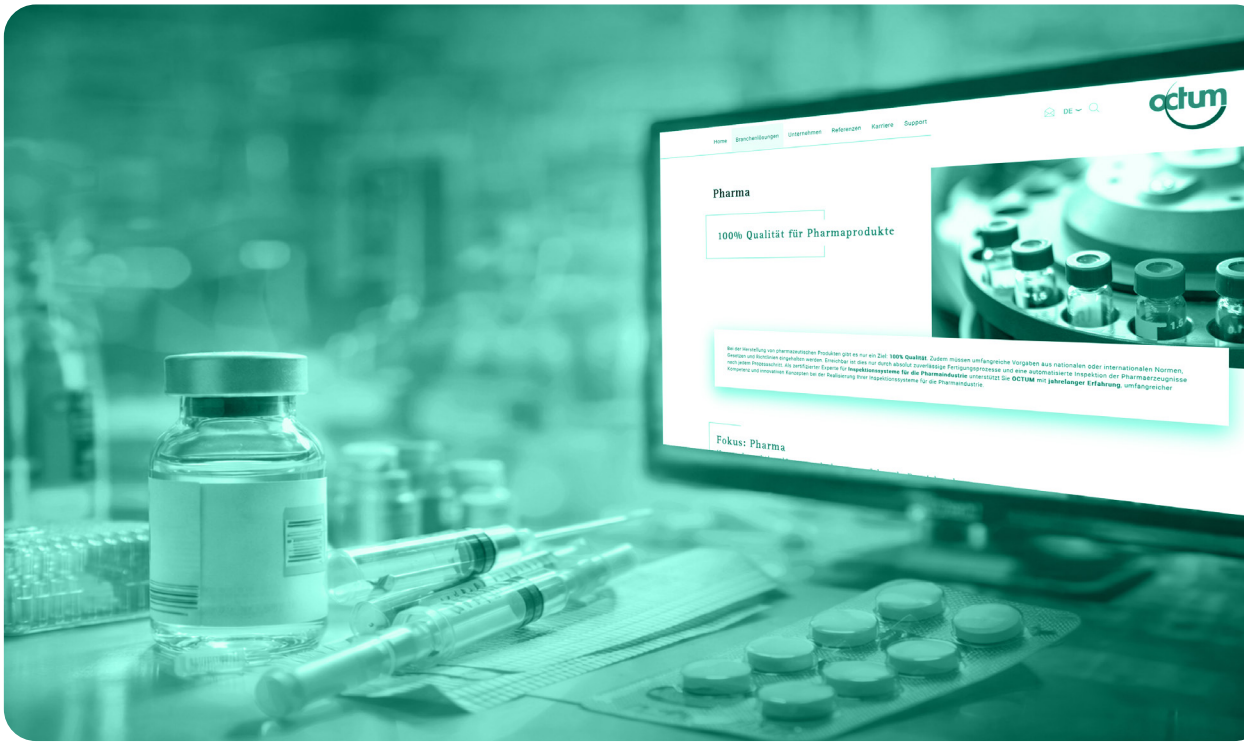
Pharmaceutical and medical technology

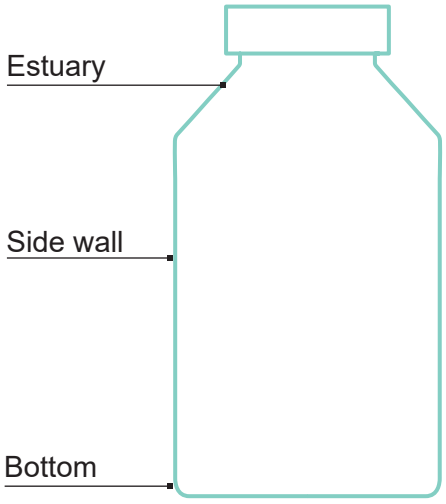


Experts in Machine Vision Solutions.

vial.inspect

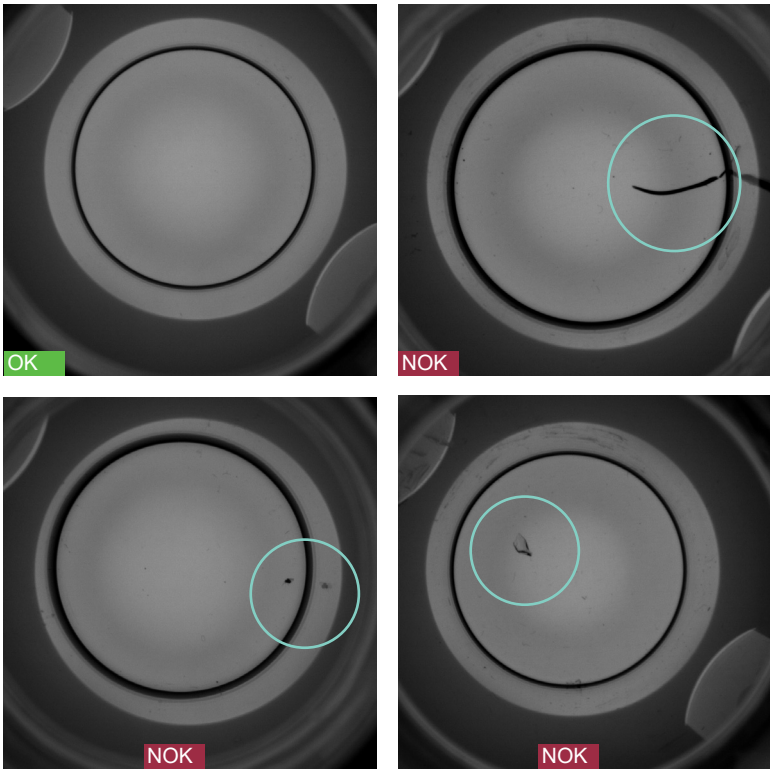
The **vial.inspect** series inspection systems were developed specifically for the vial filling process and offer the optimal system solution for protection against contamination. Whether before or after filling, optical inspections enable contaminated, damaged and improperly sealed vials to be reliably detected and ejected. With up to 600 vials/min – compliant with 21 CFR Part 11 and EU GMP.

