

MiSeq FGx™ Instrument Safety and Compliance Guide

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Introduction

The Illumina MiSeq FGx instrument uses sequencing by synthesis technology and integrates cluster amplification, sequencing, and data analysis in a single instrument with a foot print of approximately two feet square.

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

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

Safety Considerations and Markings

The purpose of this section is to clearly identify the potential hazards associated with installing, servicing, and operating the MiSeq FGx 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 herein can be avoided by following the standard operating procedures included in the MiSeq FGx Instrument User Guide.

General Safety Warnings

Before operating the MiSeq FGx, 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 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.

Electrical Connections

Plug the MiSeq FGx 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 *MiSeq FGx Instrument Site Preparation Guide* .

Power Specifications

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

Protective Earth



The MiSeq FGx 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 MiSeq FGx contains no user-replaceable fuses.

Hot Surface Safety Warning



Do not operate the MiSeq FGx 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.

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	Below 2,000 meters (6,500 feet)
Air Quality	Pollution Degree II environment or better Note: A Pollution Degree II environment is defined as one that normally includes only non-conductive pollutants.
Ventilation	Consult your facilities department for ventilation requirements for the level of heat output expected from the instrument.

Uncrating, Installing, and Moving the Instrument

Only Illumina-authorized personnel should uncrate, install, or move the MiSeq FGx. 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.

Product Certifications and Compliance

The MiSeq FGx is certified to the following standards:




- ▶ UL STD 61010-1
- ▶ CSA STD C22.2 No 61010-1
- ▶ IEC/EN 61010-1
- ▶ IEC/EN 61326-1
- ▶ IEC/EN 61326-2-6

The MiSeq FGx complies with the following directives:

- ▶ Low Voltage Directive 2006/95/EC
- ▶ EMC Directive 2004/108/EC
- ▶ R&TTE Directive 1999/5/EC

Compliance and Regulatory Markings

The MiSeq FGx is labeled with the following compliance and regulatory markings.

	This label assures that the product is tested and certified by TUV Rheinland, a Nationally Recognized Testing Laboratory (NRTL).
	This label assures that the product meets the essential requirements of all relevant EU directives.
	This label assures that the product complies with the Environmental Protection User Period - 10 years.







Environment



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

Return the instrument to Illumina for disposal.

Symbols

	Manufactured By
	Date of Manufacture
	Model Number
	Serial Number
	Off
	On

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 50364:2001 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.

Shielded Cables

Shielded cables must be used with this unit to ensure compliance with the Class A FCC limits.

Brazil Compliance

Brazil Compliance

ANATEL Compliance:

This equipment has been tested and was found to comply with ANATEL resolutions 442 and 506.

This equipment operates on a secondary basis, i.e. it is not entitled to protection against harmful interference, even from stations of the same type, and it may not cause harmful interference to systems operating on a primary basis.

Mexico Compliance

Spanish Warning-Mexico

Operation of this equipment is subject to the following two conditions: (1) it is possible that this equipment or device will not cause harmful interference and (2) this equipment or device must accept any interference, including interference that may cause undesired operation.

Taiwan Compliance

Attention! Taiwan Compliance!

In accordance with the Regulations on Electrical Devices Emitting Low-Power Electromagnetic Radiation

Article 12

Low-power radio frequency electrical devices that have passed type certification may not be subject to frequency changes, power increases or changes to the characteristics and functions of the original design without proper authorization.

Article 14

The use of low-power radio frequency electrical devices must not affect flight safety or interfere with legitimate communications; if any incidence of interference is discovered, usage must be stopped immediately, and resumed only at such time as improvements to the device mean that no further interference will occur. Legitimate communications in the preceding clause means wireless radio telecommunications operating in accordance with the provisions of the Telecommunications Act. Low-power radio frequency electrical devices must tolerate interference from legitimate communications or electrical devices and equipment for industrial, academic and medical use, which emit electromagnetic interference.

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 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 only with the attached integrated loop antenna. The use of any other antenna types are strictly prohibited for use with this device.

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Technical Assistance

For technical assistance, contact Illumina Technical Support.

Table 1 Illumina General Contact Information

Address	5200 Illumina Way San Diego, CA 92122 USA
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
Austria	0800.296575	Netherlands	0800.0223859
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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