Purpose

This Work Instruction (WI) describes the process to:

- Provide information on the shipper packing configuration used by Lifeblood to transport blood products and actions you should take on receipt of a shipper from Lifeblood.
- Provide instructions to non-Lifeblood institutions that use Lifeblood shippers for their own purpose either internally or externally.

Disclaimer

This document shows the packing configurations used by Lifeblood staff when packing Lifeblood shippers for transporting blood products to customers (Approved Health Providers). While Lifeblood considers that these procedures are appropriate for its own purposes, Lifeblood does not acknowledge, or have control of the particular circumstances of Approved Health Providers

Your attention is drawn to the following;

- *Customers must consider the transport requirements of Blood Products, the transport mechanism and environmental aspects in determining the appropriate packing configurations.*
- *Customers should note that Lifeblood strongly recommends the use of temperature recording data loggers for transportation over long distances and/or where extended transit times may be experienced, as the shippers are only validated for the transport of blood products over distances or timeframes according to Lifeblood specifications contained herein.*

Lifeblood cannot accept responsibility for the viability of blood products transported in a Lifeblood shipper that was not packed by Lifeblood staff.

Parent procedure

This WI forms part of the procedure described in *Issuing and Packing components and Products* (SOP-00326).

Before you begin

N/A

1. Receipt of shippers

The Lifeblood National Shipper Configurations ensure that blood and blood products remain within the required temperature specification during transportation. There are several packing options, the use of which will depend on:

- The component type
- The ambient temperature
- The number of components
- The anticipated transit time

Please ensure all shipments received from Lifeblood meet the criteria stated below.

If…	**then…**
the shipper or bag appears to have been tampered	• quarantine the units • contact your nearest Lifeblood Customer Service Department as soon as possible.

If…	then…
the shipper configuration does not meet the packing criteria	• take a manual surface temperature of the contents by placing a thermometer between two units and leave for 2-5 minutes to allow the temperature to stabilise • quarantine the units • contact your nearest Lifeblood Customer Service Department as soon as possible.

2. Preparation of shippers

Always check that the shippers are clean, inside and out, before use. Where there are any visible signs of damage or contamination with blood residue, the packing material is to be discarded. Deface and/or remove all old labels on the outer carton prior to discard.

2.1 Material required for shipper use

- Single insulated shipper (with foam inserts)
- Room temperature ballast packs (conditioned at +20°C to +24°C for 24hrs prior to use)
- Chilled ballast packs (conditioned at +2°C to +6°C for 24hrs prior to use)
- Frozen ballast packs (conditioned at approximately -19°C for 48hrs prior to use)
- Plastic liner bag
- Foil pouch
- Cardboard dividers with holes
- Data Loggers (data loggers for customer's own use to be supplied by customer)

NOTE: Please refer to Appendix A for supplier details

2.2 Storage of ballast material

Table 1. Pre-conditioning and storage times for ballast packs.

Store ballast packs under the relevant conditions for the minimum time as described below.			
Ballast type	**Pre-conditioned temperature**	**Minimum time**	**Configurations**
Room temperature	+20°C to +24°C	24hrs	P1, P2
Chilled	Approximately +4°C	24hrs	R1, R2, R3, R4
Frozen-19°C	Approximately -19°C **(domestic freezer)**	48hrs	R1, R4
Frozen -40°C	Approximately -40°C	24hrs	F1
NOTE: Where the use of a data logger is necessary, the data logger should be conditioned for the temperature range required in accordance with manufacturer's instructions. **Failure to condition ballast packs appropriately may adversely affect internal shipper temperature.**			

2.3 Ambient temperature range

All configurations herein were validated using an external ambient temperature range of +4°C to +42°C.

3. Red cells

Red cell components should be transported using one of **Packing Configurations R1, R2, R3 or R4,** the choice of which will depend on the anticipated transport time. If the transport time is estimated to approach or exceed the validated time, shown below, or if product is transported by independent courier (e.g. bus or aircraft), a data logger must be included.

