

Why should I upgrade to WinKQCL™ 6 Software



Times change and software progresses to address new market demands: a tool from 10 years ago is not as relevant today. In March 2009, WinKQCL™ Software Version 4 was launched, providing multi-reader capabilities, localization, robust trending, and more, all with a new look and feel. Given all of those changes, what else could the system provide that was not there already? To expand the value proposition to the end user, Lonza identified and corrected some system weaknesses and expanded the functionality of the system in several important ways

Ease of use

One of the prized capabilities of the WinKQCL™ Software System is its ease of use and adaptability. The robust template creation, selection of pre-created products and accessories, predefined assay criteria, specialized tests and a calculator catered towards the application, have kept it as best-in-class endotoxin detection software. The upgraded WinKQCL™ Software expands these core competencies to help the analyst and other associated personnel address their data analysis challenges, as described in the table below.

General feature	WinKQCL™ Software Version 4	WinKQCL™ Software Version 6
Data review from non-laboratory systems	Able to install the software on any system and connect to a centralized database.	In addition to Version 4's capabilities it may now be deployed on a Citrix® server, or other remote hosting means to mitigate the installation footprint and provide easier management for the system ¹ .
Software is translated	French, English, German, Italian, Japanese, and Spanish (Reports and documentation only in English).	French, English, German, Italian, Japanese, Spanish, Portuguese, Simplified Chinese and Traditional Chinese ² .
Rounding of data	Data were rounded if displayed on the report even if used in subsequent calculations.	Data are now rounded for display purposes only. Full precision will persist through the entire process ³ .

[1] Citrix installations are for data review purposes only. When operating devices, the computer should have a direct connection to the device.
 [2] Available in Version 6.0.2 and newer.
 [3] Historical data will not be impacted unless an action occurs to force a recalculation.

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Security and data integrity

Over the years, new guidelines surrounding data integrity have come into existence and WinKQCL™ Software was maintained to comply with these changes. As described in the table below, the WinKQCL™ Software System conforms with 21 CFR Part 11, EU Annex 11, USP <85>, EP 2.6.8, and the new EP 2.6.30 for rFC. Please note that Lonza is willing to assist in comparing the WinKQCL™ Software functionality against any other regulations.

Data integrity feature	WinKQCL™ Software Version 4	WinKQCL™ Software Version 6
SQL server backend ¹	WinKQCL™ Software instances only.	Any instance.
LIMS export	XML	XML, CSV, Direct to MODA™ Platform.
Configurable export	None	CSV
Audit information	Date and time, type, action, user, fileset, description, comment.	Tracks version, computer and workgroup ² , and expands the detail and coverage for audit entries.
Samples from other systems	Manually enter.	Copies the information directly into a product worklist.
Listed time on reports	Always displays time relative to the server.	Adjusts and reports offsets based on time zone. Tracks when the report was opened and last modified.
Audit logins	Only failures for users with the Supervisor role.	All successful and failed authentications, and logouts for all users in the system.
Unique record identification	Tests display execution time, by whom, and the name, but no at-a-glance means of assessing a retest.	Unique record number for each sample and test for an at-a-glance assessment for retests.
System configurations	Single configuration for the entire installation.	Ability to specify settings down to the workgroup or lab setting.

[1] The system never stores data in external files that can be lost or manipulated. By allowing for the client to connect to a broader configuration range for the server, enterprise installations are permitted.

[2] By tracking the additional information, it will be easier to track the root cause should an issue arise. Furthermore, the version information will now appear on all reports.

Enterprise feature	WinKQCL™ Software Version 4	WinKQCL™ Software Version 6
Permissions	Fixed rolls.	Fine grain permission control.
User authentication	Native users.	Native users and/or Active Directory authentication (Windows® Users).
Creating users	Manual process.	Manual or import process to create User Groups from Active Directory.
Data segmentation	All data in a database are accessible by all users.	Able to segregate data by functions or labs utilizing logical workgroups.
WAN performance	Slow and unreliable connections would disrupt testing, and slow operations.	Minimal performance impact running with a database hosted in a remote location. Client traffic with the server was reduced by up to 96%.

Tests and Data Review

The most critical part of the workflow is the ability to run routine endotoxin assays and get data in a quick and easily readable format. Our WinKQCL™ Software evolved over time to enhance this functionality at every level.

Tests feature	WinKQCL™ Software Version 4	WinKQCL™ Software Version 6
Entering reagent information	Manually enter the data.	Manually enter the information or utilize a 2D barcode scanner to grab the codes directly from the vials.
Supplemental assays	Quick reads, OD Validation, system tests, universal plate tests, sensitivity tests.	Quick reads, OD Validation, system tests, absorbance plate tests ¹ , fluorescence plate tests ² , sensitivity tests.
Stopping a test early	Option to stop the assay after the lowest standard reacted.	Introduced Kinetic SmartStop™ ³ .

