Endosafe® Release Notes

Endosafe® EndoScan-V™ Version 6.3.0 Revision 2

RNENDO-ESV63-02

EFFECTIVE DATE: December 2025

Revision	Effective Date	Reason for Revision
00	See effective date in footer	-New document
01	See effective date in footer	-Removed Known Limitations that were resolved in ESV 6.2
02	See effective date in footer	-Updated references to 6.2 and updated to 6.3, added resolved known limitation: Azure #124384, removed known limitation: When adding Trillium cartridges (available now) or 10-digit lot number LAL cartridges (due to roll out in 2025) to the accessory database, a message appears that states “This cartridge type is not supported by EndoScan-V”. Trillium cartridges and 10-digit lot number LAL cartridges can still be run by manually entering the lot information in the connected cartridge panel, as this was resolved as part of Azure #127249, listed in the Previous Known Limitations Resolved Section.

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Dear Valued Customer,

Charles River strives to provide the highest level of support to our global customers by delivering industry-leading scientific and technological advances. As part of our ongoing effort to better serve our customers, we are informing you of the latest update to Endosafe® EndoScan-V™, version 6.3.0.

EndoScan-V version 6 (and higher) is a software platform that now incorporates all data and settings into a PostgreSQL database allowing for secure, reliable storage, as well as providing automated backup capability. Two packages are available:

PRODUCT CODE	PRODUCT DESCRIPTION
M1260	EndoScan-V Software
M1261	EndoScan-V Client Manager

Feature Improvements:

- Email notification for early terminations of Nexus 200 automation
- Duplicate dilution mode. Note: Liquid Level Detection is turned off for this feature.
- Update to Postgres Database V16
- Centralized database support for Nexus 200
- Improved audit trail details for Nexus 200 errors
- General improvements for volume verification including addition of 1000μL tips method
- Nexus 200 dashboard can be run without remote DB connection which allows completion of and stop of new runs without intervention
- Offline functionality for Nexus 200 Assays and Audit Trails.

Note: EndoScan-V 6.3.0 or higher is only compatible with Nexgen 11.1 or higher.

Note: For instructions on how to use these new features, please refer to EndoScan-V 6.3.0 User Manual.

Key on Impact to End User:

Level	Impact Overview	Color
Low	UI errors with no impact to data or results, does not impact workflow, no workarounds required.	
Medium	Possibly impacts workflow, workaround provided, does not impact data/results.	
Medium/High	Critical issue that impacts data/result, known workaround.	
High	Critical issue that impacts data/result, no known workaround. Would require immediate software fix.	

Previous Known Limitations Resolved:

Known Limitation	Issue	Resolution (Fixed/Workaround)	Impact to End User
GLOBAL CHANGES			
Known Limitation from Previous Version	When attempting to manually enter cartridge information into the accessory database when using 10 digit-lot number LAL cartridges, the software prohibits the cartridge from being entered. The workaround is to use the CSV import function, which detailed instructions are available in the EndoScan-V Manual. If you require further instructions on how to import cartridge information via CSV, please contact technical support, nexus-support@crl.com. Additionally, upgrading to the most recent version of	Fixed in version 6.3.0 Azure # 127249	

	ESV for your instrument type will only require the workaround for the lot numbers with manufacture date between July 1st 2025 and September 3rd 2025. Lots manufactured after this date will work as expected in the accessory DB for version 6.2.2 and above.		
Known Limitation from Previous Version	If a backup is attempted and there is a failure of the backup to complete, this attempt is not logged in the audit trail.	Fixed in version 6.3.0 Azure # 73771	
Known Limitation from Previous Version	When exporting data for XML/CSV file format, the Endotoxin value on the exported data does not display leading zeros i.e. if the reported endotoxin value is <0.0100 and this is exported to XML/CSV, the value will display as <0.01. It is recommended to adjust settings to include all significant digits needed for XML/CSV reports.	Fixed in version 6.3.0 Azure # 121963	
Known Limitation from Previous Version	If a user logs into EndoScan-V, runs an assay, and a software lockout/timeout occurs, a second user can login and perform assays and shutdown the same instrument and the shutdown will be incorrectly attributed to the first user in the audit logs. It is recommended to shutdown EndoScan-V at the end of each day to prevent this issue from re-occurring.	Fixed in version 6.3.0 Azure # 99769	

