providing world-class leak test and assembly verification solutions

ENTERAL FEEDING BAG LEAK AND BLOCKAGE TESTING

Problem:

A medical device manufacturer requires 100% testing on high volumes of several models of solvent bonded Enteral Feeding (Temporal Nutrition) Sets. These are comprised of a series of spikes, tubes, drip chambers and connectors which are attached to a TPN Bag. Prior to the Enteral Feeding sets being tested each sub-component is tested separately at discreet stations using analog variable area flowmeters. (Without poke-yoke capability or having the ability to report test data for analysis) The manufacturer was having issues with:

•. **Operator subjectivity** - Mistakes and misreading of coarse lines on the analog pressure gauges and variable area flow meters were all too common.

• **Lack of resolution** - Tests performed resulted in actual flows varying from 5 to 1000 sccm showing that the flow meter's scale was not finely graduated making it difficult to resolve increments of less than 50 sccm in turn making accurate leak testing very difficult.

•**Lack of repeatability**. The small bead inside the flow meter would change position from cycle to cycle, even on the same set being tested due to a number of mechanical variables within the flow meter.

•**No quantified data**. Their system allowed no stored data to show range of actual leak or free-flow.

Test Requirement:

Blockage test each Feeding Set first using simple backpressure occlusion blockage test at 8.0 psig followed sequentially by a pressure decay leak test rejecting 2.0 sccm @ 8.0 psig.

CTS Solution:

The Sentinel Blackbelt leak test instrument with 30 psig pressure range to complete both tests in single combination test sequence of Occlusion (backpressure) followed by Pressure Decay – Leak Standard test. The Sentinel Blackbelt could very quickly detect a complete blockage within the set and immediately proceed to a leak test . CTS was able to streamline the process by no longer involving the user in the decision making process but simply loaded and unloaded the parts and leaving the pass/fail results up to the instrument. Each test quantified data (up to the last 5000 test results could be stored within instrument memory) which the customer could collect and utilize for trending purposes.

Other Features of this Application:

The instrument was used to drive (without PLC) custom fixtures built by CTS using a combination of various CTS Connects and pneumatically driven pinch mechanisms to seal and fill through the spike inlet port of the Feeding Set, pinch the tubing just outside the already tested TPN Bag and seal/unseal the outlet port connector (depending on whether blockage or leak testing). As a poke-yoke, if the part passes the leak test, the Connects and pinch mechanisms automatically release the tested Feeding Set to the operator. If the test fails, the Set is securely held in the Connects and pinch mechanisms and requires a reset action of some kind (operator pressing Stop button or requiring a key reset) to unlock the part.

Enteral Feeding

This same technology is often used in testing:
Primary and Secondary IV Sets, Extension Sets, Drug Delivery Sets, Contrast Solution Sets, Blood Transfer Sets, Irrigation/Suction Devices.

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