Development Results of the Intelligent Device for Storage of the Transfusion Environments Containing Platelets

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Abstract: Research results directed on creation of the device for safe storage of **transfusion environments containing platelets** with the use of thermal stabilization system based on semiconductor thermoelectric elements, information support of storage process monitoring and radio frequency identification (RFID) technologies are considered. Calculation results of the storage modes that differ the initial conditions of the process are given. Three-dimensional models of a device based on multi-layer walls are elaborated. Computational experiments with subsequent analysis of the temperature distribution on the computational domain are described.

1 INTRODUCTION

The transfusion environments containing platelets include the most important component of the blood-platelet concentrates. It is widely used in recent years at program therapy of blood system tumors, aplastic anemia, transplantation of bone marrow, courses of intensive chemotherapy with a pre-planned period f of prolonged agranulocytosis and thrombocytopenia, and also the performance of abdominal operations (laparotomy, splenectomy). There is especially important to provide of prescribed regimes of platelet concentrate storage, because the observance of these regimes guarantees its quality. An integral part of the quality control system of platelet concentrate is the continuous monitoring of the storage process and recording its parameters, and also ensuring the traceability of its movement along the technological chain from the donor until use, that can be achieved through the application of modern information technologies.

2 MAIN PART

According to the Guide to preparation, using and ensuring quality of blood components platelets should be stored in such conditions under which viability and haemostatic activity of cages will be kept. If it is necessary to store platelets more than 24 hours, for preparation use the closed system of polymeric containers. Polymeric containers have to possess good gas permeability to provide oxygen inflow to platelets. The need for oxygen depends on the contents in a concentrate of platelets and leukocytes. Optimum temperature of storage makes from 20 to 24 ºC. A necessary condition of platelets viability preservation is their continuous mixing. It has to be rather effective to provide access of oxygen during all storage time which under optimum conditions can be seven days. The complex of thermohydrodynamic calculations with using of computer modeling technologies was carried out in this work. The purpose of computer modeling is determination of transition process duration of temperature stabilization of the transfusion environments containing platelets that is in the polymeric container.

In the result of three-dimensional scanning of a container filled with platelet concentrate (PC) was received a numerical description of the surface geometry, which was then subjected to computer processing for receiving three-dimensional solid model of liquid volume Three-dimensional scanning was executed by means of the BreuckmannstereoSCAN 5MP device. Computer data processing was performed.

The design scheme of research object including the following elements (Figure 1): liquid volume (Ω_1),a container cover (Ω_2), a device shelf (Ω_3), air

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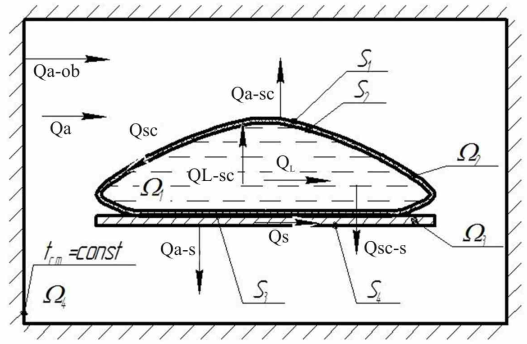


Figure 1: A design scheme for a polymeric container with transfusion environments containing platelets.

volume round the container and shelf (Ω_4) was made.

The surface section of elements: S_1 –contact surface of the container shell with the ambient air, S_2 – surface section of the sheath with liquid, S_3 – the contact surface of the sheath container with a shelf, S_4- the surface section of the shelf with the ambient air are defined in the design scheme. As boundary conditions it is assumed that the temperature of the outer boundaries of the air volume is constant and equal to the initial temperature of the air volume.

In accordance with this scheme during storage in the present volume the following processes take place: heat transfer inside the liquid volume (Q_L); heat transfer in air volume (Qa); contact heat transfer by conductivity on the shell polymer container (Qsc); heat transfer by conductivity on a shelf (Qs); contact heat transfer between a shell and a shelf (Qsc-s);convective heat transfer between the liquid and the shell polymer container (QL-sc); convective heat transfer between the shell and the ambient air (Qa-sc); convective heat transfer between the shelf and the ambient air (Qa-s);convective heat transfer between the air and isothermal outer boundary (Qa-ob).

