

Genesis Cell Isolation System

User Guide

Introduction

The Genesis Cell Isolation System enables a range of single-cell applications with Celselect Slides™ technology.

Celselect Slides capture and isolate individual circulating tumor cells (CTCs) and other rare cells based on their size, utilizing microfluidics and individual microchambers. Isolated cells can be stained for immunofluorescent applications such as enumeration, or enriched for downstream methods such as cell culture or single-cell genomics.

Features

Genesis System

- Semiautomated workflow
- Flexibility to run 1 or 2 Celselect Slides at a time
- Network-ready for remote updates and support
- Open design for user-customized applications and protocols

Celselect Slides and Consumables

- Microchambers capture CTCs based on size
- High capture efficiency
- Ability to customize staining

Components Overview

The following figures and Tables 1–8 outline the main components and details of the Genesis System for operation.



Table 1. Genesis System front.

Number	Front Component
1	USB 2.0 port
2	Genesis System touch screen
3	Power indicator light
4	Lid

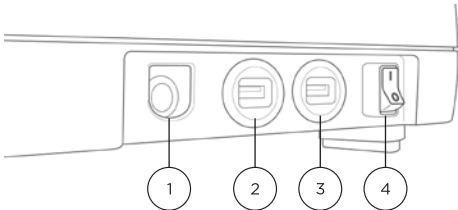


Table 2. Genesis System back.

Number	Back Component
1	24 VDC power input
2	Ethernet port
3	USB 2.0 port
4	Power switch

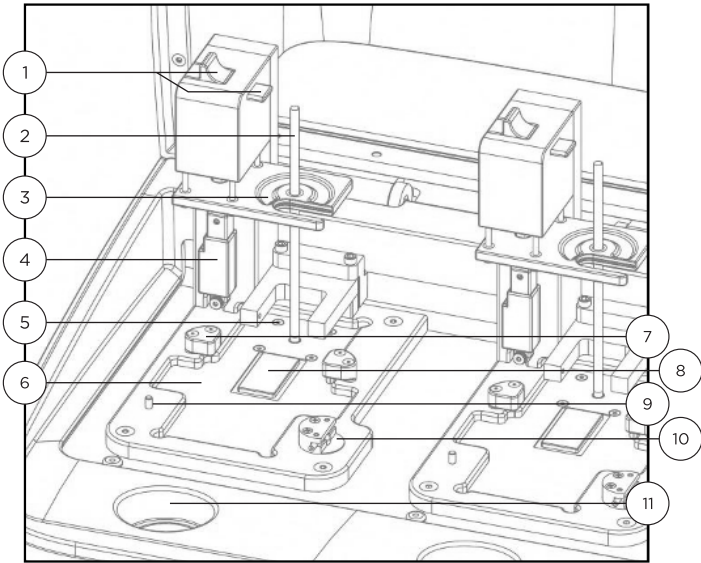
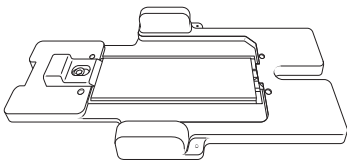
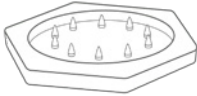
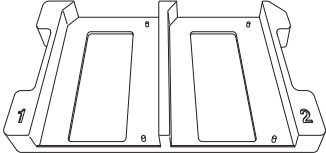
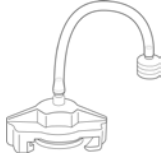


Table 3. Genesis System interior.

Number	Component	Description
1	Reagents cartridge retainer	Keeps the reagents cartridge in place during dispensing steps, while the disposable cartridge piercer pushes up on the Reagents Cartridge to pierce the bottom foil from below.
2	Reagents cartridge spindle	Holds the reagents cartridge in place during the run to control the order of reagent dispensation.
3	Piercer drip plate	Holds the disposable piercer used to pierce the bottom foil of a reagents cartridge.
4	Actuator	Moves the piercer drip plate up and down to perform reagents cartridge piercing and dispensing steps.
5	Liquid level sensor	Monitors the level of the reagents in the inlet funnel.
6	Manifold plate	Holds the slide station in place during the run.
7	Slide station clamping box	Holds the Celselect Slides stations in the manifold plate during the run.
8	Thermal block	Transfers heat to a slide, during heating and cooling steps, from an assembly below.
9	Vacuum tubing pin	Holds the free end of the vacuum tubing in place while not in use.
10	Pinch valve	Holds the waste jar tubing during the run to control the liquid flow through the slide.
11	Waste jar slot	Holds the waste jar in place during a run.

