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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
<i>Refer to the electronic signature page for approval and approval dates.</i>		
Local Issue Date:		Local Effective Date:

Review:		
Print Name	Signature	Date

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Document: WAH.BB883 [0] Status: RELEASED, Effective: 9/16/2014, Check Version Before Use

TABLE OF CONTENTS

1. PURPOSE..... 2
 2. SCOPE..... 2
 3. RESPONSIBILITY..... 2
 4. DEFINITIONS..... 2
 5. PROCEDURE..... 2
 6. RELATED DOCUMENTS 8
 7. REFERENCES 9
 8. REVISION HISTORY..... 9
 9. ADDENDA AND APPENDICES..... 9

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

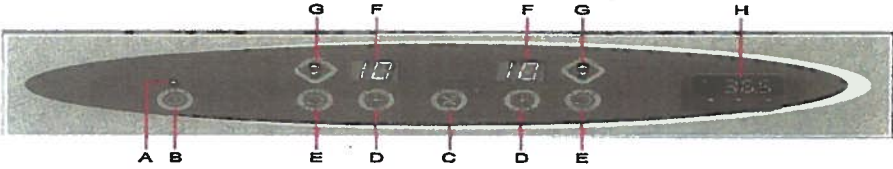
All blood bank staff members must understand and adhere to this procedure for thawing plasma and cryoprecipitate products and performing maintenance and quality control on the plasma thawer.

4. DEFINITIONS

N/A




5. PROCEDURE

General Operation

Step	Action																				
1	<p>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:</p>  <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Label</th> <th>Description</th> <th>Label</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>Power Indicator LED</td> <td>E</td> <td>CYCLE START button</td> </tr> <tr> <td>B</td> <td>POWER button</td> <td>F</td> <td>Cycle time Indicator</td> </tr> <tr> <td>C</td> <td>MUTE button</td> <td>G</td> <td>LIFT OUT button</td> </tr> <tr> <td>D</td> <td>CYCLE TIME button</td> <td>H</td> <td>Temperature controller</td> </tr> </tbody> </table>	Label	Description	Label	Description	A	Power Indicator LED	E	CYCLE START button	B	POWER button	F	Cycle time Indicator	C	MUTE button	G	LIFT OUT button	D	CYCLE TIME button	H	Temperature controller
Label	Description	Label	Description																		
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Form revised 3.3.100

Document: WAH.BB883[0] Status: RELEASED, Effective: 9/16/2014, Check Version Before Use

Step	Action
2	<p>Place each blood product to be thawed in a plasma overwrap bag. NEVER thaw without using a plastic overwrap! The overwrap bag:</p> <ul style="list-style-type: none"> 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	<p>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.</p> <div style="text-align: center;">  <p>LIFT OUT button.</p> </div>
4	<p>Place the overwrapped plasma bag in the basket. Hook the slot at the top of the overwrap bag over the tab of the basket.</p> <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> 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. <div style="text-align: center;">  </div> <ul style="list-style-type: none"> 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. <div style="text-align: center;">  <p>Removing divider from DH8 basket.</p> </div>

Form rev/sd 3.1/00

Document: WAH.BB883[0] Status: RELEASED, Effective: 9/16/2014, Check Version Before Use

Step	Action
5	<p>Press the "Cycle Time" button until the correct thaw time is displayed. Recommended thaw times are as follows:</p> <ul style="list-style-type: none"> 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	<p>Press the "Cycle Start" button to start the thaw.</p> <ul style="list-style-type: none"> 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.  <p>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.</p>
7	<p>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.</p>
8	<p>Remove the blood product(s) once the thaw is complete.</p> <ul style="list-style-type: none"> 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	<p>Read and record the temperature of the waterbath.</p> <ul style="list-style-type: none"> 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.

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Document: WAH.BB883 [0] Status: RELEASED, Effective: 9/16/2014, Check Version Before Use

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	<p>Ensure the water is at an appropriate level.</p> <p>A. The water level should be between the two marks located on the back of the thawer, between the baskets.</p> <p>B. Add water as needed to maintain an appropriate level.</p> <div data-bbox="599 632 935 869" data-label="Image"> </div> <p data-bbox="602 884 805 911"><i>Chamber fill lines.</i></p>


Weekly Maintenance

Step	Action
1	<p>Clean the baskets.</p> <p>A. Confirm that the baskets have been lowered into the chamber. Lower baskets as necessary by pressing the “Lift Out” button.</p> <p>B. Remove the baskets.</p> <p style="padding-left: 20px;">a. Unscrew the finger knobs securing the basket(s) to the lift-out system.</p> <p style="padding-left: 20px;">b. Remove the basket(s) from the lift-out system.</p> <p>C. Remove the 2 V-shaped brackets from the rear wall of the chamber.</p> <p>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.</p> <p>E. Reinstall the V-shaped brackets.</p> <p>F. Reinstall the baskets.</p> <p>G. Reinstall the fingerknob to attach each basket to the lift-out system.</p> <div data-bbox="558 1635 834 1850" data-label="Image"> </div>

Form revised 3/31/00

Document: WAH.BB883[0] Status:RELEASED,Effective:9/16/2014, Check Version Before Use

