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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 Revio™ system from Pacific Biosciences. It also provides product compliance and regulatory statements. Read this document before performing any procedures on the Revio 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 Revio system is 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 Revio system complies 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® Revio system is 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).

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




Symbols on 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 Revio system is a 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.

PacBio

Model: Revio
Part number: 102-090-600
Serial number: 8XXXX
Manufacture date: 20XX-XX-XX
Input: 200-240VAC, 50/60Hz, max 5000VA



This equipment complies with part 15 of the FCC rules. Operation is subject to the following conditions:
 1. This device may not cause harmful interference.
 2. This device must accept any interference that may cause undesired operation.
 This product complies with 21 CFR 1040.10 and 1040.11

WARNING!

High leakage current. Earth connection essential before connecting the supply.

Assembled in USA | Menlo Park, CA 94025 USA | 650.521.8000

Research use only.
 Not for use in diagnostic procedures.

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 actual or expected hazards in the work area or from the operations and processes performed.

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

- Personal protective equipment such as lab coats, eye protection and hand protection.
- Portable fire extinguisher:
- Emergency washing station (eyewash or shower).
- Adequate ventilation, including vent line/fume hood, if applicable.
- First-aid equipment.
- Spill cleanup equipment.

Personnel Safety Considerations

Laboratory personnel should be familiar with procedures for handling emergencies. This includes fire emergencies, medical emergencies, power shut-down procedures and how to notify the fire department.

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

Pinch Point Safety Precautions

Do not place your hands or fingers between the door and chassis frame when the door is closing or opening.

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 Revio system.
- 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.

Operating environment

- Temperature: $22^{\circ}\text{C} \pm 3^{\circ}\text{C}$
- Humidity: Noncondensing 20%-80%
- Altitude: Less than 2,000m (6,500 ft)
- Air quality: Pollution degree rating of II
- For Indoor Use Only

CHEMICAL SAFETY

Chemical Hazard Warnings

The system is used to conduct scientific experiments that require the use of chemicals. Chemical reagents are present on the Revio sequencing plate.

Before handling the sequencing plate, refer to the Safety Data Sheet (SDS) provided by PacBio, and observe all relevant precautions.

About Safety Data Sheets

Chemical manufacturers are required to assess the hazards of their products and communicate those hazards using an SDS. PacBio SDS are available on the PacBio website or by contacting your sales rep or tech support.

For SDS of chemicals not sold by PacBio, 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 exposure to chemicals by wearing appropriate personal protective equipment and working in a well ventilated area. Refer to the SDS for specific recommendations.
- Collect all waste in accordance with your site-specific guidelines for waste disposal. Ensure your waste containers are compatible with the waste materials and are labeled to communicate the composition and hazards of the waste.
- 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.

Preparation of DNA libraries may involve handling of infectious or biohazardous DNA source materials. Follow all site protocols for handling of biological materials. Your site may have special practices for handling Risk Group 2 or above materials. Know the source of the DNA you are handling.

Follow PacBio recommendations using the sample preparation protocols to avoid any potential contamination of source materials, DNA libraries and work surfaces. Clean work surfaces regularly to control potential contamination.

Waste Disposal

The instrument has an onboard waste collection container. Be sure to empty this container before or after each processing run. Follow your site-specific waste practices for disposal of the contents of the onboard waste container, used sequencing plate and other instrument consumables.

Refer to the SDS for information on chemical hazards of reagents. This information can help you in determining appropriate waste disposal practices.

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 Revio system has an installation (overvoltage) category of II (two) and is classified as nonportable equipment.

**Electrical
Connections**

The Revio system must be plugged into a grounded circuit for a 200-240VAC power source, 50/60Hz, and absolute maximum 5000VA / 4.5kW / 24A.

High leakage current - same as shown on label:



DANGER!

ELECTRICAL SHOCK AND LASER HAZARD Installation, maintenance and repair are only allowed for authorized service personnel. Do not remove the panels of the Revio system.

For more information, see the *Pacific Biosciences Revio system site preparation guide*.

LASER SAFETY

Laser Classifications

The Revio system is a Class 1 Laser Products that contain two Class 4 lasers. Under normal use and operation, operators are not exposed to laser radiation from the instrument lasers.

Information about the lasers located safely inside the instrument can be found on the laser safety label attached to each instrument and shown below.

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

Laser Safety Requirements

To prevent unwanted exposure to laser radiation:

- 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 laser radiation present.

DANGER!

ELECTRICAL SHOCK AND LASER HAZARD Installation, maintenance and repair are only allowed for authorized service personnel. Do not remove the panels of the Revio system.



WARNING! LASER HAZARD. Never remove instrument panels. Panels should only be removed by PacBio authorized personnel. During instrument service and maintenance abide by all signage and instructions posted by the field service engineer (FSE). Failure to follow FSE instructions could result in eye injury.

**Bar Code
Scanner**

The Revio system comes with a bar code scanner and is a Near Field Communication (NFC) Reader. NFCs create 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.