
QX700 Droplet Digital PCR System

Instrument Guide

QX700 E Droplet Digital PCR System

QX700 S Droplet Digital PCR System

QX700 HT Droplet Digital PCR System



BIO-RAD

QX700 Droplet Digital PCR System

Instrument Guide

Software Version 1.4

For Research Use Only. Not for Use in Diagnostic Procedures.



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Revision History

Document	Date	Description of Change
QX700 Essential (E) Droplet Digital PCR System, QX700 Standard (S) Droplet Digital PCR System, and QX700 High Throughput (HT) Droplet Digital PCR System (Doc ID 10000171493)	August 2025	Initial Release
QX700 Droplet Digital PCR System (Doc ID 10000171493)	August 2025	Updated with new instrument configuration names to align with labeling
QX700 Droplet Digital PCR System (Doc ID 10000171493)	October 2025	Includes ■ China RoHS and South Korea certification labels ■ Shortened instrument configuration names on the cover and introduction
QX700 Droplet Digital PCR System (Doc ID 10000171493)	November 2025	Includes antistatic wetted wipes correction to instrument, parts, and accessories table

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Safety and Regulatory Compliance

This guide cites regulatory requirements for laboratory and electrical equipment, as well as requirements for working with chemicals and hazardous substances, and also explains safety precautions and recommendations.

Important: Only trained personnel should use this instrument.

Regulatory Compliance

This instrument is a CE-marked device distributed by Bio-Rad Laboratories, Inc. Stilla Technologies is the legal manufacturer responsible for regulatory compliance.

This instrument has been tested and found to comply with

- The limits for a Class A digital device pursuant to Part 15 of FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.
- All applicable requirements of the following safety and electromagnetic standards:
 - IEC 61010-1:2010 (3rd:2016). Electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
 - IEC 61010-2-081:2019. Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes (includes Amendment 1)
 - IEC 61326-1:2020 (Class A). Electrical equipment for measurement, control, and laboratory use. EMC requirements, Part 1: General requirements
 - Restriction of hazardous substances (RoHS) directive (European Union) 2015/863
 - Waste electrical and electronic equipment (WEEE) directive 2012/19/EU

Foreign Compliance

China

This product complies with China RoHS regulations, indicating that restricted hazardous substances are within legal limits and the Environmental Protection Use Period (EPUP) is shown on the label.



South Korea

KC certification demonstrates a product's compliance with Korean safety regulations. The KC certification's primary purpose is to identify and eliminate potential hazards to the health and safety of consumers.

	1. 기 자 재 명 :	QX700 Droplet Digital PCR System
	2. 홈페이지 주소 :	https://www.rra.go.kr/selform/B1r-N40027
	3. 상 호 명 :	Bio-Rad Laboratories, Inc
	4. 제 조 연 월 :	2025. . 별 도 표 기
	5. 제 조 자 / 제 조 국 가 :	Stilla Technologies / 프랑스 DIR 10000253590 A

Symbols Lexicon

Table 1. Labeling Symbols Lexicon

 Catalog Number	 Serial Number
 CE Marking - Directives 2014/30/EU and 2014/ 35/EU	 UK Conformity Assessment (UKCA)
 Australian Regulatory Compliance Mark	 North American CSA Compliance Mark
 Temperature Limit	 Use Caution
 Waste Electrical and Electronic Equipment (WEEE)	 Manufacturer

Table 1. Labeling Symbols Lexicon, continued

 Consult Instructions for Use	 Distributor
 Chinese Restriction of Hazardous Substances Mark	 Korean Certification Mark (South Korea)

Safety Warning Labels

Warning labels alert you about sources of injury or harm. [Table 2](#) defines each safety warning label.

Table 2. Meaning of safety warning labels

Icon	Meaning
	Warning about liquids Prevent liquids from entering the QX700 ddPCR System. Load samples outside of the instrument.
	Warning about risk of electric shock In order to prevent electric shock, use caution when plugging and unplugging the instrument. Always turn off and unplug the instrument when performing maintenance procedures. Never open the instrument housing unless instructed by a Bio-Rad technical representative. Only users trained by a Bio-Rad representative should open the instrument door. Always shut down the instrument and unplug it before opening the housing or door. Opening the instrument while it is still powered on may result in unexpected robotic movements that can cause injury. Do not start any analysis while the housing or door is open, as this poses a risk of physical contact or shock from internal robotic components.

Table 2. Meaning of safety warning labels, continued

Icon	Meaning
	Warning about photobiological hazards The optical module LEDs can pose a risk of eye injury if the instrument door is opened without proper precautions. Always shut down the instrument and unplug it before opening the housing or door.
	Warning about risk of harm to body or equipment Operating the system before reading this manual can constitute a personal injury hazard. For safe use, do not operate this instrument in any manner unspecified in this manual. Only qualified laboratory personnel trained in the safe use of electrical equipment should operate this instrument. Always handle all components of the system with care and with clean, dry hands.
	Warning about risk of burning Never open the instrument housing or door unless instructed by a Bio-Rad technical representative. Always shut down the instrument and unplug it before opening the housing or door. Opening the instrument while it is still operating may expose you to hot thermoblocks that can reach temperatures above 50 °C, posing a risk of burns or scalds. Only use chips and chip plates provided by Bio-Rad, as they are heat resistant up to 95 °C. A thermal cycler generates enough heat to cause serious burns. Wear safety goggles or other eye protection at all times during operation, and do not try to open the front door. Always allow maximum clearance to avoid accidental skin burns.
	Warning about pinch or crush risk Never open the instrument housing or door unless instructed by a Bio-Rad technical representative. Always shut down the instrument and unplug it before opening the housing or door. Opening the instrument while it is still operating may result in pinch injuries due to manual or automatic movement of the thermoblock lids.
	Protective conductor terminal
	Warning about handling biohazardous materials When handling biohazardous samples, adhere to the recommended precautions and guidelines and comply with any local guidelines specific to your laboratory and location.

Safe Use Specifications

For safe operation of the instrument, Bio-Rad strongly recommends that you comply with instructions listed in this section and in [Appendix B, Cleaning and Maintaining the QX700 ddPCR System](#).

Important: This instrument is intended for laboratory use only. Bio-Rad is not responsible for any injury or damage caused by use of this instrument for purposes other than those for which it is intended, or by modifications to the instrument not performed by Bio-Rad or an authorized agent.

- This instrument is for use only by trained personnel.
- Use only the power and connection accessories supplied with the instrument, and the plug adapter corresponding to the electrical outlets in your region.
- For easy access to the back of the instrument, place the instrument on a solid, stable surface and provide adequate room at the back and on each side.
- This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructional documentation, may cause harmful interference to radio communications. Operation of the systems in a residential area is likely to cause harmful interference, in which case users will be required to correct the interference at their own expense.

Note: Bio-Rad recommends maintaining a backup power source in case of power outages. A universal power supply (UPS) can protect from brown outs and power surges, while a regular backup generator does not.

For information on environmental requirements, see [Environment Requirements on page 19](#).

Power Requirements

Ensure that your facility meets the instrument's maximum power consumption and electrical specifications:

- For 220–240 V AC operation, a grounded electrical line rated at a minimum of 10–15 A is required.
- For 110 V AC operation, a grounded electrical line rated at a minimum of 20 A is required.

An electrical ground is mandatory. The instrument is shipped with a dedicated power cable that complies with regional standards. Always confirm that the power cable matches your country's electrical regulations during installation.

Important: If voltage fluctuations exceed $\pm 10\%$, use a power line regulator.

Do not use electrical adapters.

For optimal performance, Bio-Rad recommends switching off the instrument at least once a week.

Personal Protective Equipment

Proper use of gloves is recommended with use of oils and sample plates. OSHA requirements for personal protective equipment (PPE) are set forth in the Code of Federal Regulations (CFR) at 29 CFR 1910.132 (General requirements); 29 CFR 1910.138 (Hand protection); 29 CFR 1926.95 (Criteria for standard personal protective equipment). Any gloves with impaired protective ability should be discarded and replaced. Consider the toxicity of the chemicals and factors such as duration of exposure, storage, and temperature when deciding to reuse chemically exposed gloves.

The following features aid glove selection for handling of machines, assays, oils, and cleaning solvents:

- Butyl gloves are made of a synthetic rubber and protect against peroxide, hydrofluoric acid, strong bases, alcohols, aldehydes, and ketones
- Natural (latex) rubber gloves are comfortable to wear and feature outstanding tensile strength, elasticity, and temperature resistance
- Neoprene gloves are made of synthetic rubber and offer good pliability, finger dexterity, high density, and tear resistance; they protect against alcohols, organic acids, and alkalis
- Nitrile gloves are made of copolymer and provide protection from chlorinated solvents such as trichloroethylene and tetrachloroethene; they offer protection when working with oils, greases, acids, and caustic substances

Hazards

The instrument is designed to operate safely when used in the manner prescribed by the manufacturer. If the instrument or any of its associated components is used in a manner not specified by the manufacturer, the inherent protection provided by the instrument may be impaired.

Bio-Rad Laboratories, Inc. is not liable for any injury or damage caused by the use of this equipment in any unspecified manner, or by modifications to the instrument not performed by Bio-Rad or an authorized agent. Only trained Bio-Rad personnel should perform service on the system.

Biohazards

The instrument is a laboratory product. However, if biohazardous samples are present, adhere to the following guidelines and comply with any local guidelines specific to your laboratory and location.

Note: No biohazardous substances are expended during normal operations of this instrument.

General Precautions

- Always wear laboratory coat, laboratory gloves, and safety glasses with side shields or goggles.
- Keep your hands away from your mouth, nose, and eyes.

- Completely protect any cut or abrasion before working with potentially infectious materials.
- Wash your hands thoroughly with soap and water after working with any potentially infectious material before leaving the laboratory.
- Store all infectious or potentially infectious material in unbreakable leak-proof containers.
- Before leaving the laboratory, remove protective clothing.
- Change gloves frequently. Do not use a gloved hand to write, answer the telephone, turn on a light switch, or touch anything that other people may touch without gloves. Remove gloves immediately when they are visibly contaminated.
- Do not expose materials that cannot be properly decontaminated to potentially infectious material.
- Upon completion of an operation involving biohazardous material, decontaminate the work area with an appropriate disinfectant (for example, a 1:10 dilution of household bleach).

Disposal of Biohazardous Material

Dispose of the following potentially contaminated materials in accordance with laboratory local, regional, and national regulations:

- Clinical samples
- Reagents
- Used reaction vessels or other consumables that may be contaminated

Chemical Hazards

The instrument contains no potentially hazardous chemical materials.

Explosive or Flammability Hazards

The instrument poses no uncommon hazard related to flammability or explosion when used in a proper manner as specified by Bio-Rad.

Electrical Hazards

The instrument poses no uncommon electrical hazard to operators if installed and operated properly without physical modification and connected to a power source of proper specification.

Decommissioning and Disposal

The instrument contains electrical materials that should be disposed of as unsorted waste and must be collected separately, according to European Union Directive 2012/19/EU on waste electrical and electronic equipment — WEEE Directive. The purpose of decommissioning is to make sure that the equipment is electrically and environmentally safe for disposal. Before disposal, contact your local Bio-Rad representative for country-specific instructions.

To decontaminate the instrument before decommissioning and disposal, see [Cleaning and Maintaining the QX700 ddPCR System on page 126](#).

Environment Requirements

This instrument is designed to be safely operated under the environmental conditions listed in the following table.

Table 3. Instrument environment requirements

Parameter	Specification
Environment	Indoor use only (clean laboratory)
Operating altitude	Up to 2,000 meters above sea level
Ambient room temperature	15 to 25°C*
Transport and storage temperature	5° to 40°C**
Relative humidity***	Operating: 40% to 80% (noncondensing) Storage: 10% to 95% (noncondensing)
Barometric Pressure	700 hPa to 1060 hPa
Operating power	100 to 240 V~ (±10%), 50/60 Hz****
Mains supply voltage fluctuation	±10%
Maximum power usage	<850 watts
Fuses	6.3x32 T 16A. H/250V~
Overvoltage category	II
Power consumption max (W)***	1750W
Pollution degree	2

Table 3. Instrument environment requirements, continued

Parameter	Specification
Noise	61dBA max
* Operating the instrument at 4°C should be limited to 18 hours at these conditions. Holds at 4°C can be performed for up to 72 hours if humidity is 20% to 60% (noncondensing). **Store and transport the instrument in its shipping container to meet these temperature conditions. ***Operating the instrument at 4°C should be limited to 18 hours at these conditions. Holds at 4°C can be performed for up to 72 hours if humidity is 20% to 60% (noncondensing). ****The facilities must be in equipped to adequately handle the maximum power consumption and wired with a minimum of: ■ 10-15 amp grounded line with 220-240 volts AC. ■ 20 amp grounded line with 110 volts AC.	

EMC Requirements

Table 4. Instrument EMC requirements

Item	Specification
Emission Class	Class A
Compliant with IEC 61326-1	



WARNING! Emissions exceeding the levels described above might occur if the instrument is connected to an external device such as a monitor or a USB drive.



WARNING! This instrument is not intended for use in residential environments and might not provide adequate protection against radio frequency interference in such settings.

Surface Decontamination



WARNING! To prevent electrical shock, always turn off and unplug the instrument before performing decontamination procedures.

To clean the surface of the QX700 ddPCR System, use a lint-free tissue moistened with one of the cleaning agents listed below. Allow surfaces to air dry completely.

- 10% diluted bleach
- Diluted Sodium Hydroxide (e.g., RNAase away)
- Lab grade Water
- 70% Lab grade Ethanol
- Isopropanol

Door and Housing Decontamination



WARNING! To prevent electrical shock or to prevent accidental activation, always turn off and unplug the instrument before performing decontamination procedures.



WARNING! Do not clean the internal components of the instrument, including the optical module. Cleaning the instrument interior can damage the instrument or affect its performance.



WARNING! Do not spray cleaning agents directly onto or into the system. Avoid using spray bottles.



WARNING! Follow all safety instructions provided by the cleaning agent manufacturer.

To clean the front door and outer housing, use a lint-free tissue dampened with one of the agents listed below. Wipe the surfaces carefully, avoiding the power connector.

- 10% diluted bleach
- Diluted Sodium Hydroxide (e.g., RNAase away)
- Lab grade Water
- 70% Lab grade Ethanol
- Isopropanol

Chapter 1 About Droplet Digital PCR

Droplet Digital PCR (ddPCR™) is a digital polymerase chain reaction method based on water-oil emulsion droplet technology. ddPCR uses a combination of microfluidics and proprietary surfactant chemistries to divide each sample into water-in-oil droplets. The technology uses reagents and workflows similar to those used for most standard TaqMan probe-based assays, and provides absolute quantification of nucleic acid target sequences by counting nucleic acid molecules encapsulated in discrete, volumetrically defined water-in-oil droplet partitions.

A full ddPCR cycle includes droplet generation, thermal cycling, and droplet reading. This instrument guide explains how each process is managed using the QX700 ddPCR System.

ddPCR is highly effective in the following areas:

- **Absolute quantification** — ddPCR provides a concentration of target DNA copies per input sample without the need for running standard curves, making this technique ideal for target DNA measurements, viral load analysis, and microbial quantification.
- **Genomic alterations such as gene copy number variation (CNV)** — CNVs result in too few or too many dosage-sensitive genes responsible for phenotypic variability, complex behavioral traits, and disease. ddPCR enables measurement of 1.2x differences in gene copy number.
- **Detection of rare sequences** — researchers must amplify single genes in a complex sample, such as a few tumor cells in a wild type background. ddPCR is sensitive enough to detect rare mutations or sequences.
- **Gene expression and microRNA analysis** — ddPCR provides stand-alone absolute quantification of expression levels, especially low-abundance microRNAs, with sensitivity and precision.
- **Next-generation sequencing (NGS)** — ddPCR quantifies NGS sample library preparations to increase sequencing accuracy and reduce run repeats. Validate sequencing results such as single nucleotide polymorphisms or copy number variations with absolute quantification.
- **Single cell analysis** — the high degree (10-fold to 100-fold) of cell-cell variation in gene expression and genomic content among homogeneous post-mitotic, progenitor, and stem cell populations drives a need for analysis from single cells. ddPCR enables low copy number quantification and gene expression of individual cells.
- **Genome edit detection** — ddPCR enables fast, precise, and cost-effective assessment of HDR (Homology directed repair) and NHEJ (non-homologous end joining) generated by CRISPR-Cas9 or other genome editing tools.

ddPCR has the following benefits for nucleic acid quantification:

- **Unparalleled precision** — The massive sample partitioning afforded by ddPCR enables small fold differences in target DNA sequence between samples to be reliably measured.
- **Increased signal-to-noise ratio** — High-copy templates and background are diluted, effectively enriching template concentration in target-positive partitions. This allows for the sensitive detection of rare targets and enables a $\pm 10\%$ precision in quantification.
- **Removal of PCR efficiency bias** — Error rates are reduced by removing the amplification efficiency reliance of qPCR, enabling accurate quantification of targets to near zero.
- **Simplified quantification** — There is no requirement for a standard curve for absolute quantification.

ddPCR Workflow

In Droplet Digital PCR (ddPCR), thermal cycling is performed within thousands of individual droplets after the sample is partitioned into these droplets using microfluidics. These droplets contain a small volume of the sample and any target DNA sequences, and each droplet essentially acts as a separate PCR reaction. After the PCR amplification within the droplets, the droplets are analyzed individually using a droplet reader to count PCR-positive and PCR-negative droplets, allowing for absolute quantification of the target DNA.

In ddPCR vs qPCR, qPCR is suitable for applications that require a broad dynamic range, whereas ddPCR is for those applications that require higher precision or analysis of fractional abundance. The evolution from ddPCR to nanoplate ddPCR has widened the scope of this technology to include more applications.

The ddPCR process adheres to the following workflow:

- Prepare samples for PCR by combining DNA or RNA with primers, probes dye, and Naica ddPCR mix.
- The instrument fractionates a sample in a 2D array in the RDG16 Cartridge, with target and background DNA distributed randomly into the droplets during the partitioning process.
- Following droplet generation, the droplets are run through a thermal cycler, which performs PCR amplification of the nucleic acid target in each individual droplet.
- The 2D array of droplets is then imaged to reveal positive droplets and automated data analysis and Poisson statistical formulas are used to determine absolute quantity.

Note: Positive droplets containing at least one copy of the target DNA molecule exhibit increased fluorescence compared to negative droplets.

Droplet Generation

Before droplet generation, ddPCR reactions are prepared in a similar manner as real-time PCR reactions that use TaqMan hydrolysis probes labeled with reporter fluorophores or an intercalating dye. ddPCR is performed with Bio-Rad's proprietary reagents that were developed specifically for droplet generation.

The QX700 ddPCR System runs the plates containing your DNA samples as the first component in the three-part process. The instrument uses specially developed reagents and microfluidics to partition each sample between 10,000 and 17,000 nanoliter-sized droplets per well. Target and background DNA are distributed randomly into the droplets during the partitioning process. Droplet generation produces uniform droplets for the sample, enabling precise target quantification.

PCR Amplification

After droplet generation, the plates are heated and cooled repeatedly in the thermal cycler. This amplifies one or more copies of a particular DNA segment, thereby multiplying strands of DNA sequencing into the thousands or millions.

Chapter 2 Introduction

The QX700 Droplet Digital PCR System (known in this guide as the QX700 ddPCR System) is a fully integrated platform for Droplet Digital PCR (ddPCR).

With the QX700 ddPCR System Analysis Software and the QX700 ddPCR System Control Software, the QX700 ddPCR System automates partitioning, thermal cycling, and imaging with no user intervention, and performs droplet generation, amplification, and imaging across up to seven detection channels — all in a single instrument.

The QX700 ddPCR System is available in the following configurations to support different throughput needs:

- **QX700 E Droplet Digital PCR System** – Up to 48 samples per run
- **QX700 S Droplet Digital PCR System** – Up to 192 samples per run
- **QX700 HT Droplet Digital PCR System** – Up to 384 samples per run

This instrument guide provides general information for the use of the QX700 ddPCR System for ddPCR. It explains the workflow and required hardware components. Users should read the guide carefully, follow all instructions, and observe the safety information to ensure proper operation and maintenance of the instrument.

Important: The QX700 ddPCR System is a laboratory instrument intended to be used by professional users trained in molecular biological techniques. Before operating the instrument, users must receive training from a Bio-Rad representative.

QX700 ddPCR System Components

The QX700 ddPCR System includes the following items:

- The instrument, which performs the sequential QX700 ddPCR System processes
- Attached touch screen, which is a computer that displays the software interface and connects to the instrument
- QX700 ddPCR System Control Software, which is installed on the instrument touch screen computer, and provides a user interface to
 - Control the instrument

- ☐ Set up assays
- ☐ Recover plates from run failures

Note: The QX700 ddPCR System Control Software is available in both Standard Edition and Premium Edition. The Premium Edition supports laboratories that must comply with Title 21 of the U.S. Code of Federal Regulations.

- QX700 Analyzer, which is installed on the instrument touch screen computer, and provides a user interface to
 - ☐ Collect analysis data
 - ☐ Store analysis data
 - ☐ Display analysis data

Note: The QX700 Analyzer is available in both Standard Edition and Premium Edition. The Premium Edition supports laboratories that must comply with Title 21 of the U.S. Code of Federal Regulations

- The QX700 Data Service software, which provides centralized management of the following features to comply with 21 CFR Part 11:
 - ☐ User authentication
 - ☐ Audit trails
 - ☐ Electronic signatures

Note: The QX700 Data Service works in conjunction with the QX700 ddPCR System Control Software Premium Edition and QX700 Analyzer Premium Edition.

Finding Out More

To access links to technical notes, manuals, videos, product information, and technical support, visit [bio-rad.com](https://www.bio-rad.com). The website also provides many technical resources on a wide variety of methods and applications related to PCR, Droplet Digital PCR, and gene expression.

ddPCR Experiment Overview

This section provides an overview of the ddPCR process.

To prepare, load, configure, run, and analyze a ddPCR experiment

1. Prepare a sample with a reaction mix. For more information on preparing reaction mix samples, refer to that reaction mix's instructions for use.
2. Pipette the reaction mix into the wells of the selected RDG16 Cartridge.



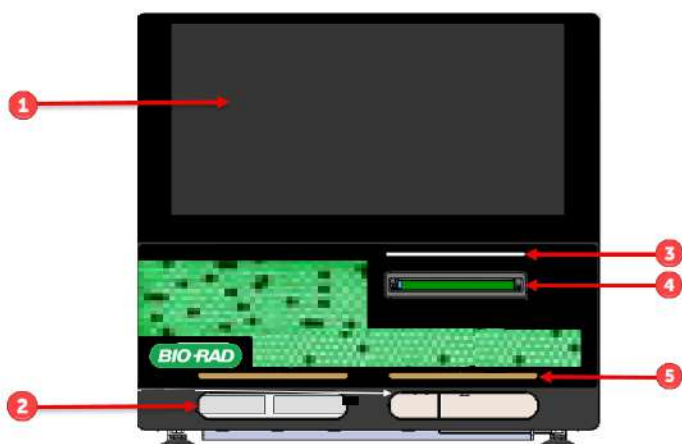
Note: For more information on pipetting samples into the cartridge, refer to the cartridge instructions for use.

3. Load the prepared plate into the QX700 ddPCR System. For more information, see [Loading Plates and Cartridges into the QX700 ddPCR System on page 62](#)
4. Create the experiment. For more information, see [Creating a ddPCR Experiment on page 66](#).
5. Launch the ddPCR protocol. For more information, see [Running a ddPCR Experiment on page 87](#)
6. Use the QX700 ddPCR System Analysis Software to perform image analysis and extract absolute quantification data. For more information, refer to the QX700 Analyzer Software User Guide.

Chapter 3 Technical Specifications

This section describes the QX700 ddPCR System technical specifications.

