
QX ONE™ Droplet Digital™ PCR System and QX ONE Software

Instrument Guide

Version 1.4



BIO-RAD

QX ONE Droplet Digital PCR System and QX ONE Software

Instrument Guide

Version 1.4

For Research Use Only

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Revision History

Document	Date	Description of Change
QX ONE Droplet Digital PCR System and QX ONE Software Instrument Guide Version 1.4 DIR 10000116512 Ver K	November 2023	Added new Software Settings tab in Version 1.4
QX ONE Droplet Digital PCR System and QX ONE Software Instrument Guide Version 1.3 DIR 10000116512 Ver J	September 2023	Add recommendation to Instrument Maintenance section to run a plate on the QX ONEmonthly, at a minimum
QX ONE Droplet Digital PCR System and QX ONE Software Instrument Guide Version 1.3 DIR 10000116512 Ver H	July 2023	Add new legal statement and Managing Waste section; remove info in General Care topic that appears in Managing Waste; doc update only.
QX ONE Droplet Digital PCR System and QX ONE Software Instrument Guide Version 1.3 DIR 10000116512 Ver G	January 2023	Update for Version 1.3, as follows: <ul style="list-style-type: none"> ■ Update screen shots to show in the software toolbar the percentage of disk space available on the touch screen computer hard drive instead of the number of plates than can be run. ■ Add bullet point in excluded wells topic regarding foil piercing on all wells in a plate (including excluded wells), although droplets are not generated or read in excluded wells

Document	Date	Description of Change
QX ONE Droplet Digital PCR System and QX ONE Software Instrument Guide Version 1.2	December 2021	Update with Version 1.2 enhancements, including the following: <ul style="list-style-type: none"> <li data-bbox="902 478 1295 537">■ Ability to cancel, recover, and reorder plates <li data-bbox="902 554 1110 581">■ New user privilege <li data-bbox="902 594 1170 621">■ Enhanced data recovery <li data-bbox="902 634 1175 661">■ Troubleshooting function
QX ONE Droplet Digital PCR System and QX ONE Software Instrument Guide Version 1.1	October 2020	Add topics for the following: <ul style="list-style-type: none"> <li data-bbox="902 726 1224 753">■ Aspirating the waste reservoir <li data-bbox="902 766 1279 793">■ Loading the plate into the centrifuge <li data-bbox="902 806 1295 833">■ Recovering the plate from a failed run

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Safety and Regulatory Compliance

This section 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

The instrument has been tested and found to be in compliance with all applicable requirements of the following safety and electromagnetic standards:

- IEC 61010-1:2010 (3rd:2016, EN61010-1:2010 (3rd ed.). Electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- IEC 61326-1:2012 (Class A), EN 61326-1:2013 (Class A). Electrical equipment for measurement, control, and laboratory use. EMC requirements, Part 1: General requirements
- IEC 61010-2-081:2015, 3.0 edition, UL 61010-2-081:2015, CAN/CSA C22.2 No. 61010-2-081:19. Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes (includes Amendment 1)
- CAN/CSA 22.2 No 61010-1-04, Safety requirements for electrical, equipment for measurement, control, and laboratory use, Part 1: General requirements
- CAN/CSA C22.2 No. 61010-2-101:2019 IEC 61010-2-101: 2018 (3rd ed.)
- EN 61326-1:2006 (Class A). Electrical equipment for measurement, control, and laboratory use. EMC requirements, Part 1: General requirements
- UL 61010-1:2004, Laboratory equipment, Test & Measurement Equipment and Industrial Process Controls
- UL 61010-2-101:2019. Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment
- Restriction of hazardous substances (ROHS) directive (European Union)

- Registration, evaluation, authorization and restriction of chemicals (REACH). European Chemicals Agency (ECHA) June 1, 2007
- Waste electrical and electronic equipment (WEEE) directive

This equipment 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.

Table 1. Regulatory symbols

Symbol	Definition
	The CE symbol indicates that the manufacturer ensures the product conforms with the essential requirements of the applicable EN directives.
	The CSA symbol indicates that a project has been tested to Canadian and U.S. standards, and it meets the requirements of those applicable standards. This equipment has been tested and found to comply with the limits for a Class A digital device pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.
	The Waste Electrical and Electronic Equipment (WEEE) Directive symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.

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
	<p>Warning about risk of harm to body or equipment</p> <p>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.</p>
	<p>Warning about handling biohazardous materials</p> <p>When handling biohazardous samples, adhere to the recommended precautions and guidelines and comply with any local guidelines specific to your laboratory and location.</p>
	<p>Warning about risk of burning</p> <p>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.</p>
	<p>Warning about pinch or crush risk</p> <p>If the instrument is used in certain states, there may be pinch/crush hazards present. Ensure the instrument is installed on a level, flat top lab bench or sturdy table that is large enough for the entire instrument.</p>
	<p>Warning about risk of electric shock</p> <p>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.</p>

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 A, Instrument Maintenance](#).

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 cord, power switch, and USB port supplied with the instrument, and the plug adapter corresponding to the electrical outlets in your region.
- Position the instrument on a solid, stable surface, with adequate room at the back and on each side so that users can easily reach the power cord and USB port.
- 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 [Environmental Requirements on page 24](#).

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.

Listed below are features to 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.

Surface Decontamination



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

Important: Do not use abrasive or corrosive detergents or strong alkaline solutions. These agents can scratch surfaces and damage the system.

The following areas can be cleaned with 10% bleach solution:

- Outer area and chassis
- Inner plate holders
- Droplet generation, thermal cycling, and droplet reading surfaces
- Control panel and display

To prepare and apply the disinfectant, refer to the instructions provided by the product manufacturer. For questions regarding the use of other cleaning agents, contact Bio-Rad Technical Support.

For more information on surface cleaning, see [Appendix A, Instrument Maintenance](#).

Important: Do not clean the handler Y-axis rail when the front door is open. This is a lubricated surface, and failures will occur if the lubrication is removed.

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 [Instrument Cleaning and Decontamination on page 117](#).

Transport

You must perform the specified decontamination procedures before moving or shipping the system. Always move or ship the instrument with the supplied packaging materials, which will protect the instrument from damage. If appropriate containers cannot be found, contact your local Bio-Rad office.

Warranty

Important: The instrument is for research use only, and not for use in diagnostic procedures.

The instrument and its associated accessories are covered by a standard Bio-Rad warranty. Contact your local Bio-Rad office for the details of the warranty. Follow the safety specifications listed in this chapter and throughout this guide.

The instrument is intended for laboratory use only. Bio-Rad Laboratories, Inc. 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 of the instrument not performed by Bio-Rad Laboratories or an authorized agent. Alteration of this instrument voids the warranty and safety certification, as it creates a potential safety hazard.

Use of unapproved supermixes or additives may harm the instrument and voids the warranty.

Use only the power cord supplied with the instrument, using only the plug adaptor that corresponds to the electrical outlets in your region.

Chapter 1 Introduction to Droplet Digital PCR

Droplet Digital™ PCR is a digital polymerase chain reaction method based on water-oil emulsion droplet technology. Droplet Digital PCR™ (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.

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

The ddPCR process adheres to the following workflow:

- You prepare your samples for PCR by combining DNA or RNA with primers, probes dye, and Bio-Rad ddPCR supermix.
- A droplet generator fractionates a sample into ~20,000 nanoliter-sized droplets 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.
- A droplet reader reads each droplet to determine the fraction of positive droplets in the original sample and uses Poisson statistical formulas to determine the 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 QX ONE™ Droplet Digital PCR System runs the plates containing your DNA samples through the Droplet Generator as the first component in the three-part process. The Droplet Generator uses specially developed reagents and microfluidics to partition each sample into approximately 20,000 nanoliter-sized droplets. 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 moved through the internal thermal cycler, which performs repeated heating and cooling processes. This amplifies one or more copies of a particular DNA segment, thereby multiplying strands of DNA sequencing into the thousands or millions.

Droplet Reader

Following PCR amplification of the nucleic acid target in the droplets, the plate moves to the Droplet Reader, which analyzes each droplet individually using a four-color detection system, depending on the number of channels specified in the experiment.

The autosampler in the Droplet Reader picks up the droplets from each well in the plate. The droplets are spaced out individually for fluorescence reading and fluorescence is then measured in each droplet. Positive droplets, which contain at least one copy of the target DNA molecule, exhibit increased fluorescence compared to negative droplets and are presented in color in the analysis displays. Negative droplets are presented in grayscale.

Finding Out More

Tap the Help tab (🔍) on the left, and then tap the Bio-Rad Website link to access links to technical notes, manuals, videos, product information, and technical support. The website also provides many technical resources on a wide variety of methods and applications related to PCR, Droplet Digital PCR, and gene expression.

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Chapter 2 QX ONE Droplet Digital PCR System

The QX ONE™ Droplet Digital PCR System combines droplet generation, thermal cycling, and droplet reading technologies into a single instrument, as described below:

- The droplet generator partitions samples into approximately 20,000 uniform droplets.
- The internal thermal cycler performs repeated heating and cooling processes to amplify one or more copies of a particular DNA segment in each droplet.
- The droplet reader streams the droplets in single file, and then counts the fluorescent positive and negative droplets to calculate and quantify target DNA concentration.

The QX ONE Droplet Digital PCR System also features a touch screen computer, which is integrated onto the instrument and has QX ONE Software already installed.



When you open QX ONE Software from the touch screen, the software automatically recognizes the QX ONE Droplet Digital PCR System.

Note: You cannot directly connect standalone computers to the instrument. However, from a standalone computer you can access files stored on the touch screen computer's internal drive, or from another shared location, as long as all units are connected through the same company network. You can also access the data with a USB drive connected to the touch screen.

QX ONE Droplet Digital PCR System Components

The QX ONE Droplet Digital PCR System ships with the following items:

- The instrument, which performs the sequential ddPCR processes
- Attached touch screen, which is a computer that displays the software interface and connects to the instrument
- QX ONE Software, which is installed on the instrument touch screen computer, and provides a user interface to
 - Control the instrument
 - Set up assays
 - Collect analysis data
 - Recover plates from run failures
 - Store analysis data
 - Display analysis data
- QX ONE Droplet Digital PCR System Accessory Kit, which includes the following:
 - PX1 GCR Sealer Support Block
 - QX ONE Droplet Digital PCR System Waste Bottles
 - Keyboard
 - Power cord (compatible within North America)
 - Warranty card

For information on additional ddPCR components and supplies, see [Appendix B, Ordering Information](#).

Instrument Specifications

Table 3. QX ONE Droplet Digital PCR System instrument specifications

Element	Specifications
Size (W x D x H)	122 cm (48 in) x 66 cm (26 in) x 38 cm (15 in) 76 cm (30 in) top of monitor
Weight	100 kg (220 lb) (includes the monitor but not reagents)
Capacity	5 plates
Samples	Up to 96 per plate
Partitions per sample	Approximately 20,000 droplets
Detection channels	4 (FAM, HEX, Cy5, and Cy5.5), plus scatter channel
Thermal gradient	Yes
Onboard computer	24 in, 1920 x 1080 resolution Holds data for approximately 100 plates
Time to results	6.5 hours for the first plate, and approximately 4 hours for each plate thereafter, based on a standard 2-step ddPCR cycling protocol
Benchtop requirements	<p>The following requirements apply to the benchtop or table on which the instrument will be installed.</p> <p>The benchtop or table must be 76 in W x 30 in D x 50 in H (193 cm x 76 cm x 126 cm), single benchtop rated for more than 250 lbs (114 kg) load. Ensure there is enough room above the instrument to ensure ergonomic safety.</p> <p>Important: Do not place instrument over multiple benchtop surfaces.</p> <p>Level within approximately 1° about each axis.</p>

Environmental Requirements

Table 4 lists the environmental requirements for the QX ONE Droplet Digital PCR System.

Important: You must use the supplied shielded cables with your instrument to ensure compliance with the Class A FCC limits.

Table 4. Conditions for safe use

Usage aspect	Requirements
Rated input power	100–240 V, 50–60 Hz, (plugs into standard AC receptacle)
Fuses	10A 250 V SLOW BLOW
Voltage fluctuations	± 10% for the included external power supply Note: Use only the power cord supplied with the equipment.
Pollution degree	2
Usage temperature	18–30° C
Relative humidity	20 to 80%
Altitude	0 to 8,200 ft (0 to 2,500 m)
Installation category	II (external power supply plugs into a standard AC receptacle) Indoor use only
Ventilation requirements	The following distances should be unobstructed for proper ventilation: <ul style="list-style-type: none"> ■ 14 in (35.5 cm) on the left and right sides of the instrument ■ 4 in (10 cm) behind the instrument

General Operating Instructions and Routine

Important: The QX ONE Droplet Digital PCR System must be installed and calibrated by a Bio-Rad service engineer.

Note the following requirements:

- Your instrument should be placed on a solid surface and away from other instruments that can cause vibration.
- To ensure adequate ventilation, leave a minimum of 4 in (10 cm) of clear space behind, and a minimum of 14 in (35.5 cm) of clear space to the right and left of the instrument.
- Position the instrument where the power cord and power source can be easily accessed when it is time for equipment service and maintenance.
- Use only the cord provided with the instrument to connect to the power source.

Turning on the Instrument

Note: If you are restarting the instrument after turning it off, ensure at least 5 min have passed before turning the instrument on again.

To turn on the instrument

1. Press the switch on the back of the instrument to power on the QX ONE Droplet Digital PCR System.
2. Press the power button on the front of the instrument. The button flashes green to indicate power is on and the system is initializing.
3. Press the switch on the side of the touch screen to power on the computer.
4. Wait 5 min, and then launch QX ONE Software on the touch screen.
5. Log in with your user name and password. For information, see [Signing into the Software on page 34](#).
6. Wait until the instrument status changes from Busy to Ready (between 2 and 2.5 min).

Important: Do not touch the instrument or touch screen while the instrument is busy initializing.

Note: If the instrument does not fully initialize after 10 min, close the software, turn off the computer, and then turn off the instrument. Wait 2 min, and then repeat steps 2, 3, and 4.

Replacing Oil and Waste Bottles

Ensure that you have enough QX ONE Droplet Digital PCR System Droplet Generation Oil and Droplet Reader Oil in the oil bottles, and enough space in the waste bottles, to complete your experiment.

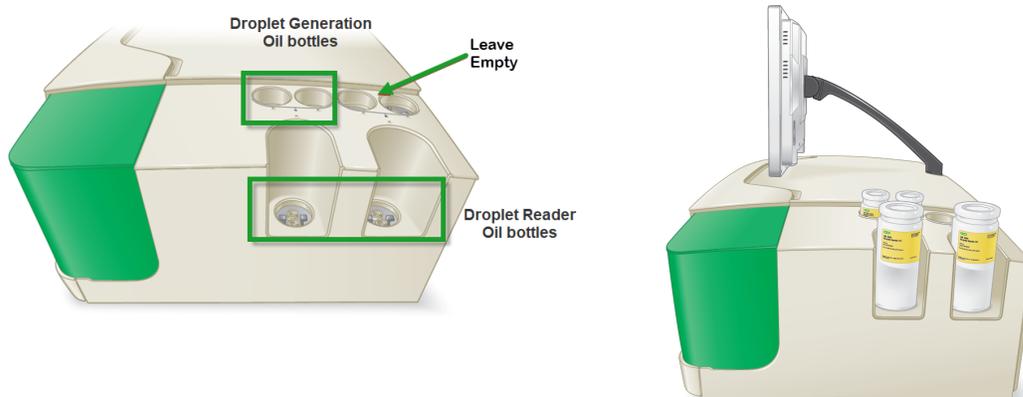
Important: Use the Bio-Rad QX ONE Droplet Digital PCR System Droplet Generation Oil for Probes and Droplet Reader Oil. For catalog numbers, see [Appendix B, Ordering Information](#).

The instrument status bar on the QX ONE Software main screen displays oil bottle levels. If current levels are not sufficient for the scheduled run, the instrument initiates an alert and QX ONE Software displays an advisory message to replace one or more bottles.

Important: If an error message appears (error #111), stating that there is not enough Droplet Reader Oil in the bottle to run the loaded plates, you must add a bottle or switch the bottle within 15 minutes. If the time elapsed exceeds 15 minutes before bottle replacement, the instrument might fail processing. For instances when the bottle has not been replaced within 15 minutes, Bio-Rad recommends restarting the QX ONE Droplet Digital PCR System.

Always use a full bottle as a replacement. Because the waste bottles fill up more quickly than the oil bottles are depleted, replace the existing waste bottle with an empty waste bottle whenever you change a droplet oil bottle. For information on waste generated by the QX ONE Droplet Digital PCR System, see [Managing Waste on page 112](#).

As shown in the following graphics, the instrument features two slots for the droplet generation oil bottles (small spaces marked with a "P") and two slots for the droplet reader oil bottles (larger spaces). Leave the two additional slots on the right (marked with "E") empty.



The QX ONE Droplet Digital PCR System Droplet Generation Oil for Probes and Droplet Reader Oil bottles are prefilled and sealed with instrument-specific caps, as shown in the following graphics:



The notched top helps with bottle alignment and insertion. The RFID label allows the instrument to recognize each bottle as correct for its position, and monitor the oil levels in each bottle.

To release an empty bottle from its position

1. Firmly push the bottle down to the bottom of the slot and then release. The bottle pops up from the slot.
2. When the bottle pops up from the slot, lift it out of its position.

To insert a bottle into its corresponding position

1. Turn the bottle upside down so the notched cap is facing down.
2. Slowly twist the bottle until the notched cap clicks into place.
3. Firmly push down on the bottle to the bottom of the slot to snap it into place. When secured, the bottle should not be easily lifted out of position and should not twist in place.

Turning off the Instrument

Bio-Rad recommends turning off and restarting the instrument one day a week. When you turn off the instrument, wait at least 5 min before turning it back on.

To turn off the touchscreen and then turn off the instrument

1. Close QX ONE Software, and then tap the Windows icon () in the lower-left corner.
2. Tap the Power icon () and select Shut down. Wait until the touch screen has powered off.
3. Turn off the power switch on the back of the instrument.

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Chapter 3 About QX ONE Software

Important: This instrument guide contains abridged information on QX ONE Software, Standard Edition. For comprehensive information on all software capabilities, refer to the QX ONE Software User Guides for the standard and regulatory editions.

A Bio-Rad field service engineer installs your software edition on the QX ONE Droplet Digital PCR 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 in the QX ONE™ Droplet Digital™ PCR (ddPCR™) System
- Create and store templates for plate layouts, thermal cycling protocols, and reports.
- Use the live analysis function during the droplet reading phase
- With the Manage Plate user privilege, cancel runs and reorder plates while they are in the instrument Inbox
- Analyze your data files in a variety of charts and tables in the Analysis module
- Generate reports on your data
- Restrict template access to ensure the use of approved templates only

For information on using the instrument, refer to the QX ONE Droplet Digital PCR System Instrument Guide.

