Bonfiglioli™ Engineering

LF-S11

Benchtop CFR21 Part 11 Compliant CCI Tester

Non-Invasive, Non-Destructive Integrity Inspection System for laboratory and in process control applications.

HIGHLIGHTS

- **Quick and sensitive test**
- **Compact & maintenance free**
- **3 configurations: BASIC, XL, SY**
- **Vacuum and positive pressure testing**
- **Applicable to any type of pharmaceutical containers**
- **Solutions in place for PFS, LVP, cartridges**

TECHNICAL FEATURES

Container Application: Vials, PFS, Pouches, Strip Packs, Strip, BFS, IV Bags, Cartridges, Ampoules, Carpules, other Medical devices

Products: Lyo, Liquid, Powder, Solid, Semi-solid

Container Dimensions: Up to 1000 ml

Testing Time: From a few seconds to about 1 minute according to container size

Technology: CCIT

Inspection Features: Non-Invasive, Non-Destructive CCIT based on Vacuum & Pressure Decay Method

Inspection Capabilities: Microleaks detection

ADDITIONAL PLUS

- **Quick format change** over
- Automatic plunger stopping device for PFS
- **Auto-diagnostics** verifies optimal working condition of the testing chamber and enables machine start-up
- Easy, quick and safe **remote access**
- **Barometric Compensation system** to avoid any vacuum level reading variations
- Highly functional, **intuitive HMI**
- **Real time display** of testing cycle diagrams, statistical raw data
- **Storage of records**: maintenance, production, alarms

TECHNOLOGY

Container Closure Integrity Testing is a non-destructive measurement technology based on the following testing methods:

- **Vacuum Decay Method**
- **Pressure Decay Method**

Measurement system comprises applying a pressure differential into an airtight testing group enclosing the container.

The test objective is to detect container leakages by measuring the reached pressure level as well as the pressure change over test time.

Lid deflection technology can also be implemented to detect leaks on foils of cups or pouches together with Vacuum Decay method.

QUALITY ASSURANCE

Equipment test method refers to:

- **FDA 21 CFR part 11** as well as **EMA Annex 11**
- United States Pharmacopoeia – **USP 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"
- Approved industry standard "**ASTM F2338-09**": "Standard Test Method for Non-Destructive Detection of Leaks in Packages"