Operational Validation of J82 Shipping Containers for the Purpose of Redistribution of Blood Components/Products between Ontario Hospitals

November 2017

Table of Contents

1.0 Executive Summary 2
2.0 Background, Purpose, Recent Developments 3
3.0. Design and Methodology: 4
3.1. Validation Objectives: 4
3.2. Method 4
3.3. Acceptance Criteria: 5
3.4. Equipment Used in the Validation Process: 5
3.5. Packing Configuration Tested: 6
3.6. J82 Container Components used for Validation Testing: 7
3.7. Validation Procedure: 7
4.0. Validation Results: 9
4.1. Deficiencies Reported 12
5.0. Discussion 12
6.0. Recommendation: 13

1.0 Executive Summary

In the fall of 2015, Canadian Blood Services (CBS) announced to its national and provincial customers (hospitals) and stakeholders including the Ontario Regional Blood Coordinating Network (ORBCoN) and the Factor Concentrate Redistribution Program (FCRP) that they were acquiring new insulated shipping containers (ISC's) for distribution of blood components and products to hospitals in Canada (excluding Quebec). The new ISC's have a pre-conditioning protocol which will not allow hospitals to use them. This change will have an impact on hospitals that presently use CBS boxes for shipping components/products to other facilities as part of their inventory management strategies, for redistribution or when transferring blood with patients to another facility. Hospitals were offered to continue to use the J82 and E38 shipping containers to facilitate redistribution and transfer of blood with a patient; however they would not provide ongoing verification that the containers are meeting the requirements set out by provincial and national standards for transporting blood. ORBCoN agreed to validate the shipping containers for the purposes of redistribution and transferring with a patient in order to maintain the established provincial redistribution programs. These programs have been successful in reducing waste of blood components and products to help ensure patients' needs are met.

The J82 shipping container was challenged at four temperature points to simulate temperature variations similar to the four seasons that the container could be exposed to during transit. Initial packing configurations that were provided by CBS were used to challenge the containers. However; the two laboratories performing the testing could not meet the preconditioning temperature of -8°C to -14°C[1] for the ice packs required to meet the validated results from CBS for this validation. A survey was conducted asking all Transfusion Services in Ontario what their current available freezer temperature range was. The majority responded indicating that they have access to a -25°C to -40°C freezer to precondition the required ice packs. The packing configuration was revised. The shipping container was then tested in triplicate at each temperature point with a minimum and maximum payload for a total of 48 runs. Results were reviewed and the acceptable times in transit were established based on the results of each of the runs. Results below in table 1 illustrate the shortest times that the container maintained the acceptable shipping temperature of the products at the four different temperature points.

Table 1 Shortest Time J82 Shipping Container Maintained Acceptable Temperature

Product/Acceptable Shipping Temperature	Target Extreme Winter Temperature (<-30°C)	Target Moderate Fall/Spring Temperature (1°C - 6°C)	Target Moderate Summer temperature (19°C to 25°C)	Target Extreme Summer temperature (> +30°C)
1-8 RBCs (1-10°C)	3 hours	24 hours	12 hours	8 hours
1- 8 vials of PPP (2-25°C)	2 hours	24 hours	24 hours	24 hours

[1] Canadian Blood Services, Directive D30220, Revision2, Ottawa, ON;2011

2.0. Acknowledgments

Special thanks to the members of the two hospitals that performed the validation on behalf of ORBCoN and FCRP. ORBCoN and FCRP personnel appreciate the time taken by all staff that took part in this validation process.

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3.0. Background, Purpose, Recent Developments

3.1. Background:

CBS has implemented new shipping containers to support a national distribution system. The current J82 and E38 containers will be available for hospitals to continue to use for redistribution and shipping blood with a patient. There have been some issues noted by CBS with the J82 and E38 containers concerning temperature excursions (especially during the fall and spring months when temperature may vary significantly throughout the day), but both containers perform well in a more controlled temperature shipping environment and will be validated to ensure they are suitable for shipping blood between hospitals .

