



Bonfiglioli
Engineering
Quality Control Solutions

AVI TECHNOLOGY

AUTOMATIC VISUAL INSPECTION



TECHNOLOGY OVERVIEW

VISUAL INSPECTION is a mandatory practice for injectable manufacturers to guarantee both quality and patient safety. The finished products must be inspected to identify and reject visible foreign matter contaminated parenteral containers and units displaying defects that could potentially affect product quality.



AUTOMATIC VISUAL INSPECTION

It is an automated camera based measurement technology detecting visual defects, such as:

- Presence of Foreign Particulate Matters
- Cosmetic Defects
- False Fill Level and Product Color.

For each inspected container, a collection of images is acquired using high resolution video cameras under designed illumination conditions. Defects on the package are identified and/or measured by dedicated image processing algorithms and the package is classified as conforming or non-conforming accordingly.

Non-conforming packages are automatically rejected.

Bonfiglioli Engineering's in-line and offline automated visual inspection machines are computer based automated systems that, taking images of packages, determine if the container is fit to comply with given standards.

The testing method conforms to:

- United States Pharmacopeia:
 - USP General Chapter <1>: "Injections"
 - USP Gen. Chap. <790>: "Visible Particulates In Injections"
 - USP Gen. Chap. <1790>: "Visual Inspection of Injections".
- European Pharmacopeia § 2.9.20:
 - "Particulate Contamination: Visible Particles"

MAIN ADVANTAGES

FLEXIBILITY

A wide range of inspection solutions have been created during the years to meet ever changing requirements of the pharmaceutical industry.



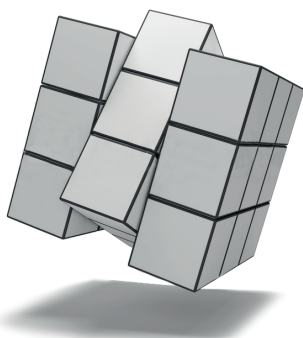
STABILITY

Each inspection system is developed on a configurable application based on Linux O.S. and validated according to GAMP5 principles.



SIMPLICITY

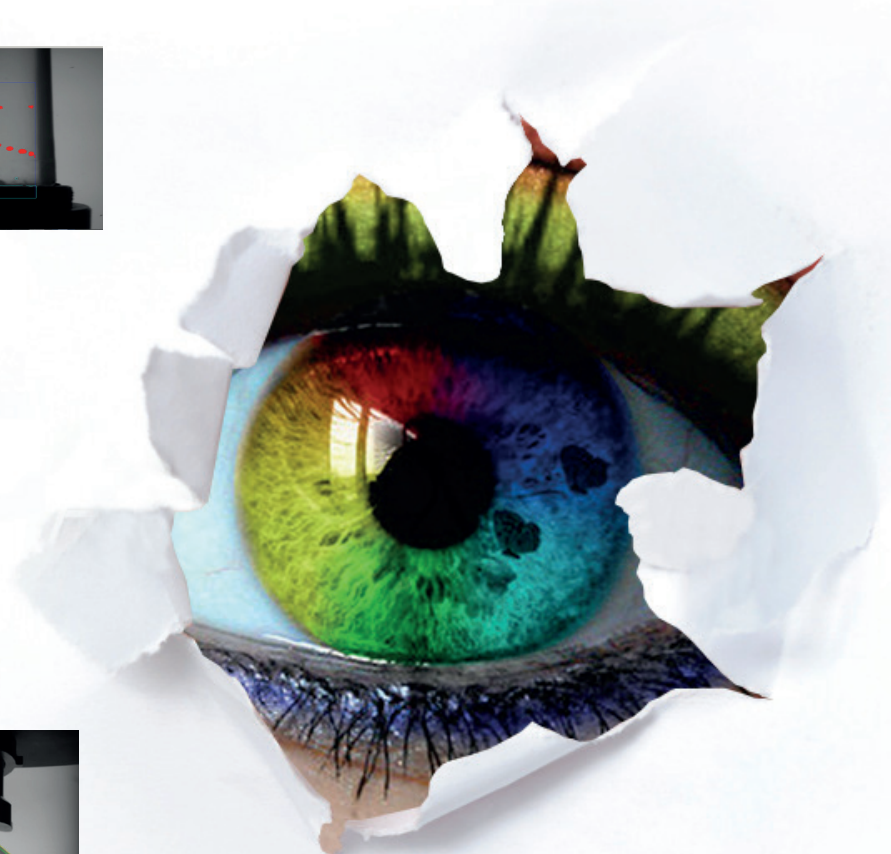
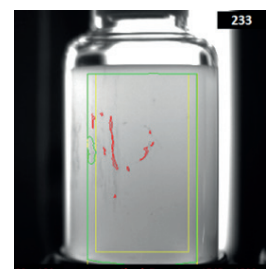
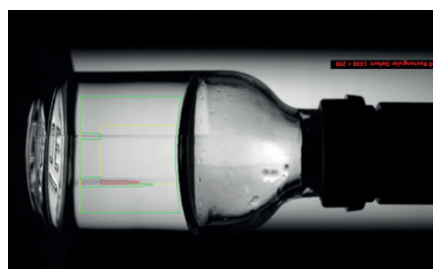
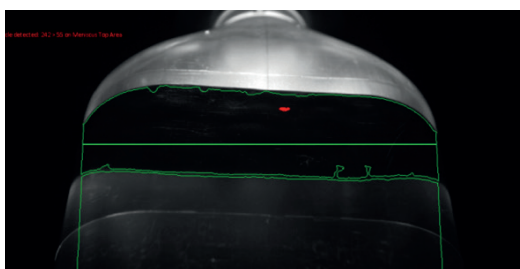
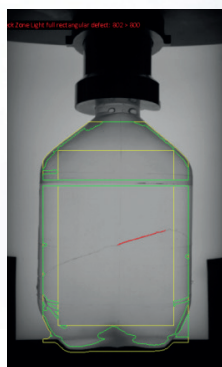
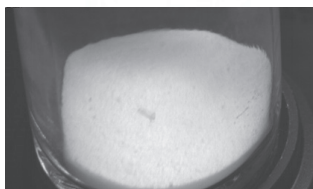
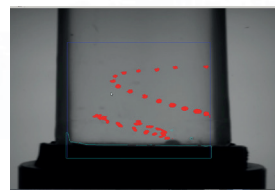
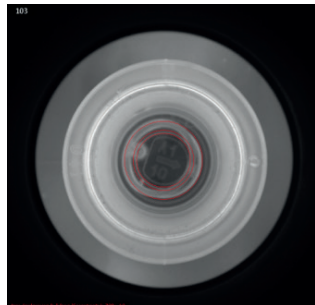
Complete internal design and development, allows to select Hardware and Software optimized according to customer URS.



