

FDA 21 CFR Part 11 support functionality installed (DI support) UV/FL Solutions TypeS Program

Strong support for FDA 21 CFR Part 11

In current analytical work, data integrity (DI) is required not only for the analysis of pharmaceutical products but also to ensure data reliability.

To maintain DI, it is necessary to prevent falsification or deletion of data.

In addition, to properly assess test results, it is necessary to retain all data and records created in the course of testing.

Software for the UV Solutions TypeS Program and FL Solutions TypeS Program has improved DI support with installed support functionality for FDA 21 CFR Part 11.



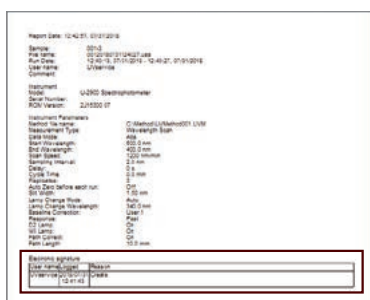
Main features

- 1 Electronic signature
- 2 Audit trail
- 3 Protection of electronic records (DI)
- 4 User permission setting
- 5 User authentication feature based on user ID and password
- 6 Operation protect feature

1 Electronic signature

Measurement results and measurement conditions are stored together as data files.

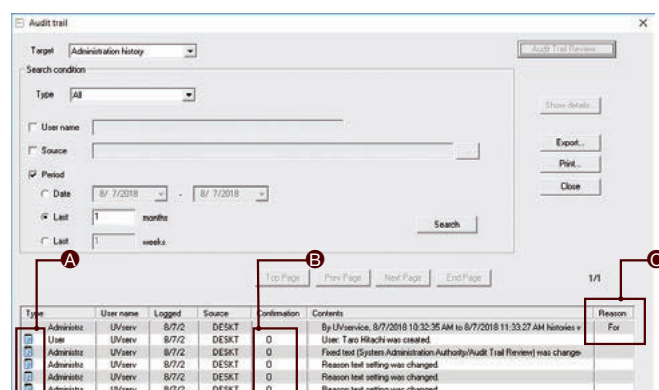
These files can be electronically signed.



2 Audit trail

Creation and modification of files, analysis operations, and event information are recorded as an audit trail.

- A History items marked with a " " indicate that there is a detailed history.
- B History items with a "O" under Confirmation have had an "Audit trail review" performed.
- C Reasons are displayed in the "Reason" section.

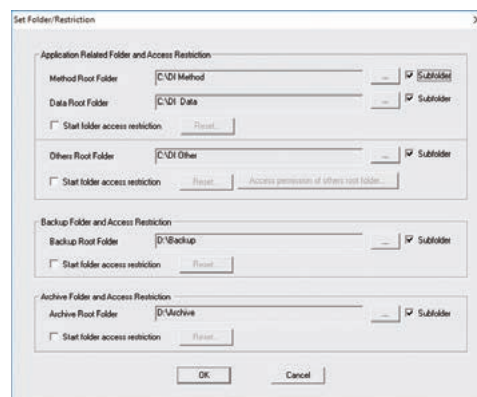


3 Protection of electronic records (DI)

Sets up saving of data and audit trail information and deletion prevention.

Records are managed in accordance with the ALCOA principle (see figure below).

Prevention of file deletion and automated backup, restoring, and archiving of data are performed by Microsoft Windows operations.

