HiG3 Automated Centrifuge



Operator's Manual



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HiG3 Part Number 14-04841



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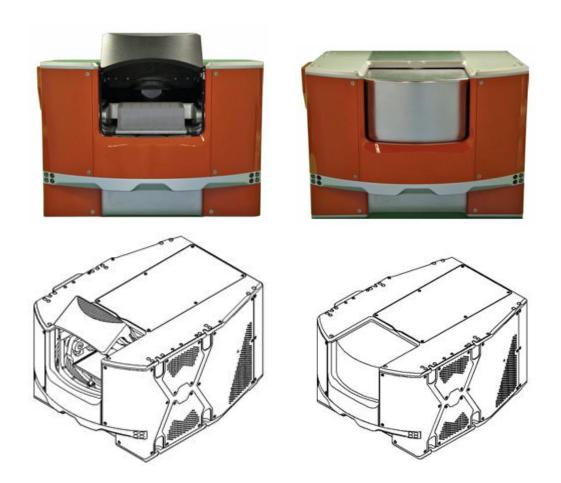
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The HiG3 Centrifuge



General Warnings

The icons on this page are used throughout the manual. They appear when information presented requires special attention. Please pay close attention to the instructions that accompany these Warnings and Cautions. Always follow the standard laboratory practices set forth by your facility and local regulatory agencies.

Always use the HiG3 Centrifuge as intended. Improper use of the system and/or its accessories may result in serious injury, damage to the system, and inaccurate results. Additionally, misuse could nullify the warranty.



Warning: Identifies conditions or practices that could result in personal injury or loss of life



High Voltage Warning: Identifies potential exposure to dangerous voltage



Must Unplug: System must be disconnected from power and communication when performing designated procedure



Biohazard Warning: Identifies potential exposure to harmful biological materials



Pinch Hazard: Pinch hazard exists when the instrument is operating



Explosive Hazard: Use of explosive materials in the HiG3 Centrifuge is not approved



Radiation Hazard: Use of radioactive materials in the HiG3 Centrifuge is not approved



Flammable: Use of flammable materials in the HiG3 Centrifuge is not approved



Corrosive Hazard: Use of corrosive materials in the HiG3 Centrifuge is not approved



Caution: Identifies conditions or practices that could result in damage to equipment or other property

1.1 Introduction to the HiG3 Centrifuge

1.1.2 Intended use

The HiG3 Centrifuge is intended for use with robotic laboratory systems. It is designed for easy integration with a variety of automation platforms. The only requirements for integration are compatible power and communication.

The HiG3 Centrifuge is for research use only. It is not intended for use in diagnostic or therapeutic procedures.

The HiG3 Centrifuge does not include independent operator controls. It is laboratory automation equipment that is designed for integration within a larger control system.



Warning: The HiG3 Centrifuge is not approved for use without personnel access safeguards. Attempting to use the centrifuge without such access safeguards may create dangerous conditions.



Fig. 1-1 The HiG3 Centrifuge

1.1.3 Approved applications

- Routine mixing
- Bubble removal
- Spinning down cells
- · Pelletizing cellular debris



Warning: Do not use the HiG3 Centrifuge with solutions that present a biohazard to the operator or maintenance personnel.









Warning: Do not use the HiG3 Centrifuge with explosive, radioactive, flammable, or corrosive solutions.

1.1.4 Key features

The BioNex HiG3 Centrifuge is a robot-accessible centrifuge capable of rapid acceleration up to 5000 x g (RCF). The HiG3 Centrifuge provides better pelletizing, cleaner supernatants, and faster filtration than lower speed centrifuges can achieve. Applications that require spin forces previously unattainable by automated systems can be executed using the HiG3 Centrifuge.

