Bonfiglioli™ Engineering

PK-VG

In-line not-standing F&B containers and Pharmaceutical on-pucks Tester

Non-Invasive, Non-Destructive, 100 % in-Line Integrity Inspection System Testing at high production speed for not standing F&B containers (such as Bags , Pouches, Doypack, Flow packs) and for all pharmaceutical containers, tested into dedicated Pucks.

HIGHLIGHTS

- **Autotest in real time**
- **Easy to validate**
- **CFR 21 part 11 compliance and 4.0 full integration**
- **Quick format changeover**
- **High flexibility of containers to be tested**
- **Automatic Drying System, no pucks contamination (for pharmaceutical containers only)**

TECHNICAL FEATURES

Container Application: Not standing F&B containers (such as Bags, Pouches, Doypack, Flow Packs) and all pharmaceutical containers tested into dedicated pucks

Products: Semi-solid, Powder, Lyo, Liquid

Container Dimensions: Up to 50 x 80 x 120 mm

Speed: Up to 220 cpm

Technology: CCIT

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

Inspection Capabilities: Microleaks detection

ADDITIONAL PLUS

- Full batch control testing: **fast, reliable and repeatable**
- Testing of **all nominal production line speed**
- **MES** (Manufacturing Execution System connection) allows remote machine data exchange & download
- **Statistical Process Control** reduces deviations for a better yield control
- **Real time display** of testing cycle diagrams, statistical raw data
- **Easy, quick and safe remote access**
- **AHE (Automatic Head Exclusion)**
- **Easy cleaning**

TECHNOLOGY

Container Closure Integrity Testing is a non-destructive measurement technology based on **Vacuum 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 vacuum level as well as the vacuum change over test time.

QUALITY ASSURANCE

Equipment test method refers to:

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

For pharmaceutical containers only:

- 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"