# Technical report for FlexAct® BT – Point-of-Use Leak Test Solution for Flexboy® & Flexsafe® 2D Bags

Technical Note

## Scope

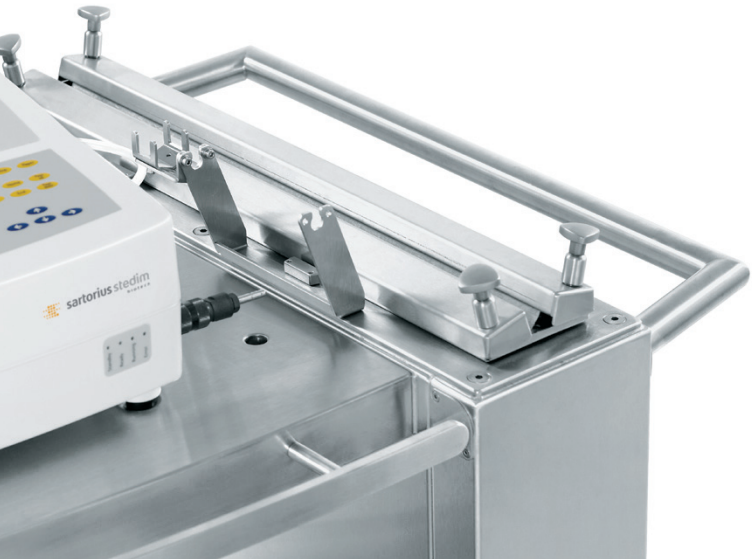
This technical report describes the validation of our pressure decay test method used for the point-of-use leak test at user site of Flexboy® 2D bags from 50 mL to 50 L & Flexsafe® 2D bags from 3 L to 50 L with the FlexAct® BT and the Sartocheck® 4 plus Bag tester. A preliminary parameter study was first performed to pre-determine the test pressure, stabilization time and test time. A complete validation study was then carried out to validate the parameters, the maximum allowable pressure decay and the leak detection limit. This validation approach demonstrates the reproducibility, accuracy, sensitivity and robustness of the leak test across the range of Flexboy® & Flexsafe® 2D bags.

## Executive Summary

Sartorius Stedim Biotech has validated a leak test method to detect leaks by means of pressure decay for Flexboy® & Flexsafe® 2D bags using the FlexAct® BT and the Sartocheck® 4 plus Bag tester.

The study is aimed at validating a leak size detection of 30 µm over the range of Flexboy® bags from 50 mL to 50 L and for Flexsafe® 2D bags from 3L to 50 L using a test pressure of 300 mbar, a stabilization time of 4 minutes and a pressure decay test time of 3 minutes.

Preliminary parameter study was performed with 60 tests for Flexboy® & 30 tests for Flexsafe® 2D bags. As for the validation study, 640 tests for Flexboy® 2D bags and 480 tests for Flexsafe® 2D bags were done.




The test reproducibility, accuracy and sensitivity for detecting a 30 µm leak have been validated using a total of 700 tests for Flexboy® 2D bags and 510 tests for Flexsafe® 2D bags with samples from multiple production lots.

The implementation of a point-of-use leak test of this sensitivity is in line with the ICHQ9 HACCP approach, based on a formal risk assessment that analyzed potential failure modes and complaints in our experience of more than 20 years and 20 million bags produced.

In addition, a risk-based approach indicates that introducing a defect of a size smaller than 30µm during the transport, handling and storage of these two bag families are very unlikely to happen.

This validation report summary provides the method and the results to demonstrate the robustness of the validation study and the reliability of the pressure decay leak test method for Flexboy® & Flexsafe® 2D bags with FlexAct® BT.

# Validation Approach

A preliminary parameter study is first performed to pre-determine the test parameters.

A complete validation study is then carried out to validate the method, the parameters and the specifications of the test and to demonstrate the reproducibility, accuracy, sensitivity and robustness of the leak test across the range of Flexboy® & Flexsafe® 2D bags.

In order to simplify implementation and validation at end user site, our pressure decay test approach was targeted to develop a single set of test parameters and test specifications for the range of Flexboy® 2D bags from 50 mL to 50 L and for Flexsafe® 2D bags from 3 L to 50 L.

The test parameters are pre-established and evaluated during the preliminary parameter study:
- Test pressure of 300 mbar
- Stabilization time from 60 to 240 seconds for Flexboy® & 240 seconds for Flexsafe® 2D bags
- Pressure decay test time from 0 to 240 seconds

The test parameters and test specifications are then validated during the validation study using the above test parameters:
- Maximum allowable pressure decay limit of 3.1 mbar for Flexboy® and for Flexsafe® 2D bags
- Test sensitivity or leak detection of 30 µm
- Test accuracy of +/- 0.3 mbar
- Test reproducibility for non-defective bags +/- 1 mbar

The reliability of the test method, i.e. the reproducibility, accuracy and sensitivity, and hence the capability of the method to give repeatable and precise results that consistently differentiate potential defective bags from non-defective bags have been demonstrated via an extensive validation test regime. Defective bags have been deliberately created using calibrated defect film samples.

**a. Tests parameters Flexboy® 2D Bags**
The test parameters have been pre-established using 60 tests (defective and non-defective units) from multiple batches of Flexboy® bags from 50 mL to 50 L.

Both test parameters and test specifications have been validated using 640 tests (defective and non-defective units) from multiple batches of Flexboy® bags from 50 mL to 50 L.

**b. Tests parameters Flexsafe® 2D Bags**
The test parameters have been pre-established using 30 tests (defective and non-defective units) from multiple batches of Flexsafe® 2D bags from 3 L to 50 L.

Both test parameters and test specifications have been validated using 480 tests (defective and non-defective units) from multiple batches of Flexsafe® 2D bags from 3 L to 50 L.

For Flexboy® and Flexsafe® 2D bags, the sensitivity of the leak detection of the test method is established with a 6 sigma confidence interval for the differentiation between non defective and defective bags.

Considering the large volume range for Flexboy® (10 different bag sizes from 50 mL to 50 L) and the volume range for Flexsafe® (5 different bag sizes from 3 L to 50 L), the minimum pressure decay results of defective 50 L bags and the maximum pressure decay of all non-defective bag volume values have been considered to set the maximum allowable pressure decay specification.

The establishment of the 30 µm minimum leak detection is based on the knowledge and control of our process capabilities and failure modes throughout the product life cycle from production to utilization.

