xMAP INTELLIFLEX® Change Log

Summary of Releases

Base Version	Bundle Version	Release Date	Support Status	Notes
2.1	2.0.1015	**10/30/2023**	Supported	
2.0	2.0.1017	**07/26/2023**	Supported	Resolves issue where instrument can run acquisitions with sheath below recommended pressure. Resolves issue where instrument can export result data out of chronological order.
	2.0.1013	**03/30/2023**	Supported	
1.1	1.1.1036	**04/08/2022**	Supported	Resolves issue with notifications and shutdown when instrument is set to a time zone east of GMT and west of the international date line.
	1.1.1035	**01/11/2022**	Supported	
1.0	1.0.103	**04/26/2021**	Supported	There are no functional differences between bundle version 1.0.103 and 1.0.108. v1.0.108 includes support for an alternate hardware configuration, with no changes to the operating system, firmware, or software.
	1.0.108	**06/11/2021**		

xMAP INTELLIFLEX v2.1   released: October 30, 2023

FEATURES AND ENHANCEMENTS
xMAP INTELLIFLEX v2.1 is a required feature release, which improves the Calibration and Verification Experience.
• **Improved Verification Routine:** Performance Verification routine improved to run more efficiently, reducing the frequency of failures.
• **Streamlined Calibration/Verification Report:** Calibration and verification are combined into a single report with enhanced information.
• **Kit Lot Management:** Users can remove Calibration and Verification kits from the system.
• **Maintenance Timers:** Maintenance routines, including calibration and verification, display estimates of time to completion.
• **User Installable:** Users with instruments running xMAP INTELLIFLEX v2.0 may install the software v2.1 themselves, without the assistance of a Luminex Field Service Engineer.

RESOLVED ISSUES	
ID	Description
25867	For operations that require authorization, the authorizing user may now select themselves via keyboard entry. Previous software versions required selection via the drop-down menu.
32561	Resolves the laser warm-up countdown issue wherein the countdown displayed the time remaining in minutes only. The laser warm-up countdown now displays both the number of minutes and the number of seconds remaining.

![Luminex logo]

RESOLVED ISSUES

ID	Description
33114	Resolves the issue wherein logs accessed via the "Plate Run Details" tab included data that was not part of the selected run.
33459	Resolves the issue wherein if a user reacquired a well after editing a plate and then selected the initial acquisition on the "Plate History" page, the "Well Acquisition Start" and "End" times reflected the times for the reacquisition instead of the times for the initial acquisition. Now, if the user selects the initial acquisition on the "Plate History" page, the initial acquisition's "Well Acquisition Start" and "End" times are displayed.
38262	Resolves the issue wherein if the user tried to rename an Analyte in Plate Configuration > Panel, the cursor jumped to the start of the text box when the user deleted the Analyte number.

REMAINING ISSUES

ID	Description
38452	When the side eject button display is enabled on DR-SE instruments, the side ejection button may overlap with 'No' button used to respond to dialog prompts on the User Interface, which can result in the user ejecting the plate carrier. Only enable the side eject button if it is necessary to load plates onto the plate carrier using the side access. In this case, it will be necessary to press and hold the 'No' response button on dialog prompts instead of tapping it to avoid ejecting of the plate carrier. Note: The side eject button does not need to be enabled to use the side eject function via the API.
33445	When the Electronic Records Compliance (ERC) module is enabled, the xMAP INTELLIFLEX system digitally signs exported .XLSX files. The online version of Excel may be unable open these files, depending on how Information Rights Management (IRM) is configured within the user's network. The user should use a desktop version of Excel to open INTELLIFLEX files or consult their IT department for guidance as needed.
37790	When exporting results for a plate run on a software version prior to v2.1 in the Excel format, the "Verification Details" tab shows the older verification data with the newer format. Consequently, not all of the data from a legacy verification run is displayed in the "Verification Details" tab. However, the overall status of the legacy run is correct, and all of the data for the verification run can be viewed by exporting the calibration/verification run from the "History" page.
38899	If a user did not start an in progress maintenance routine, that in progress maintenance routine and countdown may not be available on that user's maintenance page. However, the countdown will be available on the lock screen or maintenance page of the user account that started the routine.
38751	If a user selects a saved Panel, Layout, or Acquisition setting, edits the information on the "Configuration" page, and then reselects the saved Panel, Layout or Acquisition setting, the original saved data is not repopulated. To repopulate the original saved data, select a different saved Panel, Layout, or Acquisition setting, then reselect the desired saved Panel, Layout or Acquisition setting.
37847	If a user makes a selection on Yes/No dialog using the keyboard, the user can inadvertently select the Archive option multiple times. The user should use the touchscreen or mouse to make a selection on the Yes/No dialog instead of the keyboard .

