

CAPSULS™ Patient Isolation Unit

Item D3710



The Patient Isolation Unit (PIU) prevents particulate (biological and radiological) cross-contamination between the patient and the external environment.

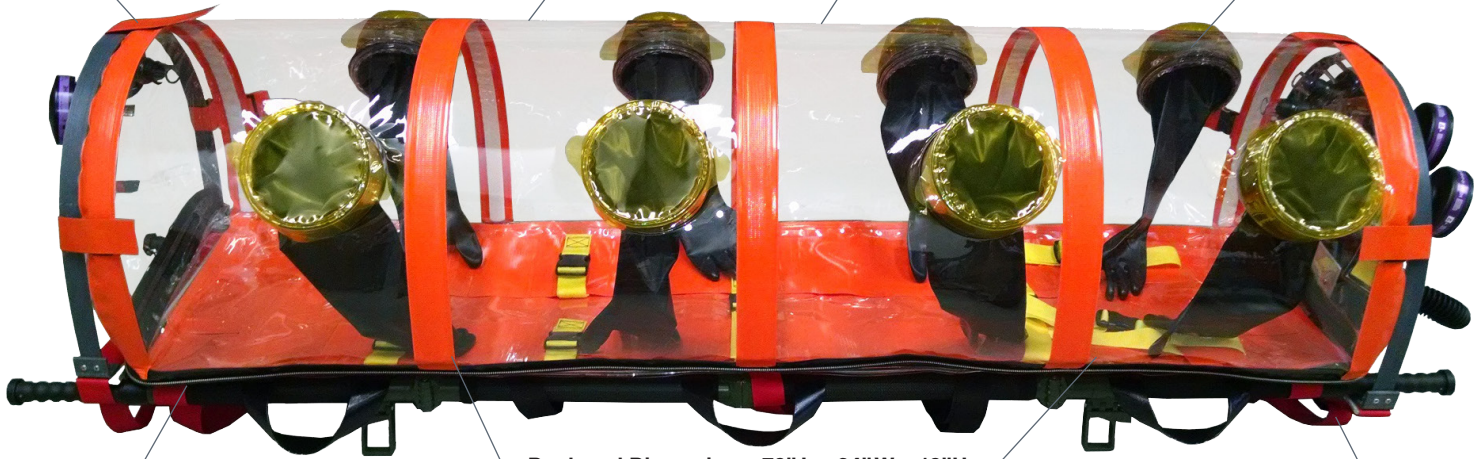
- Isolated transport of patients
- Temporary patient isolation in medical facilities
- Positive and negative pressure operation

Positive and Negative Pressure Operation for all potential scenarios of a contaminated or uncontaminated patient

Chemical Warfare Agent Barrier Withstand Testing by the United States Department of Defense (DOD)

Biological Agent & Particulate Barrier Withstand Testing by the United States Department of Defense (DOD).

Eight (8) 26" length butyl gloves for access to 100% of the patient during transport



PVC Free, Non-Hazardous and Puncture Resistant Material.

Gas and Liquid tight zipper with a suitcase style opening for ease of patient load and unload.

Deployed Dimensions: 78" L x 24" W x 18"H
Deployed Weight: 35 LBS.

Sound attenuation of ≤ 2 dB for ease of communication with the patient

Litters sold separately

External strapping for attachment to a NATO litter or gurney with 1,200 Lbs. load capacity

CAPSULS™ Patient Isolation Unit (PIU)

The CAPSULS™ (Containment and Protection System Utilizing Life Support) is a portable and economical Patient Isolation Unit (PIU). It comprises a flexible envelope that may be either positively or negatively pressurized. Under positive pressure operation it isolates and protects a patient during transport, thereby mitigating the risk of exposing the patient to external contaminants and infectious agents. Under negative pressure operation it contains and isolates an infected patient, thereby minimizing the risk of cross-infecting the external population during transport. The PIU provides filtered and directional airflow for patient life support and has features that enable medical intervention to the patient via end-user supplied medical equipment. Primary uses of the PIU are:

- 1.) Isolated transport of patients on aircraft, ambulances, ships, and any vehicle capable of safely transporting a patient on a standard litter
- 2.) Temporary isolation of patients within hospitals or other medical facilities.

CAPSULS™ is a Regulatory Class II single-use medical device. It has been cleared by the FDA for marketing in the U.S. (510(k) K052798). CAPSULS™ is covered under U. S. and European patents.

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CAPSULS™ Patient Isolation Unit (PIU) Features

