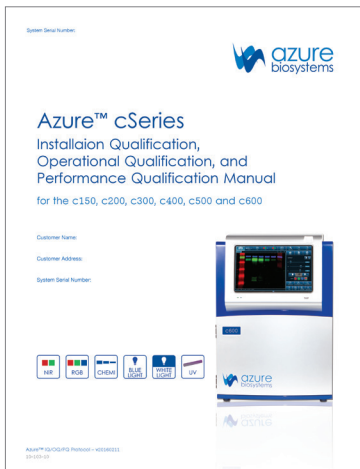


Azure Biosystems™ IQOQPQ

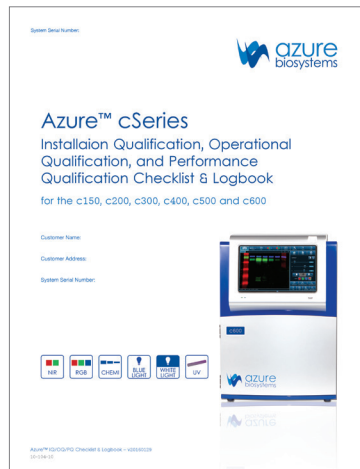
Validation package for cSeries Western Imaging Systems

Azure Biosystems IQOQPQ protocols are essential tools for verifying Azure Imaging Systems and preparing the documentation required for regulatory compliance, SOPs, and laboratory management. They include the protocol, checklist, targets, and certificates necessary to satisfy your validation requirements.



IQOQPQ Protocol

- Includes the procedures for Installation Qualification, Operational Qualification, and Performance Qualification



IQOQPQ Checklist & Logbook

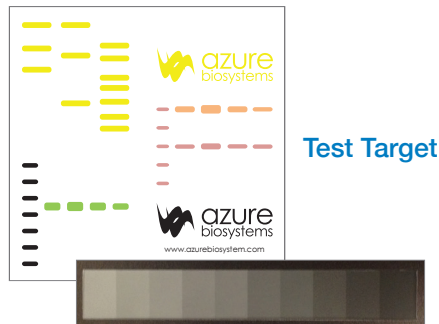
- Includes checklists and document control logs, and the step density tools for performance qualifications

Features

- Detailed procedures for Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)
- For use with cSeries imaging system
- Easy to use checklists with clear and straightforward instructions



IQOQPQ Certificates



Density Step Target



IQOQPQ phases

1 Installation Qualification (IQ)

During IQ stage, inspect the equipment to ensure it conforms to the requirements of Azure Biosystems and is installed appropriately. Once installation specifications are met, and the system is installed and operational, proceed to OQ Validation.

IQ Validation Process includes:

- Examining equipment design and supplied documentation
- Assuring that the work area has the required space to perform the research or processing and associated activities
- Determining installation parameters
- Identifying required environmental controls and procedures
- Installing the equipment
- Verifying correct installment of the equipment
- Establishing the procedures for monitoring, operating and control of the equipment including responsible operators



IQOQPQ for the
cSeries Western Imaging
Systems c150-c600

2 Operational Qualification (OQ)

This stage tests the newly installed equipment to ensure it operates as expected and gauges the conditions under which it will continue to do so. Test runs will determine that the system works in various conditions. If Operational Qualification is successful, it will validate that all aspects of the equipment performed as expected under various conditions.

OQ Validation includes:

- Validating system internal diagnostics
- Validating application operations

3 Performance Qualification (PQ)

Performance Qualification tests the equipment for expected performance criteria. Azure Biosystems provides a template for you to test system performance, and then design your own PQ for your intended applications.

PQ Validation Includes:

- Validation of system response
- Criteria for application specific PQ

Ordering Information

Part Number	Name	Description
AC1026	IQOQPQ	IQOQPQ procedure for c150-c600. Includes procedure, check off sheet, test targets, and certification



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