MVE Vapor Shippers

Instructions for Use

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Intended Use & Indication for Use for Cryogenic Storage and/or Transport
LIFE SCIENCE INTENDED USE STATEMENT STORAGE ONLY MVE FREEZERS ARE INTENDED FOR THE INDICATION OF PRESERVING HUMAN BIOLOGICAL PRODUCTS, SAMPLES, AND/OR SPECIMENS (E.G., BLOOD, BLOOD PRODUCTS, CELLS, TISSUES, ETC.) AT CRYOGENIC AND ULTRACOLD TEMPERATURES DURING STORAGE. **STORAGE AND TRANSPORT** MVE DEWARS AND VAPOR SHIPPERS ARE INTENDED FOR THE INDICATION OF PRESERVING HUMAN BIOLOGICAL PRODUCTS, SAMPLES, OR SPECIMENS (E.G., BLOOD, BLOOD PRODUCTS, CELLS, TISSUES, ETC.) AT CRYOGENIC AND ULTRACOLD TEMPERATURES DURING STORAGE AND/OR TRANSPORTATION.

1 Intended Use & Indication for Use for Cryogenic Storage and/or Transport

MVE vapor shippers are ideally suited for the transportation of cryobiological materials. The liquid nitrogen is retained in a hydrophobic absorbent material, and the cold nitrogen vapors maintain the cryo storage area below -150°C. The absorbent retains liquid nitrogen and prevents accidental spills.

Liquid nitrogen is classified as “Dangerous Goods” by the Department of Transportation (DOT). At least three regulatory agencies publish dangerous goods regulations:

- Department of Transportation (DOT)
- International Air Transportation Association (IATA)
- International Civil Aviation Organization (ICAO)

If used outside of the USA, please consult your applicable regulatory agencies. Liquid nitrogen is classified under the name “Nitrogen, refrigerated liquid” and has a UN 1977 code number. The name classification and UN Code Number must be indicated on the shipping carton in addition to a “Gas nonflammable” label. Packing and labeling requirements can be obtained from the above organizations. Also, contact your carrier for any variances in the rules that may apply specifically to the company and/or the ultimate shipping destination.

Be aware that regulations undergo periodic revisions. Please contact your air carrier for the most recent regulations before shipping your cryobiological specimen. It is your responsibility to provide correct information, such as warning or caution, on the shipping package.

1.1 General Description

The cryopreservation vessel is a double-walled, vacuum-insulated vessel made of aluminum with a fiberglass composite neck, providing the highest efficiency possible in cryogenic temperature preservation. The liquid nitrogen absorbent is a hydrophobic blanket consisting of synthetic amorphous silica and glass fiber. This absorbent is non-hazardous. Use the vessel for liquid nitrogen only. Liquid oxygen is incompatible with this unit and must not be stored inside the vessel.

The MVE vapor shipper is designed with consideration for safety, durability, and performance. However, mishandling of the equipment, including transport or shipping units in an orientation other than upright vertically, may damage the product. In addition, if a vessel experiences a drop, hit, or blow, the vacuum may immediately or prematurely fail and contents may spill.

Upon receipt of the product, examine both the vessel and packaging for any evidence of damage during shipping. If there are signs of shipping damage, contact the carrier within the carrier's guidelines. Should there be damage from shipping, some MVE shipping boxes carry the Transit Tested ISTA certificate stamp, shown to the right, which is helpful when making a claim against the carrier. Watch after the first fill for any signs of vacuum loss, such as excessive frost or sweating on the outside jacket. Some frost near the top just after filling is normal. It is also normal for some white dust or powder-like residue from the absorbent to accumulate at the bottom of the unit due to shipping vibrations. If desired, the owner may wipe or vacuum it out.

This high-quality vacuum-insulated unit is compatible with the divergent temperature extremes and broad applications of cryobiology. Its life expectancy is three (3) years.

CE 0459 Products bearing the CE marking as shown comply with the requirements of Directive 93/42/EEC concerning medical devices in the EU.

1.2 Safety

WARNING: Liquid nitrogen is extremely cold. To avoid injury by frostbite, use extreme care whenever handling liquid nitrogen, liquid nitrogen storage or transfer vessels, or any objects that have come in contact with liquid nitrogen.

- Leave no area of skin exposed.
- Always wear proper safety attire over clothing: face shield, cryogenic gloves, and cryogenic apron.
- Use extreme care to prevent spilling and splashing liquid nitrogen during transfer.
- Always keep the vessel in upright position. Do not tilt or lay the vessel on its side.
- Immediately remove any clothing or safety attire on which liquid nitrogen has spilled.
- Get immediate medical attention for any frostbite injuries due to liquid nitrogen.

WARNING: Venting nitrogen vapors may deplete oxygen in the air, possibly leading to asphyxiation or even death. Do not store or use the container in small or enclosed areas or those with poor ventilation.

⚠ **WARNING:** Do not tightly seal the liquid nitrogen container or prevent nitrogen gas from escaping. Excessive humidity levels or exposure to rainfall could result in freezing of the cork and cover, and possible explosion.