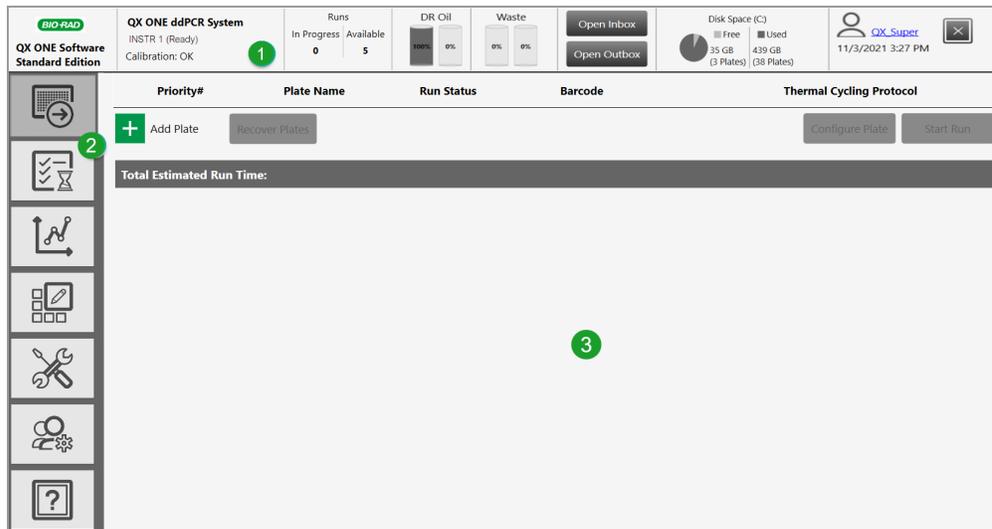
The QX ONE guides instruct you to tap options on the touchscreen. If you are using QX ONE Software with a keyboard and mouse, click the options instead.

Tip: You can download and link the software and instrument guides to corresponding buttons in the Help window. For information, see [Linking the User Guides in the Help Window on page 32](#).

The Standard Edition of the software offers the choice to enable or skip the User Management module, as follows:

- If enabled, QX ONE Software is installed with all user functionality on the Users and Preferences tab. The installer is prompted to set up the first user account, which inherits all user privileges.
- If not, QX ONE Software automatically creates a generic user to set up and run plates on the instrument and the Users and Preferences tab is not included in the left panel. The user is automatically signed in and is available to everyone. You can modify two related user preferences; for information see [Partial Preferences on page 38](#).

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



LEGEND

- 1 The status bar displays information about the instrument and user.
- 2 Tabs provide access to the main functional windows.
- 3 The main pane displays the details of the selected tab.

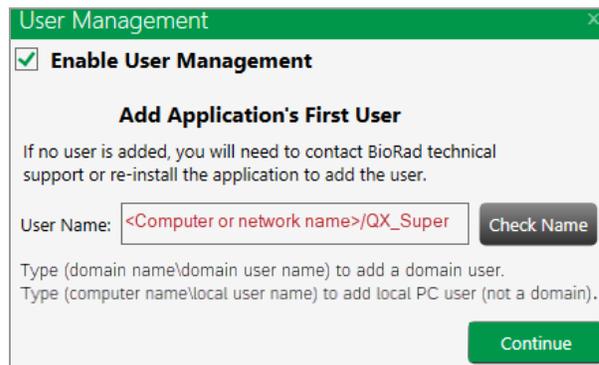
If QX ONE Software goes into standby mode after being idle, tap in the lockout screen to sign into the software again and display the last active window.

Enabling User Management

During the installation of QX ONE Software, Standard Edition, you can choose to enable or bypass the User Management module:

- If the Enable User Management checkbox is selected, all user functions are included in the installation.
- If the checkbox is not selected, User Management is not enabled and the corresponding tab is not included in the side pane. A single generic user, with a small set of user preferences, is always logged in. For information, see [Partial Preferences on page 38](#).

Important: Before you can set up users in the software, all users must be set up on the computer as local Windows users or in Active Directory on your network.



To bypass the User Management module

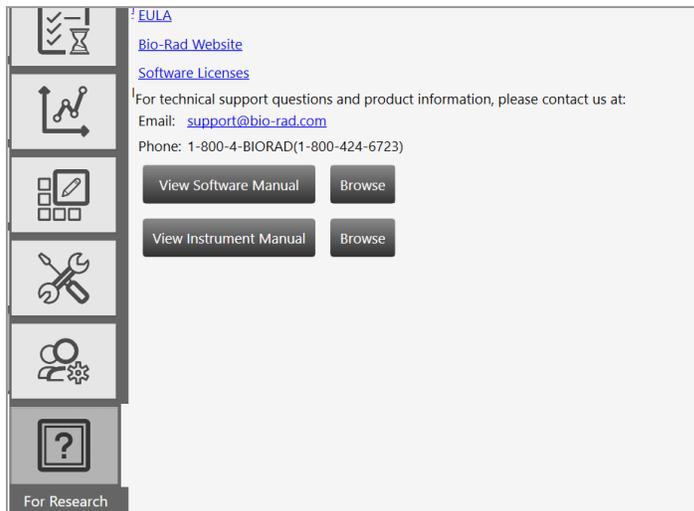
- ▶ Ensure the checkbox is cleared in the User Management dialog box, and then click Continue to complete the installation.

To enable the User Management module

1. Ensure the Enable User Management checkbox is selected.
2. Enter the user name and tap Check Name to validate the user.
3. Tap Continue to add the user and complete the installation.

Linking the User Guides in the Help Window

To facilitate access to user assistance documentation, you can link the instrument guide for the QX ONE Droplet Digital PCR System and the user guide for your software edition (standard or regulatory).



Important: If you have not received PDFs of the instrument guide and applicable user guide, you can download them from the [Bio-Rad website](#).

To link the guides

1. Navigate to the following folder:
C:\ProgramData\Bio-Rad*<Standard or Regulatory>*
2. Within the folder, create another folder and rename it UserGuides.
3. In QX ONE Software, select the Help tab, and then click the Browse button beside View Software Manual or View Instrument Manual.
4. Navigate to the User Guides folder and click Open.
QX ONE Software links the guide. To open the PDF, click the View <manual> button.
5. Repeat for the remaining guide.

Chapter 4 Getting Started

Use the information in this chapter to

- Sign into the software or change users
- Select the instrument
- Become familiar with the instrument status bar and main functional windows
- Understand the compatible file types for your software edition
- Learn the differences between the software installed on the instrument touch screen versus a standalone computer

Tip: If QX ONE Software goes into standby mode after being idle, tap in the lockout screen to log into the software again.

Signing In, Viewing Privileges, and Changing Preferences

Important: If User Management was not enabled during the software installation, QX ONE Software creates a single generic user, which is already logged in and is available to all users for setting up and running plates, and analyzing the results. The user can access a set of partial preferences using the generic user link. For more information, see [Partial Preferences on page 38](#).

Typically, a system or software administrator sets up users and privileges for QX ONE Software, and communicates the information to you.

Note the following:

- You cannot change your user privileges unless you are assigned the Add/Manage Users privilege. For information, see [Viewing User Privileges on page 35](#).
- You can change your user preferences, which are set to defaults. For information, see [Managing Your Preferences on page 37](#).

Signing into the Software

Important: If User Management was not enabled during the installation, the generic user is automatically signed in when you open the software.

To sign in

1. Tap the touch screen to open the Sign in dialog box.
2. Enter the user name and password and tap Sign in.



User Name: QXONE_User1

Password:

Sign in to: QXONE_TouchScreen

Sign in

[How do I sign in to another domain?](#)

3. Ensure the Do not show EULA on sign in checkbox is selected and tap I Agree.



Do not show EULA on sign in

I Disagree I Agree

Each user must agree to the end user license agreement on initial login in order to use the software. If you clear the checkbox, the End User License Agreement appears the next time you log into the software, and you must agree again to the terms before the software opens. If you do not agree to the EULA, the application closes immediately.

When you agree to the EULA, the dialog box closes and the application opens. Your user name appears in the Instrument Status bar.

The Add Plate window opens on the instrument touch screen.

If you are opening the software on a standalone computer, the Data Analysis window opens.

Viewing User Privileges

Important: If you did not enable the User Management module during the installation, the related functions are not available.

In the User Management window, your privileges are identified by the selected checkboxes.

To view your assigned privileges

- ▶ Select the User Management tab.



Unless you are assigned the Add/Manage Users privilege, checkboxes for your assigned privileges are selected but not enabled, as shown in the following graphic. To request changes to your privileges, contact your software administrator.

User Management

User Name: Check Name

Full Name: QX_User1

Privileges

- Add/Manage Users
- Create New Templates
- View Datafiles (created by other users)
- Overwrite Existing Datafile name
- System Settings
- Maintenance
- System Data
- Access Module Recovery Tool
- Manage Plate

[Table 5](#) lists the available privileges, which can be assigned in any combination.

Table 5. User privileges

Privilege	Purpose
Add and manage users	Add or remove users, set privileges, and change preferences. Important: Users who are assigned the Add/Manage Users privilege can create users and update privileges and preferences for any user. Only the superuser can remove this privilege from user accounts.
Create new templates	Save a design for a plate, thermal cycling protocol, or analysis report as a template.
View data files (created by other users)	See run files that were created from runs executed by other users.
Overwrite existing data file name	Save the file with a new file name. Files are always saved with the extension for the application you are using. For information, see Compatible File Types on page 42 . Note: Users without this permission can open files and perform analysis but cannot create a new file.
System settings	View logs, reprocess data with new calibration values, and change file locations. All users can view the file locations. Important: If your administrator selected the Preferred Locations checkbox in System Settings, individual user location preferences are overridden.
Maintenance	View the event log and the system data settings. Note: All users can reprocess data, view system folder settings, as well as the maintenance log and maintenance reports.
System Data	Move raw data from the touch screen computer to free up disk space. Access troubleshooting data. Recover data from a temporary file created for a failed run.
Access Module Recovery Tool	For manual plate recovery, you can specify the processes to be rerun.
Manage Plate	Cancel runs on the QX ONE Droplet Digital PCR System. Reorder plates that are still in the instrument Inbox.

Managing Your Preferences

Important: If you did not enable User Management during the software installation, the User Management module is not included and a truncated set of preferences is available. See [Partial Preferences on page 38](#) for information.

Use the User Management window to modify your personal user preferences. Default folder locations appear in your preferences, but you can change them. You can also choose to keep all data files and templates private. The software prompts you to choose either your personal folder or the shared folder each time you save a file or template.

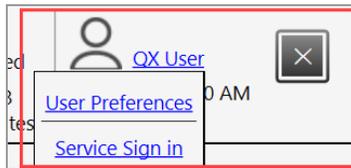
To change your preferences

1. Change any of the following preferences:
 - Enter a different file path for your data files and templates.
 - Select or clear the check boxes to change your data file and template privacy settings.

Important: The paths and checkboxes are disabled if your administrator has set Preferred Locations in System Settings.
 - Enter a different system timeout period.
 - Enter a different total of completed plates to show in the Run Status window, up to a maximum of 100.
2. Do one of the following:
 - If you are setting preferences for a new user, tap Add.
 - If you are updating preferences, tap Save.
3. When the confirmation message appears, tap Yes, and then tap OK.

Partial Preferences

If User Management was not enabled during the software installation, you can still access partial functionality.

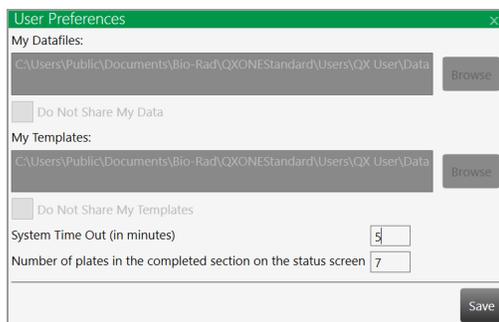


To open the menu

1. Click the user name link in the upper-right corner to display the pop-up.

Important: The Service Sign in option is used by Bio-Rad service engineers only.

2. Click User Preferences to display the dialog box.



3. You can change the following:
 - System time out in minutes (default is 5 minutes)
 - Number of plates in the completed section of the status screen (default is 7)
4. After you have made your changes, tap Save.

Signing Out or Changing Users

While the instrument is idle, one user can log out on the touch screen and another user can log in.

Important: If User Management was not enabled during the software installation, the sign in, sign out, and change users functions are not available.

Note the following:

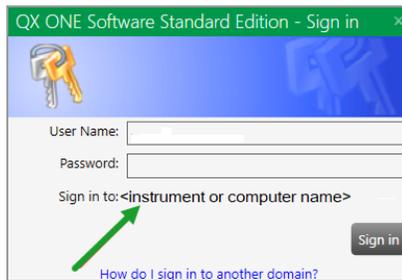
- Do not change users while a run is in progress or data might be affected.
- If the screen is locked and the initial user left unsaved changes, an advisory prompt appears. Click Save before proceeding or the previous user's work is lost.

To sign out

1. Tap the user name link in the upper-right corner and select Sign Out.
2. Tap Yes to confirm.

To change users

1. Tap anywhere in the lockout screen to display the Sign in window.
2. Enter a user name.
 - The domain name appears below the user login fields. If you are on the same domain as the previous user, you can enter your user name only.



- If the user is on a different domain, enter the domain name followed by a backslash and the user name.

<domain name>\<user name> (for example, global\john_smith)
3. Enter the password and tap Sign in.

Instrument Status Bar

An instrument status bar appears above all windows except the analysis displays, which open in a separate module.

The status bar on the touch screen displays the information and indicators shown below



LEGEND

- 1 Software name and version
- 2 Instrument name and status information
- 3 Number of runs in progress and runs available
- 4 Oil and waste levels
- 5 Open or close the Inbox or Outbox
- 6 Used and free disk space
 Storage availability is displayed in GB and by number of plates that you can run before running out of space on the touch screen computer.
Note: When QX ONE Software detects low disk space, the software displays an advisory prompt to archive data.
- 7 Name of the current user, along with the current date and time
- 8 Closes the QX ONE Software application

Tabs to Functional Windows

Table 6 describes the functional areas and primary windows in QX ONE Software. For more information, refer to the QX ONE Software User Guide.

Table 6. Window Tabs

Tab	Name	Purpose
	Add Plate	<ul style="list-style-type: none"> ■ Add and configure a plate and protocol for a ddPCR run ■ Recover a plate from a failed run
	Run Status	<ul style="list-style-type: none"> ■ In the top pane, view the runs in progress ■ In the bottom pane, view up to 100 completed runs
	Data Analysis	<ul style="list-style-type: none"> ■ Access the Data Analysis and Gene Study modules <p>Note: In QX ONE Software, Gene Study is available on a standalone computer, but not from the touch screen.</p>
	Templates	<ul style="list-style-type: none"> ■ Set up templates for plates thermal cycling protocols, and reports, and search for existing template files
	System	<ul style="list-style-type: none"> ■ View storage locations, logs, and maintenance reports ■ Archive data, access troubleshooting information, and recover data from a temporary file created for a failed run <p>Important: Available functionality depends on your assigned user privileges. Instrument calibration is available only to the Bio-Rad service engineer.</p>
	Users	<ul style="list-style-type: none"> ■ View the user privileges you have been assigned, and view and modify your personal preferences ■ Create, edit, or remove QX ONE Software users (if you are assigned the Add/Manage Users privilege) <p>Important: In Standard Edition, user functionality is available only if User Management was enabled during the installation.</p>

Table 6. Window Tabs, continued

Tab	Name	Purpose
	Help	<ul style="list-style-type: none"> Access software version information, current calibration values, End User License Agreement company website, and open source software license information <p>Tip: You can also link the user and instrument guides to the labeled buttons. For information, see Linking the User Guides in the Help Window on page 32.</p>

Compatible File Types

This section describes the file types you can open in QX ONE Software.

The following applies if your organization is using more than one edition of the software:

- You can open files created using Standard Edition only in Standard Edition.
- If you open a .qlp or .ddpcr file in QX ONE Software, Standard Edition, the file opens and is saved as a .ddpcrone file.

Table 7. Compatible file types

File Type	Extension	Details
Plate template	.ddplt	Plate template file containing setup details to perform experiments; this file type opens in the Plate Editor.
Plate template	.csv	Importable plate template file containing setup details in CSV format; this file type opens in the Plate Editor.
Protocol	.ddthp	Protocol template file containing setup details to perform experiments; this file type opens in the Protocol Editor.
Data	.ddpcrone	Contains the results of an experiment run performed on the QX ONE Instrument using QX ONE Software, Standard Edition. Note: If you open a .ddpcr file in QX ONE Software, the file is saved as a .ddpcrone file.
Data	.qlp	File type from earlier QuantaSoft™ versions, for two-channel experiment runs and data analysis; this file type opens in the Analysis module.

Touch Screen Differences

As shown in [Table 8](#), QX ONE Software functionality varies between the QX ONE Droplet Digital PCR System touch screen and a standalone computer.

Table 8. Touch Screen Differences

Feature	Instrument Touch Screen	Standalone Computer
Gene Study	Not available	Available
Files open	Only one file at a time	Up to 5 files concurrently
Run Setup	Enabled	Disabled
Run Status	Enabled	Disabled
Maintenance Log	Enabled	Disabled
Archive Data	Enabled	Disabled

When you open QX ONE Software on the touch screen, the Add Plate window appears by default. If you open the software installed on a standalone computer, the Data Analysis window appears by default and the Add Plate and Run Status tabs are not available.

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Chapter 5 Preparing a Sample Experiment

This section contains a standard protocol for sample preparation and plate setup for any assay performed on the QX ONE Droplet Digital PCR System. The following are recommended steps using the compatible GCR96 cartridges and reagents.

Important: Use only Rainin pipets and tips for all reagent and sample handling steps.

Required Components

This section describes the required equipment and materials for creating your samples. For a list of catalog numbers, see [Appendix B, Ordering Information](#).

Required Equipment

- PX1 PCR Plate Sealer
- PX1 GCR Sealer Support Block
- Centrifuge, with plate rotor capable of 1,150 RCF minimum
- Vortex mixer

Required Materials

- PCR supermix
- Buffer control
- Pipets (Rainin only)
- Pipet tips (Rainin only)
- QX ONE Droplet Digital PCR System Droplet Generation Oil
- QX ONE Droplet Digital PCR System Droplet Reader Oil
- GCR96 cartridges
- Foil plate seal
- Reagent trough
- 5 ml mixing tube

Creating the Sample Mix

This section contains a standard protocol using the ddPCR Supermix (No dUTP). You can use this protocol to prepare your samples and set up plates for any assay you perform on the QX ONE Droplet Digital PCR System. The protocol below makes enough reagent for one plate (96 wells). Volumes can be adjusted for the number of plates you need. You can insert up to five plates into the instrument.

Important: You must combine the ddPCR Supermix (No dUTP) and the Reaction Mix in a 1:1 ratio. Final concentrations for components are included in the table below for a total of 20 μ l per reaction. For Reaction Mix preparation, refer to each Supermix protocol.

To prepare the sample

1. Remove two ddPCR Supermix (No dUTP) vials of choice and two Reaction Mix vials from storage (-20° C) and let thaw at room temperature for approximately 30 min.
2. Vortex for 10 sec at medium to high speed and spin down in a small tube centrifuge.

Important: Proper mixing is critical for both the ddPCR Supermix (No dUTP) and the Reaction Mix.
3. Prepare master mix as described in the following table (use 5 ml tubes to prepare mix). Be as accurate as possible in adding the correct volume of each reagent.

Component	Volume, μl	Final Concentration
2x ddPCR Supermix (no dUTP)	1,300	1x
2x Reaction Mix	1,300	1x
TOTAL VOLUME	2,600	1x

Note: The mixes can be highly viscous. Bio-Rad recommends slow pipeting for more accurate dispensing of all liquid.

- a. Carefully pipet 650 μ l from each of the two tubes of ddPCR Supermix (No dUTP) into the 5 ml mixing tube, changing tips with each addition.
 - b. Carefully pipet 650 μ l from each of the two tubes of Reaction Mix into the 5 ml mixing tube, changing tips with each addition.
4. Cap the tube securely.
 5. To mix, vortex for 10 sec at maximum speed.

Filling the GCR96 Cartridge

You must use GCR96 cartridges with the QX ONE Droplet Digital PCR System. The GCR96 cartridge plate contains 6 DG-16 individual cartridges representing 6 sets of 16 wells. Each set of 16 must be filled with sample or control buffer for the droplet generator to perform correctly.

