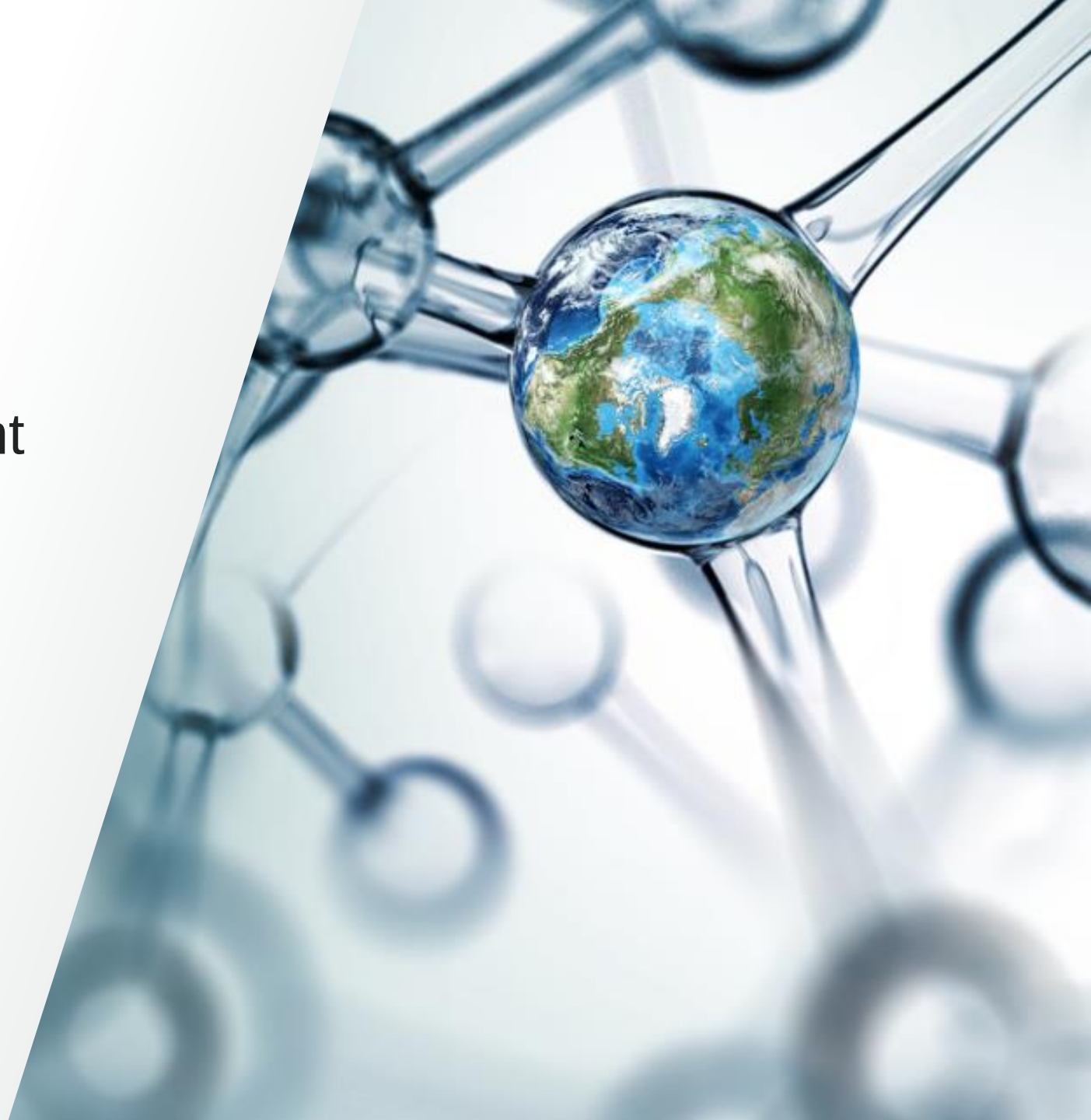
Field Verification Procedure

Biosafety Enclosure, Containment Verification



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Revisions

Revision	Change Description	Changed By/Date
A	New Release	LG 8/31/23
B	Deleted results documentation section, and instead point to separate document DF00233.	LG 4/1/24

Notice

PPE

Use personal protective equipment (PPE) including but not limited to gloves and Safety Goggles.
Follow all site-specific Safety rules and recommendations.

Notice

Tools

The following tools are required to perform this procedure:

- Standard tool kit, hex drivers, sockets
- Aerosol Generator **PS00329**
- Aerosol Photometer **PS00330**

Training

Completion of the following trainings is required prior to performing this procedure:

- Bigfoot biosafety systems basics service training
- Bigfoot containment verification service training

Why are you doing this operation?

When to perform this procedure

This procedure shall be performed in the following cases:

- Any time the **Loader Module** is removed, or the seal is temporarily compromised. This includes, but is not limited to DT00290, Loader Replacement. Any other Loader-related service activities that move the module as a unit also requires containment verification.
- Any time the **Streams Window** is removed, or the seal is temporarily compromised. Any Streams Module-related service activities that move the Streams Window also requires containment verification.
- Any time the **Sort Module** is removed, or the seal is temporarily compromised. This includes, but is not limited to DT00297, Sort Module Replacement. Any other Sort Module service activities that move the Streams Window also requires containment verification.

Theory of Ops for This Calibration

Description

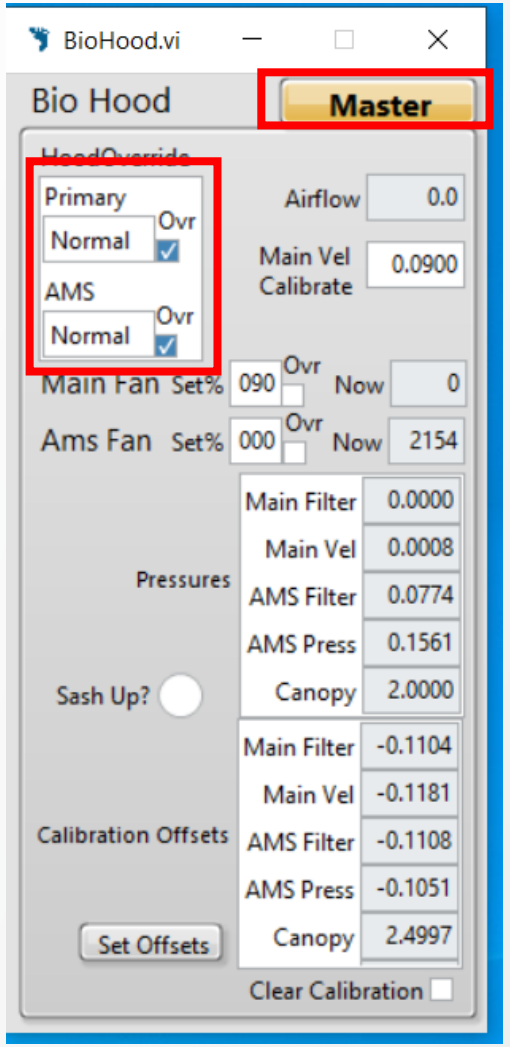
The Biosafety Enclosure Containment Verification repurposes the HEPA filter testing equipment as a tool to test for leaks. An aerosol source is placed inside the Enclosure. An aerosol detector is placed outside the Enclosure close to the seam under test. If a sustained increase in aerosol concentration is detected, then a leak is confirmed.

