

MiSeqDx Instrument

Safety and Compliance Guide

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Revision History

Document #	Date	Description of Change
15034477 v05	November 2021	Added statement for indoor use only. Removed old R&TTE directive. Added EMC Considerations, FCC Compliance, and IC Compliance statements. Added compliance statements for Brazil, Korea, Thailand, Mexico, and United Arab Emirates.
15034477 v04	August 2021	Updated EU Authorized Representative address.
15034477 v03	December 2019	Updated EU Authorized Representative address. Updated Australian Sponsor address.

Document #	Date	Description of Change
15034477 v02	January 2017	<p>Updated the FCC EMC considerations regarding radio interference in a domestic environment.</p> <p>Added the following compliance directives:</p> <ul style="list-style-type: none">• RoHS 2011/65/EU• Radio Equipment Directive 2014/53/EU <p>Updated the following compliance directives:</p> <ul style="list-style-type: none">• EMC• Low Voltage <p>Updated the Human Exposure to Radio Frequency compliance statement.</p> <p>Added a compliance statement on emission and immunity requirements in the EMC Considerations section.</p> <p>Removed some compliance directives, as they are now available at support.illumina.com/certificates.html.</p> <p>Removed the Compliance and Regulatory Markings section.</p> <p>Added a statement on radio interference to the Korea Compliance section.</p> <p>Added translations in Chinese, German, Spanish, Norwegian, French, and Italian.</p> <p>Added Australia sponsor information to the back cover.</p>

Document #	Date	Description of Change
15034477 v01	October 2015	<p>Updated regulatory markings on the back cover.</p> <p>Added a revision history.</p> <p>Reordered sections of the guide into a Product Compliance and Regulatory Statements chapter.</p> <p>Noted that date of manufacture and country of origin are on the instrument label.</p> <p>Added compliance statements for Brazil, Korea, and Mexico.</p> <p>Made the following changes to the Compliance and Regulatory Markings section:</p> <ul style="list-style-type: none">• Added Korea mark• Removed the FCC mark <p>Added R&TTE Directive 1999/5/EC to the Product Certifications and Compliance section.</p> <p>Removed information on shielded cables.</p> <p>Added a section on ethernet cables and on EMC considerations.</p> <p>Revised the hazardous voltage source location from the left side panel to the right side panel on the electrical safety warning note.</p>
Part # 15034477 Rev. A	February 2014	Initial Release

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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
MOS v1	<i>MiSeqDx Reference Guide for Instruments with Dual Boot Configuration (document # 15070067)</i> —For MiSeqDx instruments with dual boot configuration with MOS v1.
MOS v2	<i>MiSeqDx Instrument Reference Guide for MOS v2 (document # 1000000021963)</i> —For MiSeqDx instruments with MiSeqDx Operating Software (MOS) v2. (All instruments with MOS v2 have dual boot configuration.)
MOS v4	<i>MiSeqDx Instrument Reference Guide for MOS v4 (document # 200010452)</i> —For MiSeqDx instruments with MiSeqDx Operating Software (MOS) v4. (All instruments with MOS v4 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

Trained Illumina personnel must perform all service and maintenance tasks that are not described in the *MiSeqDx Instrument Reference Guide for MOS v4 (document # 200010452)*.



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 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 and DC voltages.



The instrument is powered by 100–240 volts AC operating at either 50 Hz or 60 Hz. Hazardous voltage sources are located behind the right side panel, but can 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 # 15070066)*.

Protective Earth



The instrument 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 instrument 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 can result in burns.

Heavy Object Safety Warning



The instrument weighs approximately 57 kg (126 lb) and can 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 [Technical Assistance](#).

Environmental Constraints

For indoor use only.

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.

Symbols

	For <i>in vitro</i> diagnostic use
	European Representative
	Manufactured By
	Date of Manufacture
	Model Number
	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 and its amendments

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

Restriction of Hazardous Substances (RoHS)



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 limitation 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) in an occupational or professional environment. (EN 50364:2010 sections 4.0.)

FCC Compliance

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two 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 medical 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.

This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

Electromagnetic environment should be evaluated prior to operation of the device.

Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.

This equipment is designed for use in a professional healthcare facility environment. It is likely to perform incorrectly if used in a home healthcare environment. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

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

IC Compliance

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

This device complies with Industry Canada licence-exempt RSS standards. Operation is subject to the following two 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 with the antenna types listed below with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

Allowable antenna: Internal Loop antenna

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 :

1. L'appareil ne doit pas produire de brouillage.
2. 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 isotrope rayonnée 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

해당 무선 설비는 운용 중 전파 혼신 가능성이 있음.

A급 기기(업무용 방송통신기자재)

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

Españoles advertencia-Mexico

Conformidad con Instituto Federal de Telecomunicaciones

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.

Thailand Compliance

This telecommunication equipment conforms to the requirements of the National Telecommunications Commission.

United Arab Emirates Compliance

- TRA Registered Number: ER0117765/13
- Dealer Number: DA0075306/11

Technical Assistance

For technical assistance, contact Illumina Technical Support.

Website: www.illumina.com

Email: techsupport@illumina.com

Illumina Technical Support Telephone Numbers

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New Zealand	+64 800 451 650	
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Philippines	+63 180016510798	
Singapore	1 800 5792 745	
South Korea	+82 80 234 5300	

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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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