AMI 1000

Innovative CCIT solution for the pharmaceutical industry based on Optical Emission Spectroscopy


Syringes


Blister


Vials

PFEIFFER VACUUM

AMI 1000

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Your added value

Improves sensitivity, capacity and reliability of your integrity test

Large detection range

Our know-how

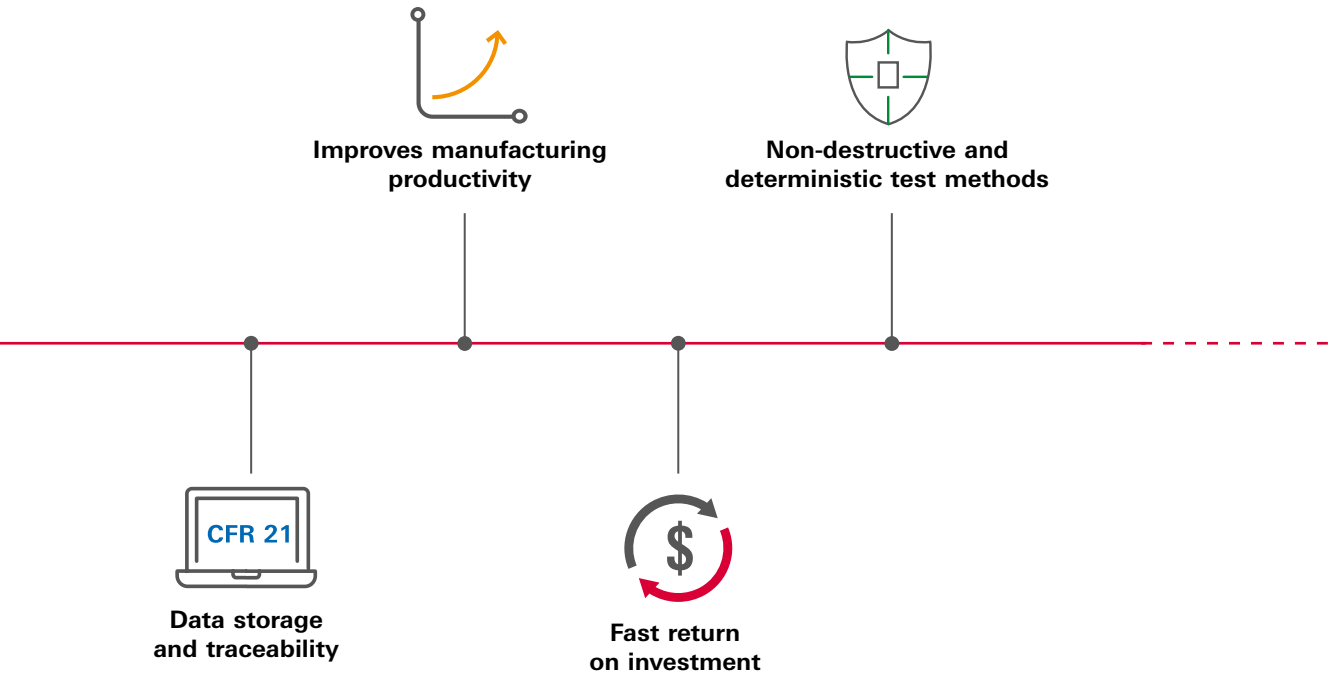
Pfeiffer Vacuum is one of the world´s leading providers of vacuum and testing solutions. The product portfolio comprises vacuum pumps, measurement and analysis devices, components, as well as vacuum chambers and high performance detection systems. Furthermore, we offer a unique portfolio of equipments based on three technologies that are dedicated to the pharmaceutical and medical markets. Leak testing and CCIT can be performed on a large variety of drug/container combinations.

Integrity challenges

Contamination such as humidity, oxygen or microbiological ingress can impact drug stability throughout the product life cycle. To prevent the risks of stability failure of highly moisture-sensitive drugs (e.g. dry powder for inhalation), or the risk of biological ingress of parenteral drugs, integrity tests with a high sensitivity are required. Most test methods are very challenging in regards to time effort, complexity or the limitation of sensitivity and detection range.

An innovative solution

Our patented O.E.S. (Optical Emission Spectroscopy) method does not require any specific tracer gas. Instead, the gas mixture present in the container headspace of the primary packaging is used to perform high sensitivity tests with high throughput. A multi-gas sensor is used to independently track the different gases (i.e. argon, nitrogen, CO_2, humidity,…)



escaping from a leaky container exposed to vacuum. Our method is non-destructive, deterministic, easy to use and to set up, and has higher sensitivity than other conventional methods. Furthermore, as sensitivity of the O.E.S. technology doesn't depend on the free volume inside the test chamber, several samples can be tested simultaneously.

