

Helium Integrity Test for Mobius® Single-use Assemblies

Protect Your Critical Applications with Increased Integrity Assurance

Helium Integrity Testing is an industry-proven manufacturing release test that provides high levels of sensitivity when detecting defects in single-use (SU) assemblies. Using helium as a tracer gas, our test is validated to detect defects as small as 2 µm. Incorporating Helium Integrity Test into your integrity assurance strategy reduces the risk of leaks or microbial ingress in your manufacturing process. This is especially critical during freezing, thawing, transportation and storage to prevent valuable product loss. Our method tests the entire SU assembly, including tubing and connection points.

Mobius® SU assemblies tested with Helium Integrity Test come with an enhanced version of our GOLD Quality Certification with the helium integrity test statement added.

Features and Benefits

- Detect assembly defects down to 2 µm
- Reduce the risk of leaks and microbial ingress contamination

Helium Integrity Test Design

Our Helium Integrity Test adopts an industry proven technology and uses helium as a tracer gas to detect single-use assembly defects. To start the test, a SU assembly is first placed inside the vacuum chamber between the restraining support plates. The vacuum pumps are turned on to evacuate the air from the vacuum chamber and from the inside of the assembly (**Figure 1**). Then, the helium supply valve is opened to fill the SU assembly with helium (**Figure 2**). While the assembly is filled with helium, the helium detector monitors the chamber for any helium leaking from the assembly (**Figure 3**).

Helium Integrity Test Design

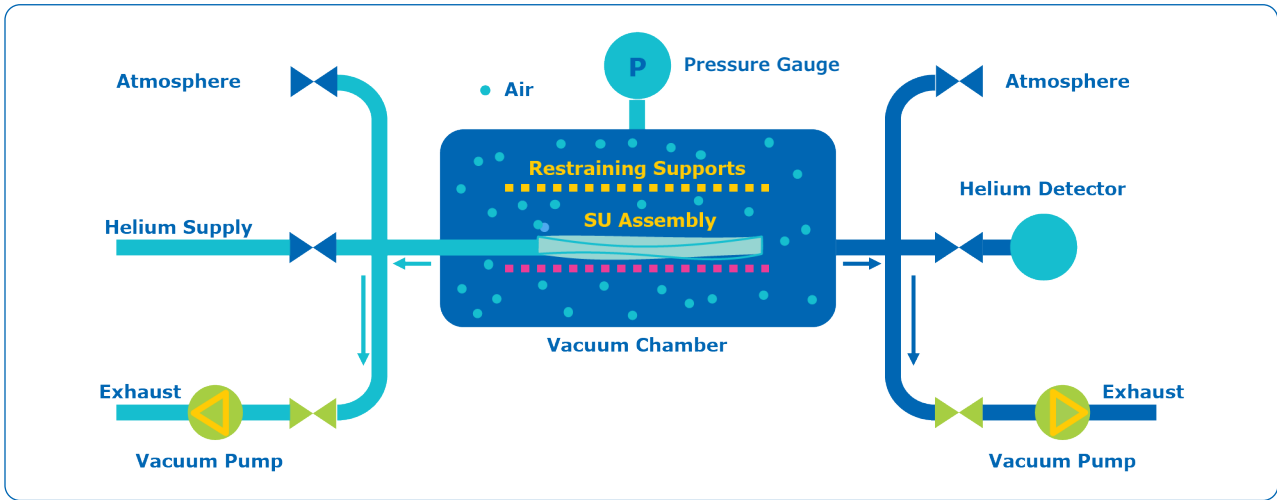


Figure 1: Air is evacuated from the vacuum chamber and from inside of the assembly.

