TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	8.28.2014
Department:	Blood Bank	**Due Date:**	ASAP

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Plasma Thawer (Helmer DH8)

Description of change(s):

1. New procedure and form were immediately released due to equipment failure of the old plasma thawer and emergency replacement of equipment.

2. WAH staff members will be trained on routine use as well as daily, weekly, monthly, and quarterly maintenance. A separate training document is required.

3. SGAH staff members will read the procedure and take the quiz for understanding of how to operate the plasma thawer.

Non-Technical SOP

Title	**Plasma Thawer (Helmer DH8)**	
Prepared by	Stephanie Codina	Date: 8.20.2014
Owner	Stephanie Codina	Date: 8.20.2014

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

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1. PURPOSE

Frozen plasma and cryoprecipitate products are thawed at temperatures between 30-37°C in an FDA-approved device. This procedure outlines the use, preventive maintenance, and quality control activities for the Helmer DH8 plasma thawer.

2. SCOPE

This procedure applies to the Helmer DH8 plasma thawer.

3. RESPONSIBILITY

All blood bank staff members must understand and adhere to this procedure for thawing plasma and cryoprecipitate products and performing maintenance and quality control on the plasma thawer.

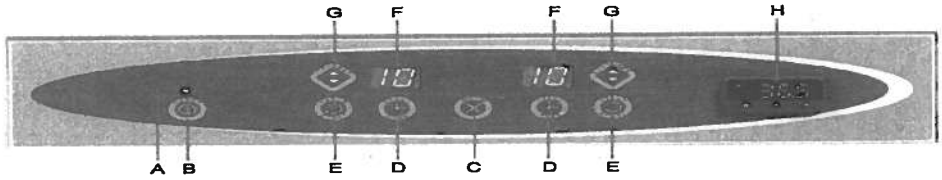
4. DEFINITIONS

N/A

5. PROCEDURE

General Operation

Step	Action
1	The Helmer DH8 plasma thawer has the ability to thaw 8 blood products at one time. The unit contains two baskets which each hold 4 products. The control panel contains the following:



Label	Description
A	Power indicator LED
B	POWER button
C	MUTE button
D	CYCLE TIME button

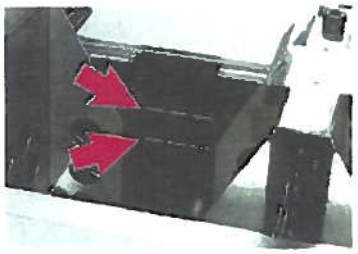
Label	Description
E	CYCLE START button
F	Cycle time indicator
G	LIFT OUT button
H	Temperature controller

Step	Action
2	Place each blood product to be thawed in a plasma overwrap bag. NEVER thaw without using a plastic overwrap! The overwrap bag: A. Secures the blood product to the basket. B. Protects the blood product from water-borne contaminants. C. Contains any product from contaminating the waterbath if the product bag breaks during thaw.
3	On the control panel, press the "Lift Out" button to raise and open the basket. DO NOT manually lift the baskets out of the chamber as this may damage the equipment.  *LIFT OUT button.*
4	Place the overwrapped plasma bag in the basket. Hook the slot at the top of the overwrap bag over the tab of the basket. A. When thawing more than one unit, place the thicker unit (unit with greater volume) in the front-most compartment(s). B. For small units that float, use security snaps to help keep the blood product in place. a. Insert the security snap through the top set of holes on the basket compartment. b. Push the snap toward the basket until it snaps against the overwrap bag.  C. For large overwrap bags, ensure both slots are hooked over the tabs. D. For jumbo units, remove the basket divider by squeezing the sides of the divider together then pulling the divider away from the basket.  *Removing divider from DH8 basket.*

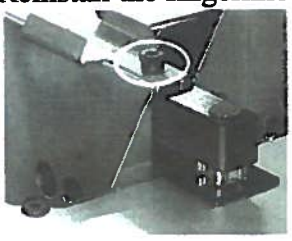
Step	Action
5	Press the "Cycle Time" button until the correct thaw time is displayed. Recommended thaw times are as follows: A. Pooled cryoprecipitate = 10 minutes B. Standard plasma bag (~250 mL) = 10 minutes C. Large plasma bag (~300 mL) = 14 minutes D. Jumbo plasma bag (~500mL) = 18 minutes E. The hold "HO" setting will continue the thaw cycle indefinitely. 
6	Press the "Cycle Start" button to start the thaw. A. The thaw cycle will not start if the plasma thawer is in alarm. B. Press the "Lift Out" button to stop a thaw cycle before completion.  Do not use the chamber cover while a thaw cycle is in progress. The lift-out system raises baskets when the thaw cycle is complete. Use of the cover during thaw may damage the lift-out system.
7	Ensure the blood product is completely thawed at the end of the cycle. Run the blood product through a shorter (~3 min or more) thaw cycle if not completely thawed.
8	Remove the blood product(s) once the thaw is complete. A. Remove the security snap from the basket(s), if applicable. B. Unhook the slot at the top of the overwrap bag from the tab on the basket. C. Remove the overwrap bag from the basket. D. Remove the blood product from the overwrap bag. E. Discard the overwrap bag.