100% inspection before filling vials



- ✓ ISO glass bottles with an opening of 13-32 mm
- ✓ In a stainless steel housing
- ✓ Modularly expandable
- ✓ User management and audit trails
- ✓ Up to 600 vial tests per minute
- ✓ 21 CFR Part 11 and EU-GMP compliant
- ✓ Fast and flexible setup

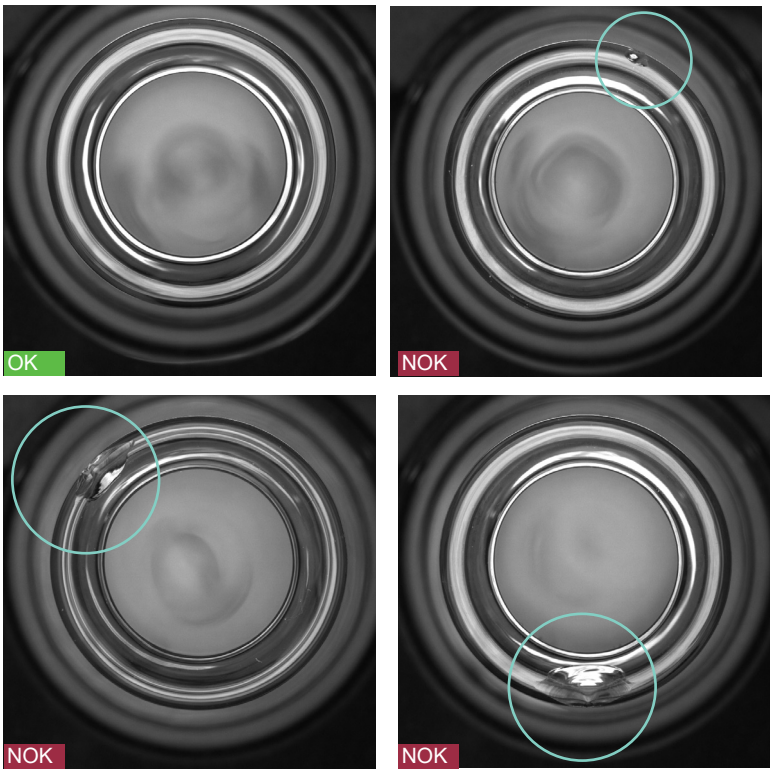
Empty glass inspection



Before filling vials with medicines and vaccines, they must be checked to ensure they are in proper condition.

vial.inspect - systems inspect bottle bottoms and bottle necks for damage, foreign objects, and contamination.
The inspection can be integrated into both the filling system and the isolator, on the linear conveyor or on the star wheel.

Estuary inspection*



*Optionally also for sloping muzzle surfaces

Quality assurance after filling vials

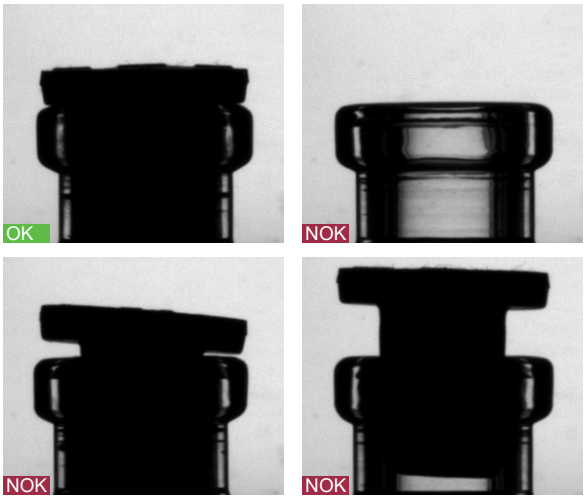
To protect against contamination, it is essential to check after filling that the bottle stopper is tight and the crimp cap has been closed properly. The verification of variable print data, such as batch numbers, also enables complete identification and traceability of the drugs.
The **vial.inspect** series inspection systems check 100% of vials after filling at a machine cycle rate of up to 600 vials per minute.

Other applications: Sidewall inspection, roundness of crimp caps, lyophilized cake, stopper detection, and much more.

