User Manual: Method for Leak Verification of Additively Manufactured Medical Devices Intended to Seal Air

Tool Reference

RST Reference Number: RST26OP12.01

Date of Publication: 09/01/2026

Recommended Citation: U.S. Food and Drug Administration. (2026). *Method for Leak Verification of Additively Manufactured Medical Devices Intended to Seal Air (*RST26OP12.01). https://cdrh-rst.fda.gov/method-leak-verification-additively-manufactured-medical-devices-intended-seal-air

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USER MANUAL: Method for Leak Verification of Additively Manufactured Medical Devices Intended to Seal Air

1. General Information

Additive manufacturing (AM), which allows for the fabrication of components outside of traditional manufacturing settings, is increasingly being used for medical device production. This RST is a leak verification test method for AM components intended to be substantially leak-free when sealing air. Although demonstrated using the StopGap RevB AM face mask design found on the NIH 3D website, this methodology is applicable to other medical devices requiring air-sealing integrity. Some of these products and components could include product code classifications (procodes) QOZ (Barrier Face Covering), FXX (Mask, Surgical), QKR (Face Mask), OBN (Humidifier, Respiratory, Mask), OXZ (Pediatric/Child Facemask), NMC (Mask, Ventilator), QOS (Continuous Ventilator), QOR (Continuous Ventilator), and MOD (Accessory to Continuous Ventilator).

This tool allows users to assess the leak integrity of AM components using their own materials and build settings through a pressure decay test. This single pressure decay test method can be analyzed in two ways: by comparing the measured pressure drop (reported in PSI) to a user-defined pressure drop limit, or by estimating an effective "flaw size" (reported in μm^2) in the component being tested. Pressure drop limits may be established via methods such as those described in Ibarra et al. [1]. When using this specific pressure vessel based on the StopGap revB geometry, users can verify performance by comparing pressure decay results.

This RST includes 3D model data files for an "All-in-One" (AIO) pressure vessel based on the StopGap RevB face mask geometry as an example use case. This AIO structure minimizes the number of components needed to fabricate a working pressure vessel. The pressure vessel allows for the evaluation of the face mask structure's leak integrity by measuring the pressure vessel's ability to hold pressurized air. Pressure decay test data for the vessel, using the authors' manufacturing and test workflow [1], are also supplied.

The tool methodology is agnostic to the AM technology used to manufacture the device and may be applied to a range of devices or components requiring air-sealing integrity, provided the user establishes an appropriate pressure drop limit or uses the method to estimate effective flaw size for the specific device, material, build settings, and intended use. It is applicable to devices or components made of either metals or traditionally formed polymers. However, the materials used must possess sufficient structural properties: rigid enough to maintain consistent volume and resilient enough to avoid brittle failure when subjected to the test pressures.

2. Safety Precautions for Pressure Vessel Testing

For safe operation, follow these precautions:

- Always wear safety glasses when working with pressurized equipment.
- Never exceed 10 PSI maximum pressure in the AIO or the pressure sensor maximum.
- Inspect all components before pressurization for cracks or defects.

- Apply pressure gradually while monitoring system behavior.
- Ensure complete depressurization before disconnecting components.
- Never leave pressurized equipment unattended.
- Position equipment so potential pressure release is directed away from anyone.
- Understand that additive manufacturing parameters, materials, and orientation affect structural integrity.
- Thoroughly clean components to prevent blockages or inconsistent results.

Following these guidelines will minimize risks associated with pressure testing. Consult your institution's safety office or applicable institutional safety protocols if you have concerns about safe operation.

3. Information for Users

This RST includes the following:

- STL computer design files for the AIO pressure vessel and accompanying twist-cap are available at https://3d.nih.gov/entries/3DPX-023650. The AIO pressure vessel is based on the "Stopgap Surgical Face Mask (SFM) Revision B" geometry available from the NIH 3D website (https://3d.nih.gov/entries/3DPX-014168) (Figure 1).).
- Pressure decay performance data for the AIO with an acrylic coating to seal flaws, nominal (no modifications), and with a flaw drilled onto the lateral side (Figure 9). This shows that the AIO performs similar with and without a seal coating.
- Pressure decay performance data for the AIO (no coatings or modifications) as a function of surrogate flaw sizes (Figure 7 and Figure 8). This shows how the vessel de-pressurizes with varying flaw sizes.

