

FlexAct® BT (Bag Tester)

Point-of-Use Integrity
Test Solution for
Flexboy® & Flexsafe® 2D Bags



Product Information

FlexAct® BT is a Bag Tester solution for end user to control the absence of leaks that could occur during transportation and handling of 2D bags at the point of use. FlexAct® BT features the Sartochek® 4 plus Bag tester and a set of two holders to perform pressure decay testing in a safe, fast, easy and reliable way. FlexAct® BT is supplied with a complete validation package and on-site service to achieve an easy validation.

Pressure Decay Integrity Test Equipment

FlexAct® BT enables end user to perform a fast and easy integrity testing of Flexboy® and Flexsafe® 2D bag assemblies at the point of use. FlexAct® BT increases the level of assurance of single-use system integrity and significantly improves process integrity, product sterility as well as patient and operator safety.

FlexAct® BT is equipped with two metal restraining plate holders between which bags are easily inserted and securely maintained during testing. The holders protect the bag from mechanical stress and allow performing the leak test with a small inflating bag volume and at a high test pressure, thus increasing the test sensitivity and reliability. The bags are

separated from the metal plates by porous spacers to avoid direct contact of the surface of the film and to prevent any leak masking effect during the test.

FlexAct® BT features the Sartocheck® 4 plus Bag tester that serves as the control unit for the pressure decay testing. The combination of the well-established Sartocheck® technology and ASTM F2095¹ pressure decay methodology provide end users with a reliable and easy-to-validate integrity test for Flexboy® and Flexsafe® 2D bags.

The device has three shelves on which bag testers can be placed. The Sartocheck® 4 plus Bag tester is placed on the upper shelf and a Sartocheck® 4 plus Bag tester MultiUnit option is available to increase test productivity by testing two bags simultaneously and to allow filter integrity testing.

FlexAct® BT is designed to support the installation, inflation and the pressure decay test of 2D bags from 3 L to 50 L in less than 10 minutes.

FlexAct® BT is supplied with a robust validation package and on site validation service to facilitate implementation of bag integrity testing in critical drug substance and drug product cGMP commercial productions.

As bags require lower test pressures and therefore higher measurement accuracies than membrane filters, the pressure range of the Sartocheck® 4 plus Bag tester is reduced to optimize the test pressure setting accuracy and the pressure decay measurement accuracy.

The Sartocheck® 4 plus Bag tester software version 3.00 achieves pressure decay measurement accuracy of $\pm 0.4\%$ with a ± 1 mbar reproducibility for non-defective bags.

Single-use 2D bag integrity testing can be implemented with the same fast, easy to implement, reproducible, accurate and sensitive pressure decay test methods as already used for decades for sterilizing-grade filters.

Using a MultiUnit filter tester connected to the Sartocheck® 4 plus Bag tester allows filter integrity testing.

Using a MultiUnit bag tester connected to the Sartocheck® 4 plus Bag tester provides parallel testing of two bag assemblies and thus reduces testing time.

Pressure Decay Integrity Test Method

The test method is derived from ASTM F2095:

“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 validated test method can detect 10 μm defects and is compatible with a 100% point-of-use integrity test: it is nondestructive, safe, fast, easy to implement and to validate, reliable and it maintains the sterility of the system during testing.

The inflation and pressure decay integrity testing are performed through a sterilizing grade vent filter line pre-assembled and pre-sterilized with the single-use bag assembly to maintain the system integrity and the sterility of the bag to be tested.

The restraining plates and porous spacers integrated into the FlexAct® BT provide a fast and easy installation, a safe inflation and a reliable test of Flexboy® and Flexsafe® 2D bag assemblies. They also reduce environmental heat transfers that could lead to erroneous integrity test results. Porous spacers avoid leak masking effect during the test. The combination of the small and reproducible inflating volume, less than 3 L for a 50 L bag, the high test pressure, up to 300 mbar, the ± 1 mbar measurement reproducibility for non-defective bags and $\pm 0.4\%$ pressure decay measurement accuracy of Sartocheck® 4 plus Bag tester provides a highly reproducible, accurate and sensitive integrity test.

