

MEDICAL BAG & BLADDER LEAK TESTING (PAGE 1 OF 2)

Problem:

The customer needed to perform 100% testing of various sizes of IV Bags for leakage. They had been using a photohelic pressure gauge based test instrument which would pressurize the part to a single pressure for a very lengthy fill step time. Afterward, the bag was isolated from the pressure source and the test step would begin by measuring the pressure within the Bag under test. The Bag would only fail if the gross pressure inside it, as indicated by the photohelic gauge needle, dropped below a minimum overall pressure as set by a limit flag on their test system by the end of the test step. The customer was unhappy with:

- Excessive time required to fill the unrestrained IV bag and leave it pressurized during the test cycle.
- Lack of sensitivity. As the system tested by gross pressure level only, the final pass/fail result was strongly affected by the natural gradual compliance/stretch of the material during the Test step.
- The test instrument had no setup or recipe storage for varying bag shapes and sizes, which meant lots of set up time and potential for errors.



CTS Tooling Solution:

To alleviate both the excessive volume and most of the compliance/stretch problems, CTS designed a single restraining plate fixture consisting of two rigid metal plates which spaced closely together. The IV Bag is slid between these two restraining plates prior to the start of the test process. This allowed a dramatic reduction of the volume of air required to fill the part to target pressure. Also, the fixture limited much of the elastic compliance/stretch of the Bag while at test pressure. The inside surfaces of each restraining plate was lined with a porous material so as to be sure not to allow any sidewall leaks to be masked by the restraining plates when the Bag was inflated.

CTS Instrument Solution:

CTS utilized their Sentinel Blackbelt leak test instrument to perform the test. The Blackbelt allows storage of up to 99 programs which allowed the customer to have pre-programmed unique setups (including all test timers and limits) for each model of IV Bag. This test was performed using a Parent test program which managed two sequential child programs to accomplish the following: Slightly over-inflate the Bag to pre stretch the bag, followed immediately by reducing to target test pressure via the target test pressure regulator and then performing the pressure decay test on the part.

Other Features of this Application:

A single electronic regulator could have been used instead of the two manual regulators on the Blackbelt instrument.

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The closer the restraining plates are positioned together, the better. However, after exhausting the test pressure at the conclusion of the test, a small amount of residual air is left within the IV Bag and remains often for some time afterward, making it difficult to quickly remove the tested Bag from the narrow gap between the plates. Therefore, the customer elected to equip the instrument with an optional vacuum exhaust to pull almost all of the air out of the Bags just tested, making removal extremely fast and easy.

The restraining plate fixture was installed with multiple CTS OD Connects with stainless steel ID support mandrels to automatically seal on the soft port tubes welded into the header of the Bag and mate it to the test port of the instrument.



If the part passes the leak test, the Connects automatically release the part to the operator. If the test fails, the part is securely held in the Connects and requires a reset action of some kind (operator pressing the Stop button or requiring a key reset) to unlock the part. This action is used to prevent the inadvertent placement of the failed Bags into the passed-part area.

This same technology is often used in testing:

- Blood Transfer, Separation & Plasma Bags
- Blood Pressure Cuffs
- Urine Collection & Colostomy Bags
- Drainage Bags
- Pressure Infusion Systems
- Enteral Feeding Bags
- Orthopedic Support Pads
- Sequential Compression Sleeves
- Anti-Bedsore & Heat Exchange Therapy Pads & Blankets

