

AUTOMATIC INSPECTION SYSTEMS

ASV
SERIES



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Laboratory of industrial research

Art. n. 14 of ministerial decree n. 593 of 8 august 2000

*Ministero dell'istruzione,
dell'Università e della Ricerca*



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Developed to process ampoules, vials and cartridges filled with sterile products, the A&V series of fully automated inspection machines represents the ideal solution to comply with GMP requirements and to ensure that injectable products are essentially free of contamination.

A&V machines combine multiple control stations and different lighting sources and techniques with optimal mechanical handling and transport systems. Servo-motor drives are largely used to finally tune the container spinning speeds and the relevant motion patterns. A neat design and structure allow easy cleaning of all working surfaces and direct access for maintenance operations. Change-over is rapid and simple thanks to pinned and quick-release parts.

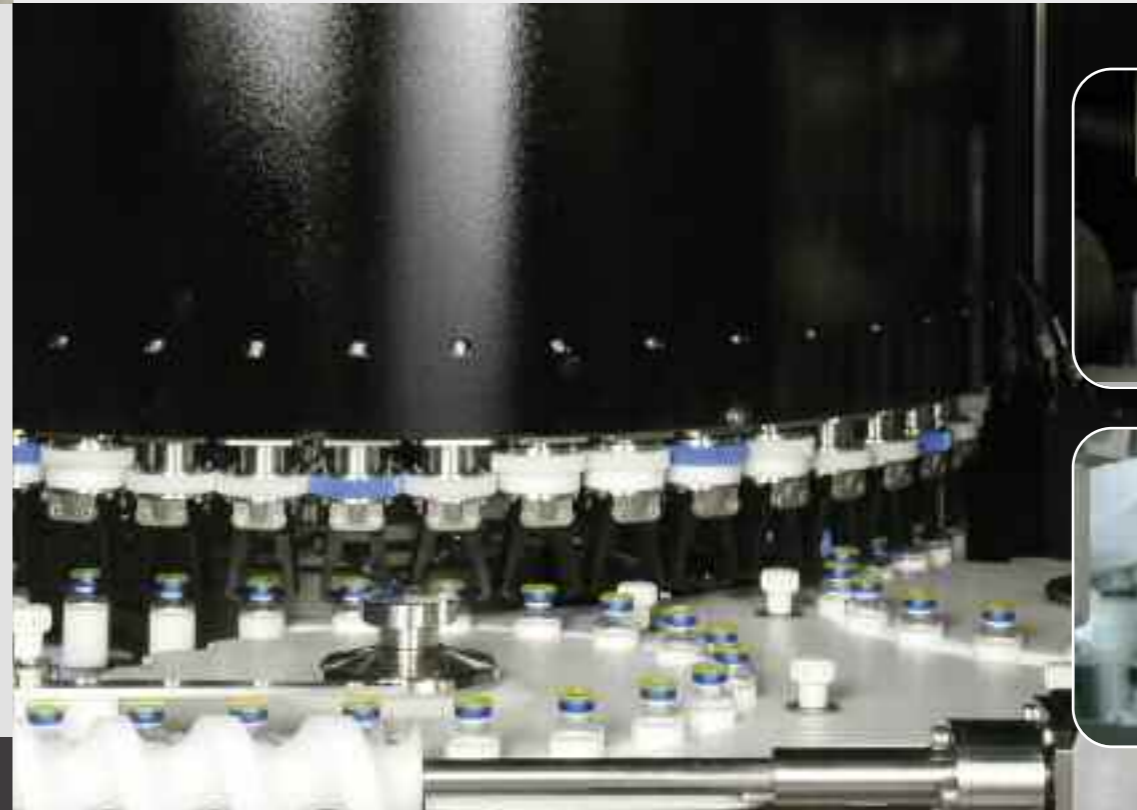
Powerful image processing hardware and tailored up detection algorithms and programs are integrated in a sound inspection system to enhance detection capabilities and to limit false rejection rates.



"The presence of particulate matter in intravenous injections represents a potentially life-threatening hazard".

International Pharmacopeia's guidelines state that, prior to dispensing, all containers of parenteral preparations have to be inspected to the extent possible for the presence of visible foreign and particulate matter in their contents. Also, containers have to be tight to prevent alteration to their physical properties.

GF Spa manufacture a complete range of optical inspection machines designed and built based on a long standing experience in mechanical handling and control systems, while ensuring a constant commitment to keep up with the fast development of visual and optical devices to finally guarantee high performances and consistent detection results.