3.2. Purpose:

In order to confirm that these shipping containers would be suitable for hospitals to use, ORBCoN had to validate the manufacturer's claim that the shipping container labelled J82 will maintain the temperature of Blood Components (RBCs) within the temperature range of 1°C to 10°C and Blood Products (PPPs) within the temperature range of 2°C to 25°C for a twenty-four (24) hour period using a standardized packing configuration (combination of ice and gel packs). The shipping container validation was completed with the assistance of the staff at hospital transfusion Services laboratories using equipment provided by their laboratory department. Temperatures were monitored and documented to determine the suitability of the shipping containers for the transfer of blood components and products within the Ontario hospital system.

3.3. Recent Developments:

The packing configuration used by CBS had ice packs that had been pre-conditioned at -8°C to -14°C. The majority of hospitals do not have access to freezers in this temperature range. Both testing facilities that performed the validation of the containers identified they had freezers that would allow preconditioning of the ice packs between -25°C and -40°C during the validation process. It was acknowledged that an environmental scan was needed to see if other hospitals had the capability to precondition the ice packs in the same temperature. A provincial survey was sent out to the 158 hospital laboratories in Ontario with a transfusion service laboratory in July 2017 asking if they have access to a freezer with a temperature range anywhere between -25°C and -40°C to precondition ice packs for the purpose of redistribution and/or transferring blood with a patient. Eighty-eight hospitals (56%) responded and the results are listed in table 2. The validation was completed using the preconditioning of ice packs at -25°C to -40°C.

Table 2: Results from Freezer Survey July 2017

Results from freezer survey July 2017	# of Hospitals	Temperature ranges for hospitals that don't have access to -25 to -40°C freezers	# of hospitals that have room in freezer for ice packs
Hospitals that have access to freezers that provide temperatures between -25 and -40°C	80	N/A	66
Hospitals that don't have access to freezers that provide temperatures between -25 and -40°C	8	-18 to -22°C (one hospital has -8 to -20°C)	7

4.0. Design and Methodology:

4.1. Validation Objectives:

To evaluate the thermal performance of the J82 shipping container at the following ambient temperatures for a period of 24 hours:

1. -30°C to -35°C
2. 1°C to 6°C
3. 19°C to 25°C
4. 30°C to 40°C

4.2. Method

Two hospital laboratories agreed to work with ORBCoN to challenge the two types of shipping containers that will continue to be supplied to hospitals through CBS. Four different temperature points were selected to simulate temperature variations similar to the four seasons that the containers could be exposed to during transit. To simulate extreme winter temperatures the first lab used a freezer with a temperature range of -30°C to -35°C and to simulate Fall/Spring temperatures they used a refrigerator with a temperature range of 1°C to 6°C. To simulate temperatures that would be similar to moderate summer temperatures the second lab incubated the containers at room temperature (19°C to 25°C), and to simulate extreme summer temperatures they used an incubator with a temperature range of 30°C to 40°C. Each container was tested in triplicate at each temperature point both with minimum and maximum payloads. Each test was assigned an expected payload, the acceptable temperature range and the target time in the testing environment. Table 3 shows the test protocol for payloads, temperature and duration of testing.

Table 3: Test Protocol

TEST#	PAYLOAD	TESTING TEMP	DURATION OF TEST	Acceptable Product Temperature Range
Test #1	Minimum 1 unit RBC	30-40°C	24 hours	1-10°C
Test #2	Maximum 8 units RBC	30-40°C	24 hours	1-10°C
Test #3	Minimum 1 vial PPP	30-40°C	24 hours	2-25°C

