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PRIMER DESIGN

genesig® q16 user manual



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Notices

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genesig® q16 Real-Time PCR

Instrument

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Safety notices

Detailed safety information is provided in the [Safety](#) section. Laboratory users must strictly adhere to the safety guidelines, warnings and notes of caution.

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Introduction

1.1 genesig q16 instrument

The q16 is a portable PCR instrument. In combination with the genesig Easy kit range, the genesig q16 can be used to detect and quantify different targets.

This user guide will teach you what you need to know to start running your genesig q16, from connecting your instrument to the network, to data analysis for your qPCR experiments.

Please read this user manual carefully before using the genesig q16.

The genesig q16 must be operated and maintained using the instructions detailed in this user manual.

1.2 About this user manual

This manual provides detailed instructions and procedures that must be followed for the safe and correct operation and maintenance of the genesig q16. The manual contains the following sections:

- [1. Introduction](#)
 - [2. Safety Information](#)
 - [3. General description](#)
 - [4. Installation](#)
 - [5. Software](#)
 - [6. Starting a q16 run](#)
 - [7. Maintenance](#)
 - [8. Troubleshooting](#)
- [Appendices](#)

Safety Information

2.0 Safety information

This section contains the following topics:

- 2.1 [Important safety advice](#)
- 2.2 [Symbols on the genesig q16](#)
- 2.3 [Technical assistance](#)
- 2.4 [genesig q16 user requirements](#)
- 2.5 [Policy statement](#)
- 2.6 [Warranty policy information](#)
- 2.7 [Intended use of the genesig q16 instrument](#)





2.1 Important safety advice







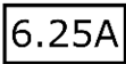

Good Laboratory Practice should be followed at all times using the relevant local and national guidelines.

- Shock hazards or unsafe practices are dangerous as they can cause severe personal injury, fire or death.
- DO NOT use combustible substances near hot objects.
- DO NOT use the equipment in hazardous atmospheres.
- DO NOT operate or handle any part of the product with wet hands or use on surfaces that may become flooded.
- NEVER move the product while still connected to the power supply.
- Power must be provided from standard indoor mains supply, Over Voltage Category II. Only the accompanying PSU should be used with the equipment and that using any other may affect the safety of the equipment.
- The mains socket shall be near the equipment and readily identifiable and accessible to users. This acts as the power disconnect device.
- DO NOT position the unit so that it is difficult to disconnect from the mains supply using the mains plug.
- HIGH TEMPERATURES ARE DANGEROUS as they can cause serious burns to operators and ignite combustible material.
- Users are responsible for wearing appropriate personal protective equipment to protect themselves against hazardous agents. Gloves made of the appropriate material should be used to avoid injury from direct contact with hazardous materials (biological and chemical hazards).
- NEVER lift or carry the instrument until it has been switched off.
- The unit should be carried using both hands, and any risk of personal injury must be avoided by following the appropriate Manual Handling procedures.
- Tubes should not be filled whilst in the instrument, they should be filled somewhere else, then place them in the instrument.

- Do NOT ship the instrument with any tubes still in place. In any instance where the instrument is being shipped (i.e. for service or repair), ensure that any tubes are removed prior to shipping.
- If in doubt, the manufacturer can be contacted using the details provided within this manual.
- This equipment must only be used in the manner specified by the manufacturer otherwise user protection may be impaired.
- In the event of Malfunction of the device (such as the indication lights flashing Red) please contact techsupport@novacyt.com with the details of the fault.
- Through the lifetime of the instrument some colours may change or fade on visible elements of the instrument. This will not affect the performance of the instrument.

2.2 Symbols on the genesisig q16

Symbol	Location	Details
	Powerpack and Instrument label	Waste Electrical and Electronic Equipment (WEEE)
	Powerpack and Instrument label	CE mark for European Conformity
	Instrument label	<i>In vitro</i> diagnostics
	Lid	<i>Warning; Hot surface. The lid contains a heater which exceeds 100°C when in operation. The outer surface of the lid may also be noticeably warm to the touch.</i>

	Instrument label and lid	Caution must be taken when using and maintaining the instrument. Mechanical and thermal risks: <i>Warning: The lid contains a heater which exceeds 100°C when in operation.</i> <i>Warning: Handle lid with care to avoid closing on hand.</i>
	Instrument label	Serial Number
	Instrument label	Part Number / Catalog Number
	Instrument label	Consult user manual
	Instrument label	Manufacturers address
	Instrument label	Manufacturing date
	Instrument label	Power supply Amperage
	Instrument label	Power supply Voltage

Other labels

The Serial Number label can be found underneath the machine.

A tamper-proof label evidences if the cover has been removed, which will invalidate the warranty (see Warranty policy information).

2.3 Technical assistance

Novacyt is dedicated to providing the highest quality support to all customers that use our products. Our technical experts can advise and solve technical issues that may arise. Our technical support team can be contacted by email (techsupport@novacyt.com) and by telephone +44 (0) 23 8074 8830.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2.4 genesisig q16 user requirements

The genesisig q16 must only be operated by trained personnel. Personnel must already be trained in potential laboratory risks and hazards. Depending on the sample type used with the genesisig q16, the appropriate laboratory hazard training must have been carried out prior to using the genesisig q16. Personnel must also be trained to use computerised equipment and automated devices.

Only a person who is qualified and aware of the hazards involved should be responsible for any adjustments, maintenance, and repair of the genesisig q32.

Both operating and service personnel must employ a safe system of work at all times and follow the detailed instructions specified in this manual.

2.5 Policy statement

Primerdesign, part of Novacyt, reserves the right to change specifications at any time.

2.6 Warranty policy information

The genesisig q16 has a 12-month manufacturer warranty.

Other than for those items defined in the maintenance procedures herein, there are no user-serviceable items in this instrument. Removal of covers and attempted adjustment or service by unqualified personnel will invalidate the warranty and may incur additional charges for repair.

In warranty conditions

For any instrument repairs, the following is covered:

1. All parts and labour are covered for any in warranty claims, except for the following conditions:
 - a) The instrument has been abused by the customer, such as fluid spillages, misuse, or extreme neglect.
 - b) Any unauthorised service intervention or tampering of the instrument prior to any claim without explicit instruction by the manufacturer.
 - c) The above exceptions may incur additional charges, and the customer/distributor will be notified before any repairs are carried out.
2. The customer/distributor will be responsible for shipping costs to Novacyt, and any return shipping will be at the cost of Novacyt.
3. Instruments repaired under the original warranty will be covered under a Repair Warranty that will expire on the later of:
 - a) Three months from the shipment of the repaired instrument, or,
 - b) The original warranty expiration date.
4. If the customer wishes to not proceed with any repairs after any additional charges have been incurred, a processing fee will be charged to cover our investigation and diagnostic costs up to that point.

Out of warranty conditions

For any instrument repairs, the following is covered:

1. Instruments repaired out of original warranty will be covered under a Repair Warranty that will expire on the later of:
 - a) Twelve months from the shipment of the repaired instrument, for the subsystem repaired, and,
 - b) Three months from the shipment of the repaired instrument for all other parts.
 - c) If an instrument comes back for repair which has been tampered with or misused, additional charges may be incurred; the customer/distributor will be notified of any charges and must be agreed upon prior to any repairs being carried out.
 - d) If the customer/distributor wishes to not proceed with any repairs, a processing fee will be charged to cover our investigation and diagnostic costs up to that point.
2. Shipping and return costs will be the responsibility of the customer/distributor unless agreed prior to any work being carried out or predetermined agreements in place.

2.7 Intended use of the genesig q16 instrument

The genesig q16 instrument can be used to identify a wide range of DNA or RNA targets by using primers and probes specific to the region of interest.

The genesig q16 instrument is intended to be used to perform real-time thermal cycling, utilising polymerase chain reaction (PCR) to amplify DNA or cDNA (following reverse transcription from RNA) for molecular biological applications.

The device is designed to amplify genetic material from clinical specimens collected for the purposes of aiding diagnosis

The thermal cycler has programmes for PCR amplification that control thermal elements in the instrument to change the temperature, or hold the temperature, of the PCR reaction for certain time periods.

The instrument monitors genetic material amplified from the target molecule by use of fluorescent probes to provide qualitative, semi-quantitative or quantitative results depending on the kit used.

The instrument is intended for professional use.

2.8 Kit compatibility

The genesig q16 instrument is compatible with:

- genesig Easy kits
- PROmate kits designed specifically for the genesig q16 instrument

Please refer to the relevant product's Instructions For Use (IFU) for the detailed methods.

For the latest kit releases, please contact enquiries (enquiry@primerdesign.co.uk).

General Description

3.0 General description

This section contains the following topics:

3.1 [Instrument description](#)

3.2 [Quality control specifications](#)

3.3 [PC requirements](#)

3.1 Instrument description

The q16 software provides a desktop application running in a Java runtime environment, allowing for:

1. Configuration of experiments using relevant settings.
2. Configuration of instruments (e.g., calibration data, network settings)
3. Execution of experiments, by either:
 - a. USB drive, which, when inserted in the instrument will trigger a run. The instrument will then output another file to the USB drive, which can be opened in the software to retrieve run data.
 - b. Network – the software can automatically discover instruments on an ethernet network and then connect to those instruments to trigger runs and retrieve data from the runs.
4. Analysis of experiment data.
5. Saving experiment or analysis result data to files.
6. Loading experiment or sample data from files.

This equipment is designed to operate under the following conditions:

- For indoor use only. **NOTE:** Pollution Degree 2: Normally only nonconductive pollution occurs. Temporary conductivity caused by condensation is to be expected.
- The equipment must not be used at an altitude exceeding 2000m.