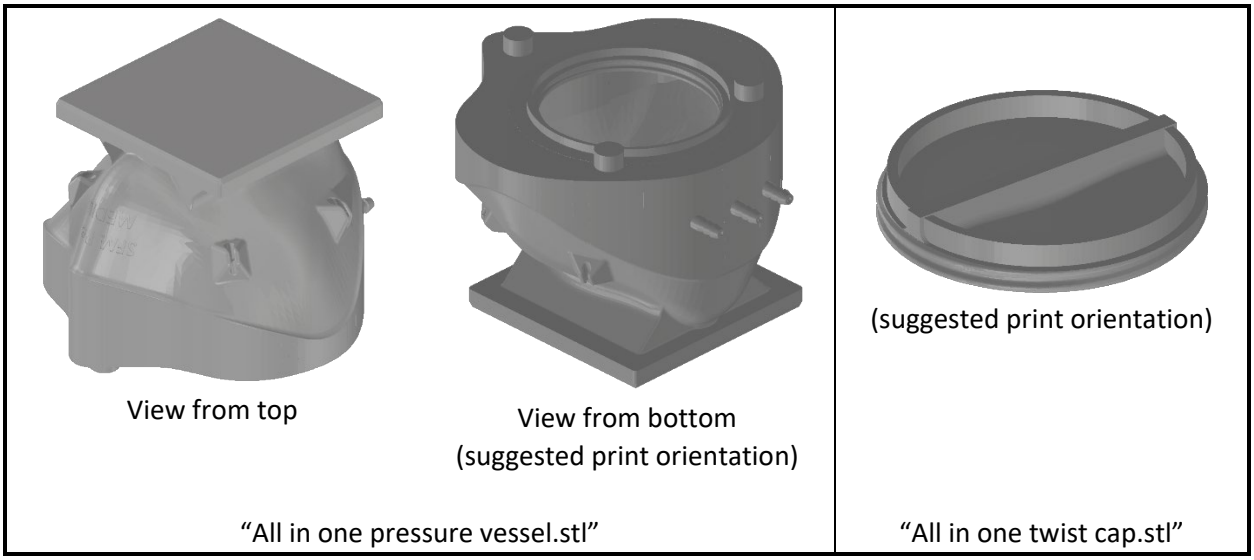

Figure 1. Rendered images of the two STLs in the RST. The AIO main body shown in top and bottom views (left) and the twist cap (right).

4. **Instructions for Utilizing This Leak Verification Method**
    a. Methods

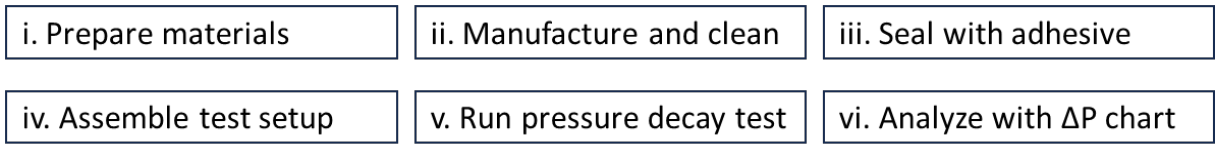

Figure 2. Graphical representation of RST instructions

i. To prepare, have the following materials on hand:
    1. STL files for AIO with three ports.
    2. Additive manufacturing system.
    3. Appropriate adhesive for sealing (e.g., RTV silicone, silicone mold rubber, acrylic spray sealant, vacuum grease, epoxy, hot glue, etc.).
    4. Pressure source and regulator capable of providing stable 5 PSI.
    5. Pressure sensor (0 - 15 PSI range recommended).
    6. Data acquisition system (minimum 10 Hz sampling rate recommended). Used to capture pressure as a function of time from the vessel.
    7. Compressed dry air source with appropriate flexible tubing.

ii. Manufacture the AIO
    1. Print the AIO pressure vessel using the same AM technology, material, build orientation, and post-processing workflow used for the corresponding "Stopgap Surgical Face Mask (SFM) Revision B" example (https://3d.nih.gov/entries/3DPX-014168).
    2. Clean the AIO thoroughly, ensuring powder is removed. Make sure to remove powder via the twist-cap hole. Remove residual powder from ports (Figure 3).

