



Accelerate Your CMM Validation With An IQ/OQ Protocol

IQ/OQ Equipment Qualification Service for CMMs and XCTs

In the medical industry, equipment that is purchased by medical device manufacturers for manufacturing, inspecting, packaging, etc. must be “validated” by performing an IQ/OQ protocol.

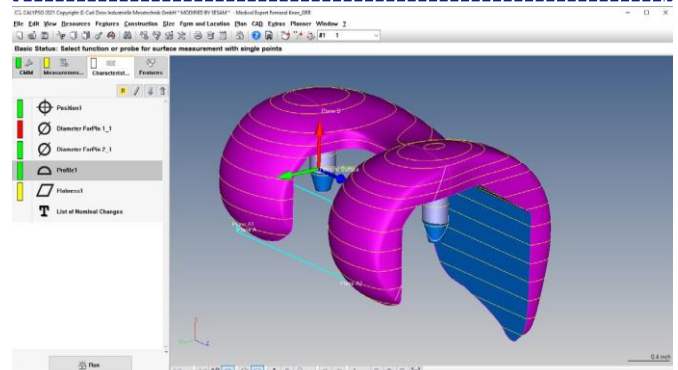
For complex equipment, it is common for the original equipment manufacturer (OEM) to provide a validation protocol or support building a protocol. This saves the end user time and effort, while ensuring that the validation protocol has been developed by someone who understands the equipment best - the OEM.

Through extensive research, ZEISS Industrial Quality Solutions has established validation methods to comply with FDA standards. ZEISS is excited to provide a comprehensive IQ/OQ equipment qualification service for medical customers that want OEM support during the validation of their Coordinate Measuring Machine (CMM) or X-ray Computed Tomography (XCT) system!

Your benefits:



- Save time – complete your CMM or XCT equipment qualification in days, not weeks
- Rely on ZEISS experts – allow a ZEISS applications engineer to perform the qualification activities
- OEM insight – execute qualification activities tailored by ZEISS to your CMM or XCT model
- Complete documentation – receive a completed protocol with documented evidence of qualification activities



Looking to accelerate your validation process?

Contact our experts: info.metrology.us@zeiss.com

zeiss.com/metrology/medical

Product Offering

CMM Validation and the FDA

Free 15-minute eLearning

This free eLearning describes common myths and misconceptions about FDA validation requirements, and how they apply to measurement systems and metrology software. It explains existing best practices for measuring equipment validation, including a detailed overview of the IQ/OQ Equipment Qualification Service available from ZEISS.

This free eLearning covers the following content:

- What does the FDA say about CMM validation?
- Industry Best Practices for Measuring Equipment Validation
- How can ZEISS support you: The IQ/OQ Equipment Qualification Service

Register at portal.zeiss.com/academy.

IQ/OQ Equipment Qualification Service

Onsite or remote options available

The IQ/OQ Equipment Qualification Service provides a comprehensive protocol script, formatted and aligned to industry standards, for the Installation Qualification (IQ) and Operational Qualification (OQ) for one ZEISS CMM equipped with ZEISS CALYPSO metrology software, or one ZEISS XCT system with ZEISS INSPECT metrology software.

Installation Qualification includes:

- Supporting documentation, provided by ZEISS
- Verification that all purchased components are present and complete
- Confirmation that all components are in good working condition
- Verification of the CMM / XCT system environment and workstation specifications
- Verification that the system is installed according to ZEISS recommendations for that CMM / XCT model

Operational Qualification includes:

- Supporting documentation, provided by ZEISS
- Operational tests of the CMM or XCT system with a ZEISS-supplied reference artifact
- Operational tests of CALYPSO or ZEISS INSPECT's algorithms, according to NIST protocols
- Tests of safety-related hardware and software functionality
- Tests of key user access functionalities

This service is offered at customer site (recommended) or remote.

Remote option requires the full participation of an onsite employee with CALYPSO / ZEISS INSPECT Basic training, stable internet access at the CMM /XCT workstation with a remote access sharing service, and support from IT. Onsite service includes travel and expenses.

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