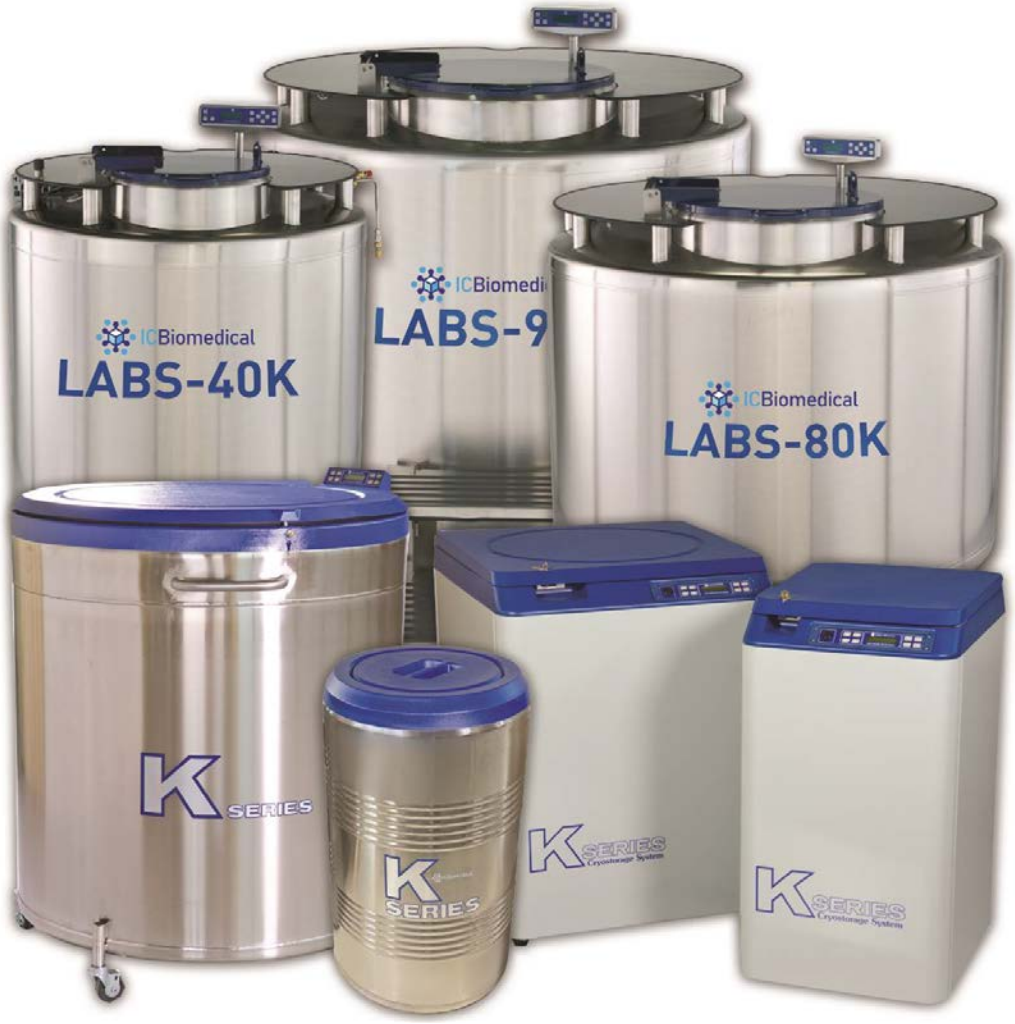
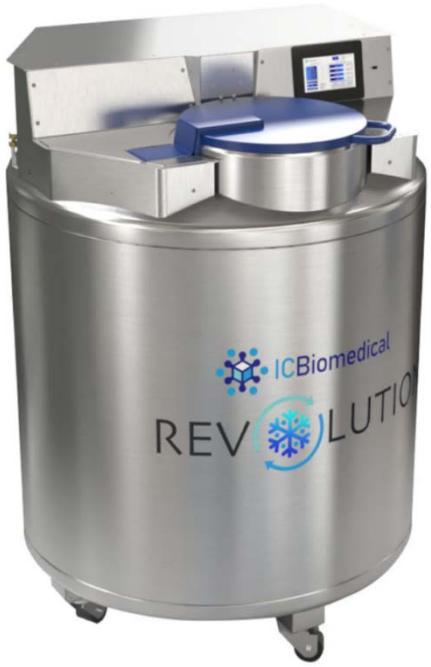
ICBiomedical

