

genesig® q32 user manual







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Notices

Document: MM060

Product part number: z-genesig-q32

genesig® q32 Real-Time PCR

Instrument

Date: December 2022 v2

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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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Table of Contents

Notices	2
Copyright Notice	2
Contact Information	2
Trademarks	2
Technical Support	2
Safety notices	2
Introduction	5
1.1 genesig q32 instrument	2
1.2 About this user manual	2
Safety Information	3
2.0 Safety Information	4
2.1 Important safety advice	5
2.2 Symbols on the genesig q32	6
2.3 Technical assistance	8
2.4 genesig q32 user requirements	8
2.5 Policy statement	8
2.6 Warranty policy information	8
2.7 Intended use of the genesig q32 instrument	10
General description	11
3.0 General description	12
3.1 Instrument description	13
3.2 Quality control specifications	14
3.3 PC requirements	14
Installation	15
4.0 Installation	16
4.1 Conditions	17
4.2 genesig q32 instrument	18
4.3 genesig q32 connections	19
4.4 Powering on your genesig q32	19
4.5 Connecting your genesig q32	20
4.6 genesig q32 heated lid	20
4.7 Installing your genesig q32 software	21
4.8 Configuring your q32	21
4.9 Tips	22
Software	23
5.0 Software	24
5.1 Software and applications	25
5.2 Configuration and data files	25







P 3 I M = 3

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5.3 Ne ⁻	tworking	25
5.4 So	ftware configuration	26
5.5 Ins	trument configurations	27
5.6 Au	tomatic IP assignment	28
5.7 Sel	f-assigned IP	28
5.8 Ne	twork hardware configurations	29
5.9 q32	2 networking details	29
Setting u	ıp an experiment	30
6.0 Set	tting up an experiment	31
6.1 Exp	periment set-up for software version 1.5 and greater	32
6.1.1	Setting up the run — general	33
6.1.2	Setting up the run — multiplex modules	34
6.1.3	Loading samples into your genesig q32	35
6.1.4	Starting the run — networked run	36
6.1.5	Starting the run — USB run	37
6.1.6	Post-run data analysis/interpretation	38
6.2.1	Setting up the run — general	40
6.2.2	Raw templates	40
6.2.3	Preloaded templates	40
6.2.4	Setting up the run — general	41
6.3 Exp	oorting data	42
6.4 Wh	at do the results mean?	43
Maintena	ance	45
7.0 Ma	intenance	46
7.1 ger	nesig q32 maintenance	49
7.2 ger	nesig q32 performance verification	49
7.3 Cle	eaning the q32 Instrument	49
7.4 Tip	s	51
7.5 De	contamination before servicing	52
7.6 Dis	posables	53
Troubles	hooting	54
8.0 Tro	publeshooting	55
8.1 Err	or messages	56
8.2 Err	ors reported by the genesig q32 display LEDs	57
8.3 Err	or log files	57
Appendi	ces	58
Appen	dix A	59



Introduction



1.1 genesig q32 instrument

This user guide will teach you what you need to know to start running your genesig q32, from connecting your instrument to the network to data analysis for your qPCR experiments.

Please read this user manual carefully before using the genesig q32.

The genesig q32 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 q32. The manual contains the following sections:

- 1. Introduction
- 2. Safety Information
- 3. General description
- 4. Installation
- 5. Software
- 6. Setting up an experiment
- 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 q32
- 2.3 Technical assistance
- 2.4 genesig q32 user requirements
- 2.5 Policy statement
- 2.6 Warranty policy information
- 2.7 Intended use of the genesig q32 instrument

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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.
- DO NOT interfere with the magnetic lid lock.
- 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 genesig q32

Symbol	Location	Details
	Powerpack and Instrument label	Waste Electrical and Electronic Equipment (WEEE)
C€	Powerpack and Instrument label	CE mark for European Conformity
IVD	Instrument label	In vitro diagnostics
<u>\$555</u>	Lid	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.

