SENSOFAR

MEDICAL

Q vix

Comprehensive solution for the inspection of stents and heart valves

Outstanding solution for in-line inspection

Making fast and reliable decisions

Q vix has been designed as a comprehensive solution for simplifying and streamlining heart valve and stent inspection in production environments. High-resolution imaging enables a full inspection of heart valves and stents, reducing inspection time and quality control costs.

Dedicated system

Optimizing the task of inspection

The Q vix is the result of more than five years of experience in the inspection of implantable medical devices. The combination of dedicated hardware and software makes it possible to simultaneously acquire and analyze images of the outer, inner and lateral surfaces of stents and valve frames. Dimensional measurements and visual inspection results are processed and displayed in a very short time, enabling operators to make fast and reliable decisions about the quality of the devices. After the final acceptance or rejection, a complete inspection report is generated and exported in compliance with 21CFR Part 11 requirements. The assisted approach of SensoINSPECT software simplifies the validation of Q vix in production.

High performance

Shortening the return on investment

The inspection cost of the devices can be dramatically reduced by the fact that a single inspector can simultaneously operate several Q vix units. Under this approach, ROIs below three years can be easily achieved.

Covering a wide range of applications

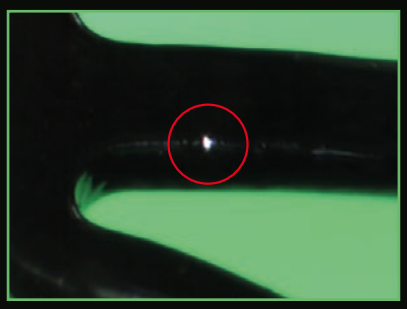
Versa

The flexibility of the hardware and software of Q vix makes it the best solution for inspection of samples ranging from coronary stents to heart valve frames up to 32mm in OD, and including the inspection of large peripheral stents and neurovascular devices.

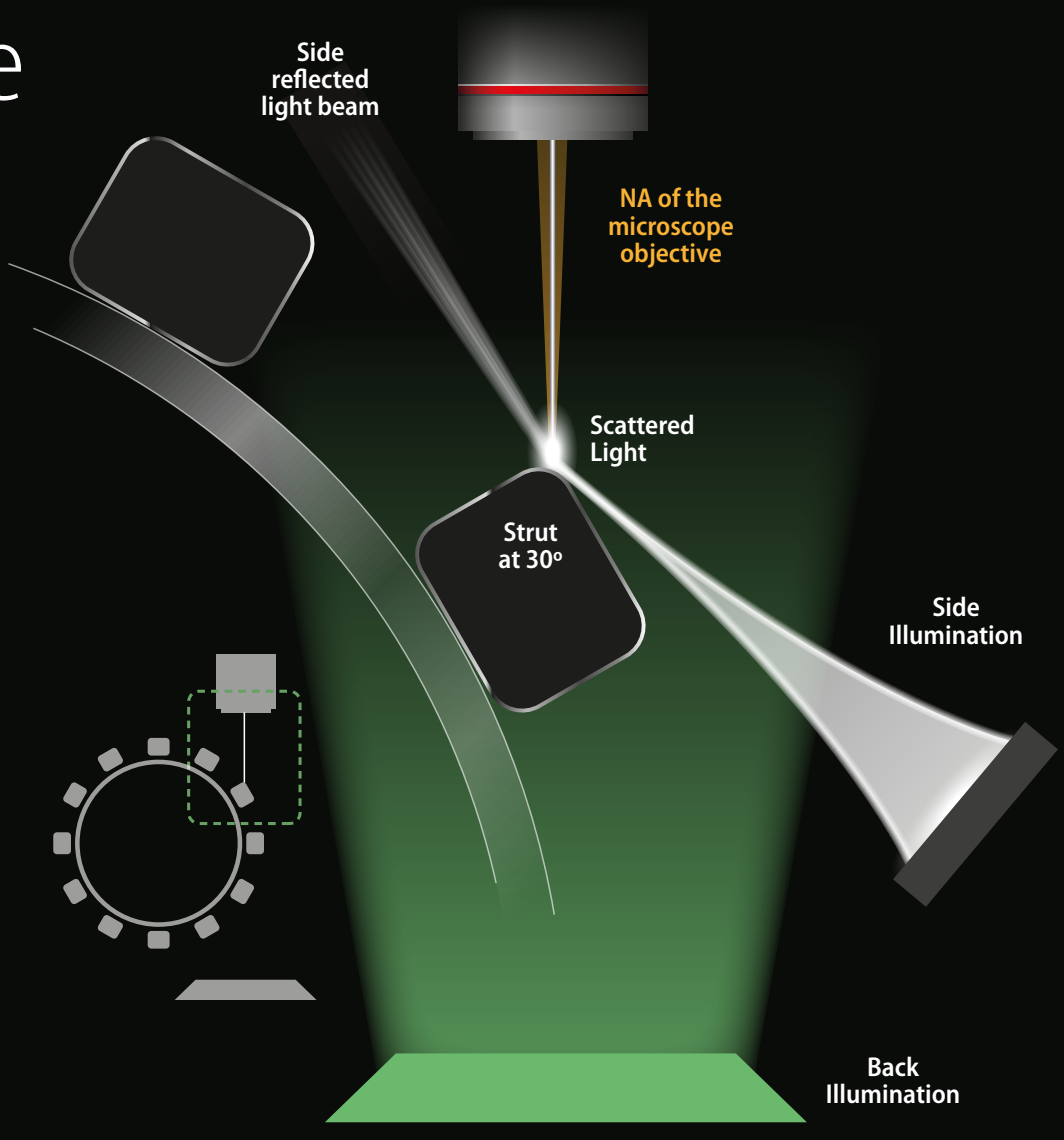
tile platform

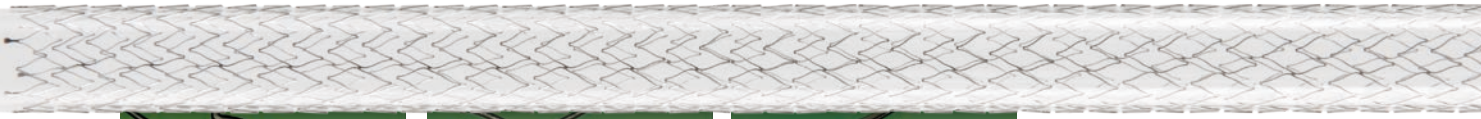
Flexible illumination setup

Finding the smallest defects



Q vix illumination system is based on high efficiency LEDs and is fully integrated into the sensor. Its flexible design makes possible numerous configurations using up to 7 independent light sources. Standard bright-field illumination setups can be combined with grazing illumination setups, which allows Q vix to detect tiny defects that can be seen "shining in the dark", even at low magnifications.





