Bonfiglioli Engineering
Quality Control Solutions

PK series

Inline Container Closure Integrity Test Machines

PHARMACEUTICAL

PK series

A complete range of products that covers all nominal production throughput/ speed of production lines.

Each Machine is designed for Non-Invasive, Non-Destructive Integrity Testing of diverse type of Pharmaceutical Containers and Contents. It is conceived for 100% in-line testing at high production speed. Testing is fast, reliable and repeatable, giving consistent results and allowing for full batch control without altering the container or content features.

Vacuum Decay or Pressure Decay Methods allow to reach full compliance with current GMP international regulations.

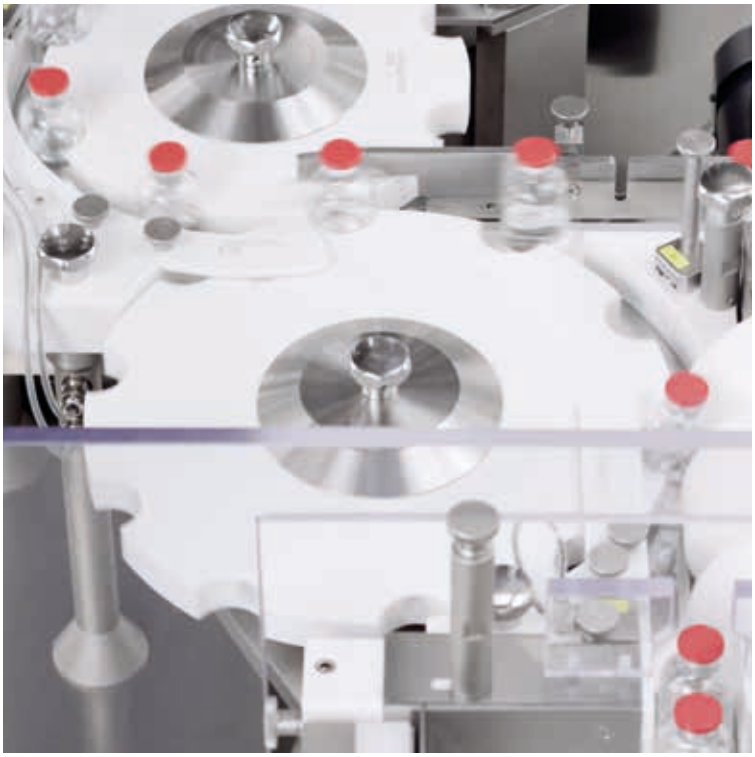
High class mechanical design and automation solutions fit for the purpose to perform, ease service and avoid downtime.

Equipment has full capability to be integrated in Industry 4.0 environment with Electronic Batch Record management or Manufacturing Execution Systems.

CONTAINER APPLICATIONS

FEATURES & BENEFITS

QUICK CHANGE OVER TIME



TESTING CHAMBER GROUP

The testing chamber group has been redesigned to obtain improved functionality. It is directly installed onto the Testing Chamber supporting flange and it can be easily accessed following safety guards opening.
It is assembled prior to being installed onto the machine and it is composed by:
- one Vacuuming/Pressuring Electrovalve (Test) completed with its own filter;
- one Relative Transducer
- one Calibrated Leaker Electrovalve (Optional)

All these components are connected to the Testing Chamber Group by means of quick coupling joints and therefore can be easily uninstalled without the need of tools.

MULTIPLE FORMAT, CONTENT TYPE AND SIZES MACHINE

With the same machine, various tests are available; in terms of contents: liquid, lyo and powder and in terms of containers: wide range of sizes.
High quality handling system, comprising State of the art electronic actuators and motor inverters, as well as high class mechanical design allow high machine adaptability to line output variations. Optimal testing results are achieved at nominal speed and also in case of speed reductions and increases.

HIGH FLEXIBILITY INSTALLATION

High machine installation flexibility, by means of rotating tables or other systems like tray loading, it is possible to install the machine in-line, off-line or next to the production line.

