

Instructions for Use

Blood Armor Duo (SKU # BADV12)



Temperature-Controlled Shipper for Whole Blood / Red Blood Cell / Liquid Plasma Units

For use by trained military field medics, dismounted units, and emergency medical personnel

READ BEFORE USE

- This device is intended solely for the temperature-controlled transport of whole blood (WB), or red blood cell (RBC) or liquid plasma units. It is not a storage device and does not replace an approved blood bank refrigerator or freezer.
- Do not exceed the qualified duration for the ambient condition encountered. Payload temperature is not guaranteed beyond the qualified duration.
- Follow your organization's blood product handling, chain-of-custody, and transfusion protocols in addition to this IFU.
- Only use the coolant packs and pack-out configuration specified for this device. Substituting coolants or payload arrangement invalidates qualified performance.
- For qualified duration and performance data please refer to the Design Qualification (DQ) report.

1. Intended Use/Indications for Use

Blood Armor Duo is a passive, coolant-based cold chain shipper purpose-built for the last-mile leg of the military blood supply chain. It is designed and validated to allow dismounted soldiers, field medics, and emergency medical personnel to carry refrigerated whole blood or red blood cell or liquid plasma units for pre-hospital and en-route Role 1/Role 2 transfusion support, without relying on powered refrigeration.

The container supports two validated pack-out configurations: a Universal pack-out for standard global operating conditions (summer, winter, extreme summer, and controlled ambient), and a specialized Arctic pack-out for use when transporting blood products in extreme cold (arctic) environments.

2. Warnings and Precautions

- Use only trained personnel to pack, transport, and monitor this device.
- Inspect the shipper (insulation) and coolant packs for damage, punctures, or leaks before every use. Do not use a damaged shipper (insulation) or a leaking coolant pack.
- Do not place payload (blood units) in direct contact with a coolant pack surface colder than the coolant conditioning specified in Section 4; always follow the pack-out arrangement in Section 5.
- Do not open the shipper more often or for longer than operationally necessary. Repeated or prolonged opening reduces hold time and was not represented in qualification testing.
- Field conditions that fall outside the tested ambient profiles may result in different performance.
- Do not use dry ice, liquid nitrogen, or any coolant type other than the qualified gel coolant packs supplied with the system.
- Keep the shipper closed and zipped during transport to maintain thermal performance.

3. System Components

Each Blood Armor Duo system includes:

- 1 x insulated shipper (soft-sided, zippered container)
- 1 x Coolant 1 (gel pack)
- 1 x Coolant 2 (gel pack)
- Temperature indicator on coolant packs (color-change type)

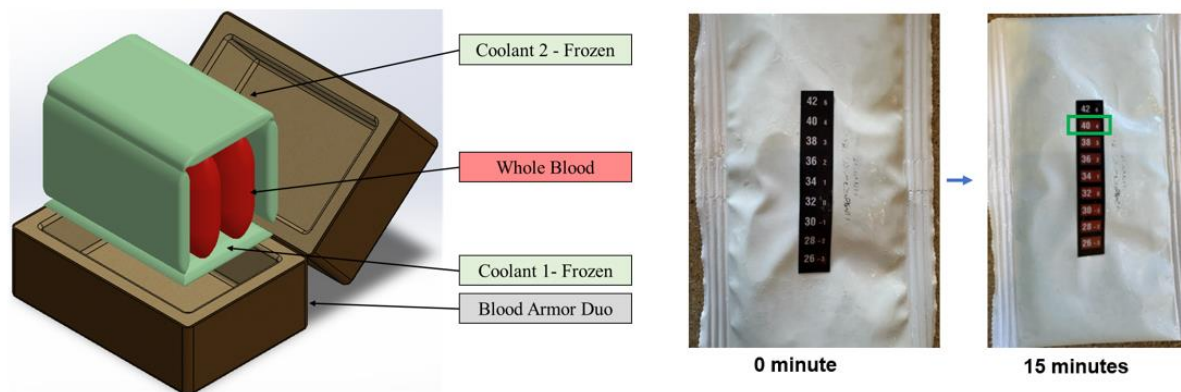
3.1 Shipper Specifications

Container (external) dimensions	8" x 5.5" x 5.75"
Internal dimensions	6.75" x 4.25" x 4"
Target payload temperature range	1-10°C
Typical temperature hold duration	Up to 24 hours, depending on ambient condition
Payload Capacity	Up to 2 x 500mL Whole Blood (WB) units or 3 x 300mL Red Blood Cell (RBC) units or 3 x 300mL Liquid Plasma units

