

Endosafe®

Release Notes

Charles River Endosafe® nexgen-PTS™/MCS™
software version 11.1.1 Revision 3

RNENDO-NEX1111-03

EFFECTIVE DATE : May 2025



Revision	Effective Date	Reason for Revision
03	See Effective Date in Footer	<p>-Clarified wording of known limitation KL3: If setting the date manually or using the daylight savings time (DST) feature, the time may change as well. The date can also change when setting the time as well. It is recommended to verify both the date and time is correct before leaving the screen.</p> <p>-Added known limitation KL6: A new user can be created with only 2 characters, which is outside the required minimum of 3 characters. However, once the user is created and login is attempted, the system will prevent login from occurring. It is recommended to create users with 3-40 characters to avoid this login issue.</p>



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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 pleased to notify you of the latest Endosafe® nexgen-PTS™/MCS™ software, 11.1.1. These release notes outline the new features and functionality included in version 11.1.1.

Feature Improvements:

- Changes to pump home movements system to reduce chance of pump errors
- Trillium cartridges enhancement. Please note that nexgen 11.1.1 is mandatory for all clients using Trillium™ cartridges.

For additional information on features and functionality, please see the nexgen-PTS 11.1 Software Manual.

Note: If connecting EndoScan-V 6.2 or higher to nexgen cartridge instruments, this is only compatible with Nexgen 11.1 and higher.

Note: Nexgen 11.1.1 is **mandatory** for all Trillium™ cartridge users.

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.	Green
Medium	Possibly impacts workflow, workaround provided, does not impact data/results.	Yellow
Medium/High	Critical issue that impacts data/result, known workaround.	Orange
High	Critical issue that impacts data/result, no known workaround. Would require immediate software fix.	Red

Previous Known Limitations Resolved:

Known Limitation	Issue	Resolution (Fixed/ Workaround)	Impact to End User
Known Limitation from Previous Version	When using Trillium cartridges (available now) or 10-digit lot number LAL cartridges (due to roll out in 2025), after a lot and calibration code is run once on the instrument, the calibration code will be paired with the lot and auto-filled for future tests using that lot. There is a known limitation where the auto-fill does not occur.	Fixed in 11.1.1. Azure #90242	
Known Limitation from Previous Version	For LAL and rCR cartridges, individual sample channel results values are not reported even if the option is turned on in settings. The individual sample channel results will only be reported as an averaged value.	Fixed in 11.1.1. Azure #87131	

Calibration

Updating the Endosafe nexgen-PTS/MCS instrument software does not impact the system calibration or the instrument's scheduled recalibration. Charles River advises the instrument is recalibrated annually to ensure optimum operation.

Software Validation

- Release File Name: pts150-master_11.1.1_31May2024_armv5te.ipk
- Release File Name: 59bac3f40a7421934324e6e0d2c2d90941851a92
- Project Name: Nexgen Version 11.1.1
- Project Number: MSCHA-nexgen-PTS-01
- Project Version Number: MSCHA-nexgen-PTS-01-11.1.1

The release of the nexgen 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. No changes were made to how the software performs calculations regarding sample and validity criteria. Please refer to nexgen Version 11.1 Installation Instructions on how to update.

Calculations performed on the Endosafe nexgen-MCS reader in conjunction with Endoscan V software were validated. For this system, the calculations are performed by the firmware on the instrument (version 11.0.0), and then displayed in Endoscan V. During internal software validation following our quality procedures, Charles River performed testing of these calculations under validation test case number MSCHA-ESV-6.1.0-CC05-UAT-07. Results of this testing was acceptable.

Additional Notes

Follow the Endosafe nexgen Version 11.1 Installation Instructions document. For an instrument not connected to EndoScan-V, the installation requires the user to copy the files to a FAT32 USB drive, and then insert the USB drive into the correct connection for the device. We advise that after updating the software a Performance Qualification (PQ) is performed. A PQ kit can be purchased from your local account manager (product code PTS902). This version of software is compatible with Charles River Cortex software version 1.1.3 or higher and EndoScan-V version 6.2 or higher. Please contact your local representative if you require an upgrade for Cortex or EndoScan-V.

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.

If you should have any questions, please contact the Charles River Technical Services Team at Endosafe-Support@crl.com.