Components

You should have the following items:

1. genesig q16 real-time PCR Instrument genesig box containing genesig q16 machine
2. MyGo Power supply unit (PSU) and mains cable relevant to the country. The MyGo PSU can be used with the genesig q16 instruments
 - The mains supply is 100-240VAC, 50-60Hz, 100W
3. Ethernet network cable
4. genesig branded USB flash drive
5. genesig q16 software (loaded onto the USB flash drive)
6. electronic copy of the genesig q16 user manual on a USB flash drive
7. USB extension cable

Please keep the outer box the genesig q16 came in, in case you need to protect your genesig q16 during storage or shipment in future.

3.2 Quality control specifications

Optical Performance	Laboratory test carried out: -Amplification observed in the FAM channel -Amplification observed in the HEX channel
Thermal Performance	Successful completion of amplification run without errors. SD of observed melt peaks in thermal uniformity test $\leq 0.1^{\circ}\text{C}$ intra-run. Mean observed DNA melting temperature $\pm 0.25^{\circ}\text{C}$ of the expected value.
System check	Successful completion of amplification run and thermal uniformity test without errors

3.3 PC requirements

The table below gives the minimum requirements to run the software

Name	Specification
Processor	Intel Core i3 2GHz (or equivalent AMD)
Memory	8 GB
Storage	250 GB
LAN	RJ-45 LAN, 100 MBit (if using network for runs)
USB	USB 2.0 (if using USB for runs)
Display resolution	1280 x 1024 or higher
Operating System	Windows 8 System Requirements (minimum)

Installation

4.0 Installation

This section contains the following topics:

[4.1 Conditions](#)

[4.2 genesig q16 instrument](#)

[4.3 Connecting the q16 instrument](#)

[4.4 Tips](#)

4.1 Conditions

Environmental conditions

Your workspace

Your genesis q16 instrument should be placed on a flat, dry surface that is not subject to draughts. Do not install your q16 instrument directly in the flow of air from an air conditioner or fan. Do not install your q16 instrument in a dusty environment. Adequate space must be left between the instrument and any other equipment and adequate space below any shelving units.

Preventing contamination

Prevent contamination by wearing gloves, using clean tube racks and filter tips. Make sure tubes are sealed, PCR product is disposed of, and leaks are cleaned immediately.

Environmental operating conditions



Humidity

MAX: 80% at +32°C

MIN: 30% at +15 to +32°C



Temperature

+15°C to +32°C

Environmental storage/transport/packaging conditions



Humidity

MAX: 10% to 95%

Non-condensing humidity



Temperature

-20°C to +60°C



4.2 genesisig q16 instrument

Lid

The lid ensures that tubes are seated correctly in the wells, provides optical isolation, prevents dust falling into empty wells and is heated during the run to reduce condensation.









To open the q16, push the lid down and twist a quarter turn anti-clockwise, then lift. The lid is replaced by repeating this operation in reverse.

USB port

Insert the USB drive here to run an experiment from the USB drive. The USB drive needs to be inserted into the USB extension cable, as the USB port is underneath the instrument, and if the USB drive is inserted directly into the USB port, you would not be able to put the unit back down on the bench

Display LEDs

The genesisig q16 uses display LEDs to help you understand what the instrument is doing. Here is a summary of these display LEDs.

-  **Amber Circling Light** = Lid off
-  **Blue Static Light** = Standby - ready for run
-  **Blue Circling Light** = Cycling - warming up
-  **Green Circling Light** = Run starting
-  **Red Circling Light** = Cycling - at maximum temperature
-  **Purple Circling Light** = Cycling - cooling down
-  **Rainbow Circling Light** = Run complete - remove and safely dispose of q16 tubes
-  **Red Flashing Light** = Machine Error

Audio status messages

The genesisig q16 gives audio updates on the instrument status, such as whether the lid is engaged, and whether the run is starting or ending.

4.3 Connecting the q16 instrument

Unpack your genesig q16 and remove all packaging. Insert the power cable (supplied) into the power jack in the base of the instrument and plug into a power source.

The q16 can be operated in three ways.

4.3.1 Direct connection to Mac/PC

If you are planning to run the instrument via a direct connection to Mac/PC, plug the Ethernet cable (supplied) into the base of the instrument and connect to a spare Ethernet port on your Mac/PC. Ideally your Mac/PC should run the most recent version of the operating system. The genesig q16 will run on OS X version 10.7.3 and newer releases for Mac (MacOS) and Microsoft Windows 8 or 10 for PC.

If you have multiple genesig q16 instruments, you can connect them all to the same Mac/PC via a network switch.

4.3.2 Direct connection to a local area network

If you are planning to run the instrument via a local area network, plug the Ethernet cable into the base of the instrument and connect to a spare Ethernet port on your network.

4.3.3 Standalone operation via a USB drive

If you are planning to run the instrument in standalone mode, no Ethernet cable connection is required. Instead, a USB drive should be loaded with the experiment setup data and then inserted into the base of the q16 via an extension cable to initiate a run.

Please ensure that you use the USB drive provided with your instrument.

If using a USB drive from an alternative supplier, the strict minimum speed limit for compatibility with the q16 software is 0.2 MiB/s average over 10 MiB of data (a 10 MiB file should be written in 50 seconds or less).

4.4 Tips

Here are some tips to keep in mind whilst running your genesig q16 instrument:

1. Lid gets warm: The genesig q16 lid can get warm during operation, this is completely normal.

2. Do not leave the lid open: If the lid is open dust may fall into the wells and affect the performance of your instrument.

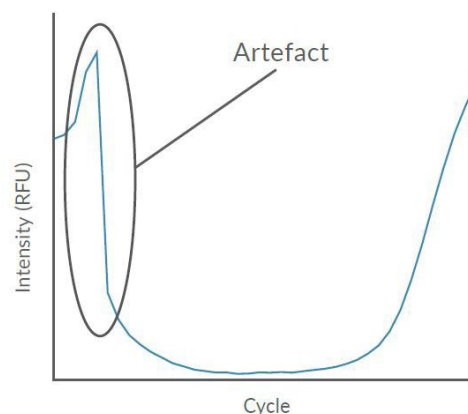
3. Spin your tubes: This should ensure that all contents are at the bottom of the tubes, and there are no bubbles present. Reaction mixtures which are viscous, or contain high levels of detergents, will require stronger centrifugation to remove bubbles. Please use sufficient g-force to ensure that no bubbles are present.

4. Remove all bubbles: Bubbles can cause optical artefacts as shown in the graph. Ensure that no bubbles are present in reaction volumes.

5. Keep your lab clean: Please keep your work space clean including all lab equipment, surfaces, pipettes and tube racks. This will keep the instrument clean and help maintain good results.

6. Keep your instrument clean: We recommend a routine cleaning of your instrument. To do so follow the cleaning guide in the Maintenance section.

7. PC settings: Please disable all power saving settings while a run is in progress (e.g., sleep and hibernate functions) as there is regular communication/network traffic between instrument and PC.



Software

5.0 Software

This section contains the following topics:

- [5.1 Software and applications](#)
- [5.2 Configuration and data files](#)
- [5.3 Networking](#)
- [5.4 Software configuration](#)
- [5.5 Instrument configurations](#)
- [5.6 Automatic IP assignment](#)
- [5.7 Self-assigned IP](#)
- [5.8 Network hardware configurations](#)
- [5.9 q16 networking details](#)
- [5.10 Selecting a test type](#)
- [5.11 The main screen layout](#)
- [5.12 Notes](#)
- [5.13 Samples](#)
- [5.14 Tests](#)
- [5.15 Well contents](#)
- [5.16 Post-run data analysis/interpretation](#)

5.1 Software and applications

Notes

Since the software uses a Java 8 runtime environment (which is installed as part of the application by the Windows MSI installer), it will run in most environments and does not require any additional software components. Earlier Windows versions may work but are not recommended.

The storage space is a recommendation to allow space for storing runs etc. but is not a strict requirement, provided there is adequate space to install the software and save experiment files as needed.

Installation

The software is provided for Windows as a standard MSI installer package. The installer creates a single installation directory, along with shortcuts for the start menu and desktop. Note that the installer does not install any additional libraries or components, and so the software can also be installed by copying all contents of the installation directory.

Your genesig q16 USB drive contains software for Windows, and MacOS operating systems. Please open the software file matching your chosen operating system. Windows Double-click on the Windows installer and follow the on-screen instructions to install your genesig q16 software on Windows. MacOS Double-click on the disk image and follow the on-screen instructions to install your genesig q16 software on your Mac PC.

Please contact technical support for any queries on the latest version of the software.

5.2 Configuration and data files

The software creates a configuration directory called “.pecan” in the user directory of the user running the software. This is used to store configuration data and logs, as well as data for samples in the sample queue.

The software can read and write files stored elsewhere in the file system, in particular “.PPF” (PCR Project File) files containing experiment and run data.

5.3 Networking

Overview

The instrument software supports running experiments on the instruments using an ethernet connection. The instrument must be connected to the network via the RJ-45 socket. A 100 Mbit network is required. The instrument supports connection to a LAN, or a direct cable connection to a PC. In this case, a cross-over cable is not generally required.

The instrument and software will use the network for two purposes:

1. Automatic discovery of instruments – the software and instrument use UDP packets (including multicast) to permit the discovery of the serial numbers and IP addresses of instruments on the network. See the “Networking – q16” below for details of the protocols used.
2. Communications during a run – the software will make connections via TCP/IP to a known port on the instrument to communicate with the instrument to send settings and retrieve data. See the “Networking – q16” (section 7.8) below for details of the protocols used.

