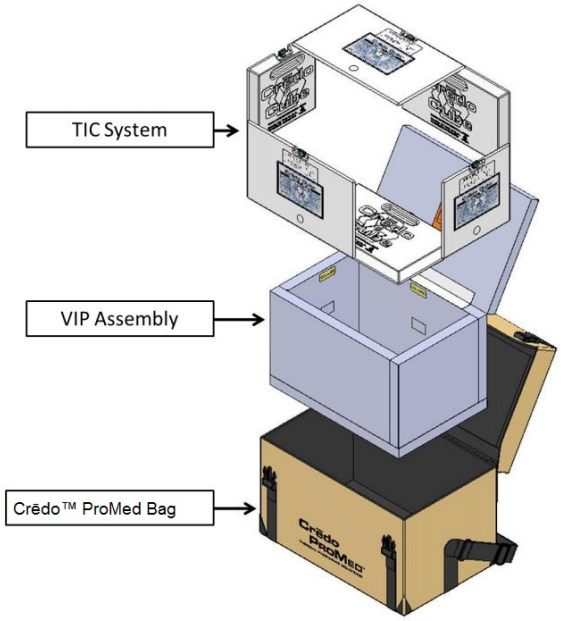
Crēdo™ ProMed Series 4 User Guide

Product Overview

Crēdo™ ProMed product line is specifically designed for the dynamic needs of pharmaceutical reps and first responders. The product line currently consists of three different sized temperature controlled portable medical transport bags that thermally protect the integrity of valuable pharmaceutical samples and medical supply payloads for 72-96 hours.

The outer bag is constructed of highly durable ballistic nylon fabric and the patented TIC™ coolants with Phase Change Material (PCM) and VIP components contained within, are qualified to consistently protect medical materials such as blood, platelets, and commercial bio-pharma product samples within two ranges (2-8˚C and 15-25˚C).

System Diagram



Crēdo™ Benefits

Easy quick assembly and single simple pack-out for all seasons.

Reusable patented technology that is recyclable reducing environmental impact.

Enhanced performance and proven payload protection eliminates temperature excursions.

Reduces overall distribution costs.

Longevity of components = lowest cost per use.

Reduce payload risk.
Reduce distribution costs.
Reduce environmental impact.

Ensuring Consistent Performance

Always condition the TIC System before use according to instructions provided in this User Guide (Section 1).

Ensure all components are clean and free of damage.

Avoid unnecessary opening of the container after loading the payload.

Ensure both TIC and VIP lids are secure before sealing the container for transport.

UG-043-EN-U Pelican Crēdo ProMed Series 4 User Guide – Rev A

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1 Preparing Your TIC™ Panels

1.1 Option 1: Freezer to Room Temperature (Small Volume Processing)

Place the TIC system in a -18˚C freezer, or below, for a minimum of 24 hours. Ensure that the TICs lay flat. Freeze times may vary depending on amount of units being frozen and equipment specifications. To ensure the TIC is fully frozen, shake the panels to verify no liquid can be heard.

The TIC system is ready to receive pack out staging-time. The pack out staging-time is the length of time immediately following the TIC removal from the freezer to the duration at room temperature wherein the PCM inside will rise to the appropriate operating temperature range.

The Staging Time Reference Chart below is a guideline for the amount of time the TIC system requires in order to warm to the operating temperature. An Infrared temperature thermometer can assist in ensuring the panels reach a safe pack out temperature but is not a requirement. Simply point laser at edge of the center stand-off (center depression) of the TIC panel for an accurate surface temperature reading. The TIC is ready to load when the IR gun reads between 3°C and 4.5°C.

Alternatively, Pelican BioThermal offers the TIC Smart Indicator for some of the Crēdo™ Series 4 TIC system with an embedded indicator mounted inside a sealed housing with a label overlay. When TIC panels have reached the accurate PCM core temperature a visible check mark will appear.

NOTE: Staging times are based on a freezer temperature of -18°C and a room temperature of 22°C. Panels are not stacked during the staging time. Ample air flow around all panel sides required. Staging times are intended to serve as a guideline and may need adjustment based on your individual operating environment.

Staging-Time Reference Chart	
TIC Panel Size	**Staging-Time Required**
5 x 5	35 Minutes
6 x 6	25 Minutes
6.5 x 6.5	30 Minutes
6.5 x 11	30 Minutes
8.5 x 8.5	45 Minutes
9 x 9	35 Minutes
10 x 10	35 Minutes
12 x 12	35 Minutes
12 x 15	40 Minutes
15 x 15	40 Minutes
15 x 18	40 Minutes
18 x 18	40 Minutes

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1.2 Option 2: Freezer to Refrigerator Processing (Rotational Conditioning)

This rotational TIC™ conditioning and pack out staging method utilizes controlled freezer and refrigerated temperatures to safely and efficiently condition the TIC panel system. This method is usually deployed for conditioning large volumes of TIC panels but can be used for small volumes as well. The primary benefit of rotational conditioning is the elimination of room temperature pack-out staging time.