# User Manual

## High-Capacity Cryostorage Freezers




Ref: MNL003, Rev D - 01/2024

# SYMBOLS GLOSSARY

| | | | |
|---|---|---|---|
|  | Name and address of manufacturer. |  | Do not dispose of the Freezer or its components with unsorted, non-recyclable residual waste |
|  | Transport and move the Freezer in an upright position |  | Packaging materials are recyclable<br>Do not dispose of packaging materials with household waste<br>Dispose of packaging in waste collection or waste recycling, if available |
|  | Stacking limit by number |  | Pinch hazard |
|  | Fragile – handle the Freezer with care |  | General Warning Sign |
|  | Keep the Freezer away from direct sunlight and heat |  | Frostbite may occur on contact with cold liquid or gaseous nitrogen, or frosted parts. Warning low temperature. To warn of low temperature or freezing conditions. |
|  | Store the Freezer in a dry location |  | This Operator Manual contains important warnings and safety instructions |
|  | Temperature range to which the Freezer can be exposed without risk |  | Wear safety gloves |
|  | Air humidity range to which the Freezer can be exposed without risk |  | Wear safety goggles |
|  | Pressure range to which the Freezer can be exposed without risk | | |

# WARNING INFORMATION

## IMPORTANT: READ THIS OPERATOR MANUAL!

**Non-compliance with the instructions in this manual may result in personal injury, damage to the device or poor performance of the device!**

<table>
<tr>
<td>  </td>
<td>The safety instructions in this Operator Manual are designed for your protection:<br><br>Please familiarise yourself with the warning and safety instructions before commissioning or maintenance.<br><br>The company operating the equipment is solely responsible for ensuring the device is used by personnel who have not received sufficient training.<br><br>Ensure that all necessary precautions have been taken before commissioning a Cryostorage Freezer.</td>
<td>  <br>  </td>
<td>Pinch hazard<br><br>Use caution when opening and closing the step assembly on certain Cryostorage Freezers.<br><br>Use caution when closing the lid as this may be heavy.<br><br>Use caution when adding or removing inventory. Inventory systems can be heavy when fully loaded with samples, take care when adding or removing racks so as not to cause injury.</td>
</tr>
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<td></td>
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<td>  </td>
<td>In the event there is a serious incident occurring with this device, the user should immediately report the incident to the provider and/or the manufacturer. A serious incident is defined as an injury, death, or potential to cause injury/death should there be a reoccurrence of the incident. The user can also report the incident to the competent authority in the country where the incident occurred.</td>
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<tr>
<td>  </td>
<td>All damage may lead to malfunctions:<br><br>Check the Cryostorage Freezer before use for defects and damage.<br><br>In the event of a suspected malfunction with the Cryostorage Freezer, stop using the device and consult the relevant warning instructions to ensure the Cryostorage Freezer is not used until the necessary repairs have been carried out.</td>
<td rowspan="2">  </td>
<td rowspan="2">Ensure there is adequate ventilation:<br><br>Inadequate ventilation in a confined area can produce an atmosphere containing insufficient oxygen for breathing and which may cause choking, dizziness, loss of consciousness or even death.<br><br>Although nitrogen is non-toxic and non-flammable, it is a colourless, odourless and tasteless gas which is not perceived by human senses and therefore can be inhaled in the air.<br><br>Therefore, ensure that the area where the Cryostorage Freezer is being used is well ventilated and store the supply container for the liquid cryogenic agent in a well-ventilated area only.<br><br>In the event first aid is required: Call the emergency ambulance service immediately and asphyxiation victims must never be left alone.</td>
</tr>
<tr>
<td>  </td>
<td>Do not proceed with any modifications:<br><br>Repair and maintenance work on CryogStorage Freezers may only be carried out by personnel who have been trained and authorised by IC Biomedical.</td>
</tr>
<tr>
<td>  </td>
<td>When utilizing liquid phase storage, use sample containers designed for immersion in Liquid Nitrogen (LN2).<br><br>If not properly sealed, liquid nitrogen can leak into the cryogenic vial over time. During retrieval, liquid nitrogen in the vial or container will evaporate. This will result in expansion of the liquid nitrogen and can result in over pressurized that can rupture the container and cause injury. Always follow the manufacturer's instructions for properly sealing sample containers.</td>
<td>  </td>
<td>Sample cross contamination is possible when infectious agents are present and samples are not protected by a properly sealed container.<br><br>To reduce the risk of cross contamination, vapor phase storage is recommended when samples can be stored in temperatures from -100C to -196C.</td>
</tr>
</table>

**Extremely cold cryogenic agent can cause freezing injuries:**

Cryostorage Freezers use liquid nitrogen, an extremely cold cryogenic liquid which reaches a temperature of -196 °C at normal pressure.

