



I²VS

INDUCTION INTEGRITY VERIFICATION SYSTEM

APRIL 2014



Induction Sealing is used for a broad range of products in different industries such as:

- Pharmaceutical
- Nutraceutical
- Food
- Dairy
- Beverage
- Cosmetics, health and beauty
- Chemical
- Animal care and medicines
- Paints

and more...





SEALING INTEGRITY METHODS



Vacuum Decay



Electro-mechanical
tester
(Height + metal detector)



Sampling



Pressure/Squeezer



Induction Integrity verification comparison table



Method	I²VS	Vacuum Decay	Pressure	EM Tester	Sampling
Real Time, 100% testing	✓	✓	✓	✓	✗
No Production Slowdown	✓	✗	✗	✓	✗
Process Control	✓	✗	✗	✗	✗
Non-interfering	✓	✗	✗	✗	✗
Report and trend analysis	✓	✗	✗	✗	✗
Small Foot print	✓	✗	✗	✓	✓
Price	\$\$	\$\$\$	\$\$	\$	\$
Reliability	✓	✗	✗	✗	✗



DIR'S SOLUTION



I²VS – Induction Integrity Verification System



TYPICAL FAILURE MODES



Bent or damaged Foil



Missing Foil



Overheating



Under-heating



Untorqued Cap



Harmed Cap border



Crooked Cap



Bottle miss position

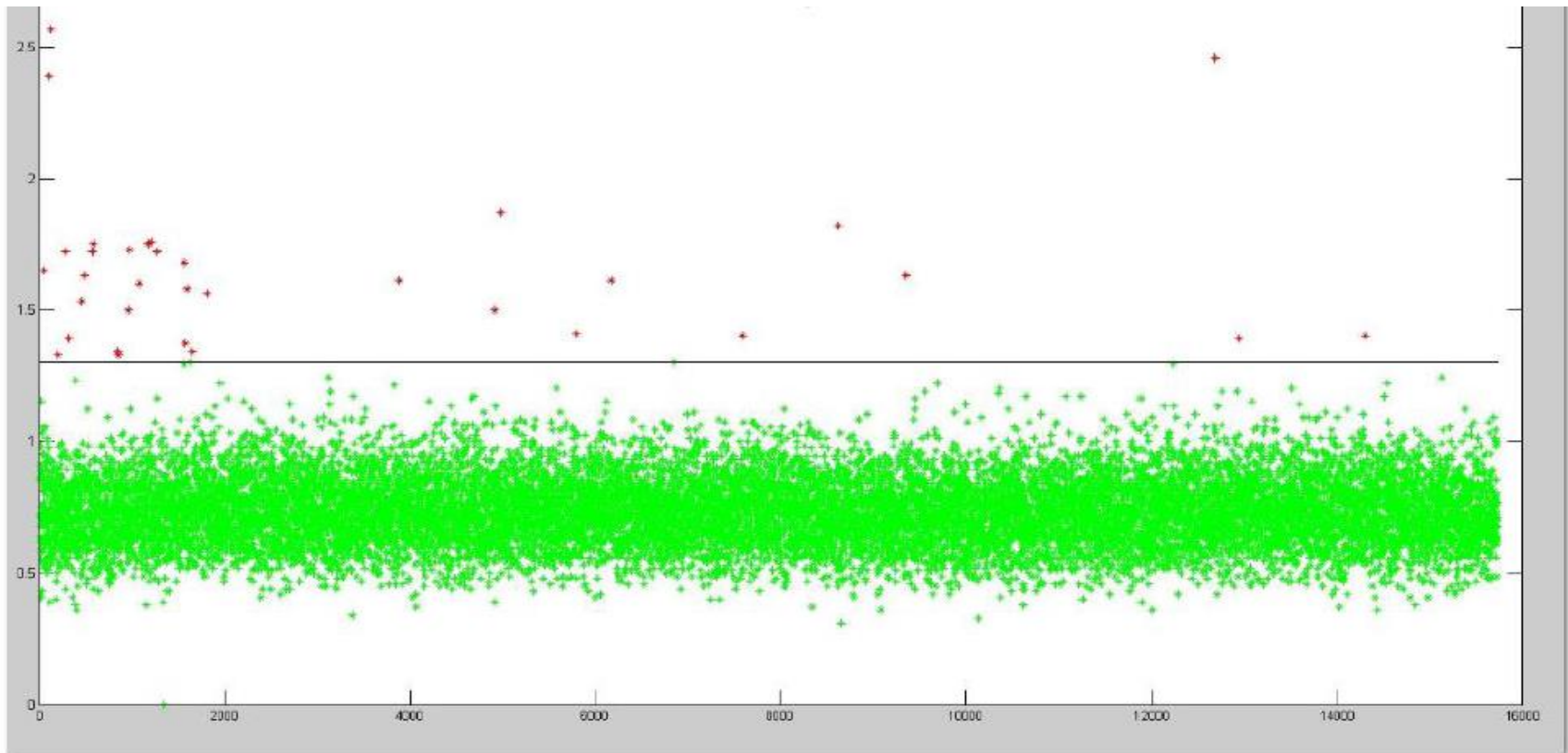




SYSTEM FUNCTIONALITY



- ✓ Identification, rejection and rejection confirmation of discrete non-compliant events
- ✓ Monitor the induction process and identify process trends
- ✓ Monitor the conveyor speed and define the conveyor speed working window (system will stop the line when speed is out of the working window)
- ✓ Control the line feeding wheel on user-defined events
- ✓ Halt line and remove all the bottles on user-defined events
- ✓ Generates a report on the number and causes of rejected bottles. (21-CFR-11 compliance optional)
- ✓ Full traceability: Records and keeps data (picture) of every single bottle that passes the line.





Discarded Bottles Log



Line Number: 10 Computer Name: CAPTEC-PC

Records in report: 879

07/10/2013	Time	Batch Number	Bottle Name	Cap Name	Result	Velocity	% Induct
	10:26:05	07-10-2013	60ml	white small	Bottle Position	247	95
	10:26:04	07-10-2013	60ml	white small	Bottle Position	247	95
