



BONFIG COMBI Series

PHARMACEUTICAL



BONFIG COMBI Series

On-line Combined CCIT, HGA and Visual Inspection Automatic Machine

The BONFIG Combi series puts Container Closure Integrity Testing, Visual Inspection and HGA **all under one roof** making it the ideal solution to ensure Quality and Safety of Parenteral Packages and verify:

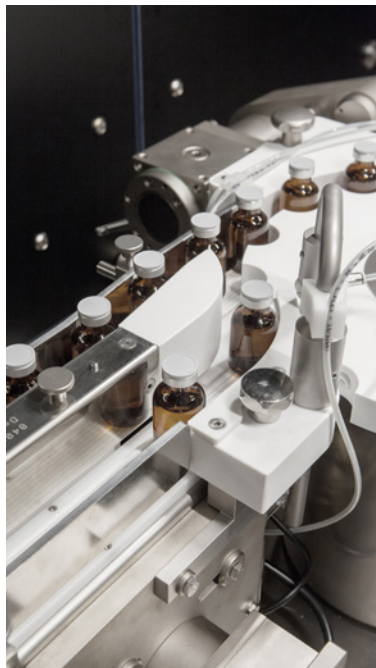
- Presence of leaks
- Headspace gas content
- Existence of visible foreign materials.

Based upon the Bonfig **state-of-the-art proprietary technologies**, the Combi series is fully customizable in order to best meet customers' needs and cover all nominal production line speeds.

They are suitable for 100% in-line testing at high production speeds without altering the container features. Testing is **quick, reliable and repeatable**, and gives consistent results for a comprehensive batch control.



OUTFEED AREA



INFEED AREA



FEATURES & BENEFITS

A **single machine** designed to provide customers with a comprehensive set of benefits:

Compact footprint with optimized floor space requirements, high flexibility in space allocation and the option of **remote electrical cabinets**.

High quality handling systems comprising of state-of-the-art electronic actuators and motor inverters, coupled with top quality mechanical design assures **high machine adaptability**.

The machines may be integrated into **Industry 4.0** environments and perform non-invasive, non-destructive inspection of diverse types of pharmaceutical containers.

The machine needs **only one operator** and a single validation & qualification procedure. This results in savings in terms of training, labour, machine start-up, set-up and operating times.

Versatility to achieve **customizable solutions** for **flexible interfacing** with downstream and upstream machines and elimination of intermediary conveying:

Infeed Area:

- by in-line conveyor loading system
- by in-feed single tray
- by accumulation rotary turntable

Outfeed Area:

- onto in-line conveyor unloading system
- onto single tray
- onto a double tray system equipped with a container counter
- onto an accumulation rotary turntable and then further to diverse processing stations within the production line.



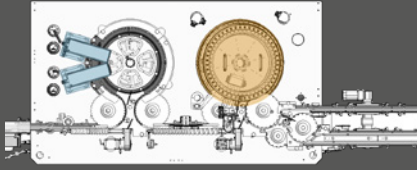
To meet the varied user requirements, the automatic ejection system can be set on a single **“One for all”** or a multiple **“One for each”** output, choosable amongst the following options:

- onto a dedicated non-compliant-products reject conveyor
- onto a dedicated segregated area, in to a non-compliant products lockable box
- onto a non-compliant-products tray or bin.

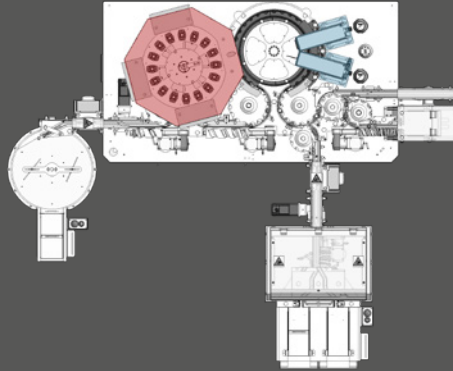
Test and Inspection results can be documented and stored together ensuring 100% traceability. Connecting to **“Manufacturing Execution System”** and **“Electronic Batch Record”** allows production data to be exchanged and/or downloaded (also remotely) to the line network for production-management and control.

Total cost reduction thanks to ease of maintenance, faster format changeovers, lower energy consumption.

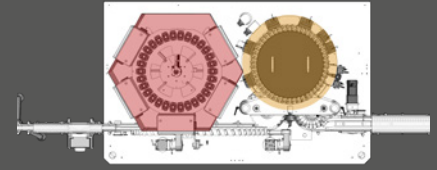
Combi HGA + AVI



Combi CCIT + HGA



Combi CCIT + AVI



3 All-in-one solutions

for high integration feasibility of different **modular inspection technology systems** in connection with a wide choice of links to the up-stream and down-stream line flow.