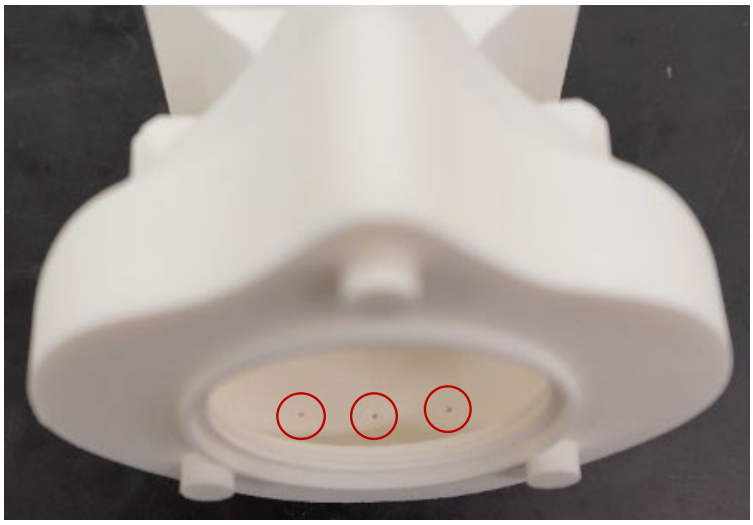

Figure 3. Photo of an AIO after powder removal, demonstrating ports are free of powder.

iii. Seal the AIO pressure vessel.

1. Apply appropriate adhesive to seal the twist-cap and allow to cure or set according to adhesive manufacturer specifications (Figure 4).
    a. To make a better seal, ensure there is sealant applied in between threads of twist-cap that cures or sets after twist-cap is twisted closed flush with the exterior surface of the AIO.
2. Apply appropriate sealant (vacuum grease) to the exterior of the port barbs before connecting tubing, being careful not to clog the ports.
3. Ensure all surfaces of the AIO pressure vessel, except the surfaces that are to be tested, are free of leaks.
    a. Visually inspect the pressure vessel for obvious flaws.
    b. Use a leak detection test (e.g., soap bubble test) to check for leaks around twist-cap and port barbs.