Network and PC security and routing

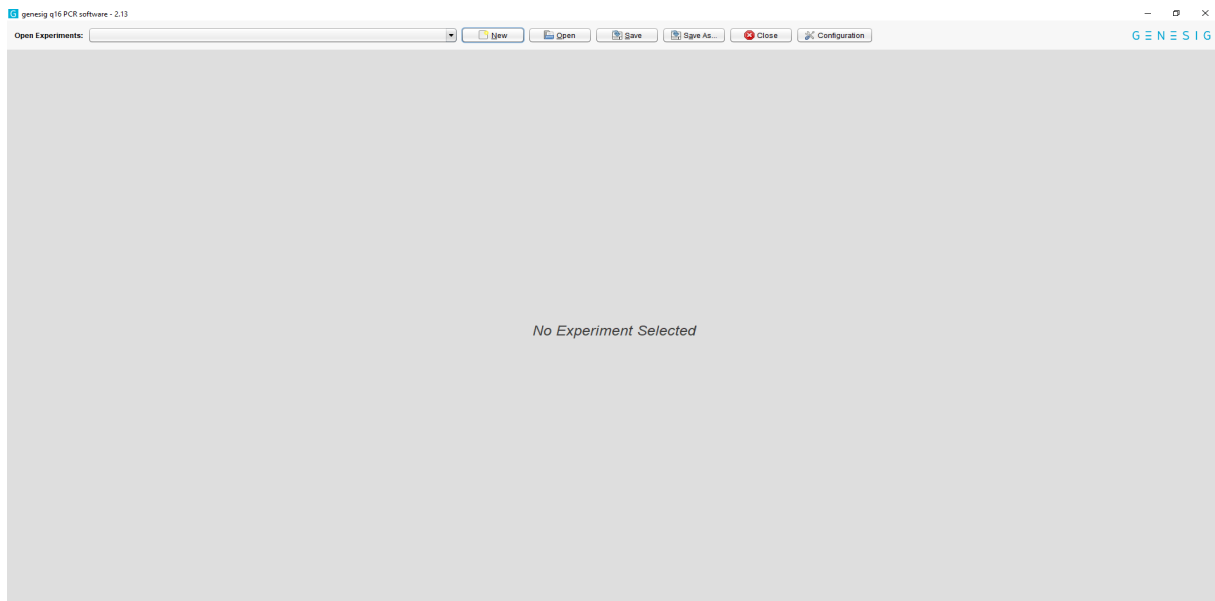
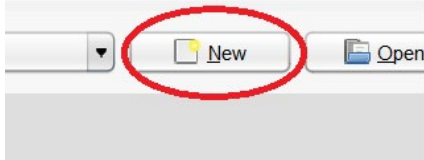
In order for the automatic discovery of instruments and communications during a run to function correctly, the network and PC must be configured to allow the required network traffic between the PC and instrument. This may involve configuring the network and associated network equipment, as well as the PC and operating system (for example, to ensure that firewalls and/or security software are not blocking the relevant traffic). Please consult the sections on “q16 networking details” for a description of the ports and protocols used by the software and instruments.

On many networks and Windows PCs, the only required step is to ensure that when the software is first run and a dialogue box is displayed requesting network access, the software is allowed to communicate on both private and public networks.

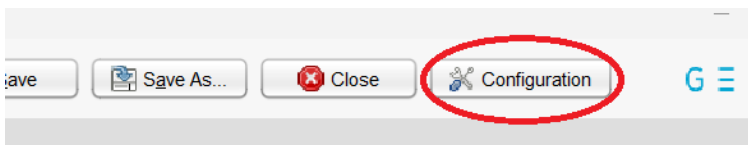
On networks and PCs with more security configuration, please consult your IT department or network administrator.

5.4 Software configuration

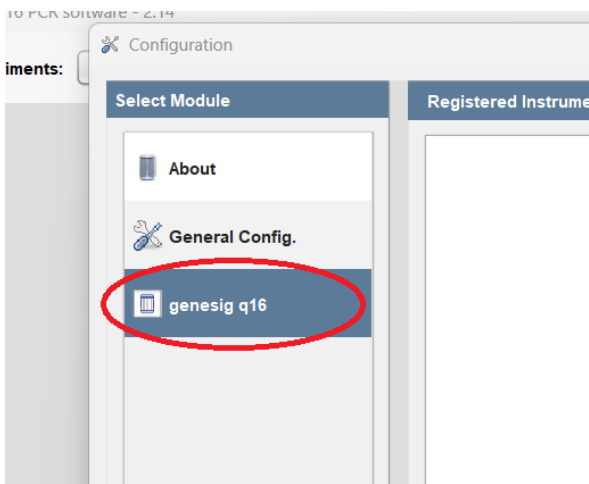
Once installed, double click on the q16 software icon to open the software. Click the 'New' button to begin a new test.



Instruments are registered using the software configuration dialogue – click the 'Configuration' button in the top right of the application:

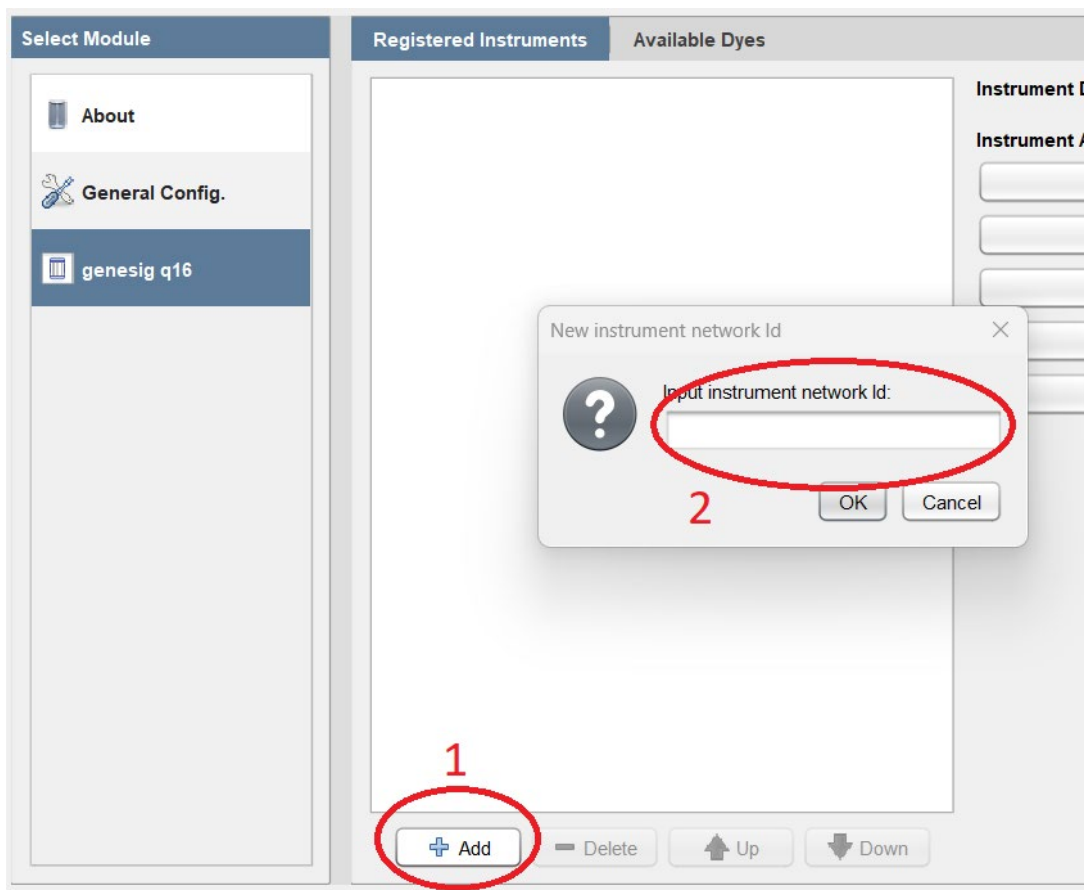


Now select the Module on the left named after the instrument type – “genesig q16”



This will display a list of registered instruments. The IP address the software will use to communicate with each instrument is displayed in the “Network Address:” text box. When an instrument is automatically discovered, its address will be filled in for you. If automatic discovery is not possible, you can also input the IP address manually. The registered instrument information, including network addresses, will be saved when the software is closed normally.

To register a new instrument, click “Add”. This will display a list of any automatically discovered instruments. If the instrument is not listed, you can also select the option to register an instrument by serial. Once this is done, you may also need to enter the IP address in the “Network Address:” text box.



5.5 Instrument configurations

The instruments can be used in several network configurations; the appropriate configuration should be chosen based on the network in use.

5.6 Automatic IP assignment

In this mode, the instrument will request an address from any DHCP server on the network. In most networks this will automatically assign an address, and the software will then automatically locate the instrument. The PC should be connected to the same network and will then usually receive a suitable address via DHCP, allowing communication between the PC and instrument.

In case this doesn't work, or if you would prefer to use a fixed IP address for the instrument, we recommend configuring your DHCP server (which may be your network router or a separate server) to assign a fixed IP to the instrument using its MAC address. To do this, please provide the Serial Number of the instrument (printed on the label on the base plate of the instrument and on the instrument packaging) to technical support. They will provide you with the MAC address of the instrument. This MAC address identifies the instrument on the network and can be provided to your DHCP server so that it will always assign the same IP address to the instrument.

5.7 Self-assigned IP

If the instrument is connected to a network without a DHCP server, it will self-assign an address in the range 169.254.0.0 to 169.254.255.255.

Please ensure that the PC is configured so that it can communicate with addresses in the range 169.254.0.0 to 169.254.255.255 – Windows 10 will default to suitable parameters if no DHCP server is found on a given interface. Alternatively, the PC can be configured to use a fixed IP in this range, with a mask of 255.255.0.0.

