Malvern Panalytical
a spectris company

ENHANCED DATA SECURITY

Securing your XRF data

DESIGNED TO MAXIMIZE **TRUST** IN YOUR **RESULTS**

The Enhanced Data Security (EDS) module is a software option that provides enhanced trust in results for users of Malvern Panalytical's XRF spectrometers.

Data security is a vital aspect of many XRF workflows . The EDS module for Malvern Panalytical's XRF software builds on the controls already present within the standard software to give users confidence that the data used to ensure product quality or process control can be trusted. It provides an additional level of security for measurement methods, analysis workflows and data storage, ensuring users have the information they required to meet regulatory audit requirements.

Key capabilities of the EDS module include advanced options for user management, action logging, data protection and application status assignment – all helping you provide a robust audit trail, minimize the risk of error, and prove that your XRF instrument is working as expected.

The 'standard' version of the EDS module was originally developed to provide the rigorous traceability needed to help pharmaceutical companies to comply with data integrity requirements, such as those set out in the US FDA's regulations for electronic record and signatures (21 CFR Part 11). The changes made in the latest 'advanced' version now make it suitable for a wider range of industries.
So whether you need to settle a discussion with your own customers, pass a lab accreditation audit, or become compliance with pharmaceutical data integrity requirements, the EDS module will help you obtain maximum trust in your results.

> *The new features of the 'advanced' version of the EDS module make it ideal for pharmaceutical applications but brings also value to the mining industry that relies on highest data quality and has to comply with data security regulations.*

KEY BENEFITS

Administrator-level user setup

Usernames and passwords are required to access the XRF software on both Zetium and Epsilon instruments. The EDS option for both software platforms allows the assignment of these is to be delegated to the operating system and therefore can only be changed by IT administrators.

New application settings

Within the advanced version of EDS, applications can be given one of three status levels: 'Developing', 'In review' or 'Finished'. In conjunction with application versioning, this means there's no confusion about which applications should be used for routine work.

Management of these application status levels is supported by:

- The option for 'four-eyes signing', meaning that a second person must always confirm a change in application status from 'Developing' to 'Finished'.
- The addition of application-related user privileges to the list of privileges already present within SuperQ. This means that only defined users can access applications with a particular status, or change the status of an application.

Requirement for electronic signatures

Both versions of EDS provides enhanced security by requiring an electronic 'signature' in certain cases. This signature comprises a password and a reason for the action, and must be entered when:

- A measurement (or batch of measurements) is started or aborted.
- A batch is restarted after being stopped for external reasons (such as opening the changer cover).
- Results are edited.

Enhanced action logging

The XRF system software offers basic action logging as standard, with details including date, time (UTC format) and username. This is extended within the standard version of EDS, which logs all actions that lead to modified results, and which requires a comment to be added against all actions.

In addition, the advanced version of EDS generates a log of all actions associated with changes in application status, offers the following capabilities to further enhance the audit trail.

