

Uson by PAC

# Medical Device Leak Testing

Engineer's Handbook



[USON.COM](http://USON.COM)

**Leak integrity defines patient safety.** As devices become smaller, thinner, and more complex, the margin for error narrows.

**This handbook provides engineering-sound guidance** for medical device leak testing, aligned with industry best practices and Uson by PAC expertise.



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# Foreword

**Leak integrity defines patient safety. As devices become smaller and more complex, the margin for error narrows. This handbook distills proven engineering principles into a practical reference for medical device development and manufacturing teams.**

**Use this guide to:**

- Establish leak rate specifications grounded in physics
- Select appropriate test methods for various device classes
- Avoid common pitfalls in fixture design and validation
- Build robust, compliant test processes aligned with modern medical manufacturing

# 1. Fundamentals of Leak Testing in Medical Devices

## 1.1 Why Leak Testing Matters

Medical devices operate in high-risk environments. Leaks can compromise sterility, dosage accuracy, or patient physiology.

Common risk categories:

- **Liquid ingress or egress** (IV sets, infusion pumps)
- **Gas containment failures** (respiratory circuits, catheters, balloons)
- **Barrier breaches** (implantable electronics, drug-delivery housings)
- **Package integrity failures** (sterile barrier systems)

Reliable leak testing reduces recalls, warranty failures, and regulatory scrutiny.

## 1.2 What Defines a Leak?

A leak is unintended fluid flow through an unintended opening. Flow rate depends on:

- Pressure differential
- Hole geometry
- Temperature effects
- Viscosity and molecular size of the test medium
- Material elasticity and creep

A leak only matters when you look at it under real-world conditions. In medical devices, engineers usually test with air because it is clean and fast, and then use those air results to predict whether liquids like water or saline would leak.





## 2. Establishing Medical Leak Rate Specifications

### 2.1 Three Sources for Initial Specification

- 1 **Industry norms** (ISO, ASTM, or internal company specifications already accepted in the market)

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- 2 **Theoretical modeling** using simplified physics equations to estimate leak behavior under ideal conditions

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- 3 **Empirical characterization** using early prototypes and real test data

### 2.2 Air-to-Liquid Conversion

Medical devices often carry water-based fluids with viscosity 50–200× higher than air. Use viscosity-ratio principles to relate performance:

$$Q_{\text{liquid}} \approx Q_{\text{air}} \times (\eta_{\text{air}} / \eta_{\text{liquid}})$$

Water at 20°C has viscosity  $\sim 1.0 \times 10^{-2}$  P, versus  $\sim 1.8 \times 10^{-4}$  P for air.

**Practical note:** the simple viscosity-ratio rule ( $Q_{\text{liquid}} \approx Q_{\text{air}} \times \eta_{\text{air}}/\eta_{\text{liquid}}$ ) is a first-order approximation valid only for small  $\Delta P$  and similar average pressures and when the leak path behaves like a long capillary (viscous laminar flow). For compressible gases use the compressible (Hagen–Poiseuille style) expression that includes the average absolute pressure term; for incompressible liquids the flow is proportional to  $\Delta P/\eta$ . For exact conversions at test pressures used in production, use the full model (Hagen–Poiseuille / Uson equation) or measure empirically.

## 2.3 Typical Starting Leak Ranges for Medical Devices — Based on Uson Field Experience (updated)

These are engineering starting points and practical customer starting bands aggregated from Uson experience. Use them as baselines for method selection and early design validation. Convert air results to liquids with the full compressible/viscous model or by empirical correlation. See handbook conversion notes.

