MiSeqDx® Instrument
Safety and Compliance Guide

FOR IN VITRO DIAGNOSTIC USE

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Revision History

Document #	Date	Description of Change
15034477 v02	August 2017	Updated the list of instrument reference guides in the Safety Considerations and Markings section. Updated the FCC EMC considerations regarding radio interference in a domestic environment. Added the following compliance directives: • RoHS 2011/65/EU • Radio Equipment Directive 2014/53/EU Updated the following compliance directives: • EMC • Low Voltage Updated the Human Exposure to Radio Frequency compliance statement. Added a compliance statement on emission and immunity requirements in the EMC Considerations section. Removed some compliance directives, as they are now available at support.illumina.com/certificates.html. Removed the Compliance and Regulatory Markings section. Added a statement on radio interference to the Korea Compliance section. Updated regulatory markings on the back cover.
15034477 v01	October 2015	Updated regulatory markings on the back cover. Added a revision history. Reordered sections of the guide into a Product Compliance and Regulatory Statements chapter. Noted that date of manufacture and country of origin are on the instrument label. Added compliance statements for Brazil, Korea, and Mexico. Made the following changes to the Compliance and Regulatory Markings section: • Added Korea mark • Removed the FCC mark Added R&TTE Directive 1999/5/EC to the Product Certifications and Compliance section. Removed information on shielded cables. Added a section on ethernet cables and on EMC considerations. Revised the hazardous voltage source location from the left side panel to the right side panel on the electrical safety warning note.
Part # 15034477 Rev. A	February 2014	Initial Release

Introduction

This guide provides important safety information pertaining to the installation, servicing, and operation of the MiSeqDx, as well as product compliance and regulatory statements. Read this document before performing any procedures on the MiSeqDx.

The MiSeqDx country of origin and date of manufacture are printed on the instrument label.

Safety Considerations and Markings

The purpose of this section is to identify the potential hazards associated with installing, servicing, and operating the MiSeqDx instrument. Do not operate or interact with the instrument in a manner that exposes you to any of these dangers.

Hazards indicated by labels on the instrument are pictured in this section.

All of the hazards described can be avoided by following the standard operating procedures included in the MiSeqDx instrument reference guide.

MiSeqDx Instrument Type	Instrument Reference Guide
Single Boot (MOS v1)	*MiSeqDx Instrument Reference Guide (document # 15038353)* —For MiSeqDx instruments with single boot configuration with MiSeq Operating Software (MOS) v1.
Dual Boot (MOS v1)	*MiSeqDx Reference Guide for Instruments with Dual Boot Configuration (document # 15070067)*—For MiSeqDx instruments with dual boot configuration with MOS v1.
MOS v2	*MiSeqDx Instrument Reference Guide for MOS v2 (document # 1000000021961)*—For MiSeqDx instruments with MOS v2. (All instruments with MOS v2 have dual boot configuration.)

General Safety Warnings

Before operating the MiSeqDx, all personnel must be trained by Illumina in the correct operation of the instrument and any potential safety considerations.

CAUTION

Follow all operating instructions as documented when working in areas marked with this label to minimize personal or instrument risk.

Electrical Safety Warnings

Do not remove any of the outer panels from the instrument. There are no user-serviceable components inside. Operating the instrument with any of the panels removed creates potential exposure to line voltage as well as DC voltages.

The instrument is powered by 100–240 volts AC operating at either 50 Hz or 60 Hz. Most of the voltage sources are located behind the right side panel, but they may also be accessible if other panels are removed. Some voltage is present on the instrument even when the instrument is powered down. Operate the instrument with all panels intact to avoid electrical shock.

Power Specifications

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

Electrical Connections

Plug the MiSeqDx into a grounded circuit capable of delivering at least:

- 10 Amps for a 100–110V power source
- 6 Amps for a 220–240V power source

For more information, see the *MiSeqDx Instrument Site Preparation Guide (document # 15038351)*. If you have a MiSeqDx instrument with the dual boot configuration, see the *MiSeqDx Site Prep Guide for Instruments with Dual Boot Configuration (document # 15070066)*.

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.

Fuses

The MiSeqDx contains no user-replaceable fuses.

Hot Surface Safety Warning

Do not operate the MiSeqDx with any of the panels removed.

Do not touch the flow cell stage in the flow cell compartment. The Peltier effect heater used in the stage area is normally controlled between ambient room temperature (22°C) and 95°C. Exposure to temperatures at the upper end of this range could result in burns.

