University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA 98195 Transfusion Services Laboratory Policies and Procedures Manual	Original Effective Date: 03-11-2016 Revision Effective Date: 05-23-2022	Number: EQ-0005.02

TITLE: Helmer Plasma Thawer: Operation and Maintenance

PURPOSE:
To provide instructions on how to use the Helmer Quick Thaw plasma thawer to thaw frozen blood components

PRINCIPLE & CLINICAL SIGNIFICANCE:
Plasma and Cryoprecipitate are stored frozen to help maintain factor activity and provide an extended shelf life and must be thawed at 30-37°C in a plasma thawer or other FDA-approved device. Components are placed into plasma overwrap bags prior to thawing in a plasma thawer to prevent contamination of the ports and limit spills in the event of component breakage.

Levels of labile coagulation factor (Factors V and VIII) and stable factors are well above 50% of immediate post-thaw levels in Thawed Plasma stored for up to 5 days. Thawed Plasma contains reduced concentrations of Factor V, VII, and VIII and is not suitable for single-factor replacement when anti-hemophilic factor concentrates are available.

POLICIES:
- Fresh Frozen Plasma and Plasma frozen within 24 hours are converted to Thawed Plasma with a 5 day expiration date limit following thawing

- Maintenance is performed according to the following table:

TASK	FREQUENCY			
	Weekly	Quarterly	Annually	As Needed
Clean the water chamber and baskets	X			X
Clean the fan		X		
Lubricate moving parts		X		
Verify temperature calibration		X		
Test the high temperature alarm		X		
Check bearing for wear and replace if necessary			X	
Clean the exterior				X

- Quarterly and annual maintenance is performed by Scientific Instruments (SI)

SPECIMEN REQUIREMENTS:
NA

REAGENTS/SUPPLIES/EQUIPMENT:

Reagents:	Supplies:	Equipment:
NA	• Helmer Overwrap bag	• Helmer Quick Thaw Plasma thawer • Thermometer

		• NIST Thermometer

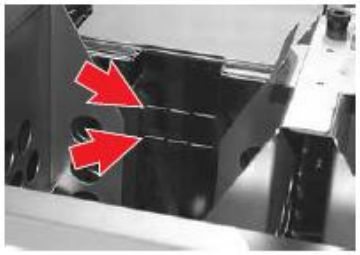
QUALITY CONTROL:
Temperatures are checked and recorded daily on the *Thaw Bath & Heatblock QC* Form

INSTRUCTIONS:

TABLE OF CONTENTS:

Operating Instructions

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td>1</td><td>Remove appropriate unit to be thawed from the freezer</td></tr>
<tr><td>2</td><td>Remove the unit from the packaging and verify the following:
Unit is not expired
Ports are intact
Unit does not contain visible cracks or leaks</td></tr>
<tr><td>3</td><td>Remove the instrument cover and set aside</td></tr>
<tr><td>4</td><td>Verify that the water level in the plasma thawer is filled between the upper and lower fill lines and adjust fill as necessary to maintain products submerged while not overflowing the equipment

NOTE: Do not use deionized water as it may be corrosive to the chamber and baskets
 
Chamber fill lines.</td></tr>
<tr><td>5</td><td>Verify that the temperature is between 30-37°C prior to starting a cycle</td></tr>
<tr><td>6</td><td>Place the frozen product into an overwrap bag</td></tr>
<tr><td>7</td><td>Push the LIFT OUT button  to raise and open the basket(s)</td></tr>
<tr><td>8</td><td>Hang the product in the overwrap bag on the tab on the top of the basket. Make sure to hang both sides of the bag on the tab</td></tr>
<tr><td>9</td><td>Select the approximate thaw time using the following table as a guideline:<table><tr><th>Component</th><th>Median Thaw Time (minutes)</th></tr><tr><td>≈ 10-15 mL cryoprecipitate</td><td>5</td></tr><tr><td>5 unit cryoprecipitate ≈ 250 mL</td><td>8</td></tr><tr><td>≈ 250 mL plasma</td><td>10</td></tr><tr><td>≈ 300 mL plasma</td><td>14</td></tr></table></td></tr>
<tr><td>10</td><td>Set the thaw time based on the above table for each basket by pressing the CYCLE</td></tr>
</table>

	TIME button  until the correct time is shown. (‘HO” means “hold” and the thawing cycle will not end automatically)
11	Press the CYCLE START  button to lower the basket and start the thaw cycle **NOTE:** A thawing process cannot be started if there is an active alarm for the basket. If there is a temperature alarm, it is not possible to start a process on either basket. If there is a lift-out malfunction for one basket arm, the other arm may be used.
12	**If** / **Then** Cycle needs to be paused or stopped → • Press the LIFT OUT button to raise the basket temporarily. • Press LIFT OUT again to resume the thaw cycle
13	Unload the blood product(s) from the basket(s) when the cycle is complete or stopped
14	Remove the product from the overwrap bag and **If** / **Then** Product is leaking → • Discard the unit. Refer to SOP: *Quarantine and Final Disposition of Blood Components* • Update the unit status in the BB LIS accordingly • Notify the blood supplier Unit is not completely thawed → Increase the thaw time on unit as necessary

