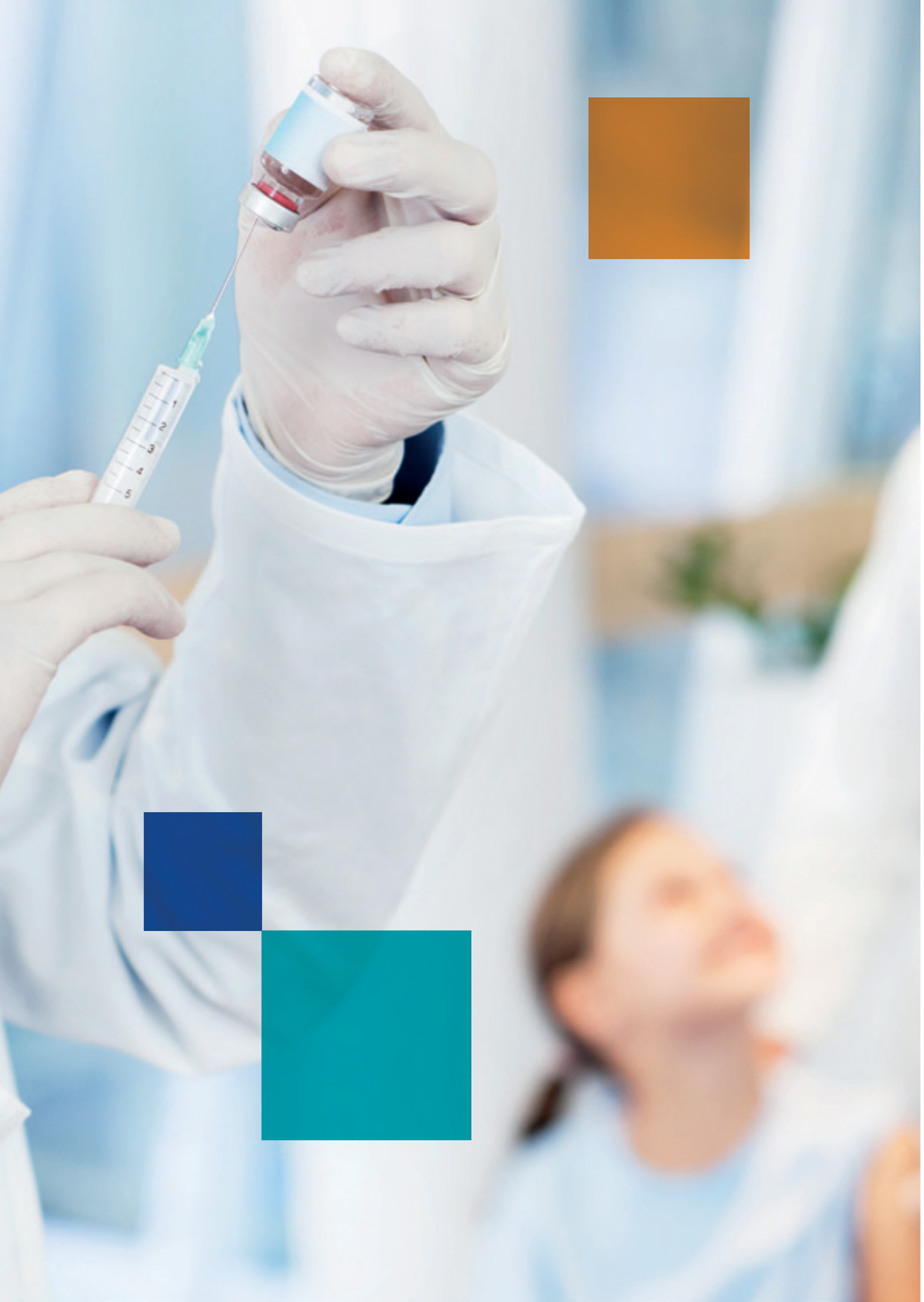
wilco

Being sure

Differential pressure testing

of vials, ampoules and syringes

Made in Switzerland



Differential pressure testing

Three test methods – many applications

Wilco's differential pressure tests allow for a wide range of applications for integrity testing of containers that meet the highest requirements. The non-destructive leak testing is ideal for a wide range of packaging types in the life sciences, pharma and biotech industry for laboratory and production applications.