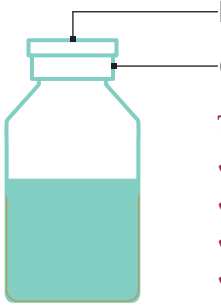
Stopper position inspection

Test criteria

- ✓ Presence of the stopper
- ✓ Correct position of the stopper
- ✓ Gap between stopper and bottle

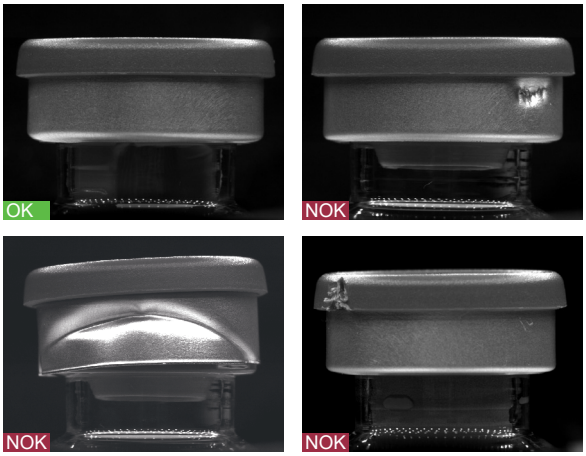


Crimp caps inspection

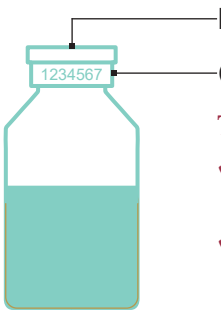


Test criteria

- ✓ Presence and qualitiy of the crimping
- ✓ Defects of the crimp cap
- ✓ Presence and color of the flip-off cap
- ✓ Defects of the flip-off cap



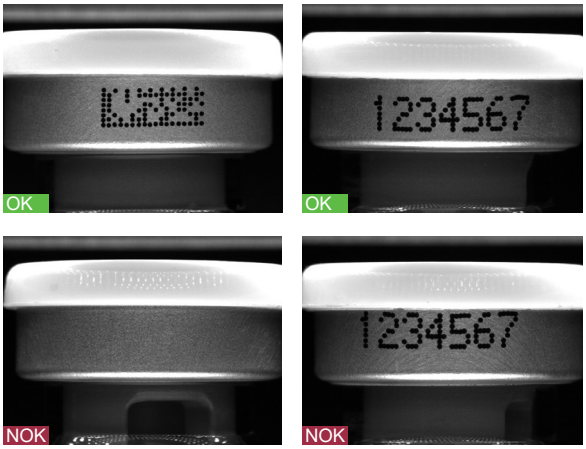
Print verification



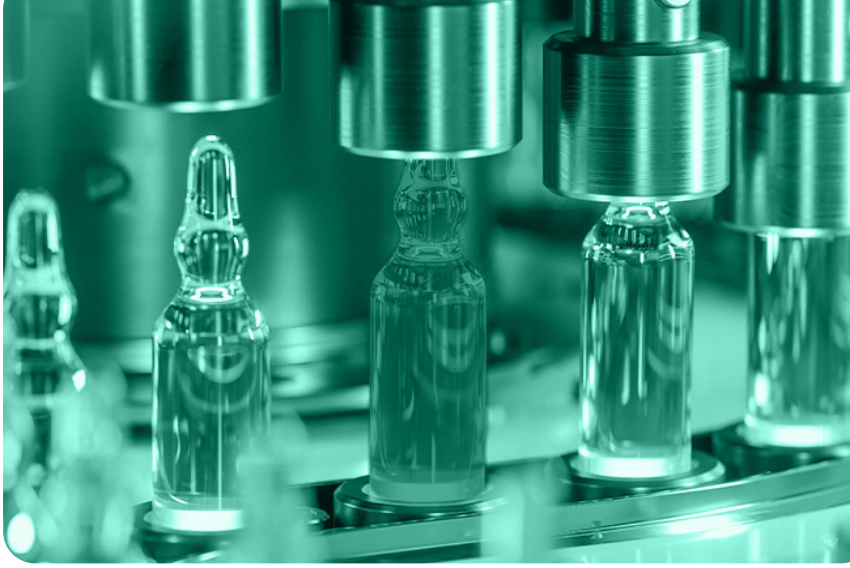
Test criteria

- ✓ Batch and serial numbers, date of manufacture and expiration date
- ✓ Code types: All common 1D- and 2D codes
- ✓ Printing methods: laser and inkjet**

**Optionally also for testing UV ink



ampoule.inspect



Ampoules are small glass vials that are often used in medicine for the sterile storage of liquids such as medicines and vaccines. Inspection of these ampoules is essential to ensure the quality and safety of the products.

With our state-of-the-art ampoule inspection systems from the **ampoule.inspect** series, defects such as inflated, collapsed, unsealed, pointed or broken ampoules as well as black burners can be detected with precision. Format adjustment is carried out efficiently via the inspection programme and the height adjustment of the camera and lighting, enabling flexible inspection of ISO ampoules. Our systems are the perfect solution for filling and sealing machines, as they inspect the ampoules immediately after sealing and cooling, thus avoiding the risk of injury from defective ampoules

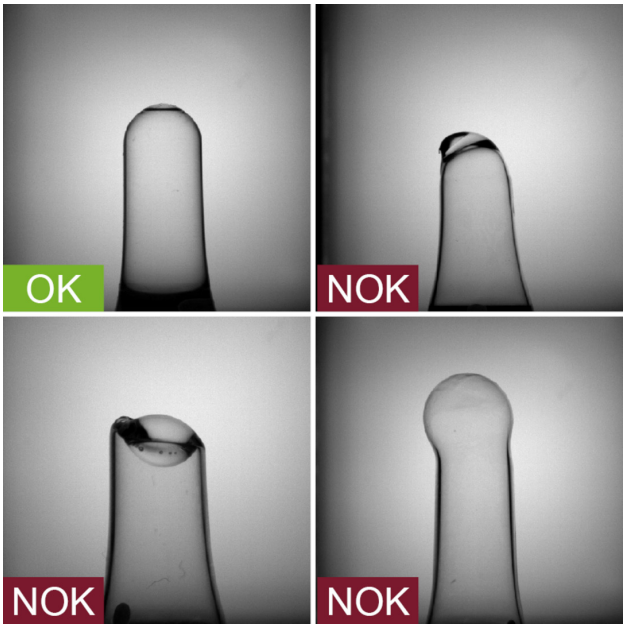
Quality assurance after the sealing of ISO ampoules

