

Introducing two new devices for blood warming

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Blood and blood products should be kept in cold temperatures to avoid hemolysis and preserve sterility and functional integrity of blood components. Patients needing massive transfusion require the blood to be warmed at bedside to avoid cardiac and general hypothermia. Hypothermia due to massive and rapid transfusion in ill and injured patients is associated with adverse side effects which are very difficult to be reversed. Here in, we describe two inventions of portable warming devices for blood and blood products and fluid solutions. These devices have several advantages including reduced contact with blood and blood products, instant preparation of blood for injections, decreased damage to blood and blood products, precise controlling of heating process, avoiding physical and chemical changes in quality of blood and blood products and also avoiding hypersensitivity symptoms due to injections.

KEYWORDS: Blood, Warmer, Transfusion

BACKGROUND

Blood and blood product should be kept in cold temperatures to avoid hemolysis and preserve sterility and functional integrity of blood components.^[1] Patients needing massive transfusion require the blood to be warmed at bedside to avoid cardiac and general hypothermia.^[2] Hypothermia due to massive and rapid transfusion (total blood volume replacement within 24 hours) in ill and injured patients has associated with adverse side effects which are very difficult to be reversed.^[3] Heart rate, blood pressure, coronary blood flow and cardiac output, all tend to fall as the body temperature drops.^[4,5] Higher mortality rate and life threatening complications in patients who received cold electrolyte solutions, blood and blood products has been reported.^[3] In general, blood warming before transfusion is indicated to avoid iatrogenic hypothermia, to increase the core body temperature in hypothermic patients and to avoid coagulation complications.^[6,7] Warmed blood is required the following clinical circumstances: (i) An adult receiving frequently more than 50 ml/kg/h blood; (ii) A child receiving more than 15 ml/kg/h blood; (iii) Blood exchange in neonates; (iv) a patient with active cold agglutinin; (v) sever forms of nocturnal paroxysmal hemoglobinuria; (vi) blood transfusion from central veins (cold blood could cause arrhythmias and cardiac arrest).^[6,7]

Currently, some unconventional methods for blood warming are sometimes utilized before transfusion which potentially could result in red blood cell

hemolysis and injuries: (i) use of normal microwave; (ii) plunging blood sac in hot water; (iii) placing blood sac near heaters; etc. These methods can result in blood hemolysis due to overheating.^[2] These transfusion conditions can only be reached with concurrent heating and transfusing, which is only possible with portable heating device for blood and blood product that has a high accuracy and quality.

Rapid and efficient blood-warming devices are of substantial interest in order to administer large volume of cold blood safely and rapidly.⁽⁸⁾ Use of coiled plastic tube that immerses in hot water bath with a temperature less than 38° C and use of plates which are heated by electricity and are in contact with blood are two conventional methods of blood warming.^[9]

Here in, we describe two inventions of portable warming devices for blood and blood products and fluid solutions. These devices have several advantages including reduced contact with blood and blood products, instant preparation of blood for injections, decreased damage to blood and blood products, and precise controlling of heating process.

A. Summary of the invention: Screw Blood Warmer (1390/08/25-72397)

This invention is officially registered with the Companies Registration and Industrial Ownership Office of Iran in 2011 (registration no. 1390/08/25-72397).

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This apparatus consists of five different parts (Figure 1): (i) thermal chamber; (ii) back cover and serum clamp; (iii) front cover; (iv) electrical circuit and (v) complementary serum tube, which are described below.

i. Thermal chamber

The thermal chamber consists of an aluminum tube with 85 mm of depth, 100 mm of diameter and 12 mm thickness (85×100×12 mm). In the middle of the external surface of this tube, a groove with 2 mm of width, 3 mm depth and twirling 10 times around the tube is curved in order to accommodate the plastic connecting tube. The end of the chamber for 10 mm of length is sealed, and there are no groove curved on this part.

In forepart of this tube, 2 symmetrical and opposite holes with 5 mm of diameter and 82 mm of depth was designed, each of which contain a 50 watts ceramic heater. Perpendicular to these 2 holes, two other holes are architected in which two 4 mm bolts with 15 mm of length are placed in order to fix the frontal door in its position.

