

design and manufacturing of inspection machines

Taipei, 14th May 2012
Seminar on leak test and particles inspection
UTEK INTERNATIONAL COMPANY



SUMMARY

Part 1 Leak detection Particles inspection

Part 2
Presentation of Convel
Products overview
TS – Leak detection machine
C2/C2D – Automatic particles inspection machine



LEAK DETECTION



METHODS FOR LEAK TEST

Method	Description	Advantages	Drawbacks
Methylene blue bath	Samples of containers are put in a bath of dye and pressure is applied.	■ Easy to be performed without skilled people	 Possibility to send out a leaking container due to wrong visual recheck
	Colour enters inside leaking containers		 Difficulty to be applied to coloured products
	changing the colour of liquid.		 Difficulty to be applied to vials
	Containers are then		■ Slow
	rechecked to recognize and reject the coloured ones		 Problem of cleaning the container of the bath and to waste the dye
			■ Low sensitivity
			 Suitable only to test samples and not 100% of production



METHODS FOR LEAK TEST

Method	Description	Advantages	Drawbacks
Vacuum/Pressure cycle in autoclave Standing ampoules	A cycle of high pressure is performed inside the autoclave. Due to the difference of pressure, the tips of leaking containers explode. The ampoules are then rechecked for missing or broken tips.	Ampoules with broken tips are easy to be recognized	 All containers must be rechecked The method can detect only big cracks present only in the tips, bottom part is excluded Sensitivity is very low
Vacuum/Pressure cycle in autoclave Upside – down ampoules	Ampoules are put upside down inside the autoclave A cycle of high pressure is performed inside the autoclave. Due to the difference of pressure, the liquid goes out from the leaking tip. The ampoules are then rechecked by automatic inspection machines for filling level	■ Easy ■ Higher sensitivity for the detection of the cracks in the tip with respect to standing ampoules method	 The method can detect cracks present only in the tips, bottom part is excluded Sensitivity is low Very slow and tedious due to the need to reverse the ampoules Inspection machines are usually not setup to detect the difference in filling level due to leaks of just some drops



METHODS FOR LEAK TEST

Name	Description	Advantages	Drawbacks
High Voltage	An high voltage (up to 35 KV) is applied to the container and the current passing through it is measured. In case of presence of microcracks, the liquid inside the ampoule becomes conductive.	 Fast automatic test on 100% of production High sensitivity (cracks in the range of micron) 100% of container surface can be tested Easy to be applied to all types of containers, vials with metallic alucap sealing too 	 Applicable only to liquid products Depending on conductivity of the product (distilled water or oily products are difficult to be tested)



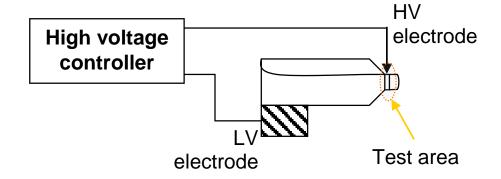
PRINCIPLES OF HIGH VOLTAGE METHOD

High voltage sparks are generated between the tip and the bottom of the container.

Glass is a perfect isolating material: only minimal current passes through a perfectly sealed container.

In case of microholes, the liquid inside makes a kind of 'short-circuit'; so a high current passes through it

Necessary condition is that liquid wets all the internal sideglass of the container from the bottom up to the top. That's why it is required the positioning in horizontal





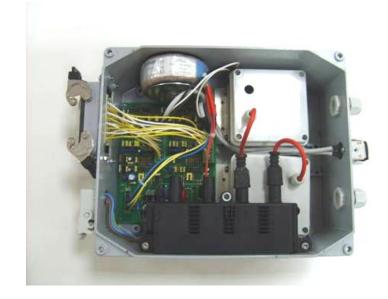
GENERATION OF HIGH VOLTAGE

The maximum voltage required for this application is in the range of 30-40 KV.

A dedicated transformer is required to generate it from low voltage and a resistors shunt to limit the current passing through the container.

Convel electronic generates trains of pulses of sparks up to 40 kV at about 800 Hz; with respect to methods based on DC current, it has the important advantage to reduce the overheating of transformer and of circuitry and to control the average energy transferred to the container.

These pulses are generated by a compact and rugged electronic device all included in a metallic box.





MEASUREMENTS

The signal coming from the system electrodes + ampoule must then be analyzed.

Two values are used to analyze the signals:

Peak value: proportional to the maximum current

Average value: Convel has patent pending a special algorythm to calculate a kind of average signal in case of pulsed sparks

Note: the measurements give information about the presence of the crack and not about its dimension





OPERATORS SAFETY AND PRODUCT DEGRADATION

Production of high voltage sparks doesn't damage the normal product.

Very few energy, even less than 0,8 J in case of Convel technology, is transferred to the container.

Inactive vaccines can be tested too.

The 'stability test', performed before and after inspection, is used to verify it.

Test isn't dangerous for the operator: only minimal current passes through the electrodes.