REMAINING ISSUES

ID	Description
39263	Selecting EDIT on the Current Run page displays the Plate Editor. From the Plate Editor, users may choose additional bead regions to include in a panel; however, if the user adds a sufficient number of bead regions such that the total number of regions in the panel exceeds 100, the 2D bead plot may display all regions for that panel concurrently without providing the option to view a single region (SINGLE) or slab of regions (SLAB). This many bead regions do not display well on a 2D plot. To access the SINGLE and SLAB options, reopen the Plate Editor, select the Panel tab (if it's not already selected), and then close the Plate Editor.
40819	Quickly logging into an INTELLIFLEX system and navigating to the CAL/VER page before the Self-Test completes can result in the Kit Management menu item being disabled. The menu item will remain disabled for that user during the session. Other users will be able to log in and access the menu. If a user's Kit Management menu item is disabled, it can be re-enabled by restarting the instrument and waiting for self-test to complete before navigating to the CAL/VER page.

xMAP INTELLIFLEX v2.0 (Bundle Version 2.0.1013 and 2.0.1017)   **released: March 30, 2023**

FEATURES AND ENHANCEMENTS

xMAP INTELLIFLEX v2.0 is a required feature release, which introduces major new software features and fixes many high-priority bugs.

- Return to previously acquired datasets and digitally reacquire them under modified parameters. Multiple parameters may be modified for reacquisition, including changing doublet discriminator gating, adding or removing microsphere regions from the dataset, modifying the well-type associated with a given plate location, and editing metadata associated with the plate or well(s).

  This feature is comparable to the 'Replay' function found within Luminex's previous xPONENT application.

- Utilize the side-eject function, which is now enabled on 'DRSE' model instruments.

- **Electronic Records Compliance** (optional): Generate and review detailed electronic records by installing multiple features that support 21 CFR Part 11 and/or Annex 11 compliant workflows, such as enhanced audit trails, digital signatures on output data, and electronic signatures.

  Electronic Records Compliance is an optional software module available for separate purchase.

- **Automation API access** (optional): Access features remotely through an Application Programming Interface (API) available to authorized users. In addition to remotely updating plate information for partial, completed, and pending plates, use of the API feature provides a secure means of editing well information and creating plates from a protocol available on the instrument.

  Automation is an optional software module available for separate purchase.

- Backup and Restore: Preserve valuable system data and customized settings by saving a backup to a network or USB, which can be used by authorized user accounts to restore lost or altered system data and settings.

- Streamlined cleaning: In a single action on the Maintenance page, easily execute the 'Stringent Cleaning' routine to remove severe clogs, as described in the *Advanced Troubleshooting Manual*.

- View new statistics available in the xPONENT-format CSV, including 'Net MFI', 'Avg Net MFI', 'Normalized Net Median', 'Avg Normalized Net Median'.

  For compatibility purposes, some statistics that were not present in outputs from the legacy xPONENT application have been removed from the 'xPONENT format' INTELLIFLEX CSV, such as Trimmed Peak Count, Peak Count, %CV of Replicates

FEATURES AND ENHANCEMENTS

- Expanded use of free text identifiers: Assign free text identifiers to 'Standard' and 'Control' well types in addition to 'Unknown' well types. This feature was previously limited to 'Unknown' well types only.

- Multiple updates to the Panel creation workflow, including:
    - A new graphical interface for selecting microsphere regions.
    - Improvements to the process of designating 'Analyte 2' values for dual-reporter acquisitions.

- Expanded auto-export functionality: Configure the software to export data from both partial and completed plates upon completion of an acquisition. When the system detects insufficient liquid in target wells, the completed plate will be categorized as 'Partially Complete', but the associated data may still be auto-exported without manual post-acquisition intervention.