By employing a risk based assessment of the 30 µm detection chosen for the validation, it is seen the risk of introducing potential defect of a size smaller than 30µm during the transport, handling and storage of the bag is low.

It is theoretically proven that a smaller leak size, down to 15 µm or even better, could be detected for smaller volume bags or with longer test times but it is not the purpose of the validation.

Any new test parameters and specifications outside of the ones defined in this validation study require additional validation tests. The purpose of validating new test conditions would be to establish the detection for a smaller defect and | or to test a different configuration than the standard one used for this validation. This service is part of our on-site validation support and can be performed on demand by our Application Specialists.

# Materials and Methods

## 1. FlexAct® BT and Sartocheck® 4 plus Bag tester

### a. FlexAct® BT

FlexAct® BT is equipped with two plate holders, each of them consisting of two metal plates with porous spacer between which single-use bags are inserted for inflation and leak testing. By using porous spacers, the film surface of the bag is not in direct contact with the stainless steel holder during the test. Any potential masking effect is eliminated. The masking effect can occur when a leak in the plastic film is pressed against a surface and therefore is blocked.

The holders protect the bag from mechanical stress and reduce heat transfers. They allow performing the leak test with a small and reproducible inflating bag volume and at a high test pressure, thus increasing the test reliability.

**Test equipment**

| | |
|---|---|
| FlexAct® BT | 26288---BTFA |
| Porous spacer for FlexAct® BT | DZ050L---SIT |

### b. Sartocheck® 4 plus Bag tester

The Sartocheck® 4 plus Bag tester is based on the same software and hardware platform as the Sartocheck® 4 plus Filter tester. As bags require lower test pressures and higher pressure measurement accuracies than membrane filters, the pressure range has been reduced to optimize the test pressure setting and the pressure decay measurement accuracies.

**Test equipment**

| | |
|---|---|
| Sartocheck® 4 plus Bag tester | 26288---BT |
| Bag tester tube set 2D | 26288---BT2D |

**Measuring ranges**

| | |
|---|---|
| Test pressure | 10-300 mbar \| 0.145-4.350 psi |
| Pressure drop | 0.1-300 mbar \| 0.0014-4.350 psi |

**Measuring Accuracy**

| | |
|---|---|
| Pressure drop | ±0.3 mbar (0.004 psi) |

**Operating Conditions**

| | |
|---|---|
| Ambient temperature | ±15°C to +35°C |
| Rel. humidity | 10 – 80 |

The Sartocheck® 4 plus Bag tester serial numbers 31503219, 31503220 were used for the test parameters study and the validation study.

# 2. Configuration of Flexboy® & Flexsafe® 2D Bags for Point-of-use Leak Testing

**a. Application**

Flexboy® & Flexsafe® 2D bags are used in a variety of process steps and applications:
– Buffer and media storage
– Harvest and storage
– Process intermediate storage
– Drug substance purification and storage
– Drug product formulation, storage and filling

The requirement for leak testing is more prevalent in the critical process steps of drug substance purification in downstream processing and drug product formulation in final fill and finish.

The design rules for Flexboy® & Flexsafe® 2D bags to be leak tested are therefore defined for meeting the requirements for these critical process steps and applications. The design namely requires the installation of a sterile vent filter line to allow performing the test under conditions that maintain the integrity and the sterility of the system.

**b. Description of Flexboy® 2D validated design**

Flexboy® 2D bags from 50 mL to 50 L intended to be leak tested need to meet specific design requirements (Figure 1a). First, the handle currently present on Flexboy® bags from 5 L – 50 L is not installed to allow the insertion of the bag in between the restraining plates of FlexAct® BT.

Second, a sterilizing grade vent filter line is pre-assembled to perform the test without breaching the sterility of the system. C-Flex®* tubing is used to disconnect the filter line after testing, using a Biosealer®.

| | |
|---|---|
| Bag Chamber | Multiple layer film construction, including an EVOH gas barrier layer and an EVA contact layer |
| Volumes | 50 mL – 50 L |
| Port tubes | EVA |
| Fittings | Sampling line: Needle-less Clave connector with slide clamp<br>Filling line: filter test line with Midisart® BV sterilizing grade vent filter<br>Clear C-Flex®* 374 L500mm<br>¾" Triclamp, pinch clamps<br>Final connection defined by end user – not in the scope of the validation<br>Draining line: pinch clamp on EVA port tube<br>Final connection defined by end user – not in the scope of the validation |
| Sterilization | Gamma irradiated 25-45 kGy |

* C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

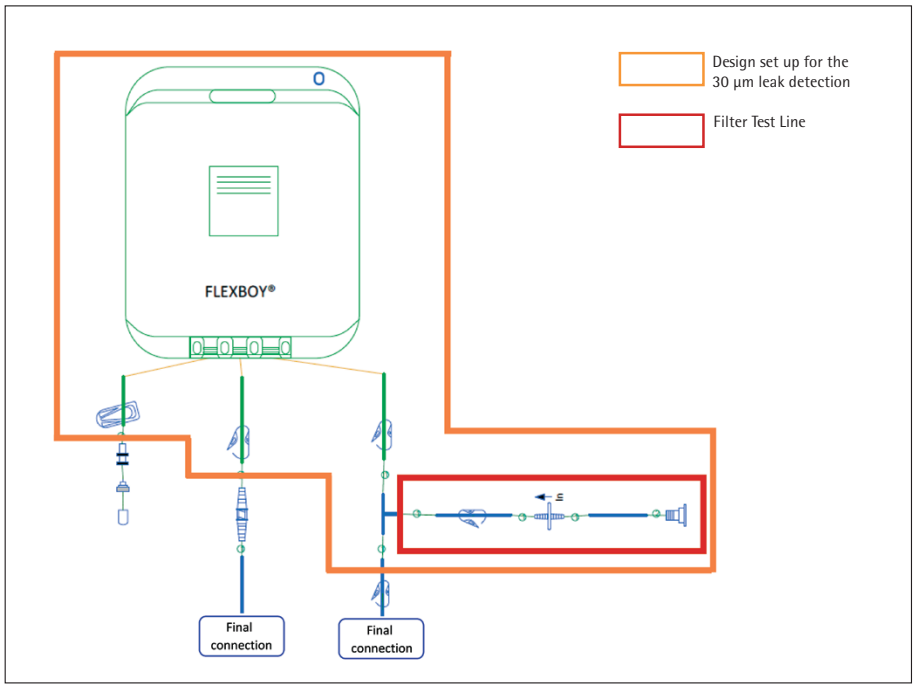



Figure 1a: Flexboy® 2D standard bag design for point-of-use leak test

### c. Description of Flexsafe® 2D validated design

Flexsafe® 2D bags from 3 L to 50 L need also a sterilizing grade vent filter line to perform the point-of-use leak test without breaching the sterility.

