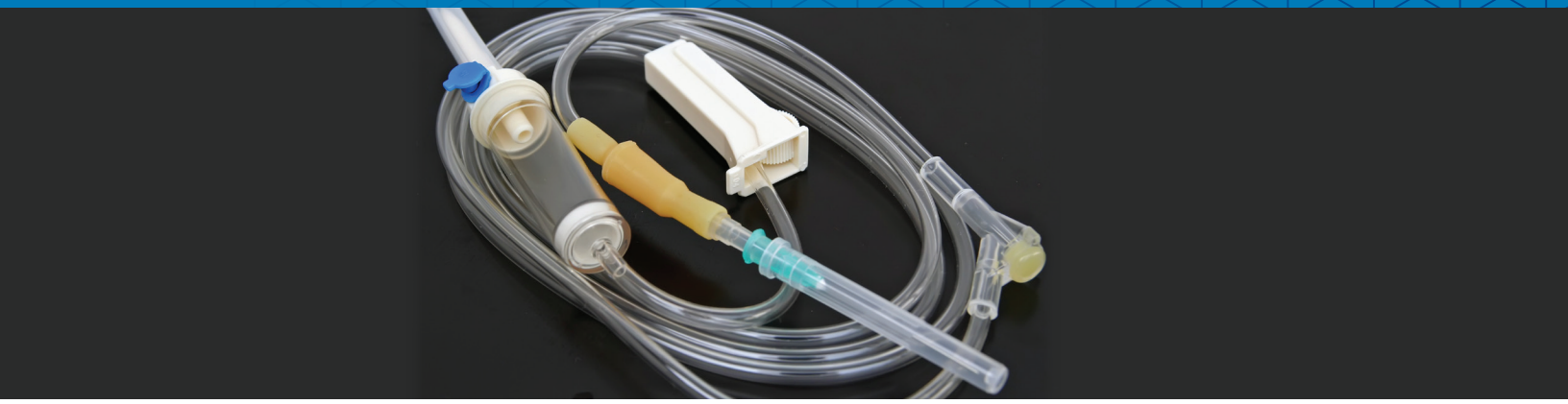
Application Note ▪ Medical

CINCINNATI TEST SYSTEMS
Your Global Leak and Function Test Solution Experts

How to Leak Test Disposable Tubing Sets



Single-use disposable tubing sets are broadly used in a range of clinical applications for the transfer of IV solutions, drugs/medications, blood, waste and other various liquids either between containment components or between a container and patient.

In nearly all cases, these tubing sets have both an inlet and one or more outlets which may later be mated by the clinician to any number of various bags/bottles and delivery needles/cannula.

Common Tubing Sets:

- IV Administration Set
- Drug Infusion Set
- Blood Transfer Set
- Chemo Infusion Set
- Venous Infusion Set
- Insulin Infusion Set
- Solution Set
- Filtered/Unfiltered Infusion Set
- Vented/Unvented Infusion Set
- Waste Transfer Set
- Gravity Administration Set
- Enteral Feeding Set
- IV Extension Set
- Contrast Solution Set
- Wound Drainage Set

Solutions for Leak Testing Tubing Sets

Sentinel Blackbelt

Single channel instrument

Sentinel Blackbelt Pro

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

CTS Connects

High quality seals and connectors for medical applications

Test Methods

Testing 100% of parts in production typically requires dry compressed air pressure decay. The single-channel Sentinel Blackbelt or multi-channel Blackbelt Pro pressure decay instruments are designed for this purpose.

Most tubing sets require testing pressures ranging from 1 psig to 200 psig with extreme cases at up to 500 psig and beyond. In limited instances, often for wound evacuation applications, are sets that are used clinically under vacuum and are most-often tested at vacuum levels between -1 and -12 psig.

