

Luminex[®]

Safe, Solid, and Secure:

Achieve 21 CFR Part 11 Compliance
with xMAP INTELLIFLEX[®] Software 2.0



Protect your data and meet security and traceability regulatory requirements with xMAP INTELLIFLEX® easy-to-use software features

xMAP INTELLIFLEX® Software provides a modern, robust platform that enables streamlined and flexible workflows for users to quickly and easily construct multiplex assays. Available in this software are the compliance features that enable companies to meet electronic records, security, and traceability regulatory requirements.

Benefits of xMAP INTELLIFLEX Software include an integration friendly architecture that allows for sites to easily integrate into existing domain infrastructure, additional support documentation detailing how the software aids in meeting Code of Federal Regulations (CFR) requirements, and optional Installation Qualification (IQ) and Operational Qualification (OQ) services performed by our Field Service Engineers to ensure that your instrument is operating according to specifications.

What is 21 CFR Part 11 and why does it matter?

21 CFR Part 11 is part of Title 21 of the CFR that establishes the United States Food and Drug Administration regulations on electronic records and electronic signatures. Every site must be familiar with the FDA regulations that apply to their industry, also known as predicate rules. By offering tools to easily meet security and traceability regulatory requirements, the xMAP INTELLIFLEX CFR software provides easy-to-use features to help facilitate 21 CFR Part 11 compliance for regulated companies as it applies to their predicate rules.

xMAP INTELLIFLEX Software helps to achieve 21 CFR Part 11 compliance through various security and traceability methods that include:

Audit Trails

Electronic Signatures

Digital Signatures

Data Integrity

Secure Login

Back Up and Archive

The xMAP INTELLIFLEX Software version 2.0 introduces an optional Electronic Records Compliance module, which provides 21 CFR Part 11 functionality to enable users to meet their electronic records, security, and traceability regulatory requirements. Also, by offering easy domain integration, user permissions can be centrally managed through a company's IT group. The following added features will enable users to achieve 21 CFR Part 11 compliance while ensuring the safeguarding of their data:

Audit Trails/Plate-Specific Reports

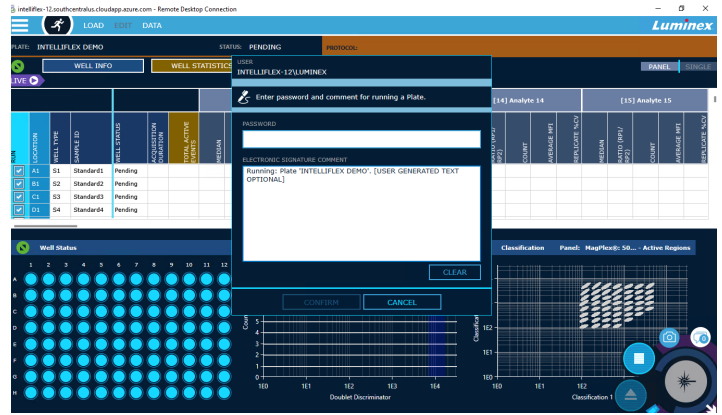
Through the tracking of system events and generating date and time-stamped records in the system log, xMAP INTELLIFLEX Software is the only xMAP software that allows users to generate plate-specific reports that include related system events. This allows for easier traceability through the audit logs contained within the xMAP INTELLIFLEX XLS reports. These system logs are easy to read, are specific to the selected plate, and offer additional plate information such as calibration and verification information.

