illumına[®]

NovaSeq Series

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[®] NovaSeq™ Series. This guide includes product compliance and regulatory statements. Read this document before performing any procedures on the system.

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 of the hazards described herein can be avoided by following the standard operating procedures included in the NovaSeq 6000 Sequencing System Guide (document # 1000000019358).

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 NovaSeq 6000 is a Class 1 laser product that contains 2 Class 4 lasers, 1 Class 3B laser, and 1 Class 3R laser.

Class 4 lasers present an eye hazard from direct and diffuse reflections. Avoid eye or skin exposure to direct or reflected Class 4 laser radiation. Class 4 lasers can cause combustion of flammable materials and produce serious skin burns and injury from direct exposure.

Class 3B lasers present an eye hazard. They can heat skin and materials, but are not a burn hazard.

Class 3R lasers present an eye hazard from direct eye exposure to the laser beam

Do not operate the instrument with any of the panels removed. When the flow cell door is open, safety interlock switches block the laser beam. If you operate the instrument with any panels removed, you risk exposure to direct or reflected laser light.

Laser Labeling

Figure 1 Class 4 and Class 3R Laser Warning (English)

DANGER – CLASS 4 AND 3R VISIBLE AND INVISIBLE LASER RADIATION WHEN OPEN. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION

Figure 2 Class 4 and Class 3R Laser Warning (French)

DANGER – RAYONNEMENT LASER VISIBLE ET INVISIBLE DE CLASSE 4 ET 3R EN CAS D'OUVERTURE EXPOSITION DANGEREUSE AU RAYONNEMENT DIRECT OU DIFFUS DES YEUX OU DE LA PEAU

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 200–240 volts AC operating at 50/60 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 turned off. Operate the instrument with all panels intact to avoid electrical shock.

Power Specifications

Туре	Specification
Line Voltage	200-240 VAC at 50/60 Hz
Peak Power Consumption	2500 Watts

For 200–240 Volts AC, your facility must be wired with a minimum 15 Amp grounded line with proper voltage. An electrical ground is required. If the voltage fluctuates more than 10%, a power line regulator is required.

For more information, see the *NovaSeq Series Site Prep Guide (document # 1000000019360)*.

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 60°C. Exposure to temperatures at the upper end of this range can result in burns.

Heavy Object Safety Warning



The instrument weighs approximately 447 kg (985 lb) shipped and approximately 576 kg (1270 lb) installed and can cause serious injury if dropped or mishandled.

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). Failure to operate the instrument within the temperature range can degrade performance or cause a run to fail.	
Humidity	Maintain a noncondensing relative humidity between 20–80%. Preferred range is a relative humidity between 20–60%.	
Elevation	Locate the instrument at an elevation below 2000 meters (6500 feet).	
Air Quality	Operate the instrument in an indoor environment with air particulate cleanliness levels per ISO 9 (ordinary room air), or better. Keep the instrument away from sources of dust.	
Vibration	Limit the continuous vibration of the lab floor to ISO operating room level (baseline), or better. During a sequencing run, limit intermittent disturbances or shocks to the floor near the instrument. Do not exceed ISO office level.	



NOTE

Avoid a combination of high temperature and high humidity. For example, 25°C and 80% relative humidity.

Product Compliance and Regulatory Statements

Simplified Declaration of Conformity

Illumina, Inc. hereby declares that the NovaSeq 6000 is in compliance with the following Directives:

- ► EMC Directive [2014/30/EU]
- ► Low Voltage Directive [2014/35/EU]
- ► R&TTE Directive [1995/5/EC]
- ▶ 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/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.)

For information on RFID compliance, see the *RFID Reader Module Compliance Guide (document # 1000000002699).*

EMC Considerations

This equipment has been designed and tested to the CISPR 11 Class A standard. In a domestic environment, it might cause radio interference. If radio interference occurs, you might need to mitigate it.

Do not use the device in close proximity to sources of strong electromagnetic radiation, which can interfere with proper operation.

The instrument must be used in a controlled electromagnetic environment using an approved uninterruptible power supply (UPS) as specified in the *NovaSeq Series Site Prep Guide (document #1000000019360)*.

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

해 당 무 선 설 비 는 운 용 중 전 파 혼 신 가 능 성 이 있 음. A급 기 기 (업 무 용 방 송 통 신 기 자 재)

이 기 기 는 업 무 용 (A급)으 로 전 자 파 적 합 로 서 판 매 자 또 는 사 용 자 는 이 점 을 주 의

하 시 기 바 라 며 , 가 정 외 의 지 역 에 서 사 용 하 는 것 을 목 적 으 로 합 니 다 .

United Arab Emirates Compliance

TRA Registered Number: ER0117765/13

Dealer Number: DA0075306/11

Thailand Compliance

This telecommunication equipment conforms to NTC/NBTC technical requirements.

Revision History

Document	Date	Description of Change
Material # 20022644 Document # 100000019357 v04	June 2018	Added Thailand Compliance statement.
Material # 20022644 Document # 100000019357 v03	September 2017	Updated EMC Consideration section with requirement to use the instrument in a controlled electromagnetic environment using an Illumina specified UPS.
Material # 20018922 Document # 1000000019357 v02	March 2017	Updated grounded line amperage requirement to 15 Amp minimum. Updated grounded line requirement to 16 Amps. Added the following translations: Arabic, Chinese (Simplified and Traditional), French, German, Italian, Korean, Portuguese, Russian, and Spanish.
Material # 20018407 Document # 1000000019357 v01	March 2017	Added the Simplified Declaration of Conformity section.
Material # 20015873 Document # 1000000019357 v00	February 2017	Initial release.

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