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A & V INSPECTION MACHINES



AMP
OULES



VIALS



CARTRIDGES

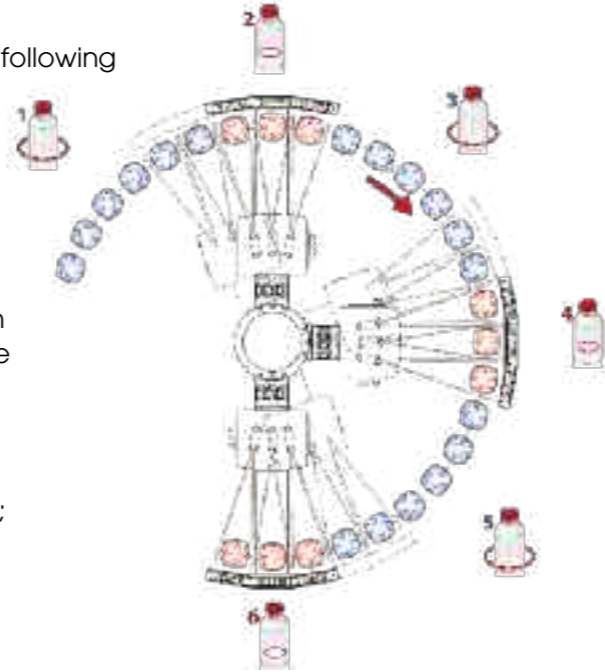


STANDARD MACHINE

In the standard execution of the A&V series machines, each container is inspected at least three times for particles. If deemed necessary a fourth station can also be installed.

The inspection process consists of the following steps:

1. the container is rotated at high speed and then abruptly stopped;
2. the solution keeps rotating by its inertia, so do particles;
3. TV cameras move synchronized with the container transport system while a sequence of images is taken;
4. the different images are processed by the subtraction method to reproduce the particle motion path;
5. a number of inspection parameters are set and considered to finally accept or reject that specific container.



Only moving particles are detected, while marks on the container surface (like printed information or logo and scratches) are ignored.

More lighting techniques are used to enhance and detect particles of various origin and nature.

Usually, the light scattering method against a dark background (Tyndall effect) is adopted for glass and similar high reflective materials.

The light transmission method (shadow detection) is instead used for fibres or low reflective bodies like rubber from the vial stoppers or carbon particles in ampoules.

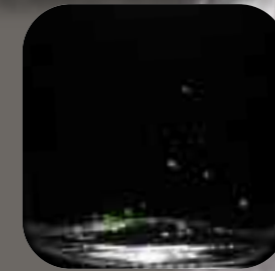
Light polarization can be also implemented to limit false rejection because of the presence of air bubbles trapped within the product.

Images and light signals can be focussed in specific areas of the container so to narrow down the inspection according to the motion behaviour of particles of different materials and sizes.

Similar inspection techniques are also used for non transparent products like antibiotic powders, freeze-dried cakes, and suspensions.

PARTICLES DETECTION

TRANSPARENT products



Light particles (bottom light)



Light particles (back light)



Level control (back light)



Heavy particles control

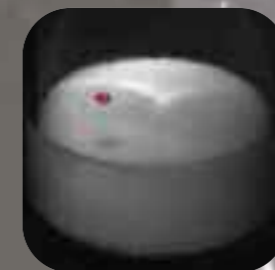


Floating particles control



Meniscus particles control

NON TRANSPARENT products



Upper surface control



Side walls control



Bottom control





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COSMETIC CONTROLS



Other than particle inspection, A&V series machines provide the so-called "cosmetic" or functional controls, meaning by that the whole categories of checks for faults and defects relevant to the container itself and its closure. These are carried out to ensure the safety of the product.

In this case we need to further differentiate between "static" and "dynamic" checks. During a static check the inspection is carried out while the container is in a fix position; vice versa, during a dynamic check the container rotates at low speed.



Single or multiple image processing as well as different lighting techniques are used depending on the properties of the fault to be detected.

Cosmetic and/or functional faults that can be inspected are:

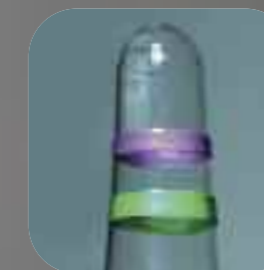
- Ampoule tip blackburns, deformation, OPC, etc.
- Cap and alu-seals presence, position, crimp quality, scratches, colour, and dents
- Side wall and base cracks, scratches and chips of glassware containers

All the checks carried out to inspect non transparent products like powder, free-drieds, and suspensions can also be assimilated to the various cosmetic controls.