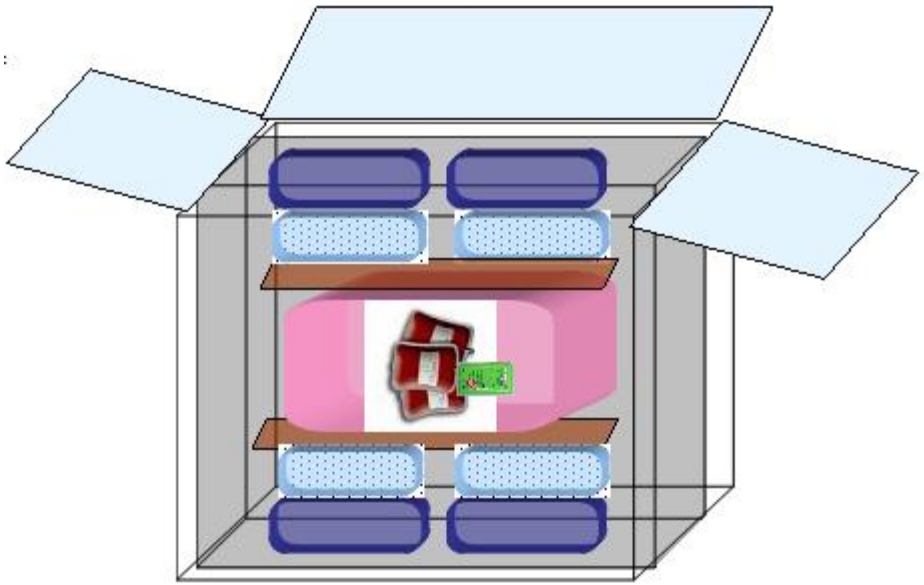
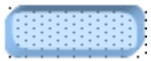
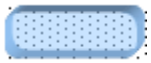
Configurations R1, R2, R3 and R4 are designed to maintain the components within a temperature range of 2ºC to 10ºC as recommended in the Council of Europe "Guide to the Preparation, Use and Quality Assurance of Blood Components", 14th edition.

Table 2 - Packing configurations and the validated transport time.

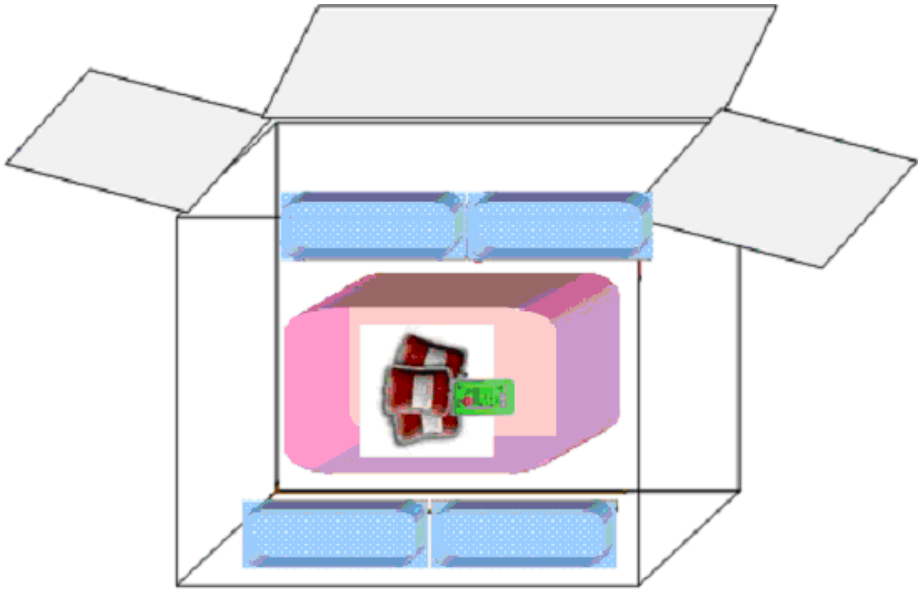
Packing Configuration	No. of components per shipper	Validated Transport time (VTT)
R1	1 to 10 red cells	6 hours** **Do not use for air transit**
R2	1 to 12 red cells	3 hours 25 mins*
R3	1 to 14 red cells	8 hours 25 mins*
R4	1 to 10 red cells	16 hours 18 mins*
* If anticipated transport time exceeds the maximum VTT, a data logger must be placed in the shipper between the components **The R1 shipper configuration cannot be used for anticipated transport times exceeding it's VTT of 6 hours, even with a data logger in use		

All configurations require a specific number of units to maintain temperature. Where fewer red cell units are to be packed, the specified number of chilled ballast packs (approximately +4 ºC) must be added. The correct number of ballast packs for each configuration is shown in the packing diagrams below.

