Genexus™ Purification System

Publication Number MAN0018477 Revision E.0

This guide contains the information needed to prepare your site for installation of the Genexus™ Purification System (Cat. No. A48148).

Site preparation workflow

IMPORTANT! Thermo Fisher Scientific does not install, service, or repair products in area designated BioSafety Level 3 (BSL-3) or BioSaftey Level 4 (BSL-4).

A Thermo Fisher Scientific service representative will contact you to schedule the installation. When the installation date is scheduled, perform the following tasks.

Site preparation workflow



Review this site preparation guide





Complete the site preparation checklist (page 2)

Complete, date, and initial all items in the checklist before the scheduled installation date.





Receive and inspect the shipment (page 14)

- Verify items ordered were shipped
- Inspect the shipping containers and report any damage
- Unpack installation kit and store as directed





Move the packaged shipment to the installation site (page 14)

Prepare installation site and move packaged instrument to the site.





Site preparation checklist

IMPORTANT! Complete, date, and initial all items in the following checklist before the scheduled installation date. If the site preparation checklist is not complete when the service representative arrives, the scheduled installation may be postponed.

1	Date	Initials	Site preparation requirement	See page	
			Customer responsibilities have been reviewed.		
			Personnel have been assigned tasks and responsibilities.	3	
			The installation site is identified and meets the following requirements:		
			☐ Space and clearance	6	
			☐ Environmental	8	
			□ Electrical	9	
			□ Safety	12	
			□ Network	11	
			☐ Instrument-to-computer connection	7	
			If required, antivirus software is available for installation on the computer provided with the product.	13	
			The shipment was received and inspected as follows:	14	
			The items shown on the shipping list are the items that were ordered at the time of purchase.		
			☐ Damage to shipping containers was reported to the shipping company that delivered the shipment and to your service representative.		
			☐ Damage or mishandling was recorded on the shipping documents.		
			☐ If provided with the shipment, all reagents and plates are unpacked and stored as specified on package labels.		
			The installation site is cleared and ready for the installation.		
			The packaged shipping containers are moved to the installation site.	14	
			All materials for installation, qualification, and operation are available.	13	
			If provided, the <i>Genexus™ Purification System IT Checklist</i> (Pub. No. MAN0019531) has been completed and returned according to the instructions in the checklist.	3	

Customer responsibilities

Personnel	Responsibilities and tasks to perform before the installation date
Site preparation/	Reviews the site preparation guide for site requirements.
installation	Coordinates personnel and tasks.
coordinator	Selects the installation site.
	Reviews checklists with applicable personnel to verify that the site is properly prepared.
	 Reviews checklists with the service representative to verify that the site is properly prepared.^[1]
	Receives and inspects the packaged shipment.
	 Unpacks and stores the reagents box (if provided) according to the specifications indicated in the product information sheets.
	Schedules the installation and informs personnel of the installation day.
	Ensures that the site is clear of unnecessary material on the installation day.
	Is available to assist the service representative throughout installation.
Laboratory safety	Reviews the safety requirements later in this guide.
representative	Ensures that all customer-provided materials for installation are present at the site.
	Ensures that primary users (responsible for training other users) are available for training during the installation.
Laboratory	Reviews the safety requirements later in this guide.
personnel/ primary	Ensures that all customer-provided materials for installation are present at the site.
users	Ensures that primary users (responsible for training other users) are available for training during the installation.
Facilities personnel	Ensures that the installation requirements are met for the installation site.
	Space at the installation site
	- Building clearances
	Humidity and temperature
	 Waste collection
	 Electrical supply
	Computer (if included with product)
	Safety and installation materials
	Moves the packaged shipment to the site before the installation date.
	Is available to assist service representative and laboratory personnel.
	 If applicable, ensures that at least two people are available to help the service representative move and position the instrument.