You should now be able to add the instrument to the software in the normal way – the instrument will be located automatically. If this does not work, you can add the instrument using its serial number, and the software will configure the IP address for you.

5.8 Network hardware configurations

The instruments support the following configurations:

1. The PC and instruments are connected to a single network with a DHCP server. The PC and instruments receive compatible addresses from the DHCP server – either assigned from a pool or fixed addresses based on their MAC addresses.
2. The PC and a single instrument are directly connected using an ethernet cable. With the default configuration in Windows 10 both the PC and instrument will fail to find a DHCP server and will assign themselves compatible addresses (see “Self-assigned IP”). Note that in addition to this self-contained network, the PC may use a second network interface to connect to an existing LAN.
3. One PC and multiple instruments are connected using a network switch, creating a self-contained network. As in configuration 2 both the PC and instrument will fail to find a DHCP server, and will assign themselves compatible addresses (see “Self-assigned IP”). Note that in addition to this self-contained network, the PC may use a second network interface to connect to an existing LAN.
4. A network without a DHCP server, where the instruments and PC are assigned static IPs.

5.9 q16 networking details

Automatic discovery of instruments

To automatically discover instruments on the network (and retrieve their serial and IP address), the system uses UPnP (only the service discovery part of this protocol is used). The settings required to allow this on a network will depend on your network configuration, but since UPnP is quite common, this should be a standard configuration, and may already be in place for the discovery of other network devices.

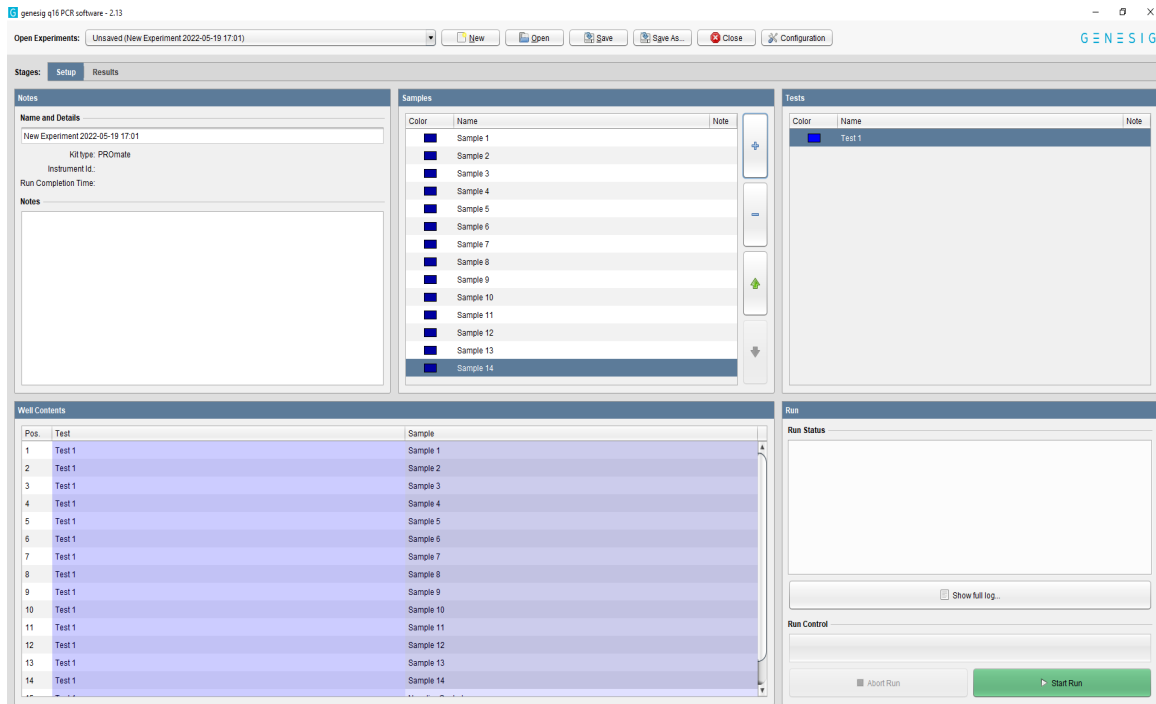
Communications during a run

During a run, the instrument communicates via TCP/IP port 80, and so it must be possible for the PC running the software to connect to port 80 of the instrument, and maintain this connection throughout the run. The PC always connects to the instrument it is not necessary for the instrument to connect to any sockets on the PC.

5.10 Selecting a test type

Once the software has started, select “New” and you will be asked to select the assay type. Please choose the one recommended by the IFU of the kit you are using, along with any further options required (e.g. wet or dry format). The software will then set up the main screen layout relevant to the kit, and load in the necessary cycling parameters.

5.11 The main screen layout



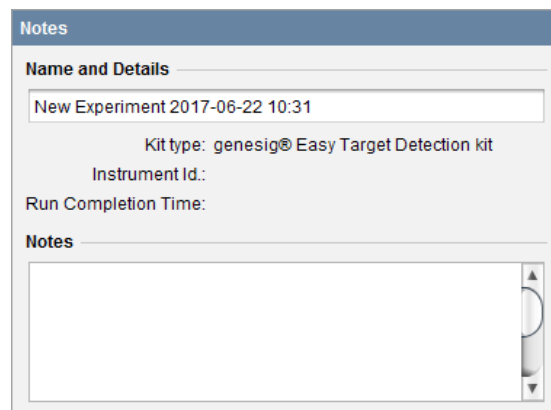
There are two tabs in the view. One for setting up your test and a second where your results will be displayed after the analysis is complete:



In the set-up screen, there are **four** simple set-up panels to consider:

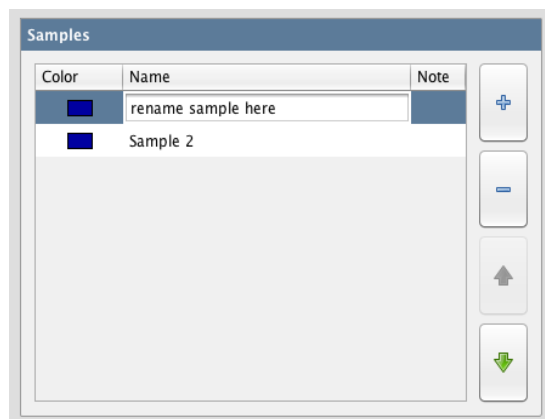
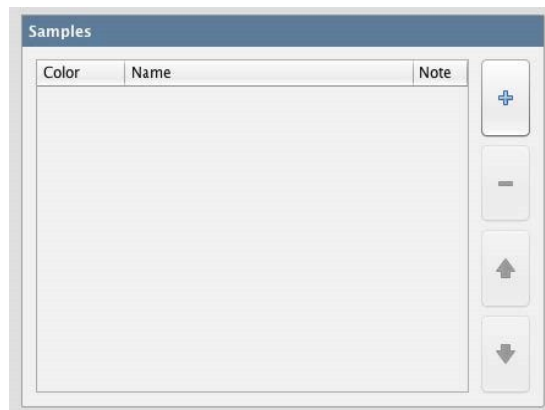
5.12 Notes

Your test will be given a default name, but this can be changed by clicking in the “Name” field and entering new text. The “Notes” field allows you to make notes on your test if required.



5.13 Samples

In this panel, you can define how many samples you wish to test. Use the + button to add more, and the – button to remove them. You can alter the order of the samples using the up and down arrows. The software automatically limits the number of samples you can have dependent on the capacity of the instrument.



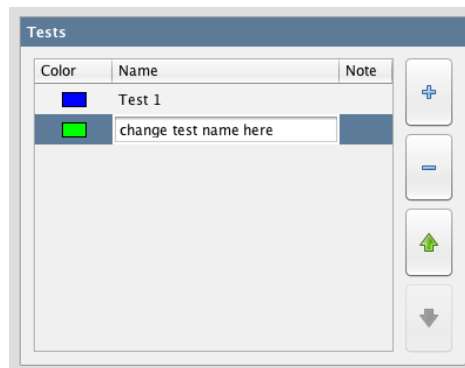
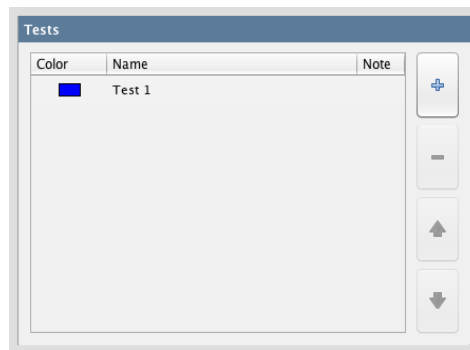
You can alter the name of your samples by clicking in the “Name” field and adding new text. You can also attach more detailed notes to a sample by clicking in the “Notes” field and adding text.

Samples are coloured to make visual identification easier. You can alter the colour associated with each sample by double-clicking on the coloured square next to it.

5.14 Tests

You can perform multiple tests on the genesig q16. In this panel, you can define how many tests you wish to perform. Use the + button to add more and the – button to remove them. You can alter the order of the tests using the up and down arrows.

The software automatically limits the number of tests you can perform dependent on the capacity of the instrument.



You can alter the name of your tests by clicking in the “Name” field and adding new text. You can also attach more detailed notes to a test by clicking in the “Notes” field and adding text.

Tests are coloured to make visual identification easier. You can alter the colour associated with each test by double-clicking on the coloured square next to it.

5.15 Well contents

Taking into consideration the number of tests and the number of samples you have specified, the software automatically allocates the well position within the genesis q16 in which each sample is to be placed. Similarly, the well-position of the Positive and Negative Controls are also defined automatically. Be sure to follow the allocated well positions carefully when loading your samples into the instrument.