Accidental contact of the skin or eyes with nitrogen liquid or gas may cause a freezing injury similar to frostbite.

Protect your eyes and cover your skin when handling stored samples, or when transferring liquid nitrogen; or in any other instance where the possibility of contact with cryogenic liquid, cold pipes, and cold gas may exist.

Use safety goggles or a face shield, and safety gloves, and long-sleeved clothing that can be easily removed.

Contact the liquid nitrogen supplier for information regarding the safe handling and use of liquid nitrogen

# DEVICE DESCRIPTION

## INTENDED USE

Cryostorage Freezers from IC Biomedical are Freezers designed for cryogenic long-term storing of bags, vials and similar containers with biological specimens. Storage is at extremely low cryogenic temperatures using liquid nitrogen as cyrogenic agent which operates under normal atmospheric pressure. Cryostorage Freezers from IC Biomedical are not medical devices unless labelled as such.

> **Note: Any other use does not comply with manufacturer recommendations!**
>
> IC Biomedical cannot be held liable in the event the use of the device does not comply with this Operator Manual.

## INTENDED LOCATION AND USER GROUPS

Cryostorage Freezers from IC Biomedical are Freezers intended for use in professional research environments and for use by trained specialist personnel, e.g. clinicians, medical and laboratory technicians, medical and laboratory assistants and other specialist healthcare personnel who have experience in working with cryogenic agents and devices.

> **Note: Untrained personnel must not use Cryostorage Freezers!**
>
> IC Biomedical cannot be held liable if the device is used by personnel who have not received sufficient training, are not familiar with this Operator Manual and all relevant points on proper use and all relevant safety instructions and if no inspection has been carried out before use and if no regular maintenance has been carried out.

## DEVICE OVERVIEW AND KEY FEATURES

Cryostorage Freezers from IC Biomedical are state-of-the-art cryogenic storage systems and come with the following key features:

- can be used in either liquid or vapor phase under normal atmospheric pressure
- uses liquid nitrogen as cryogenic agent that is non-toxic and non-flammable
- stainless steel vacuum vessel with superior vacuum performance
- robust design of smooth surfaces for easy cleaning and disinfection
- thermally insulated and lockable lid
- Liquid Level Measuring Rod
- mounted lockable casters to enable limited mobility for cleaning purposes

Optional accessories:

- microprocessor based controller with intuitive touch controls for:
  - liquid level and temperature monitoring, and alarms
  - automated filling.
  - logging of temperature, levels, alarms, fill activity etc.
  - remote alarm
- A variety of Inventory/rack System(s) are available on the market depending on the user needs and use case. Examples of standard rack configurations are detailed on the product specification sheet (see Technical Data and Performance Characteristics).

  **Note: The end user will be responsible for verification and validation of the inventory/rack system(s) used to demonstrate they meet their use case requirements**

## TECHNICAL DATA AND PERFORMANCE CHARACTERISTICS

Refer to specific product specification sheet on www.icbiomedical.com or contact IC Biomedical for further information.

## UNPACKING AND INSPECTION

Cryostorage Freezers from IC Biomedical are supplied in new condition. For your own protection, schedule enough time to check for any external damage on each delivery.

- Open the freight container
- Use the delivery note to check all items are present while the unit is being unpacked
- Check the delivery for any damage
- Record all components on the inventory list before disposing of any transport material

**Note: Any claims due to damage (visible or hidden) or incomplete delivery must be made in writing within 10 (ten) days from receipt of delivery.**

In the event of any visual damage or incomplete delivery, please contact the transport company immediately.

In the event of a shortage of spare parts or accessories, please contact IC Biomedical immediately.

IC Biomedical cannot be held responsible for missing components which have not been reported missing within 10 (ten) days from receipt of delivery.

## CONDITIONS FOR OPERATION AND STORAGE

Cryostorage Freezers from IC Biomedical are developed for operation under the following conditions:

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|---|---|
| Temperature during operation: | 0 °C to +40 °C |
| Temperature during transport and storage: | -10 °C to +50 °C |
| Relative humidity during operation: | 20% to 80%, non-condensing |
| Relative humidity during transport and storage: | 10 % to 90 %, non-condensing |
| Atmospheric pressure: | 700 hPa to 1060 hPa |
| Altitude: | up to 2000 m |

**Note: Do not operate Cryostorage Freezers in areas low in oxygen or where there is a fire risk.**

**Install the Cryostorage Freezer in a level, well-ventilated location indoors, free from vibrations and excessive dust and do not install it in direct sunlight, near a heater or other sources of heat.**

Leave enough room to fully open the lid.