However, for full safety, the spark isn't emitted when covers are open

The high voltage has the natural effect to produce ozone (O₃) that must be evacuated by the working area





VALIDATION OF HIGH VOLTAGE METHOD

Highest sensibility method: microcracks in the range of 1-10 micron, compatible with microorganism dimension, can be detected

Validation is performed testing containers with calibrated holes

A laser is used to create holes of various calibrated diameters covering the range of 10 – 100 micron for validation test

Several systems 'homemade' to create holes can be easily performed to prepare batches with holes, not calibrated, in the range 70 - 100 micron for periodical check



PARTICLES INSPECTION



METHODS FOR PARTICLES INSPECTION

Method	Description	Advantages	Drawbacks
Manual inspection	The operators check visually the presence of particles. They take by hand some containers and shake them in front of a double background (black and white)	 Operator is capable to distinguish easily particles from glass defects or printing 	 Not repetitive inspection highly depending on operator attention Slow, tedious and tiring job. Many operators are required for inspection of high volumes and they must be regularly replaced
Semiautomatic inspection	A machine transports the containers in front of operator ad provides shaking, rotation and illumination. The operator checks the containers through a lens	 The operator doesn't need to handle the containers The containers are positioned, rotated and lighted always in the same repetitive condition 	More repetitive inspection but still depending on operator attention
		 Suitable to mid volumes production: one machine replaces 4-6 operators 	
		Simple and easy maintenance	



METHODS FOR PARTICLES INSPECTION

Method	Description	Advantages	Drawbacks
Automatic inspection	A machine spins the containers and a camera controls the presence of particles. Inspection is repeated twice for more safety. Filling level is checked too as standard.	 Very fast: there are machines for 150-200-300-400 pcs/hr Repetitive Easy to be validated by means of 'Knapp test' 	 Some false rejects can be caused by presence of imperfections or large printings on glass sidewalls, Some difficulties to inspect coloured or foaming products Skilled operators required for maintenance and new products setup

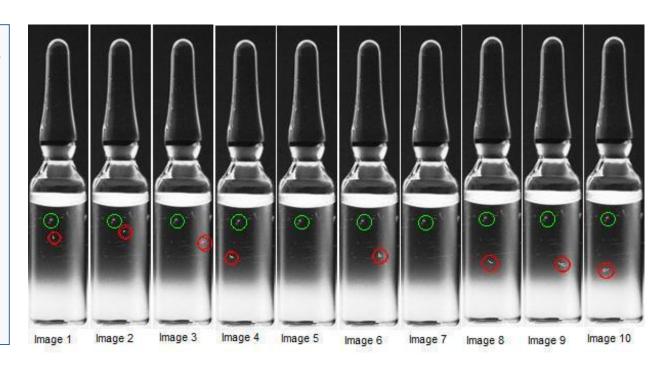


PRINCIPLES OF PARTICLES AUTOMATIC INSPECTION

The PC acquires a sequence of images of the same container that are compared each to the other using the algorithm called 'Image subtraction'.

This method allows to distinguish the fixed objects like printings or dust from moving objects like particles.

Fixed objects (green circle) are present always in the same pixels in all the images; instead, moving particles (red circle) are detected in different parts of container.



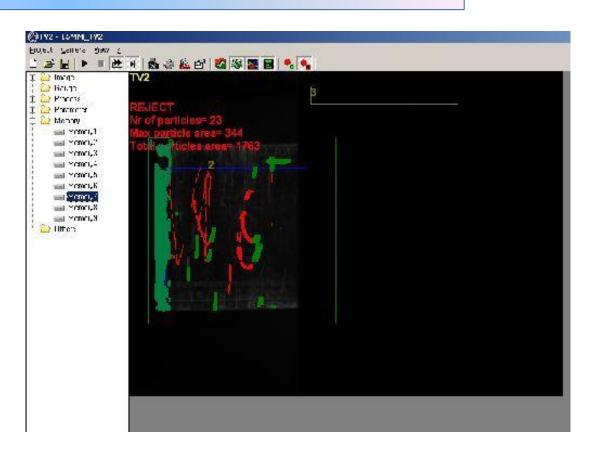


PRINCIPLES OF PARTICLES AUTOMATIC INSPECTION

Fixed particles are easily masked by the software and not analyzed (green parts of binarized image)

Moving objects can be analyzed for the dimension of their area. Group of pixels with area bigger than a selectable threshold (red parts of binarized image) are considered particles to be rejected.

Group of pixels with area lower than the threshold are considered 'acceptable' particles.





ILLUMINATION SYSTEMS

Method	Description	Advantages	Drawbacks
Bottom light (Tyndall effect)	A high power LED illuminates the container from the bottom.	■ Even very small glass particles becomes visible (below 40 micron)	 Some false rejects can be caused due to the collateral effect of undesirable reflections
Glass particles reflects the light towards the camera becoming very bright and well visible	light towards the camera		caused by imperfections or large printings on glass sidewalls,
		 The meniscus must be covered and cannot be inspected 	
			■Dark particles or low reflecting as fibers) are difficult to be detected



ILLUMINATION SYSTEMS

Method	Description	Advantages	Drawbacks
Diffused backlight	A matrix of LED illuminates the container from the back with a diffused uniform light. Dark particles produce a shadow blocking the passage of light	 Not reflecting dark particles become visible Meniscous area can be inspected too 	 Only very dark and big particles are visible; reflecting light particles are not detectable. Only in double polarized version it is possible to detect fibers



ILLUMINATION SYSTEMS

Method	Description	Advantages	Drawbacks
Collimated backlight	A structured linear light with parallel beams illuminates the	 All kinds of particles (reflecting and not reflecting) are visible 	 Sensitivity is lower than with Tyndall effect. Only particles over 50 micron can be detected.
	container from the back	Meniscus area can be inspected too	 Only the central part of the container is inspected
	Particles produce a shadow blocking the passage of light	■ Repetitive inspection	Use of linear camera doesn't allow to see the acquired images; it's difficult for the operator to understand the
	A linear camera detects the presence of particles		correct working of the machine



VALIDATION METHOD

Due to unpredictable movements and not repetitive visibility of particles, their detection is a statistical phenomenon.