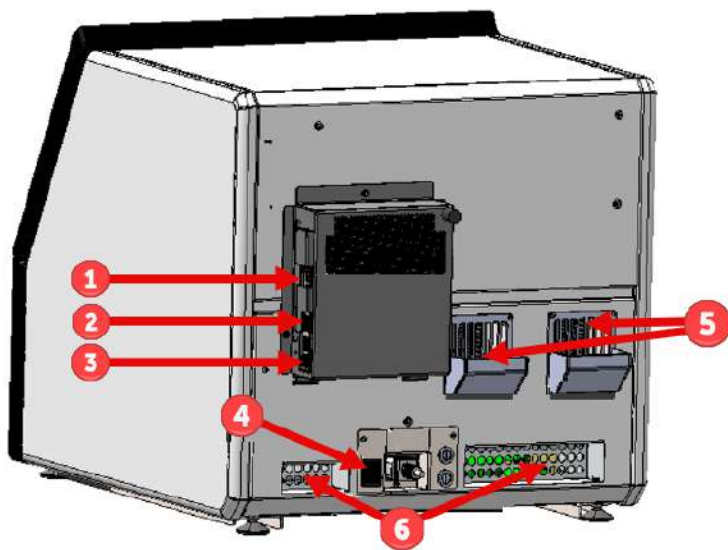
Front View



LEGEND

- | | |
|-------------------------|----------------------------------|
| 1. Touch screen display | 2. Front ventilation and handles |
| 3. Loading status bar | 4. Chip loading |
| 5. Status lines | |

Back View



LEGEND

1. Ethernet	2. HDMI port
3. USB ports	4. Power button
5. Thermal ventilation	6. Handle and ventilation

QX700 ddPCR System Dimensions

Table 5. QX700 ddPCR System dimensions

Item	Specification
Dimensions	W: 56 cm D: 65 cm H 52 cm
Weight	61kg ± 0.5kg

Imaging System Specifications

Table 6. QX700 ddPCR System Imaging System Specifications

Item	Specification
Recommended Fluorophores	FAM, HEX, Atto 550, ROX, Atto 590, Cy5, Cy5.5
Data format	.niodata, .nioexperiment, .nioprotocol, .nioassay

Technical Specifications

Table 7. QX700 ddPCR System technical specifications

Item	Specification		
	QX700 E ddPCR System	QX700 S ddPCR System	QX700 HT ddPCR System
Instrument analysis capacity*	3 RDG16 Cartridges/ 1 RDG48 Plate	12 RDG16 Cartridges/ 4 RDG48 Plates	24 RDG16 Cartridges/ 8 RDG48 Plates
Thermoblock temperature range**	25°C to 100°C		
Thermoblock control accuracy	± 0.75°C		
Thermoblock control uniformity (at 72°C)	± 0.75°C		
Thermoblock adjustable ramping	1°C to 2°C/second		
Thermoblock pressuring gas	Air		
Screen	General Touch Display module BBL228 21.5"		
Functional interfaces	1 front USB3 4 rear USB3 1 rear HDMI 1 rear Ethernet		
Barcode Reader	OEM Barcode scanner RT2058 - 1D&2D barcode		

Table 7. QX700 ddPCR System technical specifications, continued

Item	Specification
*Min capacity in a single run: 1 cartridge/ 1 plate (all QX700 ddPCR System configurations)	
Each plate can be set up for individual experimental parameters.	
After the cartridges from an individual plate are completely processed, the plate can be unloaded, and the available slot can be used to load a plate to sequence an additional experiment.	
** The thermal plate inside the QX700 ddPCR System can be set to operate at temperatures ranging from 25 to 100°C.	



WARNING! Never set the thermal plate temperature below room temperature. Doing so can damage the Peltier elements that regulate temperature and may reduce the instrument's operating life.

Important: An electrical ground is required. The instrument must be ordered with the power cable in accordance with the standards in the country of use. The instrument is shipped with the dedicated power cable. During installation, ensure that the power cable meets the standards in the country of use. If the voltage fluctuates by more than 10%, you must use a power line regulator.

For optimal performance, Bio-Rad recommends switching off the instrument at least once a week.

If the voltage fluctuates more than 10%, Bio-Rad recommends that you use a power line regulator.

Instrument Specifications

Table 8. QX700 ddPCR System instrument specifications

Item	Specification
Motherboard battery	ASROCK INDUSTRIAL IMB-1233-WV ■ BATT-LI CR2032 3V/220mAh/55mm ■ BATT-LI CR2032 3V/240mAh/55mm
CPU	I5-12400
RAM	32 GB
System drive (SSD)	2 TB
Operating system	Microsoft Windows 10 IoT Enterprise 2019 LTSC

Table 8. QX700 ddPCR System instrument specifications, continued

Item	Specification
Interfaces	■ 1 Front USB3 port + 4 Rear USB3 ports (available for mouse, keyboard or USB key/drive connection – a USB3.X external hard drive is recommended for data transfer) ■ 1 Rear Ethernet port ■ 1 Rear HDMI port

Table 9. QX700 ddPCR System recommended configuration for QX700 ddPCR System Control Software

Item	Recommended Specification
Processor	Intel Core i5 or higher, at least 2 cores of 2 GHz or higher
Graphics card	Equivalent to NVIDIA GeForce GT 1030 (or higher)
Screen	Minimum 1920 x 1080; aspect ratio 16:9
RAM	At least 16 GB
Operating system	Microsoft Windows 10 64 bits

Performance Specifications

Table 10. QX700 ddPCR System performance specifications

Item	Specification
ddPCR quantification uncertainty	+/-10% on 100-25000 cp/ μ L

Chapter 4 About QX700 ddPCR System Software

Important: This instrument guide contains abridged information on QX700 ddPCR System Control Software and QX700 Analyzer in both Standard and Premium Editions. For comprehensive information on all software capabilities, refer to the QX700 ddPCR System Software Guides for the Standard and Premium Editions.

A Bio-Rad field service engineer installs your software edition on the QX700 ddPCR System touch screen, which provides the interface to the instrument controls.

Using the software on the touch screen, you can

- Set up customized ddPCR experiments for plate runs
- Create and store templates for plate layouts, thermal cycling protocols, and reports.
- Use the live analysis function during the droplet reading phase
- Cancel runs and reorganize plates
- Analyze your data files in a variety of charts and tables in the Analysis module
- Generate reports on your data

In the Premium Edition, you can

- Produce system and experiment audit logs to ensure clear audit trails for activities and consumable/reagent use through the Event Log, Data Archive, and automatic Lot Management functions
- Safeguard user access with secure logins and traceable user activity

Important: The security controls built into the Premium Edition must be properly configured and administered by the software administrators in your organization in order to be secure and in compliance with 21 CFR Part 11.

The Premium Edition provides additional features to permit operation in compliance with Title 21 of the U.S. Code of Federal Regulations Part 11 (21 CFR Part 11) within a closed system. A closed system is defined as “an environment in which system access is controlled by the persons who are responsible for the content of electronic records that are on the system” (Section 11.3(b) (4)).

Bio-Rad makes no claim that the Premium Edition is CFR-compliant in and of itself, nor does the company guarantee compliance for the user. Your organization must establish policies and standard operating

procedures that work in conjunction with the tools provided by Bio-Rad to ensure compliance with 21 CFR Part 11.

During Premium Edition installation, users must reconfigure their credentials using QX700 Data Service Windows authentication. For more information, see [QX700 ddPCR System Control Software, Premium Edition Installation Options on page 39](#).

For information on using the QX700 Analyzer, refer to the QX700 ddPCR System Analysis Software User Guide.

This QX700 ddPCR System guides instruct you to tap options on the touchscreen. If you are using QX700 ddPCR System Software with a keyboard and mouse, click the options instead.

Installing and Updating QX700 ddPCR System Software

During installation, users can choose between QX700 ddPCR System Software Standard Edition and Premium Edition.

Important: For Premium Edition, Bio-Rad recommends switching from Standard Edition to Premium Edition during installation by a Bio-Rad specialist. The customer must ensure that an IT department administrator is available to assist the 21 CFR Part 11-compliant QX700 ddPCR System Control Software and QX700 ddPCR System Analysis Software installation. For detailed instructions on how to install and configure QX700 Data Service, see [QX700 ddPCR System Control Software, Premium Edition Installation Options on page 39](#) and [Installing QX700 Data Service on page 44](#).

You can also install the software on a personal computer and remotely connect the software to the QX700 ddPCR System.

Important: For optimal performance, Bio-Rad recommends to perform the analysis of .niodata files with QX700 ddPCR System Analysis Software on a personal computer and not on the QX700 ddPCR System instrument itself, especially when it is running.

Installing the QX700 ddPCR System Software

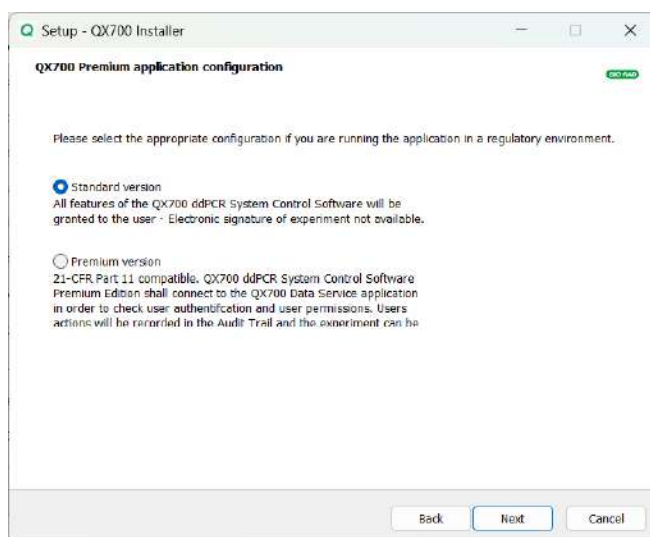
Installers of the most recent versions of the QX700 ddPCR System are available for download, free of charge, at the following link: <https://www.bio-rad.com/digital-pcr/naica-systemsupport/technical-resources/>.

Important: Please ensure that there are no more RDG48 Plates on the instrument before updating the software.

The QX700 ddPCR System Control Software installer guides you through the installation in either Standard Edition or the Premium Edition.

To install the software

1. Launch the installer. The setup wizard appears.
2. Click Next to install.
3. Select one of the versions of the QX700 ddPCR System Control Software:
 - For users that do not need to operate in compliance with Title 21 of the U.S. Code of Federal Regulations Part 11 (21 CFR Part 11), tap Standard.
 - For users required to operate in compliance with Title 21 of the U.S. Code of Federal Regulations Part 11 (21 CFR Part 11), tap Premium.



Note: If you are installing Premium Edition, the QX700 ddPCR System Control Software functions in conjunction with QX700 Data Service. See [QX700 ddPCR System Control Software, Premium Edition Installation Options on page 39](#) and [Installing QX700 Data Service on page 44](#) for the detailed instructions on how to install and configure QX700 Data Service.

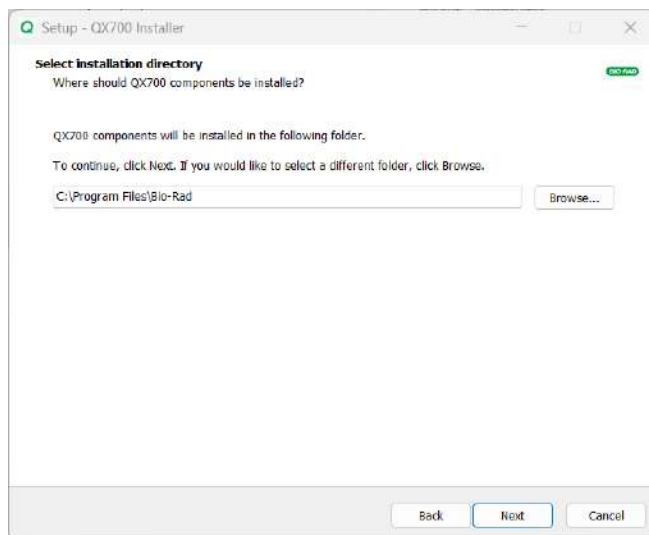
4. Click Next.
5. In the Installation Type dialog, do one of the following:
 - Tap QX700 ddPCR System Control Software Only to install the QX700 ddPCR System Control Software on a remote computer. This option installs the applications required to design experiments (Assays, Protocols and Experiment files).

You can remotely connect to the QX700 ddPCR System instrument from a personal computer, enabling you to monitor runs on the instrument in real time. Ensure that the network is correctly

configured before software installation. For more information, see [Updating Windows Defender to Enable Remote Connectivity on page 38](#).

- Tap Full QX700 ddPCR System Control Software suite to install
 - ☐ QX700 ddPCR System Analysis Software
 - ☐ QX700 ddPCR System Control Software
 - ☐ QX700 Data Service (Premium Edition only)

6. Click Next. The Select installation directory dialog appears.



7. (Optional) In the Select installation directory dialog, click Browse...to configure the network path to specify where the software components should be installed.
8. Tap Next. Depending on your software configuration, one of the dialogs appears:

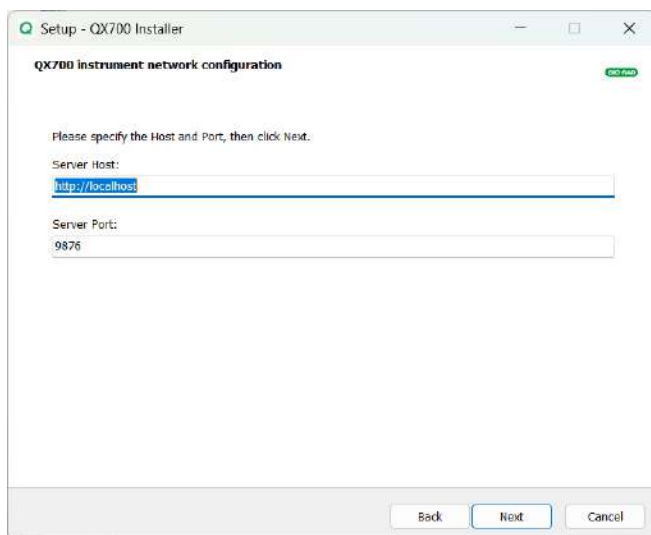


Fig. 1: QX700 ddPCR System Control Software only dialog

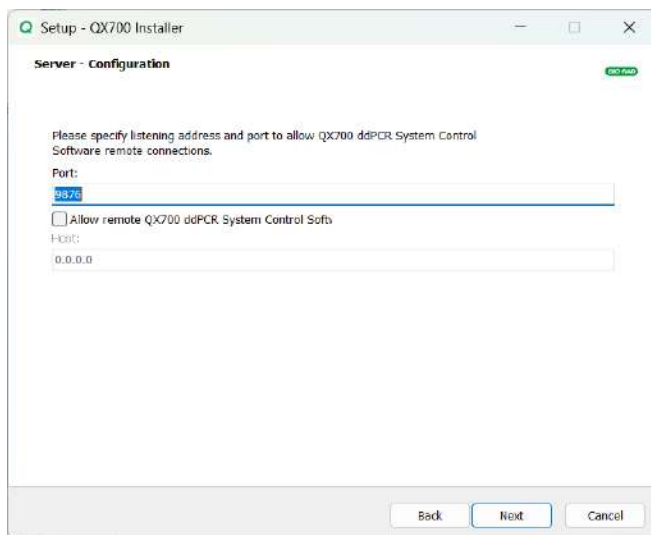
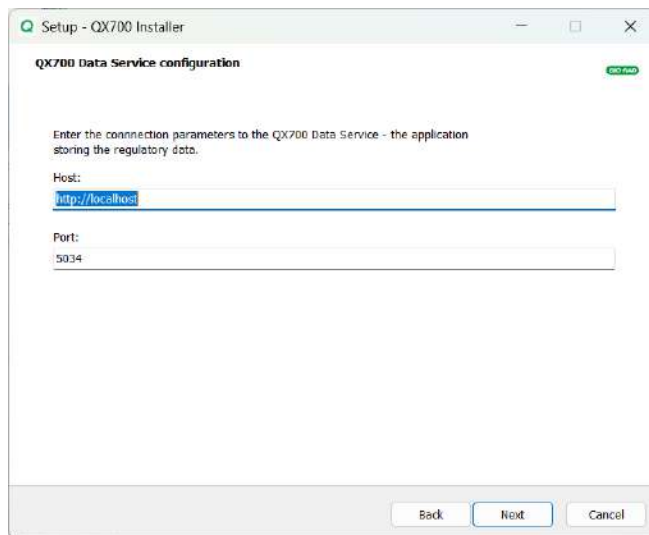


Fig. 2: QX700 ddPCR System Control Software suite configuration dialog

9. Do one of the following:
 - **QX700 ddPCR System Control Software only** – Enter the Server Host name of the computer running the QX700 ddPCR System Analysis Software. If the QX700 ddPCR System Analysis Software will not connect remotely to a QX700 ddPCR System, do not change the default Server Host and Port settings.

- QX700 ddPCR System Control Software **full suite** – Use the default settings to allow any input connection, provided Windows Defender is properly configured (see [Updating Windows Defender to Enable Remote Connectivity on page 38](#)). Contact your IT department to properly configure these parameters.

Note: For Premium Edition, the next screen prompts you to enter the connection parameters for the QX700 Data Service application.



10. Click Next. The software installation completes.
11. (QX700 ddPCR System Control Software only) After installing QX700 ddPCR System Control Software on a remote personal computer connecting connect to the QX700 ddPCR System, start the QX700 ddPCR System Control Software and check the instrument status and the server connection enabled to confirm that the installation was successful.

Note: it is possible to change the QX700 ddPCR System's server address and port directly in the QX700 ddPCR System Analysis Software in the Settings page.

Refer to the QX700 Analyzer Software User Guide user guide to install or update QX700 ddPCR System Analysis Software on either the QX700 ddPCR System or on a remote computer.

Updating Windows Defender to Enable Remote Connectivity

This section explains how to update Windows Defender to enable the software to connect to a QX700 ddPCR System remotely by creating an Inbound port rule.

Important: An IT administrator should perform this procedure once on the QX700 ddPCR System to allow remote connections from a remote personal computer.

To create an inbound port rule:

1. Open Windows Security.
2. Click Firewall & network protection.
3. Click Advanced settings to open the Windows Defender Firewall with Advanced Security window.
4. In the Rule Type field, type port.
 - Enter the rule to TCP connections and specify the port number of the QX700 ddPCR System Analysis Software server.
 - Click Allow the connection.
 - Select the network location types to which this rule applies.
 - Name the rule.
 - Click finished.

Important: Follow this procedure only if the QX700 ddPCR System uses Windows Defender as its firewall. If a different firewall is in use, apply the appropriate steps to allow external communication on the specified port between the QX700 ddPCR System Control Software (client) and the QX700 ddPCR System Control Software (server).

QX700 ddPCR System Control Software, Premium Edition Installation Options

There are three installation options for the QX700 ddPCR System Control Software, Premium Edition, depending on the customer's infrastructure and requirements. Each option requires a specific configuration:

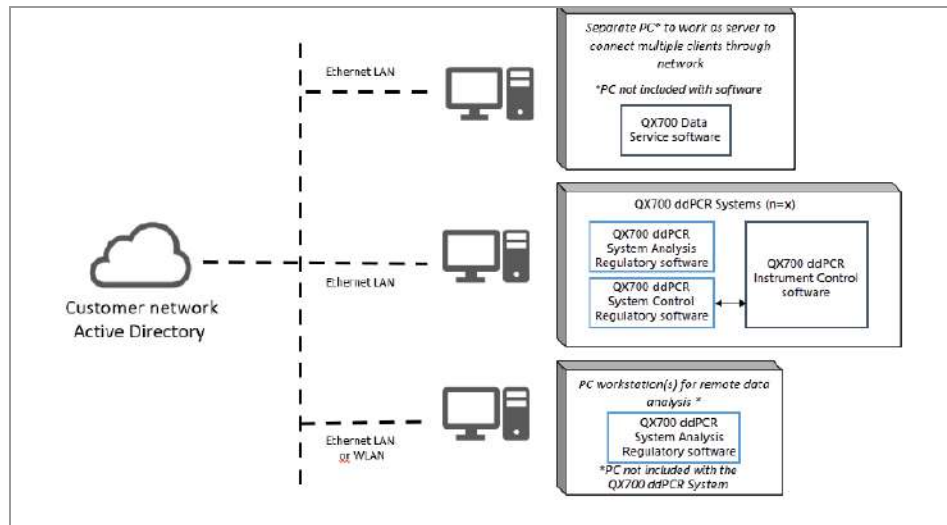
- Active Directory user authentication with a customer-hosted PC as the server
- Active Directory user authentication with the QX700 ddPCR System as the server
- Local Windows user authentication and configuration on single QX700 ddPCR System

Active Directory User Authentication with a Customer-Hosted PC as the Server

This installation option uses the user organization's Microsoft Windows Active Directory for user authentication and a user-hosted PC as the server.

- The QX700 Data Service is installed on a dedicated PC within the user's local area network (LAN).

- This server connects to multiple QX700 ddPCR Systems and other user workstations (e.g., office PCs) running the QX700 ddPCR System Analysis Software and QX700 ddPCR System Control Software, Premium Edition.
- All instruments and workstations must be connected to the same network to access the QX700 Data Service and ensure proper communication and data management.



In this configuration, the QX700 Data Service runs on a separate customer-hosted PC functioning as a server. Multiple communication sessions may simultaneously connect to this service.

During installation, verify that:

- You have established a dedicated network-hosted PC that meets all specified requirements to function as the server for the QX700 Data Service installation see [QX700 Data Service Regulatory Requirements on page 45](#).
- You have all necessary information about the designated server PC, including its I.P. address and port number.
- Microsoft Windows Active Directory user authentication can be configured on all QX700 ddPCR Systems and on all user workstations running the QX700 ddPCR System Software suite, Premium Edition.
- You have a dedicated QX700 ddPCR System guest account within Microsoft Windows Active Directory. The customer must record and securely store the guest account login credentials (user ID and password).

- A Bio-Rad representative must perform installation qualification (IQ), operational qualification (OQ), and routine service operations on the QX700 ddPCR System Software Guest accounts to comply with 21 CFR Part 11.
- If you do not have a guest account, the IQ/OQ procedure and all future service interventions will not be traceable within the 21 CFR Part 11 environment and will instead be documented separately by the Bio-Rads representative.
- Your IT department administrator is available on-site on the day of installation, as administrator privileges are required to install the 21 CFR Part 11 QX700 ddPCR System Software suite Premium Edition.

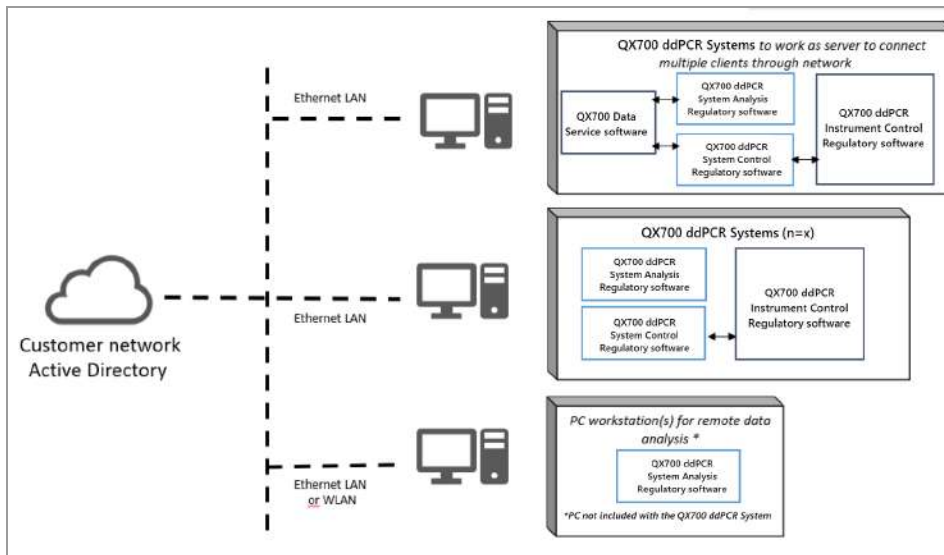
Active Directory User Authentication with a QX700 ddPCR System as the Server

Installation Requirements

In this configuration, the QX700 ddPCR System hosts the QX700 Data Service and therefore must remain powered on at all times during installation. If the instrument is powered off, the QX700 Data Service becomes unavailable to all connected QX700 ddPCR System Control Software, Premium Edition and QX700 ddPCR System Analysis Software, Premium Edition applications.