| | |
|---|---|
| Bag Chamber | Multiple layer film construction including an LLDPE gas barrier layer and a PE contact layer |
| Volumes | 3 L – 50 L |
| Port tubes | PE |
| Fittings | Sampling line: Needle-less Clave connector with slide clamp<br>Filling line: filter test line with Midisart® BV sterilizing grade vent filter<br>Final connection defined by end user – not in the scope of the validation<br>Draining line: pinch clamp on PE port tube Final connection defined by end user – not in the scope of the validation |
| Sterilization | Gamma irradiated 25-45 kGy |

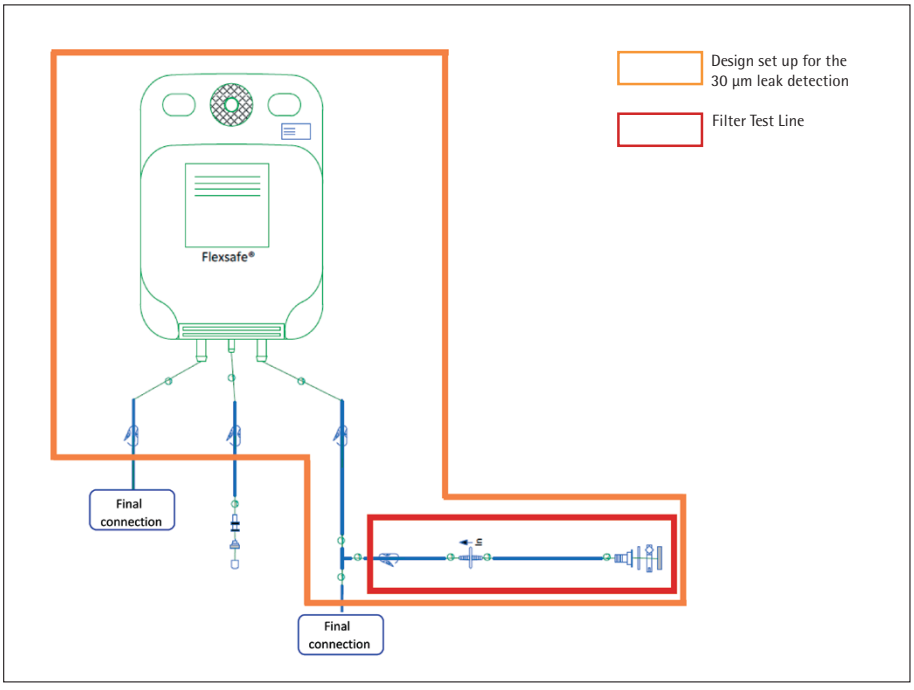



Figure 1b: Flexsafe® 2D standard bag design for point-of-use leak test

# 3. Pressure Decay Test Method

**a. Test purpose**

The test method is derived from ASTM F2095-07: "Standard Test Methods for Pressure Decay Leak Test for Flexible Packages with and without Restraining Plates."

After setting and stabilization of the test pressure, the pressure decay is measured and compared to an acceptance criteria determined during the validation of the method.

The pressure decay test method developed can detect defects according to the leak rate specification of 30 µm on the film, welds and ports of the Flexboy® & Flexsafe® 2D bags.

The validated test method is compatible with a 100% leak test at customer production facilities: the test method is non-destructive, safe, fast, easy to implement and to validate, reliable and it maintains the sterility of the system during testing.

**b. Test environment requirements**

The pressure decay test method is temperature sensitive. All the validation tests were performed under ambient temperature (laboratory conditions i.e. 22 ± 2.5°C) and precautions were taken to avoid a temperature deviation of more than ± 1°C during the measurements.

The pressure decay test method is also humidity sensitive. All the validation tests were performed in controlled environment within the accepted range of 10% – 80% relative humidity.

**c. Test samples and equipment**

To avoid temperature and humidity effects, all test sample bags and test equipment were maintained under the same temperature and humidity conditions during the entire validation study.

**d. Test procedure**

The pressure decay test (Figure 2) consists of
- pressurizing the bag at the set test pressure,
- stabilizing the test pressure to compensate for thermal effect
- measuring the pressure decay over the test time
- comparing the pressure decay to a maximum allowable pressure decay specification

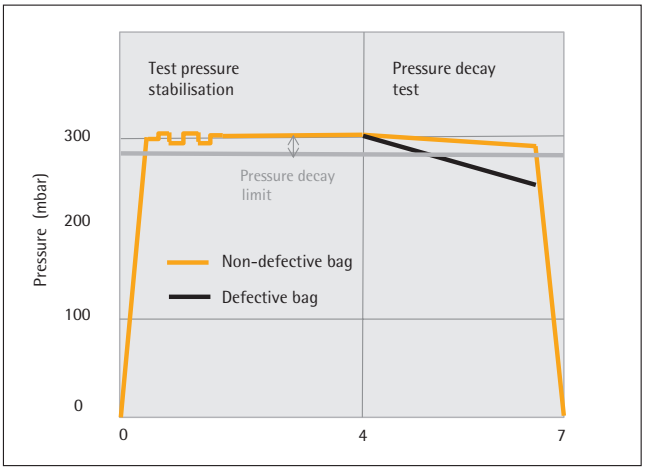



Figure 2: Pressure decay test procedure

The test parameters and the test specifications are established and validated by certified operators.
The validation tests also establish the test reliability and robustness: test reproducibility, accuracy and sensitivity.

The maximum allowable pressure decay is validated across the Flexboy® & Flexsafe® range for a leak detection of 30 µm.

An installation and Operational Qualification (IQ OQ) was performed on the FlexAct® BT System before performing the validation study.

The test parameter study and the validation study involve testing multiple bag samples from multiple production batches according to the following standard operating procedure:
For Flexboy®, 10 bag sample volumes from 50 mL to 50 L were tested, 35 times with non-defective film samples and 35 times with a 30 µm calibrated defect film sample for a total of 700 tests.

For Flexsafe®, 5 bag sample volumes from 3L to 50 L were tested, 48 times with non-defective film samples and 48 times with a 30 µm calibrated defect film sample for a total of 510 tests.