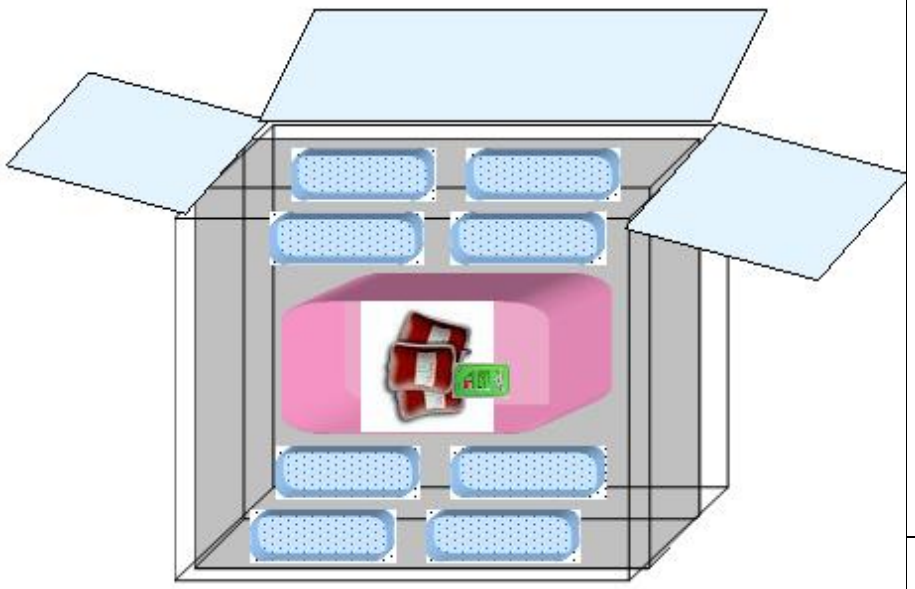
The ballast packs should be placed outside the plastic liner to prevent contamination of the red cells, should the ballast packs leak.

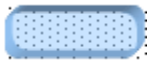
<table>
<tr><td rowspan="2">R1</td><td>No. Components per shipper</td><td>Validated Transport Time#</td><td>Legend</td><td>Name</td><td>Quantity</td><td>Note</td></tr>
<tr><td>1 to 10 red cell units</td><td>6hr</td><td></td><td>Foil pouch</td><td>1</td><td>Used to line box and contains all other items</td></tr>
<tr><td colspan="3" rowspan="9"></td><td></td><td>Frozen -19^{O}C</td><td>2</td><td></td></tr>
<tr><td></td><td>Chilled ballast</td><td>2</td><td></td></tr>
<tr><td></td><td>Cardboard divider</td><td>1</td><td>Used to stop contact with ballast</td></tr>
<tr><td></td><td>Extra chilled ballast (as per table)

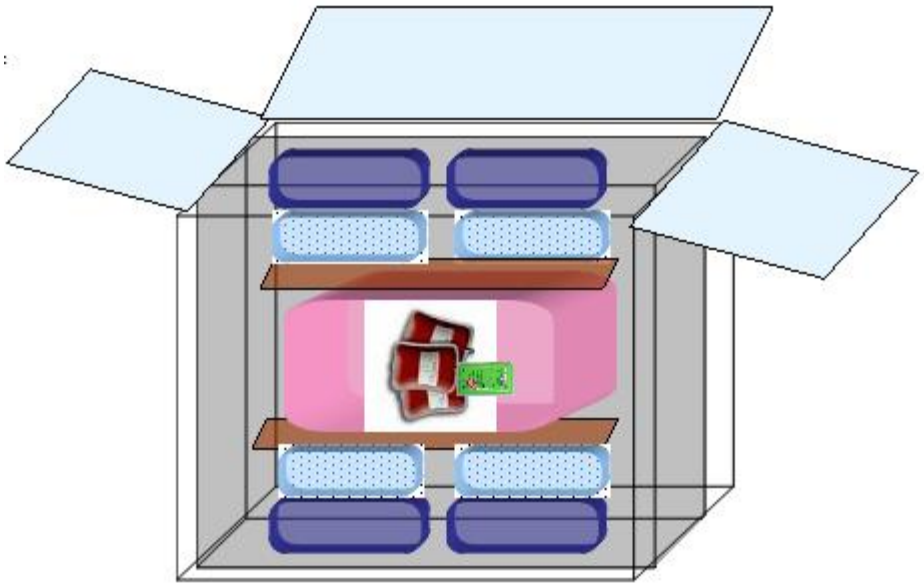
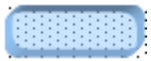
Place ballast outside the plastic liner bag</td><td colspan="2"><table><tr><th>Number of red cell units</th><th>Number of additional ballast packs</th></tr><tr><td>4 to 10</td><td>0</td></tr><tr><td>3</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>1</td><td>3</td></tr><tr><td>1 to 3 paediatric units</td><td>4</td></tr></table></td></tr>
<tr><td></td><td>Plastic liner bag</td><td>1</td><td>Used to contain red cells and logger if added</td></tr>
<tr><td></td><td>Cardboard divider</td><td>1</td><td>Used to stop contact with ballast</td></tr>
<tr><td></td><td>Chilled ballast</td><td>2</td><td></td></tr>
<tr><td>Notes:</td><td># Cannot be transported by air
Cannot be used for anticipated transport times exceeding its VTT, even with a data logger in use</td><td></td><td>Frozen -19^{O}C</td><td>2</td><td>Place on bottom</td></tr>
</table>

