University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA 98195 Transfusion Services Laboratory Policies and Procedures Manual	Original Effective Date: 12/15/21 Revision Effective Date:	Number: EQ-0016.01

TITLE: Terumo TSCD II Sterile Welder Operation and Maintenance

PURPOSE:
To provide instructions for:
- Sterile connecting PVC blood tubing
- Maintenance for the TSCD II Sterile Tubing Welder

PRINCIPLE & CLINICAL SIGNIFICANCE:
Principal
The TSCD II Sterile Tubing Welder 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
Maintenance
- At 80,000 welds; the left clamp manufacturer Terumo BCT must be contacted to determine if the left clamp unit on device needs to be replaced
- Waste disposal box must be emptied when device LCD displays indicates "**DISPOSAL BOX FULL**". TSCD II will not operate if disposal box is not emptied. See Section: *Cleaning Welder-Monthly and as needed* on how to empty wafer disposal box
- Sterile Welder will be sent to manufacturer for annual preventative maintenance

SPECIMEN REQUIREMENTS:
NA

REAGENTS/SUPPLIES/EQUIPMENT:
Reagents:	Supplies:	Equipment:
N/A	• Hemostats • 70% isopropyl alcohol • Paper towel or soft cloth	• TSCD II Sterile Welder

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

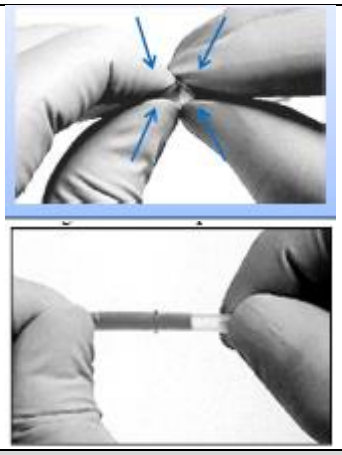
INSTRUCTIONS:

TABLE OF CONTENTS:

Welding Tubing

STEP	ACTION	
1	**If the welder is powered**	**Then**
	On	Go to next step
	Off	Press the Power switch at the back of the device to power on **Note:** It may take up to 3 minutes for device to be ready
2	Verify there are wafers in the wafer cassette for the weld. Press <RESET> button Refer to *Section: Wafer Cassette Replacement* on loading new cassette of wafers	
3	Open clamp covers	
4	Place tubing in clamps • Place dry tubing in the rear clamp slot • Place wet tubing in the front clamp slot **Note:** Tubing length must extend atleast 1 inch beyond the outer edge of both clamps	 
5	Close clamp covers by pressing down the front end of the covers until they lock in place	
6	Press <START> button to weld **Note:** Do not touch clamps during welding cycle. Do not open clamp covers until welding cycle is complete	

STEP	ACTION	
7	Open clamp covers after device beeps and “Weld Complete” message is displayed on the LCD	
8	Remove tubing and discard stubs	

9	• Remove welded tubing and visually inspect tubing for alignment by rotating 360^0
	• Inspect the weld and check for leakage
	  ○ 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
		

10	**If tubing**	**Then weld**
	Does not leak	• Passes inspection • Continue with component processing

	Leaks	• Fails inspection
		• Blood product is considered to be open to contamination
		  ○ Discontinue processing and replace the unit if possible or
		  ○ Continue processing the unit as an open system and update expiration date/times accordingly

11	Press <RESET> button to align clamps	
12	Close lid cover when device is not in use	
13	Power off device after use	

Cleaning Welder-Monthly and as needed

STEP	ACTION	
1	Turn device off and unplug the power cord	
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. Do not spill any cleaning solutions inside the device. • Go to next step
	Because of spillage into the device	• Discontinue operation • Notify a lead or manager immediately • Place equipment out of service
3	Using a cotton swab dampened with 70% isopropyl alcohol, wipe down the clamps in the following areas: • The clamp covers • The tubing holder slots and teeth	
4	Wafer Compartment cleaning • Remove wafer cassette per Section: ***Wafer Cassette Replacement*** • Using a cotton swab dampened with 70% isopropyl alcohol, wipe down the compartment • Ensure all foreign matter is removed from the compartment • Replace wafer cassette per Section: Wafer Cassette Replacement	
5	Empty and clean the Wafer Disposal Box • Pull on the insert on the front of the box to loosen from the TSCD II • Slide box forward to remove from TSCD II • Discard the used wafers into biohazardous waste sharps container • Clean the surface and inside of disposal box using isopropyl alcohol wipe • Insert the lower edge of the disposal box into the front of the TSCD II • Push the box into the TSCD II until it locks in place **Note:** TSCD II has 2 photo sensors which align with the slots of the wafer disposal box when inserted properly. The sensors will send a message to the LCD display if the box needs to be emptied. If box is not inserted properly, the sensors will not work as intended causing wafer jam or incorrect fill detection	
6	Plug the power cord in and turn on device	
7	Record completion of maintenance on *Bench Equipment Maintenance* form	

Filter Replacement- As needed

STEP	ACTION
1	Turn device off and unplug the power cord
2	Remove the filter case from the lower right side of the TSCD II by pulling gently to the right
3	Remove the air filter from the filter case gently, not bending the four claws holding the filter in place
4	Clean the filer case with a cotton swab dampened with 70% isopropyl alcohol or wipe and let dry

5	Replace air filter • Seat the filter flat on the square area and hold in place using the four claws
6	Insert the filter case in the right side of the device and push in gently

Fuse Replacement-As needed

STEP	ACTION
1	Turn device off and unplug the power cord
2	Locate the fuse holders at the back of the device above the handle
3	Using a flathead screwdriver, turn the cover of the holder counter clockwise a half turn
4	Lift the holder with fuse out
5	Remove the fuse and replace with a 4 Amp Slow Blow fuse
6	Place the fuse back in the holder and insert the holder back in the TSCD II
7	Turn the holder cover clockwise a half turn
8	Repeat the above steps for the second fuse holder Note: If the fuses frequently open, discontinue use and contact Terumo BCT for service
9	Plug the power cord in and turn on device

Wafer Cassette Replacement

STEP	ACTION
1	Press the EJECT button and the far edge of the empty cassette will pop up
2	Remove the empty cassette
3	Check that the new wafer cassette label is on top
4	Slide the cavity of the front edge of the new cassette onto the metal tab at the front edge of the wafer cassette compartment
5	Push down the back edge of the new wafer cassette until it snaps into place
6	Press RESET to align the clamps and advance an unused wafer **Note:** When replacing wafer cassette, one unused wafer remains in the device. The wafer is automatically advanced to the welding area when the RESET button is pressed, if a wafer is not already in place

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*** for instructions on how to enter weld in LIS

CALIBRATION:
None

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.
    - Outer Diameter (OD) – 3.86-5.6mm
    - Wall Thickness (WT) – 0.508-1.10mm
- A 4 inch or greater length of tubing is recommended for welding to take place without restriction
- **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.
- Avoid high temperature of humidity during storage of device
- Exposure of welded tubing to solvents or excessive stress such as heat or cold could compromise the integrity of the weld
- Refer to TSCD II Sterile Tubing Welder Operating Instructions for troubleshooting of device

REFERENCES:
TSCD II Sterile Tubing Welder Operating Instructions. Lakewood, CO;Terumo BCT, May 2013
Standards for Blood Banks and Transfusion Services. Bethesda, MD; AABB, current edition

RELATED DOCUMENTS:
SOP *Blood Component Preparation*
Form *Bench Equipment Maintenance*

APPENDIX
NA

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