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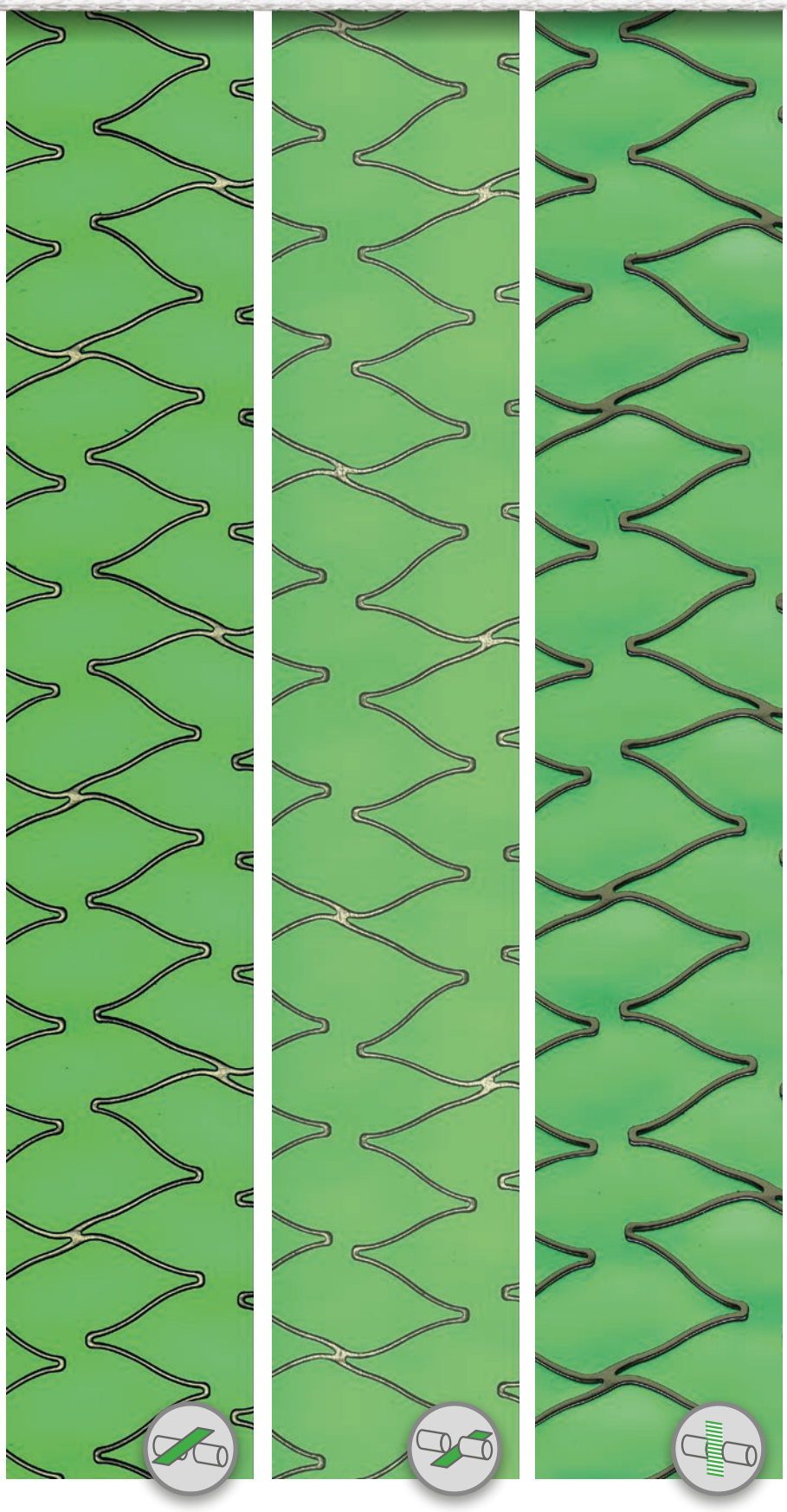


Outer surface view

Inner surface view

Lateral surface view

Providing the highest-quality real color images

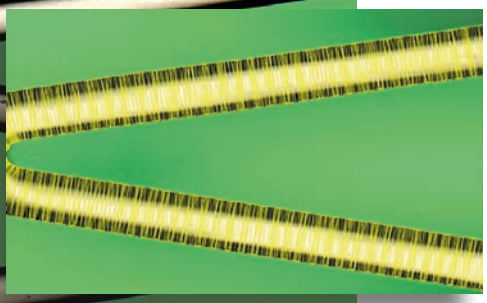
plete surface spection

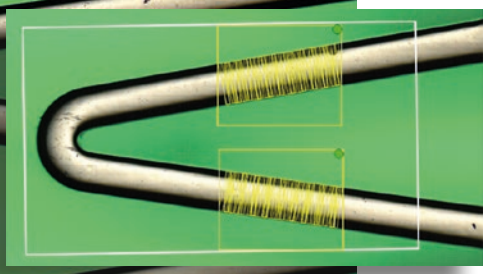
High-quality unrolled images of the outer, inner and lateral surfaces of the devices can be easily acquired with Q vix.
Unrolled images are fully focused, full color pictures of device surfaces that ensure accurate dimensional measurements and complete visual inspection for quality control.

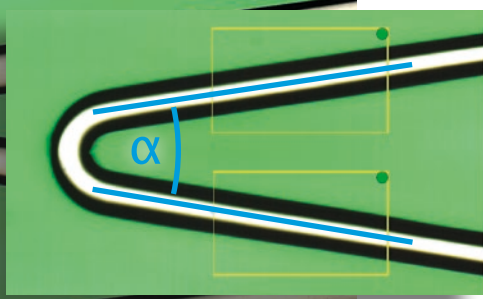
Wide variety of sharp imaging possibilities

In addition to high quality unrolled images, Q vix can provide extended focus images of any area of the device.

This technology provides an image with extended depth of focus for the highest magnification lenses by combining a set of stacked images captured at different focus positions, and are essential for the observation of the finest details in the inspected device.







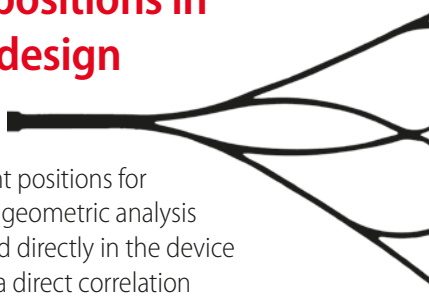
Accurate dimensional analysis

Sensofar Medical's unique technology increases inspection throughput by analyzing images as soon as they are acquired providing immediate dimensional and visual inspection results.