- Completely powered by standard electrical service; eliminates the need for compressed air or other utilities
- Rotational forces up to 5000 x g (RCF)
- Easy operation through the supplied integration application or the application program interface
- Fewer steps and shorter overall cycle times
- Dual position rotor design allows payloads of up to 350 grams per bucket.
- Easy-to-process microplate configurations, including deep well blocks and filterplate assemblies
- Handles completely filled 96-well deep well plates
- · Accommodates plate heights up to 61 mm
- Compatible with ANSI/SBS plates, PCR plates
- Balance intolerance of up to 100 grams promotes uninterrupted operation and vibrational stability for other instruments on the same platform
- Small footprint allows easy integration into laboratory automation platforms
- Stackable to conserve integration space, increase throughput
- Large door opening allows direct access of buckets by a wide range of laboratory robots
- Hardware door latch engages before operation
- Automatic shutdown when imbalance limit exceeded

1.1.5 Specifications

- Dimensions: 29 cm H X 40 cm W X 55 cm D
- Weight: 77 kg
- · Capacity: 2-bucket rotor
- Maximum Plate Height: 61 mm
- Maximum Gripper Opening: 169 mm
- Communication: USB 2.0
- Electrical: 100-127/200-240V~, 12/6 A, 50/60 Hz
- Balance intolerance: up to 100 grams
- Maximum: rotational forces: 5000 x g (RCF)
- Payload capacity: 350 grams per bucket

Safety

2.1 Safe use of the HiG3 Centrifuge

This chapter covers the safety icons and warnings used throughout the manual. Consider each warning and caution within the context of the page it appears on.

2.1.1 Integration warnings

Do not attempt to operate the HIG3 Centrifuge without personnel access safeguards. The HiG3 Centrifuge is designed to operate only as an element within an automated system. Such systems shut down when the system is approached too closely.



Warning: The HiG3 Centrifuge is not approved for use without personnel access safeguards. Doing so may result in dangerous conditions.



Caution: The HiG3 Centrifuge may be integrated with many different systems. To ensure safe integration with your system, contact the BioNex Solutions service department.



Warning: User must provide controlled access to automated systems that includes automatic shut down of operations when the door is approached.

2.1.2 Unapproved substances warnings

The HiG3 Centrifuge is designed only for separating harmless biological or non-biological material. This instrument is not approved for other applications including the centrifugation of biohazardous, radioactive, flammable, explosive, corrosive, or other hazardous solutions.



Warning: Do not use the HiG3 Centrifuge with solutions that present a biohazard to the operator or maintenance personnel.









Warning: Do not use the HiG3 Centrifuge with explosive, radioactive, flammable, corrosive, or other hazardous solutions.

2.1.3 High voltage warnings

Conditions or procedures where the user may be exposed to high voltage are designated by a high voltage warning icon.

2.1.3.1 Specific high voltage warnings



High Voltage Warning: Use only the power cord set as supplied, or an IEC320-C14 cord set appropriate for the electrical ratings of this device and approved for use in your region. Do not operate the HiG3 Centrifuge if the cord set is damaged or shows signs of wear.



Must Unplug Warning: You must disconnect all electrical connections before performing maintenance, cleaning, or inspection.

2.1.4 Regulatory compliance

The HiG3 Centrifuge bears the CE mark and has been designed to comply with international regulatory requirements, including:

• EMC: EN61326-1:2021

Safety: EN 61010-1:2010 + A1, EN 61010-2-020:2017



US/Canada

EMI: FCC: CFR 47, Part 15: Subpart B, Class A, CAN ICES-3 (A)/NMB-3(A) Safety: UL 61010-1:2012 R7.19, CAN/CSA 22.2 No 61010-1-12+GI1+GI2 (R2017)+A1

Note: 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. 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 his own expense.

2.1.5 Biohazard warnings

Always follow universal safety precautions as required by your facility concerning potential exposure to biological materials.

The HiG3 Centrifuge is not approved for centrifugation of biological materials above Biohazard Safety Level 1.

2.1.5.1 Specific biohazard warnings



Biohazard Warning: Follow Universal Precautions with all biological specimens regardless of whether the specimen is known to contain an infectious agent.



Biohazard Warning: Follow your facility's procedures for handling human specimens when cleaning and maintaining the HiG3 Centrifuge.



Biohazard Warning: Vacuum exhaust may contain biological particulates. Observe your facility's safety procedures when cleaning the centrifuge.