⚠ **WARNING:** Never use a hollow tube to measure the liquid nitrogen level. This could lead to thermal injury.

⚠ **CAUTION:** Handle the cryopreservation vessel with care.

- Never overfill vessels with liquid nitrogen. Liquid nitrogen should always be below the bottom of the neck tube. Overfilling the tank may cause immediate or premature vacuum failure and loss of contents.
-  Never ship the vapor shipper on its side or upside down. This can lead to vacuum failure and loss of product inside the vapor shipper.
- Do not scratch the neck tube area. Remove and insert inventories carefully. Scratches can cause premature vacuum failure and loss of contents.
- Tampering with or removing the vacuum port will destroy vacuum and void warranty.
- Never drop, hit, or allow the vessel to suffer a blow.
- Never spill liquid nitrogen on or near the vacuum port.
- Never leave the vessel outdoors.
- Inspect vessel for any damage before and after each shipment.
- Keep the bottom of vessel clean and away from chemicals, fertilizers, soil, and moisture.
- All performance data published for these products is based only on static conditions. Actual performance will vary upon the nature of use. Vibration or manipulation of inventories and/or accessories will decrease the working duration/Hold time of these products.

1.3 Operation

⚠ **CAUTION:** Failure to follow MVE's best operating practices as set forth in the manual can result in loss of contents.

⚠ **CAUTION:** Consider the value of your product when choosing dewar, shipping methods, and storage at destination. Splitting shipments of valuable samples reduces risk of loss.

⚠ **CAUTION:** If not using MVE protective containers, ship products in protective containers with a minimum ISTA-3A or ISTA-3B rating for the combined dewar and container to reduce risk of loss.

⚠ **CAUTION:** If storing human biological material, use appropriate liquid level monitoring equipment.

1.4 Environmental Conditions

- Indoor use only (out of elements)
- Operating temperature: -29 deg C to +60 deg C
- Relative humidity: 10% to 95%, non-condensing
- Storage temperature: -29 deg C. to +60 deg C

- Storage relative humidity: 10% to 95%

Liquid nitrogen is extremely cold. Make sure to wear proper gear before operation. Avoid spilling liquid nitrogen over the vacuum port as this can shrink the seal and allow air to leak into the vacuum space causing premature vacuum failure. To ensure maximum performance from your MVE vapor shipper simply follow the listed steps prior to shipping to the final destination:

1. Open container that the vapor shipper is in, open the lid, and remove cork and cover/accessories. Lift cork and cover straight up; do not twist.
2. Fill unit to bottom of neck tube. Liquid level should never pass bottom of neck tube.
    a. If you are working with a warm vessel, MVE recommends you cool the unit slowly by adding a small amount of liquid to the bottom of unit and allowing it to sit until the liquid nitrogen stops rapidly boiling. Position the vacuum port facing away from the operator or other personnel.
    b. To obtain the optimized Hold time, you will need to refill the unit to the bottom of the neck more than once until the liquid level is steady.
    c. Follow established safety practices and procedures for transferring LN2.
    d. Fill the vessel with a funnel or transfer line when possible. Transfer using an LN2 hose with phase separator or a pouring container using a funnel.
    e. If filling the vessel from a pressurized source, make sure it is low-pressure source (22 psi or below).
3. Replace cork and cover and allow unit to reach thermal equilibrium /charge for a minimum of 24 hours.
    a. Refer to UTILIZING THE QWICK® CHARGE TECHNOLOGY section for expedited charge solution.
    b. Excessive frost or sweating on the outside vessel after the first few hours indicates either a weak vacuum or no vacuum. Examine the unit carefully.
4. Pour off excess liquid just prior to shipment.
    a. If necessary to completely dispense all liquid nitrogen, carefully invert the unit until liquid nitrogen dripping has stopped. Set the unit upright and view if any liquid nitrogen pools at the bottom of the unit. If liquid nitrogen starts to pool, invert the unit again. Repeat as necessary until all liquid nitrogen is removed from the unit, in accordance with ICAO Packaging Instruction 202.
    b. Use a tool to hold vapor shipper when draining excess LN2.

⚠ **CAUTION:** Be careful when inverting the vapor shipper to avoid damage to the top neck area of the tank. Damage to the top neck area of the tank can cause vacuum failure and loss of contents.

5. Weigh unit and record.
    a. To ensure a proper charging process is conducted, obtain empty and charged weights. Verify that the differential between empty and charged weights is close to the data in Table 1. The differential can be calculated by using Equation 1.

    Differential = Charged Weight — Empty Weight Equation 1

    b. Please note that the Charged Weight does not indicate unit performance.

6. Place inventory into unit. Wipe water and moisture from outside of cork and inside dewar neck tube, and reinsert cork and cover into dewar.

1.5 Utilizing the QWICK® Charge Technology

Only units bearing the QWICK® charge label are equipped with QWICK® charge technology. To utilize the QWICK®Charge Technology and charge in under 2 hours, do not allow unit temperature to rise above -150°C between shipments. If the inside of the unit is above -150°C, it will need to be charged again for a minimum of 24 hours to allow the unit to reach thermal equilibrium.

