

## **INSIGHT 21 CFR PART 11 COMPLIANCE**

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Winland Electronics, Inc., headquartered in Mankato, Minnesota, is a leader in environmental monitoring products interfaced through security systems. The company focuses on products for monitoring environments from commercial food and life science environments to residential housing to commercial storage installations.

INSIGHT is a secure environmental monitoring solution deployed via a cloud-based server environment. There are three key components to the INSIGHT system: Web Access, Machine to Machine (M2M) Communications, and Data Storage. INSIGHT will facilitate logging and monitoring of regulated environments such as that needed for vaccine storage.

This report covers Winland's self-assessment of the INSIGHT remote environment monitoring solution in the context of 21 CFR Part 11 regarding electronic records and signatures. It is a review of the three main areas required for compliance: Standard Operating Procedures, Product Features, and Validation Documentation.

### **STANDARD OPERATING PROCEDURES (SOP'S)**

- System security, backups and disaster recovery are built into the Microsoft Cloud services on which INSIGHT operates.
- Software coding and source control are managed by a professional software engineering service.
- Issues are ticketed and routed through an issue tracking system.
- Software validation and testing occur on three levels. Software revisions are assigned a version number and are tested on an internal development platform. Then the software is migrated to the "Beta" level on a semi-public platform for in-service testing. Finally, it is released to the production environment.
- Winland personnel are trained to these SOP's and are committed to quality standards.

## PRODUCT FEATURES

The INSIGHT system is compliant with 21 CFR Part 11 standards in that:

- All data transfers, M2M and user communications both to and from the INSIGHT system, are encrypted for security.
- User access is only available after:
  - A User ID is set up by an account administrator or individual designated as a responsible party.
  - A system generated password is assigned. System generated passwords must be changed the first time a User logs into the system.
- User activity is collected, stored and tracked in a Database Management System (DBMS).
- Data, collected from monitored environments, cannot be modified either on the front-end collection hardware or in the back-end DBMS.

## VALIDATION DOCUMENTATION

- The INSIGHT system is validated against documented features, functions and specifications described in the INSIGHT User Guide documentation and the EA800-ip documentation. These are available on the winland.com website and through the INSIGHT user interface.
- INSIGHT users are notified of issues, bug fixes and changes through INSIGHT status information pages on the winland.com web site.

## SUMMARY

Winland is committed to the best product quality possible evidenced by its leadership over 40 years in the industry.