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MiSeqDx

Site Prep Guide for Instruments with Dual Boot Configuration

ILLUMINA PROPRIETARY
Document # 15070066 v05
November 2021
FOR IN VITRO DIAGNOSTIC USE

Revision History

Document #	Date	Description of Change
Document # 15070066 v05	November 2021	Updated to support MOS v4.0 and Local Run Manager v3.0 upgrade. Updated Network Support section to support system Windows 10 upgrade. Referenced *Illumina Instrument Control Computer Security and Networking* online documentation from the following sections: • Platform Domains • Antivirus Software • Software Restriction Policies Added deionized water to list of acceptable examples of laboratory-grade water. Minor text updates to align with Illumina documentation style and standards. Updated related document references to include new versions for MOS v4.0. Updated Technical Assistance information.
Document # 15070066 v04	August 2021	Updated EU Authorized Representative address.
Document # 15070066 v03	December 2019	Updated EU Authorized Representative address. Updated Australian Sponsor address.
Document # 15070066 v02	August 2017	Added references for the *MiSeqDx Instrument Reference Guide for MOS v2 (document # 1000000021961)*. Added template line wash supplies to the User-Supplied Consumables section. Updated regulatory markings on the back cover.

Document #	Date	Description of Change
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 *MiSeqDx Site Prep Guide (part # 15038351)*.

Table of Contents

Introduction

This guide provides specifics and guidelines for preparing 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 MiSeqDx support pages on the Illumina website provide additional resources. These resources include software, training, compatible products, and the following documentation. Always check support pages for the latest versions.

MiSeqDx Instrument Type	Documentation
All	*MiSeqDx Instrument Safety and Compliance Guide (document # 15034477)*—Provides information about instrument labeling, compliance certifications, and safety considerations.
MOS v4	*MiSeqDx Instrument Reference Guide for MOS v4 (document # 200010452)*—For MiSeqDx instruments with MiSeqDx Operating Software (MOS) v4. (All instruments with MOS v4 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.
MOS v2	*MiSeqDx Instrument Reference Guide for MOS v2 (document # 1000000021961)*—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.

MiSeqDx Instrument Type	Documentation
Dual Boot (MOS v1)	*MiSeqDx Instrument Reference Guide for MOS v1 (document 15070067)*—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 v4	*Local Run Manager v3 Software Reference Guide for MiSeqDx (document # 200003931)*—Provides an overview of the Local Run Manager software, instructions for using software features, and instructions for installing analysis modules on the instrument computer.

Delivery and Installation

An Illumina-authorized service provider delivers the system, uncrates components, and places the MiSeqDx on the lab bench. Make sure that the lab space and bench are ready in advance of delivery.

CAUTION

Only Illumina-authorized personnel can 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:

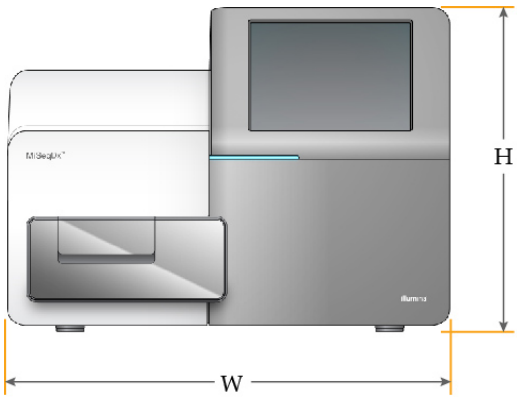
- Waste bottle, drip tray, and two labels for shipping restraint locations

- 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.
  - Network cable, shielded 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



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.

Access	Minimum Clearance
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.

Pre-PCR and Post-PCR Areas

Use the following guidelines to avoid cross-contamination.

- Establish a pre-PCR area for pre-PCR processes.
- Establish a post-PCR area for processing PCR products.
- Do not use the same sink to wash pre-PCR and post-PCR materials.
- Do not 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. Transfer them to the post-PCR area as needed.
- *The instrument must be located in the post-PCR laboratory*.

Dedicate Equipment and Supplies

- Do not share equipment and supplies between pre-PCR and post-PCR processes. Dedicate a separate set of equipment and supplies in each area.
- Establish dedicated storage areas for consumables used in each area.

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

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 connected to a UPS. Standard generator-backed power is often not uninterruptible and a brief power outage occurs before power resumes.

The following table lists region-specific recommendations to consider.

Table 1 Region-Specific Recommendations

Specification	Japan APC Smart UPS Part # SUA1500JB	North America APC Back-UPS Pro Part # BR1500MS	International APC Back-UPS Pro Part # BR1500MSI
Maximum Output Power	980 W / 1500 VA	900 W / 1500 VA	865 W / 1500 VA
Input Voltage (nominal)	100 VAC	120 VAC	230 VAC
Input Connection	NEMA 5-15P	NEMA 5-15P	IEC-320 C14
Typical Run Time (50% load)	23.9 minutes	14.5 minutes	15.8 minutes
Typical Run Time (100% load)	6.7 minutes	4.1 minutes	5.5 minutes

To obtain an equivalent UPS that complies with local standards for facilities outside the referenced regions, consult a third-party supplier such as Interpower Corporation (www.interpower.com).

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 MiSeqDx 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 Local Run Manager analysis software.
- Use Live Help, an on instrument feature that connects you to Illumina Technical Support for troubleshooting.

Use the following recommendations to install and configure 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.
- Upon connection to a network, configure Windows Update so that the MiSeqDx does not automatically update. Illumina recommends waiting one month after a Windows release before allowing an update.