In this case light sources and telecameras are positioned at different angles to enhance the response of the system to the specific false that should be rejected (for example: light dark particles laying on top of the cake, heavy glass chips at the base of the container, etc.)



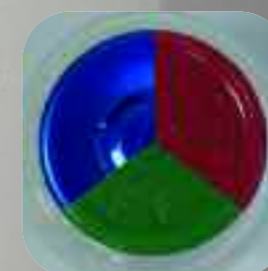
Tip quality control



Color code control



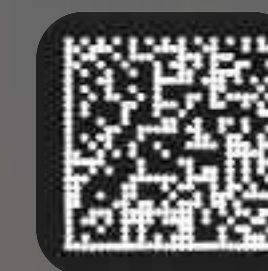
OPC presence control



Aluminum cap top control



Crimping quality & cap defects control



Data matrix code control



Side walls cracks control



Side walls scratches control



Glass air bubbles control



Rubber stopper defects



Particles between stopper & neck



Special customized applications

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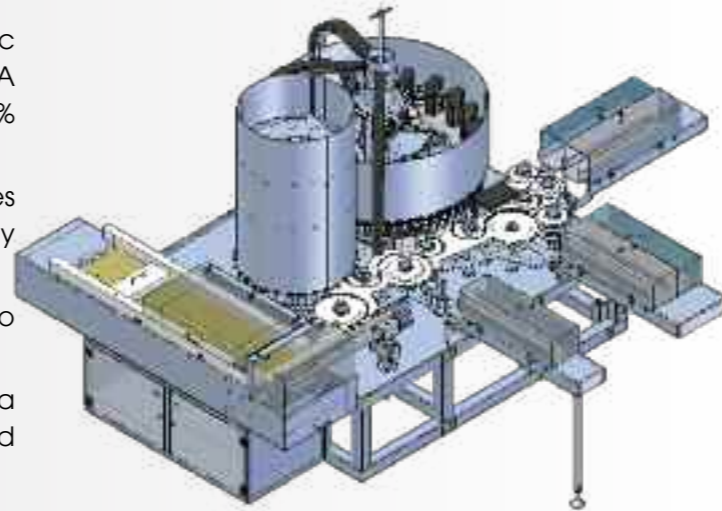
MONOBLOC SYSTEMS

GF S.p.A. integrate the benefits of particle and cosmetic inspection with the advantages of vacuum leak detection. A complete and compact modular solution to achieve a 100% inspection of pharmaceutical products.

The carousels are equipped with different gripping devices to always provide the best positioning to carry out the many checks required.

Monobloc machines can also integrate rinsing modules to wash and clean the containers externally.

These machines are run by a single operator and allow a better logistic and material handling thanks to a reduced printfoot space.



GF S.p.A. can integrate leak testing modules to ensure the integrity of both glass and plastic containers.



LEAK TESTING



Leakage prevention is a major concern when it comes to patient safety. Testing procedure consists of the following steps:

- Container positioning under a pressurized head
- Creation of air hermetically sealed environment
- Vacuum application
- Pressure drop monitoring

As alternative, high voltage leak testing can also be provided.

RINSING MODULES

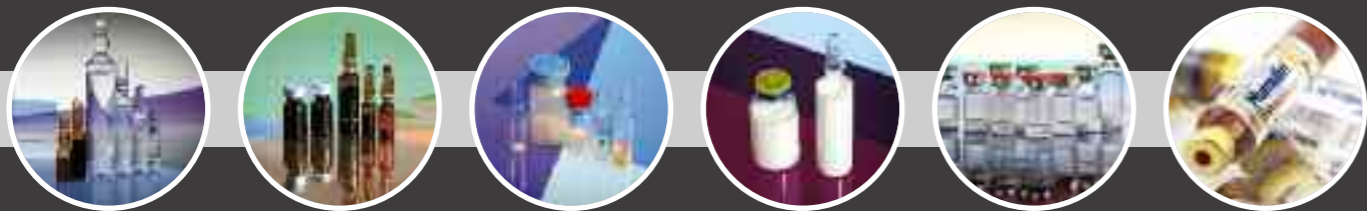
Freeze-drying processes or the need to ensure that glass containers are externally free of product residue (for example: in case of potent drugs) call for the implementation of special rinsing modules.

