NC-View™ Secure Mode Guide

Contents

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Introduction

The US regulatory agency Food and Drug Administration (FDA) Title 21 of the Code of Federal Regulation Part 11; Electronic Records; Electronic Signatures (21 CFR Part 11) came into effect on August 20th, 1997. In short, 21 CFR Part 11 defines the FDA acceptance criteria for when the use of electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records with handwritten signatures.

This document is written for IT and QA professionals and describes the NC-View™ software features relevant for setting up a 21 CFR Part 11-compliant document recording system with the NucleoCounter® NC-202™.

The NC-View™ software application can be set to a restricted mode (hereafter referred to as 'Secure Mode'), that prevents operators from violating the 21 CFR Part 11 regulations via the NC-View™ application itself. Consequently, it is possible to achieve compliance when using a computer system that is already 21 CFR Part 11-compatible.

Activating Secure Mode will block NC-View™ functionalities that could violate 21 CFR Part 11 guidelines. However, enabling Secure Mode will not in its own right ensure compliance with 21 CFR Part 11 guidelines.

The NC-View™ data files are stored in the local Results folder. The data files are protected by the NC-View™ software on workstations running Windows 10. Files can be copied from that location, but any deleting or editing of data is blocked by NC-View™.

The NucleoCounter® NC-202™ automated cell counter operated by the NC-View™ software is intended for research use only (RUO) and is not approved for diagnostic or therapeutic uses. Persons and organizations using the NucleoCounter® NC-202™ with NC-View™, hereafter referred to as 'customers', are responsible for the configuration, qualification, and validation activities required for their application.

Setting Up NC-View™

Using the Secure Mode in NC-View™ requires installation of a Secure Mode License available from ChemoMetec. Access rights and operator rights in NC-View™ Secure Mode are controlled by three user groups, defined in the Windows Active Directory.

You must create three user groups, which should be named as follows (case sensitive):

- securemodeadmin
- securemodesupv
- securemodeuser

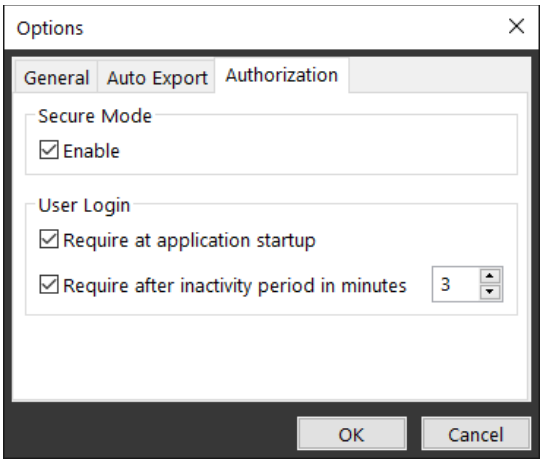
Assign Users to Predefined User Groups

Assigned users to these three user groups depending on their role.

The securemodeadmin users have full rights in the NC-View™ application and can disable Secure Mode, breaking the 21 CFR Part 11 compliance. Users belonging to the securemodesupv or securemodeuser groups have restricted user rights in NC-View™. The 'User Level Restrictions'-section summarizes the rights of each user group. It is important to note that no users assigned to any of the user groups should have local Windows administrator rights, or it will violate the security of the setup. Membership of multiple user groups in Windows Active Directory will violate the security of the setup; therefore, users should only be assigned to one user group.

Activate Secure Mode

The NC-View™ Secure Mode is enabled under (Tools > Options > Authorization).



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Secure Mode

When applying a change to the 'Enable' status, an authorization dialog appears. The user should be a member of the securemodeadmin user group to perform this activation. Enabling and disabling of Secure Mode will be registered in the Audit trail.

User Login

When 'Require at application startup' is enabled, NC-View™ requires user-authentication at startup. The user will be authenticated against the Windows Active Directory server, and be assigned to a user group, based on the Windows user group to which the user belongs.

User Level Restrictions

Enabling Secure Mode restricts several features of the NC-View™ software and restricts user rights depending on which user group the user has been assigned to. Table 1 lists the restrictions imposed on user groups in NC-View™ Secure Mode.

Function	Audit Trail	User Group Name		
		securemodeadmin or Windows Admin	securemodesupv	securemodeuser
Run application	✓	✓	✓	✓
Change user from same Windows user login session	✓	✓	✓	✓
Change user from other Windows user login session	-	✗	✗	✗
Enable/Disable Secure Mode	✓	✓	✗	✗
Change Options	✓	✓	✗	✗
Results (CM file manipulation)				
Import File	-	✗	✗	✗
Copy File	✓	✓	✓	✓
Delete File	✓	✓	✗	✗
Change Sample ID	✓	✓	✓	✗
Add Tag	✓	✓	✓	✓
Delete Tag	✓	✓	✓	✗
Add Comment	✓	✓	✓	✓
Generate PDF Report	✓	✓	✓	✓
Sign File	✓	✓	✓	✗
View Audit Trail	✓	✓	✓	✗
Protocol				
Run Protocol	✓	✓	✓	✓
Import Protocol	✓	✓	✗	✗

Table 1. User restrictions in NC-View™ Secure Mode and at different users group levels.