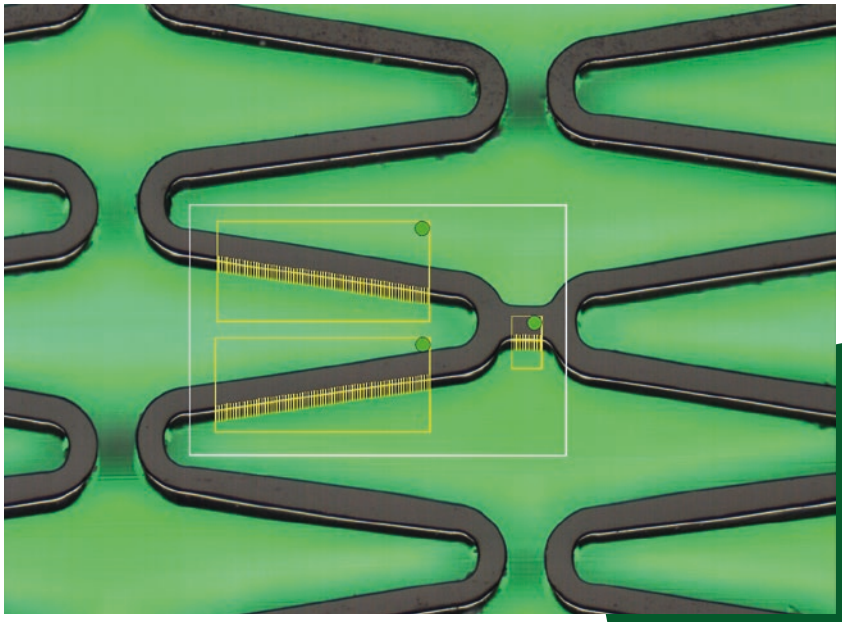
The algorithms embedded in Q vix software automatically detect the edges of the devices with sub-pixel resolution. A complete set of software tools allow the automatic analysis of their dimensions and geometry providing accurate measurements of strut width and thickness, strut angles, radius of curvatures and distances between struts.

Dimensional analysis is configured in regions of interest and performed with sub-micron repeatability. The analysis results are displayed using a color code that warns the operator with a red flag if the results are out of the defined tolerances.

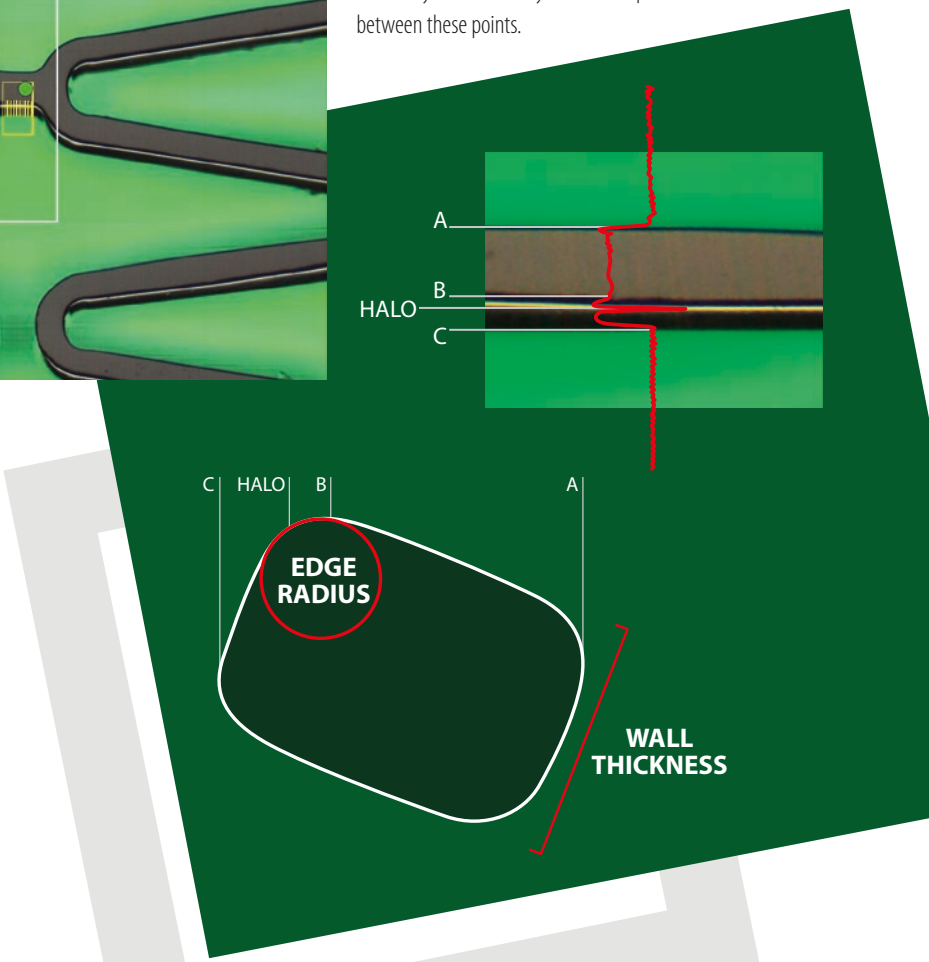
Defining positions in the stent design



The measurement positions for dimensional and geometric analysis can be configured directly in the device design enabling a direct correlation with the dimensions specified in the design drawing.

