CIPHER SOFTWARE

DISSOLUTION CONTROL FOR 21 CFR PART 11 COMPLIANCE

The Cipher Dissolution Control Software, developed by Distek, is a versatile Windows-based application that, when paired with properly developed customer policies, ensures full compliance with Data Integrity and 21 CFR Part 11 regulations. Cipher can be installed either as a self-contained local installation or on a network. It controls Distek dissolution testers, dissolution autosamplers, and tablet disintegration testers. Designed with flexibility in mind, Cipher Software allows users to customize security settings to meet both regulatory requirements and specific company policies.

DATA INTEGRITY

21 CFR PART 11 / DATA INTEGRITY

Complete 21 CFR Part 11 and Data Integrity compliance for Distek dissolution, autosamplers, and disintegration instruments.

eSIGNATURES

Electronic signatures can be applied to both methods and reports. Signatory levels can be set to originator, approver, or reviewer, with customizable permissions.

METHOD WIZARD

Guides the user through method creation and optimization for dissolution, autosampler, or disintegration measurements.

LIMS COMPATIBLE

Provides simple automatic export of result files in an ASCII format for access and use by any user LIMS package.

INSTRUMENT NETWORKING

Users can log on to a client workstation and view the current status of any compatible Distek instrument on the network, allowing real-time, remote instrument setup and monitoring.

AUDIT TRAIL

Tracks event, system, and method changes with a computer-generated date and time stamp. Additional information logged includes the user, old and new values, and the reason for the change. The report is in a human-readable format.

COMPENDIA ALERTS

Allows the user to set specific tolerances for critical operating parameters. The system alerts the user if a reading falls outside the acceptable range.



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WINDOWS REQUIREMENTS

You must have administrative privileges to install Distek Cipher software. Administrative access must also be available to the network server (domain controller) if the application will be installed in a 'client/instrument server' configuration. Access to the Server User Manager is required for adding groups and granting user access to those groups.

MINIMUM COMPUTER REQUIREMENTS
(CLIENT INSTALLATION)

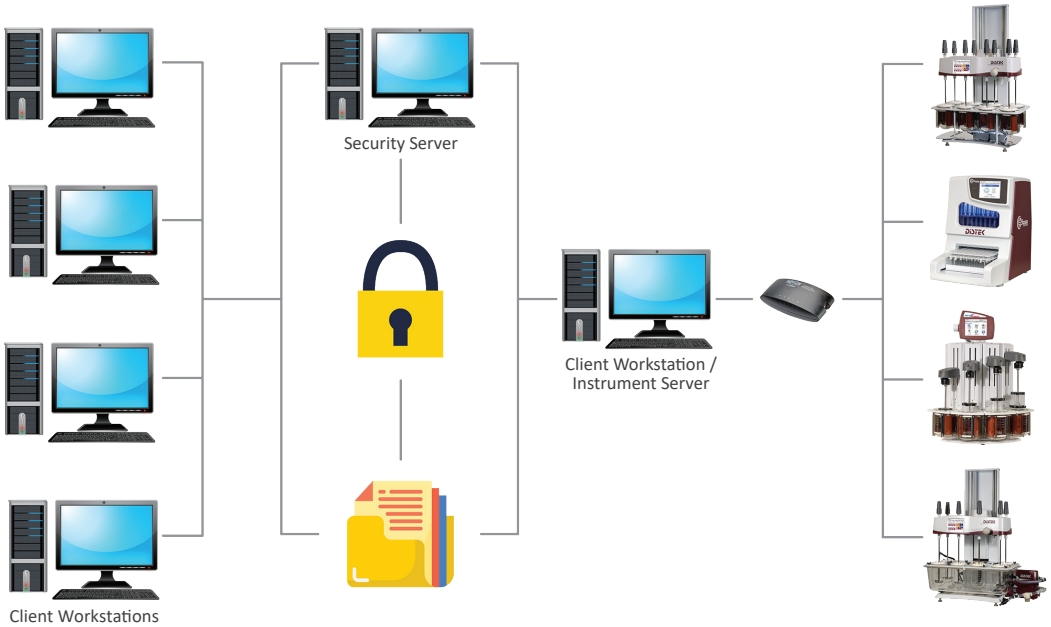
- Intel Pentium ® Processor 1.8 GHz or equivalent
- Microsoft ® Windows 10, Pro version or higher, English version only
- Microsoft .NET Framework 4.7.2 or higher
- Internet Explorer 11 or higher
- Minimum of 4GB of RAM
- 200MB of available hard disk space
- Available USB port (for a serial hub)
- Available Administration rights during installation

MINIMUM SERVER REQUIREMENTS
(CLIENT/SERVER INSTALLATION)

- Intel Pentium ® Processor 1.8 GHz or equivalent
- Microsoft ® Windows Compatible Server
- Microsoft .NET Framework 4.7.2 or higher
- Internet Explorer 11 or higher
- Minimum of 4GB of RAM
- 200MB of available hard disk space
- Available Administration rights during installation

FIRMWARE REQUIREMENTS (DISSOLUTION INSTRUMENTS)		FIRMWARE REQUIREMENTS (AUTOSAMPLER & DISINTEGRATION INSTRUMENTS)	
Model 2500 / 2500 RTD	FW Rev. 1.05 or higher	Eclipse 5300	FW Rev. 4.01 or higher
Model 2500 Select	FW Rev. 1.05 or higher	Evolution 4300*	FW Rev. 2.10 or higher
Evolution 6100*	FW Rev. 2.12 or higher	sensIR 3200	FW Rev. 2.00 or higher
Evolution 6300*	FW Rev. 2.12 or higher		
symphony 7100*	FW Rev. 2.02 or higher		

*Legacy systems, including Models 4300, 6x00, and 7100, can operate with Cipher version 3.0.3. However, Distek does not guarantee full functionality beyond Cipher version 2.2 and will not provide future updates specific only to legacy systems.



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