Important: GCR cartridges are intended for single-use only.

The following graphic highlights the two columns of the first well set in the cartridge.



Before you begin, set the PX1 PCR Plate Sealer to 180° C and 0.5 sec. You will use the plate sealer when performing the steps in the next section.

To fill the plate

1. Set the 8-channel pipet to 20 μ L.
2. Pour the vortexed and centrifuged master mix from the 5 ml tube into a reagent reservoir.
3. Use a 20 μ l 8-channel pipet to immediately transfer 20 μ l of the master mix from the reagent reservoir into the wells of the first column of the cartridge.
4. Confirm the correct positioning of the cartridge, with the notched corner in the upper left.

Note: Do not use the second depression on the pipet. While there will be a minute amount of sample left in the pipet tips, full depression can introduce air bubbles into the wells and disrupt proper droplet generation.

5. Repeat for columns 2–12 until all 96 wells are filled with 20 μ l of master mix.

Sealing the GCR96 Cartridge

This procedure describes the plate sealing procedure for the PX1 PCR Plate Sealer. If you are using a different instrument, consult the applicable user manual.

Note: References to “plate” indicate a full GCR96 cartridge holder.

To seal the plate

1. Press the Eject icon to open the PX1 PCR Plate Sealer.
2. Ensure the following:
 - The temperature is set to 180° C.
 - The time is set to 0.5 sec.
3. Load the GCR96 cartridge on the appropriate support block, making sure that:
 - The notched corner (A1) is at the upper left.
 - The cartridge is securely set into the support block.

4. Place a foil seal on top of the GCR96 cartridge.

Important: The foil seal must cover the frame of the plate with no overhang on any side. Overhanging foil can interfere with the movement of the robotic arm of the instrument.

5. Line up the top of the foil seal with the middle of the numbers on the top of the plate.

As the plate moves into the sealer, this alignment allows room for the foil to move into its final and correct position.

6. Press the green Seal button. When done, the plate sealer opens automatically.
7. Carefully rotate the plate 180° on the support block.
8. Press the green Seal button again. When done, the plate sealer opens automatically.
9. Remove the plate from the plate sealer.
10. Remove the support block from the plate sealer.



Caution: Do not leave the support block in the plate sealer, or the block will heat up. This creates a potential burn risk to users.

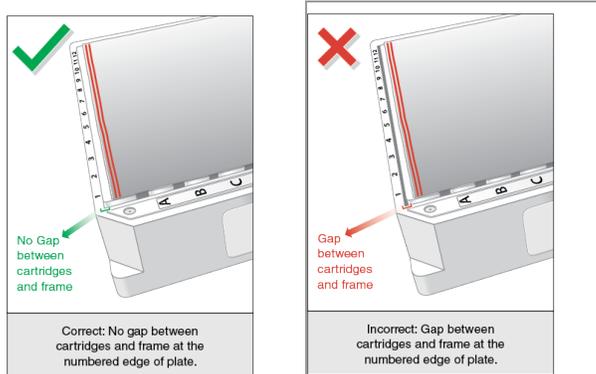
Loading the GCR96 Cartridge into a Centrifuge

Before you begin this procedure, ensure the following:

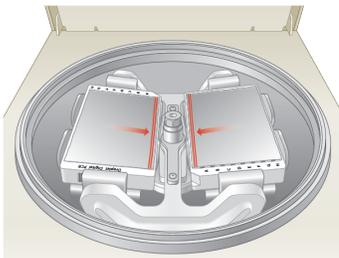
- You are wearing the proper personal protective equipment (PPE). For information, see [General Precautions on page 14](#).
- The plate is sealed. For information on using the PX1 Plate Sealer, see [Sealing the GCR96 Cartridge on page 48](#).

To load the plates

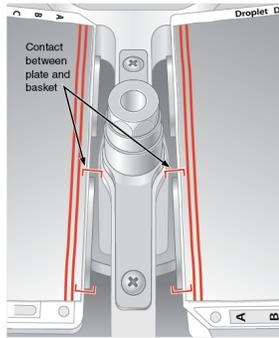
1. Push the individual DG16 cartridges in the GCR96 frame toward the numbered edge as far as they will go, to ensure there is no gap between the frame and cartridges.



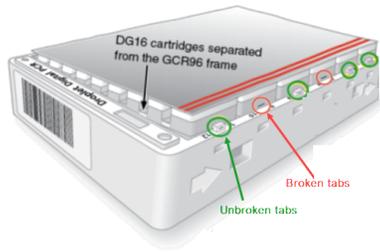
2. Open the centrifuge instrument and insert a sealed plate into each side of the plate holder.
3. If processing only one cartridge, load a dummy cartridge on the other basket to balance the centrifuge.
4. Slide each plate toward the rotor axis.



5. Ensure the numbered sides touch the edges of the centrifuge baskets.



Important: Ensure the plates are oriented correctly, or the tabs on the cartridges can break. Broken tabs can cause separation between cartridges and the cartridge holder during the centrifuge process, and cause a failure of the QX ONE Droplet Digital PCR System.



6. Close and start the centrifuge.
7. Spin for 30 sec at 1150 rcf.
8. When centrifuging is complete, open the instrument and remove the plates.
9. Press the edges of the foil seal against the plate, in case centrifuging loosened the seal.

Chapter 6 Adding and Configuring Plates

After you sign into QX ONE Software on the touch screen, the software opens to the Add Plate window.

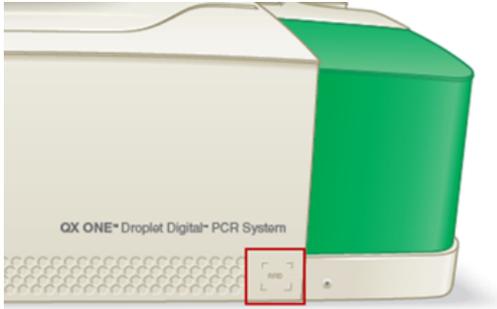
Priority#	Plate Name	Run Status	Barcode	Thermal Cycling Protocol
 Add Plate				 
Total Estimated Run Time:				

This chapter explains how to

- Scan a tracking code and add a plate in the software
- Add the physical plate to the instrument inbox
- Identify the plate and thermal cycling protocol, or select templates
- Exclude empty wells in the software
- Create the plate configuration

Adding Plates in the QX ONE Instrument and Software

The QX ONE Droplet Digital PCR System is equipped with a scanner that is used to scan cartridge (plate) RFID codes. Each GCR96 cartridge has an RFID label embedded on its side, and scanning the code allows the instrument to track the plate and its data.



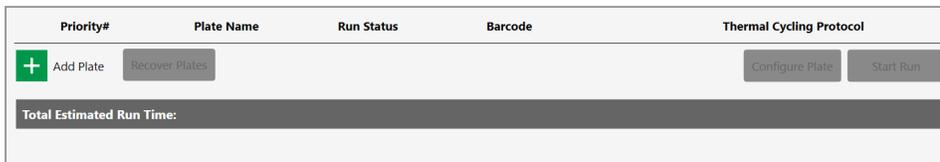
QX ONE Software prompts you to scan the RFID label on the GCR96 cartridge, and then insert the plate.

To scan the code and add the plate

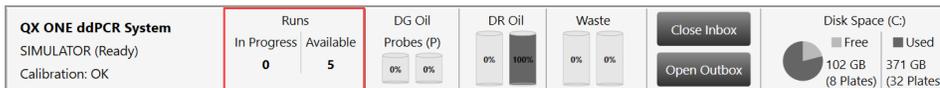
1. In the left pane, tap the Add Plate icon.



The Add Plate window appears.



If the Runs Available number in the Instrument Status bar is 1 or higher, the Add Plate button is enabled.

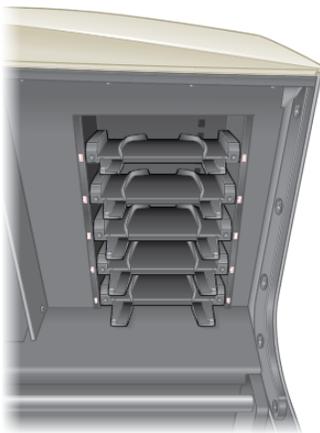


2. Tap the  icon next to Add Plate, and then scan the RFID label.

Tip: The RFID label is on the opposite side of the bar code. The bar code is not scanned.

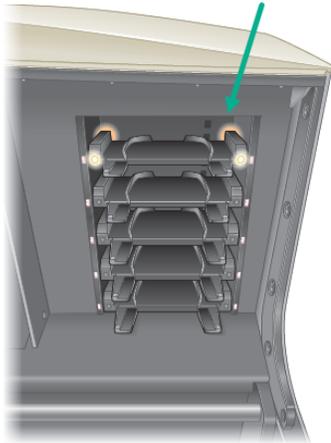


After the scan is complete, QX ONE Software displays advisory messages to indicate the Inbox door is opening and the plate should be placed in the specified slot. Slots are provided for up to 5 plates. The plate Inbox is located on the right side of the instrument, as shown in the following graphic.



Note: If plates from earlier runs occupy the QX ONE Droplet Digital PCR System Outbox, the instrument instructs you to load the plate into the Inbox slot opposite the first empty Outbox slot. If there are not enough slots available for the plates you need to run, remove the completed plates from the Outbox.

3. Position the plate with the RFID label facing the empty slot with the amber lights, and then insert the plate.



Note the following:

- If the plate is inserted properly, the amber lights turn green.



- If not, the lights turn red and you must remove and reinsert the plate.
- The Inbox remains open as long as you are adding plates. When 30 sec have passed without a plate being added, the Inbox door closes automatically.

Tip: You can also tap the Open Inbox/Close Inbox toggle button on the instrument status bar in QX ONE Software.

As each plate is added, a row containing plate information, including the plate bar code from the scan process, appears in the grid and QX ONE Software enables the Configure Plate button.

The screenshot displays the QX ONE ddPCR System software interface. At the top, there is a status bar with the following information:

- QX ONE ddPCR System**: SIMULATOR (Ready), Calibration: OK
- Runs**: In Progress: 0, Available: 2
- DG Oil**: Probes (P): 0%
- DR Oil**: 0%
- Waste**: 0%
- Disk Space (C:)**: Free: 105 GB (22%), Used: 358 GB (78%)
- User**: QX_Super, 7/24/2019 2:17 PM

Below the status bar is a table with the following columns: Priority#, Plate Name, Run Status, Barcode, and Thermal Cycling Protocol. The table contains three rows, all with a 'Loaded' status and a barcode. Each row has edit, delete, and refresh icons. Below the table is a green '+ Add Plate' button and a green 'Configure Plate' button. At the bottom, there is a 'Total Estimated Run Time:' field.

Priority#	Plate Name	Run Status	Barcode	Thermal Cycling Protocol
1		Loaded	12-02-03-04-05	[Edit] [Delete] [Refresh]
2		Loaded	01-12-03-04-05	[Edit] [Delete] [Refresh]
3		Loaded	01-02-12-04-05	[Edit] [Delete] [Refresh]

Buttons: + Add Plate, Configure Plate, Start Run

Total Estimated Run Time:

4. Tap Configure Plate and continue to the next section.

Plate Configuration Window

From the Plate Configuration window, all users can start runs on selected plate templates using the initial configuration, an altered configuration, or just the plate name, data file name, supermix, and thermal cycling protocol.

Tip: Except for the supermix, which you must select before the run, you can configure the plate experiment parameters before, during, or after a run.

The window contains the following three tabs for identifying and configuring your plates and protocols for the run:

- **Plate Information** — Default display, where you can create or select existing plate and protocol templates, or start a run immediately with a minimum of information and configure experiment parameters later
- **Well Selection** — Optional task, where you can exclude wells from processing
Note: The QX ONE Droplet Digital PCR System processes the entire plate by default. If you have filled fewer than 96 wells with sample, you should exclude those wells from processing.
- **Well Information** — Where you can create or modify the experiment parameters; optional if you are working with an existing plate layout

When configuring plates, note the following:

- Users with the Create New Template user privilege can save a new or modified plate or protocol design as a template before starting the run.
- All users can set up experiment parameters and run the plate without saving the layout.
- Users can identify experiment parameters in the Analysis module.

Important: If you are configuring a plate in which the One-Step RT kit is being used, see [Using the One Step RT ddPCR Advanced Kit for Probes on page 66](#).

Plate Information Tab

The Plate Information tab is selected by default when the Plate Configuration window opens, and provides functionality allowing you to quickly set up a plate for a run.

Note: If you have been assigned the Access Module Recovery Tool user privilege, the Module Recovery Tool section appears in the bottom-left corner. For information, see [Using the Access Module Recovery Tool to Manually Rerun ddPCR Processes on page 77](#).

The screenshot displays the 'Plate Information' tab in the configuration window. It includes a sidebar with icons for navigation, a main area with tabs for 'Plate Information (Required For Run)', 'Well Selection (Required For Run)', and 'Well Information (Optional)'. The 'Plate Information' tab is selected, showing a 'Plate Template' section with a 'Choose Existing' dropdown and a 'Create New' button. Below this is a 'Create New Plate' section with fields for 'Plate Name', 'Supermix', and 'Save data file as'. To the right is the 'Thermal Cycling Protocol' section with a 'Choose Existing' dropdown and a 'Create New' button. Below that are radio buttons for 'Acquire Wells By:' with 'Columns' selected. At the bottom left is the 'Module Recovery Tool' section with three checked options: 'Do Droplet Generation', 'Do Thermal Cycling', and 'Do Droplet Reading'. At the bottom right are 'Back', 'Next Plate', and 'Start Run' buttons.

You can

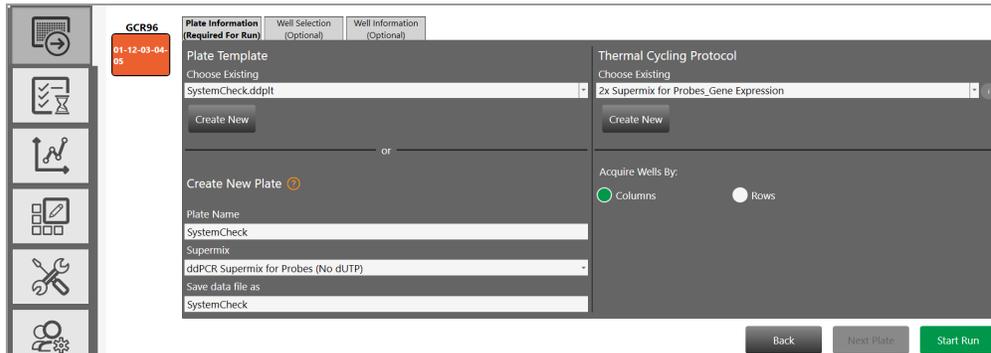
- Select, modify (optional), and run an existing template
- Create and run a new plate design
- With the applicable user privilege, save existing or new plate designs as templates
- Identify a plate, plate file, and supermix for a run

Note: You must, at a minimum, enter a plate name and select a supermix to enable the Start Run button (the data file name field is automatically populated with the plate name). You can identify the remainder of your experiment parameters either in the Plate Editor before you start the run, or in the plate editor layout in the Analysis module after the run has concluded.

- Select a thermal cycling protocol
- Select the well acquisition method the instrument should use

Specifying Plate and Protocol Information

When you select Configure Plate, the following window appears.



To specify the plate and protocol

- (Optional) To use a plate template, do one of the following under Plate Template:
 - To use an existing plate template, select a template from the Choose Existing drop-down list. To modify the configuration, select the Well Information tab.
 - To create a new template, tap Create New.
- Under Thermal Cycling Protocol, do one of the following :
 - To use an existing protocol, select a protocol from the Choose Existing drop-down list.
 - To create a new protocol, tap Create New.

For information on creating or modifying plate templates and protocols, see [Creating or Modifying Templates on page 69](#).

- Under Create New Plate, enter a plate name and file name, and select a supermix.

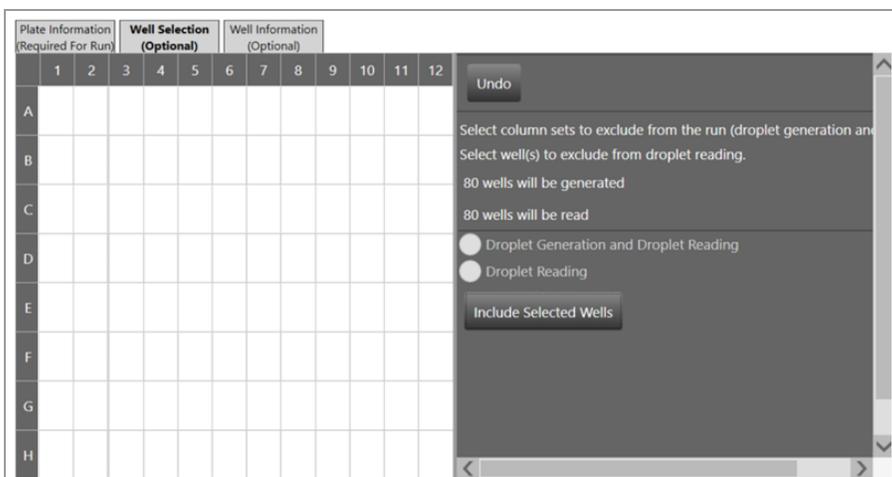
The fields under Create New Plate must be completed before the Start Run button is enabled. If you are using a template, the fields are populated automatically. You can also run the plate with just the plate name, file name, and supermix, and then configure other parameters during analysis.

- (Optional) Select the alternate well acquisition method.

Important: The QX ONE Droplet Digital PCR System processes all 96 wells in the plate by default. If you have filled fewer than 96 wells with sample, you must exclude the remainder. For information, see [Well Selection Tab on page 59](#).

Well Selection Tab

When you select the Well Selection tab, the Plate Editor grid appears. The Well Selection tab contains a blank plate grid. The QX ONE Droplet Digital PCR System processes the entire 96-well plates by default. If you have added sample to fewer than 96 wells, you must exclude the remainder.



Excluding Wells in the Plate Layout

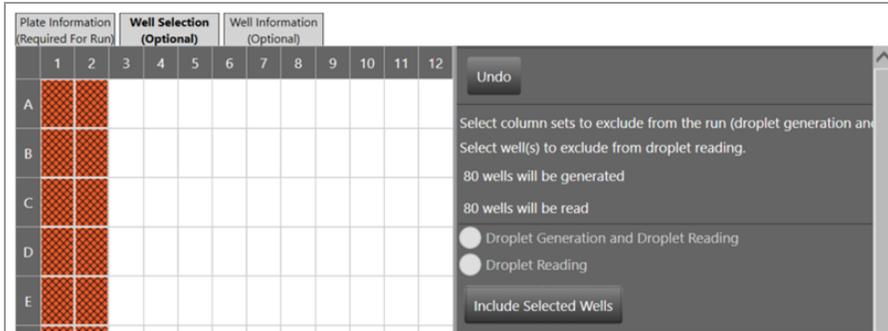
Use the Well Selection tab (or the Exclude button in the Template view) to exclude wells from the droplet generation and droplet reading run phases, or droplet reading only.

Important: The GCR96 cartridges that are inserted into the instrument contain six separate sections, each with two rows of eight wells each. The QX ONE Droplet Digital PCR System automatically generates droplets by section rather than by well or by individual column. In the QX ONE Software well exclusion design, the first two columns represent the first section, the second two columns the second section, and so forth.

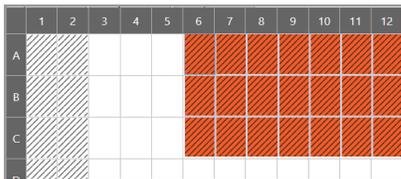
Note the following:

- When you select Droplet Generation and Droplet Reading, the software allows you to exclude each section from both processes, but if you try to exclude an odd number of columns, QX ONE Software automatically selects the remaining column.
- When you select Droplet Reading, the software allows you to exclude any well or group of wells from the droplet reading phase.
- When you exclude wells in the plate layout, the instrument pierces the foil for all wells in the physical plate, but generates and/or reads droplets for active wells only.

