

LAQUA

LAQUA 21 CFR Part 11 Software



Introduction

The 21 CFR Part 11 is a regulation issued by the American Food and Drug Administration (FDA) on the 20th of August 1997. It outlines the FDA criteria for accommodating and accepting electronic records and documents as well as signatures under the guidelines of Good Manufacturing Practice (cGMP) relating to pharmaceutical, food and healthcare industries.

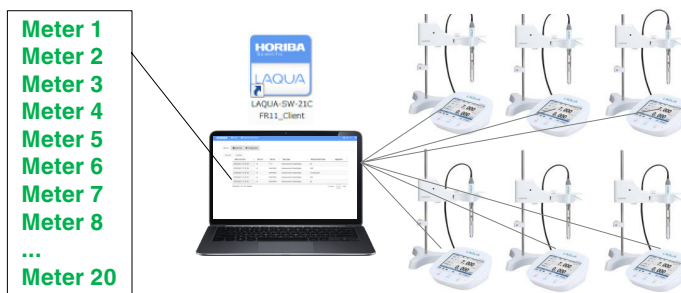
The important purposes of the 21 CFR Part 11 are:

1. the 'paperless' use and storage of electronic records
2. accepting electronic signatures
3. the authenticity/integrity of such electronic records
4. disallow manipulation of data records to falsify results
5. control the access to data
6. traceability of records generated
7. an audit trail that captures all actions performed on the meter

The 21 CFR Part 11 compliance is not achieved by an instrument alone. The organization must have their own standard operating procedures (SOPs) to support the use of electronic records and signatures that complements the functionality of the meter-software system.

- Up to 25 user accounts can be registered

- Up to 20 instruments can be registered. 6 instruments can be linked to the PC at the same time



Access authority list

Authority name	Authority No.	
System Administrator	1	Display
Administrator	2	Modify
Operator	3	Modify
Custom1	5	Modify
Custom2	6	Modify
Custom3	7	Modify
Custom4	8	Modify

Modify access authority

Authority name

Device management	<input type="radio"/> Enabled	<input checked="" type="radio"/> Disabled
User account management	<input type="radio"/> Enabled	<input checked="" type="radio"/> Disabled
Access authority management	<input type="radio"/> Enabled	<input checked="" type="radio"/> Disabled
Signature authority management	<input type="radio"/> Enabled	<input checked="" type="radio"/> Disabled
Security management	<input type="radio"/> Enabled	<input checked="" type="radio"/> Disabled
Record management	<input type="radio"/> Enabled	<input checked="" type="radio"/> Disabled
Backup	<input type="radio"/> Enabled	<input checked="" type="radio"/> Disabled
Restoration	<input type="radio"/> Enabled	<input checked="" type="radio"/> Disabled
Device administrator	<input checked="" type="radio"/> Operator	<input type="radio"/> Administrator

Signature authority

User account

Device information

Security settings

Backup

Restoration

Bulk delete

Security settings

Auto-logout ☒ Enabled ☐ Disabled

Waiting time (minutes)

Password expiration ☒ Enabled ☐ Disabled

Valid period (days)

User account lockout ☒ Enabled ☐ Disabled

Lockout threshold (times of invalid login attempts)

Data retention period (years)

Apply

HORIHA Home Software information					1 user, 18
<div> <div>Data</div> <div>Asset list</div> <div>Configuration</div> </div>					
<div>Search</div>					
Date and time	User	Instrument	Operation type	Detail	
05/02/2017 15:36:19	cs	PC 127.0.0.1	Signature to measurement data	S_1st_ver_Check	
05/02/2017 15:34:49	cs	Device 03A703010	Adding measurement data	Measurement DataChanges.pH.9	
05/02/2017 15:32:42	cs	Device 03C9F010	Adding measurement data	Measurement DataChanges.pH.7	
05/02/2017 15:28:49	cs	Device 03B0F0105	Adding measurement data	Measurement DataChanges.pH.6	
05/02/2017 15:22:42	cs	PC 127.0.0.1	Login	Pass	
05/02/2017 15:19:39	cs	PC 127.0.0.1	Logout	manual	
05/02/2017 15:18:16	cs	PC 127.0.0.1	Login	Pass	
05/02/2017 15:13:11	cs	PC 127.0.0.1	Logout	manual	
05/02/2017 15:10:46	cs	Device 03C9F010	Adding measurement data	Measurement DataChanges.pH.5	
05/02/2017 14:50:03	cs	Device 03B0F010	Login	Pass	
05/02/2017 14:50:25	cs	Device 03B0F010	Establishing communication	03B0F010_41.P30000126_1.32.P30000126_1.02.PE3.000F	
05/02/2017 14:50:08	cs	PC 127.0.0.1	Adding a device	03B0F010	
05/02/2017 14:48:55	cs	PC 127.0.0.1	Logout	Blank	

[illegible]

Target operation	Operation classification	Details
Operations on PC		
Addition of device information	Adding a device	MFG No. of the added device
Modification of device information	Modifying device information	MFG No. of the modified device
Deletion of device information	Deleting a device	MFG No. of the deleted device
Addition of a user account	Adding a user account	Added user account
Modification of a user account	Modifying a user account	Modified user account
Deletion of a user account	Deleting a user account	Deleted user account
Modification of access authority	Modifying access authority	Number of modified access authority (authority level)
Modification of signature authority	Modifying signature authority	Number of modified signature authority (authority level)
Modification of security settings	Modifying security settings	Name of modified settings
Log in	Log in	Logout results (Pass, Fail [Error No.]) In the case of a log failure, the user ID with which login was attempted is recorded in the (Operator's name)
Logout	Logout	Logout type (Auto, Manual, Fail [Error No.])
Bulk deletion of data	Deleting data in bulk	Number of deleted entries (entries per user ID) Number of deleted data records Number of deleted values of security settings <ul style="list-style-type: none"> Fail [Error No.]

Memory	4 GB or more
CPU	2.53 GHz or more
Hard disk free space	100 GB or more
Operating System	Windows 7 Ultimate, Professional, or Enterprise (64-bit) Windows 8 Pro or Enterprise (64-bit) Windows 8.1 Pro or Enterprise (64-bit) Windows 10 Pro or Enterprise (64-bit)* <small>*Anniversary update applicable edition, Version 1607 and later</small>
Web browser	Internet Explorer 11 or Microsoft Edge
Display	QVGA (1280 x 960) or above
Others	<ul style="list-style-type: none"> At least one available USB 2.0 port An optical drive (DVD) for installation

Software

Part No.	Model No
3200707161	LAQUA-SW-21CFR11

Meter Kits	
Part No.	Model No
Colour Bench Meters with electrodes, CFR software and USA pH buffer kits	
3999960210	F-72A-S-CFR
3999960212	F-73A-S-CFR
3999960214	F-74A-S-CFR
3999960216	DS-72A-S-CFR
Colour Bench Meters with electrodes, CFR software and NIST pH buffer kits	
3999960211	F-72A-NS-CFR
3999960213	F-73A-NS-CFR
3999960215	F-74A-NS-CFR
3999960216	DS-72A-S-CFR