

 inSITE
INFLATION & INTEGRITY TEST SYSTEM



THE POWER OF KNOWLEDGE

As the value of processes increase with each step downstream, the value of sterility and leak detection become even more critical. inSITE provides the confidence of a final integrity test prior to use; at the point-of-use. The inSITE Inflation and Integrity Test System provides an added level of confidence at the point-of-use by testing bags for damage that could occur from the box to the tank. More specifically, inSITE detects gross or fine leaks that can occur between the end-user's warehouse to the clean room floor from improper handling and loading procedures.

QUALITY ASSURANCE

The advantages of the inSITE System extend the level of Quality Assurance that ASI employs to the end user. Although ASI maintains stringent standards for all of its products such as raw material inspections, in-process pressure decay testing, sealing validations, packaging and shipping procedures and more, there is potential for damage after the product leaves ASI's facility; specifically during bag handling and placement. inSITE offers a level of confidence to bio-pharmaceutical manufacturers at the critical stage of fluid filling, ensuring that their product will enter an integral bag.





PRESSURE DECAY TESTING

Pressure decay refers to the change of pressure (P) inside a pressurized containment during a leak test. The test is an inflation test in which a bag is pressurized to a preset level. After the bag system has stabilized, the decay in pressure over time is evaluated to determine if a leak is present.

ASI chose the pressure decay method of testing due to its sensitive results and practicality at the point-of-use. In comparison to alternative methods of leak detection, pressure decay yields quantitative information and measurable data points that can be recorded and upon which decisions can be made. The sensitivity of pressure decay testing is dependent upon three factors: the size of the bag, the change in temperature and the amount of time allotted for the test. Any variances in these conditions can affect test results making it important to have a consistent environment and setup for each test.

There are four distinct phases to the pressure decay testing process; each step is unique to pressure decay and ultimately makes the placement and filling cycle easier for the operator and gentler to the bag.

1. INFLATION CYCLE

Inflation is the period of time in which the bag system 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 bag system 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 bag system to change and stabilize due to 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 bag system.

INSITE SPECIFICATIONS

OVERALL SIZE:

32" W x 30" D x 58" H

WEIGHT:

Approximately 340 Lbs.

STANDARD MODEL NUMBERS:

IN1003 (Battery Powered- US)

IN1005 (AC Powered – US)

IN1004 (Battery Powered – Europe)

IN1006 (AC Powered – Europe)





MORE THAN JUST A TEST

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

INFLATION CYCLE - The inflation cycle assists the operator in the loading of bags with minimal intervention and reduces the risk of flaws from handling.

GROSS LEAK DETECTION - This detection test quickly finds small leaks (between 250 μm – 1000 μm) and confirms connection and setup of the bag system.

FINE LEAK DETECTION - A unique validated detection test for each tank and bag assembly. It is dependent on time allotment and environment. Very fine leak detection is possible.

LIQUID FILLING CYCLE - This cycle moderates the internal pressure within the bag while fluid is being introduced. The cycle is configured to regulate the pump or valve and will terminate the filling process if the bag system becomes over-pressurized.

VALIDATION SETUP AND TESTING RESULTS

Due to the sensitivity of the inSITE system, the testing results can vary from any changes in external pressure, tank size or room temperature so it is a vital rule of thumb to have a consistent environment for each setup and test. During the setup procedure, the programs walk the user through a Validation Setup. The Validation is unique to each bag and tank combination and is stored for quick access for future tests.

During this phase, users are instructed to run a minimum of three or a maximum of ten successful bag tests and three to ten (intentionally) flawed tests.

