Operations Server & Viewer with Electronic Records & Signatures

Validatable to 21 CFR Part 11

Operations Server and Viewer, supplied as part of the EurothermSuite software, now can support auditor features that have been specifically designed to meet the requirements of the FDA 21 CFR Part 11 document for Electronic Records and Electronic Signatures.   Audit log files are configured to include logins, alarms, events, operator notes, recipe actions, batch actions and parameter changes and each entry can have an Electronic signature. Data is held in both Human Readable and Electronic form. Electronic data can be viewed, analysed and printed off-line using the secure Review package.

Data security is paramount for FDA approved processes – this software ensures that data is not lost or tampered with. The Auditor features provide comprehensive data security and traceability.

Secure Audit Trails Electronic Signing
Signed Operator Comments
Signature Element controls
Recorded Logins

Secure Audit Trails
A secure time-stamped audit trail records the date and time, operator details and actions taken within the Operations Viewer display windows. The Audit Trail is kept with the electronic process data, records all actions and cannot be separated from the process data, removed or modified. Audit trail can also be collected from other LIN nodes e.g. Visual Supervisor.

Electronic Signing
Auditor features allow for signing of all actions - operators will need to re-enter user name and password before an action is complete. Features are also available to request authorisation - a second signature - before the action is completed.

Signed Operator Comments
An authorised operator is able to add comments to the data record by entering his/her correct user name and password followed by the required text. The full comment complete with the operator name, date and time is recorded in the data file to become an integral part of the data record.

Signature Element Controls
Passwords will automatically expire unless renewed within a set time.

All standard user logins can be disabled and their associated passwords removed to prevent any unauthorised access.

User accounts are disabled after a number of failed attempts to log in.

Passwords can be forced to be a minimum length.

Users will be automatically logged off after a pre-defined period of inactivity

Recorded Logins
Every time an operator logs in the user name, date and time are recorded into the Audit Trail.

EUROTHERM suite
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CONTROL
RECORD
AUTOMATE
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Additional Security Features

● **Enforced Unique Signatures**
  User based security allows individuals to be granted access according to their authority level plus any additional access privileges. Each user name is unique and passwords are individual and cannot be viewed on the product. Users can be retired and not deleted to ensure user IDs cannot be duplicated and each user name will be unique within the product.

● **Protection of Records - Secure, Reliable, Accurate Records**
  Data is stored with checksum in a binary and compressed format proprietary to Eurotherm Ltd to prevent tampering with records.

● **Audit Trail across Network**
  Visual Supervisor may be configured to send its audit trail to two nominated nodes on its network. This allows applications with multiple Visual Supervisor and/or EurothermSuite Operation Server to nominate one node as the master for collecting all electronic data and producing a single consolidated log file.

Additional Features

● **A pre-engineered 'works out of the box' operator application based on Wonderware InTouch**

● **Full system wide availability of all control data**

● **Client/server architecture with master/backup servers**

● **Integrated Development Environment including autoconfiguration techniques**

● **Open I/O and system network using serial, ethernet and arcnet**

● **Supports LIN, MODBUS and OPC server connectivity with in-built communications error detection**

● **Defined display structure incorporating alarm banner, button bar, fascias and engineering point pages**

● **Support for foreign languages**

● **Sophisticated alarm functionality including alarm history Microsoft SQLServer™ relational database and acknowledgement from any viewer,**

● **Project database provides common system data repository**

● **Tag browsing to all LIN objects throughout control network**

● **Comprehensive user authorisation and security**

● **Easy to configure and deploy multiple computer nodes**

● **Provided as part of EurothermSuite**

● **ArchestrA ready system**