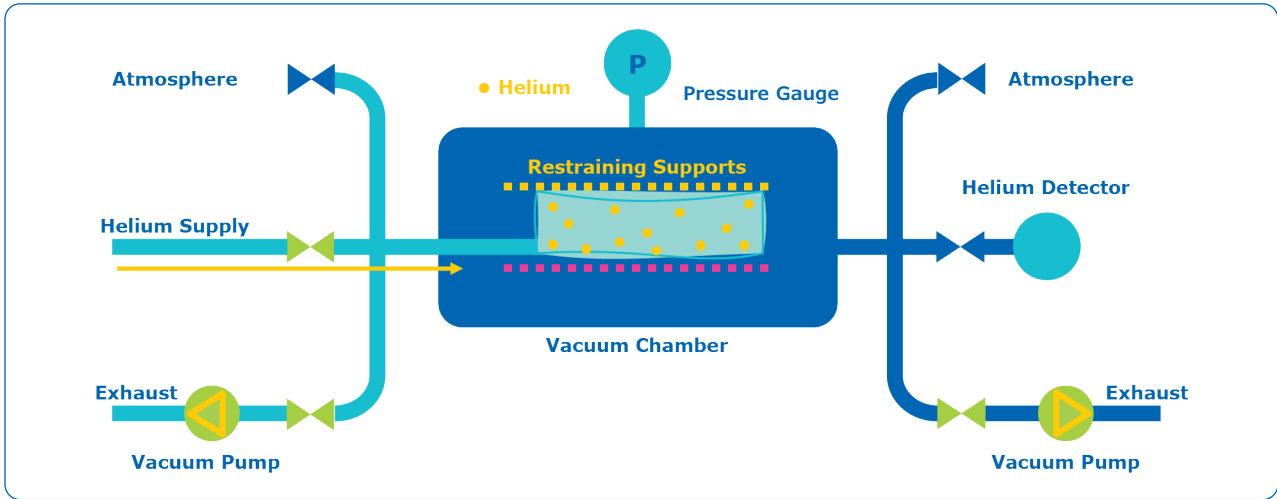


Figure 2: The test assembly is filled with helium

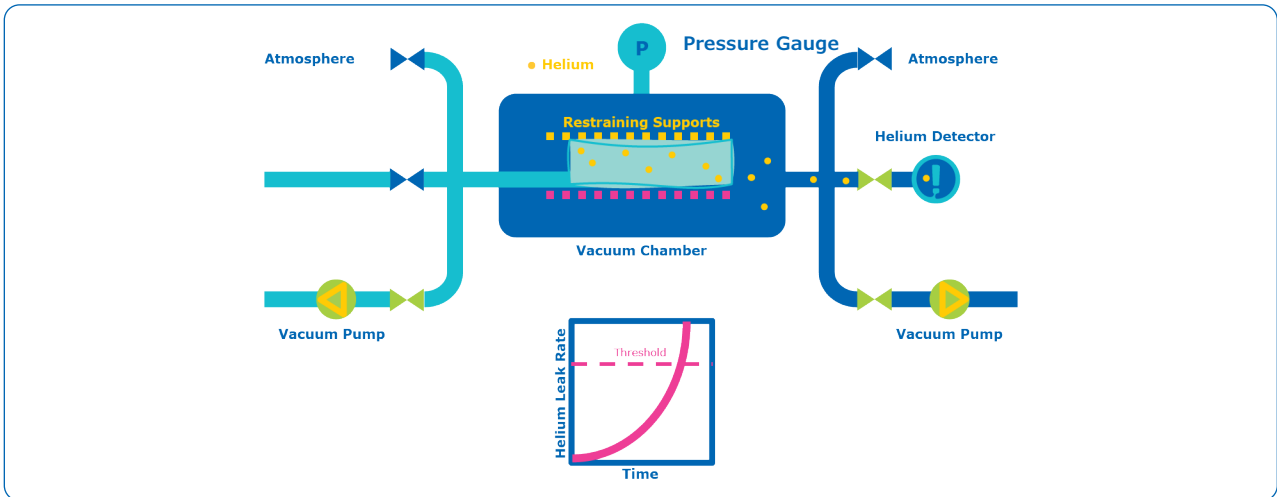


Figure 3: Helium leaked from a defective assembly is detected by the helium detector

Suitability of Your SU Assembly for Helium Integrity Test

There are 3 key design criteria to determine whether your SU assembly is in scope to be tested with our Helium Integrity Test system:

- Overall internal assembly volume
- Assembly only contains components in-scope
- Assembly fits in test chamber

Helium Integrity Test Design Space

In-Scope Assembly Components

Component	Volume/Configuration	Quantity	Example
Bag			
2D bags	50-100 mL, endported bag	Up to 6	
	5-50 L, endported bag	1	
Filter			
Opticap® XLT 10-30 filters	Any inlet/outlet configuration	1	
Opticap® XL10 filters	Any inlet/outlet configuration	1	
Opticap® XL5 or smaller filters	Any inlet/outlet configuration	Up to 2	
Millipak® Final Fill filters	Any inlet/outlet configuration	Up to 2	
Opticap® XL50 filters	1/4" HB inlet/outlet	Up to 2	
Millipak® Barrier filters	Any inlet/outlet configuration	Up to 2	
Bottle			
NovaSeptum® bottles	Up to 500 mL	Up to 5	
Sterile Connectors			
Lynx® ST connectors	All sizes	Up to 2	
Lynx® CDR connectors	All Maze sizes	Up to 2	
Lynx® S2S connectors*	All sizes and types	N/A	
Peel-strip aseptic connectors*	All sizes and types	N/A	
Colder quick-connectors*	All sizes and types	N/A	
Tubing			
Tubing	All types and sizes with at least a 1/8" wall thickness (except 1/8" ID X 1/4" OD)	Up to 31 total ft.	
Other			
TC/HB adapters, HB/HB couplers	Various sizes	N/A	

*Lynx® S2S connectors, peel-strip aseptic connectors, and Colder quick-connectors can be included in an assembly design but can't be tested due to the design of the component.