Daily Maintenance

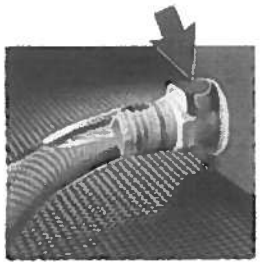
Step	Action
1	Read and record the temperature of the waterbath. A. Read and record the temperature of the upper, digital thermometer (DT1). B. Read and record the temperature of the lower, thawer display. C. Ensure that both temperatures are between 30-37°C. D. Ensure that both temperatures are within 2°C of each other.

Step	Action
2	Clean the exterior with water and a mild cleaning agent. Disinfect using a mild disinfectant solution.
3	Clean the vents as needed to maintain airflow and prevent the motors from overheating.
4	Ensure the water is at an appropriate level. A. The water level should be between the two marks located on the back of the thawer, between the baskets. B. Add water as needed to maintain an appropriate level.  *Chamber fill lines.*

Weekly Maintenance

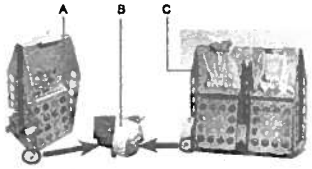
Step	Action
1	Clean the baskets. A. Confirm that the baskets have been lowered into the chamber. Lower baskets as necessary by pressing the "Lift Out" button. B. Remove the baskets. a. Unscrew the finger knobs securing the basket(s) to the lift-out system. b. Remove the basket(s) from the lift-out system. C. Remove the 2 V-shaped brackets from the rear wall of the chamber. D. Using a soft cloth and disinfectant cleaner suitable for stainless steel, thoroughly clean the baskets and brackets. If stains or discoloration remain after general cleaning, use a stain, scale, or rust remover suitable for stainless steel. E. Reinstall the V-shaped brackets. F. Reinstall the baskets. G. Reinstall the fingerknob to attach each basket to the lift-out system. 

Monthly Maintenance

Step	Action
1	Clean the chamber and change water. A. Drain the water from the chamber. a. Turn the power to the plasma thawer off and remove the power cord from AC power. b. Insert the end of the drain tube into the sink. c. Connect the drain line to the plasma thawer by inserting the drain coupling into the drain port on the side of the plasma thawer.  d. Allow all of the water to empty from the chamber. e. Disconnect the drain line. B. Remove and clean the baskets per weekly maintenance above. C. Thoroughly clean the chamber walls using a soft cloth and a disinfectant cleaner suitable for stainless steel. If stains or discoloration remain after general cleaning, use a stain, scale, or rust remover suitable for stainless steel. D. Reinstall the baskets. E. Refill the plasma thawer using tap or distilled water. DO NOT use deionized water as it may be corrosive to the chamber and baskets. F. Add 3mL of "CleanBath" to the water. G. Plug the power cord into AC power and turn the plasma thawer on.

Quarterly Maintenance

Step	Action
1	Clean the fan. A. Turn the power to the plasma thawer off. B. Clean the fan using a soft brush or vacuum cleaner. C. Turn the power to the plasma thawer on.

Step	Action
2	Check the bearings on the basket for wear and replace as needed. A. Visually inspect the bearings for wear. B. Replace bearings if wear is noted. C. Signs of worn bearings include noisy or rough agitation and markings on the chamber walls where the bearings make contact with the chamber.  *Basket and lift out system parts.*
3	Lubricate lift-out rail. A. This step should be completed in conjunction with monthly maintenance when the chamber is drained and the baskets have been removed. B. Place a maximum of 3 drops of lightweight oil on your finger. C. Spread the oil along all sides of each lift-out rail.
4	Verify temperature calibration. A. Attach the NIST-traceable thermometer to the DT1 temperature probe in the back, right-hand corner of the thawer. a. The thermometer may be attached with rubber bands. b. Ensure the thermometer and probe are at approximately the same depth of water to obtain accurate readings. B. Allow the temperatures to stabilize. C. Read and record the temperatures of the following: a. NIST-traceable thermometer b. DT1 digital thermometer (upper thermometer) c. Plasma thawer temperature controller display (lower thermometer) D. The temperatures should all agree within $\pm 1^{\circ}C$. Calibrate the thermometers and repeat calibration if outside of acceptable range. Refer to the Service Manual for calibration instructions.
5	Calibrate each of the timers (left and right basket) per laboratory procedure. A. Timers for each basket should be calibrated at 3 minutes and 20 minutes. B. The acceptable range is $\pm 5\%$. a. Acceptable range for 3-minute setting = 2 min 51 sec to 3 min 9 sec. b. Acceptable range for 20-minute setting = 19 min to 21 min