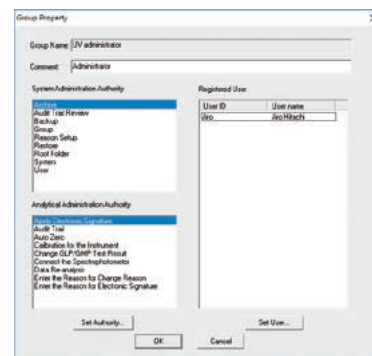
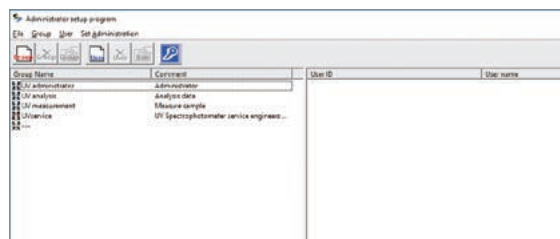


"ALCOA" principles related to DI

- Attributable:** Records are attributable, and where responsibility lies is unambiguous
User authentication, electronic signatures
- Legible:** Records are legible, and the records for each step are understandable
Collection of change history via audit trails
Deletion of data by operators is prohibited
- Contemporaneous:** Records are accurate, based on fact, and authentic
Actual conditions under which operation was performed (such as who, what, when, how)
- Original:** Recording is done at the time the work is done
Mandatory saving of collected data
- Accurate:** Data are original data
Records of all data and audit trails

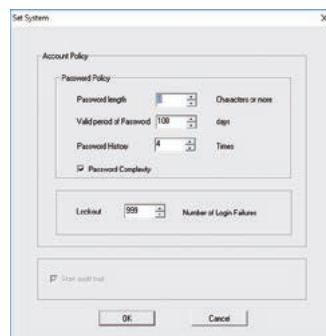
4 User permission setting

Multiple groups can be created and permissions set for each group. Permissions are also managed in the system by group registration of users. By selecting groups and users, a list of information for each group [name, description, and rights and information for each user (user name, comments)] can be printed.



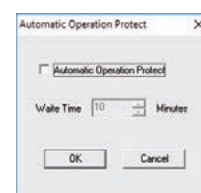
5 User authentication feature based on user ID and password

User authentication security based on user ID and password is enforced whenever a user logs in, provides an electronic signature, etc. The password policy can be set in the environment-setting program (setting content: length, expiration date, history, complexity). There is a lockout feature against unauthorized access.



6 Operation protect feature

The system has a protection feature that does not allow anyone else to use the system when the user steps away. There is also an "automatic operation protect" feature that runs if no operations are performed for a preset amount of time.



Software

	Part No.	Product Name
UV/VIS Spectrophotometer	2J0-0310	UV Solutions TypeS Program (U-2900/2910/3900/3900H)
	2J0-0311	GLP/GMP Program
	2J2-9953	IQOQ draft (U-3900/U-3900H)
	2J1-9991	IQOQ draft (U-2900/U-2910)
Fluorescence Spectrophotometer	5J0-0367	FL Solutions TypeS Program (F-7100/F-7000/F-2700)
	5J1-9117	IQOQ draft (F-7000)
	5J1-9147	IQOQ draft (F-7100)
	4J1-9145	IQOQ draft (F-2700)

PC specifications

OS		Microsoft Windows 10 Pro (64 bit)
CPU		CPU that can run above OS
Main Memory		4 GB or more
Hard Disk		Free capacity 5 GB or more
CD-ROM Drive		Maximum 24× or higher
Interface		USB 1.1/2.0 or higher or RS-232C 17-inch or greater
Display	Desktop model	17-inch or greater Resolution 1280 × 1024 (SXGA) or higher, or 21.5-inch wide or greater Resolution 1920 × 1080 (full HD) or higher
	Notebook model	15.6 inch wide or greater Resolution 1920 × 1080 (full HD) or higher

Part 11 related functional specifications

Environment-Setting Program	User permission settings
	Creation of permission groups
	Password policy setting
	Protection of electronic records
	Audit trail review
	Automatic backup / restoring / archiving of data
	Archived data access
UV/FL Solutions (Part 11 / DI Support version)	Printing of group/user lists
	Audit trail
	Electronic signature
	Operation protect
	Entering reason for change



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Hitachi High-Tech Science Corporation

www.hitachi-hightech.com/global/hhs/

Head Office

24-14, Nishi-Shimbashi 1-chome, Minato-ku, Tokyo 105-0003, Japan