Known Limitations

These pre-existing items were not addressed in this release, and should be reviewed prior to installation:

Known Limitation #	Issue/Workaround	Impact to End User
KL1	If a nexgen-PTS user is created through Charles River Cortex, the password expiration will display as January 01, 2300. The password can be reset on the nexgen-PTS, which will update the expiration date to the correct date. It is recommended to utilize the nexgen-PTS instrument's user management	

	functionality until an update can be made to Charles River Cortex.	
KL2	If a sample name is in the format CV 'space' sample name (examples "CV_1151" or "CV_water"), the results for that sample will display in the results list, but the report will not be able to open.	
KL3	If setting the date manually or using the daylight savings time (DST) feature, the time may change as well. The date can also change when setting the time as well. It is recommended to verify both the date and time is correct before leaving the screen.	
KL4	Time difference between the auto-printed time when report is actually printed and the time stamp of the "Printed report" in the audit trail may be different. 'Assay completed' is recorded in the Audit Trail when the test is complete, however "Printed on time" is recorded in the Audit Trail at the time of login from the logout state.	
KL5	In the general settings screen if a user enters an invalid number in the User Time Out, Password Expiration Period, Password History Limit, or Incorrect Login Attempt fields the input box will turn red and the save button will be disabled as expected. However, if the user moves the cursor and enters a valid number in another field, the save button is enabled thus allowing user to save the invalid number.	
KL6	A new user can be created with only 2 characters, which is outside the required minimum of 3 characters. However, once the user is created and login is attempted, the system will prevent login from occurring. It is recommended to create users with 3-40 characters to avoid this login issue.	


Additional Information

Reports generated directly from nexgen-PTS now have a checksum included at the bottom of the printed report. This checksum has always been a part of the internal report but was not made available to customers until recently. We are now including this in the printout as it provides a unique identifier for the report.

```

***** ENDOSAFE Test Record *****
          PTS150 V11.0.0
DateTime: ..... 22 Jul 2021 10:39:40
Device: ..... MCS 16480018
OperatorID: ..... TEST
Cartridge: ..... Endotoxin
Temperature: .. Start: 37.0C End: 37.0C
Method: ..... KX-122
Cartridge Lot#: ..... 6404165
Cartridge Cal Code: ..... 514436187530
Range: ..... 5-0.05
Range Time: ..... Sec: 144-761
Onset: ..... >761 >761 >761 >761
Slope: -0.362 ..... Intercept: +2.411
Dilution: ..... 1:1
Sample Lot: ..... 1122334455
Sample Name: ..... TEST123
Sample Rxn Time CV: ..... 0.0% Pass
Spike Value: ..... <0.00001 EU/mL
Spike Rxn Time CV: ..... 0.0% Pass
Spike Recovery: ..... < 0% Fail
Test Suitability: ..... Fail
Sample #1 Value: ..... <0.050 EU/mL
Sample #2 Value: ..... <0.050 EU/mL
Sample Value: ..... <0.050 EU/mL
$ea46220252997fefacb5029ce316b1e327f5ff02

```



1. If there is a sample error that causes a test to be aborted before readings are taken, and "Generate report for aborted/halted tests" is on, the Temperature shows up as:
Temperature: Start: 0.0C End: 0.0C.
2. With nexgen 11.0.0, additional changes were made to the software, so the software now behaves as follows:
 - When printing either Sample or Spike values, these are rounded to a # of digits that is based on the magnitude of the value, prior to rounding.
 - The number of digits after the decimal place is shown in the table below.
 - Note that any value less than 0.000005 always prints as "<0.00001".

Magnitude of value <i>prior to rounding</i>	# of digits after decimal when formatted for display
value ≥ 99.5	0
value < 99.5 AND value ≥ 9.95	1
value < 9.95 AND value ≥ 0.995	2
value < 0.995 AND value ≥ 0.05	3
value < 0.05 AND value ≥ 0.0001	4
value < 0.0001 AND value ≥ 0.000005	5
value < 0.000005	Prints/displayed as: "<0.00001"

- When formatting Sample or Spike CV values, the values are always rounded to 1 digit after the decimal point.
 - When determining Pass/Fail of CV values, the CVs are first rounded to 1 digit, and the rounded value is then compared to the fixed limits.
 - When formatting Spike Recovery, the value is always rounded to 0 digits.
 - When determining Pass/Fail of spike recovery, the Spike Recovery is rounded to 0 digits, and the rounded value is then compared to the fixed upper/lower limits.
 - When formatting Endotoxin Limit values, the Endotoxin limit is shown 'as-entered' by the user, unless there are more digits entered than the reported Sample Value.
 - If the user entered more digits for Endotoxin Limit than what is used to report Sample Value, the Endotoxin limit is formatted with the same number of digits as the Sample Value.
 - When determining Pass/Fail of Sample Values vs. Endotoxin Limit:
 - The two values are compared:
 - If the Sample Value is less than Endotoxin Limit, status is PASS
 - If the Sample Value is equal to or greater than the Endotoxin Limit, status is FAIL
 - The Sample Value used for the comparison is the rounded value from the test report
 - The Endotoxin Limit used for the comparison is the value that is reported on the test report, per the format specification described above.
3. Although the nexgen interface and the nexgen instruments with EndoScan-V software allow a user to enter a concentration with 6 decimal places, the report will only display a concentration of 4 decimal places.

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

Alex Killinger
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Charles River Microbial Solutions