Pharmacopoeia requirement for the validation of an automatic inspection machine is that the result of automatic inspection must be equal or better than human inspection.

Limits of human inspection are considered the detection of particles as small as 40-50 micron about. In standard human inspection, a 50 micron particles is detected in 50% of inspections.

In order to solve this problem, in early 80's Dr. Julius Knapp developed his method that is not based on the measurement of particles dimensions but on the comparison of the results of the inspection performed by operators and by the machine.

Knapp test is actually the only method for validation worldwide accepted.



KNAPP TEST

Knapp test is a statistical approach to the problem mediating the needs of the production with the needs of quality.

The manufacturer must prepare a batch with 250 containers. 80 containers must be rejects with different types of defects (fibers, small glasses, heavy glasses,...) and the remaining 170 must be taken randomly from the real production.

Each container will be identified univocally by a label with a number.

This batch must be checked visually 10 times by 5 different operators for a total of 50 inspection for each container. It's important to check the containers reproducing the conditions of standard production (speed, illuminations, etc...)

Now, the same batch must be tested 10 times by the automatic machine.



KNAPP TEST

Each container will have a 'Quality Factor', that is the number of times it was rejected (normalized to 10). For example, the container number xyz could be rejected 8 times on 10 inspection by automatic machine (QF=8) and 35 times on 50 inspection by the 5 operators (QF= 7).

I consider now only the containers with QF>=7 and I sum all the number of times they have been rejected. The result is the QF total.

A graphic, like the one in following page, must be prepared and the 'crossed quality factor' must be calculated.

The evaluation of the results is based on two concepts:

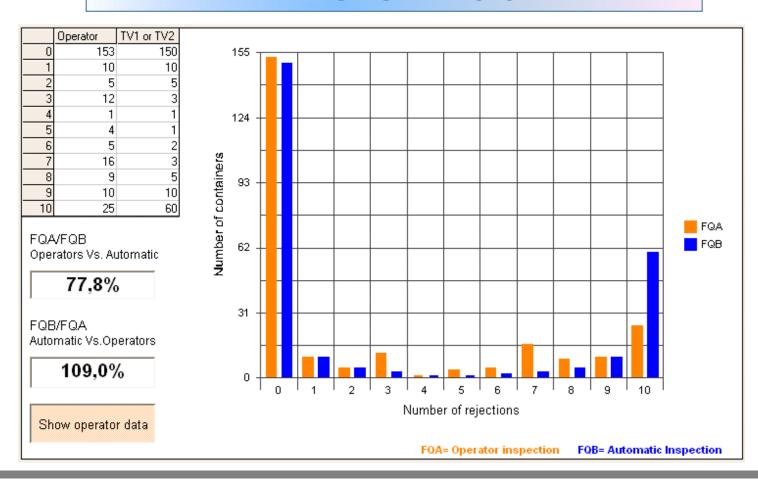
1)QF Automatic >= QF manual

2)The splitting between surely good (0 rejects on 10 inspection) and the surely bad (10 rejects on 10 inspection) must be as much clear as possible with a 'grey zone' (the containers rejected 4-5-6 times) as small as possible.

NOTE: Convel machines have software application for Knapp test automatic execution, calculation of QF factors and printing of graphic chart.



KNAPP TEST GRAPHIC CHART





PRESENTATION OF CONVEL



Convel was founded in 1994 in Vicenza, in North East of Italy.

Aim of this company was the design and manufacturing of electronics equipment.

Since the beginning Convel proposed itself as a R&D outsource group for development of fully new projects: from idea to final product.

In 1998 there was the first contact with pharmaceutical world through some companies located near Vicenza.

By means of know-how coming from the most wide sectors, Convel was capable to supply solutions highly innovative. Actually, Convel has three patents for applications in pharmaceutical inspection.





Convel became soon the supplier of core technology (leak test modules, vision systems, interface software) to well known manufacturers in pharmaceutical world.

Starting from 2009, Convel decided to become itself manufacturer of machines with its own brand and not only supplier of technology.

In only a couple of years a full range of inspection machines was developed. (automatic, semiautomatic, leak test, comby machines, test bench).

Vertex of the fast growing up and demonstration of quality of its production were the recent sales of the model TS for leak test to the multinational **Sanofi Aventis** in Italy and of the bench EasyTS to the *Laboratory of research for aseptic filling* of **Nestlè Waters** in Marysville, Ohio, USA.



PRODUCTS OVERVIEW



C2 /C2D - Automatic inspection machine

C2: up to 12000 pcs/hr C2D: up to 24000 pcs/hr

Ampoules up to 22.5 diam. Vials up to 39 mm diam.

Standard: particles inspection and filling level

Option: ampoules tip, vials alu-cap inspection

Various lighting system (backlight or bottom light) with long life LED

Intermittent motion





TS - Leak test machine

For liquid products

Ampoules and vials up to 32 mm diam.

Up to 24000 pcs/hr

High voltage method

Minimum conductivity of product 2-5 microSiemens/cm

Continuous motion





C2 + TS - Particles + leak test machine

Ampoules and vials up to 32 mm. diam.

