

# A new system for temperature stable transport of blood



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## Introduction

The storage and transportation conditions as well as the manufacturing process significantly affect the effectiveness and quality of blood products. It is therefore of great importance that the regulations for 'correct' manufacturing procedures and the storage and distribution of medications containing blood are well documented, in order to guarantee that the quality is maintained throughout the duration of transportation. With the changes of requirements for the quality and safety standards of blood products in the EU (2002/98/EU) and the 'Implementation Guidelines' 2005/62/EU that followed, definite storage and distribution requirements have been set. All methods used for the storage and transportation must be validated (Art. 7, § 2) as well as the integrity and the storage temperature being protected by a relevant packaging. (Art. 7, § 5) The adherence of required temperatures especially during transportation is made particularly difficult due to the varying and sometimes extremely precise temperature adherence requirements of each blood product.

## Aim of the study

Three systems are presently used by the German Red Cross Blood Transfusion Service East. Pre-cooled butandiol plates (Compocool, NPBI) and refrigerated vehicles are used to transport full blood from the blood collection points to the central processing plants in Dresden. Using a regular secure box system carries out the delivery of the processed blood products. Volkswagen Caddy's or T4's that been re-fitted with 2°C to 6°C refrigeration with a temperature monitoring device are used for red cell transportation. Platelets with a border between 20°C to 24°C are transported in the passenger cabin. Plasma products are packed in boxes with frozen water filled elements and transported in the refrigerated part of the vehicle. The validation of each method allows for a transportation duration of up to a maximum of 6 hours.

As the re-fitting of the cars and the pre-cooling of the vehicle before transportation is not ecologically or economically desirable, alternative methods were sought. Since 2003, deltaT GmbH, Germany supplies similarly functioning systems that had to be validated before use.

## Concept

For the transportation of temperature sensitive products, delta T developed a stable and washable foam box with an inner volume of 23 litres that is then placed inside an outer aluminium casing (see figure. 1). To guarantee the required transportation temperatures cooling elements that cool to the required various temperatures are placed inside the box and held in place by aluminium prongs. The different cooling temperatures of the cooling elements ( 4°C, 22°C and -30°C) are identified easily by the different colours of the plastic casing.



Fig.1: The 'original' aluminium box.

## Validation I

During the presentation of the system at the institute in Dresden, several of the employees considered the aluminium outer casing to be unnecessary as it increased the overall weight and proved more difficult to clean. As the foam box was considered to be actually stable enough, a re-design of the box was suggested. In order to ascertain the effectiveness of the system, the first trials were carried out using just foam box without the aluminium casing (see figure. 2).

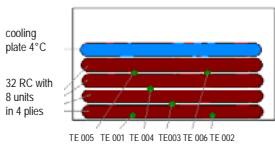


Fig. 2: Positioning of the measuring devices TE001 to TE006 in the box

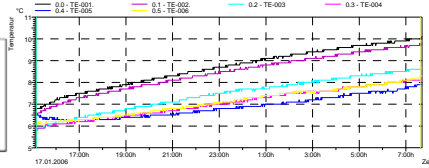


Fig. 3: Ambient temperature 21.4°C, 24 hour measurement period. Temperatures TE001 and TE002 at the base of the box increase significantly quicker

The first trials revealed that the temperature increased more quickly in the area where the elements were closest to the base of the box than in the layers above. It was therefore agreed that the base of the box should be strengthened as well as the re-design of the lid and the handles. It was also established that with only one unit of product in the box, the amount of air-space between the cooling elements and the product could not be sufficiently cooled (see figure 4 II and IV).

In order to reduce the amount of air-space between the differing volume of product and the cooling elements the positioning of the grooves for the supporting bars in the sides of the box were also re-designed. A further challenge was the sufficient cooling of the elements (see figure 4.1-II).