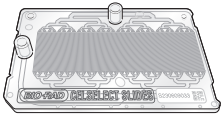
Table 4 describes the accessories used in conjunction with the Genesis System for operation.

Table 4. Genesis System accessories.

Component	Description
	
Celselect Slides station	Orients and stabilizes Celselect Slides on the Genesis System.
	
Reagents cartridge venter	Fits directly onto the chambers of the reagents cartridge and opens the chambers for use on the Genesis System. Required to prevent the formation of a vacuum and to allow proper flow of reagents.
	
Wireless barcode scanner and base	Scans barcodes that are included on consumables.
	
Celselect imaging slide adaptor	Holds up to two Celselect Slides and fits directly in any automated microscope.
	
Backflow adaptor	Seals priming reservoir for enrichment cell collection.

Consumables Overview

Table 5. Genesis System consumables.

Consumable	Description
	
Celselect Slides	Celselect Slides use Bio-Rad's proprietary CTC capture and analysis technology. Each slide has one laminated side and the other side contains inlet and outlet ports. Optical characteristics closely mimic a glass slide, rendering the slide fit for imaging.
	
Inlet funnel	The sample enters the Celselect Slides through the inlet funnel.
	
Reagents cartridge piercer	The reagents cartridge piercer is firmly placed in the drip plate of the Genesis System to penetrate the bottom of the reagents cartridge and allow reagents to enter the inlet funnel.
	
Waste jar tubing	The waste jar tubing collects reagents after processing.

User-Supplied Consumables and Equipment

See individual application protocols and site preparation checklists for complete lists of user-supplied consumables and equipment.

User-Supplied Consumables for Instrument Maintenance

Table 6. User-supplied consumables for instrument maintenance.

Consumable	Source
10% bleach	Major lab supplier
70% ethanol	Major lab supplier
Water, laboratory-grade*	Major lab supplier

* Always use laboratory-grade water or deionized water to perform instrument procedures. Never use tap water.

Getting Started

Genesis Software Overview

The Genesis graphical user interface (GUI) is the main user interface for operating the Genesis System. The GUI loads automatically after startup and logs every run. The GUI home screen has four options:

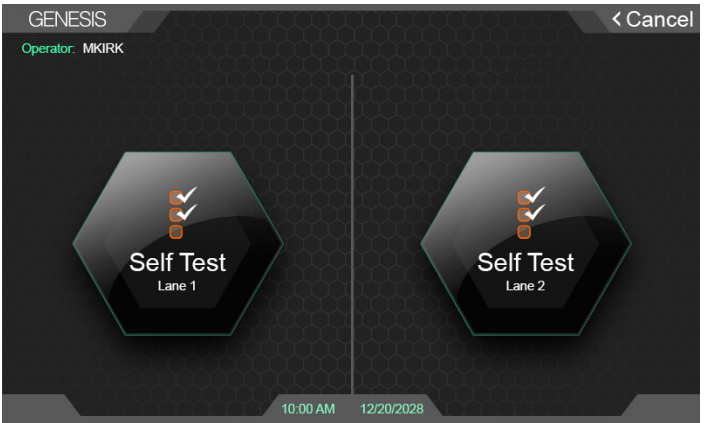
- Start
- Logs
- Maintenance
- Settings

One can also log in, gather system information, or shut down the instrument from the home screen. **Note:** Login is not required.



Start

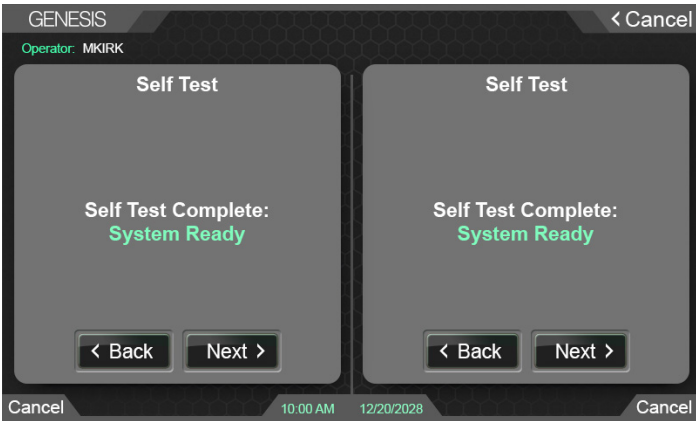
Click **Start** to bring up the Self Test screen.