RESOLVED ISSUES

ID	Description
18855	Provides an option for authorized users to mark partially completed plates as 'Complete'.
18556	Improves the function used to import Layout and Panel objects: extraneous commas in importable files are now ignored, reducing the likelihood of a failed import.
23032	Resolves a previous condition wherein the users were unable to consistently retract the plate tray.
26132 28858	Corrects the conditions that prompted the following unexpected warnings: • "An error occurred while permanently deleting results" (observed when deleting results) • "The request was cancelled due to the configured HttpClient.Timeout" (observed during Verification)
26217	Resolves the causes of inaccurate laser warm-up status. Previously, the laser warm-up status indicated the system was stalled despite the laser warm up process completing as expected.
27518	Corrects a condition that caused the software to restart if a specific sequence of characters was entered into the Sample ID field.
28352	Corrects the conditions that contributed to inaccurate fluidics pressure settings and associated data collection issues.
31302	Resolves a previous condition that prevented statistical data from properly appearing on-screen during acquisitions.
32307	Corrects the condition that caused well data to be presented outside of the expected sequence in CSV data.

REMAINING ISSUES

ID	Description
25867	For operations that require authorization, the user is selected from the Authorization User dropdown box rather than through keyboard entry.
32561	The laser warmup timer countdown value is displayed in minutes only. In the final minute of warmup, the display shows "0 minutes" remaining but completes as expected in 59 seconds.
33114	When a dataset includes both a reacquisition and an edit of a single plate, the logs in the "Plate Run Details" tab may display data that was not part of the specific run. These data can be identified by the timestamps of the events and may be disregarded at user's discretion.

REMAINING ISSUES

ID	Description
33445	When the Electronic Records Compliance (ERC) module is enabled, the xMAP INTELLIFLEX system digitally signs exported .XLSX files. The online version of Excel may be unable open these files, depending on how Information Rights Management (IRM) is configured within the user's network. The user should use a desktop version of Excel to open INTELLIFLEX files or consult their IT department for guidance as needed.
33459	If the user reacquires a well after completing an edit action and then reopens the original plate, the "Well Acquisition Start" and "End" times may reflect the times of the reacquisition rather than the times of the original acquisition.
38262	If the user tries to rename an Analyte in Plate Configuration > Panel, the cursor jumps to the start of the text box when the user deletes the Analyte number.
38452	When the side eject button display is enabled on DR-SE instruments, the side ejection button may overlap with 'No' button used to respond to dialog prompts on the User Interface, which can result in the user ejecting the plate carrier. Only enable the side eject button if it is necessary to load plates onto the plate carrier using the side access. In this case, it will be necessary to press and hold the 'No' response button on dialog prompts instead of tapping it to avoid ejecting of the plate carrier. Note: The side eject button does not need to be enabled to use the side eject function via the API.

xMAP INTELLIFLEX v1.1 (Bundle Versions 1.1.1035 and 1.1.1036)   **released: April 8, 2022**

FEATURES AND ENHANCEMENTS

xMAP INTELLIFLEX v1.1 is a required maintenance software release, which fixes many high-priority bugs.
This release also enables many enhanced features, including multi-user support.

- xMAP INTELLIFLEX now supports multiple users with different access levels (Administrator, Lab Lead, or Operator).
- Administrators may define user accounts either locally or on the network domain.
- Administrators may configure xMAP INTELLIFLEX to automatically log off after an admin-defined interval, to a new status overview page.
- Improved manual export of dual-reporter data to xPONENT-format files: export is now a single operation, and resulting filenames include the "_rp$n$" designation. Applies only to DR-SE model instruments.
- Users may customize the Current Run page to select which statistics are visible during run acquisition.
- Users may export data from multiple plates into a single xPONENT-format file. Requires that all plates must be acquired under the same Panel and Acquisition Settings.
- Users may designate an intra-well normalization region; xMAP INTELLIFLEX calculates Net and Normalized statistics.
- Limited regionalization of output data: users may define decimal- and field-delimiters, so that exported data is usable in regionalized off-instrument software, such as Excel.
- Users may halt in-progress Calibration or Verification maintenance routines.
- New output formats, including a comprehensive Excel-format file that incorporates both data and relevant log entries, a user-friendly Excel-format Calibration and Verification report, and an exportable System Log.
- Administrators may enable or disable Windows updates from within the xMAP INTELLIFLEX interface.

