

ISOVAC Products LLC

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CAPSULS[™] Patient Isolation Unit (PIU)

Model 2004CN-PUR8C – for single clinical use Model 2004TR-PUR8C – for non-clinical training use

The CAPSULS[™] (Containment and Protection System Utilizing Life Support) is a portable Patient Isolation Unit (PIU) which prevents particulate (biological and radiological) cross-contamination between the patient and the external environment, and with features that enable medical intervention to the patient via end-user supplied medical equipment. The CAPSULS[™] PIU is intended to be used for:

1) the transport and isolation of patients on aircraft, ambulances, ships, and any vehicle capable of safely transporting a patient on a standard litter.

2) the temporary isolation with or without transport of patients within hospitals or other medical facilities.

CAPSULS[™] is a Regulatory Class II 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.



The CAPSULS[™] Model 2004CN-PUR8C PIU mounted on a litter

Features:

- **Positive Pressure Patient Protection –** CAPSULSTM 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 Recommended 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** ISOVAC'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 ISOVAC'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.
 - 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 from ISOVAC at additional cost.



Backflow with HEPA filters



Primary Filters on Blower

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.



CAPSULS[™] PIU opened for loading with tethered surrogate patient

- **Easy View** The CAPSULS[™] clear barrier envelope enables visual monitoring of the entire patient and provides the patient with an unrestricted view of his/her surroundings.
- **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 tenfold 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 +122°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 enduser supplied adult diapers and/or urinary catheters, and press and seal waste bags. Secondary control of body fluids can be accomplished with end-user supplied absorbent pads placed under the patient.
- Ancillary Parts Ancillary parts and materials include with CAPSULS[™] are a user's manual, a blower user's manual, a waterproof patient ID card with wire tie and marker, a blower outlet hose and air flow indicator, and a set of HE/P-100 filters.



PIU in carry bag

• **Carry Bag** - CAPSULS[™] and all of its components are supplied packed in a carry bag for ease of transport.

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 LiSO2 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
CBR Containment	Test results available on request to qualified parties

Operational Specifications (subject to change)

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This Product Incorporates Technology Developed By Alion Science and Technology Corporation (www.alionscience.com)



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