Biohazard Warning: The HiG3 Centrifuge must be free from any infectious or toxic substances before shipping it. Fill out the decontamination clearance form and enclose with the unit prior to shipment.



Biohazard Warning: It is the user's responsibility to ensure the unit is free from any infectious or toxic substances prior to disposal. Fill out the decontamination clearance certificate and enclose with the unit prior to disposal.

2.1.6 Lift hazard warning

Two people are needed to lift and carry the unit. See the instructions in Section 4.



Lift Warning: Two people are required to lift the HiG3 Centrifuge. Do not attempt to lift the HiG3 Centrifuge by yourself. Injury may result.

2.1.7 Pinch hazard warning

Do not operate the HiG3 Centrifuge independent of the automated system it is integrated with. All automated systems should have controlled access that causes them to stop when approached. Use caution during installation and maintenance procedures that require manual rotation of the door.



Warning: Keep clothing, jewelry, hair, hands, and fingers clear of the door when it closes and when the system is operating.

2.1.8 Installation and operation warnings

Installation and operation warnings apply to installation procedures and everyday use of the HiG3 Centrifuge

2.1.8.1 Specific installation and operation warnings



Warning: Do not use the HiG3 Centrifuge until you have read all of the operating instructions and/or have been trained by an authorized BioNex Solutions service engineer.



Warning: Do not operate the HiG3 Centrifuge unless it is bolted down as instructed in this manual or by a BioNex Solutions service representative.



Warning: Do not run the HiG3 Centrifuge if any of its components or accessories are damaged, have been dropped, or have received rough handling.



Warning: Do not tamper with the HiG3 Centrifuge. Call the BioNex Solutions service department if the instrument is not working properly.

2.1.9 Installation and operation cautions

Installation and operation cautions apply to installation and everyday use of the HiG3 Centrifuge. Failure to heed cautions may result in damage to the instrument and void the warranty.

2.1.9.1 Specific installation and operation cautions



Caution: Ensure that all shipping braces and fixtures have been removed, and the internal rotor moves easily and without obstruction before applying power or operating the HiG3 Centrifuge. (See LIT-50050 HiG3 Unpacking and Setup Guide).



Caution: The HiG3 Centrifuge is designed to meet CE requirements for laboratory centrifuges. Should the HiG3 Centrifuge fail to start up, the module may be protecting itself from improper operation. Contact BioNex Solutions, Inc. to resolve the problem.



Caution: Stop using the HiG3 Centrifuge if it vibrates or makes noise above the normal level.



Caution: Do not operate the HiG3 Centrifuge if foreign objects or liquids become trapped within the chamber.



Caution: When operating the unit, use only the original accessories or approved accessories from third party suppliers authorized by BioNex Solutions.



Caution: BioNex Solutions is not responsible for the correct operation of the safety features on the unit unless skilled personnel qualified by BioNex Solutions perform all maintenance and repair of the centrifuge.

2.1.9.2 Acoustic Noise



Caution: Operation of the HiG3 centrifuge at high speeds may result in acoustical noise levels above 70 dB. Ensure appropriate measures are taken to protect personnel from excessive noise levels. These measures may include personal protective equipment, access restrictions, and operation inside an enclosure. Contact BioNex at support@bionexsolutions.com for assistance.

Section 3

Site Requirements, Unpacking, and Installation

3.1 Site preparation



The HiG3 Centrifuge should only be operated as an integrated part of an automated system with controlled access.

The HiG3 Centrifuge is intended solely for use as part of an automated system. Follow the instructions for installation and operation as directed in this manual, paying special attention to Warnings and Cautions.

Before beginning installation of the HiG3 Centrifuge, provide BioNex Solutions with a CAD model of your system so that we may verify compatibility. For assistance, contact us at 888-524-0542.



The HiG3 Centrifuge may be integrated with many different systems. To ensure safe integration with your system, contact the BioNex Solutions service department. 888-524-0542.

3.1.2 Site requirements

Ensure that all of the specifications and requirements enumerated below are met



Warning: User must provide controlled access to automated systems that includes automatic shutdown of operations when the door is approached.

