

NEW LEAK TESTING MACHINE TYPE LF

1. BASIC MACHINE FUNCTION AND DESCRIPTION: OF:

The NEW innovative "LF" leak testing machine is designed specifically for laboratory or off-line leak inspection of vials/ampoules/blisters/ffs strips etc. The inspector includes state-of-the-art measuring and control systems.

2. THE "LF-PK" INSPECTION MACHINE CONSISTS OF:

2.1 Tester Frame and Housing:

- Machine built to comply with machine norms "CE N°89/392-91268-93/94".
- The compact sleek design makes it easily transportable from one department to another.
- The standards construction is compliant with GMP requirements and with National and International Statutory Standards in respect to safety, guarding, electrical/mechanical standards and levels of protection.
- Machine constructed from stainless steel.
- The machine is specially designed to be easily and effectively cleaned, with no product entrapment areas.

2.2 Electrical, Mechanical, & Pneumatic Components:

- 6" Touch Screen Operator Interface displaying test data and cycle graph (Pressure vs. Time).
- RS232/USB/Ethernet connection for printer or for transfer of test data.
- All wiring/pneumatics etc. are tagged at either end in accordance with P & ID/electrical/pneumatic drawings.
- All removable components are marked with a drawing identification number.
- All tooling change parts are marked with a drawing identification number, type or container code, and an identification list will be part of the machine manual instruction.
- Vacuum and compressed air ports.

2.3 Leak Inspection Control System:

- Software for changing and viewing parameters such as testing data, product container database and recipes etc.
- On line testing program used for storing test cycle results for a period of time, beyond which these results can be transferred to external memory device or printer.
- Pressure transducer type DPS-04 developed by Bonfiglioli Engineering compensated in temperature.
- Testing system for filled & sealed container, with test chamber (Patent No. 1225063 of 13-9-1988) controlled by D.E.L.T.A system.
- Testing system for blister packs, with test chamber and controlled by force sensor.
- Auto-test calibrated leak installed on testing head. This enables self testing of machine and also used for Validation purposes.
- Intelligent Automatic Verification (IAV) of all parameters upon start-up.
- Auto Cleaning Procedure (ACP) for drying of chamber after detecting a leaking container.



* I.A.V. (Intelligent Automatic parameters Verification)

This feature will commence automatically upon start up of the machine. The machine will perform three verification tests:

Phase A: Cycle 1 - Electrovalves Test In this primary phase the electro valves installed are tested and checked that each one efficiently opens and closes.

Phase B: Cycle 2 - Heads equalization In this secondary phase the test chamber is subjected to a vacuum pressure. Thus warming up the total system and remove any moisture residue from the testing heads. The vacuum pressure is then released.

Phase C: Cycle 3 – Recording of Statistical head parameters In this final testing phase the statistical parameters for the testing head will be recorded and verified that all values are within tolerance limits. These parameters will be the actual values that will be compared during the A.C.P. procedure.

*A.C.P. (Automatic Cleaning of the test chamber)

This feature automatically dries the test chamber (Pocket) from residual moisture left by a previous faulty container. After a Pocket rejects a container due to a leak, some residual moisture of the product might remain inside the Pocket. This will hinder the result of the next leak test that the same Pocket will perform. Therefore, an automatic drying process will take place on this particular testing head. Therefore this particular Pocket will perform an empty cycle during which a continuous vacuum dries it. While under vacuum, any residue will be evaporated and sucked, therefore drying the Pocket. The next cycle will then also be an empty cycle but this time an actual test is done to make sure that all the parameters of the Pocket are within the original characteristics as recorded in Phase C of the I.A.V. test. If residue is still detected then another cleaning cycle will be performed until it will be perfectly dried. When the Pocket is dry it will automatically return to leak test containers and will now allow the next container to be tested. An OK signal will be displayed on the screen.

