USER MANUAL

OF

CRYO-SHIPPER EXTRA CAPACITY

WITH IATA / DOT / UN

INFECTIOUS SUBSTANCE PACKAGING CERTIFICATION

MVE Bio-Medical Systems, Applied Technologies Division, Chart Industries, Inc.
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Ref: 10779450 Rev. A

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Specifications:

MODEL	Cryo-shipper Extra Capacity w/ IATA
p/n	10777411
Maximum working cavity dimensions	8-1/2" dia * 12" deep
IATA secondary container dimensions	7-3/8" dia * 8-3/4" deep
MAXIMUM STORAGE CAPACITY	
Number of secondary containers	1
Number of 1 ml vials	450 (5 level bulk)
Number of 2 ml vials	350 (4 level bulk)
Number of 3 ml vials	250 (3 level bulk)
Number of 4 ml vials	250 (3 level bulk)
Number of blood bags stored	22
PERFORMANCE	
Liquid nitrogen capacity (liters)	11.8
Static evaporation rate (liters/day)	0.80
Static holding time (days)	14
UNIT DIMENSIONS	
Neck opening (in / mm)	8.5 / 216
Overall height (in / mm)	24 / 610
Outside diameter (in / mm)	15 / 381
Weight empty (lbs / kg)	29 / 13.1
Weight full (lbs / kg)	50.5 / 22.9

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DOT / UN INFECTIOUS SUBSTANCE PACKAGING CERTIFICATION

TEN-E PACKAGING SERVICES, INC. certifies that the **MVE CMD-20 Infectious Substance Cryogenic Packaging with Vials** has passed the standards of the **DEPARTMENT OF TRANSPORTATION'S TITLE 49 CFR; Section.173.196(f) and the Performance Test Requirements for Infectious Substance Packaging of Section 178.609**. This package is also certified under ICAO/IATA Regulations. It is the responsibility of the end user to determine authorization for use under these regulations. The use of other packaging methods or components other than those documented in this report may render this certification invalid.

PACKAGE DESCRIPTION:-	CMD-20 Infectious Substance Cryogenic Packaging with Vials
TEST REPORT NUMBER (S):	15331, 15071, 14017
UN MARKING: (ICAO Part 7;2.2.2)	(u n) IH2/CLASS 6.2/** USA/+AA1748
PACKAGING IDENTIFICATION CODE:	IH2/Class 6.2. (Infectious Substance)
YEAR OF MANUFACTURE:	** (Insert year the package is manufactured)
STATE AUTHORIZING TEE MARK:	USA
PACKAGING CERTIFICATION AGENCY:	(+AA) TEN-E Packaging Services, Inc.
THIRD PARTY PACKAGE IDENTIFICATION:	+AA1748

Dale Johnson
Packaging Engineer
TEN-E Packaging Services, Inc.

ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY THAT THE PACKAGING TESTED IS MERCHANTABLE OR FIT FOR A PARTICULAR PURPOSE, ARE DISCLAIMED. In no event shall TEN-E Packaging Services, Inc. Liability exceed the total amount paid by MVE for services rendered. In the event of future changes to the above referenced test standard, it is the responsibility of MVE to determine whether additional testing or updating of past testing is necessary to verify that the packaging we have tested remains in compliance with those standards.

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DOT / UN INFECTIOUS SUBSTANCE PACKAGING CERTIFICATION

TEN-E PACKAGING SERVICES, INC. certifies that the **MVE CMD-20 Infectious Substance Cryogenic Packaging with Blood Bags** has passed the standards of the **DEPARTMENT OF TRANSPORTATION'S TITLE 49 CFR; Section.173.196(f) and the Performance Test Requirements for Infectious Substance Packaging of Section 178.609.** This package is also certified under ICAO/IATA Regulations. It is the responsibility of the end user to determine authorization for use under these regulations. The use of other packaging methods or components other than those documented in this report may render this certification invalid.

PACKAGE DESCRIPTION:-	CMD-20 Infectious Substance Cryogenic Packaging with Blood Bags
TEST REPORT NUMBER:	15330
UN MARKING: (ICAO Part 7;2.2.2)	(un) IH2/CLASS 6.2/** USA/+AA1749
PACKAGING IDENTIFICATION CODE:	IH2/Class 6.2. (Infectious Substance)
YEAR OF MANUFACTURE:	** (Insert year the package is manufactured)
STATE AUTHORIZING TEE MARK:	USA
PACKAGING CERTIFICATION AGENCY:	(+AA) TEN-E Packaging Services, Inc.
THIRD PARTY PACKAGE IDENTIFICATION:	+AA1749

Dale Johnson
Packaging Engineer
TEN-E Packaging Services, Inc.

ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY THAT THE PACKAGING TESTED IS MERCHANTABLE OR FIT FOR A PARTICULAR PURPOSE, ARE DISCLAIMED. In no event shall TEN-E Packaging Services, Inc. Liability exceed the total amount paid by MVE for services rendered. In the event of future changes to the above referenced test standard, it is the responsibility of MVE to determine whether additional testing or updating of past testing is necessary to verify that the packaging we have tested remains in compliance with those standards.

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DISCLAIMER OF WARRANTIES

TEN-E PACKAGING SERVICES, INC. certifies that the previously described testing services have been performed in accordance with standard good laboratory practices and that the packaging tested has passed the standards of the **DEPARTMENT OF TRANSPORTATION'S TITLE 49 CFR; SECTION 173.27(c)(2), and the ICAO Technical Instructions on the Safe Transport of Dangerous Goods by Air, Part 3 1.1.6.1.** However, it is the responsibility of the end user to determine authorization for use under these regulations. ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY THAT THE PACKAGING TESTED IS MERCHANTABLE OR FIT FOR A PARTICULAR PURPOSE, ARE DISCLAIMED. In no event shall TEN-E Packaging Services, Inc. liability exceed the total amount paid by MVE, Inc for services rendered.

In the event of future changes to the above referenced test standard, it is the responsibility of Chart, Inc to determine whether additional testing or updating of past testing is necessary to verify that the packaging we have tested remains in compliance with those standards.

Dale A. Johnson
Packaging Engineer

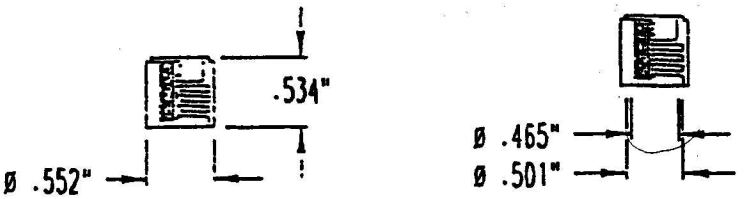
Testing was completed by Ten-E Packaging Services, Inc. on April 10, 1997. The following dimensions, weights and material audits were performed by Ten-E Packaging Services to document the package design:

PRIMARY - 4 mL Cryovial

CLOSURE

• Description:	12 mm Threaded Cap		
• Material:	Polypropylene	• Density:	.852 g/cc
• Tare Weight:	.638 Grams		
• Markings:	5		
• Gasket:	Material: Silicone Rubber Tare Wt.: .076 Grams	Thickness:	.041"

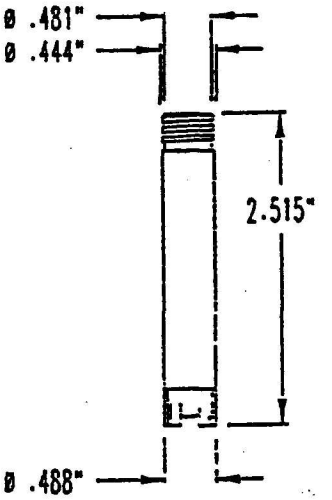
Overall & Thread Dimensions



VIAL

• Description:	4 mL Cryovial®		
• Material:	Polypropylene; Natural	• Tare Weight:	2.6 Grams
• Capacity:	Overflow: 5.0 mL 98% of Overflow: 4.9 mL		
• Density:	.913 g/cc		
• Markings:	SPI "5" PP Recycling Symbol 5		

Overall & Finish Dimensions



ABSORBENT

• Description:	(1) Sheet Absorbent folded		
• Dimensions:	11-5/8" x 4"	• Tare Weight:	2 Grams
• Usage:	Placed on top of vials in plasic box		

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Primary Receptacle

4 mL CRYOVIAL

DESCRIPTION:
Cryovial® T310-4A Self Standing Vial

MATERIAL:
- Closure: Polypropylene
- Vial: Polypropylene

CAPACITY: 4 mL

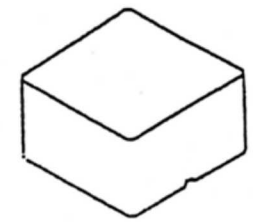
TARE WEIGHT:
Not Specified

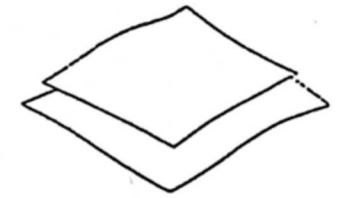
CLOSURE GASKET:
Silicone seal fitted at base of the cap

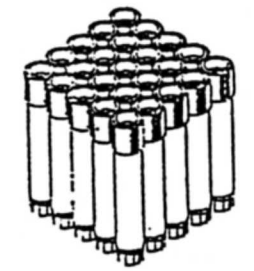
DIMENSIONS:
- Diameter (O.D.): 12.5 mm
- Height: 78 mm

