

Seidenader Inspection Machines

Pharma Technology Solutions



HSA

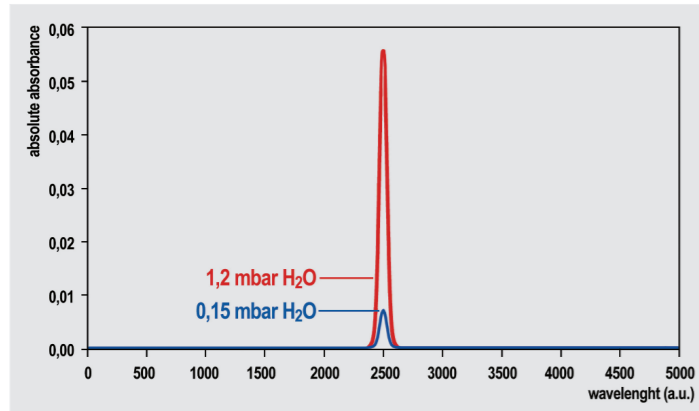
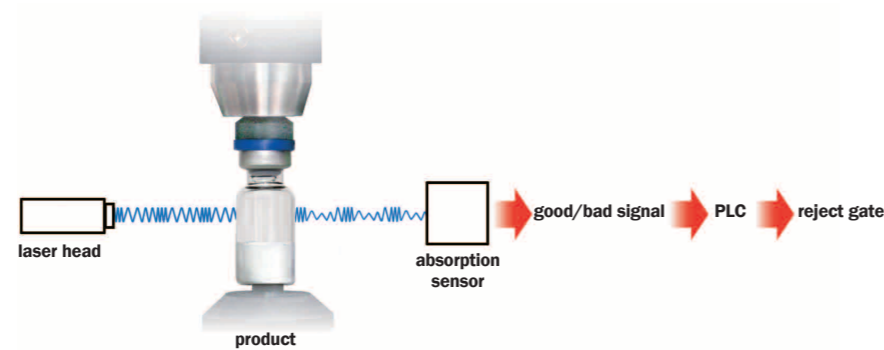
Seidenader HSA Head Space Analyzer to Detect Oxygen Content, Water Partial Pressure and Absolute Pressure



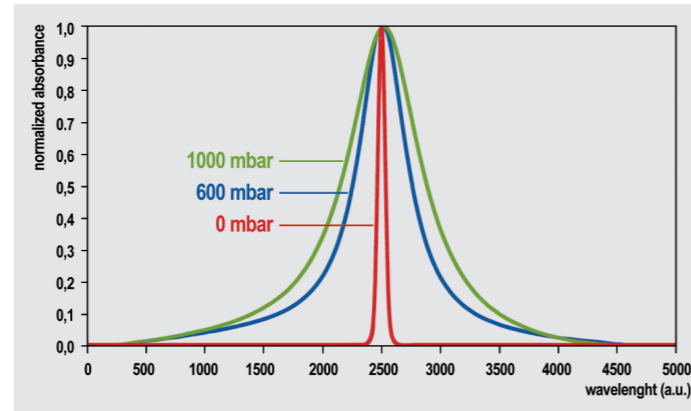
KÖRBER MEDIPAK
pharma packaging systems

Function

1. Products are passing the laser head in a precise handling system.
2. The laser is tuned over a defined wavelength range.
3. A photosensitive sensor measures the absorption profile of the head space gas.
4. Analysis of this profile results in precise information about absolute pressure and O₂ or water partial pressure.
5. These values are compared to threshold levels to generate pass/fail decisions.
6. PLC is tracking each product and activates reject gate to separate defects.



Absolute absorbance vs. wavelength for different water vapor contents



Normalized absorbance vs. wavelength for different pressures

Technical Data Seidenader Head Space Analyzer (HSA-System)

- Throughput rate: up to 600 inspections/min depending on application
- Dimensions: depending on application
- O₂ inspection range: 0 - 21 % oxygen
- Pressure inspection range: 0 - 1.5 bar
- Design: integrated design complies with current GMP recommendations, OSHA regulations, CE requirements, EN 60204-1 and 21 CFR part 11

Seidenader HSA

fast, precise and low power laser absorption technology

High speed inline 100% testing of containers for absolute pressure, O₂ or water partial pressures in the headspace of vials filled with liquid or lyophilized products – Seidenader's answer to container/closure integrity testing requirements following U.S. Pharmacopeia Appendix 1 regulations.

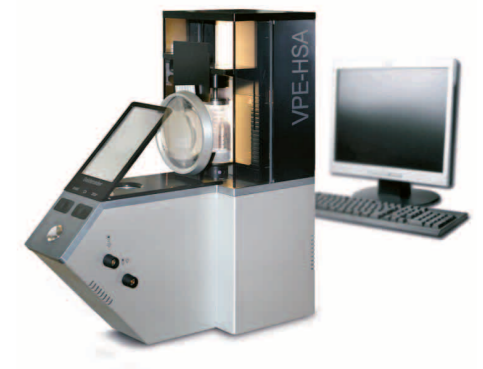
Seidenader's compact HSA module can be integrated into Seidenader automatic inspection machines as a complementary test to camera inspection, or it can be integrated onto Seidenader's IC platform as a stand-alone HSA inspection machine. A laboratory scale unit is available for validation of small batches and statistical sample testing.

Areas of Applications

- Absolute Pressure: Absolute pressure in the headspace is calculated from width, shape, and maximum position of the absorption line.
- Oxygen Detection in Lyophilized Products: Verification of oxygen in lyophilized products has been a requirement for decades. Tunable laser diode absorption spectroscopy allows to verify the oxygen concentration reliably and inline.
- Moisture Detection in Lyophilized Products: Head space analysis can also be used to determine H₂O partial pressure in the head space inline and in a non-destructive test.



HSA unit integrated in inspection machine Seidenader MS



VPE-HSA laboratory unit

Advantages

- Inspection of liquids, powders and lyophilized products
- No limitation on glass quality (tube and molded), glass color or dimensions
- Non-destructive method for inline operation and statistical data collection
- BRD, balanced ratiometric detection, a special technology for high precision testing without nitrogen flush or reference samples
- Documentation of all inspections by generating profiles of defects
- Fully embedded in Seidenader inspection machine, PLC and HMI structure
- Combination with other inspection methods: cameras, NIR, X-Ray

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The product range of Seidenader Maschinenbau GmbH includes:

- High-performance inspection machines for a wide range of pharmaceutical products and containers
- Semi-automatic machines for inspection of parenteral products
- Exterior cleaning and drying machines for ampoules, vials and cartridges
- Sorting and inspection machines for tablets and capsules

Since we are constantly working on the improvement of our high-quality machines, the texts, illustrations and figures on these pages are illustrative only and not binding.

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