



TASITEST
PACKAGING TEST
& INSPECTION

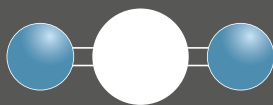
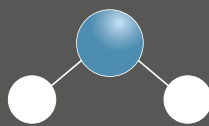
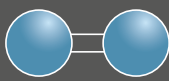
LASER-BASED TECHNOLOGY

HEADSPACE GAS ANALYSIS



TECHNOLOGY OVERVIEW

HEADSPACE GAS ANALYSIS is a laser-based, non-destructive and fully automatic inspection method for sealed packages. It allows for measuring oxygen concentration, carbon dioxide, residual moisture content and absolute pressure value. Its purpose is to verify the headspace conditions and their maintenance to confirm stability and sterility in filled and finished parenteral packages.



Mbar



HEADSPACE GAS ANALYSIS

Monitoring the maintenance of container headspace conditions is needed for sterile drugs such as oxygen sensitive liquid products and lyophilized or powdered products; any modification in the headspace pressure, moisture or oxygen level may result in the degradation of the active drug, as well as in the reduction of drug potency and product shelf life.

Traditional headspace analysis methods include testing by means of a probe, generally performed on samples at regular intervals

during the production cycle: a destructive, time consuming and unrepeatable procedure, which prompts the issue of disposing of destroyed products and leaves with no timely feedback on the filling process. Each time out of specification conditions are detected on a sample container, the entire batch is to be rejected, making it most difficult to assess if it is random package closure integrity failure or systematic process unwanted deviation. BONFIG, instead, offers a non-destructive, more deterministic and reliable procedure.

MAIN ADVANTAGES



DOUBLE PATH SYSTEM

For oxygen detection, the laser beam is reflected by a golden mirror towards the receiver allowing a double passage of the headspace target. **Double Path system** significantly increases the signal strength and makes Etalon Effect negligible by means of a small tilt.



NITROGEN FREE

The laser system performance is practically insensitive to environmental factors such as oxygen presence thanks to its electronic design. Therefore, when performing headspace level analysis, there is no need for **purging** the surroundings of the container under inspection with **nitrogen**.



NO REFERENCE DURING OPERATION

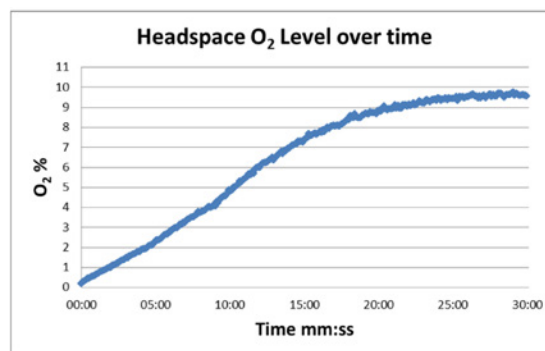
Since height & width of laser absorption signals are measured and compared to preset values (Standard Containers) during each cycle, a **reference pack** is not required in operation. If the measured parameters are not within acceptable ranges, the equipment automatically signals it.

QUALITY ASSURANCE

Specific requirements for sterile drugs packaged under full or partial vacuum are covered by EU GMP Annex 1 Manufacture of Sterile Medicinal Products, section 123: "Containers sealed under vacuum should be tested for maintenance of that vacuum after an appropriate, pre-determined period".

The testing method conforms to provisions expressed in United State Pharmacopeia, USP General Chapter <1207> "Package Integrity Evaluation – Sterile Products" (USP 39-NF34): Laser-Based Gas Analysis is listed among the Deterministic Leak Test Technologies.

Validations and qualifications are easy to perform by means of advanced protocols and documentation.



Headspace oxygen increase in vial with laser drilled hole of 5 μm equivalent diameter from the moment of stoppering.*

* measured with BONFIG Lasercube.

Applicable to:

Glass Packages (tubular, molded, clear, amber)

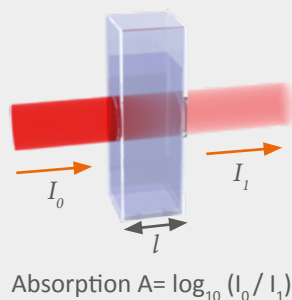
Plastic Packages optically transparent to a NIR laser radiation

Sterile products as O₂ sensitive/Lyo under modified atmosphere or vacuum

HOW IT WORKS

A Tunable Diode Laser Absorption Spectroscopy (TDLAS) based sensor is the core of the inspection system installed in our unit, a spectroscopic method allowing the detection and quantification of gaseous components concentration.

The principle underlying the TDLAS measurement is based on the Beer-Lambert Law, stating that light transmitted through a given sample at a particular wavelength is a function of the concentration of the substance that is absorbing the incident light.



A diode laser beam, at a wavelength optimized for the measurement of a particular gas species, is transmitted through the headspace region of the container and received by a detector after passing through the container itself.

Oxygen level monitoring is obtained with a light source tuning at a wavelength of 760 nm, while carbon dioxide at 2000 nm and wavelength of 1400 nm is employed to obtain measurements of residual moisture level and absolute pressure.

The inspection time of BONFIG systems is shorter compared to the ones currently available on the market: this results in a better test performance either more accurate or faster.

BONFIG

Lasercube



Quick
and
Reliable



- No Nitrogen purging required.
- Automatic height adjustment.
- Compact design.