Test #4	**Maximum # vials PPP**	**30-40°C**	**24 hours**	**2-25°C**
Test #5	**Minimum 1 unit RBC**	**19-25°C**	**24 hours**	**1-10°C**
Test #6	**Maximum 8 units RBC**	**19-25°C**	**24 hours**	**1-10°C**
Test #7	**Minimum 1 vial PPP**	**19-25°C**	**24 hours**	**2-25°C**
Test# 8	**Maximum # vials PPP**	**19-25°C**	**24 hours**	**2-25°C**
Test #9	**Minimum 1 unit RBC**	**-30-35°C**	**24 hours**	**1-10°C**
Test #10	**Maximum 8 units RBC**	**-30-35°C**	**24hours**	**1-10°C**
Test#11	**Minimum 1 vial PPP**	**-30-35°C**	**24 hours**	**2-25°C**
Test #12	**Maximum # vials PPP**	**-30-35°C**	**24 hours**	**2-25°C**
Test #13	**Minimum 1 unit RBC**	**1-6°C**	**24 hours**	**1-10°C**
Test #14	**Maximum 8 units RBC**	**1-6°C**	**24 hours**	**1-10°C**
Test #15	**Minimum 1 vial PPP**	**1-6°C**	**24 hours**	**2-25°C**
Test# 16	**Maximum # vials PPP**	**1-6°C**	**24 hours**	**2-25°C**

4.3. Acceptance Criteria:

1. J82 shipping containers are considered acceptable for use if the temperature within the shipping container is maintained between 1°C and 10°C for RBC and between 2°C and 25°C for PPP based on a determined amount of time required to support redistribution of products within Ontario using the maximum and the minimum payload for each product tested.
2. The determined amount of time will be 24 hours or the minimum duration that the container maintains acceptable temperature.
3. Three runs in each test sequence must meet the acceptance criteria without any major deficiencies.
4. Major deficiencies will result in repeat testing of the particular test or run or may result in repeating all tests and runs upon review of the deficiency and implementation of any corrective action.

4.4. Equipment Used in the Validation Process:

Each testing location used their own equipment to challenge the containers. Testing began in March 2017 and was completed in September 2017. Each testing site was provided Log-ic data logging tags and corresponding software to collect the temperature during each challenge. The temperature was logged every 15 minutes for each run on the data logger and then the data was downloaded to the Log-ic software where a Log-ic Tag report was generated. Please see tables 4 and 5 for a list of equipment used by each testing location.

Test Location #1 (Tests 1 – 8): Trillium Health Partners – Credit Valley Hospital
2200 Eglinton Avenue West, Mississauga, ON L5M 2N1

Test Location #2 (Tests 9 – 16): Halton Healthcare – Oakville Trafalgar Memorial Hospital
3001 Hospital Gate, Oakville, ON L6M 0L8

Table 4: Test Location #1 Equipment List

Equipment	Name Model	Serial Number	Calibration Date
Freezer	HEMAPRO-JEWETT BPL425	N31R119122	Jan 2017

Incubator	SANYO MCO-17A1	50704107	Feb 2017
Fridge	JEWETT BBR55	G1324-198	Feb 2017
Data logger A *(outside container)*	LOG-IC USB255	3000373701	June 2016
Data logger B *(inside bottom of container)*	LOG-IC USB255	3000365884	June 2016
Data logger C *(inside top of container)*	LOG-IC USB255	300365952	June 2016
Platelet Incubator	HELMER PC900i	971936	Jan 2017
Platelet Agitator	HELMER PF48i	971855	Jan 2017

Table 5: Test Location #2 Equipment List

Equipment	Name and Model	Serial Number	Calibration Date
Freezer	Helmer IPF125-8	993689	Sept 2016
Refrigerator	Helmer IB245	968528	Sept 2016
Data Logger A (outside shipping container - Ambient)	AeroScout Wireless Temperature Monitoring Software	Freezer: 000CCC751DE9 Refrigerator: 000CCC751BC4	Sept 2016
Data Logger B (bottom inside shipping container)	Logic USB 255 Use Logger	Set A: 3000373720 Set B: 3000216028 Set C: 3000365876	June 2016
Data Logger C (top inside shipping container)	Logic USB 255 Use Logger	Set A: 3000365833 Set B: 3000373712 Set C: 3000365952	June 2016
Thermometer	Traceable Infrared Thermometer Gun 12777-846	160631891	July 2016

