

MiSeq FGx™ Instrument Safety and Compliance Guide

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Introduction

The Verogen MiSeq FGx instrument uses sequencing by synthesis technology and integrates cluster amplification, sequencing, and data analysis in a single instrument with a footprint 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.

Symbols

	Manufactured By
	Date of Manufacture
	Model Number
	Serial Number
	Off
	On

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 Reference Guide* (document # VD2018006).

General Safety Warnings

Before operating the MiSeq FGx, all personnel must be trained by Verogen 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 Prep 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 Verogen-authorized personnel should uncrate, install, or move the MiSeq FGx instrument. If the instrument must be relocated, contact Verogen Customer Support to arrange a service visit.

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

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 Verogen for disposal.

Product Compliance

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

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.

Conformidade para o Brasil

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 que operam em caráter primário.

Cumplimiento para México

Advertencia en español: México

El funcionamiento de este equipo está sujeto a las siguientes dos condiciones: (1) es posible que este equipo o dispositivo no cause interferencia perjudicial y (2) este equipo o dispositivo debe aceptar cualquier interferencia, incluida la que pueda causar un funcionamiento no deseado.

台湾合规性

注意！台湾合规性！

根据低功率电波辐射性电机管理办法有关电子设备发射低功率电磁辐射的规定

第12条

已通过型式认证的低功率无线射频电子设备，未经许可，不得擅自更改频率、加大功率或更改原始设计的特征和功能。

第14条

低功率无线射频电子设备的使用不得影响航班飞行安全或干扰合法通讯；如果发现任何干扰情况，必须立即中止使用，并改善至无干扰时方可继续使用。上述合法通讯是指符合电信法条款进行的无线电通信。低功率无线射频电子设备必须忍受来自合法通讯或工业、科学和医疗用电波辐射性电子设备和仪器的干扰。

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.

Technical Assistance

For technical assistance, contact Verogen Technical Support.

Table 1 General Contact Information

Address	11111 Flintkote Avenue San Diego CA 92121 USA
Website	www.verogen.com
Email	techsupport@verogen.com
Phone	+1.833.837.6436 toll-free (North America) +1.858.285.4101 (outside North America)

Safety data sheets (SDSs)

- ▶ For MiSeq FGx sequencing kit safety data sheets, visit www.verogen.com/sds.
- ▶ For Research Use Only (RUO) sequencing reagent and Illumina library preparation kit safety data sheets, visit support.illumina.com/sds.

Product documentation—Available for download in PDF from the Verogen website. Go to www.verogen.com/support select the appropriate document.

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