Pos.	Test	Sample
1	Test 1	Negative Control
2	Test 1	Positive Control
3		
4		
5	ADD EMPTY TUBE TO BALANCE LID	
6		
7		
8		
9	ADD EMPTY TUBE TO BALANCE LID	

5.16 Post-run data analysis/interpretation

Following completion of the run, the amplification products pose a significant contamination hazard to further runs. We advise letting the mount cool for at least five minutes before twisting to release the lid. All used plasticware should be disposed of by double-bagging in a zip seal bag, with gloves changed after handling. NEVER open a genesis q16 reaction tube after an analysis run has been completed. Dispose of the tubes carefully and ensure that they do not open by accident, as this risks contaminating your working area and may affect future test results.

Networked runs

The results and analysis will automatically show once the run is complete.

Opening a run

To open a saved file, simply click on the “Open” button along the top, navigate to the folder location where the run is saved, select the file, and click “Open”.

Interpreting results

Most modules contain their own logic to correctly call samples according to the data obtained. This will be seen in the results tab. Some modules do not have call logic and instead require the user to interpret the data based on the results.

In both instances, please refer to the relevant IFU for further details on interpreting the results.

Starting a q16 run

6.0 Starting a q16 run

This section contains the following topics:

[6.1 Starting the analysis](#)

[6.2 Manually registering the q16](#)

[6.3 Standalone operation from a USB drive](#)

[6.4 Results](#)

[6.5 Summary results view](#)

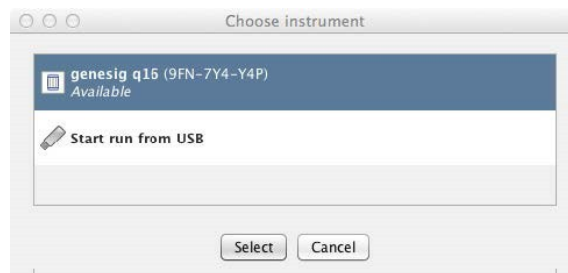
[6.6 Detailed results view](#)

[6.7 Exporting results](#)

[6.8 What do the results mean?](#)

6.1 Starting the analysis

Once all of your samples have been loaded into the instrument and the lid closed, click the “Start Run” button.



From the list, select the q16 instrument that you are using and analysis will begin automatically.

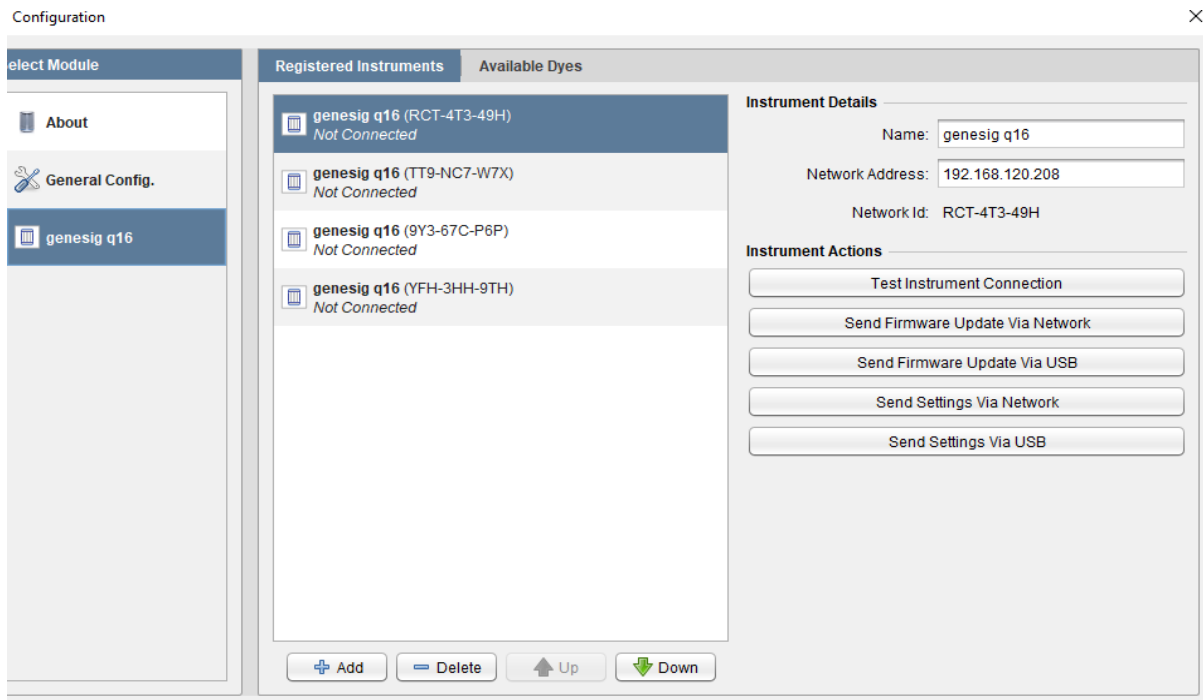
The status of the run and the remaining time is displayed in this panel during the analysis.

The run can be stopped at any time by clicking the “Abort Run” button. If you abort the run, discard your samples as they may be affected by the run beginning. Auditory and LED colour changes are used as prompts and confirmation of procedural steps.

If your instrument is not displayed, you will need to manually register the q16. This can be done using the instructions overleaf.

6.2 Manually registering the q16

- Click “Configuration” on the top right-hand corner of the software screen.
- Select the “genesig q16” tab on the left-hand side of the pop-up window.
- Click on the “Add” button now displayed at the bottom of the pop-up window.



- A list of all registered q16 instruments should appear; choose the instrument you wish to connect.
- If the software does not detect any registered instruments, you will be prompted to manually input the nine digit/letter serial id no. of your q16 (this can be found on the underside of the machine).
- Wait for a few minutes. If your q16 becomes designated as “Available”, then close the configuration pop-up window. You will now be able to start a run.
- If your instrument does not become “Available”, and is designated as “Not Connected” instead, please check the wires and ports are all connected properly, then repeat all of the steps above.
- If your instrument continues to be displayed as “Not Connected”, please see the Troubleshooting section of this user manual and contact your network administrator as it is likely that your network security is preventing a proper connection.
- Primerdesign can provide your IT department with the recommended protocols for manually configuring the instrument connection; please contact us.

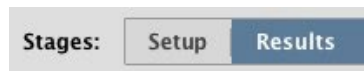
6.3 Standalone operation from a USB drive

In order to conduct a successful USB run, please follow these steps:

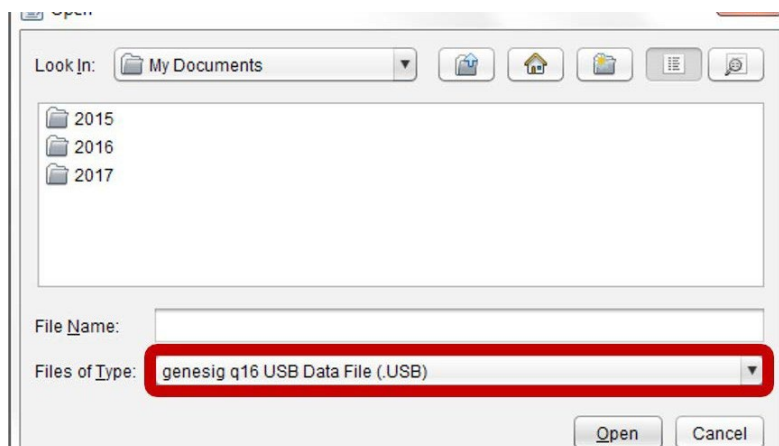
- Set up your experiment as normal.
- Connect the USB drive to the Mac/PC.
- Click “Start Run”, then select “Start run from USB”.
- In the navigation window that appears, select the drive associated with the USB.
- Wait until the “Testing USB drive speed” pop-up disappears. Safely remove the USB drive from Mac/PC (use proper USB eject protocol to ensure that the file ‘USBRUN’ has been transferred to your USB).
- Connect the USB drive to the q16 and the run should start automatically. The q16 will say ‘analysis starting’ and the LED light indicators will change to green.
- During the run, the LEDs will hold red for several minutes, then begin cycling between blue, red and purple until the analysis is complete.
- The USB drive should not be removed until the run is completed, as indicated by the q16 saying ‘analysis complete’ and the LED light indicators changing to rainbow colours.

6.4 Results

If you are running the instrument via a direct connection or over a LAN simply click the “Results” tab to view the results.



If you are running the instrument direct from a USB drive, the results will be stored as a .USB file on the USB drive. This can be opened in the software on your Mac/PC. Insert the USB drive into your Mac / PC. Open the genesig q16 software and click “Open” then change the “Files of Type” selection (underneath the file name) from ‘Experiment File (.ppf)’ to ‘genesig q16 USB Data File (.USB)’.



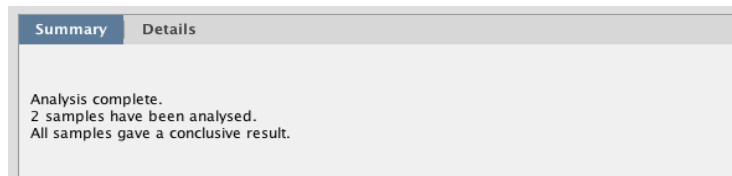
Your USB run will now be viewable in the appropriate folder (the first USB run is typically named ‘PCR01.USB’).”



The results window has two further tabs. The first shows a summary of the results complete with automated analysis. The second gives a more detailed view showing the underlying raw data and is designed for advanced users or for troubleshooting.

6.5 Summary results view

A text-based summary of the entire analysis is displayed in the top left panel.



