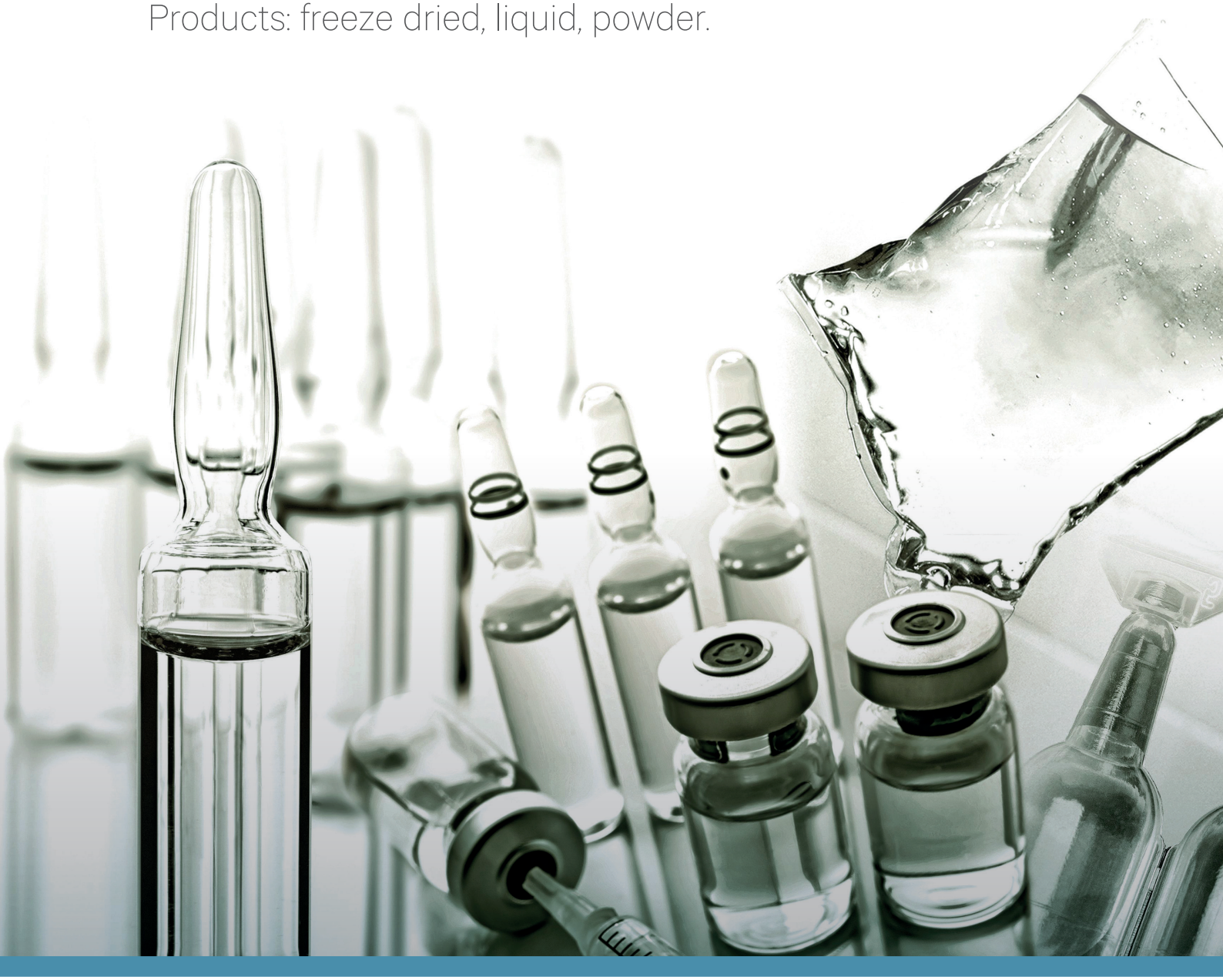
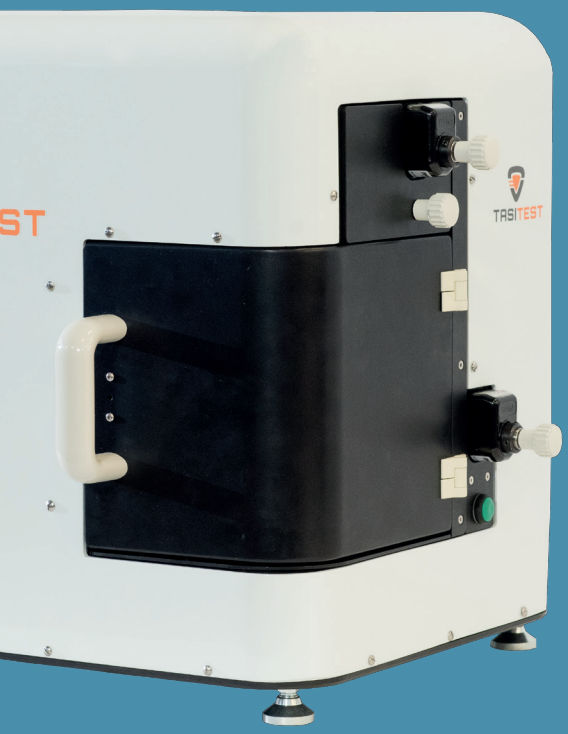
BONFIG
laser cube