Since the founding of WILCO AG we have developed, together with our customers, the vacuum and pressure decay methods with innovative solutions.

Application for highest demands

Being sure

Container Closure Integrity Testing

Differential pressure

The differential pressure test is based on a gas exchange between the test chamber and the test sample. The test sample is placed in a test chamber, which is hermetically sealed before the test. After the chamber has been sealed, either overpressure or positive or negative pressure is generated inside the test chamber. After a period of pressure stabilization, the differential pressure is measured. In the event of a leak a gas exchange takes place between the container and the test chamber. This results in a pressure change characteristic of leaks. Depending on the type of packaging and product, the appropriate test method is selected and adapted.

Pressure decay method (P)

For oily and toxic products in vials or ampoules

Vacuum decay method (V)

For loyphilizates or powders in vials

LFC method® (Deep vacuum)

For liquids in vials, syringes, ampoules or cartridges

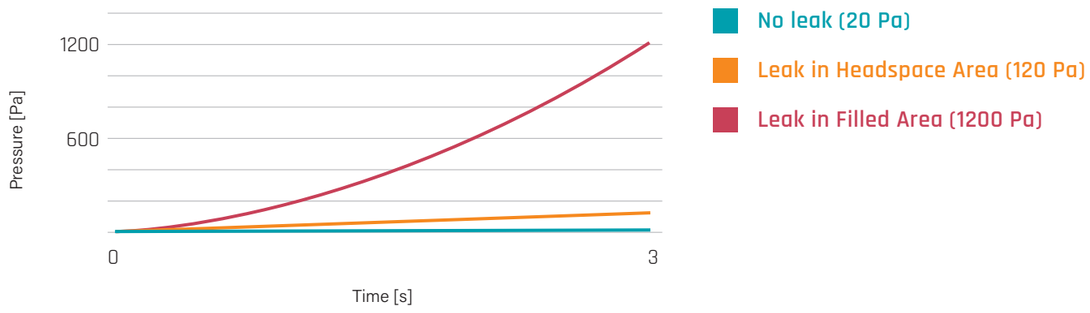
LFC method®

for highest sensitivity

The LFC method® (Liquid Filled Container) is a further development of the well-established vacuum test. The vacuum causes water in the test chamber to evaporate at room temperature. The resulting water vapor has a very large effect on the differential pressure in the test chamber. Therefore, even the smallest leaks that are covered with liquid can be detected.

The LFC method® is based on a gas exchange between the container and the test chamber. In the event of a leak, a low vacuum level allows the liquids in the container to be tested to evaporate. The LFC method® is optimized to test for leaks in both the headspace as well as the liquid-filled part of a container in a non-destructive manner.

Differential pressure



Advantages of the WILCO LFC method®

- High test sensitivity of up to 5.0e–04 mbar . l/s
- Testing the entire container at once
- Versatile use with regards to packaging and product types
- Non-destructive, deterministic test method according to USP 1207

Wide range of applications

100% leak test of vials with liquids and lyophilizates

Vials with liquids or lyophilized substances are partly produced in the same production line. For leak testing, different test methods may be required. In our laboratory, we analyze the products to be tested, prepare a risk analysis with the customer and define the inspection tasks. After the analysis the test methods are selected and the cycle times are developed.

Depending on the packaging material and the content, the testing method is developed. When different technologies and methods to cover the entire product spectrum are needed, we combine our various inspection modules on an automated platform.

Learn more about our applications

Leak test of prefilled syringes

Prefilled syringes are sealed with a rubber stopper, which can move with varying pressure conditions and thus affect sterility. Our Stopper Movement Prevention System prevents stopper movement during vacuum testing by locking the stopper in the original position. The system can be used for laboratory testing as well as for high-performance systems. Vials and syringes can be tested in the same system.

