When Inspection Needs Perfection

Inspection Machines
Ampoules, Vials, Cartridges, LVP, Pre-filled Syringes.

When Inspection Needs Perfection
The history

Since the late 1950s, Brevetti C.E.A. has been manufacturing inspection machines for injectable pharmaceutical products. The company first concentrated on the production of semi-automatic machines until when, thanks to the intuition of the Owner, the production shifted its focus on fully automated inspection systems, which now represent the core business of Brevetti C.E.A.

The first automatic inspection machine was the “ATM18S” for ampoules, manufactured in 1980 when the availability of first photodiode sensors made it possible to automatically detect particles that contaminate pharmaceutical products.

The first inspection machine for vials was launched in 1987. The machine vision system was “Nucleo”, a revolutionary technical approach to inspection methods based on the differential inspection of images (image subtraction method). This technology has been developed and improved over the years, but still represents the basic principle for our machines.

The first machine for the inspection of pre-filled syringes was manufactured in 1992 and its production capacity was 6,000 pieces per hour. In 2006 Brevetti C.E.A. applied the “High Speed Camera” technology on “K15-600” and “K32-600” machines, capable of inspecting 36,000 containers per hours and granting an acquisition of min. 24 images per each inspection device: by increasing the inspection frequency, the chances to seize defects is consequently increased. This technology enables our machines to get real efficiency values that were believed to be impossible to reach, not only on standard products but also on complex applications like vaccine and freeze-dried products.

As a further proof of Brevetti C.E.A. total commitment to continuous research and devotion to vision applications, during the years the Company developed a sophisticated in-house vision system, which includes an owned library adaptable to all different inspection requirements.

Today Brevetti C.E.A. boasts of more than 2,000 inspection machines installed worldwide, half of which fully automatic.

To be continued ……………
K15 is an automatic inspection machine for particle and cosmetic inspection of pre-filled syringes configured to be installed in a fully automated line. K15 has been designed as the right answer to the market demand in terms of high production capacity and flexibility of configurations: a single, versatile and compact machine.

K32S is an automatic inspection machine for particle and cosmetic inspection of ampoules, vials and cartridges. Design, configuration flexibility and high productivity are the key-factors of its success: a single, versatile and compact machine for liquid and freeze-dried products.

**K32S**
- Machine nominal speed: up to 400 pcs/min
- Container Diameter: up to 32mm
- Particles, fill level and cosmetic inspection
- RPV Remote Parameterization & Validation
- Manual loading
- “Fail safe” reject verification system (Optional)
- 21 CFR part 11 compliance for electronic records (recipes, batches/sub-batches, audit trail)
- Ethernet connection
- User friendly interface
- In-line connection to upstream and downstream equipments.
- Leak Detection available for freeze-dried products (Headspace Gas Analyser)
- Product colour (Spectrometer)
- Product opacity (Opacimeter)
- OCR/OCV

**K15**
- Machine nominal speed: up to 200 pcs/min
- Container Diameter: up to 14,45mm
- Particles, fill level and cosmetic inspection
- RPV Remote Parameterization & Validation
- “Fail safe” reject verification system (Optional)
- 21 CFR part 11 compliance for electronic records (recipes, batches/sub-batches, audit trail)
- Ethernet connection
- User friendly interface
- In-line connection to upstream and downstream equipments.
- Needle shield inspection with High Voltage
- Product colour (Spectrometer)
- Product opacity (Opacimeter)
- OCR/OCV

**K32-600**
- Machine nominal speed: up to 600 pcs/min
- Container Diameter: up to 20mm
- Particles, fill level and cosmetic inspection
- RPV Remote Parameterization & Validation
- Manual loading
- “Fail safe” reject verification system (Optional)
- 21 CFR part 11 compliance for electronic records (recipes, batches/sub-batches, audit trail)
- Ethernet connection
- Product colour (Spectrometer)
- Product opacity (Opacimeter)
- OCR/OCV

