



BONFIG PK series

PHARMACEUTICAL



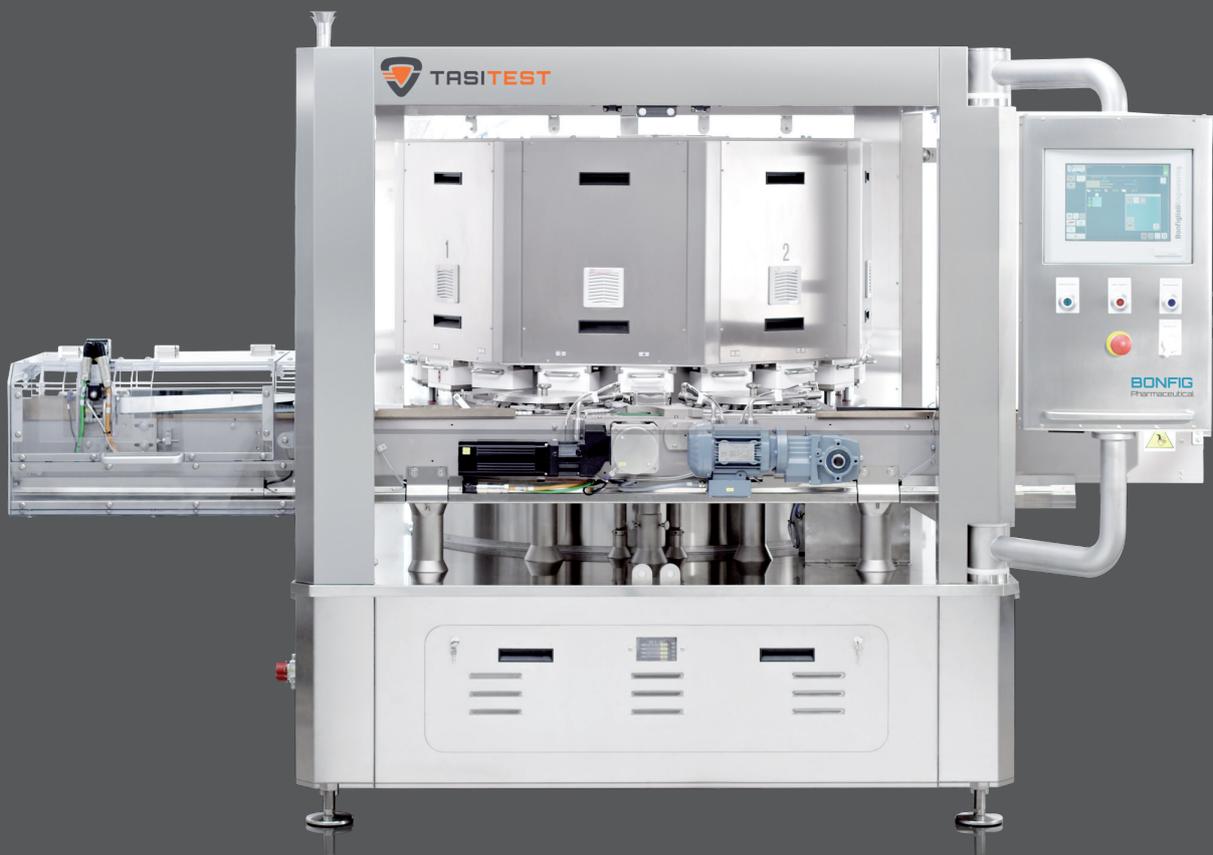
BONFIG PK Series

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

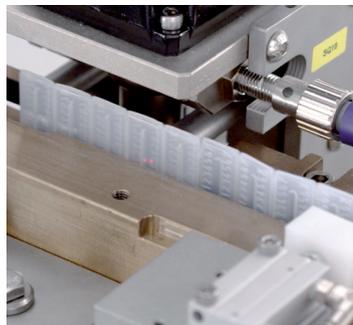
High class mechanical design and automation solutions fit for the purpose to perform, ease upkeep and service and avoid downtime.

Equipment has fully capability to be integrated in Industry 4.0 environment.

The Machine is designed for Non-Invasive, Non-Destructive Integrity Testing of diverse type of Containers (including pharmaceutical products). It is suitable for 100% in-line testing at high production speed. The 100% testing can be performed without altering the container features. Testing is fast, reliable and repeatable, giving consistent results and allowing for batch control.



**QUICK
CHANGE
OVER TIME**



FEATURES & BENEFITS

ALTERNATIVE DATA ENTRY

Possible Data Entry through RFID/Barcode/QRcode

COMPLIANT TO MACHINE DIRECTIVE

Machine is built in conformity with the provisions of the EC Machinery Directive (2006/42/EC).

MES CONNECTION

Manufacturing Execution System connection allows machine database production data exchange and download, also remotely, to the Line Network for production management and control.

