

MEDICAL DRUG INFUSION SET FLOW & LEAK TESTING

Problem:

A medical device manufacturer required 100% testing of several models of solvent bonded Drug Infusion Sets comprised of tubing, various connectors and a specific ranges of flow restrictors. Each model had a different flow restricting orifice designed to limit the drug delivery rate. They had been using a simple analog “floating-bead” variable area flow meter read visually by an operator who observes the meter to ensure the flow was within a band as measured by graduated lines on the meter. After the flow test, the outlet of the Set would be plugged and a pressure decay test was performed using a simple coarse analog gauge watching for a drop of 1 psig in 1 minute. The manufacturer was having issues with the following:

- Operator subjectivity. Mistakes and misreading of coarse lines on both the pressure and flow meters were all too common.
- Lack of resolution. As the target flow levels for the various Sets were anywhere from 600 to 2700 sccm, the flow meter’s scale was not finely graduated and it was difficult to resolve increments of less than 100 sccm.
- Lack of repeatability. The small bead inside the flow meter would change position from cycle to cycle even on the same Set being tested due to a number of mechanical variables within the flow meter.
- No quantified data. Customer had no stored data to show range of actual pressure drop (leak) or measured flow.



Test Requirement:

Air mass flow each Set at 12 psig with part models nominally measuring 600 sccm, 800 sccm, 1400 sccm and 2700 sccm followed sequentially by a pressure decay leak test at 25 psig rejecting -0.015 psig or more in 5.0 seconds.

CTS Solution:

CTS utilized the Sentinel Blackbelt leak test instrument with 0-30 psig pressure range and 0-3000 sccm mass flow capability to complete both tests in single combination test sequence of mass flow followed by pressure decay - ΔP . Using this high-resolution digital instrument, the tolerance range of each model could be much tighter (+5% of target flow range or less). Each test generated quantified data (up to the last 5000 test results could be stored within instrument memory) which the customer could collect and utilize for trending purposes.

Other Features of this Application:

The instrument was also equipped with a CTS Luer Connect to automatically seal the inlet port of the Drug Infusion Set and mate it to the test port of the instrument. If the part passes the leak test, the Connect automatically releases the set to the operator. If the test fails, the part is securely held in the Connect and requires a reset action of some kind (operator pressing Stop button or requiring a key reset) to unlock the part. Another CTS Connect was used to seal the needle on the outlet port of the Set and would engage after the flow test to plug the Set during the pressure decay leak test. The sequencing of both Connects were controlled by the Blackbelt instrument alone.

This same technology is often used in testing:
Dialysis Catheters, Needles, Irrigation/Suction Devices, IV Sets, Flow Restricting Cannula, Variable Flow Rate Devices, Drug Delivery Cassettes, Trocars and Surgical Access Ports.