[1] Universal Plate Test was replaced with Absorbance Plate Test which is the same plate (P/N 7260522) with updated acceptance criteria.

[2] Introduction of a Fluorescence Plate Test to streamline preventative maintenance and OQ activities for fluorescence readers. This replaces the sodium fluorescein assays providing a solid-state plate which grants higher reproducibility and expedites the procedure. Note this feature is not available in the initial WinKQCL™ Software version 6 launch.

[3] Kinetic SmartStop™ provides optional end conditions for the assays.

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Review feature	WinKQCL™ Software Version 4	WinKQCL™ Software Version 6
Primary test report formats	Selection from three preset options.	Rich report configurations to hide or show various settings and lock users out from modifying the configuration. At-a-glance failures on the report.
Regression Models	Selection of linear and PowerCurve™ models.	New option to have the PowerCurve™ regression model fall back to lower polynomial models if a non-monotonic solution is identified.
Utilizing the analyze feature	Able to mask and unmask wells.	Now able to zoom in on a selection of wells during the run or afterwards to assess the nature of the relative reaction curves.
Correcting assays after the test is run	Modify non-critical information which does not impact results, or calculations	User may fix layout, modify sample information, alter accessories. All changes are fully traceable and audit-able ¹ .
User responsible for analyzing data	User who ran the test.	Based on permissions may transfer this responsibility to other users ² .
At-a-glance assessment of failed assays	Need to open a test report and look through the assay to determine if there is an issue.	On the test list, the assay will appear red and when the mouse hovers over the record, it will explain why the test failed.
Trending	Able to trend on test, and sample information, generate graphs and printable reports.	Now able to also trend on standards information, provided with enhanced ease of use for selecting qualifiers, and deeper reporting configurations.

[1] By modifying tests after the run the user may be able to recover from pipetting the wells in the wrong order or inverting PPCs and samples without needing to rerun an entire plate.

[2] While operating in a multi-shift operation, or when letting a test run while the analyst leaves for the day, this permits a different user to assess the work and move the process along – ideal for in process testing and multi-shift operations.

Environment Compatibility

To keep up with new operating systems and database updates, WinKQCL™ Software must expand the matrix of systems with which it works. Windows® XP and Windows® 7 are no longer supported by Microsoft. It is critical in a validated environment to utilize robust systems that can be supported at every level. The expanded systems with which WinKQCL™ Software Version 6 is compatible are shown below.

Software	WinKQCL™ Software Version 4	WinKQCL™ Software Version 6
Operating System	Windows® XP, Windows Server® 2003, Windows Vista™.	Manually enter the information or utilize a 2D barcode scanner to grab the codes directly from the vials.
Microsoft SQL® Server	2005, 2008	2012, 2014, 2016, 2017, 2019
Tecan Freedom EVOware® for the PyroTec™ Liquid Handling System and PyroTec™ PRO Systems ¹	2.2	2.2-2.8 SP1

[1] The PyroTec™ System is a liquid handling automation tool for routine endotoxin testing of fixed samples and plate configurations. The PyroTec™ Pro System is the third generation of liquid handling automation in Lonza's endotoxin testing portfolio. It reinvents the paradigm by creating a seamless walk-away solution with automatic sample preparation saving analysts time, removing physical strain from repeated tasks, and mitigating human error. Both systems rely on the Freedom® EVOware® module by Tecan that WinKQCL™ Software controls automatically to operate the instruments.

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Device Compatibility

Over time, WinKQCL™ Software has expanded its capability to interface with new devices. The added capabilities, described below, allow users to choose the hardware that works best for their environment.

Microplate reader	WinKQCL™ Software Version 4	WinKQCL™ Software Version 6
Lonza ELx™808IU Reader [P/N 25-315S]	X	X
FLx800 ¹ Reader	X	X
Tecan® Sunrise Reader	X	X
BioTek™ Synergy 2 Reader		X
BioTek™ Eon Reader		X
Molecular Devices® SpectraMax™ M Series, 340 Series, 180 Series, and Gemini Series Reader		X
Lonza PyroWave™ XM Reader [P/N 25-345S]		X
Virtual Reader ²		X
Lonza PyroTec™ Liquid Handling System	X	X
Lonza PyroTec™ PRO System		X

- [1] The BioTek™ FLx800 has been discontinued, and Lonza has moved this functionality onto the PyroWave™ XM reader. It is recommended to replace this device.
- [2] Targeted for pre-deployment configuration, testing, and validation activities to permit groups to run data to evaluate the system without utilizing reagents.

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 RT-DS033 05/20

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