The mathematical model of the physical processes occurring during storage of PC is formulated in accordance with the presented design scheme. A number of assumptions has been introduced for the correct formulation of the calculation problem of thermo-hydrodynamic system: the movement of liquid and air is considered to be laminar; liquid and air are considered as Newtonian and incompressible environments because of the small velocities of motion; all materials are homogeneous and isotropic on thermophysical properties; physical parameters of the liquid medium (PC), gaseous medium (air) and solids are considered to be independent of temperature; since the density of the liquid medium varies insignificantly, we use the Boussinesq approximation, whereby the liquid density and air density are linear functions of temperature and are defined as (1)

$$\rho = \rho_0\left(1-\beta\left(T-T_0\right)\right) \qquad (1)$$

where ρ – the density of the liquid medium; T – temperature; β – coefficient of volume expansion of the liquid medium; $\rho_0 = \rho(T_0)$ – characteristic value of the density at the temperature T_0; thermal radiation is not considered.

Description of motion and heat transfer processes is based on a system of differential equations. Convective heat transfer between the system elements and surrounding air is described by the dependencies, which include the momentum conservation equations, the equation of energy conservation and equation of mass conservation (2)-(6).

The equations of momentum conservation for the liquid medium (2) - (4):

$$\frac{\partial}{\partial t}\left(\rho_i u\right) + \mathrm{div}\left(\rho_i \vec{\upsilon} u\right) = \mathrm{div}\left(\mu_i \mathrm{grad} u\right) - \frac{\partial p}{\partial x} \qquad (2)$$

$$\frac{\partial}{\partial t}\left(\rho_i v\right) + \mathrm{div}\left(\rho_i \vec{\upsilon} v\right) = \mathrm{div}\left(\mu_i \mathrm{grad} v\right) - \frac{\partial p}{\partial y} \qquad (3)$$

$$\frac{\partial}{\partial t}\left(\rho_i w\right) + \mathrm{div}\left(\rho_i \vec{\upsilon} w\right) = \mathrm{div}\left(\mu_i \mathrm{grad} w\right) - \frac{\partial p}{\partial z} + \rho_i g \qquad (4)$$

The equation of mass conservation for the liquid medium (5):

$$\mathrm{div}\left(\rho \vec{\upsilon}\right) = 0 \qquad (5)$$

The equation of energy conservation for the liquid medium (6):

$$\frac{\partial}{\partial t}\left(\rho_i c_i T\right) + \mathrm{div}\left(\rho_i c_i \vec{\upsilon} T\right) = \mathrm{div}\left(\lambda_i \mathrm{grad} T\right) \qquad (6)$$

The following symbols are in these equations: t– time; x,y,z– position coordinates; u,v,w – speed in different projections; $\vec{\upsilon}$ – the velocity vector; μ – dynamic viscosity; g – free fall acceleration; c– specific heat; λ – thermal conductivity coefficient

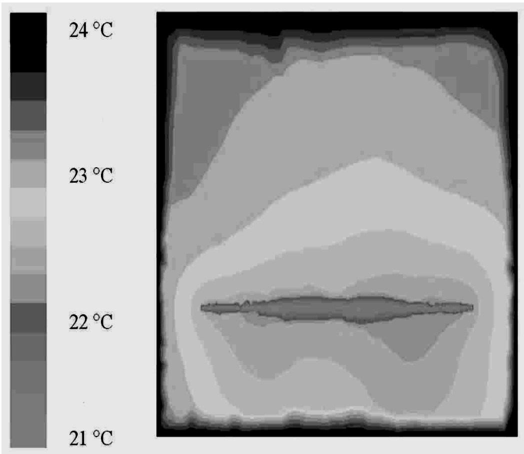


Figure 2: Temperature field in the calculation area at time t=100 s.

of the liquid medium. Dependencies are considered to the Boussinesq approximation: density of liquid medium are accepted everywhere regular, except for the term describing the buoyancy force, where the density is assumed to be linear function of temperature.

