

Date: 10th December 2025

Milli-Q® High Flow Systems data & user management and IT integration FAQ

Purpose

This document answers the most common questions regarding how the Milli-Q® System handles data and users. It also answers some questions related to the integration of the Milli-Q® System into an IT infrastructure.

This document is formatted as a Frequently Asked Questions (FAQ) for a better understanding.

In this document, the term **Milli-Q® System** refers to any of the following products:

- Milli-Q® CLX
- Milli-Q® HX
- Milli-Q® HR
- Milli-Q® HX SD

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General system design

Does the Milli-Q® System need a computer to run?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Which OS is running on the Milli-Q® System?	Custom embedded Linux	
Does the Milli-Q® System have an antivirus software?	Not applicable (custom built operating system)	
Does the Milli-Q® System allow configuration of backup/restore?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is there a validation procedure (IQ/OQ) available for the Milli-Q® System?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Can the Milli-Q® System be used by the user to access the internet?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the Milli-Q® System a certified Medical Device?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

Data storage

Does the Milli-Q® System process or store Patient Data (PII or PHI)?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Does the Milli-Q® System record personal data?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
What personal data is recorded inside the Milli-Q® System?	<p>There are 2 contact cards that can be entered with the following information:</p> <ul style="list-style-type: none"> • Contact name • Phone number • Mobile number • E-mail address <p>The creation of these contact cards is completely optional and is intended for contacting the person responsible for the system. They can be modified or erased the same way they have been entered if required.</p>	
How does the Milli-Q® System store data?	In a database inside a file system located on an internal flash memory.	
Is data encrypted?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
What kind of data does the Milli-Q® System store?	<ul style="list-style-type: none"> • Configuration • Calibration • History data 	

History / audit trail / logs

Does the Milli-Q® System keep traces of events?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
What are the events which are recorded?	<ul style="list-style-type: none"> • Alarms & alerts • User login/logout • Maintenance sequence started/canceled • Configuration change • New consumable or component installed • System power on • Software upgrade 	
Are the events timestamped?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, does the timestamp follow ISO 8601 format rules?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does the Milli-Q® System automatically adjust its time regarding summer and leap days?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Can the Milli-Q® System's date/time be synchronized with NTP service?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Does the Milli-Q® System have a limitation in time or memory size for the retention of history records?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, what are these limits?	<p>Approximately 1 year of history. The exact limits are as follows:</p> <ul style="list-style-type: none"> • 10614 events • 366 days of quality measures • 366 days of operations 	
What will happen when these limits are reached?	To regain memory, the Milli-Q® System deletes 1/3 of the oldest records in the category that has reached its limit.	
Can the history information be extracted/downloaded?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
What is the format of the history extract?	<p>XML files:</p> <ul style="list-style-type: none"> • 1 file for events • 1 file for daily quality statistics • 1 file for daily operational statistics 	
Are these files secured by digital signature or hash computation?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Can the events support electronic signature by the users?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Can a comment be added by the user to an event when it is recorded?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Can the Milli-Q® System back up history files automatically to a network drive?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
If the preceding answer is no, is it still possible to automate this process from another system?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does the Milli-Q® System allow printing of history data directly from the system?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
If no, is it possible to print indirectly by downloading history data then printing it from a computer?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

Can history data be imported into a tabular spreadsheet? (Microsoft Excel/Libreoffice Calc/Google spreadsheet)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
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User identification

Does the Milli-Q® System allow several accounts or roles with elevated rights?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Are these accounts role-based or user-based?	Role-based, with only 1 predefined account per role	
What are the roles available in the Milli-Q® System?	<ul style="list-style-type: none"> • Normal user • Lab manager • FSE (Field Service Engineer) 	
Are the users identified with their real name?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
What access types are reserved for the lab manager role?	<ul style="list-style-type: none"> • System configuration 	
What accesses are reserved for the FSE role?	<ul style="list-style-type: none"> • Advanced system configuration • Calibration • Complex maintenance 	
How is the lab manager account secured?	By entering a single password (no login identifier required)	
How is the FSE account secured?	By entering a special token (limited in time) reserved to the FSE	
Does the lab manager password expire?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Does the FSE password expire?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Are typed passwords masked while typing them in?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is there a way to disable/lock accounts?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Does the Milli-Q® System keep a trace of login failures?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is the user session timed out if no activity is detected?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

System software update

Can the Milli-Q® System software be updated?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
How often is the Milli-Q® System software updated?	Typically, for systems covered by service contracts, the system software is verified once a year. If a new software version is available, the system software is upgraded. For a connected system, the system software may be upgraded remotely (this feature can be canceled).	
Who is in charge of updating the Milli-Q® System software?	Milli-Q® Service trained FSE	

Connectivity

Can the Milli-Q® System be connected to a network?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does the Milli-Q® System support Ethernet connectivity?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does the Milli-Q® System support Wi-Fi?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Does the Milli-Q® System support 3G/4G cellular connectivity?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Can the Milli-Q® System be connected to the cloud?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
What is the URL of the cloud where the Milli-Q® System connects to?	https://api.milliqconnect.com OR https://mymilliq.com	
Is cloud connectivity mandatory for the Milli-Q® System to run?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Does the Milli-Q® System allow USB devices to be connected?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
How is the USB port intended to be used?	By plugging in a USB stick, you can: <ul style="list-style-type: none"> • Download history data • Download configuration data • Restore configuration • Download the user manual • Install new software updates 	
Can the USB port be used to insert malicious files into the system?	File reading access is protected by checking the digital signature of the imported files for the following scenarios: <ul style="list-style-type: none"> • Restore configuration • Install software update 	
Does the Milli-Q® System embed servers?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Which types of servers does the Milli-Q® System embed?	Web server (accessible from local network if connected)	

What protocols may be used by the Milli-Q® System?	<ul style="list-style-type: none"> • HTTPS (TLS 1.2) for embedded web server • HTTPS (TLS 1.2) for connection to the cloud if the Remote Care service is enabled • DHCP for IP address assignment if setup as DHCP client • DNS for resolving the cloud URL if the Remote Care service is enabled
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System security and vulnerabilities

Does the Milli-Q® System have a firewall?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Has the Milli-Q® System been tested against penetration?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Do the penetration tests performed comply with OWASP top 10?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Have vulnerabilities been detected?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Can these vulnerabilities be exploited?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

Measures & precision

Does the Milli-Q® System make any measurements?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, is the Milli-Q® System calibrated?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, what is the period of calibration/verification?	Once a year during maintenance	