

User Manual Vapor (Dry) Shippers





SYMBOLS GLOSSARY

	Name and address of manufacturer.	(* • ¢)	Pressure range to which the Vapor Shipper can be exposed without risk
<u><u><u></u></u><u></u><u></u><u></u><u></u></u>	Transport and move the Vapor Shipper in an upright position		Do not dispose of the Vapor Shipper or its components with unsorted, non- recyclable residual waste
	Stacking limit by number	A A	Packaging materials are recyclable Do not dispose of packaging materials with household waste Dispose of packaging in waste collection or waste recycling, if available
	Fragile – handle the Vapor Shipper with care		General Warning Sign
澄	Keep the Vapor Shipper 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.
Ť	Store the Vapor Shipper in a dry location	(internet in the second	This Operator Manual contains important warnings and safety instructions
	Temperature range to which the Vapor Shipper can be exposed without risk		Wear safety gloves
%	Air humidity range to which the Vapor Shipper can be exposed without risk		Wear safety goggles



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!

 The safety instructions in this Operator Manual are designed for your protection: Please familiarise yourself with the warning and safety instructions before commissioning or maintenance. The company operating the equipment is solely responsible for ensuring refresher courses are delivered. Ensure that all necessary precautions have been taken before commissioning a Cryogenic Dewar. 		 Only use approved accessories and spare parts: Vapor Shippers are supplied with accessories and spare parts approved by IC Biomedical. Only use the necktube plug supplied with the device. A tight-fitting plug or stopper will cause a pressure increase in the container which may damage the container and/or cause personal injury In the event there is a serious incident occurring with this vessel, 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.
All damage may lead to malfunctions: Check the Dewar before use for defects and damage. In the event of a suspected malfunction with the Dewar, stop using the device and consult the relevant warning instructions to ensure the Dewar is not used until the necessary repairs have been carried out. Do not proceed with any modifications: Repair and maintenance work on Vapor Shippers may only be carried out by personnel who have been trained and authorised by IC Biomedical.		Ensure there is adequate ventilation: 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. 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. Therefore, ensure that the area where the Vapor Shipper is being used is well ventilated and store the supply container for the liquid cryogenic agent in a well- ventilated area only. In the event first aid is required: Call the emergency ambulance service immediately and asphyxiation victims must never be left alone.
Extremely cold cryogenic agent can cause freezing injuries: Vapor Shippers use liquid nitrogen, an extremely cold cryogenic liquid which reaches a temperature of -196 °C at normal pressure. Inadvertent contact with liquid or gaseous nitrogen and skin or eyes can cause freezing injuries which are similar to frostbite. Ensure your bare skin does not come into contact with liquids or cold metal surfaces. Wear eye protection and skin-covering clothing when handling stored samples or carrying liquid nitrogen or in all other cases where contact with cryogenic liquid, cold pipes and cold gas is possible. Use safety goggles or a face mask, safety gloves and long-sleeved clothing, which is easy to take off. Contact the liquid nitrogen supplier for information regarding the safe handling and use of liquid nitrogen		



DEVICE DESCRIPTION

INTENDED USE

Vapor Shippers from IC Biomedical are designed for safe transportation of a variety of materials in canisters with human biological samples e.g. cord blood, stem cells or semen for subsequent research or introduction into the human body at extremely low temperatures of between -100 °C and -196 °C using liquid nitrogen as a cryogenic agent which is absorbed and released by unique absorbent material.

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. It is also important that the device use is validated to ensure safety to the biological specimens prior to use.

Note: Untrained personnel must not use Vapor Shippers!

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

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

- complies with IATA regulations for open cryogenic recetacles
- dependable, stronger necktube design
- ribbed high strength aluminium body and durable paint system
- superior vacuum performance with super insulation provides maximum holding times
- temperature loggers are available for all models
- lockable lid

TECHNICAL DATA

Refer to specific product specification sheet on <u>www.icbiomedical.com/product-information</u> or contact IC Biomedical for further information.



