

Leak Testing of Catheters and Endoscopes

Ensuring patient safety through reliable quality control | Risk reduction through 100% leak testing

Catheters and endoscopes – High standards for patient safety



Catheters and endoscopes that have direct or indirect contact with the human body are among the most technically advanced medical devices. It is therefore essential that manufacturing failures are detected at an early stage and eliminated.

Although they were developed for different medical applications, both product groups have many similarities from a quality assurance perspective. They feature complex hollow structures, flexible materials and critical joints, and must meet stringent requirements regarding patient safety and regulatory compliance.

Even the smallest leaks can impair the functionality of the products and pose significant risks to patients. In the case of catheters, for example, leaks can lead to incorrect dosages, loss of pressure or contamination.

Catheters and components (left) and endoscopes (right) are checked for leaks.

In the case of endoscopes, the ingress of fluids can damage sensitive optical or electronic components and compromise hygienic reprocessing.

For this reason, automated leak tests are carried out as part of a 100% routine inspection on the production line to minimise risk. This serves to verify leak tightness and compliance with defined quality standards. Within the framework of quality management systems in accordance with ISO 13485, as well as the requirements of the MDR and the FDA, leak testing is therefore often one of the validated production processes.

Testing methods using compressed air enable rapid, non-destructive and reproducible quality control, with full documentation of the test results.



Typical areas relevant to inspection | Complex cavities and tube systems

Both product groups feature long channels, some of which are very small, and these must be reliably inspected. The following components, in particular, are critical.

Catheters	Endoscopes
Single-lumen and multi-lumen tubes	Air/water channels
Balloon catheters	Working channels
Infusion ports	Extraction channels
Pressure measurement ports	Instrument channels
Connectors	Sealed areas for optical and electronic assemblies
Luer fittings	

Both catheters and endoscopes are often made from elastic materials such as silicone, polyurethane (PU), polyethylene (PE), PTFE, TPE and elastomers. The elasticity of these materials leads to changes in volume during pressurisation, which must be taken into account when defining test parameters.

Differences in leak testing

Catheters	Endoscopes
Small internal volumes Even minor variations in temperature or material can affect the measurement result.	Larger test volumes Larger internal volumes due to the complexity of the channel systems Longer total testing times
Balloon systems In addition to checking for leaks, the balloon's behaviour often needs to be checked too.	Sensitive components Protection of optical, electronic systems, and lighting units against the ingress of liquids
Very short cycle times Production volumes are often in the millions High demands on testing speed	Multiple test circuits Complex test procedures due to the separate testing of different areas (working channel air/water channel sealed section of the electronics)

Typical test parameters for leak testing | Test medium compressed air

Parameters	Catheters	Endoscopes
Test pressure	50 to 500 mbar up to several bar (Balloon test)	100 to 500 mbar
Test volume	a few mm ³ to several cm ³	a few cm ³ to 100 cm ³
Leakage rate	< 0.5 to a few cm ³ /min	< 0.5 to a few cm ³ /min

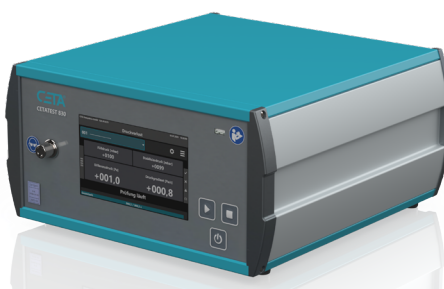
Typical examples | Actual test parameters are determined on a product-specific basis as part of capability studies and validation processes.

Testing technology | Leak testers with differential pressure sensor

When leak-testing catheters and endoscopes, leak testers with differential pressure sensors are frequently used due to the low permissible leakage rates. The test pressures are generally in the range of 100 to 500 mbar. The CETATEST 830 series of leak testers, with a pressure range of 1 bar and a measurement range of 500 Pa, is suitable for this application. Standard features include

digital I/O interfaces, RS-232, USB (host) and Ethernet. The usual industrial interfaces are available as options.

The testers are supplied with an internationally recognised calibration certificate (DIN EN ISO/IEC 17025) and a warranty of up to three years (optionally extendable to five years).



Leak tester CETATEST 830 with differential pressure sensor

CETA Testsysteme GmbH – Experience ensures product safety

CETA Testsysteme GmbH has been developing and manufacturing 'Made in Germany' leak and flow testers for 100%-end-of-line-testing for over 35 years. Based on standardised test procedures in accordance with DIN EN 1779 and DIN EN 13184, CETA offers reliable solutions for quality assurance. The

company supports manufacturers of medical devices in the qualification and documentation of their processes throughout the DQ, IQ, OQ and PQ chain. Worldwide, several thousand CETA testers ensure quality and process reliability in production. www.cetatest.com

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