Gain Access to Instrument

1	Remove all the cover from the top ½ of the instrument: - Front cover (biosafety enclosure) - Top cover - Top left cover - Top right cover - Top rear cover

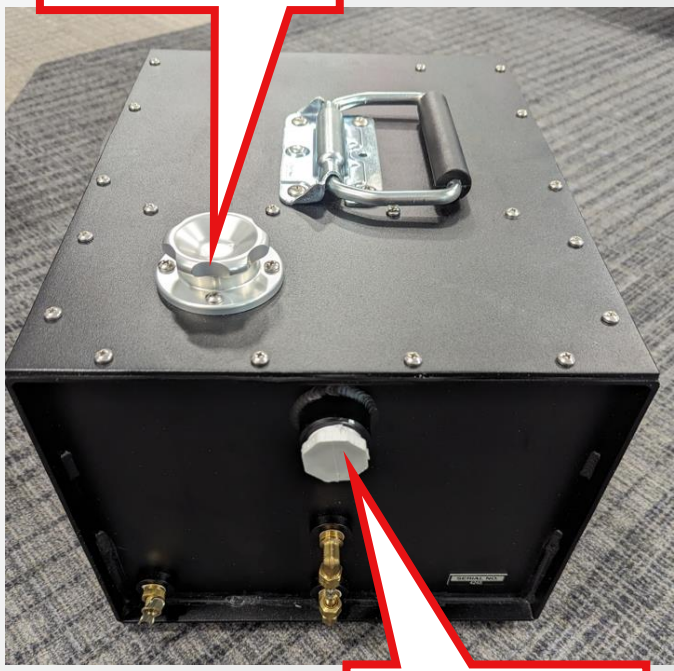
Gain Access to Instrument

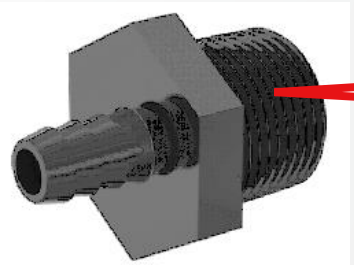
1	In the service tool, open the biohood panel.
2	Turn on the Master override
3	Adjust the state of both the Primary and AMS fans to **Normal**



Unpack Aerosol Generator

1	Unpack the Aerosol Generator kit **PS00329.**
2	Remove the reservoir cap.
3	Using the included funnel, carefully pour the 1 liter of included PAO oil into the generator reservoir. Use paper towels to clean up any spills.
4	Remove the aerosol port plug.
5	Add two wraps of Teflon tape to the barbed fitting.
6	Install into the **aerosol port**. Tighten with a wrench. Do not overtighten.
7	Add the included 3/8” ID tubing to the barb.



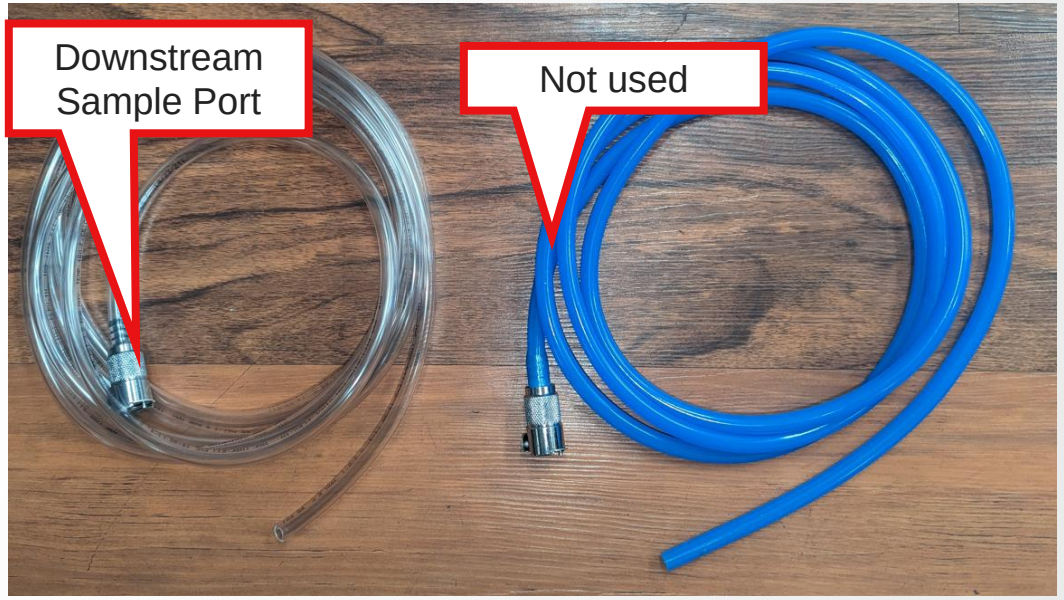


Unpack Aerosol Photometer

1	Unpack the Aerosol Photometer kit **PS00330**.
2	The items on the left side of the will be used. The items on the right side will be used

Setup Aerosol Photometer

1	Plug the photometer in.
2	Locate the 2.5 meters of blue tubing. This is the upstream sample tubing. This will be unused for this procedure
3	Locate the 4 meters of clear tubing. This is the downstream sample tubing. Plug the quick connect fitting into the downstream port of the aerosol photometer.



Setup Aerosol Photometer

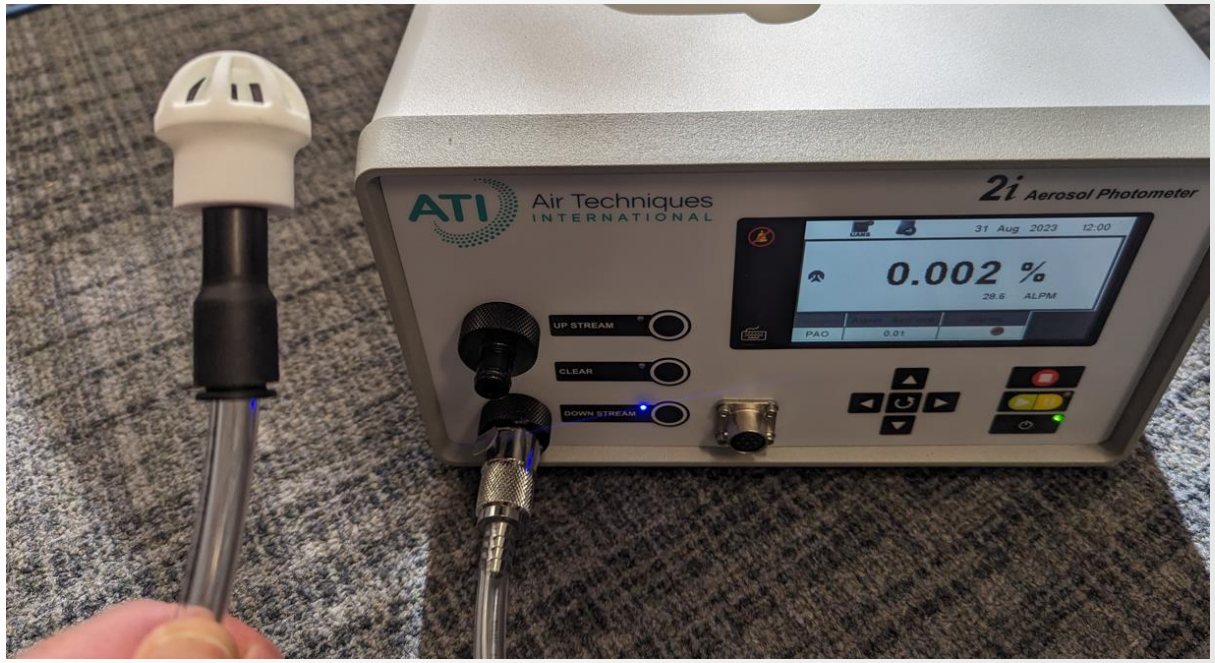
1	Select “Set Internal Reference” and select proceed
2	Adjust the upstream concentration to 50 ug/L and select proceed