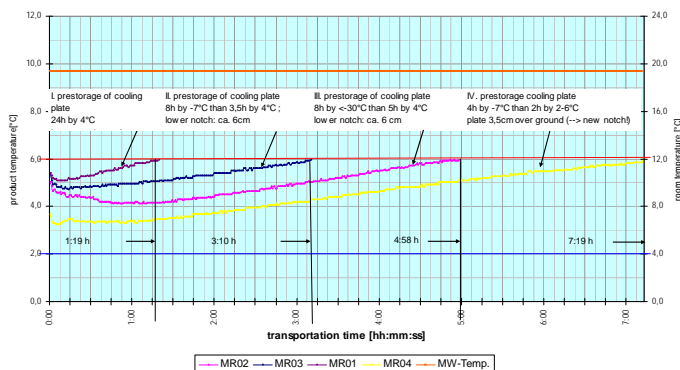


Fig. 4: Temperature curves with one red blood cell bag at different conditions of prestorage of thermal stabilizers (I-III) and reduced air space inside the box (IV).

## Re-Design

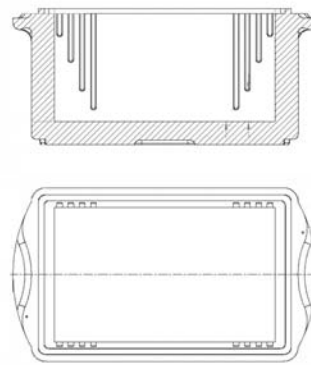


Fig. 5: Diagram of the re-designed box



Fig. 6: Box with lid and the different cooling elements

The box, now in full production, was altered as follows (see also Fig. 5 and 6):

- The walls were strengthened from 30mm to 50mm
- Grooves for the support bars are at different heights
- The lid was altered for easier use
- The shape of the box allows it to be stacked
- The handles are fixed to the sides of the box

## Validation II

In the following validation of the system, the suitability for the transportation of whole blood (WB), red cells (RC), platelets (Plt) and plasma (PL) at the following ambient temperatures was to be proven: -38°C, -6°C, 4°C, 10°C, 22°C and 33°C. Furthermore, all of the tests were carried out with the more challenging situation of using only one unit of product (except WB, full loading because of the cooling done from -36°C down to -20°C). It was discovered that two cooling elements were required, one placed under and one directly above the products in order to maintain the required temperature. The maximum transportation time are shown in figure 8. The trials with whole blood were done with one element for 6 product units or 2 elements for 12 units of product cooled from 36°C to 25°C within 5 to 8 hours (see figure 7).

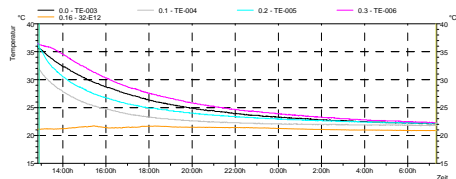


Fig. 7: transportation of 12 whole blood units using 2 elements; cooled to 25°C within 8 hours

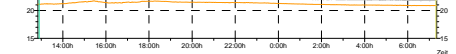
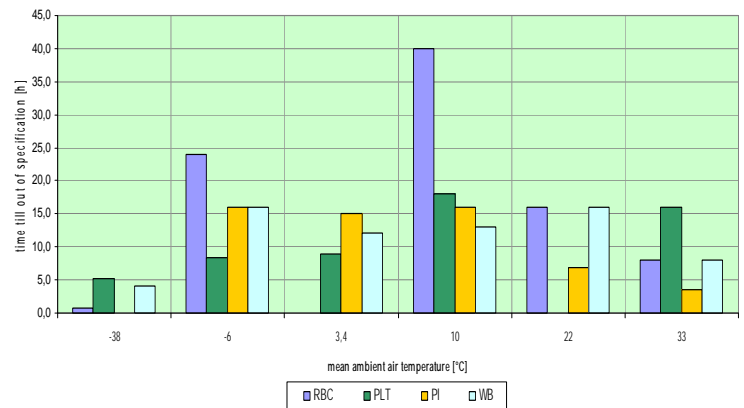


Fig. 8: max. transportation time of one single blood product at different ambient temperatures with two cooling elements into the box.

transport of blood products in the box "Blue Line 30" of Delta T with two cooling plates



## Results

The transport of all products can be done easily with the new system in a vehicle air-conditioned to between 0°C and 30°C. The results therefore show that the boxes are very well suited for the transportation of blood and blood products. This new system is still used for the transport of platelets and plasma in our blood donation service routinely. The rightful pre-storage of the cooling elements is an important part of the system. A solution to the problem of pre-cooling the RC elements is under testing.