

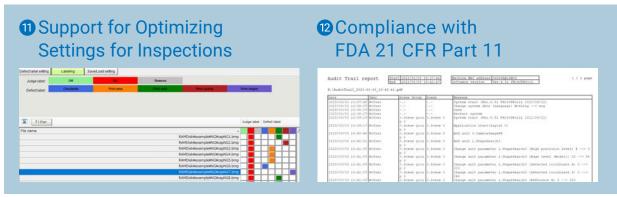
Inspection Solutions for Pharma

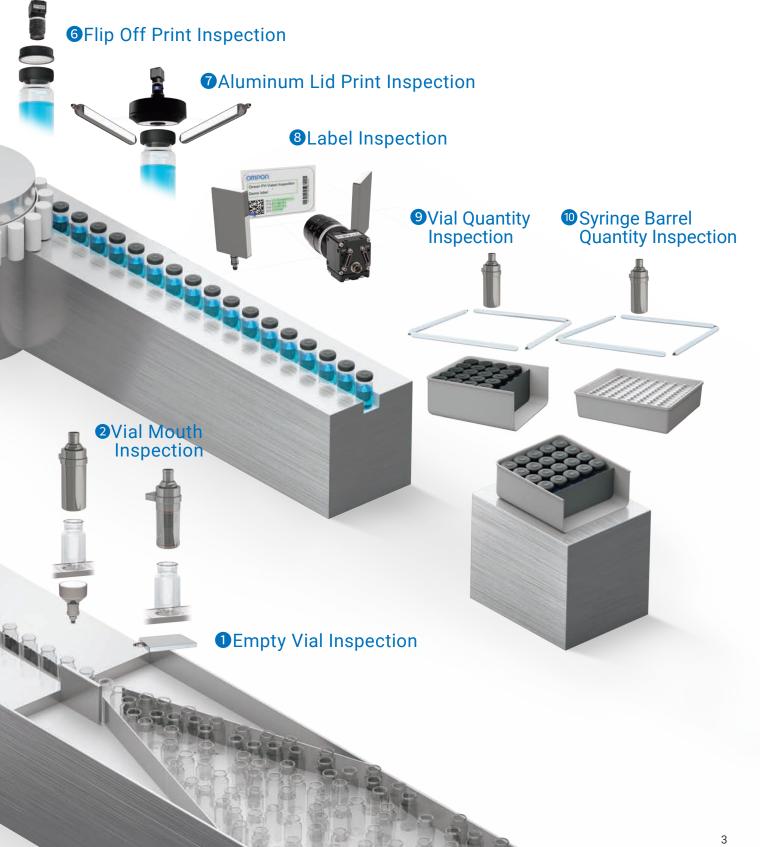


A single image inspection platform for various applications

A pharmaceutical liquid filling production line requires visual quality inspection in many of it's processes. A machine vision system can perform these complex inspections on a single platform. The inspection system increases reliability of the product without impacting the throughput of the machine. High-precision vision inspection algorithms, FDA 21 CFR part 11 software and hygienically designed hardware provides manufacturing sites with a unique solution to enable the next level in quality control.

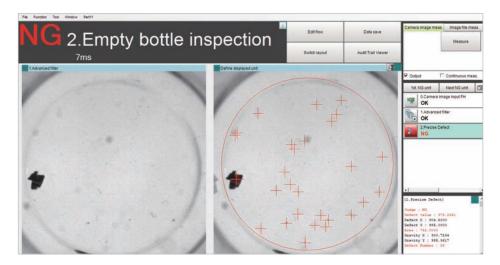






1. Empty Vial Inspection

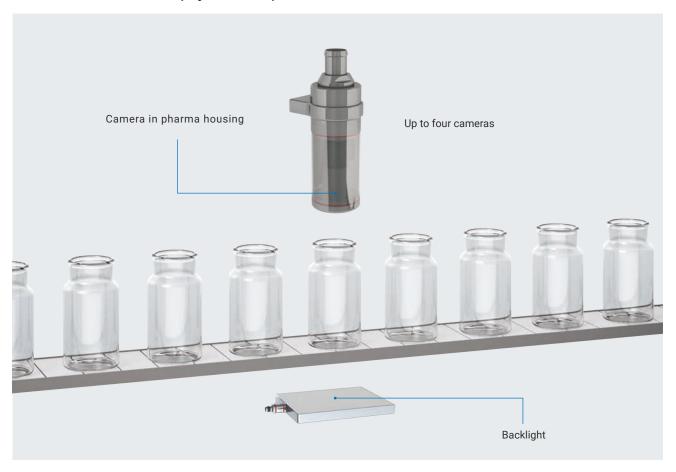
The visual inspection of empty vials checks that there is no foreign material.