– The Flexboy® or Flexsafe® 2D bags are installed between the restraining plate holder of the FlexAct® BT system (Figure 3)
– A non-defective or defective film sample is used to simulate non defective and defective bags
– The sterilizing grade filter test line pre-assembled on the bag at test is inserted on its holder (Figure 4 & 5)
– The Sartocheck® 4 plus Bag tester is connected to the filter test line with a sanitary Triclamp adapter (Figure 6)
– All bags lines are closed with the pinch clamps except the filter test line (Figure 7)
– The bag is safely inflated between the restraining plates at the pre-defined set test pressure
– The bag is stabilized at the test pressure for temperature equilibration and the pressure decay is measured
– Test evaluation – pass | fail result is printed out (Figure 8).
– The Sartocheck® 4 plus Bag tester depressurizes the bag after the pressure decay measurement
– Across the range of Flexboy® 2D bags, the test is performed 60 times for the parameter study and 640 times for the validation study
– Across the range of Flexsafe® 2D bags, the test is performed 30 times for the parameter study and 480 tests for the validation study.

The calibrated defect film sample is checked for conformity.

Figure 3: Bag insertion

Figure 4: sterilizing grade vent filter

Figure 5: Filter test line holder

Figure 6: Sanitary connection

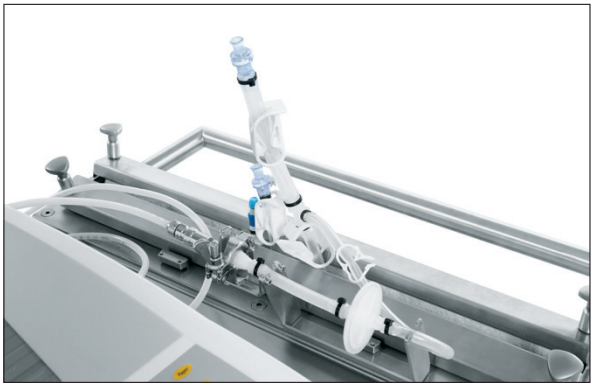


Figure 7: clamp position

Figure 8: test evaluation

# Test Results

## 1. Test Parameters Study

The aim of the study is to predetermine the test parameters necessary to reliably detect a 30µm defect over the complete volume range of Flexboy® & Flexsafe® 2D bag configurations as described in materials and methods paragraph 2.

Three test bag samples of each of the 10 Flexboy® 2D bag volumes are pressure decay tested with non-defective or defective film samples, for a total of 60 tests. Three test bag samples of each of the 5 Flexsafe® 2D bag volumes are pressure decay tested with non-defective and defective film samples, for a total of 30 tests. The defective film sample is made of circular sheet of film with a laser drilled and flow calibrated hole of 30 µm.

Tests were performed at a fixed test pressure of 300 mbar, a target defect size of 30 µm and at multiple stabilization times for Flexboy® 2D bags. One stabilization time was studied for Flexsafe® 2D bags according test parameters of Flexboy® 2D bags. The pressure decay values were recorded continuously during the pressure decay measurement time to pre-establish the optimum test parameters.

**a. Target test parameters**

Test parameters need first to be targeted to provide a reliable leak test method in a safe, fast, easy to operate and easy to validate manner.

The combination of the small and reproducible inflating volume, the high test pressure and the high accuracy of the Sartocheck® 4 plus Bag tester allows to achieve a reliable test, reproducible, accurate and sensitive, in less than 10 minutes total installation, inflation and test time.

| | |
|---|---|
| Test Pressure [mbar] | 300 |
| Stabilization Time for Flexboy® [sec] | 60 – 120 – 180 – 240 |
| Stabilization Time for Flexsafe® [sec] | 240 |
| Test Time [sec] | 0 – 240 (pressure decay record every second) |
| Max. Pressure Drop [mbar] | To be determined |

Table 1: Preliminary test parameters study

**b. Establishment of stabilization time and test time for Flexboy® 2D bags**

For each of the 10 bag sizes, 3 non-defective test samples and 3 defective test samples with 30 µm hole were prepared. All samples were tested at a fixed 300 mbar test pressure. For each test run, four different stabilization times of 60 seconds, 120 seconds, 180 seconds and 240 seconds were used. The pressure drops were continuously measured and reported every second across the entire test time period from 0 to 240 seconds at the four different stabilization time test runs.

The minimum, the mean, the maximum and the standard deviations (sigma) of the measured pressure drops are calculated for the four different stabilization times separately with non-defective and defective test samples for each different bag volume.

After analyzing the pressure drop data, the stabilization time and the test time were chosen to provide a selective test method able to differentiate defective bags from non-defective bags, i.e. the points where the error bars (+/- 3 sigma) from the defect are distinguished from the error bars (+/- 3 sigma) from the non-defective measurements.

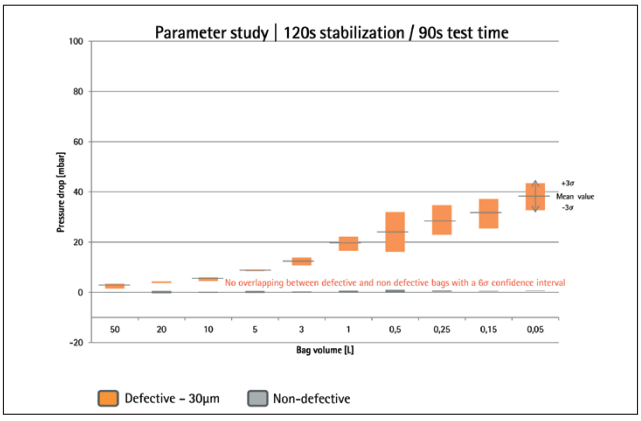



Figure 9: pressure drops intervals of +/- 3sigma around the mean values for defective and non-defective test samples at 120 seconds stabilization and 90 seconds test times