The obtained system of equations (2) - (6) has not analytical solution in the general case. Methods of the numerical solution were used to obtain an approximate solution. They include the discretization step based on the method of control volumes (MCV) and a specially developed iterative algorithm. Splitting of the solid model to mesh of finite volumes was made for the numerical simulations using the MCV. There were determined the liquid temperature in the package, the shell, shelves and air before each calculation.

The characteristic temperature distributions in the calculation area are shown in Figure 2.

The calculation results of time dependencies of the temperature PC in the polymer container at the exit of the storage device of transfusion environments containing platelets in the mode of temperature stabilization at different initial temperatures of transfusion environments containing platelets are shown in Figure 3 and Figure 4.

It was determined as a result of calculations that the thermal stabilization duration ranged from 3.7 to 5.8 min (from 220 to 350 s) depending on the initial conditions, which allows to judge about quick entering on the thermal stabilization mode. It ensures high quality and storage safety of transfusion environments containing platelets under specified conditions.

You can select the following mandatory requirements during storage of such media:

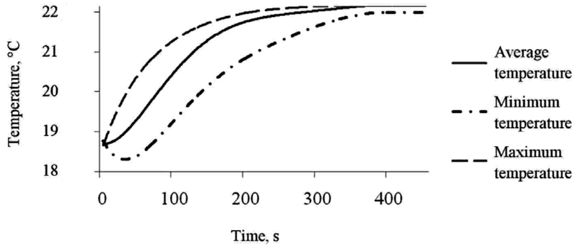


Figure 3: The graph of transient on volume in the calculation area. Initial temperature 19 ºC.

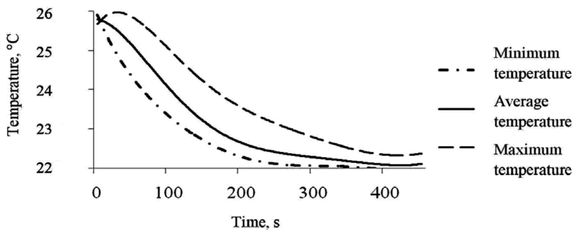


Figure 4: The graph of transient on volume in the calculation area. Initial temperature 26 ºC.

1. Protection against damage
2. Monitoring of environmental conditions
3. Ensuring stirring platelets
4. Providing the ability to identify the containers with fluids containing platelets transfusion to account for them during processing, storage and use
5. Provision of data recording observations

Analysis of the requirements below defines the requirements for the functional characteristics and capabilities of the storage device of transfusion environments containing platelets.

Medical requirements set fairly narrow limits of storage temperature platelet transfusion containing media (from + 20 to + 24 ºC), which differ from normal room temperature, which leads to the use of special devices maintain a high degree of accuracy desired temperature of the closed environment of limited volume, which stores containers with media containing platelet transfusion. To solve this problem, a camera, the walls of which have good insulating properties, is equipped with a cooling unit. High precision temperature storage transfusion media containing platelets causes use as a refrigeration unit thermostatic device with low inertia. Enhanced security of transfusion media containing requires the establishment of reliable systems for thermal stabilization, including significant positions are occupied by semiconductor thermoelectric elements (Peltier elements) that provide both heating and cooling.

Semiconductor thermoelectric elements have several advantages compared with other devices cooling - heating: small size, no moving parts, are not required to regularly change the refrigerant (freon charge), ease of operation and maintenance (no high-pressure systems), there is no sensitivity to vibrations, the possibility of smooth and precise control of temperature, environmentally friendly, quiet, arbitrary orientation in space and gravity field, low inertia, ease the transition from cooling to heating mode.

To ensure high accuracy of temperature maintenance chamber requires the use of high-precision temperature sensor and a control system for precisely and smoothly controlling the temperature inside the chamber. Figure 5 and Figure 6 shows a computer model of the thermopile using semiconductor thermoelectric elements.

