

- 21 CFR part 11 Compliance**
 Combined with the appropriate customer policies, Cipher balances the requirements of compliance with limited intrusion on user activities.

- eSignatures**
 The use of electronic signatures guarantees that only approved methods can be used and reports released.

- Audit Trail**
 Event, system and method changes are tracked with a computer generated date and time stamp. Additional information logged includes the user, old and new values, and the reason for change.

- Instrument Networking**
 Users are able to log on to a client work station and view the current status of any Distek system on the network permitting real time, remote instrument setup and monitoring.

- LIMS Compatible**
 By using the LIMS manager, two clicks of the mouse during setup result in the automatic exporting of result files in an ASCII format for access and use by a LIMS package.

- Method Wizard**
 The user is walked through method setup for a dissolution unit and attached sampler (if applicable).

- Compendia Alerts**
 The user can set the specific tolerance parameters for RPM and Temperature requiring the system to alert the user should a reading fall outside the acceptable range.

Dissolution Instrument Control

EVOLUTION 6100 S/N: 5150165

Vessel Temperature °C: 37.00, 23.55, 37.00, 37.00, 37.00, 37.00

Status: **Method Running**
 Elapsed Time: 0000:05:35
 Remaining Time: 0000:25:25

Temperature vs. Time (Minutes) graph showing a stable temperature around 37°C.

DS/EVOLUTION 4300 S/N: 4301159

Rack	Viols	Status	Head Position	Sample Row	Vol (ml)
16		Idle			
15					
14					
13					
12					
11					
10					
9					
8					
7					
6					
5					
4					
3					
2					
1					

Next: 0000:00:00
 Elapsed Time: 0000:00:00
 Remaining Time: 0000:00:00

Needle, Pump, Bath A: 16-1

Secure, Reliable, Results

Cipher dissolution control software is a Windows based application designed and developed by Distek, emerging from our many years of experience serving the dissolution market. The software was designed to take advantage of Microsoft's .NET framework and to leverage the functionality of Microsoft® Windows . Cipher offers the flexibility to set the level of security appropriate for your laboratory. When enabling all available security features and audit trails and combined with the appropriate customer developed policies, Cipher will meet 21 CFR part 11 compliance.

Cipher can be installed locally or networked providing full access to any Distek dissolution instrument on the network. The software is an easy to use, intuitive and user friendly application. Its many features make preparing, running, monitoring, and reporting the result of a dissolution test quick and easy. Cipher monitors and reports the continuous temperature readings from the waterbath or from within the vessel when using the Evolution 6100 or 6300 as well as RPM. Simple, advanced and custom test reports are user selectable and user definable to include all pertinent information. Upon completion of a test, the encrypted result file can automatically be exported to a defined secure network location in an ASCII format for integration with a LIMS package.

Cipher Requirements

Windows Requirements

Administrative privileges are required to install Distek Cipher software on a client PC.

Administrative access must also be available to the network server (domain controller) if the application will be installed in a Server/Client configuration. Access to the Server User Manager is required for adding Groups and granting User access to those Groups.

Minimum Computer Requirements (Client):

- Intel Pentium® III or 4 processor or equivalent
- Microsoft® Windows 2000 or Windows XP
- Microsoft .NET Framework 1.1 or higher
- Minimum of 256MB of RAM
- 200MB of available hard disk space
- CD-ROM drive
- Available USB port (for a serial hub)

Minimum Server Requirements (Only required for a Server/Client installation):

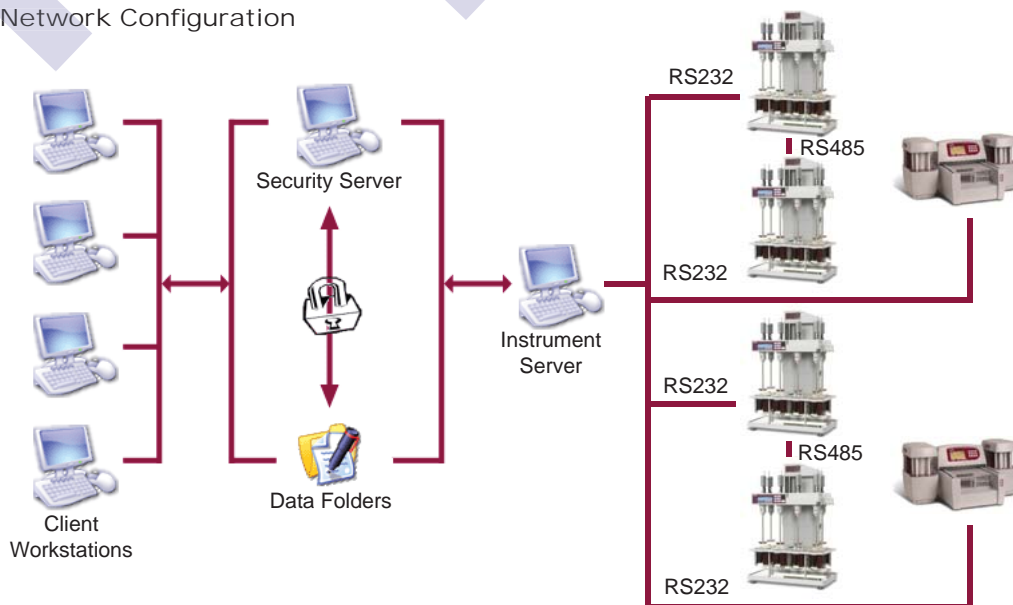
- Intel Pentium® III or 4 processor or equivalent
- Microsoft® Windows NT Server, Windows 2000 Server or Windows Server 2003
- Microsoft .NET Framework 1.1 or higher
- Minimum of 256MB of RAM
- 200MB of available disk space
- CD-ROM drive

Firmware Requirements

Cipher is capable of working with the following Distek models:

Dissolution Systems		Sampling Systems	
TCS	FW Rev. 1.40 or higher	DS 4300	FW Rev. 2.10 or higher
Model 2100C	FW Rev. 2.31 or higher	Evolution 4300	FW Rev. 2.10 or higher
Evolution 6100	FW Rev. 2.12 or higher		
Evolution 6300	FW Rev. 2.12 or higher		

Example Network Configuration



*Local - Same as Network except that Client, Security Server and Instrument

Server can be installed on one PC

**One Instrument Server is required for up to 4 each RS232 connections