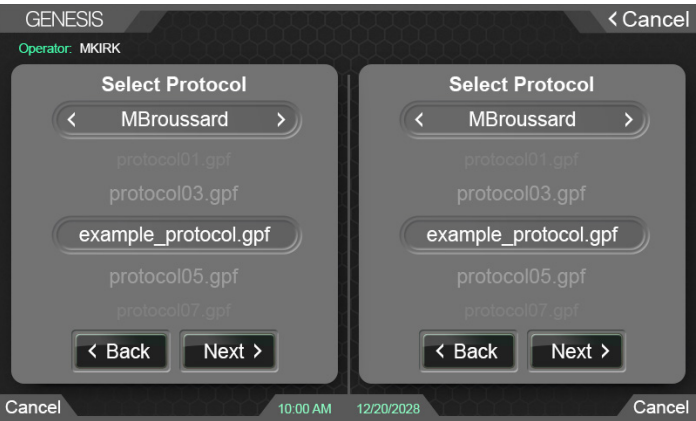
After selecting the lane, or both, to conduct a self test on, the instrument will confirm:

- Reagents cartridges are not loaded
- Level sensors are unblocked
- Waste jar inlet tubing is loaded into the pinch valve or otherwise clamped
- Lid is closed

Click **Next** to perform the self test.

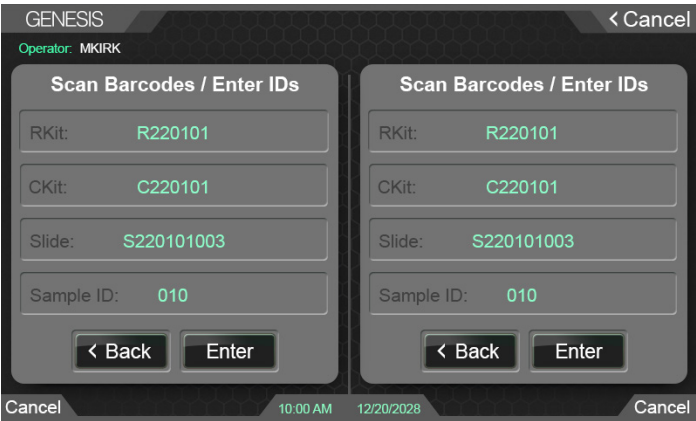


The lane(s) is now ready to configure a run, starting with a prompt to select the desired protocol to run.

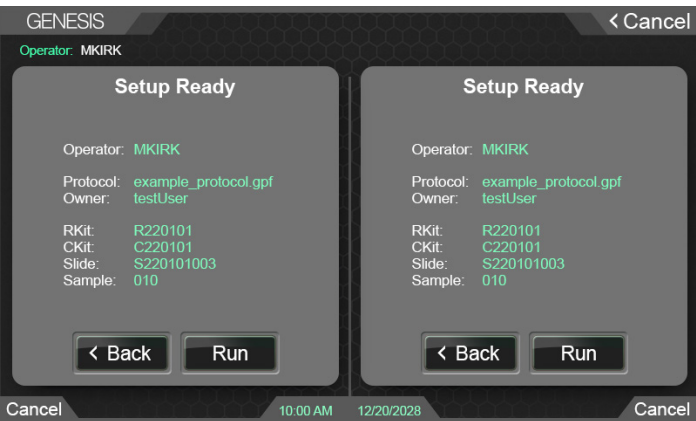


After a protocol is selected, the Celselect Slides reagents, Celselect Slides consumables, and Celselect Slides can be scanned in with the barcode scanner or manually entered with the onscreen keyboard then loaded onto the instrument. If entering manually, follow this naming scheme:

- 1. Celselect Slides reagents: R#####
- 2. Celselect Slides consumables: M#####
- 3. Celselect Slides: S#####