FlexAct® BT is validated to detect 10 μm defect across the volume range from 3 L to 50 L in less than 10 minutes total installation and test time, providing a high level of safety, which is far below the potential risk of defect size currently observed under normal production and handling conditions.

¹ASTM F2095: “Standard Test Methods for Pressure Decay Leak Test for Flexible Packages with and without Restraining Plates.”

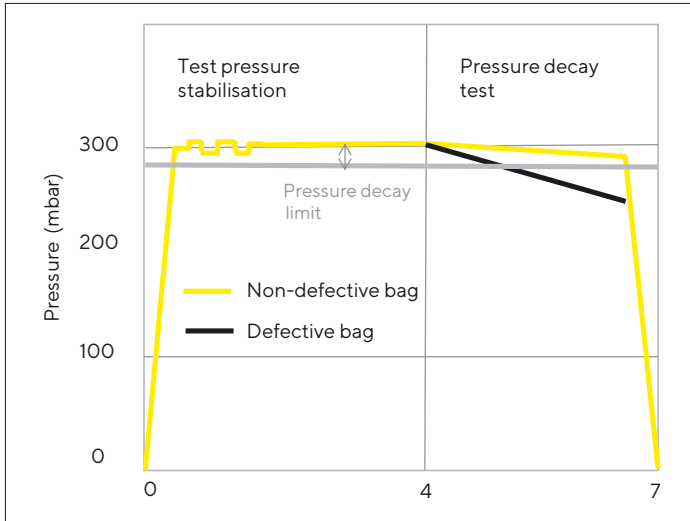


Figure 1: Illustration of the Pressure decay test procedure

The FlexAct® BT combines the benefits of well-established Sartocheck® technology and ASTM F2095 pressure decay methodology

Safe	<ul style="list-style-type: none"> ▪ Avoids processing with leaking bags ▪ Improves patient safety by reducing risks of sterility failures ▪ Improves process integrity and operator safety by eliminating product loss ▪ Restraining plates maintain bag integrity
Fast and easy to use	<ul style="list-style-type: none"> ▪ Well established Sartocheck® technology and pressure decay method ▪ Less than 10 minute total installation and test time ▪ Efficient equipment utilization with MultiUnit Bag tester option for dual testing and filter integrity testing
Reliable	<ul style="list-style-type: none"> ▪ Reproducible ± 1 mbar ▪ Pressure decay accuracy: $\pm 0.4\%$ ▪ Sensitive: $10 \mu\text{m}$ detection limit validated with 510 tests and 6 sigma confidence interval between defective and non-defective bags
Easy to validate	<ul style="list-style-type: none"> ▪ Proven ASTM F2095 pressure decay methodology ▪ Development in accordance with GAMP5 & full compliance with 21 CFR Part 11 ▪ Test reliability validated with 510 tests and 6 sigma confidence interval between defective and non-defective bags ▪ Expert on site validation support for IQ, OQ, PQ, SOP development and operator training



Validation and Qualification

FlexAct® BT is supplied with a robust validation documentation package. The Installation Qualification (IQ) and Operational Qualification (OQ) of the equipment is performed by Sartorius Stedim Biotech Service, both for the FlexAct® BT and the Sartocheck 4 plus Bag tester. It provides full certified documentation to evidence that all tests are carried out with highest reproducibility and accuracy. The Performance Qualification (PQ) is performed by Certified Application Specialists. It guarantees the sensitivity and repeatability of the validated method on the installed equipment as well as the training of the operators.

Both test parameters and test specifications have been validated using 510 tests (defective and non-defective units) from multiple batches of Flexboy® and Flexsafe® bags from 3 L to 50 L.

Non defective test samples are taken from normal production and defective test samples are deliberately achieved using 10 µm calibrated defect film samples.

The leak detection is validated at 10 µm with a pressure decay test time of less than 10' depending on bag volumes for the range of Flexboy® and Flexsafe® 2D bags using the worst case 50 L bag. The leak differentiation between defective and non-defective samples is established with a 6 sigma confidence interval.

This validation provides a robust and reliable integrity test method, i.e. reproducible, accurate and sensitive.

