SHIMADZU
Excellence in Science

Compliance with FDA 21 CFR Part 11

Shimadzu Protein Sequencer

PPSQ-51A/53A

LabSolutions PPSQ software provides compliance with FDA 21 CFR Part 11 guidelines and enables compliance with the security, user management, and audit trail requirements specified by FDA 21 CFR Part 11.

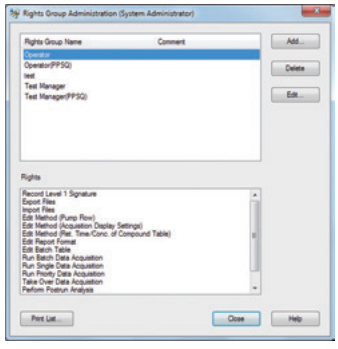
Upgrade from PPSQ-30 series

- PPSQ-50 software upgrade (LabSolutions PPSQ)
- Highly sensitive package (PPSQ-50 software and SPD-M30A high-sensitivity package)

Compliance with FDA 21 CFR Part 11

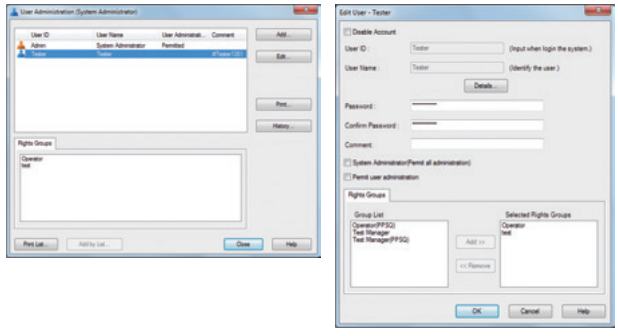
1 Security

Users are managed on the basis of groups, with each user being recognized by means of a username and password. Unique groups can be created by including persons having different access privileges. Clearly defining each user's access privileges prevents unauthorized changes to settings, instrument operation, and data access.



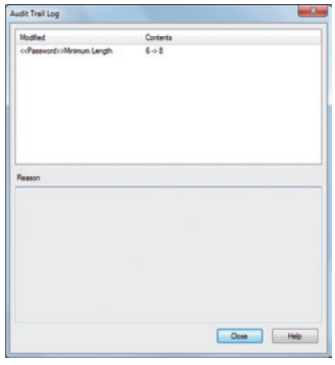
2 User Management

LabSolutions' user administration comprises the setting of rights groups and assignment of rights to users just as in Windows. Access rights required for each user can be set by assigning various levels of access to each user. This helps achieve effective user administration and more efficient laboratory operations.



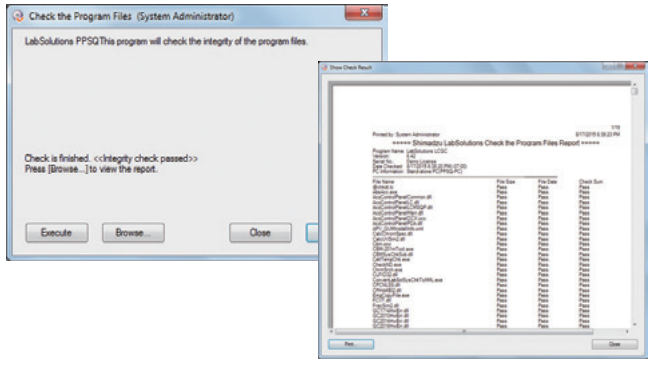
3 Audit Trail

Logins and logouts to the system, changes in users and groups, and the start and completion of acquisition, together with the username and the time, are all recorded. The recorded operational log can be registered in the database to provide traceability.



4 Software Validation

The integrity of the programs that comprise the system and the raw data acquired by instruments can be checked, ensuring the reliability of the system and data.
The results of these alteration checks can be managed as printouts.