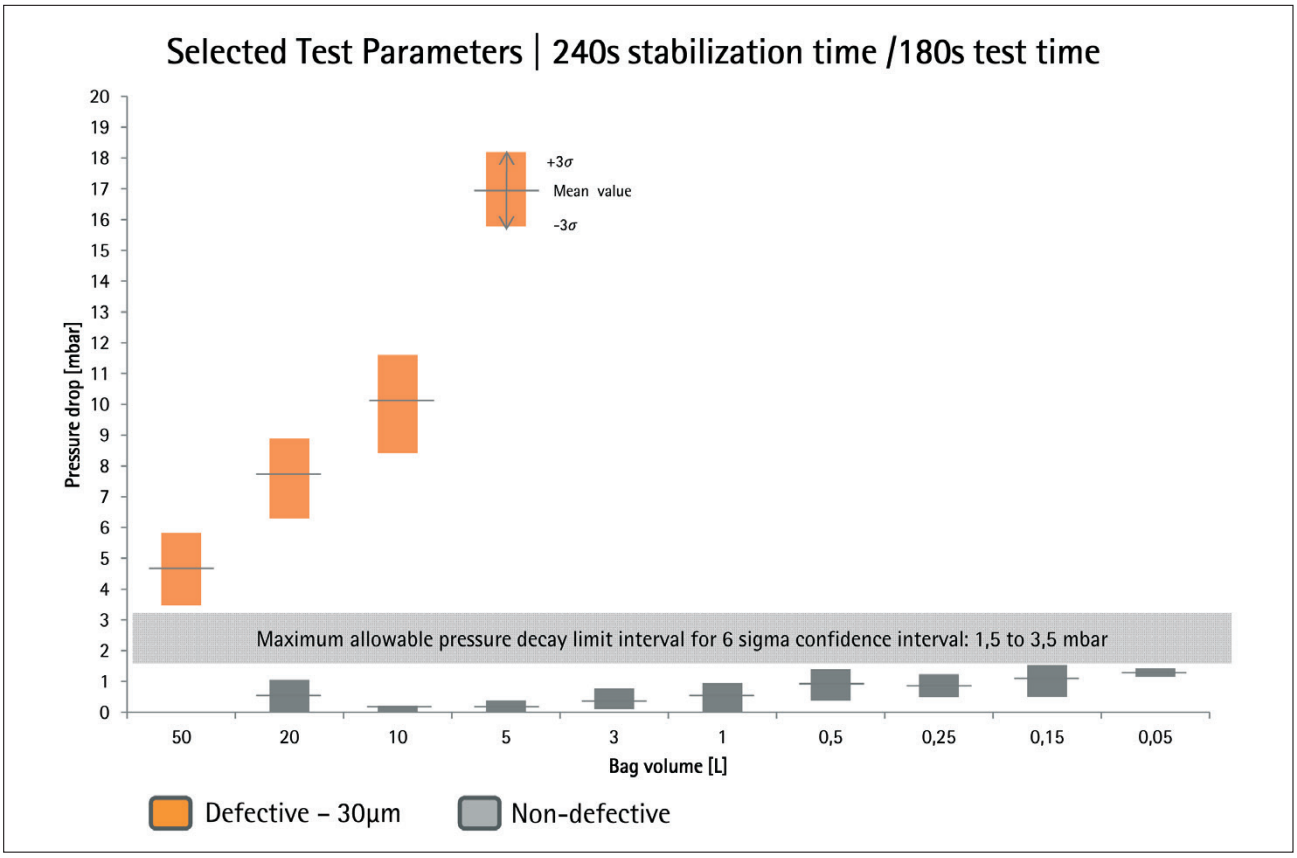



Figure 10: pressure drops intervals of +/- 3sigma around the mean values for defective and non-defective test samples at 240 seconds stabilization and 180 seconds test times

The results show a clear split-up between defective and non-defective test samples with a probability of 99,9% for 120 seconds stabilization time and 90 seconds test time (Figure 9). To provide an additional safety margin, and avoid false positive and false negative results in normal operations, these times were multiplied by two. Therefore the stabilization time of 240 seconds and the test time of 180 seconds (Figure 10) were selected for the validation study.

| | |
|---|---|
| Test Pressure [mbar] | 300 |
| Stabilization Time [sec] | 240 |
| Test Time [sec] | 180 |
| Max. Pressure Drop [mbar] | 1.5 – 3.5* (to be confirmed during the validation study) |

* The final maximum pressure drop is determined during the validation study.

Table 2: Final predetermined test parameters for Flexboy® 2D bags

**c. Establishment test time for Flexsafe® 2D bags**

For each of the 5 bag sizes, 3 non-defective test samples and 3 defective test samples with 30 µm hole were prepared. All samples were tested at a fixed 300 mbar test pressure. For each test run, only 240 seconds stabilization times was used because its stabilization times for Flexboy® 2D bags. The pressure drops were continuously measured and reported every second across the entire test time period from 0 to 240 seconds for stabilization time test runs.

The minimum, the mean, the maximum and the standard deviations (sigma) of the measured pressure drops are calculated for stabilization times separately with non-defective and defective test samples for each different bag volume.

After analyzing the pressure drop data, the stabilization time was confirmed and the test time was chosen to provide a selective test method able to differentiate defective bags from non-defective bags, i.e. the points where the error bars (+/- 3 sigma) from the defect are distinguished from the error bars (+/- 3 sigma) from the non-defective measurements.

| | |
|---|---|
| Test Pressure [mbar] | 300 |
| Stabilization Time [sec] | 240 |
| Test Time [sec] | 180 |
| Max. Pressure Drop [mbar] | 1 – 4.5* |