Container Application:
Ampoules, Vials (up to 250 ml),
Cartridges, Pre-filled syringes
Products: freeze dried, liquid, powder.



BONFIG
laser cube

Bonfig Laser cube is a benchtop system for performing Headspace Gas Analysis (HGA) of sterile pharmaceutical containers.



It is a non-destructive, non-invasive laser-based inspection technology for measuring the headspace levels of gases, such as oxygen and carbon dioxide, as well as monitoring moisture levels.

The inspection method is created to meet specific customer requirements offering extreme stability and accuracy in inspection even where the headspace is limited. Bonfig Laser Cube is a compact and lightweight system that is easy to use and set up via integrated PC and any wireless touchscreen tablet.

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:

1. Translucent containers
2. Headspace conditions for products packaged under modified atmosphere
3. Closure integrity in pharmaceutical finished containers

Features & Benefits

- Non-invasive and non-intrusive inspection method
- The technology is designed to make Etalon effect egligible
- Fast, reliable and repeatable results
- Nitrogen purging is not required during oxygen measuring
- Compact and durable design
- Maintenance-free & Quick changeover
- Cost-effective solution with low power consumption
- Fully automated test cycle sequencing with manual loading and unloading of containers.
- Data can be stored and exported (production, raw data, events, alarms)
- Enhanced easy-to-use HMIU integrated functions.
- HMI real time display of statistics and raw data
- Computerised system is designed to comply with FDA 21 CFR Part 11 and EU Annex 11
- Validation package guarantees complete and efficient regulatory compliance

Technical Specification

PACK TYPE:	Ampoules, vials (up to 250 ml), Cartridges, Pre-filled syringes
OPERATION:	Semi-automatic
CONSTRUCTION:	Anodised Aluminium and ABS/Perspex top Cover
USER INTERFACE:	10" MEDICAL TABLET PC
UTILITIES:	— Electrical 24v DC 4A — Compressed Air: 6 Bar
CONFIGURATION:	— 3 USB output ports (1 port dedicated to printer or to data download) — 2 Ethernet — 1 HDMI video
TEST CYCLE:	From 5 seconds
TOOLING CHANGEOVER:	N/A
AUDIT COMPLIANCE:	FDA 21 CFR Part 11 and EU Annex 11
MACHINE DIMENSIONS:	403 mm x 356 mm x 428 mm
WEIGHT:	Machine: 23kg Shipping Weight: 65kg
WARRANTY:	Supplied with a 12 month warranty. (Service Level Agreements and/or extended warranties are available for additional support.

Headspace Inspection Capabilities:

Oxygen level

Moisture level

Carbon Dioxide level

Absolute Pressure valve

Machine Operation

1. Load container into the inspection position
2. Close chamber
3. Push the start button on the HMI to start the test cycle
4. Measurement of target gas within container headspace is taken
5. The HMI displays clearly on the screen whether the container is conforming or non-conforming

   — 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.
6. The container is removed and managed in line with internal procedures depending on inspection outcome

TASITEST
PACKAGING TEST
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