Use the following weight table as a general guide to determine if your vapor shipper is fully charged. Values are for reference only. Weights can vary depending on the charging process. Refer to the Static Hold time and Normal Evaporation Rate (NER) specifications listed in the table below. Factors such as age of unit, quantity of inventory, ambient environment, shipping condition, and use of accessories, etc. can negatively affect unit Hold time and NER. If you do not find your model listed here, refer to the MVE Cryopreservation Catalog or contact Customer or Technical Service for assistance.

Table 1. Reference Unit Performance by Model

Model	Empty Weight		Charged Weight		Static Hold Time	NER	ISTA
	lbs	*(kg)*	*lbs*	*(kg)*	*Days*	*L/Day*	*certified*
SC 2/1V	6	(2.7)	8.3	(3.7)	8	0.19	N
SC 4/2V LEGACY	10	(4.5)	17.1	(7.7)	13	0.26	3A
SC 4/2V	12. 4	(5.6)	19.7	(8.9)	19	0.23	3A
SC 4/3V LEGACY	11.6	(5.3)	19.1	(8.7)	21	0.20	3A
SC 4/3V	12.5	(5.7)	20.5	(9.3)	26	0.19	3A
XC 30/12V	44	(20)	76	(34)	82	0.22	3A
XC 65/5V	70.9	(32.1)	132.3	(60.0)	30	0.79	3B
Cryoshipper	25.7	(11.6)	38.2	(17.3)	10	0.85	3A
Cryoshipper XC/IATA	32.3	(14.6)	48.9	(22.1)	14	0.70	3A
Cryoshipper 2000	65	(29.5)	95	(43.1)	15	0.79	3B
Doble 11	14.3	(6.4)	19.5	(8.8)	17	0.17	N
Doble 22*	23.8	(10.7)	35	(15.8)	18	0.35	N
Doble 20	23	(10.4)	30.3	(13.7)	21	0.10	N
Doble 28	32.2	(14.6)	46.8	(21.2)	21	0.35	N
Doble 34	34.5	(15.8)	47.9	(21.7)	21	0.20	N
Doble 47	41	(18.5)	54.6	(24.7)	21	0.40	N
YDH-3	11.7	(5.3)	17.9	(8.1)	25	0.14	N
YDH-8-80	20.2	(9.2)	34.3	(15.6)	36	0.22	3A
YDH-8-90	26.9	(12.2)	40.9	(18.6)	23	0.35	N
ET-24-10	36.3	(16.5)	50.4	(22.9)	23	0.35	N

Note: Use of a Data Logger adds approximately 0.16L/day NER
* Center canister required
**5% variance in actual weight is typical

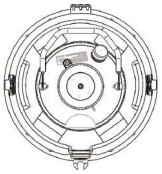
1.6 Shipping Instructions

MVE recommends a plastic protective shipping containers (PPSC) be used to help keep the vapor shipper upright and reduce the risk of damage to your valuable asset. **DO NOT SHIP THE UNIT ON ITS SIDE OR UPSIDE DOWN. SHIPPING THE UNIT IN ANY POSITION OTHER THAN UPRIGHT COULD REDUCE THE HOLD TIME TO LESS THAN 10% OF STATIC HOLD TIME, AND CAUSE PERMANENT DAMAGE TO THE UNIT AND LOSS OF INVENTORY.** This could also void the warranty.

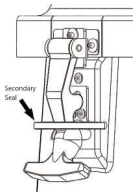
> **WARNING:** If you ship the vapor shipper in a cardboard box, it will ship on its side, as common carriers instruct their employees in sorting facilities to place boxes on conveyors with the most stable side down.

Charge the unit by following all steps listed in the OPERATION section before inserting it into the PPSC. To avoid damage to either the vapor shipper or PPSC never fill or dump the unit inside the PPSC. Fasten all locking latches tightly before shipping. You can also utilize a cable tie, tamper-proof security seal, or any other appropriate secondary locking mechanism around existing locking latches to avoid your asset from being tampered with during shipment. Before putting PPSC into service, inspect it for any damage that may jeopardize its functionality. Replace any aged/worn-out impact absorption foam cushion inside the PPSC or any defective hardware. Remove badly damaged PPSCs from service. A PPSC should be replaced after 50 to 100 shipments to provide the best protection for the product inside. Contact Customer or Technical Service for assistance in selecting the proper service parts

Typical PPSC shown. The shape of the PPSC helps keep the product upright during shipment.



Shock absorbing foam in the PPSC helps prevent damage to the dewar. The illustration shows a top view of the tank in the PPSC.



The rubber latch design allows the use of a zip tie, vet seal, safety seal, etc. to ensure the integrity of product shipped.

Select the appropriate shipping method based on the value of contents. Common carriers handle packages very roughly, with the most stable side of the packaging down. Common carriers should be used only for low-value product shipments. Contact carriers for recommended shipment methods to transport valuable and/or irreplaceable contents.

