ASM 2000

High performance CCIT solution for the pharmaceutical industry based on helium mass spectrometry
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**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.

**A proven solution**

Helium mass spectrometry based upon ASTM F 2391-05\(^2\) is applicable to non-porous packaging such as vials, syringes and cartridges. Currently, the helium leak test, a deterministic method, is being established as the gold standard for its sensitivity and versatility. Furthermore, helium leak detection offers the capability to also locate the position of a leak.

\(^2\) American Standard for Testing and Materials

**Application examples**
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Key features
ASM 2000 is a comprehensive solution completely adapted to the needs of pharma industry. Based on a high performance helium mass spectrometer leak detector, it also includes a helium charging module, and can be equipped with custom fixtures for the particular containers formats. The instrument is calibrated against NIST\textsuperscript{3}-traceable standard leaks.

Dependable, fast and sensitive
Further advantages of the ASM 2000 are its high helium pumping, its integrated automatic helium charging module as well as the optimized free internal volumes. Those features guarantee high performance measurements on helium filled sealed containers and open sub-assemblies. The ASM 2000 sustains very high throughput, ensures the accuracy and the reproducibility of the measurement results, and allows ultra fast cycle time.

Advanced software
The software proposes intuitive menus easy to navigate. User log in is required to operate the equipment, and four access levels are available (operator, advanced user, maintenance, administrator). Test recipes can be managed for each part format. At the end of the test sequence, the result is clearly displayed and PDF test and calibration reports are automatically generated at the batch closure.

\textsuperscript{3} US National Institute of Standards and Technology

Operation
## Technical data

### Test methods
Vacuum and sniffing leak detection

### Measurement range (vacuum test)
- **Quantitative range** – Fine leak Helium: \(10^{-8} - 10^{-5}\) mbar l/s
- **Qualitative range** – Gross leak Helium: \(10^{-5} - 10^{-3}\) mbar l/s
- **Qualitative range** – Massive leak Air: \(10^{-3}\) mbar l/s

### Minimum detectable He leakage (sniffing test)
> \(10^{-5}\) mbar l/s

### Power supply
90-250 V AC / 50-60 Hz

### CDA supply
Required for operation

### Pressure (min./max.)
- **Helium supply**: 0.5/8 bar rel. – 7.2/116 psig
- **Nitrogen supply**: 0.5/8 bar rel. – 7.2/116 psig

### User interface
10” Multi-touch Full HD color screen

### Software
User management, 4 access levels, PDF GMP test and calibration reports

### Operating system
Windows 10

### Network connection
1 x LAN

### Interfaces (printer, bar code reader, data export)
2 x USB 3.0 (ext.)

### Operating conditions
- Temperature (min./max.): 15–25 °C
- Humidity (min./max.): 30–80 %

### Dimensions (l x w x h) (including trolley)
1,409 x 575 x 1,194 mm
55.5 x 22.6 x 47 inch

### Weight, (including trolley)
140 kg/308 lbs.

### Noise level
< 53 dB(A)

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**Order information**

Please contact your local Pfeiffer Vacuum sales administration
Customer benefits

- High sensitivity measurements required for design and validation studies
- Turnkey solution including high performances helium leak detector, charging module and customized tooling
- Fully automatic test sequence to guarantee low helium background
- Communication interfaces
- Data storage and traceability
- Identifying the source of leaks using the “sniffer mode”

1) The laptop is not provided by Pfeiffer Vacuum
VACUUM SOLUTIONS FROM A SINGLE SOURCE
Pfeiffer Vacuum stands for innovative and custom vacuum solutions worldwide, technological perfection, competent advice and reliable service.

COMPLETE RANGE OF PRODUCTS
From a single component to complex systems:
We are the only supplier of vacuum technology that provides a complete product portfolio.

COMPETENCE IN THEORY AND PRACTICE
Benefit from our know-how and our portfolio of training opportunities!
We support you with your plant layout and provide first-class on-site service worldwide.

Are you looking for a perfect vacuum solution?
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