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PORTABLE ISOLATION UNIT WITH POSITIVE AND NEGATIVE PRESSURE, FOR CONTAMINATED PEOPLE`S TRANSPORTATION

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Abstract: *Portable isolation units (PIUs) represent a critical component in the management of chemical, biological, radiological and nuclear (CBRN) threats, as well as for addressing broader medical needs during infectious disease outbreaks. These units are designed to offer a controlled environment that can be easily deployed to isolate individuals either suspected of carrying infectious agents or contaminated with hazardous materials. The functionality of PIUs is enhanced by their ability to maintain specific atmospheric conditions, such as positive or negative pressure, to prevent the spread of contaminants. In the context of CBRN threats, PIUs provide a safe space for decontamination and initial medical treatment, reducing the risk of broader environmental contamination and exposure. Similarly, during pandemics or outbreaks of highly infectious diseases, PIUs are indispensable for containing pathogens and protecting both healthcare personnel and the public. This study outlines the design and testing of the BIOEVAC portable isolation unit, which can operate with both positive and negative pressure for transporting contaminated individuals. Originally developed as a technological demonstrator during the COVID-19 pandemic for emergency use, its capabilities have been enhanced and it has now been transferred to the industry for mass production.*

Keywords: portable isolation unit, CBRN protection

1. Introduction

Protective enclosure systems designed for transporting contaminated and wounded individuals, have become increasingly vital in healthcare and military contexts. These systems are engineered to provide a controlled environment that minimizes the risk of infection during transport, making them essential for both emergency medical services and military operations. The technology encompasses enclosures that can maintain either an overpressure to prevent external contaminated air from entering or a negative pressure to contain and control the internal environment, crucial for isolating airborne pathogens. The COVID-19 pandemic has significantly influenced the global production and development of these systems. The surge in demand for protective measures during the pandemic led to a rapid increase in the production of medical isolation and transportation systems. Manufacturers worldwide have been pushed to innovate and scale production not only to meet the immediate healthcare needs but also to prepare for future medical crises. The pandemic underscored the importance of having robust and flexible protective systems that can be quickly deployed in various emergency scenarios, leading to advancements in modular design and multi-

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functionality of enclosures [1, 2]. These developments aim to provide enhanced safety for healthcare workers and patients alike, ensuring that high-risk individuals can be transported without increasing the exposure to a virus. The focus has been on creating more efficient, user-friendly, and effective systems that can adapt to the challenges posed by different pathogens, with an emphasis on sustainability and ease of deployment in diverse conditions [3]. This study presents designing and testing of BIOEVAC portable isolation unit (Figure 1) with positive and negative pressure, for contaminated people`s transportation, which was developed as technological demonstrator during COVID-19 pandemic for the emergency purposes, have been improved its capabilities and was transferred to the industry for mass production.

2. Design and Functionality

In enclosed transportation systems intended for personnel contaminated during chemical and biological incidents, maintaining and controlling positive and negative pressure environments is pivotal for ensuring safety and containment. *Positive pressure* environments, where the internal air pressure exceeds that outside, prevent the ingress of contaminated air. This is crucial in shielding uninfected or minimally contaminated individuals inside from airborne pathogens or toxic chemicals. Such systems are typically employed in mobile medical units and transport vehicles designed to manage outbreaks, where sterility and prevention of external contamination are critical. Conversely, *negative pressure* environments involve a lower internal air pressure, drawing air into the enclosure and preventing the escape of contaminated air. This setup is instrumental in environments where containment of noxious vapours or biological agents is necessary to protect the surrounding environment and facilitate the safe decontamination of occupants. This method is vital in managing the risks associated with the external release of hazardous substances, ensuring that any potentially harmful agents remain confined within the transportation unit. Both systems are integral to safely managing and transporting individuals who have been exposed to chemical or biological hazards. The choice between positive and negative pressure depends on the primary goal - whether to protect those inside the enclosure from external contamination (positive pressure) or to protect the external environment from contaminants within (negative pressure). These systems are designed to be adaptable to the nature of the threat and the specific requirements of the response operation, ensuring both containment and protection in response to chemical and biological emergencies.

