

How to Leak Test Medical Solution, Fluid or Blood Bags



Medical solution and blood bags are used in many clinical applications today. Typically made from sheets of PVC, EVA or polyolefin which are sealed at their perimeter edges, they often have tubes or ports exiting the bags interior and sealed between the flat sheets.

Testing each bag for leaks is critical and the automated test must address the challenges of the flexible material, variable sizes likely being produced and the manufacturer's requirements for cycle time and process management. CTS has extensive experience in providing these types of leak test solutions and this application note details an example of such testing.

Solutions for Leak Testing Medical Solution, Fluid or Blood Bags



Sentinel Blackbelt

Single channel instrument



Sentinel Blackbelt Pro

Multi-channel instrument with features that support 21 CFR Part 11 and EU Annex 11

The most common uses for these bags are for the transport or delivery of solutions, blood/plasma or waste:

- Blood bags
- Plasma bags
- Anticoagulant bags
- Peritoneal dialysis solution bags
- IV solution bags
- Enteral feeding bags
- Sterile water bags
- Saline bags
- Heparin bags
- Electrolyte injection bags
- Wound drainage collection bags
- Urinary waste collection bags

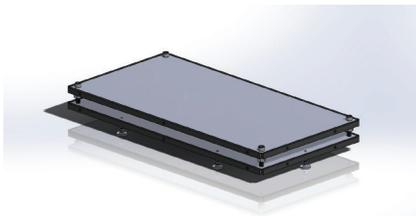
Test Methods

For 100% production testing of bags, the most common method uses pressure decay with clean and dry compressed air at positive pressures ranging from 0.1 to 30 psig. The single-channel Sentinel Blackbelt or multi-channel Blackbelt Pro pressure decay instrumentation are designed for this purpose.

LOADING THE BAGS FOR TESTING

1. The bag is placed into a restraining plate fixture similar to the image below. The restraining plates are spaced as tightly together as possible to minimize the volume of the pressurized bag and to limit the elastic creep or stretch of the material while under test.

Typically, porous media sheets (such as Porex®) are mounted to the inside surfaces of each restraining plate to allow any sidewall leak on the bag's sheet material to vent to atmosphere and not mask such leaks.



CTS-designed restraining plate

2. The operator inserts a custom CTS CO31 Connect with 316SS ID support/fill mandrel into each of the bag's open ports, allowing pressurization and/or sealing of the bag during test. The Connect is mated to one of the test ports on the instrument.



CTS CO31 Connect

3. The Start button on the test instrument is pressed by the user. The CTS Connects are activated, sealing the bag's ports radially. The pressure decay test cycle begins.

PRESSURIZATION OF THE BAG

4. The instrument pressurizes the bag with regulated compressed air, inflating it to the desired test pressure for a user-defined Fill time. This pressure is monitored by the instrument's pressure transducer and compared to user-defined min/max limits, enabling it to detect an improperly adjusted pressure supply or gross leaks.

To shorten the testing cycle,

some manufacturers add a Pre-Pressure sequence step, where a second source is used at a slightly elevated pressure—perhaps +10% above the target test pressure, or +1.0 psig. This over-inflates the bag to force it to reach its elastic limit very early in the test cycle, rather than wait for it to occur naturally during the Stabilization step.



STABILIZATION: REDUCING NATURAL PRESSURE LOSS AND FINDING GROSS LEAKS

5. Once the Fill timer expires, the isolation valve inside the instrument closes, trapping pressure inside the bag for a user-specified Stabilize time. This time is intended to minimize the natural pressure loss of even non-leaking parts due to expansion or creep, adiabatic thermal effect and potentially absorption, increasing the separation of the final measured pressure loss/decay between good parts and rejects.

The pressure is also measured by the instrument's pressure transducer and compared to min/max limits to detect slightly smaller but still gross leaks on the bag.

TEST: DETECTING FINE LEAKS

6. After the Stabilize timer expires, the pressure transducer is tared and the resulting pressure loss/decay is recorded over a user-defined Test time and compared to min/max pressure limits to determine whether fine leaks are present.

Using Leak Rate to Standardize Testing for Product Families of Different-Sized Bags

Many manufacturers opt to convert the basic pressure decay/loss value to a leak rate in standard cubic centimeters per minute (sccm). Because pure pressure loss values are dependent upon the volume under test, similarly constructed but differently sized bags will yield different pressure losses even if they are leaking at the same rate. With a fixed leak rate, large volumes have lower pressure decay/loss values vs. smaller volume bags having the same leak.

