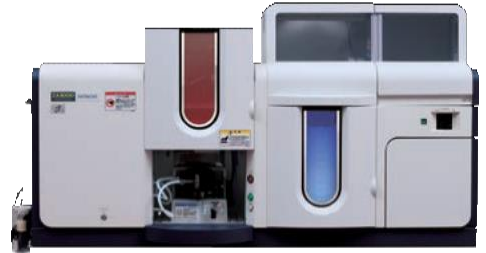


FDA 21 CFR Part 11 support functionality installed (DI support)  
System Software for ZA3000 Series  
Atomic Absorption Spectrophotometer

## 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. System Software for ZA3000 Series Atomic Absorption Spectrophotometer has improved DI support with installed support functionality for FDA 21 CFR Part 11.

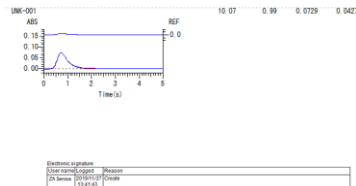


## Main features

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

## 1 Electronic signature

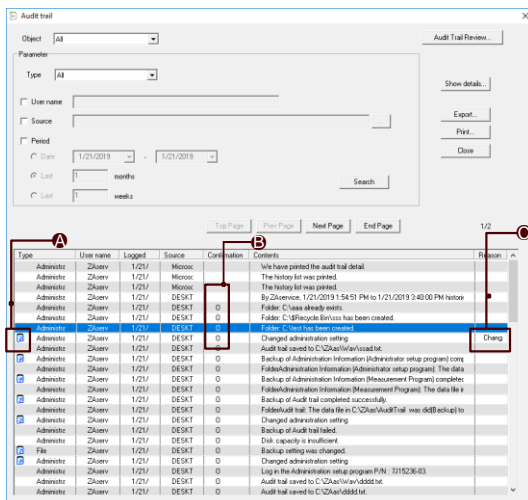
Measurement results and measurement conditions are stored together as data files.  
These files can be electronically signed.



## 2 Audit trail

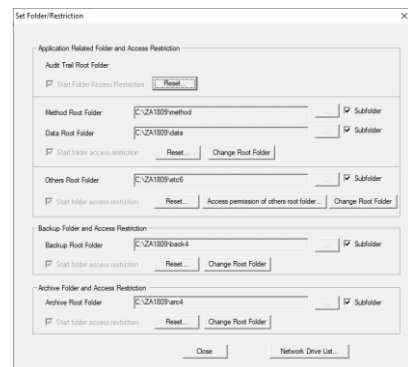
Creation and modification of files, analysis operations, and event information are recorded as an audit trail.

- A History items marked with  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 ( Data Integrity)

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.

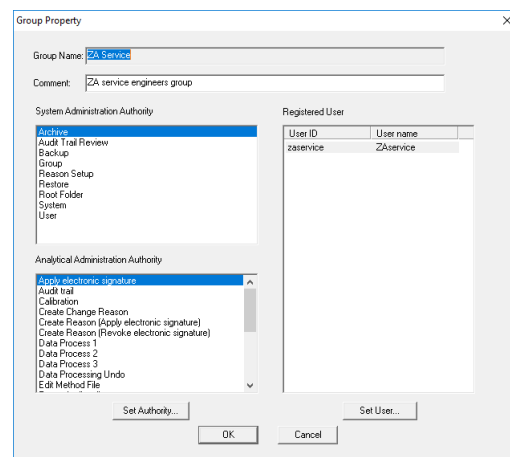
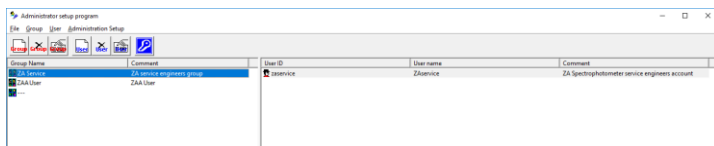


## “ALCOA” principles related to DI

- |                          |   |
|--------------------------|---|
| <b>A</b> ttributable:    | Records are attributable, and where responsibility lies is unambiguous<br>User authentication, electronic signatures  |
| <b>L</b> egible:         | Records are legible, and the records for each step are understandable<br>Collection of change history via audit trails<br>Deletion of data by operators is prohibited |
| <b>C</b> ontemporaneous: | Records are accurate, based on fact, and authentic<br>Actual conditions under which operation was performed (such as who, what, when, how)                            |
| <b>O</b> riginal:        | Recording is done at the time the work is done<br>Mandatory saving of collected data  |
| <b>A</b> ccurate:        | Data are original data<br>Records of all data and audit trails  |

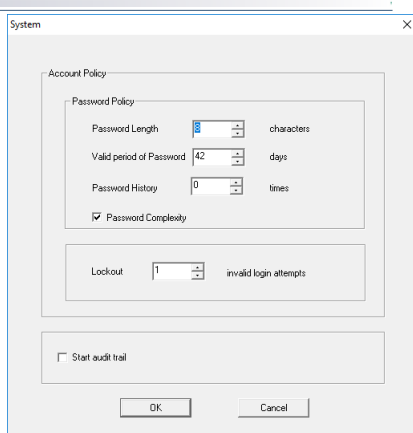
## 4 User Authority setting

Multiple groups can be created and authorities set for each group. Authorities 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

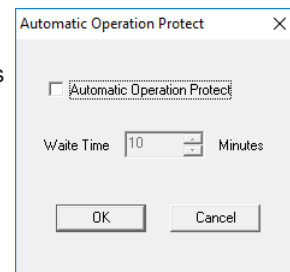
User authentication security based on user ID and password is enforced whenever a user logs in, provides an electronic signature, etc. The password policy can be set in the environment-setting program (setting content: length, expiration date, history, complexity). There is a lockout feature against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



### Part 11 related functional specifications

Environment-Setting Program	User Authority settings
	Creation of Authority groups
	Password policy setting
	Protection of electronic records
	Audit trail review
	Automatic backup / restoring / archiving of data
	Archived data access
ZA3000 (Part 11 / DI Support version)	Printing of group/user lists
	Audit trail
	Electronic signature
	Operation protect
	Reason for Change

### Software

Part No.	Product Name
7J1-8801	FDA 21 CFR Part 11 support functionality installed System Software for ZA3000 Series Atomic Absorption Spectrophotometer

### 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 2.0×1 or higher	
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



Hitachi High-Tech Science Corporation

<https://www.hitachi-hightech.com/hhs/>