Setup Aerosol Photometer

1	Locate the Leak Detection Probe from the aerosol photometer kit and add it to the end of the downstream tubing.
*	This probe prevents the inlet of the tubing from vacuuming aerosol out of the seam under test. Additionally, be aware that there will be instances where the aerosol photometer will “peak” to a high concentration due to restricting the inflow air such as when shoving the probe quickly into an interior corner with too many on the inlets covered. A quick jump in aerosol concentration does not indicate a leak. A leak will cause a sustained measurement above the leak detection threshold. Red lines indicate the required seams to inspect.

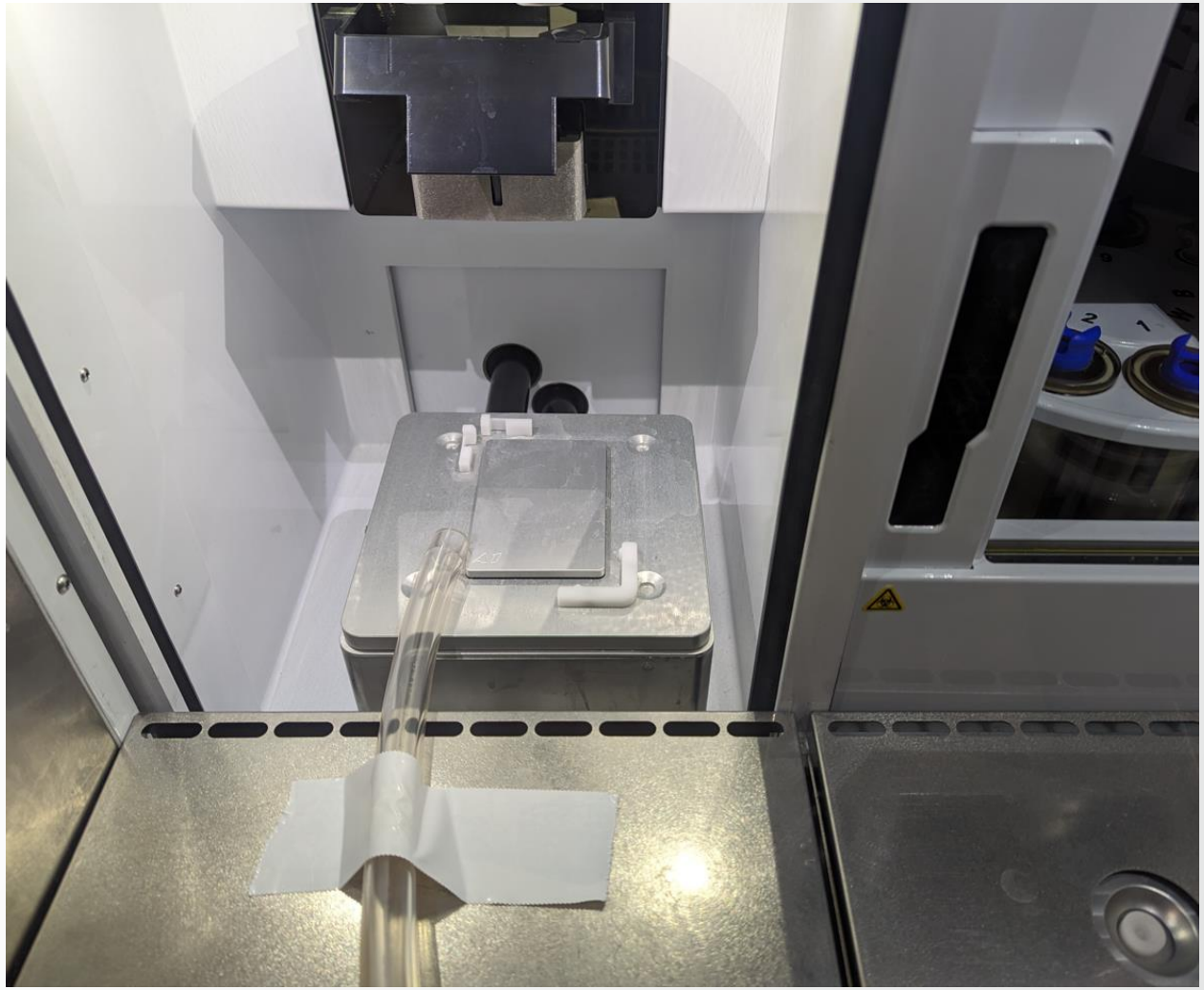
Setup Aerosol Photometer

1	All important information from this testing should be recorded. An example form is provided at the end of this document
2	Sample the ambient air for 30 seconds while observing the aerosol concentration. Record the maximum sustained value – the **Background**. This is the ambient concentration of 0.3 micron sized particles in the lab. This number should be less than 0.01%, but in an exceptionally dirty lab, could be greater than 0.01%.
3	Multiply the **Background** by 5. If this number is less than 0.012%, then the **Leak Detection Threshold** is 0.012%. If the **Background** multiplied by 5 is greater than 0.012%, then the **Leak Detection Threshold** is the **Background** multiplied by 5. For example, in the picture on the right the background concentration is 0.002%. This number multiplied by 5 is 0.010%, which is less than 0.012%. Therefore the leak detection threshold for this leak test will be 0.012%.
4	Record the **Leak Detection Threshold** for you experiment.