Ease of use

The products can be sampled directly from the production line and loaded in the test chamber without any specific conditioning. At the end of the test sequence, the result is clearly displayed and a PDF report is automatically generated at the batch closure. Full automation of the test cycle including loading/unloading of the samples can be easily implemented for in-line tests.

Dedicated to the pharmaceutical industry

AMI 1000 equipments have been qualified by leading pharmaceutical companies as in-process control (IPC) leak testing for blister packs. Our software is CFR21 part 11[1)] compliant.

[1)] Code of Federal Regulations by the United States Food and Drug Administration (FDA)

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Large detection range

Different detection methods can be combined in order to cover the complete detection range. Massive leak and fine leak tests are performed within a single test sequence, any additional gross leak test (e.g. blue dye ingress) can be omitted.

Deterministic test method

As no operator intervention is required, the measurement results are totally objective. High accuracy measurements can be achieved thanks to a calibration-validation sequence of the equipment based on certified calibrated leaks.

High sensitivity, high throughput

High sensitivity tests combined with high throughput enables trend analysis to early indicate production issues. In high sensitivity mode, O.E.S is able to detect 0.2 µm defect size on glass containers which corresponds to the sterility barrier defined as the MALL (Maximum Allowable Leakage Limit) in the USP[3] <1207> guidelines.

[3]

[2] United States Pharmacopia
[3] The laptop is not provided by Pfeiffer Vacuum

Operation

Versatile and high performance technology for various applications
Specific test chambers are designed according product format.

Samples	Sensitivity Orifice diameter[3] Air/N_2 Leakage		Test duration	Advantages
	Air/N_2 leak	Water leak		
Blisters	0.4 µm $2 \cdot 10^{-5}$ mbar l/s	n.a.	> 20-30 sec	Highest sensitivity test method available on the market Outgazing of the drug itself can be used for gross leak detection Applicable to peeling blisters
Syringes & Vials	0.4 µm $2 \cdot 10^{-5}$ mbar l/s	2 µm	> 15 sec	Air and water detected simultaneously Test per batch to increase the troughput
	0.2 µm $6 \cdot 10^{-6}$ mbar l/s		~45 sec. (high sensitivity mode)	MALL level can be achieved in high sensitivity mode
IV bags	0.4 µm $2 \cdot 10^{-5}$ mbar l/s	3 µm	> 20 sec	Air and water detected simultaneously
Plastic bottles	0.5 µm $4 \cdot 10^{-5}$ mbar l/s	n.a.	> 20 sec	Test per batch (up to 50 or 100) to increase the troughput

[3] Sharp edge orifice as defined in USP <1207> guidelines

Dry Chiller Module

Mastering Integrity
Under Cold Storage Conditions

The Dry Chiller Module is a versatile addition to both new and existing leak detection systems. Serving as an external cooling component, it is compatible with the ASM 2000 for helium pre-filled containers and the AMI 1000 without any sample preparation, utilizing naturally present gas. This module sets new benchmarks in delivering reliable data for testing container closure integrity at low temperatures. Benefit from real-time results of temperature and leak rate, optimizing your process without wasting cycle time.

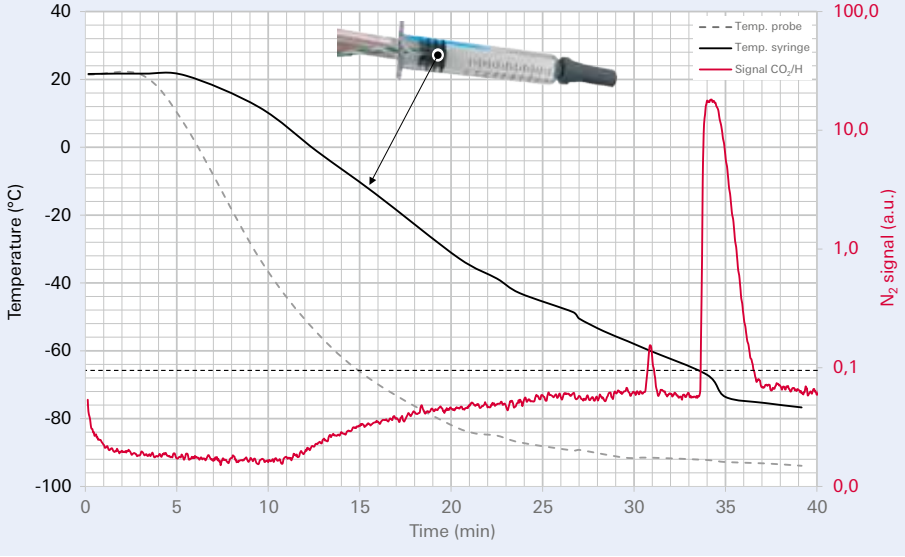
The Dry Chiller Module is designed to prove that the container closure system maintains integrity at deep cold storage temperatures, either at -80 °C (-112 °F) or even lower. It ensures the quality of substances requiring cold storage conditions, particularly in medical and pharmaceutical environments.