Test criteria
- ✓ Inflated ampoules
- ✓ Sunken ampoules
- ✓ Unsealed ampoules
- ✓ Pointed and broken ampoules
- ✓ Burn marks

Size range
- ✓ 1 ml - 20 ml (DIN EN ISO 9187-1)

Defect sizes
- ✓ At the edges: 0.5 mm
- ✓ In the centre: 0.2 mm

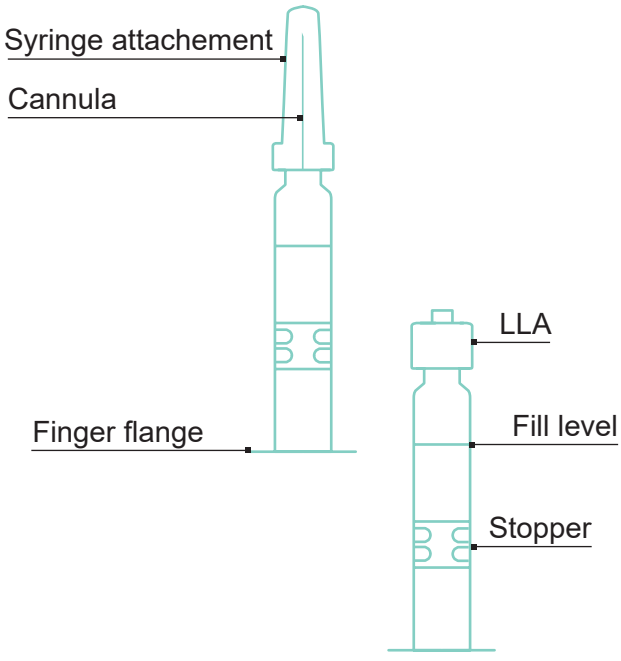
Machine cycle time
- ✓ Up to 600 ampoules per minute



syringe.inspect

Whether for assembly, filling, sealing, or packaging processes, inspection systems from the **syringe.inspect** series are the ideal solution for automated quality assurance in syringe manufacturing. The systems are specially designed to meet the high demands of the production process and enable reliable rejection of syringes and components that do not meet the required quality standards.

100% Inspection of syringes



- ✓ Assembly, geometry, and surface inspection
- ✓ Completeness and printing check
- ✓ Glass and plastic syringes
- ✓ Pre-filled syringes
- ✓ Up to 600/min
- ✓ Fully automated
- ✓ Stainless steel design
- ✓ 21 CFR Part 11 and EU-GMP compliant

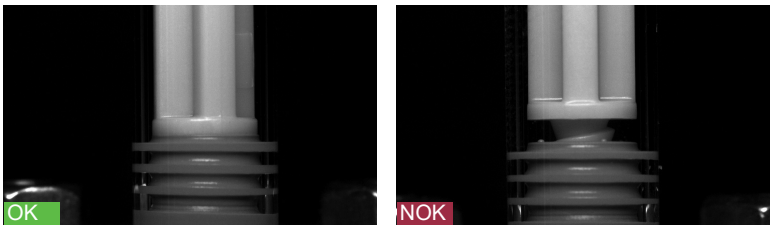
syringe.inspect - systems are suitable for quality assurance in the production of glass and plastic syringes – on high-performance machines with up to 600 syringes per minute. They can be expanded with additional inspections in a modular fashion and are visualized centrally on a control and parameterization interface. Designed to comply with the legal regulations of 21 CFR Part 11 (USA) and EU-GMP (EU), **syringe.inspect** offers maximum safety for the production of syringes of the highest quality.

Other applications: cannulas, labels, identification and much more.

Piston rod assembly test

Test criteria

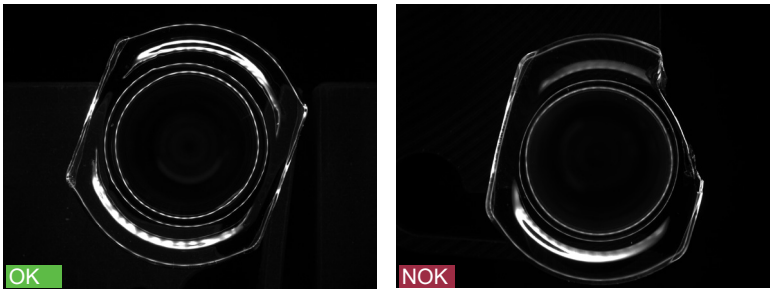
✓ Gap between the plunger rod to the stopper