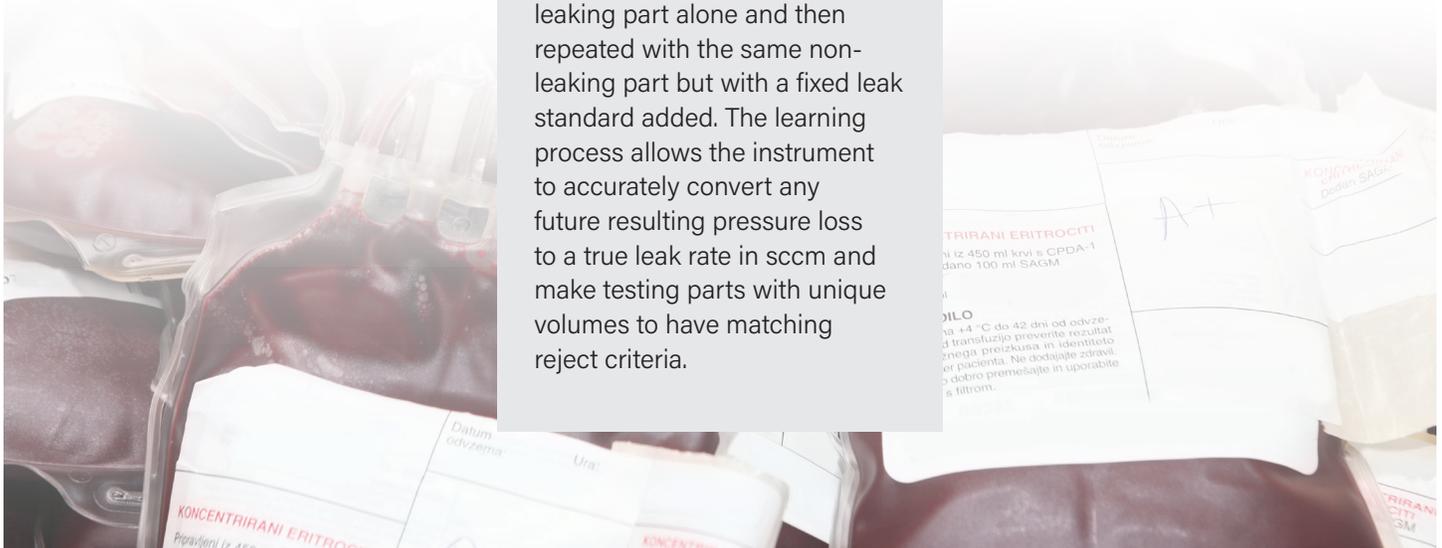
The advantage is that once the user defines a target reject leak rate in sccm, they can often apply the same leak rate criteria to an entire family of similar products having different internal volumes. Executing a simple program calibration teaches the instrument the typical decay of a known non-leaking part alone and then repeated with the same non-leaking part but with a fixed leak standard added. The learning process allows the instrument to accurately convert any future resulting pressure loss to a true leak rate in sccm and make testing parts with unique volumes to have matching reject criteria.

EXHAUST: VENTING THE PRESSURE FROM THE BAG

7. Once the Test timer expires, the pressure trapped inside the bag is vented to atmosphere, using a user-defined Exhaust time.

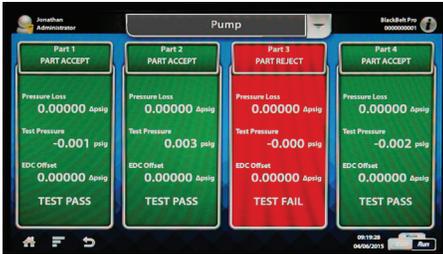
Facilitating Bag Removal

At the end of most bag tests, a small amount of air is left inside the bag, leaving it slightly inflated. In some cases, it is inflated enough that removing the bag from the restraining plate opening can be difficult. Some users purchase the Sentinel instrument with vacuum exhaust capability, where a Venturi vacuum generator mounted internally within the instrument can be activated to the part, removing most or all of the air trapped inside the bag. It then becomes as easy to remove as it was to initially load.



TEST RESULT DATA

8. After the Exhaust timer expires, the final variable test result data is displayed on the instrument. Highly visible indicators on the display and front panel make it obvious to the operator which bags have passed or failed, allowing them to disconnect from the Sentinel instrument and properly move the bags down the production line or into reject containers.



Pass/fail display on instrument

Ensuring Failed Parts Are Properly Handled

Using the CTS CO31 Custom Connect driven by the Sentinel Blackbelt or Blackbelt Pro, an option exists to set up the test program to leave failed bag ports sealed by the Connect, forcing the user to either press a reset button or alternately use a security key or password to release the failed bag. This method of forcing the operator to break rhythm limits the risk of failed parts from being inadvertently placed for downstream operations.



Turnkey Leak Test Systems

CTS can integrate its instrumentation into a complete solution.

Watch the video on medical bag testing



Total test cycle time required is dependent upon many factors, however most critically:

- Reject limit selected
- Dimensional stability of the part while under test (controlled somewhat by the use of Pre-Pressure and restraining plate setup)
- Volume of the pressurized/evacuated area of the part under test (limited by the bag dimensions and the restraining plate setup/spacing)
- Temperature stability of part and testing environment
- Repeatability requirements defined by the user
- Accuracy, precision and resolution of the instrument executing the test

Contact CTS to discuss your test application

Contact us for more information on our industry leading medical device leak testing systems, catheter testing solutions, medical bag testing and pressure decay testing, or [request a quote today](#).



Your Global Leak and Function Test Solution Experts

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