Place the TIC system in a -18˚C freezer, or below, for a minimum of 24 hours. Ensure that the TICs lay flat. Freeze times may vary depending on amount of units being frozen and equipment specifications. To ensure the TIC is fully frozen, shake the panels to verify no liquid can be heard.

After the TICs have been properly conditioned (fully frozen solid), the TIC system is then rotated and placed inside a refrigerated (2° to 8° C) environment to allow the TIC system to reach a minimum usable temperature of 2° C. The TIC system can then be stored in the refrigerated environment until it is ready for use or until the PCM begins to melt. Once the PCM has begun melting the TIC system should not be used and be returned to the freezer for reconditioning. If a refrigerated temperature of 3° C (±1° C) can be maintained within the refrigerated environment, the PCM within the TIC system will never melt and the TIC system can be held indefinitely within the refrigerated environment until it is ready for use.

Timing for each step of the process will depend on the volume of TICs, the TIC size(s), the configuration and the equipment being used. Pelican BioThermal can assist in helping you determine the timing for your specific application by performing a conditioning study or providing guidance on how to conduct one. An IR gun, TIC smart temperature indicator, or conditioning study can help you ensure the TIC system has reached a safe minimum temperature of 2° C prior to use.

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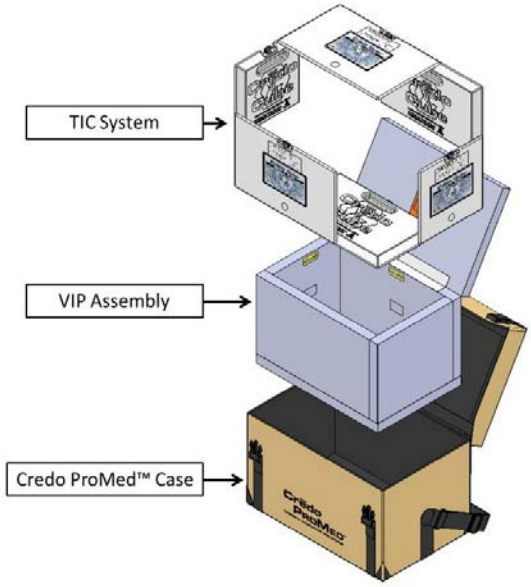
2 Packing Your Crēdo™ Thermal Packaging Solution

2.1 Standard Configuration

1. **Condition the TIC™ System**
   - After freezing, be certain to carefully perform one of the Pack Out options explained in Section 1.

2. **Assemble the TIC base**
   - Insert a TIC panel into the insulator base (inner insulator in nested configuration) with the Crēdo Cube logo embossment facing up.
   - Add the 4 TIC panels to form the side walls with the Crēdo Cube logo embossment facing in.



3. **Load payload**
   - Ensure the payload is conditioned at 5°C (+/- 3˚C) before loading into the five (5) TIC panel assembly. Do not over pack the Crēdo ProMed.
   - Add non-insulating filler to fill any excess payload space to prevent contents from shifting during transit.

4. **Insert TIC and close insulator lid**
   - Place the final TIC™ panel over the payload area with the Crēdo™ logo facing down, ensuring the panel lies flat and level without force onto the TIC side walls.
   - Close the VIP lid over the TIC system making sure it rests flat and level without forcing.

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5. **Close and secure outer container**
   - Close and secure the outer nylon bag and straps.

Note: In the unlikely event that the container may be exposed to extreme cold conditions (50% or more of the transit time), condition as follows: Place the TIC coolants in a refrigerator between 4° and 8°C for 4 to 12 hours. Verify that the PCM is liquid by shaking.

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3 Caring for your Crēdo™ Thermal Packaging Solution

3.1 How to Clean Your Crēdo Components

- **TIC™ coolants (6 panels):** Clean the TIC coolants by using warm water and soap or alcohol. Decontaminate/clean by using an isopropyl alcohol and water mixture (typically 70/30 mix alcohol to water) or other salt-based disinfectants.
- **Insulator lid and base:** Clean the insulator lid and base by using a damp towel with soap or a rag with isopropyl alcohol.
- **Outer nylon bag:** Clean the outer bag by using a damp towel with a non-abrasive soap or a rag with isopropyl alcohol.

DO NOT:

- Autoclave any of the components.
- Use any organic solvents such as acetone or methyl ethyl ketone (MEK) on any of the components.
- Expose any of the TIC components or insulator to extreme heat (+75° C or above.)
- Use any abrasive cleaners on any of the components.

