Validation Documentation, Electronic Records and Signatures

to satisfy 21CFR Part 11

Electronic data acquisition that's accurate, secure, and traceable with Honeywell's paperless recorders.

An outstanding solution for Pharmaceutical and Biotech applications

There is nothing more important to us than helping our customers achieve improved process control and fulfill production requirements in an FDA regulated environment. Electronic data acquisition helps by providing significant benefits and cost savings over traditional paper records, including:

- Increased accuracy of process data
- Faster analysis of the production process
- More in depth analysis using software tools
- Elimination of errors in transposing data manually
- Greater access of data by other departments
- Easier, more efficient report generation

Honeywell's IQ/OQ Protocol Assembler Software for Validation Documentation

Honeywell supports your Process Validation needs by supplying a "Validation Protocol" document for either the Minitrend or Multitrend Plus recorder systems. The Validation Protocol Assembler is a step-by-step guide, which includes pre-formatted documentation sign-off sheets, for Installation Qualification and Operational Qualification (IQ/OQ) of the recorder.

ESS Software enables you to comply with 21 CFR Part 11

Honeywell **Minitrend** and **Multitrend Plus** paperless recorders securely measure, display and archive process data. The **Extended Security System (ESS)** option provides traceability of changes to the recorder setup, message generation and alarm conditions. It helps you comply with the FDA issued regulation (21CFR Part 11) for electronic signatures and records:

Restricted User Access—user actions and access are restricted based on configuration. Users are prompted for a User Name and Password.

Data Encryption—data is saved in a binary encrypted format. Undetected tampering is not possible.

Audit Trail—a message or 'event' file captures such items as a user logging into the recorder, log-out actions, alarms and process events. Each event is automatically time and date stamped.

Unique Electronic Signatures—the unique User Name and Password combination can be used with free format or pre-configured messages for signing records or noting batch data.

Password Use Revision—the recorders enable flexibility in configuring password expiration time and password reuse.

Inactivity Logout—the user is logged-off if no action is performed in a specified period of time.

Unauthorized Use Lockout—a user is automatically locked-out of the system if there are failed log-in attempts.

Honeywell Minitrend and Multitrend Plus recorders with ESS provide flexibility and comply with FDA Title 21 CFR Part 11 rules.

- Provides capability for setting up unique ID and password access for up to 20 Users
- Four (4) configurable levels of User access: Engineer, Supervisor, Technician, Operator
- Seven (7) areas (setup, record, layout, screen, totals, counters, screen menus) can be protected from the different User levels.
- Password expiration is configurable from 1 to 190 days.
- Configurable recorder time-out (User inactivity) from 1 to 10 minutes
- Configurable password re-use from 4 to 12 times
- The PC based TrendManager software suite enables users to view data in an easy to understand format. Users can create reliable and accurate electronic and human readable copies.

Sales and Application Support

Our team of sales engineers, local stocking representatives and technical support specialists are available to serve you in 95 countries on six continents. In addition, Honeywell Service can provide support to aid in the development of specific IQ/OQ procedures. To find the Honeywell authorized representative nearest you, visit us at: **http://locator.micro.honeywell.com/locator.taf**

Warranty/Remedy

Honeywell warrants goods of its manufacture as being free of defective materials and faulty workmanship. Contact your local sales office for warranty information. If warranted goods are returned to Honeywell during the period of coverage, Honeywell will repair or replace without charge those items it finds defective. The foregoing is Buyer's sole remedy and *is in lieu of all other warranties, expressed or implied, including those of merchantability and fitness for a particular purpose.*

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