Wells excluded from Droplet Generation and Droplet Reading are displayed with a criss-cross pattern.



Wells excluded from droplet reading are identified by a diagonal pattern.



To exclude wells

1. Select one or more column pairs to exclude, and then tap Droplet Generation and Droplet Reading or Droplet Reading.

Note: If you selected an odd number of columns, the software automatically selects the remaining column to represent a section. You can exclude that column from droplet reading only.

2. Tap Exclude Selected Wells.

Note: The Exclude Selected Wells button is a toggle button. If you select wells that have been excluded, the button name changes to Include Selected Wells. If you excluded one or more wells that should be read, you can select the wells and then tap the button to include them again.

Well Information Tab

When you select the Well Information tab, the Plate Editor opens. You can configure your experiment parameters for selected wells before or after the run.

Note: QX ONE Software can calculate automatic thresholds for positive control wells, but you must select Pos Ctrl from the Sample Type drop-down list. You can make the selection before or after the run. For information, see [Sample Types on page 64](#).

Defining or Editing Well Information

You can assign different experiment parameters to each well or groups of wells.

Note: Each plate you configure appears as an icon on the left.

The screenshot displays the 'Well Information' configuration window. On the left, a sidebar shows icons for 'For Research', a question mark, a person, a wrench, a graph, a checklist, and a plate. The main area shows a plate grid with columns 1-12 and rows A-H. Wells A1, A2, A3, and A4 are highlighted in orange. The right panel is titled 'Well Information' and contains the following configuration options:

- Experiment Type:** Direct Quantification (DQ) [Apply]
- Sample Description1:** DNA1 [Apply]
- Sample Description2:** DNA2 [Apply]
- Sample Description3:** [Apply]
- Sample Description4:** [Apply]
- Sample Type:** Unknown
- Assay Type:** Single Target per Channel [Apply]
- Target Info:**

Target Name	Target Type	Signal Ch1	Signal Ch2	Signal Ch3	Signal Ch4
1	Unkn	FAM	None	None	None
2	Unkn	None	HEX	None	None
3	Unkn	None	None	Cy5	None
4	Unkn	None	None	None	Cy5.5

You can apply your entries at any time. You must tap Apply for the software to recognize your new or edited information. If you enter information in a field and need to apply earlier changes first, QX ONE Software displays an advisory message.

To define the configuration for the wells

1. Select a well or group of wells.
2. Select an experiment type; see [Experiment Types on page 63](#).
3. In the Sample Description fields, enter up to four words or phrases that describe the sample; see [Sample Descriptions on page 64](#).
4. Select a sample type; see [Sample Types on page 64](#).
5. Select a supermix; see [Supermixes on page 65](#).

Chapter 6 Adding and Configuring Plates

6. Select an assay type.
7. Available assay types vary, depending on the selected experiment type; see the fluorophore options in [Assay Types and Fluorophores on page 67](#).
8. (Optional) Under Target Info, change the fluorophore assigned to a channel. The fluorophore information populates automatically for each target, with the maximum number of rows allowed for the assay method. However, you can modify the default fluorophore assignments, if applicable.
 - a. Tap the dropdown arrow and select an alternative.
 - b. To delete a row, tap the minus (-) icon next to the target.
 - c. To add a row, tap the plus (+) icon.
9. (Optional) To clear one or more wells at any time, select the wells and tap Clear Selected Wells.
10. Tap Apply. After you have applied your entries and selections, you can pause the cursor on a well to see the well information.

	DQ	DQ	DQ	DQ	DQ	DQ
	NTC/1cpd	0.125 cpd	0.25 cpd	0.5 cpd	1 cpd Ch1	2 cpd Ch1
E	HSV	Experiment Type: Direct Quantification (DQ)			HSV-1	HSV-1
	B2M	Sample Description: 1: 0.5 cpd Ch1/1cpd Ch2			B2M-Hex	B2M-Hex
		Sample Type: Unknown				
		Supermix: ddPCR Supermix for Probes				
		Assay Type: Single Target per Channel				
	DQ	Target Information:			XQ	DQ
	NTC	HSV-1, Unknown, FAM			1 cpd Ch1	2 cpd Ch1
	HSV	B2M-Hex, Unknown, HEX			HSV-1	HSV-1
F	B2M-Hex	B2M-Hex	B2M-Hex	B2M-Hex	B2M-Hex	B2M-Hex

11. When you finish configuring the plate, tap Save.

Experiment Types

QX ONE Software offers the experiment types described in [Table 9](#), each enabling different assay options and analysis tools. You can assign multiple experiment types across the plate, but you can assign only one experiment type to each well.

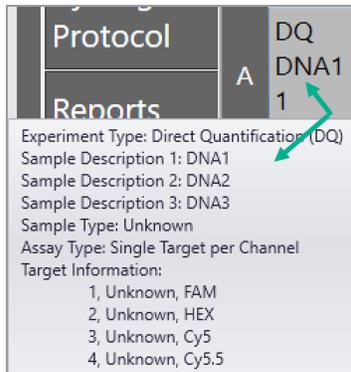
Table 9. Experiment types

Type	Description
Direct quantification (DQ)	DQ uses absolute quantification to determine the concentration (copies/ μ l) of target DNA copies in a sample. DQ measures the number of positive and negative droplets for each target in a well based on their fluorescence amplitude, and uses a Poisson algorithm to calculate the starting concentration of each target DNA molecule. Note: The ABS experiment type created in QuantaSoft Software versions 1.4 through 1.7 is automatically mapped into the software as a DQ experiment type.
Copy number variation (CNV)	CNV determines concentration (as with DQ) and calculates the copy number of an unknown (CNV) target relative to a known reference or references within the same well.
Mutation detection (MUT)	MUT determines concentration (as with DQ) and calculates the fractional abundance of an unknown mutant present at a low frequency in a wild-type background.
Rare event detection (RED)	RED determines the concentration of a known mutant or a rare target species relative to a given reference species within a large pool of background DNA.
Drop-off (DOF)	DOF determines absolute quantification of targets for assays designed to detect non-wild type sequences, such as indels and genome edits; DOF is designed to support an assay strategy where one probe counts all alleles and one “drop-off” probe sits on top of a predicted cut site or mutation site.
Gene expression (GEX)	GEX determines concentration (as with DQ) and calculates relative expression levels of an unknown target relative to a known reference or references within the same well.
Residual DNA quantification (RDQ)	RDQ provides a precise method for residual host cell DNA quantification. Note: Users can enter a conversion factor to calculate the mass for a well, up to three decimals. The software displays the result in the Molecular Weight column of the Data Table.

Sample Descriptions

QX ONE Software allows you to enter descriptive words or phrases for your sample in up to four fields per well. Descriptors can include information such as research type, dilution factors, and so forth.

Tip: Only the information from the first field appears in the Plate Editor layout. However, you can see entries in the second, third, and fourth fields in the Well Data table, or you can pause on a well to display a tool tip, as shown in the following graphic.



Sample Types

You can assign multiple sample types within the plate, but you can assign only one sample type to each well.

QX ONE Software provides four sample types for selection:

- Unknown
- NTC (no template control)
- Pos Ctrl (positive control) where one or more targets are expected
- Neg Ctrl (negative control), where no response is expected

Supermixes

QX ONE Software offers five PCR supermixes. Each supermix is optimized to deliver maximum PCR efficiency and sensitivity for the amplification and detection of DNA and RNA targets.

Important: Use of unapproved supermixes can harm the instrument and void the warranty.

ddPCR Supermix	Description
Multiplex Supermix	For use in nucleic acid sample preparations to amplify and detect DNA targets in probe-based experiments involving multiple targets. Note: Bio-Rad recommends using ddPCR Multiplex Supermix for Cy5 and Cy5.5 probes assays.
Supermix for Probes (No dUTP)	For use in nucleic acid sample preparations, with sensitivity for the amplification and detection of DNA targets using hydrolysis probe-based assays.
Supermix for Probes	For use in sample preparation with uracil N-glycosylase (UNG) decontamination protocols to prevent the reamplification of carryover PCR products between experiments.
Supermix for Residual DNA Quantification	For use in residual DNA detection.
One-Step RT Advanced Kit for Probes	For use in absolute quantification of target RNA molecules. Important: Load only one (1) one-step RT plate, using the first slot in the QX ONE Droplet Digital PCR System plate Inbox. For more information, see Using the One Step RT ddPCR Advanced Kit for Probes .
EvaGreen® Supermix	For use in gene expression.

Using the One Step RT ddPCR Advanced Kit for Probes

The One Step RT ddPCR Advance Kit for Probes supermix is time and temperature-sensitive. Therefore, if you are performing an experiment using this supermix, it is important that the plate does not sit idle in one of the Inbox slots.

To perform an experiment using this kit

1. Wait until all plates in the QX ONE Droplet Digital PCR System have processed and then place the One Step RT plate into the first slot.
2. Quickly set up and start the run.

For information, see [Plate Configuration Window on page 56](#) and [Running Experiments on page 71](#) [Running Experiments on page 71](#).

Assay Types and Fluorophores

QX ONE Software offers the assay methods explained in [Table 10](#).

Table 10. Assay types

Assay type	Description
Single target per channel	<p>Method assuming up to four probe colors (FAM, HEX/VIC, Cy5 and Cy5.5) and up to four targets per well, with a single target detected per channel.</p> <p>This is the default assay type, with the maximum four rows displayed. You can delete up to three rows.</p>
Amplitude multiplex	<p>Method to increase multiplexing up to eight targets per well, with one or two targets detected per channel. The maximum of eight rows are displayed. You can delete up to seven rows.</p>
Probe mix triplex	<p>Triplex mode that allows two groups of three targets each.</p> <p>Group 1 has one target in FAM, one target in HEX/VIC, and one target in both channels. Group 2 has one target in Cy5, one target in Cy5.5, and one target in both. You can delete a group, but not the individual targets within the group.</p> <p>Note: The channels within a group are not interchangeable; therefore FAM is always paired with HEX/VIC and so forth.</p>
Advanced classification	<p>Method to increase multiplexing rate in any combination of targets detected per channel. This method requires manual classification of droplets.</p>
Basic drop-off	<p>This mode allows two groups of two targets each. The first group appears by default, with one target in FAM <u>and</u> HEX/VIC and one target in FAM <u>or</u> HEX/VIC.</p> <p>This assay type is available only for the DOF experiment type.</p> <p>You can add one more group of two targets, with one target in Cy5 <u>and</u> Cy5.5, one target in Cy5 <u>or</u> Cy5.5. You can delete a group, but not the individual targets in the group.</p> <p>Note: The channels within a group are not interchangeable; therefore FAM is always paired with HEX/VIC and so forth.</p>

Table 10. Assay types, continued

Assay type	Description
Double drop-off	<p>This assay type is available only for the DOF experiment type, and allows two groups of three targets each.</p> <p>The first group appears by default, and looks for one target in FAM <u>and</u> in HEX/VIC (target type reference) one target in FAM (target type unknown), and one target in HEX/VIC (target type unknown).</p> <p>You can add the second group to look for one target in Cy5 <u>and</u> Cy5.5 (target type reference, with two reference copies), one target in Cy5 (target type unknown), and one target in Cy5.5 (target type unknown).</p> <p>By default, all reference copies are set to 2.</p> <p>The channels are static for each group. (Channel 1 FAM is always paired with Channel 2 HEX/VIC, Channel 3 Cy5 is always paired with Channel 4 Cy5.5..)</p>

The experiment type you select determines the available assay methods. [Table 11](#) displays the sample type associated with each assay method.

Table 11. Assay types by experiment type

Assay type	Experiment type						
	DQ	CNV	MUT	DOF	GEX	RDQ	RED
Single target per channel	✓	✓	✓		✓	✓	✓
Amplitude multiplex	✓	✓	✓		✓	✓	✓
Probe mix triplex	✓	✓	✓		✓	✓	✓
Advanced classification	✓						✓
Basic drop-off				✓			
Double drop-off				✓			

QX ONE Software automatically populates the fluorophore in each channel for each target but you can change the default selections.

Use [Table 12](#) to select from the fluorophore options for each assay method listed.

Table 12. Fluorophore options

Assay method	Signal Ch1	Signal Ch2	Signal Ch3	Signal Ch4
Single target per channel, for 1 to 4 targets	FAM	HEX	Cy5	Cy5.5
	None	VIC	None	None
		None		
Amplitude multiplex, for 1 to 8 targets	FAM Hi	HEX Hi	Cy5 Hi	Cy5.5 Hi
	FAM Lo	HEX Lo	Cy 5 Lo	Cy 5.5 Lo
	None	VIC Hi	None	None
		VIC Lo		
		None		
Probe mix triplex, for 6 targets	FAM	HEX	Cy5	Cy5.5
	None	VIC	None	None
		None		
Advanced classification	FAM	HEX	Cy5	Cy5.5
	+1-10	1 to 10	1 to 10	1 to 10
	None	VIC	None	None
		1 to 10		
		None		

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Chapter 7 Running Experiments

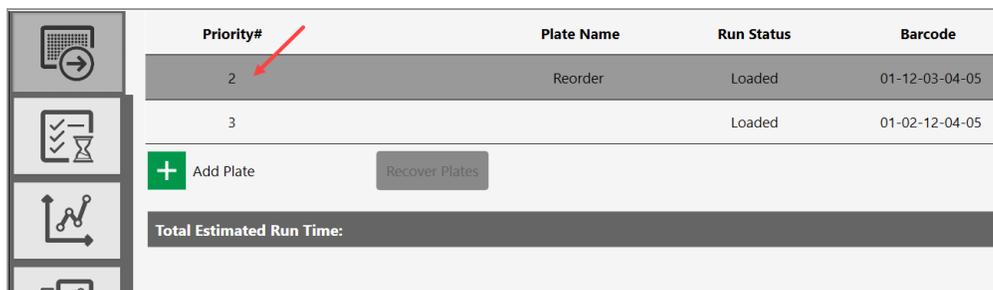
When the Start Run button is enabled for a plate, you can start the run. You can also cancel one or more runs during the droplet generation or droplet reading phases, and you can recover a canceled or failed run during the droplet generation or droplet reading phases. For information, see [Canceling a Run on page 81](#) and [Recovering Plates From Failed or Canceled Runs on page 78](#).

Changing the Plate Processing Order

If you have been assigned the Manage Plates user privilege, you can change the processing order of plates still in the instrument Inbox, even if other plates are running.

To change the plate processing order

1. Select a row representing a plate in the Inbox.

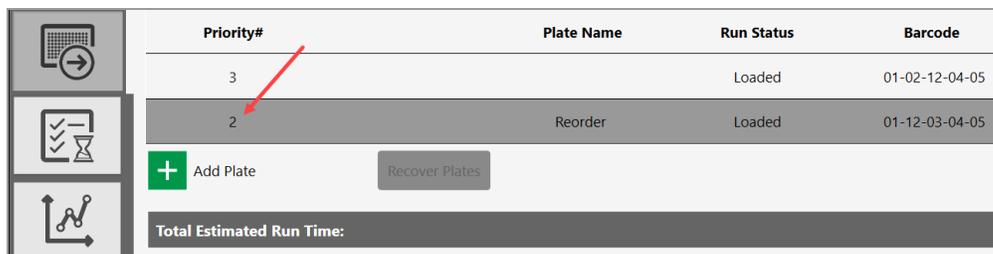


Priority#	Plate Name	Run Status	Barcode
2	Reorder	Loaded	01-12-03-04-05
3		Loaded	01-02-12-04-05

+ Add Plate Recover Plates

Total Estimated Run Time:

2. Drag the row to the new location.



Priority#	Plate Name	Run Status	Barcode
3		Loaded	01-02-12-04-05
2	Reorder	Loaded	01-12-03-04-05

+ Add Plate Recover Plates

Total Estimated Run Time:

3. Continue reordering, as applicable. You can reorder up to five plates in the Inbox.

Starting the Run

When the required elements to set up one or more plates are satisfied, QX ONE Software enables the Start Run button. You can configure the elements of the plate before you start the run, or you can run the plate with just the plate name and supermix, and define the configuration from the analysis window.

Important: Ensure that at least one full bottle of QX ONE Droplet Digital PCR System Droplet Generation Oil for Probes and one full bottle of QX ONE Droplet Digital PCR System Droplet Reader Oil are installed, and at least one waste bottle is completely empty.

To start the droplet reading run

- ▶ When all plate setup requirements have been satisfied and the Start Run button is enabled, tap Start Run.

The QX ONE Droplet Digital PCR System begins processing each plate in the specified order.

Note: The enabled button is available in the windows associated with the Add Plate function.



Running the Experiment

The instrument allows you to do the following:

- During the droplet reading phase of the run, perform real-time analysis on the droplets in each well after the well has been read
- Reorder plates while they are still in the Inbox
- Cancel a run.
- When the run concludes and the plate has been removed from the outbox, QX ONE Software moves the run to the Completed list in the Run Status window, and saves the analysis data file. Data files are always saved to your personal file location or a preferred location, and can also be saved to a shared location. For information, see [Managing Your Preferences on page 37](#).

Important: if your system administrator has designated Preferred Locations in System Settings, they override any file paths indicated in your preferences.

- During and after the run, QX ONE Software displays run information in the Run Status window.

During and after the run, the software displays run information in the Run Status window.

- During the droplet reading phase of the run, you can perform real-time analysis on the droplets in each well after the well has been read.
- You can cancel the run at any time.

Note: Canceling a run also shuts down the instrument.

Plate Name	Barcode	Status	Location	Time Remaining	Time Elapsed
Rat DQ ddPCR Multiplex	01-02-03-04-05-06-02		Shelf #3	00:00:00	00:04:48
Total Time Remaining: 18:17					
Plate Name	Barcode	Run Status	Run Completed	File Name	
Rat DQ ddPCR Multiplex	12-02-03-04-05-06-01		07/12/2018 02:23:05 PM	Rat DQ ddPCR Multiplex_20180712_140428_501	
Rat DQ ddPCR Multiplex	11-02-03-04-05-06-00		07/12/2018 02:17:43 PM	Rat DQ ddPCR Multiplex_20180712_140427_846.dd	

Tracking the Run Status

You can track each run from the Run Status window.

Plate Name	Barcode	Status	Location	Time Remaining	Time Elapsed
Rat DQ ddPCR Multiplex	01-02-03-04-05-06-02		Shelf #3	00:00:00	00:04:48
Total Time Remaining: 18:17					
Plate Name	Barcode	Run Status	Run Completed	File Name	
Rat DQ ddPCR Multiplex	12-02-03-04-05-06-01		07/12/2018 02:23:05 PM	Rat DQ ddPCR Multiplex_20180712_140428_501	
Rat DQ ddPCR Multiplex	11-02-03-04-05-06-00		07/12/2018 02:17:43 PM	Rat DQ ddPCR Multiplex_20180712_140427_846.dd	

The top pane shows the runs in progress. The run remains in the top pane for the duration of the processing.

Icons displayed in the Run Status column indicate each process point, as shown in [Table 13 on page 74](#).

Table 13. Run status indicators

Status Icon	Description
	Ready to begin first or next phase
	Droplet generation phase
	Droplets generated, plate waiting in Inbox
	Thermal cycling protocol phase
	Droplet reading phase
	Run completed, plate in Outbox
	Run completed, plate removed from Outbox
	Plate successfully recovered
	Run stopped or canceled by the system

When the run is finished and the plate is removed from the Outbox, the software moves the run to the bottom pane, where up to 100 completed runs are visible.

