



2100 expert security pack

A powerful software supporting 21 CFR Part 11 requirements

Take advantage of the digital data and speed up review and release processes. Benefit from the many advantages of the Agilent 2100 bio-analyzer and the 2100 expert software combined with the superior 2100 security pack.

The security pack is an additional component of the 2100 expert software that can be activated by a license key. It allows managing electronic data and supports the newest guidelines, including the US Food and Drug Administration (FDA) recommendations, regarding electronic records and signatures (21 CFR Part 11).



Compliance tools and services

Installation verification

Includes tests to verify that software and hardware are properly installed and that all electrical connections are correct.

System verification

Demonstrates that the 2100 bio-analyzer will function according to its operational specifications.

Compliance services are not available for the A version 2100 bioanalyzer (serial number DE13701000 or lower).

Features of the 2100 expert security pack

- **Data integrity**
Any generated electronic record is protected from modifications and deletions other than by authorized individuals on justified occasions. All data files contain the complete history. Raw and meta data are stored together with the results in a single file.
- **Access control**
Only user with valid user ID and password can log on to the application, access and modify any electronic record created or managed by 2100 expert security pack. Additional safety features such as active or timed logging of the application are available to prevent unauthorized access.
- **Audit trail**
All user activities are documented in an automatically generated, maintained, and time-stamped audit trail. It also contains details on user administration and security violations. All method, assay and analysis parameters are stored in logbooks. Every change in the data analysis is documented.
- **Workflow management**
The executable methods must include a predefined workflow. This workflow defines the users that will be allowed to perform the individual steps, such as the execution of methods, peer reviews, and the final approval. A predefined user must electronically sign every step in the review cycle, before it can be passed on to the next review/workflow level.



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User administration

The 2100 expert administrator has access to the user and roles administration in the system context. This functionality allows adding or disabling users and defining their roles.

Logbook

All user activities, e.g. administration activities, or modification of analysis setpoints, are logged in so-called audit trails and signature logs. These are records of access-controlled actions and cannot be modified.

Electronic Signature

All activities such as creating or modifying data, e.g. change of analysis setpoints, must be confirmed with an electronic signature. Signing changes will add a comprehensive list of setpoint changes to the file or method audit trail. In addition, signing the different levels of the review workflow completes them.

To find out more call:

US/Canada
Phone: Toll-free 1-800 227 9770
bioanalyzer_americas@agilent.com

Europe
bioanalyzer_europe@agilent.com

Japan
Phone: 0422 56 9393
lab_chip@agilent.com

Other Asia Pacific
Phone: +81 422 56 9392
bioanalyzer_ap@agilent.com

www.agilent.com/chem/labonachip

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Published June 1, 2005
Publication Number: 5989-3273EN