Device category	Typical air test pressure	Typical leak-rate starting range (air, sccm)	Notes
Catheters (non-balloon)	0.3–1.0 bar (4.4–14.5 psi) — increase only for connection/proof checks	1–4 sccm (air)	Standard vascular and general catheters. Geometry and compliance vary. Prefer pressure-decay for small internal volumes; use differential decay or flow methods where volume or sensitivity dictates. For micro/neuro catheters or very-high-sensitivity requirements, use lower limits and trace-gas or vacuum methods. (Uson typical customer band)
Tubing & tubing sets (single/multi-lumen, braided, PTFE)	0.3–1.0 bar (4.4–14.5 psi); precision tubing may use higher pressure for fit checks	0.5–10 sccm (IV tubing commonly ~4–10 sccm)	Volume, lumen count, and connector geometry dictate sensitivity. Multi-lumen raises method complexity.
Connectors / Luer (ISO 80369)	1.0–2.0 bar (14.5–29.0 psi)	0.1–0.5 sccm	Small sealing geometry. High test pressure often used to expose microleaks. Frequently aligned with ISO luer test methods.
Bags, manifolds, large-volume assemblies	0.2–0.4 bar (2.9–5.8 psi) typical; burst/proof separate	5–20 sccm (gross-leak band) or delta-P approach	Large volumes reduce pressure-decay sensitivity. Pair leak testing with burst/burst-margin testing as needed.
Balloon catheters (compliant balloons)	Leak testing: 0.3–1.5 bar (4.4–21.8 psi); proof/RBP often much higher (do not equate RBP with leak sensitivity)	0.01–0.1 sccm	Highly compliant; staged inflation and extended stabilization required. Low leak limits often require helium/trace-gas methods.
Flow cells / microfluidic cartridges / chips	~0.1–0.5 bar (1.45–7.25 psi)	Method dependent — 0.1–100 sccm	Small channels; differential decay or direct flow measurement preferred. Specify flow-range rather than a single sccm number when possible.
Implantable housings / hermetic enclosures	Vacuum test or 1–3 bar (14.5–43.5 psi) depending on method	<0.01 sccm (requires helium/trace-gas or precision vacuum)	Highest-reliability parts. Use helium/trace-gas or vacuum + mass spectrometry for hermeticity verification.
Respiratory circuits & filters	0.2–0.5 bar (2.9–7.3 psi)	1–10 sccm	Large volume, low-pressure systems; sensitivity depends on circuit volume. Differential decay or flow methods preferred for large systems.
IV sets (assembly level)	0.3–1.0 bar (4.4–14.5 psi)	4–10 sccm	Assemblies with multiple ports. Fixture design and paired testing reduce false fails.
Surgical assemblies / staplers / complex mechanical subsystems	1.0–2.0 bar (14.5–29.0 psi)	0.5–2.0 sccm	Multiple interacting seals; method choice driven by internal volumes and expected failure modes.

### Short technical footnotes

**Units:** pressures shown in psi + bar; leak rates in sccm (standard cc per minute).

These leak-rate bands are for air. For liquids, use the full compressible/viscous conversion model (Hagen–Poiseuille / Uson equation) or empirical conversion at production test pressures. Simple viscosity-scaling is only a first-order approximation.

Many customers specify delta-P pass/fail criteria or list method-only requirements. When a clear sccm value is required, normalize units and confirm the test method (pressure-decay, differential decay, mass flow).

**Balloons:** retain a clear separation between low-pressure leak sensitivity testing and proof/Rated Burst Pressure (RBP). Use low-pressure leak tests for sensitivity; use RBP only for mechanical strength validation.

# 3. Choosing the Correct Test Method

After establishing a set of leak specifications, one of the most critical decisions is selecting the right test method. The design of the device and the tolerance of its specifications heavily influence this choice. Even within these methods, there are variations to achieve the desired result. This emphasizes the importance of working with experienced application experts when designing a new test.

## 3.1 Method Selection Matrix

Method	Best For	Sensitivity	Limitations
Pressure Decay (Gauge)	Primary method for most medical devices	Moderate	Sensitivity depends on test pressure and volume
Differential Pressure Decay	Large volumes or when improved sensitivity is required	High	More sensitive to temperature effects and creep
Laminar Flow	Large volumes, higher allowable limits	Low	Requires stable supply pressure
Mass Flow	High-volume assemblies, higher flow ranges	Moderate	Slower response time
Helium/Trace Gas	Hermetic housings, implants	Very high	Cost, environment, cycle time

**Uson note:** for high-compliance plastics use prefill + longer stabilize/dwell times; for large system volumes prefer differential decay or flow methods because single-chamber pressure decay sensitivity reduces as volume grows.

