

MiSeqDx[®]

Site Prep Guide for Instruments with Dual Boot Configuration

FOR IN VITRO DIAGNOSTIC USE

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Revision History

Document #	Date	Description of Change
Document # 15070066 v03	April 2020	Updated EU Authorized Representative address. Updated Australian Sponsor address.
Document # 15070066 v02	August 2017	Added references for the <i>MiSeqDx Instrument Reference Guide for MOS v2 (document # 1000000021961)</i> . Added template line wash supplies to the User-Supplied Consumables section. Updated regulatory markings on the back cover.
Document # 15070066 v01	December 2016	Changed the type of water required for washing the instrument from DNase-free, RNase-free water to laboratory-grade water. Listed acceptable examples of laboratory-grade water, including Illumina PW1. The network cable recommendation was changed from a shielded CAT6 network cable to an unshielded CAT 5e Ethernet cable. Marking and formatting changes.
Part # 15070066 Rev. A	March 2015	Initial release. For customers that have an instrument with dual boot configuration, this guide replaces the <i>MiSeqDx Site Prep Guide (part # 15038351)</i> .

Introduction

This guide provides the information you need to prepare your site for installation and operation of the MiSeqDx:

- ▶ Laboratory space requirements
- ▶ Electrical requirements
- ▶ Environmental constraints
- ▶ Computing requirements
- ▶ User-supplied consumables and equipment

Additional Resources

The following documentation is available for download from the MiSeqDx support page on the Illumina website.

MiSeqDx Instrument Type	Guides
All	<i>MiSeqDx Instrument Safety and Compliance Guide (document # 15034477)</i> —Provides information about instrument labeling, compliance certifications, and safety considerations.
Dual Boot (MOS v1)	<i>MiSeqDx Reference Guide for Instruments with Dual Boot Configuration (document # 15038353)</i> —For MiSeqDx instruments with dual boot configuration with MiSeq Operating Software (MOS) v1. Provides an overview of instrument components and software, instructions for performing sequencing runs, and procedures for proper instrument maintenance and troubleshooting.
MOS v2	<i>MiSeqDx Instrument Reference Guide for MOS v2 (document 1000000021961)</i> —For MiSeqDx instruments with MiSeqDx Operating Software (MOS) v2. (All instruments with MOS v2 have dual boot configuration.) Provides an overview of instrument components and software, instructions for performing sequencing runs, and procedures for proper instrument maintenance and troubleshooting.

Visit the MiSeqDx support page on the Illumina website for access to documentation, software downloads, frequently asked questions, and online training courses. A MyIllumina login is required.

Delivery and Installation

An Illumina-authorized service provider delivers, uncrates, and places the MiSeqDx on the lab bench. The space and bench must be ready in advance of delivery.



CAUTION

Allow only Illumina-authorized personnel to uncrate, install, or move the MiSeqDx. Mishandling of the instrument can affect the alignment or damage instrument components.



CAUTION

The instrument is heavy. Improperly uncrating, installing, or moving the MiSeqDx could:

- ▶ Cause serious injury if dropped or mishandled.
- ▶ Damage or break the instrument.

An Illumina representative installs and aligns the instrument. If you plan to connect the instrument to a data management system or remote network location, have the path for data storage selected before the date of installation. Having the path already selected allows your Illumina representative to test the data transfer process during installation.



CAUTION

After your Illumina representative has installed and aligned the MiSeqDx, *do not* relocate the instrument. Moving the instrument improperly can impact the optical alignment and compromise data integrity. To relocate the MiSeqDx, contact your Illumina representative.

Crated Dimensions and Contents

The MiSeqDx is shipped in one crate. Use the following dimensions to determine the minimum door width required to accommodate the shipping container.