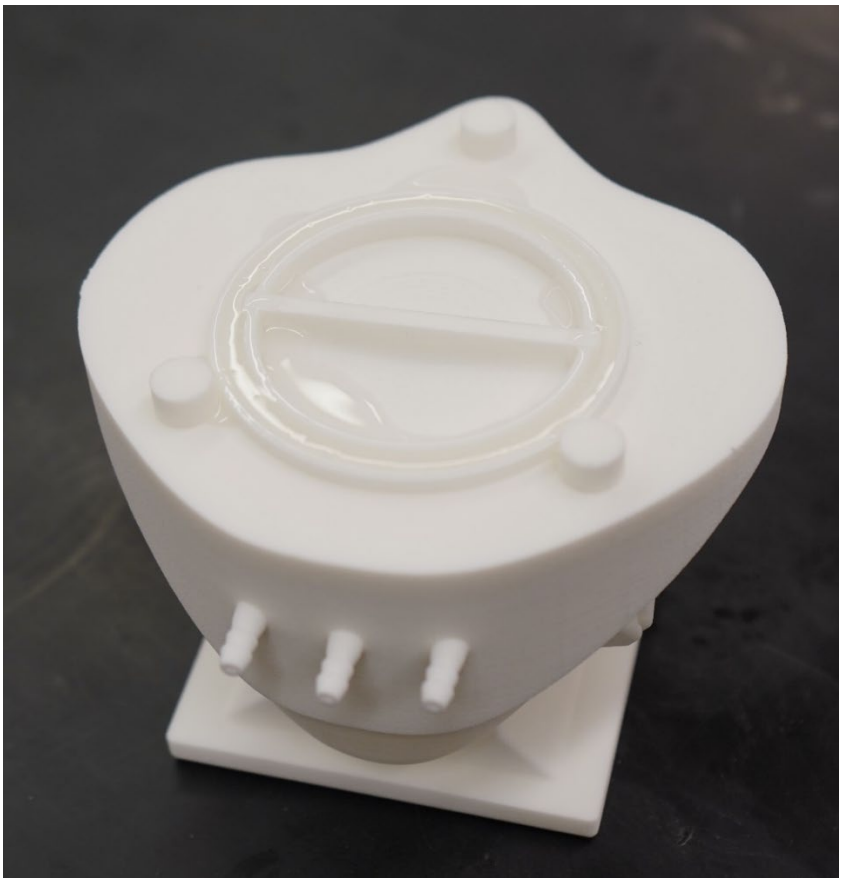

Figure 4. Photo of AIO twist-cap hole sealed using silicone as an example.

iv. Assemble the pressure decay test setup (Figure 5, Figure 6)
    1. Connect the air inlet port to the pressure regulator.
    2. Connect the sensor port to the pressure sensor.
    3. If not collecting data to calibrate the system, seal the air outlet port.
    4. Connect the pressure sensor to the data acquisition system.

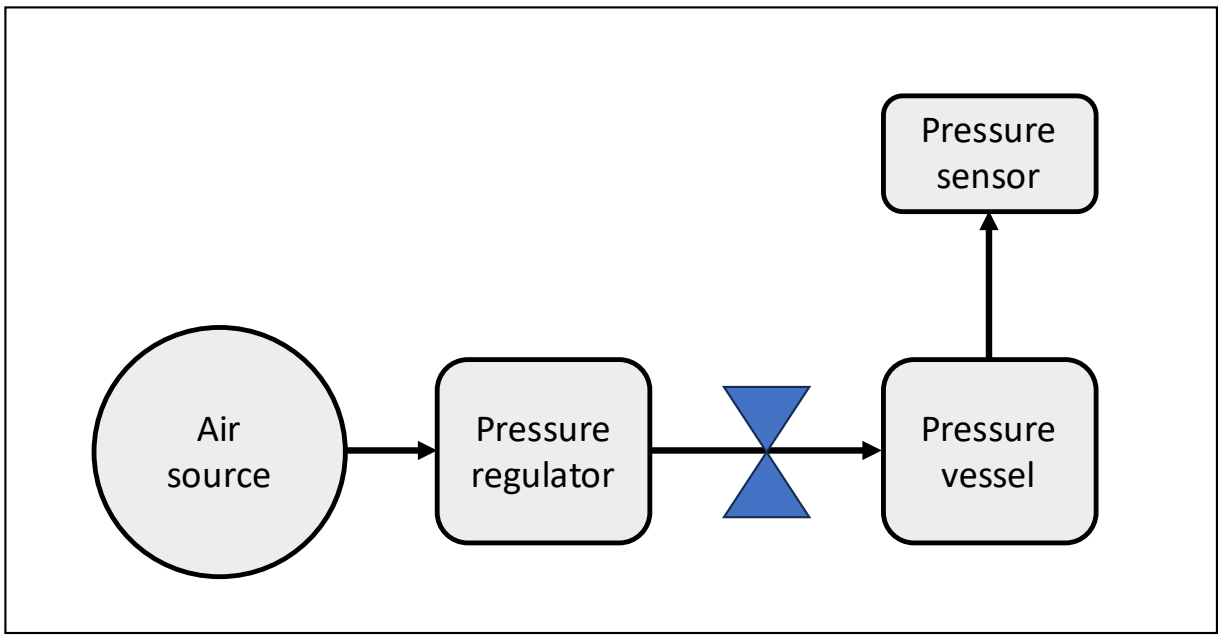

Figure 5. Diagram of AIO pressure port connections.