4.5. Packing Configuration Tested

Initial attempts to challenge the containers using the established CBS packing configurations[2] (need to add reference here) did not reproduce the acceptable criteria of maintaining temperatures between 1°C and 6°C for a 24 hour period. Upon investigation, it was identified that the testing locations were preconditioning the ice packs at -25°C to -40°C for greater than six hours. CBS procedures state that ice packs are to be preconditioned in a freezer temperature range of -8°C to -14°C[2] for at least eight hours to replicate the acceptable temperature range as per their validation protocol. Adjustments to the packing configuration were made using ice packs preconditioned at -25°C to -40°C to try and yield

[2] Canadian Blood Services, Directive D30220, Revision2, Ottawa, ON;2011

acceptable results. Figure 1 and 2 show the adjusted packing configuration used for challenging the J82 containers for both RBC and PPP.

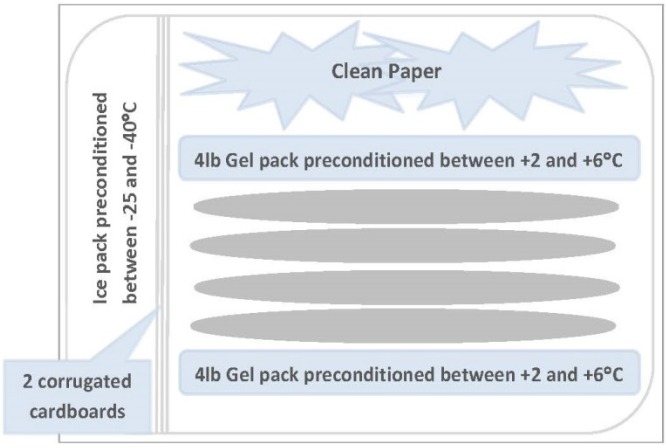


Figure1: Packing configuration for 1-8 RBC units

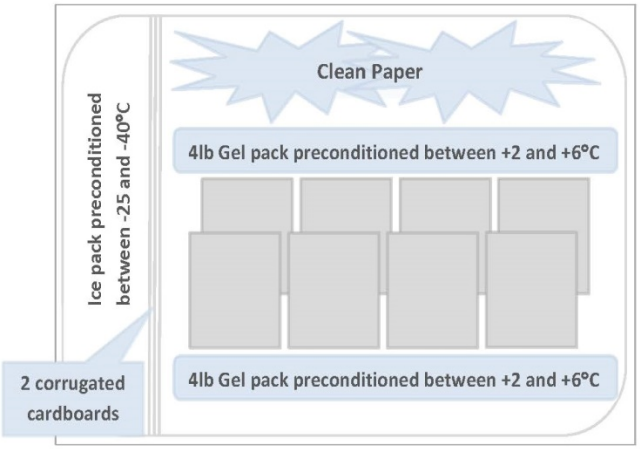


Figure2: Packing configuration for 1- 8 PPP vials

4.6. J82 Container Packing Materials used for Validation Testing

Outside corrugated sleeve
Strap with buckle
Ice pack (x1) preconditioned between -25°C and -40°C
4lb gel pack stabilized between 2°C to 6°C (x2)
7 ¾" x 7 ¾" x 1/8" cardboard (x2)
Clean packing paper
Plastic zip lock bags for gel and ice packs
Clear plastic over-wrap bag for components or plasma protein products
Tamper proof device
Data loggers (x3)

Figure 3 J82 container outer side

Figure 4 J82 container with payload

4.7. Validation Procedure

STEP	ACTION
1.0 Pre-condition the Ice Packs/Gel Packs	1.1. Determine Product to be shipped

