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

#### Version 1.4

November 2023

### **Contents**

Introduction	1
Supported Operating System	1
Upgrading to New Versions	
Fixed Issues and Improvements	
Known Issues	4
Documentation	4
Contacting Technical Support	5
Legal Notices	5

### 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 Systems**

QX ONE Software is supported on the 64-bit Windows 10 operating system. QX ONE Software Version 1.4 is compatible with hardware versions 1.2 and above.

## **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 to v1.4

- 1. Open bio-rad.com in your browser.
- 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. Locate QX ONE Software, Standard Edition, v1.4 and click Download Software.
- 5. In the Software Download window, select the *I agree with the compliance requirements* checkbox, and then click Download.
- 6. A zip file is downloaded and appears in your Downloads folder. This process can take a few minutes.
- 7. Open the Downloads folder and select the QXOneStandard\_1.4 zip file.
- 8. Right-click and select Extract All.
- 9. Select a destination folder and select the Show extracted files when complete checkbox, and then click Extract.
- 10. Open the folder containing the extracted files and locate the .exe file.
- 11. Double-click the file to begin the installation.
- 12. Follow the prompts to install QX ONE Software, Standard Edition, v1.4.

**Important:** During the installation of Standard Edition, you are prompted to either enable the User Management module, or keep the checkbox cleared and use the software with a single generic user. See Enabling User Management in QX ONE Software User Guide, Standard Edition, v1.4.

## **New Features and Improvements**

#### **Double Drop-Off Assay Type**

QX ONE Software now supports the Double Drop-Off assay type, which adds a second Unknown target to the existing Reference and Unknown targets found in the Single Drop-Off assay.

**Important:** Two thresholds are required to successfully cluster data in the Double Drop-Off Assay type. If you define only one threshold, QX ONE Software does not perform clustering.

#### **Improved Bottle Error Handling**

In previous versions of QX ONE Software, when an oil bottle was improperly placed in the instrument, the QX ONE would force the bottle to read as empty and the bottle was no longer usable. In Version 1.4, you are prompted to reinstall the bottle.

#### **New Software Settings Tab**

To address image rendering issues on systems with Intel Iris Xe graphics cards installed, a new Software Settings tab, featuring an alternate rendering method, has been added to the software.

**Important:** Because the issue is associated with certain graphics cards only, do not change the setting unless advised to do so by Bio-Rad Technical Support.

#### **Fixed Issues**

The following software issues are fixed in Version 1.4.

- When reprocessing data, the file name displayed in the progress pop-up varied from the final filename applied to the reprocessed file.
- When using file and/or path names that exceeded 259 characters, an error occurred.
- After applying an SD Threshold to data that had previously been calculated by automatic threshold, the well data table and well selector still reflected auto rather than manual as the method.
- For the Advanced Classification Method assay type, after manual clustering with the lasso (freeform) tool (), some well data was not updated with positive/negative droplet counts, and the concentration was not calculated.
- During analysis, when viewing multiple wells in the 1D Amplitude tab and using a Fixed scale, the chart did not render as expected; instead, there was a loss of divider lines and incorrect X scaling.
- When you generated a report, and then changed a threshold for the data, QX ONE Software sometimes crashed.
- If you closed the Analysis module while the PDF report was generating, the application also closed.
- When configuring multiple plates, the Next Plate button was disabled on the Well Selection and Well Information tabs.

#### **Known Issues**

You might encounter any of the following issues when using the instrument and software. Unless otherwise noted, issues can be resolved by power cycling the instrument and recovering the run.

- When you remove a plate from the inbox while the QX ONE Droplet Digital PCR System is running another plate, QX ONE Software does not recognize the missing plate, nor is an advisory message displayed.
- After you correct a misaligned plate in the Inbox, the software does not recognize that the plate has been realigned correctly and displays a message asking the user to load the plate into the correct slot. You cannot delete the plate from the software.
- If you manually open and then close the Inbox door, the automatic open/close mechanism might subsequently fail. Bio-Rad recommends using the software to open and close the instrument doors.
- Intermittent communication errors can occur during a run and might cause the instrument to automatically cancel the run.
- If you remove a waste bottle during a run, an error state in the system might occur. For best performance, do not remove bottles while the system is processing runs.
- If you install QX ONE Software, Version 1.4 on a computer with the default language set to a language other than English, the installation might fail.

Workaround: Complete the following steps:

- 1. In the Search field by the Start icon, enter Computer Management.
- 2. Select Local Users and Groups, and then double-click Groups.
- 3. Verify the Users profile is present in the list.
- 4. If not, right-click Groups in the left panel and select New Group.
- 5. For Group name, enter Users and click Create.
- 6. Restart the computer and reinstall the software.

#### **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 <a href="https://www.bio-rad.com">www.bio-rad.com</a>.

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