Headspace Gas Analysis

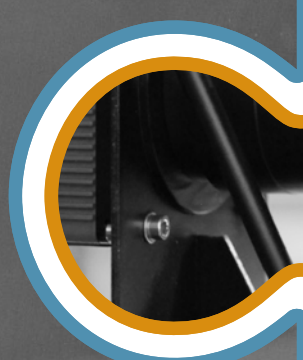
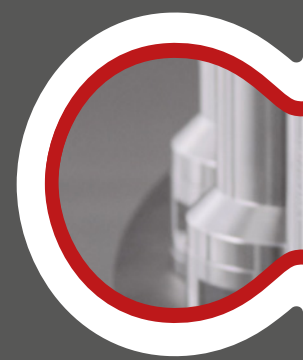
HGA

It is a non-destructive, non-invasive inspection method based upon the Tunable Diode Laser Absorption Spectroscopy (TDLAS) technology for measuring the headspace levels of gases, such as:

- Oxygen
- Moisture
- Carbon Dioxide
- Absolute Pressure value

The system conforms to:

- All specific requirements for sterile drugs packaged under full or partial vacuum and 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".
- United States Pharmacopeia, USP General Chapter <1207> "Package Integrity Evaluation – Sterile Products" (USP 39-NF34): Laser-Based Gas Headspace Analysis is listed amongst Deterministic Leak Test Technologies.



CCIT

Container Closure Integrity Test



It is a non-destructive measurement technology based on the following testing methods:

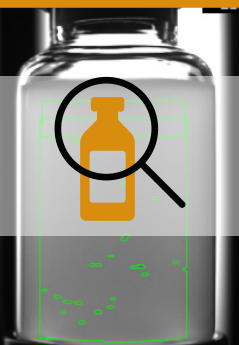
- Vacuum Decay Method
- Pressure Decay Method

Conforms to the following regulations:

- United States Pharmacopeia, USP General Chapter <1207> "Package Integrity Evaluation – Sterile Products" (USP 39-NF34): Pressure and Vacuum Decay are listed among Deterministic Leak Test Technologies.
- Approved industry standard "ASTM F2338-09": "Standard Test Method for Non-Destructive Detection of Leaks in Packages".

AVI

Automatic Visual Inspection



It is an automated camera based measurement technology detecting visual defects, such as:

- Presence of Foreign Particulate Matters
- Cosmetic Defects
- False Fill Level and Product Color

The testing method conforms to:

- United States Pharmacopeia, USP General Chapter <790>: "Visible Particulates In Injections"
- United States Pharmacopeia, USP General Chapter <1790>: "Visual Inspection of Injections".

QUALITY ASSURANCE

The system generates a series of reports:

- **Production batch record**
- **Inspection raw data**
- **Audit trails**
- **Alarm list**

Complete and accurate historical data copies are available by means of a viewer utility on the reports graphical pages (accessible as read-only) and can be downloaded to a USB stick or to an internal network.

Electronic data which are stored into the system cannot be deleted or changed by any user. In addition, the system provides a critical process parameter statistics management (mean, standard deviation and range) which is displayed on dedicated graphical pages and maintains continuous up-dates of all data.

The **Statistical Process Control** is designed to give full support to the quality management system as well as to maintenance and process control staff. It allows to improve controllability and to have a constant evaluation of the manufacturing processes. It keeps track and analyzes the collected data on different timeframes. The benefits are: reduced deviations and an improvement in production yield. Features of Statistical Process Control are:

- **Trend analysis**
- **Alarm Statistics**
- **Histogram Graphs**
- **Run Charts (X and R)**

The **Autotest** function is aimed to verify the systems capability to detect leaking containers simulating a calibrated leak. This function is useful and applicable during qualification stages as well as during the usual production cycle - it automatically confirms the correct function and behavior of each testing chamber.

The Machines **Qualification and Validation** complies with requirements stated in EU Annex 15. Validation Package guarantees complete and efficient regulatory compliance.

All computerized systems are designed according to ISPE GAMP 5 guidelines and to comply with FDA 21 CFR Part 11 and EU Annex 11.

Machine manufacturing process and materials are compliant with applicable GMP requirements.



MAINTENANCE

Remote Assistance Service: It includes several support activities to allow for remote machine maintenance via LAN connection. It is particularly useful for transferring data such as software updates or installing patches etc. as well as troubleshooting and general improvement activities.