If preconditioning for:	*Then:*
RBC /PPP	• 1 ice pack preconditioned between -25°C and -40°C for at least 6 hours prior to use • 2 Gel packs preconditioned between 1°C and 6°C for at least 6 hours prior to use • Ensure the ice/gel packs are enclosed in a

	sealed zip lock bag

2.0. Pack Out Preparations

2.1. Select J82 shipping container

If	*then*
Preparing for Shipping RBCs /PPP Vials	• Apply 1 data logger to outside of shipping container • Place 1 ice pack *(in a zip lock bag)* at one side of the shipping container • Place 2 insulated cardboards beside the ice pack to separate from the payload • Place 1 4lb gel pack *(in a zip lock bag)* on bottom of container • Place data logger on top of the gel pack and press the 'start' button to initiate data monitoring

3.0. Load Payload

3.1. Ensure payload is preconditioned before loading into the assembled shipping container. Do not over pack

If payload is	*then*
RBCs	Precondition between 1°C and 6°C for at least 6 hours before placing in shipping container
PPPs	Precondition between 2°C and 25°C for at least 6 hours before placing in shipping container

3.2. Place the payload (required number of RBC or PPP depending on the Test Protocol number in step 6.1) into a clear plastic over-wrap bag and place into the J82 shipping container on top of the gel pack.

3.3. Place a second data logger on top of the payload and press the start button to initiate data monitoring.

4.0. Close and Secure Container

4.1. Place one 4lb gel pack *(in zip lock bag)* that has been preconditioned between 1°C and 6°C on top of the second data logger.

4.2. Minimize empty air space in the container by adding clean packing material such as crumpled paper on top of the second gel pack to minimize empty air space (if applicable) and prevent shifting of the payload during testing.

4.3. Place the Styrofoam lid on top of inner Styrofoam shipping container.

4.4. Close and secure the outer corrugated plastic container with the strap.

4.5. Loop a tamper proof device through the strap buckle to ensure the container is not opened during testing.

4.6. Press the 'start' button on the data logger attached to the outside of container to begin monitoring the outside ambient temperature.

6.0. Label Container

6.1. Affix a label on outside of container to indicate Test#, Run# and payload for the applicable temperature/time.

6.0. Perform Test

6.1. Place container in the desired temperature environment for the indicated time. Refer to the table below:

TEST#	PAYLOAD	TESTING TEMP	Time Target	Acceptable Product Temperature Range
Test #1	Minimum 1 unit RBC	30-40°C	24 hours	1-10°C
Test #2	Maximum 8 units RBC	30-40°C	24 hours	1-10°C
Test#3	Minimum 1 vial PPP	30-40°C	24 hours	2-25°C
Test #4	Maximum # vials PPP	30-40°C	24 hours	2-25°C
Test #5	Minimum 1 unit RBC	19-25°C	24 hours	1-10°C
Test #6	Maximum 8 units RBC	19-25°C	24 hours	1-10°C
Test #7	Minimum 1 vial PPP	19-25°C	24 hours	2-25°C
Test# 8	Maximum # vials PPP	19-25°C	24 hours	2-25°C
Test #9	Minimum 1 unit RBC	-30-35°C	24 hours	1-10°C
Test #10	Maximum 8 units RBC	-30-35°C	24 hours	1-10°C
Test#11	Minimum 1 vial PPP	-30-35°C	24 hours	2-25°C
Test #12	Maximum # vials PPP	-30-35°C	24 hours	2-25°C
Test #13	Minimum 1 unit RBC	1-6°C	24 hours	1-10°C
Test #14	Maximum 8 units RBC	1-6°C	24 hours	1-10°C
Test #15	Minimum 1 vial PPP	1-6°C	24 hours	2-25°C
Test# 16	Maximum # vials PPP	1-6°C	24 hours	2-25°C

6.2. Run each test a minimum of three times.

6.3. At completion of each test run, stop the data loggers, return the packing materials and component/product to temperature conditioning environment.