UNPACKING AND INSPECTION

Vapor Shippers 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

Vapor Shippers from IC Biomedical are developed for operation under the following conditions:

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 Vapor Shippers in areas low in oxygen or where there is a fire risk. Install the Vapor Shippers 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 Unit malfunction!

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



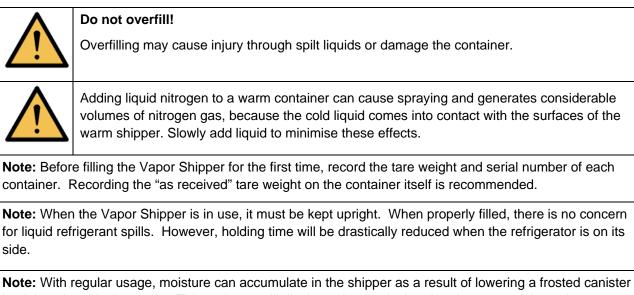
DEVICE OPERATION

FILLING FOR VAPOR STORAGE

- 1. Remove the Unit from its Shipping Container.
- 2. Remove Necktube core.
- 3. Remove any racks or canisters used for sample storage.
- 4. Set the unit on a scale and fill the shipper with liquid to the bottom of the necktube.
- 5. Allow the unit to stand undisturbed while the refrigerant is being absorbed.
- 6. About every five minutes, add liquid to maintain the refrigerant level as the liquid is absorbed by the filler. This procedure can take ten to fifteen cycles.
- 7. When the liquid levels remain at the bottom of the necktube, allow the shipper to stand for a minimum of 12 hours to reach thermal equilibrium.
- 8. At this point, the quantity of liquid standing in the central cavity of the refrigerator must be poured out to prevent spillage during shipment.
- 9. The material to be stored in the Vapor Shipper, as well as the canister or rack, should be pre-cooled before being placed in the shipper.
- 10. When the refrigerator is fully charged, place the pre-cooled material to be stored in the pre-cooled canister and lower it into the necktube. Install the necktube core and cap to hold the canisters in place.

FILLING FOR LIQUID STORAGE (TW DUAL SERIES)

- 1. Remove Necktube core.
- 2. Remove any racks or canisters used for sample storage.
- 3. Fill the shipper with liquid to desired level.
- 4. Install the racks or canisters used for sample storage and necktube core and cap to hold the canisters in place.



back into the shipping cavity. This moisture will displace nitrogen in the absorbent materials on the subsequent filling and effect the overall holding time.



Note: When filling the Vapor Shipper, avoid liquid nitrogen coming in contact with the vacuum plug. In order to accomplish this, the Vapor Shipper must be removed from its shipping carton during the "fill" operation.

STORAGE SYSTEM

In order to prevent any unnecessary loss of nitrogen, the necktube core (stopper) should remain in the container when the stored material is not accessed. When accessing the stored material, the necktube core should not be removed for longer than necessary. When removing material from the canister, pull the canister out sufficiently so that the content can be removed. When the canister is fully removed, the stored material will warm up when exposed to room temperature conditions.



Figure 1: Inserting or removing canisters



When removing the canister from the container, avoid direct contact of the canister with bare skin. The use of suitable personal protective equipment - cryogenic gloves, face shield and apron - to protect against splashes is strongly recommended.

Note: When the product is added at room temperature, slowly lower the canister into the container to reduce cryogenic agent boiling and cold shock.



REPLACING ABSORBENT SOCKS – CXR SERIES ONLY



- 1. On a clean working surface, in a well-ventilated area, warm the unit to ambient temperature. Begin by removing the cap assembly and canister or rack (depending on model), items 1 and 2.
- 2. Wearing gloves of either polyethylene, vinyl, Teflon, or Viton, and an approved dust mask, type N95 (US) or type P1 (EN 143). Reach into the unit and remove the shipping core, item 3.
- 3. Remove and discard the absorbent socks. Dispose of in accordance with applicable Federal, State, and Local regulations.
- 4. Clean the empty CXR unit with an approved disinfectant, and dry thoroughly.
- 5. Replace the absorbent socks, placing them down the necktube and standing vertically around the perimeter of vessel walls.
- 6. Carefully replace the shipper core, item 3, taking care not to tear the absorbent sock casing.
- 7. Fill the CXR unit according with the Filling Procedures found in the Operating section of this manual.