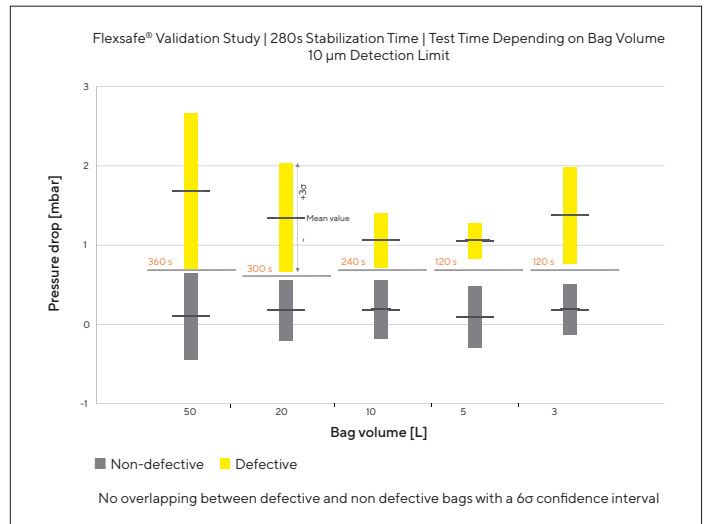
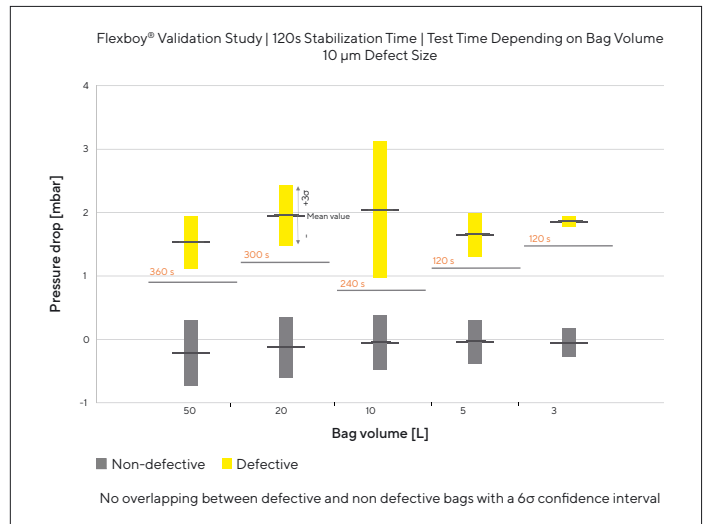


Figure 2 : Final parameters of validation for Flexboy® and Flexsafe®.

The validated pressure decay leak test method with Flexact® BT is compatible with a 100% integrity test at customer production facilities: It is easy to implement, to validate and non-destructive, maintaining the sterility of the system during testing.

Configuration of Flexboy® and Flexsafe® 2D Bags for Point-of-use Integrity Testing

a. Application

Flexboy® and 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 integrity 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® and Flexsafe® 2D bags to be integrity 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.