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<u></u>	Instrument label and lid	Caution must be taken when using and maintaining the instrument. Mechanical and thermal risks: Warning: The lid contains a heater which exceeds 100°C when in operation. Warning: Handle lid with care to avoid closing on hand.
SN	Instrument label	Serial Number
REF	Instrument label	Part Number / Catalog Number
[]i	Instrument label	Consult user manual
	Instrument label	Manufacturers address
	Instrument label	Manufacturing date
6.25A	Instrument label	Power supply Amperage
DC 24V	Instrument label	Power supply Voltage

Other labels

The Serial Number label can be found on the underside of the instrument.

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

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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 genesig q32 user requirements

The genesig q32 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 genesig q32, the appropriate laboratory hazard training must have been carried out prior to using the genesig q32. 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 genesig 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 genesig q32 has a 12-month manufacturer warranty.

Other than for those items defined in the maintenance procedures herein, there are no userserviceable 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 sub system 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 q32 instrument

The genesig q32 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 q32 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.



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 q32 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 q32 real-time PCR Instrument flight case (upper, lower and foam insert) containing genesig q32 instrument
- 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, 170W
- 3. Ethernet network cable
- 4. genesig branded USB flash drive
- 5. genesig q32 software (loaded onto the USB flash drive)

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6. electronic copy of the genesig q32 user manual on a USB flash drive

Please keep the flight case and outer box the genesig q32 came in, in case you need to protect your genesig q32 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 = 0.1°C intra-run. Mean observed DNA melting temperature +/- 0.25°C of the expected value.</th
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 2 GHz (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)

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Installation

4.0 Installation

This section contains the following topics:

- 4.1 Conditions
- 4.2 genesig q32 instrument
- 4.3 genesig q32 connections
- 4.4 Powering on your genesig q32
- 4.5 Connecting your gensig q32
- 4.6 genesig q32 heated lid
- 4.7 Installing your genesig q32 software
- 4.8 Configuring your q32
- 4.9 <u>Tips</u>

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4.1 Conditions

Environmental conditions

Your work space

Your genesig q32 instrument should be placed on a flat, dry, surface that is not subject to draughts. Do not install your q32 instrument directly in the flow of air from an air conditioner or fan. Do not install your q32 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

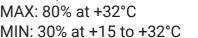
Prevent contamination by wearing gloves, using clean tube racks, and filter tips. Make sure tubes are sealed, PCR product is disposed of, and leaks are cleaned immediately.

Environmental operating conditions



Humidity

MAX: 80% at +32°C





Temperature +15°C to +32°C

Environmental storage/transport/packaging conditions



Humidity

MAX: 10% to 95%

Non-condensing humidity



Temperature

4.2 genesig q32 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.

USB port

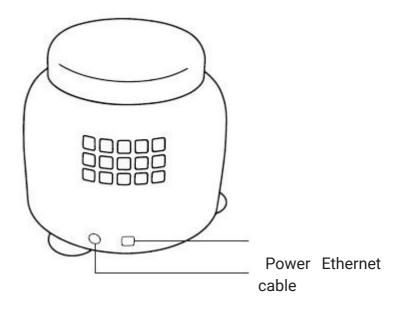
Insert the USB drive here to run an experiment from the USB drive.

Display LEDs

The genesig q32 uses display LEDs to help you understand what the instrument is doing. See section 6.1.3 Loading strips into your genesig q32.

4.3 genesig q32 connections

The genesig q32 has three connections. A USB-A port in the front and two in the back as shown.



Power

This is to connect your genesig q32 to the provided power supply unit.

Ethernet Port

This is for connecting your genesig q32 to your LAN or computer.