Standard: particles inspection, filling level and leak test (all in one)

Option: ampoules tip and vials alu-cap inspection

Up to 12.000 pcs/hr

Various lighting system (backlight or bottom light) with long life LED

Intermittent motion

3700 x 1350 x 1900 mm





EASY TS - Bench for off line leak test

Material	Glass - PET – HDPE - PE
Container	Bottles, ampoules, vials, plastic bags, all kinds of BFS
Product	Liquids, distilled water, drinks
Product conductivity	Over 5 - 10 microSiemens/cm
Sensibility	detection threshold compatible with microorganism dimensions
Method of test	non destructive control using high voltage method test
Dimension	400x360x570mm





PRODUCTS OVERVIEW

RC - Semi Automatic Inspection Machine

Inspection of foreign matters in liquid, freeze dried, powder.

Ampoules up to 22.5 diam. Vials up to 62 mm diam.

High magnfication lens

Up to 6000 pcs/hr (recommended 2000 – 4000 pcs/hr)





PRODUCTS OVERVIEW

VI - Semi Automatic inspection Machine

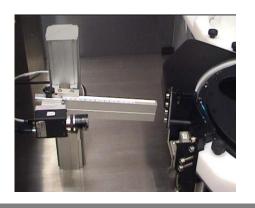
VI-L: inspection of foreign matters in liquid VI-F: inspection of freeze dried and alu-cap of vials

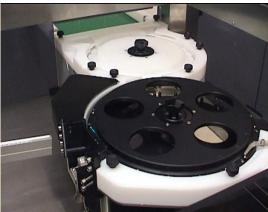
Ampoules up to 22.5 diam. Vials up to 32 mm diam.

High resolution LCD monitor to visualize defects

Up to 6000 pcs/hr (recommended 1000 – 3000 pcs/hr)







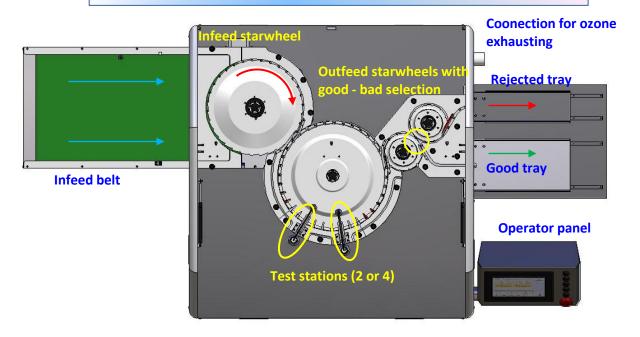


TWIN SPARK - TS LEAK DETECTION MACHINE





GENERICS



CONTAINERS
Ampoules up to 22.5 diam.
Vials up to 32 mm diam

SPEED

Up to 18.000 pcs/hr in standard version Up to 24.000 pcs/hr in special version





TECHNICAL SPECIFICATIONS

SPEED: up to 24.000 pcs/hr (small sizes)

DIMENSIONS: 2975x1500x1300

WEIGTH: 400 kg.

POWER SUPPLY: 230V 50/60 Hz. 1 Ph.

POWER CONSUMPTION: 1,5 KW

UTILITIES:

Ozone exhausting connection Compressed air

NOISE: 75 dB





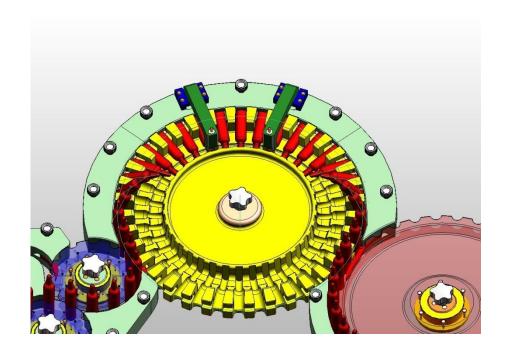
CONVEL' PATENT

To perform the test it is necessary to put the ampoules in horizontal position.

Convel patented a mechanical system to get it using a starwheel and an external cam.

Advantages:

- The machine is very compact and simple
- No need of heavy big parts
- · Incredible easyness of size change
- Incredible easyness of cleaning
- Movement of ampoules is very smooth and their position close to the electrodes is very precise and repetitive

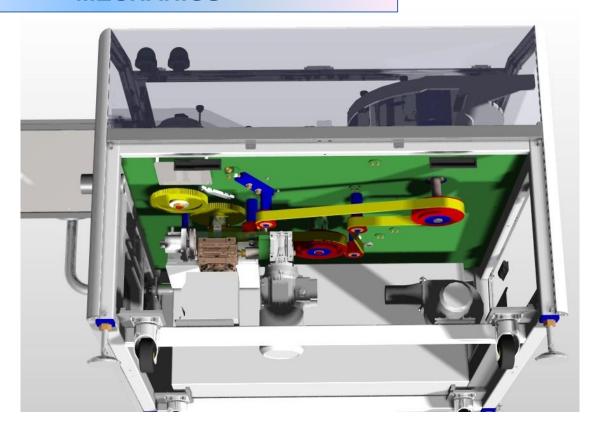




MECHANICS

The patented system for transportation allows an unique semplification of the mechanics and consequently of maintenance.

Only one motor with one power belt moves the whole machine





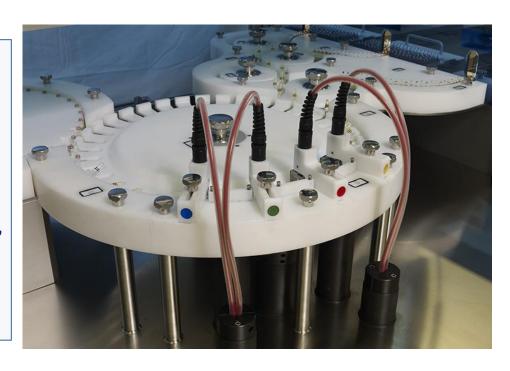
PERFORMANCE

Minimum detectable hole: 1 - 10 micron (tested with calibrated samples made by laser)

Minimum conductivity of liquid required: 2 - 5
microSiemens/cm
(under certain conditions even distilled water or oily
products can be checked)

Inspection area of ampoules (with four electrodes): tip, neck, body and bottom.

