

## Tackle Regulatory Challenges

# NanoPhotometer<sup>®</sup> CFR21 Software Compliance for Electronic Records



#### **Electronic Signature**

Save measurement data by confirming login name and password. Saved files provide user name/author, User ID, date and time.



#### **User Management**

Facilitate access of shared data and stored methods by creating multiple user accounts with different access rights. User role options are Administrator, Power User, and User.



## Audit Trail

All actions and preference changes are recorded in an audit log which contains a sequence ID, time stamp, User ID, and category for each action.





#### **Data Integrity**

Measurement data are saved as a proprietary Hash Code secured and encrypted IDS file and can also be stored in PDF format.



#### Data Backup

A proprietary IDS file is automatically saved as a backup file in an Autosave folder accessible by Administrators. Entire system backups can be performed and saved as a copy on a USB flash drive.



#### **Access Control**

Device access is limited to authorized individuals with password protected user accounts. Accessibility to folders and data depends on user's access rights.

The CFR21 software complies with FDA 21 CFR Part 11 requirements and is an optional software tool ideal for GxP laboratories, which require proper electronic record keeping. It includes user management, access control, electronic signatures, data integrity, security, and audit trail functionality.



## **User Management**

Individual Role Based Access Control (RBAC) provides password protected access and control of the NanoPhotometer<sup>®</sup>. Create multiple user accounts with different access rights which are handled in a hierarchic structure. User role options are Administrator, Power User, and User. Organize users into working groups to facilitate access of shared data and stored methods within a lab. Option for increased transparency with Four Eye Administrator Rights. Various password settings are available within the CFR21 software – for example secure password and password expiration options. Effectively improve data security and fulfill audit regulations easily with flexible and appropriate RBAC user management solutions. All features can be enabled or disabled on demand to meet your laboratory needs.

<b>^</b>	Preferer	ices	<b>(i)</b>
PREFERENCES	<	ACCOUNTS	
General	Admin Group PowerD		+
Dyes	bjones		
Warning Messages	jdoe		۲
Network			
Printer			
CFR21			

PREFERENCES	<	Add Power User	li li
General	Group	GroupA	
Dyes	First and Last Name	John Doe	
Warning Messages	Login Name	jdoe	
Network	Login Password		
Printer	Confirm Password		
CFR21	Network Folder		
	Please make your selection	and push the disk icon above to save	desired setting.

## **Electronic Signature**

Measurement data are saved by confirming login name and password. Saved files include the user name/author, login name, date and time for proper electronic record keeping. IDS and PDF files cannot be altered and ensure data integrity.

Δ	124	77. A S S S	
	піт.	Trail	
nu	uit	nun	

The audit trail automatically records all actions and preference changes in an audit log. The audit log contains a sequence ID, time stamp, user ID and category for each action. Audit trails are sorted by year and can be navigated with a search function. For documentation purpose the audit trail can be saved in PDF format by an Administrator.

