

UNIDIM-SU

Leak test for single-use equipment



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LWO
PRÜFAUTOMATION



Leak testing

Hydraulic functional testing

Electropneumatic testing

UNIDIM SU

Patented test procedure – even for small holes

APPLICATIONS:

- Single-Use Equipment
- 3D Bio-Bags & Assemblies

Single-use equipment places particular requirements on leak testing systems. Biobags and assemblies are made in many different sizes and varieties. The components consist largely of plastic films and elastomer hoses. Both of these are flexible and permeable. The requirements for detecting small holes are becoming stricter. It has now reached a point where the permeation of the test gas helium through the components of the single-use equipment is higher than the leakage through the leaks to be detected. This requires a new test method, which has now been found and patented.



NEW PATENTED TEST PROCEDURE

In collaboration with a customer, a new patented test procedure has been developed at LIWO by means of preliminary tests. This is a new helium leak test procedure that detects marginal leakage rates up to 2 µm in diameter.

FOR INSTALLATION IN A CLEANROOM

The procedure meets all cleanroom requirements for cleanliness in biocontainers. The test gas is filtered and the cable routing to the test piece is kept clean in accordance with these requirements. The pipework is made entirely from stainless steel, only FDA-approved valves and seals have been used, the vacuum grease used is NSF H1-certified and product contact parts have been manufactured from stainless steel. Dry-running vacuum pumps were also used.

BROAD PRODUCT SPECTRUM

Bags from 50 ml to 50 l can be processed, with a variety of connection hoses or with no connection hose, with connectors, T-pieces, hose clamps or filters. Various kinds of connections in the form of different connectors and sterile connectors, as well as open hoses with different diameters, can be used.

CONSTRUCTION AND MODE OF OPERATION

Two test chambers designed as drawers for two-way loading. While one drawer is being loaded, the automatic leak test will run in the other test chamber. Single large biocontainers or up to four small biocontainers can be tested simultaneously. The test chambers have a universal design so that no setup processes are required other than changing the sealing tool; they are also open for new product varieties.



LEAK TESTING SYSTEM FOR 3D BIOCONTAINER

- Up to 500 l with differential pressure method
- Cycle time 90 seconds, hole size 50 µm
- Semi-automated with ergonomic operating guide
- Easy-running workpiece carrier circulation system
- 3 workpiece carriers, can be tilted for ease of loading
- Can be integrated according to the 1-piece flow principle, ISO class 7 cleanroom.