<table>
<tr><td rowspan="2">R2</td><td>No. of Components per Shippe</td><td>Validated Transport Time#</td><td>Legend</td><td>Name</td><td>Quantity</td><td>Note</td></tr>
<tr><td>1 to 12 red cell units</td><td>3hr 25min</td><td></td><td>Chilled ballast</td><td>2</td><td></td></tr>
<tr><td colspan="3" rowspan="3"></td><td></td><td>Extra chilled ballast (as per table)

Place ballast outside the plastic liner bag</td><td colspan="2"><table><tr><th>Number of red cell units</th><th>Number of additional ballast packs</th></tr><tr><td>1 to 12</td><td>0</td></tr><tr><td>1 to 3 paediatric units</td><td>4</td></tr></table></td></tr>
<tr><td></td><td>Plastic liner bag</td><td>1</td><td>Used to contain red cells and logger if added</td></tr>
<tr><td>Notes:</td><td># If anticipated transport time exceeds the maximum transport time data logger must be placed in with the shipment.</td><td></td><td>Chilled ballast</td><td>2</td><td></td></tr>
</table>

<table>
<tr><td rowspan="2">R3</td><td>No. of Components per Shipper</td><td>Validated Transport Time#</td><td>Legend</td><td>Name</td><td>Quantity</td><td>Note</td></tr>
<tr><td>1 to 14 red cell units</td><td>8hr 25min</td><td></td><td>Foil pouch</td><td>1</td><td>Used to line box and contains all other items</td></tr>
<tr><td colspan="3" rowspan="5"></td><td></td><td>Chilled ballast</td><td>4</td><td></td></tr>
<tr><td rowspan="2"></td><td rowspan="2">Extra chilled ballast (as per table)

Place ballast outside the plastic liner bag</td><td colspan="2" rowspan="2"><table>
<tr><th>Number of red cell units</th><th>Number of additional ballast packs</th></tr>
<tr><td>12 to 14</td><td>0</td></tr>
<tr><td>11</td><td>1</td></tr>
<tr><td>9 or 10</td><td>2</td></tr>
<tr><td>7 or 8</td><td>3</td></tr>
<tr><td>5 or 6</td><td>4</td></tr>
<tr><td>3 or 4</td><td>5</td></tr>
<tr><td>2</td><td>6</td></tr>
<tr><td>1</td><td>7</td></tr>
<tr><td>1 to 3 paediatric units</td><td>7</td></tr>
</table></td></tr>
<tr><td></td><td>Plastic liner bag</td><td>1</td><td>Used to contain red cells and logger if added</td></tr>
<tr><td></td><td>Chilled ballast</td><td>4</td><td></td></tr>
<tr><td>Notes:</td><td colspan="5"># If anticipated transport time exceeds the maximum transport time a data logger must be placed in with the shipment.</td></tr>
</table>

<table>
<tr><td rowspan="2">R4</td><td>No. of Components per Shipper</td><td>Validated Transport Time#</td><td>Legend</td><td>Name</td><td>Quantity</td><td>Note</td></tr>
<tr><td>Up to 10 red cell units</td><td>16hr 18min</td><td></td><td>Foil pouch</td><td>1</td><td>Used to line box and contains all other items</td></tr>
<tr><td colspan="3" rowspan="9"></td><td></td><td>Frozen -19^{O}C</td><td>2</td><td></td></tr>
<tr><td></td><td>Chilled ballast</td><td>2</td><td></td></tr>
<tr><td></td><td>Cardboard divider</td><td>1</td><td>Used to stop contact with ballast</td></tr>
<tr><td></td><td>Extra chilled ballast (as per table)

Place ballast outside the plastic liner bag</td><td colspan="2"><table><tr><th>Number of Red Cell Units</th><th>Number of Ballast Packs</th></tr><tr><td>10</td><td>0</td></tr><tr><td>9</td><td>1</td></tr><tr><td>7 or 8</td><td>2</td></tr><tr><td>5 or 6</td><td>3</td></tr><tr><td>3 or 4</td><td>4</td></tr><tr><td>2</td><td>5</td></tr><tr><td>1</td><td>6</td></tr><tr><td>1 – 3 paediatric units</td><td>6</td></tr></table></td></tr>
<tr><td></td><td>Plastic liner bag</td><td>1</td><td>Used to contain red cells and logger if added</td></tr>
<tr><td></td><td>Cardboard divider</td><td>1</td><td>Used to stop contact with ballast</td></tr>
<tr><td></td><td>Chilled ballast</td><td>2</td><td></td></tr>
<tr><td></td><td>Frozen -19^{O}C</td><td>2</td><td></td></tr>
<tr><td>Notes:</td><td colspan="6"># If anticipated transport time exceeds the maximum transport time a data logger must be placed in with the shipment.</td></tr>
</table>

