thermo scientific

inSITE Integrity Testing System

Confidence at the point of use

ThermoFisher SCIENTIFIC

The power of knowledge

As the value of processes increases with each step downstream, the value of sterility and leak detection becomes more critical. The Thermo Scientific™ inSITE™ Integrity Testing System provides confidence to customers by offering a final, point-of-use integrity test on the Thermo Scientific™ BioProcess Container (BPC) prior to use.

Key features

- Point-of-use integrity testing
- Gross and fine leak detection
- Guided validation setup tests BPCs up to 5,000 L
- Inflation procedure improves loading and placement in tanks
- Liquid filling cycle regulates internal pressure while fluid is being introduced
- Permanent and disposable pressure sensors provide comparative pressure data

Quality assurance

The advantages of the inSITE system extend the level of quality assurance that is offered to the end user. Although stringent standards—such as raw material inspections, in-process pressure decay testing, sealing validations, and packaging and shipping procedures—are maintained for all products, there is potential for damage after the product leaves the facility, specifically during BPC handling and placement. At the critical stage of fluid filling, the inSITE system offers a higher level of confidence to biopharmaceutical manufacturers by helping to ensure that their product will enter a viable BPC.

Design features

Single-channel and multi-channel design options

Specifications

inSITE Integrity Testing System				
Description	Overall dimensions (W x D x H)	Weight	Power requirements	Cat. No.
Single-channel	66 x 74 x 147 cm (26 x 29 x 58 in.)	175 kg (386 lb)	110–220 VAC, 50–60 Hz	IN1009
Multi-channel	66 x 74 x 147 cm (26 x 29 x 58 in.)	200 kg (440 lb)	110–220 VAC, 50–60 Hz	IN1010

More than just a test

Integrity testing capabilities

Pressure decay testing

Pressure decay refers to the change in pressure (P) inside a pressurized container during a leak test. The test is an inflation test in which a BPC is pressurized to a preset level. After the BPC has stabilized, the decay in pressure over time is evaluated to determine if a leak is present. The pressure decay method of testing was chosen due to its sensitive results and practicality at the point of use.

Compared to alternative methods of leak detection, pressure decay testing yields quantitative information and measurable data points that can be recorded and used as the basis for making decisions.

Four distinct phases of pressure decay testing:

1. **Inflation cycle:** Inflation is the period of time in which the BPC is being pressurized to a predetermined test pressure through an onboard blower. The air is forced through a 0.2 micron (µm) sterilizing-grade filter.
2. **Charge time:** During the charge-time phase, the BPC stretches, allowing any creases that may be present to unfold. If necessary, the blower will add air to maintain the initial predetermined test pressure.
3. **Settle time:** The settle phase is the time allowed for the volume of the BPC to change and stabilize from stresses introduced by pressurization. The adiabatic temperature also stabilizes during the settle phase.
4. **Test time:** The test time is the period during which the decay of pressure is measured and recorded. This decay in pressure will distinguish between a flawed and non-flawed BPC.

Additional testing features

In addition to the long-term value that the integrity testing functions provide, the inSITE system has a host of features that ease the operator's tasks and manage the overall quality of the BPC all the way up to the liquid filling cycle.

1. **Gross leak detection:** This test quickly finds small leaks (100–1,000 µm) and confirms connection and setup of the BPC.
2. **Fine leak detection:** This is a unique validation test for each tank and BPC. It is dependent on time allotment and environment. Very fine leak detection is possible.
3. **Liquid-filling cycle:** This cycle moderates the internal pressure within the BPC while fluid is being introduced. The cycle is configured to regulate the open/close position of the coaxial valve mounted on the inSITE system.


SYSTEM HISTORY
QUALIFICATION TEST
VHC LEAK TEST
GROSS LEAK TEST
ADMINISTRATIVE SETUP
HYDRO BLOWN CYCLE
PRESSURE CONTROLLED INFLATION
MAINTENANCE

thermo scientific

Setting up for success

Validation setup and testing results

Because of the sensitivity of the inSITE system, the testing results can vary from any changes in external pressure, tank size, or room temperature; therefore, it is vital to have a consistent environment for each setup and test. During the procedure, the program walks the user through a validation setup. The validation is unique to each BPC and tank combination, and is stored for quick access for future tests. During this phase, users are instructed to run three to ten tests on both non-flawed and flawed BPCs (Figures 1–4).