Plate Name	Run Status	Run Date	Start Time	End Time	Active User	Authorized User	Source IP Address	Event Name	Details	Timestamp
DA1E_10112022_RUN000	Partial	2022-10-11	10:27:08 AM	10:28:08 AM	INTELLIFLEX-PC\Admin	INTELLIFLEX-PC\Admin	-1	Plate Initiation	Plate run 'DA1E_10112022_RUN000' initiated with Cal/Ver not valid.	2022-10-11 10:27:07 AM
								Acquisition	Well A1 Acquiring	2022-10-11 10:27:07 AM
								Acquisition	Well A1 Acquiring	2022-10-11 10:28:08 AM
								Acquisition	Well B1 Acquiring	2022-10-11 10:28:16 AM
								Acquisition Completion	Well A1 Acquiring - Low Count	2022-10-11 10:29:16 AM
								Acquisition	Well B1 Reading	2022-10-11 10:29:16 AM
								Acquisition	Well C1 Acquiring	2022-10-11 10:29:16 AM
								Acquisition Completion	Well B1 Completed	2022-10-11 10:29:27 AM
								Acquisition	Well C1 Reading	2022-10-11 10:29:27 AM
								Acquisition	Well C1 Reading	2022-10-11 10:29:38 AM
								Acquisition Completion	Well C1 Completed	2022-10-11 10:29:38 AM
								Plate Completion	Plate run 'DA1E_10112022_RUN000' has completed with status 'Partial'.	2022-10-11 10:29:39 AM
DA1E_10112022_RUN001	Completed	2022-10-11	10:30:19 AM	10:30:20 AM	INTELLIFLEX-PC\Admin	INTELLIFLEX-PC\Admin	-1	Plate Initiation	Plate run 'DA1E_10112022_RUN001' initiated with Cal/Ver not valid.	2022-10-11 10:30:19 AM
								Plate Initiation	Plate run 'DA1E_10112022_RUN001' initiated for setup well(s).	2022-10-11 10:30:19 AM
								Acquisition	Well A1 Acquiring	2022-10-11 10:30:19 AM
								Acquisition	Well A1 Acquiring and data will be overwritten	2022-10-11 10:30:20 AM
								Acquisition	Well A1 Reading	2022-10-11 10:30:20 AM
								Acquisition	Well B1 Acquiring and data will be overwritten	2022-10-11 10:30:20 AM
								Acquisition	Well B1 Reading	2022-10-11 10:30:20 AM
								Acquisition Completion	Well A1 Completed	2022-10-11 10:30:47 AM

Electronic Signatures

xMAP INTELLIFLEX Software enhances traceability by allowing administrators to require electronic user signatures when executing specific actions. These actions are customizable for different regulatory environments and require users to re-enter their credentials for each signature. Signatures are stored on the device with the event they accompany and can be reviewed via the Instrument Systems Log.

The electronic signatures prompt includes a standard message for each signing event and allows users to enter free text comments. Only the user signed into the system can sign for events to remove questions regarding the execution of events in a session.



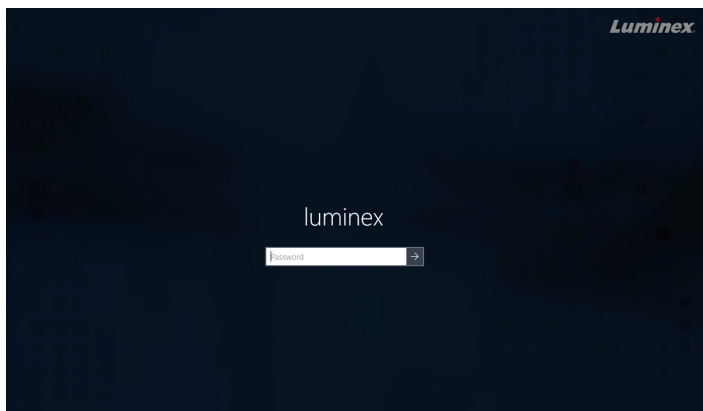
The screenshot shows a detailed report from the software. The 'RESULTS' tab is selected, displaying a table with the following columns: VERSION, SAMPLE ID, WELL LOCATION, WELL TYPE, WELL STATUS, ASSAY, ASSAY COUNT, ASSAY RATE (MP1/MP2), ASSAY BACKGROUND, and ASSAY NET AVERAGE HEIGHT. The table contains multiple rows of data for different wells and assays.