(continued)

Personnel	Responsibilities and tasks to perform before the installation date
Network or IT specialist (if the product will be connected to a network)	 Ensures that active, tested local area network (LAN) connections are in place. Ensures that network hardware is compatible with an RJ45-type connector. If necessary, supplies additional cables. Is available during installation to connect the product to the network. If applicable, provides and installs a network or dedicated printer. IMPORTANT! Do not connect the product components to the network before the service representative arrives.

^[1] Required for service representative installation of the instrument.

Installation time and training

After the shipment is unpacked, the installation takes approximately 1 business day.

During and/or after installation, the service representative calibrates the instrument, performs factory tests, and provides some basic operator training. For additional training and reference information, see the user documents that are provided with the product.

If you ordered the optional <IQ/OQ/IPV or IQ/OQ> service, the service representative also performs this service during installation.

Site requirements

Dimensions and weights

To prepare for installation, provide space for receipt and configuration of the components listed in this section. This section provides dimensions and weights for the packages you will receive, and it describes the dimensions of the components after installation and configuration.

Components (packaged)

Ensure that the building clearances allow for transport of the packaged components.

Package	Height	Length (depth)	Width	Weight
Instrument	101.6 cm (40 in.)	91.5 cm (36 in.)	111.8 cm (44 in.)	95 kg (210 lb)



CAUTION! PHYSICAL INJURY HAZARD. Do not attempt to lift or move the instrument without the assistance of others, the use of appropriate moving equipment, and proper lifting techniques. Improper lifting can cause painful and permanent back injury. Depending on the weight, moving or lifting an instrument may require two or more people.

Components (unpackaged)

Ensure that the installation site bench space can accommodate the dimensions and support the weights of the components.

Component	Height	Length (depth)	Width	Weight
Instrument	57.2 cm (22.5 in.) with door closed	68.6 cm (27 in.)	88.9 cm (35 in.)	Approximately 76 kg (168 lbs)
	88.9 cm (35 in.) with door open			



CAUTION! PHYSICAL INJURY HAZARD. Do not attempt to lift or move the instrument without the assistance of others, the use of appropriate moving equipment, and proper lifting techniques. Improper lifting can cause painful and permanent back injury. Depending on the weight, moving or lifting an instrument may require two or more people.

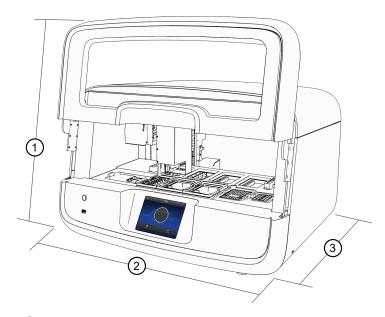
Component clearances required for installation and maintenance

During installation and maintenance, it is necessary to access the back and sides of the product. If the back of the product faces a wall, ensure that there is sufficient clearance on the bench to rotate the product.

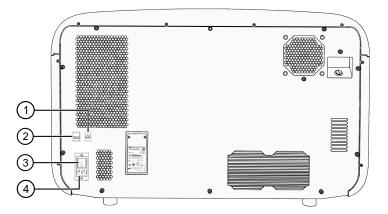
IMPORTANT! For safety reasons, the power outlet for the product must be accessible at all times.

Bench	Minimum clearance
Depth	 >101.6 cm (40 in.) for a bench against a solid vertical surface >25.4 cm (10 in.) of clearance at the back of the instrument for air flow, service access, and cable routing.
	 If the bench is at least 25.4 cm. (10 in.) from a wall, the bench can be 76.2 cm. (30 in.) deep. If the bench has wheels, it can facilitate access to the back of the instrument.
Width	>104.2 cm (41 in.) for the instrument.

Configured system dimensions and connections



- 1 88.9 cm (35 in.) with door open
- 2 88.9 cm (35 in.)
- (3) 68.6 cm (27 in.)
- 30.5 cm (12 in.) clearance above the instrument with door closed
- ≥25.4 cm (10 in.) clearance behind the instrument
- ≥7.6 cm (3 in.) clearance in front and on each side of the instrument



- (1) Ethernet port—An RJ45 port that provides Ethernet (Gigabit) communication between the instrument and a local area network.
- 2 USB port—Connects a USB device to the instrument.
- 3 On/Off switch—Power switch, where the states are on (|) or off (O).
- (4) Power port—100–240VAC port that provides power to the instrument.

