
Syringes and vials


IV bag


Glass ampoules

SpeedAir 3050

Mass Extraction Pharmaceutical
Container Closure Integrity Test (CCIT)

PFEIFFER VACUUM

SpeedAir 3050

Mass Extraction Pharmaceutical Container Closure Integrity Test (CCIT)

Covers a wide range of containers

Your added value

High sensitivity for reliable results

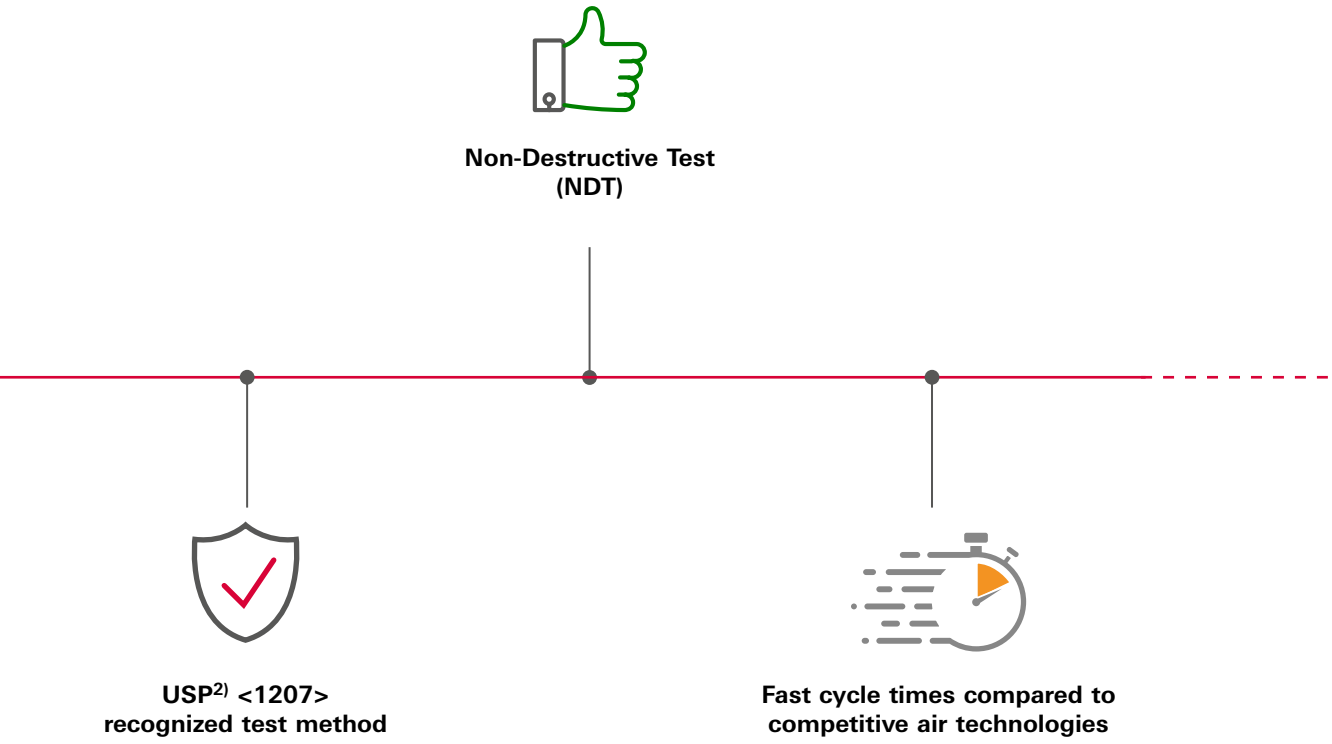
Versatile for a wide range of applications

The SpeedAir 3050 offers a CCIT solution for a wide range of nonporous pharmaceutical containers. Flexible or rigid, liquid or solid – the SpeedAir 3050 can test a wide range of products. Typically requiring only 30–45 seconds, the SpeedAir 3050 quickly and efficiently delivers results you can trust.