More detailed information is displayed in the top right “Notes” panel.



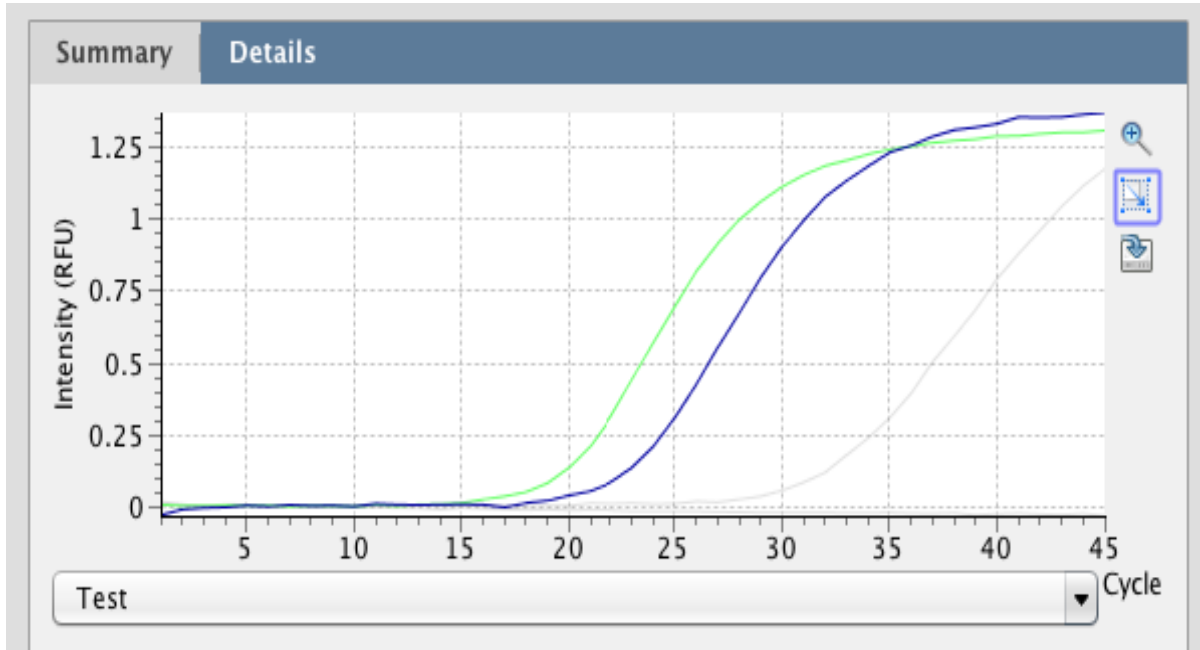
The image shows a software interface with two tabs: 'Sample Results' (selected) and 'Details'. Below the tabs is a table with the following data:

#	Test	Sample	Status
1	Test 1	Negative Control	
2	Test 1	Positive Control	
3	Test 1	Sample 1	POSITIVE
4	Test 1	Sample 2	POSITIVE
5			

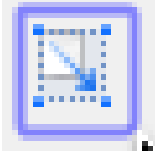
In the summary view, the samples are listed exactly as you set them up in the previous screen. The status field shows the test result as a simple, automatically analysed status.

6.6 Detailed results view

The detailed results view shows the raw underlying data and are designed for advanced users and for troubleshooting. A PIN will need to be entered to access the detailed results view for certain modules (contact techsupport@novacyt.com, if needed).



Amplification plots are visible in the top left panel. The drop down menu allows you to view the amplification plots derived from the test reaction or the Internal Extraction Control/Universal target reaction.



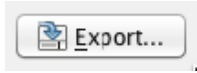
Selecting amplification plots: Amplification plots can be selected by clicking and dragging the cursor over the plot of interest. Alternatively, individual tests and samples can be selected from the table below to highlight the the amplification plot for a given reaction.



Zooming: Click the magnifying glass icon to select it. To zoom into the graph, move the mouse to the top left of the area you wish to zoom in on. Hold down the left mouse button, and move the mouse to the bottom right of the area you wish to zoom in on and release. To zoom out again, move the mouse anywhere over the data area of the graph, then hold down the left mouse button, move the mouse a short distance up and to the left, and release the mouse button.

Cq values can be read by hovering the cursor over a given amplification plot. Cq values can also be seen in the export file.

6.7 Exporting results



Detailed results can be exported by clicking the export button. A choice of export formats are available, e.g., .pdf .csv.



An image file version of the amplification plots can be exported by clicking the graph export icon.

6.8 What do the results mean?

Analysis of your data is carried out automatically by the genesig q16. The information in this section is designed to help you fully understand a result.

The following potential results may be seen when using a kit:

“Positive”

Explanation

Your sample has produced a positive result. Your target of interest is present, and you can use the reported copy number/percentage.

“Negative”

Explanation

Your sample has produced a negative result. Your target of interest is not present in your sample. For some kits, this will be dependent on internal control (IC) amplification.

“Inconclusive”

Explanation

Your sample has produced an inconclusive result. This is usually due to a lack of amplification from the internal control that should be present in the sample. As this can indicate a sample that has not been prepared or stored correctly, such samples should be rerun.

“Test failed”

Explanation – if positive control has failed

The test has failed because the positive control has not worked. The Positive Control is present to show that all aspects of the test are working correctly together. When this control test fails, the test as a whole is invalidated. This finding indicates that a problem has occurred in the reaction set-up part of the experiment and has nothing to do with sample preparation.

Solutions

1. Check the entire workflow and test set-up to look for any user errors, then repeat the test.
2. Ensure the positive and negative controls are inserted into the correct wells of your q16.
3. A component of the test may have expired due to handling errors, incorrect storage or exceeding the shelf life. When you open a new kit, run a simple test to show that changing the kit has solved the problem. Prepare a test which includes only the Positive Control and the Negative Control. If the Positive Control works, the sample result in the summary view will specify ‘Pass’ for this component.

If you are using a genesig Easy target detection kit also include one ‘mock sample’. For the ‘mock sample’ add internal control template instead of any sample DNA/RNA. If the Positive Control works, the mock sample will now be called as a negative result.

“Test Contaminated”

Explanation

The Negative Control should be completely free of any DNA/RNA. If you see this warning message, it means that at some point during the set-up, the Negative Control has been contaminated with DNA / RNA and has given a positive signal. This contamination may invalidated the test. The Positive Control and your test samples are both possible sources of contaminating DNA/RNA. The PCR tubes from previous runs will also contain very high amounts of DNA, so it is important that these are carefully disposed of after each run is completed and NEVER OPENED. It may be the case that your kits have become contaminated, which will lead to the same problem occurring repeatedly.

Solutions

1. Clean your working area using a commercial DNA remover solution to ensure the area is DNA free at the start of your run and re-run the test.
2. If the problem persists, then the kit has become contaminated, and it will have to be discarded and replaced with a new kit. When you open the new kit, run a simple test to show that changing the kit has solved the problem: Prepare a test that includes only the Positive Control, the Negative Control and one “mock sample”. For the ‘mock sample’ add water (supplied with the genesig Easy kit) instead of any sample DNA/RNA. The result for the Negative Control and the mock sample should be negative, indicating that contamination is no longer present.

Preventive action

An ideal lab set-up has a “Clean area” where the test reagents are prepared and a “sample area” where DNA/RNA samples and the Positive Control DNA are handled. The best workflow involves setting up all the test components (excluding the positive control template) in the clean area and then moving the tests to the sample area for the sample and Positive Control addition. If this method is followed, then the kit components are always kept away from possible sources of contamination. For extra security, the Negative Control can be completely prepared and sealed in a clean area. All work areas should be decontaminated regularly with DNA remover.

“Test failed and is contaminated”

Explanation

The Positive Control is indicating test failure, and the Negative Control is indicating test contamination.

Solutions

1. For appropriate solutions, read both the “Test failed” and “Test Contaminated” sections of this user manual.

Maintenance

7.0 Maintenance

This section contains the following topics:

[7.1 genesig q16 maintenance](#)

[7.2 genesig q16 performance verification](#)

[7.3 Cleaning the q16 Instrument](#)

[7.4 Tips](#)

[7.5 Decontamination before servicing](#)

[7.6 Disposables](#)

7.1 genesig q16 maintenance

There are no internal operator serviceable parts in this unit. If the power should fail, the unit must be inspected or returned to the authorised distributor for service support.

Electrical System: do not remove any covers unless you are a qualified service representative. Doing so will void the warranty.



7.2 genesig q16 performance verification

To ensure consistent results from your q16 instrument, PrimerDesign recommends the annual use of the MyGo Quant Kit (part number 5840).

- Performing this test ensures there are no thermal, optical or contamination issues with your instrument.
- Using the MyGo Quant Kit does not negate the requirement to cleaning the instrument as detailed herein.

7.3 Cleaning the q16 Instrument

It is important to keep the wells of your instrument clean. Automated background subtraction processes mean that low levels of fluorescence contamination in the wells of your instrument will not affect system performance. Dirty wells however, can result in lower fluorescence readings and can affect heat transfer from wells to tubes. Regular cleaning of your instrument's wells will help prevent dirty wells affecting the performance of your instrument. The q16 cleaning kit has been designed to enable you to clean the wells before instrument.

Note: Do not use any other method or material to clean the wells of your instrument. Doing so may damage your instrument. Should one or more wells of your instrument become contaminated with high levels of fluorescent substances, and need cleaning, please contact Technical Support for guidance.

Cleaning kit

The cleaning kit (part number M6748) includes a user guide and the consumables listed below. A Material Safety Data Sheet (MSDS) for HFE-71IPA, which can be requested from technical support.