In the middle and inside the chamber, in vertical position and along the bolts position (90 grade away from heaters), two holes with 5 mm of diameter and 5 mm of depth are embedded to place thermal sensors apparatuses (Figure 1.A).

ii. Back cover and novel serum clamp (1390/10/26-73454)

A back cover with 10 mm of thickness and 104 mm of diameter is placed as a sealing at the end of the apparatus. This part is designed and made from remarkably versatile polymer called polytetrafluoroethylene (PTFE) to hold the thermal chamber from backside in order to avoid metal to metal contact with serum stand.

On the back cover, two roller and a push-fit clamp (Figure 2) carrier is installed as a novel type of clamp (registration no. 1390/10/26-73454) which are used to lock the apparatus with serum stand by pushing the apparatus down and unlock it by pushing it up (Figure 1.C). The clamp mechanism consists of 5 pieces: (i) two rollers (Figure 2.B); (ii) one latch (Figure 2.A); (iii) one spring and (iv) a body. These pieces are fastening

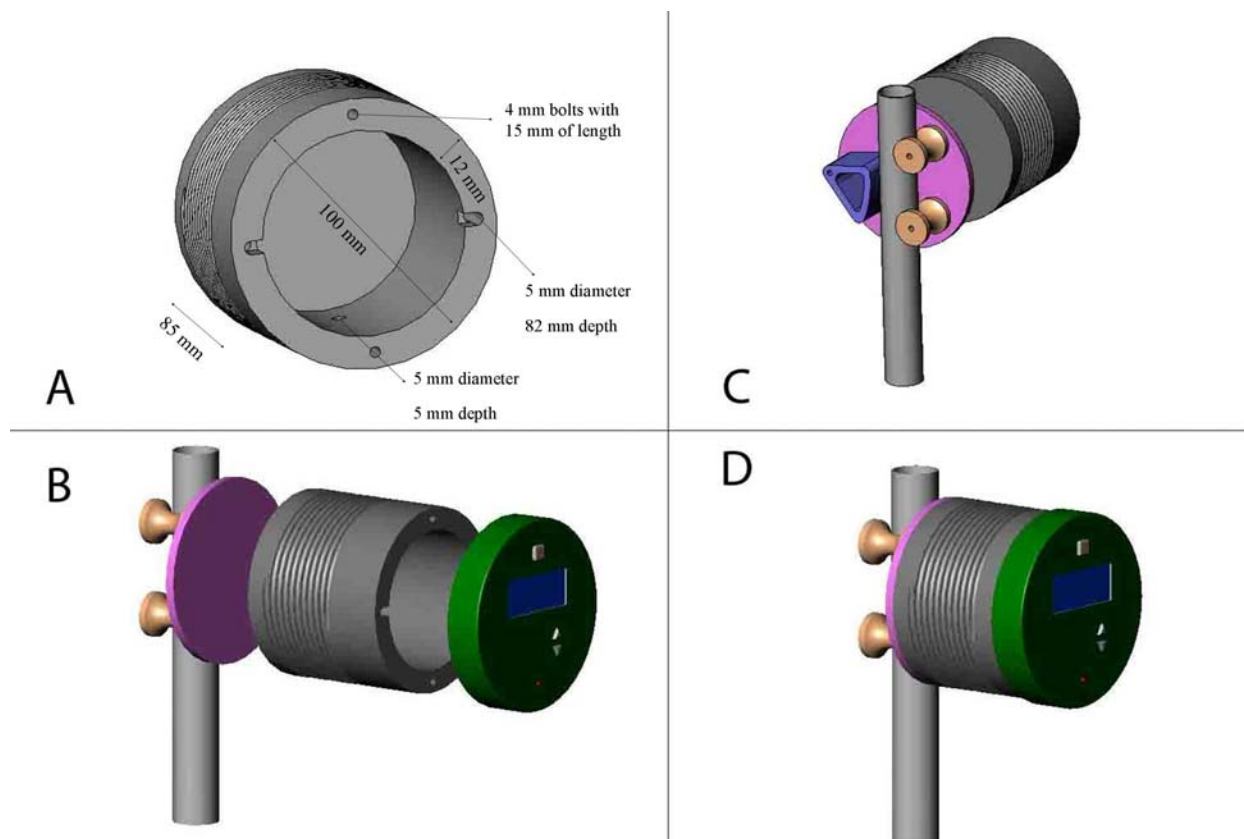


Figure 1. Different parts of the screw blood warmer; A: thermal chamber, B: forepart cover; C: back cover and serum clamp; D: screw warmer apparatus

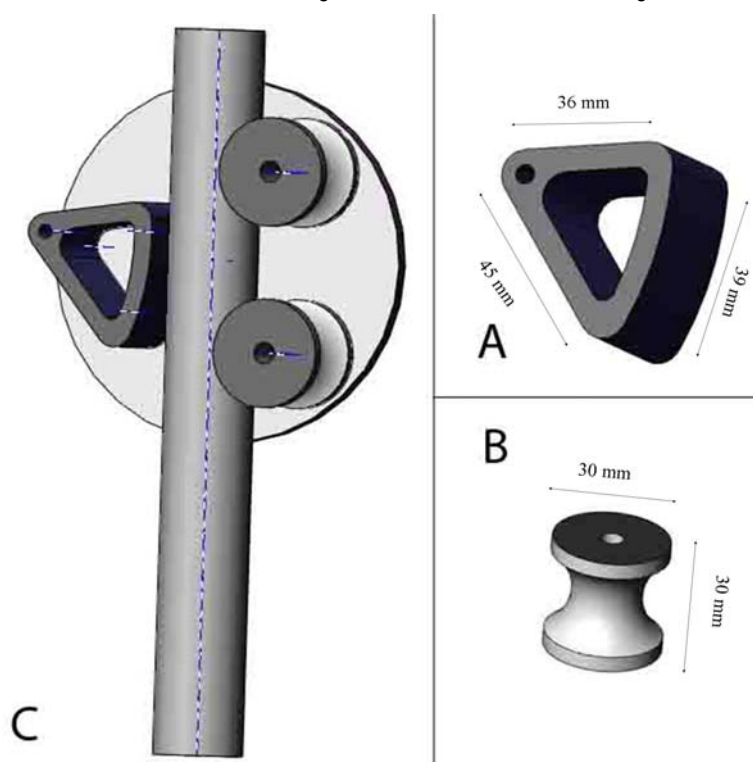


Figure 2. Clamp for easy and fast installation of medical equipments; A: Latch; B: Roller; C: Clamp