MVE vapor shippers were primarily designed as vapor shipping containers; however, they can also be used for immersion of samples. It is imperative that all liquid nitrogen be removed so the unit remains classified as a vapor shipper for transport. If liquid nitrogen is visible in the bottom of the dewar, it then becomes a liquid shipper; the exception status is void and the liquid inside is now classified as hazardous material.

1.7 General Cleaning

Do not use any petroleum-based cleaning solution.

1.7.1 Inside the Vessel

Any cleaning solution that does not react with aluminum, stainless steel, or G10 composite can be used in the sanitation process of an MVE vapor shipper. In most cases, any household detergent or mild soap solution is suitable. Other cleaners and disinfectants that can be used safely include hydrogen peroxide, chlorine/water mixture, and denatured alcohol. The generally accepted practice of using 10% chlorine bleach with 90% water solution is generally considered the best decontamination method. It is recommended that the unit be filled to its full capacity with the cleaning solution mixture, agitated, and then thoroughly rinsed. It is important that all surfaces being sanitized are thoroughly rinsed and that all cleaner solution residues are removed after cleaning. Allow the unit to dry completely before putting it into service. It is suggested that the unit be inverted to drain and dry completely.

1.7.2 Outside the Vessel

Use a light, dampened cloth with a mild soap solution.

1.8 Preventive Maintenance

The owner may follow two methods of maintenance, Continuous and/or Annual.

1.8.1 For Continuous Maintenance (Recommended before each shipment)

If the tank is warm, follow steps 1 - 3 under the preceding OPERATION section, but allow the unit with full liquid to stand undisturbed for 2 hours. Verify there is no major frost or condensation on the outside of the unit. Frost or condensation on the outside of the unit would indicate either a weak vacuum or no vacuum. Inspect the cork and cover for signs of damage that may affect NER and Hold Time. Inspect the outside of the tank for signs of shipping damage, such as large dents, especially around the neck tube area.

Remove badly damaged tanks from service.

Dump out any liquid. Clean the bottom of the unit to remove any stain, contamination, or condensation. Store the unit in a cool, clean, and dry location. These procedures can help prevent corrosion on the bottom of the vapor shipper.

1.8.2 For Annual Maintenance

1. Weigh the empty unit with cork and cover but without any inventory accessories and record as Empty Weight, [lb].

   The Empty Weight must be taken before filling, while the inside of the vapor shipper is at room temperature.

2. Fill unit to bottom of neck tube. Refer to the OPERATION section, step 2 for details.
3. Replace cork and cover and allow unit to stand for a minimum of 24 hours.
4. Weigh unit and record as First Weight, [lb].
5. Allow filled unit to sit undisturbed for another 24 (+/-0.25) hours.

   a. Consider the accuracy and resolution of your scale to determine if additional days are required between the first and second weights in order to obtain an accurate NER. Be sure to record the number of hours between the first and second weights.

b. Weigh a second time and record as Second Weight, [lb].
c. Calculate the evaporation rate by using Equation 2. The difference between the first weight and the second weight is the daily evaporation rate in lbs. This figure roughly signifies the normal evaporation rate, or N.E.R, [Liter/Day]

$$NER = \frac{(First\ Weight - Second\ Weight) \times 13.468}{Number\ of\ Hours} \qquad Equation\ 2$$

Major frost or condensation on the outside of the container during this time indicates either a weak vacuum or no vacuum.

1. Pour out LN2 per OPERATION section step 4. Replace cork and cover and take weight as Charged Weight.
2. Calculate Hold Time, [Days], by using Equation 3. Subtract the Empty Weight from the Charged Weight and divide by 1.782; then divide by NER.

$$Hold\ Time = \frac{(Charged\ Weight - Empty\ Weight) \div 1.782}{NER} \qquad Equation\ 3$$

1.9 Monitoring Temperature

MVE supplies Data Loggers for peace of mind when shipping valuable inventory in vapor shippers.

Contact Customer or Technical Service for assistance in selecting the proper Data Logger for your product. The Data Logger adds approximately 0.16L/day NER.

1.10 Letter Explaining Exception

This section regards the applicability of the USA Federal Hazardous Material Regulations for shipment of refrigerated samples in the “Dry Shipper” container. A “Dry Shipper” package consists of an inner container lined with absorbent material. The container is charged with nitrogen refrigerated liquid which is absorbed into the container lining. The charged, completed package serves as a refrigerated container for the shipment of samples.

In consideration of the above, consultation with the Research and Special Programs Administration of the DOT has determined that the use of nitrogen-refrigerated liquid-charged “dry shipper” containers for the shipment of samples fall within the regulation exception provided in 49CFR 173.320 paragraph (a) of the section states the requirements of this subchapter do not apply to atmospheric gases and helium when used in the operation of process systems such as refrigeration systems. Paragraph (c) of 173.320 pertains to air transport of same refrigeration system. For the exception status of air shipments, please refer to the IATA-Dangerous Goods Regulations for nitrogen refrigerated liquid. This falls in the class of 2.2 nonflammable gas, packing instructions 202 with special provisions A-152. If shipping outside of the USA, please consult your applicable regulatory agencies. For answers to questions regarding shipping regulations, contact an MVE, AI-Cryobiological Tech Service Representative.

