

Agilent Fragment Analyzer Security Module

Fragment analyzer controller rev. 5.0.0,
ProSize data analysis software rev 6.0.0

Key features:

- Account management
- Permission control by user role management
- Recoding and display of audit trails
- Data approval and approval workflows
- Data reporting (data and administrative reports)

Introduction

The Agilent Fragment Analyzer systems utilize automated parallel capillary electrophoresis to provide reliable quality control (QC) for nucleic acids molecules. The Fragment analyzer controller and ProSize data analysis software offer streamlined data acquisition and data review with data reporting.

The Fragment Analyzer security module software package supports using the parallel capillary electrophoresis systems in regulated laboratory environments by providing access control through account and permission management, data traceability and system verification. This software edition comes as a package consisting of the Administration software, Controller software and ProSize data analysis software. When the Fragment Analyzer security module is set up, an encrypted database file is automatically created. All data acquired with the Fragment Analyzer controller software is stored locally to be processed within the ProSize data analysis software.

Account Management

User access is controlled with Microsoft Windows account management. The User information can be set up either via local Windows accounts or Microsoft Active Directory. Fragment Analyzer system access is managed within the Administration Software. Only users who are added to the Administration Software with a user role have access to the Fragment Analyzer controller and ProSize data analysis software, e.g., by using their Windows credentials (username and password). Access level of each software can be defined independently. Users can determine timeline of software auto lock due to inactivity and log out 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 Fragment Analyzer 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 Component
Administrator	<ul style="list-style-type: none"> – User management – Role management – System global settings management – View system activity log – Create administrative reports 	Fragment Analyzer Controller ProSize Data Analysis
Project Administrator	<ul style="list-style-type: none"> – Project management – Define configuration settings – Edit array format and instrument type 	Fragment Analyzer Controller
	<ul style="list-style-type: none"> – Create data report – Set data file default path – e-Signature 	ProSize Data Analysis
Analyst	<ul style="list-style-type: none"> – Analyze samples – View event report and data event log – e-Signature 	Fragment Analyzer Controller 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 	Fragment Analyzer Controller
System Validator	<ul style="list-style-type: none"> – Run system maintenance operation – Run test on the system 	Fragment Analyzer Controller

Data Review and Approval Workflow

Data can be electronically reviewed and approved by eSignature in accordance with user customizable workflows. Workflows enforce an order of signatures, assign meaning for each step, and lock the file after a defined-level signature was placed.

Example of approval workflows is shown in Figure 1.

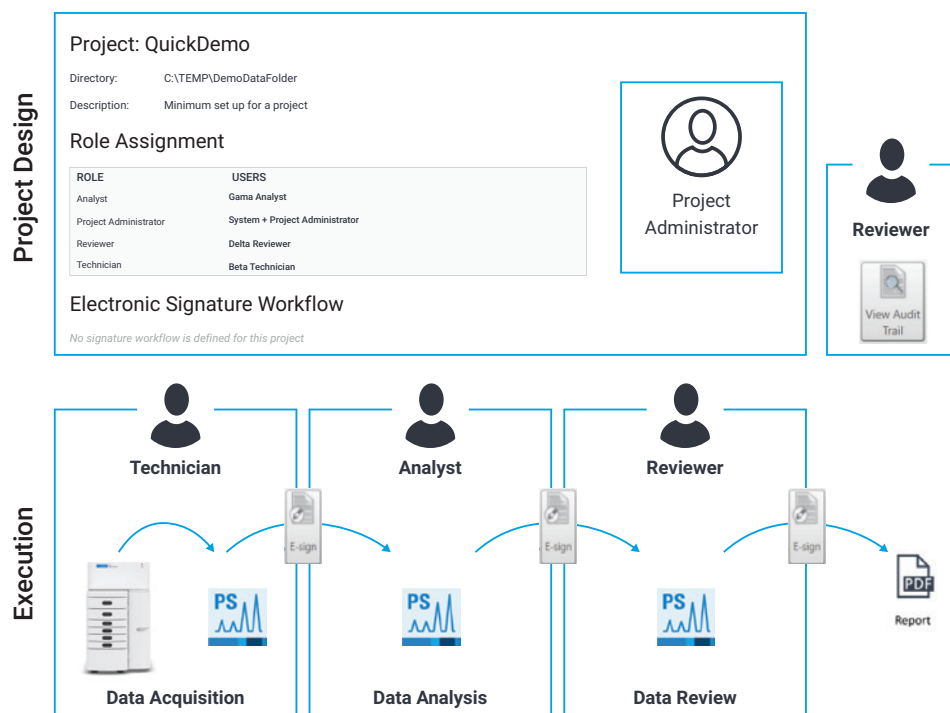


Figure 1. Illustration of data approval workflow with three User and three steps.

Audit Trails

Data event log and system event log

Changes to the data are logged in file-specific audit trails (system event log or data event log). Changes applied system wide, such as setting up new users and changing user permissions, are logged in the system activity log. All activities are recorded in chronological order and cannot be modified by any user. They are available within the software for review and can be printed or exported as a PDF and *.cvs files.

Reporting

Data reports can be generated and exported as *.csv and PDF file for specific audiences and purposes. Multiple samples are easily screened, and information shared with other users/ customers are saved as electronic documentation. A data report can include pertinent information about all the experiments done, e.g., 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 project, users, and roles.

User 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, such as installation qualification (IQ) and operational qualification (OQ), are available for the Fragment Analyzer systems.

Learn more at:

www.agilent.com/genomics/fragment-analyzer-security-module

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