3.1.2.2 Mounting surface

- Dedicated permanent mounting surface: table with 250 kg load rating per HiG3 Centrifuge
- Bench space: 460 x 560 mm (14" x 18.25")

3.1.2.3 Clearance

- Allow enough clearance behind the unit to access the on/off switch
- · Allow 10 cm clearance on either side of the unit for air flow
- Allow a minimum of 10 cm clearance behind the unit to accommodate cables
- When mounting units side by side, allow 10 cm clearance between units.

3.1.2.4 Environment

Ambient temperature: 10 °C to 35 °C

• Relative humidity: 90% or less

• Altitude: 2000 m or less

- For Indoor use only
- Pollution degree 2



3.1.2.5 Computer platform

- PC compatible computer with Windows 7 or Windows 10 operating system.
- USB 2.0 connection

3.1.3 Utility requirements

The HiG3 Centrifuge is a fully electrical device. No compressed air or vacuum is needed for its operation.

3.1.3.1 Power and power cord

- Power: 100-127/200-240V~, 12/6 A, 50/60 Hz
- Overvoltage Category II
- IEC 60320-1 C14 inlet connector with power switch
- 3 meter NEMA 5-15 power cord for US 120VAC/15A circuit (supplied) or 3 meter CEE7/7, Schuko cord set for 230V/16A circuit.



Warning: Use the supplied power cord set or an IEC320-C14 cord set appropriate for the electrical ratings of this device and approved for use in your region.

3.1.3.2 Communication

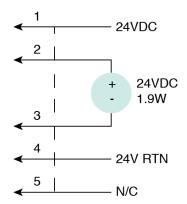
• USB 2.0 full-speed with USB type B socket on rear panel.



Caution: Use the USB cable provided with the HIG3 Centrifuge to ensure regulatory compliance.

3.1.4 Interlock

The HiG3 Centrifuge provides an interlock connection to allow the user to shut down motor power remotely. The interlock connection may be used with the provided emergency-stop mushroom switch, or it may be integrated with external safety circuits in a larger guarding system. A 5-pin male locking DIN connector, Lumberg SV50, is required to interface with the connector. When the relay shown in the diagram below is not energized, power to the HiG3 Centrifuge motors will be disabled.



3.1.4.1 Connectors, cables, switches

- External motor power interlock connector (Lumberg SV50 mating connector)
- 3meter cable with 40 mm E-stop mushroom switch (provided).
- Jumper plug may be ordered from BioNex Solutions Inc., (BioNex part number 11-00589)
- The HiG3 Centrifuge will not operate unless the interlock relay is energized.

3.1.5 Robotic access



Warning: Loading and unloading microplates in the HiG3 Centrifuge should only take place as an operation within an integrated system that does not allow personnel to approach during operation. Such a system will include automatic shut off when approached too closely.

Figure 3-2 below shows the location of a sample plate in the loaded position in the HiG3 Centrifuge. The robot should insert the plate into the HiG3 Centrifuge at a level that will clear the locating tabs in the plate nest.



Caution: Even if the dimensions shown in this section indicate that your robot is compatible with the HiG3 Centrifuge, you are advised to provide BioNex Solutions with a CAD model of your system to verify the fit.

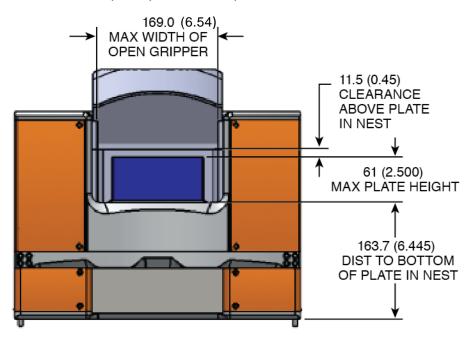


Fig. 3-2 Plate loading dimensions



Caution: The maximum height plate that the HiG3 Centrifuge can accommodate is 61 mm. Clearance between the top of this plate and the inside of the chamber is 11.5 mm. To use the maximum sized plate, the automated system must be capable of precise delivery within this target zone.