Inspection of the finger flange

Test criteria

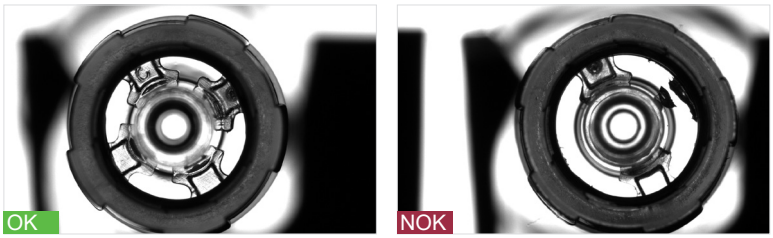
✓ Damages
✓ Chipping



LLA wing control

Test criteria

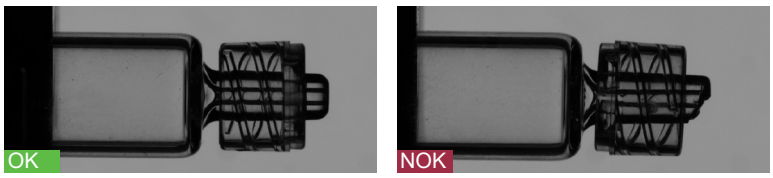
✓ Damage of the wings



LLA assembly inspection

Test criteria

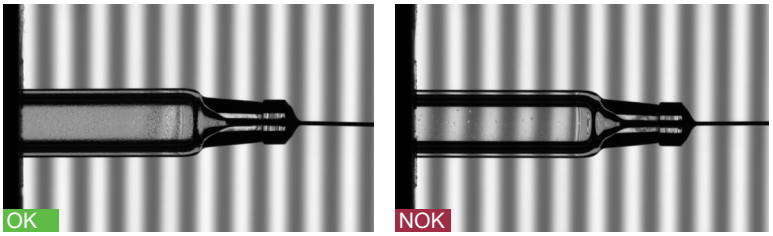
✓ Faulty assembly
✓ Orientation
✓ Breakages



Silikonisation

Test criteria

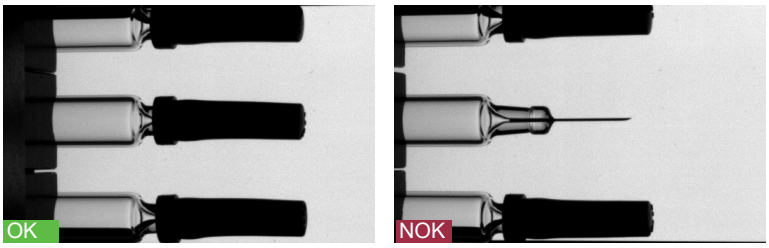
- ✓ Uniformity
- ✓ Presence
- ✓ Droplets / streaks



Assembly inspection

Test criteria

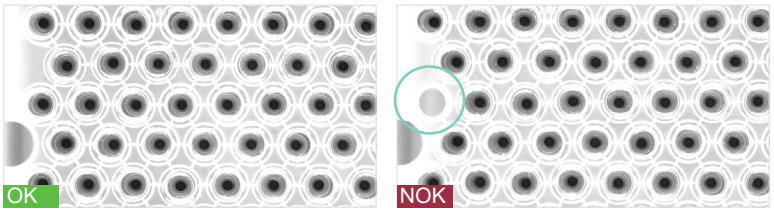
- ✓ Final inspection of the syringe attachments before packaging



Completeness inspection

Test criteria

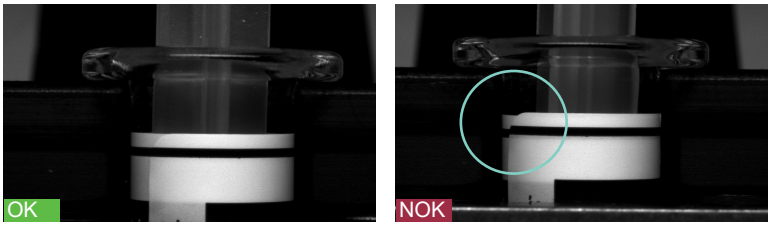
- ✓ Inspection of the correct number of syringes in the tray (nest)



Label position inspection on syringe

Test criteria

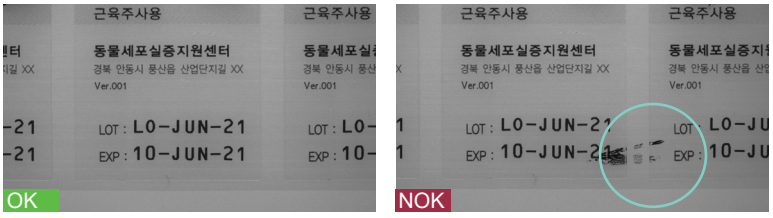
- ✓ Position
- ✓ Angle



Print inspection on syringe/label

Test criteria

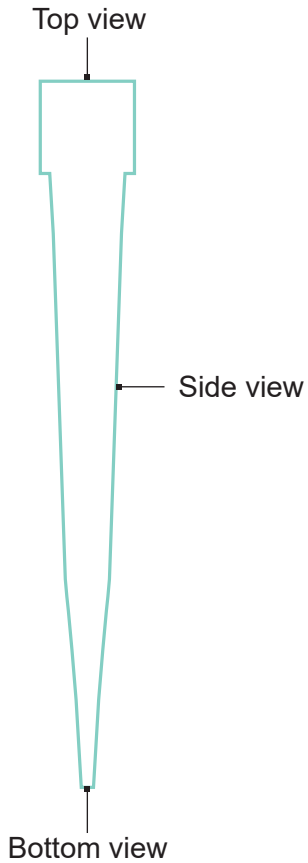
- ✓ Verification of variable data
- ✓ Verification of codes
- ✓ Verification of plain text



pipette.inspect

In everyday clinical diagnostics and in the development of new drugs, several billion samples are examined in laboratories worldwide every year. Due to the extremely high demands on accuracy and quality, pipette tips must be 100% inspected.
Inspection systems from the **pipette.inspect** series automatically analyze the geometry of each pipette tip – in compliance with EU-GMP and 21 CFR Part 11.