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 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.

PRINT/USB

Testing and production data are downloadable on USB driver and printable either local or network printer.

REPORT

Production, test and alarms reports are printable either local or network printer.

RETENTION PERIOD

Production and testing data retention available for 1 year, available for 5 years basis extension.

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 analysing 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)

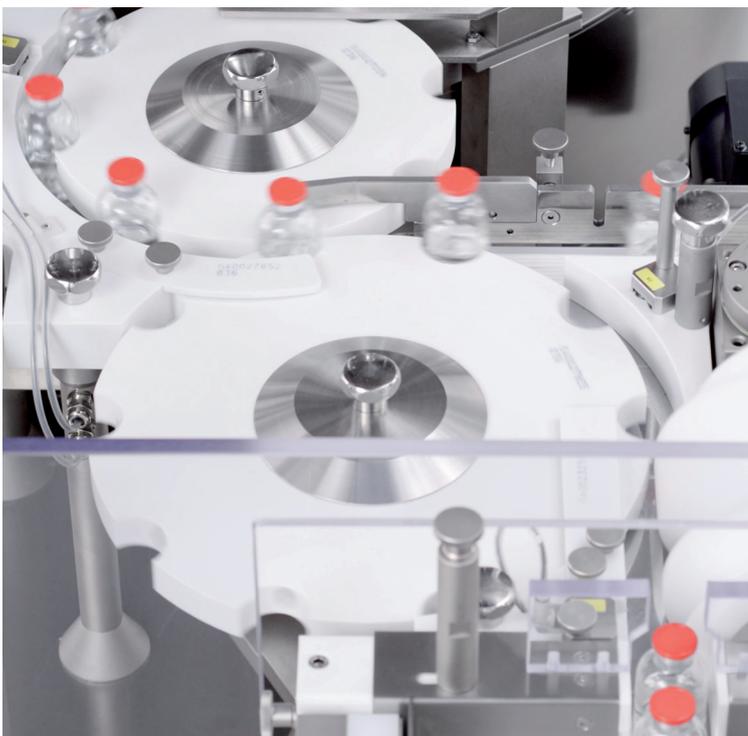
Giving statistical representation of measurement acquisitions, it is possible to calculate significant process parameters (Avg, std.dev., Cp, Cpk). From another perspective, it also saves the historical data for comparison, gives quick access to most frequent failures both of the GMP critical, business and safety ones. Pareto diagrams representations allow to highlight the most relevant failure modes, divided between primary & secondary ones and therefore calculating Statistical parameters (i.e.: MTBF – Mean Time Between Failure and MTTR - Mean Time To Repair) With larger time scales it is possible to see deviations on process giving warnings according to calculated parameters, such as Nelson rules.

PLC AND DCU

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

SPEED RANGE

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.



SAFETY LOCK

Machine equipped with interlocked safety guards to meet CE safety standards.

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. Automatic testing chamber exclusion stops the feeding of the containers when automatic drying system (A.D.S.) is enabled or when the machine is running the initialization function.

STAR WHEELS SAFETY CLUTCH

Inlet and outlet star wheels equipped with safety clutch and testing chamber shafts equipped with safety release system.

Signaling the correct activation of the Star Wheels and their unhooking in case of overload or mechanical interference.

AUTOMATIC SPEED ADJUSTMENT

Automatic Infeed and Outfeed controls are planned to stop and start the Machine automatically according to the Containers flow. This allows automatic speed adjustment according to signals coming from the line downstream (maximum load at outfeed) and upstream (minimum loading at infeed), further exchange signals can also be supplied upon request.

MACHINE STOP

In case of production line stops, machine quits rotating and testing phase of containers present on the carousel is, in any case, completed.

SENSITIVITY IMPROVEMENT

Digital analog signal transducers are mounted on the machine carousel to achieve the best signal to noise ratio and quick management of test results.

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 and
- one Calibrated Leaker Electrovalve (Optional)