Tip: You set the number of completed runs to display in your user preferences. See [Managing Your Preferences on page 37](#).

The content of each column is explained in [Table 14](#).

Table 14. Run Information Columns

Column Name	Location	Description
Plate name	Top and bottom panes	Name entered under Create New Plate Note: If you selected an existing template, the template name appears.
Bar code	Top and bottom panes	Bar code, as read by the instrument
Run status	Top and bottom panes	Icons for each process step (see Table 13 on page 74)
Location	Top pane only	Process step location (for example Droplet Reader)
Time remaining	Top pane only	Hours and minutes until the run will be finished
Time elapsed	Top pane only	Time, in hours and minutes the run has been in progress
Total time remaining	Below the top pane	Total hours and minutes remaining for all in-progress runs
Run completed	Bottom pane only	Date and time stamp showing when the instrument completed the run
File name	Bottom pane only	Plate name and system-generated identifier

After run completion, the software saves the analysis data file in a location designated by you or a system administrator.

Using Live Analysis

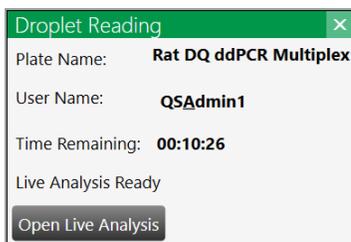
When the QX ONE Droplet Digital PCR System reaches the droplet reading phase, QX ONE Software provides an option for real-time analysis of the wells that have been read, while the process as a whole is still active.

QX ONE Software initially shows each well in the Plate Editor as disabled. As the software confirms that the instrument has acquired a well and read the droplets, the software enables the well for live analysis in read-only mode. The process continues until all wells are enabled and the process is finished.

To use live analysis

1. Tap the droplet reading icon () for the run in progress.

The Droplet Reading dialog box opens.



2. Tap Open Live Analysis.
3. Select an analysis window.

For brief descriptions of the analysis windows, see [Data Analysis Overview on page 81](#). For more detailed information, refer to the QX ONE Software User Guide.

4. In the well selector, select one or more wells that are enabled.

Important: QX ONE Software displays read-only data in the selected analysis window. You can view the data but to make changes, you must wait for the run to complete, and then change the data in the Analysis module.

Using the Access Module Recovery Tool to Manually Rerun ddPCR Processes

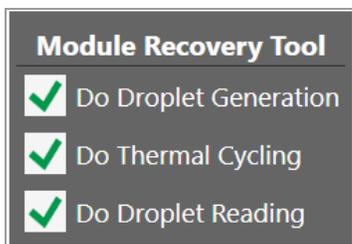
QX ONE Software also provides the capability to manually recover a plate by identifying the failed process, and then rerunning the plate from that point. Users must be assigned the Access Module Recovery Tool user privilege to omit the processes that will not be rerun.

Important: Because using the manual process requires the user to identify in the log file the precise point of failure, Bio-Rad instead recommends using the automatic plate recovery functionality described in [Recovering Plates From Failed or Canceled Runs on page 78](#). If you are using manual recovery, contact Bio-Rad Technical Support for assistance before proceeding.

To manually rerun the plate

1. Wait for plates currently in process to complete.
2. In QX ONE Software, tap Add Plate.
3. When prompted, insert the plate into the Inbox in accordance with the displayed message.
4. Tap Configure Plate.

The Module Recovery Tool pane appears below the plate and thermal cycling protocol panes.



By default, all checkboxes are selected.

5. If necessary, clear the checkbox for each process that will not be repeated.

Important: You cannot clear the Plate Handler Present checkbox.

6. Make any necessary configuration changes to the plate.
7. When the Start Run button is enabled, click Start Run.

The QX ONE Droplet Digital PCR System enables and runs each specified module.

Recovering Plates From Failed or Canceled Runs

If a user cancels a run, or if a component experiences a problem during a run, the run fails and QX ONE Software displays an error message on the touch screen.

If the failure occurred during the thermal cycling phase, the plate is not recoverable and must be discarded. However, if the run failed during the droplet generation or droplet reading phase, you can use the Recover Plate option in QX ONE Software.

When a cancellation or failure occurs, QX ONE Software moves the run to the lower pane in the Run Status screen and displays a red exclamation point under Run Status, as shown in the following graphic.

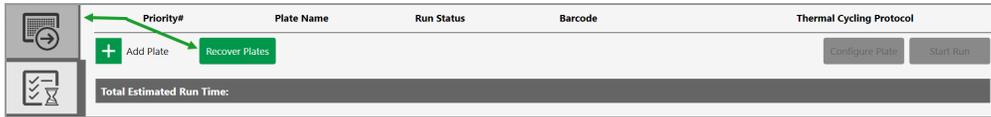
Plate Name	Barcode	Run Status	Location	Time Remaining	Time Elapsed
Total Time Remaining: 00:00					
Plate Name	Barcode	Run Status	Run Completed	File Name	
RP_Test02	12-02-03-04-05	!	09/14/2020 09:48:02 AM	RP_Test02_20200914_094726_529.ddpcr...ne	

To recover or discard the plate in QX ONE Software

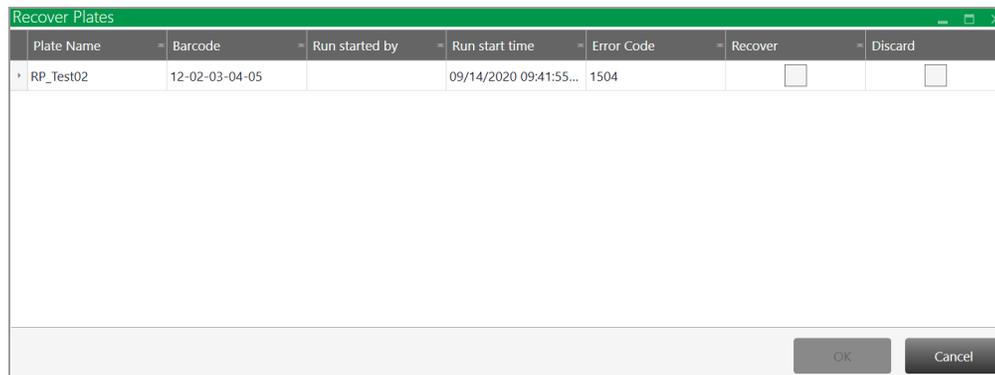
- Before you begin the plate recovery process, do one of the following:
 - If the error did not stop the instrument and plates are still running through ddPCR processes, allow the remaining runs to finish and then restart the instrument.
 - If the error did stop the instrument, resolve the instrument problem and then restart the instrument.

- When the instrument restarts, the recover plate screen appears automatically. Continue to Step 3.

Important: If the window is inadvertently closed, select the Add Plate tab and then tap Recover Plate.



- Do one of the following:
 - If the plate failed during thermal cycling, manually discard the plate using safety protocols, and then select the Discard check box and tap OK. A message appears, advising that you cannot recover the plate after it is discarded. To permanently discard the plate, tap OK again.
 - For droplet generation or droplet reading failures where you intend to recover the plate, select the Recover Plate check box and tap OK.



- Tap Add Plate.
- Follow the prompts to scan the RFID code and insert the plate into the specified slot.

If you are recovering multiple plates, the system prompts you to add and scan each plate you identified for recovery.

6. Tap Start Run.

The QX ONE Droplet Digital PCR System resumes the process where it was interrupted for each plate.

When the run for each recovered plate successfully concludes, QX ONE Software shows the plate with an amber check mark in the Run Status column, as shown in the following graphic.

The screenshot displays the QX ONE Software interface. At the top, there is a header bar with the following information:

- BIO-RAD** logo
- QX ONE ddPCR System** (SIMULATOR (Ready), Calibration: OK)
- Runs:** In Progress: 0, Available: 5
- DG Oil Probes (P):** 0%
- DR Oil:** 0%
- Waste:** 0%
- Disk Space (C):** Free: 105 GB (22%), Used: 358 GB (78%)
- User:** QX_Super
- Date/Time:** 9/14/2020 10:50 AM

The main area contains a table with the following columns: Plate Name, Barcode, Run Status, Location, Time Remaining, and Time Elapsed. The table is currently empty. Below the table, there is a status bar that reads "Total Time Remaining: 00:00".

At the bottom, there is a summary table with the following columns: Plate Name, Barcode, Run Status, Run Completed, and File Name.

Plate Name	Barcode	Run Status	Run Completed	File Name
RP_Test02	12-02-03-04-05	✓	09/14/2020 10:47:05 AM	RP_Test02_20200914_104358_653.ddpcr.me

Canceling a Run

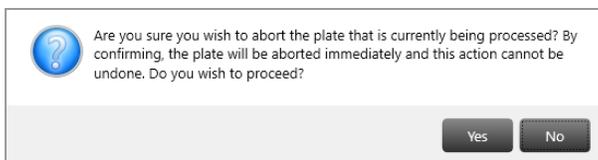
You can cancel one or more runs at any time in the process.

To cancel the run

1. In the Run Status window, tap the row for the run to be canceled and then tap the X on the right.

Run Status	Location	Time Remaining	Time Elapsed	
	Thermal Cycler	00:02	00:11	
	Finalizing	00:00	00:00	

2. When the Are you sure message appears, tap Yes.



The instrument finishes reading the current well, stops the process and either proceeds to the next plate or reverts to its pre-run state.

Note: If you tap No, or if you do not respond to the confirmation message within 30 sec, the process continues without interruption.

The  icon appears in the Run Status column.

QX ONE Software creates the data file for the wells that were processed on the canceled plate, and the status in the Event Log is specified as “run aborted by user.”

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Chapter 8 Creating or Modifying Templates

The Template Setup window allows you to

- Create new plate, thermal cycling protocol, and report templates
- Search for existing templates
- Modify existing templates

If you are assigned the Create New Template user privilege, you can save new or modified templates for reuse. You can save templates to a personal or system folder (My Templates or System Templates, respectively), or you can save them to the Shared Templates location.

Note: If your system administrator has specified Preferred Locations in the System Settings window, the System Templates location overrides the folder specified in your user preferences..



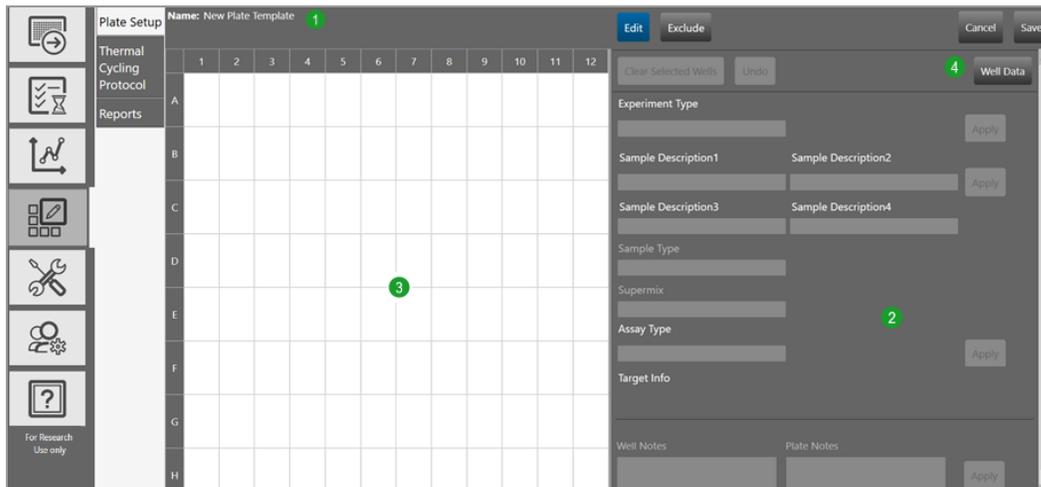
For information on creating or editing templates, see

- [Creating or Modifying Plate Templates on page 70](#)
- [Creating or Editing Thermal Cycling Protocol Templates on page 75](#)
- [Creating or Modifying Report Templates on page 77](#)

Creating or Modifying Plate Templates

If you are assigned the Create New Templates user privilege, or if User Management remains disabled, you can save a plate as a template for reuse.

When you choose to add or modify a plate template, the Plate Editor opens, featuring options to set up your samples in the plate layout and exclude certain wells from droplet generation and droplet reading or droplet reading only.



LEGEND

- 1 Buttons at the top of the window provide quick access to plate editing functions.

- 2 The right pane contains the interface for defining your experiment parameters.

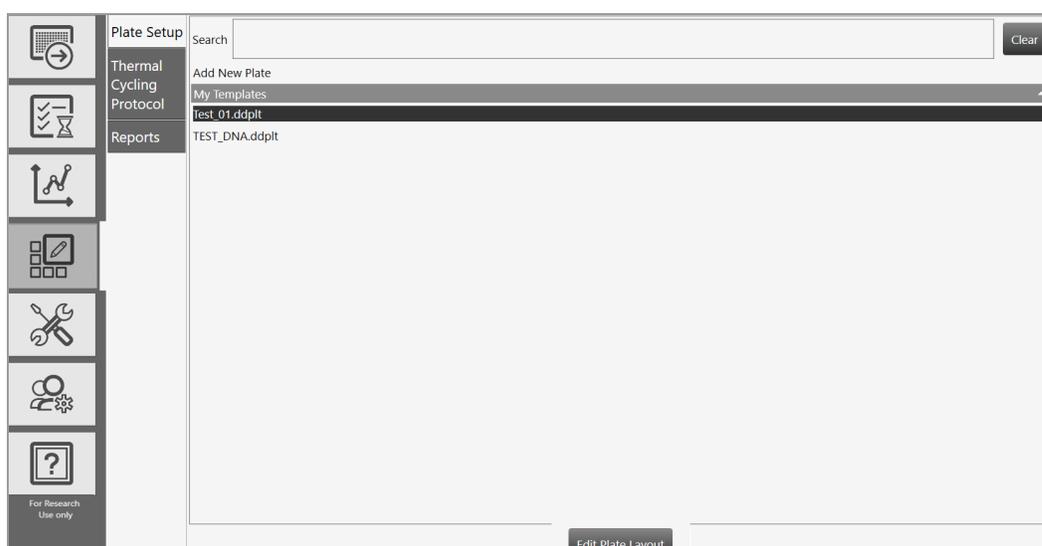
- 3 The left pane displays the plate grid and configuration information in each well.

- 4 The Well Data button toggles to the Well Data table, where you can see your plate setup in a tabular format, and then back to the Plate Editor. When the Well Data table appears, the button name changes to Plate Layout. You cannot edit the Well Data table.

Templates that are available to you appear in the default view of the Template Setup tab, as follows:

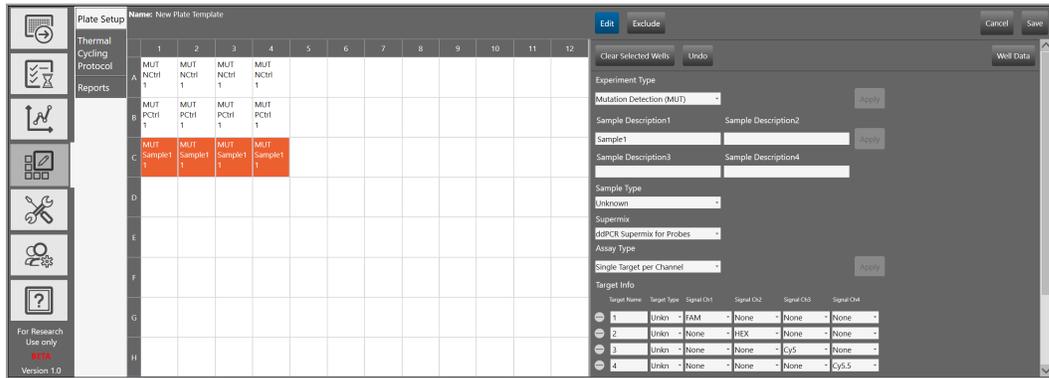
- Templates created and saved by any user, and designated as shared, appear under Shared Templates.
- Templates you created and saved, which are saved to the path you specified in your user preferences, and appear in your My Templates folder.

Important: If your system administrator has selected the Preferred Locations checkbox in System Settings, all run files and templates are saved to that location, overriding the location indicated in your user preferences.



Chapter 8 Creating or Modifying Templates

From the Template Setup or Add Plate window, you can create or modify plate templates. From the Template Setup window, you can also modify reports.



For detailed information on creating protocol templates, refer to the QX ONE Software User Guide.

Creating and Storing Plate Templates from CSV Files

You can create a plate template in a spreadsheet application, save it in .csv format (CSV), and then store it for use in your droplet reading runs.

Note the following:

- When you create a CSV template, the headings for the columns containing the experiment information must match the fields and order in the Plate Editor. If they do not match, an error message appears when you select the template.
- After you specify the information in row 1, do not change the field entries until you install a new software version or edition.
- You can store the CSV file in any location, but the Browse option defaults to your personal templates storage folder defined in your user preferences (see [Managing Your Preferences on page 37](#)), or the shared or preferred location specified by your system administrator (see [Shared Settings on page 93](#)).
- CSV templates do not appear in the Templates window. You can select a CSV template file from the Plate Setup dropdown list, or, after you tap Browse, you can navigate to the storage folder and select the file.

Creating or Editing Thermal Cycling Protocol Templates

Thermal cycling protocols are specific to the thermal cycling ddPCR phase. When you add or modify a protocol template from the Template Setup window, the Protocol Editor opens. By default, the editor opens to a generic 4-step protocol, which includes standard protocol controls to quickly create protocols, as well as the ability to

- Quickly calculate a gradient for a specific temperature range and run time for the plate type
- Edit protocol steps
- Save protocols for reuse



LEGEND

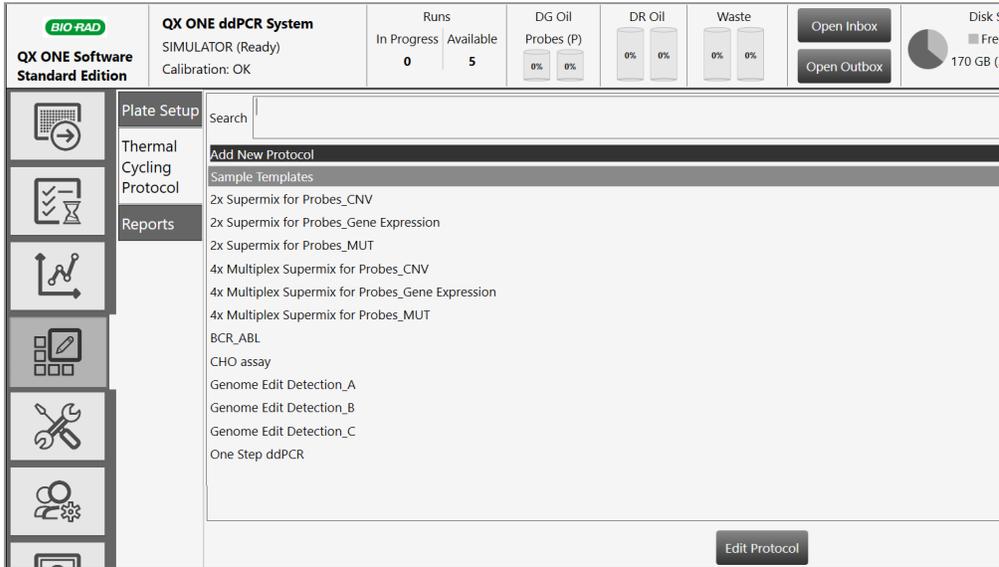
- 1 The lower pane displays the following toolbar commands:
 - The trashcan command deletes the selected step.
 - The plus sign to the left of the trashcan adds a step before the selected step.
 - The plus sign to the right of the trashcan adds a step after the selected step.

