Data Sheet

Agilent
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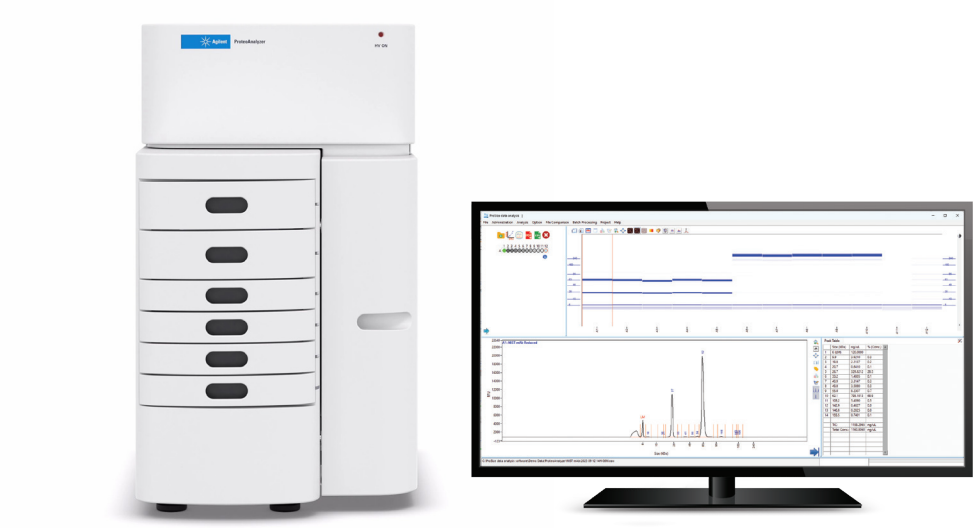
Agilent ProteoAnalyzer Compliance Solution



Achieve reliable and validated performance in laboratory workflows

The Agilent ProteoAnalyzer system offers automated parallel capillary electrophoresis to ensure reliable quality control of protein molecules. The Agilent ProteoAnalyzer controller software and Agilent ProSize data analysis software facilitate streamlined data acquisition, review, and reporting.

The Agilent ProteoAnalyzer compliance solution includes the ProteoAnalyzer instrument (p/n M5350AA), along with software, services, and application-specific consumables. With installation qualification (IQ) and operational qualification (OQ) services available for hardware and software, and the ProteoAnalyzer software security module, the system supports compliance-enabling requirements for GLP/GMP laboratories.

Key features include:

- Reproducible results: Validated consumables with standardized protocols and optimized assays
- Sample analysis: Objective information on sample size, concentration, and integrity
- Compliance services: Software and hardware IQ and OQ for purchase at any time, with a certified engineer testing and verifying functionality to ensure system qualification
- Design qualification: Functional and operational specifications outlined in the declaration of conformity for the ProteoAnalyzer consumables

GLP/GMP compliance

Good Laboratory Practices and Good Manufacturing Practices are established guidelines that ensure research facilities and manufacturers of food and pharmaceutical products meet essential quality management standards. These practices promote consistency, reliability, reproducibility, and integrity in laboratory testing.

The ProteoAnalyzer system compliance solution supports your validation process for protein samples.

Design qualification

The customer is responsible to define the functional and operational specifications for the intended purpose. With the Declaration of Conformity, Agilent demonstrates that each system component meets Agilent's stringent quality criteria.

Documents provided:

- Declaration of System Validation for the ProteoAnalyzer Software (ProteoAnalyzer Controller and ProSize Data Analysis Software)
- Declaration of Conformity for the M5350AA ProteoAnalyzer Instrument
- Declaration of Conformity for all ProteoAnalyzer Consumables and Reagents

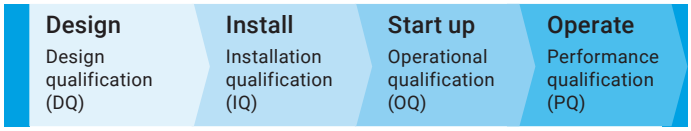


Figure 1. System validation workflow

Installation qualification

Installation qualification ensures that the ProteoAnalyzer instrument and software are installed correctly, and all electrical connections are correct. From the moment the components are unpacked to the point the system is operational, we document the completeness of shipping, the operating environment, and all system components.

Operational qualification

Operational qualification (OQ) is conducted to verify and document that the ProteoAnalyzer system meets specified performance criteria, ensuring basic accuracy after installation in the selected environment. OQ should be performed following hardware or software updates, repairs, relocations, and at regular intervals during routine use. Agilent recommends conducting preventive maintenance prior to an OQ. Audit-ready documentation confirms that ProteoAnalyzer hardware and software operate according to operational specifications.

Performance qualification

Performance qualification (PQ) verifies that the system operates according to the specific requirements of the application. It is the customer's responsibility to define the PQ. Standard Operating Procedures can be established for sample processing and analysis to ensure consistent and reliable results.

www.agilent.com/genomics/proteoanalyzer

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