4. Platelets

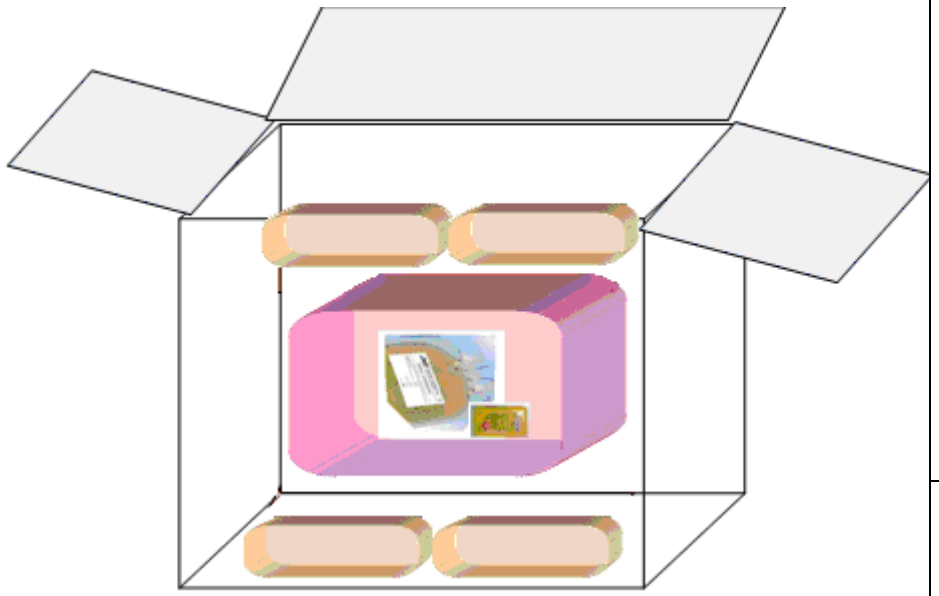
Platelet components should be transported using either **Packing Configuration P1 or P2**, the choice of which will depend on the anticipated transport time. If the transport time is estimated to approach or exceed the validated time, shown below, or if product is transported by independent couriers e.g. bus or aircraft, a data logger must be included.

Configuration P1 and P2 are designed to maintain the components within a temperature range of 20ºC to 24 ºC as recommended in the Council of Europe "Guide to the Preparation, Use and Quality Assurance of Blood Components" 14th edition.

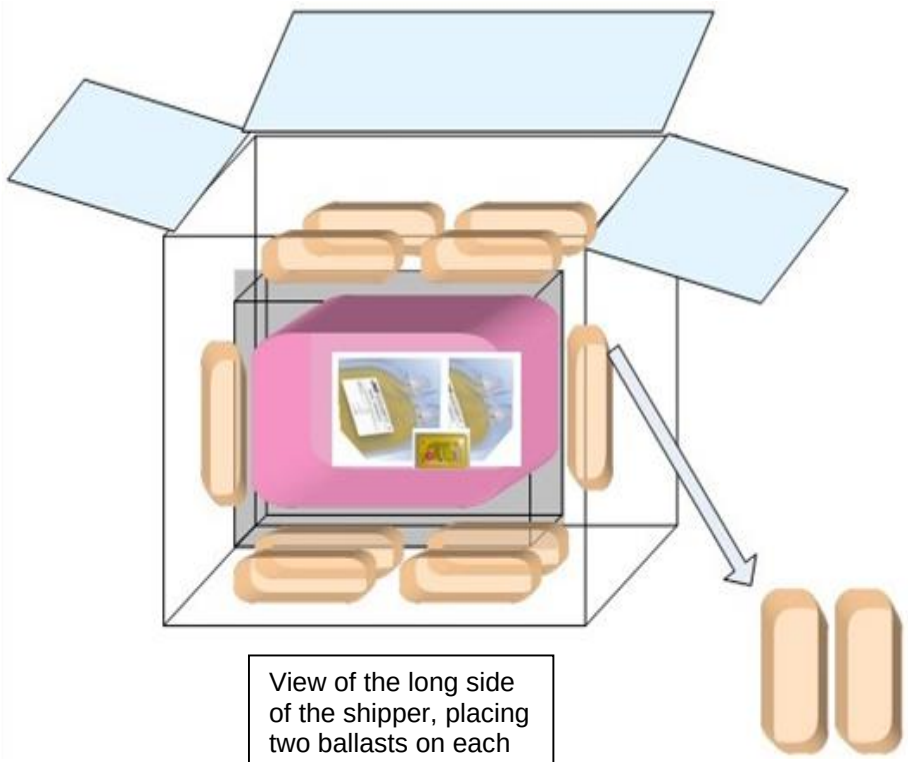
Table 3 - Packing configurations and the validated transport time.