When configuring the system, users must:

- Utilize their organization's Microsoft Windows Active Directory user authentication system.
- Ensure that the local area network (LAN) is configured to host the QX700 Data Service directly on the QX700 ddPCR System.
- Ensure that all other QX700 ddPCR System and workstations (e.g., office PCs) requiring access to the QX700 Data Service are connected to the same network.
- Ensure that the QX700 Data Service can reliably communicate with all instances of QX700 ddPCR System Control Software, Premium Edition and QX700 ddPCR System Analysis Software, Premium Edition across the network.



During this installation, multiple simultaneous communication sessions can be initiated with the QX700 Data Service.

When installing, users must:

- Ensure that their IT department will provide all required information about the QX700 ddPCR System acting as the server (IP address and port number).
- Ensure that Microsoft Windows Active Directory user authentication can be configured on all QX700 ddPCR Systems and on all user workstations running QX700 Analyzer, Premium Edition.
- Ensure that their IT department will provide a QX700 ddPCR System guest account within the Microsoft Windows Active Directory user authentication. The user must record and document the guest account login details (user ID and password).
- The guest account is required by the Bio-Rad representative. This account is necessary to perform installation qualification (IQ), operation qualification (OQ), and service maintenance routines on the QX700 ddPCR System under 21 CFR Part 11 conditions.

Note: If the user cannot provide the guest account, the IQOQ procedure and all future service maintenance routines will not be tracked or traced within the 21 CFR Part 11 configuration. These procedures will instead be documented separately by the Bio-Rad representative.

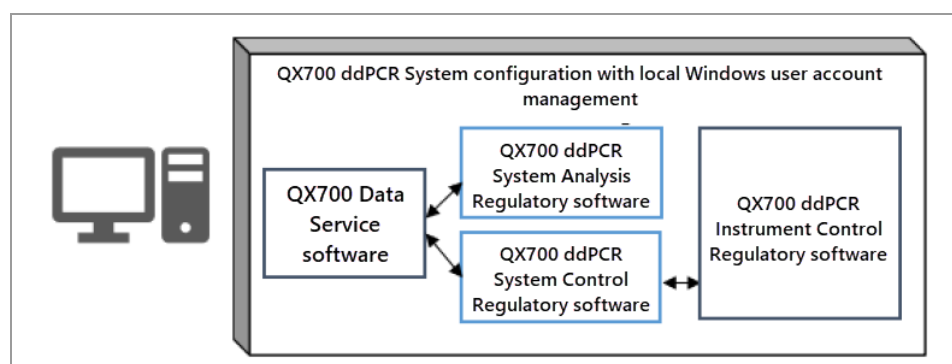
- Ensure that their IT department administrator is available on-site on the day of the installation. Administrator privileges are required for the installation of the QX700 ddPCR System Software suite Premium Edition.

Local Windows User Authentication and Configuration on Single QX700 ddPCR System

Installation Requirements

This configuration is not recommended for multi-instrument environments. Each QX700 ddPCR System functions independently and requires its own instance of the QX700 Data Service.

- Users must prepare and analyze ddPCR experiments directly on the configured QX700 ddPCR System.
- Experiments cannot be accessed or opened from any other workstation or from another QX700 ddPCR System that is not hosting the local QX700 Data Service.
- This installation uses local QX700 Data Service Windows user account authentication and does not involve network integration.
- The selected QX700 ddPCR System hosts the QX700 Data Service locally.
- The user is responsible for managing and maintaining all local Windows user accounts on the QX700 ddPCR System.
- Local Windows user account authentication must be created and maintained individually on each 21 CFR Part 11 QX700 ddPCR System.
- Custom standard experiments will not be recognized across different 21 CFR Part 11 QX700 ddPCR Systems within the same facility. Each instrument must have the standard experiments imported separately.
- Sharing experiments between 21 CFR Part 11 QX700 ddPCR Systems is not allowed.



Installing QX700 Data Service

This procedure explains how to install the QX700 Data Service and the Microsoft Windows Active Directory user authentication. The user must ensure that an IT department administrator is available to assist the 21 CFR Part 11 QX700 ddPCR System Software suite, Premium Edition installation.

The QX700 Data Service software provides centralized management for user authentication, audit trails, and electronic signatures required for 21 CFR Part 11 compliance. It works in conjunction with the QX700 ddPCR System Control Software, Premium Edition and QX700 ddPCR System Analysis Software, Premium Edition applications.

To ensure full compliance, the QX700 Data Service must be installed in addition to the QX700 ddPCR System Control Software and QX700 Analyzer software. This is network-connected application that can be installed in one of two ways:

- On a separate PC configured as a dedicated server
- Directly on the QX700 ddPCR System

Once installed and configured, the QX700 Data Service records and stores all user actions in two separate audit trails:

- The .niodata file
- The QX700 Data Service audit trail

This architecture ensures secure traceability and accountability for all system interactions.

Configuring the QX700 Data Service Web Interface

This section explains how to configure the QX700 Data Service web interface.

To configure the QX700 Data Service web interface

1. Open a web browser and enter the QX700 Data Service URL `http://<server_ip_or_dns>:<port_number>` in the address bar.
 - For network-integrated installations (for more information, see [Active Directory User Authentication with a Customer-Hosted PC as the Server on page 39](#) and [See Active Directory User Authentication with a QX700 ddPCR System as the Server](#)):
 - Replace `<server_ip_or_dns>` with the server's IP address or DNS name.
 - Replace `<port_number>` with the service port number configured during installation (default: 5034)
 - Ensure that HTTP connections are allowed on the specified port.

- For easier access, assign a DNS entry to the server (recommended).
- For local installations, use the default local URL to access the QX700 Data Service web interface <http://localhost:5034>.

Tip: Bio-Rad recommends creating a browser bookmark to the QX700 Data Service web interface URL for easier access and to avoid re-entering the full URL.

2. An IT administrator must log in using their Microsoft Windows Active Directory credentials (username and password).
3. After logging in, the IT administrator must create the first 21 CFR Part 11-compliant QX700 ddPCR System account, which must meet the following conditions:
 - The account must be assigned the Lab Manager role to enable creation of additional user accounts without further IT administrator involvement.
 - The account must be created for an end user of the QX700 ddPCR System and not for the IT administrator.

QX700 Data Service Regulatory Requirements

This section explains the QX700 Data Service regulatory requirements.

QX700 Data Service System Requirements

The QX700 Data Service can be installed directly on the QX700 ddPCR System PC or on a separate PC that meets these minimum specifications:

Table 11. QX700 Data Service specifications

Item	Specification
Operating system	Windows 10 Pro (version 21H2), 64-bit
RAM	16 GB
Processors	Intel Core i5 or higher (with at least 2 cores running at 2 GHz or higher)
Screen resolution	Resolution 1920 x 1080; 16:9 aspect ratio
Network	Wired or wireless connection supported
Disk space	Minimum of 2 GB free for software installation

The QX700 Data Service installer is available from the Bio-Rad website <https://www.bio-rad.com/digital-pcr/naica-system-support/technical-resources/>

Note: For installations that involve integration with customer networks or antivirus software, make sure that access to the following directories is not blocked:

- C:\ProgramData\Bio-Rad
- C:\Program Files\Bio-Rad
- %USERPROFILE%\Bio-Rad
- %USERPROFILE%\AppData\Local\Bio-Rad

These folders are essential for the operation and configuration of the QX700 ddPCR System Software suite.

Microsoft Windows Active Directory User Authentication

The QX700 Data Service supports Microsoft Windows Active Directory for user authentication. Bio-Rad recommends that you follow Microsoft's password policy to ensure accounts are secure and protected against unauthorized access.

If your organization's IT infrastructure allows integration with an Active Directory domain, the QX700 Data Service can be installed:

- On a separate PC configured to act as a server
- On a QX700 ddPCR System configured to act as a server

In both cases, the QX700 ddPCR System Control Software, Premium Edition and QX700 ddPCR System Analysis Software , Premium Edition applications must be configured to communicate with the QX700 Data Service on the network.

If Active Directory integration is not available, the QX700 Data Service can alternatively use local Microsoft Windows user accounts for authentication. In this configuration, the QX700 Data Service, QX700 ddPCR System Control Software, and QX700 ddPCR System Analysis Software, Premium Edition must all be installed and run on the same QX700 ddPCR System.

QX700 Data Service Security

The separate PC configured as the QX700 Data Service server must be set up so that only the IT administrator has administrative privileges to access the QX700 Data Service installation directory.

All other QX700 ddPCR System users must not have write or execute permissions for this directory.

This configuration is mandatory to ensure the security and integrity of the QX700 ddPCR System Software suite. Premium Edition. It is the customer's responsibility to implement and maintain this setup as described.

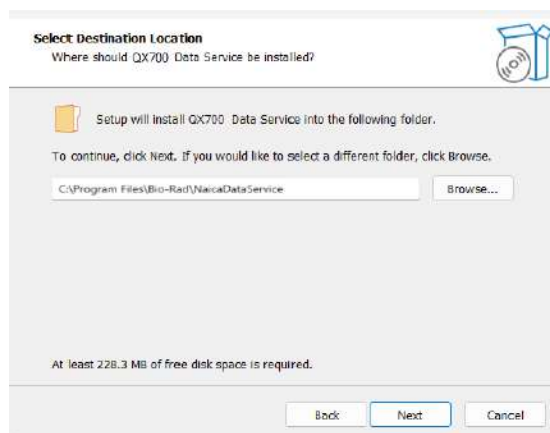
QX700 Data Service Download and Installation

You must install the QX700 Data Service on a separate PC configured as a server with IT administrator privileges.

The QX700 Data Service installer is available for download from the Bio-Rad Technical Resources page after log in at <https://www.bio-rad.com/digital-pcr/naica-system-support/technical-resources/>.

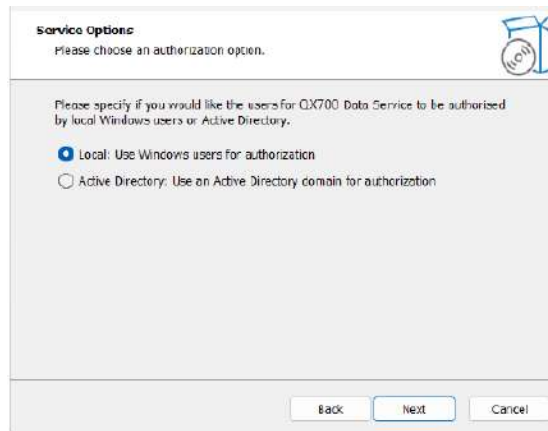
To download and install QX700 Data Service

1. Download the installation file to the PC.
2. Double-click the file to begin the installation process.
3. In the Microsoft Defender SmartScreen dialog, click More info.
4. Click Run anyway to proceed with the installation.
5. When prompted by Windows User Account Control, click Yes to allow changes to the device.
6. Select the preferred language for the installation and click Next.
7. In the Select Destination Location window, choose the installation location options:
 - Click Next to use the default location.
 - Click Browse to select a different location.

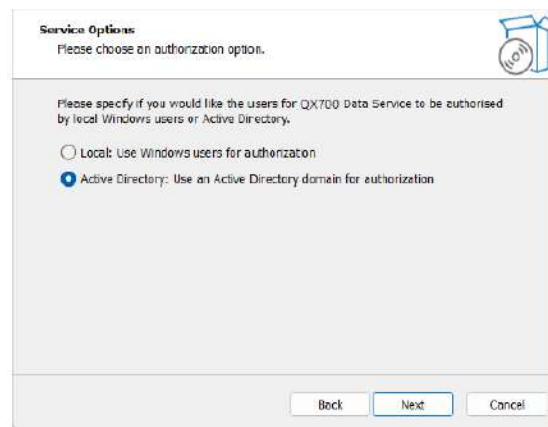


8. In the Authorization Method window, select one of the following authentication methods:
 - Local Windows user authentication (see [Local Windows User Authentication and Configuration on Single QX700 ddPCR System on page 43](#)):
 - ☐ Use this option for standalone installations on a single QX700 ddPCR System.
 - ☐ Only local access is available, and user accounts must be administered locally.

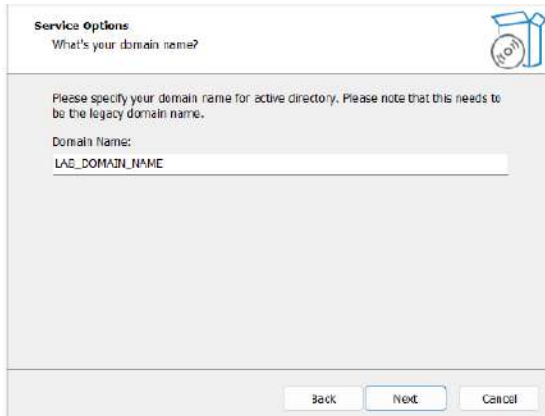
- ❑ The QX700 Data Service must be installed locally on the same instrument.
- ❑ All 21 CFR Part 11–compliant QX700 Data Service software applications can only be used locally on that instrument.
- ❑ Network access to the QX700 Data Service is not supported in this configuration.
- ❑ The user is responsible for managing and administering all local Windows user accounts on the instrument



- Microsoft Windows Active Directory authentication (see [Active Directory User Authentication with a QX700 ddPCR System as the Server on page 41](#) and [Local Windows User Authentication and Configuration on Single QX700 ddPCR System on page 43](#)):
 - ❑ Bio-Rads recommends a centralized user authentication.
 - ❑ Enables networked access for multiple instruments and workstations.
 - ❑ Allows multiple users to access 21 CFR Part 11 QX700 Data Service software applications



9. If you are authenticating with Active Directory, verify the detected domain name and modify it if necessary.



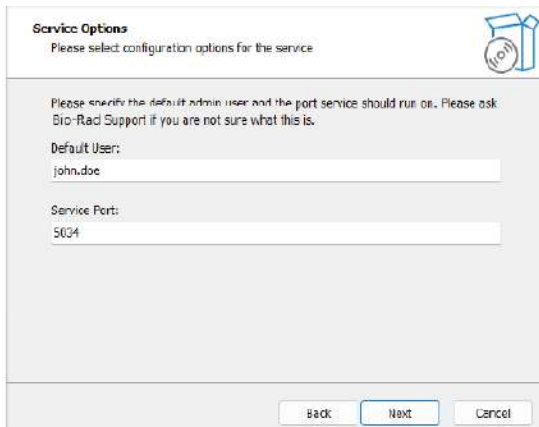
Service Options
What's your domain name?

Please specify your domain name for active directory. Please note that this needs to be the legacy domain name.

Domain Name:
LAB_DOMAIN_NAME

Back Next Cancel

- If the QX700 Data Service is to be used with Local Windows accounts (see [Local Windows User Authentication and Configuration on Single QX700 ddPCR System on page 43](#)), there is no need to provide a domain name.
- If the QX700 Data Service is to be used with Microsoft Windows Active Directory user authentication (see [Active Directory User Authentication with a Customer-Hosted PC as the Server on page 39](#) and [Active Directory User Authentication with a QX700 ddPCR System as the Server on page 41](#)), the customer-specific domain name must be configured.
- The QX700 Data Service installer will automatically detect the domain name. Verify that the detected domain is correct, and modify it if necessary.



Service Options
Please select configuration options for the service

Please specify the default admin user and the port service should run on. Please ask Bio-Rad Support if you are not sure what this is.

Default User:
john.doe

Service Port:
5034

Back Next Cancel

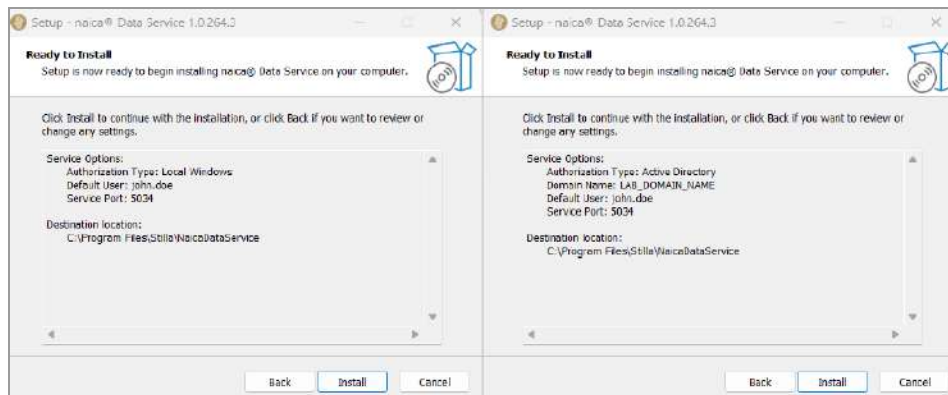
10. Specify the default Administrator user:

- The installer auto-detects the current Active Directory account as the default user.

- Verify the username and edit if needed. Bio-Rad recommends using the IT administrator's credentials.

11. Specify the Service Port number:

- Default: 5034
- You can change this value if needed.
- Ensure the selected PC allows TCP connections on the configured port.



12. Review all settings on the Ready to Install screen:

- Click Back to modify settings, if necessary.
- Click Install to proceed.

13. After installation, click Finish to exit the setup wizard. The QX700 Data Service starts automatically on the configured PC.

Note: The PC hosting the QX700 Data Service must remain powered on at all times to ensure proper 21 CFR Part 11—compliant communication between QX700 ddPCR Systems and connected workstations.

Chapter 5 Setting Up the QX700 ddPCR System

This chapter explains how to set up the QX700 ddPCR System at your site.

Important: The QX700 ddPCR System must be installed and calibrated by a Bio-Rad service engineer.

Site Requirements

Install the QX700 ddPCR System in a location that meets the following requirements

- A clean laboratory environment
- A sturdy, level surface that supports at least 65 kg and has a horizontal deviation of less than 0.3°
- A minimum of 20 cm of clearance around the QX700 ddPCR System instrument
- Room temperature between +15°C and +25°C



WARNING! The QX700 ddPCR System might consume up to 1750W. Refer to the power supply specifications in [Environment Requirements on page 19](#) for more details about power supply requirements.



WARNING! Use the instrument only in a professional laboratory environment. It may not operate properly in a domestic setting. If electromagnetic interference affects performance, restore proper function by increasing the distance between the instrument and the source of interference.

Bio-Rad recommends evaluating the electromagnetic environment before installing the instrument.



WARNING! Do not use this instrument close to high electromagnetic radiation sources (for instance “RF” sources intentionally non protected) which can disturb its right functioning.

Unpacking the Instrument

The contents of the QX700 ddPCR System includes:

- QX700 ddPCR System instrument
- Power cable
- Certificate of conformity

Note: The declaration of conformity can be downloaded in the Technical Resources web page.

Important: Use proper lifting techniques when moving and lifting the instrument to prevent damage to the instrument and personal injury. Bio-Rad recommends that three or more people lift the instrument. Use a pallet jack to move the instrument from the shipping dock to the laboratory

Important: Only a Bio-Rad representative or a user that has read this unpacking procedure can unpack the QX700 ddPCR System

Lifting the Instrument

Important: Three people are required to move the QX700 ddPCR System inside a facility.

Grip the QX700 ddPCR System by the handles shown below.



Fig. 3: Instrument Handles - Front

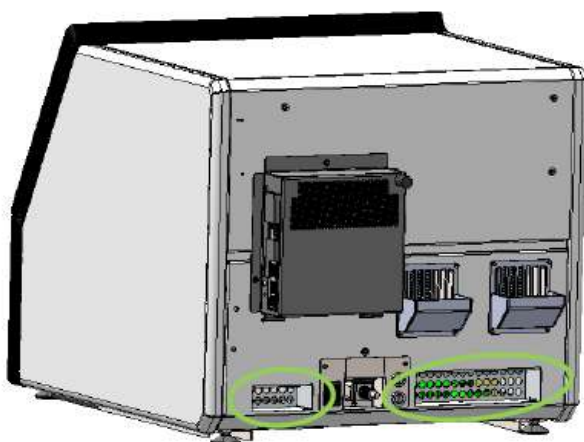


Fig. 4: Instrument Handles - Back

Instrument Setup Location

Set up the instrument in a location that supports stable operation and prevents damage by meeting the following conditions:

- Place the QX700 ddPCR System on a sturdy surface that is able to support 65 kg.
- Maintain a minimum of 20 cm of clearance around the instrument to ensure proper air circulation
- To ensure adequate ventilation and access to all interfaces and the power cord, leave a minimum of 8 in (20 cm) of clear space behind, to the right, and to the left of the instrument.
- Ensure that the back of the instrument - especially the ventilation openings – (see [Back View on page 29](#)) is protected from light (such as sun/window or artificial light). Leave a minimum of 8 in (20 cm) of clear space to avoid compromising imaging quality.
- Your instrument should be placed on a solid surface and away from other instruments that can cause vibration.
- Plug the QX700 ddPCR System using the power cord supplied by Bio-Rad into the rear of the instrument. Connect the cord at the rear of the instrument and ensure it is plugged into a grounded electrical outlet. This setup provides proper grounding and helps meet safety and regulatory requirements.
- Only use the power cord supplied by Bio-Rad to ensure that the QX700 ddPCR System operates properly and meets regulatory compliance standards.

Important: To relocate the instrument, contact a Bio-Rad representative.

Instrument Installation

A Bio-Rad specialist will configure the QX700 ddPCR System during the initial installation, which requires both hardware and software setup. A trained representative from Bio-Rad or an authorized distributor must perform this installation. The QX700 ddPCR System will be installed according to Bio-Rad specifications, and the process will be documented with an installation notice. This installation notice is required before operating the instrument.

Chapter 6 Getting Started

This section explains how to start the QX700 ddPCR System, how to adjust the screen, and the instrument status display.

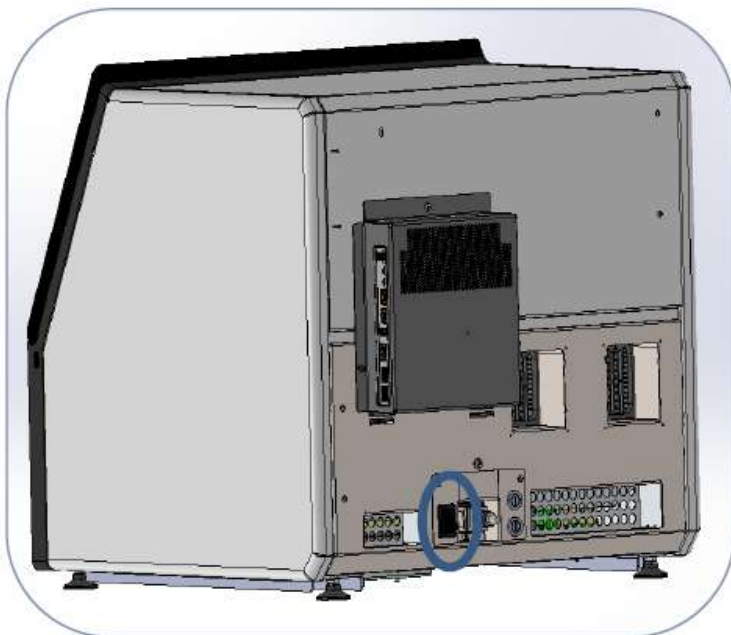
Turning on the Instrument

When the QX700 ddPCR System is powered off, the display turned off, with no lighting visible.



To turn on the instrument

1. Press the switch on the back of the instrument to power on the QX700 ddPCR System.



2. Press the power button on the front of the instrument. The button flashes to indicate power is on and the system is initializing.



Note: During initialization, the droplet panel and the two status lines on the bottom of the front door will also continue to flash.

3. After initialization:

- The start-up button disappears.
- The two status lines are illuminated in gold.
- The droplet pattern and the logo are illuminated.
- The screen displays the QX700 ddPCR System Graphic User Interface (GUI).

Adjusting the QX700 ddPCR System Screen

You can adjust the orientation of the QX700 ddPCR System's front upper panel to improve screen positioning and ergonomic use. Always grip the panel on both sides to avoid touching the touchscreen, which may activate the interface. The non-touch areas on each side of the screen are approximately 4 cm wide, as shown below.