- **Positive Pressure Patient Protection** – CAPSULS™ can be operated in positive pressure mode to protect an enclosed patient from outside contaminants. Isolator overpressure is developed by a powered air supply at its head end.
- **Negative Pressure Patient Containment** – CAPSULS™ can be operated in negative pressure mode to enclose and isolate a contaminated patient, preventing cross-contamination to the outside. A powered air exhaust at its foot end develops isolator under-pressure.
(Litter Required for Negative Pressure Operation)
- **Patient Airflow** – Airflow to the patient in positive pressure mode (or from the patient in negative mode) is provided by a battery-powered PAPR (powered air-purifying respirator) blower fitted with CBRN primary filters. The 4 cfm rated blower provides 17 to 21 air changes per hour within the isolator depending on patient volume. Regardless of operating mode, patient airflow is always supplied at the head end exhausted at the foot end. Blower run time on a replaceable, single-use BA5800/U lithium battery is approximately 7 to 10 hours.
- **Primary Filtering** – The primary filters for removal of contamination are CBRN (chemical, biological, nuclear, radiological) filter canisters similar to the military C2A1 and are mounted on the blower input ports. These canisters provide charcoal filtering of chemicals and chemical warfare agents (CWAs) and particulate filtering to HE/P-100 standards (99.97% @ 0.3µ).
- **Backflow Control** – Check valves and/or HE/P-100 secondary filters prevent backflow of air and potential cross-contamination at the air inlet ports that are not connected to the blower.
- **Particulate Barrier** – The PIU's Iso-Shell™ engineered plastic film shell material, pressure-seal zipper, and Iso-Weld™ seaming technology, together form a gas and liquid-tight envelope, providing a solid barrier to biological and radiological particulates. Barrier redundancy is achieved through the use of over or under pressurization of the envelope. The CAPSULS™ barrier system has undergone testing by U.S. military agencies responsible for chemical and biological defense.
- **Seaming Technology** – The PIU's proprietary Iso-Weld™ seaming technology fuses materials together to produce a redundant and 100% gas and liquid tight seam that is stronger than the materials alone.
- **Closure Technology** – CAPSULS™ zippers provide a gas and liquid-tight seal and undergo 100% pressure testing by their manufacturer. The zipper is attached to the CAPSULS™ Iso-Shell™ envelope barrier using the same proprietary Iso-Weld™ seaming technology.
- **Litter Transport** – CAPSULS™ has three snap-buckle cinch straps for mounting it on a standard litter. The litter provides a stable platform to lift and carry a patient without undue stress on the barrier envelope, and is required for negative pressure operation. This also allows CAPSULS™ to be transported within any medical evacuation vehicle (ambulance, aircraft, or ship) already capable of securing a litter, without vehicle modification or additional equipment.
(Litters sold separately)
- **Easy Setup** - A CAPSULS™ PIU can be unpacked from its shipping box or carry bag, unfolded, attached to a litter, setup, and loaded with a patient by two trained personnel in about fifteen (15) minutes. The required litter can be supplied by the end-user or purchased separately at additional cost.
- **Easy Load** – The CAPSULS™ “suitcase” style opening allows unrestricted access to its interior for ease of patient loading and connection of end-user supplied medical equipment.
- **Patient Tethers** – CAPSULS™ incorporates a versatile system for securing a patient including multiple individual leg straps, and a multi-point upper torso harness. The number and locations of the straps can be adjusted to accommodate a wide range of patient sizes and types of injury.
- **Medical Intervention** – CAPSULS™ is fitted with 8 glove arms (4 per side) to facilitate patient treatment, and is equipped with a number of medical access ports of various sizes for the pass-through of medical tubing and instrument leads.
- **Durability** – The CAPSULS™ proprietary Iso-Shell™ barrier materials offer a minimum improvement of ten-fold in their abrasion, puncture, and tear resistance over PVC-based materials of the same thickness. A reinforced base mat attached to the barrier envelope for added durability and protection, and provides attachment points for the carry straps and litter tethers.
- **Extended Temperature Range** - The CAPSULS™ proprietary Iso-Shell™ barrier materials and zipper offer an operating temperature range greatly exceeding that of PVC materials. They remain flexible and user-friendly from -40°F to 140°F. The blower battery has a specified operating range of from -26°F to +120°F.
- **Decontamination** - The CAPSULS™ proprietary Iso-Shell™ barrier materials, Iso-Weld™ seaming technology, gas and liquid-tight sealing zipper, coated carry straps, and glove-arm caps provide a smooth, non-absorbent surface that is free of pockets and crevices that might allow entrapment of CWAs, contaminants, and decontamination agents. This greatly improves the efficiency and efficacy of the decontamination process.
- **Fluid/Waste Control** – Primary control of patient waste is intended to be via end-user supplied adult diapers and/or urinary catheters, and press and seal waste bags. Secondary control of body fluids is accomplished with end-user supplied absorbent pads placed under the patient.
- **Carry Bag** - CAPSULS™ and all of its components are supplied packed in a carry bag for ease of transport.



Backflow with HEPA filters



Primary filters on blower



PIU in carry bag

Operational Specifications

Operational Specifications	
Envelope Size (flexible)	24"W x 78"L x 18"H (0.61m x 1.98m x 0.46m)
Weight (without litter)	~30 lbs. (14 kg)
Operating Volume	~17 ft ³ (460 l) without patient
Air Flow / Exchange	4 cfm (115 lpm) provides 17 to 21 air exchanges per hour
Primary Air Filtration	CBRN with HE/P-100 Particulate (99.97% @ 0.3µ)
Backflow Air Filtration	HE/P-100 Particulate (99.97% @ 0.3µ)
Differential Pressure	Negative: 0.12 to 0.70 in. water column, typical 0.4 in.wc (0.10 kPa) Positive: 0.10 to 0.75 in. water column, typical 0.4 in.wc (0.10 kPa)
Battery Run-time:	7 to 10 hours with a BA5800/U LiSO ₂ non-rechargeable battery 2 to 4 hours nominal with 4 alkaline "D" cell batteries 2 to 4 hours nominal with a rechargeable NiMH battery
Operating Temp. Isolator	-40°F to +140°F (-40°C to +60, C)
Patient Weight Capacity	400 lbs. (181 Kg)
Patient Height Capacity	6' 2" (1.9 m) nominal / 6' 8" (2m) max.
Unit in Carry Bag	24"L x 20"W x 18"H, (0.61m x 0.50m x 0.46m)
Boxed Size	26"L x 20"W x 20"H, (66cm x 50cm x 50cm)
Shelf Life / Storage	10 years in factory packaging
Shelf Life Storage -- Filter and Inlet-Hose Assembly	10 years from filter manufacturer's production date
CBR Containment	Test results available on request to qualified parties

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