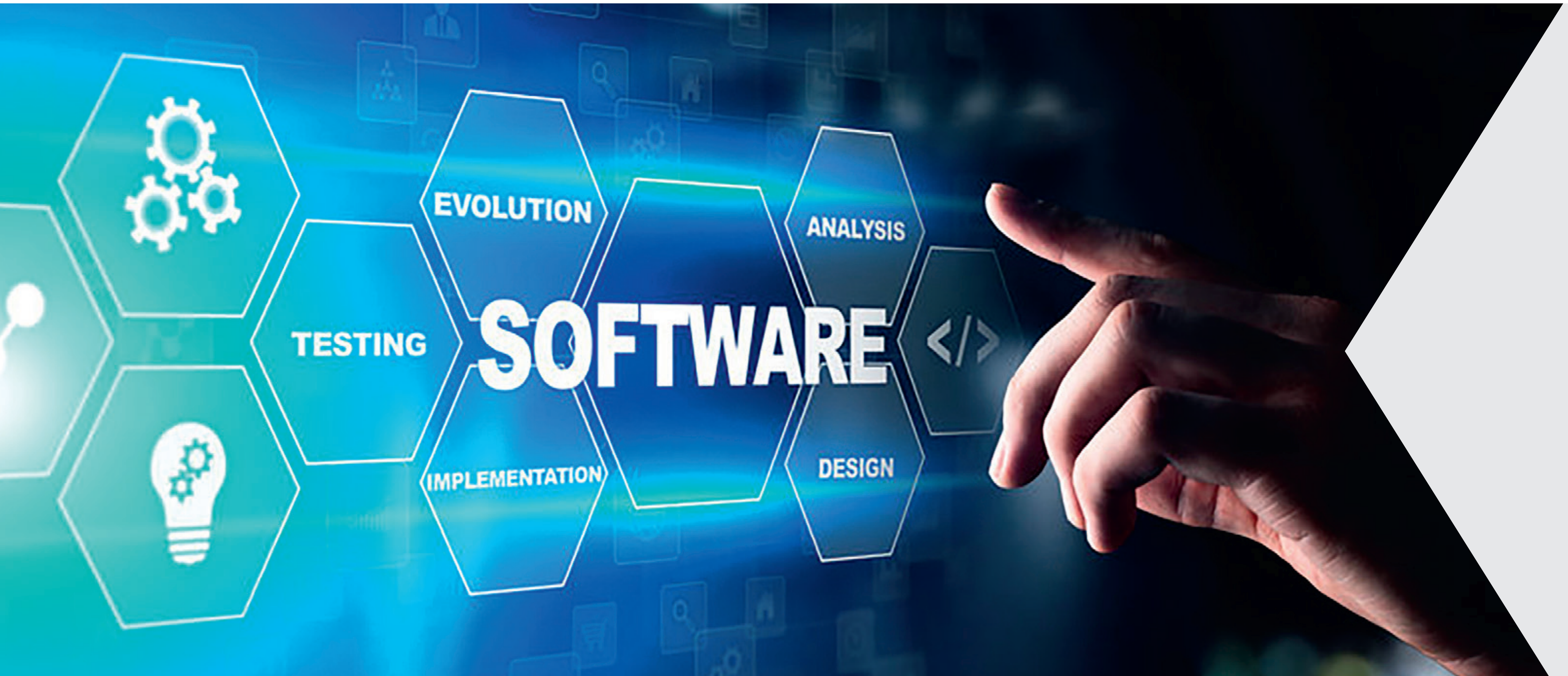
Robust data storage

Records stored within the XRF system software can only be edited within the software, and all data files and log files are protected by user privileges to prevent accidental changes or deactivation.

In addition, using both versions of within EDS, if an action leads to modified application or calibration results, a new file is created, so the original results are never overwritten (the modified results contain a link back to the original, which is read-only).

Customizable data security

Within both versions of EDS, all the above-mentioned software options are configurable, so that for customers in non-regulated environments, only part of the functionality can be implemented, if desired.



SOFTWARE VERSIONS

Two versions of EDS are currently available:

- **The standard version** is available for both SuperQ. The software platform for the Zetium XRF spectrometer and for the dedicated software for Epsilon XRF spectrometer.
- **The advanced version** is only available with SuperQ version 6.4 and upwards and suitable for the Zetium XRF spectrometer.

FEATURE SUMMARY

The table below provides a quick comparison of the added security features available when the EDS module is added to the existing instrument software.

Feature	Existing software	With standard version of EDS (SuperQ or Epsilon)	With advanced version of EDS (SuperQ version 6.4+ only)
User setup			
Usernames and passwords required	✓	✓	✓
Administrator-level assignment of usernames and passwords		✓	✓
Application settings			
Privilege levels for each task (view-only, measure, application development, etc.)	✓	✓	✓
Three status levels available for all applications			✓
Application versioning			✓
User privileges for amending application status			✓
Unauthorized applications hidden from operator interface			✓
'Four-eyes signing' on changes in application status			✓
Electronic signatures			
Electronic signatures required for actions regarding measurements, or for changes to results		✓	✓
Action logging			
Basic action logging (date, time, user name)	✓	✓	✓
Action logging in Coordinated Universal Time (UTC)		✓	✓
Logging of measurement actions		✓	✓
Logging of actions leading to modified results		✓	✓
Requirement to add comments against all actions		✓	✓
Logging of changes in application status			✓
Data storages			
Record editing only within the software	✓	✓	✓
User privileges for changes to files or deactivation of files	✓	✓	✓
Files cannot be accidentally overwritten		✓	✓
Customizable data security			
Optional implementation of all security features		✓	✓

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We are global leaders in materials characterization, creating superior, customer-focused solutions and services which supply tangible economic impact through chemical, physical and structural analysis.

Our aim is to help you develop better quality products and get them to market faster. Our solutions support excellence in research, and help maximize productivity and process efficiency.

Malvern Panalytical is part of Spectris, the productivity-enhancing instrumentation and controls company.

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Malvern Panalytical provides the global training, service and support you need to continuously drive your analytical processes at the highest level. We help you increase the return on your investment with us, and ensure that as your laboratory and analytical needs grow, we are there to support you.

Our worldwide team of specialists adds value to your business processes by ensuring applications expertise, rapid response and maximum instrument uptime.

- Local and remote support
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- e-Learning training courses and web seminars
- Sample and application consultancy

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