NO USED/PACKAGE: (238)* 4 mL Cryovials

SUPPLIER: Simport Plastics







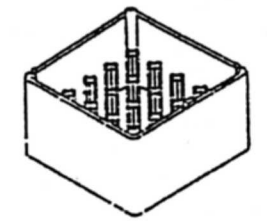
ABSORBENT

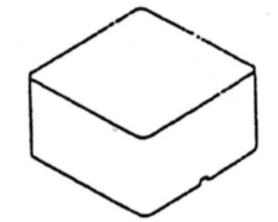
DESCRIPTION:
Paper fiber absorbent material

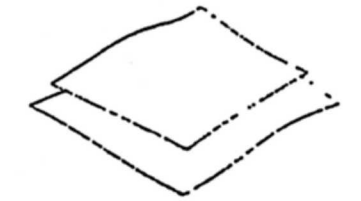
DIMENSIONS:
11-5/8" (length) x 4" (width)

USAGE:
(1) sheet folded 4-times, placed on top of vials in plastic box

SUPPLIER: Not specified







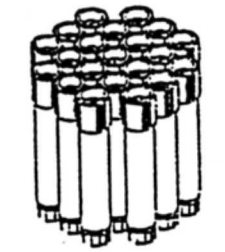
PLASTIC BOX

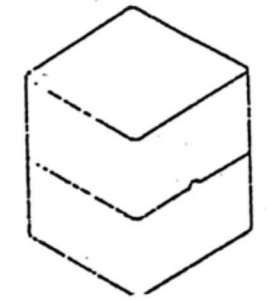
DESCRIPTION: 2-Piece plastic box

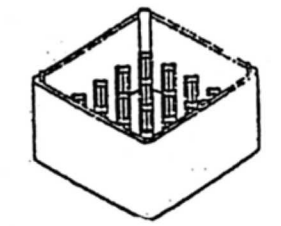
DIMENSIONS: 2-3/4" x 2-3/4" x 3-1/8"

TARE WEIGHT: 63 Grams

USAGE: *Bottom 3 boxes contain 21 plastic vials, remaining (7) boxes contain 25 plastic vials. All boxes contain (1) sheet of absorbent material on top of vials.







CHART™

Secondary Packaging

STAINLESS STEEL CAN

COVER

DESCRIPTION: Stainless Steel Cover with Pressure Release Valve and (6) screws
Release Pressure at 15 PSI

MATERIAL: Stainless Steel SS304

OVERALL DIMENSIONS:
- Height: 2.125" (W/Handle)
- Diameter: 8.375"

GASKET:
Teflon Gasket placed in groove on top of can

SUPPLIER: Not Specified

CAN

DESCRIPTION: Round Stainless Steel Can

MATERIAL: Stainless Steel SS304

TARE WEIGHT: Not Specified

CAPACITY:
- Nominal: Not Specified
- Overflow: Not Specified

OVERALL DIMENSIONS:
- Height: 9.375"
- Diameter: 8.375" (Top)
- Thickness: 0.029"

SUPPLIER: Not Specified

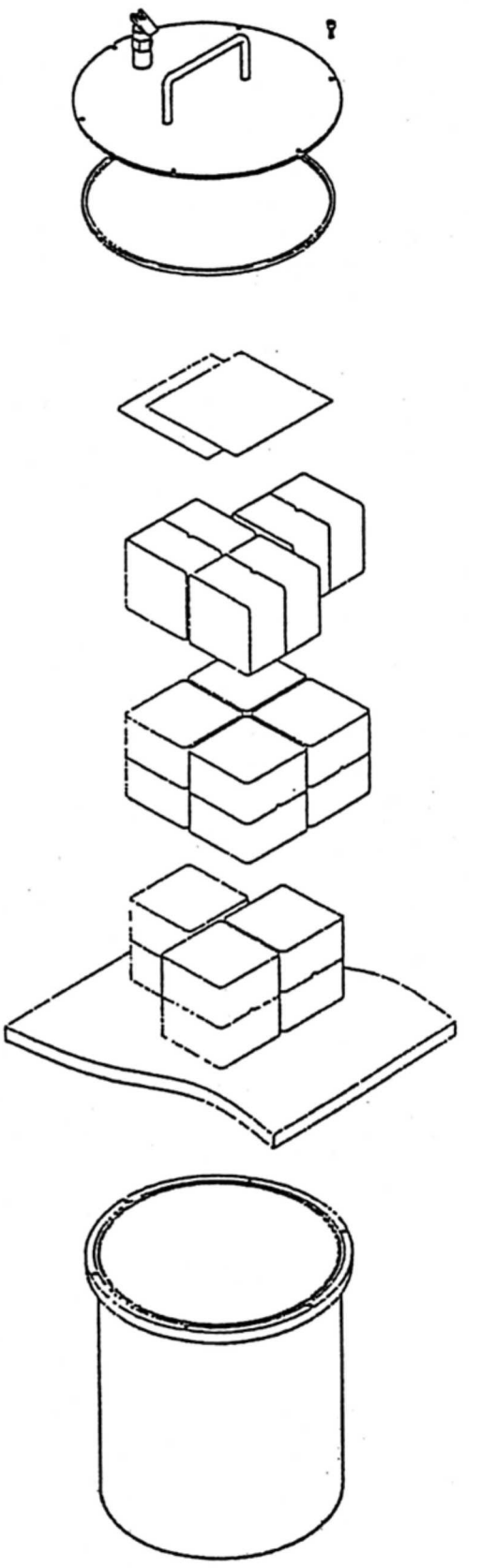
ABSORBENT

DESCRIPTION:
Paper fiber absorbent material

DIMENSIONS:
11-5/8" (length) x 4" (width)