During assembly where various adhesives or welds mate rigid injection molded components to softer flexible tubing, potential leaks and blockages may occur. Leak testing of tubing sets requires a two-step process to detect these issues

SEALING THE TUBING SETS FOR TEST

1. Either a spike/drip chamber or a female luer fitting on the tubing set's proximal/inlet end is mated to the test port(s) on a Sentinel Blackbelt or Blackbelt Pro instrument.
   a. For sets with spike fittings, the instrument is most often supplied with an optional CTS CO31 OD Connect controlled by the test instrument. This Connect is typically designed with an integral spike-locating "funnel" to ensure non-angular insertion of the spike by the operator into the Connect opening to prevent accidentally abrading the seal inside the Connect during the loading or removal of the sharp spike into or out of the Connect.
   b. For sets with a female luer fitting on the inlet, the instrument is supplied with either a standard ISO 80369 metal luer-lock fitting or optionally a CTS CO31L Luer Connect controlled by the test instrument.
2. The male luer fitting on the tubing set's distal/outlet end is sealed by one of the following methods:
   a. Mated manually by the user to their own luer cap to seal the male luer fitting to atmosphere for the leak test, and then alternately removed by the user to vent the male luer fitting to atmosphere prior to the blockage test.
   b. Placed by the user into an external, remotely mounted CTS CO31L Luer Connect with the outlet sealed to atmosphere, controlled by the instrument to seal during the leak test and then release the male luer fitting prior to the blockage test.
   c. Mated manually by the user to an external 2-way acting valve controlled by the test instrument with ISO 80369 metal luer-lock fitting mounted to its inlet, where the valve remains closed during the leak test and then opened during the blockage test.
   d. Attached by the user to a secondary custom port (containing either CTS CO31L Luer Connect or ISO 80369 metal luer-lock fitting) on the test instrument that contains an internal 2-way acting valve controlled by the test instrument to alternately seal and then vent the male luer to atmosphere as described in c. above.
3. The Start button is pressed by the user and, if equipped, the instrument activates all necessary CTS Connects and/or valves, sealing both inlet and outlet of the tubing set to atmosphere.

PRESSURIZATION OF THE SET

4. As the pressure decay leak test cycle begins the instrument pressurizes the inlet of the set with regulated compressed air or nitrogen for a user-defined Fill time. The pressure is measured by the instrument's pressure transducer and compared to min/max limits, enabling detection of improper pressure supply or gross leaks on the set.

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 set for a user-defined 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 set being tested.

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.
7. Once the Test timer expires, the pressure trapped inside the set is vented to the atmosphere using a user-defined Exhaust time. The instrument then releases the distal Connect, allowing the set to vent to atmosphere via the distal end to permit Blockage testing.

Using Leak Rate to Simplify Testing across Tubing Set Variations

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 sets which have different pressurized volumes (due to differences in length or diameter) will yield different pressure losses even if they are leaking at the same rate. With a fixed leak rate, larger volumes have lower pressure decay/loss values vs. smaller volume sets with 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 differing 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.

Option for Leak Testing with Mass Flow

For customers who reject a fixed leak rate in sccm and which test a higher-than-average number of unique tubing set models which have differing internal volumes, another option exists which typically reduces (if not eliminates) the need to perform the test calibration step required when setting up a pressure decay test. A slightly higher cost (but reduced complexity) option for leak detection exists by performing the leak test using the mass flow test type.

With this method the set is charged with pressure during the Fill time, typically in the same manner as the pressure decay test method.

After the Fill timer expires, the source air is routed through the instruments mass flow transducer where actual flow (leak) through the part to atmosphere is recorded at the end of a user-defined Test time and compared to min/max flow limits to determine whether fine leaks are present, typically in leak rate units of standard cubic centimeters per minute (sccm).

Continued on next page.

Continued from previous page.

It may be important to note that, all things being equal, the repeatability of a pressure decay test on such parts is often superior to the same test executed with mass flow. The primary reason is that the mass flow test requires source air being mated to the part the entire test cycle (including when final measurement of flow is made) and any slight fluctuations in pressure will often result in a proportionate variation in test result. Pressure decay completes its measurement of the degree of leak having source air isolated from the trapped pressure inside the part, minimizing the potential for momentary source pressure fluctuations from affecting the test result. Lastly, mass flow captures the flow value read at the end of the Test timer only whereas the pressure decay method makes a cumulative decay measurement over the entire test period, leaving less opportunity for a momentary transient from affecting the result.