**K15-C200**
- Machine nominal speed: up to 200 pcs/min
- Container Diameter: up to 14,45mm
- Particles, fill level and cosmetic inspection
- RPV Remote Parameterization & Validation
- “Fail safe” reject verification system (Optional)
- 21 CFR part 11 compliance for electronic records (recipes, batches/sub-batches, audit trail)
- Ethernet connection
- In-line connection to upstream and downstream equipments.
- Needle shield inspection with High Voltage
- Product colour (Spectrometer)
- Product opacity (Opacimeter)
- OCR/OCV

**K15-600**
- Machine nominal speed: up to 600 pcs/min
- Container Diameter: up to 10,85mm
- Particles, fill level and cosmetic inspection
- RPV Remote Parameterization & Validation
- Manual loading
- “Fail safe” reject verification system (Optional)
- 21 CFR part 11 compliance for electronic records (recipes, batches/sub-batches, audit trail)
- Ethernet connection
- In-line connection to upstream and downstream equipments.
- Needle shield inspection with High Voltage
- Product colour (Spectrometer)
- Product opacity (Opacimeter)
- OCR/OCV
A50

A50 is an automatic inspection machine for particle and cosmetic inspection of liquid and freeze-dried products. It has been designed to inspect a wide range of containers (cartridges, ampoules and vials) from 1 to 100 ml at a mid-range speed, granting high level performances.

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<td>Up to 52mm</td>
<td>Up to 32mm</td>
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<td>Particles, fill level and cosmetic inspection</td>
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<td>In-line connection to upstream and downstream equipments.</td>
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<td>Leak Detection available for freeze-dried products (Headspace Gas Analyser)</td>
<td>Leak Detection available for liquid products (High Voltage)</td>
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<tr>
<td>Product colour (Spectrometer)</td>
<td>Product opacity (Opacimeter)</td>
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<td>Product opacity (Opacimeter)</td>
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BL-S300

BL-S300 represents a complete solution for the needs of Large Volume Parenteral market. Ranging from 100 ml vials up to 1000 ml bottles, through its flexible design, the machine is able to grant high performances on all configurations.

<table>
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<tr>
<th>MAIN FEATURES</th>
<th>LVP - Large Volume Parenteral inspection machine (Liquid and Freeze-dried products)</th>
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<td>Container Diameter: Up to 110 mm</td>
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<td>Particles, fill level and cosmetic inspection</td>
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<td>User friendly interface</td>
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<td>In-line connection to upstream and downstream equipments.</td>
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</table>
A30 is an automatic inspection machine for particle and cosmetic inspection of cartridges, ampoules and vials containing liquid and freeze-dried products. A30 is configured to be loaded manually or installed in-line.

**Main Features**
- **Machine nominal speed:** Up to 300 pcs/min
- **Container Diameter:** Up to 32mm
- **Particles, fill level and cosmetic inspection**
- **RPV Remote Parameterization & Validation**
- **Manual loading**
- **“Fail safe” reject verification system (Optional)**
- **21 CFR part 11 compliance for electronic records (recipes, batches/sub-batches, audit trail)**
- **Ethernet connection**
- **User friendly interface**
- **In-line connection to upstream and downstream equipments.**
- **Leak Detection available for freeze-dried products (Headspace Gas Analyser)**
- **Product colour (Spectrometer)**
- **Product opacity (Opacimeter)**

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A35 is an automatic inspection machine for particle and freeze-dried products. A35 has been designed to inspect a wide range of containers (cartridges, ampoules and vials) from 1 to 30 ml at mid-range speed granting high level performances.

**Main Features**
- **Machine nominal speed:** Up to 200 pcs/min
- **Container Diameter:** Up to 36mm
- **Particles, fill level and cosmetic inspection**
- **RPV Remote Parameterization & Validation**
- **Manual loading**
- **“Fail safe” reject verification system (Optional)**
- **21 CFR part 11 compliance for electronic records (recipes, batches/sub-batches, audit trail)**
- **Ethernet connection**
- **User friendly interface**
- **In-line connection to upstream and downstream equipments.**
- **Leak Detection available for freeze-dried products (Headspace Gas Analyser)**
- **Product colour (Spectrometer)**
- **Product opacity (Opacimeter)**
- **OCR/OCV**
LDM performs Integrity Test through a well-known and widely proven detection principle based on the measurement of electrical conductivity of the sealed containers using a high voltage electric field. LDM introduces the new concept of leak-inspection: a special handling system combined with high conductivity electrodes lead to an accurate detection of the smallest micro-holes. Available as a modular solution, it can be combined to A35, K32S and A50-450 inspection machines, becoming the most compact and performing “Inspection Line” for ampoules, vials and cartridges available on the market.

