Custom BioGenic Systems®

Instructions for Use

Custom BioGenic Systems Cryopreservation Storage System

With 2301 Controller

Designed and Manufactured by:

Custom BioGenic Systems

www.custombiogenics.com

74100 Van Dyke ♦ Bruce Township, MI 48065 ♦ USA

1.800.523.0072 ♦ 586.331.2600

Leading the World in Innovative Cryopreservation Technology Solutions

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

FM 725612

CE 2797

NOTE: Custom BioGenic Systems Cryopreservation Storage Systems are Class A devices pursuant to FCC Part 15 Subpart B / ICES-003 IEC 61326-1 / EN 61326-1. A 'Class A' device may be marketed for use in a commercial, industrial or business environment.

CAUTION: This is a Class A product. In a domestic environment this product may cause radio interference, in which case the user may be required to take adequate measures.

Custom BioGenic Systems Cryopreservation Storage Systems have been evaluated to:

IEC 61010-1

The equipment has not been investigated for protection against ingress of water (IP code per IEC 60529).

All wiring and installation shall be in accordance with electrical codes acceptable to the authorities in the countries where the equipment is installed and used.

The equipment has been investigated for continuous operation in dry, pollution degree 2 environments, at a maximum operating ambient temperature of 40°C.

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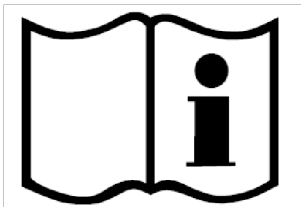
1.0 Important Information



Read and understand this manual completely before proceeding to set-up.
Save these instructions for future use.

- The suitability of the material being frozen for a specific medical application is not indicated nor claimed by the manufacturer. It is the responsibility of the user to qualify, as appropriate, the cryogenic storage equipment for their application as it pertains to long term storage and final use.
- Ensure all parts are accounted for and items are undamaged and intact upon reciept.
- The safety of any system incorporating this equipment is the responsibility of the assembler of the system.
- If this equipment is used in a manner not specified by Custom BioGenic Systems, the protection provided by the equipment may be impaired.
- Modifications or part substitutions to this unit are strictly forbidden. The unit does not have any user serviceable parts inside. DO NOT remove the protective housing.
- For maintenance, service, replacement, and/or repair needs, or if unsure of the proper setup and/or use of this product, please contact Custom BioGenic Systems:

Customer / Technical Services:
Phone: (800) 523-0072 (US ONLY), (586) 331-2600
Email: customerservice@custombiogenics.com
sales@custombiogenics.com

2.0 Warranty Information

Custom BioGenic Systems warrants all manufactured cryogenic equipment to be free from defects in workmanship or materials for a specified period as follows:

- Five-year vacuum warranty
- Two-year warranty on electronics and electrical parts

Custom BioGenic Systems' liabilities under the warranty shall be limited to correcting or replacing defective workmanship or materials. A claimant under the warranty must notify Custom BioGenic Systems within ten (10) business days after the discovery of the defect. Custom BioGenic Systems reserves the right, at their discretion, to correct the defect(s) in the field without return shipment to the factory.

This warranty does not cover defects on cryogenic equipment resulting from mishandling and/or structural failure. Warranty is automatically activated from date of receipt of the unit.

Serial Number: _____

Model Number: _____

3.0 Intended Use

A mains electricity (AC-powered) laboratory appliance designed to create a cryogenic environment below the point when most all biological activity ceases, using liquid nitrogen (LN_2) as the cooling and storage agent.

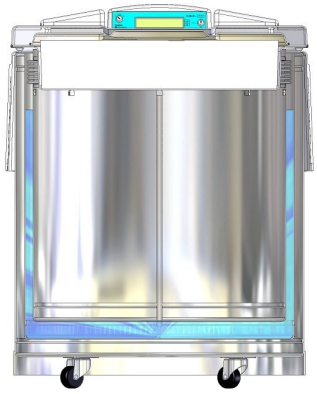
Prior to start up and operation, all authorized users must have a full and complete understanding of LN_2 usage, its potential hazards, and basic laboratory skills. Authorized users' training is the responsibility of the establishment, and training which is effective and continuous should be prioritized. Unauthorized personnel should never have access to the cryopreservation storage system or any of the components involved in the operation of the unit.

4.0 Description of Models

There are several series of cryopreservation storage systems which have specialized features to meet users' needs and functionality requirements. Each system is standardly equipped with an autofill controller, and a gas bypass feature.

4.1 Isothermal V-Series

- Dry storage environment
- LN_2 contained inside the vessel walls
- Storage samples are not in contact with LN_2
- Average internal temperature is -190°C
- Features wide lid opening



4.2 Isothermal V-Series Carousel

- Dry storage environment
- LN_2 contained inside the vessel walls
- Storage samples are not in contact with LN_2
- Average internal temperature is -190°C
- Square lid opening for ease of retrieval
- Rotating carousel with handle

4.3 Standard S-Series

- Liquid nitrogen immersion
- Features wide lid opening

5.0 Symbols

Safety Symbols

ROLLING HAZARD
This symbol indicates the cryopreservation storage system is a potential roll hazard. If the locks on the wheels are not engaged, the unit has the potential to cause damage to property, equipment, and personnel should a fully stocked freezer move.

LN2 CAUTION
This symbol indicates a Liquid Nitrogen (LN_2) warning. LN_2 is extremely cold, -196°C at atmospheric pressure, and is used as the cooling and storage agent. LN_2 can cause severe frostbite or eye damage upon exposure.

PERSONAL PROTECTIVE EQUIPMENT (PPE)
This symbol indicates that Personal Protective Equipment is required for use of the product. The cooling and storage agent used with this cryopreservation storage system is potentially hazardous. Custom BioGenic Systems recommends use of a face shield, safety goggles, cryogenic gloves, and a cryogenic apron.

LID HAZARD
This symbol indicates the lid of the cyrogenic storage system is a potential crush hazard. Caution should be exercised when opening and closing the lid of the cryogenic storage system. Ensure that the lid is opened fully and is stable prior to leaning or bending over the open freezer.

MANUAL FILL HAZARD
This symbol indicates the manual fill option is a potential hazard. Caution should be exercised when manually connecting or disconnecting the LN_2 hose, and proper PPE should be worn at all times.

LN2 HOSE CONNECTION
This symbol indicates the LN_2 hose connection is a potential hazard. Caution should be exercised around the hose, as it can become a frostbite hazard as the LN_2 flows through the hose.