No electromagnetic noise nor interference due to presence of high voltage





FEATURES

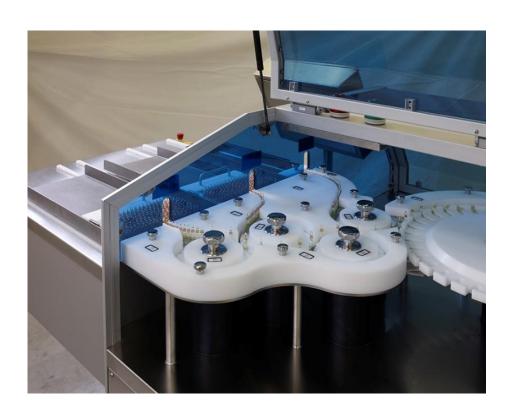
Machine is equipped with clutches, connected to a sensor, at infeed at outfeed to prevent mechanical jam.

Machine is equipped with ozone (O_3) exhausting fan to evacuate it from the machine.

A software program allows to empty easily the machine at the end of batch.

A software program allows the visualization of the correct working of all sensors for maintenance purpose.

Special outfeed with exact counting in double tray for higher speed





SIZE CHANGE

The size change is easily performed replacing the starwheels and selecting the recipes. All parameters are memorized in the PC.

No tools required nor skilled personnel.

15 minutes maximum time.

NO ADJUSTMENT REQUIRED FOR ELECTRODES! The electrodes are included in the size change it's not required to adjust their position! Every time the size has been changed, new electrodes are in use.

Position of electrodes is fundamental to avoid false results. No possibility of mistakes and higher life of electrodes is guaranteed.

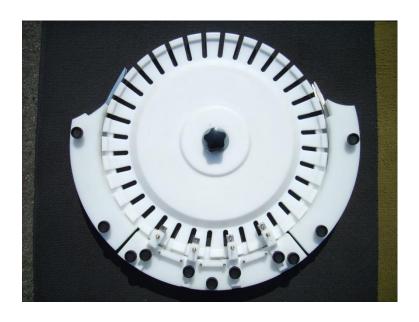




CLEANING

The steel plane allows a full, easy and fast access to all parts when size parts are removed.

Liquid doesn't remain in plastic parts like wormscrew, as in competitor' machine, but falls down over the steel plane through the big holes of the central starwheel.

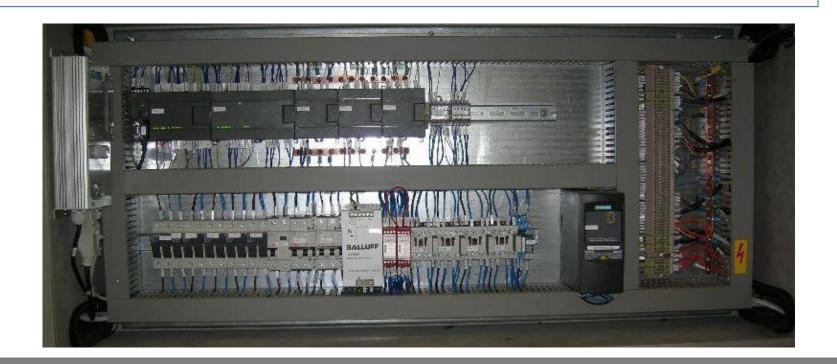






ELECTRIC CABINET

Electric components are selected among the most known worldwide distributed brands: Siemens PLC S7-200, Siemens inverter, ABB motors, Mitsubishi or Allen Bradley components.

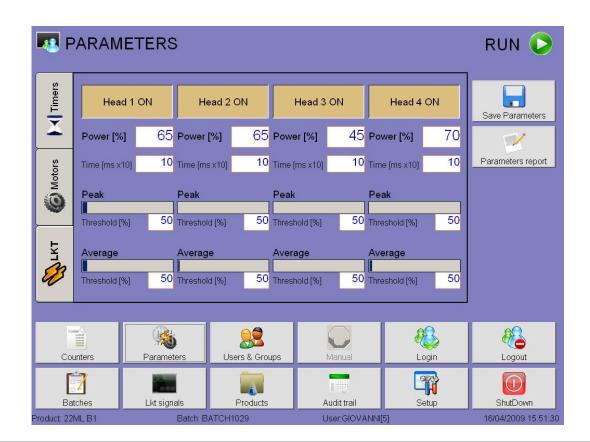




HMI - Parameters

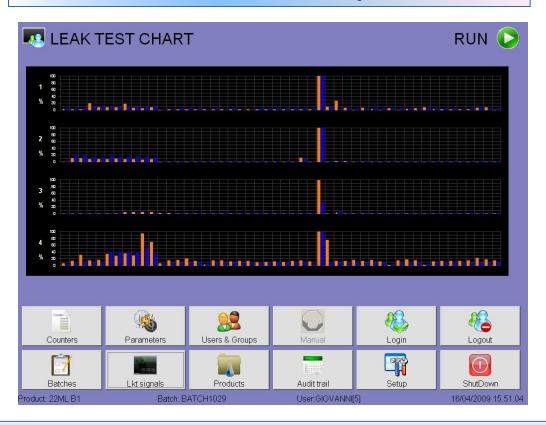
Great effort to reduce the number of parameters for easy and fast setup of new products.