Heavy Object Safety Warning

The instrument weighs approximately 126 lbs. and could cause serious injury if dropped or mishandled.

Uncrating, Installing, and Moving the Instrument

Only Illumina-authorized personnel should uncrate, install, or move the MiSeqDx. If the instrument must be relocated, contact Illumina Customer Support to arrange a service visit.

For contact information, see the inside back cover of this document.

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)

Element	Specification
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.

Symbols

IVD	For *in vitro* diagnostic use
EC REP	European Representative
	Manufactured By
	Date of Manufacture
REF	Model Number
SN	Serial Number
	Off
	On
	Humidity Range (on packaging: indicates acceptable shipping and storage limits)
	Temperature Range (on packaging: indicates acceptable shipping and storage limits)

Product Compliance and Regulatory Statements

Product Certifications and Compliance

Hereby Illumina declares that the MiSeqDx is in compliance with the following directives:

- EMC 2014/30/EU
- IVD 98/79/EC
- Low Voltage 2014/35/EU
- Radio Equipment 2014/53/EU
- RoHS 2011/65/EU
- R&TTE 1999/5/EC

The full text of the EU declarations of conformity and certificates of compliance are available at: support.illumina.com/certificates.html.

Environment

This label indicates that the instrument should not be disposed with common municipal waste.

Return the instrument to Illumina for disposal.

Human Exposure to Radio Frequency

This equipment complies with maximum permissible exposure (MPE) limits for the general population per Title 47 CFR § 1.1310 Table 1.

This equipment complies with the limitations of human exposure to electromagnetic fields (EMFs) for devices operating within the frequency range 0 Hz to 10 GHz, used in radio frequency identification (RFID) within an occupational or professional environment per EN 50364:2010 sections 4.0.

FCC Compliance

This device complies with Part 15 of the FCC Rules. Operation is subject to the following 2 conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

CAUTION

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instrumentation manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case users will be required to correct the interference at their own expense.

Ethernet Cables

Use a CAT-5e unshielded ethernet cable to ensure compliance with CISPR 11 Class A emissions limits.

EMC Considerations

- This IVD equipment complies with the emission and immunity requirements described in IEC 61326-2-6.
- This equipment has been designed and tested to the CISPR 11 Class A standard. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
- Do not use the device in close proximity to sources of strong electromagnetic radiation, as these can interfere with proper operation.
- Evaluate the electromagnetic environment before operation of the device.

IC Compliance

This Class A digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

This device complies with Industry Canada license-exempt RSS standards. Operation is subject to the following 2 conditions:

1 This device may not cause interference.

2 This device must accept any interference, including interference that may cause undesired operation of the device.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This radio transmitter (IC ID: 9859A-MISEQ) has been approved by Industry Canada to operate only with the attached integrated loop antenna. The use of any other antenna types are strictly prohibited for use with this device.

Conformité IC

Le dispositif numérique Classe A répond à toutes les exigences des Règlements canadiens sur le matériel brouilleur.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

L'appareil ne doit pas produire de brouillage.

L'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut

fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada.

Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotroperayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Le présent émetteur radio (IC ID: 9859A-MISEQ) a été approuvé par Industrie Canada pour fonctionner avec les types d'antenne énumérés ci-dessous et ayant un gain admissible maximal et l'impédance requise pour chaque type d'antenne. Les types d'antenne non inclus dans cette liste, ou dont le gain est supérieur au gain maximal indiqué, sont strictement interdits pour l'exploitation de l'émetteur.

Brazil Compliance

Conformidade ANATEL:

Este equipamento foi testado e está em conformidade com as resoluções da ANATEL 442 e 506.

Este equipamento opera em caráter secundário, isto é, não tem direito a proteção contra interferência prejudicial, mesmo de estações do mesmo tipo, e não pode causar interferência a sistemas operando em caráter primário.

Korea Compliance

A급 기기 (업무용 방송통신기자재)

이 기기는 업무용(A급)으로 전자파적합로서 판매자 또는 사용자는 이 점을 주의하시기 바라며, 가정외의 지역에서 사용하는 것을 목적으로 합니다.

해당 무선설비는 운용 중 전파혼신 가능성이 있음.

Españoles advertencia-Mexico

Conformidad con Instituto Federal de Telecommunicaciones

La operación de este equipo está sujeta a las siguientes dos condiciones:

1. Es posible que este equipo o dispositivo no cause interferencia perjudicial.
2. Este equipo o dispositivo debe aceptar cualquier interferencia, incluyendo la que pueda causar su operación no deseada.

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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