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Instrument qualification services

# Keep your instruments compliant.

# We've got your back.

Get documentation of instrument compliance with regulatory requirements and industry standards

The Services and Support team at Thermo Fisher Scientific knows Applied Biosystems™, Invitrogen™, and Ion Torrent™ instruments better than anyone because the professionals at Thermo Fisher design and manufacture them. With our instrument qualification services, you can be confident that your instruments are installed, operating, and performing according to the manufacturer's specifications. Our manufacturer-trained and certified field service engineers will conduct comprehensive tests, including software and hardware compatibility, component verification, and site requirements, to verify performance and provide reliable, audit-style documentation to support regulatory requirements.

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## Recommendations for maintaining a qualified system

| Description | Checkpoints | Services included |
|---|---|---|
| **IQ/OQ/IPV** (RUO) **or IQ/OQ/PQ** (IVD)* | | |
| Complete qualification service | When are qualification services recommended? | Comprehensive, audit-style documentation for: |
| • **Verifies and documents:**<br>  – That all instrument components and accessories match the order invoice and shipping manifest<br>  – That the customer's site meets the requirements for instrument installation<br>  – The configuration of all components of the instrument system, including software and computer<br>  – That upon installation, the instrument system is able to meet all performance specifications; comprehensive sub-system testing is included in the verification<br>• **Establishes the initial accuracy and performance of the instrument** | • At installation<br>• After a move requiring re-installation<br>• After major additions, changes, or hardware or software upgrades that require capturing the instrument configuration during re-installation | • Installation verification<br>• Order and system verification<br>• Calibrated tools certification<br>• Component verification<br>• Customer training verification<br>• Documentation verification<br>• Hardware operation verification<br>• Maintenance verification<br>• Software verification<br>• System performance verification |
| **OQ/IPV** (RUO) or **OQ/PQ** (IVD)* | | |
| Post-installation qualification service | When are qualification services recommended? | Comprehensive, audit-style documentation for: |
| • **Verifies and documents:**<br>  – The configuration of all components of the instrument system, including software and computer<br>  – The operational performance of all relevant sub-systems using comprehensive testing<br>  – That the instrument system is able to meet all performance specifications after critical service or planned maintenance events<br>• **Helps ensure the continued accuracy and precision of the instrument** | • After planned maintenance<br>• After a critical repair<br>• After minor additions, changes, or hardware or software upgrades<br>• According to SOP or site quality requirements<br>• Before a previously installed system will be used in a regulated test environment for the first time | • Calibrated tools certification<br>• Component verification<br>• Customer training verification<br>• Documentation verification<br>• Hardware operation verification<br>• Maintenance verification<br>• Software verification<br>• System performance verification |

\* IQ: Installation qualification; OQ: Operational qualification; IPV: Instrument performance verification; PQ: Performance qualification; RUO: Research Use Only; IVD: *In Vitro* Diagnostic Use.

Contact an instrument qualification specialist at
**thermofisher.com/iqoqpq**