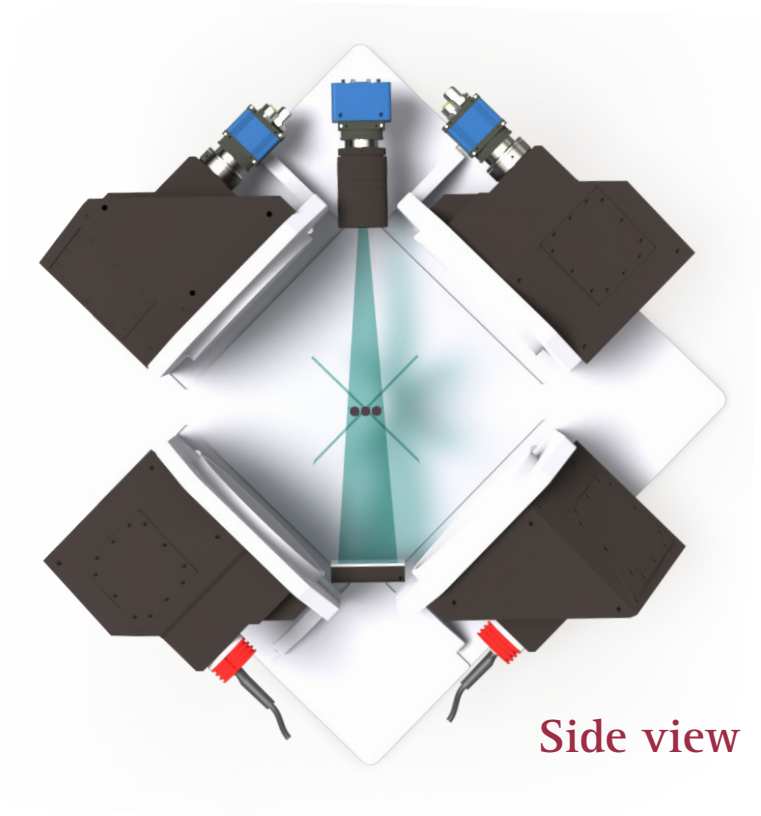
Quality assurance of pipette tips for blood and PCR tests



- ✓ All common tray and tip formats
- ✓ Black and transparent tips
- ✓ Measuring capability
- ✓ User management and audit trails
- ✓ 21 CFR Part 11 and EU-GMP compliant
- ✓ Connection to business intelligence
- ✓ Different automation concepts

To ensure manufacturing quality, **pipette.inspect** systems monitor 100% of tips during the process for injection defects, damage, and geometric features. In addition to the inner and outer diameters of the pipette opening, concentricity is also inspected with high precision. Furthermore, under-injection, burrs, and the presence of the filter are monitored to ensure that defective tips are reliably rejected. **pipette.inspect** systems are suitable for all common formats – both for black and transparent pipette tips.

*also suitable for random sampling



Side view

With **pipette.inspect**, pipette tips are captured and analyzed from up to three perspectives. The systems were specially developed for use in production environments and are compatible with various automation concepts. The test results are clearly visualized in the CV-Inspect software – in addition, a connection to the most common business intelligence solutions is possible.

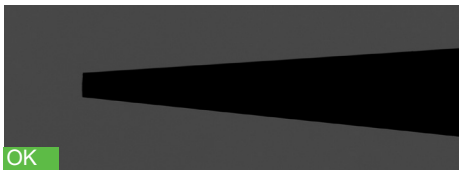
Side view: pipette tip

Test criteria

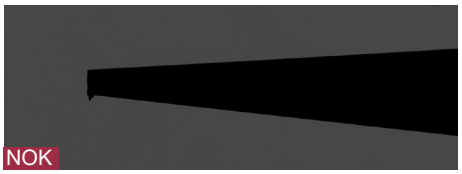
- ✓ Concentricity
- ✓ Axial flash

Error margins

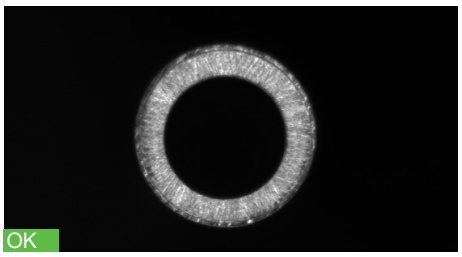
- from 0.5 mm concentricity
- from 0.05 mm x 0.05 mm ridge



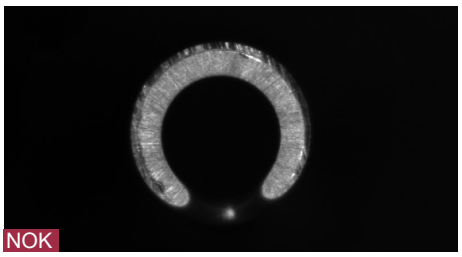
Pipette tip OK



Pipette tip with flash



Pipette tip OK



Pipette tip with injections

Bottom view: distal end of pipette tip

Test criteria

- ✓ Diameter
- ✓ Incomplete moulding
- ✓ Radial flash
- ✓ Presence filter

Error margins

- from ± 0.025 mm diameter
- from 0.5 mm x 0.5 mm flash

Top view: proximal end of the pipette tip

Test criteria

- ✓ Diameter
- ✓ Run out / bent tip
- ✓ Presence filter
- ✓ Particles

Error margins

- from ± 0.05 mm diameter
- from ± 0.05 mm run out / bent tip

Other applications: cups, blood tubes, and much more.

