**Shipping Blood Components using J82/E38 Shipping Containers**

# PRINCIPLE: Most blood components and products are ordered directly by hospitals from Canadian Blood Services. Hospitals have the option of transferring blood and blood products between facilities for optimal utilization or to ensure best patient care. In such cases, it is necessary to ensure that the blood products are properly packaged to maintain an acceptable temperature range during transportation, and the process ensures accurate tracking and disposition reporting.

Blood components or products being shipped for the purposes of redistribution, unless other agreements have been made:

* + - Red cells should have between 7 and 10 days of shelf life left prior to expiry
		- Platelets should have between 12 and 24 hours of shelf life left prior to expiry
		- Blood Products should have between 4-6 months of shelf-life prior to expiry

# PURPOSE:

# To provide a standardized process for shipping blood components and/or products to external sites using J82/E38 shipping containers, so that the acceptable temperature range is maintained during transportation and ensure accurate tracking and disposition reporting.10.1. This includes transfer for:

* Redistribution
* Provision of crossmatched units
* Provision of components during an MHP
* Transferring with a patient (see IM007)
1. **RELEVANT REQUIREMENTS:**
	1. Blood components and plasma protein and related products must be visually inspected for abnormal appearance immediately before packing for transportation. This inspection must be documented.10.1
	2. Blood components and products must be transported in a validated shipping container in a manner that will maintain the storage temperature requirements specified by the supplier.10.1 Compliance with these specifications is acknowledged by the signed Memorandum of Understandingon file with ORBCoN / FCRP.
	3. Discontinuation of agitation of platelets during transportation should not exceed 24hrs. 10.1
	4. Shipping containers for blood components and plasma protein and related products must be constructed to resist damage and must be designed to include a tamper evident seal and examined for damage prior to use.10.1
	5. Shipping containers shall have an outer label that meets provincial, territorial, or federal transport regulations and identifies: 10.1
		* The shipping and receiving facility
		* That the contents are human blood components or blood products
		* Any other cautions or descriptions
	6. All shipments of blood components and plasma protein and related products must include documentation that has the following information on shipping packing slip or issue voucher/form: 10.1
* Name of shipping facility and receiving facility
* Identification of components or plasma protein and related products shipped (unit/lot numbers)
* Description of component/product
* Total number of items shipped
* Date and time shipped
* Identity and signature of the person who packed the shipment
* A unique shipping document number to allow for traceability
* Indication if the blood component/product is not intended for transfusion (e.g. sending for research purposes)
	1. Shipment of blood components for the purpose of redistribution must include use of form IM.006F1 *Inter-hospital Redistribution Form* and appropriate Laboratory Information System (LIS) transfer voucher (if applicable)10.1
	2. All copies of shipping documentation must be retained according to facility policy.10.1
1. **RELATED POLICIES/PROCEDURES (*policies in OTTRM*)**
	1. [Glossary of Terms and Abbreviations](https://orbcon1.sharepoint.com/%3Af%3A/s/Goal2/ElO_9X0Yk_VApYJUICskoxkBfPzgcw2XHAixv8d8BA-fQA?e=I82fj9)
2. **MATERIALS:**
	* 1. **Specimen:** N/A
		2. **Equipment:** Approved and validated shipping container for redistribution of blood

components/products

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| **If shipping** | **Then use** | **And these materials** |
| **Refrigerated Blood Components (1-10C)****or** **Plasma Protein and Related Products (2-25C)** | **J82 Shipping Container** | * + 1x ice pack (8”w x8”h x1.5”d)
* 2x 4lb gel packs (10.5”w x 9.5”h)
* Plastic zip lock bags for gel and ice packs
* 2x Corrugated cardboard dividers (7.5”w x 7.5”h)
* Clear plastic over-wrap bag for product
* Clean crumpled paper
* Tamper proof device
* Purolator Healthcare Indicator label
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| **Room Temperature Blood Components (20-24C)** **or****Plasma Protein and Related Products (19-25C)** | **E38 Shipping Container**  | * 3x 4lb gel packs (10.5”w x 9.5”h)
* Plastic zip lock bags for gel packs
* Clear plastic over-wrap bag for product
* Clean crumpled paper
* Tamper proof device
* Purolator Healthcare Indicator label
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* + 1. **Reagents:** N/A
		2. **Supplies/Related Forms:**
* [Plasma Protein Product Acceptable Shipping/Storage Requirements by Product as Per Manufacturer](https://transfusionontario.org/wp-content/uploads/2020/06/Plasma-Protein-Products-Product-Information-Aug2018.pdf)
* [Packing Configuration of J82/E38 Shipping Containers](https://transfusionontario.org/wp-content/uploads/2020/06/Packing-Configuration-for-J82_E38-Shipping-Containers.pdf)
* [IM.006F1 Inter-hospital Redistribution Form](https://orbcon1.sharepoint.com/%3Aw%3A/s/Goal2/EdbbaT84IuJJgwlZD7mTbc8BHnEsRkUTm8A49BsavDQsMA?e=McMawN)
* Way bill (if required)
* [Annual Shipping Container Temperature Verification Report](https://transfusionontario.org/wp-content/uploads/2020/06/May-2021.pdf)
* [IM.006F2 Shipping Address Label](https://orbcon1.sharepoint.com/%3Aw%3A/s/Goal2/EWtIbfHfGBdNl0x7B5dC4nYBpbBa7yz_-pvmiPIcs5feFA?e=yIQZFc)
1. **QUALITY CONTROL/ASSURANCE**
	1. Periodic assessment of the shipping container shall be performed to confirm that temperatures remain consistent within the acceptable temperature range under the local conditions. Refer to ORBCoN’s Annual Shipping Container Temperature Verification Report. See Procedural Note 9.1.
	2. Shipping containers must be inspected before and after each use.
	3. The acceptable shipping temperatures for blood components are as follows: 10.1,10.2