Measurement	Crated Dimensions
Width	72.4 cm (28.5 in)
Height	76.8 cm (30.25 in)
Depth	83.8 cm (33 in)
Weight	90.7 kg (200 lbs)

The crate contains the MiSeqDx instrument along with the following components:

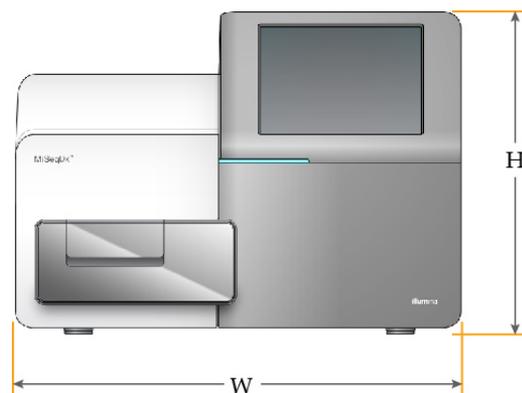
- ▶ Waste bottle, drip tray, and two labels for shipping restraint locations.
- ▶ MiSeqDx Accessories Kit, which contains the following components:
 - Wash tray
 - Wash bottle, 500 ml
 - Waste bottle stopper (red)
 - T-handle hex-drive tool, 6 mm
 - T-handle hex-drive tool, 5/64 in.
 - Ethernet cable, unshielded CAT 5e
- ▶ Power cord

Laboratory Requirements

This section provides requirements and guidelines to set up your lab space properly for the MiSeqDx. For more information, see *Environmental Constraints* on page 11.

Instrument Dimensions

Figure 1 MiSeqDx Instrument



The MiSeqDx has the following dimensions upon installation:

Measurement	Instrument Dimensions
Width	68.6 cm (27 in)
Height	52.3 cm (20.6 in)
Depth	56.5 cm (22.2 in)
Weight	57.2 kg (126 lbs)

Placement Requirements

The MiSeqDx must be positioned in such a way to ensure access to the power switch and power outlet, for proper ventilation, and for servicing the instrument.

- ▶ Make sure that you can reach around the right-side of the instrument to turn on or turn off the power switch on the back panel adjacent to the power cord.
- ▶ Position the instrument so that personnel can quickly disconnect the power cord from the outlet.
- ▶ The instrument must be accessible from all sides using the following minimum clearance dimensions:

Access	Minimum Clearance
Sides	Allow at least 61 cm (24 in) on each side of the instrument.
Rear	Allow at least 10.2 cm (4 in) behind the instrument.
Top	Allow at least 61 cm (24 in) above the instrument. If the instrument is positioned under a shelf, make sure that the minimum clearance requirement is met.

**CAUTION**

To relocate the MiSeqDx, contact your Illumina representative. Moving the instrument improperly can impact the optical alignment and compromise data integrity.

Lab Bench Guidelines

Illumina recommends placing the instrument on a lab bench without casters. The bench must be capable of supporting the weight of the instrument, which is 57.2 kg (126 lbs.).

Width	Height	Depth	Casters
122 cm (48 in)	91.4 cm (36 in)	76.2 cm (30 in)	No

Vibration Guidelines

**CAUTION**

The MiSeqDx is sensitive to vibrations.

Use the following guidelines to minimize vibrations during sequencing runs and ensure optimal performance:

- ▶ Place the instrument on a sturdy immobilized lab bench.
- ▶ Do not place any other equipment on the bench that might induce vibrations, such as a shaker, vortexer, centrifuge, or instruments with heavy fans.
- ▶ Do not install the instrument near frequently used doors. Opening and closing of the doors might induce vibrations.
- ▶ Do not install a keyboard tray that hangs below the bench.
- ▶ While the instrument is sequencing, do not touch the instrument, open the reagent door, or place anything on top of the instrument.

Lab Setup for PCR Procedures

The polymerase chain reaction (PCR) process is used to prepare libraries for amplicon sequencing. Unless you exercise sufficient caution, PCR products can contaminate reagents, instruments, and samples, causing inaccurate and unreliable results. PCR product contamination can impact lab processes adversely and delay normal operations.

**CAUTION**

You must establish dedicated areas and lab procedures to prevent PCR product contamination before you begin work in the lab.

Dedicate Physically Separate Areas

Make sure that your lab is set up appropriately to reduce the risk of PCR product contamination.

