

NextSeq 500 and NextSeq 550 Sequencing Systems

Safety and Compliance Guide

For Research Use Only. Not for use in diagnostic procedures.

This guide provides important safety information pertaining to the installation, servicing, and operation of the Illumina® NextSeq® 500 and NextSeq® 550 systems. This guide includes product compliance and regulatory statements. Read this document before performing any procedures on the system.

Safety Considerations and Markings

This section identifies potential hazards associated with installing, servicing, and operating the instrument. Do not operate or interact with the instrument in a manner that exposes you to any of these dangers.

All described hazards can be avoided by following the standard operating procedures included in the *NextSeq 500 System Guide* (document # 15046563) or *NextSeq 550 System Guide* (document # 15069765).

General Safety Warnings

Make sure that all personnel are trained in the correct operation of the instrument and any potential safety considerations.



Follow all operating instructions when working in areas marked with this label to minimize risk to personnel or the instrument.

Laser Safety Warning



The NextSeq system is a Class 1 laser product embedded with a Class 3B diode. Class 1 levels of radiation are not considered hazardous.

All laser radiation accessible to the operator is in accordance with IEC 60825-1 accessible limits for Class 1 laser products.

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 50–60 Hz. Hazardous voltage sources are located behind the rear and left side panel, but can be accessible if other panels are removed. Some voltage is present on the instrument even when the instrument is turned off. 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 Supply Rating	600 Watts, maximum

Electrical Connections

Connect the instrument to a grounded circuit capable of delivering at least:

- ▶ 15 Amps for a 100–110 Volt power source
- ▶ 10 Amps for a 220–240 Volt power source

For more information, see the *NextSeq System Site Prep Guide* (document # 15045113).

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 instrument with any of the panels removed.

Do not touch the temperature station in the flow cell compartment. The heater used in this 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 83 kg (183 lb) and can cause serious injury if dropped or mishandled.

Mechanical Safety Warning



Keep fingers away from syringes inside the reagent compartment while the instrument pump is running.

Uncrating, Installing, and Moving the Instrument

Only personnel authorized by Illumina can uncrate, install, or move the instrument. If you must relocate the instrument, contact your Illumina representative.

Environmental Considerations

Element	Specification
Temperature	Maintain a lab temperature of 19°C to 25°C (22°C ±3°C). This temperature is the operating temperature of the instrument. During a run, do not allow the ambient temperature to vary more than ±2°C.
Humidity	Maintain a noncondensing relative humidity between 20–80%.
Elevation	Locate the instrument at an altitude below 2000 meters (6500 feet).
Air Quality	Operate the instrument in an indoor environment with air particulate cleanliness levels per ISO 14644-1 Class 9 (ordinary room / laboratory air), or better. Keep the instrument away from sources of dust.
Ventilation	Consult your facilities department for ventilation requirements based on the instrument heat output specifications.
Vibration	Limit the continuous vibration of the lab floor to ISO office level. During a sequencing run, do not exceed ISO operating room limits. Avoid intermittent shocks or disturbances near the instrument.

Product Compliance and Regulatory Statements

Simplified Declaration of Conformity

Illumina, Inc. hereby declares that the NextSeq 500 is in compliance with the following Directives:

- ▶ EMC Directive [2014/30/EU]
- ▶ Low Voltage Directive [2014/35/EU]
- ▶ RED Directive [2014/53/EU]

The full text of the EU Declaration of Conformity is available at the following internet address: support.illumina.com/certificates.html.

Compliance and Regulatory Markings

The instrument 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 Use Period - 10 years.

Restriction of Hazardous Substances (RoHS)



This label indicates that the instrument meets the WEEE Directive for waste.

Visit support.illumina.com/certificates.html for guidance on recycling your equipment.

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.

Shielded Cables

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

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.

Korea Compliance

해당 무선설비는 운용중 전파혼신 가능성이 있음.

A급 기기(업무용 방송통신기자재)

이 기기는 업무용 (A급)으로 전자파적합로서 판매자 또는 사용자는 이 점을 주의

하십시오. 가정의 지역에서 사용하는 것을 목적으로 합니다.

Revision History

Document	Date	Description of Change
Document # 15046564 v03	March 2020	Removed the Compliance and Regulatory Markings section. Updated the Class A EMC Compliance section and changed the title of the section to Korea Compliance. Updated title to specify Next Seq 500 and NextSeq 550.
Material # 20005369 Document # 15046564 v02	March 2016	Corrected product certification listing to UL 61010-1:2012. Removed Peltier-effect descriptor from heater type. Added translation in Arabic.
Material # 20000084 Document # 15046564 v01	October 2015	Added translations in French, German, Italian, Korean, Portuguese, Russian, Simplified Chinese, and Spanish.
Document # 15046564 B	May 2015	Title change to NextSeq System Safety and Compliance Guide. This guide applies to the NextSeq 500 and the NextSeq 550 systems.
Document # 15046564 A	December 2013	Initial release.

Copyright and Trademarks

© 2020 Illumina, Inc. All rights reserved.

All trademarks are the property of Illumina, Inc. or their respective owners.

For specific trademark information, see www.illumina.com/company/legal.html.