Only power emitted and sensitivity threshold for average and peak values are the parameters required for leak test!





HMI - Historical report



Visualization in real time of the last 100 results of inspection for each electrode

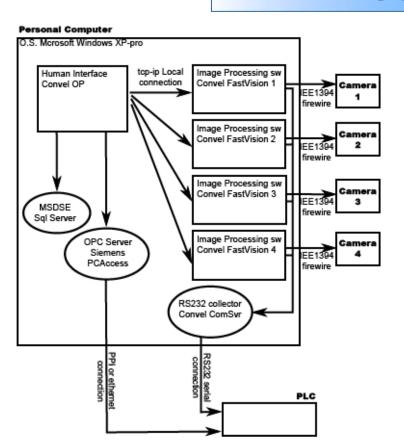


C2/C2D AUTOMATIC INSPECTION MACHINE





VISION SYSTEM



HW adaptable to inspection needs, using only standard PC and cameras.

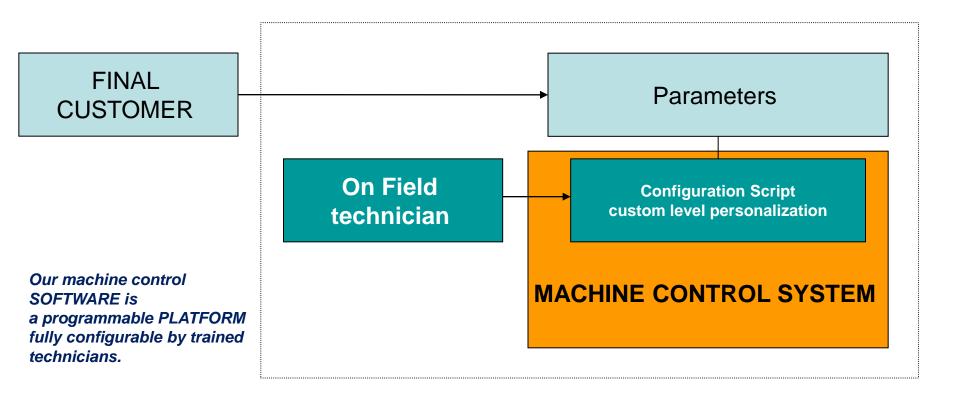
No need of interface board: cameras are connected directly to PC through IEEE 1394 port

The software of vision system (called Fast VisionTM) is fully developed by Convel and written in Visual Basic.

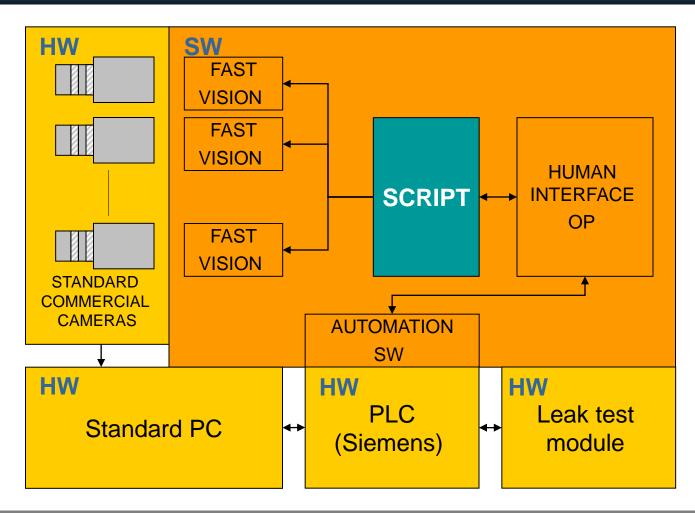
A fully programmable and configurable PLATFORM running on Windows XP integrated with vision system and PLC software.



