems can be stopped by pressing the Power button on the front of the plasma bath or by unplugging the unit.

B. Plasma Bath Maintenance
   1. Daily Quality Control
      a. Each day the temperature of the water bath will be read, and the appearance and level of the water bath will be observed and documented on site-specific temperature charts. See Results section of this procedure for acceptable ranges.
      b. If the temperature is higher than 37°C, then:
         1) The water bath cannot be used until the temperature is appropriately calibrated and is within the acceptable range as described in the procedure section, Calibration of the Temperature Controller, listed below.

2) Attach *Equipment Out of Service* form to the bath and complete a variance form found in Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals.
3) Notify the Laboratory Manager or Lead Medical Technologist.
4) Recheck the temperature later in the day and record the post calibration temperature on the site-specific maintenance form and verify that the temperature is acceptable.

c. Observe the water level of the Helmer plasma bath by observing the slotted lines (= = =) on the inside back wall of the water bath. A satisfactory water level should not exceed the upper slotted line and not drop below the lower slotted line when the baskets are in the lowered position.
1) If the water level is unsatisfactory, add distilled/tap water or drain excess water.

d. Observe the water for contamination, cloudiness, and odor. If appearance is unsatisfactory (cloudy, has an odor, or otherwise appears contaminated) proceed to section Cleaning the Helmer Plasma Bath.

2. Cleaning the Helmer Plasma Bath
a. The water bath shall be cleaned at least weekly.
b. Turn the power to the unit off by pressing the Power button.
c. Place one end of the plastic drain tube into a sink drain or empty receptacle.
d. Attach the other end of the plastic drain tube to the valve on the lower left rear of the unit. Water will begin to drain immediately. Let all the water in the bath drain out.
e. Press the button on the top of the drain plug to disconnect the drain hose.
f. Remove the plasma basket assemblies from the unit by unscrewing the top and lifting them out.
g. Thoroughly clean the interior chamber bath walls, basket assemblies, and the instrument's exterior with soap or mild cleaning agent and water with a soft cloth or sponge.
h. Reattach the basket assemblies.
i. Refill the chamber with distilled or tap water to the lower slotted line such that when the baskets are in the lowered position the water still covers the baskets.
j. Add Helmer Cleanbath (plasma bath additive) to the water in the bath following the manufacturer's instructions.
k. Turn the power on and observe the temperature later in the day to confirm that the temperature returns within the acceptable range.
l. If the temperature does not return to the acceptable range, then the temperature controller must be calibrated using procedure, *Calibration of the Temperature Controller*, found in this procedure.
m. Document the cleaning of the water bath on the site-specific forms.

3. Calibration of the Temperature Controller (Quarterly Preventative Maintenance)
a. Insert a certified thermometer into the chamber water bath and allow the thermometer to stabilize.
b. Record the thermometer reading and the temperature on the unit's temperature controller display on site-specific forms.
c. If the certified thermometer reading and the temperature controller temperature match, no further action is required.
d. If the certified thermometer reading and the temperature controller temperature do not match, then the Temperature Controller needs to be adjusted.
1) Reduce or increase the Temperature Controller to match the certified thermometer reading. Refer to the Helmer Operations manual for more information.
2) Allow the chamber temperature to stabilize after making any calibration changes to the Temperature Controller and take a new reading to verify that the controller is properly calibrated.
3) Continue to adjust until the temperature readout is properly calibrated.
4) Record any adjustments and the final stabilized temperature on site-specific forms.

5) If the temperature controller cannot be calibrated after a reasonable number of adjustments (the certified temperature reading and the temperature of the temperature controller do not match), take the following actions:
   a) Attach *Equipment Out of Service* form to the bath and complete a variance form found in Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals.
   b) Notify the Laboratory Manager or Lead Medical Technologist.
   c) Contact Biomedical if a repair/service is required.