Autoinjector leak test

Probabilistic test methods, such as the Blue Bath Test, require disassembly of the injector. For some injectors or devices, a controlled and trouble-free disassembly is not possible or involves additional steps, resulting in excessive effort or even activation of the device.
The design and method development typically result in the Vacuum Drop Technology (LFC method®), which can test complex autoinjector products under given conditions, such as the low expansion of the headspace. Thus, the time for leak testing is significantly reduced.

From the laboratory to production

with customized solutions

Differential pressure for every kind of application

Leak testing with differential pressure can be used for laboratory applications and spot checks as well as in high performance systems. By combining it with other inspection technologies, we have the right solution for you. Differential pressure testing is applicable to many packaging, product types and sizes.

Individual solutions

We take the time to understand the needs of our customers. Feasibility studies, process analysis and the subsequent method development form the basis for the successful design and implementation of an inspection system, which are individual and tailored to the specific needs of our customers.

Integrated solutions

Safe object transport

In order to prevent glass breakage and thus production downtimes, we offer various solutions for product-friendly transport systems. We support you with individual solutions from the object infeed to the object transfer.

In addition to conventional transport systems for pharmaceutical packaging materials, we work with a variety of partners in the field of robotics and multi-axis systems. The process determines the system and so, together with our customers, we define the best type of object handling.

Advantages of our leak testing systems

- Non-destructive leak testing of vials, syringes and ampoules
- Applicable for glass and plastic containers
- Applicable for liquid, lyophilized and solid products
- Testing the entire container at once
- Applicable for non-conductive products or low filling levels
- Deterministic test method preferred according to USP 1207
- Vacuum test method according to ASTM F2338-09
- Data handling in compliance with 21 CFR part 11
- Developed according to GMP guidelines
- Tool-free format changeover

Differential pressure laboratory systems

NEO DPX

The NEO DPX combines several differential pressure test methods in one device for non-destructive leak testing of various types of packaging and products. NEO stands for the new generation of compact benchtop testing systems, where measurement accuracy, ease of use and flexibility are redefined.

Intuitive

→ MAVIS user interface for easy and safe operation

Sensitive

→ Latest generation – differential pressure testing for highest accuracy

Compact

→ Small footprint for flexible use in the laboratory

Easy format change

→ Within seconds, guided by the operating system

NEO DPX

- Up to 3 test methods in one system
- Operator-independent test results
- GMP and development mode
- Stopper holding system for syringe testing
- Integrated recipe and user management
- Connection to SCADA/MES/LIMS/ Historian Systems

W07 DPX WB

- Product-specific test setup
- Large format range
- Robust design for use in GMP environment
- Ergonomic design for standing or seated workplace
- Intuitive MAVIS user interface

Automated leak testing of sterile packaging materials

R DPX

The R DPX is a test platform for the 100% leak testing of pharmaceutical primary packaging. A wide variety of packaging materials with liquid, powdery or lyophilized contents can be tested.

Latest generation

→ Differential pressure testing for highest accuracy

Safe transport

→ Prevents damage to the product and reduces downtime

Integrated system verification

→ For high process reliability even with large batches

R DPX

- For vials, bottles and ampoules
- Format range from 1 ml to 100 ml
- For liquid, powdered and lyophilized products
- Throughput up to 600/min with max. 48 stations
- Optional integration of HSA and NIRS modules

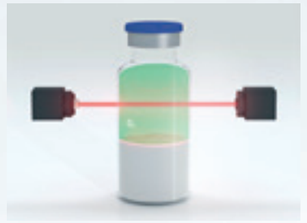
INDEX DPX

- Rotary indexing table leak test platform
- Format range from 1 ml to 250 ml
- Can be used for glass and plastic containers
- Test capacity up to 600 test samples per minute

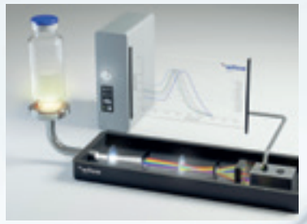
Multi-Inspection Platform

VARIO MTX

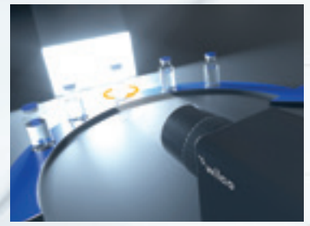
The VARIO MTX is a modular inspection platform that enables application-specific configuration for pharmaceutical packaging quality control and allows the combination of different inspection technologies.