Bottom view

well.inspect

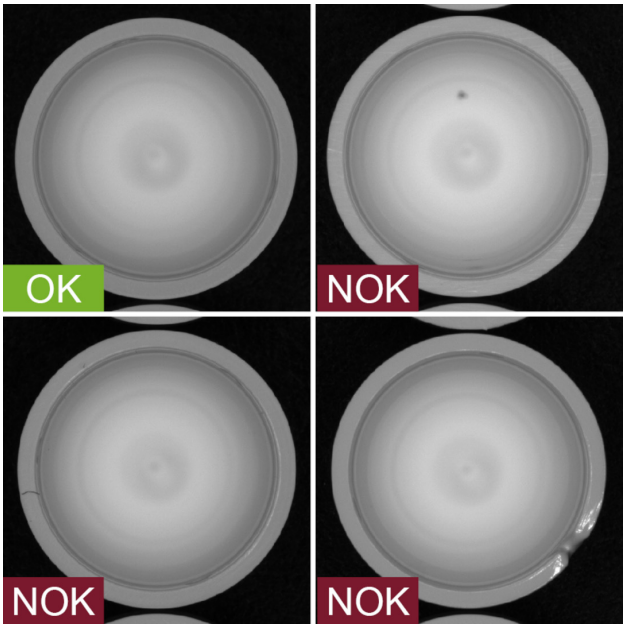
Inspection systems from OCTUM's **well.inspect** series perform 100% fully automated geometry and surface analyses, enabling the reliable rejection of defective wells in accordance with standards EU GMP and 21 CFR Part 11. **well.inspect** systems from OCTUM have been successfully installed in the production lines of various manufacturers for several years now, and enable reliable, high-precision well inspection.

Test criteria

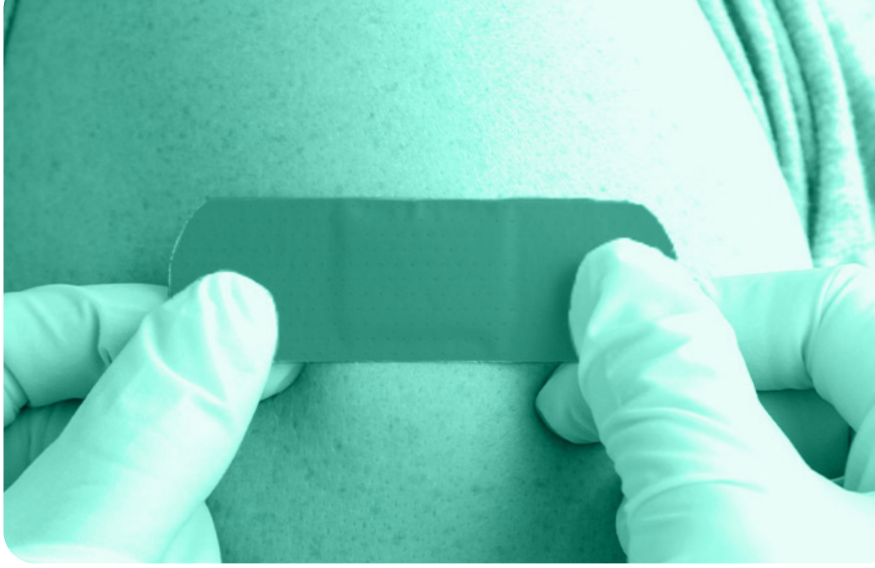
- ✓ Flaws
- ✓ Full shot
- ✓ Dark spots and stains
- ✓ Contaminations
- ✓ Completeness in the tray

Features

- ✓ Defect type classification
- ✓ New sizes can be set up quickly and flexibly
- ✓ Connection to business intelligence
- ✓ 21 CFR Part 11 and EU GMP compliant
- ✓ Modular system for easy expansion
- ✓ User management and audit trails
- ✓ Proof of measuring equipment capability
- ✓ Other well and tray sizes possible on request



patch.inspect



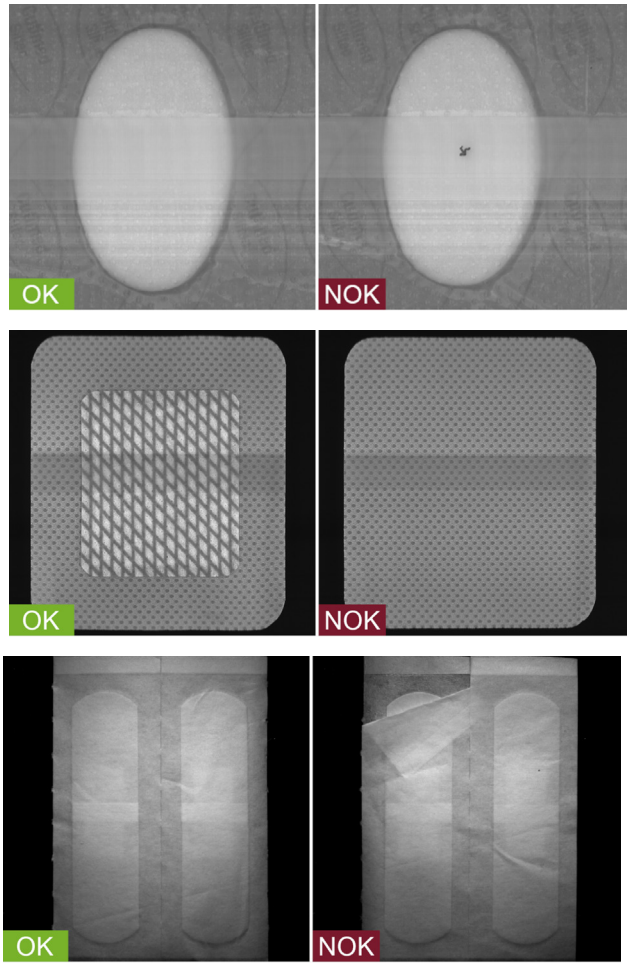
patch.inspect series inspection systems are specially tailor-made for the dressing materials under production and the in-process requirements. Adhesive plasters and Transdermal Therapeutic Plasters (TTS) are examined for material defects, cosmetic flaws and contamination by inline inspection in various stages of production. In addition, the uniform application of active ingredients is also monitored, especially where several coats are involved.

