



Safety Guide

Sequel[®] II and Sequel IIe Systems: The SMRT[®] Sequencers

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Notice of Equipment Class (Korea)
For Class A

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The Obelis Group is a Pacific Biosciences European Authorized Representative for product CE marking regulatory compliance (as per regulation 2019/1020/EU).

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Introduction

This guide provides important safety information on the Sequel[®] II and Sequel IIe Systems from Pacific Biosciences. It also provides product compliance and regulatory statements. Read this document before performing any procedures on the Sequel II or Sequel IIe Systems.

Safety Words

Four safety alert words may appear in Pacific Biosciences' documents. Each alert word represents a certain level of observation or action:

IMPORTANT!

Indicates information that is necessary for proper system operation, accurate chemistry kit use, or safe use of a chemical.

CAUTION!

Indicates a potentially hazardous event that, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.

WARNING!

Indicates a potentially hazardous event that, if not avoided, could result in death or serious injury.

DANGER!

Indicates an imminently hazardous event that, if not avoided, will result in death or serious injury. This alert word is limited to the most extreme situations.

Except for **IMPORTANT!**, each safety alert word will appear with an open triangle figure that contains a hazard symbol. These symbols are similar to the hazard symbols that are affixed to the instrument.

**Product
Certifications and
Compliance**

The Sequel II and Sequel IIe Systems are certified to the following standards:

- UL STD 61010-1
- CSA STD C22.2 No 61010-1
- EN/IEC 61010-1
- IEC 61326-1
- IEC/EN 60825-1






FCC: 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, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The Sequel II and Sequel IIe Systems comply with the following EU Directives:

- Low Voltage Directive (LVD) 2014/35/EU
- Electromagnetic Compatibility (EMC) Directive 2014/30/EU
- RoHS-3 DIRECTIVE 2015/863/EU





Compliance and Regulatory Markings



The PacBio® Sequel II and Sequel IIe Systems are labeled with the following compliance and regulatory markings.

Symbol	Description
	This label assures that the product meets requirements for all relevant EU directives.
	This label assures that the product meets Chinese RoHS regulatory requirements.
	This label assures that the product is compliant with safety standards and has been tested and certified by a third party organization.
	Korea compliance. Equipment for professional use (Class A). The seller or end user of the device with EMC requirements should use the equipment with caution and only under professional environments.
	The RCM label indicates the product is compliant with the applicable technical standards for Electromagnetic Compatibility (EMC). The RCM mark is a certification trademark registered to ACMA (for Australia and New Zealand).

Symbols on Instrument




The following are symbols or labels that may be affixed to the instrument.

Symbol	Description
	Designates the On position of the main power switch
	Designates the Off position of the main power switch
	Designates a standby switch by which the instrument is switched on to the Standby condition. Hazardous voltage may be present if this switch is on standby
	Designates a terminal that may be connected to the signal ground reference of another instrument. This is not a protected ground terminal

Symbol	Description
	Designates a protective grounding terminal that must be connected to earth ground before any other electrical connections are made to the instrument
	Designates a terminal that can receive or supply alternating current or voltage


Safety Symbols

The following are safety symbols or labels that may appear on the instrument. Each symbol may appear by itself or with other text that explains the relevant hazard.

Symbol	Description
	Indicates you should consult and follow all operating instructions when working in areas marked with this symbol. Proceed with appropriate caution.
	Indicates the presence of a laser inside the instrument. Proceed with appropriate caution when the flow cell compartment door is open. The flow cell area contains components that could cause injury when the front door is open. When this is the case, the X, Y, and Z motors are disabled by the instrument operating software.
	Indicates the presence of an electrical shock hazard and/or high leakage current. Earth connection is essential before connecting supply. Proceed with appropriate caution.

Environmental Symbols on Instrument

This environmental symbol or label may appear on the instrument.

Symbol	Description
	Designates that you should not dispose of product as unsorted municipal waste. You must follow local municipal waste ordinances and regulations for proper disposal to reduce the environmental impact of waste electrical and electronic equipment (WEEE)

Safety Symbols on Instrument

The Sequel II and Sequel IIe Systems are Class 1 Laser Products that contains two Class 4 lasers.



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

DANGER - CLASS 4 VISIBLE AND INVISIBLE LASER RADIATION WHEN OPEN AND INTERLOCK DEFEATED. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION

WAVELENGTH	MAX. POWER
0.52-0.57 μm	1.3 W
0.79-0.82 μm	20 mW
1.04-1.14 μm	200 mW

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

CAUTION! Laser testing and service maintenance must only be performed by authorized and trained Pacific Biosciences personnel. Only PacBio trained personnel are authorized to remove the instrument panels.