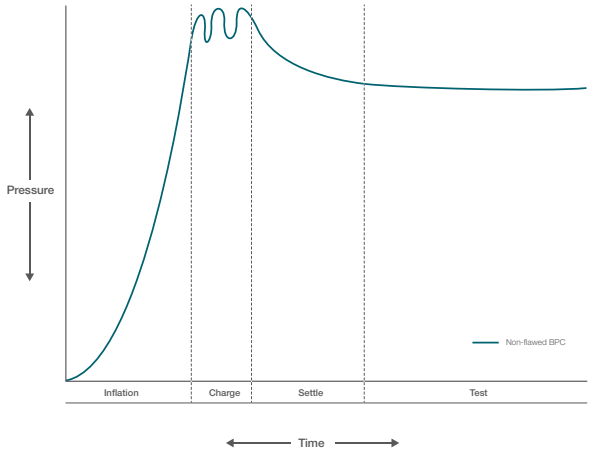

Figure 1. The four phases of the testing cycle of a non-flawed BPC.

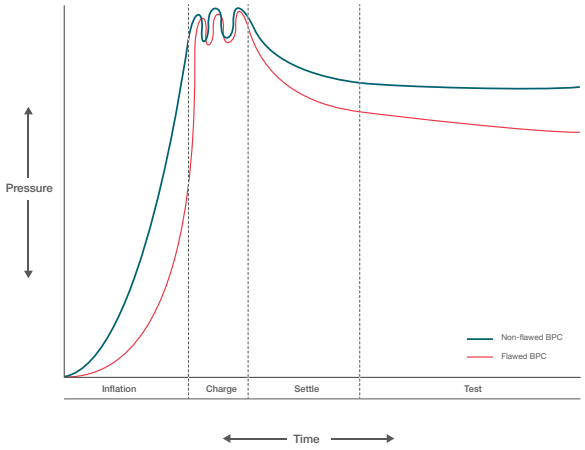

Figure 2. A comparison of a flawed BPC and a non-flawed BPC.

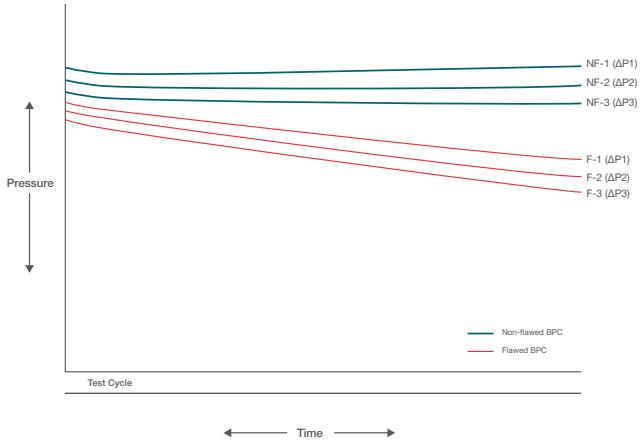

Figure 3. A comparison of the tests on three non-flawed BPCs and the three intentionally flawed BPCs. The measurements between the changes in pressure (ΔP) for each will determine the allowable variation.

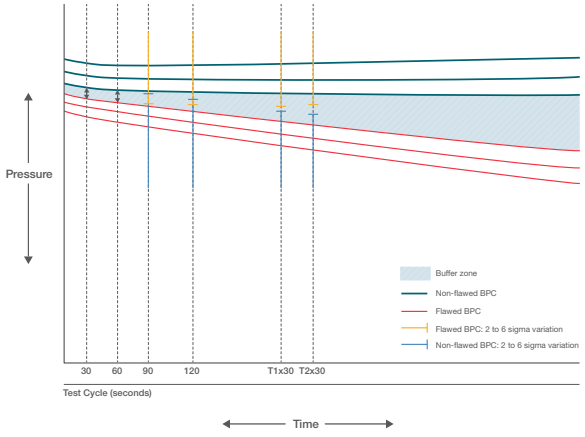

Figure 4. The variation between the lowest ΔP of a non-flawed and the highest ΔP of a flawed BPC determines the buffer zone. Separation between sigma variation noted from non-flawed BPC and Flawed BPC will determine the time and flaw size that inSITE can detect for given test conditions.

Find out more at **thermofisher.com/insite**

ThermoFisher SCIENTIFIC