NextSeq 550Dx

illumina®

Instrument Safety and Compliance Guide

Safety and Compliance

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

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

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 550Dx Instrument Reference Guide (document # 1000000009513)*.

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 550Dx 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

Table 1 Instrument 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 550Dx Instrument Site Prep Guide (document # 1000000009869)*.

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 86 kg (184 lb) and can cause serious injury if dropped or mishandled.

Mechanical Safety Warning

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

Uncrating, Installing, and Moving

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

Environmental Considerations

For indoor use only.

Element	Specification
Temperature	Transportation and Storage: -10°C to 50°C (14°F to 122°F). Operating Conditions: 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	Transportation and Storage: Non-condensing humidity between 15-80%. Operating Conditions: 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 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.
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.

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)
	Consult the Instructions for Use

Product Compliance and Regulatory Statements

Simplified Declaration of Conformity

Illumina, Inc. hereby declares that the NextSeq 550Dx instrument 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.

Restriction of Hazardous Substances (RoHS)

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

Visit support.illumina.com/weee-recycling.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.)

For information on RFID compliance, see the *RFID Reader Module Compliance Guide (document # 1000000030332)*.

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.

NOTE Harmful interference is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the International Telecommunication Union (ITU) Radio Regulations.

Shielded Cables

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

EMC Considerations

This IVD medical equipment complies with the emission and immunity requirements described in IEC 61326-2-6.

Evaluate the electromagnetic environment before operation of the device. Consult *NextSeq 550Dx Intended Use Environment* on page 6 to determine the proper electromagnetic environment.

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.

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

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.

NextSeq 550Dx Intended Use Environment

The intended use environment for the NextSeq 550Dx is limited to laboratory environments of professional healthcare facilities. The instrument is not intended to be used in any of the following environments: physician offices; intensive care units; emergency rooms or ambulatory centers; surgical or operating rooms; healthcare clinics; patient rooms; dental offices; limited care facilities; nursing homes; drugstores or pharmacies; first aid rooms; or near high sources of electromagnetic radiation (eg MRI). Based on the intended use environment defined above, the NextSeq 550Dx is considered to be a CONTROLLED ELECTROMAGNETIC ENVIRONMENT with fixed electromagnetic sources and any malfunction of the NextSeq 550Dx will not directly cause harm, serious injury, or death of a patient when the NextSeq 550Dx is used as intended. Electromagnetic sources that might be used adjacent to NextSeq 550Dx include the following:

- Radio frequency identification (RFID) systems
- Wireless local area networks (WLAN)
- Handheld mobile radios (eg, TETRA, two-way radio)
- Paging systems

• Other wireless devices (including consumer devices)

The following tables should be consulted when determining the proper EMC use environment for the NextSeq 550Dx.

Emissions	Test Limits
CISPR 11	Class A
IEC 61000-3-2	Class A
IEC 61000-3-3	Per Clause 5 of the Standard

Immunity	Test Limits
IEC 61000-4-2	IEC 61236-2-6:2020 (Professional Health Care)
IEC 61000-4-3	IEC 60601-1-2:2014/AMD1:2020 (Professional Health Care)
IEC 61000-4-4	IEC 60601-1-2:2014/AMD1:2020 (Professional Health Care)
IEC 61000-4-5	IEC 60601-1-2:2014/AMD1:2020 (Professional Health Care)
IEC 61000-4-6	IEC 60601-1-2:2014/AMD1:2020 (Professional Health Care)
IEC 61000-4-8	IEC 60601-1-2:2014/AMD1:2020 (Professional Health Care)
IEC 61000-4-11	IEC 60601-1-2:2014/AMD1:2020 (Professional Health Care)

Recommended Separation Distances for Radio Frequency Devices

Reduce the potential for electromagnetic interference by maintaining a minimum distance between portable and mobile radio frequency (RF) communications equipment (transmitters), and the system based on the maximum output power of the RF communications equipment.

The calculation formula to determine the separation distance between an IVD MEDICAL EQUIPMENT and a mobile phone is given by d = 6/E * √P, where d is the minimum separation distance in meters, P is the maximum power in watts, and E is the immunity test level in V/m.

P Rated maximum output power of RF transmitter (watts)	E Immunity test level (volts/meter)	d Minimum separation distance (meters)
0.01	3	0.20
0.1	3	0.63
0.5	3	1.41
1	3	2.00
2	3	2.83
3	3	3.46

P Rated maximum output power of RF transmitter (watts)	E Immunity test level (volts/meter)	d Minimum separation distance (meters)
4	3	4.00
5	3	4.47
6	3	4.90
7	3	5.29

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 무선 설비는 운용 중 전파 혼신 가능성이 있음.

A급 기기(업무용 방송통신기자재)

이 기기는 업무용(A급) 전자파적합기기로서 판매자 또는 사용자는 이 점을

주의하시기 바라며, 가정 외의 지역에서 사용하는 것을 목적으로 합니다.

Japan Compliance

この装置は、クラスA機器です。この装置を住宅環境で使用すると電波妨害

を引き起こすことがあります。この場合には使用者が適切な対策を講ずるよう

要求されることがあります。VCCI - A

Thailand Compliance

This telecommunication equipment conforms to NTC/NBTC technical requirements.

Nigeria Compliance

Connection and use of this communications equipment is permitted by the Nigerian Communications Commission.

Revision History

Document	Date	Description of Change
Document # 1000000009868 v05	October 2023	Updated EMC information. Added intended use environment information.
Document # 1000000009868 v04	August 2021	Updated EU Authorized Representative address.
Document # 1000000009868 v03	November 2020	Added compliance statements for Thailand, Japan, and Nigeria. Added Indoor Use Only Statement to Environmental Considerations section.
Document # 1000000009868 v02	December 2019	Updated EU Authorized Representative address. Updated Australian Sponsor address.
Document # 1000000009868 v01	August 2018	Updated regulatory markings.
Document # 1000000009868 v00	November 2017	Initial release.

Patents and Trademarks

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Product Labeling

For a complete reference of symbols that appear on product packaging and labeling, refer to the symbol key at support.illumina.com on the *Documentation* tab for your kit.