

QC - 01E • 2500 | 5300

Method Name



003:12

Finished by 5:00 PM

Operator	Test Started	Apparatus	Temperature	RPM	Volume
Cody Fish	10:21 AM	Paddle	37.0 °C	75	900 mL

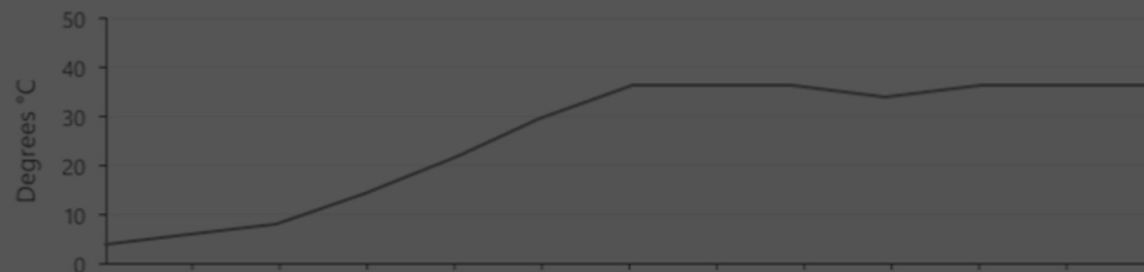
Volume	# of Sample
3 mL	3

# DISTEK

## CIPHER DISSOLUTION CONTROL SOFTWARE



Average Temperature



Average RPM



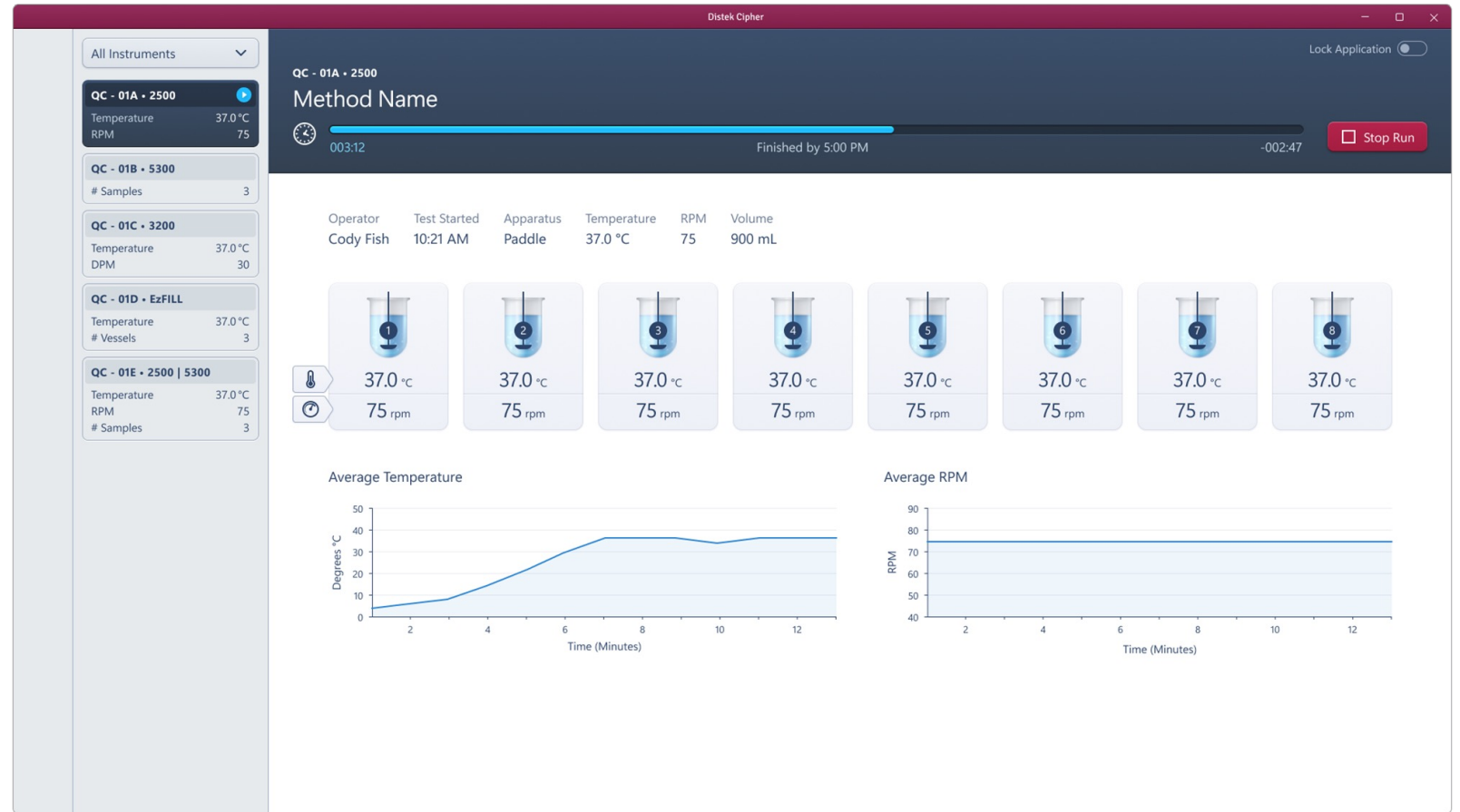
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Unrivalled Support.