Laboratory layout of the Genexus™ Purification System

The Genexus™ Purification Instrument requires connection to a local area network (Figure 1) or direct connection with a Genexus™ Integrated Sequencer (Figure 2) to access Genexus™ Software 6.8 to perform integrated Sample-to-Result runs.

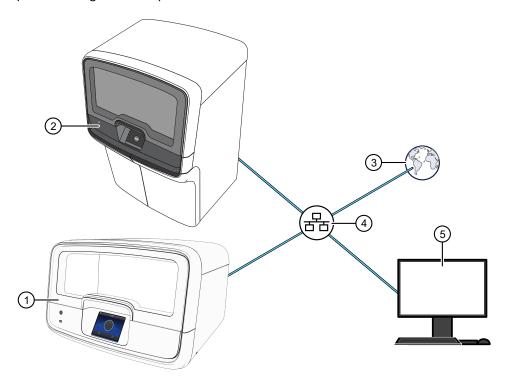


Figure 1 Genexus™ Purification System configuration

- (1) Genexus™ Purification Instrument
- ② Genexus™ Integrated Sequencer
- ③ Internet

- 4 Local area network
- 5 Client computer

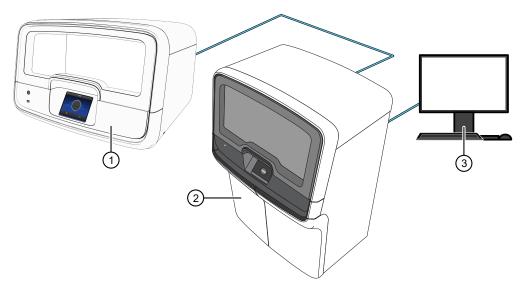


Figure 2 Genexus™ Purification System isolated private network configuration

Genexus™ Purification Instrument

3 Client computer

② Genexus™ Integrated Sequencer

Environmental requirements

Condition	Acceptable range	
Installation site	Indoor use only	
Electromagnetic interference	Do not use this device in close proximity to sources of strong electromagnetic radiation (for example, unshielded intentional RF sources). Strong electromagnetic radiation may interfere with the proper operation of the device.	
	This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference. You may need to take measures to mitigate the interference.	
	IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	
Altitude	Located between sea level and 2,500 m (8,200 ft.) above sea level	
Humidity (instrument and computer)	 Operation: 20%–70% (noncondensing) Transport and storage (packaged): 10%–90% Relative Humidity 	
Temperature (instrument and computer)	 Operation: 15°C to 30°C (60°F to 85°F) Note: The room temperature must not fluctuate more than 2°C over a 2-hour period. If the purification instrument is operated at an elevation of 1,800 m (5,900 ft) or greater above sea level, the maximum operating temperature is 23°C (73°F). Transport and storage (packaged): -20°C to 60°C 	
Transient category	Installation categories II	

(continued)

Condition	Acceptable range	
Overvoltage category	Installation categories II	
Vibration	The instrument is not adjacent to strong vibration sources, such as a centrifuge, pump, or compressor. Excessive vibration will affect instrument performance.	
Pollution degree	II	
	Install the instrument in an environment that has nonconductive pollutants such as dust particles or wood chips. Typical environments with a Pollution Degree II rating are laboratories and sales and commercial areas.	
Liquid waste collection	Dispose of the polymer, buffer, reagents and any liquid waste as hazardous waste in compliance with local and national regulations.	
Other conditions	Ensure the room is away from any vents that could expel particulate material on the components.	
	Avoid placing the instrument and computer adjacent to heaters, cooling ducts, or in direct sunlight.	

Thermal specifications for the instrument

During operation, the thermal output based on the typical current draw of the instrument is:

Component	Typical draw	Thermal output
Genexus™ Purification System	350W	1194 BTU/h

Electrical requirements



CAUTION! Do not unpack or plug in any components until they are configured for the proper operating voltage by the service representative.



