QIAsprint Connect® and 21 CFR Part 11 regulations

The QIAsprint Connect System – QIAsprint Connect instrument, the QIAsphere App, the QIAsphere-Base and the LIMS Connector – is designed to perform automated nucleic acid purification using QIAsprint Connect consumables.

Note: The QIAsprint Connect instrument is designed to perform automated isolation and purification of nucleic acids. The instrument is intended for use by professional operators, such as technicians, trained in molecular biological techniques and the operation of the QIAsprint Connect instrument. The instrument is intended for research use only and not for use in diagnostic procedures.

Electronic records and signatures

An increasing number of laboratories are using electronic records (ER) and electronic signatures (ES) for exchanging and storing data. Electronic documentation offers many benefits, including increased efficiency and productivity when storing data, as well as easier information sharing and data mining. Although QIAsprint Connect is not regulated as a medical device, compliance with US regulation 21 CFR Part 11, "Electronic Records; Electronic Signatures," ensures proper and secure management of electronic records. This Technical Information explains how the QIAsprint Connect System contributes to fulfilling the technical requirements of regulation 21 CFR Part 11.10: Controls for closed systems.

The QIAsprint Connect is a closed system, where access is controlled by users who are responsible for the content of the electronic records on that system. The software forms part of the ER system by which electronic records are created, modified, stored and secured against further modification.

The following QIAsprint Connect records may be required by the laboratory to demonstrate compliance with their internal processes. These records are maintained electronically within QIAsprint Connect, rather than on paper, and therefore fall within the scope of this Technical Information:

- Report File (.pdf): A human-readable, print-optimized file in PDF format that the user can generate after completion of a run. It contains comprehensive data from the automated experiment (e.g., protocol used, plates, operator).
- XML Report File (.xml): A file optimized for electronic data transfer and computational processing, which the user can generate after completion of an experiment. The file includes comprehensive data from the automated experiment.
- Audit trail (.csv): A log of all user interactions that modify the system, including actions that create, modify or delete the electronic records mentioned previously. The audit trail is stored in CSV format on the QIAsprint Connect file system and can be downloaded as part of the support package via the support package download functionality.

QIAsprint Connect does not implement electronic signatures.

Controls for closed systems – 21 CFR Part 11.10

The sections of 21 CFR Part 11.10, along with their respective subjects, associated requirements, system implementation and compliance status, are summarized in the following Table 1.

Table 1. Sections of 21 CFR Part 11.10 and their implementation in the QIAsprint Connect System

Section	Subject	Requirement	System implementation	Status
11.10 (a)	System validation	Validation of systems to ensure accuracy, reliability, consistent intended performance and the ability to discern invalid or altered records.	The QIAsprint Connect operating software is validated by QIAGEN to ensure accurate, reliable and consistent performance in accordance with its intended use. The records are automatically generated and cannot be altered. They can only be exported.	**Compliant**
11.10 (b)	Record generation	The ability to generate accurate and complete copies of records in both human-readable and electronic form, suitable for inspection, review and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.	Accurate and complete copies of the electronic records described previously can be generated in both human-readable and electronic formats.	**Compliant**
11.10 (c)	Record protection	Protection of records to enable their accurate and ready retrieval throughout the records retention period.	The QIAsprint Connect System does not, by default, delete any of the electronic records described previously, which remain protected. Only users with Administrator access to the system can delete the following electronic records: • Report File (.pdf) • XML Report File (.xml) The QIAsprint Connect System generates a warning when available disk space is low. Upon such notification, the system administrator canl promptly perform a backup of all relevant records to a secure, access-controlled storage location to ensure their integrity, protection and availability for the full required retention period. Backup procedures are defined in the QIAsprint Connect User Manual. The audit trail records any deletion of Report Files. Audit trail files are retained and are only deleted if a complete factory reset of the QIAsprint system is performed.	**Compliant**
11.10 (d)	Access limitation	Limiting system access to authorized individuals.	Access is restricted to authorized individuals through the use of unique usernames and passwords.	**Compliant**
11.10 (e)	Audit trails	Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	The QIAsprint Connect System records all operator actions that create, modify or delete electronic records in a time-stamped audit trail in .csv format. Changes do not obscure previously recorded information. Audit trail files are retained and are only deleted if a complete factory reset of the QIAsprint Connect System is performed. None of the user roles, including the administrator role, can perform a factory reset.	**Compliant**
11.10 (f)	Operational system checks	Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	The QIAsprint Connect System implements operational checks to ensure the correct sequencing of steps and events. These checks are based on user roles and include stratified access levels – basic operator, advanced operator and administrator – each authorized to perform only predefined functions. Refer to the User Manual for details on the corresponding user roles.	**Compliant**

Section	Subject	Requirement	System implementation	Status
11.10 (g)	Authority checks	Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record or perform the operation at hand.	User management of the QIAsprint Connect System enables the creation of user accounts based on roles. Only users with "Administrator" access can change time and date settings, network settings, update the operating software, manage user accounts and delete run data. QIAGEN Service users have the rights of an Administrator and can additionally perform special maintenance runs, performance tests and setup tasks.	**Compliant**
11.10 (h)	Device checks	Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	When protocol files are uploaded to the system, QIAsprint Connect performs a comprehensive validation of the file format. The instrument verifies the integrity and completeness of the input protocols before execution. The software only allows protocols to be initiated if they contain complete and valid information and can be fully executed by the system. This is ensured through a series of checks on the internal protocol structure. The QIAsprint Connect also performs validation checks on any additional data entered by users.	**Compliant**
11.10 (i)	Education and Training	Determination that persons who develop, maintain or use electronic record/electronic signature systems have the education, training and experience to perform their assigned tasks.	QIAGEN ensures that the QIAsprint Connect System is designed and supplied with appropriate documentation, including a user manual and training materials, to support safe and compliant operation. The determination that individuals who develop, maintain or use the system have the appropriate education, training and experience to perform their assigned tasks is the responsibility of the customer (system owner/user organization).	**Allows compliance**
11.10 (j)	Written policies for electronic signatures	The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, to deter record and signature falsification.	Access is restricted to authorized individuals through the use of unique usernames and passwords.	**Not applicable**
11.10 (k)	System documentation	Use of appropriate controls over systems documentation, including: 1. Adequate controls over the distribution, access to and use of documentation for system operation and maintenance. 2. Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.	The QIAsprint Connect System is delivered with a user manual specific to each software version. The manuals are provided in .pdf format and cannot be modified by the user. From a 21 CFR Part 11 perspective, the system does not require specific maintenance activities beyond the implementation of routine software updates. The audit trail is securely stored by QIAsprint Connect.	**Compliant**

Figure 1. The QIAsprint Connect.

To learn more about QIAsprint Connect, visit: **www.qiagen.com/QIAsprint-Connect**

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