together with 3 bolts. Rollers are designed to regulate the height of serum stand for installation of medical equipment. The needed force for stabilization of these equipment at desirable height is provided by the latch which is placed opposite of the two rollers and can produced locking force equivalent to 44 times of equipment weight. Primary locking force is provided by the spring which is installed on the latch. For installation of the equipment, the latch should be firstly pulled down in order to the serum stand to be placed between the rollers and the latch, and then by releasing the spring the clamp is locked with the serum stand (Figure 2.C).

iii. Forepart cover

The forepart cover has 20 mm of thickness and 104 mm of diameter. This door seals the heating chamber from front in order to protect the elements of chamber and avoid waste of heat. It contains a display to show current and desired temperature and 3 bottoms (one for power of apparatus and the other two for increasing and decreasing desired heat). When the desired heat increases over 40 centigrade, a flashing warning light is activated.

iv. Electrical circuit

In this electrical circuit we have two IM35 heat sensors with capacity of measuring 0 to 100 centigrade with an accuracy of 0.1 centigrade which measures the temper-

ature of two calculated points in the hardware of apparatus. IM35 is a low voltage, precision centigrade temperature sensor which provides a voltage output that is linearly proportional to the Celsius (centigrade) temperature. A powerful micro controller (Atmega 8) receives temperature from these sensors and calculates the median temperature.