INSPECTING FOR BLOCKAGES USING PRESSURE LOSS

8. Using the same method as in the pressure decay test, the instrument again charges the set with pressure during the Fill time, typically the same time setting as used for the leak test.
9. Stabilize time is always set to a bare minimum value (0.05 seconds) to minimize pressure losses through good, unblocked parts.
10. After this brief stabilization, the pressure transducer is tared and the resulting pressure loss/decay over a fixed time is recorded and compared to min/max pressure loss limits to determine whether or not the set has a total or nearly total blockage. Test time is short, typically between 0.1 and 1.0 seconds to permit an intentional loss of between 50% to 80% of the initial starting pressure seen during Fill time when testing unblocked parts.

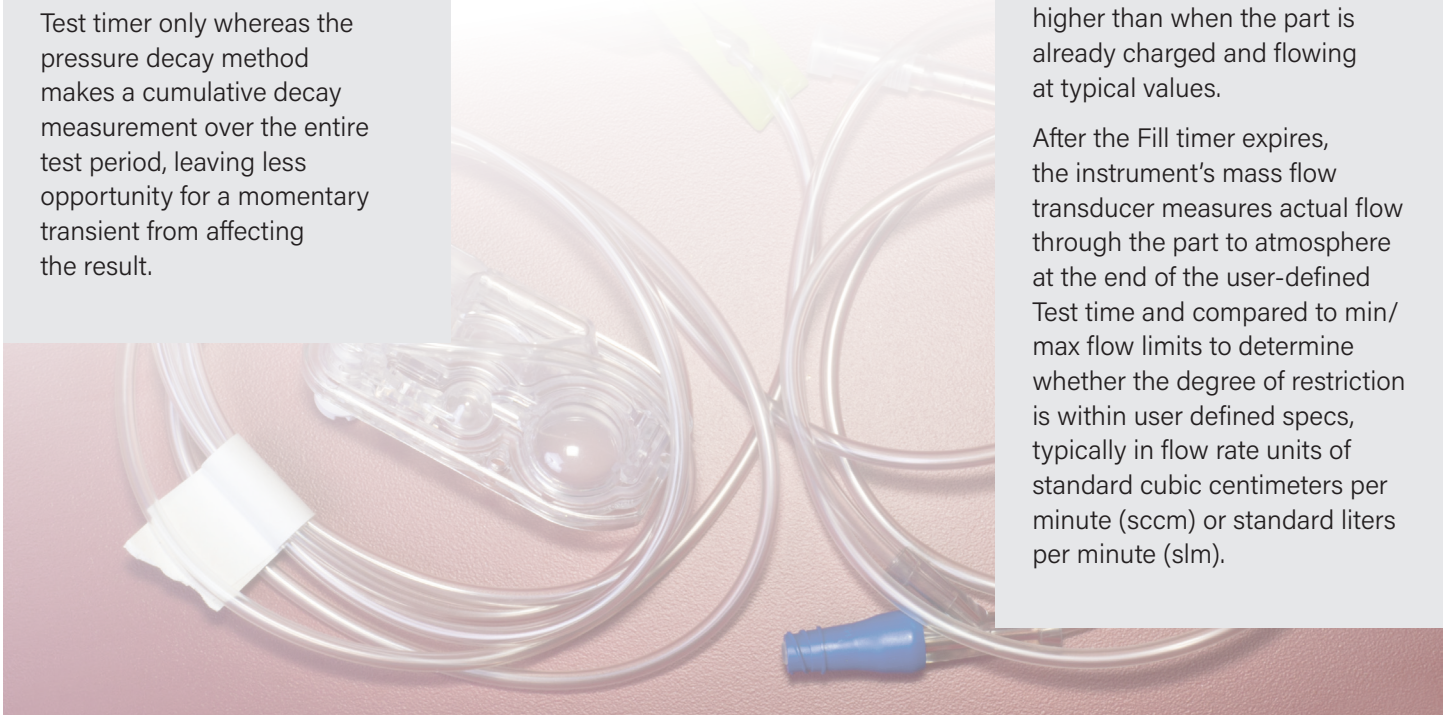
Option for Graded Blockage Testing using Mass Flow

If partial blockages must be detected, the test will typically require the use of mass flow test method.

The instrument pressurizes the set with regulated compressed air, charging it to the desired test pressure for a user-defined Fill time. This pressure is measured by the instrument's pressure transducer and compared to min/max limits, enabling it to detect improperly adjusted pressure supply or grossly incorrect sized sets.