Dual Boot Configuration

The dual boot configuration includes the hardware, software, and installation procedures to allow the MiSeqDx instrument to run both *in vitro* diagnostic (IVD) and research use only (RUO) sequencing assays. The dual boot configuration allows the user to switch between the diagnostic mode of the instrument to the research mode of the instrument. The radio-frequency identifications (RFIDs) on sequencing consumables prevent RUO sequencing reagents from being used in diagnostic sequencing runs.

Network Support

Illumina does not install or provide technical support for network connections.

Review network maintenance activities for potential compatibility risks with the Illumina system, including the following risks:

- **Removal of the Group Policy Objects (GPOs)**—GPOs can affect the operating system (OS) of connected Illumina resources. OS changes can disrupt the proprietary software in Illumina systems. Illuminainstruments have been tested and verified to operate correctly. After connecting to domain GPOs, some settings might affect the instrument software. If the instrument software operates incorrectly, consult your facility IT administrator about possible GPO interference. If the instrument needs to be bound to a domain, we recommend that you place the instrument in an organizational unit (OU) that is minimally restrictive.
- **Activation of Windows Firewall and Windows Defender**—These Windows products can affect the OS resources used by Illumina software. Install antivirus software to protect the instrument control computer. Certain URLs must be added to the allow list on your firewall for the instrument to connect to BaseSpace and Illumina Proactive. For details on the URLs to add to your allow list and how to configure your antivirus software, see *Illumina Instrument Control Computer Security and Networking*.
- **Changes to the privileges of preconfigured users**—Maintain existing privileges for preconfigured users. Make preconfigured users unavailable as needed.
- **Server Message Block (SMB) file sharing protocol**—SMB is disabled by default on Windows 10 systems. To enable, contact IlluminaTechnical Support. Due to known vulnerabilities in SMB1, it is strongly recommended that you upgrade your network connection to SMB2 or higher. If this is not an option, contact Illumina Technical Support.

Regional Platform Domains

For the regional platform domains that provide access from Universal Copy Service to BaseSpace Sequence Hub and Illumina Proactive, see *Illumina Instrument Control Computer Security and Networking*. Note that this applies to instruments running in RUO mode only.

Software Restriction Policies

Windows Software Restriction Policies (SRP) use rules to allow only specified software to run. For the MiSeqDx, SRP rules are based on certificates, file names, file extensions, and directories.

By default, SRP is turned on to prevent unwanted software from running on the control computer. Only the sbsadmin user can turn off SRP.

An IT representative or system administrator can add and remove rules to customize the security level. If the system is added to a domain, the local Group Policy Object (GPO) might automatically modify the rules and turn off SRP.

For information on configuring SRP, see *Illumina Instrument Control Computer Security and Networking*.

CAUTION

Turning off the SRP prevents the protection it provides. Changing the rules overrides the default protections.

Antivirus Software

An antivirus software of your choice is highly recommended to protect the instrument control computer against viruses. You will need to turn off Windows Software Restriction Policies (SRP) temporarily while you install the antivirus software.

For information on configuring antivirus software and SRP, see *Illumina Instrument Control Computer Security and Networking*.

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 Instrument Reference Guide for MOS v4 (document # 200010452)*

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 or deionized water to perform instrument procedures. Never use tap water. Use only the following grades of water or equivalents:

- Deionized water
- IlluminaPW1
- 18 Megaohm (MΩ) water
- Milli-Q water
- Super-Q water
- Molecular biology-grade water

User-Supplied Equipment

Item	Source	Purpose
Freezer, -25°C to -15°C, frost-free	General lab supplier	Storing the cartridge.
Ice bucket	General lab supplier	Setting aside libraries.
Refrigerator, 2°C to 8°C	General lab supplier	Storing the flow cell.

Technical Assistance

For technical assistance, contact Illumina Technical Support.

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

Illumina Technical Support Telephone Numbers

Region	Toll Free	International
Australia	+61 1800 775 688	
Austria	+43 800 006249	+43 1 9286540
Belgium	+32 800 77 160	+32 3 400 29 73
Canada	+1 800 809 4566	
China		+86 400 066 5835
Denmark	+45 80 82 01 83	+45 89 87 11 56
Finland	+358 800 918 363	+358 9 7479 0110
France	+33 8 05 10 21 93	+33 1 70 77 04 46
Germany	+49 800 101 4940	+49 89 3803 5677
Hong Kong, China	+852 800 960 230	
India	+91 8006500375	
Indonesia		0078036510048
Ireland	+353 1800 936608	+353 1 695 0506
Italy	+39 800 985513	+39 236003759
Japan	+81 0800 111 5011	
Malaysia	+60 1800 80 6789	
Netherlands	+31 800 022 2493	+31 20 713 2960
New Zealand	+64 800 451 650	
Norway	+47 800 16 836	+47 21 93 96 93
Philippines	+63 180016510798	
Singapore	1 800 5792 745	
South Korea	+82 80 234 5300	

Region	Toll Free	International
Spain	+34 800 300 143	+34 911 899 417
Sweden	+46 2 00883979	+46 8 50619671
Switzerland	+41 800 200 442	+41 56 580 00 00
Taiwan, China	+886 8 06651752	
Thailand	+66 1800 011 304	
United Kingdom	+44 800 012 6019	+44 20 7305 7197
United States	+1 800 809 4566	+1 858 202 4566
Vietnam	+84 1206 5263	

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

Product documentation—Available for download from support.illumina.com.

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