

### The Problem

Drug delivery devices typically have an inlet and outlet port, a flow restrictor, and a valve to bypass the restrictor. Makers and suppliers of these devices must ensure correct operation and integrity.

The first problem: Find all the right equipment to measure very low flow, high-flow, valve re-seating, valve leakage, and body leaks in the product.

The second problem: Organize the equipment into one integrated test. Sometimes accomplished with computers and programmable logic controllers, this can be a formidable task.

The resulting group of equipment can be bulky, difficult to calibrate, hard to operate and a burden to keep maintained.

### The Sprint iQ Solution

The Sprint iQ is the only off-the-shelf answer to fast-flush drug delivery device testing.

Incorporating a pressure sensor, two precision mass flow transducers, valving and logic control; the Sprint iQ handles the complex device testing routing in one small and easy-to-program tester.

With the press of Sprint iQ's start button, the five-step tester performs (1) a leak test using flow, (2) a low flow test, (3) a high flow test, (4) a second low flow test, and (5) a deviation limit evaluation.

No other tester in the world is manufactured to meet the demands of this specific product test.

### How Sprint iQ Works

The Sprint iQ tester works like this:

- The product is attached to both test ports and Sprint iQ is started by the operator or automated equipment. Air is routed to both Port 1 and Port 2 to conduct a leak test on the product body. (Figure 1)
- Air is routed to Port 1 through the restrictor and out to atmosphere through valve V2. Low flow is measured with Sprint iQ's low-range flow transducer [F1].
- The product's flush valve [FF] is activated by the operator or automated fixturing. The resulting high low is measured with Sprint iQ's high-range flow transducer [F2].
- Sprint iQ performs a second low-flow test.
- Sprint iQ compares the first low flow to the second low flow to make sure the flush valve [FF] has properly re-seated in the device being tested.

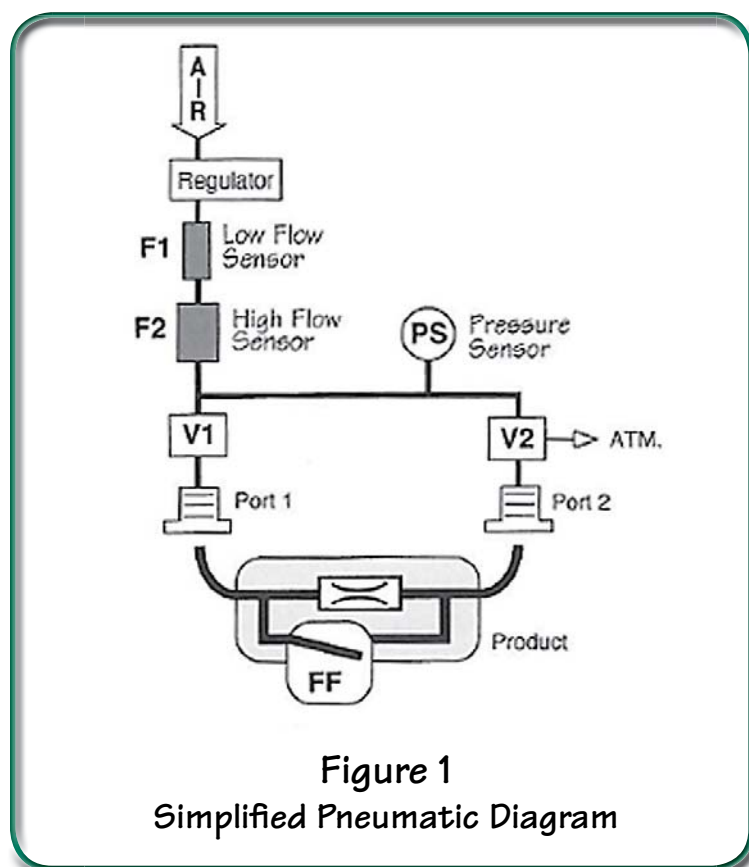


Figure 1  
Simplified Pneumatic Diagram

## Five-Step Sequence

**1. Leak Test.** The operator (or automated machine) starts the test and Sprint iQ performs a leak test using flow. During leak test time, air is sent to test ports 1 and 2 filling all passages in the device being tested. Leak testing verifies the absence of body leaks in the product.

Leak Max is the largest flow allowed during the leak test. When the flow drops below this value, the leak test ends and the First Flow test starts.

**2. First Flow.** Sprint iQ performs the first low flow test by sending air to Port 1 and opening Port 2 to atmosphere. This allows air flow through the restrictor in the device being tested. Flow is measured with the tester's low-flow transducer.

Flow Max and Flow Min are the pass and fail limits established by setup personnel. If the flow is within this window, the First Flow test passes and the High Flow test starts. If flow is outside the Min/Max window, the test fails and the message 1ST FLOW is displayed in the status box on the tester's display.

**3. Fast Flush.** At the start of this test, Sprint iQ displays FLUSH to prompt the operator to activate the fast flush valve. Or Sprint iQ can send a signal to automated fixturing. The resulting high flow rate is measured with Sprint iQ's high-flow transducer.

Sprint iQ displays the high flow rate. The operator or automated fixturing releases the flush valve. If the flow does not reach the established minimum flow rate, the test fails and FLUSH is displayed in the status box on the tester's run display.

**4. Second Flow.** Identical to the First Flow test, the second low flow test uses the same setpoints programmed in the First Flow test.

**5. Deviation.** A percent deviation of the measurement made at First Flow compared to Second Flow. A percent deviation limit is entered by setup personnel to set the boundary for acceptance. If beyond the set deviation, the product fails and Sprint iQ's reject light turns on. The deviation parameter ensures the bypass valve in the product properly re-seats after the high flow (flush) operation.

## Applications

Sprint iQ is manufactured exclusively by Uson for testing fast-flush drug delivery devices commonly included in many disposable medical procedure kits and pre-packaged drug delivery systems.

If desired, the fast-flush steps can be turned off and Sprint used for either flow measurement or leak testing using flow.

The Sprint iQ tester by Uson represents the leadership establishing the standard of testing in the medical device manufacturing industry.

Because all data concerning the operation of this tester cannot be included in this brief note, we invite you to call Uson to discuss how a Sprint iQ can be applied to your specific device testing needs.

## Features

- Completely self-contained.
- All components in one small enclosure
- Fully calibrated and simple to maintain
- Perfect for bench or automation
- Small footprint of 8.5 by 15 inches
- Resolution of 1/100 sccm at 200 full scale
- Resolution of 1 sccm at 5000 full scale
- Easy to program and calibrate
- Interface for statistical process control



for good measure

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