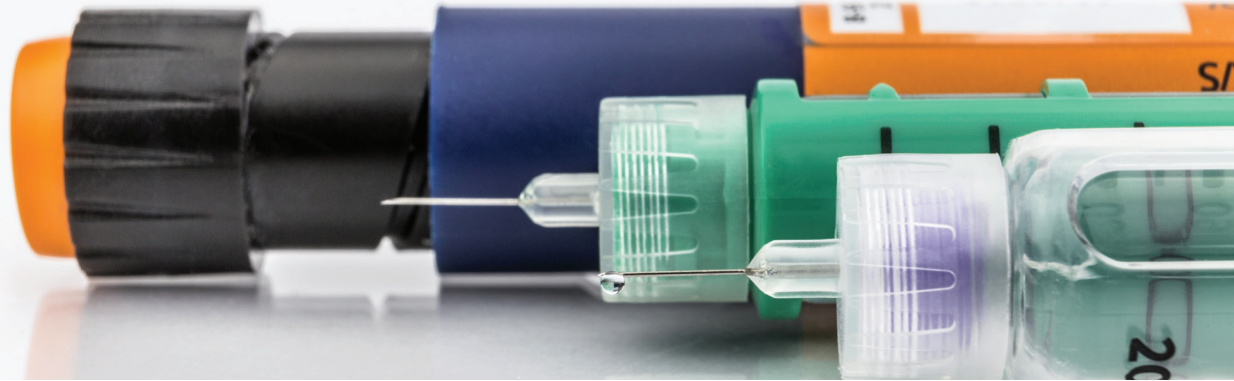


How to Restriction Test Cannula/Needles and Flow Selection/Regulation Devices



Cannula and flow regulation devices are used almost constantly in thousands of clinical applications today. These devices primarily provide a pathway for the administration or collection of solutions, blood and fluids for patients under treatment.

These devices are often designed to have a nominal expected flow rate with a given media in clinical use. During the manufacturing process, multiple opportunities exist for errors to occur which could alter the intended flow rates enough to adversely affect the person receiving care. These issues are related to the adhesive bonding, extrusion, cut length and other processes. Testing 100% of devices in production to ensure there are no blockages is critical.

Solutions for Common Cannula and Flow Regulation Devices



Sentinel Blackbelt

Single channel instrument



Sentinel Blackbelt Pro

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

Common Cannula and Flow Regulation Devices:

- Drug delivery cannula
- Drug pen needles
- Peripheral IV cannula
- Central Line IV cannula
- Midline IV cannula
- Safety IV catheter
- Butterfly IV cannula
- Huber needles
- Biopsy needles
- Hypodermic needles
- Blunt needles
- IV flow regulators
- IV flow selectors
- IV gravity controllers

Test Methods

The testing of the devices for blockages or restrictions typically requires dry positive pressure mass flow restriction grading testing with a single-channel Sentinel Blackbelt or multi-channel Blackbelt Pro instrument. For most applications, the test is executed using clean, dry compressed air or nitrogen at anywhere between 0.1 and 100 psig positive pressure.

SEALING THE CANNULA

1. The proximal (inlet) end of the cannula or needle is mated to the test port on the Sentinel Blackbelt or Blackbelt Pro instrument while the distal (outlet) is vented to atmosphere.

The test instrument can optionally be supplied with a CTS Connect on each of the instrument's test ports to mate to the Cannula proximal (inlet) end while the distal (outlet) end remains vented to atmosphere.

2. Once the Start button is pressed by the user, the instrumentation activates the proximal CTS Connects (if supplied).

PRESSURIZATION OF THE CANNULA

3. The instrument pressurizes the cannula 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 cannula diameters.

When testing large volume parts, the user has the option of having this pressure temporarily bypass the flow transducer to protect against significantly higher initial flow values/spikes while the part is still

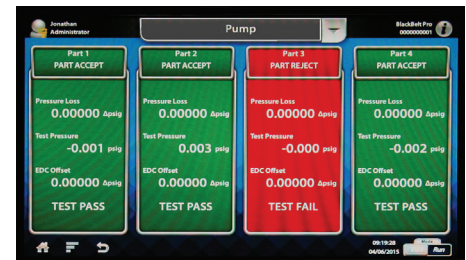
charging vs. when it has already reached target pressure and flow in the measurement circuit is closer to expected values.

FLOW RATE MEASUREMENT

4. 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. This is compared to min/max flow limits to determine 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).

EXHAUST

5. After the Test time, source pressure is disconnected from the mass flow measurement circuit and any pressure trapped inside the cannula is vented to atmosphere for a user-defined Exhaust time.
6. After Exhaust, 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 cannulae 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.



Pass/fail display on Blackbelt Pro instrument

Ensuring Failed Parts Are Properly Handled

Using the CTS CO or CI Connects driven by the Sentinel Blackbelt or Blackbelt Pro, the test program can be set to leave failed parts sealed by the Connect, forcing the user to either press a reset button or use a security key or password to release it. 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 required is dependent upon many factors, however most critically:

- Min & max reject limits 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



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