Known Limitation from Previous Version	In global settings, when checking the option “for invalid assay, show N/A for sample value”, this may lead to both valid and invalid results displaying as N/A. This can also occur when samples are run with no spike. The workaround is to un-check the option in settings after results have been produced to display valid results properly.	Fixed in version 6.3.0 Azure # 99101	
	When exporting cartridge data for CSV file format, the data contained in the Product ID column and Group Designator column is switched. The exported data in the Product ID and Group Designator columns are correct, but in the incorrect columns.	Fixed in version 6.3.0 Azure # 111743	
Known Limitation from Previous Version	If a user enters a space either at the beginning or end of the dilution/concentration field when running a cartridge assay, the assay will fail to generate results. Additionally, assay results will not be able to be downloaded. It is recommended to verify that no errant spaces are added in the dilution/concentration field to avoid this issue.	Fixed in version 6.3.0 Azure #124384	

Calibration

This software update does not impact the EndoScan-V connected instrument’s current calibration or the instrument’s calibration schedule. Charles River continues to advise that the instrument is recalibrated and serviced annually to ensure optimum operation. This software release is considered a patch to EndoScan-V version 6.0 and above and as such Charles River does not advise that the IQ/OQ/PQs are

performed if upgrading from version 6.0 and above. However, if EndoScan-V version 6.0 and above was not previously installed, IQ/OQ/PQs are necessary.

Software Validation

- Project Name: EndoScan-V 6.3
- Project Version Number: ESV-6.3.0
- Project Number: PIN0109-24

The release of the EndoScan-V version 6.3 software was tested and validated to operate accurately and reliably according to the predetermined system requirements, quality attributes, and intended use. As per standard Charles River Laboratories procedures, when the system has not satisfied all requirements, appropriate administrative and procedural controls were implemented to assure the quality and integrity of data. In the testing of this release, no situations were encountered where the requirements were not satisfied.

Known Limitations

Known Limitation #	Issue/Workaround	Impact to End User
GLOBAL LIMITATIONS		
G1	Windows: If a prior version of ESV is pinned to the task bar in Windows and that version is uninstalled, the ESV icon pinned to the task bar will be replaced by a white box. Workaround: Un-pin and re-pin ESV to the Windows task bar.	
G2	Changes to the Nexus 200 or Cartridge tabs in global settings do not show in the audit trail when searching based on criteria. The events are present in the audit trail, but they will not show up in the search by category.	
G3	If a digital signature meaning is more than 200 characters, it will not be saved, and if more than 75 characters are used, it may cause the footer to not appear on the report.	
G4	There is a possibility that a completed assay cannot be opened in EndoScan-V if it is imported with duplicate accessories in the assay. If duplicate lot numbers in assay accessories cause an issue, Charles River may provide a script to correct the issue in the database.	
G5	If EndoScan-V user utilizes copy-paste when there is a hidden character in sample name prior to generation of assay run report, the	

	report will not be able to be generated. It is recommended that the user not utilize copy-paste for sample name to ensure report generation occurs correctly.	
G6	When special characters "/" and ";" are used for an accessory lot number and the accessory is added to plate, the information is not able to be modified. It is recommended that these special characters not be used for accessory lot numbers.	
G7	When digitally signing, if the password is input incorrect twice, the user will be locked out, even if the third attempt is successful. Admin account will need to unlock user account.	
G8	An issue can occur when entering an item in the accessory database in which the date is incorrectly displayed if an attempt is made to enter a date that does not exist. The solution to this is to adjust short and long date in regional date and time settings to dd-mm-yyyy.	
G9	There is a chance of installation issues occurring when updating from EndoScan-V 6.0 or higher and utilizing non-English regional settings. This will be fixed in future software release.	
G10	Complications can arise with the EndoScan-V service account when changing the backup location from default to a network location. The resolution is to change the EndoScan-V database service to run under a domain account instead of default EndoScan-V service account.	
G11	When upgrading or downgrading from different EndoScan-V versions, the database path key in the registry is not updated correctly. This is not letting the software backup the database in manual mode as expected. This will be fixed in future software release.	
G14	When copying an existing template that was created in ESV 6.1 with a LAL collection type of Kinetic Turbidimetric or Endpoint to rCR assay, the collection type does not update to rCR Kinetic Chromogenic. This will be fixed in future software release.	

