

A new blood storage refrigerator design for ATEX Directive

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Abstract: Blood storage refrigerators are one of the indispensable products of the medical sector. Blood storage refrigerators are produced in various capacities and per different blood components. Although there are commercial refrigerators with various features among our company's products, we do not have a blood storage refrigerator for the medical sector. Although there are a few companies that manufacture blood storage cabinets in our country, there is no company that fulfills high-security requirements per the ATEX Directive (2014/34/EU). In the field of an industrial kitchen, our various international competitors develop blood storage refrigerators and offer them to the market as a product with high added value compared to industrial refrigerators. Innovative blood storage refrigerator, which meets the safety requirements by the ATEX Directive for the first time in our country with studies based on R&D systematics, is a prototype that can compete and commercialize with international products in the medical field, after testing and evaluating it with its original design and prototype developed.

Our prototype is designed to meet high safety requirements according to the ATEX directive (2014/34/EU). The innovative blood storage refrigerator meets the safety requirements of the ATEX directive. Simulation of the cooling process of the innovative prototype is made together in cooperation with a local university. In contrast to our commercial refrigerators, we meet the refrigeration, hygiene, health, and safety requirements of the original blood storage refrigerator prototype, which meets with all international standards for the medical device sector (EN 60079-0, EN 60079-15, etc.) and ATEX directive (2014/34/EU).

Keywords: BLOOD STORAGE REFRIGERATORS, ATEX DIRECTIVE AND SAFETY REQUIREMENTS, REFRIGERATION TECHNOLOGY

1. Introduction

Blood storage refrigerators stand out as critical products that are used to preserve blood and its products in hospitals and blood centers at certain times and temperatures. Over 100 million blood units are collected worldwide each year [1]. Although there are commercial refrigerators with various features among our company's products, we do not have a blood storage refrigerator product for the medical sector. Although there are a few companies that manufacture blood storage cabinets in our country, there is no company that fulfills high-security requirements under the ATEX Directive (2014/34/EU).

In the sector of the commercial kitchen, our various international competitors develop blood storage refrigerators and offer them to the market as a product with high added value compared to commercial refrigerators.

Innovative blood storage refrigerator, which meets the safety requirements under the ATEX Directive for the first time in our country with studies based on R&D systematics, is a prototype that can compete and commercialize with international products in the medical field, after testing and evaluating it with its original design and prototype developed.

The blood that is used without any treatment after it is taken from the donor is called whole blood. It is mainly used as a source for the preparation of blood components. The temperatures of the storage conditions vary according to the differences in various blood components. The storage temperature for whole blood is +4°C [2-6].

There are very few studies on innovative blood storage refrigerator applications that meet the safety requirements for the medical sector by the ATEX Directive. The main reason for this is that these products are commercial.

The average global Research & Development investment rate (R&D spending as a percentage of sales) is estimated to be around 8% in the medical technology sector [7].

In 2020, more than 14,200 patent applications were filed with the European Patent Office (EPO) in the field of medical technology representing a 2.6% growth in patent applications

compared to the previous year [8]. Patents in the field of medical technology climbed to the top in 2020 (Fig. 1).

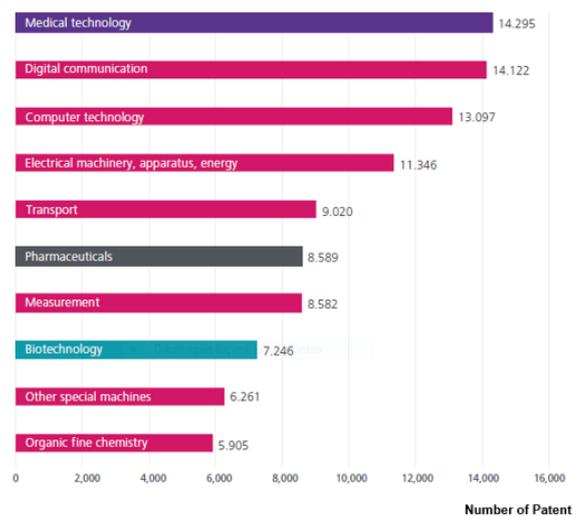


Fig. 1 Number of patent applications filed with EPO, 2020 [8].