* The final maximum pressure drop is determined during the validation study

Table 3: Final predetermined test parameters for Flexsafe® 2D Bags

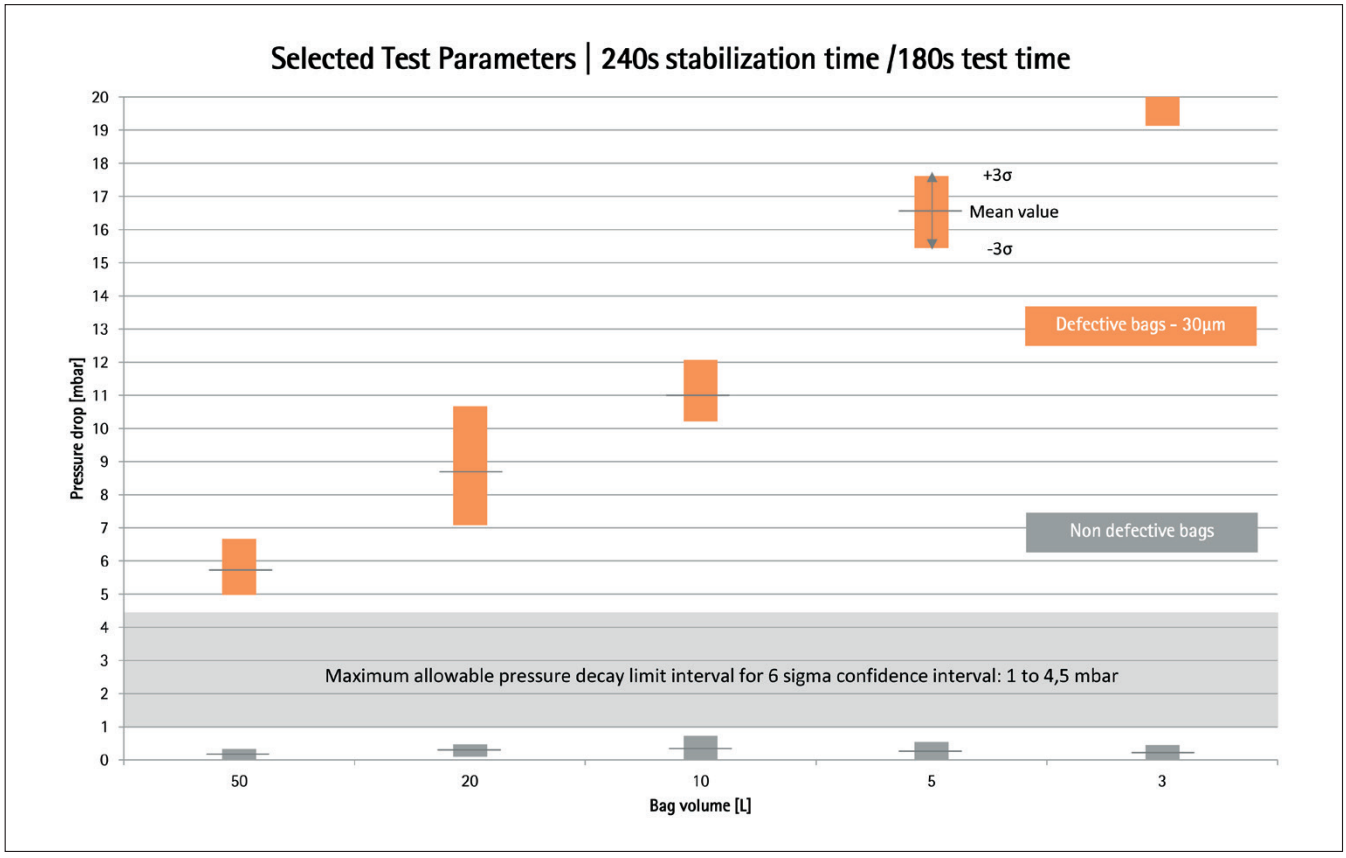



Figure 11: pressure drops intervals of +/- 3sigma around the mean values for defective and non-defective test samples at 240 seconds stabilization and 180 seconds test times

These results show a clear split-up between defective and non-defective test samples (Figure 11), therefore confirm these test parameters for the validation study.

# 2. Validation Study

The purpose of the validation study is to verify the ability of the pre-established test method and test parameters to reproducibly and accurately detect a 30 µm defect over the volume range for Flexboy® or Flexsafe® 2D bags as defined in materials and methods in paragraph 2.

The validation study is performed with a statistically significant number of bags from different routine production lots to provide a robust validation and test method.

As for the parameter study, every calibrated defect film sample is checked for its calibrated hole size before use.

Tests were performed for Flexboy® and Flexsafe® 2D bags using the predetermined test pressure of 300 mbar, stabilization time of 240 sec., test time of 180 sec. and defect size of 30 µm, and the pressure decay values were analyzed to finally validate the optimum leak test parameters and specifications.

Based on the maximum pressure drop value for the non-defective test samples and the minimum pressure drop value for the 50L defective test samples and using a 6 sigma confidence interval, the following set of test parameters has been defined, using the same principles as per the test parameters study.

**Flexboy® bags:** 32 test samples of each volume (50 ml – 50 L) with and without defect – 640 test samples

For each of the 10 bag volumes, 32 non-defective test samples from production with representative raw material and process variability and 32 test samples with a 30 µm defect are used, which represents a total of 640 test samples tested during the validation study.

| Product identification | Bag batch number | Volume | Sterilization dose |
|---|---|---|---|
| FFB123674_D | 1403124PRS | 50 L | 25 – 45 kGy |
| FFB123675_D | 1403125PRS | 20 L | 25 – 45 kGy |
| FFB123682_D | 1404025PRS | 10 L | 25 – 45 kGy |
| FFB123681_D | 1404024PRS | 5 L | 25 – 45 kGy |
| FFB123684_D | 1404125PRS | 3 L | 25 – 45 kGy |
| FFB123685_D | 1404026PRS | 1 L | 25 – 45 kGy |
| FFB123686_D | 1404080PRS | 500 mL | 25 – 45 kGy |
| FFB123687_D | 1404124PRS | 250 mL | 25 – 45 kGy |
| FFB123688_D | 1404081PRS | 150 mL | 25 – 45 kGy |
| FFB123689_D | 1404082PRS | 50 mL | 25 – 45 kGy |