The installed optocoupler/optoisolators in this circuit can power on/off the heater with high accuracy by comparing the calculated temperature to the desired input obtained with the potentiometer. An optoisolator, also called an optocoupler, photocoupler, or optical isolator, is "an electronic device designed to transfer electrical signals by utilizing light waves to provide coupling with electrical isolation between its input and output. A liquid crystal display (LCD) is used in order to show system's current temperature and our desired temperature.

v. Complementary serum tube

Serum complementary tubes are designed to increase tube length for optimal function of heating apparatus. Tubes containing blood and blood product must twirl additional rounds around the heating chamber. In order to avoid shortening increase the contact of the tube with the heating chamber we designed a complementary serum tube which is similar to the common normal tube (4 millimeter of diameter and in plastic) but

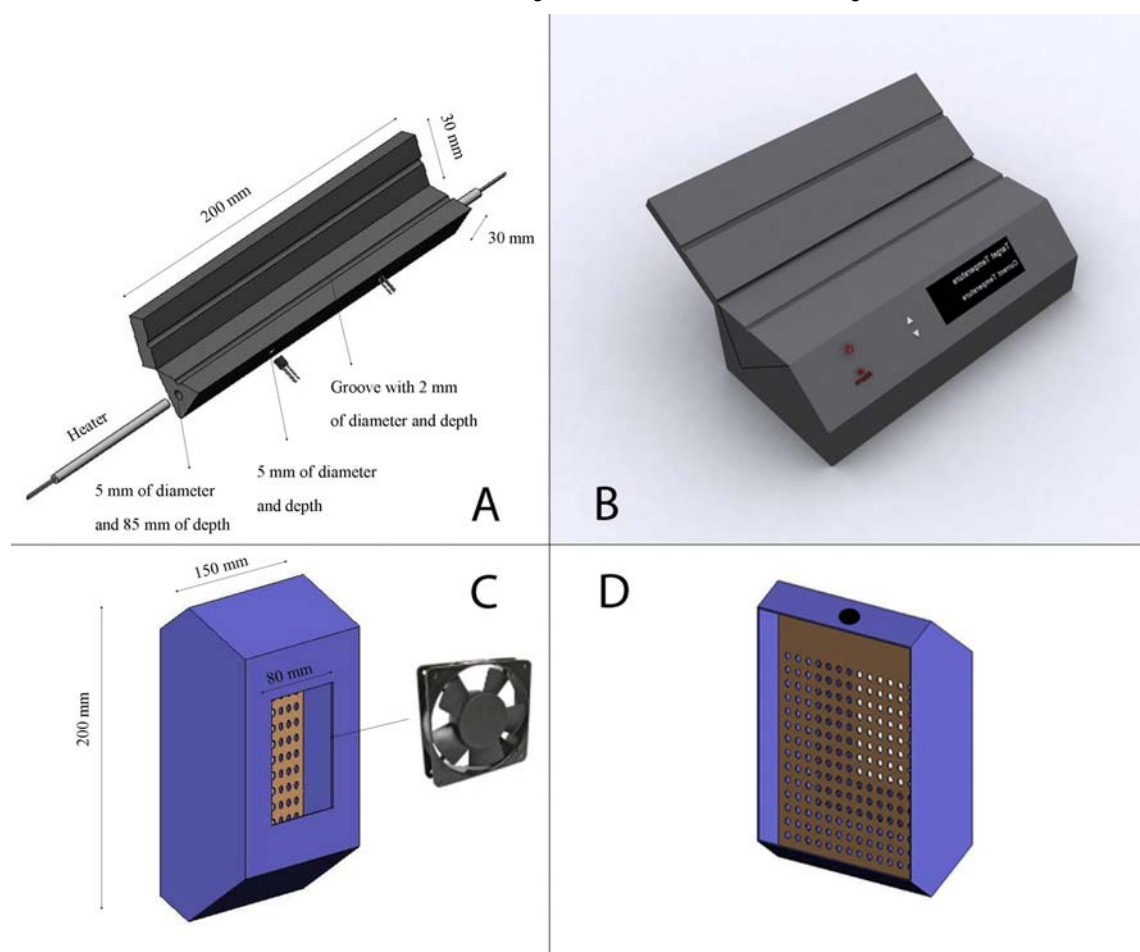


Figure 3. Different parts of the split blood warmer; A and B: contact heater; C and D: hot air ventilation box

has a longer length of 1500 mm. The proximal end of this tube has a male connector for attaching the distal part to the serum bag and on the other end it has a female connector at the distal part for connection with IV link or injecting needle.