MES/LIMS/EBR CONNECTION

The network connection allows machine database production data exchange and download, also remotely, to the Line/ Laboratory Supervisor for data management and control.

REPORTS & DATA MANAGEMENT

Production, test and alarms reports are printable either local or network printer. Testing and production data are downloadable on USB driver and printable either local or network printer.

STATISTICAL PROCESS CONTROL

Statistical Process Control is conceived to give full support to the quality system, maintenance and process control staff. It allows to improve control ability and to have a constant evaluation of the manufacturing processes, keeping track and analyzing the collected data on different time frames. This brings to reduced deviations and basically helps to improve the yield. Features of Statistical Process Control are:
- Trend analysis
- Alarm Statistics
- Histogram Graphs
- Run Charts (X and R)

Giving statistical representation of measurement acquisitions, it is possible to calculate significant process parameters (Avg, std.dev., Cp,Cpk). From another perspective, it also saves the historical data for comparison, gives quick access to most frequent failures both of the GMP critical, business and safety ones. Pareto diagrams representations allow to highlight the most relevant failure modes, calculating Statistical parameters (i.e.: MTBF – Mean Time Between Failure and MTTR - Mean Time To Repair).

PLC AND DCU

PLC manages all Machine actuation commands.
D.C.U. manages Leak Testing Data elaboration.

AUTOMATIC HEAD EXCLUSION

This function allows any testing chamber to be excluded from the leak testing process. When one (or more) testing chamber is out of operation, the central carousel feeding containers is mechanically blocked. This control can be also manually managed through the HMI.

REGULATORY COMPLIANCE

Equipment test method complies with:

- FDA Guidance for Industry "Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products".
- United States Pharmacopoeia General Chapter «1207» "Packaging Integrity Evaluation".
- EU Guidelines to GMP Medicinal Products for Human and Veterinary Use – Annex 1 "Manufacture of Sterile Medicinal Products".
- PDA Technical Report No. 27 "Pharmaceutical Package Integrity"