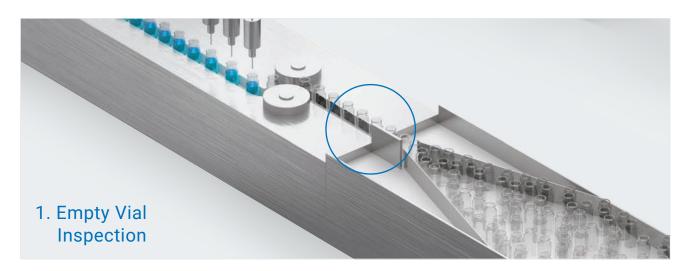


Scope of inspection

- · Checking for contamination in vial
- Detects pieces of broken glass
- · Foreign material detection
- Display of foreign material
- Optional: Up to four cameras for simultaneous inspection of multiple objects

Machine infeed: Empty vial inspection





- Format range from 2R up to $50R^*$ * \square R is a size of vials defined by ISO.
- Single optical setup for vials of various sizes.
- Typical evaluation time <100 ms
- Inspection of moving objects (on the fly)

Machine: Module Empty vial inspection

Pcs	Model	Description
1	FH-SMX05	High resolution FH camera 5 Megapixels
1	PCHI023	Hole inspection optics Manufacturer: Opto Engineering
1	CBS-P70-220-GK-21-21-00E-VA0-CC	Protection Housing for camera and optics, Suitable for pharma applications Manufacturer: ETW Wollmershäuser GmbH
1	3Z4S-LE SV-EXR	Spacer set
1	FZ-VS3 10M	Camera connection cable straight 10 m
1	BL-050-050-GD-RT-12-M04-VA0	Backlight 50 mm x 50 mm, LED, red Manufacturer: ETW Wollmershäuser GmbH
1	XS3F-E421-410-A	Lighting Cable

Panel: Vision Controller with accessories (optional)

Pcs	Model	Description
1	FH-5551/5051/2051	Vision controller
2	XW2K-34G-T	I/O Connector MIL
2	XW2Z-0050EE-L	Cable for XW2K-34G-T I/O Connector
1	S8VK-S24024	Power Supply 24 V 240 VA

HMI: Display with accessories (optional)

Pcs	Model	Description
1	NYM15W-C1000	15" Industrial Multitouch Display
1	FH-VUAB 5M	5 m USB cable
1	NY000-AC00 5M	5 m DVI cable

Note: Ask your Omron representative for FH software for the pharmaceutical industry.

2. Vial Mouth Inspection

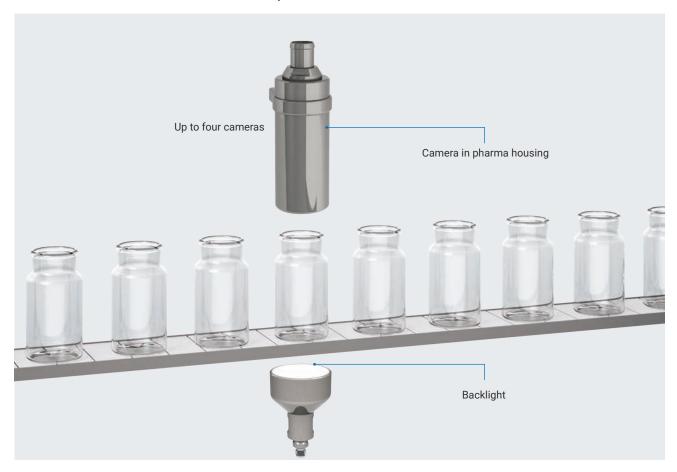
The visual inspection of vial mouths detects defects (scratches and bursts) and dirt on vial mouths.

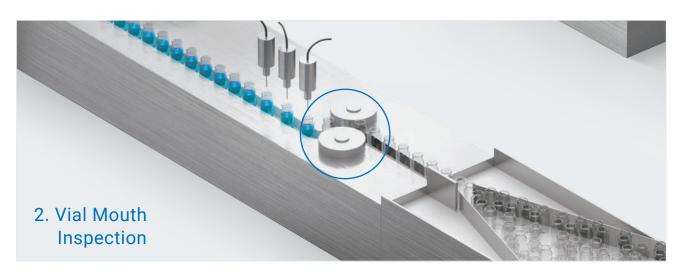


Scope of inspection

- Detection of defects (scratches, burst) on vial mouth
- · Dirt detection included
- · Display of detected defects
- Optional: Up to four cameras for simultaneous inspection of multiple objects

Machine infeed: Vial mouth inspection, schematics





- Single optical setup for vials of various sizes(from 2R up to 30R)
- Typical evaluation time <75 ms
- Inspection of moving objects (on the fly)
- · Lighting design highly optimized for utilisation under laminar flow conditions

Machine: Module Vial mouth inspection

Pcs	Model	Description
1	FH-SM04	High resolution FH camera 4 Megapixels
1	3Z4S-LE SV-10028H	High resolution lens 100 mm
1	3Z4S-LE SV-EXR	Spacer set
1	F-BP850-37.5	Daylight cut filter
1	CBS-P70-220-GK-21-21-00E-VA0-CC	Protection Housing for camera and optics, Suitable for pharma applications Manufacturer: ETW Wollmershäuser GmbH
1	FZ-VS3 10M	Camera connection cable 10 m
1	BLR-D40-GD-IR-12-D12-VA0-S1	ED Backlight 40 mm diameter, IR, Laminar Flow suitable design Manufacturer: ETW Wollmershäuser GmbH
1	BR01-02A	Lighting controller; Manufacturer: ETW Wollmershäuser GmbH
1	30004595	Lighting cable 5 m

Panel: Vision Controller with accessories (optional)