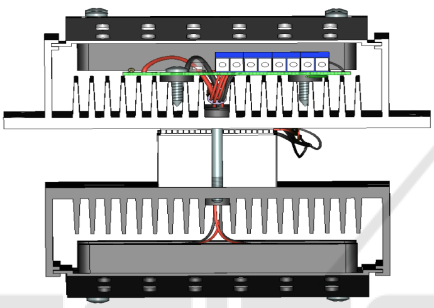


Figure 5: A computer model of the thermo battery using thermoelectric semiconductor elements (side view).

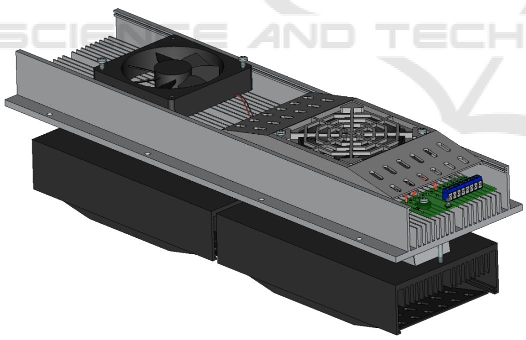


Figure 6: A computer model of the thermo battery using thermoelectric semiconductor elements (view from the external radiator).

To reduce the non-uniformity of temperature distribution by volume containing platelet transfusion media inside the container used stirring of this medium. To ensure the agitation of the platelets transfusion media containing a special device with a mobile platform and mounted on her shelves for plastic containers transfusion media containing platelets.

To reduce the possibility of damage transfusion media containing platelets due to failure of the thermostatic device or agitation, use of sound and light warning of a fault with the fact that the staff took measures to ensure the necessary conditions of storage media containing platelet transfusion in any other way and made emergency repairs device.

Thus, based on the analysis of requirements for functional performance storage device for transfusion environments containing platelets, in principle it should be composed of the following devices and components:

1. Mixing device transfusion environments containing platelets;
2. Thermostatic chamber thermally insulated storage media containing platelet transfusion;
3. Thermostat device of the inner chamber storage media containing platelet transfusion;
4. System control device temperature control;
5. System sound and light warning of a fault;
6. Registration system (logging) of the parameters of the device and the process of storage media containing platelet transfusion;
7. AC power supply with automatic connection autonomous electric generator.

Figure 7 shows the appearance of intelligent storage devices containing platelets transfusion environments.

a) b)

Figure 7: The appearance of intelligent storage devices for transfusion environments containing platelets. 7a) - heat insulated chamber with thermostating electronic device and control system of storage regime parametres and 7b) – presents electro mechanic module.

The research object is a device for safe storage of transfusion environments containing platelets, loaded with 24 polymeric containers, filled with transfusion environments containing platelets. The containers are arranged on pallets of an electro-mechanical module without touching each other by four packages per pallet. The electromechanical module is housed within the chamber so as to provide free access to the cooling air from all sides. The module is driven by an electric motor connected via a reduction gear and an eccentric transmission with the mobile platform. According to preliminary evaluations the thermal power loss during operation of the system is 6 watts.

The device is designed as a metal enclosure that houses the thermally insulated chamber made of stainless steel, as well as ventilation, temperature control system, alarm system and recording parameters. On the front side of the device is hermetically sealed the door with a transparent glazing that allows to control the operation of the electromechanical module, as well as to monitor the number of containers filled with filled with transfusion environments containing platelets without opening the door and violations of the thermal regime.

To ensure a predetermined temperature two thermopile thermoelectric module based on Peltier elements are set at the back wall of the chamber.

As containers for transfusion environments containing platelets there are widely used special packages - products of company MacoPharma (France) in Russian hospitals. The container is produced of a soft polypropylene. In frames of presented research the volume of container is assumed to be 0.35 liters.

Thermal processes in solids are described by the heat equation, known an equation of energy conservation. The heat equation for a solid is obtained from the energy equation for the liquid medium in the absence of movement ($\vec{v} = 0$)

The heat equation is:

$$\frac{\partial}{\partial t}(\rho_i \cdot c_i \cdot T) = div(\lambda_i \cdot gradT) \quad (7)$$

In order to account heat transfer by means of radiation, the present mathematical model of thermal processes comprises radiation model (surface-to-surface), by means of which the radiant heat exchange between surface segments, which are the boundaries of individual regions is calculated.