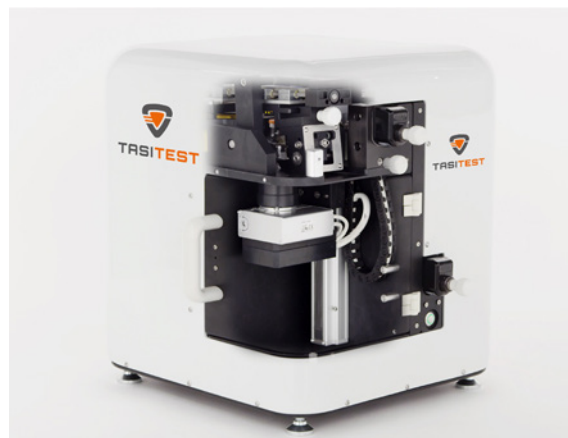
TECHNICAL SPECIFICATION

| LASERCUBE | |
|------------------|----------------------------------|
| Packages | Vials, Ampoules, PFS, Cartridges |
| Package size | ∅ [10 - 69] mm |
| Fill level | [1- 250] mm |
| Glass Type | Tubing, Molded, Clear, Amber |
| Product | Lyo, Liquid, Powder |
| Test method | HGA by TDLAS |
| Acquisition time | 100 - 400 msec |

OVERVIEW

LASERCUBE is a benchtop instrument conceived for performing Headspace Gas Analysis (HGA) of sterile pharmaceutical containers.

- Fully automated test cycle sequencing with manual loading and unloading of containers.
- HMI realtime display of statistics and raw data.
- Computerised system is designed to comply with 21 CFR Part 11.
- Light weight (only 22 Kg) and compact design (36 x 37 x 40 cm).
- Low power consumption.
- Easy to use and setup via integrated PC and any wireless device.
- Available connections to Active Directory and VPN router for machine remote access.
- Format change negligible by means of adjustment knobs.
- Etalon effect negligible thanks to reduced incidence angle beam.
- Motorised height adjustment for best measurement point search.
- Automatic spinning plate to offer more accurate acquisition with complete container rotation.
- Extreme stability and accuracy in the inspection of overfilled containers with limited headspace.
- Validation package guarantees complete and efficient regulatory compliance.



BONFIG

Lva 600



Nitrogen
free



- Up to 4 laser inspection units.
- Up to 600 cpm.
- Easily upgradeable.

TECHNICAL SPECIFICATION

| LVA | |
|--------------|------------------------------|
| Packages | Vials, Ampoules, Cartridges |
| Package size | ∅ [14 - 54] mm |
| Fill level | [1- 100] mm |
| Glass Type | Tubing, Molded, Clear, Amber |
| Product | Lyo, Liquid, Powder |
| Test method | HGA by TDLAS |
| Output rate | 100- 600 ppm |

OVERVIEW

LVA 600 is an in-line fully automated test unit for performing Headspace Gas Analysis (HGA) of sterile pharmaceutical containers.

- Versatility to achieve customizable solutions for flexible interfacing with downstream and upstream machines and elimination of intermediary conveying.
- HMI realtime display of statistics and raw data.
- Computerised system is designed to comply with 21 CFR Part 11.
- Compact footprint (1600 x 1600 mm).
- Single PLC and optimised automation.
- Maximum accessibility of electrical and mechanical component for easy maintenance.
- Available connections to Active Directory and VPN router for machine remote access.
- Quick and tool-less changeover.
- Automatic spinning plate to offer more accurate acquisition with complete container rotation.
- Extreme stability and accuracy in the inspection of overfilled containers with limited headspace.
- Validation package guarantees complete and efficient regulatory compliance.
- Multiple laser heads can be installed to increase the speed.



BONFIG

Combi series



All
in one



- No quarantine required.
- Up to 600 cpm.
- Two inspection processes, one chassis.

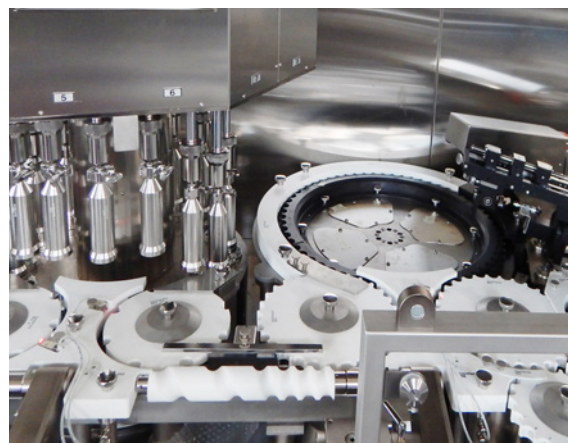
TECHNICAL SPECIFICATION

| COMBI SERIES | |
|--------------|------------------------------|
| Packages | Vials, Ampoules, Cartridges |
| Package size | ∅ [14 - 54] mm |
| Fill level | [1- 100] mm |
| Glass Type | Tubing, Molded, Clear, Amber |
| Product | Lyo, Liquid, Powder |
| Test method | VDM/AVI + HGA |
| Output rate | Up to 600 ppm |

OVERVIEW

Combi series is an in-line fully automated test unit for performing Headspace Gas Analysis (HGA) of sterile pharmaceutical containers in combination with CCIT or VI technology.

- Versatility to achieve customizable solutions for flexible interfacing with downstream and upstream machines and elimination of intermediary conveying.
- HMI realtime display of statistics and raw data.
- Computerised system is designed to comply with 21 CFR Part 11.
- Compact footprint (1200 x 1200 mm). 1600???
- Single PLC and potimised automation.
- Maximum accessibility of electrical and mechanical component for easy maintenance.
- Available connections to Active Directory and VPN router for machine remote access.
- Quick and toolless changeover.
 - Automatic spinning plate to offer more accurate acquisition with complete container rotation.
- Extreme stability and accuracy in the inspection of overfilled containers with limited headspace.
- Validation package guarantees complete and efficient regulatory compliance.
- Multiple laser heads can be installed to increase the speed.





TASITEST

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& INSPECTION**

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