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Security Software for NanoDrop One Spectrophotometers

Enables Title 21 CFR Part 11 compliance

PC Control software for NanoDrop One/One^{C} spectrophotometers enables 21 CFR Part 11 compliance

Thermo Scientific™ NanoDrop™ One PC Control software allows analysts to operate the spectrophotometer from a computer as well as the built-in touch screen. Security Suite software, a proven compliance component of many other Thermo Scientific systems, integrates directly into the NanoDrop One PC Control software so analysts can confidently operate the trusted NanoDrop One/One^{C} spectrophotometer in compliance with regulatory requirements.

› See the software download page at **thermofisher.com/nanodropsw** for the NanoDrop PC Control software.

Security Suite for NanoDrop One/One^{C} Spectrophotometers

Security Suite software for NanoDrop One/One^{C} Spectrophotometers can integrate into new and older instruments so all users can be compliant with this new software.

› To purchase the Security Suite software, contact your local sales representative or visit **thermofisher.com/nanodrop21cfr.**

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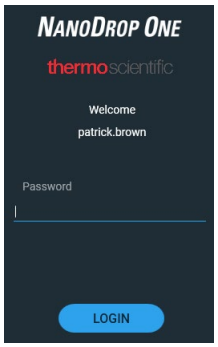
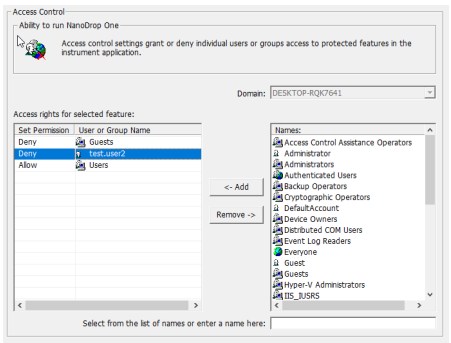
Security Suite for the NanoDrop One/One^{C} PC Control software makes compliance easy

Compliance doesn't have to be complicated. The table below shows an example of how Security Suite manages regulatory requirements.

For a more in-depth review of how the Security Suite software addresses compliance requirements, visit **thermofisher.com/nanodrop21cfr**.

"Limiting system access to authorized individuals."

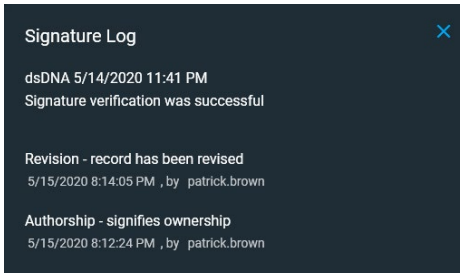




Administrators grant access through the Security Suite software. User account access is managed through the Windows login system.

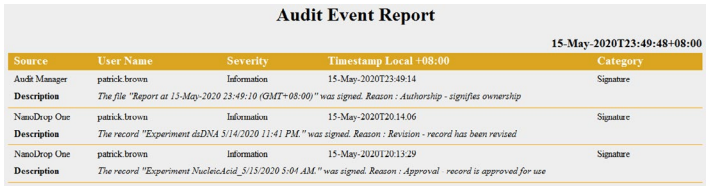
"Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

1. The printed name of the signer;
2. The date and time when the signature was executed; and
3. The meaning (such as review, approval, responsibility, or authorship) associated with the signature."



Experiments are signed immediately after they are completed. Users can also revise, review, and approve experiments from the History page.

"Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying."



Audit Event Report

15-May-2020T23:49:48+08:00

Source	User Name	Severity	Timestamp Local +08:00	Category
Audit Manager	patrick.brown	Information	15-May-2020T23:49:14	Signature
Description	*The file "Report at 15-May-2020 23:49:10 (GMT+08:00)" was signed. Reason : Authorship - signifies ownership*			
NanoDrop One	patrick.brown	Information	15-May-2020T20:14:06	Signature
Description	*The record "Experiment dsDNA 5/14/2020 11:41 PM." was signed. Reason : Revision - record has been revised*			
NanoDrop One	patrick.brown	Information	15-May-2020T20:13:29	Signature
Description	*The record "Experiment NucleicAcid_5/15/2020 5:04 AM." was signed. Reason : Approval record is approved for use*			

The Audit Manager creates an electronic audit trail of actions such as logons, data creation, signatures, and more. Audit logs reports can be generated and printed as needed.

Description	Part Number
Security Suite for NanoDrop One/One^{C}	840-329700

[1] US Food and Drug Administration, September 2003, Part 11, Electronic Records; Electronic Signatures – Scope and Application: Guidance for Industry, viewed May 15, 2020 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application.

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