Release Notes for the QX ONE Droplet Digital PCR System and QX ONE Software

Version 1.1.1 (includes v1.1)

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Introduction

The QX ONE Droplet Digital PCR System and QX ONE Software provide users with the capability to set up and run up to five plates concurrently through three ddPCR phases (droplet generation, thermal cycling, and droplet reading), and then analyze the results.

Supported Operating System

QX ONE Software is supported on the Windows 10 operating system.

Software Builds

The original build of QX ONE Software version 1.1 (build number 1.1.0.323) is superseded by build number 1.1.1.326, which is a maintenance release for version 1.1, and contains fixes and improvements only.

This release notes document contains information covering both builds (1.1.0.323 and 1.1.1.326). Changes specific to build number 1.1.1.326 appear in the Fixed Issues and Improvements section.

Upgrading to New Versions

Using the instructions below, you can download and install Standard Edition. If you are using Regulatory Edition, contact Bio-Rad Technical Support.

To upgrade the software from v1.0 to v1.1

- 1. Enter the following URL in your browser: http://www.bio-rad.com
- 2. Log into the website with your Bio-Rad user name and password.
- 3. Enter QX ONE Software into the Search field and click the Search icon.
- 4. Select the Downloads tab.
- 5. Locate QX ONE Software, Standard Edition, v1.1 and click Download Software.
- 6. In the Software Download window, select the *I agree with the compliance requirements* checkbox, and then click Download.
- 7. A zip file is downloaded and appears in your Downloads folder. The download process can take a few minutes.
- 8. Open the Downloads folder and select the QXOneStandard_1.1 zip file.
- 9. Right-click and select Extract All.
- 10. Select a destination folder and select the Show extracted files when complete checkbox, and then click Extract.
- 11. Open the folder containing the extracted files, and locate the .exe file.
- 12. Double-click the file to begin the installation.
- 13. Follow the prompts to install QX ONE Software, Standard Edition, v1.1.

New Features

The following features were introduced in build number 1.1.0.323.

Automatic Plate Recovery

The QX ONE Droplet Digital PCR System and QX ONE Software provide options to recover a plate that failed during the droplet generation or droplet reading phase of the experiment run.

If a process phase experiences a problem during a run, the run fails and QX ONE Software displays an error message on the touch screen and moves the run to the lower pane of the Run Status window, displaying a red exclamation point in the Run Status column. For failures during droplet generation or droplet reading, QX ONE Software provides the functionality to recover and reprocess the plate from the failure point. When the run is reprocessed successfully, a gold check mark appears in the Run Status column.

Important: You cannot recover a plate that fails during the thermal cycling phase.

For instructions on recovering failed plates, refer to the QX ONE Droplet Digital PCR System and QX ONE Software User Guide, v1.1.

Vent Reservoir Maintenance

The QX ONE Droplet Digital PCR System has a reservoir to collect liquid that escapes from waste bottle as plates are processed. When the liquid approaches capacity, it must be aspirated from the reservoir to continue plate processing.

In v1.1, the capacity has been increased to 50 mL. QX ONE Software displays a prompt when the liquid collected exceeds 25 mL, and Bio-Rad recommends aspirating the reservoir at this time. You can aspirate the liquid while the instrument is processing plates.

If you do not aspirate the reservoir at 25 mL, and the volume continues to increase, QX ONE Software displays a more urgent message when it approaches 50 mL. If the volume reaches 50 mL, the instrument shuts down and QX ONE Software displays an error message. You must aspirate the liquid before you can restart the instrument.

Refer to the QX ONE Droplet Digital PCR System and QX ONE Software User Guide, v1.1, for instructions.

Centrifuge Loading

The QX ONE Droplet Digital PCR System and QX ONE Software User Guide, v1.1, contains a section with instructions on loading a GCR96 frame filled with cartridges into a centrifuge as part of preparing a sample experiment.