The Japanese research group detected ammonia, lactate, pH of the preserved blood by sensing the temperature of the material and its surface in the cooling system they developed for whole blood protection. and analyzed ATP levels [9].

The project activities of obtaining the innovative blood storage refrigerator by the ATEX Directive (2014/34/EU) for the first time in our country through R&D studies were carried out in line with international standards (EN 60079-0, EN 60079-15 etc.).

2. Methodology

The design validation data (the placement of blood units according to the original designs, the cooling performance evaluations according to the air circulation and temperature distributions, etc.) made important contributions before the prototype fabrication.

The cooling system hardware and the placement of the shelves are provided specifically to the design of the innovative blood storage refrigerator prototype. The main body of the innovative prototype is made of stainless steel (AISI 304) material. Polyurethane printing was carried out between the stainless steel material for insulation purposes.

The innovative prototype has an audible and visual warning system against the door being left open for a long time and/or forgetting to close the door. In addition, there is a lock system to prevent it from being used by unauthorized personnel. Double glass is used in the door of the innovative prototype to maintain the temperature inside the cabin.

A front view of the innovative blood storage refrigerator prototype is given in Fig. 2.



Fig. 2 Front view of the innovative blood storage refrigerator prototype.

Images of the temperature data recording system and warning system of the innovative blood storage refrigerator prototype, which meets the safety requirements for the medical sector by the ATEX Directive, are given in Fig. 3.

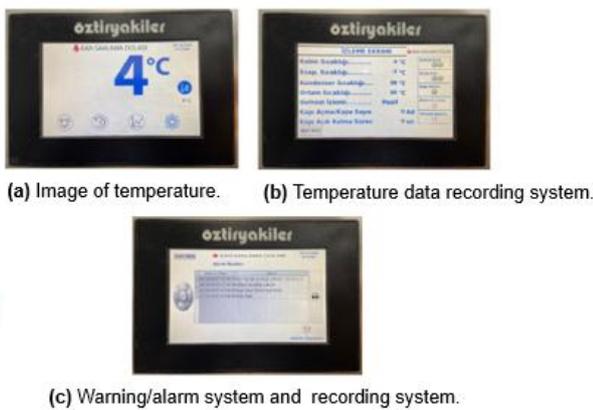


Fig. 3 Images of the temperature data recording system and warning system of the innovative blood storage refrigerator prototype.

The images of the blood storage bags (450 ml.) used in the testing and evaluation phase of the innovative blood storage refrigerator prototype that meets the safety requirements for the medical sector by the ATEX Directive are given in Fig. 4 and Fig. 5.



Fig. 4 (a) Image of blood storage unit packed, (b) Blood storage unit (450 ml).

Gross capacity 500 Lt. of innovative blood storage refrigerator prototype and 250 blood units (450 ml/piece) capacity (Fig. 5).



Fig. 5 Placement of blood units (450 ml/piece) inside the innovative prototype.

3. Experimental procedure

After the design validation studies of the innovative blood storage refrigerator, prototype manufacturing and assembly stages were completed. The innovative prototype includes 5 different blood storage shelves and an inner door made of plexiglass material is placed in front of each shelf so that the temperature distribution between the shelves is not adversely affected when the outer door is opened.

Simulation studies and design validation studies were carried out to ensure that the innovative blood storage refrigerator prototype provides effective cooling specific to the design. In the testing and evaluation phase, glycerol was used instead of whole blood.

In the work on the innovative prototype, ATEX directive (2014/34/EU) and EN 60079-0, EN 60079-15 etc. related to the medical equipment sector. standards were used. It has been determined that the innovative prototype is suitable for Zone 2 according to the ATEX directive. In addition, IIB (gas group) and T2-T6 (temperature) are valid for the innovative blood storage refrigerator prototype.

