

USER MANUAL

Cellanome Instrument



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Version history

Version	Date	Description
Version 1.0	August 2024	FCC Early adopter version

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Section 1: About this manual

Purpose

This user manual provides instructions for the safe operation and maintenance of the Cellanome instrument (V1, V2).



IMPORTANT! Before using this product, thoroughly review the information provided in this manual, and refer to [Section 3](#) for relevant safety information. Wear appropriate personal protective equipment (PPE) when operating the system and handling your samples.

The information in this manual is subject to change without notice.

General information

FCC compliance: 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 used in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction 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 the user will be required to correct the interference at their own expense.

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. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

IC/ISED: This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Transportation

The Cellanome instrument relies upon many delicate alignments for proper operation. Consult your Cellanome representative if you wish to transport or relocate the instrument.



Ventilation and disconnect

Provide at least 3 in (~8 cm) of clearance behind the instrument to maintain proper ventilation. Do not position the instrument so that it is difficult to disconnect the power cord. The instrument has feet that keep the intake fans on the bottom of the instrument at least 1 in (~3 cm) above the table that it rests on. Keep debris (including tubes, paper, pens, etc.) at least 3 in (~8 cm) away from the instrument on all sides to prevent blockage of the filter in the bottom enclosure.

Cleaning

Refer to [Section 5](#) for cleaning and maintenance instructions. Dispose of waste using proper precautions and in accordance with local regulations.

Preventative maintenance

Follow routine maintenance as described in this User Manual. Access to other parts of the instrument for preventative maintenance is restricted to Cellanome personnel.

Access to moving parts

Movement of mechanical parts within the instrument can cause injury to fingers and hands. Access to moving parts inside the instrument is intended for Cellanome personnel only.

Protection impairment

Use of controls or adjustments other than specified in this User Manual may result in hazardous exposure to laser radiation, biohazards, or injury from the mechanical or electrical components.

Section 2: Product overview

Product functions and features

The Cellanome instrument (V1, V2) is an automated platform that enables a richer understanding of individual cell behaviors, interactions, and functions across a range of conditions and parameters.

The platform enables iterative live cell phenotypic, functional and genomic assays, at scale, clearly linking each cell's response to specific perturbations. This allows for a more granular view of the heterogeneity of cellular responses, highlighting individual cellular responses over bulk measurements, and facilitating combinatorial assays without needing to switch platforms or consume additional samples.

The platform is compatible across a range of cell types, including large and challenging cell types, and enables observation of cell-to-cell interactions over time. It is designed to integrate seamlessly into existing cell biology workflows, offering flexibility for modifying or creating new live cell assays.

Platform components

The Cellanome platform consists of the instrument, 8-lane flow cells that allow for multiple analyses and conditions per run, kitted reagents that can be flexibly combined with user-provided reagents, simple-to-use operation software that be controlled on-instrument or remotely, and a powerful cloud platform for data storage and analysis.

Cellanome-provided consumables

List of available kits and reagents below:

- Cellanome Multiomic Core Kit for suspension cells (2 x 4 lanes)
- Cellanome Non-Genomic Core Kit for suspension cells (2 x 4 lanes)
- Cellanome Whole Transcriptome Assay Kit (2 x 4 lanes)



About the product

System overview



EXTERIOR VIEW: DOOR OPEN



EXTERIOR VIEW: DOOR CLOSED

- 1: Reagent deck
- 2: Reagent drawer
- 3: Water, ethanol, and liquid waste
- 4: Display
- 5: Vent
- 6: Vent
- 7: Status light

Instrument set up

Open the door and ensure the work deck is clean before initiating a run. See [Section 5](#) for cleaning and maintenance instructions.

Empty liquid waste container into hazardous liquid waste and ensure there are sufficient levels in the ethanol and H₂O containers.

Empty any used tips in the tip disposal bin into hazardous waste and place a new biohazard bag in the container.

Place new pipet tip containers into position ensuring lids are removed.

Place all required reagents and materials into position as indicated on the instrument.

After the run finishes, remove eluted DNA if applicable, place all used consumables in hazardous solid waste, and empty the liquid waste container into hazardous liquid waste.

Section 3: Safety

⚠ WARNING! GENERAL SAFETY. Using this system in a manner not specified in the user documentation may result in personal injury or damage to the system or device. Ensure that anyone using this system has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using a system or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the system or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, etc.).
- There are no user-serviceable parts inside the instrument. Service of any internal parts should be performed by a qualified Cellanome service technician.

⚠ CAUTION! Do not remove system protective covers. If protective system panels are removed, there may be risk of exposure to serious hazards including, but not limited to, severe electrical shock, high intensity emission exposure, crushing, or chemical exposure. The instrument is only safe to operate with the covers in place. External covers must not be removed during operation.

