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1.0 Purpose

This describes the operation of the Sartorius BioWelder.

2.0 Scope

The scope defines operation of the Sartorius BioWelder by BDP personnel to weld thermoplastic tubing. This unit should be operated in a room temperature environment.

3.0 Authority and Responsibility

This section defines the personnel, supervisors, and/or departments and their individual responsibilities.

3.1 The Manufacturing Manager, Late Process Sciences, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

3.2 BDP Personnel are responsible for training on this procedure and documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 BDP personnel are responsible for the performance of this procedure.

3.4 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.


4.0 Procedure

4.1 Item List


Part Name	BDP Number
Decon-Ahol	30129
BioWelder TC Disposable Cutting Blades	22518

4.2 Setup

4.2.1 Plug welder into an electrical outlet

4.2.2 Flip power switch on the back of the welder toward the  side to power on the machine.

4.2.3 Press the Login button  to open the login menu.

4.2.4 Press the Next button  to scroll through user names until "LPS" is selected.

4.2.5 Press the OK Button  to confirm the username selection.

4.2.6 When prompted, remove all accessories (blades, tube holders, etc.) from the welder.

4.2.7 Press cover down until it clicks shut.


4.2.8 Wait for the welder to initialize axes. Initialization is complete when the "Weld" screen displays.

4.2.9 Determine whether tube type displayed on "Weld" screen is correct. If tube type is correct, proceed to section 4.3. Otherwise, process to Step 4.2.10.

4.2.10 Press the Cancel button  to return to the welder menu.

4.2.11 Press the Tube Type button  to open the tube type menu.

4.2.11.1 The unit can accept tubing ranging in size from 1/8" I.D. up to 1" I.D.

4.2.12 Press the Next button  to scroll through tubing types until the correct type is selected.

4.2.13 Press the OK button  to confirm tube type selection and return to the "Weld" screen.


4.3 Install Cutting Blade

4.3.1 Cutting blades are single-use only. Once a blade has been used, it must be disposed of appropriately and a new blade installed.

4.3.2 Carefully remove a single cutting blade from the blade pack.

4.3.3 Hold the blade so that the matte dot is oriented at the bottom, facing right.

4.3.4 Press the blade firmly into the far-left groove on the blade holder. Ensure that the matte dot is still positioned at the bottom, facing right.

- 4.4 Install Tube Holders
 - 4.4.1 Ensure that the tube holder diameter matches the diameter of the applicable tubing.
 - 4.4.2 Place tube holders onto magnetic prongs in the welder, ensuring that the clamp bars are facing each other.
- 4.5 Operation – Perform a Weld
 - 4.5.1 Place objects being welded together in positions so that:
 - 4.5.1.1 Tubing can be placed into tubing holders without causing kinks, stretching or any other mechanical strain on the tubing.
 - 4.5.1.2 Welder cover can still close.
 - 4.5.2 Position tubing so that desired lengths are diagonally opposite one another:
 - 4.5.2.1 Back left and front right
 - 4.5.2.2 Front left and back right
 - 4.5.3 Press tubing firmly into the tube holders, ensuring the tubing is taut but not stretched.
 - 4.5.4 Press the cover down until it clicks shut.
 - 4.5.5 Place a clamp or hemostat on each desired length of tubing, ensuring that the tubing is completely sealed by the hemostat/clamp and:
 - 4.5.5.1 As close as possible to the welder
 - 4.5.5.2 Cover still closes completely
 - 4.5.6 Ensure that tubing is completely sealed by clamp/hemostat.
 - 4.5.7 Tubes on the left side of the welder must move without restriction when tubes rotate about one another/ switch places during the welding process. Ensure the following:
 - 4.5.7.1 Enough slack in the tubing to move freely
 - 4.5.7.2 Hemostats/clamps will not restrict movement
 - 4.5.7.3 Other objects near the welder will not impede the path of movement
 - 4.5.8 Confirm tubing parameters on the "Weld" screen are correct.
 - 4.5.9 Press the Start button  to begin the welding process.
 - 4.5.10 Gently hold the tubing to support and guide as the tube holders move closed.
 - 4.5.11 Wait for the welding process to complete. The welding process is complete when the cover opens and "Remove blade" displays on the touch screen.