ASPHYXIANT HAZARD
This symbol indicates that LN_2 vaporization is a potential hazard. One liter of liquid nitrogen expands to 24.6 cubic feet of nitrogen gas and displaces oxygen. The displacement of oxygen can lead to suffocation without warning if the work area is not properly ventilated.

CRUSH HAZARD
This symbol indicates that the lid of the cryogenic storage system is a potential crush hazard for appendages. Caution should be exercised when opening and closing the lid of the cryogenic storage system. Ensure that the lid is opened fully and is stable. Keep hands clear of the lid when closing.

SENSITIVE ELECTRONICS
This symbol indicates that there is a potential for electrical shock. Caution should be exercised when in contact with the sensitive electronics. Never operate the control panel or touch any electronics if wiring has become damaged or if it is wet, as this can lead to electrical shock. Never tamper with the electrical components or the power cord, as this can lead to electrical shock.

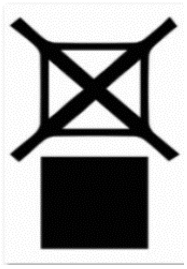
Product Symbols

EARTH GROUND CONNECTION

DIRECT CURRENT

FUSE

WARRANTY INFORMATION
The warranty is automatically activated with purchase. For information and exclusions, see *Section 2.0 Warranty Information* of this document.



DO NOT STACK
This unit is not intended to be stacked during shipment, storage, or at any other time. Stacking the cryogenic storage system will void the warranty of the device.

TWIST TO OPEN
In order to fully close the lid, engage the lid latch by twisting the handle clockwise until the spring secures the latch. In order to open the lid, disengage the lid latch by twisting the handle counter clockwise until the spring releases the latch.

6.0 Liquid Nitrogen Safety

Properties of Liquid Nitrogen

Property	Specification
Boiling Point @ 1 atm	-195.8°C, -320.4°F, 77.4K
Thermal Conductivity (Gas)	25.83 mW/(m·K)
Heat of Vaporization (Liquid)	198.38 kJ/kg
Density @ 1 atm (Liquid)	1.782 lbs/L, 807.4 g/L, 808.6 kg/m^3

Review the *Safety Symbols* descriptions, located in *Section 5.0* of this document, as they pertain to Liquid Nitrogen Safety.

Prior to the start up or operation of the cryopreservation storage system which utilizes liquid nitrogen as the cooling and storage agent, all personnel should have a complete understanding of handling and potential hazards involved. Authorized personnel should have adequate chemical useage training to safely use liquid nitrogen. Review the Safety Symbols (in *Section 5.0 Symbols*), **and** refer to the Safety Data Sheet (SDS) provided by your liquid nitrogen supplier for hazards, warnings, safety recommendations, and appropriate first aid measures related to liquid nitrogen.

Caution: Liquid Nitrogen evaporation may cause rapid oxidation that may increase fire hazard potential if exposed to ambient combustible organic materials. Refer to the Safety Data Sheet (SDS) provided by your liquid nitrogen supplier for fire safety measures.

Always wear the proper Personal Protective Equipment (PPE) when working with liquid nitrogen. Custom BioGenic Systems recommends the following PPE when working with the cryopreservation storage system: face shield, safety goggles, cryogenic gloves, and cryogenic apron. Gloves should be loose fitting, so they can be quickly discarded should liquid nitrogen enter the glove.

Custom BioGenic Systems recommends developing and following safety rules, protocols, training, and operational requirements to ensure all users have an understanding of the hazards, warnings, safety recommendations, and appropriate first aid measures related to liquid nitrogen. All safety rules, protocols, training, and operational requirements as they relate to the use of liquid nitrogen and the operation of the cryopreservation storage system, beyond what is covered in this document, are the responsibility of the user to develop and follow.

Custom BioGenic Systems recommends developing procedures surrounding:

- Proper PPE requirements
- Acceptable work wear/attire
- Proper storage and transport containers for liquid nitrogen
- Proper handling of liquid nitrogen (splashing, boiling, etc.)
- Ventilation requirements, and related safety equipment
- Proper first aid and contingency measures
- Use of liquid nitrogen around, and with, other substances
- Any other best-practice guidelines, as necessary

7.0 Product Safety

Review the *Safety Symbols* descriptions, located in *Section 5.0* of this document, as they pertain to Product Safety.

Prior to the set up or operation of the cryopreservation storage system, personnel involved with the installation, set up, or operation should be fully trained. Authorized personnel should have a complete understanding of the usage and associated hazards of liquid nitrogen, and a basic understanding of laboratory equipment. Proper PPE should be worn when using liquid nitrogen and when reasonable, during set up and operation of the cryopreservation storage system.

Refer to *Section 13.0 Installation and Startup* for instructions on how to set up the cryopreservation storage system, and *Section 14.0 Controller* through *Section 27.0 Manual Fill* for operational instructions. Custom BioGenic Systems recommends developing safety rules, protocols, training, and operational requirements which incorporate the instructions in these sections. All safety rules, protocols, training, and operational requirements as they relate to the use of the cryopreservation storage system, beyond what is covered in this document, are the responsibility of the user to develop to best suit their facilities' needs.

Caution: Glass vials contaminated with LN2 can explode from rapid pressure expansion when trapped LN2 changes to vapor phase.

Custom BioGenic Systems recommends developing procedures surrounding:

- Proper PPE requirements
- Acceptable and unacceptable operational conditions for the device
- Environmental controls for operation (temperature, humidity, etc.)
- Daily inspection, usage criteria, and activity monitoring of the device
- Working knowledge of the alarm system and remedial action plans for all alarms
- Proper first aid and contingency measures
- Proper handling of sample inventory
- Maintenance plan and schedule to ensure device remains in good condition
- Any other best-practice guidelines, as necessary

8.0 Operating Parameters

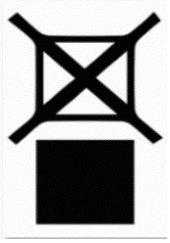
The cryopreservation storage system is designed to operate under the following conditions:

- Indoor use only
- Altitude (maximum): 2000m
- Ambient temperature range: 5°C to 40°C
- Relative humidity (maximum for ambient temperature): 80% for temperatures of up to 31°C, decreasing linearly to 50% at 40°C
- Use of provided casters is highly recommended as the cryopreservation storage system is intended to be used as stationary equipment. Casters and handles are provided to assist in the positioning of the device during initial installation ONLY.