7.0. Download Temperature Data

7.1. Download data from data loggers and print/save reports.

8.0. Complete Documentation

8.1. Complete all worksheets and deficiency reports.

8.2. Attach all documentation to the protocol. Title each attachment with the corresponding test number and run number.
e.g. Test#1: Test at 30-40°C Run#1 attachment #1

5.0. Validation Results:

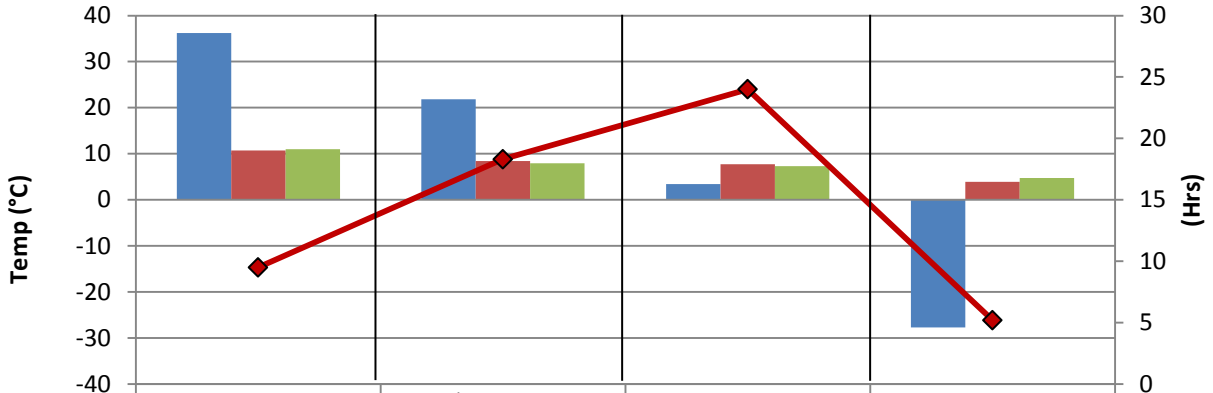
The validation process was completed for all temperature challenges in a controlled environment in the laboratory setting. The project team evaluated each of the test runs and were able to troubleshoot any deficiencies identified during the testing. Each test run that demonstrated deficiencies was repeated. Data was downloaded for all three runs for each test and then a minimum and maximum temperature was established for each data logger as well as the average temperature outside of the container as well as inside the container. The time intervals were recorded and reviewed to see how long each container held the acceptable temperature range inside the container. The shortest acceptable performance times are shown in Table 6 and Table 7.

Table 6: J82 maintaining payload 1-8 RBC units between 1°C and 10°C

	Data Logger	Min Temp (°C)	Max Temp (°C)	Average Temp (°C)	Shortest Acceptable Time (hrs)
Extreme Summer Temp 30 to 40°C	A (Ambient)	32.8	38.7	36.2	8.0
	B (Bottom)	4.8	18.2	10.7	
	C (Top)	4.7	18.5	11.0	
Moderate Summer Temp 19 to25°C	A (Ambient)	19.8	22.7	21.8	12.0
	B (Bottom)	4.8	14.0	8.4	
	C (Top)	4.1	14.0	7.9	
Fall/Spring Temp 1 to 6°C	A (Ambient)	2.6	4.1	3.4	24.0
	B (Bottom)	2.3	20.3	7.7	
	C (Top)	2.7	16.7	7.3	
Extreme Winter Temp -30 to -35°C	A (Ambient)	-30.0	-24.9	-27.7	3.0
	B (Bottom)	-4.2	16.1	3.9	
	C (Top)	-4.8	14.8	4.7	