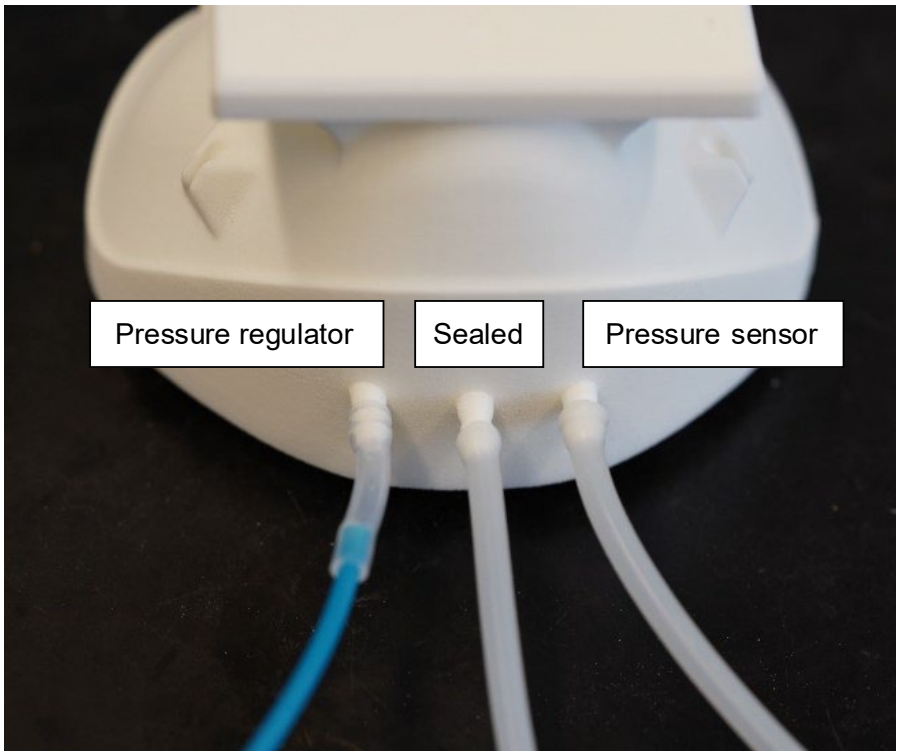

Figure 6. Photo of AIO pressure port connections. During normal pressure decay verification tests, one port will be sealed.

v. Run the pressure decay test
    1. Use a pressure regulator to fill AIO with enough air to reach 5 PSI and stabilize within ±0.1 PSI.
        a. Allow sufficient time for the pressure to stabilize at 5 PSI before proceeding. Different pressure regulators may require varying amounts of time to reach a stable reading without significant fluctuations from the set point.
    2. Starting at 5 PSI, initiate data acquisition and close the pressure regulator port connection.
        a. Data acquisition can be started earlier and then truncated to the starting timepoint.
    3. If there is a leak, the pressure will decay over time. Continue collecting data for 60 seconds or until the pressure decays to 0 PSI, whichever occurs earlier.

vi. Analyze acquired data using ΔP contour plot.
    1. Pick a hold time for the analysis. This should be within the data collection time specified above.
    2. Determine the ΔP of the test for the chosen hold time (e.g., ΔP = 5 PSI – $Pressure_{5sec}$).
    3. Locate the measured pressure drop value given the chosen hold time on the ΔP contour plot and determine the corresponding flaw area (Figure 7).
    4. Use this estimated flaw area to support evaluation of the device's performance based on its intended use (e.g., filtration efficiency vs flaw size, blood infiltration propensity vs flaw size).

b. Empirical data examples (Figure 9)

Table 1: Examples of RST Use cases

Example	Test condition	Initial pressure	Hold time	Result
Example 1: Sealed control vessel	AIO pressure vessel with all potential leakage paths covered with 6 coatings of acrylic sealant	5 PSI	10 sec	Pressure drop < 1% (< 0.05 PSI), confirming effective sealing and system integrity
Example 2: As-manufactured vessel without defects	Randomly selected AIO pressure vessel as manufactured, without intentional defects	5 PSI	10 sec	Pressure drop < 1% (< 0.05 PSI), indicating minimal inherent leakage
Example 3: Vessel with controlled defect	AIO pressure vessel with a drilled hole on lateral side	5 PSI	10 sec	Pressure drop of ~3.8 PSI, indicating significant leakage compared to examples 1 and 2