**MAIN FEATURES**

- **Machine nominal speed:** up to 400 pcs/min
- **Container Diameter:** up to 32mm
- **Manual loading**
- **“Fail safe” reject verification system (optional)**
- **21 CFR part 11 compliance for electronic records (recipes, batches/sub-batches, audit trail)**
- **Ethernet connection**
- **User friendly interface**
- **In-line connection to upstream and downstream equipments.**
- **Leak Detection for liquid products (High Voltage)**

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**A35 LD**

Integrated Leak Detection Module

**K32S LD**

Integrated Leak Detection Module

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**MAIN FEATURES**

- **Machine nominal speed:** up to 300 pcs/min
- **Container Diameter:** up to 32mm
- **Particles, fill level and cosmetic inspection**
- **RPV Remote Parameterization & Validation**
- **Manual loading**
- **“Fail safe” reject verification system (optional)**
- **21 CFR part 11 compliance for electronic records (recipes, batches/sub-batches, audit trail)**
- **Ethernet connection**
- **User friendly interface**
- **In-line connection to upstream and downstream equipments.**
- **Leak Detection available for liquid products (High Voltage)**
- **Leak Detection available for freeze-dried products (Headspace Gas Analyser)**
- **Product colour (Spectrometer)**
- **Product opacity (Opacimeter)**
- **OCR/OCV**
A1 revolutionary concept merges the human into the automatic visual inspection, combining the advantages of motion and optics flexibility with the stability of inspection results. The wide set of software tools specifically developed for A1 make the robot a powerful system very easy to setup and validate.

### Main Features
- **Machine nominal speed:** up to 50 pcs/min
- **Container Diameter:** up to 95mm
- **Particles, fill level and cosmetic inspection**
- **Manual loading**
- **“Fail safe” reject verification system (Optional)**
- **21 CFR part 11 compliance for electronic records (recipes, batches/sub-batches, audit trail)**
- **Ethernet connection**
- **User friendly interface**
- **In-line connection to upstream and downstream equipments.**
- **Leak Detection available for liquid products (High Voltage)**
- **Leak Detection available for freeze-dried products (Headspace Gas Analyser)**
- **Product colour (Spectrometer)**
- **Product opacity (Opacimeter)**
- **OCR/OCV**
- **21 CFR part 11 compliance for electronic records (recipes, batches/sub-batches, audit trail)**
- **Ethernet connection**
- **User friendly interface**
- **In-line connection to upstream and downstream equipments.**

### Features

#### High Speed Cameras
High Speed Cameras can acquire hundreds of images for each object to be inspected. Compared with other standard technologies, High Speed Cameras allow an efficiency increase and a reduction of false reject. More images = more accuracy in defects detection and less false rejection rate = Higher Efficiency.

#### PFS Leak Inspection with high voltage spark test
The measure of the electrical conductivity on the PFS is an efficient method to detect leakages which are typically due to cracks or to sealing defects. The syringe passes between two electrodes placed on the main turret and a high voltage source (10 to 20 kV) is applied. The system is capable to detect variations in conductivity by measuring the current flow in the circuit.

### Process Analytical Technology

#### Head space gas analyzer
HGA is a no-contact measurement device, suitable for the inspection of containers filled with powder or freeze dried products. Both Oxygen and Moisture concentration can be controlled by the TDLAS spectroscopic technology (Tunable Diode Laser Absorption Spectroscopy).

#### Optical density measuring system
CDMS device allows to discriminate the opacity or turbidity of a liquid product and it is mainly used to verify the vaccine/suspension concentration. This technology includes a visible laser diode modulated in intensity and stabilized in temperature and a phase-sensitive detector to reduce outside interferences and electronic drifts.

#### Spectrometer
Through the spectrum analysis, this instrument allows to detect possible product degradation and to implement anti-mix-up functions. Based on new LED lighting system, the Color Analyzer is available for all type of containers.