Containers are first externally washed and then dried to finally undergo leak testing and/or particulate and cosmetic inspection.



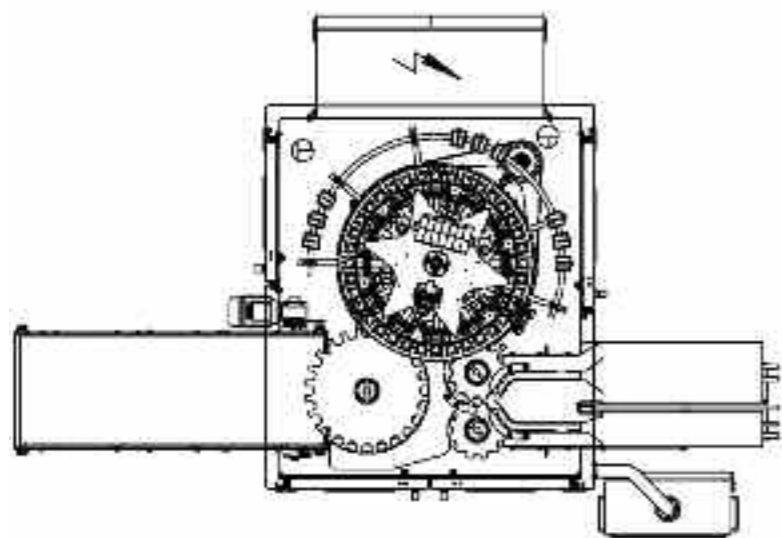
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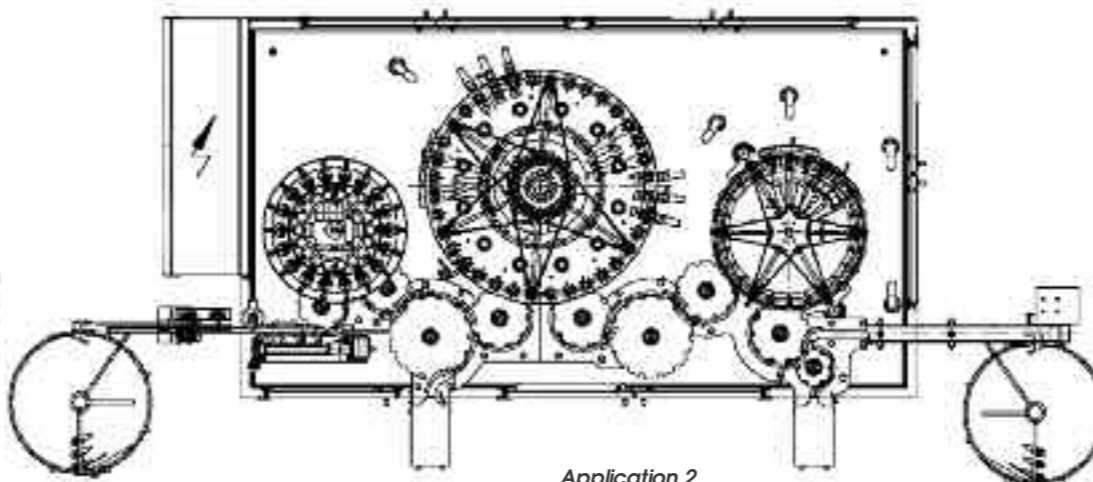