Weekly Maintenance

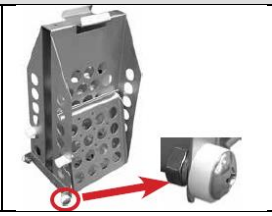
STEP	ACTION
1	Verify the baskets are lowered in the chamber. If not, press LIFT OUT to lower the baskets
2	Switch the power button OFF and disconnect the power cord
3	Drain the plasma thawer • Place the open end of the drain tube in the drain • Push the coupling valve on the other end of the drain tube into the drain port
4	Remove the baskets • Unscrew the finger knobs securing the baskets to the lift-out system • Remove the baskets
5	• Clean the chamber and baskets using a soft cloth and disinfectant cleaner suitable for stainless steel • Rinse with water
6	Remove the drain tube from the drain port

7	Reinstall the baskets with finger knobs to the liftout system
8	Clean the exterior of the plasma thawer using a soft cloth and disinfectant **NOTE:** Clean the vents as needed to maintain airflow and prevent motors from overheating
9	Reconnect the plasma thawer to A/C power and turn the plasma thawer On
10	Refill the plasma thawer with water
11	Record maintenance on the Bench Equipment form

Quarterly Maintenance- Performed by Scientific Instruments (SI)

STEP	ACTION
1	Clean the Fan: • Press the AC ON/OFF button to OFF • Clean the fan using a soft brush and a vacuum cleaner • Press the AC ON/OF button to ON
2	Lubricate moving parts: • Drain thawer and remove baskets according to previous section • Lubricate the lift-out rail with about 3 drops of lightweight oil. Using your finger, spread oil along the length of all 4 sides of each rail • Reinstall baskets and finger knobs, reconnect power and refill thawer with water
3	Compare the temperature controller readout to the NIST calibrated thermometer. If the temperature difference is > ±1°C, recalibrate according to *Calibration* section below
4	Perform high alarm check • Change the plasma thawer setpoint to 37.5°C according to *Plasma Quick Thaw DH8 Service Manual* • Watch the temperature on the display and verify the following occurs with the high alarm setpoint of 37°C is reached: o High Temperature alarm activates o “AL.hi” flashes on the temperature controller o baskets lift out of chambers o “E1” flashes on both cycle time indicators • Change the plasma thawer setpoint back to the original value of 36°C • Allow the temperature to stabilize at the setpoint before use

Annual Maintenance- Performed by Scientific Instruments (SI)

STEP	ACTION	
1	Check bearings on baskets for wear **NOTE:** Signs of worn bearings include noisy or rough agitation, and markings on the chamber walls where the bearings make contact with the chamber	
2	Replace bearings if necessary	

CALCULATIONS/INTERPRETATIONS/RESULTS REPORTING/NORMAL VALUES/CRITICAL VALUES

Results Reporting in Sunquest
Thaw the product prior to capturing the process in Sunquest. Follow the SOP ***Blood Component Processing*** to modify the product code and expiration date/time.

CALIBRATION

STEP	ACTION
1	Verify the Plasma Thawer is turned ON, chamber is filled correctly with water and water is at the required temperature
2	Place the NIST thermometer in the chamber. Do not allow the thermometer to touch the sides or bottom of the chamber
3	Allow the temperature to stabilize for 30 minutes
4	Record temperature displayed on NIST thermometer. Wait 5 minutes, record temperature. Wait another 5 minutes, record temperature
5	Calculate the average temperature using the three values from above
6	Remove the NIST thermometer from the plasma thawer
7	Determine the change in value to reach desired setpoint by subtracting the average temperature from the displayed set point
8	Refer to *Plasma Quick Thaw DH8 Service Manual* for instructions on how to enter the new offset value

PROCEDURE NOTES AND LIMITATIONS:
NA

REFERENCES:
Plasma Quick Thaw DH8 Service Manual
Plasma Quick Thaw DH8 Operation Manual

RELATED DOCUMENTS:
FORM Bench Equipment
SOP Blood Component Processing

ADDENDUM:
NA

UWMC SOP Approval:			
UWMC CLIA Medical Director	Andrew Bryan, MD	Date	
Transfusion Service Manager	Nina Sen	Date	
QA Manager	Tayler Reeves	Date	
Transfusion Service Medical Director	Monica Pagano, MD	Date	
UWMC Biennial Review:			
		Date	
		Date	

05/02/2022: Updated to reflect maintenance performed by SI