	10:24:29	07-10-2013	60ml	white small	Bottle Position	247	95
	10:22:57	07-10-2013	60ml	white small	Bottle Position	247	95
	10:22:56	07-10-2013	60ml	white small	Bottle Position	247	95
	10:21:27	07-10-2013	60ml	white small	Bottle Position	247	95
	10:21:24	07-10-2013	60ml	white small	Bottle Position	247	95
	10:19:51	07-10-2013	60ml	white small	Bottle Position	247	95
	10:19:49	07-10-2013	60ml	white small	Bottle Position	247	95
	10:16:42	07-10-2013	60ml	white small	Bottle Position	247	95
	10:15:09	07-10-2013	60ml	white small	Bottle Position	247	95
	10:13:37	07-10-2013	60ml	white small	Bottle Position	247	95
	10:11:13	07-10-2013	60ml	white small	Unclosed Cap	247	95
	10:08:54	07-10-2013	60ml	white small	Bottle Position	247	95
	10:07:22	07-10-2013	60ml	white small	Bottle Position	247	95
	10:05:47	07-10-2013	60ml	white small	Bottle Position	247	95
	9:59:58	07-10-2013	60ml	white small	Bottle Position	249	95
	9:59:57	07-10-2013	60ml	white small	Bottle Position	249	95
	9:59:46	07-10-2013	60ml	white small	Bottle Position	249	95
	9:59:41	07-10-2013	60ml	white small	Bottle Position	249	95
	9:59:41	07-10-2013	60ml	white small	Bottle Position	249	95
	9:59:36	07-10-2013	60ml	white small	Bottle Position	249	95
	9:59:35	07-10-2013	60ml	white small	Bottle Position	249	95
	9:59:34	07-10-2013	60ml	white small	Bottle Position	249	95
	9:59:33	07-10-2013	60ml	white small	Bottle Position	249	95
	9:59:32	07-10-2013	60ml	white small	Bottle Position	249	95
	9:59:31	07-10-2013	60ml	white small	Bottle Position	249	95

Day Summary Report



Line 10 System Name: BUILD5RV

Batch Name	Start Date	End Date	Bottle Name	Cap Name
7676	15/09/13 16:14	15/09/2013 16:19	9090	90

Good Bottles Summary	0	0.00%
Invalid Bottles Summary	14	100.00%
Bad Induction Temp	0	0.00%
Bottle Position	13	92.86%
Turned-in edge	0	0.00%
Large Folded Induction	0	0.00%
Local Intensity	0	0.00%
Tilted Cap	0	0.00%
Unclosed Cap	0	0.00%
Ring Value	0	0.00%
Checked Bottles Summary	14	

AUDIT TRAIL (21-CFR-11)

