STUDY ON DRY TYPE BLOOD WARMERS

A cooperative study by
The Japan Red Cross Pharmacists Association
and
The Blood Center Research Group

Academic Technology Division
of the Japan Red Cross
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I. Introduction

Blood warmers currently in use can be roughly classified into two categories: WET TYPE – the blood passes through a coiled polyvinyl chloride (PVC) tube immersed in a heated water bath (Fig. 1), and DRY TYPE – the blood runs through a bag sandwiched between two heating plates (Figs. 2, 3, 4).

Problems that can occur during the use of either type of blood warmer are listed in Table 1.

The use of WET TYPE blood warmers has been declining outside of Japan due to various problems specifically associated with that type of warmer, such as sterility in the warmed water bath where growth of microorganisms can occur.

In Japan, an incident where electrical circuits in a WET TYPE warmer got wet and caused the warmer to overheat, resulting in hemolysis of the blood, has been recorded. The device had to recalled by the manufacturer.

Due to the various problems that have now been recognized, we believe that DRY TYPE blood warmers will replace WET TYPE warmers in the future, and therefore, we have conducted studies on the DRY TYPE blood warmer to realize the following objectives.

1. Test Dry Type blood warmers and provide members of the Red Cross Pharmacists Association and general medical organizations with introductions to and information on these products.
2. Based on results of the tests, define specifications that must be required of these devices to be used in blood transfusions.

Table 1. Possible Side Effects from the Use of Blood Warmers

• Denaturation of blood components due to temperature control defects – Hemolysis and denaturation of protein.
• Creation of air bubbles.
• Electrical shock from current leakage.

II. Methods

• Blood Warmers

We have tested the ANIMEC AM-4 (Fig. 2) and ANIMEC AM-2 (Fig. 3) produced by Elltec Co., Ltd. and the BW-5 (Fig. 4) made by Baxter. Specifications for these devices are listed in Table 2.

• Temperature Measurement

Y-shaped tubes were connected to the inlet and outlet of each blood warming bag (in the case of the AM-2, they were connected to the inlet and outlet of the blood transfusion set). Thermistor sensors (Shibaura Works, NST) were inserted in one side of the Y-shaped tubes and temperature changes were recorded by a pen recorder (Chino, EX 830, EB22005).

In situations where pressure was required for higher flow rates, a Blood Pump II (manufactured by Musashi Engineering) was mounted between the blood packet bag and the blood warmer.

In gravity flow, the distance between the blood packet peel tab and the tip of the 18G injection needle was 70 cm.

• Hemoglobin Measurement of Supernatant Fluid

The Hb value of the supernatant fluid was obtained by the oxyhemoglobin direct color comparison method after each warming test with blood plasma separated earlier and centrifuged for five minutes at 3000 rpm.

• Test Materials

Stored blood, within 7 to 10 days of sampling, or concentrated red blood cells were used.

Table 2. Blood Warmer Specifications

	AM-4	AM-2	BW-5
Weight (kg)	3.0	0.4	6.3
Dimensions H x W x D (cm)	26.6 x 18.2 x 7.8	17.6 x 6.5 x 3.6	40.8 x 21.4 x 15.9
< Flow Rate >			
Under pressure ml/min (Water)	0 – 160	—	0 – 150
Gravity – maximum (Blood @ 70 cm drop)	– 50	0 – 12	– 30
< Priming Capacity >			
Disposable Set (ml)	≈ 50	Transfusion Set	≈ 60
Bag Capacity	≈ 15	Transfusion Set	≈ 32
Warm-up Time (min)	2	—	2
< Temperature Display >			
Display Method	LED	—	LED
Display Range (°C)	0 – 50	—	0 – 99
Minimum Display Unit	0.1	—	0.1
< Heaters >			
Types	********** Silicon Rubber Heater **********		
Number in Use	2	1	2
Power Requirements (W)	400	50	700
Heat Exchange Area (cm^2)	360	32.5	1,060
< Temperature Control >			
Control Method	********** Thermistor **********		
No. of Temperature Sensors	3	3	4
< Safety Circuits >			
Alarms	Yes	—	Yes
Alarm Temperature (°C)	39 ± 0.5	—	37 – 38
Heat Plate Safety Cir.	Yes (3 stage)	Yes	—
Leakage Current	< 10 μA	—	< 50 μA
Water Resistance	Excellent (Washable)	Good (Usable after drying)	Not Good