4.4 Powering on your genesig q32

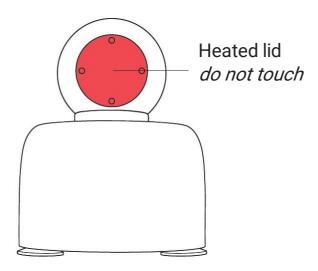
Place the genesig q32 on your lab bench, and then connect AC power to the power supply unit. Your instrument will now turn on after a few seconds. The display LEDs will light up blue, and then turn green if a lid is closed or red if not. Your genesig q32 is ready to run.

The genesig q32 power supply unit (PSU) requires an earthed mains connection.

4.5 Connecting your genesig q32

To a network, PC or laptop: Connect one end of the Ethernet cable to the instrument and the other end to a LAN port, or directly to your computer. Once your genesig q32 is connected to a LAN, you can connect to your instrument via Wi-Fi if your network supports it.

4.6 genesig q32 heated lid



The genesig q32 heated lid will get hot. Please do not touch it. The heated lid will be preheated to 105°C once tubes have been loaded and the lid closed. This enables your run to start as soon as possible. After 5 minutes of inactivity the heated lid will be turned off to conserve energy.

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4.7 Installing your genesig q32 software

Your genesig q32 USB drive contains software for Windows, and MacOS operating systems. Please open the software file matching your chosen operating system.

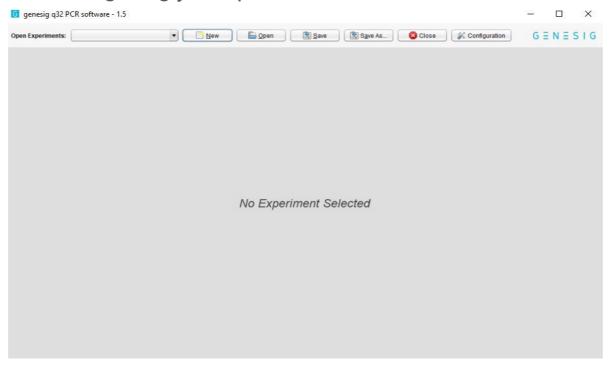
Windows

Double-click on the Windows installer and follow the on-screen instructions to install your genesig q32 software on Windows.

MacOS

Double-click on the disk image and follow the on-screen instructions to install your genesig q32 software on your Mac PC.

4.8 Configuring your q32



With your genesig q32 software open, and your q32 connected to the network, please connect to your genesig q32 instrument.

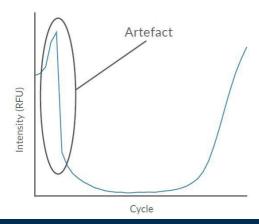
To add your new genesig q32, select configuration. This will produce a pop-up screen, at the left-hand side of this pop-up, select genesig q32. There will now be an "Add" button available at the bottom of the pop-up screen, select this "Add" option.

You will now be presented with a list of available instruments.

4.9 Tips

Here are some great tips to keep in mind whilst running your genesig q32 instrument.

- **1. Lid gets warm**: The genesig q32 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.



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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 q32 networking details



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, so the software can also be installed by copying all contents of the installation directory.

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

5.3.1 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 - q32" below for details of the protocols used.

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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 – q32" (section 5.8) below for details of the protocols used.

5.3.2 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 "q32 networking details" for a description of the ports and protocols used by the software and instruments.

On many networks and 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.

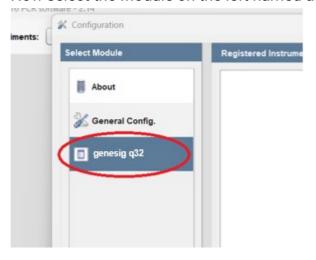
On networks and PCs with more security configuration, please consult your IT department or network administrator.