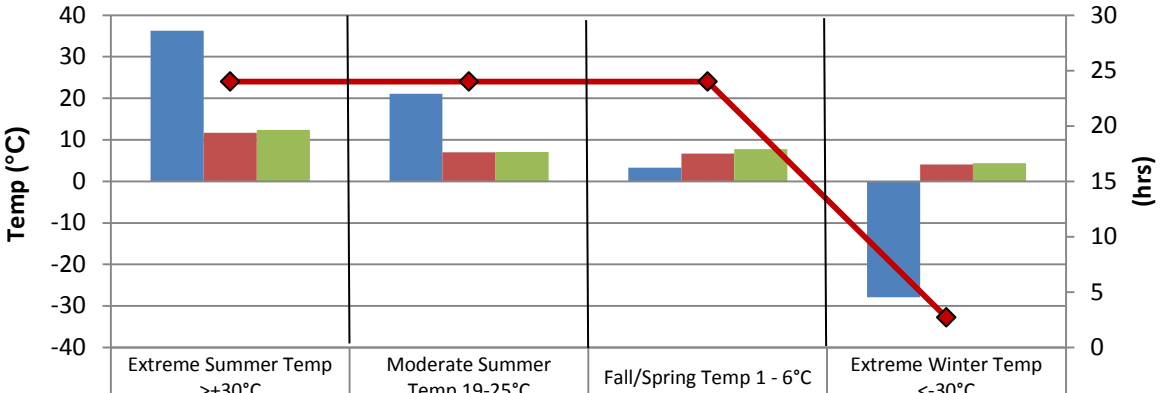
Table 7: J82 maintaining payload of 1-8 PPP vials between 2°C and 25°C

	Data Logger	Min Temp (°C)	Max Temp (°C)	Average Temp (°C)	Shortest Acceptable Time (hrs)
Extreme Summer Temp 30 to 40°C	A (Ambient)	32.1	38.7	36.3	24.0
	B (Bottom)	4.7	19.8	11.7	
	C (Top)	4.6	21.2	12.4	
Moderate Summer Temp 19 to 25°C	A (Ambient)	20.2	22.8	21.1	24.0
	B (Bottom)	3.8	11.2	7.0	
	C (Top)	3.2	12.7	7.1	
Fall/Spring Temp 1 to 6°C	A (Ambient)	2.2	4.1	3.3	24.0
	B (Bottom)	2.1	12.9	6.7	
	C (Top)	1.8	17.3	7.8	
Extreme Winter Temp -30 to -35°C	A (Ambient)	-30.0	-26.6	-27.9	2.0
	B (Bottom)	-3.6	13.8	4.1	
	C (Top)	-5.8	15.1	4.4	



	Extreme Summer Temp >+30°C	Moderate Summer Temp 19-25°C	Fall/Spring Temp 1 - 6°C	Extreme Winter Temp <-30°C
Data Logger A (Ambient)	36.2	21.8	3.4	-27.7
Data Logger B (Inside Bottom)	10.7	8.4	7.7	3.9
Data Logger C (Inside Top)	11	7.9	7.3	4.7
Average Acceptable Time	9.5	18.3	24	5.2

Figure 5 Average temperature recorded for J82 container with RBC payload and average acceptable time



	Extreme Summer Temp >+30°C	Moderate Summer Temp 19-25°C	Fall/Spring Temp 1 - 6°C	Extreme Winter Temp <-30°C
Data Logger A (Ambient)	36.3	21.1	3.3	-27.9
Data Logger B (Inside Bottom)	11.7	7	6.7	4.1
Data Logger C (Inside Top)	12.4	7.1	7.8	4.4
Average acceptable Time	24	24	24	2.7

Figure 6 Average temperature recorded for J82 container with PPP payload and average acceptable time

The above graphs illustrate the minimum and maximum temperatures of the data loggers inside the container and the average time that the container maintained the acceptable temperatures.

5.1. Deficiencies Reported

Three deficiencies were reported during the validation of the J82 shipping containers.

Deficiency 1: The first deficiency was noted after the first run for Test #1. The data indicated that the inside temperature of the container got too cold too quickly using the CBS packing configuration. The packing configuration consisted of two ice packs that were each placed on opposite sides of the container, then the payload of one unit was added and then one gel pack placed on top of the payload. Clean crumpled paper was placed on top of the gel pack to reduce the dead air space before placing the Styrofoam lid on and closing the container. The two ice packs had been preconditioned in a freezer with a temperature range of -25°C to -30°C which was well below the precondition temperature range recommended by CBS of -8°C to -14°C. The validation team reviewed the data and agreed to change the packing scheme using only one ice pack preconditioned at -25°C to -40°C and repeated the first run for test #1. This new packing configuration yielded an acceptable temperature inside the box for a greater amount of time.