Saving time and money

The SpeedAir 3050 is a global non-destructive test (NDT) on the container – not just specific areas or access points. Per ASTM[1)] Standard F3287-17, Mass Extraction has demonstrated capability in independent third party labs to 1 micron.

[1)] American Society for Testing and Materials
[2)] United States Pharmacopeia
[3)] Food and Drug Administration (USA)



High sensitivity for reliable and repeatable results
The SpeedAir 3050 is the most sensitive air-based technology for liquid products. Results are repeatable and reliable – eliminating risks associated with false negatives and positives.

Compliant with USP <1207> and FDA 21 CFR Part 11
The SpeedAir 3050 utilizes USP <1207> recognized and deterministic Mass Extraction technology and FDA 21 CFR Part 11 compliant software.

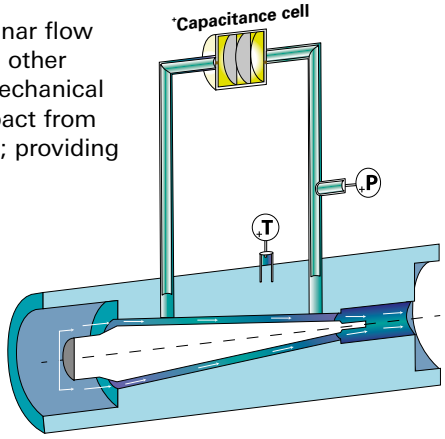
Applications
- Ampoules
- Autoinjectors
- Bottles
- Cartridges
- Flexible bags (IV Bags, pouches, etc.)
- Syringes
- Vials
- others

SpeedAir 3050

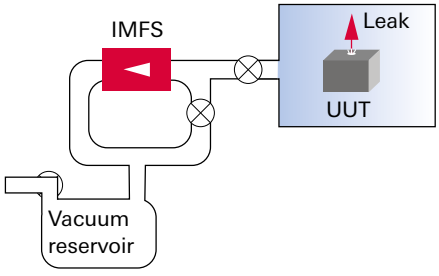
Equivalence between defect size & air leak rate

Sensor design

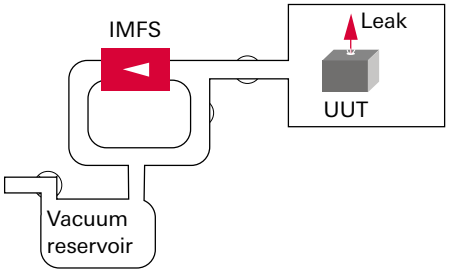
Mass Extraction leak testers use an accelerated laminar flow design to measure flow directly. The design is unlike other flow meters that use principles of heat transfer or mechanical movement. As a result, these sensors have less impact from environmental pressure and/or temperature changes; providing fast, highly sensitive and repeatable measurements.



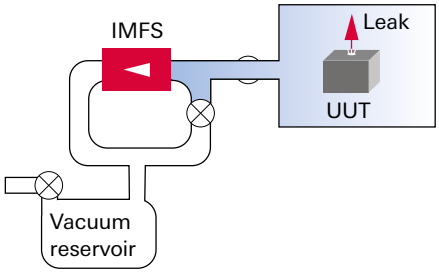
Air leak testing with Mass Extraction at vacuum (molecular flow) conditions



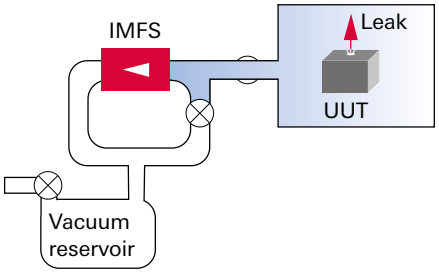
1 Standby – Vacuum Reservoir: P_0
– IMFS: no flow