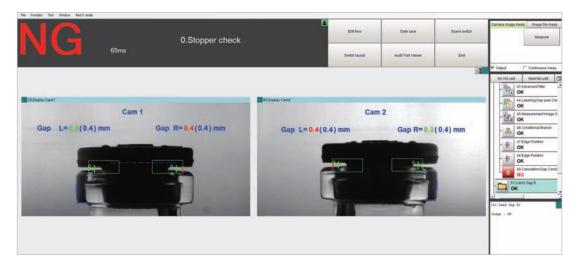
Pcs	Model	Description
1	FH-5551/5051/2051	Vision controller
2	XW2K-34G-T	I/O Connector MIL
2	XW2Z-0050EE-L	Cable for XW2K-34G-T I/O Connector
1	S8VK-S24024	Power Supply 24 V 240 VA

HMI: Display with accessories (optional)

Pcs	Model	Description
1	NYM15W-C1000	15" Industrial Multitouch Display
1	FH-VUAB 5M	5 m USB cable
1	NY000-AC00 5M	5 m DVI cable

3. Multi Camera Stopper Position Inspection

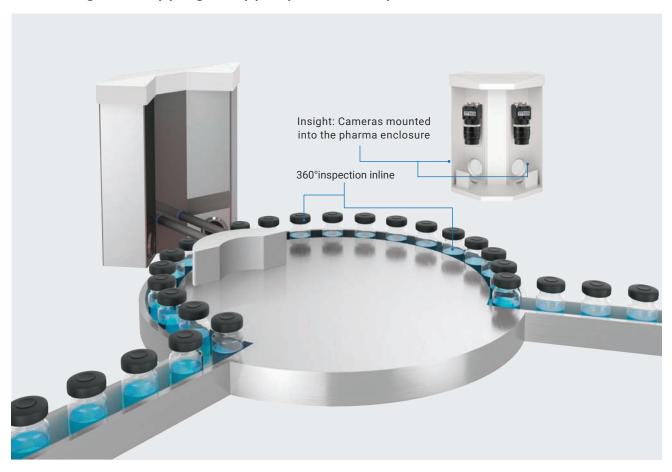
The multi camera stopper position inspection checks for the presence of a stopper and measures gaps on both sides of the stopper.

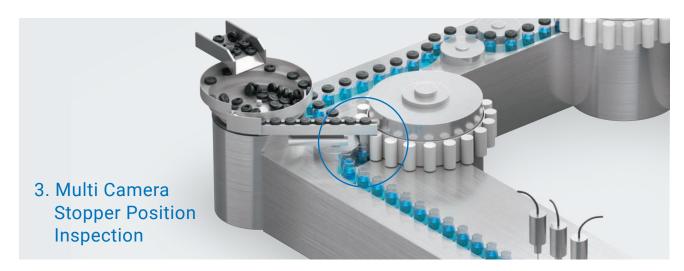


Scope of inspection

- Stopper presence check
- Gap measurement on both sides of the stopper
- · Gap and tilt display
- Two inspections in one display
- · Optional: third camera checking for correct stopper type

Vial filling and capping: Stopper position inspection, schematics





- Stopper formats: Up to 32 mm
- Transparent and colored vials supported
- Typical evaluation time <150 ms
- Inspection of moving objects (on the fly)

Machine: Module Stopper position inspection

Pcs	Model	Description
2	FH-SM02	High resolution FH camera 2 Megapixels
2	3Z4S-LE VS-2514H1	High resolution Lens 25 mm
8	3Z4S-LE SV-EXR05	Spacer 0,5 mm
2	FZ-VS3 10M	Camera connection cable 10 m
1	SKS-200-SA1	Camera enclosure with LED light Manufacturer: ETW Wollmershäuser GmbH

Panel: Vision Controller with accessories (optional)

Pcs	Model	Description
1	FH-5551/5051/2051	Vision controller
2	XW2K-34G-T	I/O Connector MIL
2	XW2Z-0050EE-L	Cable for XW2K-34G-T I/O Connector
1	S8VK-S24024	Power Supply 24 V 240 VA

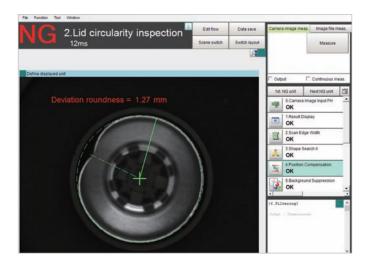
HMI: Display with accessories (optional)

Pcs	Model	Description
1	NYM15W-C1000	15" Industrial Multitouch Display
1	FH-VUAB 5M	5 m USB cable
1	NY000-AC00 5M	5 m DVI cable

 $\label{thm:continuous} \textbf{Note: Ask your Omron representative for FH software for the pharmaceutical industry.}$

4. Lid Circularity Inspection

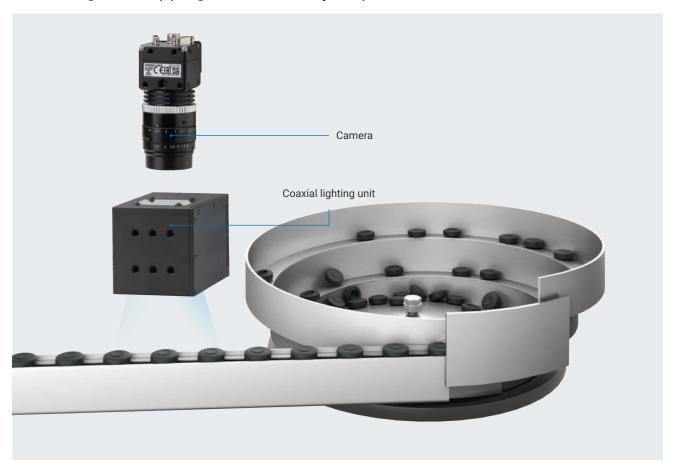
The lid circularity inspection checks the shape of an aluminum lid and detects damage.