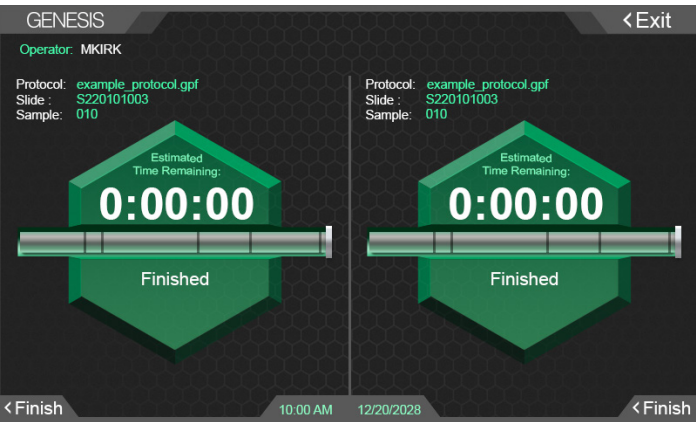
When prompted, confirm that the proper consumables were entered, then click **Run**.



Run in progress



Run complete



Settings

The Settings screen allows the user to control several functions.

User Login

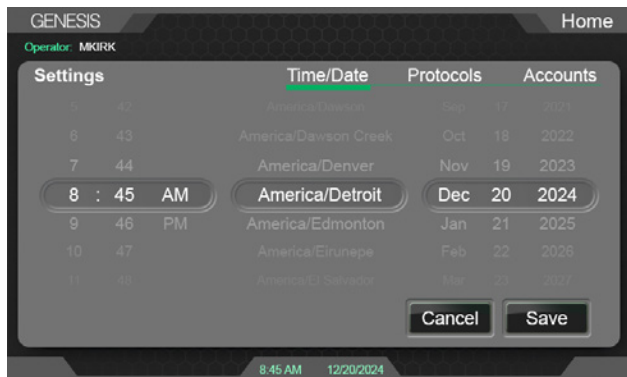
The system can be run without logging in, but an Admin must log in to access and manage user accounts in the system settings. The default user login and password:

User name: genesis

Password: Genesis01

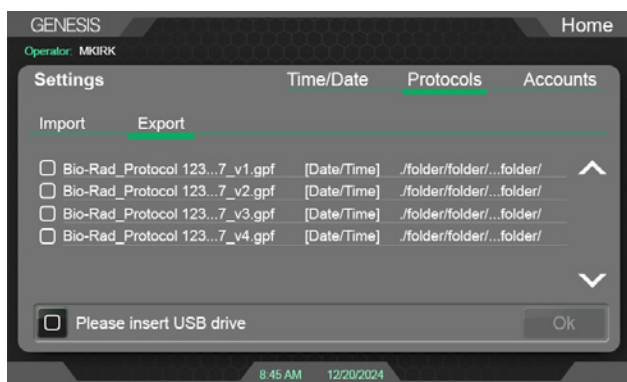
Time and Date

Set the time and date for the device.



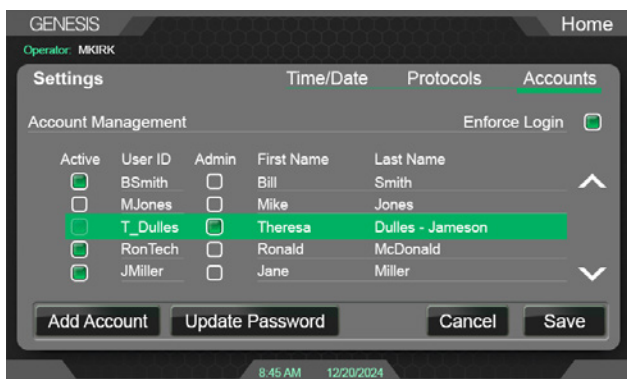
Protocols

View currently installed system protocols, file names, and timestamps. Insert a USB drive to import or export files.



Accounts

Add or modify accounts on the device.



- The user can touch a text item on the highlighted line to select it for modification
- User identifications (IDs) cannot be modified once a user is successfully saved
- The Enforce Login button updates login enforcement immediately; it does not require clicking **Save**
- When an Admin is logged in, that person's Admin checkbox will be grayed out and cannot be unchecked. Admins cannot remove their own Admin privileges
- The Save button will only be enabled once all changed data is validated
- When adding a new user, the Admin must input a valid user ID, first name, and last name, and set the new user's password
- Once a user is created and the Admin wishes to change someone else's password, the Admin will be prompted to re-enter the Admin password before changing the other user's password

Best Practices

Good Laboratory Practices

Wear appropriate personal protective equipment.