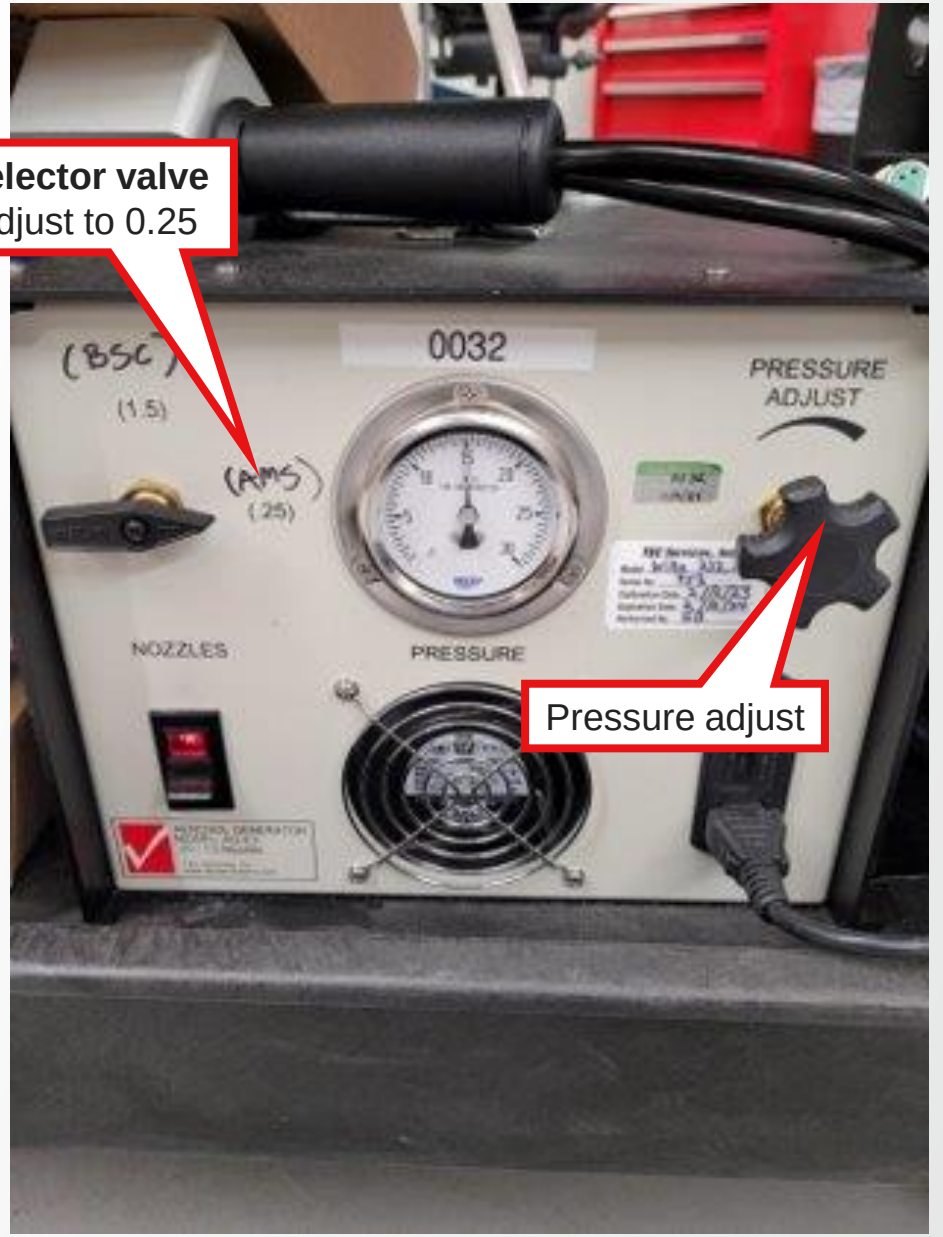
Turn on Aerosol Source

1	Open the sort chamber door. **The sort chamber must remain open for the remainder of the test.**
2	Tape the aerosol generator tubing such that it is **inside the Sort Chamber**. **The tubing must remain inside the sort chamber for the remainder of the test.**
3	Turn the aerosol generator on



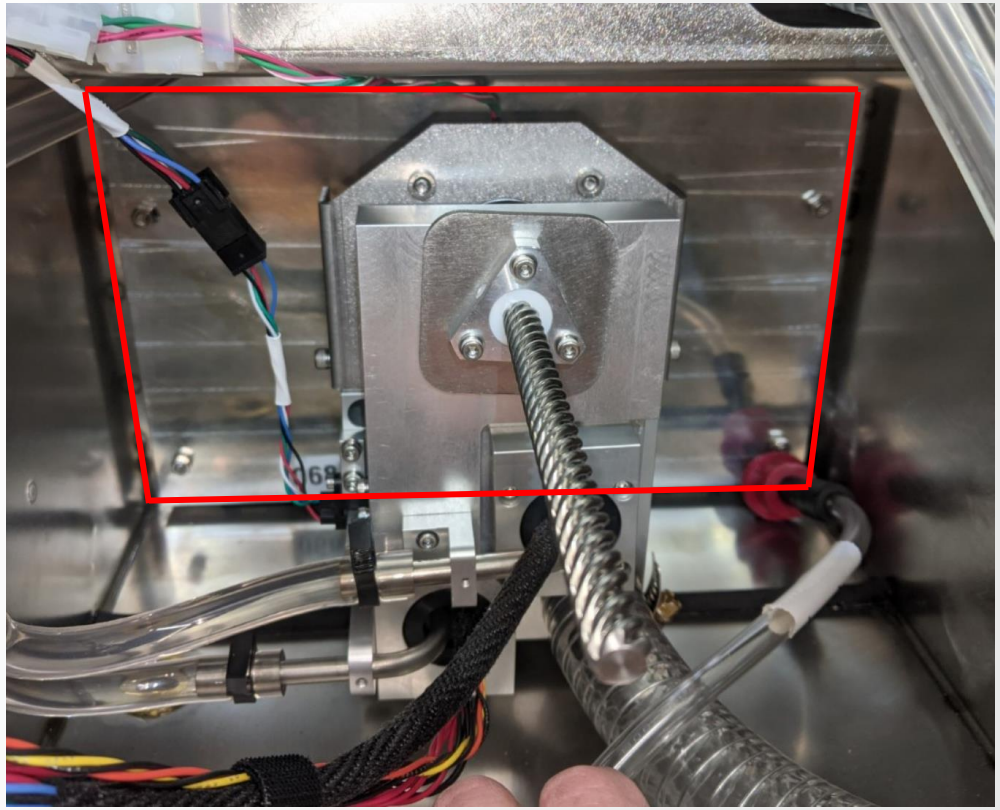
Adjust Aerosol Source

1	Adjust the selector valve on the aerosol generator to 0.25 nozzles. This valve must be rotated completely. It is not a scale; it should only be in the 1.5 location or the 0.25 location.
2	Adjust the pressure until 10 psi is displayed on the gauge.