B. Summary of the invention: Split blood warmer (1390/08/25-72396)

This invention is officially registered with the Companies Registration and Industrial Ownership Office of Iran in 2011 (registration no. 1390/08/25-72396). This apparatus consists of three subunits: (i) contact heater; (ii) hot air ventilation and (iii) Electrical circuit.

i. Contact heater

Contact heater consists of an aluminum part with an equilateral triangle (each side measuring 30 mm) based rod with a length of 200 mm. On one surface, there is a groove with 2 mm of depth and width throughout the rod for placement of the serum tube. On another surface, 2 holes with 5 mm of diameter and depth had been designed for placement of heating sensors. In center of the contact heater, a hole with 5 mm of diameter is sought to contain two 50 watts ceramic heater providing

the apparatus with the needed heat (Figures 3.A, 4.B).

A cover with 200 mm of length, 30 mm of width and 8 mm of height was designed, with a groove with 2 mm of depth and width which passes along it and is hinged to the rod which fits with the other groove on the rod to contain the blood and blood products tubes (Figures 3.A, 4.B).

ii. Hot air ventilation box

This part consists of a box with dimension of 150×200×60 mm. This box is divided into two parts with a grid plate. One part of this box which does not have an external wall is designed to contain blood and blood products, and the other part is architected to contain the fan and heater, while a fan of 80×80 mm dimension is placed on the external wall of which conducts hot air to blood bag. For hanging this box to the serum stand a hole with 8 mm of diameter is placed on the top of the box (Figures 3.C, 4.D).

iii. Electrical circuit

The electrical circuit for this design is the same as described in the previous section.

Applying the inventions to clinical settings

There are currently four different types of blood warming devices: (i) a single coiled immerse in a heated water bath, (ii) single and (iii) multiple parallel channel units using countercurrent extracorporeal heat exchangers and (iv) a single channel electrical heater.⁽⁹⁾

Currently in the United States, two inventions similar to ours had been approved: Blood Warming Apparatus (4167663) and Intravenous Fluid Warming Cassette with Stiffening Member and Integral Handle (US 2007/0173759 A1). However, in comparison with these two models, our models use the metal contact method for heating the blood products and also they utilize a different way of increasing contact surface. Our devices can work automatically and control heat precisely which is much easier to use and can be installed on serum stand

To use screw blood warmer, one would only need to lock the apparatus to the serum stand and plug it to the electricity source, connects the complementary tube with the blood or blood product bag and twirl it in the groove on the external side of the apparatus, and then connect the other end to the needle. The apparatus should be then turned on and a desired temperature should be set using the bottoms on the apparatus and finally the tube clamp should be released.

To use the split blood warmer, first the blood or blood products bag should be inserted in the container box and be hung to the serum stand. The connecting tube should be connected to the bag and passed through the groove on the contact heater and the cover closed, so the tube is locked into the contact heater. The device should be plugged in and powered on. The desired temperature should be set using adjusting bottoms on the control panel. After about 10 minutes, the other side of serum tube should be connected to the needle and the clamp could be released to start the transfusion. Furthermore, its user friendly characteris-

tics and simple application make this device as a suitable and applicable choice for infusion and transfusion in emergency department and operation rooms.

Low production fees (estimated as about 400 US dollar) of these blood-heating devices is a bonus point which enables their universal use. These devices could reduce mortality and morbidity rate by means of contracts and mass production and also with classes and briefings for general practitioners, emergency room specialists, pediatrician, internists, operating room technicians, blood banks and blood transfusion organizations.

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