Monthly Maintenance

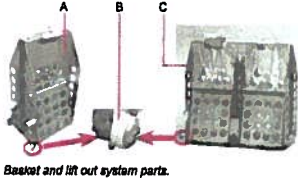
Step	Action
1	<p>Clean the chamber and change water.</p> <p>A. Drain the water from the chamber.</p> <ol style="list-style-type: none"> a. Turn the power to the plasma thawer off and remove the power cord from AC power. b. Insert the end of the drain tube into the sink. c. Connect the drain line to the plasma thawer by inserting the drain coupling into the drain port on the side of the plasma thawer.  <ol style="list-style-type: none"> d. Allow all of the water to empty from the chamber. e. Disconnect the drain line. <p>B. Remove and clean the baskets per weekly maintenance above.</p> <p>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.</p> <p>D. Reinstall the baskets.</p> <p>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.</p> <p>F. Add 3mL of “CleanBath” to the water.</p> <p>G. Plug the power cord into AC power and turn the plasma thawer on.</p>

Quarterly Maintenance

Step	Action
1	<p>Clean the fan.</p> <ol style="list-style-type: none"> 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.


Form rev:Jan 13/1000

Document: WAH.BB883[0] Status: RELEASED, Effective: 9/16/2014, Check Version Before Use

Step	Action
2	<p>Check the bearings on the basket for wear and replace as needed.</p> <ul style="list-style-type: none"> 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.  <p style="text-align: center; font-size: small;">Basket and lift out system parts.</p>
3	<p>Lubricate lift-out rail.</p> <ul style="list-style-type: none"> 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	<p>Verify temperature calibration.</p> <ul style="list-style-type: none"> A. Attach the NIST-traceable thermometer to the DT1 temperature probe in the back, right-hand corner of the thawer. <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 $\pm 1^{\circ}\text{C}$. Calibrate the thermometers and repeat calibration if outside of acceptable range. Refer to the Service Manual for calibration instructions.
5	<p>Calibrate each of the timers (left and right basket) per laboratory procedure.</p> <ul style="list-style-type: none"> A. Timers for each basket should be calibrated at 3 minutes and 20 minutes. B. The acceptable range is $\pm 5\%$. <ul style="list-style-type: none"> 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

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Document: WAH.BB883[0] Status: RELEASED, Effective: 9/16/2014, Check Version Before Use

Step	Action
6	<p data-bbox="467 268 860 300">Test the high temperature alarm</p> <div data-bbox="576 317 776 428" style="text-align: center;">  <p data-bbox="576 436 784 457"><i>Temperature controller display.</i></p> </div> <ul style="list-style-type: none"> <li data-bbox="511 474 1287 506">A. Verify the temperature display has been calibrated (step 3). <li data-bbox="511 510 1274 541">B. Identify the current setting for the plasma thawer setpoint. <ul style="list-style-type: none"> <li data-bbox="605 546 1008 577">a. Press the asterisk "*" button. <li data-bbox="605 581 1105 613">b. Review the temperature that appears. <li data-bbox="605 617 1125 648">c. The manufacturer's setpoint is 36.5°C. <li data-bbox="511 653 902 684">C. Change the thawer setpoint. <ul style="list-style-type: none"> <li data-bbox="605 688 1122 720">a. Press and hold the asterisk "*" button. <li data-bbox="605 724 1372 756">b. Press the up "▲" button to increase the setpoint to 37.5°C. <li data-bbox="605 760 1240 791">c. Release all buttons. The new setpoint will save. <li data-bbox="511 795 1312 863">D. Observe the chamber temperature reading on the temperature controller. The displayed temperature will increase slowly. <li data-bbox="511 867 1403 934">E. The high alarm will activate when the displayed temperature reaches the high alarm setpoint of 37.0°C. <ul style="list-style-type: none"> <li data-bbox="605 938 1008 970">a. An audible alarm will sound. <li data-bbox="605 974 1243 1005">b. "AL.hi" will flash on the temperature controller. <li data-bbox="605 1010 1138 1041">c. The baskets will lift out of the chamber. <li data-bbox="605 1045 1271 1077">d. "E1" will flash on the cycle time indicators (both). <li data-bbox="511 1081 1300 1148">F. Document the temperature at which the alarm sounded. The acceptable range is ≤37°C. <li data-bbox="511 1152 1312 1184">G. Change the plasma thawer setpoint back to the original value. <ul style="list-style-type: none"> <li data-bbox="605 1188 1117 1220">a. Press and hold the asterisk "*" button. <li data-bbox="605 1224 1357 1291">b. Press the down "▼" button to decrease the setpoint to the original value. <li data-bbox="605 1295 1240 1327">c. Release all buttons. The new setpoint will save. <li data-bbox="511 1331 1412 1398">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)

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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

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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: _____ Tech: _____

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
Stopwatch Time	Right Side
Within Acceptable Range of 19-21"? Y or N	
Setting 2: 3 min	
Stopwatch Time	
Within Acceptable Range of 25" - 39"? Y or N	
Completed By	Date: _____ Tech: _____

Check (v) 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: _____