Component	Detail	
CONTROLLER DIMENSIONS	CLAMSHELL	TRAY
LENGTH inches (mm)	9.38 (238)	8.47 (215)
WIDTH inches (mm)	16.17 (411)	12.5 (318)
HEIGHT inches (mm)	5.74 (146)	3.77 (96)
WEIGHT LBS (kg)	5.7 (2.59)	3.9 (1.77)

Component	Detail
MATERIALS OF CONSTRUCTION	
VESSEL	304 Stainless Steel
SURROUND	Fiberglass, polyester resin, Class 1 flame rating ASTME-84
ELECTRONICS / PCB	ROHS
SMT & CONVENTIONAL COMPONENTS	UL94V rating
DISPLAY	Liquid Crystal Display
TYPE	STN Positive Yellow Green backlit
SIZE	40x4
VIEW AREA (WXH)	148.0mm x 30.3mm
CHARACTER SIZE (WXH)	2.78mm x 4.89mm
KEYPAD	6 button multifunction membrane switches
KEY-LOCK	Power / Program locking
ELECTRICAL AC MAIN POWER	
INPUT POWER	100VAC~240VAC
INPUT FREQUENCY	50HZ/60HZ
INPUT CURRENT (max)	2 AMPS (fused)
POWER CONSUMPTION (max)	222mA @ 120VAC/60HZ (144mA@220VAC/60HZ)
POWER CONSUMPTION (typical)	77mA @ 120VAC/60HZ
MAIN FUSE	2 AMP @ 250VAC TYPE 3AG/AB SLO-BLO
ELECTRICAL DC POWER SUPPLY	**CLASS II** / EARTH GROUNDED UL 60601-1, CUL TO 22.2NO.601, TUV TO EN60601 cTUVus CE FOR EMC, PSE TO J60950 / ROHS
MODEL	GLOBTEK / GLOBTEK / GTM21097-5024 / TR9CI2100LCP-Y-MED-R
AC POWER CORD / PROTECTION	18AWG, 3-PINS, Class I with functional earth
INPUT VOLTAGE / FREQUENCY (min / max)	100VAC~240VAC, 50/60HZ
OUTPUT VOLTAGE	24VDC +/- 5% Regulated
OUTPUT CURRENT	2.1 AMP MAX
OUTPUT POWER (max)	50W
POWER CONSUMPTION (monitoring)	9 watts
POWER CONSUMPTION (2 valves energized / filling)	26 watts
HOUSING	94V0 Polyester
I/O CONNECTIONS	
GLOBAL REMOTE CONTACTS	3-PIN: DRY CONTACTS, 24VDC / 2A (max)
FILL SOLENOID	24VDC@2A (max)
VENT SOLENOID	24VDC@2A (max)
4-20Ma (**2301 only**)	400-ohms max loop impedance
0-5V analog output (**2301 only**)	25mA maximum to load
THERMOCOUPLES	3 total (VENT/LID-A/LID-B)
TYPE	Type T (copper-constantan) suited for measurements in the −200°C to +200°C range in oxidizing atmospheres.
ACCURACY (standard type-T)	+/- 1.0C or +/- .75%
TEMPERATURE MEASUREMENT	
RESOLUTION	1°C resolution on display (-200°C to +25°C)
ACCURACY	+/-2.0°C or 1% range (2-point calibration)
LEVEL MEASUREMENT	
PRESSURE SENSOR	Differential type
RANGE	0~1-PSI (6.9kPa) +/- 1%, 20psid proof
RESOLUTION	+/- 0.1-inch display (1" set-point adjustment)
ACCURACY	+/- 0.5-inch (12.5mm) LN_2 actual level

9.0 Transport, Handling, and Storage



The above symbol indicates the cryopreservation storage system should not be stacked. Stacking the device during transport, storage, or any time thereafter will void the warranty of the device.

Vehicles used to transport the device should be designed and equipped to ensure protection from adverse environmental and weather conditions. The use of vehicles with defects that could affect the quality or functionality of the device should be avoided.

The cryopreservation storage system must be transported in an upright position, with casters locked and on a level surface. Do NOT lift the device by the handles, and use of lift-specific machinery is only recommended for unpackaging purposes (review Section 10.0 *Unpacking* information in this document).

The cryopreservation storage system must be stored on a level surface, with the casters in the *locked* position as the device is a roll hazard (review *Section 7.0 Product Safety* information in this document). Custom BioGenic Systems recommends designated storage areas meet the following conditions:

- Area is clean and dry
- Floor should be level and capable of supporting the weight of the fully stocked cryopreservation storage system
- Area should have outward opening doors, adequate space to maneuver around the device safely, and adequate space to allow for cleaning and inspection of the unit (review *Section 6.0 Liquid Nitrogen Safety* in this document)
- All surfaces surounding the device should be impermeable for proper cleaning
- Area should be adequately lit and ventilated to meet safety requirements
- In case of recall, the unit should be positioned in a way which allows access to lot / batch / serial information

10.0 Unpacking

Inspect both the Bill of Lading and any associated packaging for accuracy and potential damage prior to accepting the shipment. Each cryopreservation storage system is packed securely on a wood pallet, and in a cardboard box wherein the device is surrounded by a protective layer of foam.

To unpack the cryopreservation storage system:

1. Remove the top of the box.
2. Using a box cutter, cut down any corner of the box, and peel the cardboard and foam away from the unit. Discard the packaging material.
3. Using side cutters, cut the tie down straps around the unit and discard.
4. Using a forklift, lift the cryopreservation storage system from the BASE of the unit off the pallet, and onto a stable and level surface.

NOTE: White glove delivery service is available upon request for all cryopreservation storage systems.

11.0 Cleaning and Decontamination

Prior to ANY cleaning or decontamination activities, ensure the cryopreservation storage system has been powered down, and is disconnected from its power source. Use of liquid cleaning supplies may result in electrical shock or injury if the device becomes over saturated when powered. Use solutions that do not react with stainless steel ONLY.

NOTE: The device is not provided in sterile condition.

Custom BioGenic Systems recommends use of an alcohol-based solution to disinfect the device. Specifically, an isopropyl alcohol solution (70% solution) sprayed onto a lint-free or microfiber cloth is recommended. All equipment should be allowed to thoroughly dry prior to the device being reintroduced to service.

To maintain the integrity of the device, DO NOT:

- Remove or deface equipment labels, warnings, or product information by any cleaning or disinfectant
- Spray or saturate liquids on any electrical components

- Apply corrosive or petroleum-based substances or agents onto any part of the equipment
- Fog equipment with any disinfecting agent or chemical substance

Recommended cleaning procedure for the cryopreservation storage systems:

1. Spray chosen disinfectant onto a lint-free or microfiber cloth until damp.
2. Wipe all surfaces (both inner and outer) with this cloth and allow to sit for 30-minutes.
3. Spray a lint-free or microfiber cloth with a soapy water mixture until damp.
4. Wipe all surfaces which were previously in contact with the isopropyl alcohol.
5. Allow unit to fully dry prior to the device being reintroduced to service.