- Dedicate physically separate pre-PCR laboratory space where pre-PCR processes are performed (DNA extraction, quantification, and normalization).
- Dedicate physically separate post-PCR laboratory space where PCR products are made and processed.
- Never use the same sink to wash pre-PCR and post-PCR materials.
- Never share the same water purification system for pre-PCR and post-PCR processes.
- Store all supplies used in pre-PCR protocols in the pre-PCR area, and transfer to the post-PCR area as needed.
- *The instrument must be located in the post-PCR laboratory.*

Dedicate Equipment and Supplies

- Dedicate separate full sets of equipment and supplies (pipettes, incubator, heat block, vortexer, centrifuge, etc.) to pre-PCR and post-PCR lab processes, and never share between processes.
- Dedicate separate storage areas (freezers and refrigerators) for pre-PCR and post-PCR consumables.

Electrical Requirements

This section lists power specifications and describes electrical requirements for your facility.

Power Specifications

Type	Specification
Line Voltage	100–240 Volts AC @ 50/60 Hz
Power Consumption	400 Watts

Connections

Your facility must be wired with the following equipment:

- ▶ **For 100–110 Volts AC**—A 10-amp grounded, dedicated line with proper voltage is required.
North America and Japan—Receptacle: NEMA 5-15
- ▶ **For 220–240 Volts AC**—A 6-amp grounded line with proper voltage is required.
- ▶ If the voltage fluctuates more than 10%, a power line regulator is required.

Protective Earth



The MiSeqDx has a connection to protective earth through the enclosure. The safety ground on the power cord returns protective earth to a safe reference. The protective earth connection on the power cord must be in good working condition when using this device.

Power Cords

The MiSeqDx comes with an international standard IEC 60320 C13 connection and is shipped with a region-specific power cord.

Hazardous voltages are removed from the instrument only when the power cord is disconnected from the AC power source.



CAUTION

Never use an extension cord to connect the instrument to a power supply.

Fuses

The MiSeqDx contains no user-replaceable fuses.

Uninterruptible Power Supply

The use of a user-supplied uninterruptible power supply (UPS) is highly recommended. Illumina is not responsible for runs affected by interrupted power regardless of whether the instrument is on a UPS or not. Standard generator-backed power is often not uninterruptible and a brief power outage occurs before power resumes, which interrupts a sequencing run.

Environmental Constraints

Element	Specification
Temperature	Transportation and Storage: -10°C to 40°C (14°F to 104°F) Operating Conditions: 19°C to 25°C (66°F to 77°F)
Humidity	Transportation and Storage: Non-condensing humidity Operating Conditions: 30–75% relative humidity (non-condensing)
Elevation	Locate the instrument at an altitude below 2000 meters (6500 feet).
Air Quality	Operate the instrument in a Pollution Degree II environment or better. A Pollution Degree II environment is defined as an environment that normally includes only nonconductive pollutants.
Ventilation	Consult your facilities department for ventilation requirements based on the instrument heat output specifications.

Heat Output

Measured Power	Thermal Output
400 Watts	1,364 Btu/h

Noise Output

The MiSeqDx is an air-cooled instrument. Noise from the fan is clearly audible when the instrument is running.

Noise Output (dB)	Distance from Instrument
< 62 dB	1 meter (3.3 feet)

A measurement of < 62 dB is the level of a normal conversation at a distance of approximately 1 meter (3.3 feet).

Network Considerations

A network connection is recommended due to the amount of data generated by the MiSeqDx.

- ▶ An unshielded CAT 5e Ethernet cable of 3 meters (9.8 feet) in length is provided with the instrument.

To use the following features, network and internet connections are required:

- ▶ Receive and install software updates from the MiSeq Operating Software (MOS) interface.
- ▶ Access manifest files, sample sheets, and references located on a network server from the MOS interface.
- ▶ Easily move data from previous runs and analyses to a server location for storage, and to manage disk space on the integrated MiSeqDx computer.
- ▶ Monitor and manage secondary analysis using the MiSeq Reporter analysis software.
- ▶ Use Live Help, an on-instrument feature that connects you to Illumina Technical Support for troubleshooting.



