

Instrument Qualification (IQ)/Operational Qualification (OQ) Documentation Manual

Key Features

- Hardware validation protocol for guided instrumentation setup
- Complete list of needed part numbers for all qualification procedures
- Provides protocols for Octet system installation and operational qualification
- Qualification of both quantitation- and kinetics-based assays

OVERVIEW

The Octet Installation Qualification (IQ) and Operational Qualification (OQ) manual provides the procedures to document and verify that the correct Octet System was ordered, delivered and installed according to ForteBio specifications. ForteBio offers Octet customers the documentation and services needed to assure successful validation of the Octet System. The manual can be ordered as a package with the Compliance Validation Software Module or can be ordered separately.

INSTALLATION QUALIFICATION

The installation qualification procedure confirms and documents the proper and safe installation of the Octet System and is comprised of the following:

- System verification
- Document verification
- Software verification
- Installation verification

OPERATION QUALIFICATION

The operation qualification procedures confirm that key aspects of the analyzer and software perform as intended by operating satisfactorily and attaining consistent, reproducible results within stated specifications and process requirements. The operation qualification is applicable only to Octet Software version 4.0 and higher and tests the following:

- Quantitation assay qualification
- Import standard curve
- Abort verification
- Setting up custom quantitation assays
- Kinetic assay qualification (only performed on Octet QK systems)



MATERIALS REQUIRED

- Octet Q or QK instrument
- Octet Software 4.0 or later installed

ORDERING INFORMATION

Part No.	UOM	Description
41-0062	Each	Instrument Qualification/Operational Qualification Manual for the Octet System
90-9003	Each	Instrument Qualification/Operational Qualification Service for the Octet Q and QK system
90-9004	Pkg	Octet QK Complete Validation Package: <ul style="list-style-type: none"> • Octet QK Compliance Validation Software Module (1) • Octet IQ/OQ Manual (1) • Service, Octet IQ/OQ Validation (1)
90-9005	Pkg	Octet Q Complete Validation Package: <ul style="list-style-type: none"> • Octet Q Compliance Validation Software Module (1) • Octet IQ/OQ Manual (1) • Service, Octet IQ/OQ Validation (1)

Special Note

Purchase of the IQ/OQ manual or the Compliance Validation Module for the Octet System does not ensure compliance with the FDA's 21 CFR part 11 guidelines. It is the user's responsibility to establish and follow policies and standard operating procedures that satisfy compliance requirements.

For more information about FortéBio's Octet System for label-free, real-time detection, applications and services, visit our website at www.fortebio.com or contact us directly.



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