A Portable BVM-based Emergency Mechanical Ventilator

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***Abstract*—The paper deals with development of an artificial lung ventilation. The aim of the paper is to present developed ventilator based on bag-valve-mask, which could be used as alternative to mechanical ventilator in critical situations related to COVID-19. At first, we present basic principles of positive pressure ventilation. Subsequently, we introduce a requirements to emergency mechanical ventilator in order to be suitable alternative in hospitals as well as in households. The mechanical and control design are presented in the next section. Finally, we experimentally verify developed ventilator with focus on measured pressure of patient airways. The presented results show a potential of developed ventilator to be used at practical level.**

***Index Terms*—artificial lung ventilation, control system, coronavirus, COVID-19, IoT, pneumatic system**

I. Introduction

COVID-19 (Coronavirus disease 2019) has became global world pandemic with exponential growth rate. The virus is manifests commonly with little or any symptoms, but can also lead to a rapidly progressive fatal pneumonia of infected [1]. Up to now (October 2020), COVID-19 reaches 2,98% mortality from all infected subjects [2] [3].

In general, the process of mechanical ventilation controls a flow, volume, and pressure of air and gases to a patient´s lung [4]. An artificial lung ventilation (ALV) represents the way of respiration. The respiration device provides flow of a gas through a respiration system. ALV is either used for short-term or long-term support for patients with serious damage of their respiration system. From the clinical point of view, ALV is support with potential risks and complications, which need to be known in order to get suitable clinical results [5]. Study from 2013 declares, that it is estimated, that ALV is required by roughly 1.5 millions of patients in United States every year [6]. According to [7] [8], the mortality of patients undergoing ventilation during critical disease is 31–37%. A decision to use ALV is based on several factors and should be carefully evaluated. The rough factors are evaluation of parameters of oxygenation, ventilation, lung mechanic, and condition of infected person. However, very significant is evaluation of past condition as well as supposed progress of patient condition. This concept seems to be more suitable rather than only evaluation of boundary values of concrete indicators. Each patient is unique and its condition can be specific, and therefore, ALV should be optimized according to patient´s lung mechanics [5].

Since, the situation with COVID-19 has grown to a global scale, our research team has focused on development of robust, portable, and stable alternative solution resulting in emergency mechanical ventilator. The paper is organized as follows. At first, previous solutions of BVM-based mechanical ventilator are introduced. The 3rd section deals with design of our solution. We introduce the basic principles of ALV and also our requirements to developed ventilator. Next, we introduce

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mechanical design and subsequently control system design of mechanical ventilator. Finally, we present experimental results obtained during a ventilation.

II. Related works

There are several different techniques of mechanical ventilation such as mouth to mouth and mouth to nose, but bag-valve-mask (BVM) teqnique is still commonly used in emergency situations [9]. As have been mentioned, this work is focused on simple and low-cost mechanical ventilation, which has potential to be produced quickly and in large quantities. The importance of this mechanical ventilator occures in very critical pandemic situations, where the number of critical patients exceeds the number of available high-level ventilators in a hospitals.
The following section described related works with focus on BVM ventilators.
In [10] authors developed microcontrolled-based mechanical ventilator with BVM mechanism. The ambu bag is pressed by arm based on CAM principle. The system is able to work in several modes such as child mode, pediatric mode, and adult mode. In [11] authors deal with low-cost, open-source mechanical ventilator. The work was initiated by worldwide shortage of mechanical ventilators for treating with COVID-19. The system uses ambu bag, which is pressed by Raspberry Pi-controlled mechanism. The ventilator uses pressure sensor, which is able to measure maximum pressure up to 70 cmH_20. Another low-cost portable mechanical ventilator based on compressing BVM with pivoting CAM arm is described in [12]. The ventilator is controlled by Arduino. The prototype had user-controlled breath rate and tidal volume. It features assist control and an over-pressure alarm. Next work dealing with simple ventilator is [13]. The experimental results were consistent with clinical requirements from the view of achieved volume and pressure. The authors discussed challenges for the future work of their ventilator such as reliability of the mechanisms and software, mass production with appropriate standards, and regulatory approval or exemption. In [14] the authors developed simple and easy-to-build portable automated BVM compression system which can serve as emergency ventilator. The system is controlled by Arduino. The device provides a controlled breathing mode with tidal volumes from 100 to 800 mL, breathing rates from 5 to 40 breaths/minute, and inspiratory-to expiratory ratio from 1:1 to 1:4. The experimental results showed repeatability and accuracy exceeding human capabilities in BVM-based manual ventilation.
Based on above mentioned works as well as on other BVM-based ventilations, the most of them use electrical motor to compress a BVM. Our solution is based on pneumatic system which compress BVM, since in the hospitals commonly are the supplies of compressed air. In the case of absence of compressed air supply, the system can use mobile air compressor. The following section describe development of our ventilation system.