Ensure there is sufficient ventilation to prevent condensate deposits.

**Note: Deviations from admissible environmental conditions may lead to Cryostorage Freezer malfunction!**

Note: The Cryostorage Freezers do not contain any functions which give off any intended radiation and do not use or receive any radiation energy for operation.

# DEVICE OPERATION

## INITIAL FILL

Prior to the initial fill of your Cryostorage Freezer, you should determine whether the liquid phase or the vapor phase cryostorage will be utilized.

The cooling effect required for the cryogenic storage of the samples is maintained by continuous evaporation of the liquid nitrogen. The necessary evaporation heat is removed from the environment by heat transfer. Over a certain evaporation period time the liquid nitrogen level in your Cryostorage Freezer drops permanently and will need to be refilled. The liquid level should be monitored and maintained using the supplied Liquid Level Measuring Rod.

The liquid phase storage is normally utilized when liquid nitrogen temperatures are required to maintain stored sample viability and the storage medium is adequate for storage in liquid nitrogen.

When samples are immersed in liquid nitrogen, they will assume the temperature of the liquid -196 ºC.

During operation, the upper levels of the inventory control system will at times become exposed as the liquid level fluctuates.

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| **Note**: **Exposure to liquid nitrogen may result in physical damage to the lid:**<br>Care must be taken to ensure that the liquid level remains below the bottom of the refrigerator lid. |

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|  | **When utilizing liquid phase storage, use sample containers designed for immersion in Liquid Nitrogen (LN2). If not properly sealed, liquid nitrogen can leak into the cryogenic vial over time. During retrieval, liquid nitrogen in the vial or container will evaporate. This will result in expansion of the liquid nitrogen and can result in over pressurized that can rupture the container and cause injury. Always follow the manufacturer's instructions for properly sealing sample containers.** |

In the vapor phase storage the samples are stored over the liquid, where the liquid nitrogen is still a very cold refrigerant, but the refrigerator's interior temperature increases somewhat as samples are stored higher over the liquid.

| | |
|---|---|
|  | **Sample cross contamination is possible when infectious agents are present and samples are not protected by a properly sealed container. To reduce the risk of cross contamination, vapor phase storage is recommended when samples can be stored in temperatures from -100C to -196C.** |

It is recommended that the freezer be allowed to cool for 48 hours before putting any product in the freezer.

| | |
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|  | **Always protect your eyes and cover your skin when opening the lid:**<br>Use safety goggles or a face shield, and safety gloves, and long-sleeved clothing that can be easily removed.<br>Operating the Cryostorage Freezer with high liquid levels characteristic of liquid phase storage may result in turbulence during fill cycles. |

**Note: Sample transfers can cause fluctuations in temperature:**
Temperature can be affected by the amount of product stored in the refrigerator, the type and size of the inventory control system, and the liquid level in the unit.

### ADDING AN INVENTORY CONTROL SYSTEM




**Protect your eyes and cover your skin when handling stored samples:**
Always wear safety goggles or a face shield, and safety gloves, and long-sleeved clothing that can be easily removed when handling the inventory control system racks or stored samples, as they are very cold.

When removing racks to retrieve samples, protect the labels, non-metallic, and electronic areas of the freezer from liquid nitrogen that may spill from the rack inserts. These parts of the freezer are subject to damage from the extreme low temperature of the nitrogen.

**Note: Use only suitable inventory control systems**

**Note: Learn to locate your samples quickly to avoid unnecessary warming:**
It is important to note that when you lift an inventory control system rack from the freezer it is being moved to a warmer environment.
Keep rack inserts (drawers or boxes) and dividers in good condition.