Digital Signatures

xMAP INTELLIFLEX reports include cryptographic features that authenticate the origin of the exported files and confirm that the files have not been altered after export. This helps ensure that data isn't susceptible to corruption or manipulation.

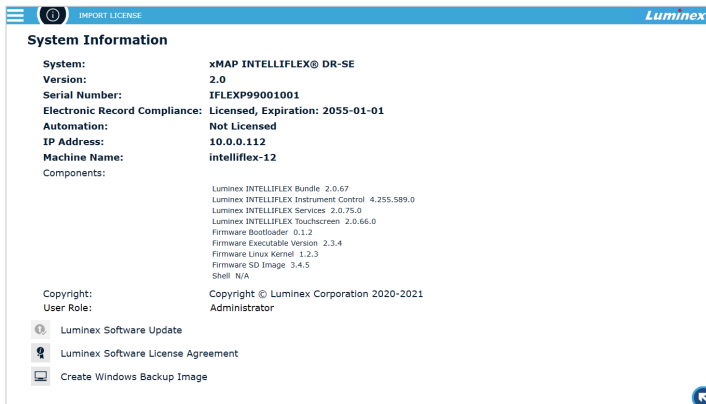
Data Integrity

xMAP INTELLIFLEX Software enables Electronic Record Management by securely storing plate history, results, and maintenance data on a secured SQL Server Database, and allows users to encrypt the hard drive. This detailed method of data storage will provide confidence in data integrity while complying with CFR regulations.



Secure Login

xMAP INTELLIFLEX Software offers additional security by utilizing Microsoft Windows® Authentication to manage instrument access. User accounts can be created locally on the instrument or by connecting to an existing network domain for management by an IT administrator; wherein users need not remember an additional password.



Back up and Archive

xMAP INTELLIFLEX Software aids in preventing data loss by allowing users to create backup images of the Windows operating system and the xMAP INTELLIFLEX Software, which includes user-generated data. Users can also archive data off the instrument as needed.

What factors are excluded from xMAP INTELLIFLEX Software's 21 CFR Part 11 compliance?

In addition to system technical controls, 21 CFR Part 11 requires that regulated companies have established procedural and administrative controls, which include defined and documented policies, standard operating procedures, personnel training, and other controls that apply to their industry. These regulated factors will vary depending on the industry.

Additional benefits of xMAP INTELLIFLEX System:

Integration Friendly—The dynamic platform of xMAP INTELLIFLEX Software allows sites to easily integrate into existing domain infrastructure, meaning that IT can manage access to software resulting in one less password for users to remember.

Support Documentation—In addition to the xMAP INTELLIFLEX Administrative Guide, which provides key information for IT users to set up the system into the already existing domain, the xMAP INTELLIFLEX Regulatory Matrix outlines the CFR requirements and details how xMAP INTELLIFLEX addresses each requirement, where applicable.

IQOQ Available—Installation Qualification (IQ) and Operational Qualification (OQ) services are performed by our Field Service Engineers and are critical to ensuring that your instrument is properly installed and operating according to specifications.

Catalog Number	Description
IFX-CFR2.0-RUO	xMAP INTELLIFLEX® Electronic Record Compliance Software Module
VP-INTELLIFLEX-IQOQ	xMAP INTELLIFLEX® IQ/OQ with Installation

For Further Information:

Be Secure, Be Compliant, and Protect Your Data...

Provide confidence in your data integrity by upgrading to xMAP INTELLIFLEX CFR Software for your multiplexing needs. xMAP INTELLIFLEX CFR Software provides a durable and dependable platform that enables streamlining and flexibility among multiplex assay workflows, as it helps to facilitate compliance for regulated companies by offering easy-to-use tools that meet security and traceability regulatory requirements. For more information on how you can upgrade to xMAP INTELLIFLEX 2.0, or if you would like to learn more about xMAP INTELLIFLEX systems as the solution for your multiplexing needs, please contact your local sales representative.

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For more information, please visit luminexcorp.com/INTELLIFLEX

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