12.0 Liquid Nitrogen Supply Tank

NOTE: Review *Section 6.0 Liquid Nitrogen Safety* and *Section 5.0 Symbols* prior to operation of any liquid nitrogen supply tanks.

Liquid Nitrogen (LN_2) supply tanks must be operated in accordance with the manufacturer or supplier instructions. The requirements to operate the site-specific LN_2 supply tanks, accessability and training for use of the tanks, and maintenance of the tanks and any additional equipment required, is the responsibility of the establishment. Custom BioGenic Systems recommends replenishing the LN_2 supply tanks at regular intervals to ensure proper operation of the cryopreservation storage system.

13.0 Installation and Startup

NOTE: Review *Section 6.0 Liquid Nitrogen Safety*, *Section 7.0 Product Safety*, and *Section 5.0 Symbols* prior to installation, startup, or operation of any cryopreservation storage system.

After unpacking and cleaning the cryopreservation storage system (*Section 10.0 Unpacking* and *11.0 Cleaning and Decontamination* of this document), position the unit in the location where it will be installed and validated. Lock the casters prior to starting the unit. If a caster locking mechanism is provided with the unit, install the locking mechanism, and ensure that it is engaged prior to starting the unit. The cryopreservation storage system requires an LN_2 supply source; either an independent supply tank or a pipeline connected to a bulk tank which is between 18-25 psi (1.24-1.72 Bar).

Included with each cryopreservation storage system:

- 6 ft LN_2 Transfer Hose
- 2 sets of Controller Keys
- 1 set of Lid Lock Keys
- LN_2 Level Measuring Stick (**S-Series Only**)

Tools required for Startup:

- Adjustable wrench
- Two (2) supply tanks, 180 liters or larger (or a bulk tank LN_2 source)

NOTE: Only authorized personnel should be performing the installation and startup for the cryopreservation storage system (see *Section 3.0 Intended Use* for more information). Custom BioGenic Systems recommends maintaining a back-up supply of LN_2 should an interruption in supply occur.

To perform the Startup of the cryopreservation storage system:

1. Connect the provided 6 ft LN_2 transfer hose to the liquid side of the LN_2 supply tank. Connect the opposite end to the cryopreservation storage system to the connection port labeled with the LN_2 HOSE CONNECTION label. 
2. Plug the power cord into the appropriate power source.
3. Insert the Controller Key into the Power Key Swtich, and turn it to the ON position. The factory default set points are:

Model	Low	High
V-Series	10 inches / 25 cm	17 inches / 43 cm
S-Series	4 inches / 10 cm	6 inches / 15 cm

4. The lid should remain open for the entire duration of the first fill.
5. Open the valve to the LN_2 supply tank. The unit will automatically begin to fill.

All cryopreservation storage systems regardless of model have the option to vent nitrogen gas. Custom BioGenic Systems recommends utilizing this function, especially when a pipeline to a bulk tank is being adopted as the LN_2 supply. To enable the bypass option, see *Section 20.0 Gas Bypass and Vent* for instructions.

The unit will initiate a low-level alarm during the initial fill while the LN_2 level is below the *default* set point. It will take between 30-90 minutes for the initial fill, depending on the volume of the cryopreservation storage system. Fill times may vary depending on the supply source. While the fill is ongoing, the operational status will present with the **FILLING** designation alongside the current status.

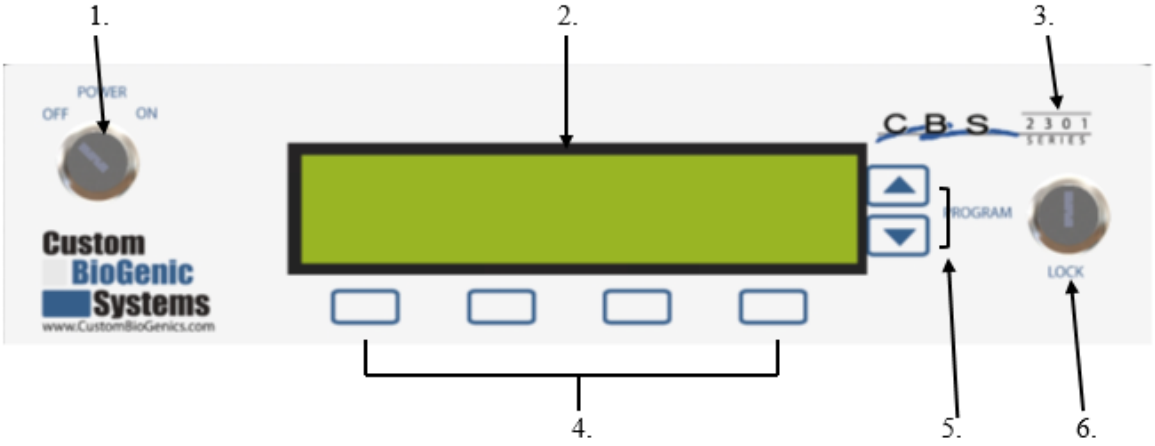
The unit will automatically stop filling when the LN_2 level (LIQ'D LEVEL) reaches the high set point. The controller status will reflect when the filling operation has concluded, and the **FILLING** designation will be removed.

After the cryopreservation storage system stops filling, the lid can be closed. Allow the temperature to stabilize for 2-3 days with the lid closed before changing the high temperature set point, performing Installation Qualification/Operational Qualification (IQ/OQ), performing any testing, or storing of any product.

14.0 Controller

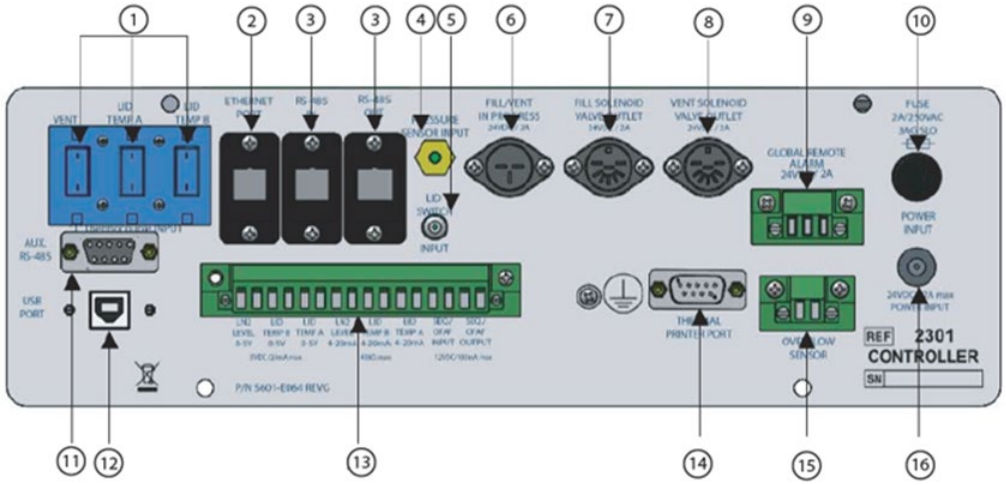
14.1 Front Panel Controls

NOTE: Do NOT use pointed objects for selections, as this will cause damage to the display.