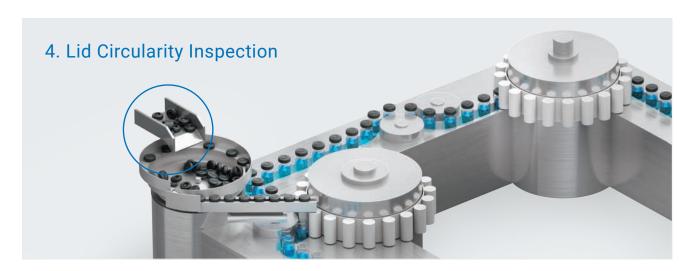


Scope of inspection

- Checks the shape of the aluminum lid
- Detects damaged parts of the lid
- Prevents machine blocking by early rejection of deformed lids

Vial filling and capping: Lid circularity inspection, schematics





- Cap formats: up to 32 mm
- Supports colored aluminum lids and flip offs
- Typical evaluation time <100 ms
- Inspection of moving objects (on the fly)

Machine: Module Lid circularity inspection

Pcs	Model	Description
1	FH-SMX	Standard resolution FH cam 0,4 Megapixels
1	3Z4S-LE SV-1214H	High resolution lens 12 mm
1	3Z4S-LE SV-EXR	Spacer set
1	FZ-VS3 10M	Camera connection cable 10 m
1	FLV-CL60W	Coaxial light, LED, white
1	FLV-TCC1	Lighting controller

Panel: Vision Controller with accessories (optional)

Pcs	Model	Description
1	FH-5551/5051/2051	Vision controller
2	XW2K-34G-T	I/O Connector MIL
2	XW2Z-0050EE-L	Cable for XW2K-34G-T I/O Connector
1	S8VK-S24024	Power Supply 24 V 240 VA

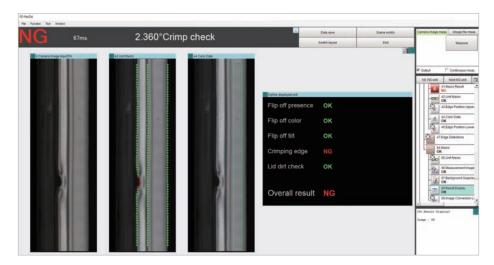
HMI: Display with accessories (optional)

Pcs	Model	Description
1	NYM15W-C1000	15" Industrial Multitouch Display
1	FH-VUAB 5M	5 m USB cable
1	NY000-AC00 5M	5 m DVI cable

Note: Ask your Omron representative for FH software for the pharmaceutical industry.

5. 360° Crimp Inspection

The 360° crimp inspection checks for the presence of a flip off and for dirt and damage on an aluminum lid.

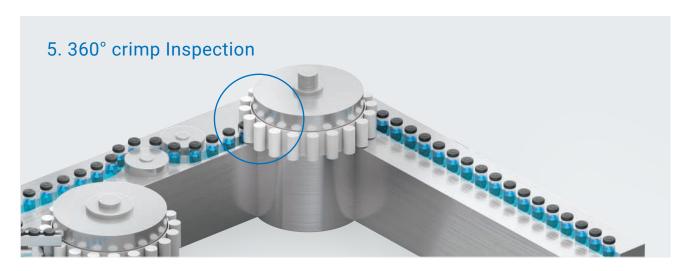


Scope of inspection

- · Flip off presence and color check
- · Checking for dirt and damages on aluminum lid
- Detection of partially or fully uncrimped aluminum lids
- Chattermark detection
- Optional: Additional cameras for simultaneous inspection of up to four vials

Vial filling and capping: 360° crimp inspection, schematics





- Formats from 8 R up to 20 R
- Typical evaluation time <500 ms(rotation of vial included)
- High speed synchronisation between rotation and image acquisition
- Optional: Additional liquid lense for format change without mechanical readjustment

Machine: Module 360° Crimp inspection

Pcs	Model	Description
1	FH-SCX	Standard resolution FH color camera 0,4 Megapixels
1	3Z4S-LE VS-3514H1	High resolution lens 35 mm
1	3Z4S-LE SV-EXR	Spacer set
1	3Z4S-LE SV-PL405-SS	Polarisation filter
1	FZ-VS3 10M	Camera connection cable 10 m
2	ABE-Z30-050-GD-WS-12-D12-VA	Barlight, LED white, 50 mm, pharma design
2	XS3F-E422-410-A	Lighting cable 10 m
1	NX701-1600	Machine controller
1	NX-PD7001	Machine controller power supply
1	NX-ECC203	EtherCAT coupler
1	NX-EC0142	Encoder unit
1	NX-OD4256	Digital output unit
1	NX-ID4442	Digital input unit
1	R88M-1M10030T-BS2	Servo motor
1	R88D-1SN01H-ECT	Servo controller

Panel: Vision Controller with accessories (optional)

Pcs	Model	Description
1	FH-5551/5051/2051	Vision controller
2	XW2K-34G-T	I/O Connector MIL
2	XW2Z-0050EE-L	Cable for XW2K-34G-T I/O Connector
1	S8VK-S24024	Power Supply 24 V 240 VA

HMI: Display with accessories (optional)

Pcs	Model	Description
1	NYM15W-C1000	15" Industrial Multitouch Display
1	FH-VUAB 5M	5 m USB cable
1	NY000-AC00 5M	5 m DVI cable

6. Flip Off Print Inspection

This inspection reads and compares a 2D code printed on a flip off and checks the print position.