WARNING! For safety, the power outlet for the instrument must be accessible at all times. See "Component clearances required for installation and maintenance" on page 6 for information about the space needed between the wall and the instrument. In case of emergency, you must be able to immediately disconnect the main power supply to all the equipment. Allow adequate space between the wall and the equipment so that the power cords can be disconnected in case of emergency.

- Dedicated line and ground between the instrument and the main electrical service.
- Maximum power dissipation: ~417 VA, 371 W
- Mains AC line voltage tolerances must be up to ±10 percent of nominal voltage

Device	Rated voltage	Circuit required	Rated frequency	Rated power
Instrument	100-240 ±10% VAC ^[1]	2.5–5 A	50/60 Hz	350 W

^[1] If the supplied power fluctuates beyond the rated voltage, a power line regulator may be required. High or low voltages can adversely affect the electronic components of the instrument.

Electrical protective devices

We recommend several protective devices in environments with large voltage and power fluctuations.

Recommended devices

Power line regulator

- 1.5-kVA power line regulator
- Use in areas where the supplied power fluctuates in excess of ±10% of the normal voltage.
- Power fluctuations can adversely affect the function of the instrument and computer.

Note: A power line regulator monitors the input current and adjusts the power supplied to the instrument or computer. It does not protect against a power surge or failure.

Surge protector

- 10-kVA surge protector (line conditioner)
- Use in areas with frequent electrical storms or near devices that are electrically noisy, such as refrigerators, air conditioners, or centrifuges.
- Short-duration, high-voltage power fluctuations can abruptly terminate the function of, and thereby damage the components of, the computer and the instrument.

Note: A dedicated line and ground between the instrument, computer, and the building's main electrical service can also prevent problems caused by power fluctuations.

Uninterruptible power supply (UPS)

- 1.5-kVA uninterruptible power supply (UPS)
- Use in areas prone to power failure.
- Power failures and other events that abruptly terminate the function of the instrument and computer can corrupt data and possibly damage the system.



CAUTION! PHYSICAL INJURY HAZARD. Do not attempt to lift or move the UPS unit without the assistance of at least two people. Improper lifting can cause painful and permanent back injury. See the UPS manufacturer user guide for more information.

IMPORTANT! A UPS provides power for a limited time. It is meant to delay the effects of a power outage, not to serve as a replacement power source. In the event of a power loss, power off the instrument and computer unless you expect to regain power within the battery life of the UPS.

Network requirements

The instrument is factory-configured for IPv4 TCP/IP communication and uses an Ethernet adapter (100/1,000 Mbps) with an RJ45-type connector for local area network (LAN) connection.

If the instrument will be installed by a service representative:

- (LAN connection only) An active, tested 1 GB LAN connection must be in place before the scheduled installation date.
- The assigned IT or network specialist from your organization must be available during the installation to help connect the instrument to your network.

Network configuration

If you plan to connect the Genexus™ Purification Instrument to your network, then the following requirements must be met before the installation can take place. Discuss any discrepancies with your concierge representative prior to the visit.

- If necessary, an information technologies resource must be available to assist with the network connection on the date of the installation.
- The room in which the instrument will be installed must contain at least one active network jack.
- If the instrument will be located more than 10 feet from the network jack, you must provide a standard Category 6 Ethernet cable of sufficient length.
- If dynamic network configuration (DCHP) is not available or will not be used, a static IP address
 must be reserved for the instrument.
- The onsite domain name system (DNS) server must be configured to resolve the URL of the Ion Torrent™ Server to be accessed by the Genexus™ Purification Instrument.
- The Genexus[™] Purification Instrument can see only one Ion Torrent[™] Server. Planned Run sharing will need to be enabled to see multiple Ion Torrent[™] Servers connected to a LAN. Refer to the *Ion Chef*[™] and *Ion Torrent*[™] Server Network Setup User Guide (Pub. no. MAN0013444) for information on enabling Planned Run sharing.
- If your network employs a firewall that restricts traffic between devices, it must be configured
 to permit HTTPS-443, SSH-22, FTP-8021, and FTP-20/21 communication between the Genexus™
 Purification Instrument and the Ion Torrent™ Server.
- The Genexus™ Purification Instrument requires outbound internet access through HTTPS-443 and SSH-22 to allow remote support via the Axeda Remote System Monitoring (RSM)
 Agent. The instrument includes the Axeda Agent to assist you in maintaining your Genexus™
 Purification Instrument and to provide timely technical support (for more information, see http://www.axeda.com/community/customers/applied-biosystems).

