Bonfiglioli Engineering
Quality Control Solutions


# LASERCUBE

Benchtop Headspace Gas Analyzer

## PHARMACEUTICAL

# LASERCUBE

Benchtop Headspace Gas Analyzer

BONFIGLIOLI ENGINEERING Lasercube is a benchtop instrument conceived for performing the Headspace Gas Analysis (HGA) of sterile pharmaceutical containers.

HGA is a non-destructive, laser-based inspection method not only for measuring the headspace levels of gases, such as **Oxygen** and **Carbon Dioxide**, but also for monitoring **Moisture levels** and A**bsolute Pressure values**.

This analytical method is developed to meet specific customer requirements, offering **extreme stability and accuracy** in the inspection of overfilled containers with limited headspace.

The BE Lasercube is a **compact and lightweight easy to use system** - setup by means of the integrated PC and any wireless device.

Quick and Reliable

## TECHNOLOGY OVERVIEW

The HGA inspection process is based on the **Tunable Diode Laser Absorption Spectroscopy** (TDLAS) method which uses a laser beam to detect the target molecules within container headspace.
HGA is therefore ideal for the accurate investigation of:
— Glass Packages (tubular, molded, clear, amber)
— Plastic Packages optically transparent to a NIR laser radiation
Filled with Sterile products as $O_2$ sensitive/Lyo under modified atmosphere or vacuum.
The equipment can integrate one or two laser systems capable of detecting:

1. **Oxygen**
2. **Carbon Dioxide**
3. **Moisture**
4. **Internal Absolute Pressure.**

Features include:
– **Motorised height adjustment** for best measurement point search.
– **Double Path system** significantly increases the signal strenght.
– **Etalon effect negligible** thanks to reduced incidence angle beam.

## USER EXPERIENCE

Fully automated test cycle sequencing with manual loading and unloading of containers.
Inspection cycle is composed of the following steps:

1. The container is loaded into testing group
2. The testing group is closed
3. The testing cycle is started by pushing the dedicated button on the HMI
4. Measurement of target gas within container headspace is taken
5. The container is unloaded from testing group and managed according to test outcome
6. The system gets ready for the next cycle.

Depending on the inspection process decisions, containers are classified as Non Conforming if the target gas level within the headspace has been exceeded. In all other cases, containers are classified as Conforming.

## FEATURES & BENEFITS

— **Lightweight** (22 Kg) and **compact design** (36x37x40 cm).
— Available connections to Active Directory and VPN router for **machine remote access**.
— HMI **real-time display** of statistics and raw data.
— **No need for nitrogen purging**.
— Format change negligible by means of **adjustment knobs**.
— **Automatic container rotation** ensures highly accurate test results.

$N_2$

DOUBLE PATH
DOUBLE LASER

## QUALITY ASSURANCE

— The computerised system is designed to comply with **21 CFR Part 11 and EU Annex 11**.
— The testing method conforms to provisions expressed in United States Pharmacopeia **USP General Chapter <1207>**.
— **Validation package** guarantees complete and efficient regulatory compliance.

## CONTAINER APPLICATION

Ampoules, Vials (≤ 250 ml), Cartridges, Pre-filled Syringes.
Products: freeze dried, liquid, powder.

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