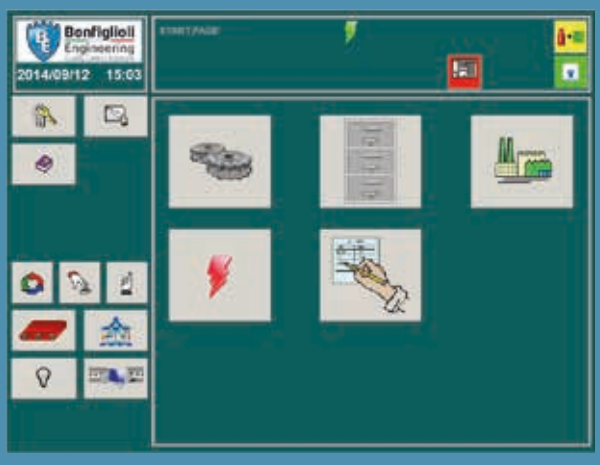
FDA 21 CFR Part 11 and EU Annex 11

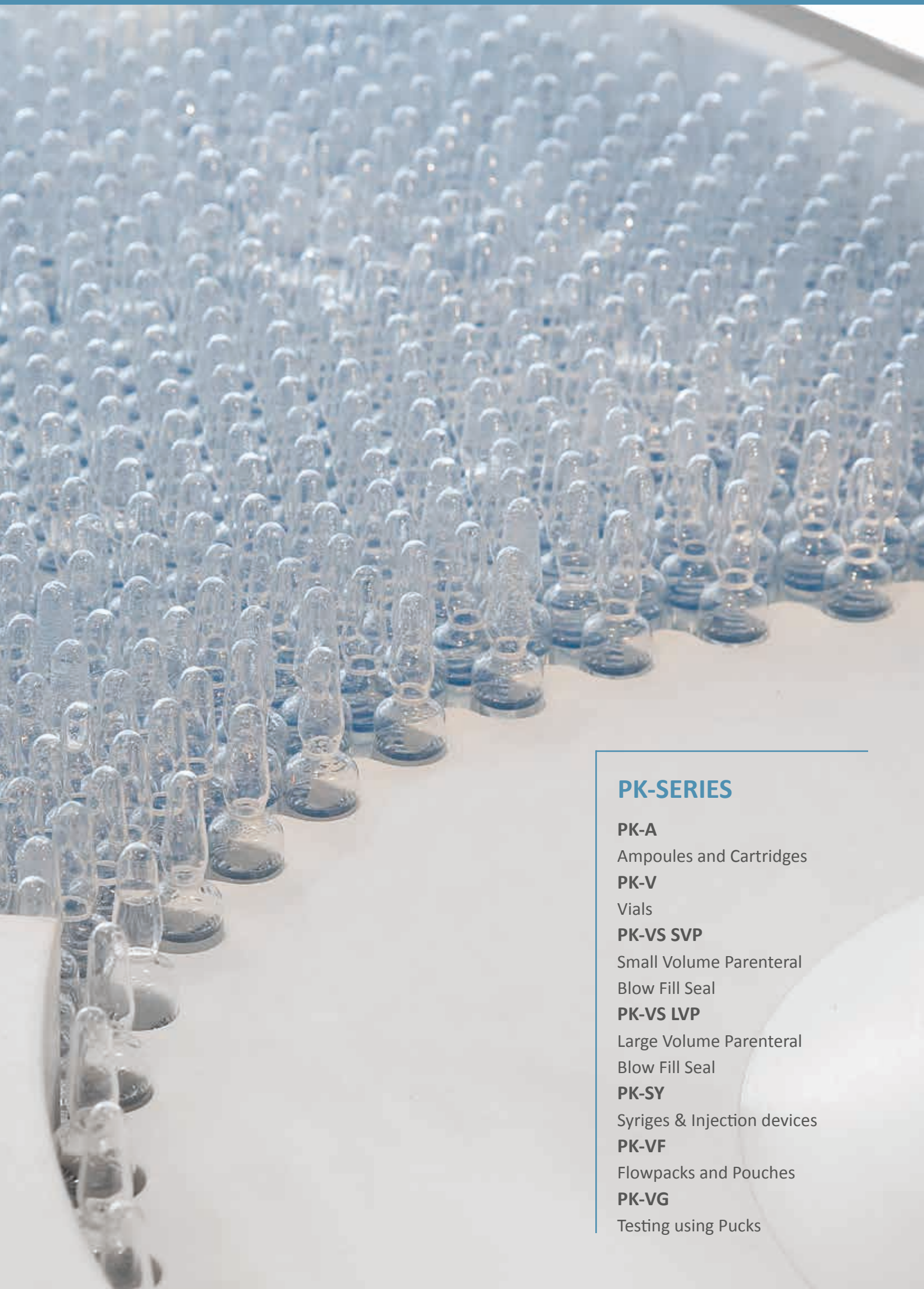
DATA INTEGRITY
The system generates the following logfiles: Production report, Tests report, Events report, Alarms report. Complete and accurate historical data copies are available through the use of a viewer utility on Report graphical pages (accessible as read-only) and can be downloaded. Electronic data which are stored into the System cannot be deleted or changed by any user.
Electronic signature is available for verification and authorization of most critical process steps.

HMI
Operator interfacing is featured by a SCADA System made up of interactive graphical pages allowing to:
- Manage Electronic Records, Operators accounts and System accesses
- Report and record Operator critical actions, process activities, anomaly conditions (Audit Trail)
- Control Testing Process and access to online Troubleshooting
- Set Machine critical parameters (Recipes, Operators, Configuration)

HMI Real Time display of Leak Testing Cycle diagram.

GAMP 5 COMPLIANCE
Equipment computerized system is designed according to ISPE GAMP 5 guidelines.