Safety Practices

A safety representative from your facility must ensure that there are established safety practices and policies to protect laboratory personnel from potential hazards.

Required Safety Equipment

Your laboratory should have specific safety devices and equipment to protect personnel from any sources of hazardous chemicals, radiation (for example, lasers, radioisotopes, radioactive wastes, and contaminated equipment), and potentially infectious biological material that may be present in the area where the Pacific Biosciences service representative will work.

The following safety protection and equipment must be available at the installation site:

- Appropriate fire extinguisher:
 - The types and sizes of fire extinguishers shall be suitable for use on electrical and chemical fires as specified in current codes, regulations/ or standards, and with approval of the Fire Marshall or other authority having jurisdiction.
 - The installation of appropriate fire extinguishers shall be in addition to other fire-protection systems and not as a substitute or alternative to them.
 - Overhead sprinklers can be used if the water heads are not located above or directed at the equipment or it's fan intake/exhasut path.
- Eyewash.
- Safety shower.
- Eye and hand protection.
- Adequate ventilation, including vent line/fume hood, if applicable.
- Biohazard waste container, if applicable.
- First-aid equipment.
- Spill cleanup equipment.
- Applicable SDS.

Personnel Safety Considerations

Facility personnel (especially laboratory personnel) should be familiar with the emergency power shut-down procedure and with how to notify the fire department.

Laboratory personnel are adequately protected from electrical shock, however, all personnel trained in first aid for electrical shock and burns should always be available.

Unauthorized personnel should not remove any of the system's panels. The panels are provided for system cooling and protection of electronics.

Site Preparation Considerations

The overall site preparation recommendations are summarized below:

- Ensure your site is appropriately stocked with the needed materials. Note that only supported consumables and accessories may be used with the Sequel II and Sequel IIe Systems.
- In cases of limited user accessibility to the instrument work deck or controls, appropriate accommodations must be made by the customer site according to local regulations.

CHEMICAL SAFETY

Chemical Hazard Warnings

Before handling any chemicals, refer to the Safety Data Sheet (SDS) provided by the manufacturer, and observe all relevant precautions.

The system is used to conduct scientific experiments that require the use of the following reagents:

- Template Prep Buffer
- ATP Hi
- dNTP
- End Repair Mix
- Adapter
- ATP Lo
- Ligase
- ExoIII
- ExoVII
- dATP
- Klenow
- OS Enzyme
- DTT
- MagBeads
- MagBead Binding Buffer
- MagBead Wash Buffer
- AMPure PB beads
- SMRT Cell Oil

These items are transferred from disposable tips to SMRT[®] Cells which are then transferred to an internal waste bin in an automated fashion. Once the system's internal waste bin is full, it must be emptied by the user. The system does not generate any additional waste.

About Safety Data Sheets

Chemical manufacturers supply current Safety Data Sheets (SDS) with shipments of hazardous chemicals to new customers. They also provide an SDS with the first shipment of a hazardous chemical to a customer after an SDS has been updated. Safety Data Sheets provide the safety information you need to store, handle, transport, and dispose of the chemicals safely.

Each time you receive a new SDS packaged with a hazardous chemical, be sure to replace the appropriate SDS (supplied by Pacific Biosciences) in your files.

To Obtain an SDS

Any chemical supplied by Pacific Biosciences will have an SDS available on our website: www.pacificbiosciences.com.

For the SDS of chemicals not distributed by Pacific Biosciences, contact the chemical manufacturer.

General Chemical and Chemical Waste Safety Guidelines

To minimize the hazards of chemicals and chemical waste:

- Read and understand each Safety Data Sheet provided by the chemical manufacturer before you store, handle, work with, or dispose of any chemicals, chemical waste, or hazardous materials.
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing). For additional safety guidelines, consult the SDS.
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with adequate ventilation (for example, fume hood). For additional safety guidelines, consult the SDS.
- Provide primary and secondary waste containers. A primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage.
- Handle chemical wastes in a fume hood. After emptying a waste container, seal it with the cap provided.
- Dispose of the contents of the waste tray and waste bottle in accordance with good laboratory practices and local, state/provincial, or national environmental and health regulations.
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer's cleanup procedures as recommended in the SDS.
- Comply with all local, state/provincial, or national laws and regulations related to chemical storage, handling, and disposal.