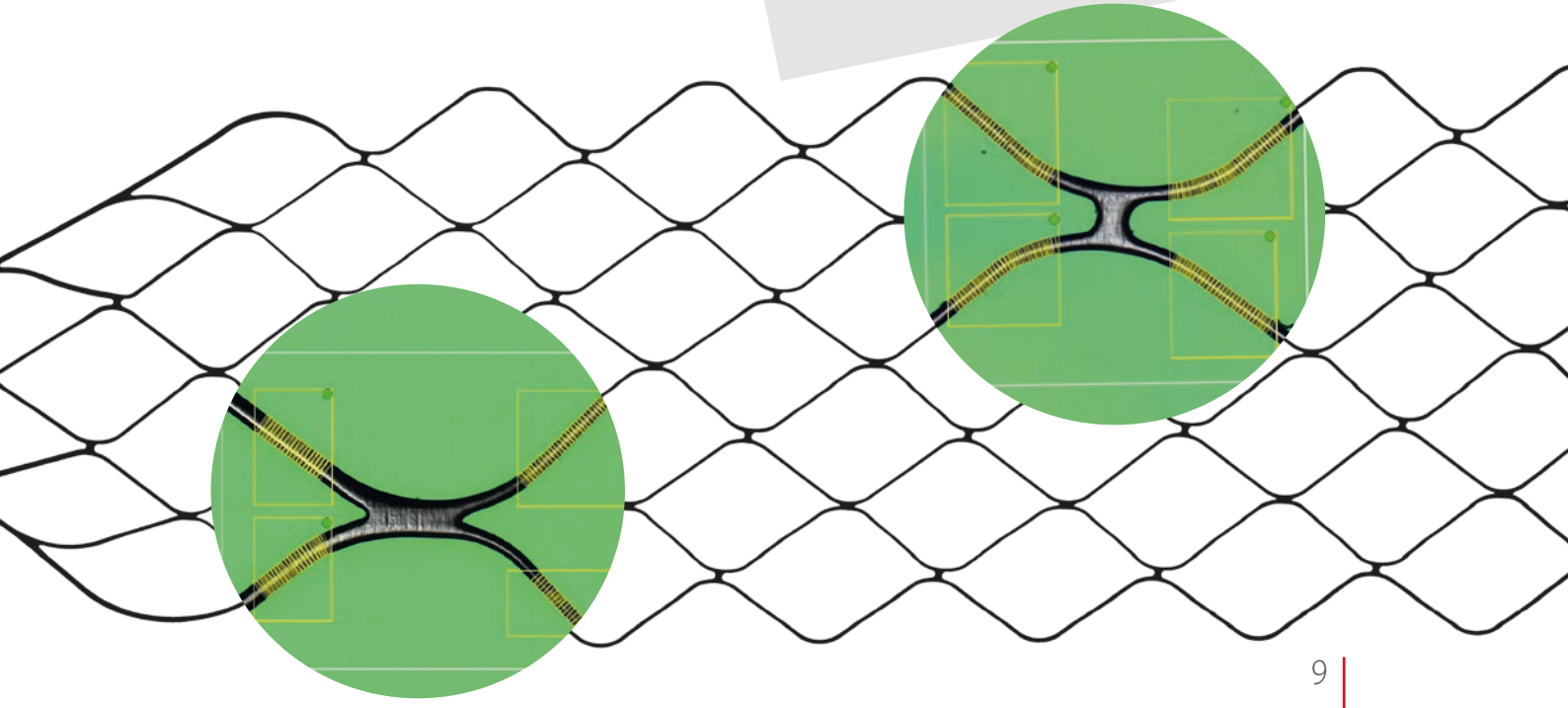


Images are processed to detect the light transitions that define the device limits (points A & C), the transition from outer to lateral surface (point B), and the reflection halo generated in the rounded edge of the device. The wall thickness and edge radius are accurately determined by the relative positions between these points.



Measuring wall thickness and edge radius

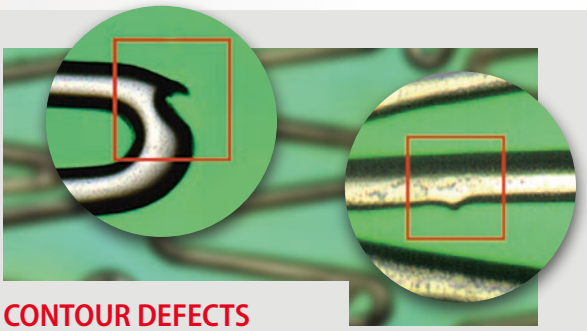
The strut wall thickness and curvature edge radius are optically measured in the predefined regions of interest. A proprietary correction model is used to obtain accurate measurements based on the image acquisition speed and the illumination and observation angles.



Defect detection

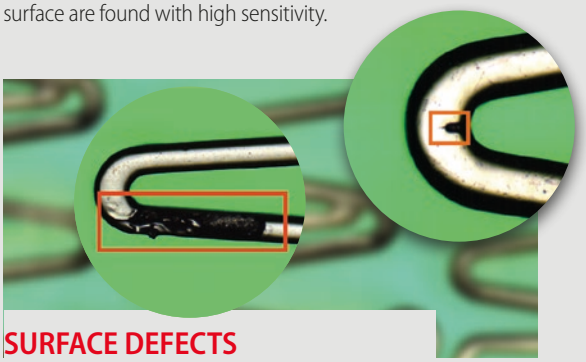
Automatic visual inspection

The time spent in visual inspection, usually the bottleneck of the production line, is dramatically reduced by the introduction of automatic visual inspection. Defects are automatically detected in parallel to dimensional measurements at any surface of the device providing a complete inspection in a single operation.



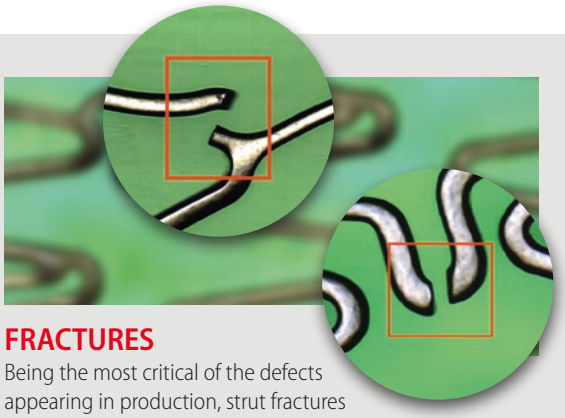
CONTOUR DEFECTS

Irregularities in the contour of the struts arising from the laser cutting process or from material inclusions in the lateral surface are found with high sensitivity.



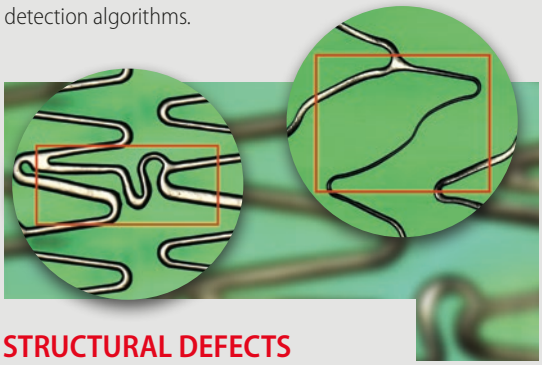
SURFACE DEFECTS

Surface irregularities related with material inclusions, contamination, or polishing defects are seen as contrast changes in either surface of the device. Surface defects detection methods are adapted to brightfield and grazing illumination configurations.



FRACTURES

Being the most critical of the defects appearing in production, strut fractures are automatically detected by robust detection algorithms.