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| **PRODUCT** | **TEMPERATURE** |
| Red Blood Cell Units | 1 - 10ºC (within 24 hours) |
| Platelets | 20 - 24ºC |
| Plasma Protein and Related Products | See [Plasma Protein Acceptable Shipping and Storage Requirements](https://transfusionontario.org/en/plasma-protein-product-acceptable-shipping-and-storage-requirements/) |

1. **PROCEDURE:**

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| **Steps** | **Work Instructions** |
| 7.1 Inform Receiving Site | **FOR BLOOD COMPONENTS** |
| 1. Inform receiving facility by phone and/or fax at least one day prior to redistribution to advise on the number of units being shipped and the approximate arrival time. Notify the receiving facility as soon as possible if the shipment is urgent e.g., short expiry date.

***Note:*** *If the maintenance of minimum inventory depends on the arrival of products from the blood supplier, avoid shipping “near to expire” products until the new shipment has been received*. |
| **FOR PLASMA PROTEIN PRODUCTS** |
| * + 1. When products have been identified by the site to be redistributed, then ORBCoN or FCRP will contact other facilities to see where the products can be used prior to expiry.

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| **If**  | **Then** |
| ORBCoN facilitates the redistribution | * ORBCoN will contact the facility that has the product to be redistributed to indicate where the product will be shipped to
* The facility has to indicate the best pick up date and time (excluding Fridays and weekends) to have the product picked up, and where in the facility the products will be picked up
* ORBCoN will make the arrangements with the courier for pickup and delivery.
* Shipping documentation will be sent electronically to the shipping facility along with packing instructions
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| FCRP facilitates the redistribution | * FCRP will contact the shipping facility and indicated where the product should be sent and dates it should be sent on.
* FCRP will provide courier account information along with packing instructions and shipping documentation electronically to shipping facility.
* The shipping facility will make the arrangements for pick through the designated courier provided by FCRP
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| 1. Pre-condition gel pack(s) and/or ice pack(s).
 | 1. Determine what materials need to be pre-condition
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|  | **J82 Container** | **E38 Container** |
| **Gel pack(s)** | Between 2ºC and 6ºC for at least 6 hrs. | Between 20ºC and 24ºC for at least 6 hrs. |
| **Ice pack(s)** | Between -25ºC and - 40ºC for at least 6 hrs. | N/A |
| ***Note:*** *if freezer temperature is warmer, this procedure must be validated to ensure acceptable shipping temperatures will be maintained using ice packs pre-conditioned at warmer temperatures. See Procedural Notes 9.1.* |
| 1. Complete Documentation
 | * + 1. Follow facility specific instructions for documenting the transfer of products in the lab information system (LIS) or manual system
		2. Complete Section A and B of Form [IM 006F](https://transfusionontario.org/en/category/toolkits/inventory-management/)
		3. Make a copy of the completed form.
		4. Retain the copy in laboratory for specified amount of time according to facility specific documents and records retention policy
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| 1. Prepare Shipping Container
 | 1. Determine which shipping container and configuration can be used to ship the components or plasma products.

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| ***If*** | ***Then*** |
| *Plasma Protein Products* | Select the shipping container acceptable for the shipping temperature range for the product. Refer to the Plasma Protein Product Acceptable Shipping/Storage Requirements by Product as Per Manufacturer  |
| *Components* | Select the shipping container acceptable for the shipping range of the component. Refer to section 5.4 |

Retrieve shipping container and all required supplies for selected shipping container. Refer to section 4.0 for materials, supplies and packing configuration requirements. See procedural note 9.2

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| ***If***  | ***Then*** |
| Shipping using the J82 container | Refer to the packing configuration for the maximum number of units that can be placed in the shipping container. Do not overfill. |
| Shipping using the E38 container | Refer to the packing configuration for the maximum number of units that can be placed in the shipping container. Do not overfill. |
| Label each shipping container with “Do Not Refrigerate – Keep at Room Temperature. |