The calculation of the total density of radiation flow on the surface is performed by the matrix method.

The boundary terms are:

- the condition of constant temperature at the outer edge of a device chamber $T_{CT} = T_{OKP\_CP}$ that is equal to ambient air temperature (is settled by regime parameters);
- the velocity of air flow on input and output faces of the ventilator is orthogonal to the input flatness and is constant $v_{vent} = const$;
- on the cold side of the thermoelectric module the heat flow is settled equal to a thermoelectric cooling module;
- radiant flow of thermal energy from the camera window is evenly distributed over the surface of the window. The integral value of the heat flow is equal to 5 W;
- heat dissipation from the engine module electromechanical uniformly is distributed over the surface of the engine. The integral value of the heat flow is equal to 6 watts;
- the ideal contact condition allows us to take the same temperature in the border areas on both sides of the interface.

As initial conditions the following are accepted:

- the same temperature of all objects in a design scheme, with the exception of container temperature are equal to the ambient air temperature;
- container temperatures are equal to temperature loads;
- the pressure inside the chamber is uniformly distributed and equal to atmospheric pressure.

In general, this equation system has no analytical solution. In order to get an approximate solution the numerical solution methods were used. To sample initial differential equations the method of finite volume was used.

The SIMPLE-like iterative algorithm was used for solving a system of differential equations. SIMPLE is derived from the Semi-Implicit Method for Pressure-Linked Equations (semi-implicit method for pressure bonding equations).

A simplified three-dimensional model of the device in accordance with the previously developed design has been developed to carry out the thermal design shown in figure 8.

As a boundary condition it is assumed that the temperature of the outer boundary of the chamber is constant and equal to the characteristic temperature for the selected thermal regime.

The thermopile is represented as a three-layer wall, through the middle layer of which is held constant heat flow, equal to the cooling capacity of the thermoelectric element. The maximum temperature difference between the hot and cold side is 69 ° C. Each of the inner presented as a parallelepiped, on one face of which is defined a velocity of suction flow, while the other is the velocity of injection.

Each of the containers for storage of the transfusion environments containing platelets is presented as a uniform medium parallelepiped, placed on the flat shelf. For each interface between the liquid and solid phases the process of convective heat transfer is considered.

Each homogeneous object design scheme the conduction heat transfer process is considered. Between each pair of segments of surfaces is considered the presence of radiant heat transfer,

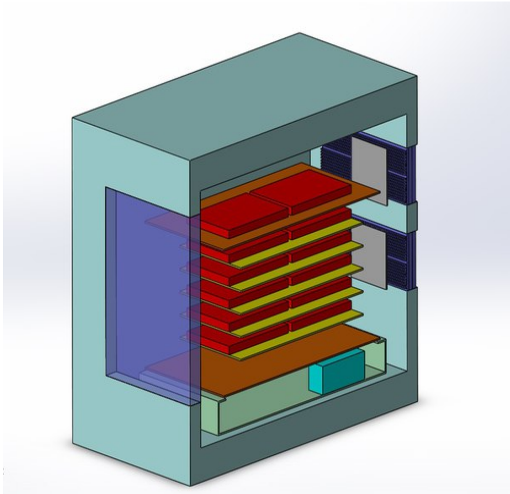


Figure 8: Cross-section of three-dimensional model of device for storage of the transfusion environments containing platelets.

which depends on the surface temperature. In case of shadowing the radiation heat transfer between the two segments is not considered.

To carry out the necessary calculations the material properties were selected on standard bases materials.

The change of the temperature distribution of the computational domain is shown in Figure 9. Each figure corresponds to a different time: 9a - the beginning of the calculation; 9b - 1min; 9c - 10min; 9d - 15min; 9e - 60min.

