

Luminex[®]



Luminex[®] System Installation Qualification
and Operational Qualification (IQ/OQ)



Luminex® 100/200 and MAGPIX® System Installation Qualification and Operational Qualification (IQ/OQ)

Installation Qualification and Operational Qualification (IQ/OQ) are an integral part of any validation program for newly installed or relocated instruments. The Luminex 100/200 and MAGPIX IQ/OQ Protocols provide the documentation that laboratories need to prove that their Luminex reader was installed correctly and is operating according to specifications. These documents can be used to fulfill ISO, CLIA, and GLP quality management requirements.

Installation Qualification

The system IQ provides a formal check and documentation to confirm that the instrument, operating software, and other accessories have been supplied as ordered and that the system has been installed per Luminex guidelines.

The IQ will:

- ✓ Confirm that the installation site meets the environmental requirements for the reader (bench space, power, temperature, etc...)
- ✓ Review hazards and safety precautions pertinent to the use of the Luminex system
- ✓ Provide installation instructions or confirm factory installation of software
- ✓ Provide hardware installation checklist, including tubing and cables
- ✓ List preventative maintenance requirements so they can be added to the laboratory's PM schedule
- ✓ Document recommended cleaning and/or maintenance schedule so it can be incorporated into the laboratory's standard operating procedures

Operational Qualification

The Operational Qualification (OQ) is performed after installation to demonstrate that the instrument is functioning according to its operational specifications.

The OQ will:

- ✓ Test all modules of the Luminex instrument for proper functionality
- ✓ Perform instrument calibration and performance verification operations
- ✓ Produce the documented evidence needed to meet internal and external validation requirements

The IQ/OQ are available directly from Luminex. Information on how to order this product can be found on the Luminex website at www.luminexcorp.com

Item Number:

Luminex 100/200 xPONENT 3.1 System: **VP-xPONENT 3.1***

Luminex MAGPIX xPONENT 4.1 System: **VP-xPONENT 4.1**

* The Luminex 100/200 xPONENT 3.1 System IQ/OQ can be performed by laboratory personnel or by Luminex Field Service Engineers. Please contact your Luminex representative for details.

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