5.4 Software configuration

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



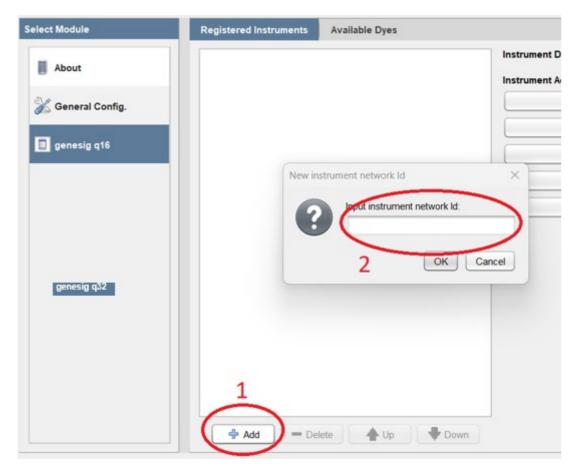
Now select the Module on the left named after the instrument type – "genesig q32"



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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.

5.9 q32 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.



Setting up an experiment

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6.0 Setting up an experiment

This section contains the following topics:

- 6.1 Experiment set-up for software version 1.5 and greater
- 6.1.1 Setting up the run general
- 6.1.2 Setting up the run multiplex modules
- 6.1.3 Loading samples into your genesig q32
- 6.1.4 Starting a run networked run
- 6.1.5 Starting the run USB run
- 6.1.6 Post-run data analysis/interpretation
- 6.2 Experiment set-up for software version 1.2 and greater
- 6.2.1 Setting up the run general
- 6.2.2 Raw templates
- 6.2.3 Preloaded templates
- 6.2.4 Setting up the run general
- 6.2.5 Runs in software version 1.2 or greater
- 6.3 Exporting data
- 6.4 What do the results mean?

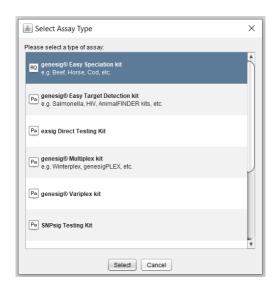
6.1 Experiment set-up for software version 1.5 and greater

This section will teach you everything you need to know to get started with the genesig® q32 for software version 1.5 and subsequent versions. For previous versions, see section "Experiment Set Up for software version 1.2". You will learn how to create, save, open, and close experiments. You will also learn how to set up an experiment from the modules provided, according to the software version you have installed. Finally, we will show you how to run your new experiment via network connection or using a USB drive.

New Experiment

Clicking the "New" button will display a selection box showing the available modules to run on the q32.

To load a module, either double-click it or select it, then click "Select" at the bottom of the dialogue box. You may also click "Cancel" to exit without using a module.



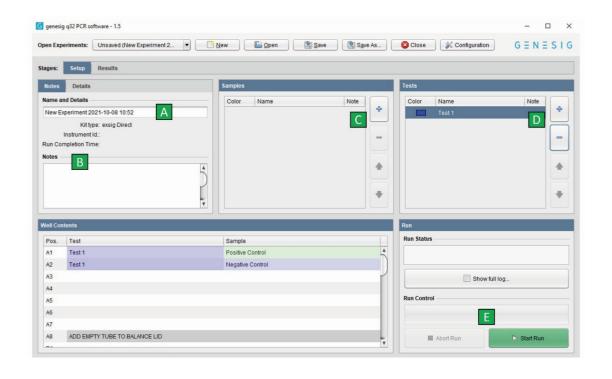
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6.1.1 Setting up the run — general

The guide below is applicable to all modules, but it is worth nothing that some modules will allow you to add additional tests with different targets. This is explained under "Setting Up the Run — Multiplex modules".

These steps may be carried out in any order, and the screenshot indicates where each step matches to:

- A. Name your experiment. It is advisable to keep the date and time stamp.
- B. Add any notes relevant to your experiment.
- C. Add the correct number of samples. Label the samples by double-clicking the sample label. You may also change the colour of any samples by double clicking the colour box.
- D. Add additional tests as required; adding a new test will replicate the same samples, including any labels and colour. This is useful if you have multiple samples from the same donor that need to be tested on different targets. This option is not available in all modules.
- E. Once the samples have been added to the q32 and the lid has been firmly shut, click "Start Run".