Note: If your preferred cleaning method is not mentioned above, please contact your Sales Account Manager at Pelican BioThermal.

3.2 How to Perform a Thermal and/or Transit Qualification

Pelican BioThermal offers thermal and transit qualification services, to industry standards, via our thermal laboratory. We also offer a NIST traceable PC-based temperature data logger that fits inside the container and provides accurate, continuous time and temperature data in a spreadsheet format. We utilize and follow ISTA procedure 7D or 7E, which are ASTM D3103 compliant to guide you through your thermal testing process. We recommend ISTA procedure Series 1, 2, or 3, or ASTM D4169 to guide you through your transit testing. Many of our units are already transit tested to ISTA procedure 3A. The certification can be found on the bottom of the shipper.

3.3 How to Inspect and Replace Vacuum Insulation Panels

The Vacuum Insulation Panels (VIPs) in Crēdo containers are extremely effective as long as they hold an internal vacuum. Periodically inspect the VIP lid and base surfaces. Loss of rigidity indicates a compromised panel. A loose skin or non-rigid panel indicates vacuum loss and the product should be recycled (refer to Section 4). Avoid removing the VIP base from the outer bag. Replace the VIP lid and VIP base before the expiration date printed on each panel.

3.4 Refrigerated Hold

The Crēdo Series 4 thermal shipping containers can be put into a refrigerated hold immediately after loading or any time during transit to reduce, or stop altogether, the heat transfer into the shipper. If the ambient inside the refrigerated environment is between 2.0° C and 4.0° C there will be no positive heat flow into the container and therefore no performance degradation. This is because temperatures are below the phase point of the Series 4 PCM but above the minimum allowable temperature of 2.0° C. At temperatures above 4.0° C, a small thermal gradient exists and heat flow across the insulator into the container is established. This will result in a small thermal performance degradation since the PCM will be slowly melting.

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4 Pelican BioThermal End-of-Life Component Recycling Program

Pelican BioThermal is strongly committed to reducing the environmental impact of its product components throughout and beyond their functional life. When Crēdo™ container components do reach end of usefulness, Pelican BioThermal is pleased to offer the ability to send retired shippers back to our manufacturing facility in Plymouth, MN where they will be dismantled, sorted and their materials recycled.

Important:

Prior to sending Crēdo system components (VIPs, TICs, and outer containers) back to Pelican BioThermal for disposition, you are required to send a Certificate of Non-Contamination (see page 11) to your Pelican BioThermal Sales Account Manager declaring the product to be free of any substances/materials considered hazardous to human health (OSHA Standards). You will then be issued a Return Authorization to include with your shipment.

COMPONENT RECYCLING LOCATION:

Please send* all Crēdo components (VIPs, TICs, and outer containers) to:

PELICAN BIOTHERMAL
Attn: Shane Miller
3020 Niagara Lane N.
Plymouth, MN 55447

For Customer Assistance, please call 877.537.9800

COMPANY PROGRAM DISCLAIMER:

*Client is responsible for freight charges for shipment to Plymouth MN USA
A two week advance notice is required prior to product delivery date in Plymouth MN
The ownership of returned product is relinquished once received at Pelican BioThermal docks in Plymouth MN
No refunds or reimbursements

Take the next step… **REDUCE**, **RECYCLE** and **REUSE**.

Thank you!

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Certification of Non-Contamination

(Please copy and paste into your company letterhead)

CERTIFICATE OF NON-CONTAMINATION

As a company representative of (enter company name), I hereby certify the following Crēdo™ components, being returned to Pelican BioThermal for disposition, are to the best of my knowledge free of any bio-hazard substances/materials harmful to human health as subject to and currently established by OSHA guidelines.

Description and quantities of Crēdo components:

Authorized Company Representative:

Company Name: _____

Name: _____

Signature: _____

Title: _____

Date: _____

Please return completed form via email at shane.miller@pelican.com or fax to: 763.413.4801

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Crēdo™ ProMed Series 4 (Dimensions - Imperial)

Type	Liters	Exterior Dimensions - Inches	Interior Dimensions - Inches	Tare Weight - lbs
SERIES 4				
Series 4	2L	10 x 9 x 8	6 x 5 x 4	8
Series 4 472	4L	12 x 12 x 11	6 x 6 x 6	12
Series 4 872	8L	16 x 11 x 11	11 x 7 x 7	18

Crēdo™ ProMed Series 4 (Dimensions - Metric)

Type	Litres	Exterior Dimensions - mm	Interior Dimensions - mm	Tare Weight - kg
SERIES 4				
Series 4	2L	257 x 235 x 210	152 x 127 x 108	4
Series 4 472	4L	292 x 292 x 279	150 x 150 x 150	5
Series 4 872	8L	406 x 286 x 286	282 x 165 x 165	8

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