At minimum, whitelist the following outbound addresses for the instrument:

- drm.appliedbiosystems.com on HTTPS-443
- rssh.iontorrent.net on SSH-22

IMPORTANT! Without access through HTTPS-443 and SSH-22, we cannot support your instrument in a timely fashion and we may forego remote support for your site altogether at our discretion.

Note: The Axeda Agent is already in use on many of our products to perform instrument diagnostics, preventive maintenance, failure prediction, and proactive notification. The agent does not collect any sequencing reports, results, or data. For more information on the Axeda Agent, see: http://lifetech-it.hosted.jivesoftware.com/message/1546#1546

 If the Genexus™ Purification Instrument will use Network Time Protocol (NTP) for date/time synchronization, the instrument must have outbound Internet access through UDP-123 to the server pool at pool.ntp.org.

Safety requirements

Safety practices

A safety representative from your facility must ensure that:

- Personnel establish and follow all applicable safety practices and policies to protect laboratory personnel from potential hazards.
- All applicable safety devices and equipment are available at all times.

Required safety equipment

Your laboratory has specific safety practices and policies designed to protect laboratory personnel from potential hazards that are present. Follow all applicable safety-related procedures at all times.

The following safety equipment and protection from hazards must be available at the installation site:

- Protection from any sources of hazardous chemicals, radiation (for example, lasers, radioisotopes, radioactive wastes, and contaminated equipment), and potentially infectious biological material that may be present in the area where the service representative will work.
- · Appropriate fire extinguisher:
 - You are responsible for providing an appropriate fire extinguisher for use on or near the equipment.
 - The types and sizes of fire extinguishers shall be suitable for use on electrical and chemical fires as specified in current codes, regulations, and/or standards, and with approval of the Fire Marshall or other authority having jurisdiction.
 - The installation of appropriate fire extinguishers shall be in addition to other fire-protection systems and not as a substitute or alternative to them.
- Eyewash
- Safety shower
- Eye and hand protection
- · Adequate ventilation, including vent line/fume hood, if applicable
- Biohazard waste container, if applicable
- First-aid equipment
- Spill cleanup equipment
- Applicable Safety Data Sheets (SDSs)

Antivirus software requirements

Antivirus software is not provided with the Genexus™ Purification System.

In standalone configuration antivirus software is not required. In integrated configuration, the computer provided with the Genexus[™] Integrated Sequencer does not include antivirus software because customer preferences and network requirements vary.

Thermo Fisher Scientific has tested Genexus™ Software with the following antivirus software products and found them compatible as antivirus solutions.

- Bitdefender GravityZone™ Business Security
- Avast Antivirus

Antivirus software definition files are updated frequently, sometimes daily. Definition file updates for antivirus software can bring added settings or updates to the system, which can affect the function of Genexus™ Software.

Materials for installation and operation

Additional required installation materials

Ensure that the following materials are available before installation of the product:

Table 1 Ion Torrent™ Genexus™ Purification Install Kit (Cat. No. A48549)

Component	Amount
12-Well Tip Comb	1
6-Well Tip Comb	1
Quantitation Tube	1
96 Deep-well Plate	1

- Safety glasses, lab coats, and chemical-resistant, disposable gloves (powder-free)
- · Mobile bench to allow access to the instrument for maintenance and service
- Mini vortexer, centrifuge, and sample tubes
- Easily accessible specified power outlet
- (Optional) Electrical protective devices (universal power supply unit, surge protector, and/or power line regulator)
- (Optional) External network connection
- Freezer (-20°C)
- Refrigerator or cold-room (4°C)
- Lint-free tissues
- Glassware washing solution
- Methanol or isopropanol, HPLC-grade or better
- Water

- Three sizes of micropipettors and tips:
 - 1- to 10-μL
 - 10- to 100-µL
 - 100- to 1,000-μL

Operation materials

Additional supplies and consumables are necessary for routine operation. Contact a sales representative to order these additional supplies. Use only supplies as specified by Thermo Fisher Scientific.