USAGE:
(4) Sheets placed on bottom, (27) Sheets used to fill void area

SUPPLIER: Not Specified



CHART™

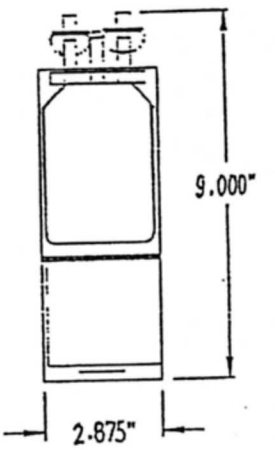
Testing was completed by Ten-E Packaging Services, Inc. on April 10, 1997. The following dimensions, weights and material audits were performed by Ten-E Packaging Services to document the package design:

PRIMARY - Blood Bag in Aluminum Cassette (20 Used/Shipper)

BLOOD BAG

• Description:	Baxter Cryocyte™ Bag with manifold set	
• Material:	PL-269 Plastic; Single-Ply	• Thickeness: .013"
• Gross Weight	33 Grams (with simulated product)	• Markings: None

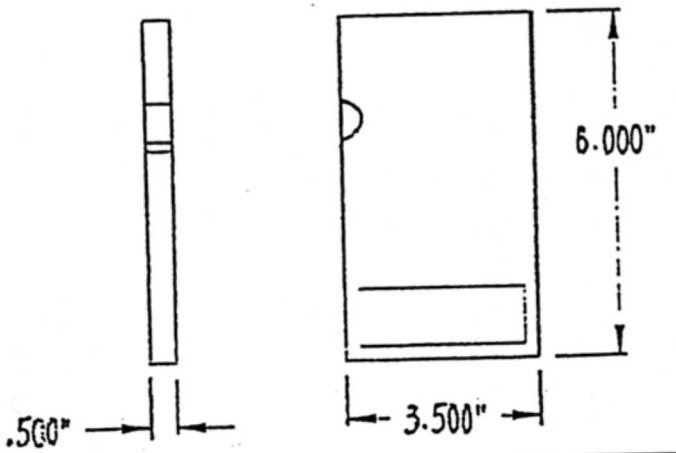
Overall Dimensions



CASSETTE

• Description:	Freezing and Storage Cassette for Individual Blood Bag. Cassette has rivet hinge and thumb latch	
• Material:	Aluminum	• Tare Weight: 88 Grams
• Markings:	None	

Overall Dimensions



ABSORBENT

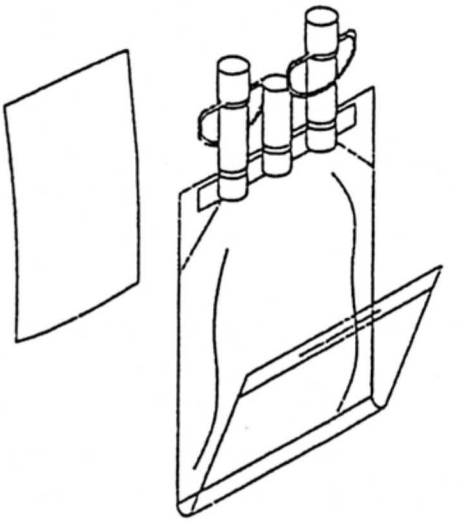
• Description:	(1) Sheet Paper Fiber Absorbent	
• Dimensions:	11-5/8" x 4"	• Tare Weight: 2 Grams Each
• Usage:	Placed in Cassette	

CHART™

Primary Receptacle

BLOOD BAG

DESCRIPTION:
50 mL Cryocyte™ Freezing Container fitted with male and female syringe adapters to facilitate aseptic filling and removal of contents