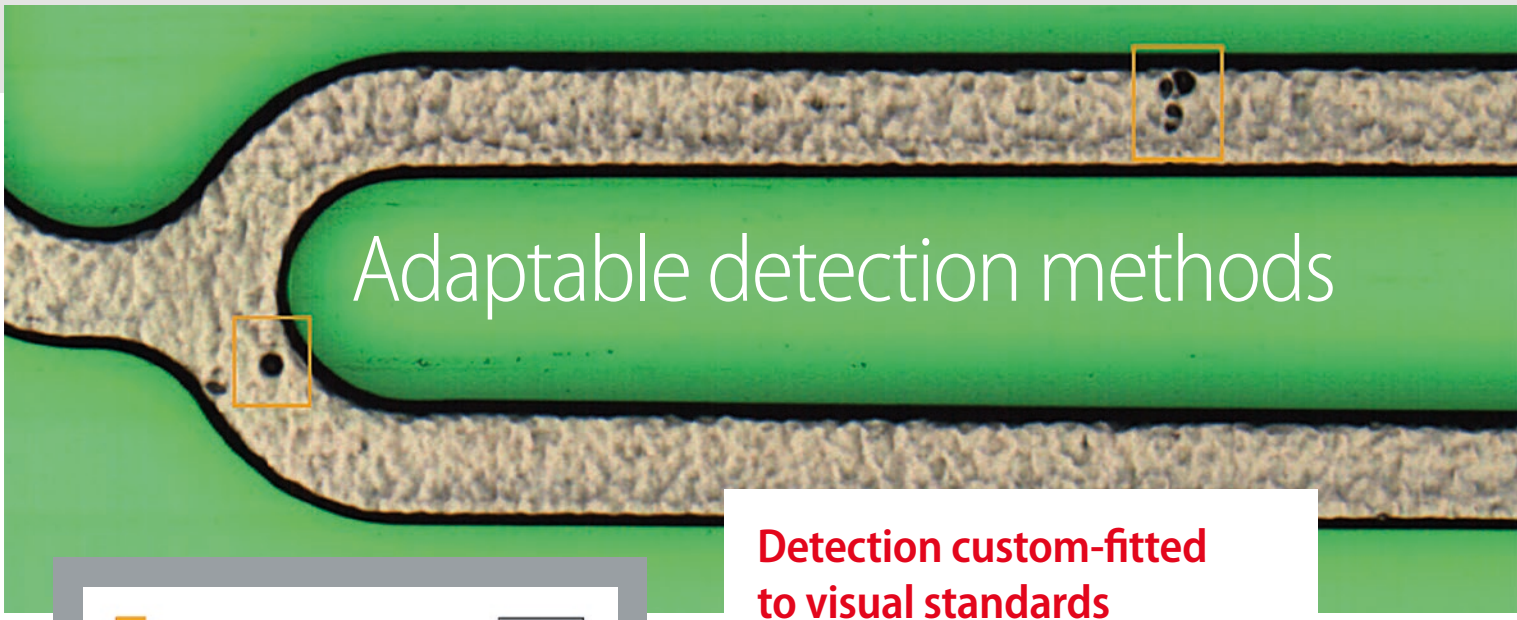
STRUCTURAL DEFECTS

Powerful detection algorithms enable the automatic detection of larger scale irregularities like deformations and dimensional deviations from the ideal stent design.

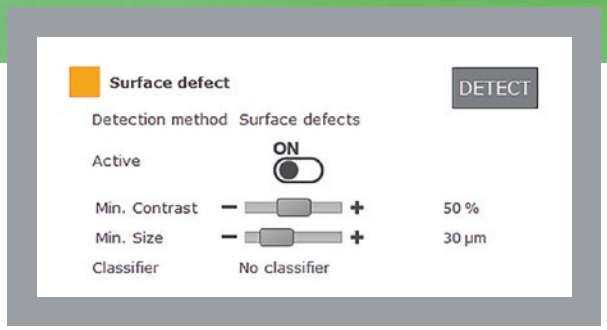
Defects Summary

Order		Defect name	Secction #	Area
1		Surface defect	1	0.065 %
2		Surface defect	2	0.049 %
3		Contour defect	3	N/A
4		Contour defect	4	N/A
5		Fracture	5	N/A
6		Deformation	6	N/A
7		Deformation	7	N/A

Different detection methods are automatically applied based on the type of the irregularities that need to be found, allowing the detection of defects in the device surface, contour and structure.



Adaptable detection methods



Detection custom-fitted to visual standards

Detection sensitivity control is adjusted when creating digital defect libraries enabling the possibility to set the difference between cosmetic features and critical defects in the devices.

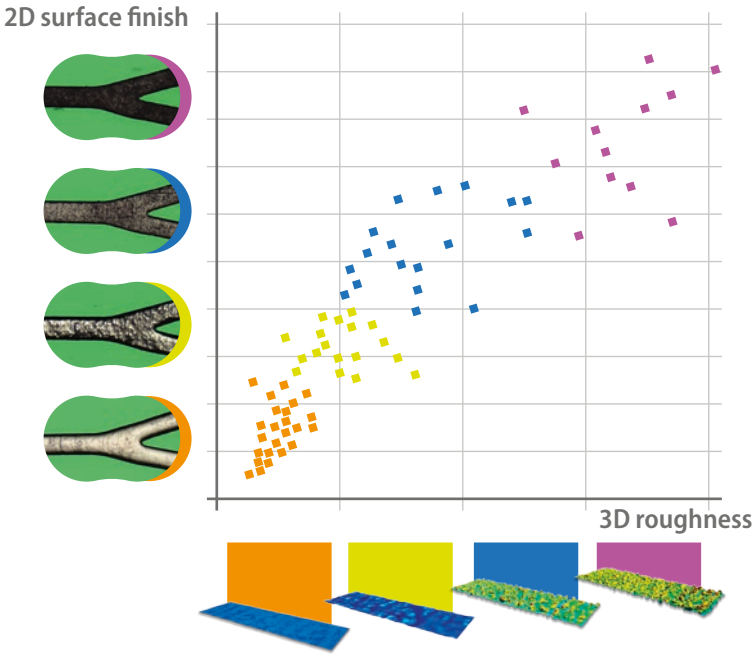
A warning for the operator will be displayed only if the irregularity detected meets certain criteria that qualifies it as a critical defect.