Table 4: Validation study test samples traceability

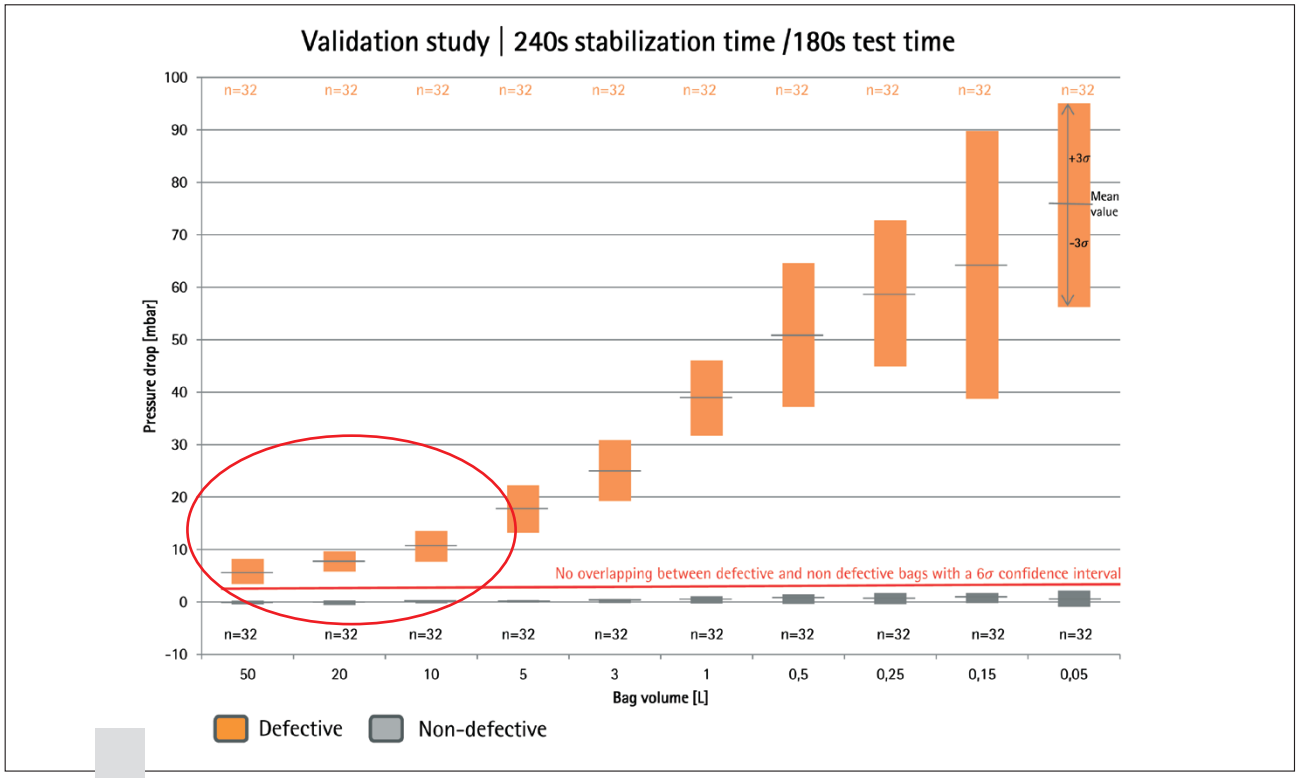



Figure 12a: Validation study test results at 240 s stabilization time, 180 s test time and 300 mbar test

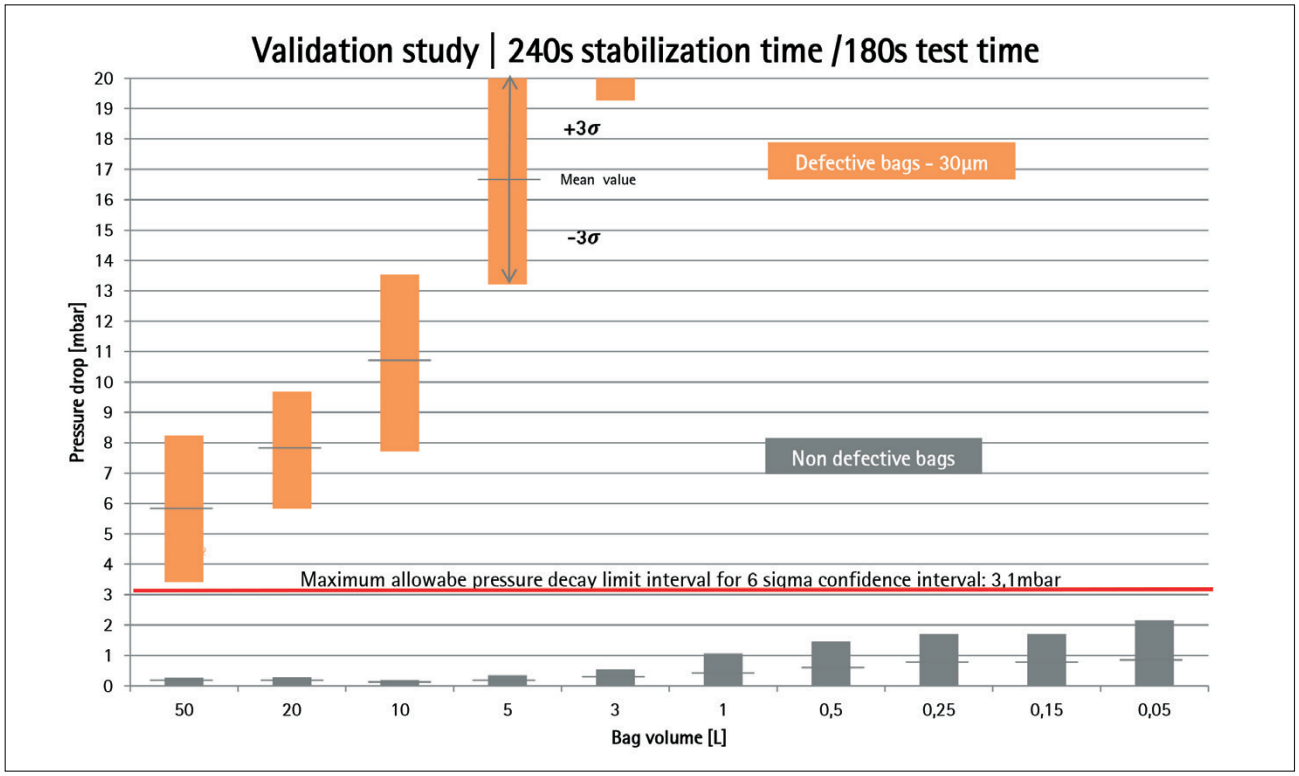



Figure 12b: validation study results in a 3.1 mbar maximum allowable pressure drop at 240s stabilization time and 180s test time

This robust study allowed the validation of the pre-established test parameters and setting a maximum allowable pressure decay specification at 3.1 mbar. The validated pressure decay method using Flexact® BT is capable to reliably detect and differentiate defective bags from non-defective bags with a leak detection of 30 µm in less than 10 minutes total installation and test time.