1.11 Limited Warranty Statement

MVE Biological Solutions, 3055 Torrington Dr., Ball Ground, GA 30107

1.11.1 General Terms

"New Product" – MVE Biological Solutions ("MVE") warrants to the original purchaser ("Purchaser") that each new vapor shipper Dewar (collectively, the "New Products"), shall be free from defects in materials and workmanship for a period of two (2) years from the date of shipment, except as provided in the Limited Warranty Provisions below. MVE warrants that the dewar vacuum integrity shall be free from defects in materials and workmanship as listed below, except as provided in the Limited Warranty Provisions below.

Table 2. Limited Warranty Period

Covered Products	Limited Warranty Period Subject to the exclusions, exceptions, and other limitations included herewith
SC Series, XC Series, Lab Series, Spectrum Series, YDS-L, and certain ET Series	5 years
Vapor Shipper Series, Doble Series, and CryoSystem Series	3 years
YDS Series, YDH Series, GP Series, and CT Series	2 years
BL-7 and Cryocube	1 year from the date of first delivery, or the date of completion of the first shipment transaction, whichever occurs first

"Repair/Blemished Product" – MVE warrants to the Purchaser that all repaired equipment and factory blemished equipment (collectively, the "Repair/Blemished Products") shall be free of defects in materials and workmanship for a period of (90) days from the date of shipment, except as provided below. MVE warrants that the dewar vacuum integrity shall be free from defects in materials and workmanship for a period of (1) year from date of shipment, except as provided below.

"Service Part" – MVE warrants to the Purchaser that all Service Parts and Accessory Items (each a "Service Part") are warranted for (90) days from date of shipment to be free of defects in material and workmanship, except as provided below.

1.11.2 End of Product Life

Decontaminate the product and recycle cardboard, aluminum, stainless steel, and plastic PPSC per local regulations and procedures.

1.11.3 Limited Warranty Provisions

Purchaser agrees that before this limited warranty shall become effective, Purchaser shall fully inspect each New Product, Repair/Blemished Product, or Service Part within three (3) days of delivery and before such Product is put to use. Purchaser also agrees to operate the New Product, Repair/Blemished Product, or Service Part in accordance with MVE's operating instructions and that failure to do so shall void this limited warranty. Purchaser further agrees that any claim for breach of warranty must be made in writing within 60 days of discovery of a purported defect. MVE will not be responsible for any alleged breach of warranty, which, as a result of MVE's inspection, MVE determines to have arisen from a cause not covered by this limited warranty. In this case, MVE will charge the purchaser a nominal fee to repair the unit.

This limited warranty does not apply to: (A) Normal routine service items; (B) Repair or replacement necessitated by misuse, abuse, accident, or repairs made by persons other than MVE or persons not authorized by MVE, (C) Use of external equipment or parts with the New Product, Repair/Blemished Product, or Service Parts other than those approved by MVE, (D) Defects caused by effects of normal wear and tear; and (E) Acts of God, or other causes not within the control of MVE.

If Purchaser believes that a New Product, Repair/Blemished Product, or Service Part does not comply with the limited warranty stated above, Purchaser should contact MVE at the address stated above, describing the problem and providing proof of the date of purchase. If directed by MVE, Purchaser shall return the New Product, Repair/Blemished Product, or Service Part freight prepaid, properly packaged in an MVE-approved shipping container and properly identified by a Return Material Authorization Number issued by MVE. New Products, Repair/Blemished Product, or Service Parts returned without a Return Material Authorization Number will be refused and returned at Purchaser's expense.

The remedies available for any breach of this limited warranty are limited to repair or replacement of the defective New Product, Repair/Blemished Product, Service Part, or refund of the purchase price, at the sole discretion of MVE. MVE warrants that replacement or repaired New Product, Repair/Blemished Product, or Service Part shall be free from defects in material and workmanship for the duration of the unexpired portion of the original warranty or ninety (90) days from the date of re-shipment to Purchaser, whichever is longer. PURCHASER'S RECOVERY FROM MVE FOR ANY CLAIM SHALL NOT EXCEED PURCHASER'S PURCHASE PRICE FOR THE NEW PRODUCT, REPAIR/BLEMISHED PRODUCT, OR SERVICE PART GIVING RISE TO SUCH CLAIM, IRRESPECTIVE OF THE NATURE OF THE CLAIM, WHETHER IN CONTRACT, TORT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE. MVE SHALL NOT BE LIABLE FOR AND PURCHASER SHALL INDEMNIFY, DEFEND AND HOLD MVE HARMLESS FROM ANY CLAIMS BASED ON MVE'S COMPLIANCE WITH PURCHASER'S DESIGNS, SPECIFICATIONS OR INSTRUCTIONS, OR MODIFICATION OF ANY PRODUCTS BY PARTIES OTHER THAN MVE, OR USE IN COMBINATION WITH OTHER PRODUCTS.