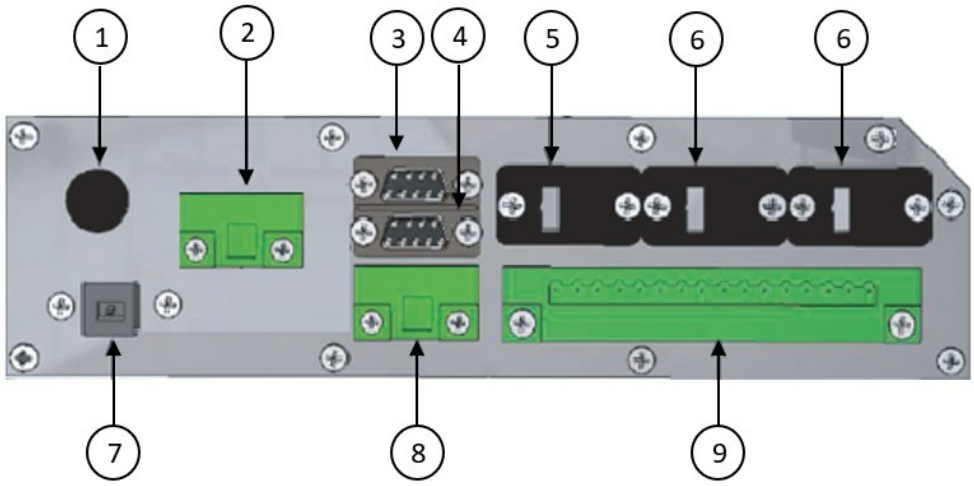
Front Panel Controls		
1	Power Key Switch	Main power control for the unit
2	LCD Display	40 x 4 LCD Display with backlight
3	Label	Identifies the model number of the controller
4	Menu Buttons	Navigate controller and select options shown on the display
5	Up/Down Arrows	Used to toggle or scroll through values.
6	Program/Lock Key Switch	Changes the mode between standard and Program. This protects unauthorized users from changing controller programming.

14.2 Back Panel Controls



Back Panel Controls		
1	Female Temperature Probe Assembly	Plugs for Vent, Temp A thermocouple, and Temp B thermocouple
2	Ethernet Port	Connections for future expansion
3	RS-485 IN, RS-485 OUT	Connections for future expansion
4	Sensor Port	Port for the sensor hose which connects from the vessel to the controller
5	Lid Switch Input	Connection for Lid Switch
6	Fill/Vent in Progress Plug	Outputs 24V DC when filling or venting (Optional Use)
7	Fill Solenoid Valve Outlet	Plug for FILL valves
8	Vent Solenoid Valve Outlet	Plug for VENT valve
9	Global Remote Alarm	Dry contact which switches status when any alarm occurs
10	2 Amp Fuse Housing	Holds 2 Amp Slow Blow fuse
11	AUX RS 485 Port	Connection for future expansion
12	USB Port	Connection for future expansion
13	16 Port Connector	0-5VDC and 4-20mA Outputs for Temp A, Temp B, and Level.
14	Thermal Printer Port	Plug to connect thermal printer for reports
15	Overflow Sensor Port	Discontinued
16	Power Supply Plug	Plug for the 24V medical power supply

14.3 Back Panel Controls – 5000 Series



Back Panel Controls 5000 Series		
1	2 Amp Fuse	VAC 2 amp buss fuse; 220 volts slow-blow (T2A-250V)
2	Global Remote Alarm	Dry contact which switches status when any alarm occurs. All Global Remote Alarm connections are dry contact relays with a max output of 24VDC@2A
3	Thermal Printer Port	Plug to connect thermal printer for printing alarms and data
4	AUX RS-485 Port	Connection for futher expansion
5	Ethernet Port	Connection for futher expansion
6	RS-485 IN, RS-485 OUT	Connection for future expansion
7	USB Port	Connection for future expansion
8	Overflow Sensor	Discontinued
9	16 Port Connector	0-5VDC and 4-20mA Outputs for Temp A, Temp B and Level.

15.0 Secure Program Mode

The controller features a built-in security function by requiring controller key usage before changes can be made to any setting. Prior to enabling PROGRAM mode, the Power Key Switch must be in the ON position. The Program Key Switch can then be turned to the PROGRAM position, and settings changes can be initiated.

16.0 Liquid Nitrogen Level Control and Alarms

The controller activates the fill solenoid valve when the liquid nitrogen level drops below the low-level set point. The solenoid valve deactivates when the liquid nitrogen level reaches the high-level set point, stopping the fill. The set points can be adjusted with a range from 0 inches (0 cm) to 30 inches (76 cm).

The liquid nitrogen level is controlled in the PROGRAM mode. To adjust the LN_2 level:

1. Turn the Program Key Switch to the PROGRAM position
2. Select **LIQ'D LEVEL**
3. Select either **INCHES** or **CENTIMETERS**
4. Use the buttons below the horizontal arrows to toggle between **HI SET** and **LO SET**
5. Press the up and down arrows on the *right side* of the controller to adjust the set level value
6. Press **ENTER** when finished (settings will NOT be saved if **ENTER** is not pressed)
7. Turn the Program Key Switch to the LOCK position

When the liquid nitrogen level drops to the low set point, an autofill is triggered and the solenoid valves open. If the LN_2 level remains at or below the low set point for seven (7) minutes, an audible and visual alarm activates, displaying the ****LOW ALARM**** designation**.**

When the liquid nitrogen level reaches the high set point during a fill, the solenoid valves close and the fill is stopped. If the LN_2 level exceeds the high set point for two (2) minutes, an audible and visual alarm activates, displaying the ****HIGH ALARM**** designation**.**

17.0 Temperature Measurement and Alarms

The controller measures temperature using two (2) Type-T thermocouple probes, shown on the controller as **TEMP-A** and **TEMP-B**. The default length of the probes into the probe holder tube are shown in the table below.