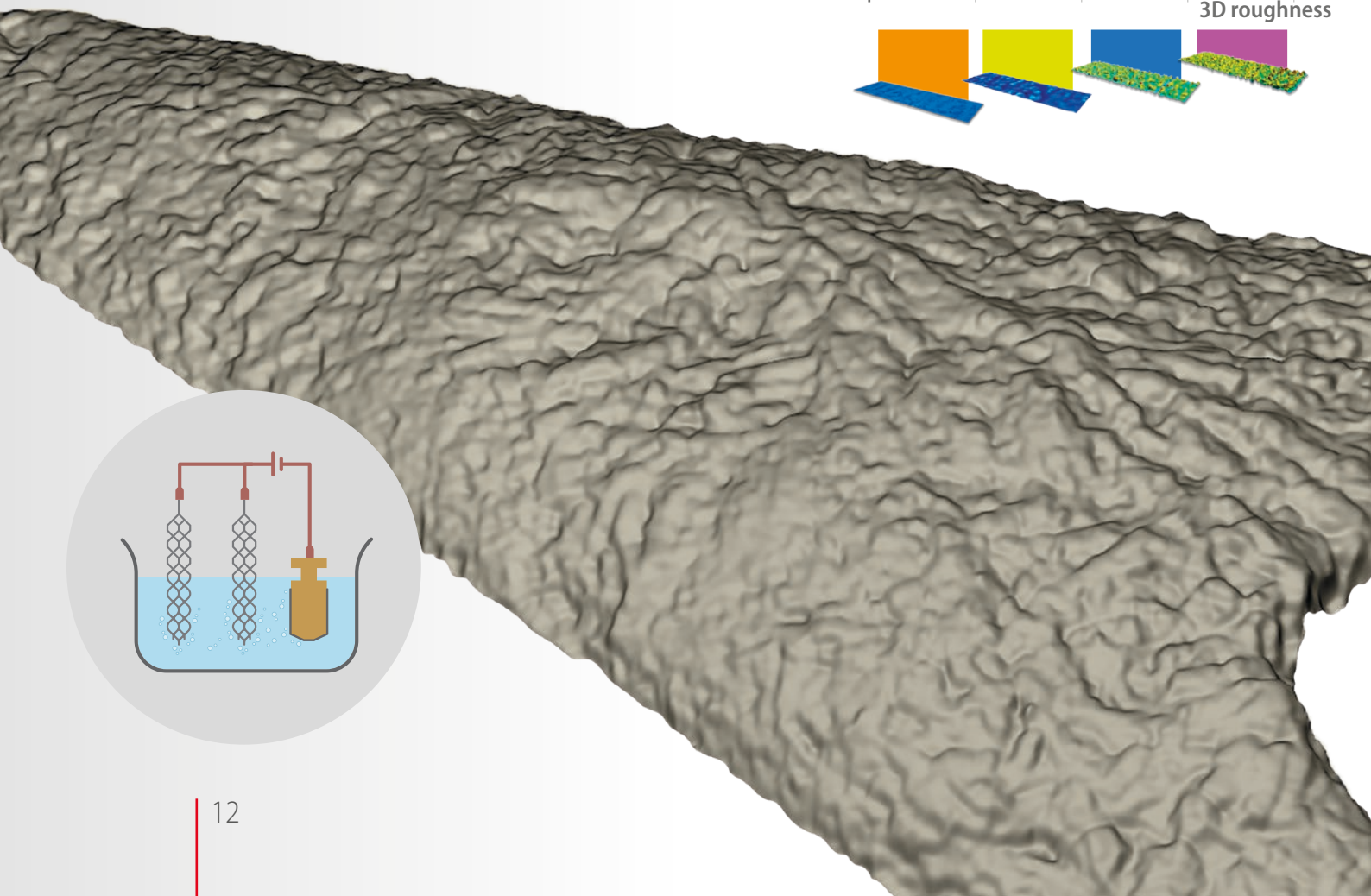
Surface finish assessment

Roughness measurement

The exceptional combination of 2D and 3D technologies in Q vix allows a direct correlation of a 3D roughness measurement in the surface of the device with a 2D image of the surface in the exact same point.

Surface roughness is measured with nanometric accuracy according to ISO20178 standard using Coherence Scanning Interferometry (CSI) embedded in Q vix sensor head. Measurement positions of 3D roughness can be configured in the stent design for an automatic mapping of the surface roughness.





Surface characterization from 2D images

Surface finish can be characterized from 2D unrolled images by the automatic measurement of specific structural parameters calculated in regions of interest.

By establishing tolerance values of these parameters, it is possible to set an objective criteria for the surface quality of the stent at selected points. This allows the system to determine and display surface finish results together with the rest of the inspection results.

Sensofar Medical has successfully established statistical and structural parameters measurable from 2D images of the stent surface that consistently correlate with surface roughness parameters calculated from 3D measurements. Assessing the surface quality from 2D images provides valuable information about the device while not compromising inspection throughput.

Customized mandrels

Q vix mandrels are custom manufactured using state-of-the-art techniques, which guarantees a rotation accuracy below the micrometer level. Mandrels are composed by transparent thin-walled tubes that allow inspecting the inner surface of the devices while not affecting the quality of the images.

Mandrels are available for sizes ranging from 1mm to 32mm in diameter, and for lengths up to 200mm.

High-accuracy positioning stage

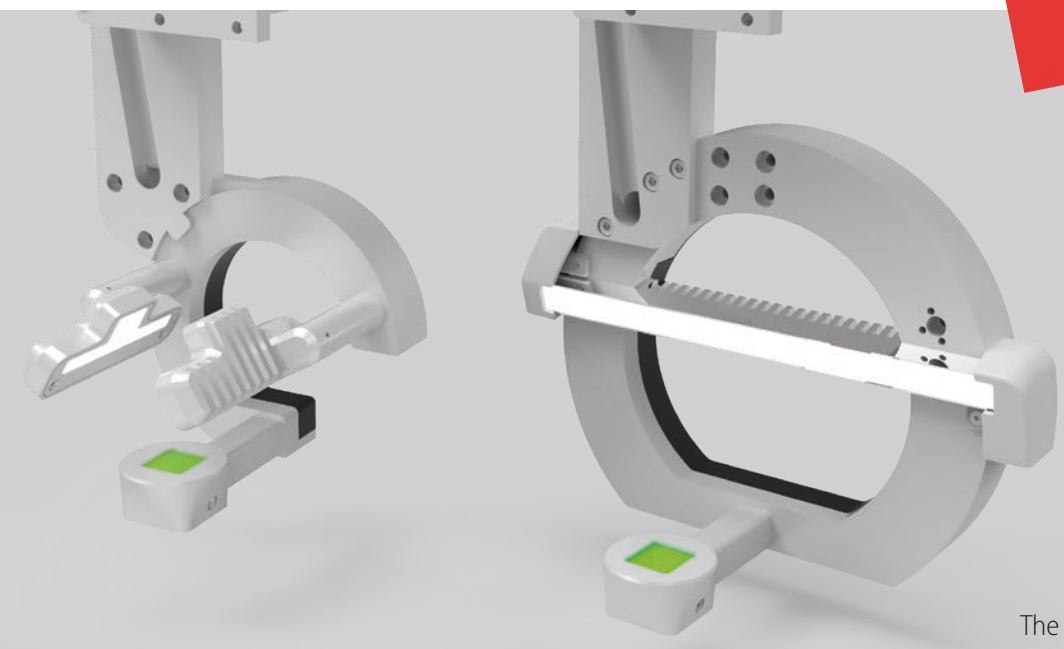
State of the art technology

The new generation of dedicated tools for medical device inspection

The rotation stage in Q vix platform is able to rotate with unprecedented accuracy at high rotation speeds providing high quality unrolled images of the inspected sample at a very high throughput.

Loading stent module

An optional module for autonomous loading allows a rapid and unmanned loading and unloading of the samples in the mandrels. In the case of large Nitinol peripheral stents, this ensures a correct and repeatable positioning of the sample on the mandrel. This module can be used as an independent module to Q vix or as an integrated module loading the stents directly to the mandrel used for inspection.



Advanced illumination control

The side ring of Q vix enables hundreds of combinations of light sources to obtain the optimal illumination for each application.