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Change the Sample ID of a CM File

It is possible to change the Sample ID for one or more CM files by choosing this option after right-clicking on the selected file(s). When changing a Sample ID, it is optional to enter the 'Reason for change'. Any Sample ID change is tracked in the Audit Trail along with the 'Reason for change'. Only users belonging to the securemodeadmin or securemodesupv groups have edit rights to Sample IDs in Secure Mode. Once a data file has been signed, it is no longer possible to change the Sample ID.

Sign a CM File

It is possible to Sign one or more CM files via the right-click option. Signing a CM file is tracked in the Audit Trail. Only users belonging to the securemodeadmin or securemodesupv group have rights to sign CM files in Secure Mode.

Add a Comment to a CM File

It is possible to add comments to one or more CM files in the file browser. Comments are tracked in the Audit Trail.

Editing Tags for a CM File

It is possible to add or delete Tags to one or more CM files in the file browser. Adding or deleting Tags is tracked in the Audit Trail. Only users belonging to the securemodeadmin or securemodesupv groups have editing rights to delete Tags in Secure Mode.

Auto-Export of CSV Files and PDF Reports

It is possible to setup auto-export of CSV files and/or PDF reports (see Software Options in the NC-View™ Software User Guide). Note that users of the system are required to have user rights in the Windows Active Directory to create files in the destination folder. Changes in Tags, Comments, Sample ID and Signature status are tracked in the Audit Trail and can be set to trigger export of CSV and/or PDF files (see Software Options in the NC-View™ Software User Guide for details).

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File Types and Data Storage Locations

Data Files

The CM files and the Audit Trail file are stored in a fixed location. CM files are generated by the NC-View™ software contain all primary analysis data: Sample ID, images, result data, instrument serial number, User ID and other meta data. These files use a ChemoMetec proprietary file format with the extension .cm and are named based on date and data recording sequence.

It is not possible to overwrite data files within the NC-View™ system when Secure Mode is enabled. Data files are stored in the NC-View™ Results folder, in a directory named: (yyyymmdd), according to the local date settings on the computer controlling the NucleoCounter® NC-202™.

The Audit Trail file stores the NC-View activities and is continuously updated in a proprietary format with the extension .log and can only be inspected in NC-View™.

Data Storage Location

CM files are stored in the 'NC-View™ Results' folder. This is the public folder on the local drive, allowing all users to access the same data.

NC-View™ file type	Save location
CM files	*C:\Users\Public\Documents\ChemoMetec\NC-View\results*
Audit Trail file (.log)	*C:\Users\Public\Documents\ChemoMetec\NC-View\results*

Table 2. Example of data storage location for NC-View™ files using a US Windows installation setup

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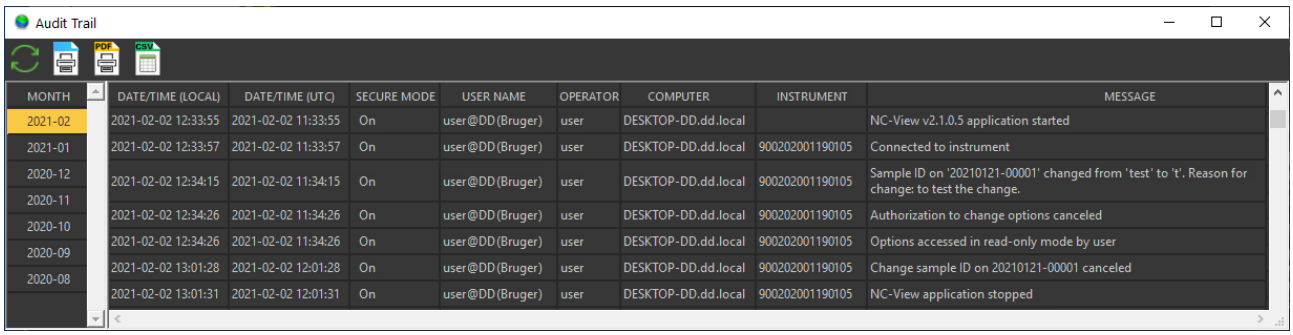
NC-View™ Functionalities

Audit Trail

User activity within NC-View™ is recorded in the Audit Trail. The Audit Trail can be inspected in NC-View™ in the menu View > Audit Trail.