Caution: Additional constraints may apply to automation depending on the geometry of the robotic gripper.

3.1.5.1 Other Constraints

Additional constraints may apply depending on the geometry of your system's gripper.

- No part of the gripper may extend below the top of the locating tabs (167 mm) for a horizontal distance of 127 mm from the center of the plate.
- Above the plate, no part of the gripper can extend higher than the target zone (167+69=236 mm) for a horizontal distance of 108 mm from the center of the plate.

3.2 Unpacking the HiG3 Centrifuge

Refer to LIT-50050 shipped with the HiG3 Centrifuge on the Production Documentation USB Drive. Contact BioNex Solutions if an additional copy is required.



Caution: Failure to follow the unpacking instructions could result in significant equipment damage.

3.3 Mount the HiG3 Centrifuge to its permanent surface



Warning: The HiG3 Centrifuge must be mounted to a secure surface large enough to accept all the mounting points. See 3.1.2.2 for mounting surface specifications

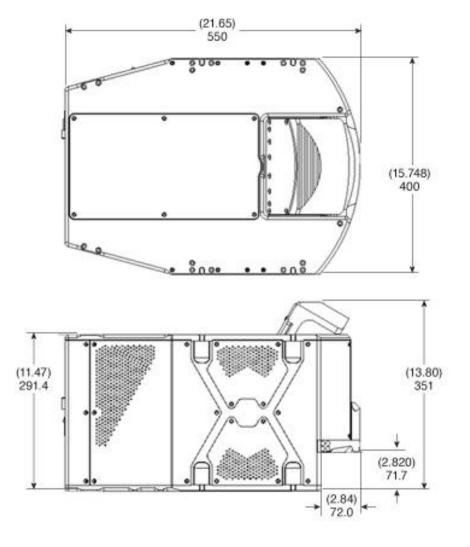


Fig. 3-3 Overall dimensions of HiG3 Centrifuge in millimeters and inches (in parentheses).

3.3.1 Mounting instructions

- 3.3.1.1 Hardware needed: (not included)
 - Four 6 mm or ¼" screws
 - Two 6 mm dowel pins
 - · Four heavy duty fixturing washers
- 3.3.1.2 Alternative mounting hardware: (not included)
 - Four 28 mm wide x 30 mm tall toe clamps to fit in pockets (see arrows)
 - · Four heavy duty fixturing washers

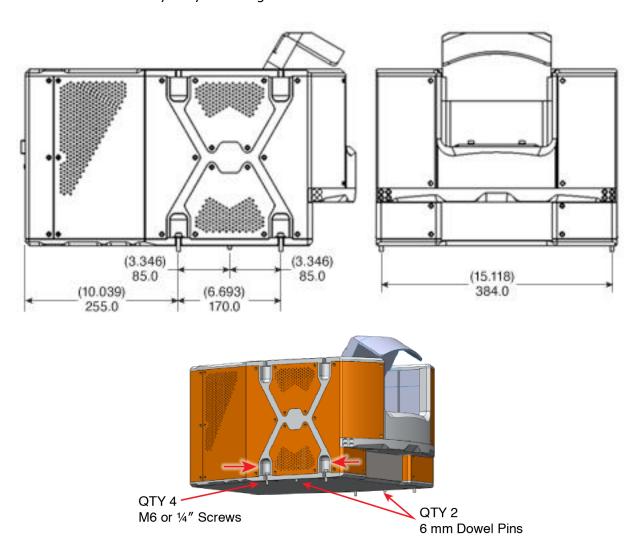


Fig. 3-4 Location of mounting points and alignment to mounting surface.

Slots are 7.5 mm wide to accommodate reasonable discrepancy between the mating holes. Arrows point to toe clamp pockets. Dimensions are given in millimeters and inches (in parentheses).

3.3.2 Mounting more than one unit

Two HiG3 Centrifuge units can be stacked on top of each other to increase throughput. Units can also be mounted side by side. Contact BioNex Solutions (888-524-0542) for instructions on mounting multiple units.