Model	TEMP-A	TEMP-B
V-Series	12 inches / 30.5 cm	20 inches / 50.8 cm
V-Series Carousel	11 inches / 28 cm	11 inches / 28 cm
S-Series	12 inches / 30.5 cm	20 inches / 50.8 cm

The default temperature set point is 30°C to prevent temperature alarms from occurring during the initial fill. To adjust the temperature set point:

1. Turn the Program Key Switch to the PROGRAM position
2. Select **NEXT** to advance to **MAIN MENU 2**

3. Select **TEMP**
4. Select either **F** (for Fahrenheit) or **C** (for Celsius) to set unit
5. Press the up and down arrows on the *right side* of the controller to adjust **TEMP-A ALARM**
6. Select **ENTER** (settings will NOT be saved if **ENTER** is not pressed)
7. Press the up and down arrows on the right side of the controller to adjust **TEMP-B ALARM**
8. Select **ENTER** (settings will NOT be saved if **ENTER** is not pressed)
9. Turn the Program Key Switch to the LOCK position

If the temperature value on either **TEMP-A** or **TEMP-B** exceeds the preset temperature, an audible and visual alarm activates. The controller will reflect the alarm status as **TEMP-A HIGH** or **TEMP-B HIGH** designation.

18.0 Source Alarm

A timer automatically initiates when a fill is started. If the high level set point is not reached with the default time of 30 minutes, a source alarm will activate. The source alarm is intended to prevent filling with an empty or low-pressure supply source. The source alarm timer can be extended only in specific instances. Contact Custom BioGenic Systems to determine if the conditions are met and for more information.

19.0 Lid Switch

Some models are equipped with a lid switch. The controller will display the **LID OPEN** designation in the event that the lid is open. The lid open event will be recorded in the ALARMS Report, which can be reviewed once all alarms have been cleared. To view the ALARMS report, see *Section 21.0 Data Logs* of this document. Units which have lift-off lids and carousel models are NOT equipped with a lid switch.

20.0 Gas Bypass and Vent

All cryopreservation storage systems, regardless of model, are equipped with a bypass or vent valve to release LN_2 gas from the transfer lines prior to the activation of the fill solenoid valves. The bypass is typically enabled when the liquid nitrogen supply source is at a distance greater than 6 feet (1.83 meters). When the bypass is enabled during a fill cycle, the vent valve will open first. The controller will close the vent valve automatically when the

temperature reaches approximately -160°C, and the fill valves will open. To enable the bypass function:

1. Turn the Program Key Switch to the PROGRAM position
2. Select **NEXT** to advance to **MAIN MENU 2**
3. Select **BYPASS**
4. Select **ON**
5. Turn the Program Key Switch to the LOCK position

NOTE: In order to disable the bypass function, select **OFF** in *step 4* above.

21.0 Data Logs

The controller records various data logs to fufill user requirements. The ALARM log records fill start, fill stop, and lid open events. The DATA log records liquid nitrogen levels, TEMP-A and TEMP-B reports on an hourly interval, as specified. These logs are recorded in a first-in/first-out manner, and up to 999 events can be stored. To enable the DATA and ALARM logs:

1. Turn the Program Key Switch to the PROGRAM position
2. Select **NEXT** three (3) times to advance to **MAIN MENU 4**
3. Select **LOG**
4. Press the up and down arrows on the *right side* of the controller to choose an **HOURS** interval (i.e. 1 for every hour, 2 for every other hour, 3 for once every three (3) hours, etc.). Intervals can be programmed to sample on an **HOURS** interval from 1-99 HOURS.
5. Press **ENTER** when complete (settings will NOT be saved if **ENTER** is not pressed)
6. Turn the Program Key Switch to the LOCK position

To view the ALARMS log or DATA log:

1. Select **REPORT**
2. Select the appropriate log (**ALARMS** or **DATA**)

3. Use the arrow keys to select a report start date.
4. Select **ENTER**.
5. Use the arrow keys to select a report end date.
6. Select **ENTER**
7. Choose **DISPLAY** to view the report on the controller, or select **PRINT** to print the report using a thermal printer (see *Section 25.0 Printer Connection* for more information).
8. When **DISPLAY** is pressed, cycle through the report log by using **PREV** (previous) or **NEXT** to view the corresponding record.

22.0 On Screen Functional Validation

The controller is equipped with a functional validation feature. To access this validation feature:

1. Turn the Program Key Switch to the PROGRAM position
2. Select **NEXT** two (2) times to advance to **MAIN MENU 3**
3. Press **VALIDATION**

Validation can be performed on the overlay buttons, buzzer (audible alarm), remote contacts, all temperature probes, printer (optional), valves, and the lid switch (model dependent). For optional or model dependent functions, the option to SKIP the validation is available.

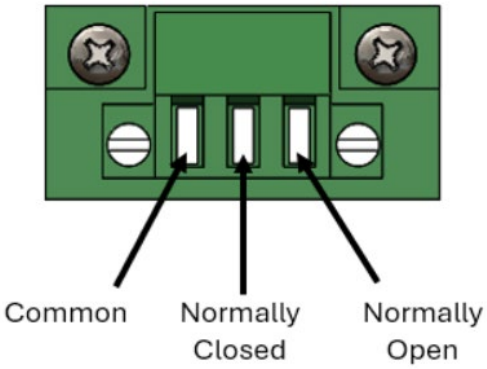
The validation results can be printed when complete (see *Section 25.0 Printer Connection* for more information).

23.0 Global Remote Alarm Connection

The Global Remote Alarm Connection allows for remote monitoring. The Global Remote Alarm Connection will change state in the event of a system alarm condition or power loss, indicating that an alarm has been triggered.

Contacts can be used to interface with accessory items such as a remote dialer or a local alarm system for notification of the alarm condition.

Global Remote Alarm
Contacts are DRY or unpowered, rate at 24VDC @ 2A



24.0 Electrical Outputs

The controller is equipped with outputs which allow for the use of either 0-5VDC or 4-20mA for monitoring temperature and LN_2 levels. Review *Section 8.0 Operating Parameters* for input/output specifications.

NOTE: Scaling is to the operational range of the controller. Contact Custom BioGenic Systems for questions or more information.

Temperature		
0-5VDC	0V = -200°C	5V = +50°C
4-20mA	4mA = -200°C	20mA = +50°C

Level		
0-5VDC	0V = 0.0”	5V = 33.0”
4-20mA	4mA = 0.0”	20mA = 33.0”

Accuracy:	+/- 3°C for Temperature	+/- 0.5” for Level

To ensure the controller is outputting the correct signal:

1. Turn the Program Key Switch to the PROGRAM position
2. Press **TANK ID**
3. Press **NEXT MENU** two (2) times
4. Press the up and down arrows on the *right side* of the controller to toggle

between 0-5V and 4-20mA

5. Press **ENTER** (settings will NOT be saved if **ENTER** is not pressed)
6. Turn the Program Key Switch to the LOCK position

25.0 Printer Connection

A printer port is available on 2301 controllers to connect a thermal printer. No additional steps are required to install or utilize printers of this type. Reports can be printed from the **REPORT** function of the controller. Validation test results can also be printed (see *Section 22.0 On Screen Functional Validation* for more information).