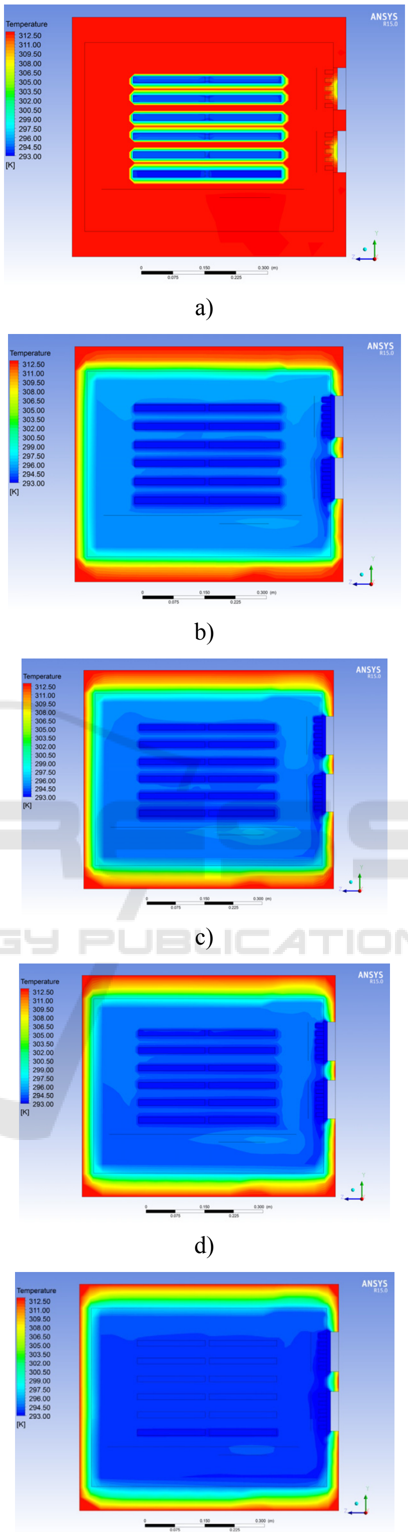
According to Fig. 9 it can be seen that the warmest air masses are concentrated in the top of the device for safe storage, and the coldest - in the region of the radiator of the thermoelectric module sensor.

The heat from the engine electromechanical module does not lead to a significant redistribution of temperatures.

As a result of this work has been developed a mathematical model of the thermogashydrodynamic processes during the incubation of biological objects in their storage devices.

In general, difference in temperatures between different zones of the cavity is small, and therefore the containers should have thermostated uniformly regardless of the position on the shelves of the electromechanical module.

To improve the reliability of the device and reduce the likelihood of a sudden its failure developed a system of registration of all of its settings and thus keep a record of the process of storage media containing platelets transfusion.



a)

b)

c)

d)

e)

Figure 9: Temperature distribution in calculation domain.

Protocol analysis parameters of the device reveals how repetitive unstable fault and mismatch control system temperature readings actual values. Conclusion protocol for printing entails the use of a switching system or directly with the printer, or a personal computer to which it is connected. In order to implement additional storage capabilities of protocols in electronic form for a long time it is advisable to connect the device to store environments containing platelets transfusion to a personal computer. For this purpose a corresponding interfaces.

One of the main criteria of quality assessment of transfusion environments containing platelets are the parameters of storage process that reflect the time dependence of storage temperature and allow to control observance of the temperature rates. Ensuring traceability of the movement and temperature control of these blood components at all stages of their storage and transportation in real climatic conditions of the environment from the moment of receipt in the blood bank to the transfer to the consumer is difficult, but actual task at the present stage of medicine development. It can be solved using radio frequency identification.

The development level of RFID technology allows to use for this purpose special tags using radio frequency electromagnetic radiation with a frequency of 13.56 MHz. Labels are fixed on the polymer containers with transfusion environments containing platelets and can be used for reading and writing of information up to 10 Mb (a bar code - about 100 bytes) with multiple overwrites. A donation number, a product code and temperature regimes of storage are fixed in the label. This information can be used in a central information system with the subsequent registration of all movements of the container with transfusion environments containing platelets.

The fig. 10 shows the structural scheme of the intelligent device for storage of the transfusion environments containing platelets.