III. Test Results

3. Tests were conducted with the three subject blood warmers.

1) Temperature measurements of blood under gravity flow from a height of 70 cm were taken before and after warming.
2) With the AM-4, warming capability was studied under various pressures up to 330 mmHg (Flow rate up to 160 ml/min) maximum with a blood transfusion pump.
3) Blood flow was interrupted and held within the warmer for a length of time up to a maximum of 90 minutes to simulate an intermittent use situation where blood flow is temporarily stopped and restarted.

Test results were as follows:

Table 3 shows the warming capability of the AM-2 at flow rates of 3 ml/min and 6 ml/min under gravity flow.

Blood stored at room temperature and blood stored at 4°C in ice water were tested. The capabilities of the devices are more accurately displayed in the later case. Rated capability of the AM-2 is up to 12 ml/min, however testing was confined to the above rates, because rates in clinical situations are generally comparatively low.

A slightly lower temperature value than published by the maker was obtained in the room temperature experiment using water – about 35°C at 3 ml/min and about 31°C at 5 ml/min. On the other hand, in the experiment using chilled water at 4°C, a higher temperature was exhibited. This may be partly due to differences in test environments and also to the possibility that the lower-temperature fluid activated the warmer continuously.

Test results for the AM-4 Blood Warmer are shown in Table 4.

Stable warming was obtained under gravity flow for both stored blood and for concentrated red blood cells. A pump should be used for flow rates of greater than 30 ml/min with concentrated red blood cells.

It was learned that a consistent temperature of 34°C could be obtained during transfusion with the AM-4 using blood stored under refrigeration at 4°C at flow rates of 60 and 160 ml/min under pump pressures of 65 and 330 mmHg respectively.

Table 5 shows test results for the BW-5 under gravity flow compared to the AM-4.

The BW-5 is not commonly used in Japan, but is widely used in Europe. Warming temperature was found to be very stable, however a flow rate greater than 30 ml/min was not obtained. Temperatures shown by the device's electronic display averaged 1.9°C lower than our instruments recorded, however we believe that further study is required on this point.

Table 6 shows the Hb value of supernatant fluid in an interrupted flow situation.

No significant differences were found in the AM-2 and BW-5 in the few samples taken immediately after interrupting flow and 90 minutes after interrupting flow.

On the other hand, the AM-4 displayed a significant difference with a 5% threat index 60 minutes after interruption of flow, however under continuous heating no abnormal temperature was displayed.

We believe that there is no clinical significance on this point since the Kanagawa Prefectural Center reported that there was no conspicuous development of hemolysis even with the use of 20-day-old concentrated red blood cells in situations were flow was stopped for as long as 60 minutes, although we do believe that further study on this point should be conducted.

Table 3. Study on Warming Capability I
AM-2 (Gravity)

ml/min / °C	CRC Room Temp.		WB Room Temp.		WB (+4°C)	
min	3	6	3	6	3	6
1	32.0 ± 0.1	30.1 ± 0.3	29.3 ± 0.1	28.0 ± 3.2	29.6 ± 1.7	28.9 ± 3.7
2	32.5 ± 0.5	30.3 ± 0.3	29.3 ± 1.9	27.5 ± 2.4	34.5 ± 2.3	29.8 ± 2.0
3	32.2 ± 0.8	30.2 ± 0.6	29.3 ± 2.5	27.5 ± 2.4	34.6 ± 2.2	30.8 ± 3.3
4	32.2 ± 0.3	30.5 ± 1.0	29.3 ± 2.5	27.5 ± 2.4	34.9 ± 1.9	30.9 ± 3.1
5	32.0 ± 0.5	30.8 ± 1.0	30.0 ± 3.4	27.5 ± 2.4	35.0 ± 2.0	30.9 ± 3.1
6	32.2 ± 0.3	30.8 ± 1.0	30.5 ± 1.0	27.5 ± 2.4	35.1 ± 1.8	31.2 ± 3.1
7	32.0 ± 0.5	31.2 ± 0.8	30.3 ± 1.0	27.5 ± 2.4	35.2 ± 1.8	31.3 ± 3.2
8	32.0 ± 0.1	31.2 ± 1.3	30.5 ± 0.6	27.8 ± 1.7	35.2 ± 1.8	31.9 ± 3.5
9	32.3 ± 0.4	31.2 ± 1.0	31.0 ± 1.2	28.0 ± 2.2	35.4 ± 1.8	31.7 ± 3.1
10	32.7 ± 0.6	31.0 ± 1.3	31.0 ± 1.2	28.5 ± 2.5	35.5 ± 1.8	31.8 ± 2.9
	(n = 4)	(n = 3)	(n - 4)		(n - 4)	

