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-0007.02
TITLE: **Genesis Sterile Welder Operation and Maintenance**		

PURPOSE:
To provide instructions for:
- Sterile connecting PVC blood tubing
- Monthly cleaning of the Rapidweld STW GRW-430

PRINCIPLE & CLINICAL SIGNIFICANCE:
Principal
The GENESIS RAPIDWELD™ STW provides sterile connection technology for the purpose of connecting sterile blood product containers without opening the system and compromising the sterility of the contained fluids.

Clinical Significance
Use of a sterile connecting device allows the blood processing system to remain functionally closed preventing bacterial contamination of the blood and preserving component outdate. Any blood product exposed to a leaking weld is considered contaminated and discarded or processed as an open system with any applicable outdate limits applied as appropriate.

POLICIES:
- When more than one weld is made during processing of the same component, the first weld is documented in Sunquest and subsequent weld(s) shall be documented on the *Downtime Blood Component Prep Log* – refer to SOP *Blood Component Preparation*

- Maintenance:
    - Cleaning of the sterile welder is performed monthly and as needed

SPECIMEN REQUIREMENTS:
NA

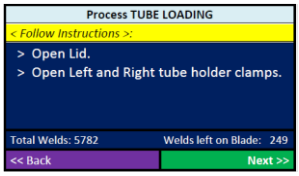
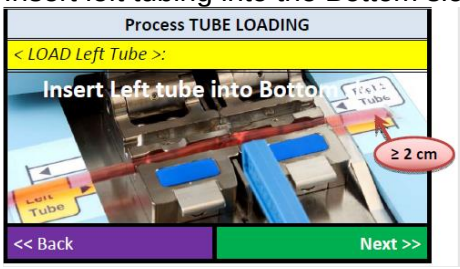
REAGENTS/SUPPLIES/EQUIPMENT:
Reagents:	Supplies:	Equipment:
N/A	• Hemostats • 70% isopropyl alcohol • Paper towel or soft cloth	• Genesis Rapidweld STW GRW-430

QUALITY CONTROL:
Each connection is visually inspected for integrity and leaks at the time of welding and acceptability documented in the LIS

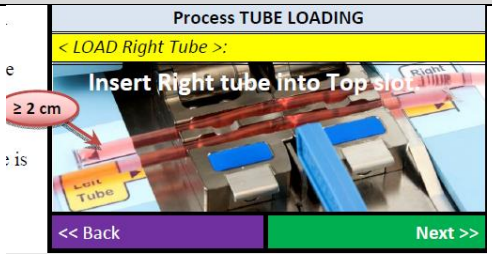
INSTRUCTIONS:

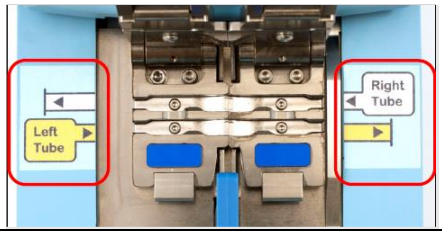
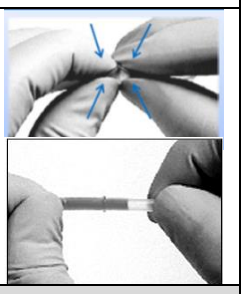
TABLE OF CONTENTS:

Welding Tubing

<table>
<tr><th>STEP</th><th colspan="2">ACTION</th></tr>
<tr><td rowspan="3">1</td><td>If welder is powered</td><td>Then</td></tr>
<tr><td>On</td><td>Go to next step</td></tr>
<tr><td>Off</td><td>• Press the Power Button to power on and perform the self-check
• Acknowledge all safety requirements displayed during the heater warm up by pressing <OK> on the touch screen
 
</td></tr>
<tr><td>2</td><td colspan="2">Verify there are enough welds left on the blade to complete the required number of welds</td></tr>
<tr><td>3</td><td colspan="2">Press <START Welding> on the Main Menu touch screen</td></tr>
<tr><td>4</td><td colspan="2">Follow the instructions on the display screen:
• Open lid
• Open Left and Right tube holder clamps
• Press <Next>
 
</td></tr>
<tr><td>5</td><td colspan="2">Load the tubing following instructions as they appear on the display screen:
• Insert left tubing into the Bottom slot
 

NOTE: Allow at least ¾” (2 cm) of tubing to overhang outside of the clamps. Place tubing in the slots according to the labels located on the sides of the tube holder clamps as shown in the figure above
• Press <Next>
• Insert right tubing into the Top slot</td></tr>
</table>

<table>
<tr><th>STEP</th><th>ACTION</th></tr>
<tr><td></td><td> 

Press <Next>
NOTE: Tubing must be loaded according to labels located on the sides of the tube holder

</td></tr>
<tr><td>6</td><td>Close and latch the tube holder clamps</td></tr>
<tr><td>7</td><td>Close the lid</td></tr>
<tr><td>8</td><td>Press <WELD> to start the process</td></tr>
<tr><td>9</td><td>Open lid when the lid case unlocks, and the screen displays “Process Tube Unloading”</td></tr>
<tr><td>10</td><td>Remove tubing and discard stubs</td></tr>
<tr><td>11</td><td>Inspect weld and establish fluid pathway
Examine the weld for leaks by visual inspection of the weld area
Open the weld by squeezing the flared edges of the weld between your thumbs and forefingers and slightly rolling it to restore the original tubular shape
Squeeze the contents just past the weld to verify tubing is open and gently pull on the tubing
 </td></tr>
<tr><td>12</td><td>
<table>
<tr><th>If tubing</th><th>Then weld</th></tr>
<tr><td>Does not leak</td><td>Passes inspection
Continue with component processing</td></tr>
<tr><td>Leaks</td><td>Fails inspection
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Able to repeat weld</td><td>Continue processing the unit as an open system
Update expiration date/times for all involved components to an open system expiration</td></tr>
</table></td></tr>
</table></td></tr>
</table>