PURCHASER SHALL NOT IN ANY EVENT BE ENTITLED TO, AND MVE SHALL NOT BE LIABLE FOR, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY NATURE INCLUDING, WITHOUT LIMITATION, BUSINESS INTERRUPTION COSTS, REMOVAL AND/OR REINSTALLATION COSTS, REPROCUREMENT COSTS, LOSS OF PROFIT OR REVENUE, LOSS OF DATA, PROMOTIONAL OR MANUFACTURING EXPENSES, OVERHEAD, INJURY TO REPUTATION OR LOSS OF CUSTOMERS, EVEN IF MVE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

EXCEPT FOR THIS LIMITED WARRANTY, MVE HAS MADE NO WARRANTIES OR REPRESENTATIONS, EXPRESSED OR IMPLIED, AND HEREBY DISCLAIMS ANY OTHER WARRANTIES, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NO REPRESENTATION OR STATEMENT OF MVE MAY CHANGE OR ALTER THIS LIMITED WARRANTY.

Any claims for breach of this limited warranty shall be governed by Georgia law and without regard to conflict of law rules thereof and must be brought in a state or federal court in Georgia.

Some states do not allow limitations on implied warranties or on incidental or consequential damages, so the above limitations may not apply. This limited warranty gives the Purchaser specific legal rights. Purchaser may also have other rights, which vary from state to state.

This product may be covered by one or more patents, US and international. Please visit our website below for the listing of applicable patents:

https://mvebio.com/intellectual-property-and-patents/

1.12 Supplement to MVE Biological Solutions Limited Warranty Statement for Sales in Australia (AI)

1.12.1 General Terms

"New Product" – MVE Biological Solutions ("MVE") warrants to the original purchaser only (meaning the party from whom MVE accepts the purchase order), whether such purchaser is a wholesaler, distributor or end user ("Purchaser"), that each new Liquid Nitrogen Dewar (collectively, the "New Products"), shall be free from defects in materials and workmanship for a period of two (2) years from the date of shipment, except as provided below. MVE warrants that the dewar vacuum integrity shall be free from defects in materials and workmanship as listed below, except as provided in the Limited Warranty Provisions below.

Table 2. Limited Warranty Period

Covered Products	Limited Warranty Period Subject to the exclusions, exceptions, and other limitations included herewith
SC Series, XC Series, Lab Series, Spectrum Series, YDS-L, and certain ET Series	5 years
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BL-7 and Cryocube	1 year from the date of first delivery, or the date of completion of the first shipment transaction, whichever occurs first

"Repair/Blemished Product" – MVE warrants to the Purchaser that all repaired equipment and factory blemished equipment (collectively, the "Repair/Blemished Products") shall be free of defects in materials and workmanship for a period of (90) days from the date of shipment, except as provided below. MVE warrants that the dewar vacuum integrity shall be free from defects in materials and workmanship for a period of (1) year from date of shipment, except as provided below.

"Service Part" – MVE warrants to the Purchaser that all Service Parts and Accessory Items (each a "Service Part") are warranted for (90) days from date of shipment to be free of defects in material and workmanship, except as provided below.

1.12.2 Sales of Product in Australia

Where the Purchaser is the end user of the Product, the following additional information is provided in relation to the warranty against defects (the Warranty) provided by MVE (as set out in the Limited Warranty Statement).

1. In circumstances where a New Product, Repair/Blemished Product or Service Part does not comply with the Warranty, MVE will at its expense repair or replace that defective New Product,

Repair/Blemished Product or Service Part, or refund the purchase price at the sole discretion of MVE. MVE warrants that the replacement or repaired New Product, Repair/Blemished Product or Service Part shall be free from defects in materials and workmanship for the duration of the unexpired portion of the Warranty, or 90 days from the date of reshipment to the purchaser, whichever is longer.

2. The Warranty is subject to the Limited Warranty Provisions set out below and all exclusions and limitations set forth in the MVE Limited Warranty Statement.
3. **To claim the Warranty, the Purchaser must contact MVE's affiliate in Australia for further instruction, including the return of the defective New Product Repair/Blemished Product or Service Part (at the Purchaser's expense), to the following address:**

   MVE Biological Solutions Australia Pty Ltd 7 Meridian Place, Unit 9
   Bella Vista NSW 2153 Australia
   Phone number: +1 404-383-1900 Email: mve.australia@mvebio.com

4. The Purchaser must otherwise comply with the requirements set out in the Limited Warranty Statement when making a claim under the Warranty.
5. **Notwithstanding the Limited Warranty Statement, our Products come with guarantees that cannot be excluded under the Australian Consumer Law (ACL). You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the Products repaired or replaced if the Products fail to be of acceptable quality and the failure does not amount to a major failure.**
6. The provider of the Warranty is MVE. Relevant contact details are set out below for MVE **(to claim the Warranty, please use the contact details provided in paragraph 3 above):**

   Customer Service Department MVE Biological Solutions 3055 Torrington Drive
   Ball Ground, GA 30107 (USA)
   Toll free 844-683-2796 or 404-383-1900 EXCEPT for Europe Email:
   customerservice.usa@mvebio.com

1.12.3 Repair of Products Sold in Australia

Where the Purchaser is the end user of the Product, the following additional information is provided in relation to the repair of Products:

The Products may contain "user-generated data" as defined under the Australian Consumer Law (ACL). Repair of Products may result in the loss of user-generated data.