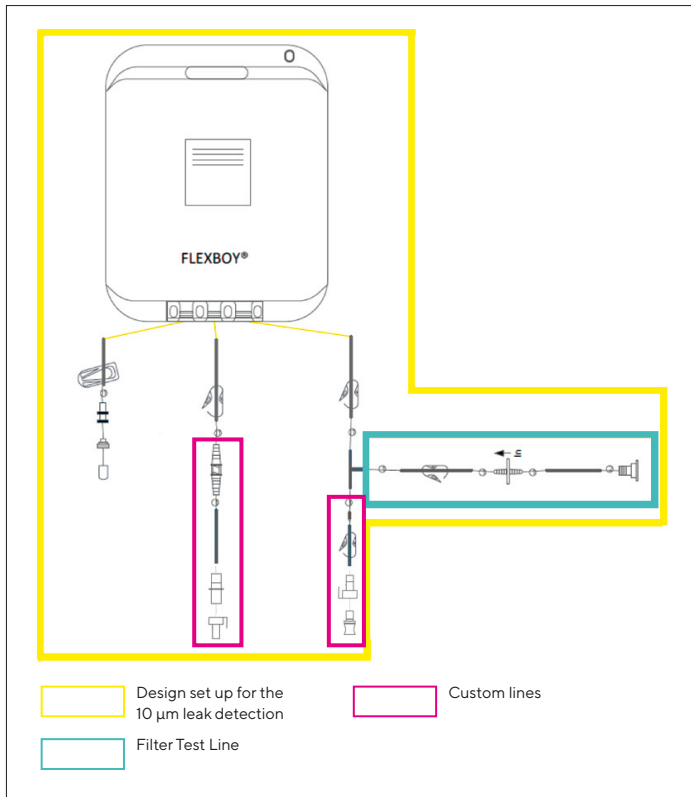


Figure 3: Example of a Flexboy® 2D Pre Designed Solutions for point-of-use integrity test

b. Description of Flexboy® and Flexsafe® 2D Validated Design

Flexboy® and Flexsafe® 2D bags intended to be integrity tested need to meet specific design requirements. First, the handle currently present on Flexboy® bags from 3 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	Flexboy® Multiple layer film construction,
Chamber	including an EVOH gas barrier layer and an EVA contact layer
Volumes	3 L - 50 L
Port tubes	EVA
Fittings	Sampling line: sampling connector with slide clamp Filling line: filter test line with Midisart® BV sterilizing grade vent filter Clear C-Flex®* 374 L500 mm ¾" Triclamp, pinch clamps Customized lines defined by end-user are not in the scope of this validation Draining line: pinch clamp on EVA port tube Customized lines defined by end-user are not in the scope of this validation

Sterilization	Gamma irradiated 25 – 45 kGy
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Bag	Flexsafe® multiple-layer S80 film construction
Chamber	including an EVOH gas barrier layer and a PE contact layer
Volumes	3 L - 50 L
Port tubes	TuFlux® Silicone
Fittings	Sampling line: Needlelessclave connector Filling line: Filter test line with Midisart(R) BV sterilizing grade vent filter Clear C-Flex®* and distal connection Draining line: Silicone or C-Flex®* tubing with distal connection. Customized lines defined by end-user are not in the scope of this validation

Sterilization	Gamma irradiated 25 – 45 kGy
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* C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

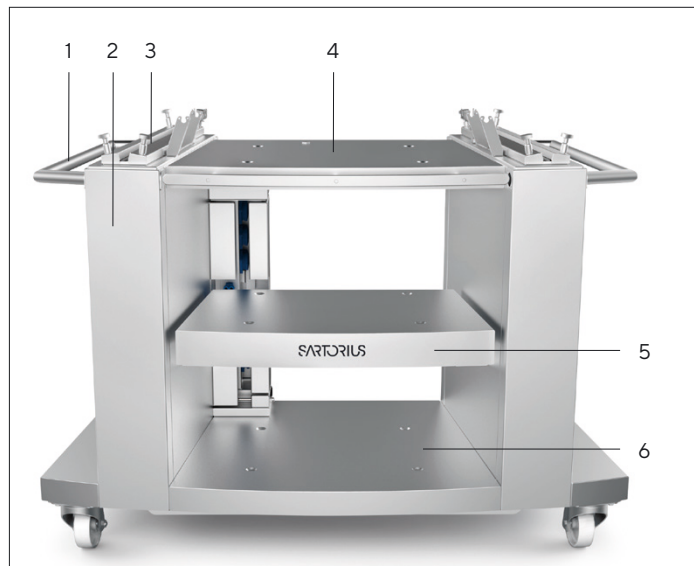
Technical Data

Specifications

	FlexAct® BT	Sartocheck® 4 plus Bag tester
Power requirements	100 - 240 V AC 50 60 Hz	100 - 240 V AC 50 60 Hz
Max. power Input	400 VA	74 watts
Operating pressure	4 - 10 bar g	4 - 10 bar g
Dimensions (W × D × H1 × H2)	1405 × 699 × 1043	460 × 390 × 140 × 245
Weight	375 kg 326 lbs	

