HORIBA Scientific

JOBIN YVON Technology

Raman Spectroscopy

Achieving regulatory compliance with the LabSpec 6 ProtectionPlus module

Technical Note

Software TN07

HORIBA Scientific's range of Raman spectrometers can be used with assurance in regulated environments with the LabSpec 6 ProtectionPlus module. This highly configurable security and data integrity module offers all of the tools necessary for users to be compliant with laboratory and data regulations, including 21 CFR Part 11.

The fully integrated ProtectionPlus module for LabSpec 6 provides advanced tools that allow users to meet the requirements of Part 11 of the FDA's Code of Federal Regulations, Title 21, relating to electronic records and electronic signatures. Within the scope of Raman spectroscopy, an electronic record is data represented in digital format that is created, modified and archived by a computer system. The regulations are used to ensure the validity of the data throughout its lifetime, tracking how the data was acquired and modified, and recording which user was responsible for all such actions. The optional use of electronic signatures allows users to electronically authenticate data, and provide a legally binding commitment to its validity.

Note that compliance with the regulations requires more than just installation and use of the ProtectionPlus module. Specific company policies and laboratory best practice must also be strictly followed, and users must be suitably trained to work in a compliant manner.

Since the regulations are not highly prescriptive, the ProtectionPlus module is designed to be a configurable unit, offering a wide range of tools which can be enabled and configured by a security administrator - this ensures that a company's specific interpretation of the regulations can be accommodated with ease.

The key functional blocks of ProtectionPlus are as follows:

- User access management and control
- Electronic record audit trail
- Event log application audit trail
- Electronic signatures
- System policies and file management control

Together they offer a robust suite of tools for system security administrators to ensure compliance to regulations such as 21 CFR part 11.

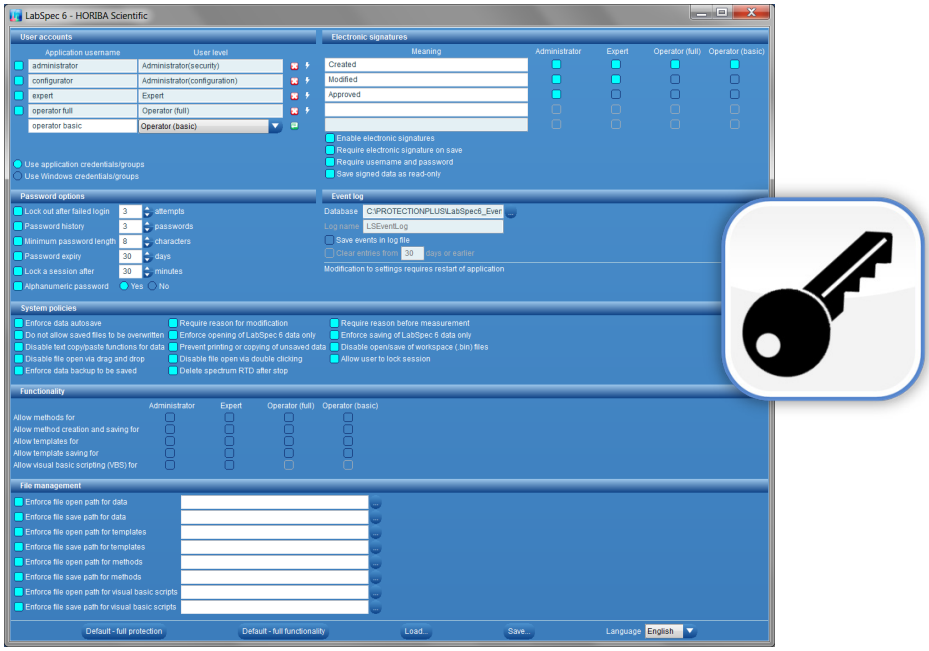

Fig. 1: The ProtectionPlus configuration window provides the ultimate control to security administrators to configure settings exactly as required

Key features of ProtectionPlus

Full user account management and access control to LabSpec 6 is available, both as a fully integrated module completely managed by ProtectionPlus or alternatively using re-authentication from the user's Windows® operating system account. In both cases policy settings including lock outs after failed login attempts, password history and expiry, password length/complexity and automatic idle time session locking can be enabled and configured to match specific security requirements.

Each user can be assigned to one of five user levels, split first between security control (ProtectionPlus configuration) and business function (spectroscopic measurements), and then offering different degrees of functionality to match a user's experience and measurement requirements.

ProtectionPlus maintains a full audit trail through two main functions. A read-only history for each individual electronic record ensures full traceability of the data, which is saved as an integral part of the electronic record. The history records with user details and full time stamp (including time zone) the following:

- Full acquisition parameters (hardware configuration and experiment settings).
- All modifications to data (including key parameters of the modification).
- All requested reasons for measurements and modifications.
- Any electronic signatures applied to the data, with the signature meaning.

Fig. 2: Tthe audit trail for each electronic record summarizes all instrument and experiment parameters, and lists all acquisition, modification and signing events.

The second part of the audit trail is an independent event log, which tracks software activity and a secondary record of basic electronic record actions:

- Software start/stop
- Log in attempts (successful and failed)
- Modifications to ProtectionPlus security settings and instrument configuration
- Data acquisition
- Electronic record save/open
- Electronic record modifications
- Application of electronic signatures

The optional electronic signatures module allows customized signature meanings to be available to the different user levels; once enabled, users can electronically sign data with an associated signature meaning. Additional policies can enforce re-authentication of the user's credentials as part of the signing action, and require that only signed data can be saved. All signing events are recorded within the electronic record's audit trail.

Additional tools are also presented including a range of system policies to heighten data integrity (for example, requiring reasons to be input for data acquisition and modification), and file management tools which can be used by security administrators to facilitate data archiving (for example, enforcing file save/open locations).

Other tools

Complementary tools offered by HORIBA Scientific to accompany regulatory compliance include formal qualification protocols for system installation and operation (IQOQ). These help a user to demonstrate system validity, a user responsibility within the 21 CFR part 11 regulations.

Conclusion

The LabSpec 6 ProtectionPlus module provides a platform for use of the HORIBA Scientific Raman systems whilst meeting compliance with regulations such as 21 CFR part 11. The full power of LabSpec 6 for data acquisition and analysis remains, with ProtectionPlus working seamlessly to provide full assurance of data security and integrity.

MORE INFORMATION:

If you would like more detailed information about HORIBA Scientific's compliance to 21 CFR Part 11 with its LabSpec 6 ProtectionPlus software, including a point-by-point response to the regulation requirements, please request our document *21CFR11 - HORIBA response for LabSpec 6 with ProtectionPlus.*

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info.sci@horiba.com **www.horiba.com/scientific**

HORIBA Scientific

USA: +1 732 494 8660
UK: +44 (0)20 8204 8142
China: +86 (0)21 6289 6060
France: +33 (0)1 69 74 72 00
Italy: +39 2 5760 3050
Brazil: +55 (0)11 5545 1500
Germany: +49 (0)89 4623 17-0
Japan: +81 (0)3 6206 4721
Other: +33 (0)1 69 74 72 00