Application Note ▪ Medical

CINCINNATI TEST SYSTEMS
Your Global Leak and Function Test Solution Experts

How to Leak and Blockage Test Microfluidic Chips

Microfluidic chips are used in a multitude of biological diagnostic applications, including analytical separation, detection, fluid control (sampling/mixing) and more. Once placed within durable analytical instrumentation, these devices typically have multiple unique micro pathways isolated from one another for liquid media passage, sampling and analysis.

Today, many mass-produced chips are manufactured using injection-molded polymer layers which are laminated, or bonded, together to form tiny sealed pathways for liquid media passage. These pathways are sometimes only a few microns wide and deep. As liquid flow control is paramount to the functionality of these devices, assembly failures due to either leakage or blockage must be detected in production.

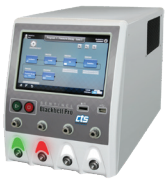
Commonly used names for Microfluidic Disposable Devices:

- Lab-on-a-chip
- Microfluidic cartridge
- Microfluidic cassette
- PCR chip
- PCR cartridge
- PCR cassette
- Molecular diagnostic chip
- Molecular diagnostic cartridge
- Molecular diagnostic cassette
- Point-of-care chip
- Point-of-care cartridge
- Point-of-care cassette

Solutions for Microfluidic Chips

Sentinel Blackbelt

Single channel instrument



Sentinel Blackbelt Pro

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

Test Methods

Testing 100% of parts in production typically requires dry positive air or nitrogen pressure and/or vacuum leak testing with a single-channel (often multi-port sequential) Sentinel Blackbelt or multi-channel concurrent Blackbelt Pro instruments.

These devices commonly require a two-step process to detect both leaks and potential blockages on each unique microfluidic pathway within each chip.

SEALING THE CHIP FOR TEST

1. Each of the chip's pathways are mated to a separate test port on the Sentinel Blackbelt or Blackbelt Pro instrument, typically using custom-built fixturing supplied by CTS. Any outlets of these pathways are sealed to atmosphere by the same fixturing.

Depending upon the sealing fixture's design, some automated sealing motions (which do not require two-hand start or extensive safety guarding), may be user-programmed and controlled by optional valves within the instrument. Up to 5 unique motions and their sequence of events may be controlled by a single-channel Blackbelt and up to 8 with the multi-channel Blackbelt Pro.

PRESSURIZATION OF THE PATHWAY

2. The Start button is pressed by the user and the pressure decay leak test cycle begins. The instrument pressurizes each pathway separately in sequential fashion with regulated compressed air/nitrogen or vacuum for a user-defined Fill time. All pathways not currently under test are vented to the atmosphere.

   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 pathway.

   Concurrent testing using Blackbelt Pro can be performed; however, adjacent pathways inside the chip can never be tested simultaneously with the same pressure as pathway-to-pathway leaks can be masked.