This product may be covered by one or more patents, US and international. Please visit our website below for the listing of applicable patents:

https://mvebio.com/intellectual-property-and-patents/

1.13 Additional Copies of Manual

Please visit https://mvebio.com/resources/to download a digital copy of the manual and/or request a hard copy.

Intended Use & Indication for Use for Cryogenic Storage and/or Transport
LIFE SCIENCE INTENDED USE STATEMENT **STORAGE ONLY** MVE FREEZERS ARE INTENDED FOR THE INDICATION OF PRESERVING HUMAN BIOLOGICAL PRODUCTS, SAMPLES, AND/OR SPECIMENS (E.G., BLOOD, BLOOD PRODUCTS, CELLS, TISSUES, ETC.) AT CRYOGENIC AND ULTRACOLD TEMPERATURES DURING STORAGE. **STORAGE AND TRANSPORT** MVE DEWARS AND VAPOR SHIPPERS ARE INTENDED FOR THE INDICATION OF PRESERVING HUMAN BIOLOGICAL PRODUCTS, SAMPLES, OR SPECIMENS (E.G., BLOOD, BLOOD PRODUCTS, CELLS, TISSUES, ETC.) AT CRYOGENIC AND ULTRACOLD TEMPERATURES DURING STORAGE AND/OR TRANSPORTATION.

2 Instructions for Use for MVE Vapor Shippers (SI Version)

M.D.D. Representative: Medical Product Services, Borngasse 20, 35619 Braunfels, Germany

MVE vapor shippers are ideally suited for transporting cryobiological materials. Liquid nitrogen is retained in hydrophobic absorbent material, and the cold nitrogen vapors maintain the cryo storage Area below -150°C. The absorbent retains liquid nitrogen and prevents accidental spills.

Liquid nitrogen is classified as “Dangerous Goods” by the Department of Transportation (DOT). At least three regulatory agencies publish dangerous goods regulations:

- Department of Transportation (DOT)–
- International Air Transportation Association (IATA)
- International Civil Aviation Organization (ICAO)

If used outside of the USA, please consult your applicable regulatory agencies. Liquid nitrogen is classified under the name “Nitrogen, refrigerated liquid” and has a UN 1977 code number. The name classification and UN Code Number must be indicated on the shipping carton in addition to a “Gas nonflammable” label. Packing and labeling requirements can be obtained from the above organizations. Also, contact your carrier for any variances that may apply specifically to the company and/or the ultimate shipping destination.

Be aware that regulations undergo periodic revisions. Please contact your air carrier for the most recent regulations before shipping your cryobiological specimen. It is your responsibility to provide correct information, such as warning or caution, on the shipping package.

2.1 General Description

The cryopreservation vessel is a double-walled, vacuum-insulated vessel made of aluminum with a fiberglass composite neck, providing the highest efficiency possible in cryogenic temperature preservation. The liquid nitrogen absorbent is a hydrophobic blanket consisting of synthetic amorphous silica and glass fiber. This absorbent is non-hazardous. Use the vessel for liquid nitrogen only. Liquid oxygen is not compatible with this unit and must not be stored inside the vessel.

The MVE vapor shipper is designed with consideration for safety, durability and performance. However, mishandling of the equipment, including transport or shipping units in an orientation other than upright vertically, may damage the product. In addition, if a vessel experiences a drop, hit, or blow, the vacuum may immediately or prematurely fail and the contents may spill.

Upon receipt of the product, examine both the vessel and packaging for any evidence of damage during shipping. If there are signs of shipping damage, contact the carrier within the carrier's guidelines. Should there be damage from shipping, some MVE shipping boxes carry the Transit Tested ISTA certificate stamp, shown to the right, which is helpful when making a claim against the carrier. Watch after the first fill for any signs of vacuum loss, such as excessive frost or sweating on the outside jacket. Some frost near the top just after filling is normal. It is also normal for some white dust or powder-like residue from the absorbent to accumulate at the bottom of the unit due to shipping vibrations. If desired, the owner may wipe or vacuum it out.

This high-quality vacuum-insulated unit is compatible with the divergent temperature extremes and broad applications of cryobiology. Its life expectancy is three (3) years.

CE 0459 Products bearing the CE marking as shown comply with the requirements of Directive 93/42/EEC concerning medical devices in EU.

2.2 Safety

WARNING: Liquid nitrogen is extremely cold. To avoid injury by frostbite, use extreme care whenever handling liquid nitrogen, liquid nitrogen storage or transfer vessels, or any objects that have come in contact with liquid nitrogen.

- Leave no area of skin exposed.
- Always wear proper safety attire over clothing: face shield, cryogenic gloves, and cryogenic apron.
- Use extreme care to prevent spilling and splashing liquid nitrogen during transfer.
- Always keep the vessel in upright position. Do not tilt, or lay the vessel on its side.
- Immediately remove any clothing or safety attire on which liquid nitrogen has spilled.
- Get immediate medical attention for any frostbite injuries due to liquid nitrogen.