Instrument Type Version Serial Number Setiltest passed Autosave File Name Reason User ID User Name esign Date esign Date esign Time Parameter Method Type Mode Protein Factor Volume (ul)	M807 2019 No Grouy Autho msmi Mark 2019 13:29	4.2 build 1 98 -09-05; 13: pA/msmith/ or ith Smith -09-05 9:46	02	Read/Sc bjones Becky Jr 2019-05 13:39:1	ines 1-05			
Serial Number Seitlest passed Autosave File Name Resson User ID User Name eSign Time eSign Time Parameter Method Type Mode Protein Factor	M807 2019 No Grouy Autho msmi Mark 2019 13:29	98 -09-05; 13: pA/msmith/ pr ith Smith -09-05 9:46	02	bjones Becky Jo 2019-09 13:39:1	ines 1-05			
Selftest passed Autosave File Name Reason User ID User Name eSign Date eSign Time Parameter Method Type Mode Protein Factor	2019 No Group Autho msmi Mark 2019 13:29 Protein	09-05; 13: pA/msmith/f or ith Smith -09-05 9:46		bjones Becky Jo 2019-09 13:39:1	ines 1-05			
Autosave File Name Resson User ID User Name eSign Date eSign Time Parameter Method Type Mode Protein Factor	No Grouy Autho msmi Mark 2019 13:29 Protein	pA/msmith/ pr ith Smith -09-05 9:46		bjones Becky Jo 2019-09 13:39:1	ines 1-05			
File Name Resson User ID User Name eSign Date eSign Time Parameter Method Type Mode Protein Factor	Group Autho msmi Mark 2019 13:29 Protein	or Ith Smith -09-05 9:46	BSA.ids	bjones Becky Jo 2019-09 13:39:1	ines 1-05			
Reason User ID User Name eSign Date eSign Time Parameter Method Type Mode Protein Factor	Autho msmi Mark 2019- 13:29 Protein	or Ith Smith -09-05 9:46	BSA.ids	bjones Becky Jo 2019-09 13:39:1	ines 1-05			
User ID User Name eSign Date eSign Time Parameter Method Type Mode Protein Factor	msmi Mark 2019- 13:29 Protein	Smith -09-05 9:46		bjones Becky Jo 2019-09 13:39:1	ines 1-05			
User Name eSign Date eSign Time Parameter Method Type Mode Protein Factor	Mark 2019- 13:29 Protein	Smith -09-05 9:46		Becky jo 2019-09 13:39:1	-05			
eSign Date eSign Time Parameter Method Type Mode Protein Factor	2019- 13:29 Protein	-09-05 ):46		2019-09 13:39:1	-05			
eSign Time Parameter Method Type Mode Protein Factor	13:29 Protein	9:46		13:39:1				
Parameter Method Type Mode Protein Factor	Protein				5			
Method Type Mode Protein Factor		UV						
Type Mode Protein Factor		UV						
Mode Protein Factor	0.04			Wavele	ngth (nm)		280	
Protein Factor	BSA		Backgro	und Correct	tion	320 nm		
1100cm110ccon	Mode NanoVolume			Air Bubl	de Recognit	ion	Off	
Volume (ul)	1.500	1.500		Manual	Dilution Fac	tor	1.000	
volume (ui)	1-2							
# Name	Conc.	Units	A230	A260	A280	A320	A260/A280	Dilution
1 Blank1	0.0000	mgimi	0.000	0.000	0.000	0.000	0.000	
2 Sample 1	0.0000	mgimi	0.002	0.001	0.006	0.005		15
3 Sample 2	3.3345	mgimi	18.02	2.756	2.230	0.007	1.237	15

Vear 2022 ID	T Date/Time	Login Name	Category	Action	Details
65492	2022-03-15 17-38-27	Admin	Administrator	Sample measurement	1092473
65491	2022-03-15-17:38:18	Admin	Administrator	Sample measurement.	109747.2
65490	2022-03-15 17 38-12	Admin	Administrator	Sample measurement.	1097471
65489	2022-03-15-17:38:04	Mmin	Administrator	Sample measurement	109747
65488	2022-03-15 17:37:44	Admin	Administrator	Sample measurement.	109760_turn 2
65487	2022-03-15 17:37:39	Admin	Administrator	Sample measurement	109260_turn 1
65486	2022-03-15-17:37:26	Admin	Administrator	Sample measurement	109760_hum
65485	2022-03-15 17:37:07	Admin	Administrator	Sample measurement.	109760.2
65484	2022-03-15 17:36:56	Admin	Administrator	Sample measurement	1097001
65483	2022-03-15 17:36:52	Admin	Administrator	Sample measurement.	109760
65482	2022-03-15 17:36:25	Admin	Administrator	Sample measurement.	Air
65481	2022-03-15 17:36:15	Ndmin	Administrator	Blank measurement	Blank 2
65482	2022-03-15 17:36:02	Admin	Administrator	Blank measurement.	Blank 1
15479	2022-03-15 17-31:43	Admin.	Admusistrator	Logn	NanoPhotometer
65478	2022-03-15 17:04:16	System	System	Warning message	Battery is low. Please connect to power!
05477	2022-03-15 12:13:50	Admin	Administrator	Logol!	Control Device
65475	2022 03 15 12:10:33	Admin	Administrator	File opened successfully	NanoPhotometer/Admin/Graukeil-IN.id
65475	2022-03-15 12:10:17	Admin	Administrator	Login	Control Device