Deficiency 2: After the first run it was noticed that the J82 box would not last the 24hrs as previously thought to maintain appropriate temperature. Test #5 Run #1 had failed to demonstrate that the box could meet the required minimum of 24 hours to maintain the appropriate temperatures. The validation team agreed to continue the challenge for 24 hours and using the data collected, assign the acceptable time based on the results.

Deficiency 3: The bottom data logger did not record during Test #7 Run#2. The logger had been turned on and then accidently turned off. The data logger was checked for functionality and was confirmed to be working. The other data logger in the box recorded the temperature with no incidents. The run was accepted based on the second data logger's recording of the temperature inside the container.

Deficiency 4: In the extreme cold temperature environment it was determined that the box could not maintain acceptable temperature for longer than about three to four hours therefore, the project team made the decision to shorten the required testing time to six hours instead of the original 24 hours for test runs nine through twelve.

6.0. Discussion

The thermal performance of the J82 shipping container in the extreme cold ambient temperature as well as the extreme hot ambient temperature did not maintain the acceptable shipping temperature range of 1°C to 10°C as expected for shipping RBCs. In the extreme heat (>30°C) the container only was able to maintain the acceptable temperature for an eight (8)hours and only three (3) hours in extreme cold (<-30°C). When exposed to temperatures between 19°C and 25°C the container maintained acceptable temperatures for an average of 12 hours. At ambient temperature between 1°C and 6°C the container maintained the required acceptable temperature for 24 hours.

Most plasma protein products (PPP) can be shipped in a temperature environment of 2°C to 25°C within a 24 hour period. There are exceptions that some products can only be shipped between 2°C and 8°C which is the same as their storage temperature. The J82 shipping container maintained acceptable temperature for PPP for at least 24 hours in extreme hot temperature, room temperature and mild cold temperatures, but could not

maintain it longer than two (2) hours in extreme cold temperatures.

In most cases the container will not be exposed to these extreme temperatures for prolonged periods of time due to the fact that the majority of shipments will be occurring inside vehicles that are temperature controlled by couriers. Most of the shipments will be short distances (less than six hours).

7.0. Recommendation:

As most facilities are using a courier system to ship products between facilities, and shipping blood components with a patient are in most cases inside a temperature controlled vehicle, the likelihood of products being exposed to a constant extreme temperature over a prolonged period of time is very small. The J82 shipping container can continue to be used for redistributing (or transferring) RBCs and PPP within the provincial hospital system based on the validation completed (see table 8). It is suggested that hospitals delay redistributing blood components and PPP when extreme temperatures are forecast to avoid the possibility of shipping containers being exposed to temperatures that may exceed the shortest acceptable time.

Table 8 Shortest Time J82 Shipping Container Maintained Acceptable Temperature

Product/Acceptable Shipping Temperature	Target Extreme Winter Temperature (<-30°C)	Target Moderate Fall/Spring Temperature (1°C - 6°C)	Target Moderate Summer temperature (19°C to 25°C)	Target Extreme Summer temperature (> +30°C)
1-8 RBCs (1-10°C)	3 hours	24 hours	12 hours	8 hours
1- 8 vials of PPP (2-25°C)	2 hours	24 hours	24 hours	24 hours

All hospitals that will participate in the redistribution program should ensure that the pre conditioning of ice packs and gel packs are in accordance to the validation parameters.

Due to the shortened time containers maintain acceptable temperatures in extreme ambient temperatures, it is recommended that transporting components and products should be done in a vehicle that allows placing the shipping container inside the passenger area of the vehicle where ambient temperatures are maintained closer to room temperatures. Facilities should confirm with their couriers that the shipping container can be placed inside the vehicle's passenger area. This confirmation should be documented.

Annual random checks will be conducted on the shipping containers to ensure that they are continuing to meet the expected requirements to ship blood components and products between facilities. ORBCoN will facilitate this with the help of FCRP and participating hospitals.

The validation protocols along with the data results will be made available for facilities that are implementing the use of the J82 shipping containers for shipping blood between hospitals.