III. Design of Artificial Lung Ventilator

A. *Principle of Artificial Lung Ventilator*

This section will describe basic principles of positive pressure ventilation. By incorrect application of mechanical ventilator can be caused a destruction of a lung - VILI (ventilator-induced lung injury). In the case of excessive expansion of the lung can be caused an excessive mechanical pressure acting on lung structures by pulling. In other words, this effect can occur either for too high end-inspiratory lung volume (EILV) or for too low end-inspiratory lung volume. Next factors affecting affecting VILI are endotoxinomy, temperature, lung capillary pressure, respiratory rate, and genetic predisposition [5].
With consideration of mechanism which ensures a gas flow through a respiration system during breathing, there are four groups of artificial ventilation, namely positive pressure ventilation (PPV), negative pressure ventilation, jet ventilation, and high-frequency ventilation [5]. A ventilation mode is defined by control algorithm, which is based on information about pressure and/or gas flow through a ventilator. Considering the gas motion direction, it is possible to divide a respiratory cycle to the following four phases.

- Inspiration phase - An activity of ventilator is controlled by some control parameter like pressure or gas flow. In the next process of inspiration phase, the ventilator is limited for pressure or gas flow increase. Once the condition of limitation has been fulfilled, the ventilator leaves an expiration valve closed until inspiration phase does not finish. Then the ventilator continue to a inspiration pause or directly to an expiration phase.
- Inspiration pause - Standstill of gas flowing through an airways and intrapulmonary redistribution of tidal volume is in a progress. By applying of inspiration phase, a distribution homogeneity of ventilation should be improved.
- Expiration phase - From the view of ventilator, this is a passive phase of respiratory cycle. An exhalation is achieved by expiratory muscles of patient.
- Expiration pause - A phase started by ending of air flowing from patient up to next respiratory cycle, which starts with inspiration phase again.

Due to the fact, that patient has to overcome a valve resistance during a spontaneous breathing, it is necessary to add a pressure support ventilation (PSV) with minimally value of 5-10 cmH_20. In general, at the end of expiration, there is the pressure in airways, which is higher than atmospheric pressure. This is known as positive end-expiratory pressure (PEEP). PEEP pressure can be low, middle, and high. The low PEEP is up to 5 cmH_20, middle is up to 5-10 cmH_20, and high PEEP is above 15 cmH_20. Within this work we will do experiments with consideration of low PEEP, which are generally used for patients without pulmonary pathology. This is a group of patients, to whom is this kind of emergency ALV dedicated. However, when PEEP levels are too high, over distension of alveoli may cause VILI [15]. On the other hand, an inspiratory positive airway pressure (IPAP) or peak inspiratory pressure

(PIP) is the maximum pressure applied to the subject by a mechanical ventilator during inhalation.

B. Requirements on Mechanical Ventilator

Immediately, when COVID-19 officially has appeared in Central Europe (February 2020), our research team from Cognitics Lab, started work on own mechanical ventilator. The requirements on mechanical ventilator were as follows:

- Portability - A mechanical design should offer a option to use a mechanical ventilator in hospitals or in households. Hence, the portability is important property. A ventilator should be easily displaced from one to the next required place. In the case of need, developed ventilator should have also a potential to be used in outdoor applications. From this reason, our ventilator can be used in version with wheels as well as without wheels with consideration of manual transmission.
- Simplicity - Considering today´s situation, a simplicity of ventilator is one of the key elements. The ventilator consists of components which can be very easily replaceable. Some of used components are printed by 3D printer and some of them are conventional industrial components which are commercially available. The simplicity of ventilator ensures fast production of many others ventilators for the cases of unmanageable pandemic situations, where there may be a shortage of professional ventilators in the hospitals.
- Fast reproducibility - Since, one of the main aims of our ventilator is utilization in very critical situation in the case of shortage of professional ventilators, we designed ventilator which is able to be fast reproducible. From this reason, a mechanical and electrical design is adapted to this point.
- Robustness - A mechanical robustness of ventilator is important point especially for an outdoor applications such as field hospitals.
- Hospital - Household utilization - Except for hospital utilization of our ventilator, it has also potential to be applied in households especially for seniors.
- IoT - Next important requirement to ventilator was an internet access ability. By this way can be collected data during ventilation process and save to database. Consequently can be done necessary statistics and analyses of ventilation process of patients.

