



Bonfiglioli
Engineering
Quality Control Solutions



LF-S11

Benchtop CFR21 Part 11 Compliant Container Closure Integrity Tester

PHARMACEUTICAL



LF-S11

Designed for Non-Invasive, Non-Destructive Container Closure Integrity Testing of diverse types of Pharmaceutical Containers filled with liquid, lyo, powders, etc..

Suitable for **In-Process Control** and **Laboratory** use without altering container and/or content features.

The integrated software system allows full compliance to provisions stated in **FDA 21 CFR part 11** as well as **EMA Annex 11**.

3 Configurations of the machine available to meet all specific requirements:

- **BASIC**, for most of the container formats
- **XL**, designed specifically for large formats (more than 100ml)
- **SY**, designed for syringes, carpoules including automatic plunger stopping device

CONTAINER APPLICATIONS



FEATURES & BENEFITS

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"



MULTIPLE FORMAT, CONTENT TYPE AND SIZES MACHINE

Several tests available in a single machine. Possible contents: liquid, lyo and powder. Possible containers: a wide range of types and sizes (virtually any kind of rigid and flexible containers used in the pharmaceutical industry).

TESTING CHAMBER

All dedicated test chambers are designed according to the container characteristics for a maximum of leak detection sensitivity and are monitored by specially developed electronics during the testing process. The group has been recently redesigned to obtain improved functionality (quick single-handed opening and closing). It is directly installed onto the Testing Chamber supporting flange and it is composed by:

- A fixed bottom part;
- A removable top cap (upper part) that allows plugging up the testing group corresponding to Container loading and unloading operations.

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 available directly on HMI, downloadable on a network path and printable either locally or on network printers.

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).

INSTALLATION

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

DOUBLE TESTING

Convertible method of testing (vacuum VS positive pressure) with no need to change mechanical components.

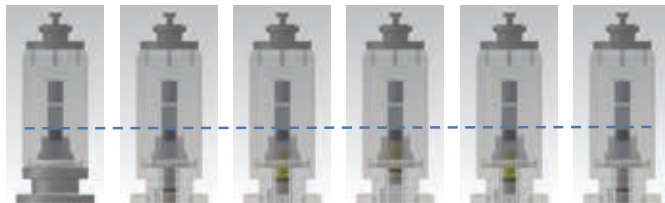
QUICK TEST
EXECUTION



LF-S11 SY

DEDICATED SOLUTION FOR PRE-FILLED SYRINGES & CARPOULES

The system, applying a differential pressure between the inside and the outside of the PFS to perform the Container Closure Integrity Testing, based on Vacuum Decay Method, ensures complete maintenance of product's sterility and safety.



HOW IT WORKS

The test chamber fixed bottom part is equipped with a mobile piston, plunger stopping device (PSD), having vertical motion between two limit positions, "upper" and "lower", and having a section equal to that of the PFS plunger.

The initial vacuum, generated in the test chamber, produces an upward movement of the PSD.

The same "upper" position is kept until the second reading; at that time, the action of a dedicated pneumatic actuator provides for exhaust of vacuum in the test chamber bottom area and produces the PSD downward movement towards the "lower" position.



COMPLIANCE WITH 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.
 A GMP compliant "Audit Trail" is available and is permanently stored on the machine. The data can be viewed on the HMI in either Graphical and/or list formats.
 Electronic signature is available for verification and authorization of most critical process steps.

HMI

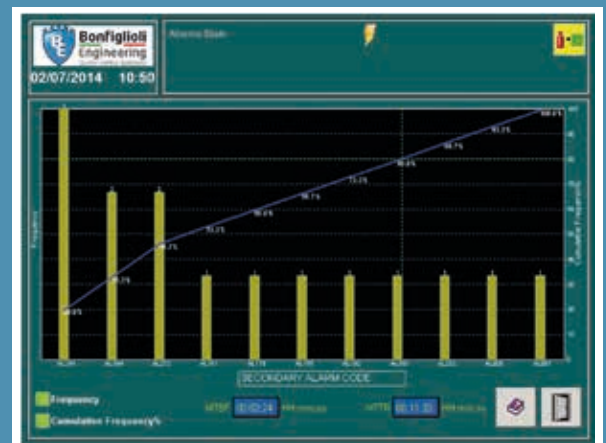
Operator interfacing is featured by a SCADA System made up of interactive graphical pages allowing to:

- 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.