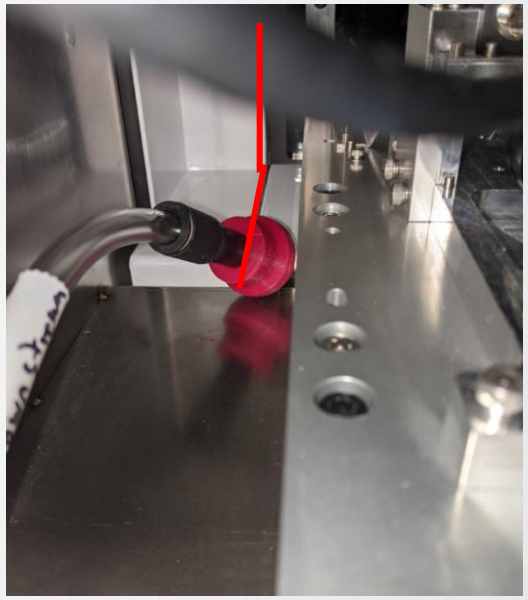
Leak Testing - Output

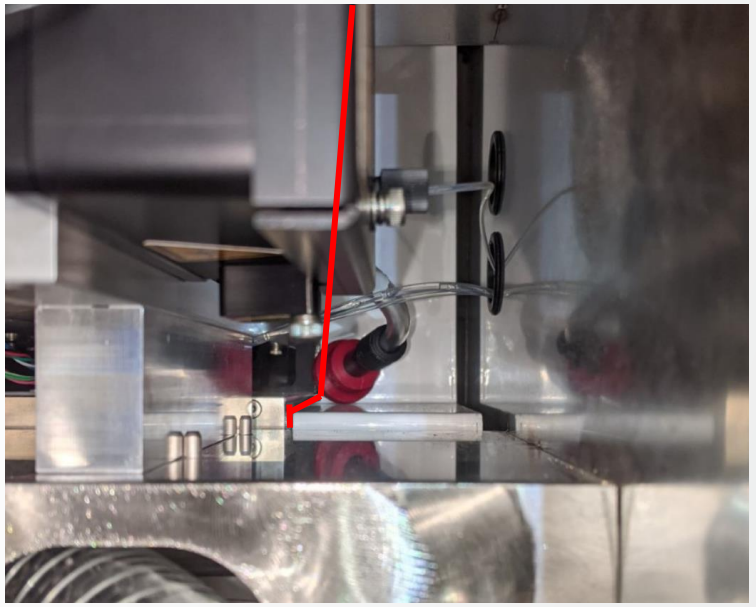
1	Probe the interface between the atrium and Output.
2	Enter the maximum detected value **Output Area (%)** The value must be less than the Leak Detection Threshold



Leak Testing – Streams Module & Sort Module

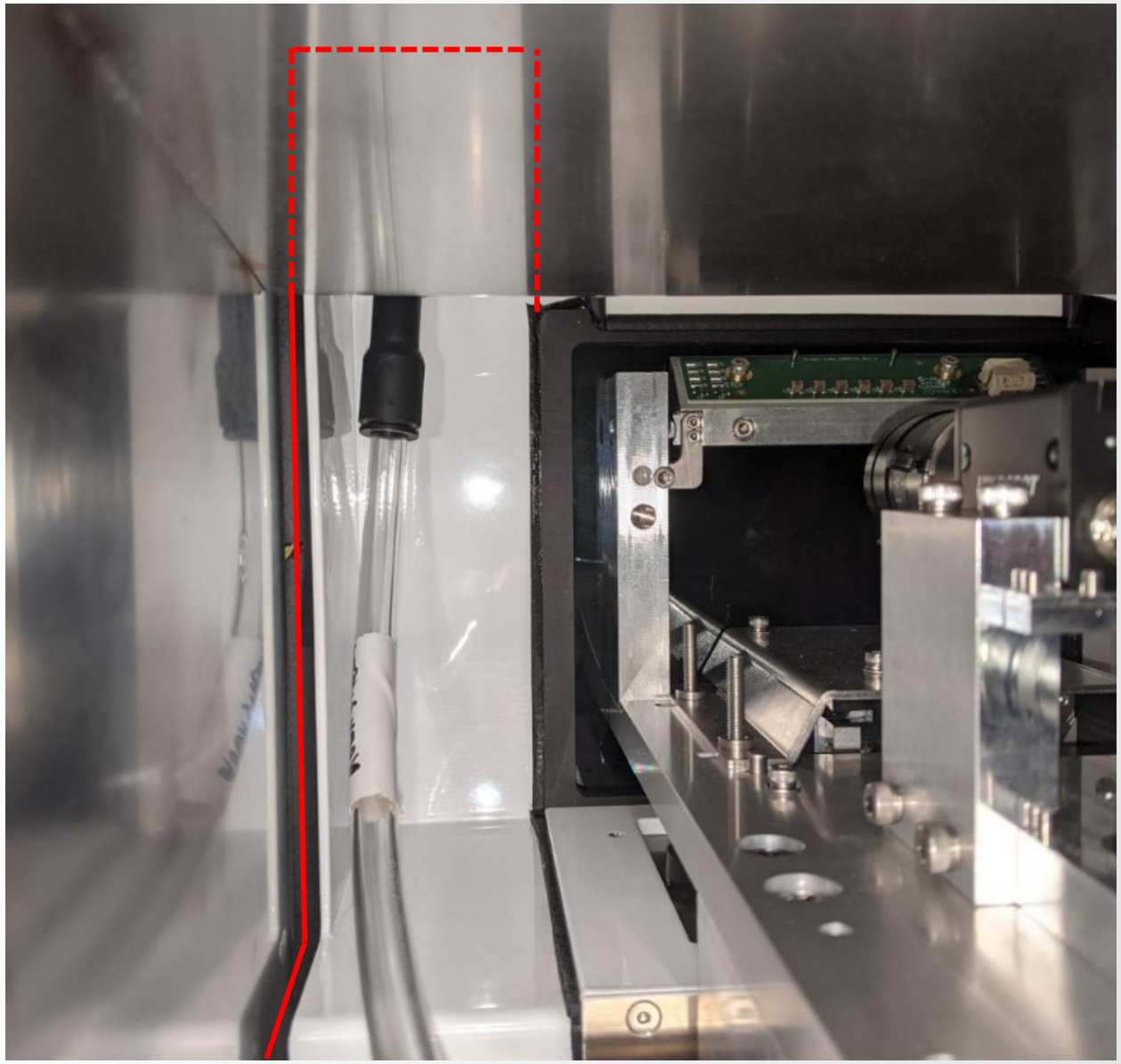
1	Perform the leak testing of this area slowly and methodically, as the Streams Module and the Sort Module perimeter are the most prone to leak.
2	Probe all the accessible interfaces between the streams module and the atrium.
3	Enter the maximum detected value **Streams Module Area (%)**





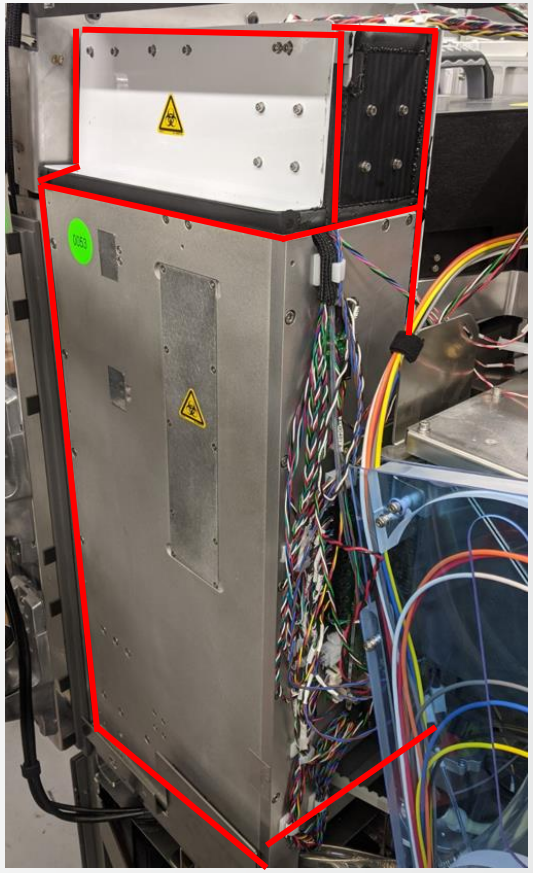
Leak Testing – Optics Plate

1	Study how the bottom of the optics plate interfaces with the atrium.
2	Probe all the accessible interfaces between the optics plate and the atrium. Note that only the right side of the sort chamber is shown in this image. Both the left and right sides need to be probed.
3	Enter the maximum detected value **Optics Plate Bottom (%)**