G15	When running rCR cartridges on nexgen-PTS or nexgen-MCS instruments and using a custom Endotoxin Limit, the value will not be used and will display “No Limit” on the cartridge panel and will display “N/A” on the cartridge report. This will be fixed in future software release.	
G16	Kinetic noise report fails to open when an assay is signed and cancelled simultaneously when the setting "Require comment when cancel signatures" is unchecked. This will be fixed in future software release.	
G17	The following error may occur when applying digital signature L2 to an assay: “Due to modifications on the signed document, it is not possible to sign the document in the desired digital signature role.” It is recommended to clear the grid (if using microplate interface), open the assay, apply signature, close assay, and then re-open between each subsequent digital signature to correct this.	
G18	If the user enters a comma to separate dilution factors on Inhibition/Enhancement (I/E) cartridge dilutions, the software will attempt to copy the entire entry 4 times. Example: "1:25, 1:50, 1:100, 1:250; 1:25, 1:50, 1:100, 1:250; 1:25, 1:50, 1:100, 1:250; 1:25, 1:50, 1:100, 1:250". When entering these dilution factors, only a semicolon should be used for I/E cartridges.	
G19	When exporting cartridge data for CSV file format, the data contained in the Product ID column and Group Designator column is switched. The exported data in the Product ID and Group Designator columns are correct, but in the incorrect columns.	
PLATE READER INTERFACE LIMITATIONS		
B1	Reports: When viewing kinetic noise reports, if the user switches between kinetic noise and detailed reports and then back to kinetic noise, the kinetic noise report can change value from “Valid” on the first report, to “N/A” on the second report. The work around is to close the report window between generating kinetic noise reports. This error applies to both PRS 3 and Elx808 instruments.	

B2	Assay Properties: Setting AutoSpike = Yes and there are blocked cells on the grid, then dragging and dropping from the sample database may not create the samples in the wells properly. Workaround: If a sample has the AutoSpike set to Yes, then do not block the cells before dragging and dropping the sample. It occurs in both Elx808 & PRS 3 Interfaces.	
B3	When a completed ELx808 assay is opened by a logged in user who does not have an activated ELx808 instrument, the software will generate an audit trail entry stating the read interval was changed to 60 seconds from 30 seconds. If the read interval on the opened ELx808 assay was originally 60 seconds, no audit entry will be created. **ELx808 only customers**: Any user that logs in to EndoScan-V 6.2 or EndoScan-V 6.2.1 must have an activated ELx808 to ensure this known limitation does not occur. Upgrading to EndoScan-V 6.2.2 will remove this workaround if desired. **A setup with both ELx808 and PRS 3, or PRS 3 only opening ELx808 data, or any customer using client manager**: Required to upgrade to EndoScan-V 6.2.2.	
B4	When using Biotek ELx808 instrument and the unit is disconnected during self-test, EndoScan-V will still display the report as successful and the PDF generated will have minimal or no data. It is recommended to avoid disconnecting ELx808 instrument during self-test.	
B5	When a template is configured in PRS3 Reader mode and saved, but later opened in BioTek ELx808 mode, the shake intensity setting is changed from Linear to Slow. This behavior occurs due to differences in shake mode support between the two instruments as PRS3 supports only one shake mode (Linear) and BioTek ELx808 supports four shake modes (Slow, Medium, Fast). As a result, when a template created in PRS3 mode is opened with an ELx808 reader, the shake mode is automatically set to Slow (the default	