2 Fill – All branches: P_0
– IMFS: no flow
– UUT: leaks



3 Stabilize – Leak: increases $P_{chamber}$
– IMFS: begins flow



4 Test – Steady flow from leak
– IMFS: measure flow from leak

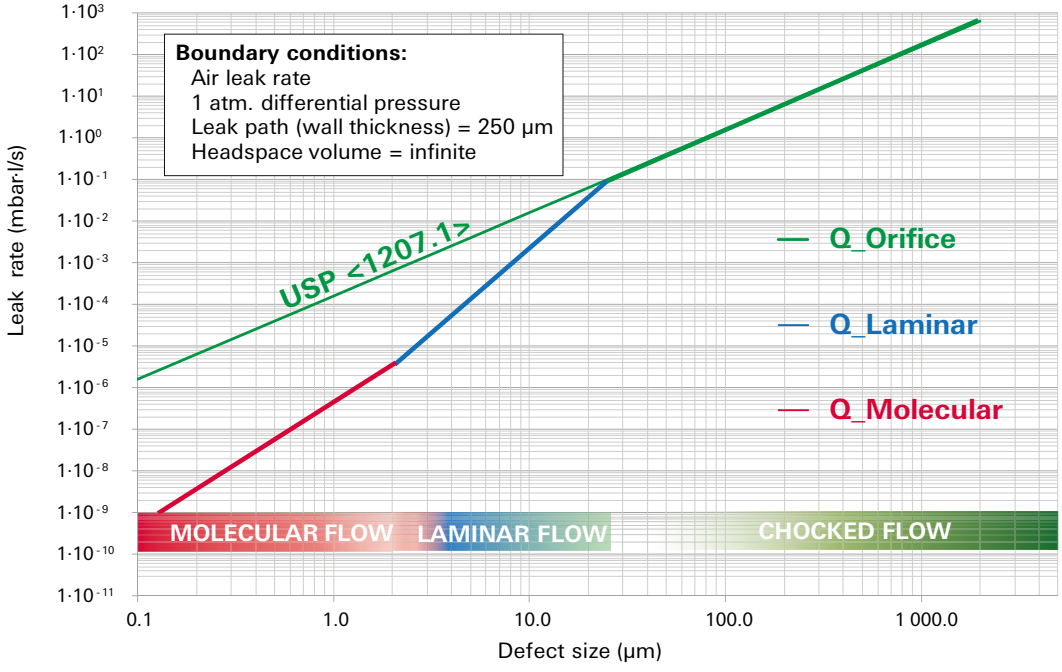
UUT: Unit under test
IMFS: Intelligent Molecular Flow Sensor

Equivalence between defect size and air leak rate

Traditionally, tightness in the pharmaceutical industry is expressed as an equivalent hole diameter in µm. However, the leak path (length) should be stated when defining the tightness criterion.

- For large diameters, the leak can be generally considered as an orifice with leak path of negligible length as defined in USP <1207.1> section 3.9. This corresponds to "Chocked Flow" regime.
- In "Laminar Flow" regime, the viscosity of the gas (depending on the gas temperature) determines gas-to-gas variations of media transfer through the leak.
- In "Molecular Flow" regime, the molecular mass of the gas and its temperature are the driving parameters.

General introduction (leak rate / defect size)