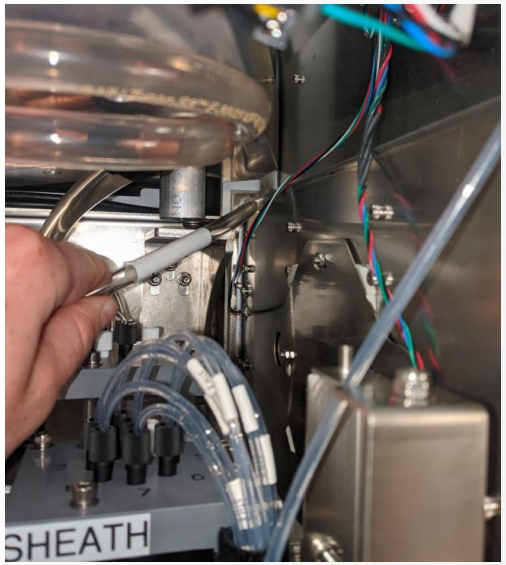
Leak Testing – Loader

1	Study how the loader interfaces with the atrium.
2	Probe all the accessible interfaces between the loader and the atrium.
3	Enter the maximum detected value **Loader Area (%)**



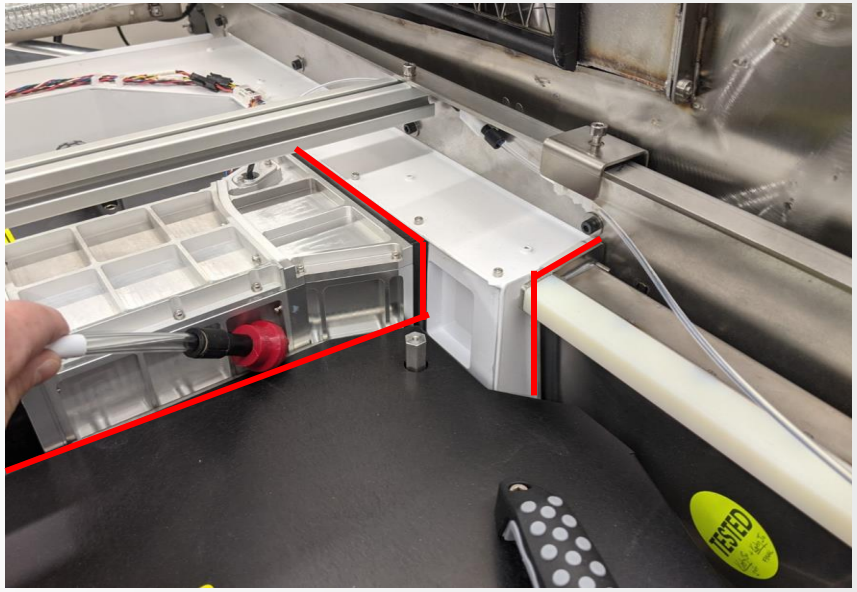
Leak Testing – Sort Door

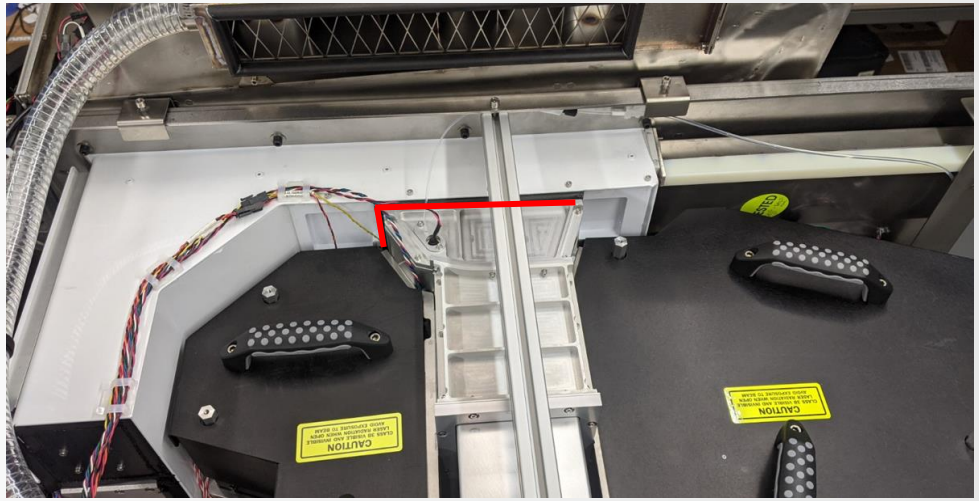
1	Study how the sort chamber door interfaces with the atrium.
2	Probe all the accessible interfaces between the sort chamber door and the atrium.
3	Enter the maximum detected value **Sort Chamber Door (%)**



Leak Testing – Optics Plate Top

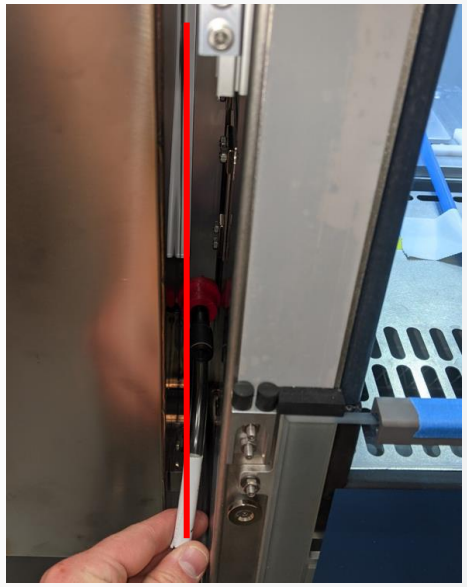
1	Study how the 5 axis mover interfaces with the atrium.
2	Probe all the accessible interfaces between the 5 axis mover and optics plate and the atrium.
3	Enter the maximum detected value **5-Axis/Optics Plate Top (%)**