Packing configuration	No. of components per shipper	Validated transport time#
P1	1 to 7 pooled platelets 1-8 apheresis platelets 1 to 16 paediatric platelets	4hr 43min
P2	1 to 6 pooled platelets 1-8 apheresis platelets 1 to 16 paediatric platelets	7hr 38min
# If anticipated transport time exceeds the maximum transport time a data logger must be placed in the shipper between the components.		

Both configurations require a specific number of units to maintain temperature. Where fewer platelet units are to be packed, the specified number of **room temperature (+20 ºC to +24 ºC) ballast packs** must be added. The correct number of ballast packs for each configuration is shown in the packing diagrams below. The ballast packs should be placed outside the plastic liner to prevent contamination of the platelet units, should the ballast packs leak.

<table>
<tr><td rowspan="2">P1</td><td>No. of Components per Shipper</td><td>Validated Transport Time#</td><td>Legend</td><td>Name</td><td>Quantity</td><td>Note</td></tr>
<tr><td>1 to 7 pooled platelets
1 to 8 apheresis platelets
1 to 16 paediatric platelets</td><td>4 hr 43min</td><td></td><td>Room temperature ballasts 20-24^{O}C</td><td>2</td><td></td></tr>
<tr><td colspan="3" rowspan="2"></td><td></td><td rowspan="2">Extra room temperature ballast (as per table)

Place ballast outside the plastic liner bag</td><td colspan="2" rowspan="2"><table><tr><th colspan="2">Number of platelet units</th><th>Number of additional ballast packs</th></tr><tr><td>4 - 8 (apheresis)
4 - 7 (pooled)</td><td>Mixed total of 7</td><td>0</td></tr><tr><td colspan="2">3</td><td>1</td></tr><tr><td colspan="2">2</td><td>2</td></tr><tr><td colspan="2">1</td><td>3</td></tr><tr><td colspan="2">1 to 16 paediatric</td><td>4</td></tr></table></td></tr>
<tr><td></td></tr>
<tr><td></td><td>Plastic liner bag</td><td>1</td><td colspan="2">Used to contain platelets and logger if added</td></tr>
<tr><td>Notes:</td><td colspan="2"># If anticipated transport time exceeds the maximum transport time a data logger must be placed in with the shipment.</td><td></td><td>Room temperature ballasts 20-24^{O}C</td><td>2</td><td></td></tr>
</table>

<table>
<tr><th rowspan="2">P2</th><th>No. of Components per Shipper</th><th>Validated Transport Time#</th><th>Legend</th><th>Name</th><th>Quantity</th><th>Note</th></tr>
<tr><td>1 to 6 pooled platelets
1 to 8 apheresis platelets
1 to 16 paediatric platelets</td><td>7hr 38min</td><td></td><td>Room temperature ballast 20-24^{O}C</td><td>4</td><td></td></tr>
<tr><td colspan="3" rowspan="5">
View of the long side of the shipper, placing two ballasts on each side.</td><td></td><td>Foil pouch</td><td>1</td><td>Used to line shipper. Contains platelets, data logger and additional ballast packs (if required)</td></tr>
<tr><td></td><td>Room temperature ballast 20-24^{O}C</td><td>6</td><td>Place 2 along each of the long sides and 1 at each short side of the box</td></tr>
<tr><td></td><td>Extra room temperature ballast (as per the table)

Place ballast outside the plastic liner bag but inside the foil pouch</td><td colspan="2"><table><tr><th colspan="2">Number of platelet units</th><th>Number of additional ballast packs</th></tr><tr><td>2 - 8 (apheresis)
2 - 6 (pooled)</td><td>Mixed total of 7</td><td>0</td></tr><tr><td colspan="2">1</td><td>1</td></tr><tr><td colspan="2">1 to 16 paediatric</td><td>2</td></tr></table></td></tr>
<tr><td></td><td>Plastic liner bag</td><td>1</td><td>Used to contain platelets and logger if added</td></tr>
<tr><td></td><td>Room temperature ballast 20-24^{O}C</td><td>4</td><td></td></tr>
<tr><td colspan="7">Notes: # If anticipated transport time exceeds the maximum transport time a data logger must be placed in with the shipment.
Configuration P2 requires 14 room temperature ballasts: 4 placed on the bottom, 2 on each of the longer sides, 1 on each of the shorter sides and another 4 ballast placed on the top.</td></tr>
</table>