Fast cool down and heat up

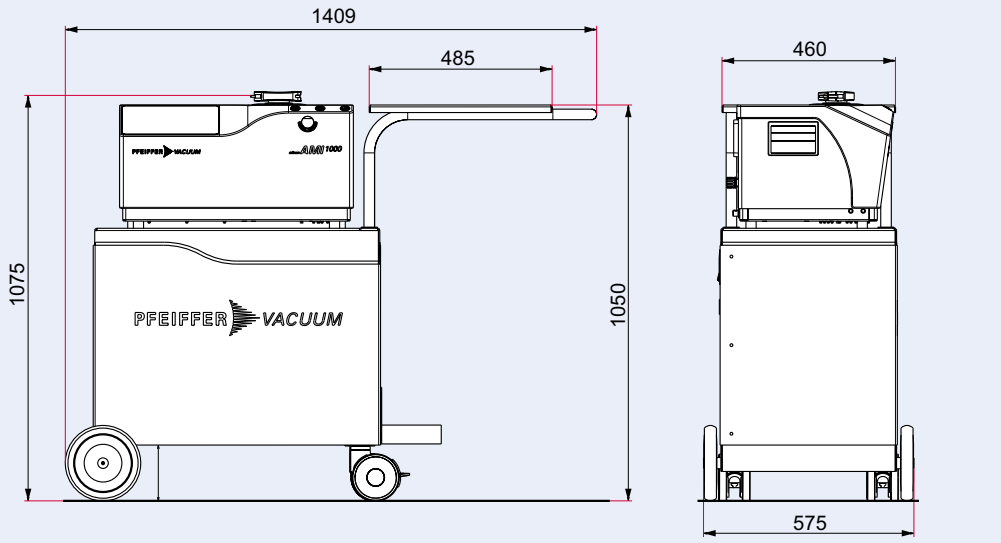
Control over entire temperature profile

Continuous leak rate measurement

Low Temperature Test on syringe filled with Air (N_2 80%) on AMI 1000



Dimensions



Dimensions in mm

Technical data

	AMI 1000
Power supply	90-250 V AC / 50-60 Hz
Typical power consumption	1,200 W
Sensitivity	Down to 0.4 µm $2 \cdot 10^{-5}$ mbar·l/s
CDA supply	Required for operation
Quality	(1.3.1 according to ISO 8573-1)
Pressure (min./max.)	6.3/10 bar rel. – 91/145 psig
Typical consumption	2 Nl/cycle
Calibration gas supply (CDA, N_2, Ar, ….)	Optional
Pressure (min./max.)	6.3/10 bar rel. – 91/145 psig
Venting gas (Ambient, CDA, Ar, ….)	Optional
Pressure (min./max.)	0/1.5 bar rel. – 0/22 psig
User interface	10" Multi-touch Full HD color screen Possibility to use a customer laptop via Ethernet or WiFi connections.
Software	21 CFR part 11 compliance PDF GMP test and calibration reports authentication local or domain (LDAP) Remote access to data (optional)
Operating system	Windows 10
Network connection	1 x LAN (RJ45) WiFi AP
Interfaces (printer, bar code reader, data export)	2 x USB 3.0 (ext.) 1 x HDMI
Operating conditions	
Temperature (min./max.)	20–25 °C
Humidity (min./max.)	30–65 %
Dimensions (l x w x h) (Including trolley)	1,409 x 575 x 1,075 mm 55.5 x 22.6 x 42.3 inch
Weight, (Including trolley)	130 kg/287 lbs.
Noise level	< 53 dB(A)

AMI 1000

CFR 21 part 11

compliant Software

Down to 0.4 µm

$2 \cdot 10^{-5}$ mbar·l/s

Sensitivity

Order information

Please contact your local Pfeiffer Vacuum sales adminstration

Your Success. Our Passion.

We give our best for you every day – worldwide!

Are you looking for an optimal vacuum solution? Please contact us:

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