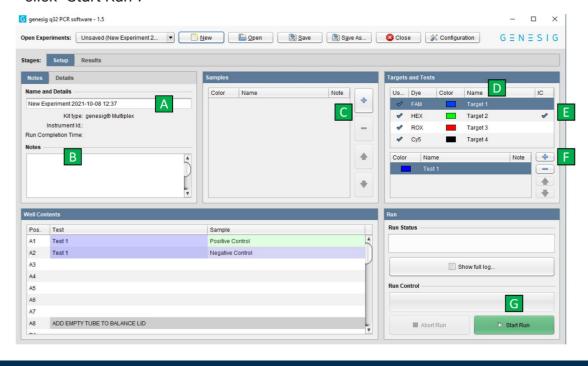


6.1.2 Setting up the run — multiplex modules

The genesig Multiplex modules (shown below) also contain a window for you to change the targets, tests and internal control channel used for custom assay set-up.

These steps may be carried out in any order, and the screenshot indicates where each step matches up to:

- A. Name your experiment. It is advisable to keep the date and time stamp.
- B. Add any notes relevant to your experiment.
- C. Add the correct number of samples. Label the samples by double-clicking the sample label. You may also change the colour of any samples by double clicking the colour box. This colour will be reflected in the results section if the module you are using gives you an amplification plot which is useful to highlight a specific sample.
- D. Select which dyes will be required and rename the targets as required, see kit instructions for use (IFU) for details.
- E. Tick the "IC" (Internal Control) column in the correct channel. This can be unticked if no IC is present in the assay well.
- F. Add additional tests as required; adding a new test will replicate the same samples, including any labels and colour. This is useful if you have multiple samples from the same donor that need to be tested on different targets. This option is not available in all modules.
- G. Once the samples have been added to the q32 and the lid has been firmly shut, click "Start Run".



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$D \equiv S \mid G \mid N$

6.1.3 Loading samples into your genesig q32

In order to ensure that the heated lid is balanced, please make sure that the mount contains at least a strip in rows A and D (as shown in blue below) or single tubes in wells A1, A8, D1 and D8.

These positions can be filled with tubes containing reagents or empty tubes.

Blue = Initialising

Green Idle

Red Lid open all the way

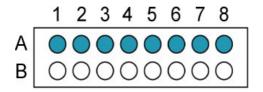
Yellow Tubes loaded

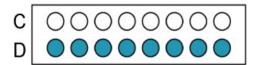
Blue Running, low temp

Pink Running, medium temp

Red Running, high temp Cyan Experiment complete

Red Flash Fault detected



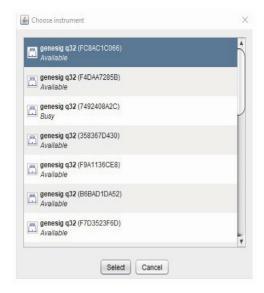




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6.1.4 Starting the run — networked run

- 1. Once you have clicked "Start Run", an autosave option will appear. Click on "Browse" to select a location to save the run. Once selected, it is recommended to select the "Automatically save" option.
- 2. You will then see the instrument selection screen. Choose the instrument on your network that you have loaded the samples into.
- 3. If the instrument you require is not displayed, you can add a new instrument. To do this, return to the main screen and select "Configuration" at the top right of the soft- ware display. Select the "genesig q32" tab and then select the "+ Add" button. Either choose one that has been automatically identified on the network or add manually using the serial number.
- 4. Once selected, the run will begin automatically, and you will see this from the lights on the q32 turning from yellow to blue.
- 5. Above the "Start Run" button, the "Run Control" box will indicate how long is left until completion of the run.
- 6. You may also abort the run using the "Abort Run" button to the left.
- 7. The run will proceed and continue until the lights turn light blue and the lid pops open upon completion.