Table 4. Study on Warming Capability II
AM-4

ml/min / °C	Gravity (WB)		Gravity (CRC)	With Pump (WB +4°C)		
min	30	50	30	30	60	160
1	37.0 ± 0.8	36.5 ± 1.0	36.4 ± 0.3	37.2 ± 0.1	36.9 ± 0.2	30.5 ± 0.7
2	36.5 ± 0.6	36.3 ± 0.5	36.4 ± 0.3	37.7 ± 0.1	37.0 ± 0.1	33.6 ± 0.3
3	36.5 ± 0.6	36.5 ± 0.6	36.4 ± 0.3	37.8 ± 0.0	36.9 ± 0.2	33.9 ± 0.1
4	36.5 ± 0.6	36.5 ± 0.6	36.4 ± 0.3	37.8 ± 0.0	36.9 ± 0.2	34.0 ± 0.2
5	36.5 ± 0.6	36.5 ± 0.6	36.4 ± 0.3	37.8 ± 0.0	36.9 ± 0.1	34.0 ± 0.3
6	36.5 ± 0.6	36.5 ± 0.6	36.4 ± 0.3	37.8 ± 0.1	36.9 ± 0.1	—
7	36.5 ± 0.6	36.5 ± 0.6	36.5 ± 0.0	37.8 ± 0.1	36.9 ± 0.1	—
8	36.5 ± 0.6	36.5 ± 0.6	36.3 ± 0.5	37.8 ± 0.1	36.9 ± 0.1	—
9	36.5 ± 0.6	36.5 ± 0.6	36.3 ± 0.5	37.8 ± 0.1	36.9 ± 0.2	—
10	36.5 ± 0.6	36.5 ± 0.6	36.1 ± 0.5	37.8 ± 0.1	36.9 ± 0.2	—
	(n = 4)		(n = 4)	Display Temperature (n = 4)		

Table 5. Study on Warming Capability III
BW-5

Model: BW-5 Gravity (30 ml/min)		
min °C	Sensor Temperature	Display Temperature
1	32.0 ± 0.1	30.1 ± 0.3
2	32.5 ± 0.5	30.3 ± 0.3
3	32.2 ± 0.8	30.2 ± 0.6
4	32.2 ± 0.3	30.5 ± 1.0
5	32.0 ± 0.5	30.8 ± 1.0
6	32.2 ± 0.3	30.8 ± 1.0
7	32.0 ± 0.5	31.2 ± 0.8
8	32.0 ± 0.1	31.2 ± 1.3
9	32.3 ± 0.4	31.2 ± 1.0
10	32.7 ± 0.6	31.0 ± 1.3

WB (n = 4)

Table 6. Supernatant Fluid Hb Value during Interrupted Flow

Hb mg/dl Model / Min	AM-4 (CRC)	AM-2 (CRC)	BW-5 (WB)
0	12.9 ± 8.5	13.1 ± 7.4	18.2 ± 5.8
30	16.7 ± 7.2	14.7 ± 6.9	21.6 ± 9.9
60	23.0 ± 7.6*	15.1 ± 7.7	27.2 ± 7.5
90	28.3 ± 7.1*	17.2 ± 8.7	25.2 ± 7.7
	(n = 4)	(n = 6)	(n = 3)

* $P < 0.05$

V. Summary

DRY TYPE blood warmers, the three models we have tested and others, are manufactured and sold in many countries. The level of safety of these warmers is considered high as they come under the safety standards for electrical devices in these countries.

WET TYPE blood warmers are still dominant in Japan, but we hope that this report might prompt the recognition that DRY TYPE blood warmers are safer.