26.0 Filling Features

26.1 Fill Timer

The fill timer will fill the unit at 24, 48, or 72-hour intervals, as selected. The automatic fill setting will always override the fill timer setting. To activate the fill timer:

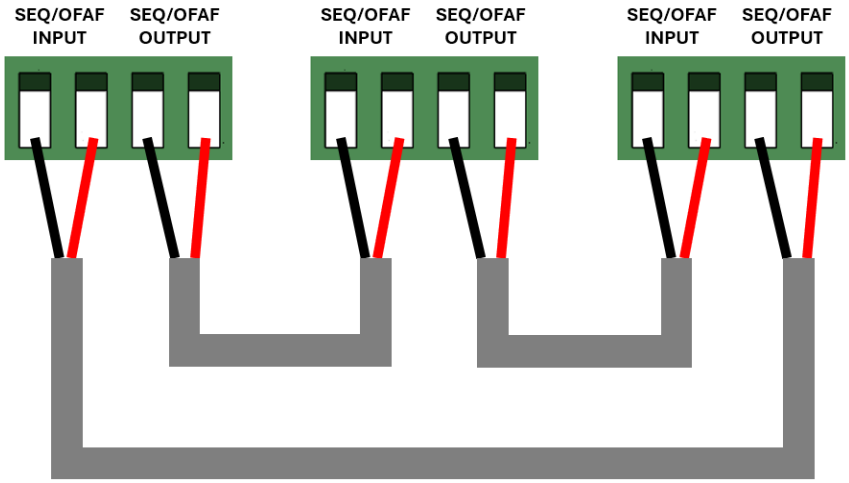
1. Turn the Program Key Switch to the PROGRAM position
2. Select **NEXT** two (2) times to advance to **MAIN MENU 3**
3. Select **FILL TIMER**
4. Select **ENABLE**
5. Select the interval (**24**, **48**, or **72** hours)
6. Select the right and left arrows on the *bottom* to toggle between **HR<->MIN** (both *steps 5 and 6* must be completed to set the fill start time)
7. Select **ENTER** when complete (settings will NOT be saved if **ENTER** is not pressed)
8. Turn the Program Key Switch to the LOCK position

26.2 Fill/Vent in Progress

The Fill/Vent in Progress provides a signal to activate the CBS TS-1B LN_2 Supply Tank Switcher. This enables an additional 24VDC valve to control the liquid nitrogen supply. The signal is provided whenever filling or venting occurs.

26.3 SEQ/OFAF System

The SEQ/OFAF System is an option for units connected to a bulk supply liquid nitrogen source. The controllers are connected using a two-conductor wire connecting one controller's SEQ/OFAF output to the next controller's SEQ/OFAF input. Continue these connections until all the controllers are connected in a complete loop. To reset the system each controller must be powered OFF and ON. The connectors are located on the rear panel.

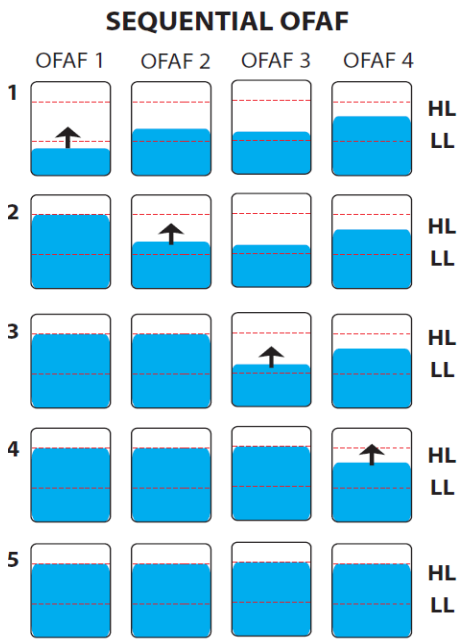


After the controllers are connected:

1. Navigate to the **RUN MENU**
2. Select **PROGRAM**
3. Select **NEXT** three (3) times to advance to **MAIN MENU 4**
4. Select **OFAF**
5. Select **SIMULTANEOUS** or **SEQUENTIAL**
6. Select **ENTER** (settings will NOT be saved if **ENTER** is not pressed)
7. Turn the Program Key Switch to the LOCK position

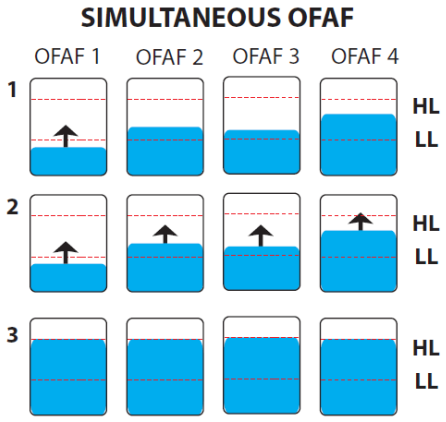
Sequential Fill

The Sequential Fill option will maintain optimal fill pressure and significantly reduce LN_2 transfer loss. This option will automatically activate the next controller once the primary controller reaches its high level. This process will proceed until all linked controllers have reached their high level set points.



Simultaneous Fill

The Simultaneous Fill option will fill the units simultaneously until all linked controllers have reached their high level set point.



27.0 Manual Fill

Manual filling may be necessary during a power outage or malfunction. All cryogenic storage systems are equipped with a manual fill port located near the rear of the unit. Contact Custom BioGenic Systems for troubleshooting, repairs, and other questions. To perform a manual fill:

1. Turn off the liquid nitrogen supply valve at the supply tank.
2. Disconnect the supply line from the auto fill port.
3. Remove the cap from the manual fill port and replace it where the hose was removed. Tighten the cap.

4. Connect the liquid nitrogen supply line to the manual fill port and tighten.

5. Open the lid.

6. Open the valve on the liquid nitrogen supply.

7. **V-Series Models**: fill until the liquid nitrogen begins to "spit" from the vent closest to the fill line, then close the supply source valve. Standard height units will contain approximately 25 inches of liquid nitrogen when the LN_2 begins to "spit."