The different designs of the side ring allow easy and fast loading and unloading of the stents and the heart valves. These rings can accommodate up to seven high-intensity light sources that are simultaneously controlled from the Q vix software.

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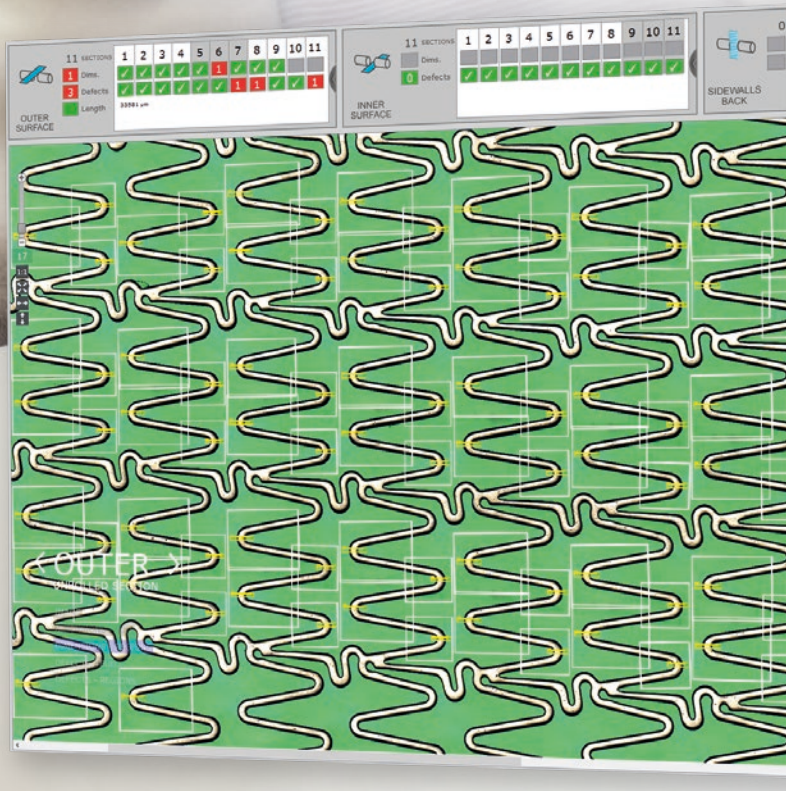
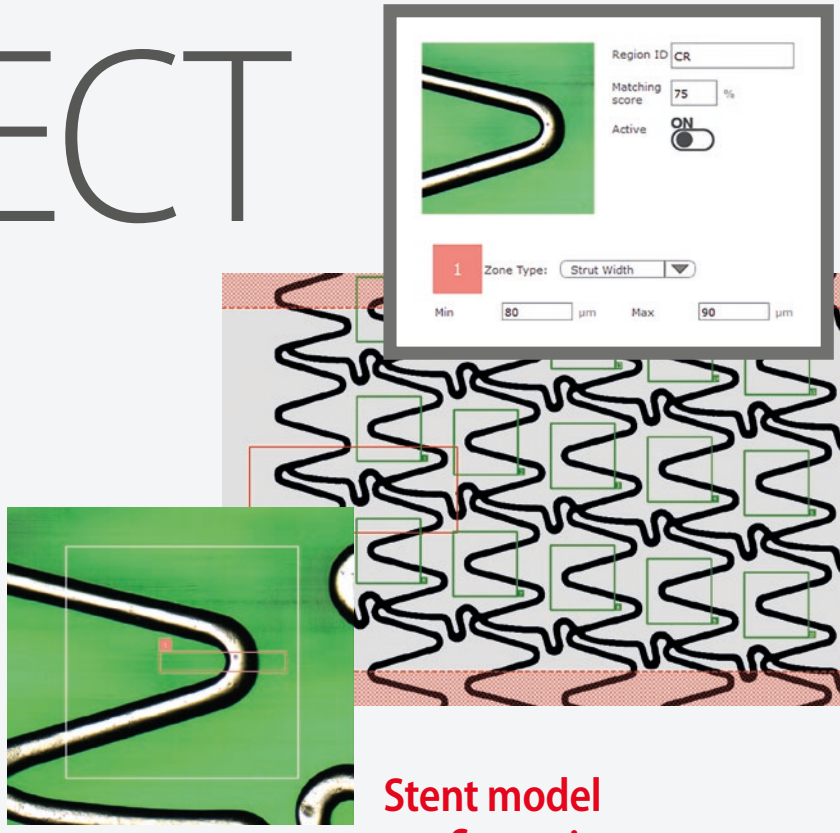
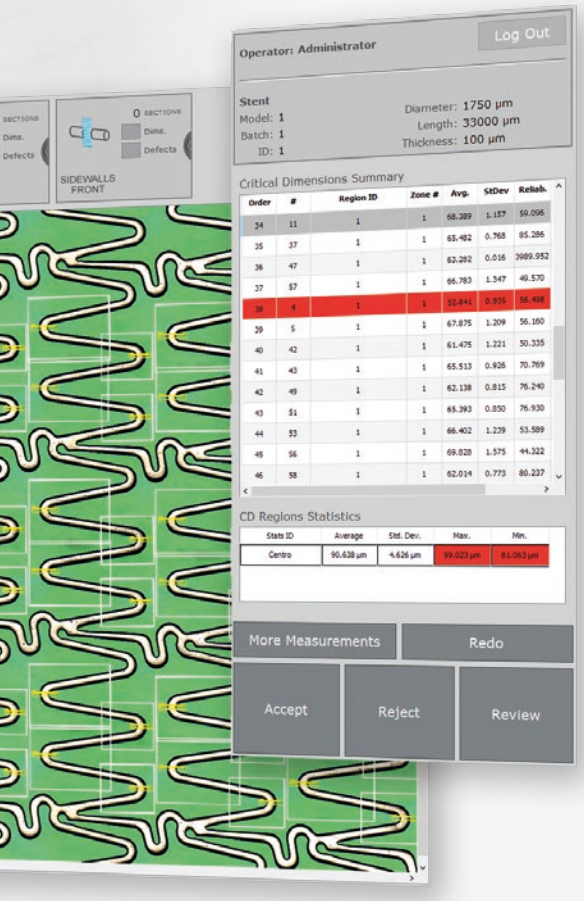

11 SECTIONS
1 2 3 4 5 6 7 8 9 10 11
Dims.
Defects
Length
OUTER SURFACE
INNER SURFACE
SIDEWALLS BACK
OUTER

Dedicated Inspection Software adapted to any aplication

soINSPECT

Q vix software, SensoINSPECT, has been designed to assist quality inspectors in the challenging task of inspecting medical devices. SensoINSPECT provides immediate feedback of the quality of the devices showing warnings if any of the inspected features is found out of the defined tolerances.





