



CFR COMPLIANCE PACK™

Delivering Total Environment Management

The Continuum™ CFR Compliance Pack™ software product range enhances the Andover Continuum system to provide FDA-regulated businesses with the information they need to achieve regulatory compliance for their facilities. Using 21 CFR Part 11 electronic record and signature standards, CFR Compliance Pack maintains a complete archive of all events and parameters related to the environmental and security conditions of a facility.

A Continuum CyberStation™ workstation with a CFR Compliance Pack option provides multiple benefits to FDA-regulated businesses:

- Comprehensive password management features
- Enforced operator prompts for all system changes and alarm acknowledgments
- User account management enhancements
- Alarm generation for invalid and disabled user logon attempts
- Secure data point and event logging and archiving
- Powerful report generation capabilities
- Detailed audit trails

BASIC AND ADVANCED FEATURES AVAILABLE

The Continuum CFR Compliance Pack is available in two versions, Basic and Advanced. Both versions include the rigorous password management and operator prompting features described above; the difference is in the archiving and archive reporting levels. Choose the version that best meets your site's requirements:

- **CFR Compliance Pack Basic**
Includes the basic CFR compliance feature set plus the encrypted Extended Log Archiver and Archive Reporter, providing secure logging and viewing of any critical analog, digital, or derived point value or parameter in the system.
- **CFR Compliance Pack Advanced**
For the site with more comprehensive logging and archiving needs. Includes all of the functionality of CFR Compliance Pack Basic plus additional encrypted Archivers and Archive Reporters for:
 - Alarm Events – all alarm, return-to-normal, silence, and acknowledgment conditions, including operator acknowledgment text for each alarm
 - User Activity Events – all operator actions performed through the CyberStation, including operator text and the previous and new values for any changes made
 - Access Events – all card access events, including the person, door, area entered, type of event (valid or invalid), and status of the event.

Note: CFR Compliance Pack, Basic and Advanced, requires CyberStation Version 1.6 or greater.

- CyberStation Enhancement Helps Life Sciences Facilities Achieve Regulatory Compliance
- Provides Facility-wide Accountability and Traceability of Environmental and Security Conditions
- Answers the Who?, What?, When?, Where?, and Why? Questions of a Regulated Facility
- Two Versions Available to Meet Basic and Advanced Archiving and Reporting Requirements
- Archivers Available:
 - Extended Logs
 - Alarm Events
 - User Activity Events
 - Access Events
- Archive Reporters Available:
 - Extended Logs
 - Alarm Events
 - User Activity Events
 - Access Events
- Automatic and On-demand Secured PDF Format Report Generation

CFR Compliance Pack

CFR Compliance Pack is installed on a Continuum LAN system, with one or more CyberStation workstations. One workstation must be designated as the archiving workstation, collecting and archiving data from the various log files. Additional workstations do not require the Archivers, but can be installed with the appropriate Archive Reporters, enabling the operator to select parameters and filters for a report, and to view the report's output. CFR Compliance Pack, Basic and Advanced versions, are ordered by appending the following suffixes to any Programmer's Edition of CyberStation LAN software:

For a System using CFR Compliance Pack Basic:

- CFRB CFR Compliance Pack Basic, includes the Extended Log Archiver and Archive Reporter, for the first Workstation ONLY
- CFRBV CFR Compliance Pack Basic Viewer, for additional Workstations, includes the Extended Log Archive Reporter

For a System using CFR Compliance Pack Advanced:

- CFRA CFR Compliance Pack Advanced, includes the Extended Log, Alarm, User Activity and Access event Archivers and Archive Reporters, for the first Workstation ONLY
- CFRAV CFR Compliance Pack Advanced Viewer, for additional Workstations, includes the Extended Log, Alarm, User Activity, and Access event Archive Reporters

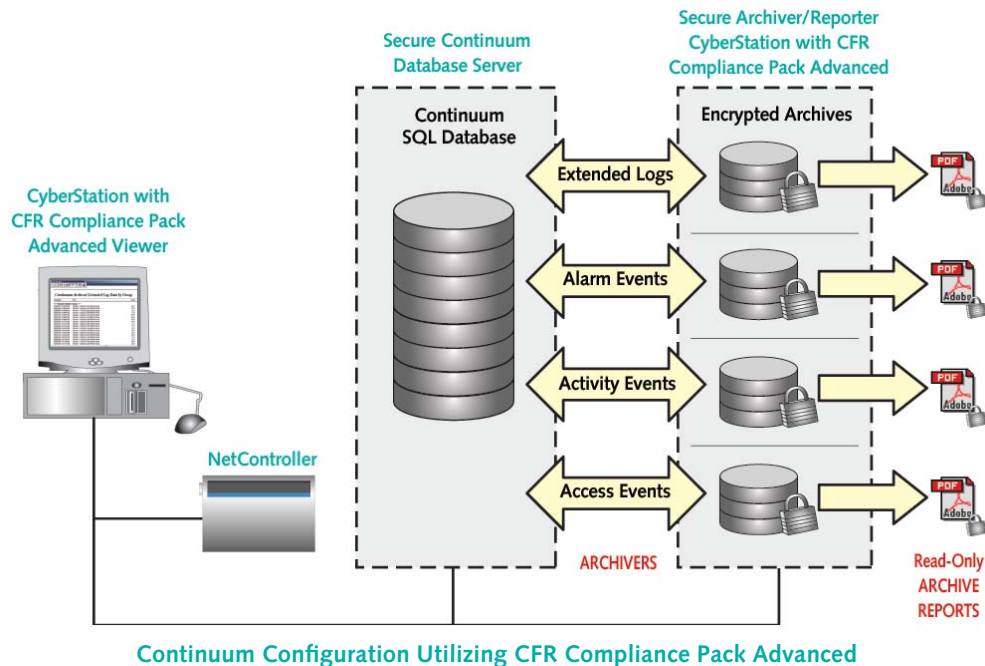
The Archivers also offer the ability to truncate SQL database records once a known good archival back-up has been made. This feature helps manage the running database size and maximize the performance of the SQL server application.

WHAT DO THE ARCHIVE REPORTERS OFFER?

The four Archive Reporters provide detailed selection and report formatting for all archived records, including:

- Decryption of encrypted data and record integrity checking
- Precise record selection using groups, time, user identity and facility area-based criteria
- Report preview and read-only Adobe Acrobat PDF file generation
- Ability to reload the Continuum database with archived data for viewing and graphing

In addition, alarm and access event reports can be automatically e-mailed to a predetermined recipient list.



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