Audit Trail Log



Line Number: 10

Computer Name: BUILDsrv

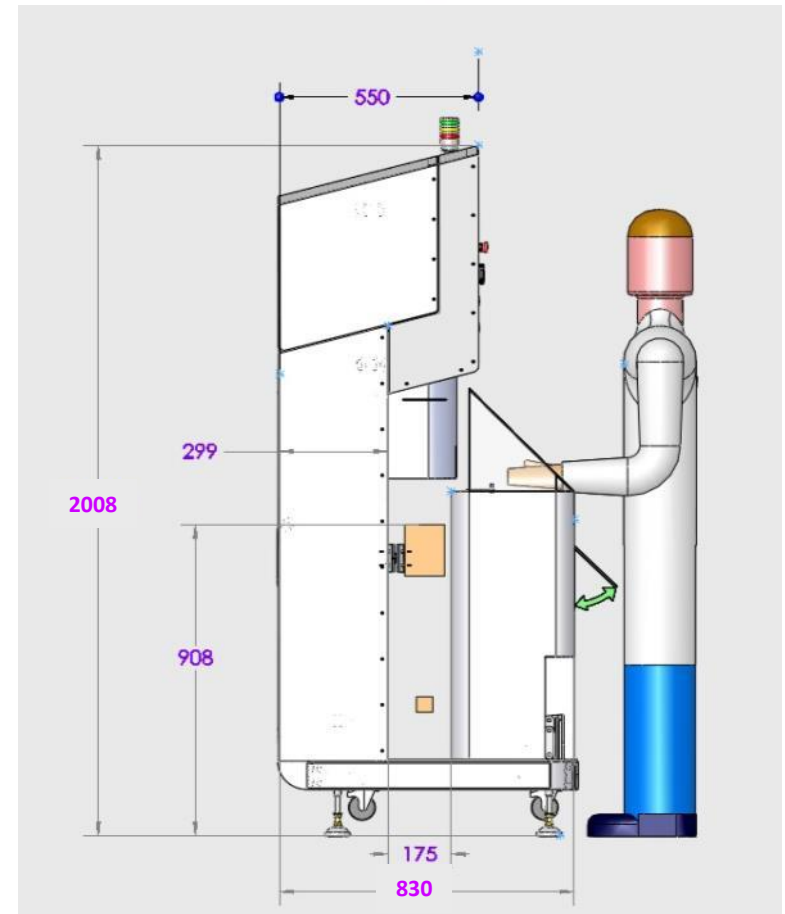
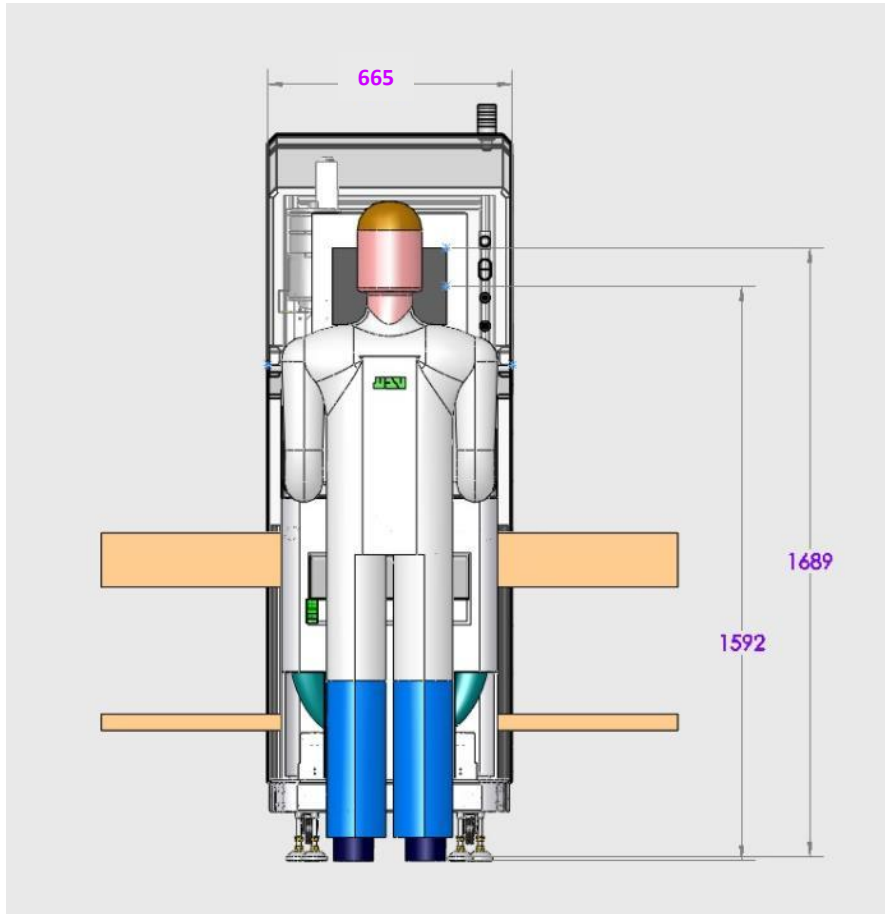
Records in report: 20

