



Validatable Data Loggers and Software for CFR 21 Part 11 Reporting Systems

If you need to capture, record and archive data for CFR 21 Part 11 compliance reporting, CAS has several data logging solutions to meet your needs. We can provide data loggers and sensors that are suitable for measurement of many common parameters including temperature, humidity and voltage or current. Along with the loggers is software that provides security and traceability for the measured data. Finally, we can offer calibration and validation services for the entire system.

TandD RTR-5 Wireless Data Loggers and VLD for Windows Software

TandD Recorder VLD for Windows is a software package for companies that need to meet CFR21 Part 11 requirements for tamperproof electronic data recording. It works with the RTR-5 series of wireless data loggers and the RTR-57 Data Collector. Logged data can be downloaded to a PC as a secure, encrypted file with electronic signature access control. It also maintains a record of data base access for audit trail tracking and reporting. Other features of the VLD software include:

- Secure Administrator Mode
- Secure Logger Configuration
- Tamper Proof Data Files
- Archived Data Viewer
- Configurable User Permissions
- Secure Temperature/Humidity Graph

The RTR-5 series of data loggers can be used to collect temperature data (internal and external sensor versions), humidity, or voltage/current/event data.

Key benefits of the RTR family of loggers are:

- **Wireless Logger/Transmitters eliminate cabling costs and are ideal for temporary survey's**
- **Water resistant loggers are ideal for damp/high humidity environments such as refrigerators or freezers and do not require additional protection**
- **Handheld data collector allows convenient transport of data to a PC for analysis**



DARCA Secure Software and Eltek Data Loggers

DARCA Secure is an enhanced version of the standard DARCA software that has been designed to meet the requirements of CFR21 Part 11 by providing a tamperproof audit trail of events, secure data storage and managed data access. It works with the Gen II telemetry systems and 1000SC receiver logger. Key features include:

- Enhanced user and password management
 - Mandatory login
 - Tamperproof audit trail
 - Enhanced memory integrity checking
 - Encrypted data files
 - Mean kinetic temperature calculation and graphing
- The wireless Gen II transmitters are available in a wide variety of versions to support temperature, humidity, voltage/current and pulse/event inputs.

Benefits of the Eltek GenII/DARCA secure include:

- **Wide variety of transmitters for different sensors**
- **Extended transmission range covers larger areas**
- **Up to 10 year transmitter battery life reduces support costs**





Validatable Data Loggers and Software

Veriteq vLog Software and Validateable Data Loggers

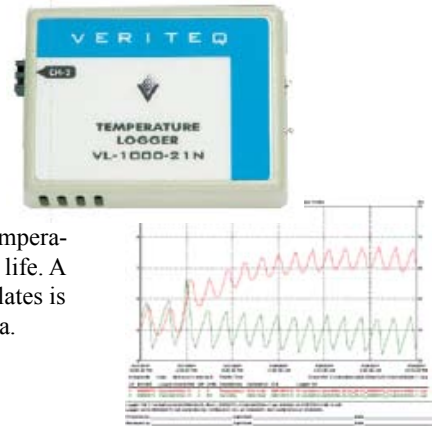
Veriteq provides a very easy to use CFR 21 Part 11 temperature and humidity validation system. The vLog software features:

- Encrypted electronic data records
- Tamper-proof data logger files
- User verification
- Graphical, tabular and statistical analysis
- ASCII data export
- Complete end to end validation protocol available
- Ideal for warehouse, refrigerator and freezer validation

The palm sized VL series data loggers are available in temperature and temperature/humidity versions. They offer easy set-up and up to a 10 year battery life. A comprehensive validation protocol including procedures, forms and templates is available to simplify the task of assuring the accuracy and integrity of data.

Advantages of the Veriteq Validatable Loggers include:

- Comprehensive validation protocol available
- Up to 10 year battery life for reduced support costs
- Simple installation



BrainChild VR18 Paperless Chart Recorders

For applications that require real-time visual feedback along with secure electronic record keeping, the VR18 paperless chart recorder from BrainChild is an ideal solution. The VR18 has several features that can be used to ensure that the record keeping system meets the FDA requirements of CFR21 Part 11

- Process data is recorded in a tamper-proof, read only format
- Encrypted digital signature feature to validate data integrity
- Password protected access to configuration information with audit log
- Time stamped audit log of system and operator actions
- Alarm/event log
- Solid state Flash memory data and log file storage

A document is available which gives guidance on the use of the VR18 for electronic record keeping in FDA processes.

The VR18 provides a number of benefits:

- Real-time data display
- Secure removeable CF card data storage
- Ethernet connectivity
- Plug and Play I/O cards for flexible configurations



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