The described device includes heat-insulated corpus 1 with transparent door of multi-layer glass with air space 2, door lock 3, control system 4,

connected with (n+1) temperature sensors 5 and 25 and with voltage sensor 6, first 7 and second 8 independent power supply, secondary power supply 9, that by means of voltage sensor is connected with electric power system, (n+1) units of semiconductor thermopiles 10 and 27, forced air circulation system 11, consisting of (n+1) ventilators 29, unit of alarm system and registration system of storage process parameters 12, connected with control system, with first independent power supply, with alarm light and sound system 13, interface box with personal computer 14 and sensor of door position 15, stirring system 16, including (n+1) mobile netted or perforated platforms 17 and 23 with nests for distribution of polymeric containers with transfusion environments containing platelets 18 and connected through movement interface box 19 with electro engine 20, switching unit of power supply facilities 21, the first entrance of it plugged into secondary power supply, control input of it is plugged into control system, and output – to electric engine, movement sensor 22, that is connected with mobile platform by optic or electromagnetic connection and is plugged into alarm system and registration system of storage process parameters, (n+1) simulators of polymeric containers (tubes with liquid) with transfusion environments containing platelets 26, inside of which temperature sensors are disposed, first commutator 28, connected with outputs with

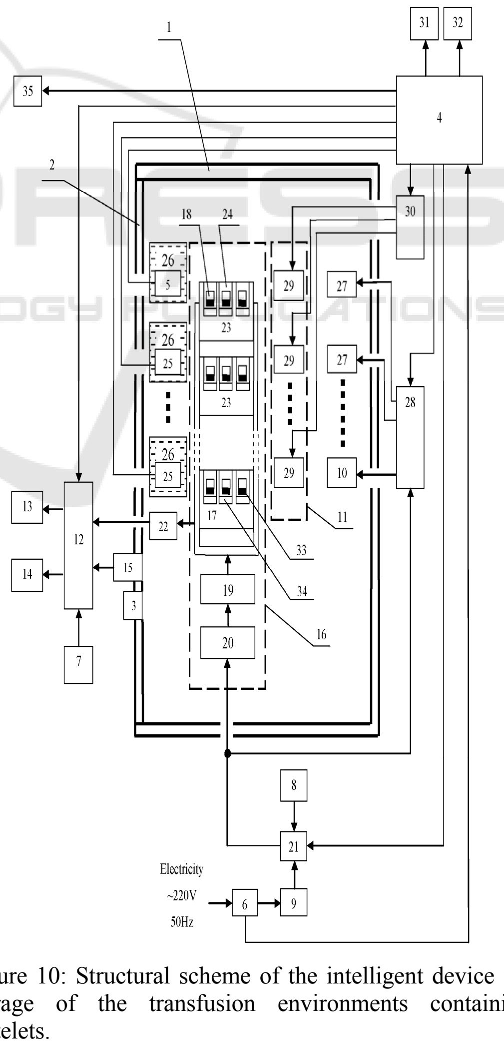


Figure 10: Structural scheme of the intelligent device for storage of the transfusion environments containing platelets.

(n+1) units of semiconductor thermopiles, input with switching unit of power supply facilities, second commutator 30, connected with outputs with (n+1) ventilators 29 of forced air circulation system, input with switching unit of power supply sources (at fig.1 the connection doesn't show), and control input with control system, bar-code reader 31, connected with control system, printer of RFID marks 32, connected with control system, RFID identification marks 32, connected with control system, RFID identification marks 33, anchored on polymeric containers with transfusion environments containing platelets, readers of RFID identification marks 33, disposed on platform nests for arranging polymeric containers with transfusion environments containing platelets and connected with control system, alphameric or graphic display 34, connected with control system.

3 CONCLUSIONS

Physical processes research of safe storage of biological objects under the temperature control conditions at high requirements to the temperature accuracy and temperature uniformity on the volume within ± 1 °C was carried out. The simulation of thermal processes in polymeric containers with PC was realized. These theoretical and experimental studies, as well as the development of new mathematical models of thermophysical processes will allow to create a scientific-methodical base for development of the optimizing technique of the device design for safe storage the transfusion environments containing platelets.

The results of these studies were used to create the experimental sample of the device for safe storage of transfusion environments containing platelets in which provides WHO requirements to PC storage modes , and remote monitoring and logging of PC storage modes using a personal computer.

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