# WHAT IS CIPHER?

Cipher dissolution control software is a Windows based application designed and developed by Distek which can be installed locally or networked providing full access to any Distek dissolution instrument on the network.

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.

It's ability to capture and record run data from all connected instrumentation, and store it in a secure, readily accessible digital format provides additional data, and data security for all solid dose laboratories.



# HOW DOES IT WORK?



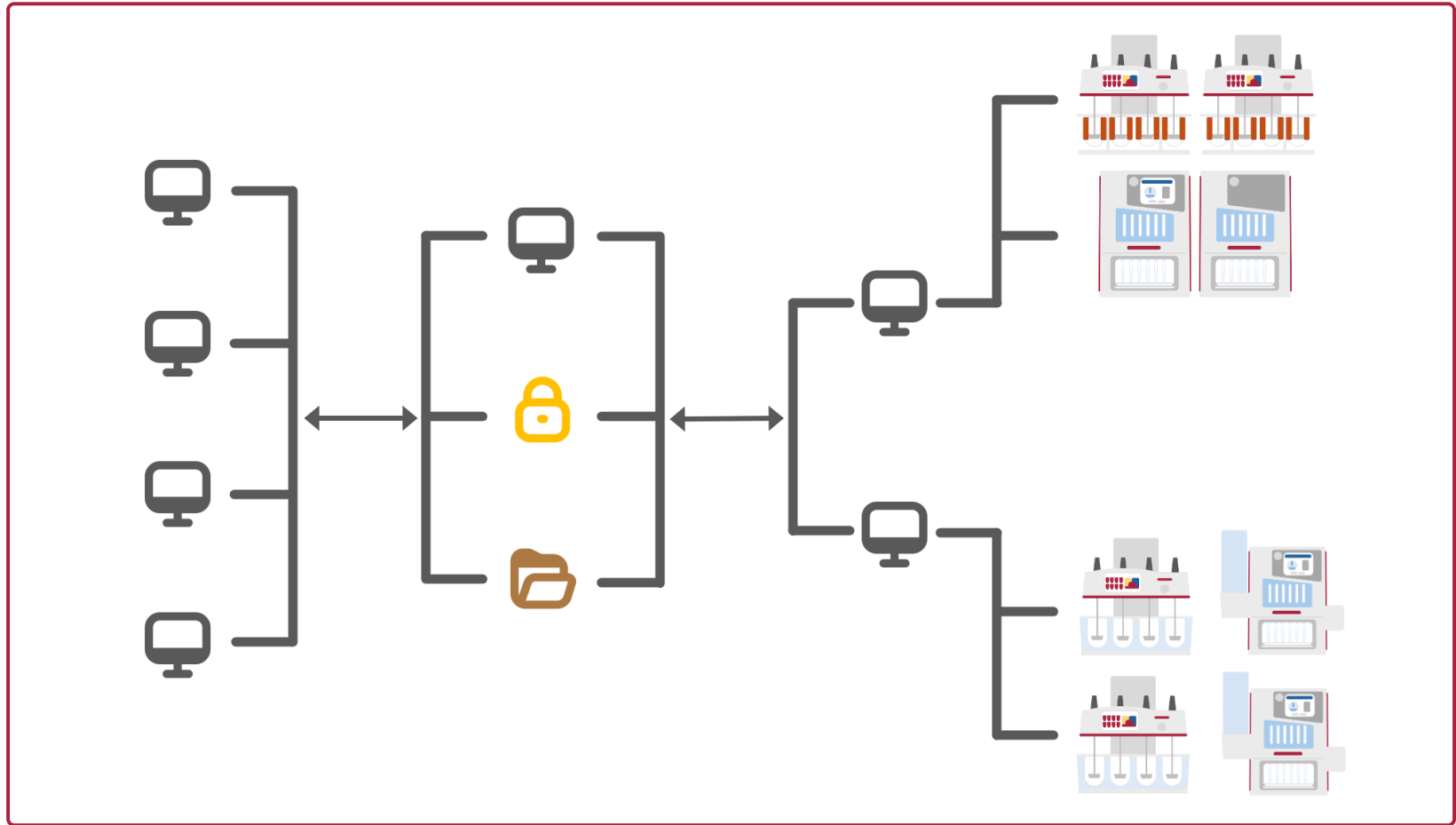
Cipher can be configured to work on a standalone system or can be networked across multiple installations on the network.