*AUTO TEST

This test verifies that the transducer on the testing head can detect the leakage that is guaranteed. This feature is activated prior to the testing cycle. During the test, the vacuum is applied until the testing pressure is achieved. A calibrated flow valve is then actuated and simulates a pressure in the testing chamber corresponding to the minimum leakage that is expected to be detected. The vial is then rejected.

DUAL TESTING SYSTEM – Vacuum / Pressure (OPTIONAL)

The system operates with Vacuum decay or Pressure decay technology depending what type of test would be preferred. With a touch of a button the testing system can be changed. A specific product can be saved with the specific testing technology and hence when choosing the product to be tested from the database, the relative testing method is automatically selected. Vacuum decay is chosen for water-based products. If liquid escapes from the container, this will evaporate under vacuum and hence will change our vacuum level inside the test chamber. As a result the machine will see this product as a leaker. Pressure decay is chosen for oil-based products. If the container leaks, the pressure inside the test chamber will force air inside the container thus reducing the pressure level inside the test chamber. As a result the machine will see this product as a leaker.

2.4 Documentation:

- 1 copy of Operating & Maintenance Manual Instructions.
- Manuals written in English.
- A detailed Functional Specification.
- The CE Marking Technical File.
- Electrical diagrams and I/O card drawings.
- Certification of electrical signal, power, continuity and earthing test certificates.
- Operating & maintenance instructions (fully indexed).
- Fault finding guide.
- Data sheets for critical components and assemblies.
- Cleaning procedures.
- Parts list with recommended spares identified.
- Fully documented pre-installation with all the testing parameters, Factory Acceptance Tests (FAT's).
- Details of all hardware used.
- Full Functional Design Specification.
- Back ups of all software on floppy disc/CD-ROM/EPROM as appropriate.

3.OPERATION / TEST CYCLE:

Filled & sealed containers are manually loaded into the appropriate test chamber. On pressing the cycle start button the testing process commences. During the leak test process the test chamber is subjected to a vacuum. The pressure pattern in the chamber is analyzed in a specific time. The smallest leak would increase the pressure in the test chamber and compared to preset values. Whether the test result is good or bad, the operator interface shows the result clearly on the screen accordingly.

Blister packs are manually loaded into the appropriate test chamber. On pressing the cycle start button the testing process commences. During the leak test process the test chamber is subjected to a vacuum. The force sensor monitors precisely the swelling of each tablet cell. If there is a leak this force reduces and hence shows that a leak is present. Whether the test result is good or bad, the operator interface shows the result clearly on the screen accordingly.

4.SPECIFICATION:

- Test Cycle: from 5 sec. (programmable)
- Tester Details: 1 Leak Testing Head (to be chosen from optionals)
- Tester Dimensions: 0.40m X 0.30m X 0.37m (approx.).
- Weight: 22 kg (excluding vacuum pump)
- Leak Tester Sensitivity: Validated at 5 microns (hole diameter) Depending on test cycle time and container
- Product Requirement: Product must be Clean and Dry
- Installed Power: 0,5 kW
- Primary Power: 220 V/ 50 Hz, 1 Phase

5. EXTRA OPTIONS :

- 1 set of tooling for filled & sealed containers (vials/ampoules/ffs strips)
- 1 set of tooling for blister packs
- Extra set of tooling for blister packs - each
- Dual testing system (vacuum / pressure)
- Validation Documents IQ/OQ
- Vacuum Pump (Edwards)
- Printer

Further information may be obtained from our website www.bonfigliolipharma.com

Or contact us at:

NCM International, Inc. 894 Eider St.; San Juan, Puerto Rico 00924
E-mail: sales@ncminternational.com - Tel 787-977-0230 – Fax 802-609-0361

Bonfiglioli Trading Ltd, UBT20 Industrial Estate, San Gwann – MALTA
Email: hermann@bonfiglioli.com.mt Tel: +356 21 482206 Fax: +356 21 482208