4. Pack-out configurations

4.1 Universal pack-out illustration and packing steps:

4.1.1 Pack-out schematic



4.1.2 Coolant conditioning

- Store Coolant 1 and Coolant 2 inside a Freezer ($<-15^{\circ}\text{C}$) for a minimum of 24 hours.
- Remove both the coolants from the freezer and place them on a bench top (~**15 minutes**) till the indicator changes to **Red** at **40°F (4°C)** mark before packing the shipper.

4.1.3 Packing Steps

Step 1: Unzip the shipper and place the frozen coolant 1 at the bottom of the shipper.

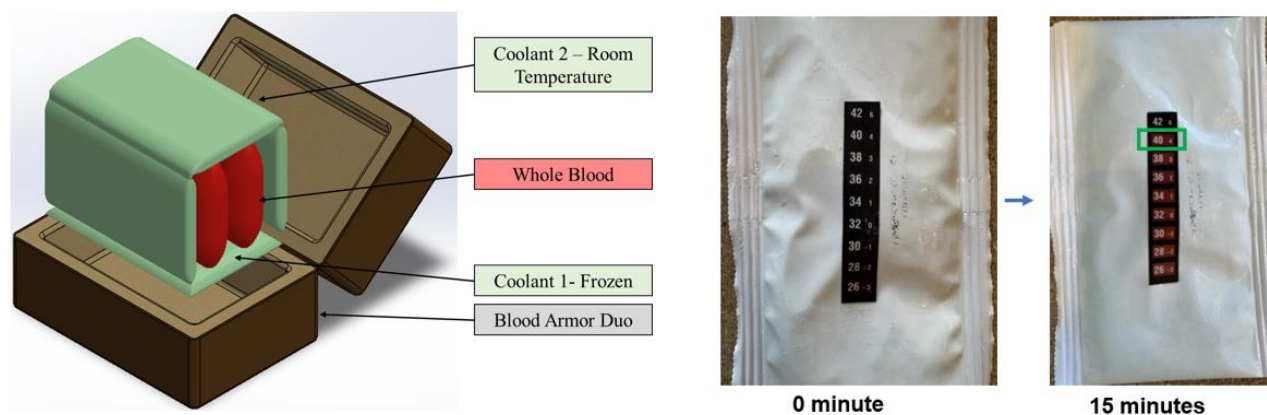
Step 2: Place up to two WB units or three RBC units on top of the frozen coolant 1.

Step 3: Place the frozen coolant 2 around the WB units as shown in the schematic

Step 4: Close the zipper, Blood Armor Duo is ready for transport.

4.2 Arctic pack-out illustration and packing steps:

4.2.1 Pack-out schematic



4.2.2 Coolant conditioning

- Store Coolant 1 inside a Freezer ($<-15^{\circ}\text{C}$) for a minimum of 24 hours.
- Store Coolant 2 under room temperature conditions ($18-26^{\circ}\text{C}$) for a minimum of 24 hours.
- Remove Coolant 1 from the freezer and place them on a bench top (**~15 minutes**) till the indicator changes to **Red** at **40°F (4°C)** mark before packing the shipper.

4.2.3 Packing Steps

Step 1: Unzip the shipper and place the frozen coolant 1 at the bottom of the shipper.

Step 2: Place up to two WB units or three RBC units on top of the frozen coolant 1.

Step 3: Place the room-temperature coolant 2 around the WB units as shown in the schematic

Step 4: Close the zipper, Blood Armor Duo is ready for transport.

5. After use / care of the shipper

- Remove all blood/coolant units promptly after transport is complete.
- Inspect the shipper and coolant packs for damage before returning them to storage or use in a future mission.
- Store the empty shipper in a clean, dry location away from sharp objects that could puncture the insulation or shell.
- Re-freeze coolant packs per Section 4 before the next use; do not reuse a coolant pack that is leaking or damaged.

6. Reference Document

This IFU is based on the Design Qualification report for Blood Armor Duo, V2.0, dated 7/20/2026.