Receive and inspect the shipment

- 1. Verify that the items shown on the shipping list are the items that were ordered at the time of purchase.
- 2. Carefully inspect the shipping containers. Report any damage to the shipping company and to your service representative. Record any damage or mishandling on the shipping documents.
- 3. Immediately unpack the reagents or installation kit box (boxed separately from the instrument components). Store the reagents at the temperatures specified on the product packaging or labels.

IMPORTANT! Other than reagents or plates that require storage at specific conditions, do not unpack shipping containers at this time. To protect yourself from liability for damage that occurred during shipping, inspect the shipping containers and report damage as described above.

Move the packaged shipment to the installation site

- 1. Clear the installation site of all unnecessary materials.
- 2. Move the packaged shipment to the installation site.



CAUTION! PHYSICAL INJURY HAZARD. Do not attempt to lift or move the instrument without the assistance of others, the use of appropriate moving equipment, and proper lifting techniques. Improper lifting can cause painful and permanent back injury. Depending on the weight, moving or lifting an instrument may require two or more people.



CAUTION! Do not tip the package on end. Tipping may damage the hardware and electronics.

Note: After installation, keep the packaging in case you need to relocate the components.

Documentation and support

Related documentation

Document	Publication number
Genexus™ Purification System User Guide	MAN0018475
Genexus™ Integrated Sequencer User Guide	MAN0017910
Genexus™ Integrated Sequencer Quick Reference	MAN0017912
Genexus™ Integrated Sequencer Site Preparation Guide	MAN0017918
Genexus™ Software 6.8 User Guide	MAN0026409

Customer and technical support

Visit thermofisher.com/support for the latest service and support information.

- Worldwide contact telephone numbers
- Product support information
 - Product FAQs
 - Software, patches, and updates
 - Training for many applications and instruments
- Order and web support
- Product documentation
 - User guides, manuals, and protocols
 - Certificates of Analysis
 - Safety Data Sheets (SDSs; also known as MSDSs)

Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

Thermo Fisher Scientific Concierge contact information

Contact your Thermo Fisher Scientific Concierge Team or your local Field Service Engineer (FSE) for any questions you may have.

Location	Support contact information
Americas	AMER.Concierge@themofisher.com
Asia, Pacific, Japan	APJ.Concierge@thermofisher.com
Europe, Middle East, Africa	EMEA.Concierge@thermofisher.com
Other regions	thermofisher.com/askaquestion

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at www.thermofisher.com/us/en/home/global/terms-and-conditions.html. If you have any questions, please contact Life Technologies at www.thermofisher.com/support.



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Revision history: E.0 MAN0018477 (English)

Revision	Date	Description
E.0	29 August 2023	 Added "Thermo Fisher Scientific Concierge contact information" on page 15. Update compatible antivirus software requirements (page 13).
D.0	5 April 2022	 Added "Thermal specifications for the instrument" on page 9. Updated altitude limit and added a temperature limit when operating the sequencer at high altitude in "Environmental requirements" on page 8. Updated LAN connection speed needed in "Network requirements" on page 11.
C.0	10 November 2021	 Update the envirionmental requirements: humidity = 20–70%. Include networking requirements for integrated configuration runs.
B.0	17 June 2021	New site prepartion guide for the Genexus™ Purification System in standalone configuration.
A.0	4 November 2020	Draft site preparation guide for the Genexus™ Purification System for early access customers.

The information in this guide is subject to change without notice.

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