Compatible Distek instruments are connect to a local instrument server (PC), via an RS232 cable and a USB hub. Each instrument server can accommodate up to 8 Distek units.

All the settings, methods, data and reports pass through a security server before being stored securely. The entire system is operated through a Client Application installed on each workstation.

If installed locally (standalone), the security server, instrument server and client are on the same PC.

If networked, then the security server can be located anywhere on the network, and the clients can be installed on any compatible PC on the network. The instrument server always needs to be connected locally to the instruments.



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# FEATURES

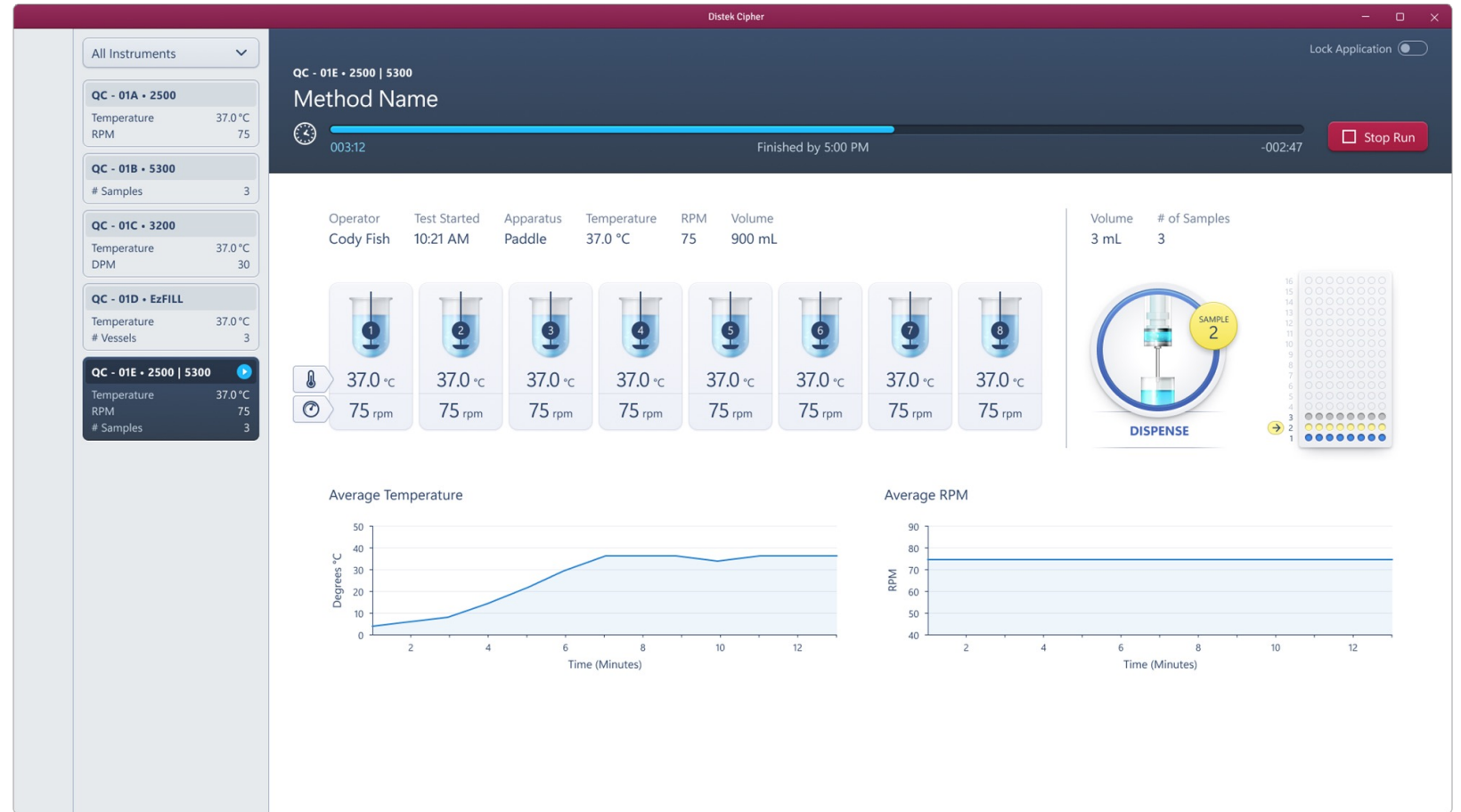


## INSTRUMENT NETWORKING

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.

## LIMS COMPATIBLE

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



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## 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.

Distek Cipher

### All Reports

Method Name	Description	Date Created	Approved Status	e-Signature
Prednisone	QC Test 6 Tablets	02/05/2023 10:11 AM	Approved	D. Istek
Salicylic Acid	Validation Test	12/14/2023 03:18 PM	Pending	V. Service

### Prednisone

Print Export as CSV Apply e-Signature

Method Name	Prednisone	Max.	Min.	Delta	USP
Lot #	RPM	75.1	74.9	0.2	Pass
Batch ID	V1 °C	37.11	36.98	0.03	Pass
Created on	V2 °C	37.00	36.96	0.04	Pass