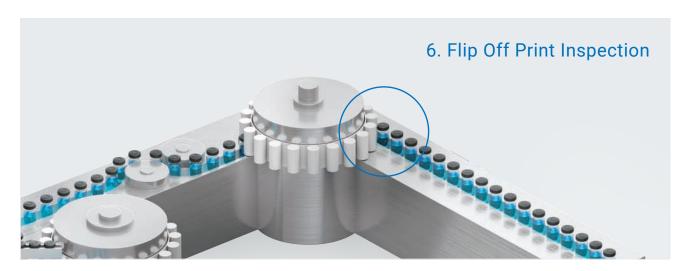


Scope of inspection

- Print position check
- · 2D code reading
- Reading of plain text
- Code and text comparison against user specified content or serialised information
- Optional: alternative lighting for UV print inspection

Marking and Labeling: Flip off print inspection, schematics





- Cap formats: up to 20 mm
- Typical evaluation time <75 ms
- Supports colored flip offs
- Inspection of moving objects (on the fly)

Machine: Module Flip off print inspection

Pcs	Model	Description
1	FH-SCX	Standard resolution FH color camera 0,4 Megapixels
1	3Z4S-LE VS-2514H1	High resolution lens 25 mm
1	3Z4S-LE SVPL270SS	Polarizing filter
1	FZ-VS3 10M	Camera connection cable 10 m
1	FLV-DR7030W	Ring light, LED white
1	FLV-DR7030PL	Polarizing filter for FLV-DR7030 ring light
1	FLV-TCC1	Light controller

Panel: Vision Controller with accessories (optional)

Pcs	Model	Description
1	FH-5551/5051/2051	Vision controller
2	XW2K-34G-T	I/O Connector MIL
2	XW2Z-0050EE-L	Cable for XW2K-34G-T I/O Connector
1	S8VK-S24024	Power Supply 24 V 240 VA

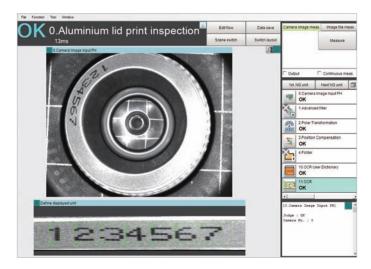
HMI: Display with accessories (optional)

Pcs	Model	Description
1	NYM15W-C1000	15" Industrial Multitouch Display
1	FH-VUAB 5M	5 m USB cable
1	NY000-AC00 5M	5 m DVI cable

Note: Ask your Omron representative for FH software for the pharmaceutical industry.

7. Aluminum Lid Print Inspection

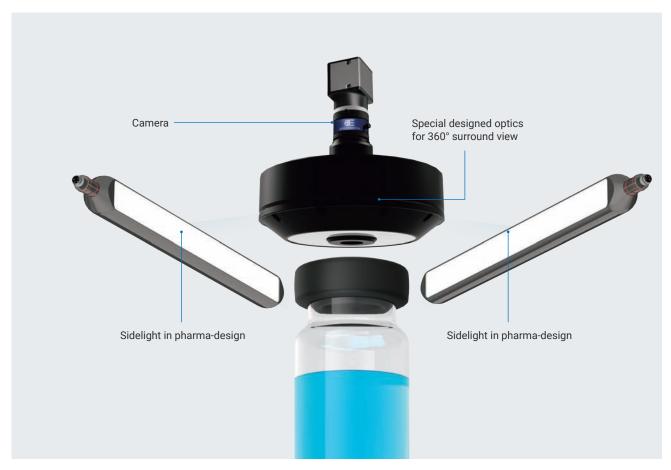
This inspection reads plain text printed on an aluminum lid and compares decoded 2D code data.

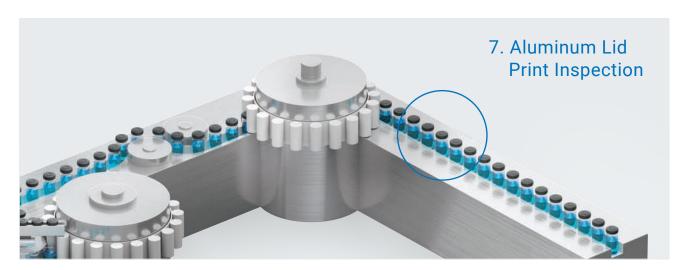


Scope of inspection

- 2D code reading and comparison against user specified content or serialised information
- Detection and reading of printed plain text and numbers
- Specialised optics for single-shot 360° surround view of the aluminum lid
- Two inspections in one display
- Optional: Alternativ standard optics and setup with side-mounted camera for inspection of a small part of the aluminum lid

Marking and Labeling: Aluminum lid print inspection, schematics





- Formats up to 30 R
- Typical evaluation time <125 ms
- · Colored aluminum lids supported
- Supports types with or without Flip Off
- Inspection of moving objects (on the fly)