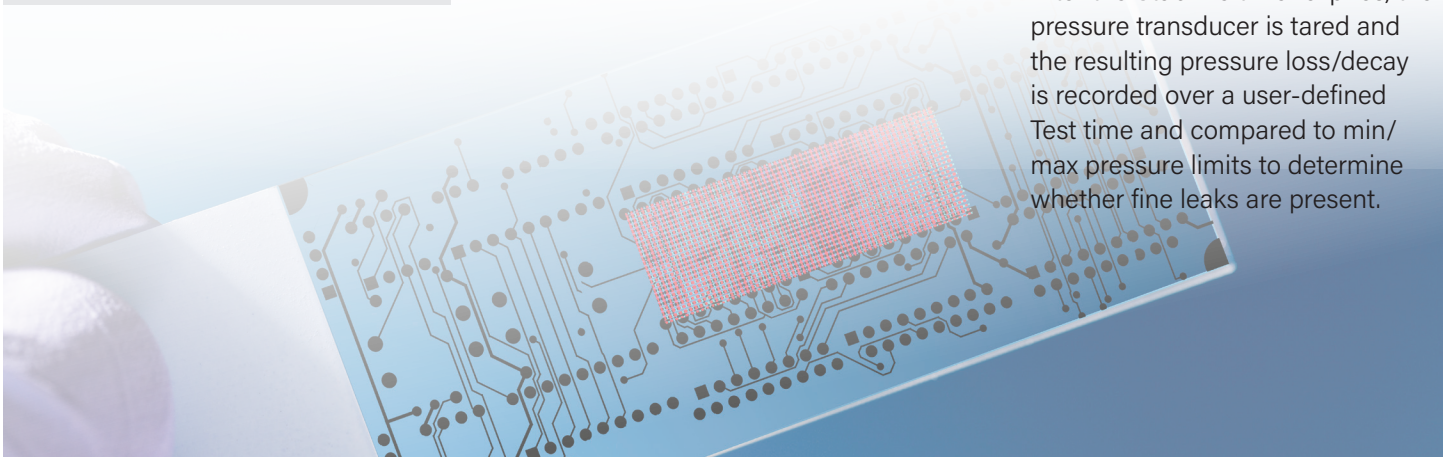
STABILIZATION: REDUCING NATURAL PRESSURE LOSS AND FINDING GROSS LEAKS

3. Once the Fill timer expires, the isolation valve inside the instrument closes, trapping pressure inside the pathway 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 pathway being tested.

TEST: DETECTING FINE LEAKS

4. 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 Simplify Testing across Pathway 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 pathways (within the same chip or on different model chips) which have different pressurized volumes (due to differences path dimension) 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 pathways 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.

5. Once the Test timer expires, the pressure trapped inside the pathway is vented to the atmosphere for a user-defined Exhaust time. The full test cycle is then repeated for each untested pathway mated to a different test port until all have been individually tested. These sequential tests inspect for both pathway-to-exterior and pathway-to-adjacent-pathway leakage.

   Following the completion of all tests, the custom fixturing releases any outlet blocking seals, allowing all pathways to vent to atmosphere to permit Blockage testing.

INSPECTING FOR BLOCKAGES WITH MASS FLOW

6. Using the same method as in the pressure decay test, the instrument pressurizes one pathway. Once the Fill timer expires, the mass flow transducer inside the instrument is introduced to the circuit, and the flow through the pathway is permitted to reach a stable value, measured in standard cubic centimeters per minute (sccm) or standard liters per minute (slm).

   The final flow value is recorded and compared to min/max flow limits to determine whether some degree of blockage is present.

Option for Blockage Testing without Mass Flow

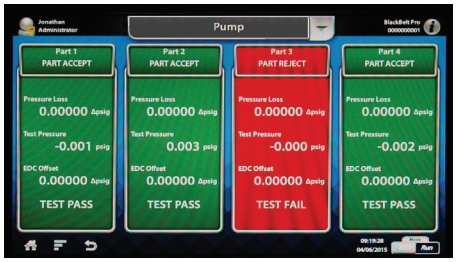
A lower cost option for detection of only complete or near-complete blockage can be done by performing a rapid pressure decay test and inspecting for some minimum loss in a user-defined Test time.

In this process the pathway is again charged with pressure during the Fill time, typically the same as for the leak test. Stabilize time is set to a bare minimum value (0.05 seconds) to minimize pressure losses through good, unblocked paths. After 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 pathway has a total or nearly total blockage during the test time.

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 pathways. Once the test is done, the pressure in the pathway is vented to the atmosphere.

7. The test is repeated on each pathway mated to a different test port until all are tested for blockages. 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 pathways have passed or failed, allowing them to disconnect from the Sentinel instrument and properly move the chips down the production line or into reject containers.



Pass/fail display on Blackbelt Pro instrument

Ensuring Failed Parts Are Properly Handled

If the sealing fixture is being controlled by the Sentinel Blackbelt or Blackbelt Pro, the test program can be set to leave failed chip sealed by the fixture, 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, catheter testing solutions, medical bag testing and pressure decay testing, or **request a quote today**.

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