Warning: Units must be bolted together per BioNex Solutions' specifications. Do not attempt to use units that are stacked but not bolted together. Contact BioNex Solutions for instructions.



Warning: Do not attempt to stack more than 2 units. Contact BioNex Solutions for help with configuring multiple units.

3.4. Integrate the HiG3 Centrifuge with your system

The HiG3 software is written in .NET for easy integration with third party software. The HiG3 Centrifuge can only be controlled through software and does not include independent operator controls.



Warning: Before proceeding to the next step, ensure that all packing material has been removed from the unit as instructed.

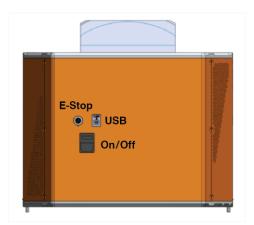


Fig. 3-5 Back view: clockwise from top left, emergency stop (E-stop) port, USB port, on/off switch

3.4.1 Power up the HiG3 Centrifuge

- Ensure that all shipping blocks have been removed as described in LIT-50050 (packaged with unit and available on included USB Stick) and that all personnel are clear of the rotating shield and door.
- 2. Connect the appropriate power cord, E-stop switch and USB cable. Refer to Fig. 3-5.
- 3. Ensure the E-stop switch is not engaged by rotating the red mushroom switch.
- 4. Turn on power to the unit by pressing the power switch on the rear panel of the centrifuge.

3.4.2 Install the BioNex Solutions software

This step may have been completed during the unpacking operation. If using a different computer, uninstall any older version of the software that may already be present.

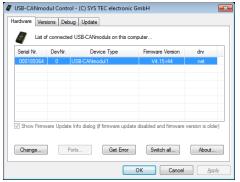
1. Insert the BioNex HiG3 Integration Software USB drive (the HiG Integration software USB drive is included in the HiG3 Accessory Kit) and run the installer executable. The installation wizard will walk you through the process.

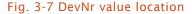
The screen shown in Fig. 3-6 will appear.



Fig. 3-6 Screen showing completion of software installation

- 2. Click Finish to exit. If you have not installed the device driver yet, select the check box. It will install automatically.
- 3. Launch the USB-CANmodul control application, located in Start -> All Programs -> USB-CANmodul Utilities. Make a note of the "DevNr" value (Fig.3-7).





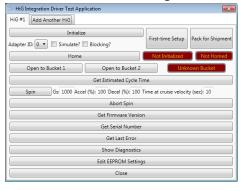


Fig.3-8 HiG Integration Driver Test Application screen

- 4. Locate the HiG3 software desktop shortcut and launch the HiG3 Integration Driver Test Application. The screen shown in Fig. 3-8 will appear.
- 5. Ensure that the Adapter ID value is the same as the DevNr value that you identified in Step 3.

To connect to the HiG3 Centrifuge, select Initialize; select Home; select Spin to verify basic functionality of the device.

Section 4

Centrifuge Maintenance, Cleaning, Shipping, and Disposal

4.1 HiG3 Centrifuge maintenance

The HiG3 Centrifuge requires cleaning and maintenance once every 3 months or 2000 plate spins.



Caution: Contact BioNex Solutions before using cleaning solutions or methods other than those specified here.

4.1.1 Prepare the HiG3 Centrifuge for maintenance



Warning, Must Unplug: System must be disconnected from power and communication when performing maintenance procedures.



Pinch Hazard: Use caution when manipulating the instrument doors.

- 1. Verify unit is not spinning.
- 2. Turn off rear power switch and remove all electrical connections.
- 3. Manually rotate the outer shield counterclockwise until the inner door opens.
- 4. Use a wooden stick to prop the inner door open as shown in Figure 4-1 below. The wooden stick used in packing for shipment can be used.



Fig. 4-1 Inner door propped open for cleaning and maintenance.





Biohazard Warning and Radioactive Solution Warning: The HiG3 Centrifuge is not intended for use with pathogenic or radioactive solutions, or with substances or in environments at or above Biosafety Level 1. BioNex Solutions does not guarantee safety, sterilization, or disinfection of the centrifuge if it is used with these hazardous substances.