⚠ WARNING! Ensure appropriate electrical supply. The Cellanome instrument is rated to the following specifications: AC 100-240V, 50-60Hz, and 10 Amps. For safe operation of the system:

- Plug the system into a properly grounded receptacle with adequate current capacity.
- Ensure the electrical supply is of suitable voltage.
- Never operate the system with the ground disconnected. Grounding continuity is required for safe operation of the system.
- Use properly configured and approved line cords for the power supply in your facility.

⚠ WARNING! Disconnecting Power. To fully disconnect power, either detach or unplug the power cord, positioning the system such that the power cord is accessible. Do not position the equipment so that it is difficult to operate the power switch or remove power cord. Only the power cord provided by the manufacturer should be used. Do not replace cord with an inadequately rated cord.

⚠ CAUTION! Cleaning and Decontamination. It is the responsibility of the operator (or other responsible person) to ensure the following requirements are met:

- Before using any cleaning or decontamination methods (except those recommended by the manufacturer), users should confirm with the manufacturer that the proposed method will not damage the equipment.
 - No decontamination or cleaning agents are used that could cause a hazard as a result of a reaction with parts of the equipment or with material contained in the equipment.
 - The system is properly decontaminated:
 - If hazardous material is spilled onto or into the equipment, and/or prior to having the system serviced at your facility or sending the system for repair, maintenance, trade-in, disposal, or termination of a loan (decontamination forms may be requested from customer support).
 - See [Section 5](#) for specific cleaning instructions.
-

⚠ WARNING! General Chemical Handling. To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below, and consult the relevant SDS for specific precautions and instructions:

- Read and understand the Safety Data Sheets (SDS) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials.
 - Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
 - Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with adequate ventilation (for example, fume hood).
 - Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer's cleanup procedures as recommended in the SDS.
 - Handle chemical wastes in a fume hood.
 - Ensure use of 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.
 - After emptying a waste container, seal it with the cap provided.
 - Characterize (by analysis if necessary) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
 - Ensure that the 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.
-

⚠ **CAUTION! Do not dispose of this product in unsorted municipal waste.** To minimize the negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.

⚠ **CAUTION! Moving the instrument.** Contact Cellanome technical support if you need to move the instrument after it has been installed.

⚠ **CAUTION! Laser Safety.** The Cellanome instrument is a Class 1 laser product in IEC 60825-1:2014 and through Laser Notice 56, and complies with the US FDA Center for Devices and Radiological Health 21 CFR Chapter I, Subchapter J. No laser radiation is accessible to the user during normal instrument operation as a disabling circuit disables the laser when the front door is opened. A Class 3B laser is in operation within the instrument enclosure (max output: 5.0mW continuous (CW), wavelength: 775-785nm, invisible laser radiation) and while it is suitably embedded within the instrument's enclosure, it should be noted that it is a potential hazard internal to the system and laser emissions should generally be avoided at all times.

Symbols on the system and in the user documentation

Abbreviated Safety Alerts: Hazard symbols may be found on the system and in user documentation to warn against potential hazards or convey important safety information. In this document, the hazard symbol is used along with one of the following user attention words:

⚠ **CAUTION!** – Indicates a potentially hazardous situation that, if not avoided, may result in loss of data, damage to the system, minor or moderate injury. It may also be used to alert against unsafe practices.

⚠ **WARNING!** – Indicates a potentially hazardous situation that could result in serious injury to the user or damage to the system, if not avoided. The protection provided by the equipment may be impaired if the system is operated outside the environment and use specifications, the user provides inadequate maintenance, or the equipment is used in a manner not specified by the manufacturer.

⚠ **DANGER!** – Indicates an imminently hazardous situation that, if not avoided, could result in death or serious injury.

Table of hazard symbols

Symbol	Description	Location
	Grounding symbol Protective conductor terminal	Near power entry on system
	Caution, hot surface	Near potentially hot surface on system
	Caution, possible hazardous optical radiation emitted	Optics area (service accessible only)
	Potential biohazard	Near sample tray and waste bins on system
	Potential laser radiation	Outside and inside optical compartment (service accessible only)
	Pinch hazard	At sliding front door



CAUTION! Hot surface. During instrument operation, the temperature of the flow cell loader plate can be as high as 95 °C. The instrument has a software interlock to prevent the sliding door from opening when the instrument is in operation, but if the system appears to be malfunctioning use caution when operating near the plate nest.



CAUTION! Possible UV light hazard. Possible hazardous optical radiation emitted from this product. Do not stare at operating lamp. May be harmful to the eyes. There is a physical separation of the reagent deck and the optics area that should prevent exposure of user to UV light. The instrument also has a hardware interlock that shuts off UV-C power if and when the door is not fully closed.



WARNING! Potential Biohazard. Depending on the samples used with this system, the surface may be considered a biohazard. Use appropriate decontamination methods when working with biohazards.

Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. All work should be conducted in properly equipped facilities using the appropriate safety equipment (for example, physical containment devices). Safety equipment also may include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Individuals should be trained according to applicable regulatory and company/ institution requirements before working with potentially biohazardous materials. Follow all applicable local, state/provincial, and/or national regulations.

Table of consumables symbols

The following table describes the symbols that may be found on the consumables packaging or consumables documentation.

Symbol	Description
	Expiration date – indicates the date after which the product is not to be used
	Indicates the manufacturer
	Item is for Research Use Only (RUO)
	Indicates part number of the item
	Indicates the batch code so that the batch or lot can be identified
	Indicates the serial number so a specific item can be identified
	Indicates a health hazard
	Indicates caution, a hazard warning
	Storage temperature range in deg Celsius. Store product within the indicated range.
	Indicates that item requires protection from light or heat. Store away from sunlight.

Safety and regulatory compliance standards and directives

Standards/Directives	Descriptions
US Regulations: FCC Part 15b, Class A FCC Part 15c, FCC ID approval for RFID function	Federal Communications Commission: Radio Frequency Devices Unintentional Radiators Intentional Radiators
Canada Regulations: ICES-003:2016 ISSUE 6 RSS-102, ICES-003 CSA-C22.2 No. 61010-1	Information Technology Equipment, Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirement
EU/UK: EN/IEC 61010-1 EN/IEC 61010-2-081 EN/IEC 61010-2-010 EN/IEC 61326-1 ETSI EN 300 330-1, ETSI EN 301 489-1, -17 CE RED IEC 60825-1:2014, EN 60825-1:2014 + A11:2021 Laser Notice 56	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-010: Particular requirements for laboratory equipment for the heating of materials. Part 02-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes. Electromagnetic compatibility (EMC) standard for radio equipment and services Radio Equipment Directive (RED) Safety of Laser Products – Part 1: Equipment Classification and Requirements

Section 4: Installation site requirements

Installation and environment requirements

The installation room is to be kept within operational environment conditions.

Condition	Acceptable range
Installation site	For indoor laboratory use only (Applicable pollution degree 2)
Operating temperature and humidity	15-30°C (60-85°F), 20-65% RH at 30°C (~86°F)
Storage temperature and humidity	5-40°C (40-105°F), 10-80% RH
Vibration	The system should not be placed adjacent to strong vibration sources. Excessive vibration during use will affect system performance.
Altitude	Up to 6,562 ft (<2000 m)
Input voltage tolerance	+/- 10%
Overvoltage category	II

Setup instructions

⚠ IMPORTANT! The system can only be uncrated and installed by Cellanome Technical Support personnel or authorized representatives.

Space requirements: The equipment is approximately 24 cu ft.

⚠ IMPORTANT! Be sure to keep all packaging materials in good condition, as they are required if the system needs to be returned to Cellanome for any reason.

⚠ WARNING! Do not attempt to move the system alone as serious injury may occur. A Cellanome Technical Support personnel will verify that the installation location meets the power and environmental requirements specified in their Site Readiness Guide.

Moving a system after installation

⚠ IMPORTANT! The system can only be moved by Cellanome Technical Support personnel or authorized representatives who will perform the following:

- Ensure there is no plate inside as it may become dislodged and jam mechanical parts during transport.
- Ensure the shipping lock screw has been installed. Moving a system without the shipping lock screw may cause damage to the system.

Section 5: Cleaning and maintenance

Cleaning

The outside of the system can be cleaned by wiping with a damp, lint-free cloth using:

- Mild soap
- 70% ethanol in water

The work deck area shown below should be cleaned with a damp, lint-free cloth using:

- 70% ethanol in water
- 10% bleach in water

All surfaces should be dry and free of dust and lint before operation.

Maintenance

Perform regular cleaning of the flow cell holder and work deck area before each run.

Contact Cellanome Technical Support for maintenance and service plan details.

Section 6: Product specifications

General specifications

Dimensions (unpacked)

- **Width:** 1067.5 mm (42.0 inches)
- **Depth:** 785.80 mm (30.9 inches)
- **Height:** 813.50 mm (32.0 inches)

Dimensions (crated)

- **Width:** 1510 mm (59.5 inches)
- **Depth:** 1050 mm (41.3 inches)
- **Height:** 1160 mm (45.7 inches)

Package weight: 415 kg

Unit weight: ≤ 380 kg

Power rating: AC 100-240V, 50-60 Hz, 10A

Maximum Noise level: 65 dB

Input power Socket: IEC320-C13

RJ-45 LAN port. Two USB 3.0 ports.



Instrument Rear I/O

1. On/Off Switch
2. Power input
3. USB 3.0 ports
4. Ethernet port

Company and support information

Cellanome, Inc.

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Technical Support: support@cellanome.com