The exact number and type of components that can be tested will vary depending on the overall assembly design and is subject to engineering assessment.

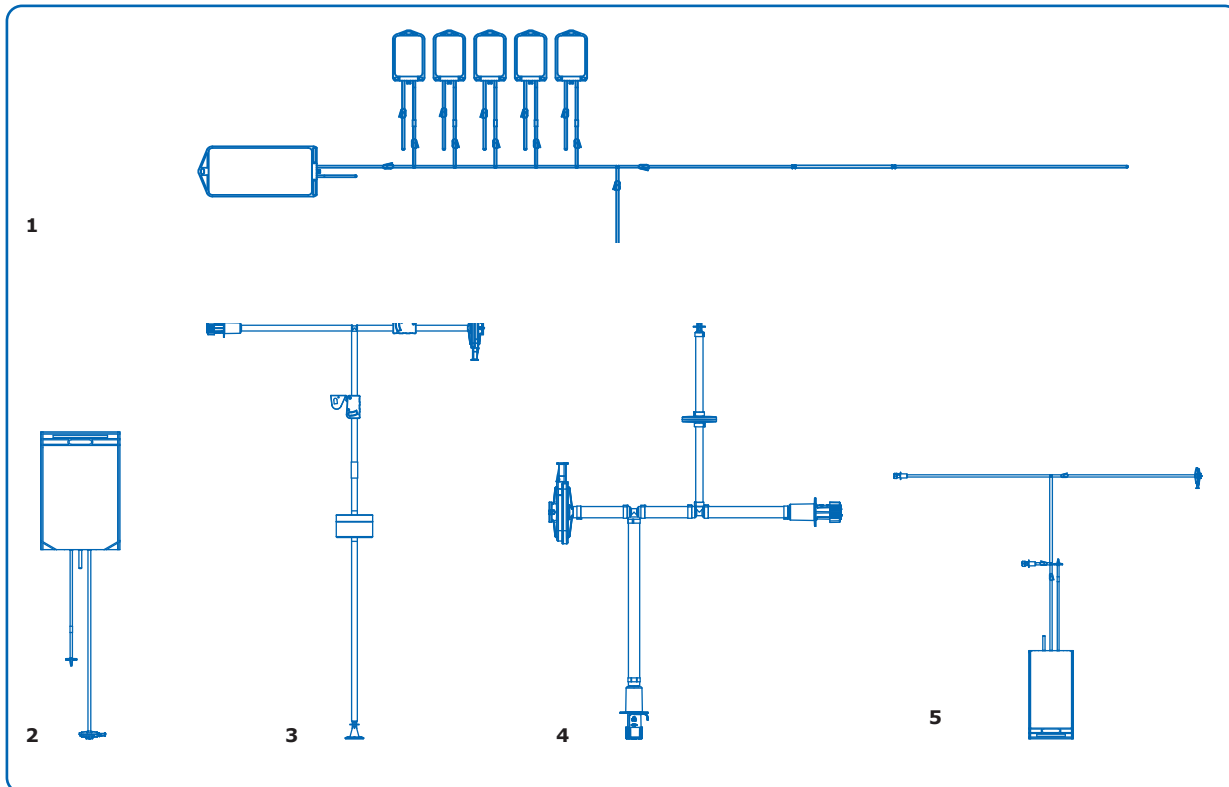
Helium Integrity Test Design Space

Out-of-scope Assembly Components

Component	Configuration
Bags	2D bags (> 50 L), 3D bags, Faceported 2D bags
Filter*	Millipak® filters (Except for Millipak® Final Fill filters and Millipak® Barrier filters)
Sensors	PendoTech pressure sensors
Others	BetaBags, Filling needles, Luers

*Filter vent design is not compatible with Helium Test.

Examples of Helium Integrity Test Compatible Assemblies



1. Example of a 2D bag assembly with Opticap® XL50 filter and Lynx® S2S connector
2. Example of a manifold sampling bag assembly
3. Example of a Millipak® Barrier filter assembly with Lynx® S2S connector
4. Example of a transfer assembly with Lynx® S2S
5. Example of a 2D bag assembly with Lynx® S2S connector

To design your single-use assembly or to learn if your assembly can be tested with Helium Integrity Test, please contact your sales representative.

For additional information,
please visit: MerckMillipore.com/singleuse
To place an order or receive technical assistance,
please visit: MerckMillipore.com/contactPS

MerckMillipore.com

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