Adjusting the Upper Panel

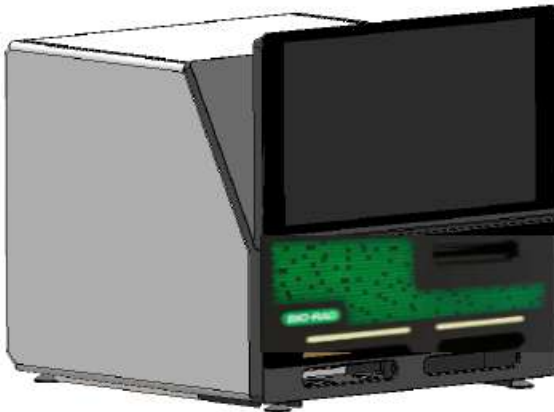
You can adjust the orientation of the upper panel between two fixed positions:

- Tilted at approximately 30° from vertical, resting against the front cover of the instrument



- Fully vertical.

Note: A mechanical stop prevents adjusting the screen beyond the vertical position.



Important: Do not force the screen beyond the specified positions (30° vertical and vertical position). Doing so can damage the instrument or cause the screen to disconnect.

Important: Do not adjust the screen while anyone's hand is behind it to avoid the risk of pinching or injury.

The QX700 ddPCR System Status Display

The front panel of the QX700 ddPCR System displays the instrument's status using two types of status lights:

- **Bottom Status Lines** – Indicates the overall status of the instrument:
 - **Off** – The instrument is turned off.
 - **Solid gold** – The instrument is ready for use.
 - **Blinking gold** – The instrument starting up and initializing.
 - **Solid red** – The instrument is in alert mode.
- **Loading status lines** – These lines are located above the RDG48 Plate, indicating the plate status:
 - **Off** – No plate loading/unloading action planned.
 - **Solid light** – The QX700 ddPCR System awaiting user action to load or unload a plate.
 - **Blinking light** – Plate is currently being loaded or unloaded.

Important: Do not obstruct the plate loading area when the light is blinking.

Logging into the QX700 ddPCR System

When the QX700 ddPCR System starts, a Windows login appears. At this screen, users can log into the system either as a User or Admin.

Note: Bio-Rad strongly recommends that users log in with the Windows User (non-Admin) account for daily operations to ensure cybersecurity best practices.

Time Synchronization

The ETA displayed on the QX700 ddPCR System Analysis Software and the timestamps recorded in the .niodata file are based on the QX700 ddPCR System local time. Modifying the system time may cause inconsistencies when connecting with other computers in different time zones.

Please refer to local IT procedure for session password updates and cybersecurity policy.

Opening the QX700 ddPCR System Software

To begin using the QX700 ddPCR System, click the QX700 System Control icon.



Note: Bio-Rad recommends running only one instance of the QX700 System Control application on the QX700 ddPCR System at a time. Do not launch multiple instances of the software within a single Windows session or across multiple user sessions. Running multiple instances may prevent the instrument from responding correctly.

At startup, the following warning might appear in the following cases:

- Multiple instances of the QX700 System Control are open under the same user session. Only one instance should remain open.
- An instance of QX700 ddPCR System Analysis Software is already running under a different user session on the QX700 ddPCR System. In this case, either switch to the active session or close the other instance before continuing.

Chapter 7 Preparing a Sample Experiment

This section contains a standard protocol for sample preparation and plate setup for any assay performed on the QX700 ddPCR System. The following are recommended steps using the compatible RDG16 Cartridges and reagents.

The QX700 ddPCR System is compatible with the following PCR mixes:

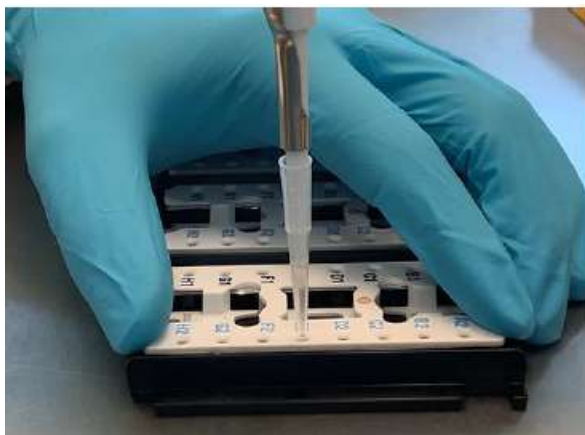
- naica multiplex PCR mix (for experiments with DNA target(s) and fluorescent probes)
- naica PCR mix (for experiments with DNA target(s) and EvaGreen® reporter)
- qScript XLT One-Step RT-qPCR ToughMix® (for experiments using RNA targets)

Note: Prepare the sample for the reaction mix only using validated ddPCR mix reagents to ensure quantitative results.

Filling the RDG16 Cartridge

To load the reaction mix

1. Pipette the reaction mix into the wells of the selected RDG16 Cartridge, which is provided in the plate for transportation and instrument operation.



Note: Both the cartridge and the plate are compatible for sample loading with automated liquid handling stations.

2. Place the prepared plate into the QX700 ddPCR System.
3. Launch the Digital PCR protocol combining partition, amplification and read-out parameters for data acquisition using up to seven fluorescent channels (FAM, HEX, Atto550, ROX, Atto590, Cy5, Cy5.5).
4. Use the QX700 ddPCR System Analysis Software to perform image analysis and extract absolute quantification data.

Required Components

This section describes the required equipment and materials for creating your samples. For a list of catalog numbers, see [Appendix C, Catalog Numbers for the QX700 ddPCR System and Accessories](#).

Required Materials

- **PCR mix** – The QX700 ddPCR System is compatible with the following PCR mixes:
 - naica multiplex PCR mix (for experiments with DNA target(s) and fluorescent probes)
 - naica PCR mix (for experiments with DNA target(s) and EvaGreen® reporter)
 - qScript XLT One-Step RT-qPCR ToughMix (for experiments using RNA targets)
- **RDG16 Cartridge** (known in this guide as cartridge)
- **RDG48 Plate**– Plates that hold 3 RDG16 Cartridges (known in this guide as plates)

Note: For more information on how to pipette samples into a cartridge, refer to the Instructions for Use for the RDG16 Cartridge.

Loading Plates and Cartridges into the QX700 ddPCR System

You must use RDG48 Plates and RDG16 Cartridges with the QX700 ddPCR System. Never attempt to load a cartridge directly into the instrument without the appropriate plate.

Cartridges are delivered in boxes of twelve, stacked in groups of four plates, with each plate holding up to three cartridges. These plates serve as both packaging and processing supports. Each cartridge must be placed in its designated well. Do not stack cartridges or load them incorrectly.

Plates can be reused up to three times only if fewer than three cartridges were processed previously. Reuse requires cleaning, following the instructions provided in the cartridge's Instructions for Use.

Do not reuse cartridges that have already been processed for thermal cycling. Also, never load a plate with a broken pin, as this can damage the instrument.

Each plate can accommodate up to three cartridges. The QX700 ddPCR System can operate with as few as one cartridge per run and accommodate varying capacities depending on the system model:

- **QX700 HT ddPCR System** – Can be loaded with up to 8 plates of 3 cartridges each (24 cartridges total)
- **QX700 S ddPCR System**– Can be loaded with up to 4 plates of 3 cartridges each (12 cartridges total).
- **The QX700 E ddPCR System** – Can be loaded with one plate of cartridges each at a time (3 cartridges total).

Loading a Plate

To load a plate

1. Configure an experiment in the QX700 ddPCR System Control Software and launch the run.
The Plan and Start page displays plate loading instructions.
2. Ensure that the loading area is available (indicated by the loading status line being steadily illuminated in white) and wait for confirmation from the GUI.
3. Insert the plate in the correct orientation and push gently until it reaches the stop position. The QX700 ddPCR System will detect the full insertion.

After the plate is correctly seated, the instrument's loading status light will begin blinking, indicating the plate has been properly detected and processing has started according to the experiment parameters.

Plate and Cartridge Loading Requirements

- Do not insert another plate until the first one has been fully loaded and the status light stops blinking.
- Loading two plates in succession without waiting may shift the position of a stored plate and crash the loading module.
- Only insert validated plates. No other objects should be placed in the loading area.
- Do not insert plates in the wrong orientation, as this may damage the loading mechanism.
- Do not manually remove a plate after inserting it. If you need to retrieve a plate, allow the instrument to load it fully into the storage area, then use the software to initiate unloading.
- Do not load a plate while an unloading process is active. Wait until the status light stops blinking and the loading area becomes available.

- Do not re-insert a previously processed cartridge for another thermal cycling program. Additionally, never attempt to load a plate that has a broken pin, as this can damage the QX700 ddPCR System instrument.
- Do not load a plate with a broken pin



Fig. 5: Damaged cartridge with broken pin

Loading Cartridges with Altered Barcodes

The QX700 ddPCR System automatically reads the barcodes of up to three cartridges onto a plate.

During the cartridge loading phase, the barcode readers detect the cartridges and identify their barcodes to:

- Associate each cartridge with its assigned experiment

- Ensure full traceability of the process and results

If a barcode cannot be read, you can manually enter the barcode and associate it with the correct cartridge position and experiment. In this case:

- The instrument cannot verify the format or content of manually entered barcodes
- You are responsible for ensuring the accuracy of the barcode information
- The cartridge will still be processed, but the system cannot confirm that the result matches the correct cartridge during unloading
- You must confirm that the cartridge is in the expected position and orientation in the plate as shown on the GUI

When the system detects a missing barcode, it ejects the plate to enable you to:

- Check the position and orientation of all cartridges
- Correct any mistakes in cartridge placement or alignment
- Manually enter the barcode if needed

You must completely remove the plate from the instrument before reloading it. This allows the QX700 ddPCR System to properly position the plate.

Chapter 8 Creating a ddPCR Experiment

This section explains how to create a ddPCR experiment. To create a new experiment, you must:

- Define a new or open an existing protocol
- Design a new or open an existing assay
- Configure a new or run an existing experiment

Important: Do not operate other instruments or perform any actions near the QX700 ddPCR System that could cause shocks or vibrations while it is running (especially during cartridge imaging).

Vibrations can interfere with system performance and compromise results.

Note: You can import or export setup experiment setup information with a USB stick. Always ensure that the USB stick is not infected by malicious software before connecting it to the system.

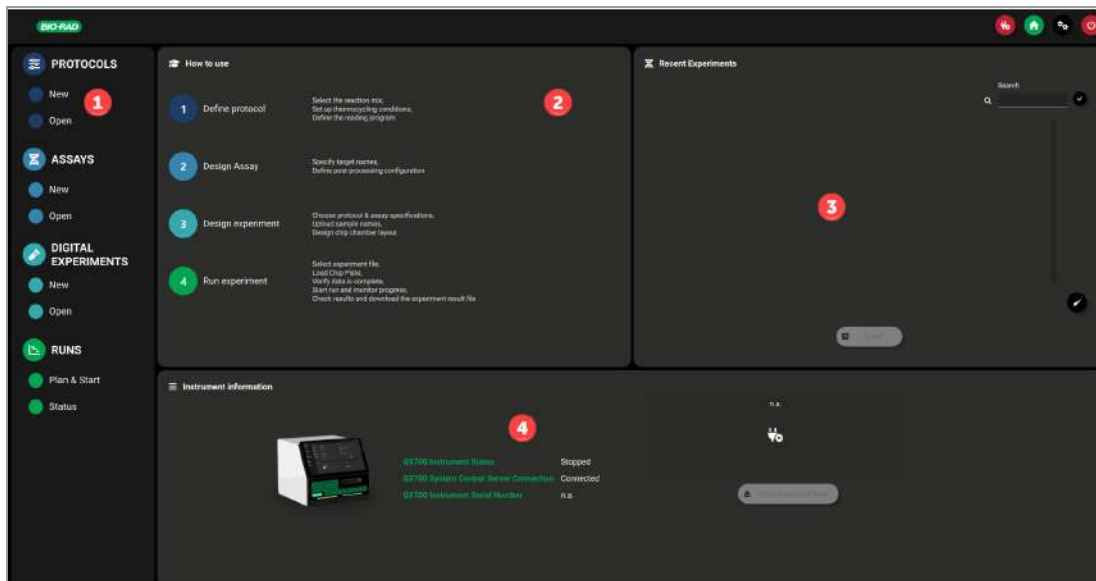
The Home Screen

The Home screen displays after the QX700 ddPCR System Analysis Software launches.

On the Home screen, users can:

- Create new or open existing protocols, assays, experiments, or runs
- Access recent experiments
- Unload plates
- View the instrument status

The system provides all necessary functionality to create, run, and analyze ddPCR experiments on your samples. The following image highlights functional areas:



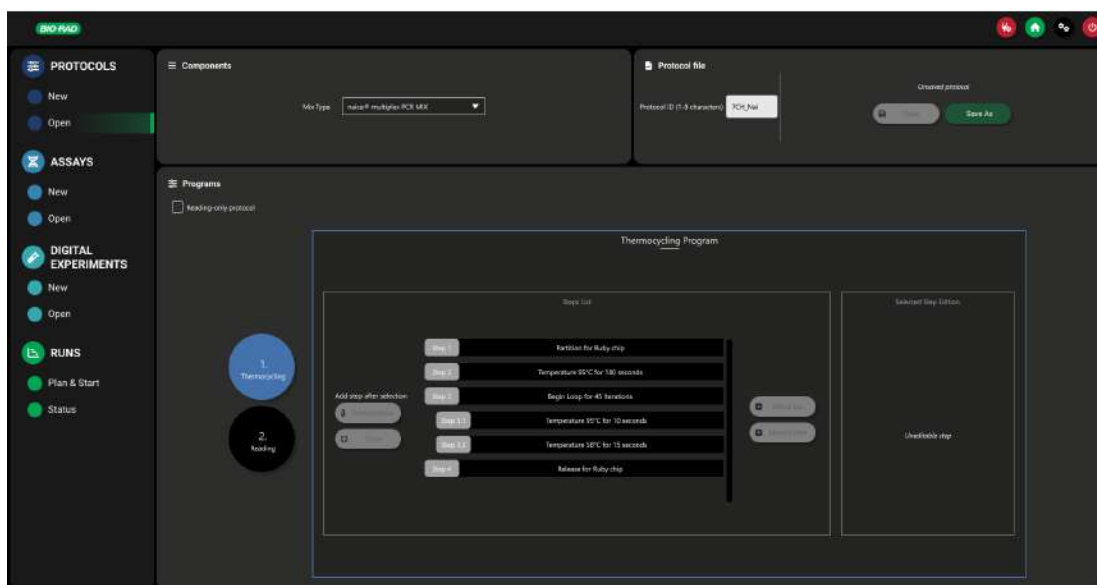
LEGEND

- | | |
|---|--|
| 1 | Left navigation bar |
| 2 | Overall experiment procedure |
| 3 | List of recent experiments |
| 4 | QX700 ddPCR System status plate unloading pane |

Defining the Protocol

To run an experiment, you must either create a new protocol or select an existing one. A protocol specifies the instructions the instrument will follow, including mix type, PCR program, and scanning conditions such as activated channels and their corresponding exposure times.

Click **New** in the Protocols section of the left navigation menu to create a new protocol. Click **Open** to open an existing one.



Note: By default, all experiments include two options: Thermocycling and Reading. For read-only protocols, you can remove the thermal cycling step by clicking the Reading-only protocol check box in the upper left of the Programs section.

From this screen, you can

- Save the protocol and define its file name
- Set a protocol ID (from 1 to 8 characters). This ID is used to tag the protocol for easier identification on the Experiment screen and in split results (see [Composite Experiments on page 81](#)).

Note: If the system uses a protocol created with former versions of QX700 ddPCR System Control Software (v 1.0 or v1.1), a default protocol ID will be automatically assigned in the format PRT+I, where "I" is a sequential number.

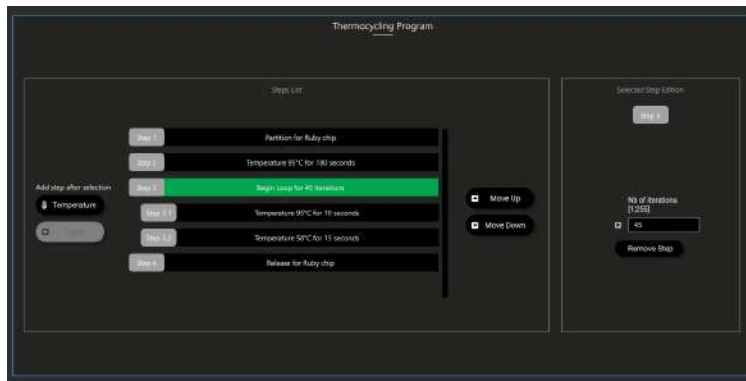
- Select a PCR mix. For more information on mixes, see [Required Components on page 62](#).

Note: Use the naica ddPCR Mix for experiments with DNA target(s) and EvaGreen® reporter. Select Blue reference or Infra-Red reference to use the blue or infra-red channel, respectively, as the reference channel for droplet detection.

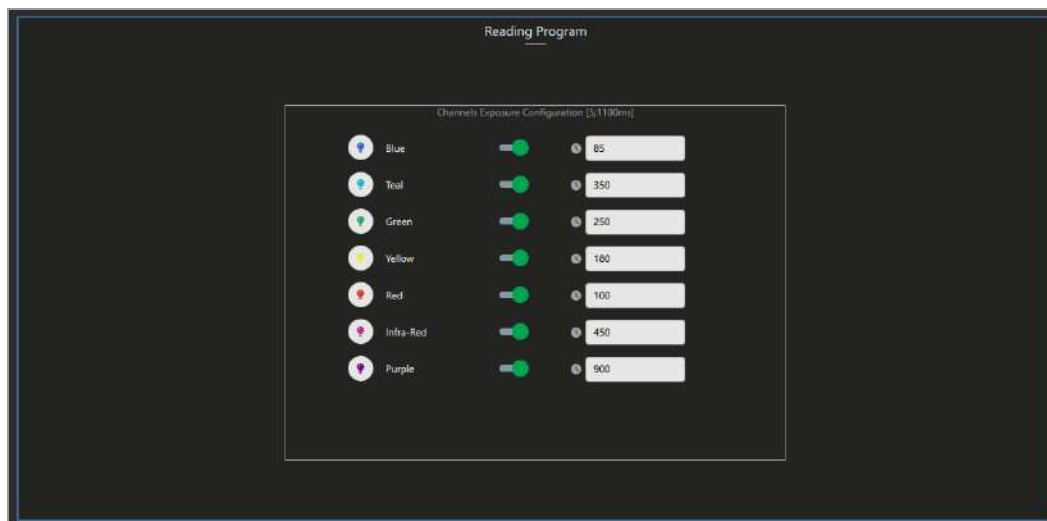
Important: The mix type defines the droplet size used by QX700 ddPCR System Analysis Software to calculate target concentration. It is important to select the correct mix type to match the PCR mix used in the experiment. By default, no mix type is selected. For a list of PCR mixes, see [Preparing a Sample Experiment on page 61](#).

- Set the PCR run step parameters:

- ☐ Add, move, or delete run steps
- ☐ Set the temperature (in °C), run duration (in seconds), and ramp rate (in °C per second) for per step
- ☐ Set the number of PCR cycles for per step
- ☐ Adapt the altitude for the partitioning step to >500m



- ☒ Configure the Reading Program channel exposure:
 - ☐ Enable or disable channels
 - ☐ Set the exposure times for each channel (in milliseconds)



Protocol Templates

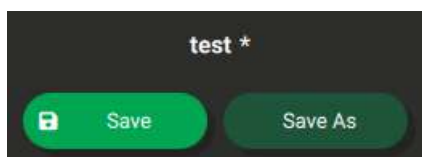
When creating a new protocol, the software provides an option to start either from scratch or from an existing protocol. Four protocol templates are pre-loaded and can be used as starting points:

- **Template_PCR-45-cycles_7channels_naica-multiplex-PCR-MIX_RubyChip_v1.1** – for experiments targeting DNA with TaqMan probes.
- **Template_PCR-45-cycles_Evagreen-BlueDetection_naica-PCR-MIX_RubyChip_v1.1** – for experiments targeting DNA with EvaGreen and using the blue channel as reference channel for droplets recognition.
- **Template_PCR-45-cycles_Evagreen-InfraRedDetection_naica-PCR-MIX_RubyChip_v1.1** – for experiments targeting DNA with EvaGreen® and using the infrared channel as reference channel for droplets recognition.
- **Template_PCR-45-cycles_7channels_Quantabio-qScript-XLT-1-Step-RT-qPCRToughMix_RubyChip_v1.1** – for experiments targeting RNA with TaqMan probes.

Saving Protocols

After creating the protocol, click Save or Save As to store it as a .nioprotocol file, which is used in the Digital Experiments panel.

- Before saving the protocol, the label “unsaved protocol” appears above both the Save and Save As buttons.
- When editing an existing protocol, an asterisk (*) appears next to the protocol name to indicate that there are unsaved changes.



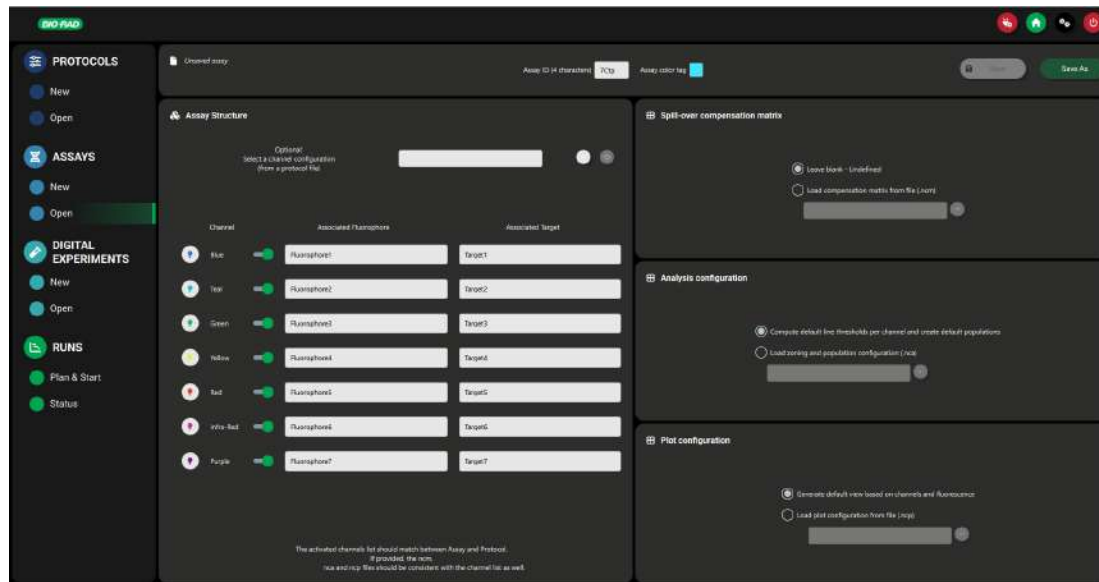
Tip: You can create a protocol definition using the QX700 System Control on a personal computer without requiring a connection to the QX700 ddPCR System instrument.

Designing the Assay

To run an experiment, you must design a new assay or open an existing one. Assays contain information related to the targets and fluorophores, as well as the parameters used to analyze and display results in

the QX700 ddPCR System Analysis Software.

Click New in the Assays section of the left navigation menu to create a new assay. Click Open to open an existing one.



From the Assays screen, you can

- Assign a 4-digit assay ID
- Apply a color tag to the assay
- Name the fluorophore or target
- Configure the assay structure:
 - Activate or deactivate fluorophores to each channel, and rename associated fluorophores
 - (Optional) Import a list of activated channels from the protocol by loading a .nioprotocol file. To do this, click the ellipses (...) button.



- Activate or deactivate targets to each channel and rename targets
- Define how to analyze and display the results in QX700 ddPCR System Analysis Software by:
 - Loading a spill-over compensation matrix (ncm file)

- ☐ Loading an analysis configuration file (nca file)
- ☐ Loading a plot configuration file (ncp file)

Note: These configuration files can be created or modified in the QX700 ddPCR System Analysis Software. For more information on how to use or customize these files, refer to the QX Analyzer Software User Guide.

After configuring the assay, click Save or Save As in the upper right.