Reagents Cartridge

Avoid pipetting bubbles into the reagent cartridge or inlet funnel.

Operation

Introduction

To perform any of the Bio-Rad certified protocols on the Genesis System, initial setup steps are required. Different assays will have different setups, which are addressed in the individual assay protocols. This section provides a high-level overview. Once the setup is complete, the Genesis System will perform a system self test followed by a set of software prompts to configure a run.

Prepare Samples, Prime Slides, and Load Samples

Follow the instructions detailed in the assay-specific protocol to prepare samples, prime slides, and load samples.

Prepare Reagents and Load Reagents Cartridge

Follow the instructions detailed in the assay-specific protocol to prepare and load the reagents as well as to load the slides into their slide stations.

Perform Self Test on the Genesis System

Follow the instructions in the Start section of this guide to run a self test.

Maintenance

Routine Cleaning

Clean the Genesis System and slide stations after each use or weekly when not in use.

- Wipe instrument deck with 10% bleach solution on a towelette
- If 10% bleach solution is not available, wipe instrument deck with 70% ethanol on a towelette

As-Needed Cleaning

1. System Decontamination

WARNING! To prevent electrical shock, always turn off and unplug the instrument prior to performing decontamination procedures. To prepare and apply the disinfectant, refer to the instructions provided by the product manufacturer. Do not use abrasive or corrosive detergents or strong alkaline solutions. These agents can scratch the surfaces of the thermal block, resulting in loss of precise thermal control.

The following areas can be cleaned with any hospital-grade bactericide, virucide, or fungicide:

- Outer enclosure lid and chassis
- Inner lane components, including the thermal block
 - Rinse the thermal block several times with water after applying disinfectant. Thoroughly dry the thermal block after rinsing with water
- LCD screen

2. Cleaning Spills

Clean up all spills immediately. Dispose of all samples and waste according to proper handling procedures and local regulations.

- Always dispose of all consumables coming into contact with the sample after each sample run in an appropriate manner
- Consult appropriate Safety Data Sheets when necessary

Remote Access

The Genesis System comes with networking capabilities. Once the Genesis System is installed, the field service engineer will, with permission from the customer, establish a connection from the instrument to the internet using a standard Ethernet port and LAN connection. This connection can be used to update software and firmware, to collect and analyze log files from previous runs, and to operate the device.

At any point, the user may terminate the connection and end remote access. In addition, the user can request in-person local updates and maintenance, though this support is pending service contracts and technician availability.

Software Updates

Regular updates to software and firmware are necessary to enable the most current and effective programming. Updates can be performed in one of four ways:

- Remote access (see prior section)
- Locally through the Settings page on the Genesis System control module
- During an on-site visit
- With update files and instructions shared by an engineer

Loading Protocols Using Protocol Builder

In addition to running supported and validated protocols, the Genesis System can carry out customized protocols based on user requirements using Protocol Builder. The Protocol Builder process and supporting guidelines are described in the Protocol Builder User Guide.

Shutting Down the Instrument

The Genesis System can be left idle for up to 1 week. If the Genesis System is not going to be used for more than 1 week, the slide stations and all consumables should be removed from the machine. The machine should be turned off and cleaned. Once the machine is off for more than 1 week, it is recommended that preventive maintenance is performed.

Appendix 1: Troubleshooting

1. Self Test Failure

If either lane fails a self test, check the following to correct the issue:

- Tighten all fittings between the instrument and waste
- Confirm waste jar tubing is not pinched or clamped
- Make sure the level sensor is unobstructed

2. Single Lane Failure

If one lane fails when processing two samples in parallel:

- Allow the other lane to complete its processing
- Contact your field application specialist for troubleshooting help

Appendix 2: Warnings, Hazards, and Safety Considerations

This section identifies potential hazards associated with operating the Genesis System. Do not operate or interact with the system in a manner that causes exposure to these dangers.

Some hazards are indicated on the instrument by labels shown in this section.

The Genesis System is designed to operate safely when used in the manner prescribed by the manufacturer. If the Genesis System or any of its associated accessory components are used in a manner not specified by the manufacturer, the inherent protection provided by the instrument may be impaired.