Exporting Individual Droplet Amplitudes

In the Analysis module, you can use the Import/Export option to export individual droplet data per well to a .csv file in a specified folder. The file contains a row of amplitude data for each droplet in each well.

Fixed Issues and Improvements

Build Number 1.1.1.326

- QX ONE sample utilization has been improved.
- Increased frequency of Piston Pump and DR Z-axis errors due to firmware anomaly.
- QX ONE crashed and displayed a runtime error for hardware events that were incorrectly handled by the software.

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- QX ONE Software crashed after users selected multiple wells for thresholding in triplex experiments.
- QX ONE Software incorrectly calculated values in Open mode.
- QX ONE Software did not apply the change after a user added and then removed a conversion factor in an RDQ experiment.
- QX ONE Software incorrectly reported the concentration is No Call rather than zero (0) for targets with no positive droplets.
- QX ONE Software experienced issues exporting Well Notes, moving or omitting information.
- In Advanced Classification Method experiments, QX ONE Software incorrectly reported the concentration as No Call when users created a threshold cluster with droplets.
- When users added plates, and then deleted a plate, QX ONE Software did not enable the Start Run button.

- When users created and saved a plate template, and then set up a run with a supermix and a thermal cycling template, QX ONE Software did not enable the Start Run button.
- QX ONE Software displayed an error message when users added a second target group in a Drop Off experiment.
- When users deleted one of two or more plates from an experiment, QX ONE displayed the instrument status as Assistance Needed, and disabled the Add Plate and Start Run buttons rather than maintaining the Ready status.
- After a user scanned a plate in the QX ONE Droplet Digital PCR System, and then deleted the plate in QX ONE Software, the plate remained in the software display and all plate-related buttons were disabled.
- When users placed a plate into the wrong Inbox slot, the instrument status changed to Assistance Needed. When the user removed the plate, the instrument status remained Assistance Needed rather than changing to Ready.
- QX ONE Software did not display an error message when the user put a plate into the wrong Inbox slot.
- In the QX ONE Software Analysis module, users were able to import a plate template with a different configuration into the .ddpcrone file.
- When a user imported a plate template into a .ddpcrone file in the Analysis module, QX ONE Software overwrote original supermix.
- When the Waste bottle contained insufficient room for the number of expected runs,
 QX ONE Software did not display an error message or change the instrument status to Assistance Needed.
- QX ONE Software would not open a .ddpcrone file from a Probe Mix Triplex experiment with 1 sample well and buffer in the remaining wells.
- QX ONE Software did not display results for all wells when the user generated a report with Run Setup data.

Known Issues

- QX ONE Software does not move aborted plate runs to the completed runs list.
- The Analysis Report includes duplicated rows.
- If no matches are returned from a plate template search, and you clear the search field, QX ONE Software clears all template files from the dropdown list.

Workaround: Close the template search dropdown, and retry.

The QX ONE Droplet Digital PCR System does not prompt an error message in QX ONE Software when
the droplet reading oil bottle is empty or the waste bottle is full. As a result, plates are not moved
forward to the next process.

Workaround: Ensure the droplet reading oil bottle is full and at least one waste bottle is empty before you start plate runs.

- When you select and enter the default value for Assay Type, and then modify the target information, QX ONE Software crashes.
- Errors do not include the full text in the error pop-up screen.
- Upon startup, the waste overflow sensor does not detect the current level in the waste bottle.

Documentation

For information on the QX ONE Droplet Digital PCR System and QX ONE Software, refer to the following documents:

- QX ONE Droplet Digital PCR System and QX ONE Software User Guide
- QX ONE Software User Guide. Standard Edition
- QX ONE Software User Guide, Regulatory Edition

Contacting Technical Support

The Bio-Rad Technical Support department in the U.S. is open Monday through Friday, 5:00 AM to 5:00 PM, Pacific time.

Phone: 1-800-424-6723, option 2

Email: Support@bio-rad.com (U.S./Canada Only)

For technical assistance outside the U.S. and Canada, contact your local technical support office or click the Contact Us link at www.bio-rad.com.

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