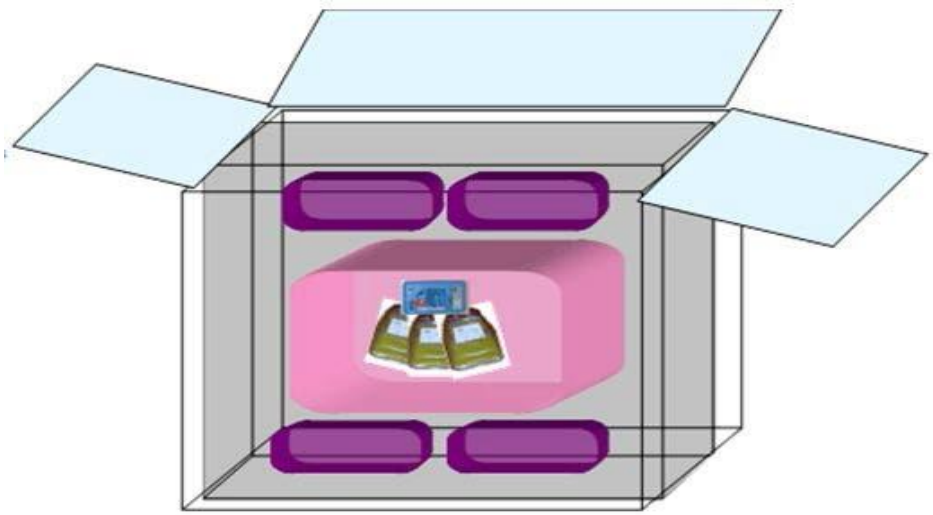
5. Frozen components (plasma and cryoprecipitate)

The F2 Shipper configuration is used by Lifeblood for routine transport of frozen components. There are specific steps that must be taken when transporting shippers containing dry ice by road. Please refer to Appendix B for further information.

The F1 shipper configuration is available to use in the event that no dry ice is available, however it is not recommended for routine transport. If the use of this configuration is required, a data logger must be included in the shipment.

Configuration F1 and F2 are designed to maintain components at -25 ºC as recommended in the Council of Europe “Guide to the Preparation, Use and Quality Assurance of Blood Components” 14th edition.

F1	Number of components per polystyrene lined shipper	Validated Transport Time
	1 to 5 WB cFFP or APH cFFP	**45min**
	5 – 25 cryoprecipitate (no packaging)	***Refer to note below**



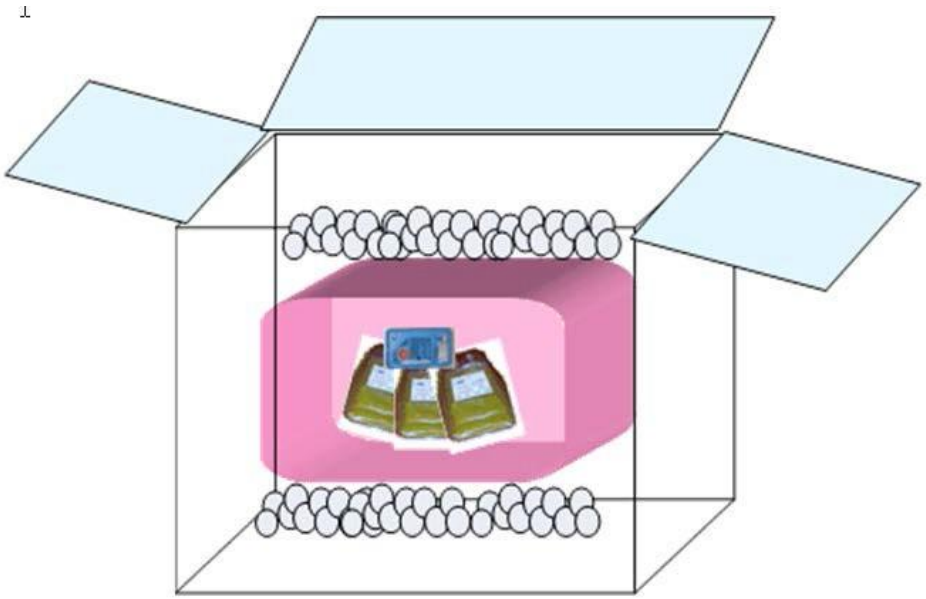
Notes:	*Use of configuration F1 is not recommended for the routine transport of cryoprecipitate. If use of this configuration is required a data logger must be included in all shipments.