WARNING: Venting nitrogen vapors may deplete oxygen in the air, possibly leading to asphyxiation or even death. Do not store or use the container in small or enclosed areas or those with poor ventilation.

⚠**WARNING:** Do not tightly seal the liquid nitrogen container or prevent nitrogen gas from escaping. Excessive humidity levels or exposure to rainfall could result in freezing of the cork and cover, and possible explosion.

⚠**WARNING:** Never use a hollow tube to measure liquid nitrogen level. This could lead to thermal injury.

⚠ **CAUTION:** Handle the cryopreservation vessel with care.

- Never overfill vessels with liquid nitrogen. Liquid nitrogen should always be below the bottom of the neck tube. Overfilling the tank may cause immediate or premature vacuum failure and loss of contents.
- Never ship vapor shipper on its side or upside down. This can lead to vacuum failure and loss of product inside the vapor shipper.
- Do not scratch the neck tube area. Remove and insert inventories carefully. Scratches can cause premature vacuum failure and loss of contents.
- Tampering with or removing the vacuum port will destroy the vacuum and void the warranty.
- Never drop, hit, or allow the vessel to suffer a blow.
- Never spill liquid nitrogen on or near the vacuum port.
- Never leave the vessel outdoors.
- Inspect the vessel for any damage before and after each shipment.
- Keep the bottom of vessel clean and away from chemicals, fertilizers, soil, and moisture.
- All performance data published for these products is based only on static conditions. Actual performance will vary upon the nature of use. Vibration or manipulation of inventories and/or accessories will decrease the working duration/Hold time of these products.

2.3 Operation

⚠ **CAUTION:** Failure to follow MVE's best operating practices as set forth in the manual can result in loss of contents.

⚠ **CAUTION:** Consider the value of your product when choosing dewar, shipping methods, and storage at destination. Splitting shipments of valuable samples reduces risk of loss.

⚠ **CAUTION:** If not using MVE protective containers, ship products in protective containers with a minimum ISTA-3A or ISTA-3B rating for the combined dewar and container to reduce risk of loss.

⚠ **CAUTION:** If storing human biological material, use appropriate liquid level monitoring equipment.

2.4 Environmental Conditions

- Indoor use only (out of elements).
- Operating temperature: -29 deg C to +60 deg C.
- Relative humidity: 10% to 95%, non-condensing
- Storage temperature: -29 deg C. to +60 deg C.
- Storage relative humidity: 10% to 95%

Liquid nitrogen is extremely cold. Make sure to wear proper gear before operation. Avoid spilling liquid nitrogen over the vacuum port as this can shrink the seal and allow air to leak into the vacuum space causing premature vacuum failure. To ensure maximum performance from your MVE vapor shipper simply follow the listed steps prior to shipping to final destination:

1. Open container that the vapor shipper is in. Open the lid and remove cork and cover/accessories. Lift cork and cover straight up; do not twist.
2. Fill unit to bottom of neck tube. Liquid level should never pass bottom of neck tube.
    a. If you are working with a warm vessel, MVE recommends you cool the unit by slowly adding small amount of liquid to the bottom of unit and allow it to sit until the liquid nitrogen stops rapidly boiling. Position the vacuum port facing away from the operator or other personnel.
    b. To obtain the optimized Hold time, you will need to refill the unit to the bottom of the neck more than once until the liquid level is steady.
    c. Follow established safety practices and procedures for transferring LN2.
    d. Fill the vessel with a funnel or transfer line when possible. Transfer using an LN2 hose with phase separator or a pouring container using a funnel.
    e. If filling the vessel from a pressurized source, make sure it is a low-pressure source (1.52 bar or below).
3. Replace cork and cover and allow unit to reach thermal equilibrium /charge for minimal 24 hours.
    a. Refer to UTILIZING THE QWICK®CHARGE TECHNOLOGY section for expedited charge solution.
    b. Excessive frost or sweating on the outside vessel after the first few hours indicates either a weak vacuum or no vacuum. Examine the unit carefully.
4. Pour off excess liquid just prior to shipment.
    a. If necessary to completely dispense all liquid nitrogen, carefully invert the unit until liquid nitrogen dripping has stopped. Set the unit upright and view if any liquid nitrogen pools at the bottom of the unit. If liquid nitrogen starts to pool, invert the unit again. Repeat as necessary until all liquid nitrogen is removed from the unit, in accordance with ICAO Packaging Instruction 202.
    b. Use a tool to hold vapor shipper when draining excess LN2.

⚠ **CAUTION:** Be careful when inverting the vapor shipper to avoid damage to the top neck area of the tank. Damage to the top neck area of the tank can cause vacuum failure and loss of contents.

5. Weigh unit and record.
    a. To ensure a proper charging process is conducted, obtain both empty and charged weights. Verify that the differential between empty and charged weights is close to data in Table 1. The differential can be calculated by using Equation 1.

        Differential = Charged Weight — Empty Weight Equation 1

    b. Please note that the Charged Weight is not an indication of unit performance.