## 3.2 Quick Rules

- Use **pressure decay** for most medical device parts with internal volumes less than **500 mL** (This is a guideline, not a strict cutoff).
- Use **differential pressure decay** for parts **greater than 500 mL** or when **increased sensitivity** is required.
- Use **mass flow** when continuous flow is expected and an actual **flow measurement** is required.
- Long-term implants typically require leak rates <0.01 sccm and require helium mass spec.





## 4. Controlling Test Variables

The real world introduces complexity to what is otherwise a straightforward test. Two examples are the effects of temperature and component elasticity.

### 4.1 Temperature Effects

Changes of 1 °C can shift internal pressure by approximately 0.35%, which can compromise the accuracy of leak tests. The following strategies help mitigate temperature effects and ensure reliable results:

- Minimize fill-induced adiabatic heating
- Use short measurement windows once stabilized
- Avoid fixtures near HVAC turbulence

### 4.2 Component Elasticity and Creep

Soft medical polymers expand under pressure, and the resulting pressure drop can register as a false leak. Control for this effect using the following strategies:

- Prefill 10–20% above test pressure
- Allow a defined stabilization dwell
- Use dual-sample (paired) testing for high-creep devices

# 5. Fixture & Seal Design for Medical Components

## 5.1 Principles

- Avoid dynamic seal compression during test
  - Use O-rings in dovetail grooves where possible
  - Apply fixed mechanical stops to prevent over-compression
  - Minimize sealed area to reduce creep masking
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## 5.2 Special Considerations for Medical Plastics

Thin, flexible materials require:

- Wider seals to distribute force
  - Lower compression ratios (10–20%)
  - Consistent pneumatic clamping for repeatability
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## 5.3 Automatic Connectors

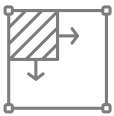
Automatic couplings can be controlled directly by the leak tester and integrated into the test method. This reduces the need for additional hardware such as PLCs, toggle switches, and external regulators. Tester-controlled couplings also improve patient safety by enforcing different behaviors on pass versus fail, for example holding the part on reject to prevent unintended release.



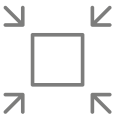
## 6. Method Development Strategies

### 6.1 Developing a Stabilization and Measurement Strategy

Rather than fixed times, develop the test method using a structured approach that responds to part behavior.



**Fill** the part until it reaches the target test pressure, then continue filling to approximately **20%** above the target pressure.



**Isolate** the test volume consistently after filling to separate the part from the supply. This step is required in modern leak testers and should be approximately 0.1 s.



**Stabilize** the part at test pressure. Stabilization will be longer for flexible parts as the material expands and then relaxes. High-pressure tests will also require longer stabilization due to adiabatic temperature effects.

The most reliable way to confirm stability is by reviewing the **pressure profile chart**. Stability is achieved when the slope of the curve visibly flattens.



**Measure** leakage once stability is reached. The measurement step is driven by the required leak specification and sensitivity.

**General guidance:** Stabilization should be **at least as long as, and often longer than, the measurement step** to ensure reliable and repeatable results.

### 6.2 Application Considerations

- **Rigid parts** typically stabilize faster due to minimal elastic expansion.
- **Flexible parts** require extended stabilization to account for material creep and relaxation.
- **High-pressure tests** demand additional stabilization time due to adiabatic heating effects.

### 6.3 Balloon Catheters

Balloon catheter testing requires additional care due to high compliance and large elastic expansion.

1. **Staged inflation profile** to control expansion and avoid shock loading of the material.
2. **Extended stabilization** to allow the balloon to fully expand and relax before measurement.
3. **Profile-based monitoring** to observe pressure behavior and confirm stability rather than relying on fixed timing.
4. **Drift awareness** during measurement, as material relaxation can mimic a leak if not properly stabilized.



## 7. Interpreting Results & Preventing False Fails

### 7.1 When Pressure Drop Is Not a Leak

- **Thermal drift:** Add additional stabilization time and confirm pressure has thermally equilibrated before measurement.
- **Creep expansion:** Increase stabilization to allow flexible materials to fully expand and relax before measuring leakage.
- **Fixture seal instability:** Run a seal-only leak test to isolate tester performance from the fixture. Inspect seal condition, alignment, and coupling actuation pressure.
- **Regulator hunting in flow systems:** Verify pressure supply stability, add upstream volume if required, or isolate the regulator during the measurement phase.