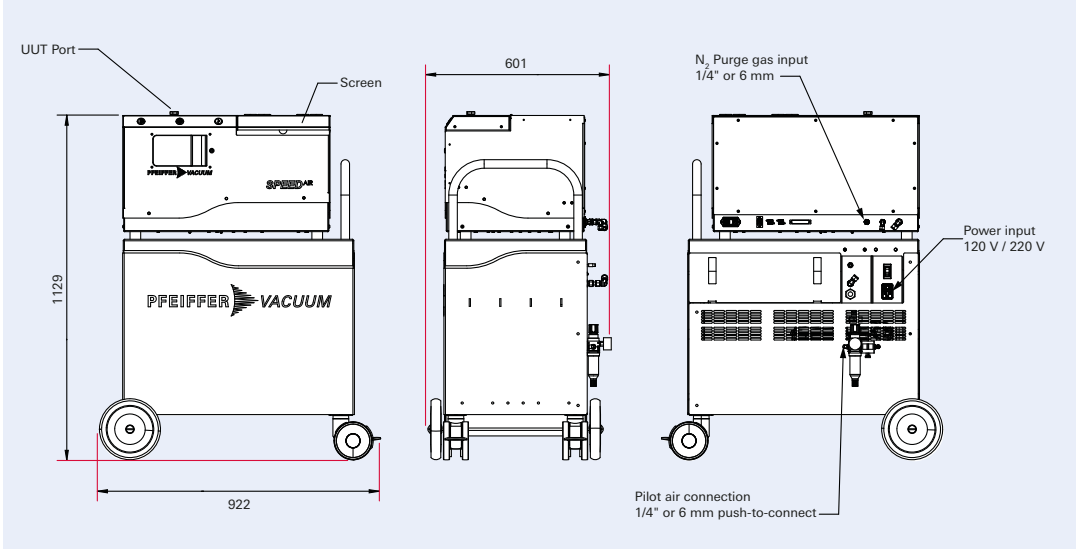


SpeedAir 3050

Technical data, accessories, order number matrix

Dimensions

SpeedAir 3050



Dimensions in mm

SpeedAir 3050

1 micron
Sensitivity

CFR 21 Part 11
Compliant software

Technical data

	SpeedAir 3050
Test method	Mass Extraction
Power	90–250 V AC / 50-60 Hz
Flow sensor	IMFS (Intelligent Molecular Flow Sensor)
Sensitivity	to 1 micron defect size
Operating conditions:	
Temperature (min./max.)	15–45 °C (59–83 °F)
Humidity (min./max.)	30–80 %
Test Pressure range	1–20 Torr (1.3–27 mbar abs)
Pneumatic supply:	Air (pilot operated valves)
Quality	1.3.1 according to ISO 8573-1
Pressure (min./max.)	4.5/10 bar rel. (65–145 psig)
Nitrogen supply	Recommended for chamber venting
Pressure (min./max.)	140/690 mbar rel. (2–10 psig)
Operating system	Windows 10
User interface	10" Multi-touch Full HD color screen
LeakRx Software	21 CFR part 11 compliant
Stored test recipes	Unlimited
Network connection	1 x LAN (RJ45)
Interfaces	USB, Wired Ethernet
Discrete inputs	Start, Stop, Test Type Change
Analog inputs	2 x 0–5V
Discrete outputs	Clamp, Exhaust, Custom, Test Type, A-D
Analog outputs	2 x AO
Dimensions (l x w x h):	
Display closed	922 x 601 x 1,129 mm (36 x 24 x 44 inch)
Display open	922 x 601 x 1,397 mm (36 x 24 x 55 inch)
Weight (Including trolley)	127 kg / 280 lbs
Noise level	< 53 dB(A)

Order number matrix SpeedAir

S3050Cabc

Sensor sizes	a
2 microgram per minute, Full Scale	**B**
10 microgram per minute, Full Scale	**E**
50 microgram per minute, Full Scale	**G**
100 microgram per minute, Full Scale	**H**

Flow	b
km	**3**
ug/min	**5**

External press sensor	c
0–010 Torr	**0**
0–050 Torr	**1**
0–100 Torr	**2**

Accessories

	SpeedAir 3050
LeakTek software (included)	**I91601**
Leak Rx (included)	**I91610**
Verification orifice	
1 micron	**I91564**
2 micron	**I91566**
3 micron	**I91569**
5 micron	**I91570**
10 micron	**I91565**
15 micron	**I91572**
20 micron	**I91567**

Further accessories can be found on our website at
www.pfeiffer-vacuum.com

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

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