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]. 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.

GMP COMPLIANT

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

VALIDATION

Machine Qualification and Validation comply with requirements stated in EU Annex 15. Protocols and documentation are available for periodic re-qualification of the machine.

AUTOTEST

A Calibrated Leak implemented by Bonfiglioli Engineering is provided and installed on to the Testing Chamber. Calibrated Leaks Calibration Certificate is issued and attached to Validation Package for qualification traceability.

URS TEMPLATE

We offer technical support to customer's developing and designing URS documents for their own individual and specific applications, and allowing to reach the best possible machine solution.

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 the production phase, pressing a dedicated button on the HMI.

A.D.S. (AUTOMATIC DRYING SYSTEM)

(applicable to Leak Test under Vacuum only) This system automatically dries up the Testing Chamber which might have been contaminated by liquid or moisture left by leaking Containers.

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.

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).

ALTERNATIVE USER LOGIN:

Additional login possibilities are offered via RFID, Barcode, Badge, Active Directory, Qr-code

STERILITY
GUARANTEE



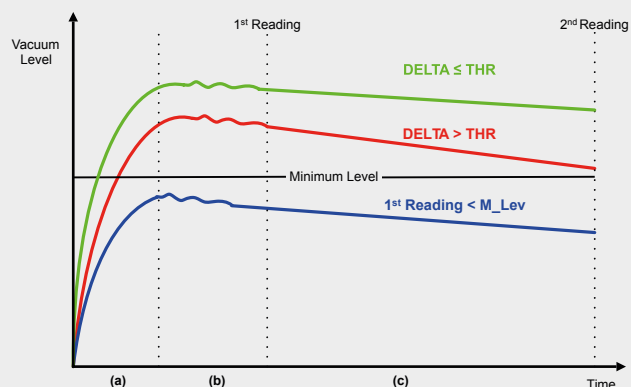
TEST CYCLE

Leak-testing cycle is composed of the following steps:

1. The container is loaded into the testing group;
2. The testing group is closed;
3. The testing cycle is started by pushing the dedicated button on the HMI;
4. A pressure differential is generated by the pneumatic system (a);
5. Testing group is allowed to stabilize for a preset time prior to test start (b);
6. The container is tested (c);
7. Atmospheric pressure is restored by means of exhaust activation and testing group is opened again;
8. The container is unloaded from testing group and managed according to test outcome;
9. The system gets ready for the next cycle.

As a consequence of leak testing process decision making, containers are classified as Non Conforming in the following cases:

- The preset minimum level of vacuum/pressure was not reached;
 - The preset threshold of vacuum/pressure change throughout test time was exceeded.
- In all other cases, containers are classified as Conforming. The HMI displays clearly on the screen whether the result is Conforming or Non Conforming. The results are qualitative (Conforming = Good / Non Conforming = Reject).





LF-S11 XL

LARGE VOLUME PARENTERALS

Technical solutions, such as alternative pneumatic systems and components, are available to increase test sensitivity and quickness in case of large volume containers.

ADDITIONAL FUNCTION

Lid deflection Sensor (BHS) control for Packages having a lid or flexible foil such as cups, pouches, IV bags. The sensor is used to detect significant changes in pack surface deflection during the execution of vacuum decay testing cycle.

COMPONENTS MATERIAL

Critical Mechanical components are marked according to their own drawing ID number. Critical mechanical components (which are in contact with the Container to be tested) are made of FDA approved materials.

MAINTENANCE

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.

Machine remote access:

The Remote Access feature is an easy, quick and safe way for providing technical support for the Machine.

Worldwide Maintenance with contracts:

Customized maintenance contracts with world-wide dedicated technical services are available.




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