Assay Templates

When creating a new assay, the software provides an option to start either from scratch or from an existing assay. Two assay templates are pre-loaded and can be used as starting points:

- **Template_multiplex_7channels_RubyChip_v0.1** – Activates all seven fluorescent channels.
- **Template_naica-PCR-MIX_Evagreen_RubyChip_v0.1** – Activates the following channels:
 - ☐ Blue for Evagreen fluorescent reporters
 - ☐ Infra-red for AlexaFluor647 fluorescent reporters

Note: The green channel does not activate fluorescent reporters.

Saving Assays

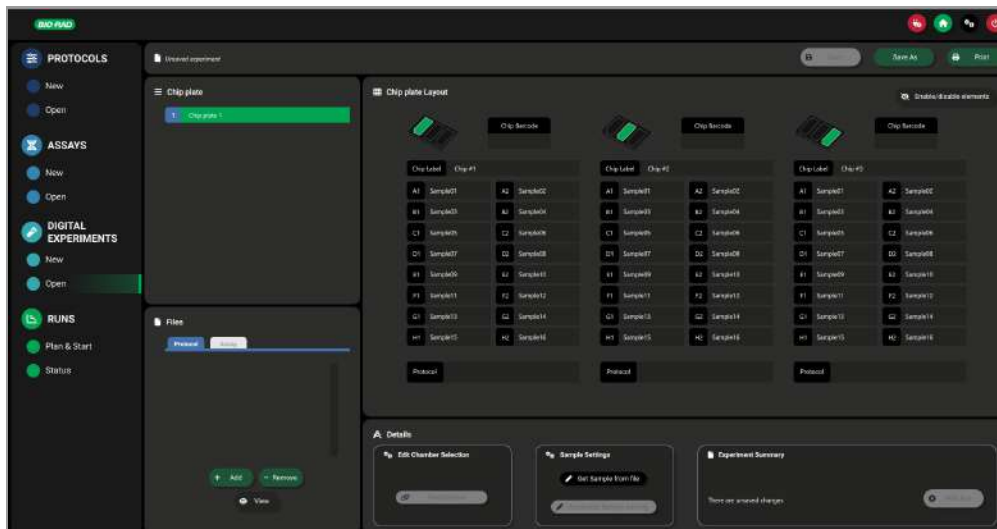
After creating or modifying an assay, click Save or Save As. This stores the assay as a .nioassay file which you can use in the Digital Experiments panel.

- While the assay is unsaved, the label “unsaved assay” appears above both the Save and Save As buttons.
- When editing an existing assay, an asterisk (*) appears next to the assay name to indicate that there are unsaved changes.

Note: You can create an assay definition using the QX700 ddPCR System Analysis Software on a personal computer without connecting to the QX700 ddPCR System instrument.

Configuring the Experiment

To run an experiment, you must create a new one from scratch, load a Standard Experiment file (.niostexperiment), or open an existing experiment.



From this screen, you can:

- Create a blank experiment or use a template.
- Assign protocols and assays
- Define the cartridge or well layout
- Manually enter modify cartridge bar codes and labels as well as sample data.
 - Double-click the well ID label (next to the sample name field) to open the editor.
 - To rename a sample directly, double-click the sample field in the Chip Plate Layout.

Note: You can assign different assay files to different wells within a plate. When this occurs, the experiment is treated as a composite experiment, and the results may be split into multiple .niodata files. For more information, see [Composite Experiments on page 81](#).

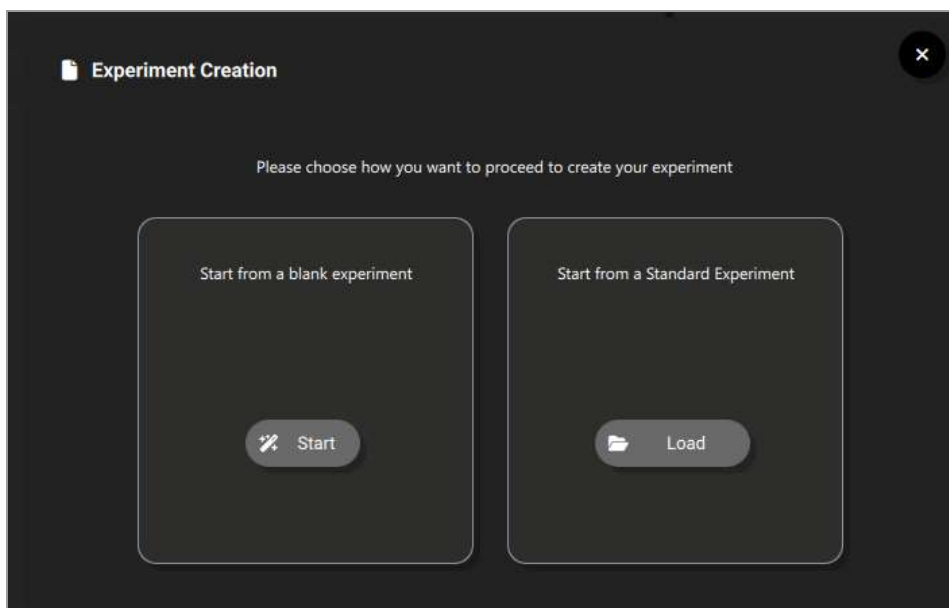
Tip: Use the Enable/disable elements button to exclude specific wells from assay assignment.

Creating a New Experiment

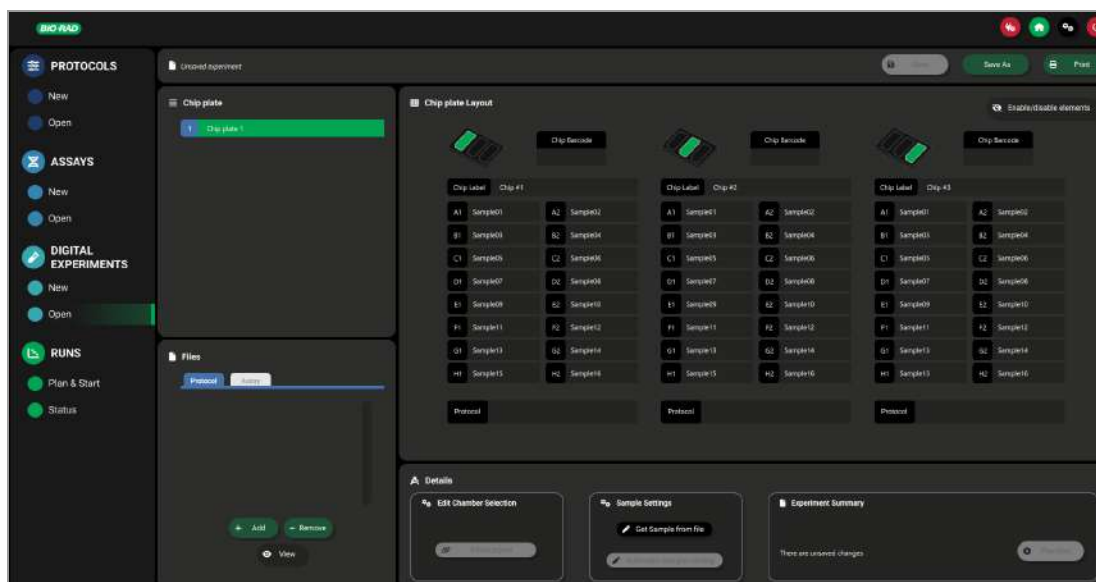
This section explains how to create a new experiment.

To create a new experiment

1. Click New in the Digital Experiments section of the left navigation menu.
The Experiment Creation dialog opens.



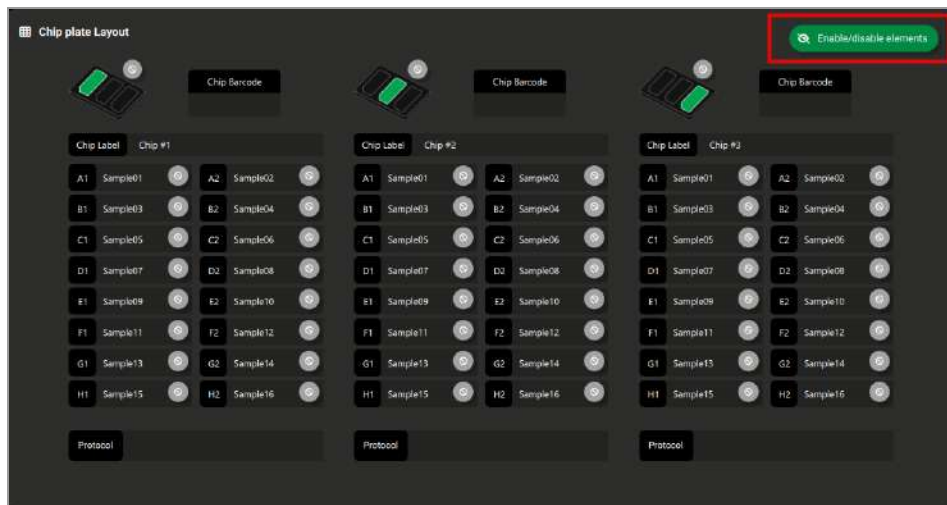
2. Do one of two things:
 - Tap Start to start from a blank experiment (no template)
 - Tap Load to load a template.
3. The screens populates with the experiment details.



In this screen you can:

- Name the experiment.
 - Specify the layout of the plate:
 - At this stage, cartridge barcodes can be entered manually or left blank until scanned by the QX700 ddPCR System
 - The cartridge label (and Sample name) fields are optional and can be used to assign custom names to cartridges (or wells).
- Note:** The cartridge label is not visible in the QX700 System Control software. Bio-Rad recommends using it to identify cartridges during loading, but not for software-based traceability.
- Use the Enable/disable elements button to activate or deactivate a custom set of wells and/or cartridges.

Important: To create an experiment you must assign at least one protocol and one assay. For more information on creating protocols and assays, see [Protocols Screen on page 1](#) and [Assays Screen on page 1](#).



- Assign a protocol (or assay) to each enabled cartridge (or well) on the plate. To do this, load the corresponding .nioprotocol (or .nioassay) files into the experiment beforehand.
- Load a protocol (or assay) by clicking Add in the Protocol (or Assay) section of Files menu

Tip: You can import multiple protocol (or assay) files at the same time in by selecting them in your browser window.

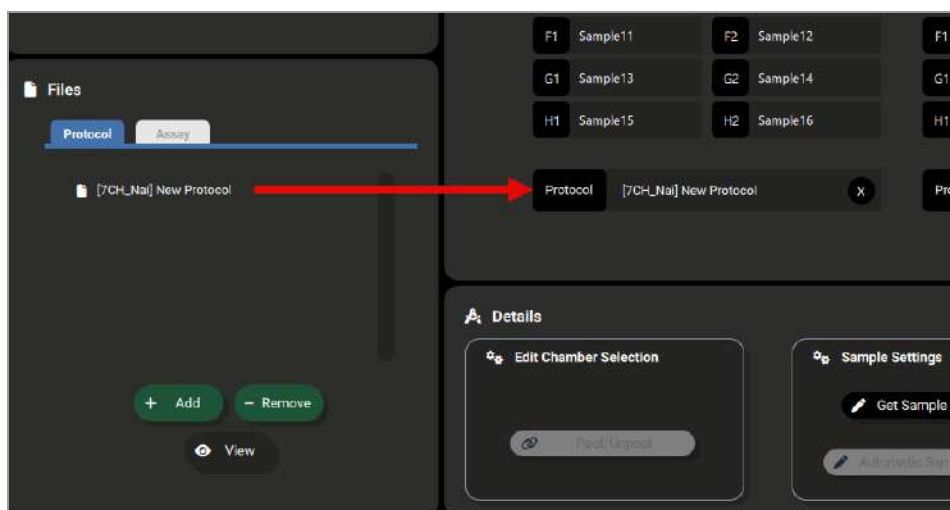
Assigning a Protocol to a Cartridge

To assign a protocol to a cartridge

1. Select a protocol from the Protocol tab of the Files section.

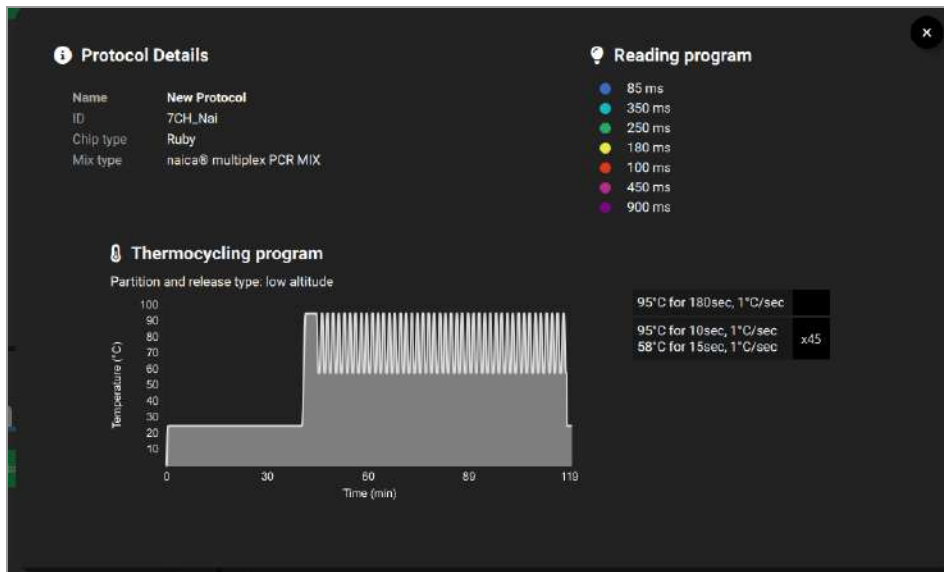
Note: You must create a protocol before assigning a protocol to a cartridge. For more information, see [Protocols Screen on page 1](#).

2. Drag the protocol from the protocol library to the Protocol box under the cartridge.



Viewing Protocol Details

To view protocol details, select a protocol and click the View button. The Protocol Details window appears, summarizing the protocol contents, including thermocycling (if applicable) and reading programs.

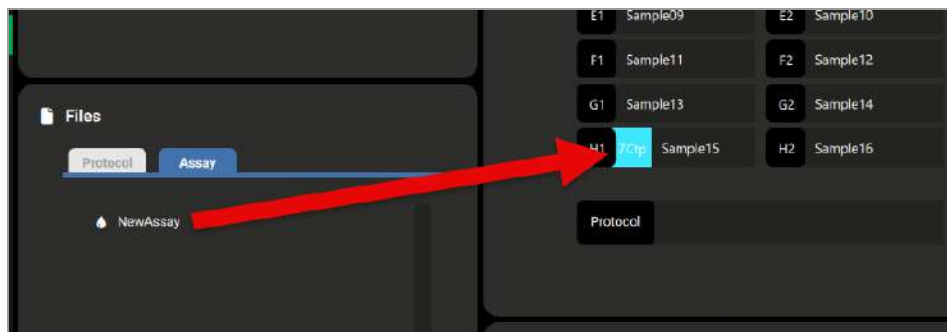


Note: Protocols can vary between cartridges on the same plate. In this case, the experiment is treated as a composite experiment, and the results may be split into multiple .niodata files. For more information see [Composite Experiments on page 81](#)

Assigning an Assay to a Cartridge

To assign an assay to a cartridge

1. Select an assay from the Assay tab of the Files section.
2. Drag the assay from the protocol library to the assay box under the cartridge .

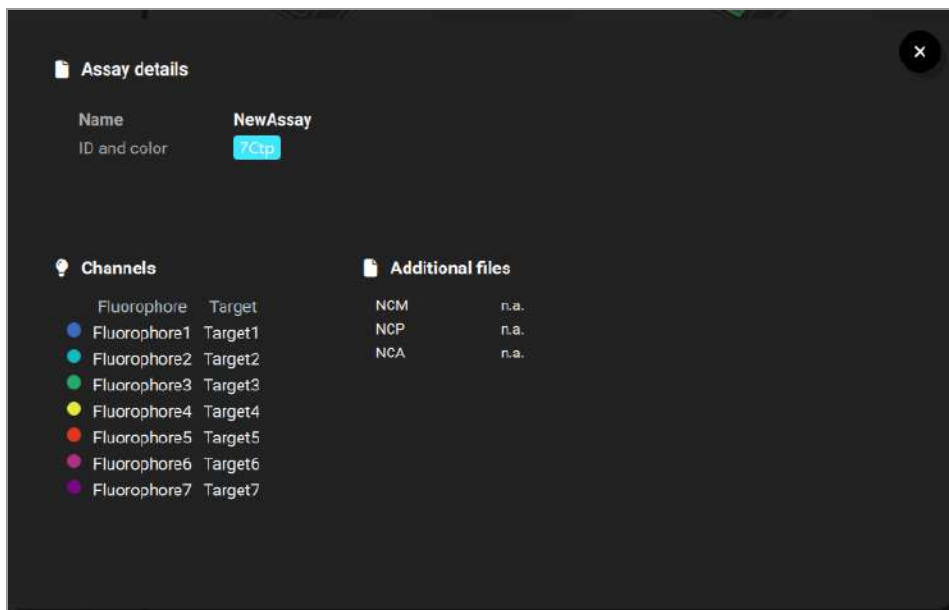


Note: When you drag and drop an assay onto a well, the assay is assigned to that well. If multiple wells are selected (including the one where the file is dropped) the assay is assigned to all selected wells.

Tip: To select all wells on a cartridge, click the cartridge icon next to the cartridge barcode field.

Viewing Assay Details

To view assay details, select an assay and click the View button. The Assay Details window appears, summarizing the assay contents.



Note: You can assign different assay files to different wells within a plate. When this occurs, the experiment is treated as a composite experiment, and the results may be split into multiple .niodata files. For more information, see [Composite Experiments on page 81](#).

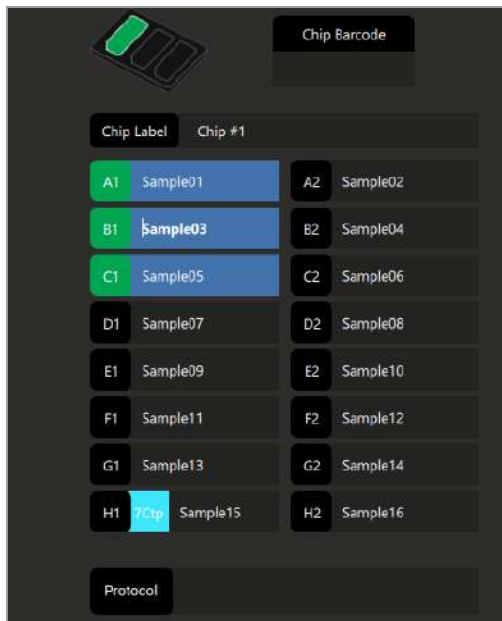
Tip: Use the Enable/disable elements button to exclude specific wells from assay assignment.

Details Panel

The Details panel of the Digital Experiments screen allows you to enter additional information about each well.

Edit Chamber Selection

In the Edit Chamber Selection menu, you can pool wells that contain the same reaction mix (for example, the same sample) for a combined analysis. To pool wells, select them and click Pool.



After wells are pooled, the software automatically assigns the same sample name with an index.



To unpool samples, select the pooled wells and tap Unpool in the Edit Chamber Selection menu.

Note: Pooled wells must share the same protocol and assay.

Sample Settings

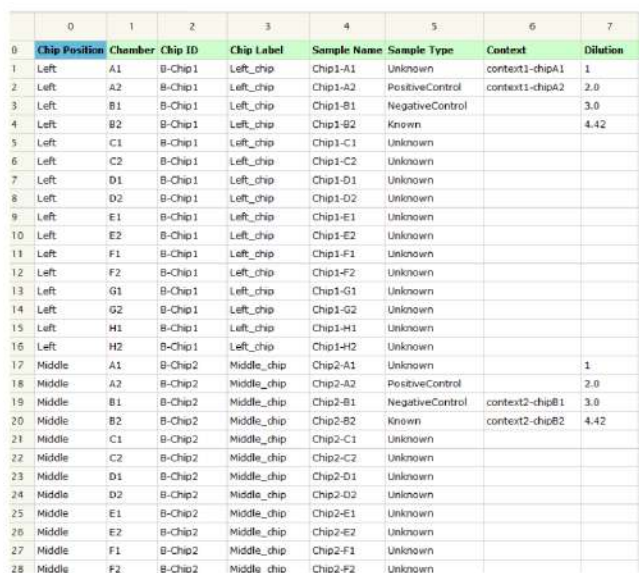
Use the Sample Settings menu to load sample information from a CSV file. The CSV file should include the following information:

- Well position
- Sample name
- Sample type (Positive Control, Negative Control, Known, or Unknown)
- Dilution factor
- Additional contextual details

Template CSV files for sample import are available at: C:\Users\Public\Bio-Rad\QX700SystemControl.

Two formats are available:

- **Template_NCT_Input_sortByColumn.csv** – Wells ordered by column
- **Template_NCT_Input_sortByRow.csv** – Wells ordered by row



	0	1	2	3	4	5	6	7
	Chip Position	Chamber	Chip ID	Chip Label	Sample Name	Sample Type	Context	Dilution
1	Left	A1	B-Chip1	Left_chip	Chip1-A1	Unknown	context1-chipA1	1
2	Left	A2	B-Chip1	Left_chip	Chip1-A2	PositiveControl	context1-chipA2	2.0
3	Left	B1	B-Chip1	Left_chip	Chip1-B1	NegativeControl		3.0
4	Left	B2	B-Chip1	Left_chip	Chip1-B2	Known		4.42
5	Left	C1	B-Chip1	Left_chip	Chip1-C1	Unknown		
6	Left	C2	B-Chip1	Left_chip	Chip1-C2	Unknown		
7	Left	D1	B-Chip1	Left_chip	Chip1-D1	Unknown		
8	Left	D2	B-Chip1	Left_chip	Chip1-D2	Unknown		
9	Left	E1	B-Chip1	Left_chip	Chip1-E1	Unknown		
10	Left	E2	B-Chip1	Left_chip	Chip1-E2	Unknown		
11	Left	F1	B-Chip1	Left_chip	Chip1-F1	Unknown		
12	Left	F2	B-Chip1	Left_chip	Chip1-F2	Unknown		
13	Left	G1	B-Chip1	Left_chip	Chip1-G1	Unknown		
14	Left	G2	B-Chip1	Left_chip	Chip1-G2	Unknown		
15	Left	H1	B-Chip1	Left_chip	Chip1-H1	Unknown		
16	Left	H2	B-Chip1	Left_chip	Chip1-H2	Unknown		
17	Middle	A1	B-Chip2	Middle_chip	Chip2-A1	Unknown		1
18	Middle	A2	B-Chip2	Middle_chip	Chip2-A2	PositiveControl		2.0
19	Middle	B1	B-Chip2	Middle_chip	Chip2-B1	NegativeControl	context2-chipB1	3.0
20	Middle	B2	B-Chip2	Middle_chip	Chip2-B2	Known	context2-chipB2	4.42
21	Middle	C1	B-Chip2	Middle_chip	Chip2-C1	Unknown		
22	Middle	C2	B-Chip2	Middle_chip	Chip2-C2	Unknown		
23	Middle	D1	B-Chip2	Middle_chip	Chip2-D1	Unknown		
24	Middle	D2	B-Chip2	Middle_chip	Chip2-D2	Unknown		
25	Middle	E1	B-Chip2	Middle_chip	Chip2-E1	Unknown		
26	Middle	E2	B-Chip2	Middle_chip	Chip2-E2	Unknown		
27	Middle	F1	B-Chip2	Middle_chip	Chip2-F1	Unknown		
28	Middle	F2	B-Chip2	Middle_chip	Chip2-F2	Unknown		

Figure 31: Example of a filled .csv input file from the Template_NCT_Input_sortByRow.csv template

Naming Samples

You can manually edit sample information in the Chip Plate Layout by:

- Double-clicking the sample name field in a chamber to edit it directly.
- Double-clicking the chamber ID label (next to the sample name) to open the Chamber Editor, where you can edit sample details.

For repetitive naming patterns, use the Automatic Sample Naming allows you configure naming rules, such as:

- Add a date (multiple formats available)
- Add a static sample name
- Add an index (custom start value)
- Set a separator character
- Define the order of elements

- Preview the generated names

Printing

After the experiment's assay and protocols are configured, you can print the layout by clicking Print in the top-right corner of the Digital Experiments page. This generates a printable PDF file.