5. **AIO Pressure Decay Performance Comparator**

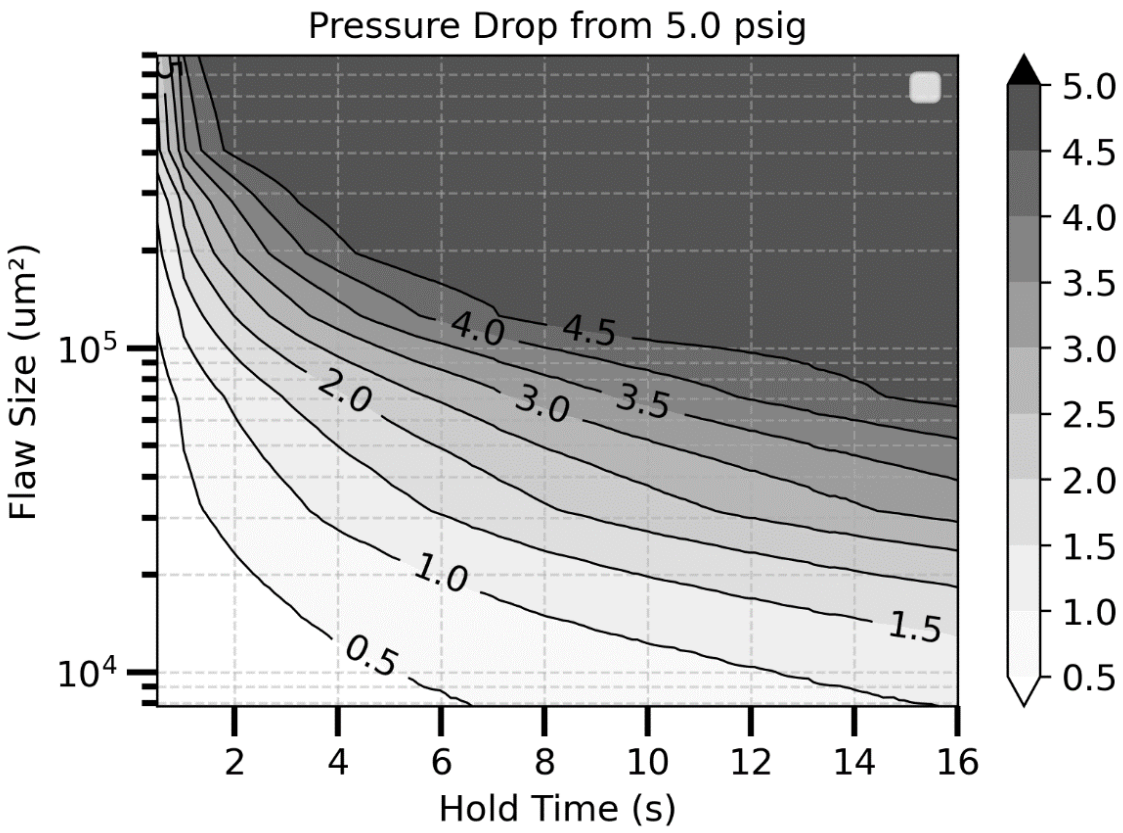

Figure 7. Pressure drop contour plot for the AIO as a function of hold time (seconds) and flaw area (µm²). The contour plot was generated from pressure decay test data using laser-drilled orifices of known sizes (shown in Figure 8). Users can compare their own pressure decay measurements against this reference chart to estimate the effective flaw area in their pressure vessels, which can then be used to support evaluation of the performance for the specific device and intended use.

