

iQue® Audit Trail, Electronic Records, and Electronic Signature Features to Support 21 CFR Part 11 Workflows



Secure Your Most Valuable and Important Data Derived From Precious Samples

Have you ever had to repeat an experiment or study because it was not documented correctly? Record keeping is a critical and time-consuming laboratory task, especially for submissions to the FDA, EMA, or other regulatory agencies.

Our new 21 CFR Part 11 software module for iQue® lets you replace monotonous manual record keeping with an intuitive and secure electronic record keeping system. Whether you are in development, quality control (QC), or manufacturing, record keeping just got easier with iQue® 21 CFR Part 11.

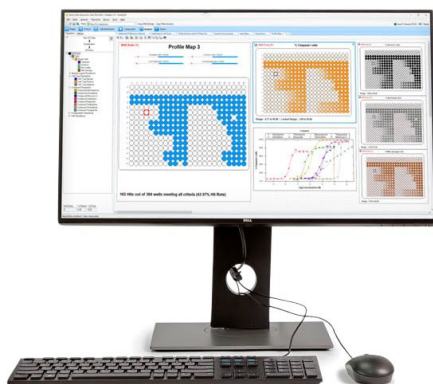


Designed With Regulated Environments in Mind

Specifically designed to meet the increasing requirements for regulated laboratories. Produce high-quality data with accountability. Secure user roles to ensure everyone has the appropriate level of access. Electronic record keeping of all user activities from experiment design through to QC, through data analysis are included. Control the level of electronic signature frequency. Create standardized log comments for organizational consistency and ease of use. Customized audit reports can display all records or be filtered by time frames, users, or experiments.

21 CFR Part 11 Enabling Module Includes:

- Electronic signatures and comments
- Global system event tracking
- Traceable electronic record keeping
- Filterable and searchable audit logs
- Export customized audit reports
- Control access to the iQue® platform
- Windows Authentication security
- Documentation for initial setup and daily usage
- Enable entire organizations with Enterprise
- Works with automation systems



Specifications

Audit Trail		Electronic Records		Electronic Signatures	
11.10 (a)	<p>The system performs accurately, consistently, and has the ability to discern invalid or altered records.</p> <p>iQue Forecyt® was developed and validated under a development process. iQue Forecyt® possess the ability to discern invalid or altered records. Any files that have been directly tampered with will result in an error occurring in iQue Forecyt®.</p>	11.10 (f)	<p>Only permitted actions in the correct sequence are authorized during equipment usage.</p> <p>iQue Forecyt® provides sequential layout and wizards to guide the user on usage.</p>	11.50	<p>The operator, date, time, and action are to be included as part of a human-readable electronic record.</p> <p>The username, date/time stamp, and action performed are all stored in data files, the database, and the global audit log, and can be exported to a pdf report.</p>
11.10 (b)	<p>Record generation and exporting is provided in a human-readable format.</p> <p>Data can be exported for electronic record keeping and can be opened in programs such as Excel for direct data interaction.</p>	11.10 (g)	<p>Only authorized individuals can control actions executed by the equipment through the software.</p> <p>Multiple permission levels are provided to ensure each authorized user is only able to perform the required control over the system that they need.</p>	11.70	<p>Electronic signatures are locked with the recorded action. Records cannot be falsified.</p> <p>iQue Forecyt® utilizes Windows Authentication preventing tampering with User IDs. The username and date/time stamp are stored in data files, the database, and printed on the report. Both the data file and reports are read-only and cannot be modified.</p>
11.10 (c)	<p>Records are protected within the software.</p> <p>The data files are write-protected on the equipment's local server.</p>	11.10 (h)	<p>Only valid actions and data files are inputted into the system.</p> <p>iQue Forecyt® is a secure system providing the only access that enables users to interact with the equipment. iQue Forecyt® applies checks to ensure only untampered data files created by iQue Forecyt® can be loaded into the system.</p>	11.100	<p>Only unique users are allowed access to the system and able to sign for electronic signatures.</p> <p>iQue Forecyt® utilizes Windows Authentication for both ease of use and to ensure the security and singularity of User IDs.</p>
11.10 (d)	<p>Limiting system access to authorized individuals.</p> <p>iQue Forecyt® has security features that allow Admin Users to customize individual user roles for both access and specific system permissions.</p>	11.10 (i)	<p>Customized education for users to properly run the equipment and the software.</p> <p>Sartorius professional support teams provide demonstrations for users on how to utilize all the iQue® 21 CFR Part 11 Software module features.</p>	11.200	<p>Two distinct identification components are used for both continuous and non-continuous sessions.</p> <p>iQue Forecyt® utilizes Windows Authentication enabling only an Admin User to provide unique User IDs and password control for access to the system and recording of actions.</p>
11.10 (e)	<p>Audit trails are secure, human-readable, and contain the relevant information about the instrument and analysis activities.</p> <p>The iQue Forecyt® audit trail is stored in a secure database recording the date, time, operator, and specific action that was performed. The audit trail can be viewed and filtered within the software as well as exported as a pdf.</p>	11.10 (k)(1)	<p>Documentation is available for system operation and maintenance.</p> <p>Sartorius provides documentation for the general usage and maintenance of the equipment along with guidance for setting up the iQue® 21 CFR Part 11 Software module</p>	11.300	<p>System provides secured unique user and password controls.</p> <p>iQue Forecyt® utilizes Windows Authentication to provide and maintain secure control over User IDs and passwords.</p>
		11.10 (k)(2)	<p>Documentation and the source code for the software is under a version control system.</p> <p>Engineering and hardware are under a version control system.</p>		
		11.30	<p>Ensure the authenticity, integrity, and confidentiality of electronic records.</p> <p>iQue Forecyt® is designed to run as a closed system. Both the equipment and the data can only be accessed through the iQue Forecyt® user interface by authorized users.</p>		
				Part Numbers	
				60038	iQue® 21 CFR Part 11 Software Module

Germany:
Sartorius Lab Instruments
Phone +49 551 308 0

USA:
Sartorius Corporation
Phone +1 631 254 4249
Toll-free +1 800 635 2906