RESOLVED ISSUES		
ID	**Description**	**Notes**
6996	Acquisition time shown on CURRENT RUN page differed from acquisition time shown on RESULTS page.	Acquisition time shown on CURRENT RUN page now matches the longer acquisition time shown on the RESULTS page, which includes the time needed for data processing operations.
8933	Fluidics results and reports did not list Fluidics 2 reagent lot number.	
9112	The Export Results dialog box did not refresh after inserting a USB drive.	
9772	If the calibration status is changed before completing a partial plate, the most recent calibration status is displayed in the xPONENT file format.	If the calibration status is changed before completing a partial plate, or if data from multiple plates are exported into a single file, the xPONENT file format will show the lowest calibration state.
9848 18338	Lot number(s) shown on the Calibration/Verification page did not always match the active lot(s) selected in the drop-down lot selection box(es).	
10347	The calibration/verification state could be improperly displayed when turning on the instrument or when switching between Admin and User accounts.	
10733 18624 18626 19037 19150 19732	Fixed various issues that could cause the software to become sluggish or crash/freeze, including working with large datasets on the RESULTS page, inaccurate warnings/errors when turning the instrument on or off or running Verification, and crashes when clicking the yellow 'Running Person' indicator during startup.	
11176	The SEQUENCE and LOCATION selection columns to the left of the full screen bead map could be expanded, making navigation and use difficult.	
11406	The xMAP INTELLIFLEX output file did not provide the Fluidics 2 reagent lot number, only the Fluidics 1 reagent lot number.	
11411	Shutting down the instrument could take an excessive amount of time in various circumstances.	
12993	The xPONENT file format from xMAP INTELLIFLEX does not follow the same sequential option for the Export Location Style. The sequence relates to the order the well was run, not the location on the plate.	The location field of the xPONENT file format now adheres to the xPONENT CSV File Specification (available upon request from Luminex Technical Support).
13012	The DD GATE LOW and DD GATE HIGH shown on-screen in the RESULTS page displayed as "0" rather than displaying the actual values used for the acquisition.	

RESOLVED ISSUES

ID	Description	Notes
13102	The system would not warn the user when attempting to run a dual-reporter panel in a mode which would collect only single-reporter data.	
13332	System would display an error if the RESULTS page was configured to show <u>all</u> available data points.	
13334	The system could report false pressure warnings in-between well acquisitions.	
13398 18531 18628	Various problems with the Classification Map and Histogram on the CURRENT RUN page, including not displaying properly when switching users, data not populating during a run (requiring a reboot), and microsphere events shown in the wrong location on the Classification Map.	
13412	If a Plate Layout file was defined as a 384-well plate but contained 96 or fewer wells, the file would improperly import as a 384-well plate, excluding any well locations outside of the top-left quadrant of the 384-well plate.	

REMAINING ISSUES

ID	Description
22250	The CRC file appended to the xPONENT-format file is not calculated correctly. Users are unable to use the CRC value to verify the integrity of the CSV.
22269	In some circumstances Operator-level users may be unable to re-select wells for reacquisition when resuming a partial plate. To resolve, reload the plate onto the Current Run page.
22787	Users will be unable to export the new XLS format introduced in v1.1 when running plates which were created in the v1.0 software.

xMAP INTELLIFLEX v1.0 (Bundle Versions 1.0.103 and 1.0.108)   **released: April 26, 2021**

FEATURES AND ENHANCEMENTS

xMAP INTELLIFLEX v1.0 is the initial public release of the xMAP INTELLIFLEX® System software.

- Rich options to easily and quickly configure plates for acquisition: workflows are intuitive, fast, and flexible, enabling customized, import-friendly workflows emphasizing the rapid acquisition of high-quality data.
- New methods to monitor acquisitions and assure run integrity: in addition to the classic xMAP dot plot and histogram views, new heat maps support at-a-glance assessment of run performance.
- Flexible results management: freely customize the software to display only the datapoints of interest, and export data in either xPONENT format (which is compatible with many existing xMAP analysis software packages), or the new xMAP INTELLIFLEX format (which is customizable and designed for ease of interpretation).
- Streamlined maintenance: quickly import calibration and verification target values from a simple barcode scan.

REMAINING ISSUES

xMAP INTELLIFLEX v1.0 release notes are available upon request from support@luminexcorp.com.