Automatic inspection routines

The inspection routines contain the measurement positions and visual inspection details for the analysis that will be automatically performed. When running an inspection routine, the software will automatically acquire and analyze the images required to carry out the desired inspection.

Summary tables containing the numerical results and the detected defects are always available for fast navigation of the inspection results reducing the operator decision time and increasing inspection throughput.

Stent model configuration

Stent information is stored in SensoINSPECT as stent models. These are loaded by operators in the system during the inspection, and contain the data needed for the automatic inspection and analysis of the devices.

Inspection results and reports

SensoINSPECT automatically exports the inspection results once the device is accepted or rejected.

The images of the detected defects and an inspection report containing numerical results and inspection information traceability are exported. Additionally, the full set of acquired images can be exported after the inspection.

New paradigm for Production

Towards a fully automatic inspection solution

It is not necessary for the inspector to remain in front of one system during the inspection, which allows a single inspector to manage up to 4 Q vix working in parallel depending on the application. In addition, after an exhaustive qualification of the system is conducted, the assisted decision made by the operator can become an automatic decision made by the software in a completely unmanned inspection facility.

Services

Sensofar Medical has designed a set of services that make up a complete inspection solution adapted to any inspection application and environment:

- A calibration service is available to guarantee the reliability of the inspection results. Periodic calibration is performed together with preventive maintenance.
- Customized training packages are available for basic and advanced users, which will be essential to make the most of Q vix when using it for R&D, product development or production.
- A validation package is available to provide the documentation and support needed to have a production-ready system compliant with regulatory requirements.
- A configuration package, designed as a turn-key solution for inspection, is available to guarantee a seamless transition from a manual inspection to a semi-automated or fully automated inspection.

System Specifications

Stent type	Metallic (steel, CoCr, Nitinol, Mg), braided, welded, polymer
Stent OD	1 - 32 mm
Stent length	Up to 200mm
Camera	Color 2044 x 1084 effective pixels
Frame rate	50 fps (array), 3000 fps (linear)
Z scan linear stage range	40 mm range, 5 nm resolution
XY stage range	250 x 215 mm with linear encoders, ±0.3µm resolution
Rotation stage	360º, 1.5µrad resolution
Overall positioning accuracy	Better than ±1µm
Illumination system	Flexible illumination setup (up to 7 independent LED light sources)
Nosepiece	5 position fully motorized
Imaging modes	Live, unrolled (FoV and section), extended focus
Inspection capabilities	Outer surface, inner surface, lateral surfaces, edges (grazing illumination)
CD measurement repeatability	Better than ±1% rms (typical σ figures lower than 1µm)
CD measurement accuracy	Better than ±3% PV (typical σ figures lower than 3µm)
Surface inspection	Automatic defect detection
3D modes	Surface topography, roughness, thickness of transparent coatings
3D measurement technique	CSI (Coherence Scanning Interferometry)
Assisted concept	Decision Accept / Reject made by the operator
Computer	HP platform
Operating system	Microsoft Windows, 64bit
Electrical requirements	Line voltage 100-240V AC; frequency 50/60Hz single phase
Power consumption	Lower than 100W
Weight	75 Kg (vibration isolation table not included, 37Kg)
Working conditions	Temperature 18ºC to 25ºC; Humidity < 80% RH

Dimensions units: mm (in)

Weight: 75 kg (165 lbs)

550
(21.7)

750
(29.5)

575
(22.6)

Imaging Objectives

3D Objectives

MAG	2X	5X	10X	10XDI	20XDI	50XDI
Numerical aperture	0,055	0,14	0,28	0,3	0,4	0,55
Working distance (mm)	34	34	34	7,4	4,7	3,4
Horizontal FoV (mm)	9	3,6	1,8	1,8	0,9	0,36
Spatial sampling (µm)[1]	4,4	1,76	0,88	0,88	0,44	0,18
Optical resolution (µm)[2]	2,77	1,09	0,54	0,51	0,38	0,28
Unrolled acquisition rate (mm^2/s)[3]	120	20				
Vertical resolution (nm)[4]				1	1	1

1 Pixel size on the imaged surface **2** L&S: Line and Space (500nm wavelength)
3 Frame rate 3000 fps **4** Vibration isolation table is required

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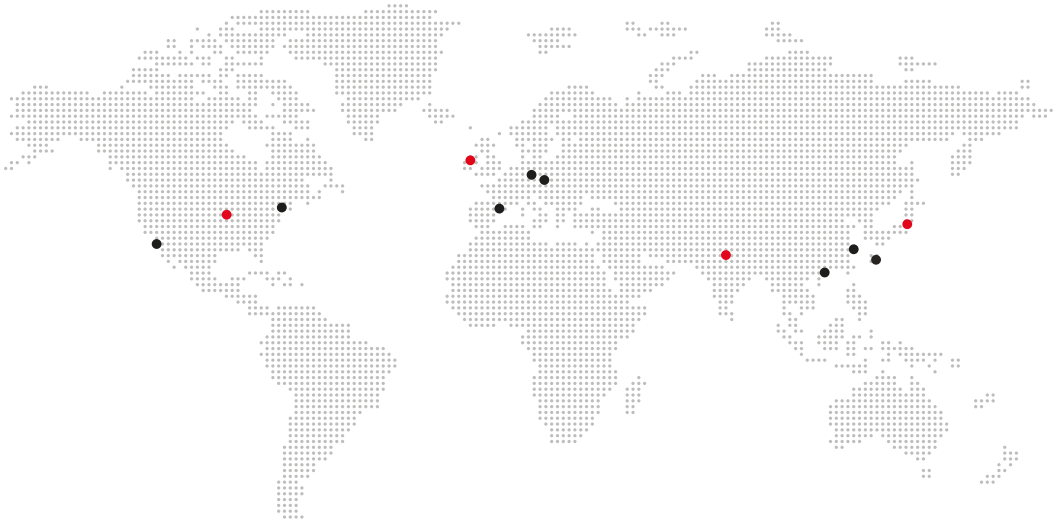
MEDICAL



SENSOFAR is a leading-edge technology company that has the highest quality standards within the field of surface metrology

Sensofar Medical provides state-of-the-art technology for the inspection of implantable medical devices and components as well as leading-edge solutions for R&D worldwide, with each system designed to incorporate the highest quality standards within the field.

The Sensofar Group headquarters are located in Barcelona, the technological heart of Spain. The Group is represented in over 20 countries through a global network partners and has its own offices in Asia, Germany and the United States.

HEADQUARTERS
SENSOFAR MEDICAL | BARCELONA (Spain) | T. +34 93 700 14 92 | info@sensofar.com

SALES OFFICES
SENSOFAR ASIA | SHANGHAI - China | T. +86 21 61400058 | info.asia@sensofar.com
SENSOFAR USA | NEWINGTON (CT) - USA | T. +1 617 678 4185 | info.usa@sensofar.com

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