- 2 The upper pane displays the protocol controls that you can use to customize the protocol.

- 3 The main pane displays a graphical representation of the protocol.

- 4 The information bar provides quick access to the name of the protocol, view the estimated protocol run time, and to save or cancel changes to the protocol.

From the Templates tab you can access the Protocol Templates window, where you can create a new or open an existing protocol template in the Protocol Editor window. Using the Protocol Editor, you can create custom protocols that are specific to the thermal cycling phase of the QX ONE Droplet Digital PCR System.



For detailed information on creating protocol templates, refer to the QX ONE Software User Guide.

Creating or Modifying Report Templates

If you are assigned the Create New Templates user privilege, you can create and save a report template by editing the default report structure or by opening and editing an existing report.

To create or edit a report template

1. Select the Template Setup tab.

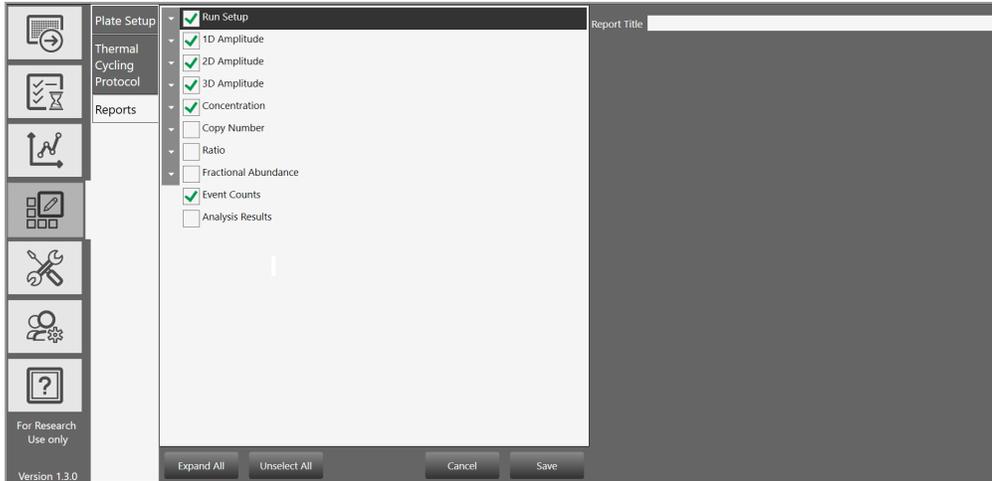


2. Tap Reports and do one of the following:

- To create a new template, tap Add New Template. and tap Edit Report Template.
- To open an existing template, select the template and tap Edit Report Template.



3. Tap the arrow to the left of each category to expand the list of reportable items.



4. Select and clear checkboxes to create the report structure.

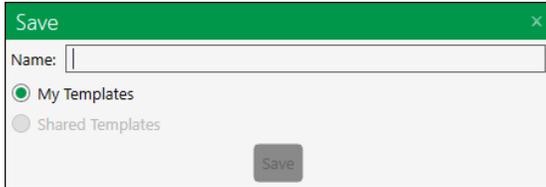
Note: Use the buttons at the bottom of the screen to expand or collapse all categories at once, or to select or clear all checkboxes at once. You can also drag and drop the section to rearrange the order of appearance in the report, and drag and drop items in the section to reorder them.



5. Enter a name for your report in the Report Title field and tap Save.



6. When the Save dialog box appears, enter a file name.

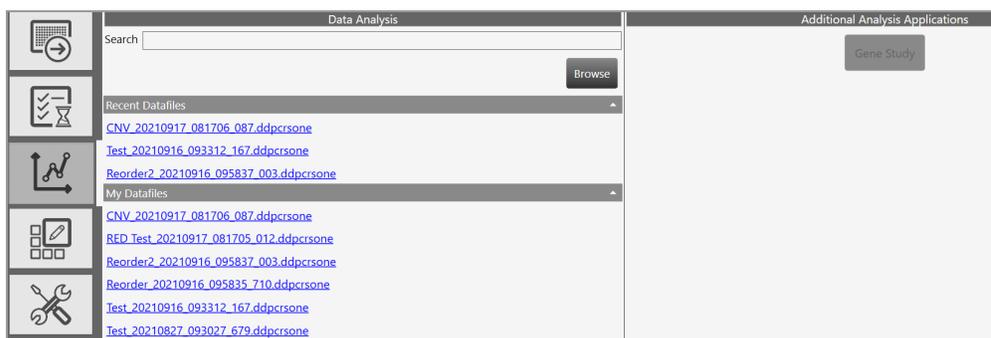


7. Select a storage location. Choose from the following:
 - System Templates (preferred location, if specified by the administrator)
 - My Templates (personal storage location specified in user preferences)
 - Shared Templates (files saved to this location are available to all users)
8. Tap Save again to save the report format as a template.

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Chapter 9 Data Analysis Overview

From the Data Analysis tab, you can browse for a particular data file, or open a data file that has been recently viewed.



This section summarizes the functionality available in the Analysis module, and also describes the general options governing your chart displays. See the QX ONE Software User Guide for detailed information on analyzing run files in the Analysis module and the Gene Study module. Gene Study functionality is not available from the touch screen.

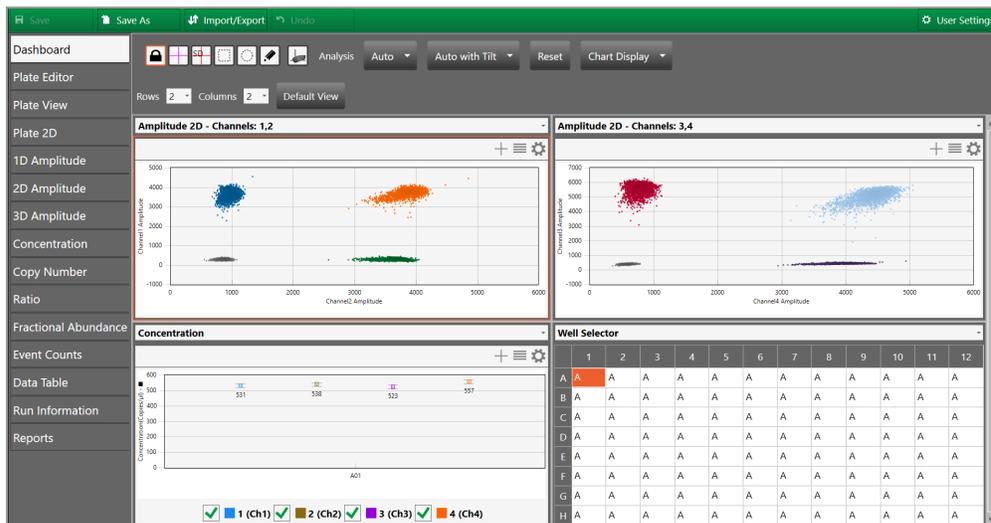
Data Analysis Module

The Data Analysis module functionality allows you to

- View your droplet data in 1D, 2D, and 3D amplitude
 - View thresholds automatically assigned by the software based on the distance of the threshold from the means and standard deviations of the positive and negative clusters
 - Manually adjust thresholds or classify droplets using cluster modes
 - View data in amplitude plots, histograms, and heat maps
 - Apply tilt correction to automatic analysis
- View charts reflecting calculated data visualizations for concentration, copy number, ratio, and fractional abundance
- Analyze multiple targets within a well using amplitude multiplexing and probe mixing strategies
- Detect genomic editing events and non-wild type events with a “drop-off assay” analysis option
- Visualize and export data with improved flexibility
- Generate reports for different analysis types

Analysis Dashboard

When you open a data file, the Analysis module opens to a Dashboard window containing default analysis and data panes in a summary view. You can customize the view to change panes, or increase or decrease the number of panes. For information on the available options in the Dashboard view, see [Dashboard Options on page 84](#). For more information on the Analysis Dashboard, refer to the QX ONE Software User Guide.



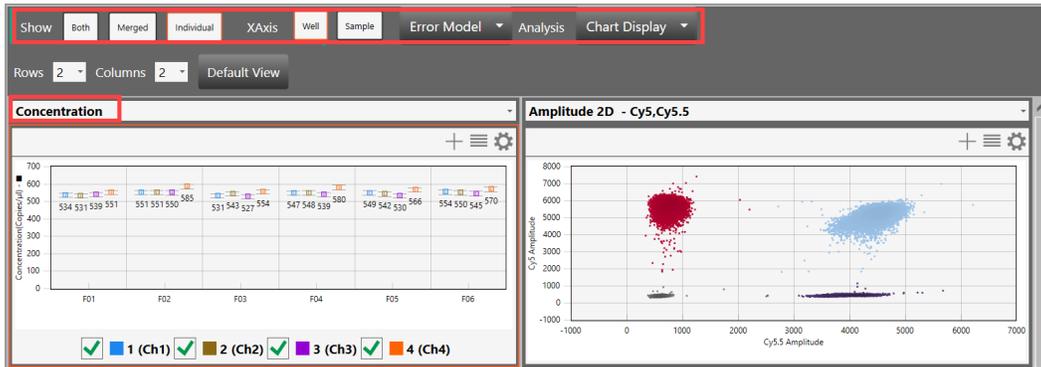
Note: If you open a .qlp file, the Plate Editor opens as the default view and you must select the Dashboard tab to open it.

From the tabs on the left, you can access plate views, amplitude charts, data visualization distribution charts, droplet counts, and a complete data table. You can also view data specific to the run in the Run Information window, and run reports on any of the analysis charts from the Reports window.

Dashboard Options

From the Dashboard window, depending on the individual dashboard window you have selected, you can use a range of options as described below:

- When you select a window, the options that appear in the menu bar correspond to the options you see if you open the same window from the side menu. For example, if you select the Concentration chart in the Dashboard, the Concentration menu options appear.



- You can reset the entire dashboard display by adding or removing rows or columns to display more or fewer individual windows. For information, see [Modifying the Dashboard Display on page 86](#).



Tap Default View to return to the default display of two rows and two columns.

- From any window you can
 - Expand or collapse the window
 - Copy, save, or print the image
 - Select display, scale, axis, and logarithmic options
 - Use the dropdown list to replace the current display with a different display
 - Use the menu bar options for the particular chart type

Table 15 describes the option sets identified in the following graphic.

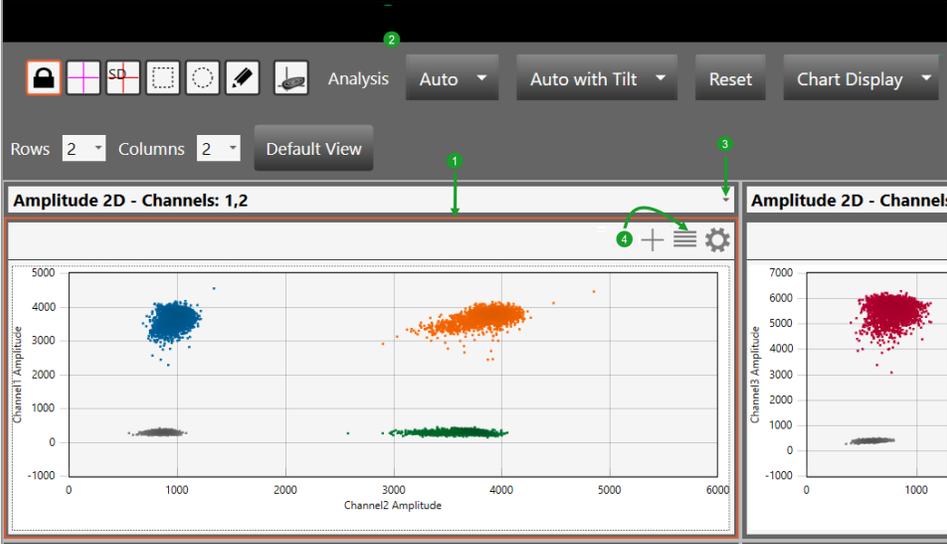


Table 15. Dashboard options

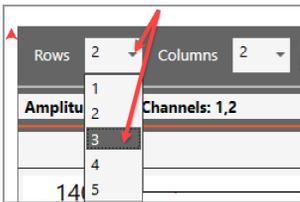
Item	Description
1	Border to identify selected window
2	Toolbar corresponding to the selected window type in the Dashboard
3	Dropdown arrow to replace the current display with a new display
4	Chart options

Modifying the Dashboard Display

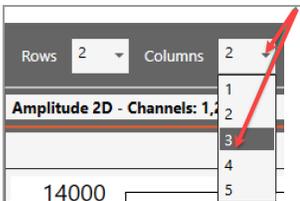
You can modify the column number and row number to display any or all of the analysis windows simultaneously.

To change the number of windows in the display

1. Tap the dropdown arrow for Rows and then select a different number.



2. Tap the dropdown arrow for Columns, and then select a different number.



You can also use the dropdown menus to change the windows that appear in the Dashboard.

To display a different window in a particular Dashboard slot

1. Tap the dropdown arrow in the upper-right corner to display the list of available windows, and then select a window. The dropdown list closes and the window changes immediately.

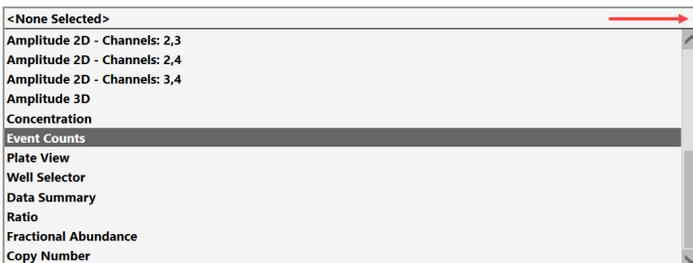


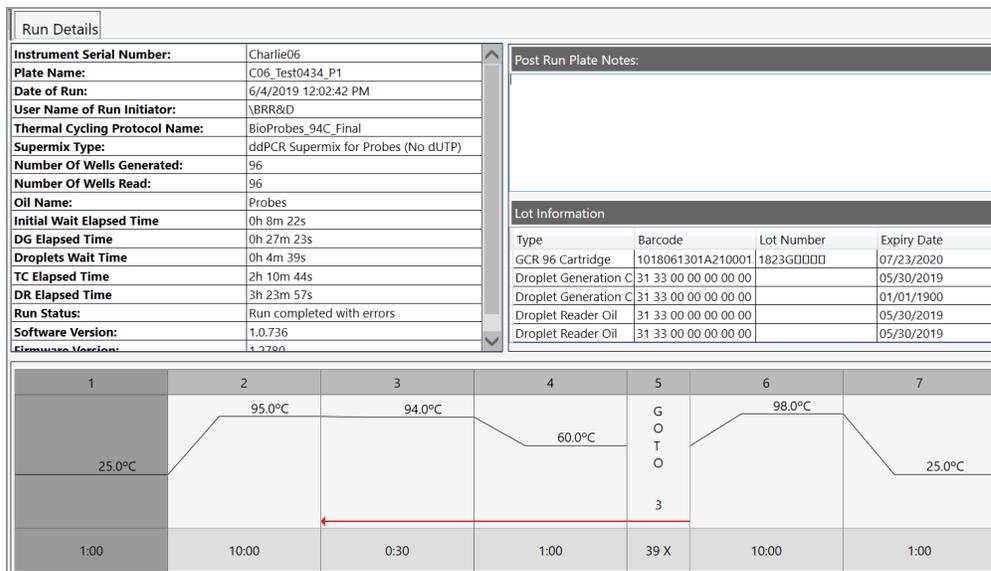
Plate View Windows

In the QX ONE Software Analysis module you can open the following windows that contain data on all wells in the run:

- **Plate Editor (analysis view)** — Displays the experiment type, sample names, sample types, supermixes, and assay type for each well in the run (similar to the Template Setup Plate Editor)
- **Plate View** — Displays concentration results in a text format for each processed well
- **2D Plate View** — Displays a two-dimensional amplitude chart for each processed well

Viewing Run Information

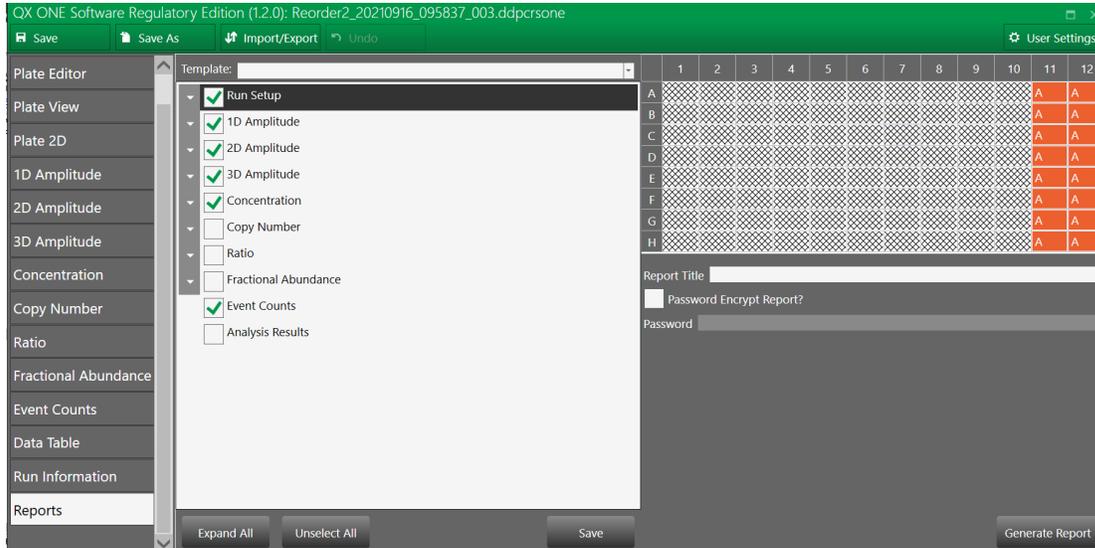
Use the Run Information window to view the information about the plate and run. You can also view or add post-run notes regarding the plate. .



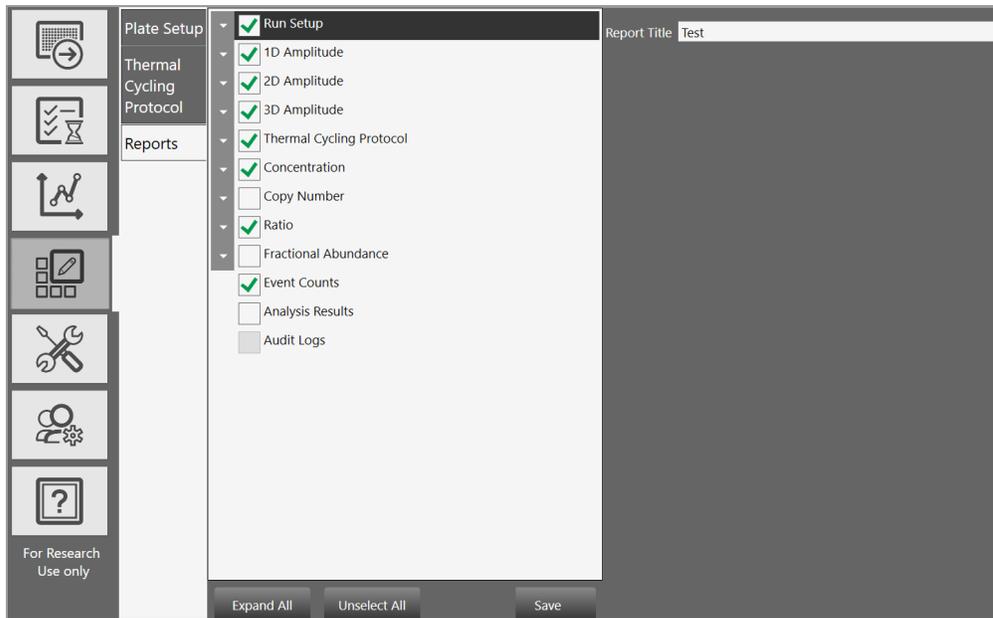
Analysis Reporting

Use the QX ONE Software Reporting function to generate a variety of reports.

