

# 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.

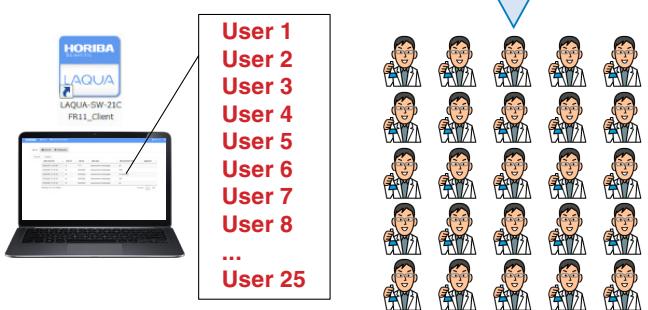
The important purposes of the 21 CFR Part 11 are:

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

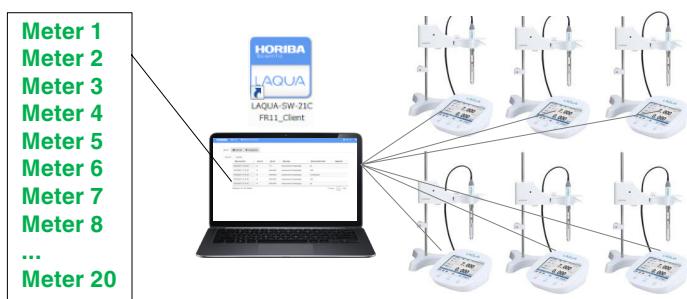
The 21 CFR Part 11 compliance is not achieved by an instrument alone. The organization must have their own standard operating procedures (SOPs) to support the use of electronic records and signatures that complements the functionality of the meter-software system.

## Features

- 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



## Functions

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	Operator
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
Restore	<input type="radio"/> Enabled <input checked="" type="radio"/> Disabled
Device administrator	<input checked="" type="radio"/> Operator <input type="radio"/> Administrator

Signature authority	Security settings		
User account			
Device information	Auto-logout	<input checked="" type="radio"/> Enabled <input type="radio"/> Disabled	
	Waiting time (minutes)	120	
Security settings	>Password expiration	<input checked="" type="radio"/> Enabled <input type="radio"/> Disabled	
	Valid period (days)	90	
Backup	User account lockout	<input checked="" type="radio"/> Enabled <input type="radio"/> Disabled	
Restoration	Lockout threshold (times or invalid login attempts)	10	
Bulk deletion	Data retention period (years)	10	
		<input type="button" value="Apply"/>	

One system administrator and six types of user access authority. (system administrator can assign access authority for each user)

Limit permissions for each user

Settings: auto log out, password expiration date, user account lockout, and data storage period

Date and time	User ID	Instrument	Operation type	Detail
05/05/2017 11:36:11	ctf	PC 127.0.0.1	Signature to measurement data	8_ctf_user_Check
05/05/2017 11:34:08	ctf	Device 029F0301	Adding measurement data	Measurement Data[geige].pr.8
05/05/2017 11:32:42	ctf	Device 029F0301	Adding measurement data	Measurement Data[geige].pr.7
05/05/2017 11:28:46	ctf	Device 029F0301	Adding measurement data	Measurement Data[geige].pr.6
05/05/2017 11:22:22	ctf	PC 127.0.0.1	Login	Pass
05/05/2017 11:19:30	ctf	PC 127.0.0.1	Logout	manual
05/05/2017 11:16:15	ctf	PC 127.0.0.1	Login	Pass
05/05/2017 11:13:11	ctf	PC 127.0.0.1	Logout	manual
05/05/2017 14:46:06	ctf	Device 029F0301	Adding measurement data	Measurement Data[geige].pr.5
05/05/2017 14:40:24	ctf	Device 029F0301	Login	Pass
05/05/2017 14:35:25	ctf	Device 029F0301	Establishing communication	BSF01015_41.F2001601E..132.P200919B..1.02.FES.BSF
05/05/2017 14:33:06	ctf	PC 127.0.0.1	Adding a device	BSF0105
05/05/2017 14:33:06	ctf	PC 127.0.0.1	Login	Pass

## Audit trail and security

ORIBIA
Home
Logout
Information
Alerts
...

Unit
 Audit test
 Configuration

---

Validity of data

Unit: g

Unit: mL

Unit: mm

Measurement item

Valid

0.0

100

100

Measurement Categories

pH

---

Measurement results

Unit: g

Unit: mL

Unit: mm

Unit: °C

Unit: pH

Unit: °C

Unit: mm

10.000000

10.000000

10.000000

10.000000

6.800

20.0 °C

0.0 mm

Measurement condition

Calibration results

Signature

No signature
Write signature
Reject data

### Detailed measurement data display

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 a device information	MFG No. of the modified device
Deletion of device	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	Setting security settings	Name of modified setting
Login	Login	Login results (Pass, Fail, Err No.)
Logout	Logout	Logout type (Auto, Manual), Fail count (The # of attempts when login was attempted) is recorded in the [Operator] column
Bulk deletion of data	Deleting data in bulk	
	<ul style="list-style-type: none"> <li>• Data, Data reference number, Deleted number of data records</li> <li>• Setting value of security settings</li> </ul>	
	<ul style="list-style-type: none"> <li>• Fail [Err No.]</li> </ul>	

#### Detailed recording of operations

## System Requirements

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"><li>At least one available USB 2.0 port</li><li>An optical drive (DVD) for installation</li></ul>

## Ordering Information

## Software

Only compatible with HORIBA LAQUA Colour Bench Meters:  
F-72, F-73, F-74 & DS-72

Part No.	Model No
3200707161	LAQUA SW-21CEB11

## **Motor Kite**

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