The operating principle of BIOEVAC portable isolation unit is based on the circulation of a controlled flow of filtered/decontaminated air (through CBR filters at the inlet in the case of positive pressure systems or through HEPA/ULPA filters at the outlet in the case of negative pressure systems) inside the isolation enclosure, enclosure made of materials with high protection capacity against CBR agents, which provides a “barrier” between the injured / patient and the surrounding environment.

Major components of BIOEVAC are: *The transport system* arranged on a folding metal frame, stretcher type and made of light materials that can support a load of over 130 kg. *The protective enclosure against toxic chemical and biological agents* is made of polyester material rubberized with flame retardant brominated butyl-polyethylene rubber. Blocks of valves are arranged on the protective enclosure to remove the air in case of an overpressure inside the enclosure, out of defined range. The enclosure is provided on the sides with a strengthening and support system and with straps for fixing in the transport system. *The windows* of the protective

enclosure are made of multi-layer polyethylene-polyamide-polyethylene film resistant to toxic agents. *The filter module*, which allows operation both in air intake and exhaust mode, is found inside a stainless-steel case, equipped with gaskets to ensure its sealing. *The transport bag* is made of laminated polyester fabric, material resistant to tearing, tearing and rainproof.

Figure 1: BIOEVAC portable isolation unit design and prototype

3. Methods and Results

The testing strategy consisted in checking the technical, safety and performance parameters of the product in accordance with the technical documentation.

For this, the testing-evaluation was conducted in three main directions defined by *testing the transport resistance capacity* (load, mechanical resistance), *testing the protection capacity of the patient or the medical staff* depending on the contaminated part using positive or negative pressure (filter protection capacity, materials resistance to toxic agents, filter-ventilation system autonomy) and *demonstration of the functionality of the entire system in relevant conditions.*

3.1. Physical and Mechanical Tests

After inspection, it was demonstrated that the product is provided with a system for fixing and securing the patient during transport, made of a strap equipped with fixing buckles, it allows monitoring the patient through 4 windows, it has 4 connected gloves that allow the provision of first aid by specialized personnel, without coming into direct contact with the patient and allows the patient to be connected to medical equipment located outside the premises. The transport resistance of the system was demonstrated by loading it with a load of 150 kg and carrying out specific transport movements for 10 minutes, the enclosure showing no signs of wear or damage. The tear resistance and tensile strength of the materials were tested in accordance with SR EN ISO 1421 [4] and SR EN ISO 4674-1 [5]. The determinations were made using a machine for the static tensile test at a nominal moving speed of the mobile clamp of 100 mm/min, determining the tear resistance and tensile strength in each direction, warp and weft. The warp consists of stationary lengthwise threads on the fabric loom, parallel to the selvage. They support the weft, which are horizontal threads woven over and under the warp. Testing was performed on samples that were conditioned at temperatures of -32°C and +49°C for 24 h. Values of over 703 N were determined for each tear resistance test on the warp direction and over 477 N for the samples on the weft direction (initial and conditioned at extreme temperatures), considering the minimum standard requirement of 600 N for the warp, respectively 400 N for the weft. Values of over 15.0 N were determined for each tensile strength test on the warp direction

and over 12.8 N for the samples on the weft direction (considering the minimum standard requirement of 14 N for the warp, respectively 12 N for the weft. Same tests were performed for multi-layer polyethylene-polyamide-polyethylene film, in accordance with SR EN ISO 527-3 [6] and SR EN ISO 6383-1 [7]. The values measured for the tear resistance were over 15 MPa for the longitudinal direction and over 13 MPa for the transverse direction, taking into account the provisions of the standard to obtain a resistance of at least 14 MPa longitudinal and at least 12 MPa transverse. For tensile strength measures were obtained values of over 21 N/mm for longitudinal direction and over 16 N/mm for transversal direction, at a minimum standard requested value of 20 N/mm, respectively 15 N/mm. All the measurements were performed on initial materials, after exposing the batches at of -32°C for 24 h, and at +49°C for 24 h. The determination of the resistance to perforation was carried out by moving the test needle with a speed of 100±10 mm/min towards the sample. Values between 28 and 41 N were obtained, at a minimum requirement of the SR EN ISO 863 standard, of 25 N. Figure 2 summarizes the measured values compared with the minimum values requested by standards, for the protective enclosure material and for the window multi-layer material.