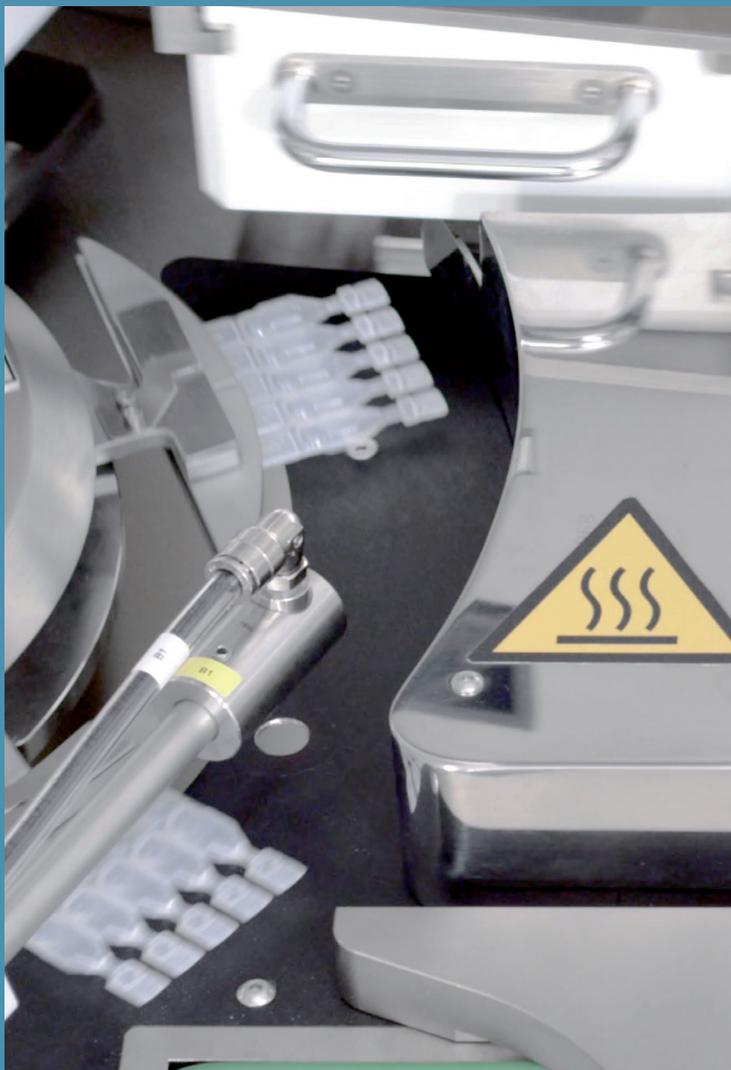
All these components are connected to the Testing Chamber Group by means of quick coupling joints and therefore can be easily uninstalled without the need of tools.

INSTALLATION

Machine is designed and manufactured for installation in clean areas for less critical phases of sterile product fabrication (Class C and D).

TEST METHOD

The Leak Test takes place into an airtight Testing Chamber in which a pressure differential is applied (Patent No. 1225063 of 13-9-1988). The test objective is to detect Container leakages by measuring the reached pressure level as well as the pressure change over test time.

**QUALITY ASSURANCE****AUTODIAGNOSTICS - VDM - KEY OBJECTIVES AND BENEFITS**

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.

HMI FUNCTIONS: BASIC STATISTICS

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 on USB stick. Electronic data which are stored into the System cannot be deleted or changed by any user. In addition the System provides critical process parameters statistics (mean, standard deviation and range) management, display onto dedicated graphical pages and it continuously maintains up to date all data.

A.D.S. (AUTOMATIC DRYING SYSTEM)

(applicable to Leak Test under Vacuum only with Option "A.H.E." and with liquid filled containers) 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. No containers will be supplied to the reference testing chamber also during the next cycle, but this time a verification will be done to make sure that all relevant parameters of the Testing Chamber correspond to the original data recorded



in Phase C of the I.A.V. test. This will continue until the original condition of the reference testing chamber will be fulfilled (totally dried). Only at this point, the Testing Chamber will be automatically returned to the Leak Testing process. If after a configurable number of cycles it will still result out of specification, this will result both in a HMI alarm and the permanent Testing Chamber exclusion.

Automatic Drying System is managing the condition of a potentially contaminated Testing Chamber:

- to bring it back to the optimal condition
 - to exclude it permanently in case the Drying operation is unsuccessful
- A.D.S. is automatically operated when a Testing Chamber rejects a number of consecutive Containers over a value preset from HMI. It requires Automatic Head Exclusion (A.H.E.) function

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.

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.

EQUALIZATION

DELTA Adaptive Algorithm. Allowing the evaluation of Containers Conformity based on Vacuum Decay to refer to statistical indicators measured during the running of the Leak Testing Machine and consequently equalise the behaviour of the single Testing Chambers.

RELATIVE TRANSDUCER FUNCTION

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

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.

GAMP 5 COMPLIANCE

Machine's computerized system is designed according to GAMP 5 guidelines. The following design and development documentation is available for review upon audit: Software Design Specifications, Software Functional Specifications, Software Configuration Specifications, Software Life Cycle, Module Design Specifications and Module Design Tests.

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].

TEMPLATE URS

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

GMP COMPLIANT

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

SAFE COMPUTERISED SYSTEM

Computerised system is designed to comply with FDA 21 CFR Part 11 and EU Annex 11

VALIDATION

Machine Qualification and Validation complies with requirements stated in EU Annex 15.

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

Syringes & Injection device

PK-VF

Flowrapped device

PK-VG

Small serial pack in Puck

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.O's.

Components Accessibility (Electrical/Electronics 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 fram 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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& INSPECTION

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