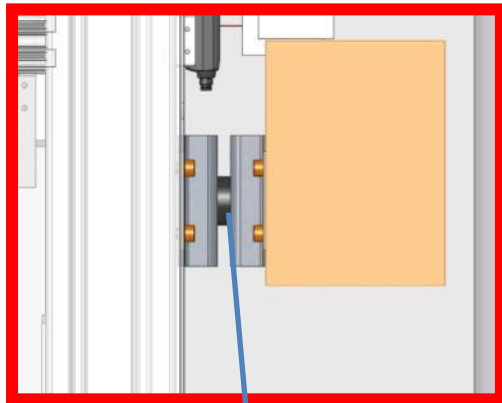
22/05/2013	Time	User Name	Event	Old Value	New Value
	09:56:29	none	System Start		
	09:57:34	none	System Start		
	09:58:22	none			
	09:59:40	none	System Start		
	10:00:09	none			
	10:00:16	admin	Login		
	10:00:19	admin			
	10:01:50	none	System Start		
	10:01:53	none			
	10:02:53	none	System Start		
	10:02:57	none			
	10:08:26	none	System Start		
	10:08:29	none			
	10:08:35	admin	Login		
	10:13:18	none	System Start		
	10:17:30	none	System Start		
	10:17:35	none	Error Occured		
	11:29:38	none	System Start		
	11:29:40	none	Error Occured		