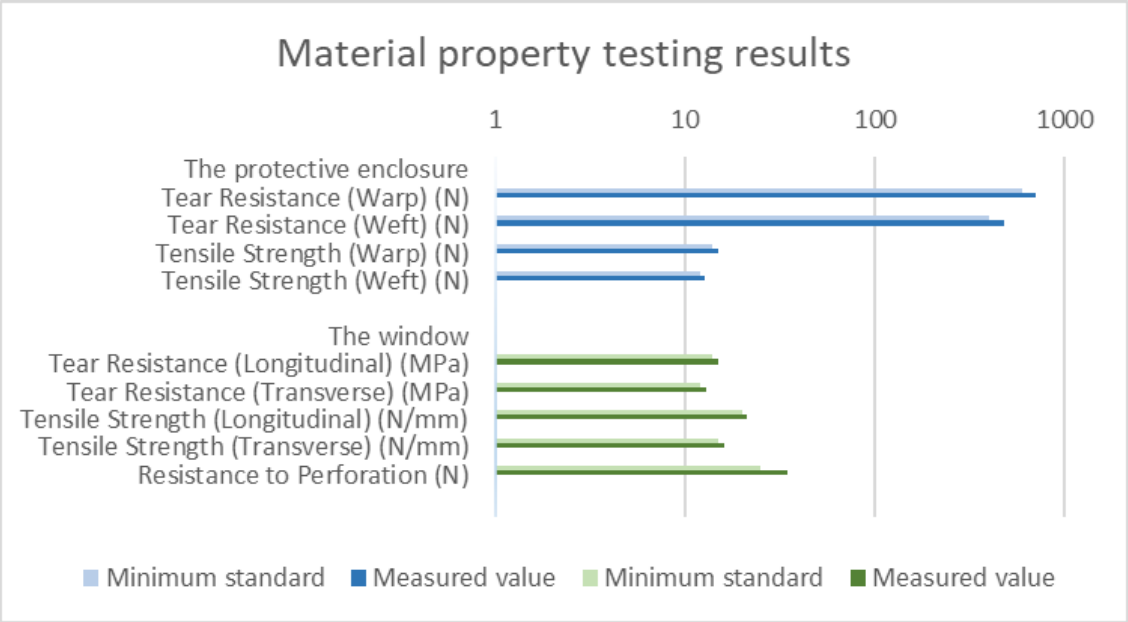

Figure 2: Material property testing results

3.2. The Capacity to Protect against Chemical and Biological Hazards

The method used to determine the protection time against droplets of chemical warfare agents was the static test with mustard gas droplets with a contamination density of 10 g/m^2. The tests were carried out at a temperature of 36.5±0.50°C, in a thermostated oven. Toxic substances diffuse through the protective material in the direction of decreasing concentration gradient, until they pass through the entire thickness of the material and come out on the side opposite to the contaminated one. From the material subjected to testing, circular samples of the material were taken which were contaminated. The sampling was done from different places, representative for the tested products. The testing was also performed on samples that were conditioned at temperatures of -32°C, respectivle +49°C for 24 h. The results obtained showed a protection of over 8 hours, at the action of a penetrating

chemical agent. After determining the efficiency of the anti-aerosol filter for particles simulating a biological load, it was demonstrated that the filter element is class H14. In addition, a series of tests were performed on the aerosol penetration coefficient/filtration efficiency, using paraffin oil aerosols with dimensions of approximately 0.3 μm, the demonstrated efficiency being > 99.995%. The positive and negative pressure was checked by direct measurement. Following the measurements carried out with the help of a differential manometer, values were obtained in the range of 80÷110 Pa for the positive pressure and between -60÷ -40 Pa for the negative pressure, depending on the position of the speed variator. The portable isolation unit was decontaminated with an alcohol-based solution and no damages were observed.

3.3. Functionality of the System

The functionality of the entire system was demonstrated by carrying out some exercises in simulated conditions and by using it in real conditions during the COVID-19 pandemic. The operating time of the filter-ventilation module, mounted in the complete configuration of the product, it was measured, and was concluded that the filter-ventilation system has an operating autonomy of over 4.5 h.

4. Conclusions

The presents study summarized a full range of tests and measurements realized over a newly developed product. Comparing the results with the standards requirements, it can be concluded that the BIOEVAC portable isolation unit with positive and negative pressure successfully passed the developmental assessment testing program, at industrial prototype – zero series production level.

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