Machine: Module Aluminum lid print inspection

Pcs	Model	Description
1	FH-SMX05	High resolution FH camera 5 Megapixels
1	PCCD023	Catadioptric lens for 360° top and lateral view Manufacturer: Opto Engineering
1	PCCDLFAT	Interchangeable attachment for extra-wide field of view Manufacturer: Opto Engineering
1	3Z4S-LE SV-EXR	Spacer set
1	FZ-VS3 10M	Camera connection cable 10 m
2	ABE-Z30-050-GD-WS-12-Z12-VA0	Barlight, LED white, special pharma design Manufacturer: ETW Wollmershäuser GmbH
2	XS3F-E422-410-A	Lighting cable 10 m

Panel: Vision Controller with accessories (optional)

Pcs	Model	Description
1	FH-5551/5051/2051	Vision controller
2	XW2K-34G-T	I/O Connector MIL
2	XW2Z-0050EE-L	Cable for XW2K-34G-T I/O Connector
1	S8VK-S24024	Power Supply 24 V 240 VA

HMI: Display with accessories (optional)

Pcs	Model	Description
1	NYM15W-C1000	15" Industrial Multitouch Display
1	FH-VUAB 5M	5 m USB cable
1	NY000-AC00 5M	5 m DVI cable

8. Label Inspection

The label inspection reads and compares plain text printed on a label, checks the position and quality of logos and symbols, and reads and compares symbols.

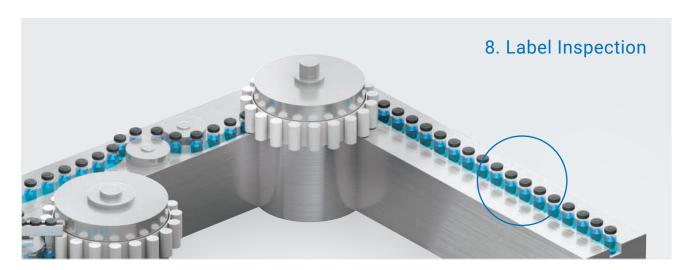


Scope of inspection

- · Check presence and position of the print
- Plain text reading and comparison to user specified content
- · Checking position, quality and defects of logos, symbols, etc. Detection of missing print or additional print/dirt
- Reading of 1D and/or 2D codes and comparison to user specified content or serialised information

Marking and Labeling: Label inspection, schematics





- Labelsize up to 100 mm x 70 mm
- Typical evaluation time <100 ms
- Inspection of moving objects (on the fly)
- Easy and quick input of user specific print content

Machine: Module Label inspection

Pcs	Model	Description
1	FH-SM04	High resolution FH camera 4 Megapixels
1	3Z4S-LE VS-2514H1	High resolution lens 25 mm
1	3Z4S-LE SV-EXR	Spacer set
1	FZ-VS3 10M	Camera connection cable 10 m
2	BL-100-100-AD-RT-12-004-AL1	Rectangular light 100 mm x 100 m, LED red Manufacturer: ETW Wollmershäuser GmbH
2	XS3F-E422-410-A	Lighting cable 10 m

Panel: Vision Controller with accessories (optional)

Pcs	Model	Description
1	FH-5551/5051/2051	Vision controller
2	XW2K-34G-T	I/O Connector MIL
2	XW2Z-0050EE-L	Cable for XW2K-34G-T I/O Connector
1	S8VK-S24024	Power Supply 24 V 240 VA

HMI: Display with accessories (optional)

Pcs	Model	Description
1	NYM15W-C1000	15" Industrial Multitouch Display
1	FH-VUAB 5M	5 m USB cable
1	NY000-AC00 5M	5 m DVI cable

 $\label{thm:local_equation} \textbf{Note: Ask your Omron representative for FH software for the pharmaceutical industry.}$

9. Vial Quantity Inspection

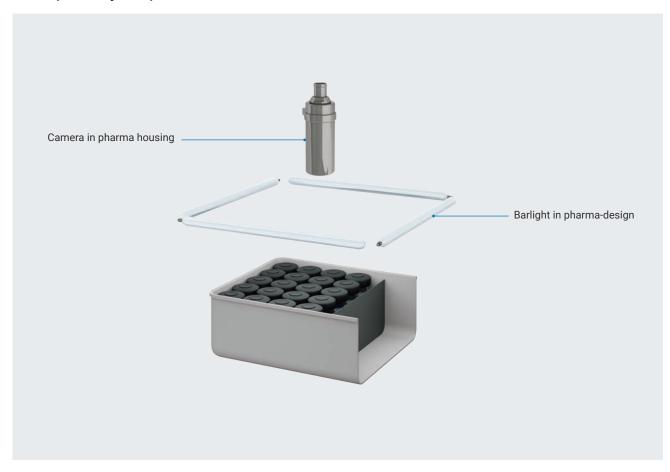
The combination of a special light and image processing enables reliable quantity inspection of vials.