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6.1.5 Starting the run — USB run

- 1. Once you have clicked "Start Run", an autosave option will appear. Click on "Browse" to select a location to save the run. Save the location. It is recommended to select the "Automatically save" option.
- 2. You will then see the instrument selection screen. Choose "Start run from USB". Alternatively, if no instruments have been configured, you will be given the option to "Run using USB".
- 3. At this point, select the drive letter that the USB is inserted into. A new file in the top level directory of the drive will be created named "USBRun".
- 4. Check that this file is present, remove the USB drive from the PC and then insert this USB into the q32 you have set up for your run.
- 5. The run will begin automatically, and you will see this from the q32 lights turning from yellow to dark blue.
- 6. The run will proceed and continue until the lights turn light blue and the lid pops open upon completion. Do not remove the USB drive during the run.
- 7. Transfer the USB drive to a PC running the genesig q32 software and use the "Open" button to proceed with analysis and interpretation of results.



6.1.6 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 fully opening the lid. All used plasticware should be disposed of by double-bagging in a zip seal bag, with gloves changed after handling.

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.

6.2 Experiment set-up for software versions 1.2 to 1.4

As before, this section will teach you how to use the q32 if you are running software version 1.2, however, we recommend installing version 1.5 to ensure you have the latest features, and access to our preloaded modules, which allow you to run all of our products.

New Experiment

Clicking the "New" button will display a selection box showing available templates.

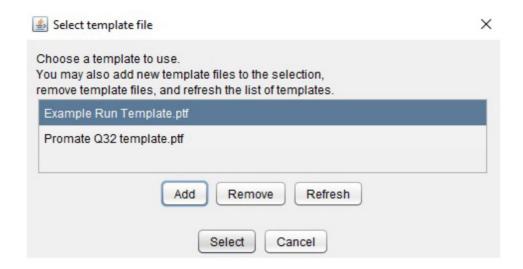
To load a template, either double-click it or select it, then click "Select" at the bottom of the dialogue. You may also click "Cancel" to exit without using a template.

Clicking "Add" will display a file dialogue (see below) — use this to navigate to any new ".ptf" files you would like to use.

To remove a template you are no longer using, select it in the list and click "Remove".

Templates are stored in a ".pecan/var_templates" directory in the home directory, in a subdirectory named after the genesig q32.

Any valid .ptf files for the genesig q32 will be available for use as templates. If you add new files manually (e.g. using the file browser), click "Refresh" to add them to the dialogue.





6.2.1 Setting up the run — general

You will now learn how to set up samples and targets. The approach slightly differs depending on whether you are using a raw template or a preloaded template to run your new experiment.

- Raw templates: useful for qualitative detection or where quantification will be performed manually from Cq values.
- Preloaded templates: useful for automated copy number quantification when using a genesig® Pathogen Detection Kit. Wells do not need to be labelled before starting a run. This can be performed whilst an experiment is running or once it has finished.

6.2.2 Raw templates

Raw template files come with all wells unlabelled.

- The required channels are already active in each well.
- Label each well with the name of the sample and target to be assigned to that well.

6.2.3 Preloaded templates

Preloaded templates come with wells A1 – A7 preloaded with a negative control and serial dilution standards for one assay, all other wells are unlabelled:

- The required channels are already active in each well. Some preloaded templates contain standards with concentrations in a serial dilution already set.
- Label each well with the name of the sample and the target to be assigned to that well.
- Results include efficiency calculations and automated copy number results for the samples.
- Please load the correct tubes into each well, or your data will not be analysed appropriately

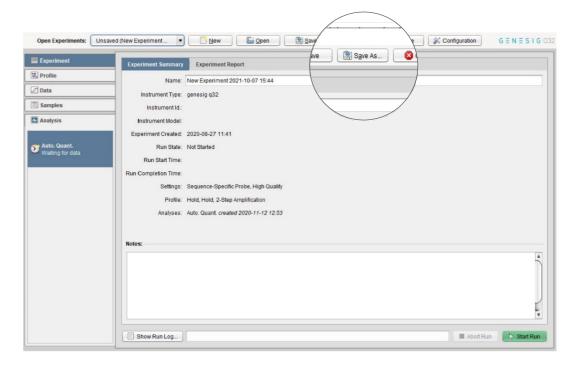
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6.2.4 Setting up the run — general

If you wish to save or open sample and target information set-up you can select "Save As", or "Open", respectively.