Executed by	V3 °C	37.12	36.97	0.05	Pass
Status	V4 °C	37.00	36.96	0.04	Pass
Test description	V5 °C	37.00	36.96	0.04	Pass
System name	V6 °C	37.12	36.97	0.05	Pass
Instrument ID	V7 °C	37.11	36.98	0.03	Pass
Autosampler ID	V8 °C	37.00	36.96	0.04	Pass

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## METHOD WIZARD

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

## 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.

The screenshot displays the Distek Cipher software interface. The top window title is "Distek Cipher". On the left, there is a sidebar with navigation icons for "Methods", "Results", "Run Status", and "Settings". The main content area is titled "Methods" and contains a table with the following data:

Method Name	Description	Date Modified	Approved Status	e-Signature
Acetaminophen	QC Test 16	01 Feb 2023	Approved	Jon Smith
Prednisone	Metrology	22 Nov 2022	Approved	J. Tuner
Tylenol	QC Test 03	18 Jan 2023	Approved	David G.

Below the table, there is a section for the "Tylenol" method. It includes tabs for "Instrument Parameters", "Sampling Times", and "Pump Settings". The "Instrument Parameters" tab is active, showing the following details:

Category	All	Test duration	000:45
Method name	Tylenol	Vessels enabled	1, 2, 3, 4, 5, 6, 7, 8
Apparatus	USP2-Paddle	Stagger drop sec	20
Temperature °C	37.0	iRPM	0
Volume mL	900	iRPM duration	00:00
RPM	75.0		

At the bottom left of the sidebar, there is a "Help" icon. At the top right of the main content area, there is a "Lock Application" toggle and an "Add New Method" button.