As shown in the following graphic, any user can open, modify, and run the default layout to generate a report from the Reports window in the Analysis module.



If specific reports are required on a regular basis, users who are assigned the Create New Templates user privilege can modify the default layout and save it as a new template report file for reuse.



For the checkboxes you select in the report configuration, QX ONE Software displays corresponding charts and data for the selected wells. In each report header, the software automatically displays the user name of the person creating the report, date and time stamps, and the name of the analysis file used to generate the report.

For more information on the Reporting function, refer to the QX ONE Software User Guide.

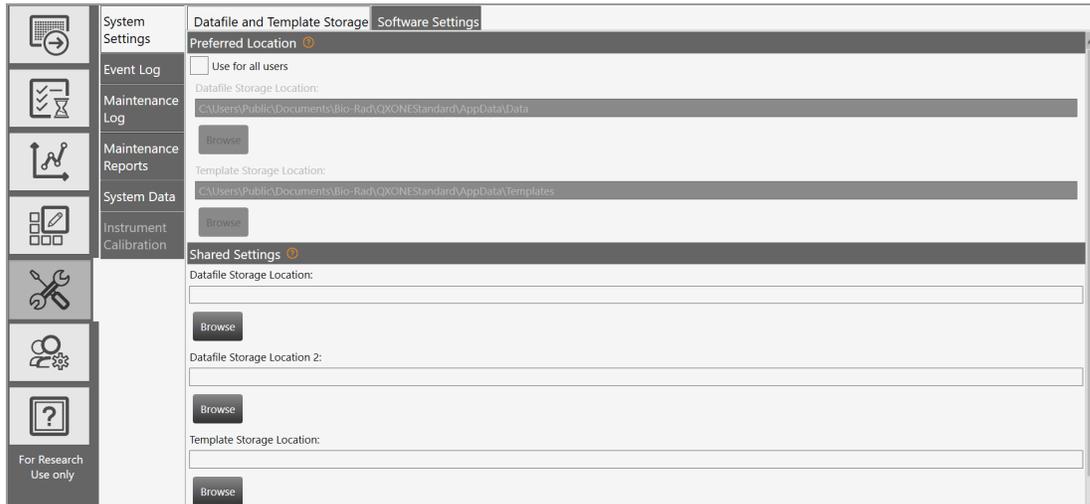
Chapter 9 System Utilities

From the System tab, you can manage tasks related to the instrument, software, data, and storage.

- **System Settings** — View shared and assigned storage locations, and select an alternate graphics rendering method.
- **Event Log** — View logged data about all software activities.
- **Maintenance Log** — Record maintenance activities.
- **Maintenance Reports** — PDF maintenance records from Bio-Rad maintenance.
- **System Data** — Archive raw data to clear up space in your primary storage areas, access data for troubleshooting, and use the data recovery function.

System Settings Tab

When you select the System tab, the System Settings window opens by default.



- Use the Datafile and Template Storage tab to view storage locations:
 - **Preferred Locations** — if the checkbox selected, storage for all users is limited to a single folder for data files and a single folder for templates.
 - **Shared Settings** — if the Preferred Locations checkbox remains cleared, then shared locations can be defined, but remain optional. Users can choose to save their files to their personal folders specified in User Preferences or to the shared location.

Note: The system administrator specifies shared and preferred storage locations, and can also define a backup location for data file storage if the priority folder is full.

- Use the Instrument tab to select the instrument model that is connected to QX ONE Software.
- Use the Software Settings tab to change the graphics rendering method.

Preferred Location

If the administrator sets Preferred Location file paths, then data files and templates for all users are automatically saved to the specified folders. Preferred Locations override selections in individual user preferences.

Important: Only users assigned the System Settings user privilege can set preferred locations.



To specify preferred locations

1. Select the Use for all users checkbox.
2. (Optional) Keep the default paths or modify them to alternative secure storage locations.
3. Tap Save.
4. When the confirmation message appears, tap OK.

Shared Settings

Under Shared Settings, you can choose to save your files to locations that are available to all users.

The screenshot shows the 'System Settings' window with a sidebar on the left containing categories like System Settings, Event Log, Maintenance Log, Maintenance Reports, System Data, Reprocess Data, Instrument Calibration, Instrument Check, and Tools. The main content area is titled 'Datafile and Template Storage' and 'Instrument'. The 'Shared Settings' section is highlighted with a red border and contains the following fields:

- Preferred Location** (with a help icon)
- Use for all users
- Datafile Storage Location:** C:\Users\Public\Documents\Bio-Rad\Q\Mgr\Standard\AppData\Data (with a 'Browse' button)
- Template Storage Location:** C:\Users\Public\Documents\Bio-Rad\Q\Mgr\Standard\AppData\Templates (with a 'Browse' button)
- Shared Settings** (with a help icon)
- Datafile Storage Location:** <location available to all users> (with a 'Browse' button)
- Datafile Storage Location 2:** <backup location available to all users> (with a 'Browse' button)
- Template Storage Location:** (with a 'Browse' button)
- Save** button

The software allows the software administrator to set a primary storage folder and a backup storage folder. Bio-Rad recommends routinely checking available storage space and if necessary, using the Archive function.

Important: Only users assigned the System Settings user privilege (typically your software administrator) can change storage locations in the System Settings window.

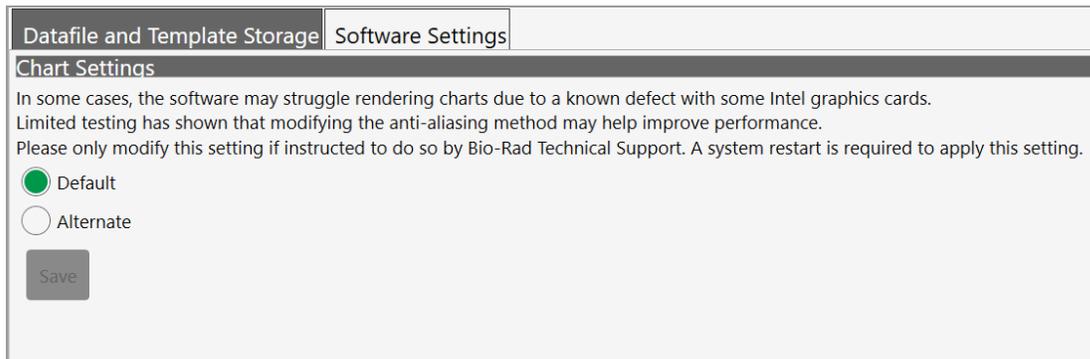
To specify shared folder locations

1. In each of the storage path fields, enter a file path or tap Browse to search for the folder.
2. Tap Save.
3. When the confirmation message appears, tap OK.

Software Settings

The Software Settings tab provides an option to modify the chart rendering process to improve the chart appearance.

Important: The poor rendering is associated with Intel graphics cards only. For more information, contact Bio-Rad Technical Support. Do not change the setting unless instructed to do so by Bio-Rad Technical Support.



Complete the following steps if directed to do so by Bio-Rad Technical Support.

To change the graphics rendering method

1. Under Chart Settings, tap Alternate.
2. Click Save.
3. Close QX ONE Software.
4. To enable the change, restart the touch screen computer, and then reopen the software.

System Log Files

From the System tab, you can access log files for system and software events (event log), and maintenance activities (maintenance log).

Event Log

Users who are assigned the Maintenance user privilege can view the system event log, which contains timestamped information on all software activities.

The screenshot displays the 'Event Log' section of a software interface. The log file is identified as 'Log File: QXONEStandard.History.log'. The interface includes a search bar and buttons for 'Open Log...', 'PDF Password', and 'PDF Report'. The main area contains a table with the following data:

Date Time	Message	Severity	User Name
11/4/2021 9:19:49 AM	System Settings Changed. Preferred Location - Datafile Storage Location Changed...	Info	USPLEC0TKYF2\QX_Super
11/4/2021 9:14:37 AM	System Settings Changed. Preferred Location - Template Storage Location Change...	Info	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_EXIT_HOTEL_RFID_ERROR_CORR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_EXIT_HOTEL_RFID_ERROR_CORR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:47 AM	There was valid instrument info when comparing information acquired from the Q...	Info	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:46 AM	There was valid instrument info when comparing information read from the Calibr...	Info	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:46 AM	Connected to instrument (Try 1) - Serial Number - SIMULATOR, FW Version - 221.8...	Info	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:38 AM	User Logged in. User Name: QX_Super, User Full Name:	Info	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:24 AM	Application StartUp. Application Version: 1.2.0.200, OS Version: Microsoft Windows...	Info	USPLEC0TKYF2\QX_Super
11/2/2021 2:13:17 PM	Application Closed	Info	USPLEC0TKYF2\QX_Super
11/2/2021 2:10:47 PM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/2/2021 2:10:47 PM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/2/2021 2:10:47 PM	Instrument Error Cleared: Code: ERROR_CHASSIS_EXIT_HOTEL_RFID_ERROR CORR...	Error	USPLEC0TKYF2\QX_Super

Selected Row Message:
System Settings Changed. Preferred Location - Datafile Storage Location Changed. Old Value: C:\Users\Public\Documents\Bio-Rad\QXONEStandard\AppData\Data New Value: C:\Users\Public\Documents\Bio-Rad\QXONEStandard\AppData\

To view the Event Log

1. Select the System Utilities tab.



2. Select Event Log.
3. Tap Open Log to choose either the debug log or the history log.
4. Review the log entries.
5. (Optional) To automatically generate and display a PDF document, tap PDF Report.

Tip: To restrict access to the file, you can assign a password. Select the PDF Password check box and then enter a password in the field. The file is saved in the Log Reports folder and can be opened only by entering the password.

Maintenance Log

All users can view the maintenance log, which contains a list of maintenance records. The Maintenance Log tab is available from the instrument touch screen only. Users who are assigned the Maintenance user privilege can set up maintenance records, specify associated activities, and generate PDF reports.

Tip: This guide also contains a form on which you can document completion of maintenance activities. For information, see [Instrument Maintenance Log on page 118](#).

System Settings						Cancel	Save
Event Log	+ New Activity						
Maintenance Log	Date Time	User	Product Version	Firmware Version	Activity		
	11/4/2021	USPLEC0TKYF2\QX_Super	1.2.0	221.8272	System Flush		
Maintenance Reports							
System Data							
Instrument Calibration	Date Time	User	Product Version	Firmware Version			
	11/4/2021 12:57:32 PM	USPLEC0TKYF2\QX_Super	1.2.0	221.8272			
	Activity						
	System Flush						
							PDF Report

To add or view an activity

1. Select the System Utilities tab.



2. Select Maintenance Log. Note that activities that are already scheduled appear in the grid, sorted by newest activity first.
3. Do one of the following:
 - Scroll to view a particular activity.
 - Important:** You can view or add static activities; you cannot modify them.
 - Add an activity; tap the + icon next to New Activity.

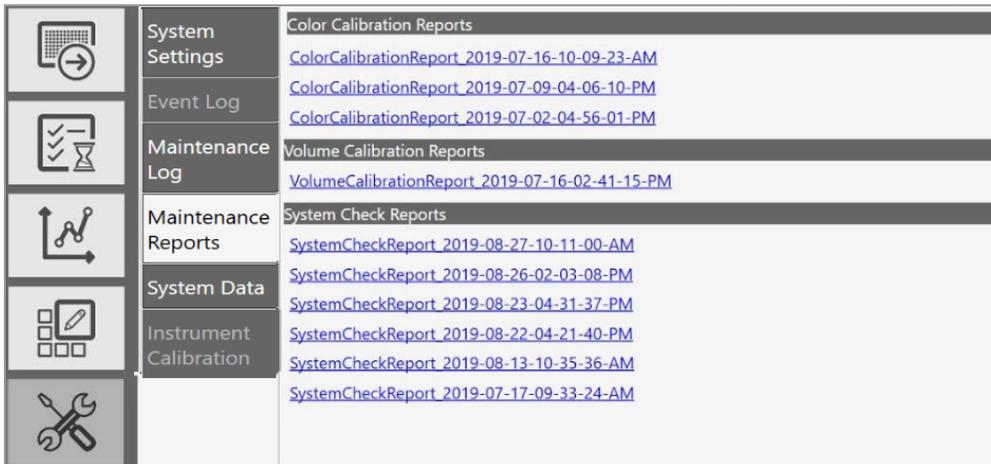
A line item appears in the bottom section, with all fields except Activity completed automatically.
4. In the Activity field in the bottom section, type the activity into the Activity field, and tap Save.
5. Repeat to add another activity.
6. (Optional) Tap PDF Report to create a report of the added activities.

Maintenance Reports

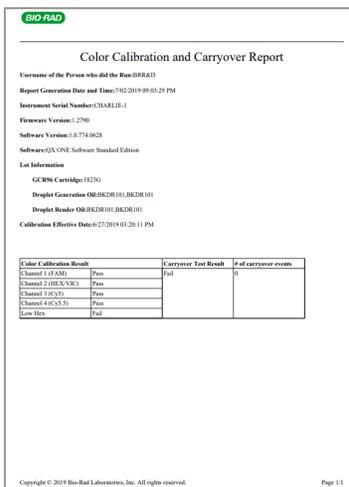
Reports generated from the Bio-Rad service engineer when performing maintenance on your instrument are stored on the Maintenance Reports tab. The Maintenance Reports tab is available from the instrument touch screen only.

To open a report

- ▶ Tap the list item.



Following is an example of a Color Calibration report:



System Data

In the System Data window, you can

- Archive raw data
- Access troubleshooting data
- Recover data

Archiving Raw Data

When the storage space on the QX ONE Droplet Digital PCR System touch screen approaches the limit displayed under Disk Space, you can archive raw data to an archive storage folder in a different location . The software also displays an advisory message, as shown in the following graphic:



Important: You must be assigned the System Data user privilege to archive data.

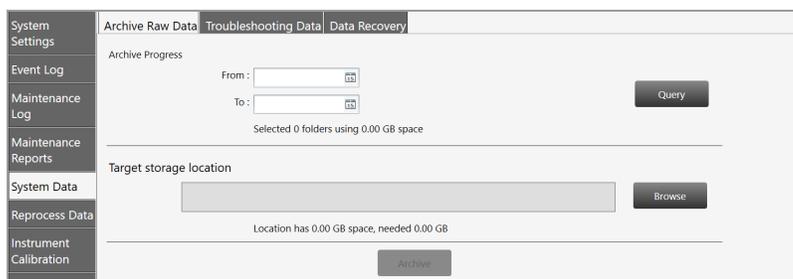
To archive raw data

1. Select the System Utilities tab.



2. Select System Data.

The window opens to the Archive Raw Data screen by default.



3. In the Archive Progress section, tap the calendar icons and select a From date and a To date.

4. Tap Query to search within the defined date span.
5. Tap Browse to find the archive location on your network, and then tap Archive.

Troubleshooting Data

If issues occur with the QX ONE Software, you can access data to assist in troubleshooting the problem.

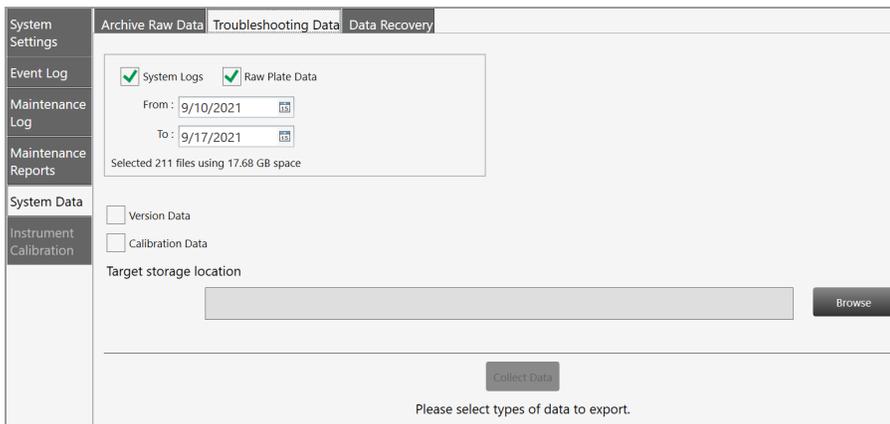
Important: You must be assigned the System Data user privilege to access troubleshooting data.

To access data for troubleshooting purposes

1. Select the System Settings tab.



2. Select System Data > Troubleshooting.



3. Tap the From and To calendar icons to select a date range.
4. Select any of the following checkboxes:
 - System Logs
 - Raw Plate Data
 - Version Data
 - Calibration Data
5. Tap Browse and navigate to the data folder in the target storage location.
6. Tap Collect Data.

Recovering Data

If a run fails on the QX ONE Droplet Digital PCR System, you can use the Data Recovery tab in System Data to recover data that has been saved to a temporary file.

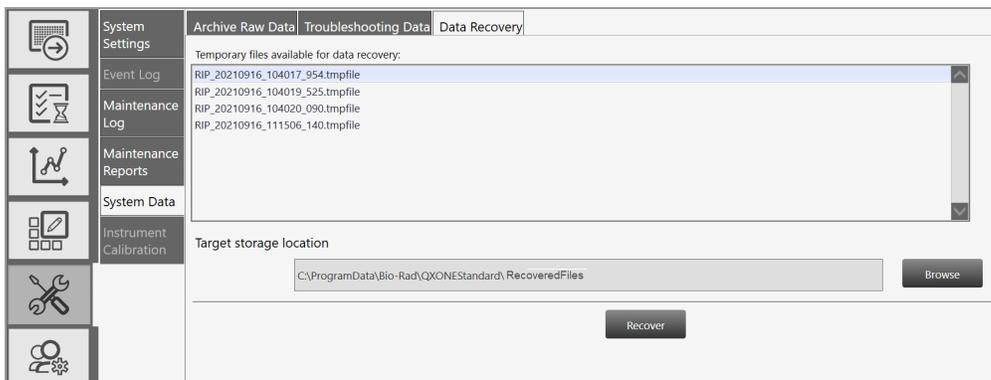
Important: You must be assigned the System Data user privilege to access the Data Recovery tab.

To create a `..ddpcrone` file from the data in the temporary file

1. Tap the System Utilities tab.



2. Tap System Data, and then tap Data Recovery.

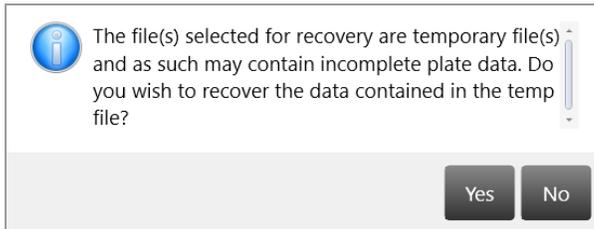


Temporary files that are available for conversion are listed in the top pane, which is scrollable.

3. Tap a file, and then tap Browse

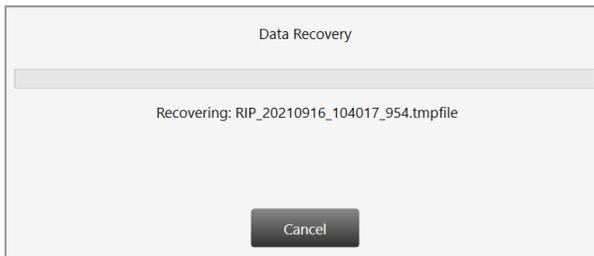
4. Navigate to the target storage location on your computer or network, and then click Recover.

The following advisory message appears.