Waste Disposal

If potentially hazardous waste is generated when you operate the instrument, you must:

- Characterize the waste generated by the particular applications, reagents, and substrates used in your laboratory.
- Ensure the health and safety of all personnel in your laboratory.
- Ensure that the instrument waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.

IMPORTANT! Radioactive or biohazardous materials may require special handling and disposal limitations may apply. Consult the SDS of the chemical for disposal information.

General Power Requirements

Input power and grounding must be available prior to system installation. Sufficient AC power must be available for all equipment. A separate earth safety ground connection is also required for the whole system.

Please note that an electrical conduit is not an acceptable separate earth ground path. However, water pipes or other known good earth ground paths may sometimes be used. Consult your local code and regulations to determine if water pipes or other earth ground paths are acceptable forms of grounding.

Locate the fuse or circuit-breaker-protected AC outlets and safety ground connections as close to the system as possible (in order to keep cable runs as short as possible).

System Input Power Requirements

WARNING! ELECTRICAL HAZARD. Grounding circuit continuity is vital for the safe operation of equipment. Never operate equipment with the grounding conductor disconnected. Wiring must conform to country and local electrical codes.

DANGER! ELECTRICAL SHOCK HAZARD. Severe electrical shock can result from operating the instrument without the instrument panels in place. Do not remove the instrument panels. High-voltage contacts are exposed when instrument panels are removed from the instrument.

DANGER! ELECTRICAL HAZARD. Use properly configured and approved line cords for the voltage supply in your facility.

DANGER! ELECTRICAL HAZARD. Plug the system into a properly grounded receptacle with adequate current capacity.

Overvoltage Rating

The Sequel II and Sequel IIe Systems have an installation (overvoltage) category of II (two) and is classified as nonportable equipment.

Electrical Connections

The Sequel II and Sequel IIe Systems must be plugged into a grounded circuit capable of delivering at most 30 Amps for a 200-240V power source.

The maximum power consumption is 3000 Watts.

DANGER!

ELECTRICAL SHOCK AND LASER HAZARD Installation, maintenance and repair are only allowed for authorized service personnel. Do not remove the panels of the Sequel II or Sequel IIe Systems.

For more information, see the *Pacific Biosciences Sequel II and Sequel IIe Systems Site Preparation Guide*.

LASER SAFETY

Laser Classifications

The Sequel II and Sequel IIe Systems are Class 1 Laser Products that contain two Class 4 lasers.

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.

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

DANGER - CLASS 4 VISIBLE AND INVISIBLE LASER RADIATION WHEN OPEN AND INTERLOCK DEFEATED. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION

WAVELENGTH	MAX. POWER
0.52-0.57 μm	1.3 W
0.79-0.82 μm	20 mW
1.04-1.14 μm	200 mW

Indicates the presence of a laser inside the instrument. Proceed with appropriate caution.

Laser Safety Requirements

To ensure safe laser operation:

- The system must be installed and maintained by a Pacific Biosciences representative.
- All instrument panels must be in place on the instrument while the instrument is operating. When all panels are installed, there is no detectable radiation present and the instrument is Class 1. If any panel is removed when the laser is operating (during service), you may be exposed to laser emissions in excess of the Class 4 rating.
- Do not remove safety labels or panels.

DANGER!



ELECTRICAL SHOCK AND LASER HAZARD Installation, maintenance and repair are only allowed for authorized service personnel. Do not remove the panels of the Sequel II or Sequel IIe Systems.

WARNING! LASER HAZARD. Lasers can burn the retina, causing permanent blind spots. Never look directly into the laser beam. Remove jewelry and other items that can reflect the beam into your eyes. Do not remove the instrument panels. Wear proper eye protection and post a laser warning sign at the entrance to the laboratory if the panels are removed for service.

**Bar Code Scanner
Laser Safety
Requirements**

The Sequel II and Sequel IIe Systems come with a bar code scanner. Bar code scanners are categorized as Class 2 lasers.

Class 2 lasers are low-power, visible-light lasers that can damage the eyes. Never look directly into the laser beam. The scanner is designed to prevent human access to harmful levels of laser light during normal operation, user maintenance, or during prescribed service operations.

WARNING! LASER HAZARD. Class 2 lasers can cause damage to eyes. Avoid looking into a Class 2 laser beam or pointing a Class 2 laser beam into another person's eyes.