Application Note ▪ Medical

CINCINNATI TEST SYSTEMS
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How to Leak Test Respiratory Breathing Tubes/Circuits

Respiratory breathing tubes, also called ventilator breathing sets, ventilator breathing circuits, anesthetic breathing sets or anesthetic breathing circuits, are primarily used to provide an umbilical connection between a ventilator and the patient for inhalation and exhalation gas management. In some cases, they are also used for anesthetic delivery. Most frequently manufactured from corrugated polymer tubing, common variants include single limb, dual limb, coaxial in both heated and non-heated variants.

To test 100% of production, medical device manufacturers typically use dry positive pressure mass flow leak testing with a single-channel Sentinel Blackbelt or multi-channel Blackbelt Pro instrument. For most applications, the test is executed using clean and dry compressed air at approximately 60 cmH2O (0.85 psig) positive pressure. This pressure is largely driven by the audit testing specifications prescribed under ISO-5367.

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

- 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 and resolution of the instrument executing the test

Sentinel Blackbelt

Single channel instrument

Sentinel Blackbelt Pro

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

SEALING THE TUBE

1. The proximal (inlet) end of the ventilator breathing tube is mated to the test port on the Sentinel Blackbelt or Blackbelt Pro instrument while the distal (outlet) is sealed to atmosphere.

   The test instrument can optionally be supplied with a CTS CO32 or CO33 or alternately a CI32 or CI133 Connect on each of the test ports to mate to the tube's proximal end and an additional Connect to seal off the distal end.

CI Connects

CO Connects

2. Once the Start button on the instrument is pressed by the user, it activates the proximal and distal CTS OD or ID Connects (if supplied), sealing the tube to atmosphere. The mass flow test cycle begins.

PRESSURIZATION OF THE TUBE

3. The instrument pressurizes the breathing tube with regulated compressed air, inflating 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 gross leaks on the part under test.

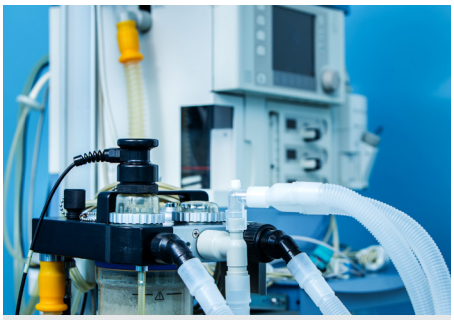
LEAK RATE MEASUREMENT

4. After the Fill timer expires, the source air is routed through the instrument's mass flow transducer where actual flow (leak) through the part to atmosphere is recorded at the end of the 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).

EXHAUST

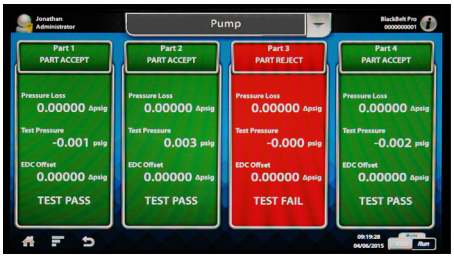
5. After the Test time, source pressure is disconnected from the mass flow measurement circuit and any pressure trapped inside the breathing tube is vented to atmosphere for a user-defined Exhaust time.

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 tubes 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 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.



Pass/fail display on instrument

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