Equipment provided

- Large swabs
- Small swabs
- Soap solution (plastic bottle)
- HFE-71IPA (metal bottle)
- Alcohol wipes
- Disposable cups

EQUIPMENT TO BE PROVIDED BY CUSTOMER:

- Powder-free disposable gloves
- Eye protection.

Cleaning procedure: safety first

- Turn off the power and disconnect the power connector from the instrument.
- Move the power supply unit to a safe location.
- Ensure the instrument has cooled to ambient temperature (usually 20 minutes unpowered is sufficient).
- Do not attempt to remove any parts.

General daily cleaning

- For day-to-day cleaning, wipe the external surface of your instrument with a damp, soft, lint-free cloth. Then dry your instrument with another soft, lint-free cloth.

Note: Avoid abrasive cloths, towels, paper towels, and similar items that might cause damage. Before cleaning your instrument unplug all external power sources, devices, and cables. Don't get moisture into any opening.

General weekly cleaning

- Clean all exposed surfaces using alcohol wipes.

Monthly: cleaning wells

1. Decant a small amount of soap solution from the plastic bottle into a disposable cup.
2. Dip a new large swab into the decanted soap solution. Shake off any excess.

3. Proceed to clean the first four wells. Clean each well with a circular twisting motion ensuring the swab reaches fibres at bottom of the well. Do not place the swab back in the soap solution.
4. Repeat this for the remaining wells, using a new swab for every four wells.
5. Using new large swabs, dry any remaining water from each well. Use one new swab per four wells.
6. Decant a small amount of HFE-71IPA from the metal bottle into a new disposable cup.
7. Dip a new large swab into the decanted HFE-71IPA. Shake off any excess
8. Clean the first four wells as before. Do not place the swab back in HFE-71IPA.
9. Repeat this for the remaining wells, using a new swab for every four wells.
10. Inspect all wells after cleaning. If any contamination remains visible on the well walls, they can be further cleaned with a small swab and HFE-71IPA.

7.4 Tips

DO:

- Clean the instrument regularly.
- Use only equipment recommended by Primerdesign.
- Use one new swab per four wells.
- Discard decanted liquids, holders and swabs after use.

DO NOT:

- Do not use liquids directly from the bottle. This will cause cross-contamination.
- Do not use excessive amounts of cleaning solution.
- Do not reuse disposable equipment.

REMEMBER

- Pre-emptive maintenance will keep your instrument running at its peak capability.
- Do not wait until your instrument is underperforming before cleaning.
- Good laboratory hygiene practices should always be followed.
- Do not write on the sides of PCR tubes.
- Always use clean tube racks.
- Keep instrument lid closed when not in use.

7.5 Decontamination before servicing

The equipment must be decontaminated before servicing, storage, and transport.

Please note that for health and safety reasons, you must print and complete a physical copy of the decontamination form before returning an instrument. An electronic version of the decontamination form is sent pre-shipment of the instrument and is also available on request from techsupport@novacyt.com. The customer will not receive a returns number until a completed electronic decontamination form is first received, and this must be included as hard copy with the returned instrument or lid. Failure to comply with these guidelines will result in a charge for decontamination.

Decontamination Guide: To enable us to comply with local laws and to avoid exposure to hazardous materials during handling or repair, please complete this form and declaration prior to the equipment leaving your laboratory. This guide is for the decontamination of PCR reagents only. As with all potentially bio-hazardous specimens, universal safety precautions should be taken when handling and processing samples. Handling and disposal of infectious material should be performed according to local safety guidelines. Do not clean when the q16 is plugged in or pour liquids into the wells of the mount. Please wear safety goggles and protective clothing, including gloves, when cleaning the instrument.

Materials Required for Cleaning/Decontamination

- 1a. A clean, lint-free cotton bud slightly damp with 70% Isopropyl Alcohol.
- 1b. A clean, dry, lint-free cotton bud.
- 1c. Isopropyl Alcohol wipe.
- 1d. A clean, lint-free cloth, slightly damp with 70% Isopropyl Alcohol.
Note: Squeeze all excess solution from the cloth before use.
2. A clean, lint-free cloth slightly damp with 10% bleach 90% DI solution.
Note: squeeze all excess solution from the cloth before use.
3. A clean, lint-free cloth slightly damp with pure water.
4. A clean, dry, lint-free cloth.

If the instrument needs further cleaning, please use (1c) or (1d).

Procedure:

To clean the wells use 1a, dry the wells using 1b.

Make sure all particles are removed. If your instrument is dirty or is contaminated with PCR product, then wipe down the bench surface around the instrument using (1c) or (1d), making sure the surface is not visibly wet. Wait for 5 minutes and then wipe down the instrument with (2), again making sure the surface is not visibly wet. Wait an additional 5 minutes and then wipe down with (3) followed by (4). Wipe all external surfaces, including the outer casing, mount plate, heated lid, and feet. If the instrument needs further cleaning, please use (1c) or (1d).

7.6 Disposables

We recommend the use of disposables supplied in the appropriate kit for optimal results:

genesig 0.1 ml tubes, 500 (Cat. no. Z-genesig-0.1)

If you wish to use third party disposables please note the following:

- A. Physical dimensions should be the same as the genesig q16 disposables to ensure that they fit into your instrument without damaging it.
- B. Caps should seal tubes effectively in order to prevent variability caused by evaporation and to minimise the risk of contamination with PCR products.
- C. Disposables should have reproducible wall thickness, which are thin enough to ensure rapid temperature equilibration but thick enough to avoid breakages.
In many cases, third party disposables will have inferior thermal and optical characteristics, which will reduce the quality of results obtained from the system.

Troubleshooting

8.0 Troubleshooting

This section will help you troubleshoot your genesig q16 if you think something is wrong.

This section contains the following topics:

8.1 [Error messages](#)

8.2 [Errors reported by the genesig q16 display LEDs](#)

8.3 [Error log files](#)

8.4 [Other common problems](#)

8.1 Error messages

Your genesig q16 will let you know when something is wrong by displaying an error. Most errors are reported as messages in the Status Bar in the genesig q16 software. Some errors are reported by the instrument display LEDs.

If you encounter an error, please make sure that the instrument is running in a lab within the specified environmental conditions, tubes have been loaded correctly, the lid has been fitted correctly, and all cables are attached correctly and securely. If the error still occurs, you may need to contact technical support with the following actions described below.

Error messages in the status bar Action

Saturation Warning	Please use the log button to view the detailed message – this will tell you which wells saw a saturated reading.
Run Prepare Error (followed by one of the following messages) a) No tubes loaded. b) Instrument has had a hardware error and is in failsafe mode. c) Instrument is not yet ready to run. d) Instrument has finished a run and is waiting for tubes to be removed. e) Open lid, remove tubes and then add new ones.	Please follow the instructions in the error message and continue as normal.
Failure	This message will be followed by a short code. Please contact Technical Support.
Instrument connection too slow	May be reported at the start of a run. Please check that your network is properly configured and is operating at 100 Mb/s or more.
Network error	Please check that your network is properly configured and is operating at 100 Mb/s or more. Always leave your laptop or PC turned on throughout the run, and do not use any sleep, power-save or hibernate function. Do not close the laptop lid if you are using one. Alternatively, perform the run using a USB drive.

8.2 Errors reported by the genesig q16 display LEDs

Some errors are reported by the instrument display LEDs flashing red. If your instrument display LEDs are flashing red, please contact Technical Support.

8.3 Error log files

In the unlikely event that you encounter a problem, the software will log this information into two separate files. These files help to diagnose the problem. Once exported, please make sure you send the error file, the serial number, and the experiment file that contained the error to Technical Support. It is okay to send experiments that have not completed and/or were aborted.

Software errors

For software issues click on Show Run Log, and click on Export. Please contact Technical Support with the exported information.

Hardware errors

For Hardware faults go to Configuration > genesig q16 and select Retrieve Instrument Report Files.

8.4 Other potential problems

<p>Network connection problems</p>	<p>The software can connect to one or more instruments via an Ethernet network. There are two ways of configuring the network to allow this:</p> <p>Standard Network: The software and instruments will connect automatically to a standard network, where TCP/IP addresses are assigned automatically by a DHCP server. Connect the instrument to the network in the same way you would connect a printer, using the supplied Ethernet cable to connect to a wall socket or network switch/hub. The software will automatically connect to the instrument when it has been turned on.</p> <p>Direct Network: The software and instruments can also be used on a local network that does NOT have automatic address assignment. Ask your network administrator to help you set up in this instance. IP address "169.254.88.1"/Subnet Mask "255.255.0.0".</p> <p>Contact technical support for the full protocol on manually configuring q16 instruments.</p>
<p>USB run fails to start</p>	<p>Check that you have the latest version of the q16 software. To do this, click 'Configuration' at the top right hand corner of the software screen.</p> <p>Underneath the q16 insignia the version number of the software will be displayed.</p> <p>Contact technical support to ensure that you are using the latest version of the software.</p> <p>If the experiment still fails to start, check that your USB drive has not been corrupted. If it has been, then use a different USB drive.</p>
<p>Unusual looking data: If your test results are not as you expect and you can see that the raw data looks unusual – poor quality amplification plots etc.,</p>	<p>Bubbles in your reaction tubes can cause problems. Tap the tubes on a work surface or shake them down to burst any bubbles before placing them in to the q16. Make sure that the contents of each tube have collected at the base of the tube.</p>
<p>Failed results: The instrument is reporting failed results.</p>	<p>Check that you have put all reaction tubes in the correct wells. If the positive and negative controls are in the wrong place this will cause problems. Please contact Primerdesign technical support for advice on manual data interpretation.</p>

Appendices

Appendix A

A1.1 Technical data

Primerdesign, part of Novacyt, reserves the right to change specifications at any time.