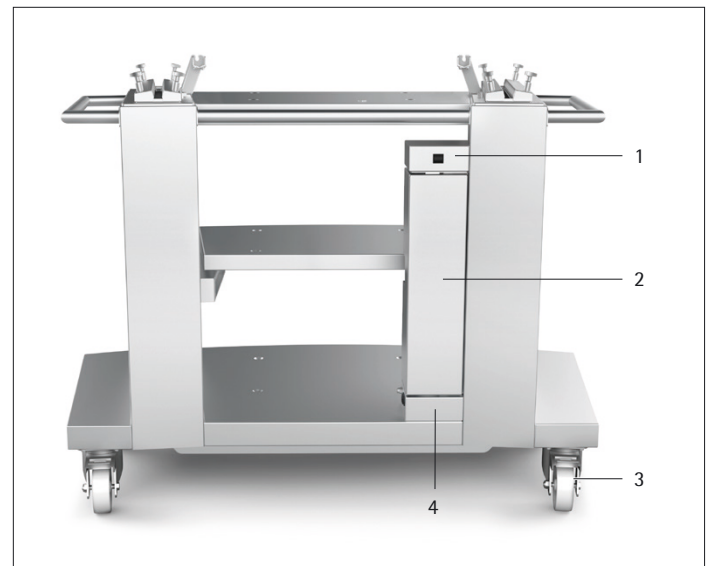
	FlexAct® BT	Sartocheck® 4 plus Bag tester
Measuring Ranges		
Test pressure	na	3 - 300 mbar 0.044 - 4.350 psi
Pressure drop	na	0.3 - 300 mbar 0.004 - 4.350 psi
Measuring Accuracy		
Pressure	na	± 0.05% full scale
Pressure decay	na	± 0.4%
Operating Conditions		
Ambient temperature	+ 15 °C to 35 °C	+ 15 °C to 35 °C
Rel. humidity	10 - 80%	10 - 80%

Front View



Pos.	Description	Function
1	Handle	for moving the device
2	Bag Holders	for inserting the bags to be tested
3	Non-woven fabric holder	for inserting the non-woven fabric into the bag holder
4	Upper shelf	to place the Sartocheck® 4 plus Bag tester on
5	Middle shelf (can be pulled out)	to place the Sartocheck® 4 plus Bag tester MultiUnit on
6	Lower shelf	to place additional MultiUnits on

Back View



Pos.	Description	Function
1	Main switch	for turning the device on and off
2	Cover unit	cover of the connector strip (power connections)
3	Lockable castors	for moving the device and securing it in place
4	Manufacturer's ID label	

Ordering Information

Configured to Order Product

Equipment Supplied for 2D Bag testing

FlexAct® BT 2D

BT Fleece for FlexAct® BT 2D

Test tube 2D

Inlet tube BT on FlexAct® BT

Power supply

Installation and operating instructions FlexAct® BT

Sartocheck® 4 plus Bag tester

Sartocheck® 4 plus Bag tester

Inlet tubing for compressed gas

Ribbon cassette

Rolls of printer paper

Power cord

Test certificate

Calibration certificate

Installation and operating instructions Sartocheck® 4 plus Bag tester

Validation package Bag tester

Part No.

Accessories FlexAct® BT

FlexAct® BT 2D trolley

26288---BTFA

BT Fleece for FlexAct® BT 2D

DZ050L---SIT

Test tube 2D

26288---BT2D

Inlet tube BT on FlexAct® BT

26288---BTIT

Power supply FlexAct® BT to Sartocheck®

1EE---0001

Accessories Sartocheck® 4 plus Bag tester

Sartocheck® 4 plus Bag tester

26288---BT

Sartocheck® 4 plus Bag tester MultiUnit

26288---BM

Sartocheck® 4 plus Filter tester MultiUnit

26288---FM

External temperature sensor

26288---ETS

Ribbon cassette

6982141

Rolls of printer paper

6982142

Inlet tubing for compressed gas

18104

Serial Port Interface cable TU|TU

2 m

1ZE---0009

5 m

1ZE---0010

Network Cable

2 m

1ZE---0029

5 m

1ZE---0030

10 m

1ZE---0031

20 m

1ZE---0032

Power cord

Region specific

Validation Packages

Clean Room Venting Adapter

1ZE---0021

Validation package Bag tester

26288---VPBT

Validation package Bag tester MultiUnit

26288---VPBM

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