PK-SERIES

PK-A
Ampoules and Cartridges
PK-V
Vials
PK-VS SVP
Small Volume Parenteral
Blow Fill Seal
PK-VS LVP
Large Volume Parenteral
Blow Fill Seal
PK-SY
Syriges & Injection devices
PK-VF
Flowpacks and Pouches
PK-VG
Testing using Pucks

QUALITY ASSURANCE

TEST METHOD
Machine Leak Testing Measurement System follows the approved industry standard "ASTM F2338-09": "Standard Test Method for Non-Destructive Detection of Leaks in Packages".
The Test method is a Recognised Consensus Standard by the United States Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), effective March 31, 2006 (Reference: Federal Register Notice FR Notice (list #014) [Docket No. 2004N-0226].

AUTOTEST
Autotest function has the aim to verify the measurement system capability to detect leaking Containers simulating a Calibrated Leak. This function is useful and applicable during qualification stages as well as during usual production cycle, to automatically confirm proper functioning and behavior of each testing chamber.

RELATIVE TRANSDUCER FUNCTION
Relative Transducer Functionality Algorithm Checking every Relative Transducer both for incorrect Atmospheric Pressure Reading and for overpressure. The monitoring operation is executed in continuous during run-time.

AUTOMATIC DRYING SYSTEM
This system automatically dries each Testing Chamber which might have been contaminated by liquid or moisture left by leaking Containers. To avoid the possibility of producing false rejects, it is necessary that every potentially contaminated Testing Chamber is brought back to its optimal state of operation before this is allowed to test other Containers. With A.D.S. enabled, Containers are not fed into the Testing Chamber to be dried but passed on to the next available one. As a result, this particular Chamber will perform an empty cycle during which a continuous vacuum dries it. Whilst under vacuum, any residue will be evaporated, therefore drying the Testing Chamber.

BAROMETRIC COMPENSATION ALGORITHM
This system has the function to avoid variations in Pressure readings coming from the Relative Transducer by means of compensating any changes due to atmospheric pressure fluctuations.

TEMPLATE URS
Support to customer's URS development for specific application to reach, considering a common definition (customer and supplier), the best possible solution.

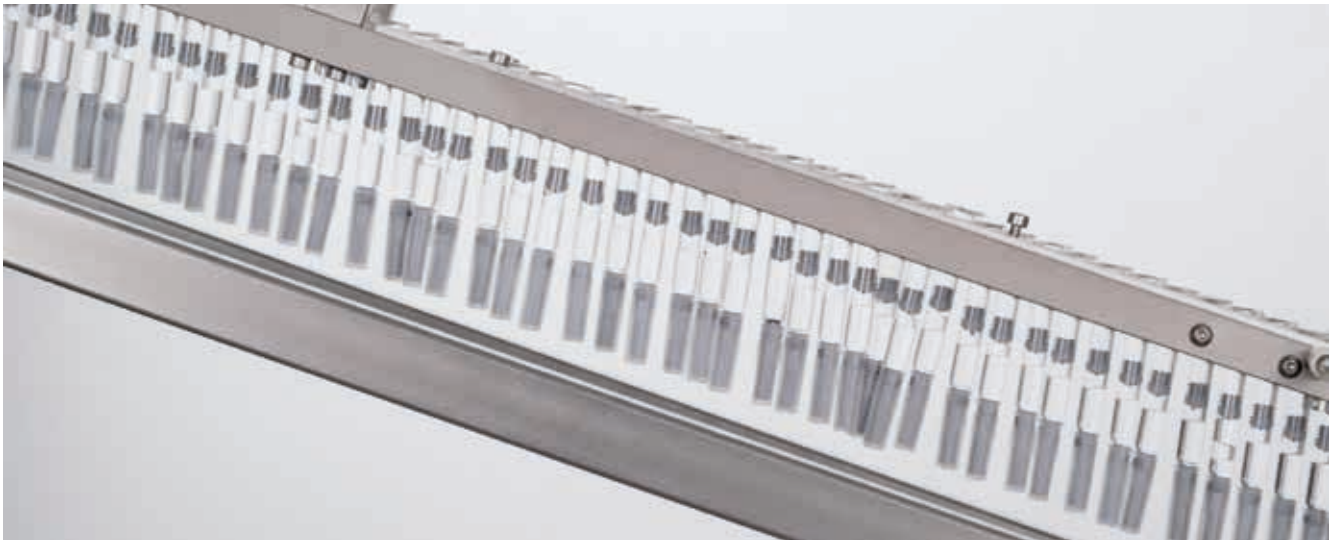
AUTODIAGNOSTICS
Autodiagnostics automatically verifies the optimal working condition of: Pressure and Exhaust Electrovalves, Relative Pressure Transducers, Testing Chamber (in terms of airtightness). Autodiagnostics is automatically enabled at Machine Start-Up and can also be manually activated while Machine is in production phase, pressing a dedicated button on the HMI. Container feeding to the Central Carousel is mechanically blocked during the Autodiagnostics execution.