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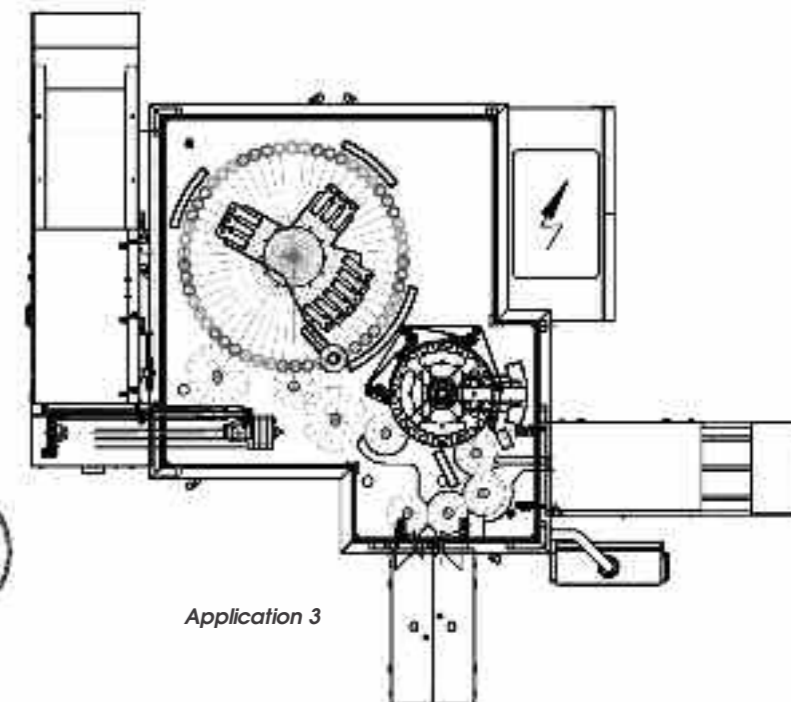
APPLICATIONS & MONOBLOC EXAMPLES



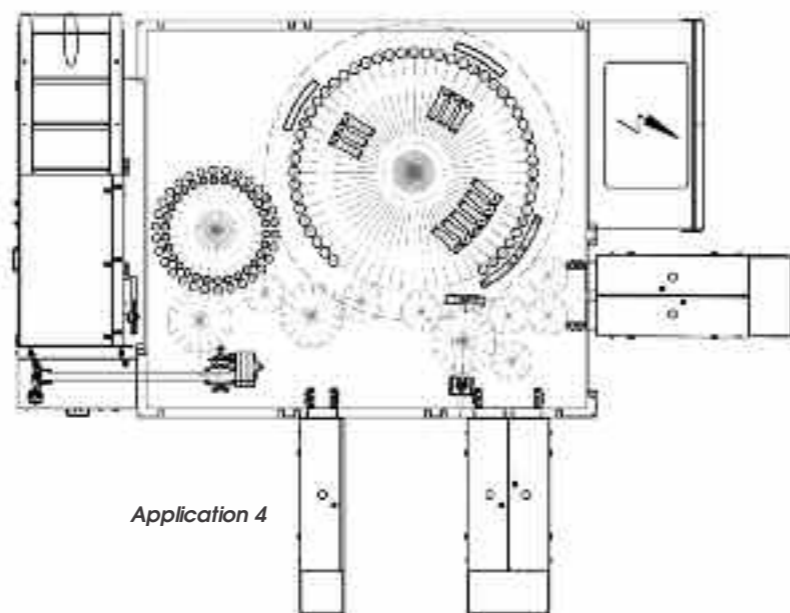
Application 1



Application 2



Application 3



Application 4

MODELS & MACHINE MAIN FEATURES

Machine Model	Containers type	Containers formats	Maximum speed	Liquid	Lyo	Susp	Powder
A&V 150	Ampoules Vials Cartridges	From 1ml up to 30 ml From 1 ml up to 100 ml From 1 ml up to 10 ml	9.000 container/hour	√	√	√	√
A&V 250	Ampoules Vials Cartridges	From 1ml up to 30 ml From 1 ml up to 100 ml From 1 ml up to 10 ml	15.000 container/hour	√	√	√	√
A&V 300	Ampoules Vials Cartridges	From 1ml up to 30 ml From 1 ml up to 100 ml From 1 ml up to 10 ml	18.000 container/hour	√	√	√	√
A&V 400	Ampoules Vials Cartridges	From 1ml up to 30 ml From 1 ml up to 100 ml From 1 ml up to 10 ml	24.000 container/hour	√	√	√	√
A&V 600	Ampoules Vials Cartridges	From 1ml up to 30 ml From 1 ml up to 100 ml From 1 ml up to 10 ml	36.000 container/hour	√	√	√	√

The models indicated in the table represents standard machines. Special applications are also available for treating bigger containers. All the technical data given in this brochure are therefore subject to change without prior notice or without liability.

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A&V INSPECTION MACHINES



A&V series machines is the answer to the ever increasing market demands of high production capacities and configuration flexibility.

Versatile units can be designed and engineered, tailored up to solve complex inspection processes, while still maintaining ease of use, or whenever the floor space occupation in the workshop represents a constraint.

Loading/unloading operations can be adapted to the in-place handling logistics.

Multiple rejection segregation can be provided to assist spot quality inspection.