QUALITY ASSURANCE

Each system is built in full compliance to International pharmaceutical regulations from Manufacturing standpoint to Data Integrity (21 CFR part 11) as well as qualification and validation.





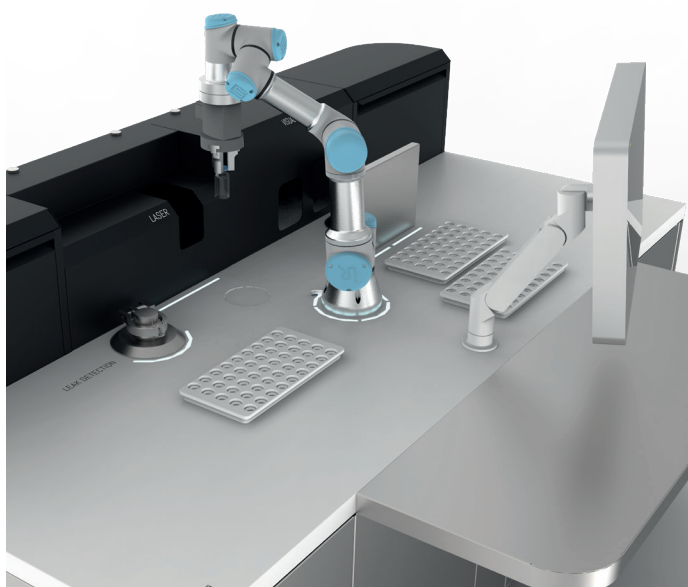
...seeing
through...

SAIL

Smart Automated Inspection Laboratory



COBOT
Inside



- A complete inspection laboratory.
- Expansion capability from VI to CCIT/HGA.
- High Versatility.

TECHNICAL SPECIFICATION

SAIL	
Packages	BFS, Vials, Ampoules, PFS, Cartridges
Package size	Ø [10 - 69] mm
Fill level	[1- 250] ml
Container Material	Glass (Tubing, Molded, Clear, Amber) Plastic (PE, PP, etc)
Product	Lyo, Liquid, Powder
Test method	AVI- CCIT- HGA
Output rate	50 - 500 cph

OVERVIEW

SAIL is an automated inspection laboratory especially designed to conjugate sensitivity performance, productivity as well as flexibility to inspect different containers types and sizes as well as contents.

It features:

- One or more stations for Automatic Visual Inspection allowing to perform any kind of foreign particles inspection and cosmetic analysis.
- Enhanced defect identification thanks to improved algorithms to perform simultaneous analysis based on different criteria.
- Automatic container handling, spinning and tilting to ensure precise and complete inspection results.
- Extreme stability and accuracy in the inspection of difficult to inspect parenterals.
- Extended recording volume to collect images for subsequent verifications.
- Additional stations for Vacuum-Decay based CCIT and/or Laser- Based HGA for Oxygen/Moisture/CO2/ Vacuum level control.
- HMI real-time display of acquired and analyzed images on 22" Touchscreen
- Computerised system fully compliant with 21 CFR Part 11.
- Format change negligible by means of automatic support
- In-line interfacing possible.
- Industry 4.0 compliant.