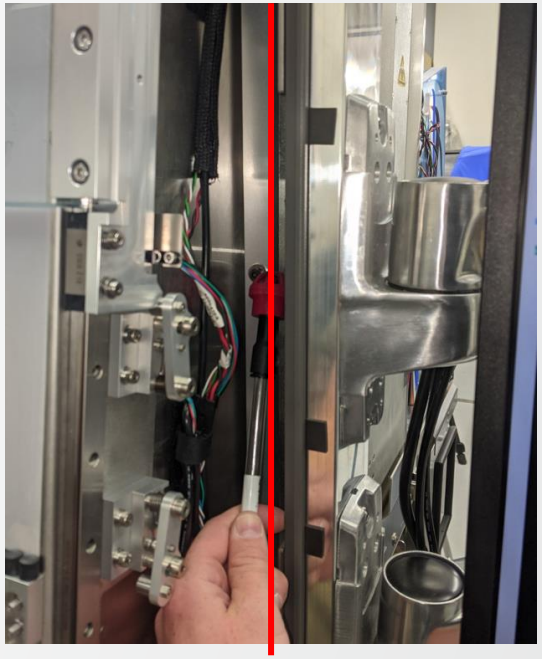


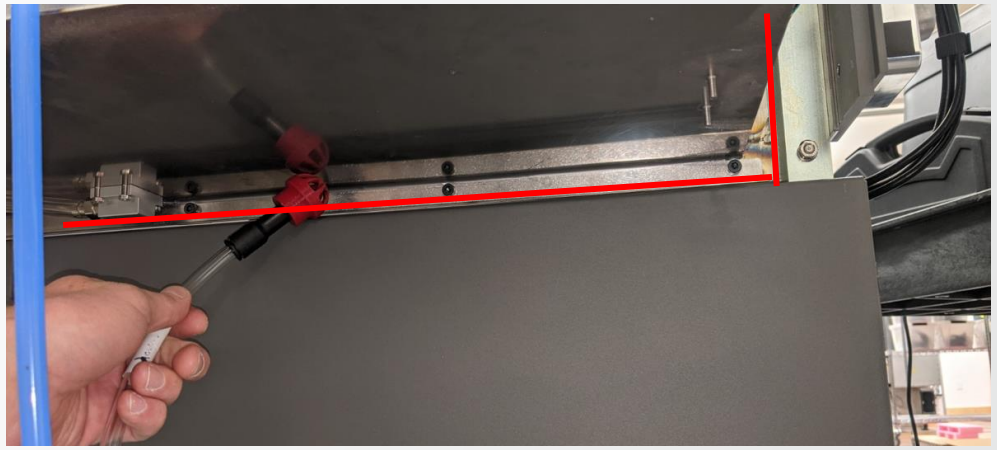


Leak Testing -

1	Study how the biosafety cabinet front assembly interfaces with the atrium
2	Probe all the accessible interfaces between the biosafety cabinet front assembly and the atrium.
3	Enter the maximum detected value **Biosafety Enclosure Front Assembly Area (%)**
4	Turn off the aerosol generator.





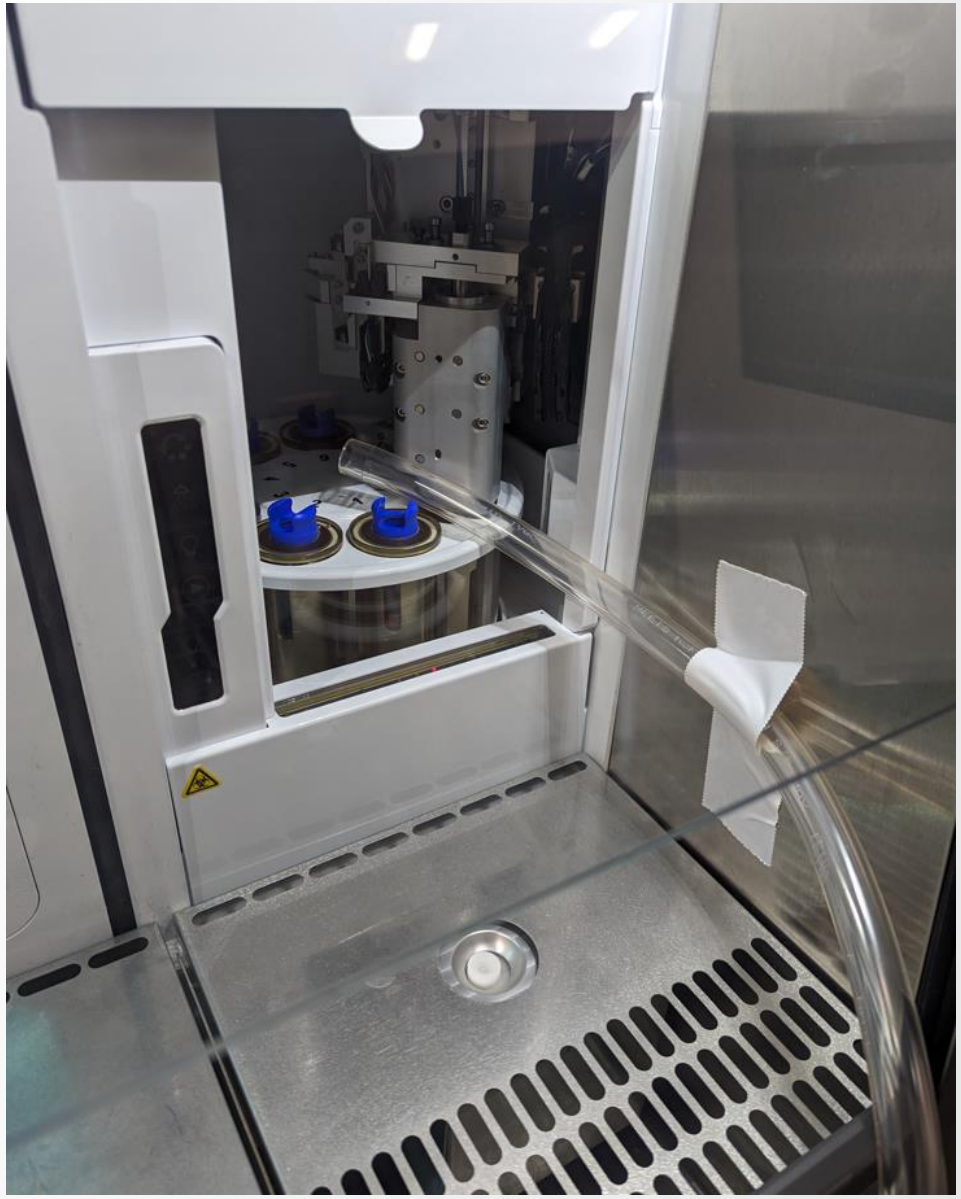


Leak Testing – Positive Control

1	If any leaks are detected, fill the seams that leak with the black RTV provided with the aerosol generator. For areas with restricted hand access such as the Streams Module, add the RTV silicone to a 10mL syringe, which are provided with the generator. Dispense the RTV onto the streams window seam using the RTV-filled syringe. Let cure for 30 minuets and repeat leak testing procedure until no leaks remain.
2	At the end of the test insert the sampling tube into the sort chamber for 1-2 seconds to confirm a detection as a positive control at the end of the test.
3	Enter the maximum detected value. This value must be greater than 1% **Positive Control (%)**
4	For all BSL1 and BSL2 labs (CL1 or CL2), the testing is complete. Proceed to the **Pack up** section at the end of this procedure. For the small minority of BSL3 labs, proceed to the next slide.