Scope of inspection

- · Counting registered vials
- Display of counted vials

Vial quantity inspection, schematics





- Presence inspection of registered vials
- ullet Detection of vials of similar colors to the background using a special light and image processing

Machine: Module Vial quantity inspection

Pcs	Model	Description	
1	FH-SMX05	4 Megapixel High Resolution Camera	
1	3Z4S-LE VS-2514H1	25 mm High resolution optics	
1	FZ-VS3 10M	Camera connection cable straight 10 m	
4	ABE-Z30-350-GD-WS-12-D12-VA0	Barlight, LED white 350 mm, pharma design	
4	XS3F-E422-410-A	Lighting cable 10 m	

Panel: Vision Controller with accessories (optional)

Pcs	Model	Description	
1	FH-5551/5051/2051	Vision Controller	
1	XW2K-34G-T	I/O Connector MIL	
1	XW2Z-0050EE-L	Cable for XW2K-34G-T I/O Connector	
1	S8VK-S48024	Power Supply 24 V 480 VA	

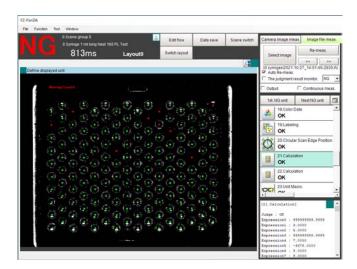
HMI: Display with accessories (optional)

Pcs	Model	Description
1	NYM15W-C1000	15" Industrial Multitouch Display
1	FH-VUAB 5M	5 m USB Cable
1	NY000-AC00 5M	5 m DVI Cable

Note: Ask your Omron representative for FH software for the pharmaceutical industry.

10. Syringe Barrel Quantity Inspection

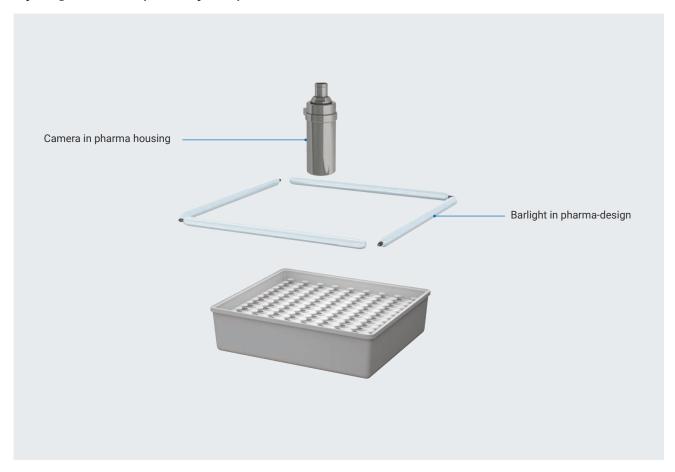
The combination of a polarization camera and image processing enables quantity inspection of translucent syringe barrels.



Scope of inspection

- Presence inspection of syringe barrels
- Counting detected syringe barrels and detecting positions

Syringe barrel quantity inspection, schematics





- Presence inspection of registered syringe barrels
- Detection of translucent syringe barrels using polarization camera

Machine: Module Syringe barrel quantity inspection

Pcs	Model	Description	
1	FH-SMX12	12 Megapixel High Resolution Polarization Camera	
1	3Z4S-LE VS-3514H1	35 mm High Resolution optics	
1	CBS-P70-180-GK-21-21-00E-VA0-CC	Protection Housing for camera and optics, suitable for pharma environment	
1	FZ-VS3 10M	Camera connection cable straight 10 m	
2	ABE-Z30-300-GD-WS-12-D12-VA0	Barlight, LED white 300 mm, pharma design	
2	ABE-Z30-250-GD-WS-12-D12-VA0	Barlight, LED white 250 mm, pharma design	
4	XS3F-E422-410-A	Lighting cable 10 m	

Panel: Vision Controller with accessories (optional)

Pcs	Model	Description	
1	FH-5551/5051/2051	Vision Controller	
1	XW2K-34G-T	I/O Connector MIL	
1	XW2Z-0050EE-L	Cable for XW2K-34G-T I/O Connector	
1	S8VK-S48024	Power Supply 24 V 480 VA	

HMI: Display with accessories (optional)

Pcs	Model	Description
1	NYM15W-C1000	15" Industrial Multitouch Display
1	FH-VUAB 5M	5 m USB Cable
1	NY000-AC00 5M	5 m DVI Cable

Note: Ask your Omron representative for FH software for the pharmaceutical industry.

11. Support for Optimizing Settings for Inspections

Strict quality validation in the medical industry requires final inspection to distinguish between good and defective products. This in-line inspection can be reproduced offline using large numbers of logged images and setting optimization support software, streamlining work.

Large-capacity image logging: 19.2 GB

- The controller stores up to 19.2 GB of image data in memory. Images used for defective product inspection, which is severe final inspection required for validation in the pharmaceutical industry, can be stored and used to adjust setting parameters offline.
- The use of the stored image data in setting optimization support software facilitates adjustment of settings whose data is required for validation in the pharmaceutical industry.