### 7.2 Trend-Based Diagnostics

Use batch analytics:

- Rising near-limit failures → fixture seals degrading
- Increase in gross leaks → upstream process defect
- Flattened distribution curve → systemic instability

## 8. Validating a Medical Leak Test Process

Validation confirms that the leak test method is capable, repeatable, and suitable for its intended medical application. Validation activities should align with internal IQ/OQ/PQ or equivalent process validation frameworks. This section outlines core requirements and points to additional practical guidance available on [Uson.com](https://www.uson.com).

### 8.1 Verification Requirements

- **Repeatability & reproducibility (gage R&R):** Demonstrate that variation is dominated by the part, not the test system.
- **Sensitivity validation using calibrated leaks:** Confirm the system can reliably detect leaks at or below the specification limit.
- **Environmental robustness:** Verify performance across expected temperature and humidity ranges.
- **Sensor & flow standard calibration:** Document the flow standard used to calibrate flow sensors (Flow Master or equivalent), show NIST-traceable calibration certificate, record ambient conditions during calibration, and retain calibration interval. If using pressure sensors, document zero/span checks and reference the device owner's calibration procedure

Related reading on Uson.com:

- Articles covering **baseline drift, zero compensation, and false-fail reduction**
- Articles covering **production validation and pass/fail separation strategies**



# 9. Engineering Tools & Reference Tables

## 9.1 Viscosity Reference (Selected)

- Air at 20°C:  $1.81 \times 10^{-4}$  P
- Water at 20°C:  $1.00 \times 10^{-2}$  P
- Saline:  $\sim 1.2 \times$  water viscosity

**Notes:** (1) The formula assumes constant temperature and that pressure changes are small relative to absolute pressure; for large  $\Delta P$  or temperature drift you must correct for compressibility/temperature or use an absolute-pressure model. (2) Test volume must include the fixture/test-line volume (not just part internal volume)

## 9.2 Conversion: Pressure Decay to Leak Rate

$$\text{Leak Rate} = (\text{Test Volume} \times \text{Pressure Drop}) / \text{Test Duration}$$

## 9.3 Recommended Minimum Detection Levels

- General fluid-tight or gross-leak medical devices: 1–10.0 sccm
- Long-term implants typically require leak rates  $< 0.01$  sccm and require helium mass spec

# 10. Quick Reference: Test Method Selection Guide



### For Small, Rigid Components

Use **pressure decay** as the primary method. Consider **differential pressure decay** only when higher sensitivity is required.



### For High Compliance Plastics

Use prefilling, longer dwell, and paired testing.



### For Large Volume Systems

Use DP (differential pressure) or mass flow.

# Glossary

- **sccm:** Standard cubic centimeters per minute
  - **Differential Pressure Decay:** Measurement of pressure drop relative to reference volume
  - **Laminar Flow:** a flow regime where viscous forces dominate and flow layers do not mix. For incompressible liquids in long, narrow paths  $Q \propto \Delta P/\eta$  (linear). For compressible gases, laminar theory for narrow paths produces  $Q$  that depends on  $\Delta P$  and the average absolute pressure across the path (e.g., Hagen–Poiseuille modifications); when converted to standard volume units this can appear non-linear. Use the compressible formula or empirical calibration for gas→liquid comparisons.
  - **Creep:** Time-dependent material deformation under pressure
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## About this Handbook

Based on established leak testing principles and adapted for modern medical engineering use cases. Intended for design engineers, manufacturing engineers, quality teams, fixture designers, and process validation specialists.

## Final Notes

**Leak testing is both science and systems engineering. The best results depend on tight control of pressure, temperature, mechanics, and data. Use this handbook as your baseline framework and adapt for your specific device geometries, materials, and risk classifications.**



**SCAN TO GET STARTED**

**Explore leak testing solutions  
and connect with our experts.**

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