A1.2 Declaration of Conformity

This product meets the applicable harmonised standards for radio frequency interference and may be expected not to interfere with, or be affected by, other equipment with similar qualifications. We cannot be sure that other equipment used in its vicinity will meet these standards, and so we cannot guarantee that interference will not occur in practice. Where there is a possibility that injury, damage, or loss might occur if equipment malfunctions due to radio frequency interference, or for general advice before use, contact the manufacturer.

Name and address of the legal manufacturer:

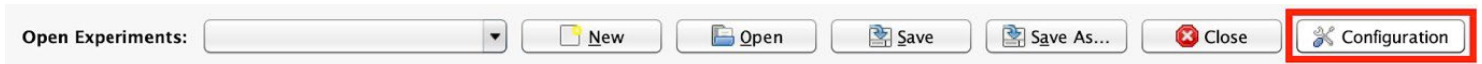
Primerdesign Ltd

York House
School Lane
Chandlers Ford
SO53 4DG
United Kingdom

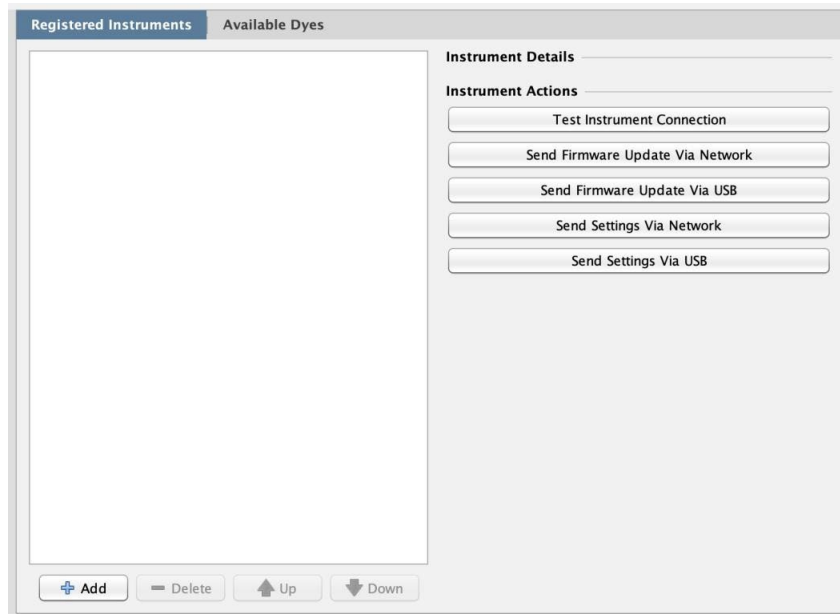
An up-to-date declaration of conformity can be requested from Primerdesign Technical Services (techsupport@novacyt.com).

Appendix B – Setting a static IP on the q16

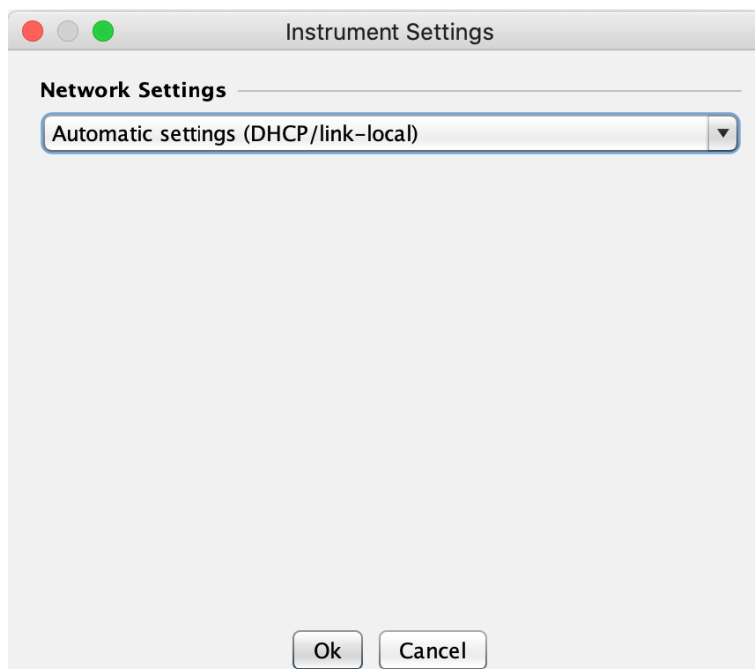
Run the software, and click the “Configuration” button in the top right:



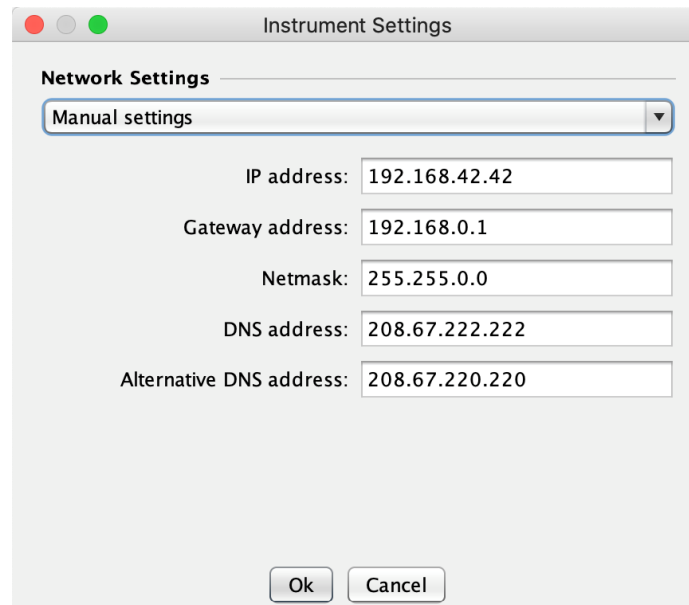
In the “Select Module” area on the left of the dialogue, select the type of instrument you are working with, this will display the instrument management pane:



Click “Send Settings Via USB”, this will display the settings dialogue box:

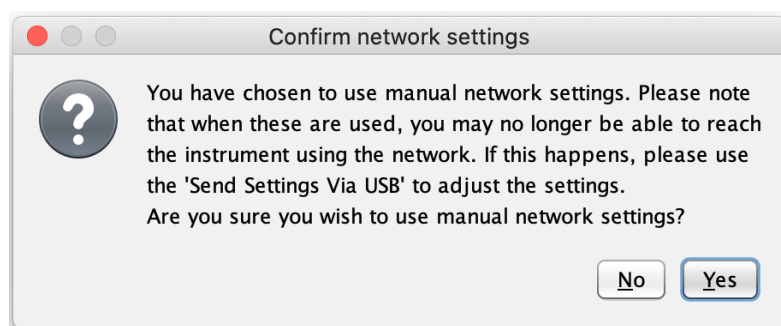


By default, the instruments use automatic network settings - click the drop-down box and select "Manual settings":

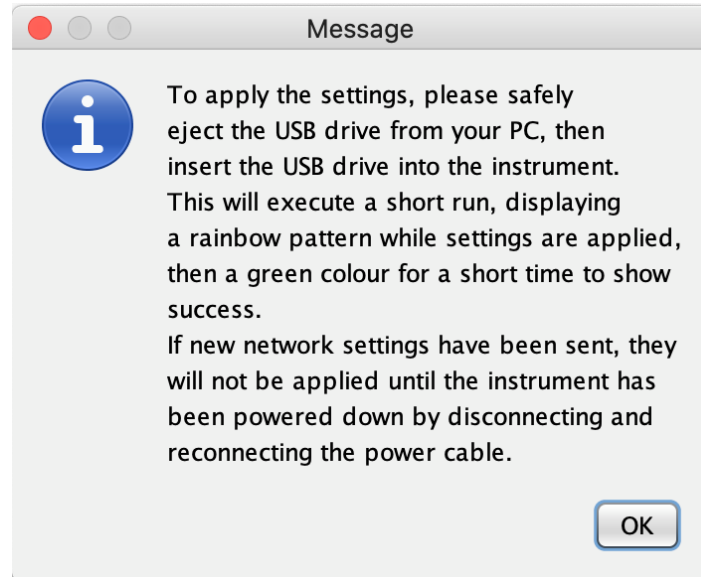


You can now enter settings to match the network the instrument will be connected to your system administrator should be able to provide these. Note that the "IP address:" must be set to an unused address on your network, so that it does not conflict with any other devices, and must be reachable from your PC to allow you to run the instrument using the network.

When the settings are correct, click "Ok" – a message will be displayed giving information on the settings:



After reading the message, click “Yes” to proceed. You will then see a dialogue allowing you to select the USB device to use (this is the same as when starting a run via USB). On MacOS and Windows you should select the “root” of the USB drive you wish to use, this is the top level of the drive. On Windows, select the appropriate drive letter. When you have selected the USB drive, the following message will be displayed explaining the process to follow:

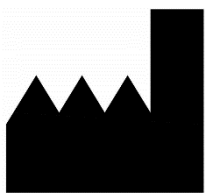


Click OK and proceed as described.

At this point, you may also need to update your PC/laptop network settings to match those on the instrument – for example if you are using a direct cable connection (where an ethernet cable is connected directly from the PC to the instrument) you should make sure that the PC and instrument are on the same subnet and so can communicate. You can also specify the IP address of the instrument by selecting the instrument in the “Configuration” dialogue (after adding it if necessary) and entering the address in the appropriate text field.

Please note that if you are still unable to connect to the instrument, you should revert the network settings to “Automatic” by following the same procedure above, but leaving the network settings at their default value, to avoid any confusion in the future as a result of the custom network settings.

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