Sample and target set-ups can be saved in the following formats:

- CSV Editable .csv files.
- PSD A proprietary locked file format.
- RDML The Real-Time PCR Data Markup Language (RDML) is a structured and universal data standard for exchanging quantitative PCR (qPCR) data.



6.2.5 Starting and analysing runs in software versions 1.2 to 1.4

Please see the above "Starting the Run" sections for information on how to start a run. The process is the same for all software versions, as is the post-run data analysis/interpretation. See <u>section 6.1</u>.

P R I M E R

6.3 Exporting data

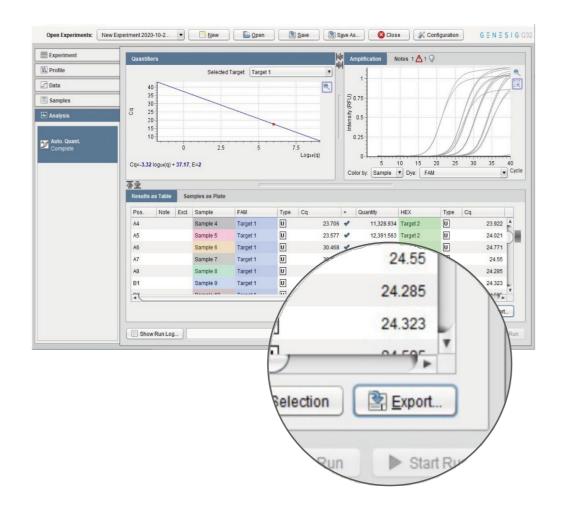
When you have finished analysing your data in the genesig q32 software, you can export the results in a variety of ways, from raw data to user defined custom reports.

Table Export

From the display showing results table, you can export data using the "Export" button.

To export data, click the "Export" button, data can be exported in the following formats:

- CSV This is an editable data file that can be opened in many spreadsheet applications.
- PDF This file format is suitable for archiving, printing, and presentations but cannot be edited.



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P R I M E R

6.4 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.

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Maintenance

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7.0 Maintenance

This section contains the following topics:

- 7.1 genesig q32 maintenance
- 7.2 genesig q32 performance verification
- 7.3 Cleaning the q32 Instrument
- 7.4 <u>Tips</u>
- 7.5 Decontamination before servicing
- 7.6 Disposables







7.1 genesig q32 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 q32 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 q32 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 q32 cleaning kit has been designed to enable you to clean the wells.

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 can be requested via Technical Support.

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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. Do not 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.

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- 5. Using new large swabs, dry any remaining liquid 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.

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51

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 (available on request from techsupport@primerdesign.co.uk) and include this with any instrument or lid that is returned. The form must be sent with the instrument, and we cannot accept electronic versions of the form. 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 q32 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 genesig q32 disposables or those provided in e.g., PROmate kits for optimal results:

genesig 0.1 ml tubes, 500 (Cat. no. Z-genesig-0.1) genesig 8-strip tubes, 120 (Cat. no. Z-genesig-8STRIP)

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

- A. Physical dimensions should be the same as the genesig q32 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 q32 if you think something is wrong.

This section contains the following topics:

- 8.1 Error messages
- 8.2 Errors reported by the genesig q32 display LEDs
- 8.3 Error log files

P R I M E R

8.1 Error messages

Your genesig q32 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 q32 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 using one. Alternatively, perform the run using a USB drive.

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56

8.2 Errors reported by the genesig q32 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 q32 and select Retrieve Instrument Report Files.



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).



P R I M E R



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