**Note: Do not let ice or debris collect in the bottom of the chamber:**
Schedule periodic cleanings if the racks no longer stand upright

# CARE AND MAINTENANCE OF THE DEVICE

### INSPECTION AND MAINTENANCE SCHEDULE

IC Biomedical strongly recommends inspecting and to maintain your Cryostorage Freezer as follows:

| **Inspection and maintenance activities** | **Frequency** |
|---|---|
| Defrost the Cryostorage Freezer | Annually or whenever the ice buildup exceeds approx. 5 mm |
| Disinfect the Cryostorage Freezer | Prior to change of the type of stored samples or before the device is taken out of operation |
| Perform Normal Evaporation Rate test | If there are signs of abnormally high nitrogen consumption |

## DEFROSTING THE CRYOSTORAGE FREEZER

As with all liquid nitrogen storage systems, ice and frost build up over time on Cryostorage Freezer from IC Biomedical. Ice and frost can form on the lid if the lid is left open or if the liquid level gets too close to the underside of the lid.

Open the lid fully to defrost the lid. Remove ice and frost from the underside of the lid while waiting for defrosting to complete and then wipe down the relevant areas with a clean, lint-free cloth.

## CLEANING AND DISINFECTING THE CRYOSTORAGE FREEZER

Cryostorage Freezers from IC Biomedical may require cleaning and disinfecting if the type of stored samples is modified or if the device is decommissioned.

Proceed as follows to clean and disinfect the Cryostorage Freezer:

- Remove all stored samples and components
- Allow the residual liquid nitrogen to evaporate and the cryogenic vessel to warm to ambient temperature,
- Increasing air flow with a room fan or blower will expedite the evaporation,
- Spray the entire inner vessel surface with ample amounts of an approved disinfectant,
- Allow surface contact to be maintained for a minimum of five minutes,
- Rinse the inner vessel with water,
- Remove all water and debris, and towel dry the surface
- Spray the inner vessel surface with a 70 % alcohol/water solution,
- Allow surface contact to be maintained for a minimum of fifteen minutes,
- Rinse the inner vessel surface with water,
- Remove all water, and towel dry.

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| Note: Always clean and disinfect the Cryostorage Freezers regardless of the type of stored samples before returning it to IC Biomedical for repairs or maintenance. A decontamination form must be obtained from IC Biomedical customer service and returned with the device when completed. |
| **Never use chlorine-based disinfectants or abrasive cleaning agents, steam pressure or high-pressure cleaners to clean the Cryostorage Freezers.** |

## TESTING NORMAL EVAPORATION RATE

Nitrogen consumption results from a combination of evaporation through all components of the the Cryostorage Freezer and evaporation brought about by the user.

If there is major frost or condensation on outside of container during this time, it would indicate either a weak or no vacuum.

Factors such as age of unit, quantity of inventory, ambient environment, shipping condition, and use of accessories, etc. can negatively affect unit NER.

If you believe a NER test is should be performed, contact IC Biomedical for instructions for your the Cryostorage Freezer.

**Note for K-Series: If your measurement indicates a drop in excess of 50 mm / 2 inch per day, contact IC Biomedical for further information.**

**Note for LABS Series, Revolution and Evolution: If your measurement indicates a drop in excess of 19 mm (3 / 4 inch) per day, contact IC Biomedical for further information.**

## DEVICE TRANSPORT

When moving your Cryostorage Freezer to or from its current location to a transport vehicle or new location for any reason, make sure to use a suitable forklift or pallet truck.

**Always move your Cryostorage Freezer in an upright position and in empty and defrosted condition, and without inserted inventory control system.**

Use straps to secure the Cryostorage Freezer onto a pallet.

Take particular care to lock all casters and use wheel chocks.

Fix flexible parts with low tack tapes or preferably bungee cords.

Protect the Cryostorage Freezer with a blanket.

## DEVICE RETURN

In the event the Cryostorage Freezer needs to be returned for repair, maintenance, or replacement, contact IC Biomedical for an RMA number and shipping address to return the Freezer.

**Note: Any Cryostorage Freezer returned to IC Biomedical without an RMA number will be returned to the sender's address.**

You are responsible for ensuring that the goods are packed appropriately for return shipment.

If required, contact IC Biomedical for instructions on shipment and packaging.

All Cryostorage Freezers returned to IC Biomedical must be cleaned and disinfected before sending. A decontamination form must be obtained from IC Biomedical customer service and returned with the device when completed.

## DEVICE DISPOSAL

Cryostorage Freezers from IC Biomedical are made of high-quality, recyclable materials and components.

**Note: Do not dispose of Cryostorage Freezer with normal waste:**

All materials from stainless steel, aluminium and aluminium foil can be reused as recyclable materials. All plastics, epoxy tube, glass paper and the molecular sieve must be disposed of as industrial waste or incinerated.

**Dispose of this device and rejected samples in accordance with local regulations.**

**Manufacturer**
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