The panel to the left shows the list of months, for which an Audit Trail data has been recorded.

The panel to the right lists the events recorded during NC-View™ operation with NucleoCounter® NC-202™. The columns contain the following information:

- DATE/TIME (LOCAL) – Registers the local time
- DATE/TIME (UTC) – Registers the time in Coordinated Universal Time, which serves as a time zone stamp
- SECURE MODE – In this column, ‘On’ will indicate that Secure Mode was activated during the event
- USER NAME – This is the Windows user name, used to log in to NC-View™ at startup, when login is enabled (Option > Authentication > Secure Mode > Require at startup). If the login option is disabled, the User ID used to sign into the Windows OS will be listed
- OPERATOR – The information entered in the ‘Operator field’ at acquisition. The ‘Operator field’ is locked when Secure Mode is enabled or user login is set to be required at application startup
- COMPUTER – Registers the computer name and network location
- INSTRUMENT - The serial number of the NucleoCounter® NC-202™ used in association with an event. When NC-View™ is not connected to an instrument, this field will be empty
- MESSAGE – Description of the event

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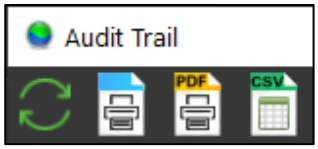
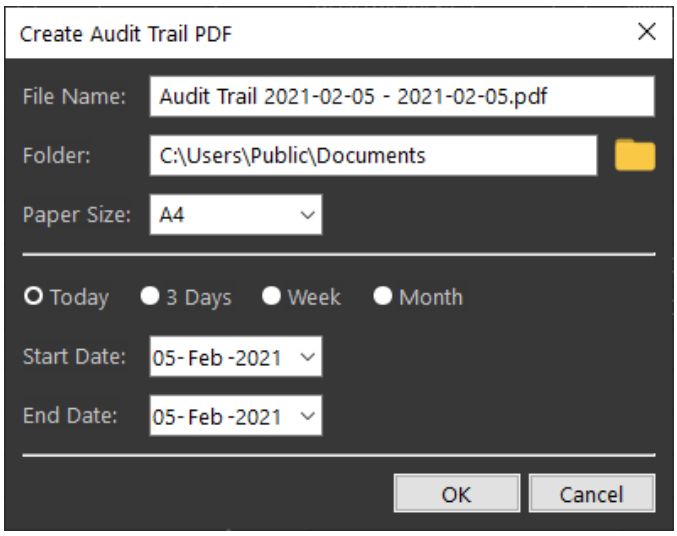
Audit Trail Export

Three icons in the top left corner of the Audit Trail window facilitate the export of the Audit Trail in either a printed version, PDF version or CSV file version.



Choosing the print option will open a dialog opting you to print the Audit Trail for the selected month(s). Choosing the PDF or CSV option will open a dialog where you can select the date interval for the desired Audit Trail data. This dialog will also allow you to choose the destination folder for the Audit Trail data exported.



Integrity of Local Files

The locally stored NC-View™ data files are automatically protected. Specifically, NC-View™ instructs Windows to block writing access to the following folder structure as represented in a US Windows installation setup: C:\Users\Public\Documents\ChemoMetec\NC-View

Access rights in the NC-View™ folder: C:\Users\Public\Documents\ChemoMetec\NC-View		
	Secure Mode Enabled	**Secure Mode Disabled**
Copying files to destination	Prevented	Prevented
Copying files from destination	Allowed	Allowed
Reading files	Allowed	Allowed
Editing files	Prevented	Prevented
Creating files	Prevented	Prevented

The CM files are secure while in the protected folder.

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Terms and Acronyms

Term / Acronym	Description
NC-View™ Results folder	Folder, which is defined to receive data recorded by NC-View™
Active Directory	Active Directory is a Microsoft directory service used for e.g. authentication of users and computers in a Windows domain network
Secure Mode	A collection of software functionalities that are made available to the user after purchasing and installing a Secure Mode license
User Group	Windows users can be assigned to specific user groups. Thus, the access rights can be managed for the whole group, instead of configuring the access for each user individually

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Product Notes

The NucleoCounter® NC-202™ instrument is marked "NOT FOR USE IN DIAGNOSTIC OR THERAPEUTIC PROCEDURES", since it is only validated for research purposes.

The NucleoCounter® NC-202™ instrument is not considered a Medical Device and was not designed or validated according to 21 CFR Part 820 (GMP for Medical Devices).

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ChemoMetec A/S assumes no liability regarding the cited text from the 21 CFR Part 11 regulative and always directs the reader to FDA for correct and full information regarding all 21 CFR Part 11 regulations.

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