Step	Action
6	Test the high temperature alarm  *Temperature controller display.* A. Verify the temperature display has been calibrated (step 3). B. Identify the current setting for the plasma thawer setpoint. a. Press the asterisk "*" button. b. Review the temperature that appears. c. The manufacturer's setpoint is 36.5°C. C. Change the thawer setpoint. a. Press and hold the asterisk "*" button. b. Press the up "▲" button to increase the setpoint to 37.5°C. c. Release all buttons. The new setpoint will save. D. Observe the chamber temperature reading on the temperature controller. The displayed temperature will increase slowly. E. The high alarm will activate when the displayed temperature reaches the high alarm setpoint of 37.0°C. a. An audible alarm will sound. b. "AL.hi" will flash on the temperature controller. c. The baskets will lift out of the chamber. d. "E1" will flash on the cycle time indicators (both). F. Document the temperature at which the alarm sounded. The acceptable range is ≤37°C. G. Change the plasma thawer setpoint back to the original value. a. Press and hold the asterisk "*" button. b. Press the down "▼" button to decrease the setpoint to the original value. c. Release all buttons. The new setpoint will save. H. Allow the temperature to stabilize at the setpoint before using to thaw blood products.

6. RELATED DOCUMENTS

SOP: Plasma for Transfusion
SOP: Cryoprecipitate for Transfusion
SOP: Thermometer Calibration and Installation
SOP: Timer Accuracy Check
Form: Helmer DH8 Plasma Thawer Maintenance Log (AG.F305)

7. REFERENCES

A. Plasma Thawing System Service Manual, 360097-1/I. Helmer Scientific. Noblesville, IN.
B. Plasma Thawing System Operation Manual, 360094-1/M. Helmer Scientific. Noblesville, IN.
C. Digital Thermometer Manual, DT1, Version B. Helmer Scientific. Noblesville, IN.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

9. ADDENDA AND APPENDICES

None

Diagnostics

Helmer DH8 Plasma Thawer Maintenance Log

Month/Year:

Daily	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Temperature of DT1 (upper)																															
Upper Temp within 30-37°C range? Y or N																															
Temperature of Plasma Thawer (lower)																															
Upper Temp within 30-37°C range? Y or N																															
Upper and Lower Temps Within 2°C? Y or N																															
Water Level Adequate? Y or N																															
Vents Free of Debris? Y or N																															
Exterior Clean? Y or N																															
Tech Initials																															

Weekly	Week 1	Week 2	Week 3	Week 4	Week 5
Clean Baskets	Date: Tech:	Date: Tech:	Date: Tech:	Date: Tech:	Date:

Monthly	Date Completed	Tech
Clean Chamber		
Change Water		
Add 3mL Cleanbath		

Quarterly Maintenance

Temperature Calibration		Temp Within 1°C of NIST-Traceable Thermometer? Y or N
SN of NIST-Traceable Thermometer		
Temperature of NIST-Traceable Thermometer		
Temperature of DT1 (Upper) Thermometer		
Temperature of Thawer (Lower) Thermometer		
Completed By	Date:	Tech:

Timer Calibration		
Stop Watch Serial Number		
Stop Watch Timed Against Telephone (60s)		(Must be 60s)
Setting 1: 20 min	Left Side	Right Side
Stopwatch Time		
Within Acceptable Range of 19-21"? Y or N		
Setting 2: 3 min		
Stopwatch Time		
Within Acceptable Range of 2'51" - 3'9"? Y or N		
Completed By	Date:	Tech:

○ Check (√) if quarterly maintenance not due in current month

Miscellaneous	Date	Tech
Clean Fan		
Check Basket Bearings; Replace As Needed		
Lubricate Lift-Out Rail		

High Alarm Check	Result	Date	Tech
Alarm Activation Temperature			
Alarm Activates ≤37.0°C? Y or N			

Reviewed by/date: _____