8. Close the lid.

9. Repeat daily or until the auto fill function is restored.

28.0 Preventative Maintenance

Procedure	Daily	Weekly	6-months	Annually	5-years
Overall visual inspection	☒	☐	☐	☐	☐
Removal of ice build-up on the underside of the lid. Wipe away any condensation before closing.	☒	☐	☐	☐	☐
Verify supply tank contains an adequate amount of LN_2	☒	☐	☐	☐	☐
Inspect all LN_2 plumbing for leaks	☐	☒	☐	☐	☐
Run On-Screen Functional Validation	☐	☐	☒	☐	☐
Inspect lid hinge for proper functionality and potential wear	☐	☐	☒	☐	☐
System calibration, temperature, and liquid level	☐	☐	☐	☒	☐
Perfomance evaluation or preventative maintenance service	☐	☐	☐	☒	☐
Perform system thaw	☐	☐	☐	☐	☒
Clean or replace solenoid valves	☐	☐	☐	☐	☒

29.0 Troubleshooting

Condition	Potential Cause	Solution(s)
High Alarm Visual alarm SYSTEM STATUS ALARM **HIGH ALARM** Audible alarm present. Liquid level has risen above the high-level set point.	• FILL/START button damaged.	• If the unit is filling, turn off the LN2 supply. Push the STOP button after the alarm is reset. Check that the FILL/START button is not damaged.
	• Valves frozen due to long fill time or debris obstruction.	• Allow valves to thaw if frozen open. Check the pressure of supply; ensure it does not exceed 25 PSI. If after being thawed the unit continues to overfill, there may be an obstruction. Remove solenoid valves and disassemble for service.
	• Ice in sensor tube.	• Contact Custom BioGenic Systems for Fill Test. Unit may require system thaw.
Low Alarm Visual alarm SYSTEM STATUS ALARM **LOW ALARM** Audible alarm present. Liquid level has fallen below the low-level set point.	• The supply tank is empty, or the pressure is too low.	• Check supply tank pressure and level. Replace it if needed.
	• The supply tank is turned off.	• Open manual valve on supply tank or supply line.
	• Sensor tube is not secure.	• Check clear sensor hose connections on the tank and controller. Re-clamp or replace as needed.
	• Solenoid valve malfunction.	• Reset the alarm and press FILL/STOP. After releasing, the “click” of the valves should be heard. If a click is not heard, the valve(s) or a connection to them may be defective.
Source Alarm Visual alarm SYSTEM STATUS ALARM **SOURCE ALARM** Audible alarm present. Liquid level did not achieve the high level during a fill within a preset amount of time.	• The supply tank is empty, or the pressure is too low.	• Check supply tank pressure and level. Replace it if needed.
	• The supply tank is turned off.	• Open manual valve on supply tank or supply line.
	• Unit is connected to a bulk supply with a long transfer line.	• Source timer may be extended. Call Custom BioGenic Systems for instructions.

Condition	Potential Cause	Solution(s)
Temperature Alarm Visual Alarm SYSTEM STATUS ALARM **TEMP A** or **TEMP B** Temperature has risen above the programmed set point.	• The lid was left open. • Probe has been moved. • Probe has been damaged. • Low LN_2 level.	• Close the lid, and/or press FILL/START to lower temperature rapidly. • Ensure probe is placed correctly. • Inspect probe for damage. • Check level. Press FILL/START and check supply.
Open Fill Visual Alarm SYSTEM STATUS ALARM **OPEN FILL** Fill valve(s) are disconnected from controller.	• Fill valve(s) are disconnected from power source. • Fill valve(s) defective.	• Check connection on the controller, check wire connection near valves. • Replace fill valve(s).
Open Bypass Visual Alarm SYSTEM STATUS ALARM **OPEN BYPASS** Bypass valve is disconnected from the controller.	• The bypass valve is disconnected from the power source. • The bypass valve is defective.	• Check connection on the controller, check wire connection near valves. • Replace the bypass valve. *Note: Bypass may be turned off until repair is made.*
Open Probe Alarm Visual Alarm SYSTEM STATUS ALARM **TEMP A PROBE** or TEMP B PROBE** or **OPEN BP PROBE** Controller cannot read the temperature from affected probe.	• Thermocouple probe is damaged. • Thermocouple probe plug is disconnected or damaged.	• Replace damaged probe. • Plug in probe or unplug and plug back in. Replace female connector if required.
No power.	• Blown fuse. • Power supply failure. May cause controller to flash and “chirp.”	• Replace it with a 2-amp slow blow fuse. • Replace power supply.

30.0 Parts List

Part Number	Part Description
V001-0008	Solenoid Valves 24V
LP-500	Lid Probe for Series 5000 & Carousel Models
LP-153	Lid Probe for Series 1500 & 3000
E001-0380A	Replacement 2301 Controller, Series 1500 & 3000
E001-0380B	Replacement 2301 Controller for Series 5000
E001-0380C	Replacement 2301 Controller for Carousels
17E9-0003	Power Supply (North American Cord) for 2301
17E9-0005	Power Supply (North American Cord for Carousel or Series 5000) for 2301
17E9-0004	Power Supply (Euro Cord) for 2301
17E9-0006	Power Supply (Euro Cord for Carousel or Series 5000) for 2301
R001-0030	Safety Relief Valves 60PSI

For questions regarding spare / replacement parts, contact:

Customer / Technical Service:

Phone: (800) 523-0072 (US Only), (586) 331-2600

customerservice@custombiogenics.com

sales@custombiogenics.com

31.0 Disposal

The Waste Electrical and Electronic Equipment (WEEE) symbol inidicates compliance with the European Union Directive. This directive sets requirements for the labeling and disposal of certain products in affected countries. When disposing of this product in countries affected by this directive:

- Do not dispose of this product as unsorted municipal waste.
- Collect this product separately.
- Use the collection and return systems available locally. For more information on the return, recovery or recycling of this product, please contact your local distributor or Custom BioGenic Systems.

Revision History

Revision	Description of Change	Effective Date
A	Initial Release	04SEP2019
B	Medical Device CE mark added as required by MDD	28FEB2020
C	Revise power supply ratings to reflect power supply TR9C12100LCP-Y-MED-R.	09SEP2020
D	Updating replacement parts list, updating Global Remote Alarm connection orientation.	01NOV2021
E	Updated company information and branding. Introduction of new safety symbols including all definitions – see Section 5.0.	07AUG2024
E	See addendum for 24-099. No change to revision level.	15DEC2025
F	Added User responsibility statement in Section 1.0, added glass contamination and procedure handling statement in Section 7.0, added caution statement regarding liquid nitrogen combustion in Section 6.0.	06MAR2026

NOTES