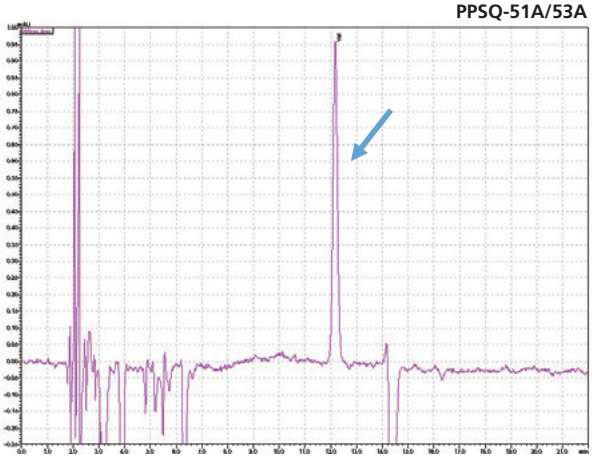


Higher sensitivity

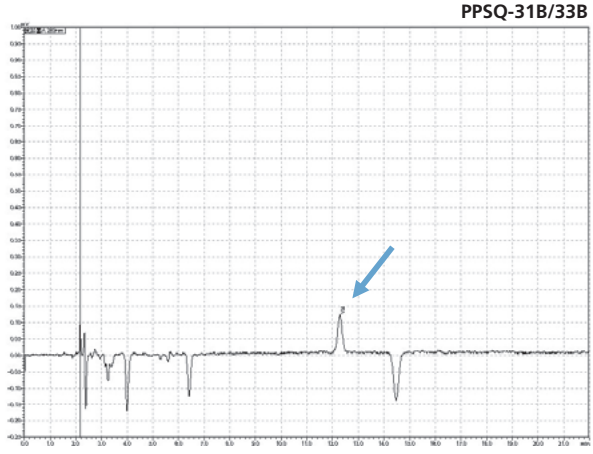
The PPSQ-51A/53A employs the SPD-M30A photodiode array detector, which features a high-sensitivity capillary cell. This results in a higher S/N ratio and allows detection of lower-concentration samples.

Cycle 10 PTH-Val

PPSQ-51A/53A

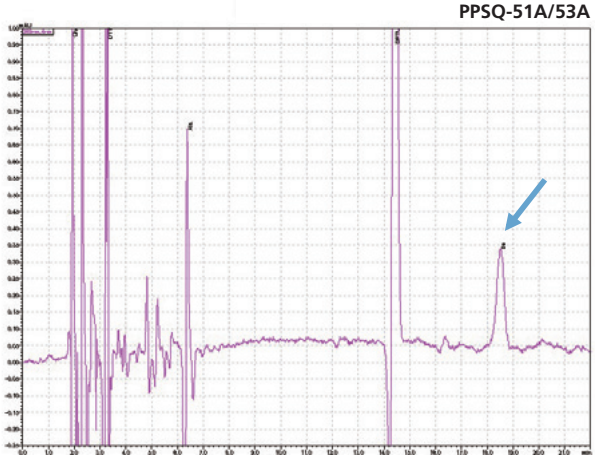


PPSQ-31B/33B

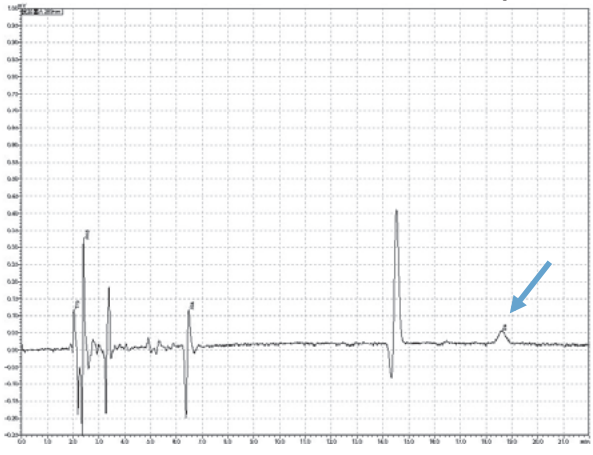


Cycle 21 PTH-Ile

PPSQ-51A/53A



PPSQ-31B/33B



Sample: Horse myoglobin 10pmol

Results show the subtraction chromatograms by SPD-M30A (PPSQ-51A/53A) and SPD-20A (PPSQ-31B/33B) connected tandemly after Edman degradation.

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