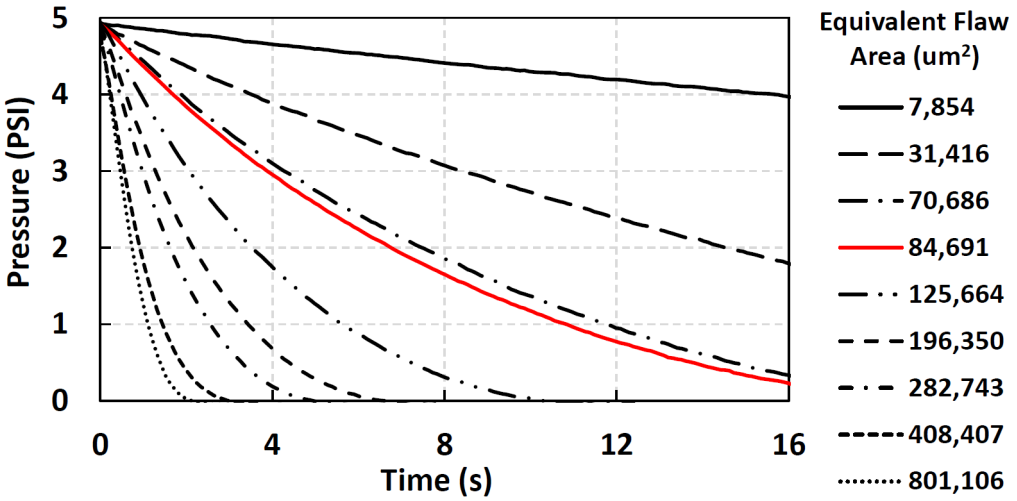

Figure 8. Pressure decay profiles for various flaw sizes in the AIO. The plot shows pressure decay over time for laser-drilled orifices (connected via one port) serving as surrogate flaws. For the two largest flaw sizes, multiple orifices were connected in parallel to achieve larger effective flaw sizes. Additionally, the graph includes the pressure decay profile of a directly drilled 84,691 µm² flaw in the lateral wall of the AIO. The AIO was fabricated using an EOS P396 system with PA2200 material at standard 120 µm layer height, with the twist cap opening oriented in the +Z direction relative to the build plate.

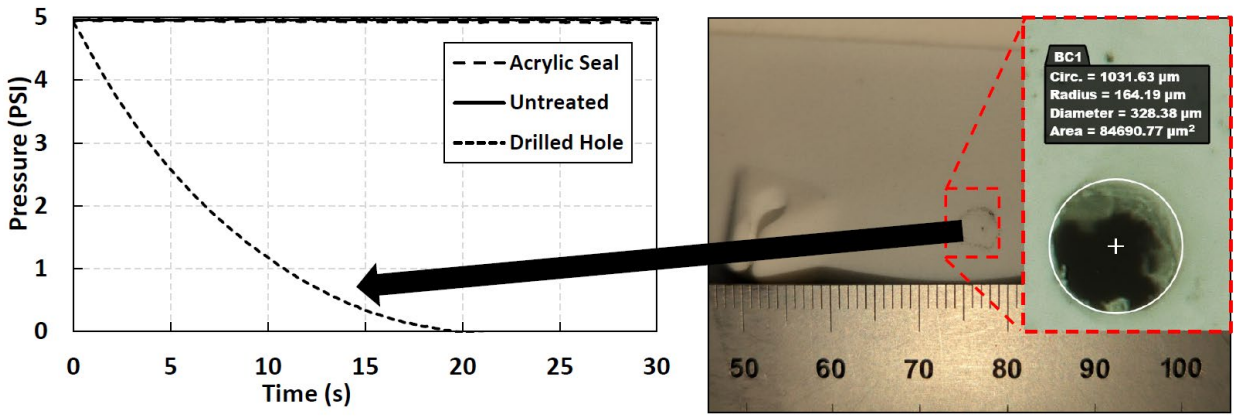

Figure 9. Plot demonstrating "no leakage" from Examples 1 and 2 and pressure drop from Example 3 (left). Microscope image of drilled orifice (~84,691 um²) on lateral side on AIO mask surface (right).

6. Troubleshooting

Common problems	Possible causes	Potential solutions
Rapid pressure loss; too quick for data acquisition.	Major leak in AIO (not in the mask region).	Re-check all seals and connections (using a leak detector or soapy water to detect locations of any potential leaks), reapply adhesive/grease and wait for it to cure or set, or inspect AIO for large defects.
Inconsistent pressure readings.	Sensor drift or incorrect electronics wiring.	Recalibrate pressure sensor and re-check electrical wiring and connections.
Pressure inside AIO is not measured to be changing.	Blocked port(s).	Ensure powder is removed from inside ports.
Unable to reach target pressure inside AIO.	Inadequate air supply pressure, leak too large, or regulator malfunction.	Ensure air source pressure is greater than 6 PSI, inspect AIO for large defects, and verify regulator performance.

7. References

[1] Ibarra, B., Schwerin, M., Hasani, A. et al. Leak verification method for additively manufactured medical devices. Int J Adv Manuf Technol 140, 1427–1440 (2025). https://doi.org/10.1007/s00170-025-16362-5