

Tackle Regulatory Challenges

NanoPhotometer® CFR21 Software

Compliance for Electronic Records



Electronic Signature

Save measurement data by confirming User ID 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.



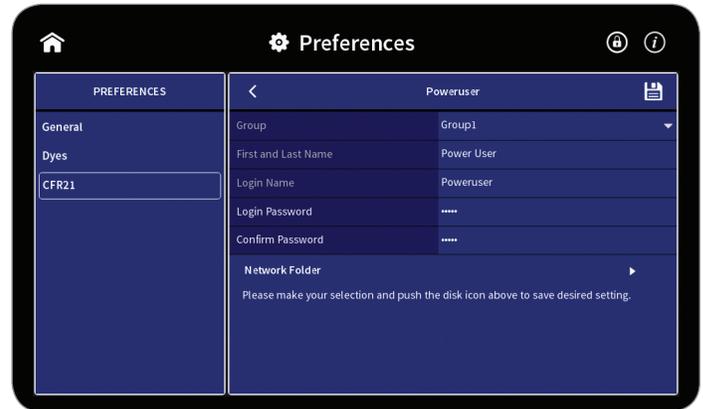
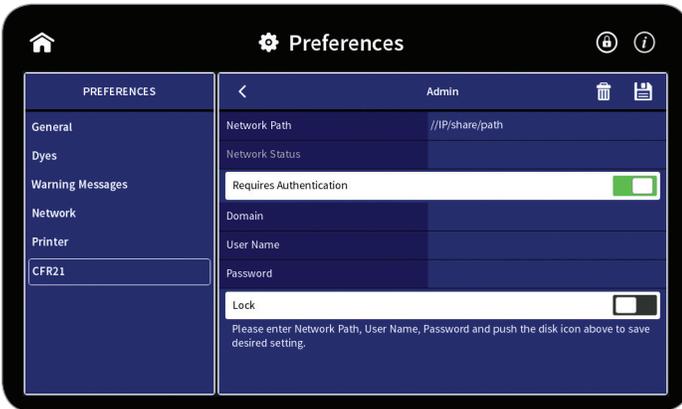
Access Control

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®. 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.



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.

Implen NanoPhotometer®										
Instrument Type	N120									
Version	NPOS 4.0 13220									
Serial Number	M120100									
Selftest passed	2019-02-25; 15:56									
Autosave	No									
Reason	Author	Read/Save/Print								
User ID	bjones		msmith							
User Name	Becky Jones		Mark Smith							
eSign Date	2019-02-26		2019-02-26							
eSign Time	09:23:31		16:49:32							
Parameter										
Method	Protein UV		Wavelength (nm)		280					
Type	BSA		Background Correction		320 nm					
Mode	MultiChannel		Air Bubble Recognition		Off					
Protein Factor	1.500		Sample Loading		Horizontally					
Position	Sample ID	Content	Conc.	Units	A230	A260	A280	A320	A260/A280	Dilution
A01	BLK01	B	0.0000	mg/ml	0.000	0.000	0.000	0.000	0.000	
A02	BLK02	B	0.0000	mg/ml	0.000	0.000	0.000	0.000	0.000	
A03	BLK03	B	0.0000	mg/ml	0.000	0.000	0.000	0.000	0.000	
B01	SPL01	S	0.0090	mg/ml	0.024	0.016	0.009	0.003	2.167	10
B02	SPL02	S	...	mg/ml	-0.004	-0.003	-0.014	-0.003	-0.000	10
B03	SPL03	S	...	mg/ml	-0.003	-0.007	-0.006	-0.004	1.500	10

Audit Trail

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 can be saved as a PDF and printed by an Administrator for documentation purposes.

ID	Date/Time	UserID	Category	Action	Details
77	2019-03-11 13:08:18	Admin1	Administrator	Login	
78	2019-03-11 13:08:26	Admin1	Administrator	File opened successfully	NanoPhotometer/Admin1/Test.ids
79	2019-03-11 13:08:52	Admin1	Administrator	File opened successfully	NanoPhotometer/Admin1/singleTest96.ids
80	2019-03-11 13:09:35	Admin1	Administrator	Blank measurement	
81	2019-03-11 13:09:36	Admin1	System	Warning message	AtLeastOneBlankHighAbsorbance
82	2019-03-11 13:10:21	Admin1	Administrator	Blank measurement	
83	2019-03-11 13:10:26	Admin1	System	Warning message	CloseId
84	2019-03-11 13:10:43	Admin1	Administrator	Sample measurement	
85	2019-03-11 13:14:22	Admin1	Administrator	Blank measurement	
86	2019-03-11 13:14:23	Admin1	System	Warning message	AtLeastOneBlankHighAbsorbance
87	2019-03-11 13:20:57	Admin1	Administrator	Method closed without saving data	Backup-BSA-13-20-190311.ids
88	2019-03-11 13:20:58	Admin1	System	autosave	Backup-BSA-13-20-190311.ids
89	2019-03-11 13:21:09	Admin1	Administrator	File opened successfully	NanoPhotometer/Admin1/Test96.ids
90	2019-03-11 13:21:47	Admin1	Administrator	Measurements saved	method: IgGMouseLabel, file: My NanoPhotometer/Test96-2, formats: Excel, PDF
91	2019-03-11 13:22:49	Admin1	Administrator	Logout	