NOTE

Upon connection to a network, configure Windows Update so that the MiSeqDx does not automatically update. If automatic updates are left on, the MiSeqDx might restart in the middle of a run. If this occurs, start the run from the beginning.

Dual Boot Configuration

The MiSeqDx features a dual boot configuration, with two operating systems. One operating system is for use in diagnostic mode, while the other is for use in research (RUO) mode. These two different operating systems connect to the same port. Each OS has a different computer name, therefore you see only one of the two operating systems on the network at one time. Seeing a different computer name on the port is normal system activity indicative of the MiSeqDx switching modes between diagnostic and research.

Networking Support

Illumina does not provide installation or technical support for networking the instrument.

Use the following recommendations to install and maintain a network connection:

- ▶ Use a 1 gigabit connection between the instrument and your data management system. This connection can be made directly or through a network switch.
- ▶ Ask your IT professional to review network maintenance activities for potential compatibility risks with the system.



NOTE

Do not install additional software on the MiSeqDx instrument. The effect of additional software cannot be predicted, and can disrupt the functioning and performance of the MiSeqDx instrument.

Anti-Virus Software

Illumina strongly recommends installation of user-supplied anti-virus software to protect the computer against viruses.

To avoid interfering with MiSeqDx operation or losing data, configure the anti-virus software updates as follows:

- ▶ Set for manual scans, not automatic scans.
- ▶ Perform scans only when the instrument is not in use.
- ▶ Set updates to download but not install without user authorization.
- ▶ Do not automatically reboot the computer upon update.
- ▶ Exclude the data drive and application directory from any real-time file system protection.

User-Supplied Consumables and Equipment

The following consumables and equipment are required for performing sequencing runs on the MiSeqDx. For more information, see the *MiSeqDx Reference Guide for Instruments with Dual Boot Configuration* (document # 15038353), or if your instrument runs MOS v2 software, the *MiSeqDx Instrument Reference Guide for MOS v2* (document # 1000000021961).

User-Supplied Consumables

Make sure that the following user-supplied consumables are available before beginning a run.

Consumable	Purpose
Alcohol wipes, 70% Isopropyl or Ethanol, 70%	Cleaning the flow cell glass and stage
Lab tissue, low-lint	Cleaning the flow cell stage
Lens paper, 4 x 6 in.	Cleaning the flow cell
MiSeq tubes	Washing the template line (optional)
NaOCl, 5%	Washing the template line (optional)
Tween 20	Washing the instrument
Tweezers, square-tip plastic (optional)	Removing flow cell from flow cell shipping container
Water, laboratory-grade	Washing the instrument

Guidelines for Laboratory-Grade Water

Always use laboratory-grade water to perform instrument procedures. Never use tap water. Any of the following are acceptable examples:

- ▶ Illumina PW1
- ▶ 18 Megaohm (MΩ) water
- ▶ Milli-Q water
- ▶ Super-Q water
- ▶ Molecular biology-grade water

User-Supplied Equipment

- ▶ Freezer, -25°C to -15°C, frost-free
- ▶ Ice bucket
- ▶ Refrigerator, 2°C to 8°C

Technical Assistance

For technical assistance, contact Illumina Technical Support.

Table 1 Illumina General Contact Information

Website	www.illumina.com
Email	techsupport@illumina.com

Table 2 Illumina Customer Support Telephone Numbers

Region	Contact Number	Region	Contact Number
North America	1.800.809.4566	Italy	800.874909
Australia	1.800.775.688	Netherlands	0800.0223859
Austria	0800.296575	New Zealand	0800.451.650
Belgium	0800.81102	Norway	800.16836
Denmark	80882346	Spain	900.812168
Finland	0800.918363	Sweden	020790181
France	0800.911850	Switzerland	0800.563118
Germany	0800.180.8994	United Kingdom	0800.917.0041
Ireland	1.800.812949	Other countries	+44.1799.534000

Safety Data Sheets

Safety data sheets (SDSs) are available on the Illumina website at support.illumina.com/sds.html.

Product Documentation

Product documentation in PDF is available for download from the Illumina website. Go to support.illumina.com, select a product, then click **Documentation & Literature**.



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