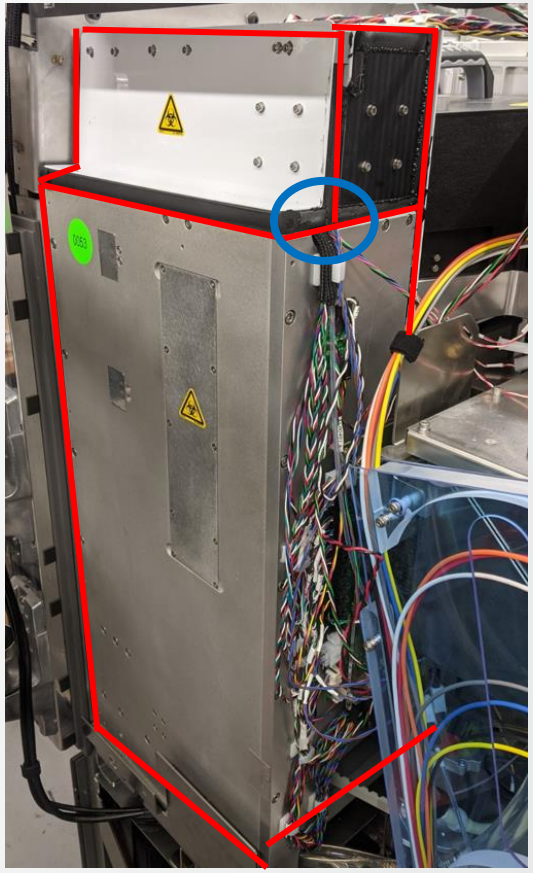
Additional Required Testing for BSL3 (CL3) Labs

1	Move the aerosol generator hose from the sort chamber to the loader area.
2	Turn on the aerosol generator.



Additional Required Testing for BSL3 (CL3) Labs

1	Repeat the seam testing on the exterior seams of the Loader module. Pay special attention to the cable penetration circled blue.
2	Enter the maximum detected value **BSL 3 lab additional testing, Loader Area (%)**
3	If any leaks are detected, fill the seams that leak with the black RTV provided with the aerosol generator. For areas with restricted hand access such as the Streams Module, add the RTV silicone to a 10mL syringe, which are provided with the generator. Dispense the RTV onto the streams window seam using the RTV-filled syringe. Let cure for 30 minuets and repeat leak testing procedure until no leaks remain.

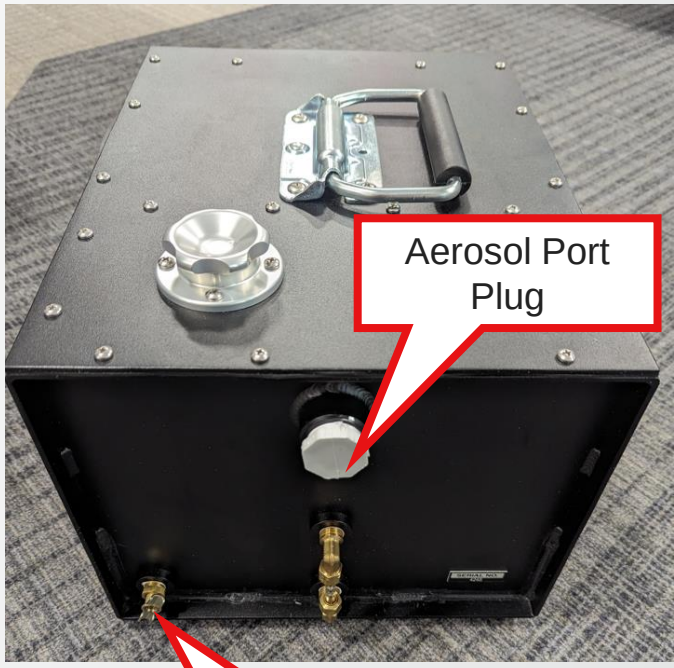


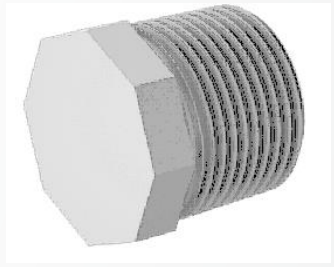
Pack up

1	Turn off the aerosol generator
2	Turn off the aerosol photometer
3	Remove tubing, test equipment, and all supplies that were in use.
4	Undo all **Overrides** that were used in the service tool during this procedure.
5	Replace all instrument covers

Pack up

1	Use the included funnel to drain the PAO oil back into the 1 liter bottle so the generator is fit for shipment. Lift the generator onto an elevated stable surface (do not use the Bigfoot user table). Open the reservoir drain valve and reservoir cap. Empty out as much oil as possible.
2	Replace the reservoir cap and drain plug.
3	If needed, add fresh Teflon tape to the plug. Replace the plug on the generator.
4	Replace the aerosol port plug.
5	**Confirm that at least one unopened tube of RTV silicone is present in the box**. If it is not, order more (Part number PS00387)
6	Repack the Aerosol Generator kit **PS00329.**





Add 2 wraps Teflon tape

Pack up

1	Repack the aerosol photometer kit **PS00330.**

Document Results

1	From the knowledge base, download a copy of the document DF00233.
2	Fill out the form, save the results as a pdf, attached a copy of the pdf to your trip report, and email a copy of the results to the customer.
3	**If an instrument failed inspection:** The fill out two forms: 1) The results of the instrument in the as-found condition 2) The results of the instrument after refurbishment. In the testing notes section, record that one form was the as-found condition, and the other form was the inspection results after refurbishment was completed as shown below.

Testing Notes

Streams Module right side seam leaked at a rate of 0.300% when inspected.

This form reflects the inspection results for the as-found condition of the instrument.

Testing Notes

Streams Module right side seam as refurbished.

This form reflects the inspection results after refurbishment was completed.

Instrument Data

Date	April 1, 2024
Tester	Lincoln Gulley
Instrument Serial Number	BSSA-Example
Instrument Location	Fort Collins, CO

Biosafety Enclosure Chassis Condition

Test Location	Value	Units	Pass/Fail	Notes
Background Concentration	0.001%	ug/L	N/A	No pass/fail criteria
Leak Detection Threshold	0.012%	(%)	N/A	0.012 % OR (Background Concentration * 5), whichever is greater
Output Area	0.000%	(%)	Pass	Must be less than Leak Detection Threshold
Streams Module Area	0.000%	(%)	Pass	Must be less than Leak Detection Threshold
Optics Plate Bottom	0.000%	(%)	Pass	Must be less than Leak Detection Threshold
Loader Area	0.000%	(%)	Pass	Must be less than Leak Detection Threshold
Sort Chamber Door Area	0.000%	(%)	Pass	Must be less than Leak Detection Threshold
5-axis/ Optics Plate Top	0.000%	(%)	Pass	Must be less than Leak Detection Threshold
Biosafety Enclosure Front Assembly Area	0.000%	(%)	Pass	Must be less than Leak Detection Threshold
Positive Control	5%	(%)	Pass	Must be greater than 1%
BSL 3 lab additional testing, Loader Area	0.000%	(%)	Pass	Must be less than Leak Detection Threshold. For BSL3 labs only.