- 4.5.12 Carefully grasp the blade and pull it out of the welder slot.
- 4.5.13 Allow the weld to cool for approximately 1 minute before proceeding.
- 4.5.14 Carefully remove welded tubing from the tube holders. DO NOT remove hemostats/clamps until the weld has been inspected, per Section 4.6.
- 4.6 Weld Inspection
 - 4.6.1 Visually inspect the weld to ensure that a uniform flange is present around the entire circumference of the tube.
 - 4.6.2 Visually inspect the weld to ensure that both sides of the weld are axially aligned with one another.
 - 4.6.3 Pull GENTLY on the weld to ensure that it does not peel, come apart, crack or demonstrate any other physical defect.
 - 4.6.4 If the weld meets all inspection criteria in this section, proceed to Section 4.8. Otherwise, proceed to Section 4.7 to repeat the weld. DO NOT remove clamps/hemostats from tubing.
- 4.7 Repeat a Weld
 - 4.7.1 If a weld does not meet all inspection criteria in Section 4.6, a new weld must be performed, per the following steps.
 - 4.7.2 Carefully cut the tubing INSIDE the hemostats/clamps to separate the welded tube.

Place additional hemostats/clamps near the weld to contain liquid, if necessary.
 - 4.7.3 Install a new cutting blade per Section 4.3.
 - 4.7.4 Position tubing so that:
 - 4.7.4.1 Lengths that will be welded together are diagonally opposite one another.
 - 4.7.4.2 Entire length of tubing from bad weld to hemostat/clamp will be discarded.
 - 4.7.5 Press tubing firmly into the tube holders ensuring the tubing is taut but not stretched.
 - 4.7.6 Press cover down until it clicks shut.
 - 4.7.7 Place a new clamp or hemostat on each desired length of tubing and ensure the tubing is completely sealed by clamp/hemostat:
 - 4.7.7.1 As close as possible to the welder
 - 4.7.7.2 Cover still closes completely
 - 4.7.8 Complete the welding process, as normal per, Step 4.5.
 - 4.7.9 Inspect the weld per Step 4.6.

4.8 Unseal a Weld

4.8.1 Gently squeeze and roll the weld between fingers to unseal the two ends and allow fluid to flow freely between the tubes.

4.8.2 Remove all clamps/hemostats from the welded length of tubing.

4.9 Cleaning

4.9.1 Dispose the blade into a sharps container.

4.9.2 Dispose the discarded tubing lengths into the appropriate waste receptacle.

4.9.2.1 Tubing containing liquid into Biohazard waste receptacle

4.9.2.2 Tubing not containing liquid into a trash receptacle

4.9.3 Remove tube holder set from the welder.

4.9.4 Press Logout  button to logout of the machine.

4.9.5 Flip power switch on the back of the welder toward the **O** side to power off the machine.

4.9.6 Wipe all visibly soiled surfaces of the welder with a 70% IPA-saturated wipe.

4.10 Troubleshooting

4.10.1 Tube Holder Errors

4.10.1.1 When a tube holder is not recognized by the welder. An error message will display on the touch screen.

4.10.1.2 If this error message is shown, remove the tube holders from the welder and wipe the magnetic contacts on the tube holders and welder with a 70% IPA saturated wipe.

4.10.1.3 Replace the tube holders into the welder.

4.10.1.4 Contact a Supervisor if the error is not corrected by wiping the magnetic contacts.

4.10.2 Other Errors

4.10.2.1 If other errors occur, consult the equipment manual for cause and corrective actions.

4.11 Documentation

4.11.1 Document the use, cleaning, maintenance and/or calibration of the Sartorius Stedim BioSealer in the Equipment Logbook. Be sure to include a date, time, lot number, and initials.

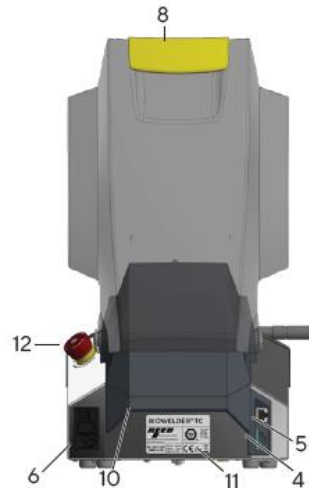
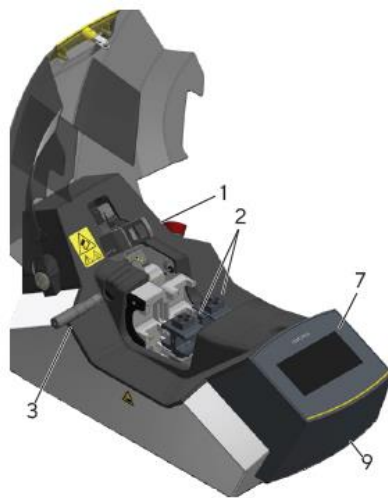
5.0 References and Related Documents

5.1 SOP 19102

5.2 Attachment 1 **Component Identification**



Attachment 1
Component Identification



1	Blade remover tool	7	Touch screen
2	Tube holder set (by pair)	8	Closing handle for cover
3	Validation sensor with holder	9	Carrying handle, front
4	SD memory card slot	10	Carrying handle, rear
5	Ethernet cable terminal	11	Nameplate with serial number
6	Device socket with main switch and fuse	12	Emergency off button