VALIDATION PACKAGE
Machine Qualification and Validation complies with requirements stated in EU Annex 15. Validation Package guarantees complete and efficient regulatory compliance. Standard Validation Package includes:
Project Quality Plan, Functional Design Specifications, Mechanical/ Hardware / Software Specifications, FAT /SAT, IQ and OQ.
Moreover, following documents are available for delivery:
Performance Specifications, Performance Qualification, Design Qualification, 21 CFR Part 11 Compliance Table, Traceability Matrix to supplied URS.

AUTOMATIC DRYING SYSTEM

USER EXPERIENCE

HMI User friendly:	Quick and efficient product quality management through an intuitive HMI and user friendly operator panel that shows the real time leak test cycle results and diagrams using icons, graphs and charts.
On-line Help:	Online Troubleshooting Manual allows to display on HMI both root causes for each single anomaly and respective corrective actions. Online HMI Operating Manual allows to display on HMI information about graphical pages, icons, pushbuttons (meaning, functionality, methods to be followed).
Password protected HMI:	HMI allows to set password management to increase safety access in most critical aspects of the test and machine settings.
Alternative User Login:	Possible Login through RFID/Barcode/Badge/Active Directory/Qrcode
Safety Pressure Discharge:	In case of E-STOP or Safety Guards opening, the production line pressure is automatically discharged to avoid safety risks.
Viewing, Safety Guards:	Machine is equipped with Polycarbonate Transparent Safety Guards, in order to prevent crushing in case of accidental collision, and Internal Lighting.
Manual Mode:	A Remote Control Jog button allows executing maintenance operations (step by step movements).



MAINTENANCE

Easy bypass:	If any interference hinders the containers production line, the machine can easily be 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, electrovalves, sensors and PLC I/O's.
Components Accessibility (Electrical/Electronic Panels and Connections):	Machine electrical and electronic parts, panels and connections can be easily reachable and removed to facilitate machine maintenance operations.
Solid State HDD:	Machine hard-disk is a Solid State type that avoids any effect of machine mechanical vibrations.
Commercial Components:	Electrical, Electronics and Pneumatic components mounted on the machine are part of first-tier commercial component suppliers to enable the global availability and accessibility to pursue the machine ease of maintenance.
Worldwide Maintenance with contracts:	Available customized maintenance contracts complete with world-wide dedicated technical services.
Safety LOTO:	Lock Out Tag Out procedure are in place for electrical and pneumatic components.
Components Accessibility (Motorisation Group):	The motorisation group has been designed with the objective to speed-up both the required maintenance and possible replacement times. Main motorisation supporting flange is skewed in the frame bottom side; it has the possibility to rotate outwards allowing ease of accessibility.
Ease of maintenance:	Free access to all moving parts.
Automatic cam unhook:	Mobile Bottom Part for Container Holding Unhook Safety System and automated reset. If any Mechanical Interference hindering the Testing Chamber closure is present, the Mobile Bottom Plate shaft is automatically unhooked thus avoiding any risk of breakage. Following the opening of safety guards and mechanical interference removal the machine is restarted and is automatically run at reduced speed for a few seconds until the shaft is reset to its operation, then the nominal production speed is restored.

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