CARE AND MAINTENANCE OF THE DEVICE

DEFROSTING THE DEWAR

As with all liquid nitrogen storage systems, ice and frost build up over time on Vapor Shippers 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 DEWAR

Vapor Shippers 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 Dewar:

- Remove all stored samples and components
- Remove the shipper from the shipping case (if applicable)
- Allow the shipper to warm to room temperature to ensure all LN2 has evaporated
- Weigh the shipper when warm and dry to determine empty (tare) weight.
- Remove the cap and foam core assembly.
- For CXR shippers only, remove the perforated sleeve from the inner vessel taking care to not tear the absorbent 'socks' used to contain the absorbent material.
- For CXR shippers only, remove the absorbent 'socks' from the inner vessel and set aside.
- Flush the inner vessel with a 10-1 water-to-bleach solution. Circulate the cleaning solution to thoroughly cover all interior surfaces of the inner vessel.
- Pour off the cleaning solution and rinse the inner vessel with clean fresh water. Repeat 3-4 times to remove the cleaning solution.



- For CXR shippers only, re-install the absorbent 'socks' and the perforated sleeve.
- Weigh the container again to determine how much, if any, of the cleaning solution and/or rinse water has been absorbed or remains in the shipper.
- Using a cylinder of 'dry' grade nitrogen gas, a low-pressure regulator, and a flexible hose, circulate dry nitrogen gas regulated to 4-5 psig into and throughout the inner vessel until the container is completely dry. The dry nitrogen will serve to evaporate any residual moisture. If this method isn't available, the shipper can be dried by circulating warm air from a heat gun or hair dryer throughout the inner vessel until the unit reaches the empty (tare) weight as noted above.



Heated air should NOT exceed 160°F / 70°C

Note: It is not recommended to remove the lid/necktube core to warm cold containers. Removing the lid allows moisture to enter the cryogenic chamber, and the moisture will be absorbed by the container in the same manner that LN2 is absorbed. This absorbed moisture will reduce the amount of LN2 absorbed, and hence will affect thermal performance and hold time. It's best to either let the container warm on its own with the lid on or warm it as noted in the cleaning instructions mentioned above.

Note: Always clean and disinfect Vapor Shippers 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.

Note: Never use chlorine-based disinfectants or abrasive cleaning agents, steam pressure or highpressure cleaners to clean the Vapor Shippers.

A suitable disinfectant is a glutaraldehyde-free cold sterilisation agent from Alcide Corporation, commercialised under the name of EXSPORTM

TESTING NORMAL EVAPORATION RATE

If high evaporation rates are apparent under normal operating conditions, the shipper may be losing its vacuum. Sweating and the formation of frost on the outer casing are indications that the vacuum integrity of the shipper is not normal. All necessary steps should be taken to protect the refrigerator's contents.

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

If these conditions persist, contact IC Biomedical for information how to conduct a normal evaporation rate (NER) test in the field.

DEVICE TRANSPORT

Although the Vapor Shippers are robust, they can be damaged if not handled properly.

A specially designed hard-shell shipping container should be used whenever the shipper is transported. This shipping container helps to extend the life of the shipper and should be replaced if it is damaged during use.

When moving or transporting the shipper, hold the shipper upright. Take all necessary precautions to avoid slipping, tipping, bumping or falling.

Also note, although there is no safety risk, that if the properly filled shipper is lying on its side, the refrigerant consumption will increase significantly, and the holding time will be significantly reduced.



DEVICE RETURN

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

Note: Any Vapor Shipper 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 shippers 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

Cryo Exchange Vapour Shippers from IC Biomedical are made of high-quality, recyclable materials and components.

Note: Do not dispose of Cryo Exchange Vapour Shippers with normal waste:

The assembled materials including aluminium and aluminium foil can be recycled. Plastics, epoxide pipes, glass paper and the molecular sieve must be disposed of with industrial waste or be burnt.

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



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