Important: You can only edit .nioprotocol, .nioassay, and .nioexperiment files in QX700 ddPCR System Control Software.

Users without Admin rights should not access the ProgramData directory to avoid altering temporary run data.

Composite Experiments

A composite experiment includes multiple protocols and/or assays in a single experiment. It can include wells with varying parameters such as mix type, target names, fluorophores, etc.

Composite experiments enable you to take full advantage of the QX700 ddPCR System's high-throughput capacity and flexibility by allowing:

- Assignment of different protocols with distinct scanning conditions to cartridges on the same plate
- Assignment of different assays to different wells on the same cartridge

Note: Assays and protocols are linked by their activated channels. All assays assigned to wells on a given cartridge must match the channel configuration of the protocol assigned to that cartridge.

For wells to be analyzed together in the QX700 ddPCR System Analysis Software, they must share the following experimental parameters:

- Mix type
- Activated channels
- Exposure times of the activated channels
- Target names
- Fluorophores
- Thresholding mode
- Defined populations
- Compensation matrix

As a result, the output from a composite experiment might be split into multiple .niodata files based on the similarity of protocol and assay characteristics. When you click Get Results, the software generates

separate .niodata files for wells that share the same protocol and assay layout. Each .niodata file contains wells that share both the same protocol and the same assay.

The data is split first by protocol, and then by assay.

Note: If the only difference between two protocols is the PCR program (e.g., annealing temperature), the data will not be split into separate .niodata files. This allows you to post-process assay optimization experiments run under varying thermal conditions. However, if other characteristics differ (e.g., mix type or scanning parameters), the data will be split.

When the QX700 ddPCR System Control Software splits results into multiple .niodata files, it applies a naming convention based on the plate layout defined in the experiment.

Consider a composite experiment configured as follows:

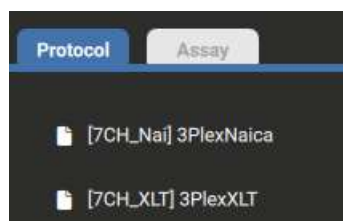
	Chip1		Chip2		Chip3	
	Column1	Column2	Column1	Column2	Column1	Column2
Protocol	1	1	1	1	2	2
Assay	1	2	1	1	1	1

- Protocol 1: Named “3Plex naica”, with tag 3PlexNai
- Protocol 2: Named “3PlexXLT”, with tag 3PlexXLT

These protocols differ in mix type, which affects the analysis in QX700 ddPCR System Analysis Software and qualifies the data to be split.

Note: If the only difference between protocols were the number of PCR cycles, the data would not be split, as that does not impact analysis in QX700 ddPCR System Analysis Software.

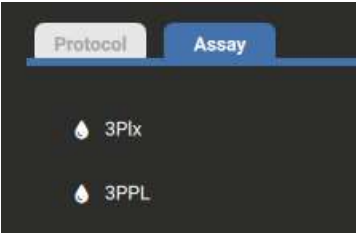
When loading these assays in the Digital Experiments menu, the protocol tags are displayed before the file names.



In this instance:

- Assay 1 is named “3Plx”, has the tag 3Plx, and is assigned the color green.
- Assay 2 is named “3PPL”, has the tag 3PPL, and is assigned the color red

When these assays are loaded in the Digital Experiments menu, their respective tags (3Plx and 3PPL) are displayed alongside their names.



When assigning protocols and assays to the cartridges, the assay tag and its assigned color appear in each assigned well. The protocol tags are displayed below the corresponding cartridges.

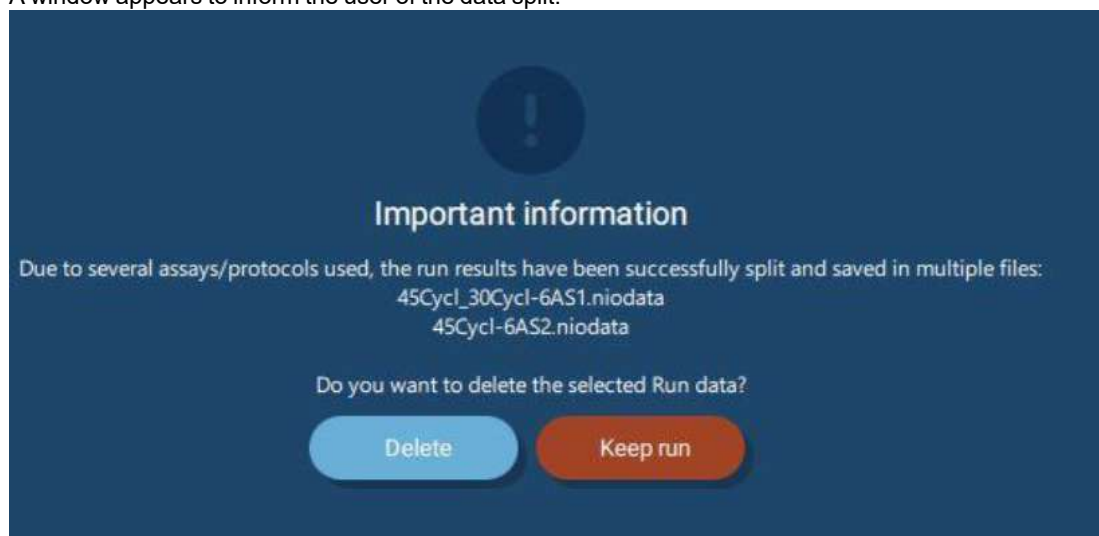


Clicking Get Results in in the Runs section prompts the software to scan the run data and group wells that use the same protocol–assay pair into a single .niodata output file. Each unique protocol–assay combination produces one .niodata file, so you will retrieve as many files as needed to capture all results from the experiment.

The QX700 ddPCR System Control Software splits the data into three .niodata files, as represented by gold, blue, and red colors.

	Chip1		Chip2		Chip3	
	Column1	Column2	Column1	Column2	Column1	Column2
Protocol	1	1	1	1	2	2
Assay	1	2	1	1	1	1

A window appears to inform the user of the data split.



In the .nioresults folder, three .niodata files are generated with the following naming convention:

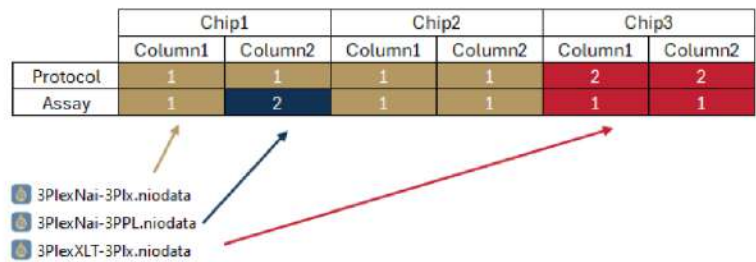
 3PlexNai-3Plx.niodata
 3PlexNai-3PPL.niodata
 3PlexXLT-3Plx.niodata

- The assay name appears directly in each .niodata filename
- The protocol name is replaced by its corresponding tag.

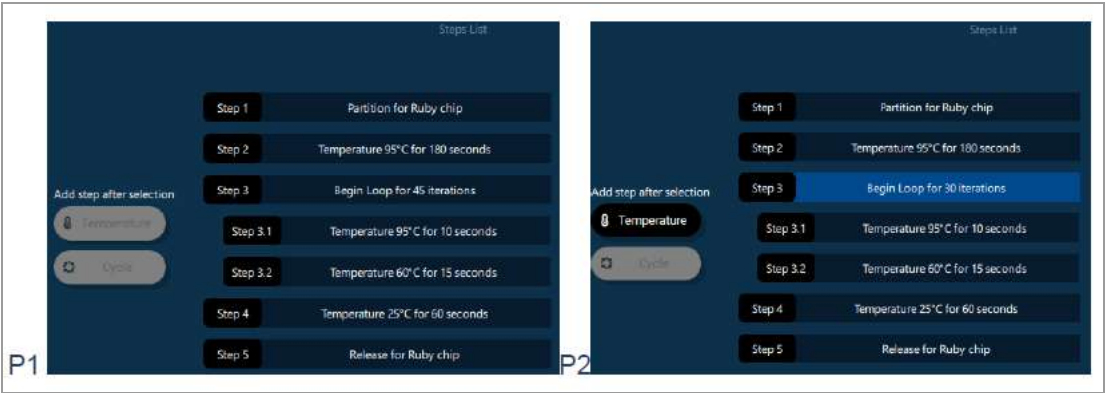
In this example:

- 3PlexNai is the tag for Protocol 1 (3plex naica)
- 3PlexXLT is the tag for Protocol 2 (3PlexXLT)

Because Protocol 1 is paired with two different assays on the left cartridge (Cartridge 1), an additional split occurs, resulting in a third .niodata file: 3PlexXLT-3Plx.

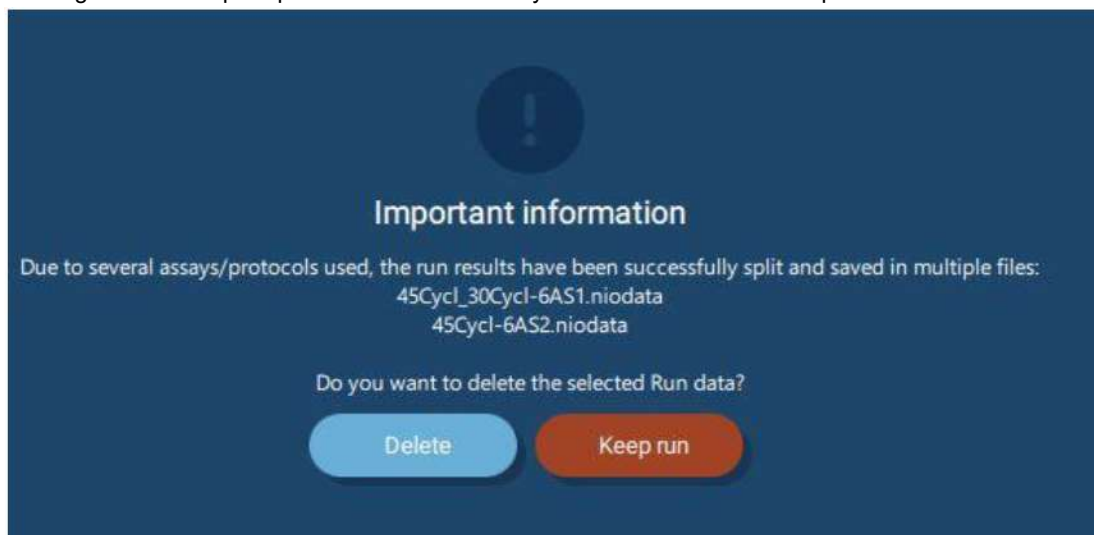


In this example, Protocols 1 and 2 differ only by the number of PCR cycles, and the same assay, “6AS1,” is assigned to every well in the experiment.

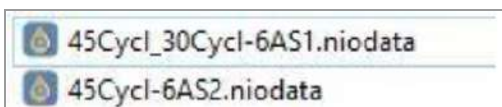


- P1 is saved as “45Cycles.nioprotocols” with the tag “45Cycles”
- P2 is saved as “30Cycles.nioprotocols” with the tag “30Cycles”.

Clicking Get Results prompts the QX700 ddPCR System Control Software to split the data.



The generated files will display as:



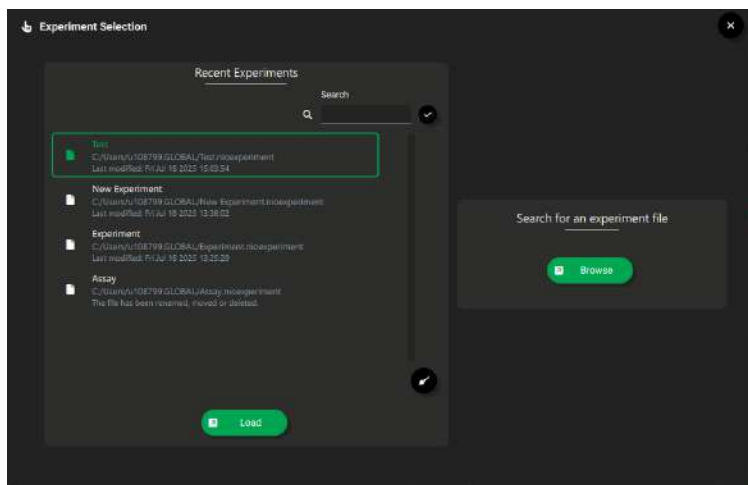
Chapter 9 Running a ddPCR Experiment

The Runs screen is used to launch and monitor experiments on the QX700 ddPCR System. This is the only step that requires a direct connection to the instrument; all previous steps can be performed on a personal computer.

Note: When QX700 ddPCR System Control Software is not running directly on the instrument (i.e., remote access), certain features are disabled. These include instrument control actions (e.g., shutdown, unloading, failure acknowledgments) and run data handling (e.g., loading/unloading). These actions must be performed locally on the instrument.

To run a recent experiment

1. In the Runs section, click Plan & Start.
2. Do one of two things:
 - Select an experiment from the Recent Experiments menu and clicking Load
 - Click Browse in the Search for an experiment File section to browse for a specific experiment.



3. Continue following the work flow instructions displayed by the software to complete the run setup steps.

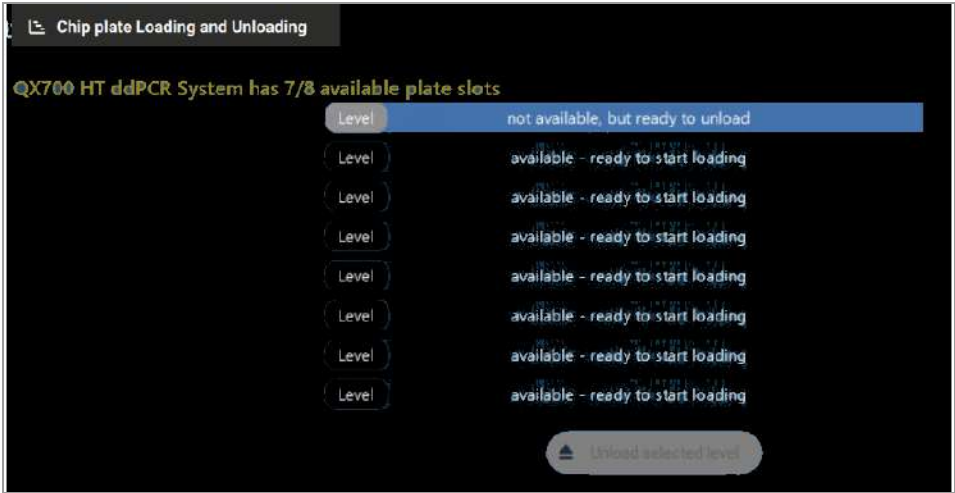


- 4. Load the plate. Before loading, the experiment plate loading order section displays a visual representation of the expected layout.



Note: If a plate lacks a specified barcode, the software reads it automatically using the barcode reader during cartridge loading through the front panel.

The plate loading and unloading menu also lets you retrieve cartridges from previous experiments. The instrument displays its current occupancy status.



After you load the cartridge, the plate displays the barcodes for each cartridge and their positions.

1	Chip plate 1 - Chip plate 1	Chips detected	✓
1.1	RD240800305833		✓
1.2	RD240800299574		✓
1.3	RD240400247436		✓

Note: You can also directly insert cartridges into the instrument. Since no experiment is associated, QX700 System Control will prompt you to link an existing experiment, which will start automatically once the cartridges are loaded.

- Click Start Run.
- Navigate to the Status page.

The Status page shows the progress and status of each cartridge for up to 8 plates in the QX700 HT ddPCR System, 4 plates in the QX700 S ddPCR System, and 1 plate in the QX700 E ddPCR System.

The Run section displays a progress bar for each experiment, with statuses indicating the current step:

- **Queued** – Cartridges are inside the instrument and will be processed automatically—no user action needed.
- **Thermocycling** – Partitioning, thermal cycling, and release steps are in progress.
- **Reading**– Scanning is in progress; the counter increases as each well is read and becomes available for review.
- **Done**– The experiment is complete.
- **ETA:** The estimated time when data will be available for download.

When the run is in the Queued state, the software provides an estimated starting time.

Run Information

The Selected Run Information panel displays more information about a specific experiment.

Setting Run Priority

The QX700 ddPCR System Analysis Software allows two priority levels for plates: Normal and High.

If multiple experiments are queued, you can change the processing order.

To change the experiment processing order

1. Select an experiment.
2. Click Set High Priority.

Note: This feature is only available while the experiments are still in the queue. After experiment processing has started, the system processes experiments based on the order in which they began. High priority does not override an experiment already in progress.

Assigning high priority changes the queue order so that the plate is processed before other queued, lower-priority experiments. You can set multiple plates to high priority; in that case, the software processes them in the order they entered the instrument, but ahead of all normal-priority plates.

Note: Changing the priority affects the Estimated Time of Arrival (ETA) for all plates. However, both those promoted to high priority and the remaining ones in the queue.

To revert the experiment processing order back to normal priority

1. Select an experiment.
2. Click Set Low Priority. The system will then process that plate according to the order it was loaded into the instrument.

Once processing begins, the plate is marked In Progress and listed as onboard the instrument.

Each cartridge will show one of the following real-time status indicators:

- **Thermocycling**– Indicated by a blinking thermometer icon followed by In Progress.
- **Scanning**– Indicated by a blinking light bulb icon followed by In Progress.

Additional details about the thermal cycling process are also displayed.

The run status updates to reflect the progress of the run. For example, it will change from Queued to Thermocycling, Reading, and then Done as the experiment advances.

Canceling a Run

You can cancel a run for a single cartridge or for the entire plate

To cancel a run

Do one of two things:

- To cancel a single cartridge run, select the cartridge and click Cancel Selected Cartridge .

Important: Canceling a cartridge run during the thermal cycling step, the thermal plate stops heating or cooling immediately. This ends the PCR, and the instrument will not scan the wells on the canceled cartridge.

Note: If you cancel the run during the reading step, you can rescan the cartridge later since the PCR step has already completed.

- To cancel the run for the entire plate, select the plate and click Cancel Plate.

Important: Canceling an entire plate run has the same effect as canceling a single cartridge run. PCR ends for the canceled cartridges, and they will not be scanned. However, when you cancel a complete plate run, the instrument automatically returns to atmospheric pressure, removes the cartridges from thermal cycling, and allows immediate retrieval. When canceling only one cartridge run, the instrument continues processing the remaining cartridges. You can retrieve the canceled cartridge only after the entire plate run has completed.

Note: The cancellation is not immediate. After canceling a run, wait until the instrument indicates it is safe to unload the cartridges.

After the cancellation completes, you can retrieve the cartridges by selecting the run and clicking Unload Plate.

Chapter 10 QX700 ddPCR System, Premium Edition Features

This section explains how to operate the QX700 ddPCR System, Premium Edition.

An overview of the 21 CFR Part 11 requirements supported by the QX700 ddPCR System Analysis Software and QX700 ddPCR System Control Software, Premium Edition is provided in the QX700 Analyzer Software User Guide.

QX700 ddPCR System Control Software, Premium Edition Features

The QX700 ddPCR System Control Software, Premium Edition includes specific features designed to comply with 21 CFR Part 11 regulations. This section explains those features.

For general software features that apply to both Standard Edition and Premium Edition, see [About QX700 ddPCR System Software on page 33](#).

Individual User Authentication

To comply with 21 CFR Part 11, access to QX700 ddPCR System Control Software Premium Edition is restricted to authorized individuals. Users must log in using individual authentication credentials (username and password).

Failed login attempts may occur due to incorrect credentials.

Note: Multiple failed attempts might lock a user's QX700 Data Service account, which requires an IT administrator to reset the Windows account for reactivation. Login failures can also occur due to connectivity issues with QX700 Data Service. Users should contact their IT department to resolve connection problems.

When a session expires, the software prompts users to re-authenticate. If they attempt to bypass authentication, the system automatically exits, which may result in unsaved changes.

Microsoft Windows account settings determine automatic logout, but users should close QX700 ddPCR System Control Software, Premium Edition when not in use to ensure security.

Note: Login attempts may also fail if Windows authentication is denied or if the software loses its connection to QX700 Data Service.

Experiment Audit Trail

The Experiment Audit Trail records all experiment file modifications in QX700 ddPCR System Control Software, Premium Edition and QX700 ddPCR System Analysis Software, Premium Edition. This feature ensures traceability and compliance by tracking changes made during experiment processing.

For detailed information on the Experiment Audit Trail, refer to the QX700 ddPCR System Analysis Software User Manual.

QX700 Data Service User Roles and Permissions

This section explains how the QX700 Data Service user roles and their permissions.

QX700 Data Service Permissions

The QX700 Data Service assigns predefined sets of operational permissions to users based on their roles. These roles control access to features in the QX700 ddPCR System Control Software and QX700 ddPCR System Analysis Software.

Permission details include:

- Permissions are managed under the Roles / Permission tab in the QX700 Data Service interface.
- Granted permissions are shown with a check mark; those not granted are unchecked.
- Users are responsible for assigning roles and limiting Manage Users permission to authorized personnel.

Available permissions include:

- Open or edit protocols and assays
- Create new experiments (blank or standard)
- Import or remove assays/protocols
- Start, scan, rescan, and save experiments

Note: Users who can start runs but not create experiments must use ones created by someone with creation permissions

Note: Users with permissions to start runs, but without the ability to create experiments, can only read experiments that were previously created by a user with experiment creation permissions.

- Set high priority on experiments
- Cancel or delete other users' runs
- Download other users' data
- Manage Users:
 - ☐ Assign roles

- ❑ Create, edit, or delete user roles and permissions
- ❑ Activate user access in the system

Note: Only users with the manage users permission can create, modify, or delete user roles and user permissions.

Users with the manage users permission can assign a user role for new QX700 ddPCR System users and manage all created users within the QX700 Data Service software.

Note: The user is responsible for assigning role management duties and ensuring that only authorized personnel receive the Manage Users permission.

For more information on operating the QX700 ddPCR System, see [QX700 ddPCR System, Premium Edition Features on page 92](#)

QX700 Data Service User Roles

User Roles are managed through the Roles/Permissions tab in the QX700 Data Service user interface.

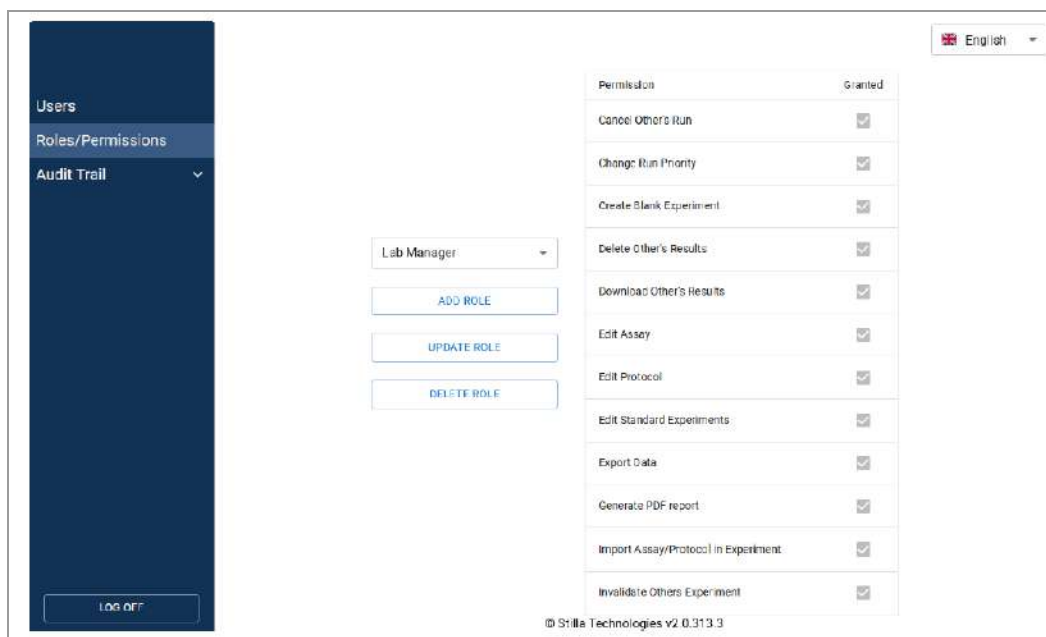
Roles details include:

- All available user roles are listed in a drop-down menu.
- Each user role determines the permissions assigned to users.
- Roles control access to predefined permissions for both QX700 ddPCR System Control Software and QX700 ddPCR System Analysis Software applications.