VISION SYSTEM

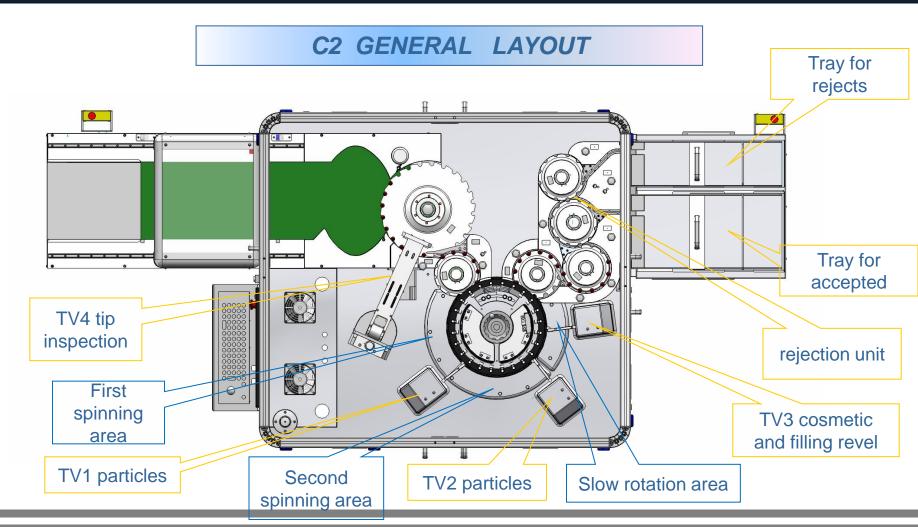












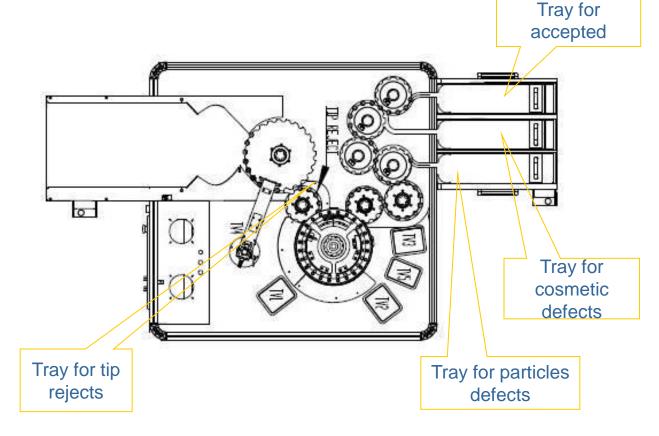


LAYOUT WITH MULTIPLE REJECTIONS

One tray for tip defects before entering in the turret (rejection by falling in a trap)

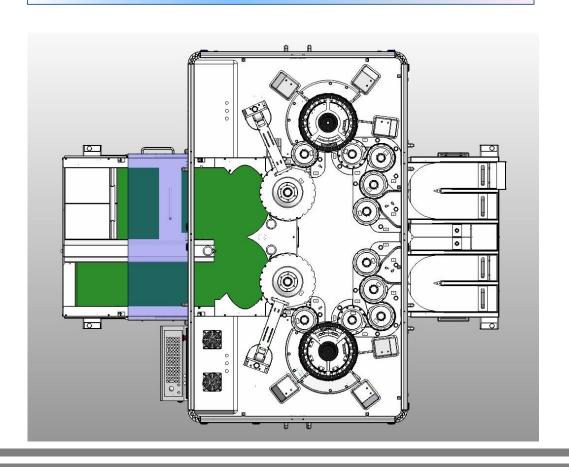
One tray for cosmetic defects

One tray for particles defects





C2D GENERAL LAYOUT





TECHNICAL SPECIFICATIONS

C2: Up to 12000 pcs/hr C2D: Up to 24000 pcs/hr (for 1ml ampoules)

DIMENSIONS:

C2: 2835x1284x2294 C2D: 2826x2408x2294

WEIGTH:

C2: 600 kg. C2D: 1.100 kg.

POWER SUPPLY: 400V 50/60 Hz. 3 Ph. +N+GND

POWER CONSUMPTION:

C2: 2,5 KW C2D: 5 KW

UTILITIES: Compressed air

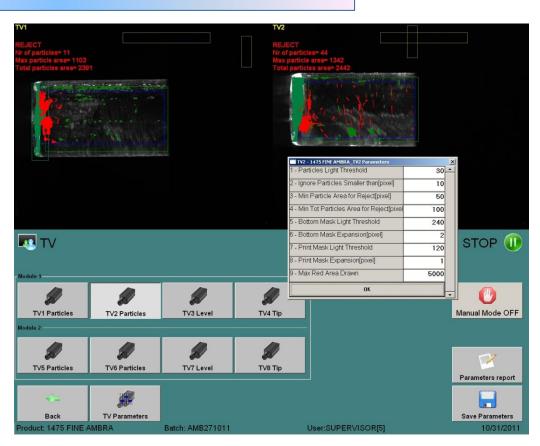




INSPECTION PARAMETERS

In order to allow the customer to setup easily the machine, Convel put a great effort to reduce the number of sensible parameters for the particles detection.

The effect of parameters modification is visualized in real time on acquired binarized images.





TIP INSPECTION

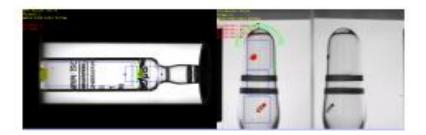
A diffused light illuminates the tip from the back.

The ampoule is framed by one camera taking a double image at 90° through a prism.

The container doesn't need to be rotated (static inspection).

Tip is inspected for height, shape, presence of code rings.





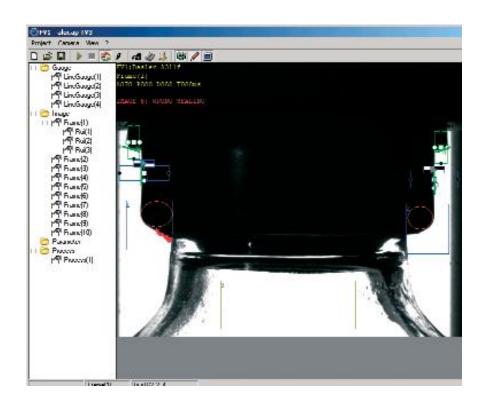


ALU-CAP SEALING INSPECTION

A diffused light illuminates the sealing from the back.

The vial is rotated slowly in front of camera (dynamic inspection). The camera takes a fast sequence of images of the profile of the sealing.

All 360° of the circumference is inspected.





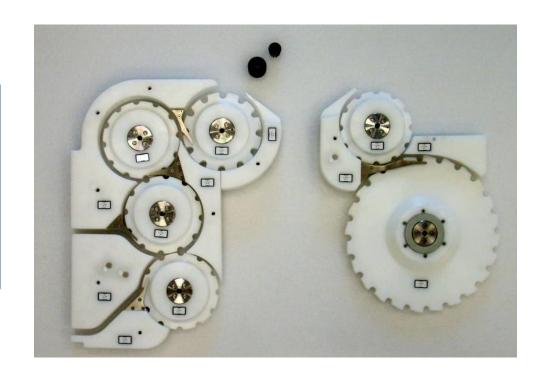
SIZE CHANGE

The size change is easily performed replacing the starwheels and selecting the recipes.

