

PacBio



The Onso™ system
and cluster
generator -
Safety guide



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Pacific Biosciences of California, Inc.
1305 O'Brien Dr.
Menlo Park, CA 94025
www.pacificbiosciences.com

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).

Contact information: Obelis Group

Address: Bd Général Wahis, 53 B-1030 Brussels Belgium. Tel:
+3227325954; Fax: +3227326003; mail@obelis.net

Introduction

This guide provides important safety information on the Onso™ system, which includes the sequencer and a cluster generator from PacBio. It also provides product compliance and regulatory statements. Read this document before performing any procedures on the Onso system.

Safety words

Four safety alert words may appear in PacBio 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 system.

Product certifications and compliance

The Onso 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


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 Onso system complies with the following EUDirectives:

- 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® Onso 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 system.

Symbols on the system

Symbol	Description
	Designates the On position of the main power switch
	Designates the Off position of the main power switch
	Designates a terminal that may be connected to the signal ground reference of another instrument. This is not a protected ground terminal
	Designates a protective grounding terminal that must be connected to earth ground before any other electrical connections are made to the system
	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 system. 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 an electrical shock hazard and/or high leakage current. Earth connection is essential before connecting supply. Proceed with appropriate caution.

Environmental symbols on the system


This environmental symbol or label may appear on the system.


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 the system


PacBio


Model: Onso System
Part number: 102-837-000
Serial number: OS10XXX
Manufacture date: YYYY-MM-DD
Input: 100–240V~, 50/60Hz, Max 800VA



FCC Class A



N136











UL



UL


UL


UL


UL


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


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


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Not for use in diagnostic procedures.


PacBio


Model: Onso Cluster Generator
Part number: 102-837-100
Serial number: OC10XXX
Manufacture date: YYYY-MM-DD
Input: 100–240V~, 50/60Hz, Max 400VA



FCC Class A



N136











UL



UL


UL


UL


UL

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

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

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Safety practices

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

Recommended 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 are recommended 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 the procedures for handling emergencies. This includes fire emergencies, medical emergencies, power shut-down procedure and how to notify the fire department.

Unauthorized personnel must not remove any of the system's panels. The panels are in place to protect unauthorized personnel from hazards present inside the instrument. The panels also help the system remain cool during operation and protect internal components and 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 Onso system.
- In cases of limited user accessibility to the system work decks or controls, appropriate accommodations must be made by the customer site according to local regulations.

Operating environment for the sequencer

- Temperature: 18-26°C
- Humidity: Noncondensing 20%-80%
- Altitude: Less than 2,000m (6,500 ft)
- Air quality: Pollution degree rating of II
- For Indoor Use Only

Operating environment for the cluster generator

- Temperature: 18-26°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 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:

Provided by PacBio:

- Onso clustering reagent plate'
- Onso Sequencing reagent kit

Provided by others:

- DNA Library
- Laboratory grade water
- 70% Isopropanol
- 1N sodium hydroxide solution
- Concentrated TE buffer
- 10% w/v Tween 20 (molecular biology grade)
- 0.1% sodium hypochlorite solution (diluted bleach)

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 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 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 material and are labeled to communicate hazard associated with 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 and DNA libraries. Clean work surfaces regularly to control potential contamination.

CAUTION! Biohazardous materials may require special handling and disposal limitations may apply.

**Cross
contamination**

Note that cross contamination of amplicons is possible with Onso libraries. Consult the appropriate library preparation procedures and checklists for further information.

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 and any left-over reagents.

The sequencing reagent pack may be dismantled to allow for different disposal practices for different reagents.

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 sequencer without the sequencer panels in place. Do not remove the sequencer panels. High-voltage contacts are exposed when sequencer panels are removed from the sequencer.

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

**Electrical
connections**

The Onso system sequencer must be plugged into a grounded circuit for a 100 – 240 VAC power source, 50/60Hz, and absolute maximum 800 VA.

The Onso cluster generator must be plugged into a grounded circuit for a 100 – 240 VAC power source, 50/60Hz, and absolute maximum 400 VA.



DANGER!

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

For more information, see the *PacBio Onso system site preparation guide*.

BARCODE SCANNER

Optional Barcode Scanner

The Onso system can optionally come with an LED source barcode scanner. LED source barcode scanners are used for close-range scanning applications and read barcodes when placed close to the scanner.