The 3.1 mbar maximum pressure decay specification is established with a 6 sigma interval of confidence for the full range of Flexboy® bags from 50 mL to 50 L to avoid false positive or false negative results under real testing conditions

| | |
|---|---|
| Test Pressure [mbar] | 300 |
| Stabilization Time [sec] | 240 |
| Test Time [sec] | 180 |
| Max. Pressure Drop [mbar] | 3.1 |

Table 5: Final Test Parameters from the validation study for Flexboy® 2D Bags

**Flexsafe® bags:** 48 test samples of each volume (3 L -50 L) with and without defect – 480 test samples

For each of the 5 bag volumes, 48 non-defective test samples from production with representative raw material and process variability and 48 test samples with a 30 µm defect are used, which represents a total of 480 test samples tested during the validation study.

| Product identification | Bag batch number | Volume | Sterilization dose |
|---|---|---|---|
| FLS128950_D | 1611P258 | 50 L | 25 – 45 kGy |
| FLS128034_D | 1607P238<br>1608P179 | 20 L | 25 – 45 kGy |
| FLS128935_D | 1608P090<br>1608P004 | 10 L | 25 – 45 kGy |
| FLS128936_D | 1608P005<br>1608P091<br>1608P181 | 5 L | 25 – 45 kGy |
| FLS128962_D | 1611P262<br>1611P297<br>1611P302 | 3 L | 25 – 45 kGy |

Table 6: Validation study test samples traceability

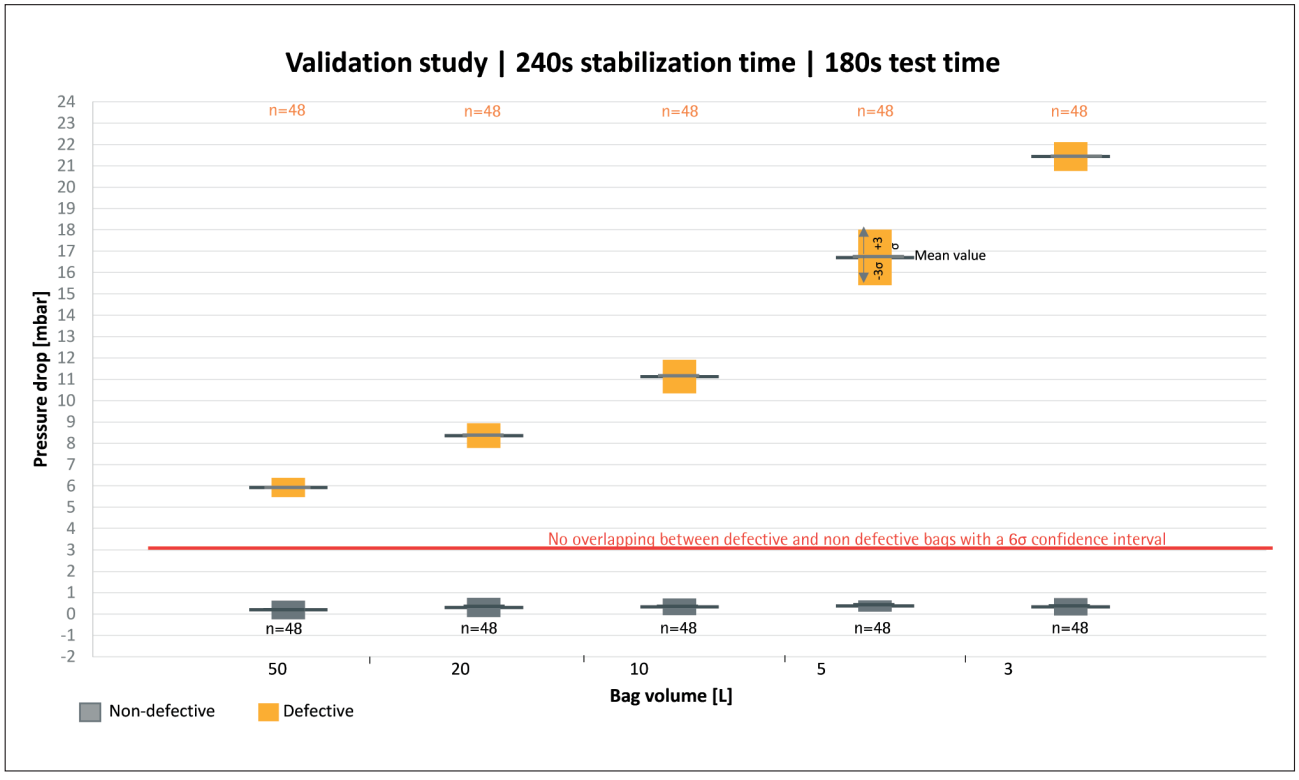



Figure 13: validation study results at 240s stabilization time and 180s test time with 3.1 mbar maximum allowable pressure drop

This robust study allowed the validation of the pre-established test parameters and setting a maximum allowable pressure decay specification at 4.1 mbar. The validated pressure decay method using FlexAct® BT is capable to reliably detect and differentiate defective bags from non-defective bags with a leak detection of 30 µm in less than 10 minutes total installation and test time.

The 4.1 mbar maximum pressure decay specification is established with a 6 sigma confidence interval for the full range of Flexsafe® 2D bags from 3L to 50L to avoid false positive or false negative results under real testing conditions.

| | |
|---|---|
| Test Pressure [mbar] | 300 |
| Stabilization Time [sec] | 240 |
| Test Time [sec] | 180 |
| Max. Pressure Drop [mbar] | 3.1 |

Table 7: Final Test Parameters from the validation study for Flexsafe® 2D Bags

# Conclusion

Our pressure decay leak test method for Flexboy® & Flexsafe® 2D bags using FlexAct® BT and Sartocheck® 4 plus Bag tester was successfully validated and proved to be a robust and predictive method for reliable detection of leaks.

The test parameters study and the test validation study both passed all acceptance criteria and allowed to establish reliable and robust test parameters, methods and specifications with a statistically significant number of test samples, 700 tests for Flexboy® 2D bags and 510 tests for Flexsafe® 2D bags and the application of a 6 sigma confidence interval for critical parameters.

All tested bag samples passed acceptance criteria. 2D bags out of normal production and supposed as non-defective show results below the maximum pressure drop specification and 2D bags with a deliberate 30 µm defect show results above the maximum pressure drop specification and fail the test.

In addition to this validation study, FlexAct® BT is supplied with an integrated IQ/OQ/PQ, SOP development and training service at the end user production facility. Our service provides validation, compliance and assurance that the FlexAct® BT system operates under the validated test parameters and is capable of detecting 30 µm leaks for a standard Flexboy® & Flexsafe® 2D bag configuration.

The 30 µm detection is a science and risk based approach that combines our 20-year experience of leak testing and bag production with more than 20 million of 2D bags produced. We have additionally calculated the theoretical minimum hole size that can be validated under these methods with this test equipment. By varying the internal volume (bag size) and test time, it can reasonably be concluded that a smaller leak size, down to 10 µm, could be detected with Flexact® BT with the same reliability and confidence.

Finally, we also provide service to establish and validate specific test parameters for custom Flexboy® & Flexsafe® 2D bag configuration with different volumes, tubing lengths and connections to be tested.

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