I²VS

SYSTEM STRUCTURE

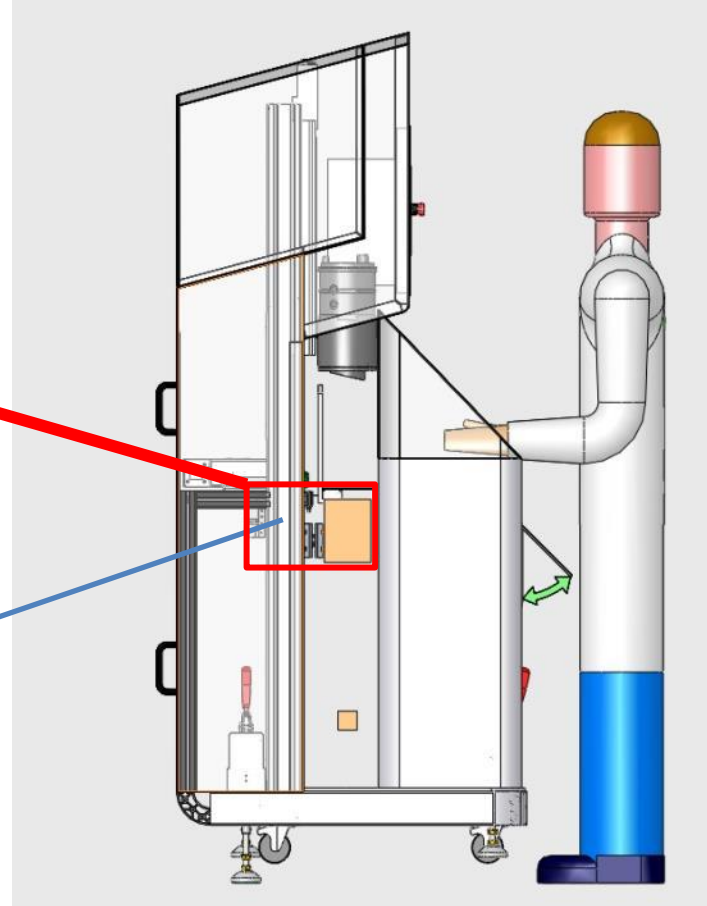


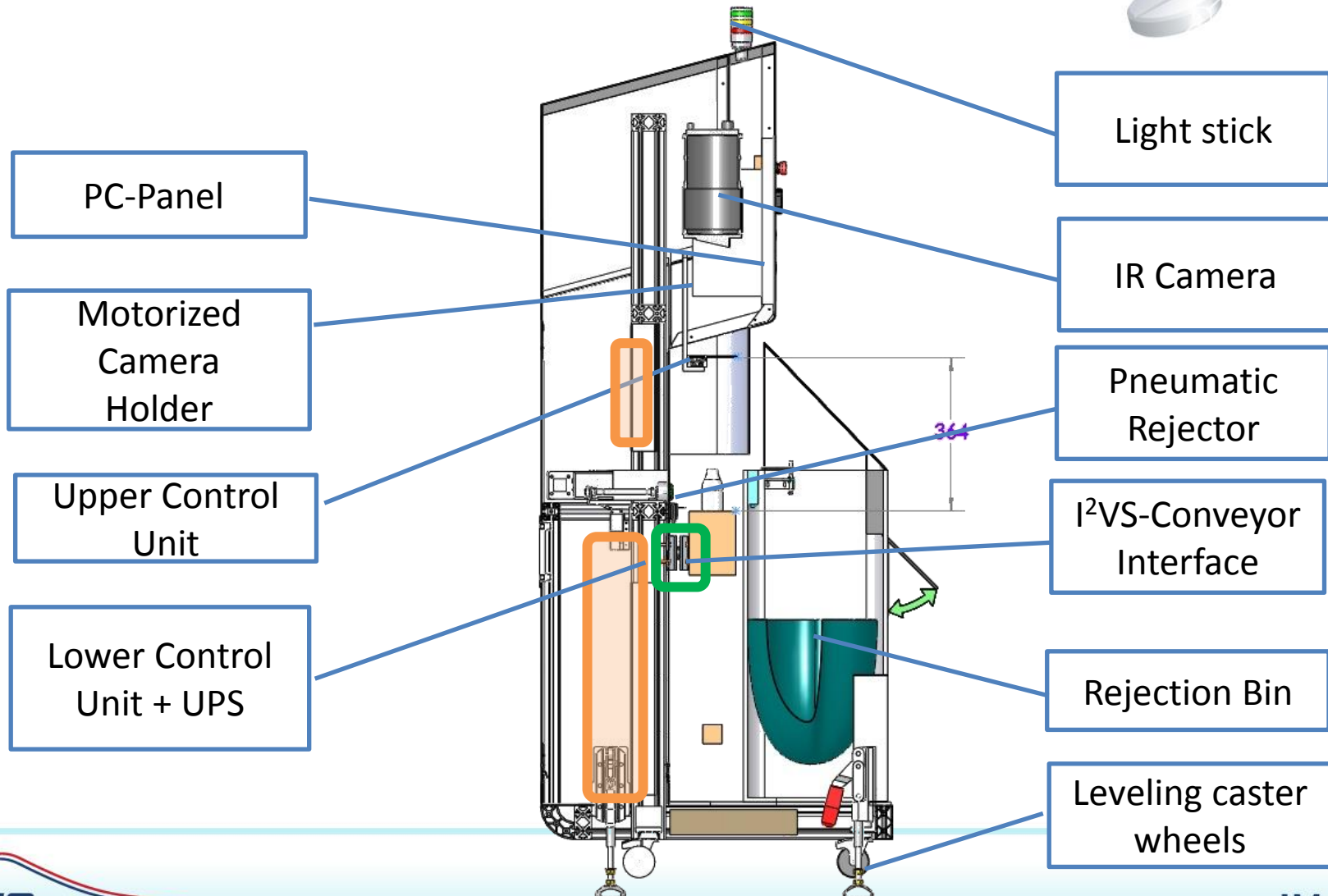




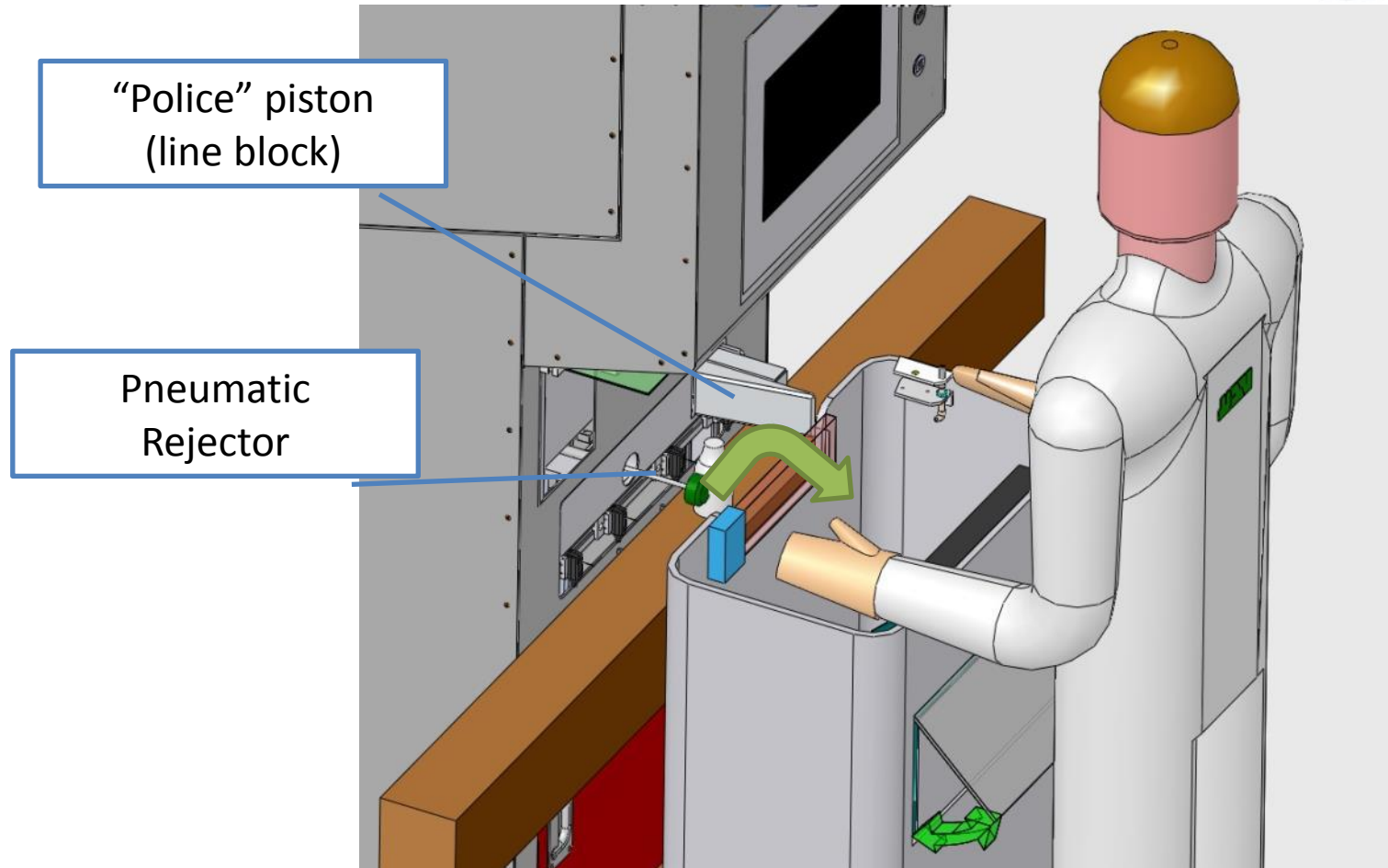
Rubber dumpers

Fixation to conveyor
after system leveling





PISTONS LOCATION





SYSTEM ADVANTAGES



- **100% verification at Real Time = Enhanced Quality**
- **Continuous Process Verification (stage 3 of FDA 2011 process validation guidance).**
- **Non interfering with process**
- **Non interfering with product**
- **Process monitoring**
- **Adaptable to any existing line**

WHO WE ARE

- Established:** 2009.
- Location:** Haifa, Israel
- Team:** Experts in Physics, Analytical Chemistry, Electronics, Pharmaceuticals, Infrared technology, Image processing, Programming and Data management.
- IP:** Patents in the fields of counterfeit drugs authentication, PAT, package integrity and microbiology. Extensive accumulated Know-How in IR technology from the defense market.
- Shareholders:** Life Sciences Fund - SCP Vitalife
ELBIT Systems (NASDAQ: ESLT)
RAFAEL Advanced Defense Systems



DIR SOLUTIONS



DIR Technologies utilizes sophisticated **infra-red detectors** and **thermal imaging** technology combined with **high throughput imaging & analysis** software to provide innovative solutions for the pharmaceutical industry.





**THANK YOU
FOR YOUR ATTENTION**