Default User Roles

The QX700 Data Service installation includes two predefined user roles:

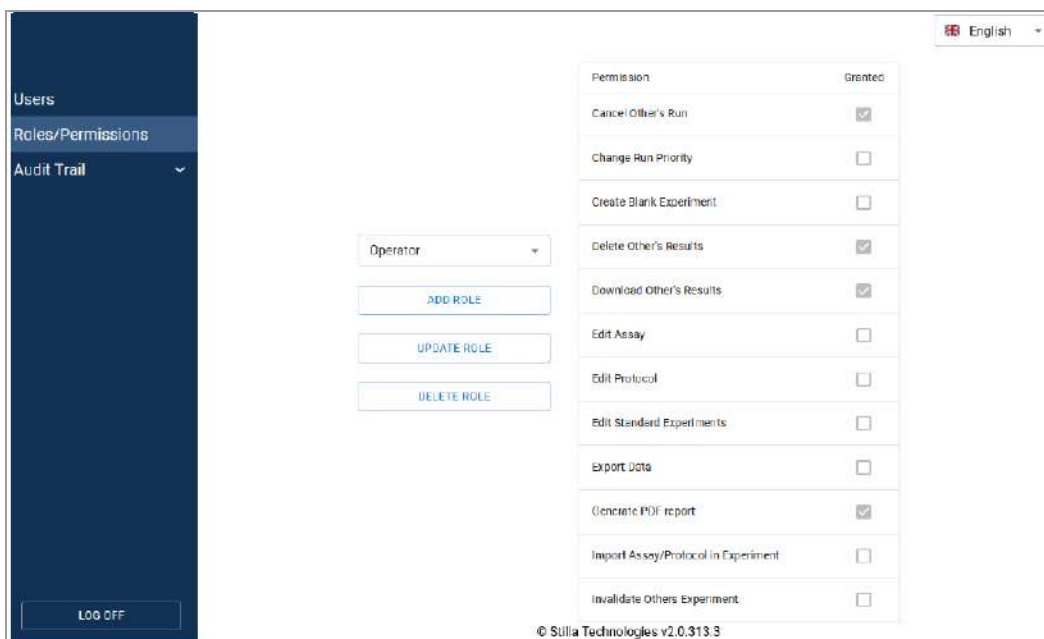
- **Lab Manager** – Lab managers have full permissions for QX700 ddPCR System Control Software and QX700 ddPCR System Analysis Software.



- **Operator**— Operators have limited permissions for QX700 ddPCR System Control Software, including:

- Generating PDF reports
- Running experiments
- Validating experiments

The Operator role is restricted to validated standard experiment files that comply with the customer's SOP and have been approved by a Lab Manager for routine operation.



QX700 Data Service Custom User Roles

The QX700 Data Service enables Lab Managers to create user roles or change existing user roles.

Creating a Custom Role

To add a user role

1. Open the Roles/Permissions Tab in the QX700 Data Service user interface.
2. Select "Add Role" to begin creating a new user role
3. Enter the role name in the designated field.
4. Select the user role permissions by checking all permissions to be included in the new role.
5. Click Create Role.

The new User Role appears in the User Role drop-down menu in the Roles/Permissions tab.

Updating an Existing Role

To update an existing role

1. Open the Roles/Permissions Tab in the QX700 Data Service user interface.
2. Click Update Role
3. (Optional) Edit the Role Name.
4. Modify permissions by activating or deactivating permission settings.
5. Click Update Role. The updated User Role will appear in the User Role drop-down menu in the Roles/Permissions tab.

Changes take effect when assigned users log in to QX700 ddPCR System Control Software or QX700 ddPCR System Analysis Software.

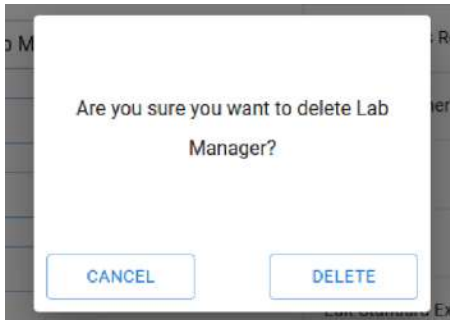
Deleting an Existing Role

To delete an existing role

Important: User Roles assigned to at least one user cannot be deleted.

1. Open the Roles/Permissions Tab in the QX700 Data Service user interface.
2. Select the user role you want to remove.

3. Click Delete Role,
4. In the confirmation modal, click Delete.



The deleted User Role is removed from the User Role drop-down menu in the Roles/Permissions tab.

Managing Users

To comply with 21 CFR Part 11, only authorized individuals can access QX700 Data Service. Additionally, each user must log in using individual credentials (username & password).

 The screenshot shows the "Users" management page. On the left is a dark blue sidebar with a "LOG OFF" button at the bottom. The main content area has a top navigation bar with "Users", "Roles/Permissions", and "Audit Trail" (with a dropdown arrow). Below this is a search bar labeled "Search Users" and a refresh button. A table lists users with columns for Username, Full Name, Role, Update (pencil icon), and Delete (trash icon). At the bottom of the table is an "ADD USER" button and a pagination control showing "1 / 2". The footer of the page reads "© Stilla Technologies v2.0.313.3".

Username	Full Name	Role	Update	Delete
alexandre.lacroix	Alexandre Lacroix	Lab Manager		
amal.bahloul	Amal Bahloul	Lab Manager		
anaelle.buserolle	Anaëlle Buserolle	LabUser&D		
benjamin.foret	Benjamin Foret	Lab Manager		
florant.fouche	Florant Fouche	LabUser&D		
louis.gimenez	Louis Gimenez	LabUser&D		
myrtille.ramy	Myrtille Ramy	LabUser&D		
oriane.gourdy	Oriane Gourdy	Lab Manager		
stephanie.roy	Stephanie Roy	LabUser&D		
Test.cfr2	Test.cfr2	Operator		

Users Menu

The users menu

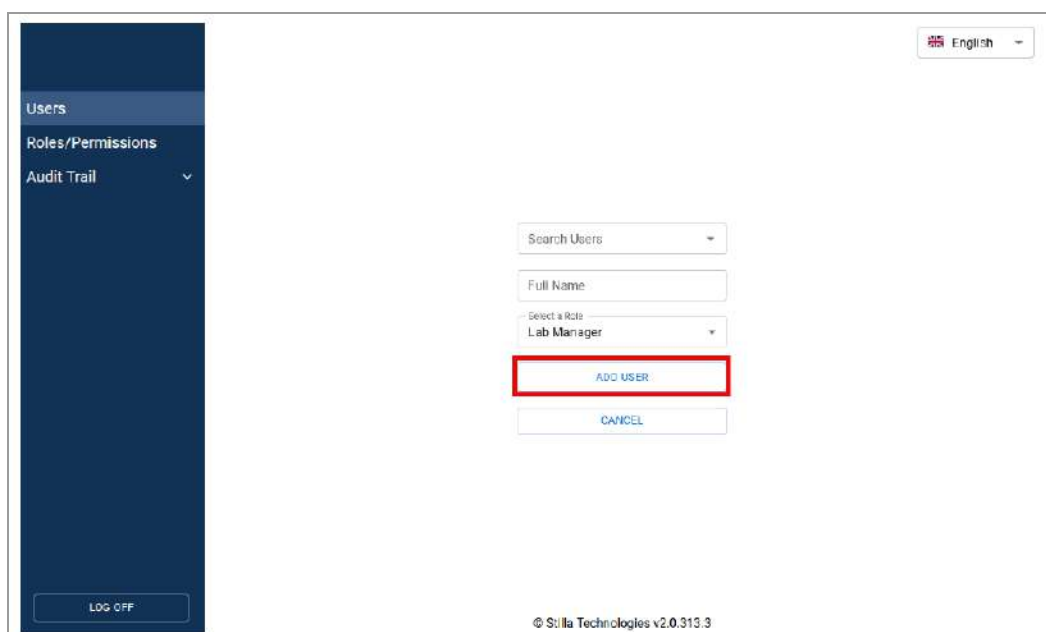
- Displays all QX700 Data Service user accounts within the organization.
- Lists users that can access all 21 CFR Part 11-compliant QX700 ddPCR System software applications.

Only users with the Manage Users permission can add, update, or delete user accounts. To modify a user account, click on the respective icon in the Users menu.

Creating a New User Account

To create a user account

1. Navigate to the Users Menu and click Add User.

The screenshot shows the 'Users' menu in the QX700 Data Service interface. On the left is a dark blue sidebar with a menu containing 'Users', 'Roles/Permissions', and 'Audit Trail'. The 'Users' option is highlighted. The main content area is white and contains a search bar labeled 'Search Users', a text input for 'Full Name', a dropdown menu for 'Select a Role' with 'Lab Manager' selected, and two buttons: 'ADD USER' (highlighted with a red rectangle) and 'CANCEL'. At the bottom left of the sidebar is a 'LOG OFF' button. At the bottom center of the main area is the copyright notice '© Stilla Technologies v2.0.313.3'. In the top right corner, there is a language selector showing 'English'.

2. Enter the Microsoft Windows username in the Search Users field.

Note: The username source depends on the organization's authentication setup:

- Active Directory user authentication. For more information see [Active Directory User Authentication with a Customer-Hosted PC as the Server on page 39](#) and [Active Directory User Authentication with a QX700 ddPCR System as the Server on page 41](#).

- Local QX700 ddPCR System authentication. For more information, see [Local Windows User Authentication and Configuration on Single QX700 ddPCR System on page 43](#).

3. Select the correct username from the list of matching accounts. The system automatically populates the Full Name field based on the Windows account.
4. Assign a User Role using the Select a Role drop-down menu.
5. Click Add User.

The system activates the new user account, and the user can log in with their Windows authentication credentials.

Note: Any inactive user will be automatically logged out to comply with 21 CFR Part 11. The system displays the login prompt after timeout.

The image shows a login interface for the BIO-RAD system. It features a dark blue background with the BIO-RAD logo at the top. Below the logo are two white input fields: the first is labeled 'username' and the second is labeled 'password'. To the right of the username field is a small icon of a person. Below the password field is a dark blue button with the word 'LOGIN' in white capital letters.

Deleting a User Account

To delete a user account

1. Open the Users Menu in the QX700 Data Service interface.
2. Select the User Account to be deleted.
3. Click Delete.
4. Click Delete on the Delete User confirmation modal.

The user account will be removed from the system.

QX700 Data Service Audit Trail

The QX700 Data Service Audit Trail automatically generates time-stamped electronic records that document the history of events related to the creation or modification of electronic records, based on individual user accounts.

The Audit Trail is divided into three categories, each with filtering options.

Users Tab

The Users tab

- Tracks changes to User Role management.
- Can be filtered by Role ID (the affected role)

User Id	Detail	Performed By	Date / Time
Item Kus	User was updated with following data [Role: Operator, Item Kus]	benjamin.foret	2024-07-04 10:06:12
Test.chr2	User was updated with following data [Role: Operator, Test.chr2]	amel.bahoui	2024-06-10 14:23:24
Item Kus	User was updated with following data [Role: LabUserR&D, Item Kus]	benjamin.foret	2024-06-10 12:20:37
Item Kus	User was updated with following data [Role: Operator, Item Kus]	benjamin.foret	2024-06-10 11:49:58
Item Kus	User was updated with following data [Role: LabUserR&D, Item Kus]	benjamin.foret	2024-06-06 11:49:34
Item Kus	User created with following data [Role: LabUserR&D, Item Kus]	benjamin.foret	2024-06-04 14:30:54
jean.roman	User created with following data [Role: LabUserR&D, Jean Roman]	benjamin.foret	2024-06-03 16:20:19
anais.copod	User created with following data [Role: LabUserR&D, Anais Copod]	benjamin.foret	2024-06-03 16:19:58
celine.sers	User created with following data [Role: LabUserR&D, Celine Sers]	benjamin.foret	2024-06-03

Roles Tab

The Roles tab

- Tracks changes to User Role management.
- Can be filtered by Role ID (the affected role)

English

Filter by Role Id

Filter by Performing User

From: //mm/aaaz

To: //mm/aaaz

Clear

Clear

Role Id	Detail	Performed By	Date / Time
Test-amal	Role updated with following permissions [Cancel Others Run, Download Others Results]	amal.behloul	2024-05-07 14:24:00
Test-amal	Role updated with following permissions []	amal.behloul	2024-05-07 11:56:29
LabUserRSD	Role created with following permissions [Cancel Others Run, Change Run Priority, Create Blank Experiment, Delete Others Results, Download Others Results, Edit Assay, Edit Protocol, Edit Standard Experiments, Export Data, Generate PDF report, Import Assay/Protocol in Experiment, Invalidate Experiment, Open Assay, Open Protocol, Remove Assay/Protocol from Experiment, Start Run, Validate Experiment]	benjamin.foret	2024-05-03 16:18:21
Test-amal	Role updated with following permissions [Download Others Results]	amal.behloul	2024-05-03 10:36:00
Test-amal	Role updated with following permissions []	amal.behloul	2024-05-03 10:34:25
Test-amal	Role updated with following permissions [Edit Assay, Edit Protocol, Open Assay, Open Protocol]	amal.behloul	2024-05-03 10:31:43
Test-amal	Role updated with following permissions []	amal.behloul	2024-05-03 10:28:49
Test-amal	Role updated with following permissions [Open Assay, Open Protocol]	amal.behloul	2024-05-03

EXPORT AUDIT TRAIL

7/4

Users

Roles/Permissions

Audit Trail

Users

Roles

Electronic Records

LOG OFF

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Electronic Records Tab

The Electronic Records tab

- Logs the history of any QX700 ddPCR System file.
- Can be filtered by Electronic Record ID (a unique ID created by QX700 Data Service for each QX700 ddPCR System file).
- Includes an electronic record checksum (a condensed version of the QX700 ddPCR System file) required by the QX700 Data Service to verify file integrity.

Electronic Record Id	Detail	Performed By	Date / Time
8a70ff95-0545-4d23-9b4b-144fec578d56	Checksum 2e4f4ab3aacc04a182c030142930ff9b added to electronic record	amal.bahloul	2024-07-16 14:55:59
8a70ff95-0545-4d23-9b4b-144fec578d56	Electronic record created	amal.bahloul	2024-07-16 14:55:57
3e929e9c-1dfd-416a-a814-6656f0a30c86	Checksum af3261ef120a7c0ea020d1cf944124d added to electronic record	amal.bahloul	2024-07-09 15:54:06
3e929e9c-1dfd-416a-a814-6656f0a30c86	Electronic record created	amal.bahloul	2024-07-09 15:54:03
bab73951-f0d7-401e-91ff-800401d4d57a	Checksum 167e3cd19a063c109c3e3b0e558867cd added to electronic record	amal.bahloul	2024-07-09 15:53:17
bab73951-f0d7-401e-91ff-800401d4d57a	Electronic record created	amal.bahloul	2024-07-09 15:53:07
da602550-43db-4a28-95ab-729095261d4b	Checksum 9802baba18e8b0733c020b0c3d29c32 added to electronic record	amal.bahloul	2024-07-09 15:29:38
da602550-43db-4a28-95ab-729095261d4b	Electronic record created	amal.bahloul	2024-07-09 15:29:38
5a308bc-5ff1-bc4edca3da60f0a4e596f4	Checksum 5e11426ae2412b8a30c5a51e5f8f16a0 added to	amal.bahloul	2024-07-09

Backing Up the System

Regular backups of the QX700 Data Service Audit Trail database are essential. The database file is stored at: C:\Program Files\Bio-Rad\QX700DataService\Naica.db. Users are responsible for establishing and maintaining a backup routine to safeguard audit records.

To ensure consistent Audit Trails, all computers running 21 CFR Part 11 QX700 ddPCR System, Premium Edition software must be correctly configured with the appropriate date and time settings. This responsibility of the user and the user's organization.

Audit trail categories in QX700 Data Service can be filtered by date and time to track events chronologically or by the Performing User (the QX700 Data Service user account executing the recorded event) to identify the user who executed a recorded action. To ensure consistent audit trails, all computers running QX700 ddPCR System Software, Premium Edition must be correctly configured with the appropriate date and time settings, which is the responsibility of the customer's organization.

All QX700 Data Service audit trail categories can be exported as a PDF document by clicking EXPORT AUDIT TRAIL .

Appendix A Troubleshooting

This appendix explains how to troubleshoot problems that you might have.

Contacting Bio-Rad Technical Support

To contact Bio-Rad Technical Support, call 1-800-424-6723, option 2.

Before contacting Bio-Rad Technical Support, ensure you have the following details:

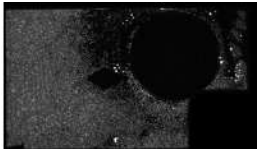
- Instrument serial number and software version
- Sample material
- Logs and .niodata

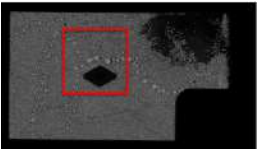
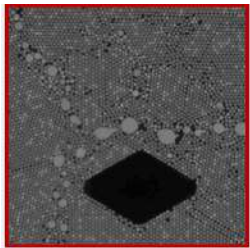
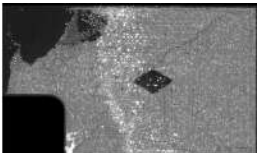
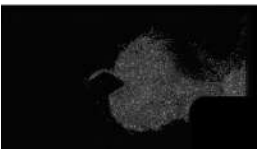
Address:

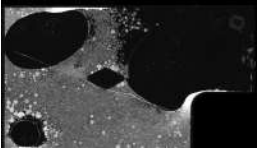
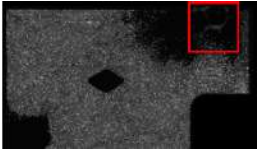
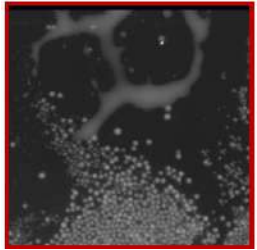
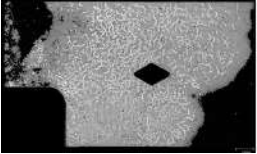
Biopark 1, Mail du Professeur Georges Mathé

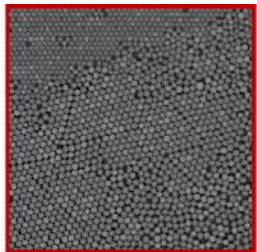
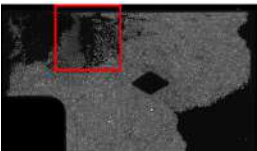
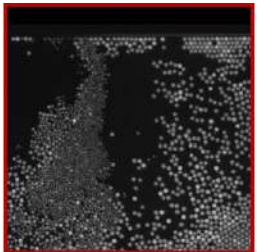
94800 Villejuif, France

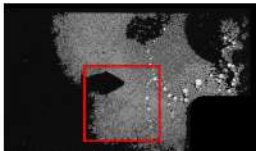
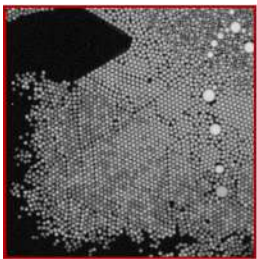
Experiment Troubleshooting

Error	Possible Causes	Troubleshooting Steps
Empty Well 	■ The sample was not pipetted into the correct well. ■ The sample was ejected from a tip. ■ The tip was introduced too deep, touching the bottom of the well, or too shallow, landing at the air-oil interface. ■ Misalignment of a multichannel pipette caused some tips to be either above the oil or touching the bottom of the well.	■ Check the numbering on the wells to ensure correct sample pipetting. ■ Stabilize the pipette tip about 1 mm above the bottom of the well. Lift slightly so it's neither touching the bottom nor out of the oil before ejecting the sample. ■ For detailed pipetting instructions, refer to the RDG16 Cartridge Instructions for Use.
Bubble 	■ Small bubbles can sometimes form during the PCR run due to heat and pressure cycles. ■ If large or frequent bubbles appear, the inflated bag containing the cartridge might have been damaged during transport.	Check that the inflated pouch is still airtight upon reception.

Error	Possible Causes	Troubleshooting Steps
Electrocoalescence  	The procedure using the antistatic wipes was omitted or not properly performed.	Apply antistatic wipes to all cartridges as described in the instructions for use. Contact Bio-Rad Technical Support for further assistance.
Traces of antistatic product 	Residual antistatic product under the cartridge generates artifacts in the blue channel.	After applying the antistatic treatment, wipe off excess antistatic product with a Precision Wipe as instructed in the instructions for use.
Low number of droplets 	■ The sample was ejected from a tip introduced too deep (touching the bottom of the well) or too shallow (landing at the air-oil interface). ■ Misalignment in a multichannel pipette caused some tips to be above the oil or touching the well bottom.	Stabilize the pipette tip about 1 mm above the bottom of the well before ejecting the sample. Refer to the cartridge instructions for use for proper pipetting techniques.

Error	Possible Causes	Troubleshooting Steps
Tension on transparent foil leading to oil traces 	■ Incorrect pipette tips were used to pierce the RDG16 Cartridge ■ Not all 16 wells were pierced before launching the PCR program. A dust particle on the heating plate created tension on the foil. ■ The heating plate was not clean, causing a dust particle to create tension on the transparent foil.	■ Only use 10 μL and 20 μL universal pipette tips as specified in the instructions for use. ■ Always pierce all 16 wells (even empty wells) before launching the PCR program. ■ If there is oil leaking, wipe the cartridge with an antistatic wipe and then a Kimwipe (once only) before loading the cartridge and rescanning the impacted well(s). The impacted well(s) can be rescanned if needed
Oil Traces  	The cartridge contains oil that may condense outside the wells under normal use.	Oil will evaporate naturally. No internal cleaning is required. Bio-Rad recommends yearly preventive maintenance by their technical support team, during which technicians clean the thermal cycler. Contact your local Bio-Rad representative for maintenance contracts.
Wetting Droplets 	A higher concentration of qScript XLT 1-Step RT-qPCR ToughMix can cause droplets to wet the well surface rather than remain spherical during RT-PCR experiments.	These droplets are excluded during analysis. Use the recommended XLT mix concentration (1x) and avoid leaving the RT-PCR mix exposed to air before injection.

Error	Possible Causes	Troubleshooting Steps
Bigger Droplets  	Temperature and pressure cycling can cause these artifacts in rare cases.	The software excludes these droplets during analysis and considers them as artifacts. This does not normally affect assay output.
Small Droplets  	Temperature and pressure cycling can cause these artifacts in rare cases	The software excludes these droplets during analysis and considers them as artifacts. This does not normally affect assay output.

Error	Possible Causes	Troubleshooting Steps
Non-homogeneous distribution of positives  	A part of the sample was injected into the well after PCR cycles had begun, leading to bulk amplification before partitioning and a higher ratio of positive droplets. Possible reasons include: ■ The sample being ejected from a tip introduced too deep, touching the bottom of the well, or too shallow, landing at the air-oil interface. ■ Misalignment when pipetting with a multichannel pipette, causing the eight tips to be either above the oil or touching the bottom of the well.	Stabilize the pipette tip about 1 mm above the bottom of the well before ejecting the sample. Refer to the instructions for use for proper pipetting techniques in the cartridge.

Instrument Troubleshooting

Error messages for the QX700 ddPCR System Control Software will appear in the top right corner of the software interface. If the instrument is functioning without errors, this area displays only the Home and Shutdown/Restart buttons.



Error messages will also appear in the same area with an error icon.



Clicking the Error button opens a dropdown displaying status categories: Instrument, Connections, and Features.

- A green icon next to a status element indicates no errors.
- A red icon signals an error, with the dropdown also providing detailed error information.

Most errors can be addressed by clicking the Acknowledge button, prompting the instrument to attempt self-correction. Allow up to two minutes for this process.