The user has the option of having this pressure initially bypass the instrument's flow transducer for large fill volume part applications where the initial flow values when attempting to reach target pressure may be significantly higher than when the part is already charged and flowing at typical values.

After the Fill timer expires, the instrument's mass flow transducer measures actual flow through the part to atmosphere at the end of the user-defined Test time and compared to min/max flow limits to determine whether the degree of restriction is within user defined specs, typically in flow rate units of standard cubic centimeters per minute (sccm) or standard liters per minute (slm).



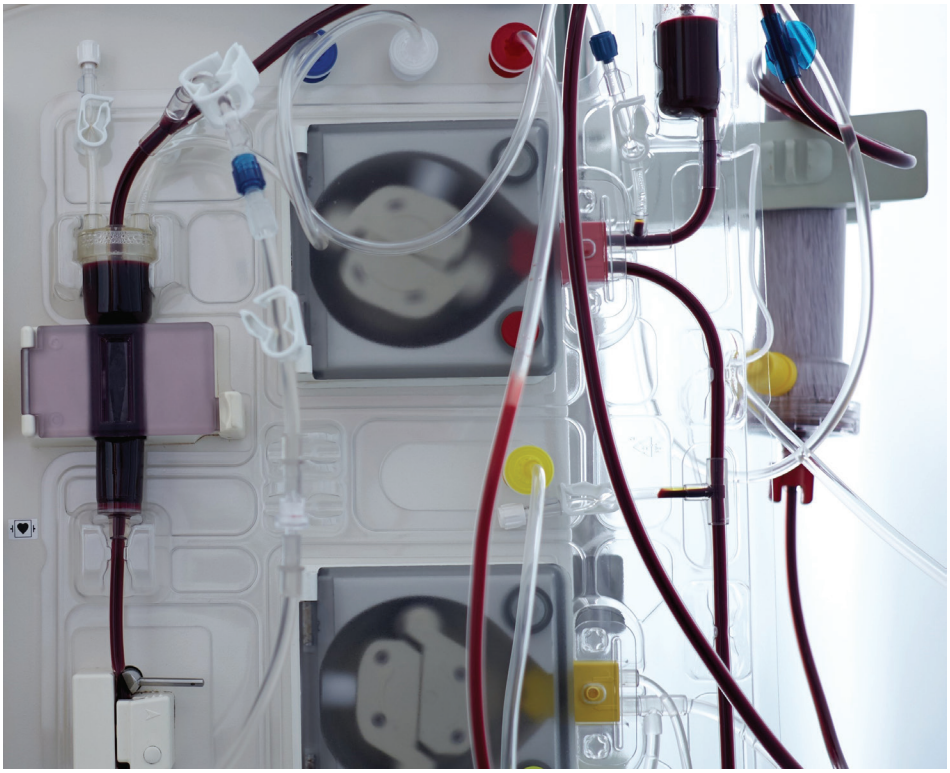
11. After the Exhaust timer expires, the final variable test result data and highly visible indicators are shown on the display and front panel make it obvious to the user which parts have passed or failed, allowing them to disconnect from the Sentinel instrument and properly move the parts down the production line or into reject containers.

Ensuring Failed Parts Are Properly Handled

Using CTS Connects driven by the Sentinel Blackbelt or Blackbelt Pro, the test program can be set to leave failed tubing sets sealed by the Connect, forcing the user to either press a reset button or use a security key or password to release the failed part. This method of forcing the operator to break rhythm limits the risk of failed parts being inadvertently placed for downstream operations.

Total test cycle time is dependent upon different factors, most importantly:

- Reject limit selected
- Volume of the pressurized/ evacuated area of the part under test
- Temperature stability of part and testing environment
- Dimensional stability of the part while under test
- Repeatability requirements defined by the user
- Accuracy, precision & 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. We will help you determine the right leak test for your device and process. **Request a quote today**.

CINCINNATI TEST SYSTEMS

Your Global Leak and Function Test Solution Experts

CINCINNATI TEST SYSTEMS Corporate Headquarters – 10100 Progress Way, Harrison, OH 45030
Phone (513) 367-6699 | International (513) 202-5100 | cincinnati-test.com