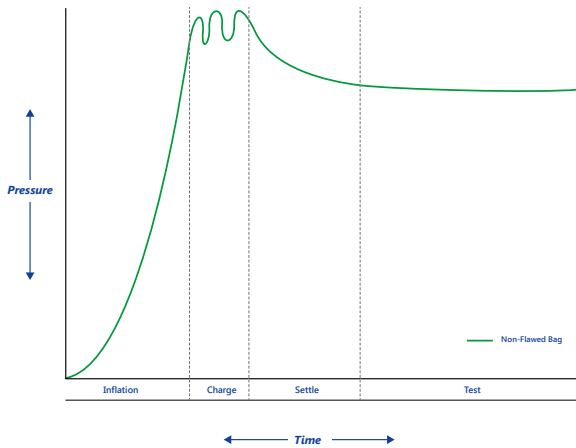


Figure 1: The four phases of the testing cycle of a non-flawed Bag.

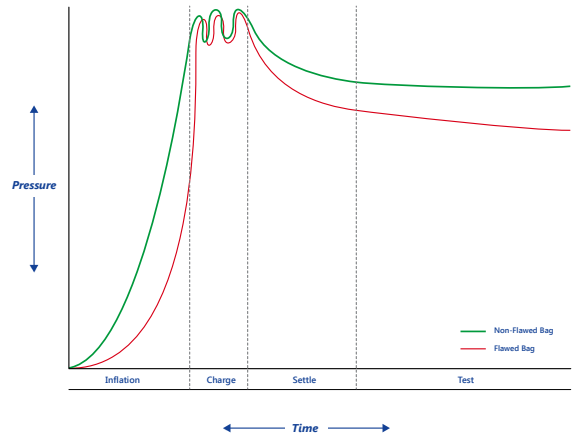


Figure 2: A comparison of a flawed bag and a non-flawed bag.

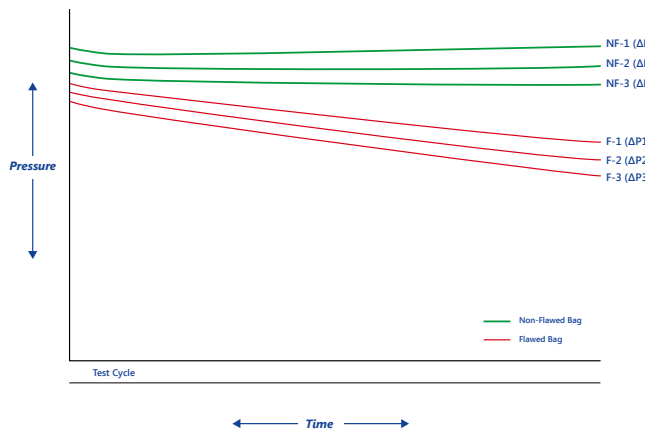


Figure 3: A comparison of the three successful bag tests and the three intentionally flawed bags. The measurements between the Delta P's for each will determine the allowable variance.

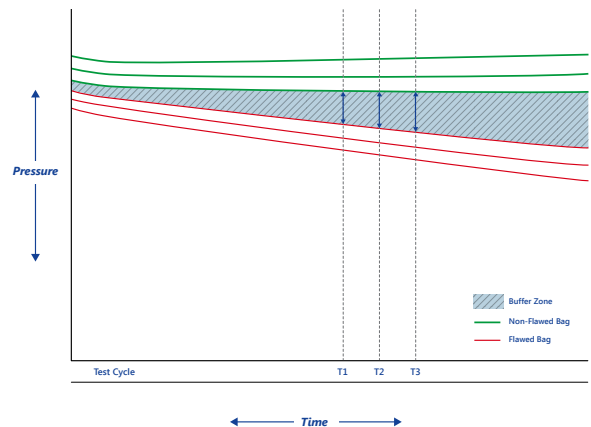


Figure 4: The variance between the highest Delta-P of a non-flawed bag and the lowest Delta-P of a flawed bag determines the buffer zone. The buffer zone is the established point of time for the fine leak flag. This also establishes the validated pass / fail point criteria.



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ASI is an FDA Registered, ISO 13485:2003 Certified Manufacturer



Rev: 04-03-13
MK-00213