Tackle Regulatory Challenges

NanoPhotometer® 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®. 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.
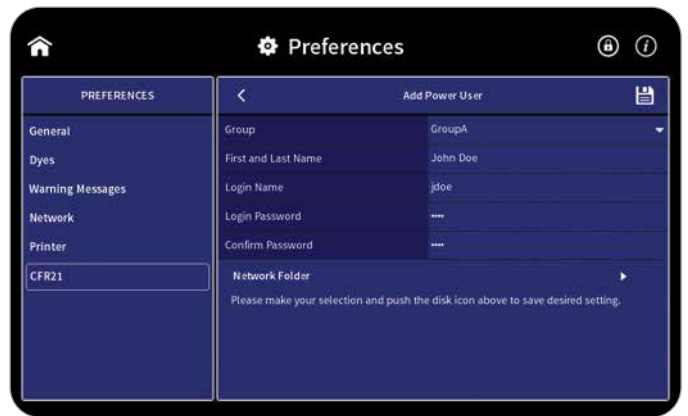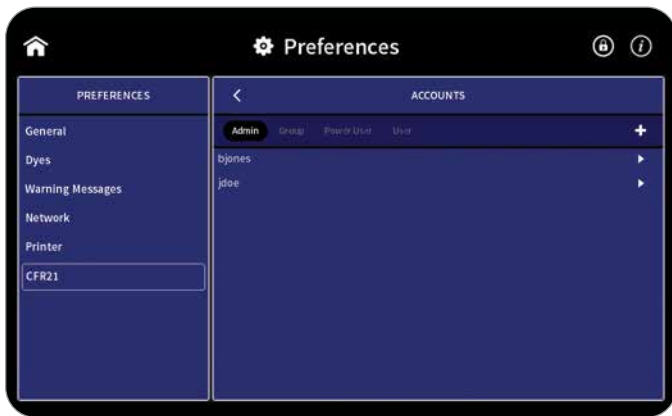
Electronic Signature

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.

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 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.