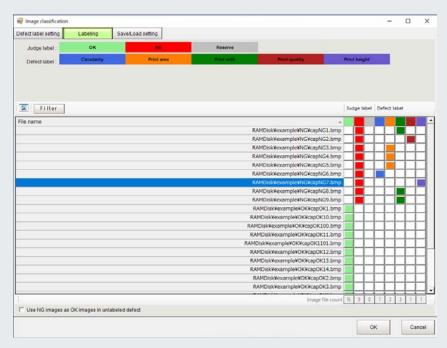


Vision System FH Series

Series	CPU	Memory	Performance
High-speed, Large- capacity Controller FH-5551	Intel® Core™ i7 processor 4 cores	RAM 32 GB, ROM 64 GB	****

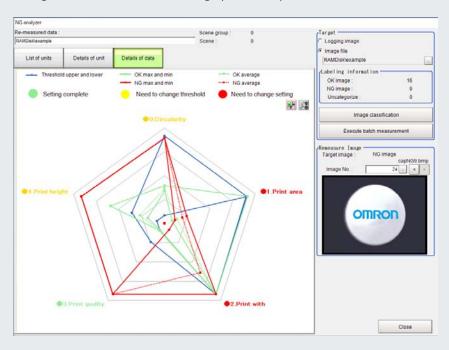
Classification of image data

The support software provides the functionality to link images of defective products to inspection items. Since this enables definition of defects in defective product images, the system can judge whether a fail for each inspection item is detected correctly.



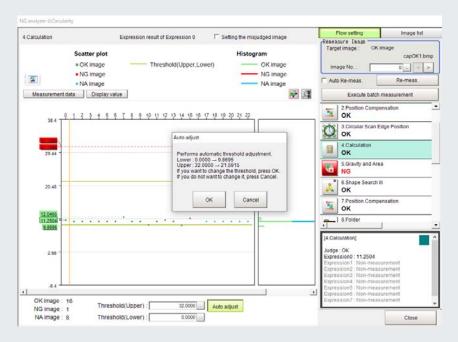
Radar chart useful for judging whether setting change is required

Measured values of good and defective products for inspection items are plotted in different colors on a radar chart, facilitating identification of inspection items that require setting change. The color-coded setting status label of each inspection item indicates the next action (green: setting completed, yellow: change threshold value, red: change parameter).



Automatic adjustment of threshold values

The automatic threshold adjustment function automatically set appropriate threshold values to classify between good and defective products.

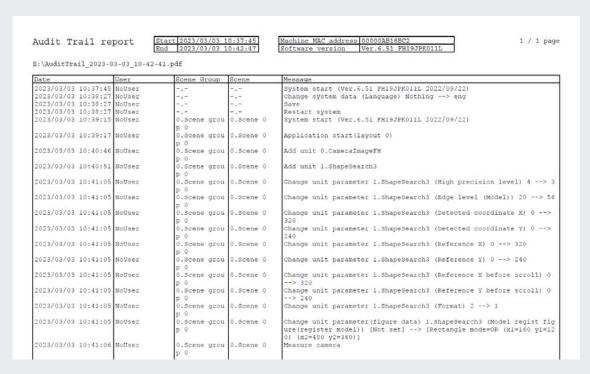


12. Compliance with FDA 21 CFR Part 11

The functionality to meet FDA 21 CFR Part 11 requirements of electronic records and electronic signatures in the medical industry supports you to make your entire system compliant with the standard. The functionality includes recording setting changes made by users, data encryption, and user access and password control.

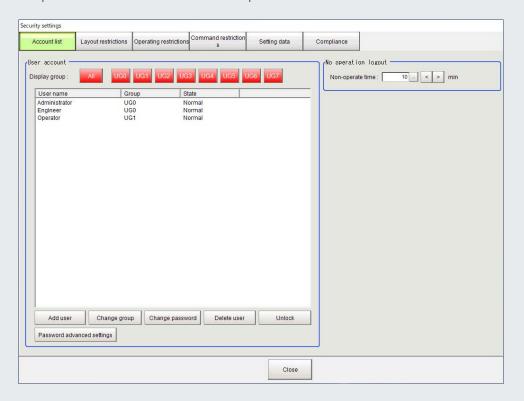
Audit Trail

Records of when and who changed controller settings clearly show the causes of setting changes.



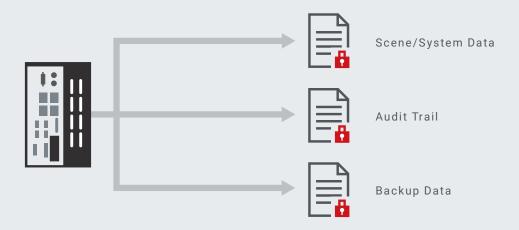
Password management

Unique combinations of usernames and passwords ensure that users are linked to records.



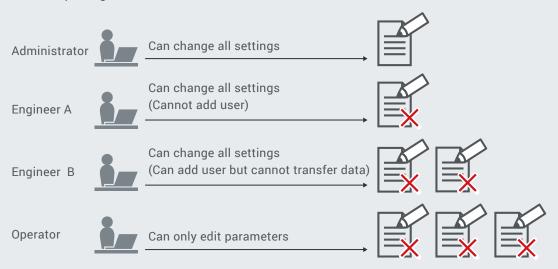
Data encryption

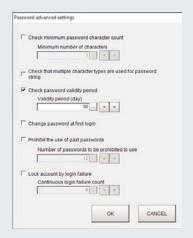
Setting data in the controller is encrypted and stored in an unchangeable format.

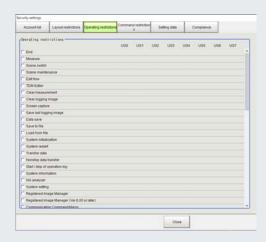


User access control

Privilege levels can be assigned to individual users, and access to settings can be customized for different privilege levels.







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Note: Do not use this document to operate the Unit.

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