All parameters are memorized in the PC.

No tools required nor skilled personnel.

20 minutes maximum time.





FEATURES COMMON TO ALL CONVEL MACHINES

MATERIALS:

All frame is in SS AISI 304

Parts in contact with containers are in SS AISI 316L

Starwheels are in low friction autolubricant plastic (PE or POM C)

All alluminum parts are anodized

Infeed belt is in sylicon with low friction coefficient

All mechanical parts are long lasting and maintenance free

COMPONENTS:

MAIN COMPONENTS ARE FROM WORLDWIDE DISTRIBUTED BRANDS:

PLC Siemens S7-200
PC Proface touchscreen
Cameras Baumer, Allied, ...
Asynchronous motors ABB
Servomotors Mitsubishi
Inverter Siemens
Electromechanic Siemens
Ball bearings SKF
Laser printer Hewlett Packard
Sensors Yamatake, Balluff, IFM
Safety switch Allen Bradley

SENSORS:

Inductive sensors for clutches insertion

Ultrasonic sensors for containers counting

Ultrasonic sensors for rejection verification

Air pressure presence sensor

Sensors for trays presence

Sensor for minimum load

Sensor for spinning verification (C2/C2D)



HMI - Counters

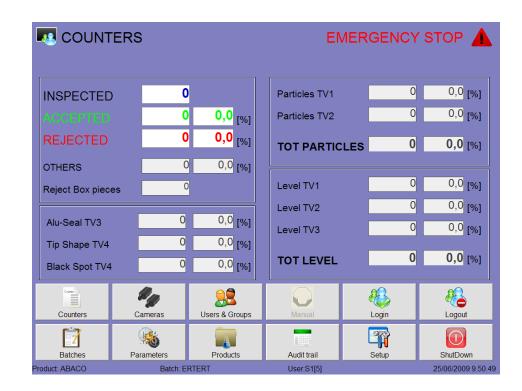
Visualization in real time of all counters

Visualization of alarms with link to user manual on line

Possibility to print, save and export as pdf file on USB key; connection to ethernet line and SCADA systems.

Cameras and high voltage parameters are automatically setup through product selection.

Unlimited number of recipes is memorizable on PC hard disk and they remain in memory for years.

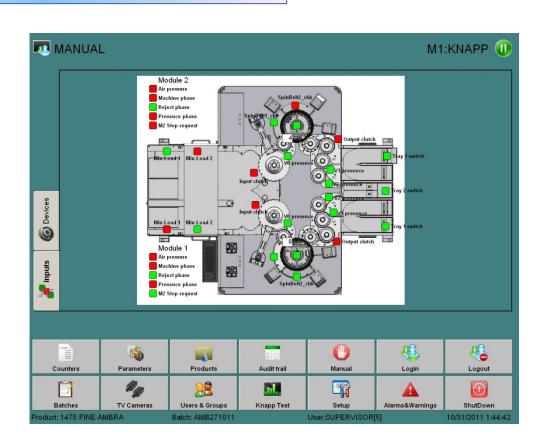




HMI - Maintenance page

For maintenance and service purpose, the functioning of all sensors appear in a dedicated screen.

All devices are activable individually by means of a jog pushbutton.

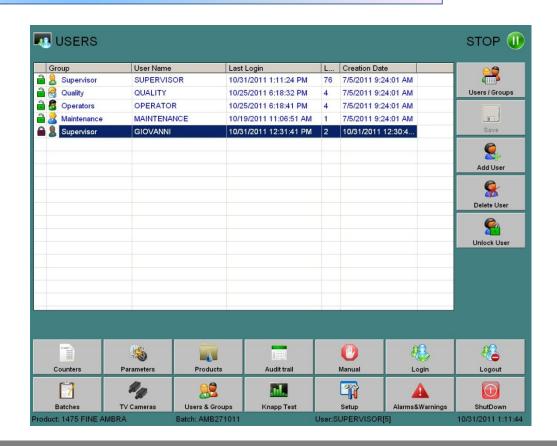




HMI - Passwords levels

Different alphanumeric password levels (administrator, supervisor, operator, maintenance) with automatic logoff and expiring time.

Unlimited number of users

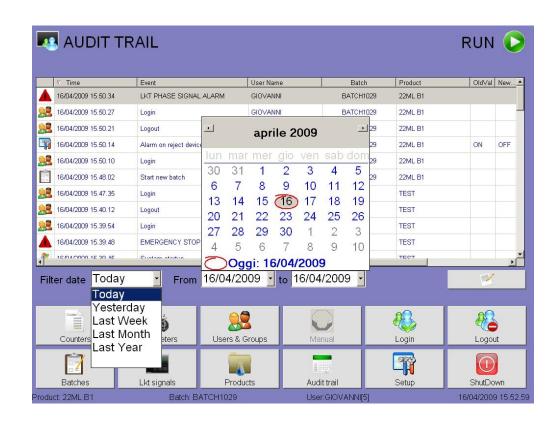




HMI - Audit trail & CFR21/PART11

Function 'Audit trail' to trace the history of all events memorized in the hard disk of PC (all alarms, login, logout, modification of parameters, batch history, ...)

Possibility of connection to local network for data backup and restore





Thanks for your kind attention ...

... now it's questions time