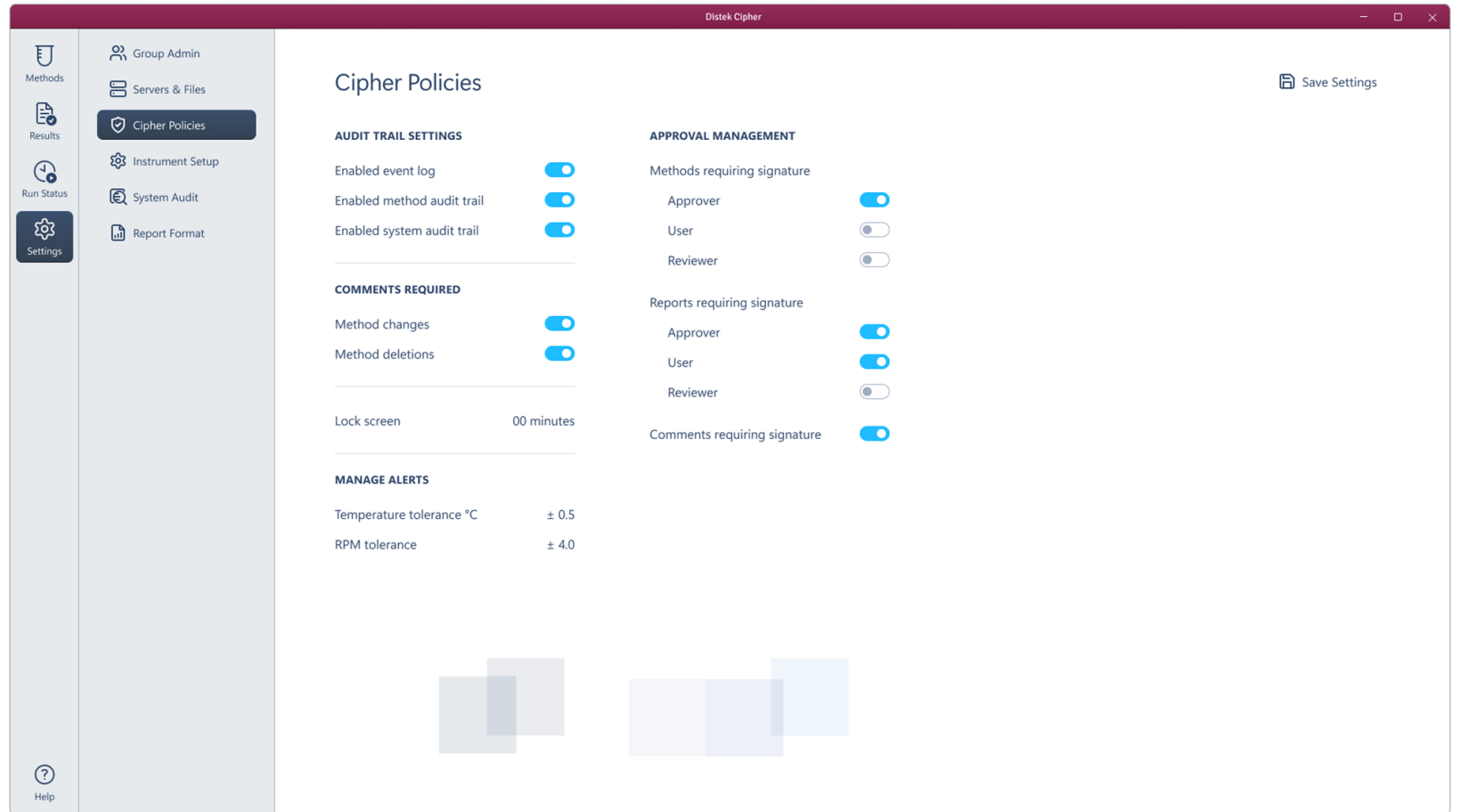
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# FEATURES



## 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.



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TO LEARN MORE ABOUT CIPHER, OR TO SCHEDULE  
A DEMONSTRATION, CONTACT OMICRON

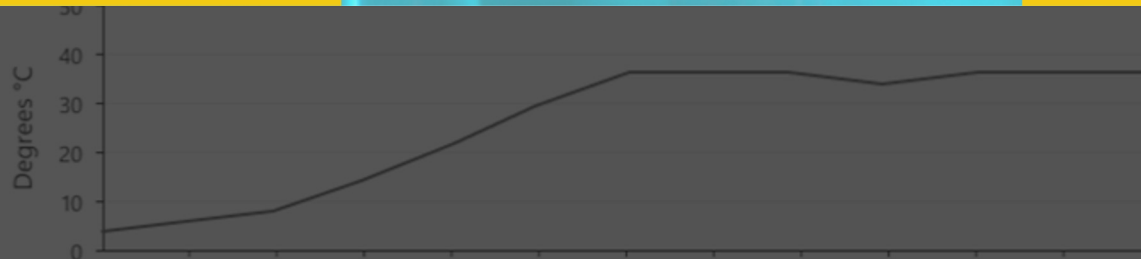
W: [www.omicron-uk.com](http://www.omicron-uk.com) T: +44 1488 682 700 E: [info@omicron-uk.com](mailto:info@omicron-uk.com)

**L A B**  
INNOVATIONS

30 & 31 OCTOBER 2024  
NEC, BIRMINGHAM

**OMICRON**

STAND **G21** Meet us there →



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