Headspace Analysis



NIR Spectroscopy



Visual Inspection

Headspace Analysis

→ Automated leak test or residual oxygen measurement

NIR Spectroscopy

→ Non-destructive testing of defects and residual moisture in lyophilizates

Visual Inspection

→ Camera-based inspection of cosmetic defects

Flexibility

→ Inspection of multiple packaging and product types

VARIO MTX 600

- Different inspection technologies in one platform
- Test capacity of up to 600 samples per minute
- Configurable product outlet
- Optional integration of code reader

DUO MTX

- CCIT test platform
- Test capacity up to 600 test samples per minute
- Format range from 2 ml to 100 ml
- Applicable to glass and plastic containers

WILCO 360° Services

Cooperation based on trust

The process determines the solution. We focus on the long-term success of your test and inspection processes. We offer a wide range of services to meet your individual challenges both today and in the future.

Our Service for You

Step by step to success

Feasibility studies

For the testing of a new packaging material or product, the early clarification of the possibilities for a leak test or visual inspection is essential. We support you in this process and carry out the corresponding feasibility studies.

Method development

Our method development is based on process analysis. As a result a risk analysis is generated. This forms the basis for the control strategy and the corresponding test procedure.

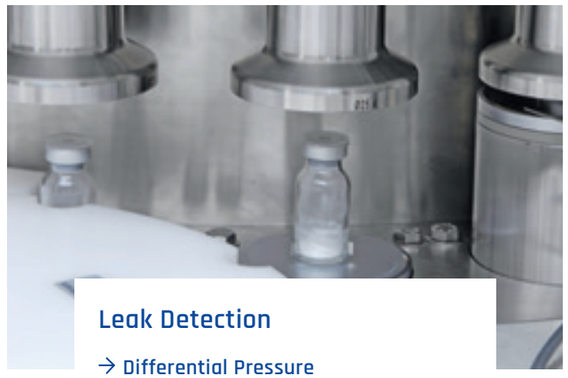
Positive/Negative controls

For verification of your test system with positive/ negative controls, we create test samples with controlled microleaks.

Inspection Technologies

Precision through combination

We combine the most important inspection technologies in modular systems for your individual needs. We offer the right technology for every product and the right machine for every requirement.



Leak Detection

- → Differential Pressure
- → Headspace Analysis
- → Force Sensor Technology
- → Mass Spectroscopy

Visual Inspection

- → Camera based Visual Inspection
- → X-ray based Visual Inspection
- → Image processing

Process Analytical Technology (PAT)

- → Near-infrared spectroscopy
- → Headspace Analysis

Handling & Coding

- → Object transport
- → Robot handling
- → Tray loading
- → Object coding

Leading Solutions

Made in Switzerland

WILCO AG is a Swiss solution provider of leading inspection systems for the pharmaceutical, biotech, diagnostic, medical device and packaging industries around the globe. With 50 years of innovation tradition, we offer our customers tailor-made solutions for Container Closure Integrity Testing (CCIT) as well as visual inspection.

About us

- Founded in 1971 in Wohlen, Switzerland
- 130 inspired employees
- Represented worldwide
- Part of the Bausch+Ströbel group
- ISO 9001 certified
- Over 5000 machines in operation
- Holder of various patents

Please contact us.

Together we will find the optimal solution tailored to your needs.

wilco.com

atb group
+48 668 625 820
info@atbgroup.pl
www.atbgroup.pl

WILCO AG
Rigackerstrasse 11
5610 Wohlen
Switzerland

T: +41 56 618 43 43
info@wilco.com
www.wilco.com

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10/2021

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