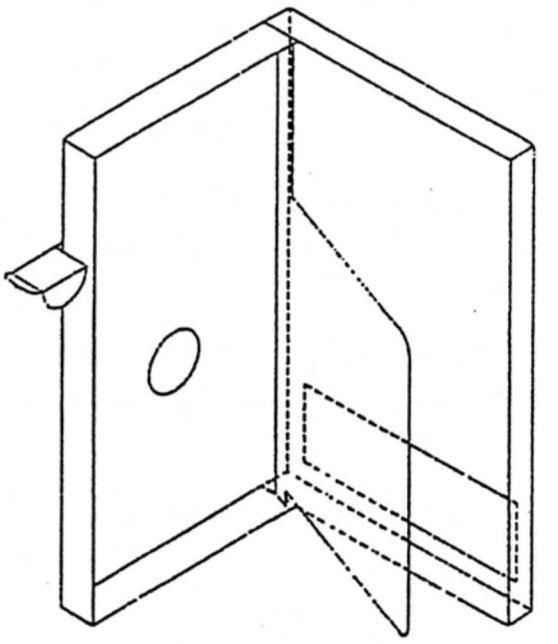
MATERIAL:

• Bag:	PL 269 Plastic
• D-Ring Port Seals:	Silicone
NOMINAL SIZE:	50 mL
FREEZING CAPACITY:	10-20 mL
TARE WEIGHT:	Not Specified

SEALING:
Pre-attached Fill Tube is sealed using a dielectric sealer

DIMENSIONS:	Not specified
NO USED:	20
SUPPLIER/ID:	Baxter/4R9951

ABSORBENT



DESCRIPTION:	Paper Fiber Absorbant Material
DIMENSIONS:	11-5/8" (length) x 4" (width)
USAGE:	(1) sheet folded 4-times, placed next to blood bag in cassette

CASSETTE

DESCRIPTION:
Freezing and Storage Cassette for use with Baxter Heathcare Minicyrocyte Container Cat. #4R9951

MATERIAL:	Aluminum
THICKNESS:	.032"
DIMENSIONS (ID):	5.85" (L) x 3.36" (W) x .47" (H)
FEATURES:	Aluminum Rivit Hinge Aluminum Thumb Latch 1/4" Close Cell Rubber Spring 20 mL Volume
NO. USED:	20
SUPPLIER/ID:	CWF Incorporated/#CW-199-1-2

Secondary Packaging

STAINLESS STEEL CAN

COVER

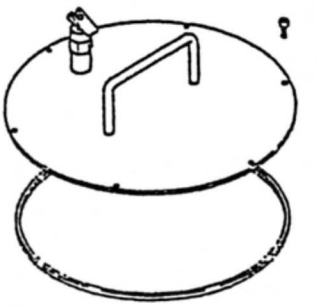
DESCRIPTION: Stainless Steel Cover with Pressure Release Valve and (6) screws
Release Pressure at 15 PSI

MATERIAL: Stainless Steel SS304

OVERALL DIMENSIONS:
- Height: 2.125" (W/Handle)
- Diameter: 8.375"

GASKET:
Teflon Gasket placed in groove on top of can

SUPPLIER: Not Specified



CAN

DESCRIPTION: Round Stainless Steel Can

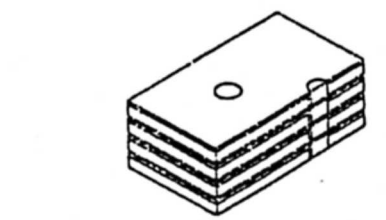
MATERIAL: Stainless Steel SS304

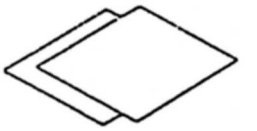
TARE WEIGHT: Not Specified

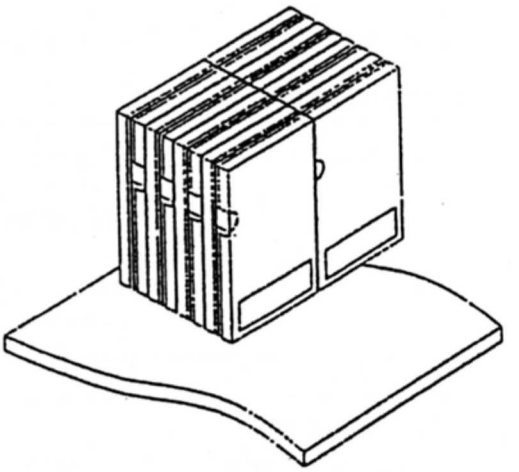
CAPACITY:
- Nominal: Not Specified
- Overflow: Not Specified

OVERALL DIMENSIONS:
- Height: 9.375"
- Diameter: 8.375" (Top)
- Thickness: 0.029"

SUPPLIER: Not Specified







ABSORBENT

DESCRIPTION:
Paper fiber absorbent material

DIMENSIONS:
11-5/8" (length) x 4" (width)

USAGE:
(8) sheets total, 6 sheets folded and placed on bottom, 2 sheets folded and placed between cassette layers

