

Agilent ProteoAnalyzer Software Security Module ProteoAnalyzer Controller Software Rev. 2.0.0 and ProSize Data Analysis Software Rev. 6.0.1

Introduction

The Agilent ProteoAnalyzer systems utilize automated parallel capillary electrophoresis to provide reliable quality control (QC) for size and purity of proteins of interest. The Agilent ProteoAnalyzer controller software and ProSize data analysis software offer streamlined data acquisition and data review with data reporting.

The Agilent ProteoAnalyzer software security module supports the use of the ProteoAnalyzer system in regulated laboratory environments by providing account and system management permission, data traceability, and system verification. This software edition comes as a standalone package consisting of the Administration software, ProteoAnalyzer controller software, and ProSize data analysis software. When the ProteoAnalyzer software security module is set up, an encrypted database “*.psda” file is automatically created. All data acquired with the ProteoAnalyzer controller software is stored locally to be processed within the ProSize data analysis software.

Key features:

- Account management
- Permission control by user role management
- Data approval and approval workflows
- Audit trails (data and system event logs)
- Data reporting (data and administrative reports)

Account management

User access is controlled within Microsoft Windows account management. The user information can be set up either via local Windows accounts or Microsoft Active Directory. ProteoAnalyzer system access is managed within the Administration software. Only users who are added to the Administration software with a specified user role have access to the ProteoAnalyzer controller and ProSize data analysis software, using their Windows credentials (username and password). Access level of each software can be defined independently. Users can determine the timeline of software autolock due to inactivity or of lockout due to failed login attempts.

Role management

Role management defines user access level and permissions to perform certain tasks available within the system. Various user role levels are available with ProteoAnalyzer controller and ProSize data analysis software to be granted based upon privileges to access the system or at a project level. A set of user roles is available by default and, in addition, fully customizable roles and permissions can be defined based on user laboratory SOPs. Summary of the default roles is available in Table 1.

Table 1. User role management: Feature description and accessible software.

User Role	Feature	Accessible Software
Administrator	<ul style="list-style-type: none"> User management Role management System global settings management View system activity log Create administrative reports 	Administration software
Project Administrator	<ul style="list-style-type: none"> Project management Define configuration settings Edit array format and instrument type 	ProteoAnalyzer controller
	<ul style="list-style-type: none"> Create data report Set data file default path eSignature 	ProSize data analysis
Analyst	<ul style="list-style-type: none"> Analyze samples View event report and data event log e-Signature 	ProSize data analysis
Reviewer	<ul style="list-style-type: none"> Review data Create report e-Signature 	ProSize data analysis
Technician	<ul style="list-style-type: none"> Operate the system Run measurements 	ProteoAnalyzer controller
System Validator	<ul style="list-style-type: none"> Run system maintenance operation Run test on the system 	ProteoAnalyzer controller

Data review and approval workflow

Data can be electronically reviewed, approved, and signed according to user-defined workflows. Each workflow follows a specific signature sequence, and file locking is enforced after a designated approval level is reached. An example of approval workflow is shown in Figure 1.

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Audit trails: Data event log and system event log

All the events performed within the system, such as data acquisition, data review, and approval workflow, are recorded in a file-specific audit trail (system or data event log) or in the system activity log. These activities are recorded in chronological order and cannot be modified by any user. Changes applied system-wide, such as setting up new users and changing user permissions, are logged in the system activity log. Audit trail entries and user log information are available within the software and can be reviewed, printed, or exported as a PDF or *.csv file.

Reporting

Data reports can be generated and exported as a *.csv or PDF file for specific audiences and purposes. Multiple samples are easily screened and information can be shared with other users or saved as electronic documentation. A data report can include pertinent information about all the experiments done, such as run summary, method details, electropherograms and gel images, analysis results, and data approval records.

Administrative reports can be created as PDF file with information about the project, users, and roles.

Users can customize their reports to include a customer name or credentials. Once a report is created and saved with the desired file format, it cannot be further edited.

Security module qualification services

Comprehensive functionality services for software and hardware are available as installation qualification and operational qualification.

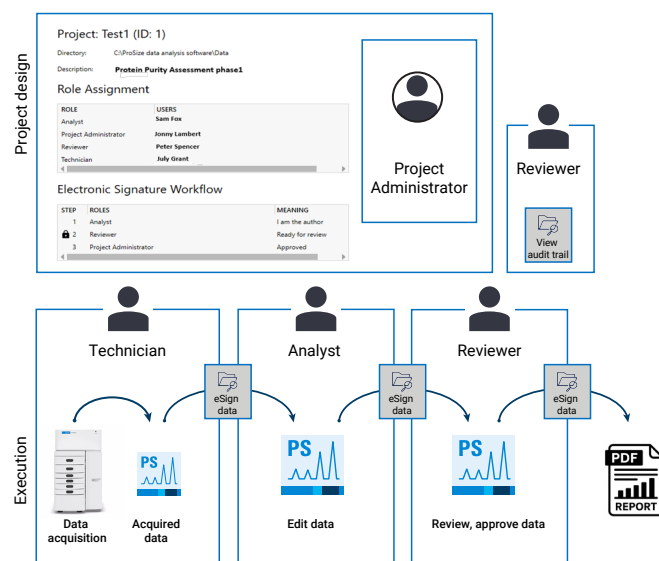


Figure 1. Illustration of data approval workflow with three users and three steps