Biohazard Warning: Follow your facility's procedures for handling human specimens when cleaning and maintaining the HiG3 Centrifuge.

If the HiG3 Centrifuge has been used with hazardous substances as listed in the warnings above, it must be decontaminated. Contact BioNex Solutions to obtain a decontamination form.



Warning, Must Unplug: System must be disconnected from power and communication when performing decontamination.

4.1.2 Inspection

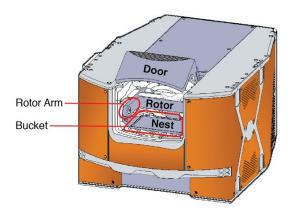


Fig. 4-2 Open door view of HiG3 Centrifuge

Perform the following inspection steps with every maintenance cycle.



Warning, Must Unplug: System must be disconnected from power and communication when performing inspection.



Warning, Pinch Hazard: Use care when moving the doors manually.



Fig. 4-3 Inner shield of HiG3 Centrifuge

4.1.3.1 Inspection checklist

- ☑ Inner shield, rotor, and buckets are free of accumulations of sample, dust, or other foreign matter
- ☑ Buckets and rotor move freely

☑ Rotor, rotor arms, and buckets show no signs of damage, including fractures, cracks, and corrosion.



Warning: Contact BioNex Solutions if damage to rotor, rotor arms, or buckets is detected. Discontinue using the centrifuge until damaged parts have been replaced.

4.1.3 Cleaning

Before cleaning the HiG3 Centrifuge, follow all the steps in Section 4.1.1, Prepare the HiG3 for maintenance.



Warning, Must Unplug: System must be disconnected from power and communication when performing cleaning procedures.



Warning, Pinch Hazard: Use care when moving the doors manually.



Biohazard Warning: Vacuum exhaust may contain biological particulates. Observe your facility's safety procedures.

4.1.4.1 Perform the following cleaning steps with every maintenance cycle.

Cleaning checklist

- ☑ Ensure that the HiG3 is powered off and that the power cord is not connected
- ☑ Use a vacuum to remove plastic or other particulate matter
- Remove any fluids that may be present inside the inner shield using a fiber free cloth
- ☑ Clean inner shield, rotor, spindle, and buckets using a fiber free cloth
- ☑ Clean outer shield and exterior surfaces using a fiber free cloth
- Dispose of used cleaning materials in a manner consistent with the hazards present in the solutions and materials in use.
- ☑ Remove the stick used to prop the door open.
- ✓ Plug electrical connectors back into the unit and wall.

4.2 Shipping the HiG3 Centrifuge to BioNex Solutions

4.2.1 Obtain authorization number

If you must send your HiG3 Centrifuge back to BioNex Solutions for any reason, call our service department at 888-524-0542 and request an authorization number. BioNex Solutions will not take receipt of the unit unless it is accompanied by the authorization number we issue to you.

4.2.2 Packaging materials

The HiG3 Centrifuge must be returned in its original packaging. If you no longer have the packaging, additional packaging may be purchased from BioNex Solutions.

4.2.3 Decontamination



Warning: The HiG3 Centrifuge must be free from any infectious or toxic substances before shipment to BioNex Solutions.

The HiG3 Centrifuge must be decontaminated before shipment. Contact BioNex Solutions to obtain the decontamination clearance form and instructions. Enclose the completed form with the unit.

4.3 Disposing of the HiG3 Centrifuge

4.3.1 Choose an authorized disposal facility

Do not dispose of the HiG3 Centrifuge at public collecting points. Have the device disposed of professionally by a recycling company that has been certified according to national and regional law.

4.3.1.1 Decontaminate the unit before disposing of it. Obtain the decontamination clearance form from BioNex Solutions and follow the instructions in the form.



Warning: It is the user's responsibility to ensure the unit is free from any infectious or toxic substances prior to disposal. Obtain the decontamination clearance form from BioNex Solutions, complete it, and enclose it with the unit.