



## Industry-Leading Test Solutions

### Market Application Case Study:

## MULTI-PART CONCURRENT NON-COMPLIANT BALLOON CATHETER TESTING

### Market driver:

A medical device manufacturer needed a semi-automated system to test non-compliant PTA and PTCA Balloon Catheters. The tests include pressure decay testing at 425 psig and vacuum decay testing at 12 psiv to test the catheter both before and after installation of a metal stent over the balloon.

### Test requirements:

- Perform pressure decay test to inspect for leakage prior to stent installation
- Perform vacuum decay test to inspect for leakage following stent installation

### CTS solution:

The CTS Blackbelt Pro benchtop instrument was an ideal fit for this application offering multi-test, multi-port, and multi-channel testing and performing automated Pressure and Vacuum Decay tests on the PTA & PTCA Balloon Catheters.

For this application the Blackbelt Pro was configured with 4 test ports/channels, each equipped with unique 500 psig electronic pressure regulators, internal venturi vacuum generators, and 14.5 psiv electronic regulators, providing the ability to independently test up to four balloon catheters simultaneously (synchronously or asynchronously).

As the manufacturer utilized bottled nitrogen as the source for positive pressure, the Blackbelt Pro was equipped with unique Auto-Supply Shutoff options for each channel which cut off the flow of nitrogen to the normally relieving pressure regulators to minimize loss of tank pressure when the instrument was not in use.

Each Blackbelt Pro test port was equipped with CTS Connect female luer seal to minimize the time to connect the part to the instrument and begin the test. The operator connects each proximal lumen to the assigned Blackbelt Pro port.

This customer also requested the ability to check the inflated balloon for dimensional measurement following the completion of the automated test program. The Blackbelt Pro provides a 'Retain Part Pressure' feature that allows the operator the ability to measure the balloon following the conclusion of the test to perform a visual inspection to observe the balloon diameter at rated operating pressure on demand.

After all test connections are established, pressing the Pro's start button initiates the program testing for leakage either by pressure or vacuum decay depending on whether the catheter has or has not yet had the stent installed. If any test does not meet set-point values for a pass condition, the test program stops and the part is deemed a 'Reject', indicated by audible alarm and red indicator lamp on that test port. Only if all tests pass for each individual part will the Blackbelt Pro instrument 'Accept' the part under test and yield a green indicator lamp on that test port.

At the conclusion of each test cycle the Blackbelt Pro instrument will record the test results, including record of the operator executing the tests, and save it to on board memory. Up to the last 1,000,000,000 unique test records can be accessed by the user at any time.



**Blackbelt Pro 'Benchtop' instrument provides both pressure and vacuum leak testing for this medial catheter test application.**