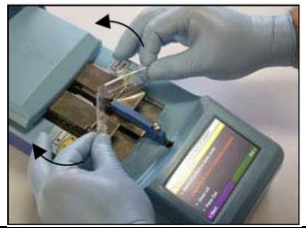
STEP	ACTION			
				• Obtain approval for use from the TSL MD on-call to issue and document approval if given
			Unable to repeat weld	• Discontinue processing, discard product and document waste and reason for waste on a QI • Obtain a new component for processing and start over
13	Press <Next> then <Reset>			
14	Lower clamps and close lid. Device will automatically power off			

Cleaning Welder

STEP	ACTION	
1	Turn device off	
2	**If cleaning is**	**Then**
	Routine	• Use a 70% isopropyl alcohol wipe or cotton tipped applicator dampened with 70% isopropyl alcohol to wipe and disinfect the surface area of the device **NOTE**: The operator should not use solvents or abrasives to clean the device. Never submerge in liquid • Go to next step
	Because of spillage into the device	• Discontinue operation • Notify a lead or manager
3	Allow the unit to air dry before use	
4	Document the following on the *Bench Equipment Maintenance* form: • Date of cleaning • Tech ID	

Blade Module Replacement

STEP	ACTION
1	Select “Options” on Main Menu
2	Select “Change Blade” to reposition clamps allowing for blade replacement
3	Place protective blade cover over used blade module and close plastic snaps **NOTE:** If reinstalling the same blade module, the protective blade cover is not required 
4	Press <Next>

STEP	ACTION
5	Turn thumb screw counterclockwise to loosen
6	Pull blade module vertically out from the mounting base and discard into a sharps container
7	Remove new blade from package **NOTE:** Do not remove protective cover until blade module is fully installed
8	Align new Blade Module with mounting base and push blade module down until it stops moving and is fully seated in place
9	Turn thumb screw clockwise to tighten and lock blade module in place
10	Press <Next>
11	Remove protective blade cover by pulling wing tabs apart 
12	Ensure thumb screw is tightened completely
13	Close lid and press <Exit> to return to MAIN MENU
14	Check to see the welds left number is now 500 if installing a new blade

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

Interpretation
Results of weld inspections are recorded as PASS or FAIL in the LIS according to the table below

If weld	Interpretation
Leaks	FAIL
Does NOT Leak	PASS

Results Reporting in Sunquest
See SOP Blood Component Preparation in Sunquest for instructions on how to enter weld in LIS

CALIBRATION:
NA

PROCEDURE NOTES AND LIMITATIONS:

- Only standard, blood bank size, medical PVC tubing of the following specification may be welded and must be long enough to allow welding to take place without restriction. The manufacturer recommends ≥5.5 inches
    - Outer Diameter (OD) – 3.95 mm to 4.55 mm
    - Inner Diameter (ID) – 2.8 mm to 3.1mm
    - Wall Thickness (WT) – 0.55 mm to 0.85 mm

- **WARNING:** Precautionary measures are required if the welder fails to complete a weld cycle. The tubing will likely be cut but NOT SEALED if the device failed to reach the heating position.

- In the event of a stalled motor, the device will attempt to move the tube holders back to the Unload position to allow removal of the tubing. Before releasing the tubing holder clamps, it is recommended that hemostats or other appropriate tube clamps be used near the tube holders to reduce spillage.

- Stub ends are heat sealed but the seal is not strong. Reseal the end using a tube sealer if a stronger seal is required. Excessive pulling, bending or abusive handling of the welded tubing could result in a leak.

- Exposure of welded tubing to solvents or excessive stress such as heat or cold could compromise the integrity of the weld

- Tubing must be placed in the slots according to the labels located on the sides of the tube holder clamps. This ensures Top Right main line is welded to the Bottom Left main line. Reversed tubing loading will result in heat sealed stub ends, but the main lines will not be welded together.

- A 5.5 inch (14cm) or greater length of tubing is recommended for welding to take place without restriction

- The **GENESIS RAPIDWELD™ STW** will enter a reduced power “Heater Standby” mode if left idle for five (5) minutes. To conserve energy, the device will enter a sleep mode where the heaters and fan will turn off after thirty (30) minutes of inactivity. The welding process can be resumed by simply touching the display screen and waiting for the heaters to go through a 30 to 45 second warm up cycle. It will shut down automatically after six (6) hours of inactivity.

REFERENCES:

The Genesis Rapidweld STW Model: GRW-430 Operator’s Manual, Printed 4/2015
Standards for Blood Banks and Transfusion Services. Bethesda, MD; AABB, current edition

RELATED DOCUMENTS:

FORM *Bench Equipment Maintenance* form
FORM *Downtime Blood Component Prep Log*
SOP *Blood Component Preparation*

APPENDIX:

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	

07/14/2021: Added policies for documenting all welds and to specify monthly cleaning. Added instructions for documenting cleaning on the *Bench Equipment Cleaning* form. Added manufacturer name to SOP title.