



Release Notes for QX700 Droplet Digital PCR System Analysis Software Standard and Premium Editions, Version 1.5

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For research use only. Not for use in diagnostic procedures.

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Intended Use

Important: The QX700™ Droplet Digital™ PCR (ddPCR™) System and its software applications (QX700 ddPCR System Control Software and QX700 ddPCR System Analysis Software) are intended **for research use only** by laboratory personnel who have completed the appropriate training provided by Bio-Rad™ Laboratories, Inc. **Do not use the instrument or software for diagnostic procedures.**

Overview

This document describes the new features and enhancements added to Version 1.5 of QX700 ddPCR System Analysis Software, which uses the images acquired by the QX700 instrument to calculate the absolute concentrations of the targeted nucleic acids. The software is available in Standard and Premium Editions and can be installed on all instrument models (QX700 E, QX700 S, and QX700 HT).

Premium Edition can enable QX700 customers to meet Food and Drug Administration (FDA) regulations on good laboratory practices (GLP) and good manufacturing practices (GMP) for the pharma and biotech industries. When the naica Data Service is also installed to serve as the user account manager, the system can be configured to operate in compliance with Title 21 in the Code of Federal Regulations Part 11 (21 CFR Part 11) within a closed system¹.

Important: To be compliant with 21 CFR Part 11, the security controls built into the software must be properly configured and administered by the system admins in your organization. Bio-Rad makes no claim that QX700 ddPCR System Analysis Software is 21 CFR Part 11-compliant in and of itself, nor does the company guarantee compliance for the user. The customer organization must establish policies and standard operating procedures (SOPs) that work in conjunction with the tools provided by Bio-Rad to ensure compliance with 21 CFR Part 11.

¹ A closed system is defined as an environment where access is restricted to authorized users who are responsible for electronic records content.

Installing or Upgrading the Software

The QX700 ddPCR System Control Software is preinstalled on the QX700 ddPCR System. The Bio-Rad website product page provides access to an installation executable file to install or upgrade the software on a PC for additional plate setup capabilities.

This section explains how to download and install both editions of the software. If you purchased Premium Edition, a Bio-Rad field service engineer (FSE) will install and configure Premium Edition and its companion component, the QX700 Data Service. The user guides also contains instructions for installing your edition on additional computers. If you have questions, contact Bio-Rad Technical Support.

To install or upgrade the software to this version (Standard Edition)

1. Open bio-rad.com and log in with your Bio-Rad user name and password.
2. Enter QX700 into the Search field and then click the search icon.
3. Click Downloads and then locate and click the Download Software link for your edition of the QX700 ddPCR System Analysis Software.
4. In the Software Download window, select the *I agree with the compliance requirements* checkbox, and then click Download.
5. A zip file is downloaded and appears in your Downloads folder. The download process can take a few minutes.
6. Open the Downloads folder and select the zip file, and then right-click and select Extract All.
7. Keep the default location or click Browse and navigate to a different folder, and then click Extract.
8. Open the folder containing the extracted files and locate the .exe file.
9. Double-click the .exe file to begin the installation.
10. Follow the prompts to install the software.

New Features and Enhancements

This section briefly describes new and enhanced features that are added to the software. For more information, see the QX700 ddPCR System Analysis Software User Guide for your software edition.

Separate Analysis Software Installer Files and User Guides

Each edition of the QX700 ddPCR System Analysis Software (Standard and Premium) has its own installer file and separate user guides have been developed. Premium Edition contains the Standard Edition functionality plus features which, when properly configured, can operate in compliance with CFR 21 Part 11.

Compressed Images in Data Files

The .niodata files created by the QX700 Droplet Digital PCR System now contain compressed images, which reduces the typical file size from 4 GB to less than 1 GB.

Post-Processing Wait Intervals

Since post processing results can take a few minutes to calculate, a “waiting time” animation (spinner) appears during the calculation processing interval to alert the user that the software is working and has not stalled.

Updated Concentration Calculation

For improved accuracy, the *average* droplet size (volume) detected in each chamber is used to calculate the concentration value.

New Channel Names

All channels that appear in the software are named by fluorophore instead of the matching LED color.

Note: For alternative fluorophores (such as EvaGreen® or FITC), channel recommendations are provided according to the supermix you are using.

Reduced Data Recalculation Waiting Times

Population data recalculation factors have been optimized to eliminate unnecessary recomputing and reduce waiting time.

Polygon and Dilution Edition Displays

Improvements have been made to the appearance and usability of polygons and Dilution Edition entries:

- When you create a polygon and pause on the Apply button under Polygon Edition, the button color changes to green to indicate it is selectable.
- In the Edit Experiment table, the Dilution Factor background color has been lightened to improve field content visibility.

Fixed Issues

The following issues have been fixed in this software version:

- The dilution factor used in calculating post-processing results has been adjusted to apply the user-defined dilution factor except for Linkage Analysis, which always uses a dilution factor of 1.
- In 3D dot plots, the labels for the x, y, and z axis now display the fluorophore name and the text appears in the corresponding LED color.
- If an experiment is compensated, an asterisk (*) appears after the fluorophore name in the dot plots; if not, then the fluorophore name only appears.
- The software no longer crashes if you set a negative threshold value .
- Where populations are defined under Populations in the Plots & Populations view, the eye icon to the right of a defined population identifier sometimes disappeared when a population was replaced and was unrecoverable.
- If a population is deleted, the next population in the list is automatically moved up so there is no longer an empty space. .
- In the Population Editor Zones List, the font size has been adjusted, and the Name field content wraps the text, so longer zone names in experiments are no longer truncated.
- If you import chambers from an experiment that uses a compatible protocol, but which has a different protocol ID, the new ID is shown next to the imported chambers. *Chamber imports must still match experiment parameters in the source experiment to be valid.*
- If you change minimum and/or maximum boundary values in the axis dialog for a particular channel, the new axis values in the dialog are also reflected in the chart boundary range.

Documentation

- QX700 Droplet Digital PCR System Instrument Guide, Version 1.5
- QX700 ddPCR System Analysis Software, Standard Edition, User Guide, Version 1.5
- QX700 ddPCR System Analysis Software, Premium Edition, User Guide, Version 1.5
- Release Notes for QX700 ddPCR System Control Software, Version 1.5
- Release Notes for QX700 ddPCR System Analysis Software, Standard and Premium Editions, Version 1.5

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

E-mail: 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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