

MDT AutoSave

Electronic Signature and Audit Trail Module

AUTOSAVE OVERVIEW:

The AutoSave suite of products provides the software tools needed to track and sign all your automation programs and plant documents. It controls and tracks the changes to your industrial programmable devices and program sources, as well as plant documentation with the optional Documents Module (any mix of Word, Excel, PowerPoint, CAD drawing, PDF, CSV and Windows files). AutoSave provides:

- Centralized secure access to your program files and plant documents
- Historical Tracking and Audit Trails
- Quick Disaster Recovery
- Compliance with **FDA 21 CFR Part 11**. To find out how AUVESY-MDT can help manufacturers comply with these regulations ask your AUVESY-MDT representative for our white paper.

MODULE FEATURES

For areas that require the added features of electronic signatures and workflow approval for device programs and plant documents, AUVESY-MDT's AutoSave **Electronic Signature and Audit Trail Module**, combined with the AutoSave Reports Module (included at no additional cost) provides the following features:

- **Electronic Approvals**

- Create approval groups containing common users who are authorized to approve a change.
- Create approval lists that contain one or more approval groups to provide overall multi-group approval.
- Associate approval lists with programs or documents that require formal approval.
- Automatic email notification to approvers when a review and approval of a device program or document change is required.
- Complete revision history and in-process status of active development projects available on-demand through AutoSave.
- Audit trail information is automatically captured including the approver's user ID and comments complete with the activity date and time stamp.
- Complete revision history and in-process status of active development projects available on-demand through AutoSave.



DATASHEET: Electronic Signature and Audit Trail Module

• Verification Processes

- Require users to re-enter their password for all device operations, thereby verifying active user status.

• Confirmation Processes

- Require a second user to confirm that the initial user is who they say they are.

• Multiple Review Statuses

- View program or document versions that are in different statuses:
 - Request for Approval
 - Test
 - Validate
 - Implemented
- Complete history of review and approvals.

• Additional Security Features

- Augment existing activity logs with additional, electronic log messages supporting the approval process.
- Additional reports available in the reports module tracking validation states.