Legend	Name	Quantity	Note
	**Foil pouch**	**1**	**Used to line box and contains all other items**
	**Frozen - 40^{O}C ballast**	**2**	**Place inside foil pouch – face down**

No. of Components per Shipper	Min	Max
FFP whole blood / apheresis	1	5
Cryoprecipitate	5	25

	**Plastic liner bag**	**1**	**Used to contain frozen components and logger if added**
	**Frozen - 40^{O}C ballast**	**2**	**Place inside foil pouch**

F2	No. of Components per Shipper	Validated Transport Time#
	See table insert on right	



Notes:	# If anticipated transport time exceeds the maximum transport time a data logger must be placed in with the shipment.

Legend	Name	Quantity	Note
	**Dry Ice**	**1.8 Kg**	**On top plastic liner pouch**
	**Plastic liner bag**	**1**	**Used to contain frozen components and logger if added**
	**Dry Ice**	**1.8 Kg**	**At bottom of shipper**

Number of Components	Min	Max	Validated Transport Time#
Cryoprecipitate WB (1-4 per cardboard box)	1	4	17hr:50min
Cryoprecipitate WB (5 per cardboard box)	5	25	18hr:30min
Cryodepleted APH 750ml (no packaging)	1	3	19hr
Cryoprecipitate APH (1 per cardboard box)	1	6	17hr:50min
WB cFFP or APH cFFP (1 per cardboard box & vacuum sealed)	1	6	20hr:40min

Mixing Components:

Any combination of components up to six boxes total can be mixed. The component in a mixed shipper with the shortest validated transport time (VTT) dictates the VTT that should be used for that shipper.

Appendix A: Details of suppliers of shipper consumables

Item	Company	Phone
Pink plastic bags (shipper liners)	Valpak	(02) 9984 0777
Shipper carton (outer cardboard box)	OJI Fibre Solutions	(02) 9724 8408
Shipper divider	OJI Fibre Solutions	(02) 9724 8408
Foil bags	Qualtape Australia	(03) 9729 8401
Polystyrene (Foam) inserts	R Max Rigid Cellular Plastics	(02) 9609 6088
Ballast pack with bubble wrap on one side	Sancell Pty Ltd	(03) 8796 5555
Temprecord data logger	Temprecord (NZ)	+64 9 274 9825
TempTale data logger	Sensitech	(03) 9686 5622

Appendix B: Transport of blood products using dry ice

The use of couriers must be taken into consideration as the use of dry ice in transporting items by vehicle can be hazardous to the driver, who may be unaware of the potential risk of exposure to CO_2 gas. Drivers need to be aware of the hazards and what to do in an emergency.

Below are two references which may be helpful for formulating policies and procedures.

- www.iata.org
- Technical Manual American Association of Blood Banks (AABB), 14th edition, pg 659

Definitions

Term/abbreviation	Definition
Ballast pack	A gel pack that is preconditioned to maintain temperature for the transportation of blood products. Extra ballast packs (in excess of the base number of ballast required for a configuration) are added to provide temperature stability during transportation.
Blood products	The result of a procedure in which blood is withdrawn from a donor, separated into individual components e.g. platelets and/or retained as individual products for transfusion/fractionation.

Referenced external documents

N/A

Referenced internal documents

Document number	Document title
SOP-00326	Issuing and Packing Components and Products

Change history

Version number	Effective date	Reference	Summary of change
-	-	-	For previous change history contact National Document Control.
5	24/05/2021	CCR-20-000805	TempTale data logger supplier details added
6	12/07/2021	-	Minor grammatical changes to align with corresponding PPM configurations
		CCR-20-000781	Update validated transport times for R1, R2, R3, P1, P2 Update unit and ballast numbers for R1, R3. Remove R4 configuration.
7	16/07/2021	CCR-21-000600	Reinstate R4 configuration Updated R1 shipper to have VTT of 6 hours and not to be used for air travel
8	20/07/2021	CCR-21-000600	R4 – add ‘1’ to number of red cell units.
9	Refer to footer	CCR-21-000380	Validation transport time table updated to remove option of packing WB cryoprecipitate, include the validated transport time when 1-4 units are sent and provide instruction for mixing components.
		N/A	R4 - Rh red cell removed as this was added to v4 in error. P2 - clarified note for foil pouch and corrected spelling error

Electronic signature

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