1. Examine the shipping container and material to be used.

 **Do not use if** :* + - the Styrofoam liner is not clean
		- the Styrofoam liner shows cracks or breaks
		- the straps or buckles are not in good workable condition
		- the outer cardboard box shows breaks or tears
		- gel or ice packs have cracks or leaks
1. Discard defective containers/materials as appropriate.
2. Ensure all old address labels from the outside of the shipping container are removed or covered.
3. Do not over fill shipping container
4. Prepare the shipping container no more than **1 hour before** scheduled pickup time to ensure that temperature remains within the acceptable range for the duration of the shipment.
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| 1. Packing Component or Plasma Protein and Related Product for Shipping
 | 1. Pack any products for shipping **within 1 hour** of courier pick up to ensure that acceptable temperatures are maintained within the allowable shipping time.
2. Obtain components or products to be shipped
3. Perform a visual inspection of the products
4. Compare the information on each component or product to the information written on the shipping documents
5. Place in plastic bag
6. Follow the packing configuration chosen in step 7.4.1 to place products in container
7. Fill any dead air space with loosely crumpled paper to reduce the likelihood of movement, while still allowing air to circulate within the container.
8. Place Styrofoam lid to close.
9. Close the outer cardboard container and fasten the strap securely.

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| ***If***  | ***Then*** |
| Shipping via Purolator | * Check the shipping label created for Purolator for correct shipper information and receiver information.
	+ If shipping information is incorrect notify the person who arranged the shipment with Purolator to rectify.
* Place the original shipping documents first inside the plastic pouch.
* Then add the Purolator shipping label on top, so that it is visible for Purolator to scan.
* Ensure the Purolator Health Indicator label is affixed to the outside of the shipping container.
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| All other courier | * Complete IM006F2.
* Place the original shipping documents first inside the plastic pouch.
* Then, place the completed IM006F2 form inside the plastic pouch so that the receiving address is visible to the courier.
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| 1. Apply Security Device/ Seal
 | 1. \****IMPORTANT***\*Apply the security device/seal around the buckle of the strap so that the box cannot be opened unless the seal is removed.
2. Ensure there is no tail that can be caught in a sorting machine. Cut any extra material that may get caught in a sorting machine.
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| 1. Prepare for pick up
 | 1. Place shipping container with completed documents in designated courier pick-up area where courier can retrieve easily.
2. Reconfirm that the security seal/device is visible and intact.
3. Notify the courier that shipment is ready for pick up, if required.
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| **RECEIVING COMPONENTS/PRODUCT FROM OTHER FACILITY** |
| 1. Receiving Components/ Plasma Protein or RelatedProducts
 | 1. Upon receipt, the receiving facility reviews the [IM 006F1](https://transfusionontario.org/en/im-006f1-inter-hospital-redistribution-form-2/) form, confirm that the blood components or products were delivered to the correct facility.
2. Complete section C of IM 006F1 to document the shipment conformed with acceptable shipping criteria.

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| If | then |
| Shipment is found acceptable  | Proceed to step 7.8.3 |
| Shipment is found unacceptable  | Follow facility specific process to resolve. See procedural note 9.3 |

1. Follow all facility specific procedure for receiving components/products into inventory.
2. Receiving facility will confirm receipt with shipping facility by either faxing the completed IM 006F1 form back to the shipping facility or sending confirmation email to designated contact.
3. File completed IM006F1 in its designated location and retained for specified amount of time according to facility specific documents and records retention policy.
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1. **PROCEDURE NOTES:**
	1. If sites precondition the ice packs at warmer temperatures than stated in step 7.2, then those sites will need to perform their own validation to show that the containers can maintain acceptable temperatures for an established duration of time and provide the results to those sites that may receive the containers with products inside. [Refer to Redistribution Toolkit section 5](http://transfusionontario.org/en/download/provincial-redistribution-program-for-transfusion-services-in-ontario/)
	2. Where applicable, confirm with the courier that the shipping container can be transported inside the cab of the vehicle to ensure the container will not be exposed to extreme temperature.
	3. If there is evidence that the shipping box’s internal temperature did not maintain the required temperature range consult with your TS Medical Director before accepting units into inventory or discarding. Follow established facility procedure for accepting products into inventory.
2. REFERENCES:
	1. CSTM/SCTM Standards for Hospital Transfusion Services v5. CSTM Markham, 2021, 5.7.1 Transportation, 5.1.1.3, 5.1.1.4.
	2. CSA Z902-20 Canadian Standard for Blood and Blood Components; March 2020, 9.5
3. REVISION HISTORY

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| Revision Date | Summary of Revision |
| Aug 2014 | * Revised name of manual
* Changed title of document to include shipment of blood components
* Revised sections 1.0, 4.0 & 5.0
* Revised and renumbered sections 2.0, 6.0 & 8.0
* Added *Reporting* as section 7.0
* Updated list of references to include most recent editions
* Revised list of appendices
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| Nov 2017 | * Revised title of document.
* Revised sections 1.0, 4.0,6.0, 9.0, 11.0 to ensure compliant with updated Standards
* Added procedural note 8.5
* Revised list of references to reflect current standards.
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| Feb 2018 | * Added step 6.8.6 completing the shipping label
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| Mar 2021 | * Updated references
* Updated IM006F to include contact email
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| Oct 2022 | * Addition of Policy
* Rewording of all sections
* Updated references
* Removal of appendices
* Addition of links
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