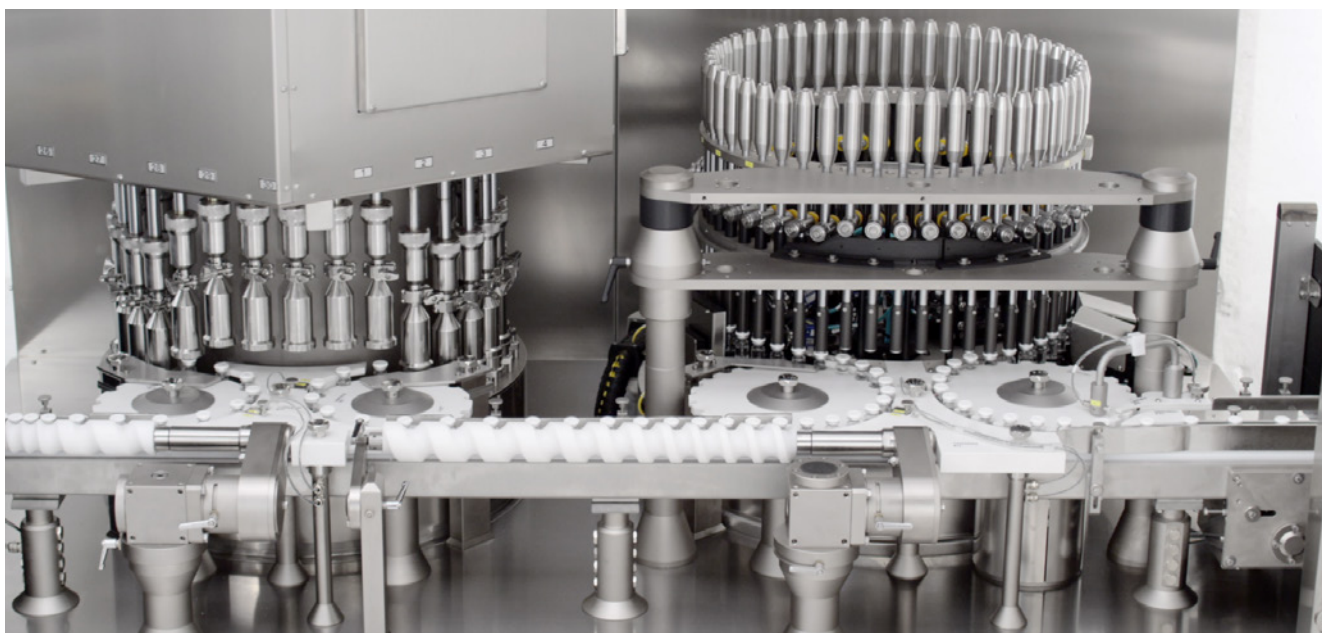
Easy bypass: If any interference hinders the containers production line, the machine can easily be fully or partially bypassed by removing the central arch guides and the inlet and outlet star wheels.

Diagnostics: HMI dedicated software section, for maintenance and troubleshooting purpose, allows to perform diagnostics of the main pneumatic, electrical and electronic components, such as transducers, electro valves, sensors and PLC I/O's.















Safety LOTO: Lock Out Tag Out procedures are in place for electrical and pneumatic components.

Component Accessibility (Motorisation Group): All of the motorised groups and electrical panels on board the main central frame have been designed to allow ease of accessibility and to speed-up both the required maintenance and possible service component replacement times.

World-wide maintenance: Comprehensive customized service and maintenance packages, complete with worldwide dedicated technical services, are provided to support customers in managing the optimal utilization of the machine ensuring cost reduction and minimum downtimes.



CONTAINERS INSPECTION RANGE

CONTAINER	PRODUCT	SIZE (mm)	VOLUME (ml)	SPEED RANGE (cph)	TECHNOLOGY
Vials	Liquid/Lyo/Powder	Ø 16 - 52	1 - 50	6.000 - 36.000	  
Ampoules	Liquid	Ø 10 - 25	1 - 30	6.000 - 24.000	  
Carpules/Cartridges	Liquid	Ø 6 - 25	0,5 - 30	6.000 - 24.000	  
PFS	Liquid	Ø 6 - 15	0,5 - 5	6.000 - 24.000	 
SVP	Liquid	48/180 (L) 40/100 (W)	0,1 - 20	3.000 - 12.000	 
LVP (Bottles BFS)	Liquid	Ø 30 - 95	100 - 1.000	2.000 - 7.200	 

USER EXPERIENCE

HMI User friendly:	Quick and efficient product quality management through an intuitive HMI and user-friendly operator panel which shows the real-time leak test cycle results and diagrams by implementing icons, graphs and charts.
On-line Help:	The Online Troubleshooting Manual displays both the causes and the respective corrective actions on the HMI. The Online Operating Manual gives information regarding graphical pages, icons, pushbuttons.
Alternative User Login:	Possible Login through RFID/Barcode/Badge/Active Directory/QR-Code
Smooth operation:	<p>The machine is equipped with the following preventative features in order to avoid possible production line stops:</p> <ul style="list-style-type: none"> - Poka-yoke mechanical solutions, stop and go controls and chicane tracks. - Safety clutches placed on container handling components. - Automatic unhooking system to avoid any risk of breakage should a mechanical interference arise. The system is also fitted with a gradual speed acceleration for the re-start this allows the drive shaft to automatically re-set before the nominal production speed is restored. - A series of sensors, photocells & fiber optics and cameras constantly check the infeed area for irregularities such as tipped or overturned containers, incorrect fill levels or broken or burnt tips of glass ampoules etc. - Polycarbonate Transparent Safety Guards that allow quick and detailed view of the machines internal operations and status.



TASITEST

**PACKAGING TEST
& INSPECTION**

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