SUPPLIER: Not Specified

CHART™

Cryo-shipper extra capacity unit

Cryo-shipper extra capacity / cork and cover

DESCRIPTION:
Slip-Fit Cover with 7-1/2" (diameter) Neck Tube

MATERIAL:
Aluminum; Painted Blue

OVERALL DIMENSIONS:
- Height: Not specified
- Diameter: Not specified

NECK TUBE:
8-1/2" Diameter Expanded Polystyrene Tube

SUPPLIER / MANUFACTURER & ID:
MVE

Cryo-shipper extra capacity / tank

DESCRIPTION:
CMD-20 Vacuum Insulated Vapor Shipper

MATERIAL:
- Outer Shell: Aluminum
- Outside Wall/Inner Shell: Aluminum
- Inside Wall/Inner Shell: Stainless Steel

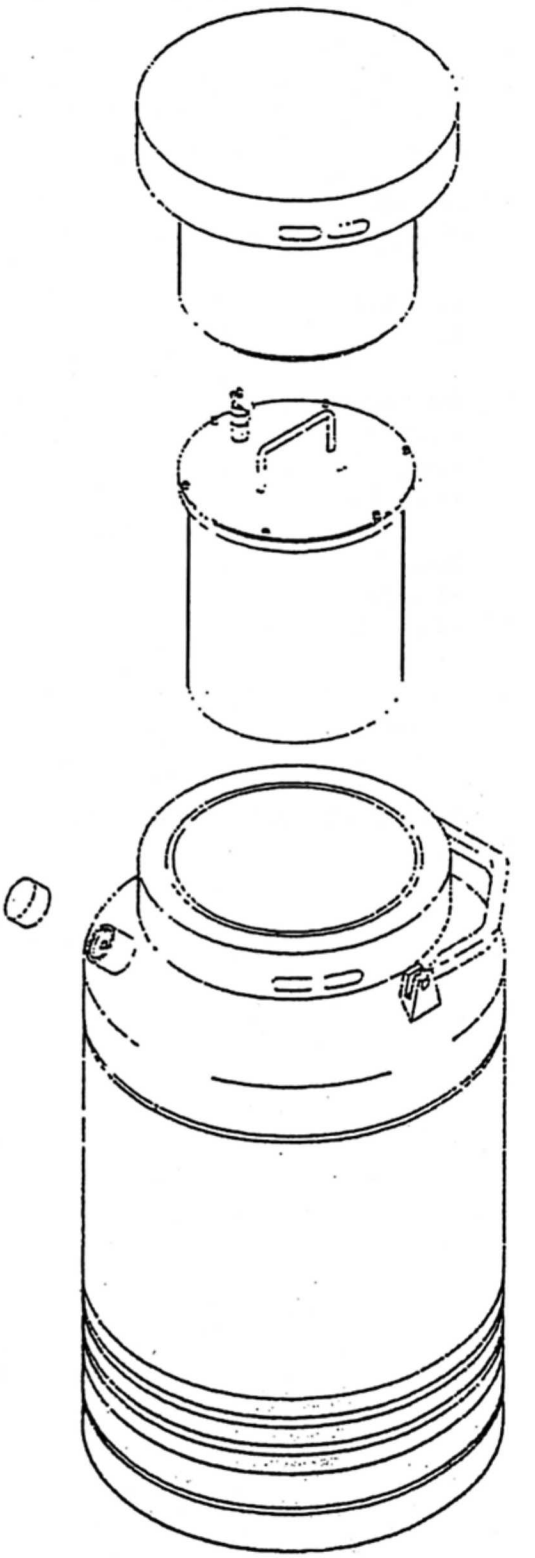
ABSORBENT:
Cab-o-Sil Aborbent Material placed between outside and inside wall of inner shell

VAPOR SHIPPER WEIGHTS:
- Empty: Not specified
- Liquid Nitrogen Charged: 50.05 Lbs.
- Liquid Nitrogen Capacity: Not specified
- Liquid Nitrogen Capacity: Not specified

DIMENSIONS:
Inner Shell:
- Diameter/ID: 8-1/2"
- Diameter/OD: 12-7/8"
- Height: 12-3/4"

Body:
- Height (w/cover): 22"
- Diameter: 22"
- Neck Opening: 8-1/2"

SUPPLIER / MANUFACTURER & ID:
MVE



CHART™

Cryo-shipper extra capacity unit

Cryo-shipper extra capacity / shipping container

DESCRIPTION:
CMD-20 Plastic Shipping Container with Domed Cover attached to overpack using (3) bolted metal latch assemblies