Test criteria

- ✓ Contamination (impurities, foreign bodies)
- ✓ Cosmetic defects
- ✓ Material defects
- ✓ Product condition, shape and size
- ✓ Quality of cut
- ✓ Application of active ingredients (one or more coats)
- ✓ Sealing defects
- ✓ Print and code

Error margins

- Foreign bodies from 0.2 mm

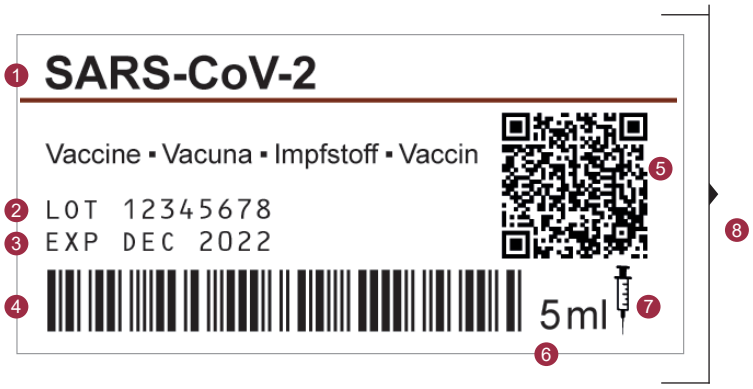


label.inspect

label.inspect: Suitable for label inspection across all format ranges and colour variants. Reliable, fast and objective. Specifically for the pharmaceutical and medical technology sectors, the systems include comprehensive life cycle documentation in accordance with GAMP5 (FS, DS, RA, IQ/OQ protocols) with reference to the specific customer URS. The format-dependent qualification of the inspection systems is carried out directly by OCTUM.

Quality assurance when labeling medical products

- ✓ Area of application: Printed labels for vials, syringes, cartons, bundles, films, etc.
- ✓ Inspection position: Directly behind the labeller or after application to the product
- ✓ Text verification, label position, comparison with default values
- ✓ Batch number, serial number, date of manufacture, expiry date, etc.
- ✓ Verification of all common 1D and 2D codes (barcodes, data matrix, etc.)
- ✓ Print quality: legibility, grading, symbols, positions
- ✓ Printing methods: laser, thermal transfer, inkjet
- ✓ Optionally also for testing UV ink
- ✓ Machine cycle: up to 600/min (depending on the number of test criteria)
- ✓ Optionally available in stainless steel housing with integrated lighting



1. Product name
2. Batch number
3. Expiry date
4. Barcodes
5. QR-Code
6. Fill level
7. Symbols
8. Print image

octum Experts in Machine Vision Solutions.

Regulatory-compliant visual inspection in the pharmaceutical industry

There‘s hardly any other industry where quality requirements are as strict as in pharmaceuticals and medical technology. In addition to product quality, the integrity of test data is a big deal – because automated inspection systems are computer-based and need to be traceable, controllable, and auditable.

Regulatory landscape – a brief overview

Automated quality assurance is governed by requirements from various levels: laws and regulations, guidelines/ directives and recommendations (e.g. from associations). This combination determines how inspection systems are designed, operated, modified and documented.

USA: FDA & 21 CFR

In the USA, the FDA defines key requirements. Particularly well known is 21 CFR Part 11, which specifies the conditions under which electronic records and signatures are considered reliable. Depending on the application, other parts may also be relevant, including 21 CFR Part 210/211 (cGMP), Part 820, Part 801 and Part 890.

EU: EMA & EU-GMP

In the EU, the EMA regulates on behalf of the European Commission. EU GMP Annex 11 is central to computerised systems (including operation and change controls). Annex 15 describes the principles of qualification and validation of facilities and processes.

GAMP5: Proven methodology for validation

GAMP5 (ISPE) is not a law, but an established process model: requirements are derived from URS via FS and DS, then implemented and verified via IQ and OQ – risk-based and well-documented.

OCTUM in practice

OCTUM inspection systems have been established in pharmaceutical production environments since 1996 and are designed for applications such as vials, syringes, pipettes and plasters. Our services range from consulting and planning to compliant implementation and qualification – including the necessary regulatory documentation

Since 1996 OCTUM GmbH has been developing and distributing system solutions for the optical quality control of products and manufacturing processes worldwide. The company produces image processing solutions for the detection and inspection of a wide variety of parts for the pharmaceutical and medical technology, packaging technology, automotive, and other target industries.

OCTUM develops and implements customized image processing solutions based on globally available and proven technologies. A competent, flexible, and dedicated team innovatively translates customer requirements into reliable solutions.

OCTUM is a reliable partner whose expertise you too can benefit from. Depending on customer requirements,we supply image processing solutions or complete solutions in collaboration with our partner companies. With more than 6,000 production-reliable, installed system solutions, OCTUM is one of the most successful providers in the industry.

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