Bio-Rad is not liable for any injury or damage caused by the use of this equipment in any unspecified manner, or by modifications to the instrument not performed by Bio-Rad or an authorized agent. Service of the Genesis System should be performed only by Bio-Rad personnel.

General Safety Warnings

Before operating the Genesis System, all personnel must be trained in the correct operation of the instrument and any potential safety considerations.

Electrical Safety Warnings

Do not remove any of the outer enclosure components from the Genesis System. There are no user-serviceable components inside. If the instrument is operated with the enclosure removed, the user may be exposed to line voltage as well as to DC voltages.

The Genesis System is powered by 100–240 volts AC operating at either 50 or 60 Hz. Most of the voltage sources are located at the back right side, under the enclosure. Some voltage is present on the instrument even when the instrument is powered down. Operate the instrument with the enclosure intact to avoid electrical shock.

Electrical Connections

The Genesis System should be plugged into a dedicated, grounded circuit capable of providing at least 10 amps for a 100–120 V power source or 6 amps for a 220–240 V power source.

For more information, see the Genesis System Site Preparation Guide.

Hot Surface Safety Warning

Do not operate the Genesis System with any of the enclosure panels removed.

Do not touch the thermal block of the slide station manifold plate. The Peltier controller used in the thermal block normally operates at ambient temperature (22°C) but can range from 5 to 105°C. Exposure to temperatures at the upper end of this range could result in burns.



WARNING! Hot surface! This symbol identifies components that pose a risk of personal injury due to excessive heat if improperly handled.

Important: The thermal blocks can become hot enough during normal operation to cause liquids to boil and explode.

A thermal cycler generates enough heat to cause serious burns. Always allow the thermal block(s) to return to ambient temperature before opening the lid and removing the slide. Always allow maximum clearance to avoid accidental skin burns.

Biohazards

The Genesis System is a laboratory product. However, if biohazardous samples are present, adhere to all laboratory, local, regional, and national guidelines. See Routine Cleaning section for more information on decontamination.

Chemical Hazards

The Genesis System contains no potentially hazardous chemical materials.

Explosive or Flammability Hazards

The Genesis System poses no uncommon hazard related to flammability or explosion when used in a proper manner as specified by Bio-Rad.

Electrical Hazards

The Genesis System poses no uncommon electrical hazard to operators if installed and operated properly without physical modification and connected to a power source of proper specification.

Battery

The Genesis System uses a 3 V lithium manganese dioxide nonrechargeable coin cell battery to maintain time and date settings in the event of AC power loss. If the time and date settings do not remain set after the unit is turned off, it may be an indication that the battery is weak or has no charge. If this occurs, contact Bio-Rad Technical Support for assistance.

WARNING! Do not attempt to change the battery. Contact Bio-Rad Technical Support.

For the State of California, USA, only:

- Perchlorate material — special handling may apply.
See dtsc.ca.gov/hazardouswaste/perchlorate
- Perchlorate material — lithium battery contains perchlorate

Transport

Before moving or shipping the Genesis System, decontamination procedures must be performed. Always move or ship the Genesis System with the supplied packaging materials to protect the instrument from damage. If appropriate containers cannot be found, contact your local Bio-Rad representative.

Transport/Storage Environmental Conditions

The Genesis System can be stored under the following conditions:

- Temperature range: –20 to 60°C
- Relative humidity: maximum 80%

Disposal

The Genesis System contains electrical materials; it should be disposed of as unsorted waste and must be collected separately according to the EU Directive 2002/96/CE on waste and electronic equipment. Before disposal, contact your local Bio-Rad representative for country-specific instructions.

Disposal of Instrument Waste

- Waste jars — the Genesis System has a dedicated waste jar for each run. Collect and dispose of all waste jars using proper precautions in accordance with local safety regulations
- Disposal of instrument — contact Bio-Rad Tech Support

Disposal of Biohazardous Material

The Genesis System contains no hazardous chemical materials. Dispose of the following potentially contaminated materials in accordance with laboratory, local, regional, and national regulations:

- Clinical samples
- Reagents
- Used reaction vessels or other consumables that may be contaminated

Symbols Used on the Instrument or Kits

Table 7. Symbol list.

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Batch code
	Catalog number
	Serial number
	Consult instructions for use
	Warning: hot surface
	European conformity
	Waste Electrical and Electronic Equipment Directive
	Biological risks
	Temperature limit
	Do not reuse

Safety Specifications and Compliance

Safety specifications for the Genesis System are listed in Table 8. Shielded cables (supplied) must be used with this unit to ensure compliance with the Class A Federal Communications Commission (FCC) limits.