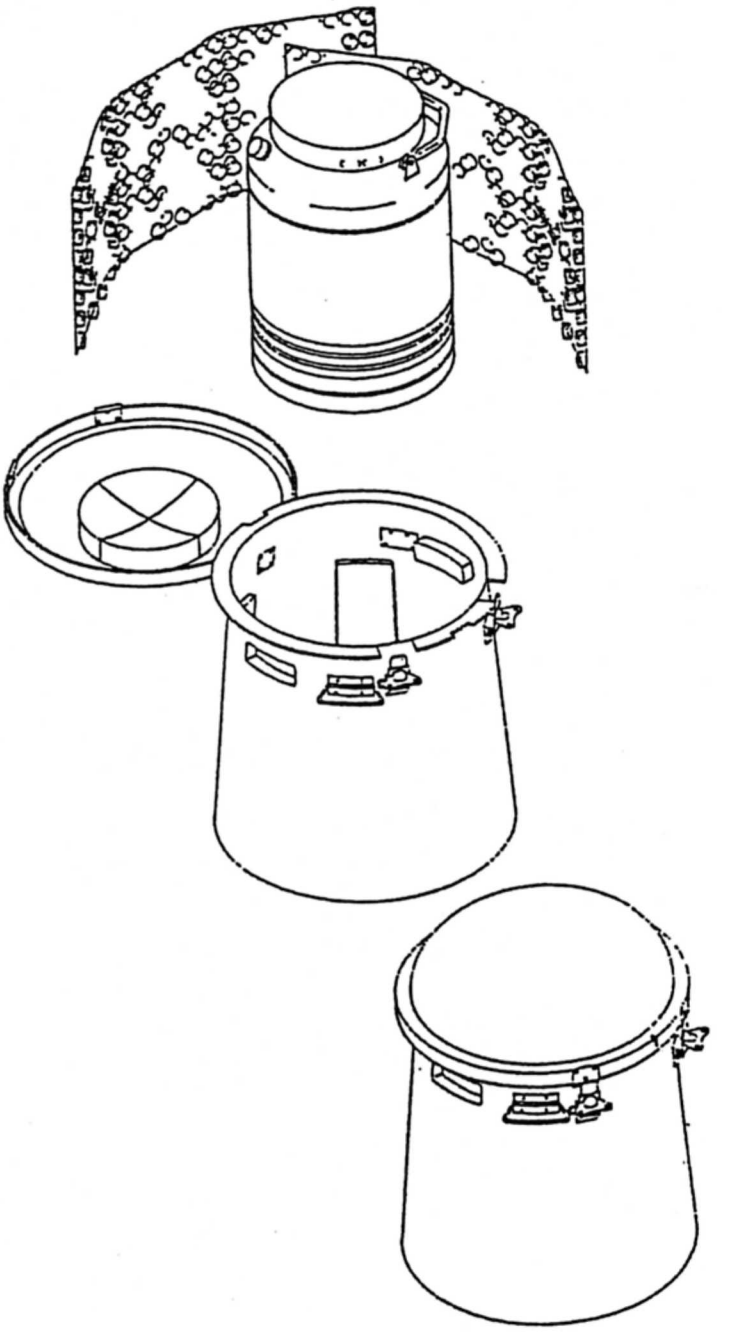
MATERIAL:
Medium Density Polyethlene

PIGMENT:
Tan

DIMENSIONS:

Cover:	
• Height:	5-1/2"
• Diameter:	22"
Body:	
• Height:	22"
• Diameter:	22"
Overall:	
• Height:	27-1/2"
• Diameter:	22"

SUPPLIER / MANUFACTURER & ID:
MVE



Caution

- After removing secondary container from cryogenic vessel, ALWAYS release pressure/vacuum inside this container immediately by LIFTING UP THE HANDLE of relief valve.

- Always LIFT UP THE HANDLE of relief valve, before opening the lid of secondary container.

- Always seal the lid with six screws.

- Remove secondary container when filling liquid nitrogen into vessel.

- Do not put dry ice or liquid nitrogen in secondary container.

- Keep top flange dry before sealing secondary container.

- Pre-cool secondary container in liquid nitrogen vapor phase or -70°C mechanical freezer, before placing samples inside.

GENERAL DESCRIPTION:

The SC and XC vapor series dewar is a vacuum insulated container of aluminum with fiberglass neck construction providing you with the highest efficiency possible in nitrogen vapor storage. Use the container for inert fluids only. Liquid oxygen is not compatible with fiberglass material and should not be stored.

These high quality vacuum insulated units are constructed of durable material, compatible with the divergent temperature extremes and broad applications of cryobiology . The absorbent material used in construction after 1993 is hydrophobic (will not absorb water) which unlike calcium silicate does not need to be periodically heated to remove absorbed moisture.

A) SAFETY

Note: Fill the container with a funnel or transfer line when possible. Avoid spilling liquid nitrogen over the vacuum cap near the neck as this can shrink the seal and allow air to leak into the vacuum space.

CAUTION: (Using Aluminum SC or XC vapor shipper series). To avoid injury by frostbite use extreme care whenever handling liquid nitrogen, liquid nitrogen storage or transfer vessels, or any objects which have come in contact with liquid nitrogen.

- Leave no area of skin exposed.
- Always wear proper safety attire over clothing: face shield, cryogenic gloves, cryogenic apron.
- Never overfill vapor shippers with liquid nitrogen.
- Always keep vapor shippers in upright position.
- Do not tightly seal liquid nitrogen container or prevent nitrogen gas from escaping.
- Use extreme care to prevent spilling and splashing liquid nitrogen during transfer.
- 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.