In the innovative blood storage refrigerator prototype, which meets high safety requirements by the ATEX Directive (2014/34/EU) for the first time in our country in the medical sector, whole blood storage is provided at +4°C (±1.5°C), (Fig. 6).

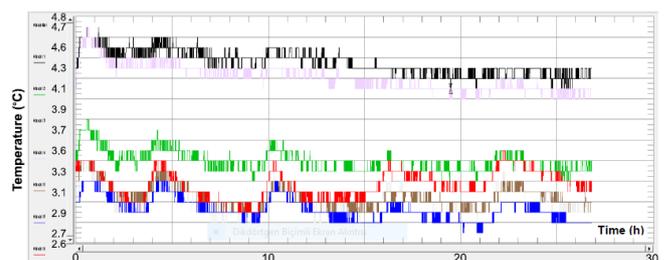


Fig. 6 The cooling performance of the innovative blood storage refrigerator prototype is at +4°C (±1.5°C).

At least 15% energy saving (1,071 kWh/day) was achieved in the energy consumption value of the innovative blood storage refrigerator prototype, which meets high safety requirements by the ATEX Directive (2014/34/EU) for the medical sector (Fig. 7).

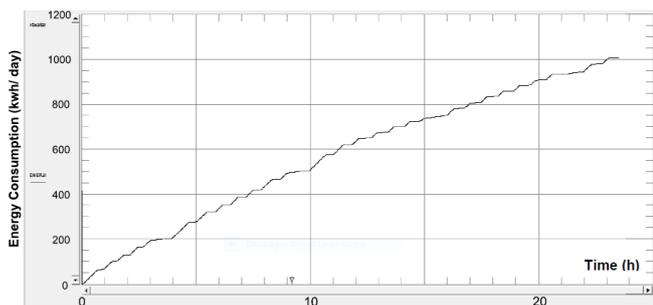


Fig. 7 Energy consumption of the innovative blood storage refrigerator prototype.

The noise level measurement value (53.6 dBA) during the working process of the innovative blood storage refrigerator prototype is given in Fig. 8.



Fig. 8 The noise level measurement value of the innovative blood storage refrigerator prototype.

With the R&D activities, for the first time in our country, unlike our commercial refrigerators, the uniquely designed blood storage refrigerator prototype, which operates by the international standards of the medical device sector and the ATEX Directive (2014/34/EU), provides the cooling, hygiene, health and safety requirements at a high level with R&D gains.

In this context, it has been achieved to obtain an innovative prototype by making use of the effective operation of the innovative prototype, engineering calculations obtained during the design verification phase, simulation data (air circulation in the cooler chamber and temperature distributions, etc.) and test and analysis data.

4. Conclusions

Following the R&D studies on the innovative blood storage refrigerator prototype, the following outputs were achieved;

It has been achieved to meet the high safety requirements of the innovative blood storage refrigerator prototype with the ATEX Directive (2014/34/EU) compared to the standard domestic blood storage refrigerators in our country, with studies based on R&D systematics in the medical device sector.

In the innovative blood storage refrigerator prototype, which meets the high safety requirements in the medical sector by the ATEX Directive (2014/34/EU), whole blood storage has been achieved at +4°C ($\pm 1.5^\circ\text{C}$).

The design-specific innovative blood storage refrigerator prototype has been provided with a gross 500 Liter and 250 blood units (450 ml/piece).

In the innovative blood storage refrigerator prototype, which meets the high safety requirements in the medical sector by the ATEX Directive (2014/34/EU), the energy consumption value has been at least 15% energy saving (1,071 kWh/day) compared to the imported similar product.

The innovative blood storage refrigerator, which meets the safety requirements by the ATEX Directive for the first time in our country with studies based on R&D systematics, has been tested and evaluated with the original design and prototype production. A prototype that can be commercialized in the medical field has been developed with the cooperation of industry-university.

Acknowledgement

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