FDA CFR21 Part 11 Compatible Software Description for Aqualink4

Take advantage of operating system security and domains

Aqualink4 makes efficient use of the security features built into the underlying Windows operating systems. For compliance, all computers in a closed system must be part of the same Windows domain. All Aqualink4 computers must run Windows XP or Windows 7. Windows XP and Windows 7 encrypt passwords using the operating system's built-in encryption mechanism

Restrict access to the application

Aqualink4 Part11 is used to manage and view data collected from decagons Aqualab line of products. Security can be applied to the application through the standard Windows User Environment described later in this document. To restrict users from making unauthorized, changes to the application, it is recommended that access be restricted to users that are assigned with appropriate security.

Use Windows account password aging and management

User account and password management and aging is done using Windows User Management. User accounts and passwords should be set up so that the passwords expire after a certain time and with appropriate lockouts after multiple failed login attempts, and to re-prompt users for their login credentials after brief periods of inactivity. This information is usually part of a company IT department Standard Operating Procedure, or SOP. For more information, refer to your Windows documentation.

Where possible, operators should be required to log completely off Windows when not physically at the station.

Users log on requirements for the Aqualink4 Part 11 Environment

Each user must log onto the Windows 7 or XP computer at the start of their session, and log out when they are done.

Do not allow the operator to allow anyone else to perform operations using their user name and password. If it is necessary for a supervisor to perform or approve certain operations, the operator should log off Windows, and the supervisor should log on.

Electronic Record (Data) Security

- All core data is encrypted using 128 bit AES encryption
- Create hash value (fingerprint) for each file that contains or affects acquired data
- All hash values are stored in a table and encrypted (128-bit encryption scheme)
- Data verification program to ensure data bundles cannot be tampered with (even outside of the secured environment)
- Full audit logs available for tracking data history
- Print verified reports that uniquely identify data sequences
- Generate PDF's that can be digitally signed by the operator(s)

Remember that no software package can enforce Part 11 Compliance, only Part 11 compatible. It is up to the end user to set up an entire Part 11 compliant system.

Quick Start Guide For Aqualink4 Part 11 Compatible

The First time you start the Aqualink4(Part 11) you will be prompted to setup your private encryption key and to setup your administrator accounts. Administrators have additional privileges such as to restore a previous database if the data becomes corrupted.

To View the audit trail of any data in the system use your mouse to select blocks of data from the table view and select the appropriate audit history option from the context menu.

When exporting data from Aqualink4 Part11, you will export as PDF report by default. You can choose to export as an excel file, however the excel file is not part 11 compatible and should only be used for data analysis.

Windows System Log Events

Several Events within the Aqualink4 Part11 system generate entries to the system(Windows) log for administrators to review later. This section will contain a brief explanation of the various events generated by Aqualink4 Part11. All events will be found in the Windows Event Viewer under Windows Logs/Application. All events will have an event source of "Aqualink4".

Event Type	Event Code	Description
Rollback	48045	An Admin Has Rolled a corrupted database back to a known good database
Rollback	47826	A User has done a minor rollback due to corrupted data
Information	47827	A User or Admin Has Been notified of a corrupted database
Information	2989	First Start. Aqualink4's first time starting on this system
Information	4013	User management performed by admin
Warning	51966	Bad Login Attempt Detected (allows 3 attempts)
Error	57005	User locked out due to too many attempts with a bad password