Table 8. Safety specifications.

Safety Guideline	Specification
Operating condition	Indoor use
Temperature	65–83°F (18–28°C)
Humidity	20–80% noncondensing
Elevation	Below 6,500 feet (1,981 meters)
Installation (overvoltage) category	II (external power supply plugs into standard AC receptacle)
Air quality	Pollution Degree 2 per IEC 60664-1
Electrical supply	100–240 VAC, 50/60 Hz, 200 W
Main supply voltage fluctuations	Not to exceed ±10% of nominal voltage

Regulatory Compliance

This instrument has been tested and found to be in compliance with all applicable requirements of the following safety and electromagnetic standards:

- UL 61010-1:2018, Third Edition Dated May 11, 2012
- UL 61010-2-010, Fourth Edition Dated June 27, 2019
- UL 61010-2-101, Third Edition Dated July 31, 2019
- IEC 61010-1 Electrical Equipment for Measurement, Control, and Laboratory Use, Edition 3 (2010-06)+AMD1 (2016-12)
- IEC 61010-2-010 Particular Requirements for Laboratory Equipment for the Heating of Materials, Fourth Edition
- IEC 61010-2-101 In Vitro Diagnostic (IVD) Medical Equipment (2018-10)
- EN 61326-1:2006 (Class A) Electrical Equipment for Measurement, Control, and Laboratory Use. EMC Requirements, Part 1: General Requirements



The CE mark indicates that the manufacturer ensures the product conforms with the essential requirements of the applicable EN directives.



The UL mark indicates that a product has been tested to Canadian and U.S. standards, and it meets the requirements of those applicable standards.

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.

Bio-Rad Technical Support

The Bio-Rad Technical Support department in the U.S. is open Monday through Friday, 5:00 AM to 5:00 PM, Pacific time.

Phone: 1-800-424-6723, option 2
Email: support@bio-rad.com (U.S./Canada only)

For technical assistance outside the U.S. and Canada, contact your local technical support office or click the Contact us link at bio-rad.com.

Legal Notices

No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopy, recording, or any information storage or retrieval system, without permission in writing from Bio-Rad Laboratories, Inc.

Bio-Rad reserves the right to modify its products and services at any time. This guide is subject to change without notice. Although prepared to ensure accuracy, Bio-Rad assumes no liability for errors or omissions, or for any damage resulting from the application or use of this information.

BIO-RAD and CELSELECT SLIDES are trademarks of Bio-Rad Laboratories, Inc. in certain jurisdictions. All trademarks used herein are the property of their respective owner.

© 2024 Bio-Rad Laboratories, Inc.

For research use only. Not for use in diagnostic procedures.



Bio-Rad
Laboratories, Inc.

Life Science
Group

Website bio-rad.com USA 1 800 424 6723 Australia 61 2 9914 2800 Austria 00 800 00 24 67 23 Belgium 00 800 00 24 67 23 Brazil 4003 0399
Canada 1 905 364 3435 China 86 21 6169 8500 Czech Republic 00 800 00 24 67 23 Denmark 00 800 00 24 67 23 Finland 00 800 00 24 67 23
France 00 800 00 24 67 23 Germany 00 800 00 24 67 23 Hong Kong 852 2789 3300 Hungary 00 800 00 24 67 23 India 91 124 4029300 Israel 0 3 9636050
Italy 00 800 00 24 67 23 Japan 81 3 6361 7000 Korea 82 080 007 7373 Luxembourg 00 800 00 24 67 23 Mexico 52 555 488 7670
The Netherlands 00 800 00 24 67 23 New Zealand 64 9 415 2280 Norway 00 800 00 24 67 23 Poland 00 800 00 24 67 23 Portugal 00 800 00 24 67 23
Russian Federation 00 800 00 24 67 23 Singapore 65 6415 3188 South Africa 00 800 00 24 67 23 Spain 00 800 00 24 67 23 Sweden 00 800 00 24 67 23
Switzerland 00 800 00 24 67 23 Taiwan 886 2 2578 7189 Thailand 66 2 651 8311 United Arab Emirates 36 1 459 6150 United Kingdom 00 800 00 24 67 23