	option). Users can manually update the shake intensity in the Assay Properties section if a different mode is desired.	
B6	When creating a template and the regression is set to linear, the microplate template report will show regression as polynomial even though it is linear for the assay. It is recommended to view the assay report for referencing the correct regression.	
PTS/MCS INTERFACE LIMITATIONS		
C1	If two cartridges with the same lot number but different calibration codes are incorrectly entered into the accessory database, then the PTS and/or MCS panel will not display. It is recommended to ensure that all cartridges entered have the correct calibration code associated with it, so all panels display properly.	
C2	When any assay data is generated for glucan cartridges, the log (.txt) files displays as “EU/g” or “EU/mL” instead of “x/g” or “x/mL” where x is the unit desired. It is recommended that the assay report is referenced for the correct units.	
NEXUS 200 INTERFACE LIMITATIONS		
N1	**Automation Run:** When the first reagent container is emptied during an automation run, it is removed from the UI deck image. When the second, third, or fourth containers are emptied, they are not removed from the deck image due to a UI defect. This does not affect the running of the system or the results.	
N2	**Automation Run:** If the last sample tube in a run is empty, the automation will not complete and will need to be ended manually. No sample data will be lost, but the user must press the End Automation button.	
N3	**Automation Run:** During a pause, if a user adds samples that require dilutions, and there are empty reagent containers on the deck, the software will not consider that those containers are empty during the submit and verify step. This will lead to the automation encountering an error and needing to be ended manually. Workaround: Load enough full reagent containers before the start of	

	automation to perform all the dilutions that are planned for the run.	

Compatibility with other Endosafe Software

EndoScan-V 6.3 can be used with the following instruments: Biotek microplate instrument (Elx808 IU), PRS 3, nexgen-PTS, nexgen-MCS and Nexus 200.

EndoScan-V version 6.3 is compatible and validated with nexgen software version 11.1 and above.

EndoScan-V version 6.3 is compatible with Cortex version 1.1.3 and above.

Additional Information

Nexus 200 Additional Information
Resetting tips to 'full' during a pause in automation will not lead to the robot resetting where tips are being picked up. The robot will continue to pick up tips from the tip position just after the last used location.
If there is not an empty tip rack in position 1 (on the left side), then the robot may fail to properly dispose of empty nested tip racks. The empty tip rack on the left side is used to store tips while discarding empty nested racks.

If the user copies and pastes information from an external source, note that any special characters within the information copied could cause an issue within EndoScan-V when generating a report. Data copied and pasted from an external source may contain hidden characters, which may not be supported with in the software. Additionally, when entering Sample Name, the "&" symbol is not supported in EndoScan-V and cannot be used.

The rCR cartridge is using a test table feature called Preparation Time, as this change has been shown to improve the linearity of the rCR reaction. The system will use Preparation Time to determine when to start counting the start of the reaction. For example, with a Preparation Time of 300, the test counter will start 300 seconds prior to the first actual reading. Now that this feature is being used, the nexgen display has been simplified, for all tests (including Endotoxin tests), to show only the following states after Sample has been added: "Preparing Assay" (when sample is being brought into cartridge, and mixing prior to start of Preparation Time) and

"Test In Progress, __ seconds" (reaction time counter, that may include mixing and settling time, if a Preparation Time value is being used). Note that with a Preparation Time, it is possible to see the "Test in Progress" counter while the pump is still mixing/moving.

In addition, the rCR cartridge is using a Polynomial calculation to generate the Sample and Spike values.

There are many factors that contribute to our overall decision-making process regarding software updates, including rapid advancements in technology, the constantly evolving standards of care and maintenance, and specific mandates regarding regulatory compliance. We continually strive to incorporate advancements in technology to better serve our customers and provide solutions that ultimately put patient safety first. If you should have any questions, please contact the Charles River Technical Services team at Endosafe-Support@crl.com

Sincerely,

Alex Killinger

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