4. Helmer Alarm System Check (Quarterly Preventative Maintenance)
   a. Remove any plasma or cryoprecipitate products from the unit.
   b. Temporarily increase the Set Temperature value at least 0.5°C above the High Alarm set point.
      1) Reference the Helmer Operation Manual for detailed directions in order to adjust the Set Temperature value.
      2) The High Alarm is normally set at 36.9°C, so change the Set Temperature value to 37.5°C. This will allow the unit to raise the temperature of the water beyond acceptable levels for use.
   c. Watch the chamber temperature digital readout until it reaches the High Alarm setting. The following visual and audible alarms should activate:
      1) Audible alarm should sound.
      2) Visual alarm should be displayed (the display should indicate “HI” or “AL”).
      3) Basket assembly should lift out of the chamber.
      4) Digital agitation timers should blink “E1".
   d. If any of the alarms fail to activate then:
      1) Attach *Equipment Out of Service* form to the bath and complete a variance form found in Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals
      2) Notify Laboratory Manager or Lead Medical Technologist.
      3) Contact Biomedical if a repair/service is required.
   e. Reset the chamber Set Temperature to 36°C ± 1°C and allow the chamber temperature to stabilize before using.
   f. Document the alarm checks on site specific forms.
5. Inspection of the Helmer Rail Arm Lubrication (Quarterly Preventative Maintenance)
   a. Remove any plasma or cryoprecipitate products from the bath and raise the basket assembly.
   b. Inspect the Helmer rail arm for lubrication and check the bearings on the baskets for wear.
   c. Indications that lubrication is required are noisy or rough agitation, and markings on the chamber where the bearings contact it.
   d. If the Helmer rail arm or the bearings need service, take the following actions:
      1) Remove the plasma bath out of service.
      2) Attach *Equipment Out of Service* form to the bath and complete a variance form found in Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals
      3) Notify Laboratory Manager or Lead Medical Technologist.
      4) Contact Biomedical for repair/service.
   e. Document the rail arm lubrication on site-specific forms.
6. Cleaning of the Fan (Quarterly Preventative Maintenance on the Helmer DH8 100 V models Only - Trenton)
   a. Turn the power to the unit off by pressing the Power button.
   b. Clean the fan using a soft brush or vacuum cleaner.
   c. Turn the power on and observe the temperature later in the day to confirm that the temperature returns within acceptable range.

1) If the temperature does not return to the acceptable range, then the temperature controller must be calibrated using the procedure*, Calibration of the Temperature Controller*, found in this procedure.

d. Document the cleaning of the fan on the *Quarterly Maintenance of the Plasma Bath* form.

Results

Daily QC	
Temperature of the plasma bath	35°C-37°C
Appearance of the water	Clear, not cloudy, and without an odor or other signs of contamination
Water level	The water level should not exceed the upper slotted line and not drop below the lower slotted line when the baskets are in the lowered position.
Helmer Alarm System Check	
Initial Temperature	35°C-37°C
Temperature increased to	37.5°C
Audible alarm	Should alarm ≥ 36.9°C
Visual alarm	Should alarm ≥ 36.9°C
Basket assembly	Should lift ≥ 36.9°C
Digital timers	Should blink ≥36.9°C
Temperature at which alarms activate	≥ 36.9°C
Temperature reset to 36°C ± 1°C	Yes
Temperature restabilized to 36°C ± 1°C	36°C ± 1°C

7. Limitations

Running consecutive cycles will not damage the unit but will result in slower thawing cycles if the bath water is not allowed to return to the set operating temperature.

8. Revisions

Corewell Health reserves the right to alter, amend, modify, or eliminate this document at any time without prior written notice.

9. Procedures Superseded and Replaced: This procedure supersedes and replaces the following procedures as of the effective date of this procedure: [33999 Corewell Health East- Helmer Water Bath Maintenance- Blood Bank Wayne, Plasma Thawer (Water Bath) Maintenance- Taylor (paper).]

10. References

Helmer Plasma Thawing System Operation-Service-Maintenance Manual, Noblesville, IN 46060.

11. Procedure Development and Approval

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12. Keywords

Not Set