B) FILLING INSTRUCTIONS

To ensure maximum performance from your MVE vapor dewar simply follow the listed steps just prior to shipping to final destination:

Open container that dewar is in and remove cork/cover (do not twist).

2. Fill unit to bottom of neck tube.
   a) Follow established safety practices and procedures for transferring LN_2.
   b) Transfer using LN_2 hose with phase separator or pouring container and approved funnel.
   c) Canisters are to remain inside.
3. Replace cork/cover and allow unit to stand for 24 hours (cooling down unit).
4. Weigh unit (first weight) and record.
5. Pour off excess liquid just prior to shipment.

TO TEST FOR DEWAR EFFICIENCY FOLLOW STEPS 1 - 4 AND PROCEED TO #6.

6. Allow filled unit to sit for another 24 hours.
7. Weigh second time.
8. Never overfill your dewar with liquid nitrogen. Overfilling the tank may cause immediate or premature vacuum failure to occur.
9. Calculate evaporation rate. The difference between the first weight and the second weight is the evaporation rate in lbs. This can be converted to liters by multiplying lbs. x .5606. This figure roughly signifies the N.E.R. (first weight - second weight) x .5606 = liters/day.
   a) Also, during this time take note of any uncommon occurrences such as excess frosting or sweating along the outside of dewar. Take note of excess nitrogen boil off especially after the second weight. LN_2 should settle (cease boiling) after an hour.

MVE vapor shippers were primarily designed as vapor shipping containers; however, they can also be used for immersion of samples. A sharp blow to the outer vessel can damage the neck tube or start a vacuum leak. Use caution and common sense in handling the container. Use the weight table below as a general guide to determine if your vapor shipper is fully charged.

1. Model	Empty Weight	Sugg. Wt. Full	Static Hold Time Days
Cryoshipper XC IATA	30	47	14

C) REPLACEMENT PARTS

Models	Cryo XC
Canister	see brochure
Cork / Cover	10509556

WARNING: the venting of nitrogen vapors will create a dilution of the air's oxygen concentration necessary to support like. Exposure to this diluted atmosphere can cause asphyxiation or even death. Do not store or use container in areas that have poor ventilation. Place container in a well-ventilated area. Failure to comply with this warning may cause serious personal injury including death.

D) SHIPPING INSTRUCTIONS

Dewar is charged for 24 hours for full absorption capacity. Generally dewar will be 60% charged at 8 hours, 80% charged at 12 hours and 100% charged at 24 hours. Prior to packaging dewar for shipment the entire contents of liquid nitrogen must be removed. This is usually done by pouring out excess liquid nitrogen until no liquid is visible on the bottom of the inner dewar. Place in bio samples, package dewar and ship. The plastic shipping container provided by MVE/Chart is recommended to help keep dewar in upright position. **IF DEWAR IS SHIPPED ON ITS SIDE IT WILL ONLY PROVIDE 40% OF THE SPECIFIED HOLD TIME. IF SHIPPED UPSIDE DOWN IT WILL ONLY PROVIDE 10% OF HOLD TIME CAPACITY.** Remember that all MVE vapor shippers can also be used for liquid nitrogen storage as well, so it is imperative that all liquid nitrogen be removed so dewar remains classified as a vapor shipper. If liquid nitrogen is visible in the bottom of the inner it then becomes a liquid shipper and the exception status is void. The liquid inside is now classified as hazardous material.

LETTER EXPLAINING EXCEPTION

This is concerning the applicability of the Federal Hazardous Material Regulations to the shipment of refrigerated samples in the "Dry Shipper" container.

A "Dry Shipper" package consists of an outer container that is lined with an 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.

Because of the manner in which it is absorbed and because there is no free liquid present in the packaging, the liquid nitrogen does not exhibit the characteristic of a "cryogenic liquid" as defined in 49 CFR 173.115(g) and does not pose a hazard in transportation. Therefore, it is not subject to regulation under the Department of Transportation's Hazardous Material Regulations.

However, if the packaging is improperly offered for transportation WITH free liquid present, it would be subject to regulation when offered for transportation by air (see 49CFR 173.320) and must be offered in accordance with the International Civil Aviation Organization's (ICAO) Technical Instructions. Note the packaging does not conform to ICAO Packaging Instruction 202 and therefore, is not an authorized packaging when containing free liquid.
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 falls 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 the process system, such as a refrigeration system. Paragraph (c) of 173.320 pertains to air transport of same refrigeration system. For exception status of air shipments please refer to IATA-Dangerous Goods Regulations for nitrogen refrigerated liquid. This falls in the class of 2.2 non-flammable gas, packing instructions 202 with special provisions A-800. For answers to questions regarding shipping regulations contact a MVE, AI-Cryobiological Tech Service Representative @ 886-819-5897.