5. Click Yes.

A dialog box appears with a progress bar, and automatically closes when the conversion is complete.



The .ddpcrone file is stored in the folder you specified.

System Calibration

You cannot execute runs on the QX ONE Droplet Digital PCR System unless the instrument is properly calibrated. Only a Bio-Rad service engineer can calibrate your instrument and use the Instrument Calibration options in QX ONE Software. The option is available from the touch screen only, and is disabled for all other users.

If your instrument requires service, contact Bio-Rad Technical Support.

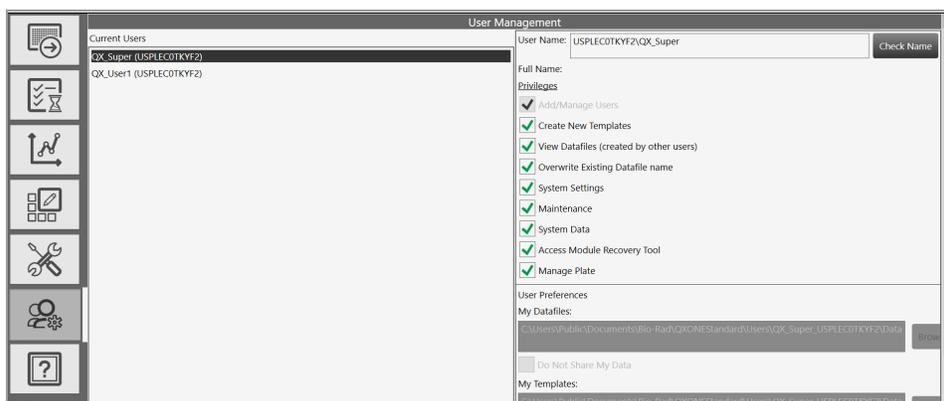
The Tools functions are currently applicable only to instrument maintenance. For information, see [Appendix A, Instrument Maintenance](#).

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Chapter 10 Managing Users

Important: This chapter applies only if you enabled the User Management module during the installation of QX ONE Software Standard Edition. If you did not enable the module, QX ONE Software creates a generic user with the ability to set up, run, and analyze experiments.

Use the User Management window to add, change, or remove QX ONE Software users, and set or change user privileges and preferences.



The Bio-Rad service engineer sets up an initial user with all privileges, including Add/Manage users, on the touch screen. Your software administrator can use this account to set up additional users with appropriate privileges.

You can set up local or domain accounts. If the instrument touch screen computerconnected to the QX ONE Droplet Digital PCR System

- Cannot access your company's network, your IT department or system administrator can set up user names as local Windows accounts.
- Can access your company's network, QX ONE Software can recognize the Active Directory user names.

You can create user accounts with any user name convention and password character structure, as long as it complies with your organizational requirements. The software is designed to validate each user against the name it finds in either the Active Directory or local domain, so users must log in with the proper domain and user name.

Adding Users

This section applies only if the User Management module was enabled during the installation of QX ONE Software Standard Edition.

Before you can add users to QX ONE Software, you must be logged in with the initial superuser account, or another account that is assigned the Add/Manage Users privilege.

Important: Before you begin, ensure that all users either have local Windows user accounts on the local computer or user accounts in Active Directory (network domain).

To add a user

1. Open QX ONE Software and sign into the application.
2. Tap the User Management tab on the left



3. In the User Name field on the right, enter the user name as follows:
 - If the computer is connected to a network and you are using Active Directory accounts, enter <domain name>/<user name>. For example, **global/johnsmith**.

Important: Active Directory users must log in every time with the domain name preceding the user name.

 - If the computer is not connected to a network, enter <local computer name>/<user name>. For example, **analysiscomputer/johnsmith**.

Important: To locate the computer name, right-click on the yellow folder in the lower menu bar and select File Explorer. When the dialog box appears, the computer name is located at the top of the left panel. Local users are not required to reenter the computer name after the initial login.

4. Tap Check Name.

One of the following occurs:

- If the software recognizes the network domain or computer name and the user name, the software displays a validation message.
- If the user is not recognized, an error message appears. Do one of the following:
 - For network users, ensure there is a working connection to the network and then verify your entry is accurate.
 - For local users, verify the entry is accurate. If the user is not set up locally or on the network, contact your system administrator for assistance.

5. When the This user is valid message appears, tap OK, and then tap Add at the bottom of the pane.

An Are you sure you want to add this user? message appears.

6. Tap Yes.

A confirmation message appears.

7. Tap OK.

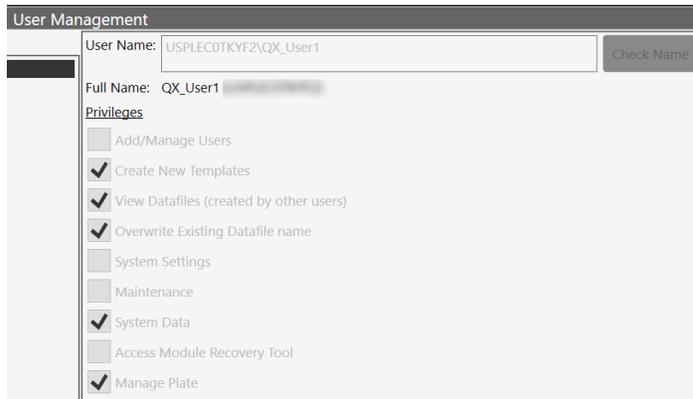
8. Continue until all users are added.

Adding or Removing User Privileges

This section applies only if the User Management module was enabled during the installation of QX ONE Software Standard Edition.

Only a user assigned the Add/Manage users privilege can add or remove user privileges. By default, individual users without privileges can set up and execute a run, open files, view and analyze results.

For descriptions of all user privileges, see [Viewing User Privileges on page 35](#).



[Table 16](#) contains a sample set of privileges assigned by user roles common to a laboratory. User roles can be defined and used in any scenario, but might be required in regulatory environments.

Table 16. Example User Roles

Privilege	Superuser	Lab Manager	Group Lead	Technician/ Student Intern
Add/manage users	✓	✓		
Create new templates	✓	✓	✓	
View data files created by other users	✓	✓	✓	✓
Override existing ddPCR file name	✓	✓	✓	
System settings	✓			
Maintenance	✓			

Table 16. Example User Roles, continued

Privilege	Superuser	Lab Manager	Group Lead	Technician/ Student Intern
Archive data files	✓	✓	✓	✓
Access the module recovery tool	✓	✓	✓	✓
Manage Plates	✓	✓	✓	

You can assign the Create new templates privilege to non-administrative roles if anyone can create and save a template. If template formats are restricted, then you should assign this permission to administrative or supervisory roles only.

Note: Bio-Rad recommends defining at least one additional superuser as a backup, as well as other administrative and standard roles based on your needs. Guest users can open shared templates, execute runs, and perform analysis but are not typically assigned other privileges.

To add or modify privileges

1. Tap the Add/Manage Users tab to open the User Management window.
2. Select a user from the Current Users list. The name appears in the User Name field. A network or computer name and backslash might appear before the user name.
3. Select or clear the checkbox for each privilege in accordance with the user's role in using the software. You can assign user privileges in any combination.
4. When the confirmation message appears, tap Yes to save the changes, and then tap OK to close the pop-up.

Modifying User Preferences

This section applies only if the User Management module was enabled during the installation of QX ONE Software Standard Edition. If User Management was not enabled, only the options for system timeout duration and the number of completed plates displayed in the Runs window are available. For information, see [Partial Preferences on page 38](#).

Users assigned the Add/Manage Users privilege can change the preferences for other users. Individual users can also change their own preferences.

To modify a user's preferences

1. Tap the Add/Manage Users tab, and then enter the user name.
2. Change any of the following preferences for the user:
 - Enter a different file path for user data files and templates, and choose to keep them private.
Important: You can also specify Preferred Locations in System Settings, to override all file paths specified in individual preferences. For information, see [System Settings Tab on page 91](#).
 - Enter a different default system timeout period.
 - Enter a different number of completed plates to show in the Status section, up to a maximum of 100.
3. Tap Save. QX ONE Software displays a confirmation message.
4. Tap Yes to save the changes, and then tap OK to close the dialog box.

Removing Users

This section applies only if the User Management module was enabled during the installation of QX ONE Software Standard Edition.

Only a user assigned the Add/Manage Users privilege can remove users. Removing a user from the software does not remove the user from other systems, such as Windows, or databases.

To remove a user

1. Tap the Add/Manage Users tab to open the User Management window.
2. In the Current Users pane, select the user and tap Remove. QX ONE Software displays a confirmation message.
3. Tap Yes to remove the user, and then tap OK to close the dialog box.

Appendix A Instrument Maintenance

Bio-Rad recommends regular maintenance of your equipment, which includes

- Keeping the surface areas clean, post-run or as necessary
- **Note:** Wipe down external panels and the plate holder with 70% ethanol.
- Regularly checking the fluid levels
- Inspecting the equipment for damaged parts or wiring
- Running a plate on the instrument at least once per month during periods of inactivity

Note: The QX ONE Droplet Digital PCR System is a high throughput instrument that was designed and tested for frequent usage. Due to its complexity and fluidics, if the instrument will be idle for a month or more, Bio-Rad recommends running a plate monthly to maintain instrument reliability. For more information, contact Bio-Rad Technical Support.

Bio-Rad also recommends that a Bio-Rad service engineer perform annual preventive maintenance on your instrument. Contact Bio-Rad if your instrument requires service or recalibration.

General Care and Cleaning

Follow these guidelines to properly maintain your instrument.

- For surface cleaning, use a cloth, slightly dampened with deionized/distilled water, to wipe down the instrument.
- For regular cleaning and decontamination, use 10% bleach solution in distilled water, followed by 70% ethanol in distilled water. For information and instructions, see [Instrument Cleaning and Decontamination on page 117](#).

Important: Do not use acetone or tap water.

- Do not replace the included detachable power cord with an uncertified or an inadequately rated cord.
- Inspect the equipment regularly for damaged external components or wiring. Do not use if damaged.
- Bio-Rad strongly recommends semi-annual preventive maintenance on the instrument by a Bio-Rad service engineer or authorized agent.

Managing Waste

You must apply standard Material Safety Data Sheet (MSDS) and OSHA practices when handling and disposing of generated waste. A typical waste profile should contain the following:

Table 17. Managing Waste

Chemical name	Weight %
Fluorinated fluids	>50%
Water	<50%
Bleach	<10%
Other materials (proteins, nucleic acids, fluorescent dye)	<10%

Note: The chemical identities and exact percentages in the above table are withheld as trade secrets.

Bio-Rad droplet generation and reader fluids are based on fluorinated hydrocarbon chemistry, and should be disposed of in accordance with institutional, state and local regulations. Avoid release to the environment and prevent entry into sewer systems or bodies of water. As a disposal alternative, incinerate in a permitted high-temperature waste incineration facility.

These nonflammable fluids are inert and have low environmental impact and low toxicity.

Toxicological Information

Chemical name: (mixture)

Oral LD50: >5000 mg/kg (Rat)

Dermal LC50: >5000 mg/kg (Rabbit)

Inhalation LD50: >8838 ppm (Rat/8-hr)

Ecological Information

Acute aquatic hazard: LC50 > 500 mg/l (96-hr./static; Pimephales promelas/Fathead minnow)

Chronic aquatic hazard: No information available (GHS Chronic 4)

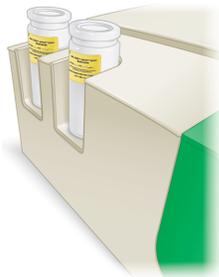
Waste Removal

Empty droplet reader oil bottles can be moved to the waste positions on the left side of the instrument.



Waste bottle replacement is identical to oil bottle replacement procedures.

Important: Use each empty oil supply bottle as a new waste bottle only once, then discard. Reuse of a waste bottle might lead to microbial growth, instrument damage, or run failures.



Important: Waste bottles are filled more quickly than the QX ONE Droplet Digital PCR System Droplet Generation Oil or Droplet Reader Oil bottle contents are depleted. Bio-Rad recommends purchasing QX ONE Droplet Digital PCR System waste bottles each time a total of 20 plates have been run. For the catalog number, refer to the Consumables section in [Appendix B, Ordering Information](#). Bio-Rad does not recommend reusing waste bottles.

Vent Reservoir Maintenance

The reservoir in the QX ONE instrument collects liquid that escapes from waste bottles as the plates are being processed in the QX ONE Droplet Digital PCR System. As the liquid accumulates, QX ONE Software prompts you to remove the liquid:

- When the liquid level in the reservoir exceeds 25 ml, QX ONE Software displays an advisory message, prompting you to aspirate the reservoir before adding new plates to the Inbox.

Bio-Rad recommends aspirating at this time. You can perform the aspiration procedure while the instrument is processing ddPCR runs.

- When the liquid in the reservoir approaches 50 ml, QX ONE Software displays a more urgent message advising immediate action.

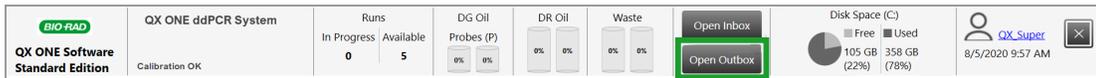
If you do not aspirate the reservoir before the volume reaches 50 ml, the instrument stops and QX ONE Software displays an error message.

Aspirating the Vent Reservoir

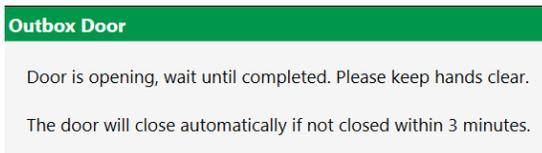
You can aspirate the liquid in the vent reservoir at any time, but you must aspirate the reservoir when the level reaches 50 ml, as instructed by QX ONE Software.

To aspirate the liquid

1. From the QX ONE Software touch screen, tap Open Outbox on the toolbar.



The following message appears.



Important: You must perform this procedure within the allotted 3 min, at which time the outbox door automatically closes.

2. Locate the red luer-lock port on the bottom-left side of the outbox.

- Using a twisting motion, attach a 50 ml luer-lock syringe to the port.

Tip: Bio-Rad recommends the 50 ml BD Luer-Lok Tip Syringe. For information, see [Appendix B, Ordering Information](#).



- Draw liquid into the syringe, up to the 50 ml point.



- Remove the syringe from the port.
- Dispose of the syringe using required procedures for bio-hazardous materials. For information, see [Disposal of Biohazardous Material on page 14](#).

Important: Use each syringe only once.

Instrument Cleaning and Decontamination

The following protocol can be used to clean and decontaminate the QX ONE Droplet Digital PCR System, Bio-Rad recommends performing this procedure weekly, at a minimum, as outlined on the Maintenance Log.

To clean and decontaminate the QX ONE Droplet Digital PCR System, you must have 10% bleach solution (either spray or pre-soaked wipes). If you have questions regarding the use of other cleaning agents, contact Bio-Rad Technical Support.

Important: You do not need to pass 10% bleach through the system itself.

To clean the instrument surface and touch screen using 10% bleach

1. Wipe down all external panels.

Important: Do not clean the handler Y-axis rail when the front door is open. This is a lubricated surface, and failures occur if the lubrication is removed.

2. Wipe the plate holders and surrounding areas in each Inbox and Outbox.
3. Wipe the touch screen.
4. Identify the equipment as Decontaminated.

Instrument Maintenance Log

Instrument Serial Number Last Annual Maintenance Date		Ox ONE Droplet Digital PCR System Maintenance Log																																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31					
Date																																					
Year																																					
As necessary																																					
Replace droplet generation oil																																					
Replace droplet reader oil																																					
Discard waste bottle after one-time use																																					
Note: Use Bio-Rad waste bottles																																					
Aspirate fluids from overflow reservoir																																					
Initials																																					
Daily																																					
Clean work area (before and after use)																																					
Discard used consumables																																					
Initials																																					
Weekly (at start of week)																																					
Check oil expiration dates																																					
Restart the instrument																																					
Restart the touch screen computer																																					
Initials																																					
Monthly																																					
Flush droplet reader oil																																					
Clean entire instrument per maintenance instructions																																					
Initials																																					
Quarterly																																					
Back up the raw data (or when the "disk space full" message appears)																																					
Initials																																					
Annually																																					
Call Bio-Rad for service																																					
Initials																																					

Appendix B Ordering Information

This appendix contains descriptions and catalog numbers for new or replacement items.

QX ONE Droplet Digital PCR System

Table 18 contains information on the QX ONE Droplet Digital PCR System components.

Table 18. QX ONE Droplet Digital PCR System

Product	Description	Catalog number
QX ONE Droplet Digital PCR System	<p>Instrument used for droplet generation, PCR, droplet reading, and data analysis</p> <p>This purchase includes the QX ONE Accessory Kit (formerly catalog number 12011478), which contains the following:</p> <ul style="list-style-type: none">■ PX1 GCR Sealer Support Block■ QX ONE Droplet Digital PCR System ddPCR System Waste bottles■ Keyboard■ Power cord, compatible within North America■ Warranty card	12006536
QX ONE Software	Connects to the QX ONE Droplet Digital PCR System for instrument control, assay setup, and data collection and analysis	Standard Edition, N/A Regulatory Edition, 12012078
Plate Sealer	PX1 PCR Plate Sealer	1814000

ddPCR Materials and Consumables

Table 19 contains information on additional items for performing ddPCR.

Table 19. Additional ddPCR materials and consumables

Product	Description	Catalog Number
Reagents for Probe Detection		
PCR Supermix	■ ddPCR Supermix for Probes (No dUTP)	1863023
		1863024
		1863025
	■ ddPCR Supermix for Probes	1863026
		1863010
		1863027
		1863028
	■ ddPCR Multiplex Supermix	12005909
		12005910
		12005911
	■ ddPCR Supermix for Residual DNA Quantification	1864037
1864038		
1864039		
1864040		
■ One-Step RT-ddPCR Advanced Kit for Probes	1864021	
	1864022	
DTT (dithiothreitol)	2 ml DTT	12012171
Control	ddPCR Buffer Control for Probes	1863052
QX ONE Droplet Digital PCR System Droplet Generation Oil	QX ONE Droplet Generation Oil for Probes, 15 plates	12006058
QX ONE Droplet Digital PCR System Droplet Reader Oil	QX ONE Droplet Reader Oil, 10 plates	12006057
Consumables		

Table 19. Additional ddPCR materials and consumables, continued

Product	Description	Catalog Number
Cartridge	■ GCR96 Cartridge, pk of 1	12006858
	■ GCR96 Cartridges, pk of 10	12006859
Foil plate seal	GCR96 Foil Heat Seal	12006843
Waste bottle	QX ONE Droplet Digital PCR System ddPCR System Waste bottle	12006060
Materials from Other Suppliers		
Pipets (Rainin)	■ 8-channel multichannel pipet, 2–20 µl	L8-20 XLS
	■ Single channel pipet, 2-20 µl	L-20 XLS
	■ Single channel pipet, 100–1,000 µl	L-1000 XLS
Pipet tips (Rainin)	■ 20 µl filter tips	GP-LTS-A-10µL-/F-960/10
	■ 1,000 µl filter tips	GP-LTS-A-1000µL-/F-768/8
Reagent trough	Matrix Reagent Reservoirs (Thermo Fisher Scientific)	8093
Vortexer	Any	N/A
Centrifuge	Centrifuge with plate rotor capable of at least 1,150 rcf	N/A
50 ml BD Luer-Lok Tip Syringe	Syringe for removing liquid from the overflow reservoir	309653
Services		
Bio-Rad service	QX ONE Droplet Digital PCR System IQ/OQ/PQ service	IQ 12012331 OQ 12012333 PQ 12012332

Appendix B Ordering Information



**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 1 905 364 3435 **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