

# How to Leak Test Bags and Flexible Products

The second in a series of guides to tackling manufacturing problems.

**T**he function of many medical devices is related to getting fluids into or out of the body. In most instances the fluid will be contained in a flexible bag. Typical examples of these include intravenous bags, feed systems, drainage bags and ostomy bags, inflatable supports and airway products. These products are typically produced in large numbers in well-proven processes such as radio-frequency and ultrasonic welding, and adhesive or solvent bonding. One of the challenges is to ensure that the occasional faulty product is identified prior to release from the factory. This requires

- leak testing the joints that go into the bag/container
- testing welds and material surfaces for perforation
- verifying that the desired flow can be achieved.

Because of the production rates involved it can be difficult to test every product, although this may be worthwhile for products with a critical application or to maintain customer confidence in a particular brand.

## The principle

The best way to carry out tests on finished product is by electronic pressure decay air testing. This is a process whereby the test article is pressurised with air and then isolated and monitored for a reduction from the applied pressure over time. In addition, to eliminate faults prior to manufacture or assembly, sheet

materials may be tested using high frequency conductivity methods that find pinholes through the conduction they allow.

## Points to bear in mind

There are two principal difficulties with air-pressure testing flexible products: the time required for the test and how to calibrate the system when the component being measured is extremely pliant.

The latter is addressed by constraining the bag to be tested. In this way, its internal volume and stretching maybe limited. For infusion or collection bags often all that is required is a clamshell tool with porous plates either side of the bag. This is easy to load and provides the required constraint. For products with a more complex shape it may be necessary to make a tool that conforms closely to the product outline. This applies particularly to products that comprise a balloon that is sensitive to over stretching.

The constraining plates also help with calibration. Soft, flexible plastic products by their nature will stretch if an internal pressure is applied. It is frequently the case that it will take several minutes for the test system to stabilise, time that is generally not available in the production process. Historically, the answer is to compare the test bag with a reference bag. This has some drawbacks: one bag is continually used as the comparison and this bag may deteriorate over time; or two production bags are

compared, but this leaves the possibility that two faulty bags are tested together.

The recommended approach is a variation of the first method. A good bag is used as the comparison, but its characteristic behaviour under pressure is recorded within the test system's electronic memory. This profile can then be used as the "standard" with no danger of drift in the parameters. Another way of defining this approach is that the test machine is "taught" the standard characteristics of a product for reference.

## The process

This approach requires a leak-test system that can keep pace with production. The steps are as follows:

- Drop the bag or product into restraining fixture and close the lid.
- Connect air supply and use high pressure fill to inflate the product to near the test pressure.
- Use a sensitive pressure regulator to fine-tune the applied test pressure.
- Isolate the test system and compare pressure decay with the standard.
- Use a vacuum to deflate the product for easy packing.
- Eject from test fixture.

A single-channel system of this nature should be able to process up to ten 500 cc bags per minute. Multiple loading fixtures can be used to increase the throughput. It is possible to calibrate the machine at the beginning of each shift, if necessary, because it takes approximately 1 min.

A robust and accurate test system

can keep pace with most production processes at a minimal cost; the typical cost is £10 000 (€16 400).

**Recommended reading**

- BS 2463, Part 1, Transfusion Equipment for Medical Devices. Specification for Collapsible Containers for Blood or Blood components.
- BS 2463, Part 2, Transfusion Equipment for Medical Devices. Specification for Administration Sets.
- EN ISO 8670 Ostomy Collection Bags, Parts 1–3.

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