PK-VIS

Rotary Visual Inspection machine



Defect
Free



- 100% In line and Off-line.
- Up to 600 cpm.
- New algorithms.

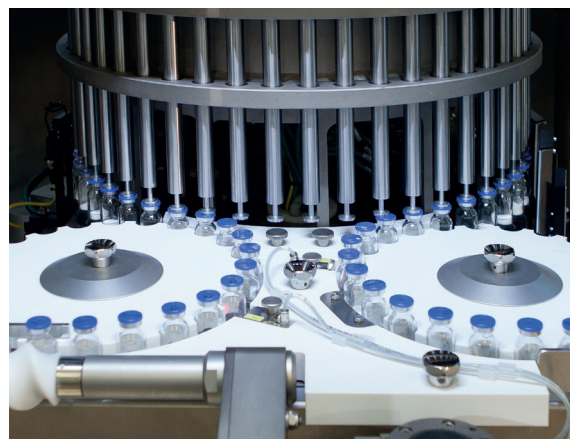
TECHNICAL SPECIFICATION

PK-VIS	
Packages	Ampoules, BFS, Carpoules, PFS, Vials
Package size	Ø [14 - 54] mm
Fill level	[1- 100] ml
Container Material	Glass (Tubing, Molded, Clear, Amber) Plastic (PE, PP, etc)
Product	Lyo, Liquid, Powder
Test method	AVI
Output rate	100- 600 ppm

OVERVIEW

PK-VIS is designed for non-destructive and non-intrusive Automatic Visual Inspection (AVI) of containers with pharmaceutical products. It features:

- The machine is suitable for 100% in-line and off-line inspection at high production speed.
- AVI is performed using high resolution cameras coupled with illuminators automatically positioned so to magnify regions of interest and designed according to defect type.
- The measurement system is a computer based automated system that, taking images of packages, visually inspect them to detect visual defects through image acquisition, processing and decision making.
- Compact footprint (1600 x 1600 mm).
- Defects that can be detected using AVI include but are not limited to: presence of foreign contaminants (particles or fibers) inside the product (liquid or solid), cosmetic defects present on the container body and cap, product fill level, color and product out of specifications.
- Maximum accessibility of electrical and mechanical component for easy maintenance.
- Connections to Active Directory and VPN router for machine remote access are optionally available.
- Validation package guarantees complete and efficient regulatory compliance.



COMBI Series

On-line Combined CCIT, HGA and Visual Inspection Automatic Machine

All
in one



- Two inspection processes, one operator.
- Optimized solution.
- Custom design.

TECHNICAL SPECIFICATION

COMBI SERIES

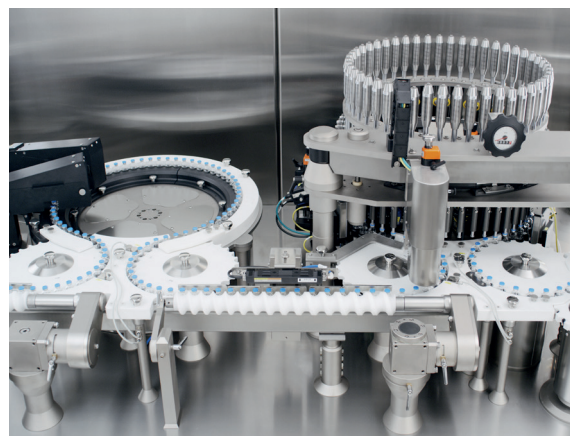
Packages	Ampoules, BFS, Carpoules, PFS, Vials
Package size	Ø [14 - 54] mm
Fill level	[1- 100] ml
Container Material	Glass (Tubing, Molded, Clear, Amber) Plastic (PE, PP, etc)
Product	Lyo, Liquid, Powder
Test method	VDM/HGA + AVI
Output rate	Up to 600 ppm



OVERVIEW

The COMBI series puts CCIT, AVI and HGA all under one roof as the ideal solution to ensure Quality and Safety of Parenteral Packages and verify: the existence of leaks, headspace gas content and the presence of visible foreign materials. A single machine designed to provide customers with a comprehensive set of benefits:

- Compact footprint with optimized floor space requirements, high flexibility in space allocation and the option of remote electrical cabinets.
- Only one operator and a single validation & qualification procedure.
- All-in-one solutions for high integration feasibility of different modular inspection technology systems in connection with a wide choice of links to the up-stream and down-stream line flow.
- The automatic ejection system can be set on a single “One for all” or a multiple “One for each” output.
- Test and Inspection results are documented and stored together ensuring 100% traceability. Connecting to “Manufacturing Execution System” and “Electronic Batch Record” allows production data to be exchanged and/or downloaded (also remotely) to the line network for production, management and control.
- Total cost reduction thanks to ease of maintenance, faster format changeovers, lower energy consumption.





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