If the issue persists, contact Bio-Rad Technical Support.

The table below outlines recommended actions for errors that require troubleshooting.

Error Code	Description	Troubleshooting steps
0xA0000502 0xA0050A01 0xA0050A02 0xA0050A04 0xA0060A01 0xA0060A02 0xA0060A04 0xA0070A01 0xA0070A02 0xA0070A04	Loading Module positioning error	If a power outage occurs, the instrument might require a restart. In these cases, or if the instrument stops unexpectedly, follow the procedures described in the following: ■ Opening the QX700 ddPCR System Front Panel on page 114 ■ Unblocking the QX700 ddPCR System Loading Module on page 117 ■ Closing the QX700 ddPCR System Front Panel on page 120 If the error persists, click Acknowledge, and contact Bio-Rad Technical Support.
0xA0000503	Unexpected object insertion in Loading area.	Remove any object other than a plate from the Loading area.

Error Code	Description	Troubleshooting steps
0xA0000504	Insertion of two plates at the same time	Remove the second plate from the Loading area.
0xA0000913	Missing cartridge barcode during plate unloading	Wait for the plate to fully eject before retrieving it. Ensure the loading area status indicator has stopped blinking. Verify that the cartridge is present in the unloaded plate. If the cartridge is missing, contact Bio-Rad Technical Support.
0xA0000914	Software failure causing inversion of cartridge run results	■ Unload all cartridges from the instrument ■ Invalidate all results
0xA00A0301 0xA00A0302	Robotic error during lid opening	■ Follow procedure in Opening the QX700 ddPCR System Front Panel on page 114 ■ Close the thermal cycler lids

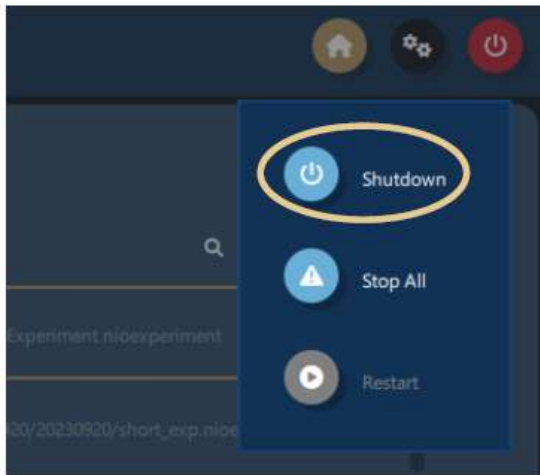
Opening the QX700 ddPCR System Front Panel

Required Tool – 3 mm hex allen wrench

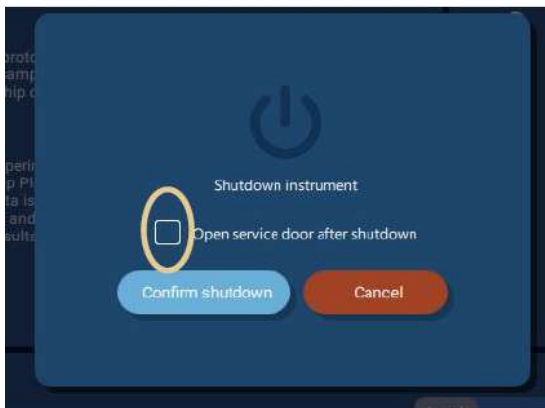
Safety Gear – Safety glasses, mask, gloves, and lab coat

To open the QX700 ddPCR System Front Panel

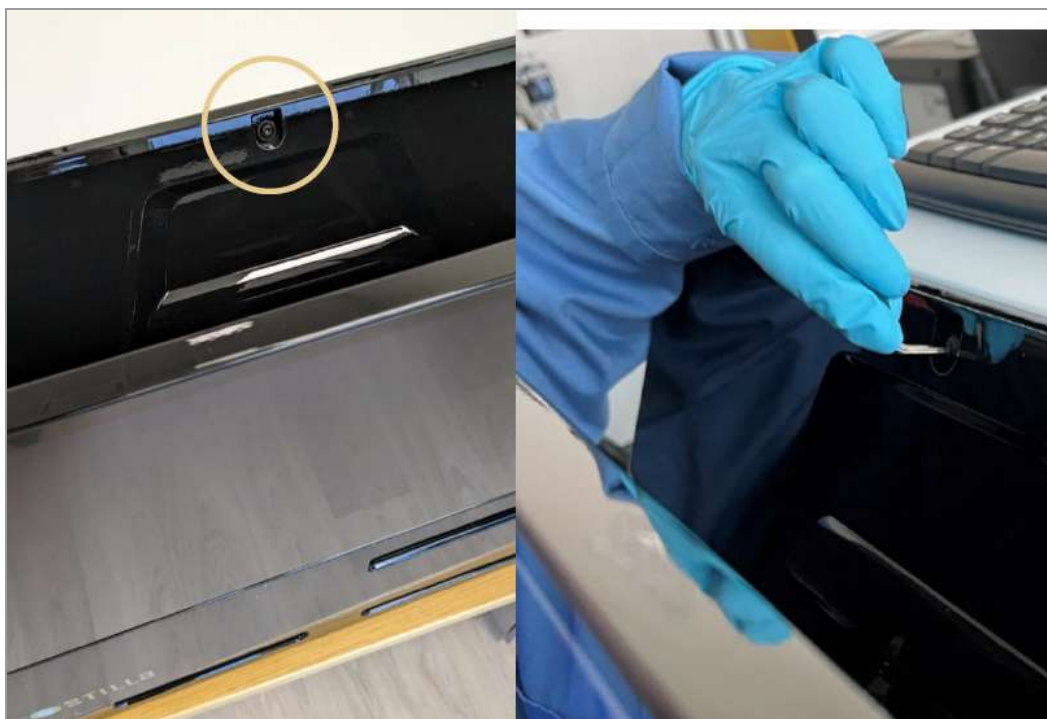
1. (Optional) Power on the instrument if necessary using the rear power switch.
2. (Optional) Press the Start-Up button on the front panel to initialize the system.
3. Tap the Home button.
4. Tap Shutdown.



5. In the Shutdown instrument modal, select the Open service door after shutdown check box.



6. Allow the instrument to power off completely, ensuring that the status lights turn off. The magnetic lock will automatically disengage.
7. Close the QX700 ddPCR System Control Software.
8. Perform a Windows shutdown on the instrument.
9. Turn off the rear power switch and unplug the power cable from the instrument.
10. Using the 3 mm hex Allen wrench, unscrew the safety lock located behind the top screen panel. Hold the front door securely with one hand while unscrewing.



11. Slowly open the door, allowing the mechanical stop to hold it in place.

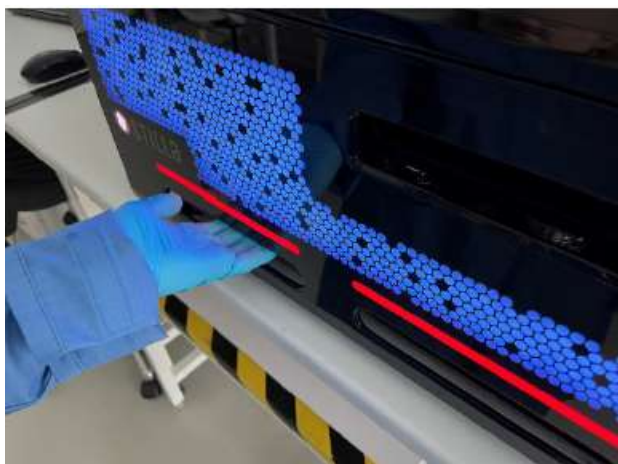




Fig. 6: QX700 ddPCR System with front panel open

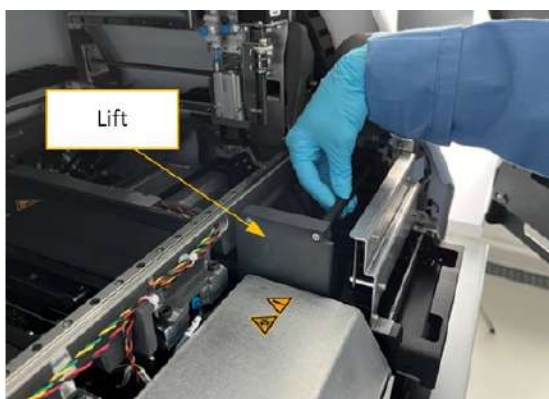
Unlocking the QX700 ddPCR System Loading Module

This procedure explains how to unblock the QX700 ddPCR System loading module. If a plate is locked in the fork,

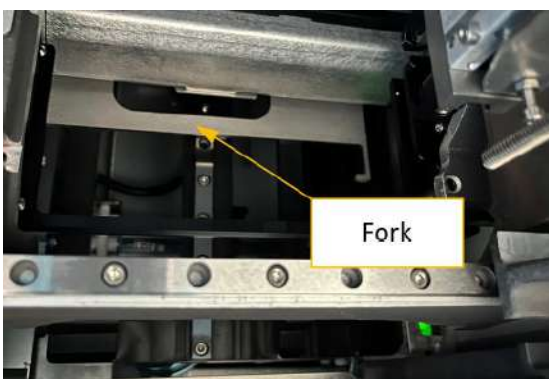
To unblock the loading module

1. Gently move the lift up and down and the fork back and forth to release the plate. You may encounter slight resistance.

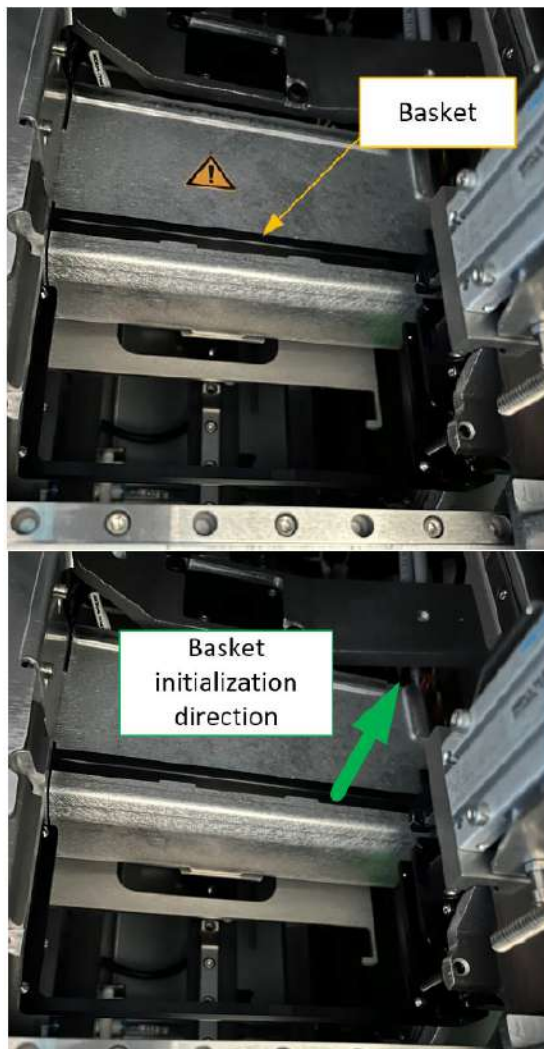
Important: Do not force any of the instrument components if they do not move freely. For assistance with components, contact Bio-Rad Technical Support.



2. Gently push the fork backward to its initialization position until it locks fully in place.



3. Gently pull the basket upward to return it to its initialization (top) position.



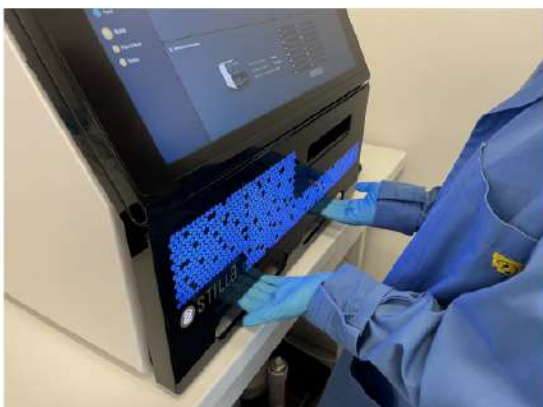
- 4.
5. Close the instrument panel (see [Closing the QX700 ddPCR System Front Panel on page 120](#)).
6. Restart the instrument.
7. Unload all the RDG16 Cartridge from the instrument.

Closing the QX700 ddPCR System Front Panel

This procedure explains how to close the QX700 ddPCR System front panel

To close the front panel

1. Push the door back until the magnetic lock secures it in the closed position.
2. Slightly lift the door while pushing, and use the two lower openings to close it more easily.



3. Place the security screw at the top of the door behind the screen cover.
4. Tighten the screw until it contacts the door, then turn it an additional quarter-turn to secure it.

Temperature Warnings and Errors

The QX700 ddPCR System must operate in a temperature-controlled environment to function correctly. The internal temperature is monitored continuously.

Initially, the system will issue a temperature warning. If the temperature continues to rise, the system will issue a temperature error.

Temperature Warning

The temperature does not affect instrument operation but indicates that the room temperature is too high and needs to be lowered. If the temperature continues to rise, a temperature error appears.



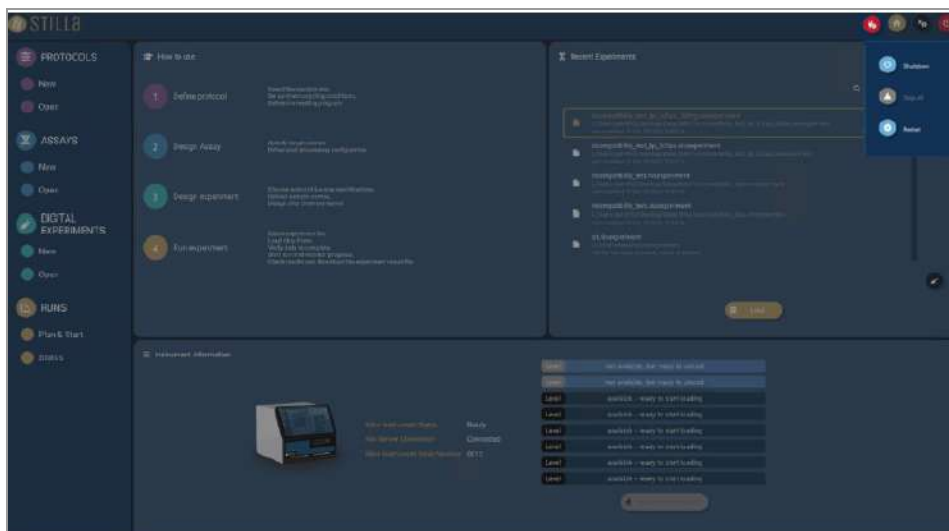


Instrument Not Ready

If the instrument fails to initialize, the system displays a red Instrument Status indicator turns red.



When this occurs, tap Restart in the Power menu QX700 ddPCR System Control Software.



If the problem persists, contact Bio-Rad Technical Support.

Automatic and Repeated Restarts of the QX700 ddPCR System

This procedure explains how to shut down the QX700 ddPCR System if it repeatedly or automatically after shutting down the Windows session.

To shut down the instrument

1. Shut down the QX700 ddPCR System Control Software.
2. Shut down the Windows session.

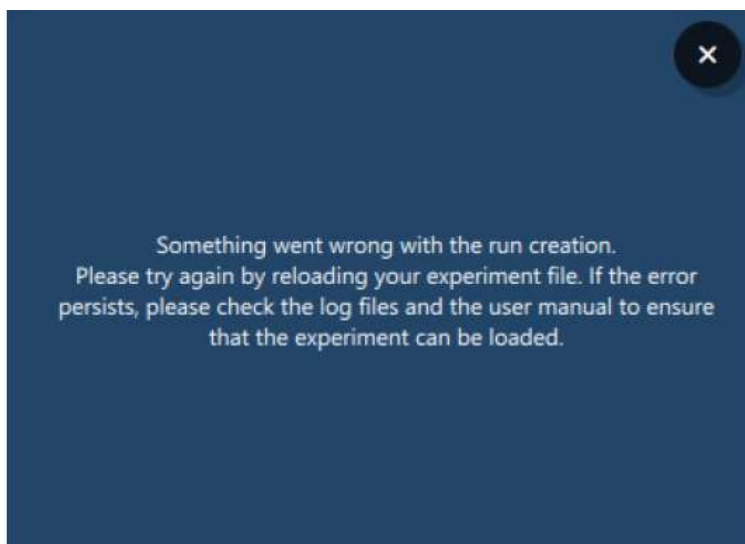
Note: If the instrument restarts automatically again, wait for the Windows login screen to appear.

3. Then turn off the power switch at the back of the instrument.

If the problem persists, contact Bio-Rad Technical Support.

Experiment Launching Errors from a Local Area Network (LAN)

An error might occur when the system is launching a run from a file stored on a LAN location that requires different credentials from the active Windows session.

**To resolve LAN errors**

1. Copy the experiment file to a local folder on the QX700 ddPCR System.
2. Launch the run from the local copy.

Note: If you frequently use network-based files, contact Bio-Rad Technical Support for best practices.

Run Result Download Errors

This section explains how to resolve run result download errors both on the QX700 ddPCR System and from a remote computer.

To resolve remote computer run result download errors

1. Check the network connection for stability and speed.
2. If the issue persists, download the results directly from the instrument.

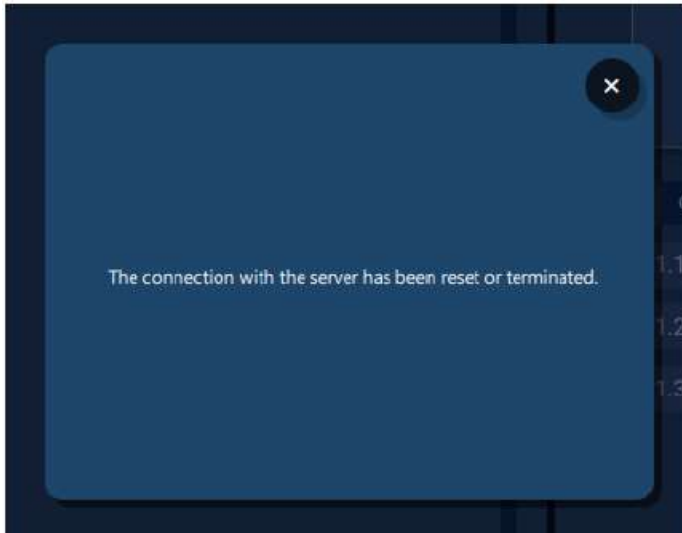


Fig. 7: Run Result Download Error (Remote Computer)

To resolve QX700 ddPCR System(local) run result download errors

1. Try retrieving the results a second time.
2. Check disk space to ensure the storage is not full.

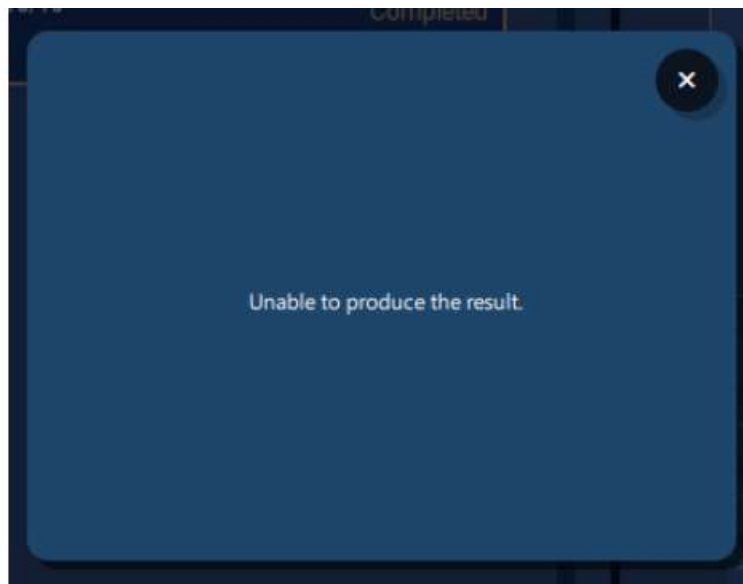


Fig. 8: Run Result Download Error (Local)

Appendix B Cleaning and Maintaining the QX700 ddPCR System

With long and constant use, the QX700 ddPCR System will require some cleaning and other maintenance.

QX700 ddPCR System Cleaning and Maintenance Safety Warnings

When cleaning and maintaining the QX700 ddPCR System, always consider and follow the warnings listed in [Table 12](#) that follows.

Table 12. Cleaning and maintenance safety warnings

Warning	
	To prevent electrical shock, always turn off and unplug the instrument from the electrical outlet before cleaning it.
	When handling biohazardous or radioactive samples, adhere to the recommended precautions and guidelines specific to your laboratory and location. These guidelines should include cleaning, monitoring, and disposal methods for the hazardous material (s) you are using.
	

Table 12. Cleaning and maintenance safety warnings, continued

Warning	
	Always use gloves, safety glasses, a mask, and a laboratory coat when cleaning or decontaminating the system. Do not clean internal components, including the optical module. Doing so may impair instrument performance. Do not spray cleaning agents directly onto or into the instrument. Do not use spray bottles on any part of the QX700 ddPCR System. Always follow the cleaning agent manufacturer's safety instructions.

Disposal

At the end of the instrument's service life, dispose of the QX700 ddPCR System according to your country's regulations for electrical and electronic waste.

- Do not dispose of the instrument in general waste.
- Take it to an authorized recycling or disposal center.
- Follow all applicable local and national guidelines

Appendix C Catalog Numbers for the QX700 ddPCR System and Accessories

This appendix lists the catalog numbers for the QX700 ddPCR Systems and accessories.

Instruments and Accessories

Table 13. Catalog numbers for QX700 ddPCR System and accessories

Catalog Number	Description
17011036	QX700 Essential Droplet Digital PCR System
17010638	QX700 Standard Droplet Digital PCR System
17010628	QX700 High Throughput Droplet Digital PCR System
12025252	RDG16 Cartridges, Pack of 12
12025260	naica IQ/OQ kit
12025257	naica ddPCR Mix 5X
12025258	naica ddPCR Mix 10X
12025253	naica Multiplex ddPCR Mix 5X
12025255	naica Multiplex ddPCR Mix 10X
SW12	Antistatic wetted wipes (ACL Staticide)
	Precision Wipes*
	Reagents or consumables for nucleic acid purification.
	Standard consumables and equipment for PCR mix preparation.
	Assay-specific digital PCR reagents, primers and probes.
* These wipes must be purchased using the reference - Precision Wipes (Kimtech™ Science, 7552, 1 ply, 213 x 114 mm) from global standard laboratory suppliers	



**Bio-Rad
Laboratories, Inc.**

Life Science
Group

Website bio-rad.com **USA** 1 800 424 6723 **Australia** 61 2 9914 2800 **Austria** 00 800 00 24 67 23 **Belgium** 00 800 00 24 67 23 **Brazil** 4003 0399
Canada 1 800 361 1808 **China** 86 21 6169 8500 **Czech Republic** 00 800 00 24 67 23 **Denmark** 00 800 00 24 67 23 **Finland** 00 800 00 24 67 23
France 00 800 00 24 67 23 **Germany** 00 800 00 24 67 23 **Hong Kong** 852 2789 3300 **Hungary** 00 800 00 24 67 23 **India** 91 124 4029300 **Israel** 0 3 9636050
Italy 00 800 00 24 67 23 **Japan** 81 3 6361 7000 **Korea** 82 080 007 7373 **Luxembourg** 00 800 00 24 67 23 **Mexico** 52 555 488 7670
The Netherlands 00 800 00 24 67 23 **New Zealand** 64 9 415 2280 **Norway** 00 800 00 24 67 23 **Poland** 00 800 00 24 67 23 **Portugal** 00 800 00 24 67 23
Russian Federation 00 800 00 24 67 23 **Singapore** 65 6415 3188 **South Africa** 00 800 00 24 67 23 **Spain** 00 800 00 24 67 23 **Sweden** 00 800 00 24 67 23
Switzerland 00 800 00 24 67 23 **Taiwan** 886 2 2578 7189 **Thailand** 66 2 651 8311 **United Arab Emirates** 36 1 459 6150 **United Kingdom** 00 800 00 24 67 23