C. Design of Mechanical System

A mechanism of BVM compression is based on pneumatic system. Many of hospitals in Slovakia have compressed air supply (5 bar) within their buildings. From this reason our system works on pneumatic-based mechanism. The main parts of our ventilator are frame, air compressor, bag-valve-mask, sensors, cover box and PLC, see Fig. 1. The frame consists of Bosch Rexroth aluminum profiles which are suitable for fast assembling of constructions. They are standardly used in industry as a part of production lines. An air compressor serves as energy supply for pneumatic system, placed inside a cover box. As have been mentioned, the system is uses BVM, which is compressed by double acting pneumatic actuator. We have used test lung for experimental verification of ventilator functions and suitability. As can be seen in Fig. 1, there is sensors interface between test lung and inlet hose. This interface contains sensor of pressure and sensor of air flow. An operator can set necessary parameters trough touch screen of PLC B&R. The operator is also able to check parameters of ventilation such as pressure, air flow, etc.

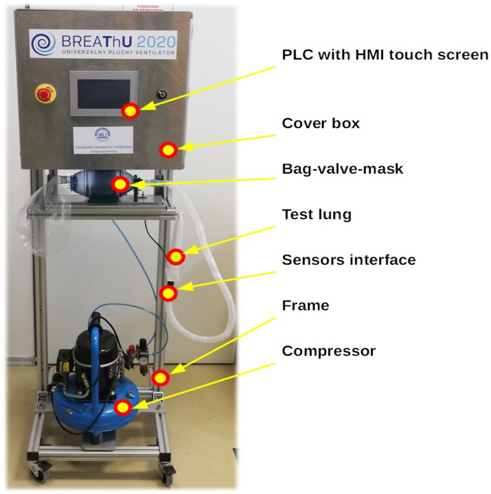

Fig. 1. Developed mechanical ventilator

D. Design of Control System

We have developed a control system of mechanical ventilator on two levels. The first one is low-level and the second is high-level. The low-level control system is based on microcontroller Atmel ATxmega16E5 which communicates with pressure and flow sensors. We have used pressure sensor SPD005g which has analog output and air flow sensor SFM3300-250 communicating with microcontroller through I^2C. ATxmega16E5 works on frequency 32 MHz. The data from sensor SPD005g are filtered by trimmed mean filter because of sensor signal noise [16]. Microcontroller processes data from sensors and transmits them with frequency 20 Hz through RS-422 half-duplex to PLC. The high-level control system works on PLC B&R 4PPC70.0702-20W. The PLC receives the data from microcontroller and using fuzzy algorithm it controls pneumatic cylinder which compresses BVM. The aim of designed algorithm is to positioning of pneumatic cylinder in order to achieve desired pressure incoming to a patient [17] [18]. Constant pressure 4.5 bar from air compressor is achieved by electro-pneumatic regulator SMC ITV1050-31F2N. The air flow, which flows to the pneumatic cylinder is controlled by electro-pneumatic regulator ITV3050-03F4BN2-X15. The concept of whole system is shown in Fig. 2.

The data signals are denoted by black colour on Fig. 2. There is also possibility to connect PLC to internet and send data from ventilation to database. Subsequently, these data can be monitored or processed by user through PC, tablet,

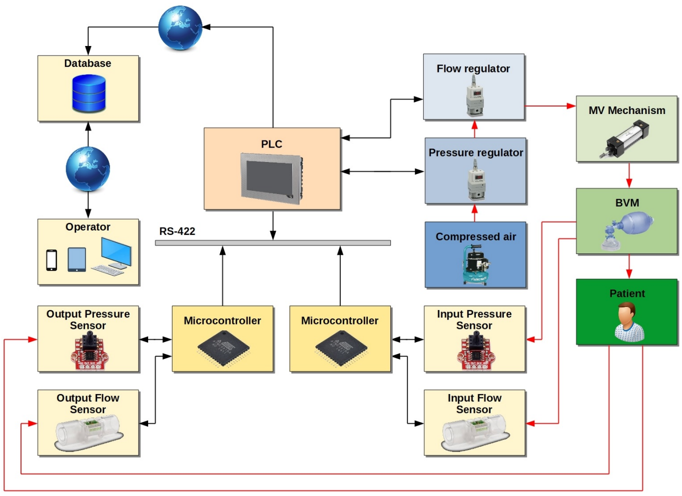

Fig. 2. Control system of BVM-based mechanical ventilator

mobile phone, etc. HMI (human machine interface) offers clear and simple environment, which ensures comfortable service. An operator has several options how to adjust the ventilation process. At first, it is possible to set a pressure of inspiration and expiration in cmH_2O units. Next important parameter is a time of inspiration and expiration phase. A real-time course of individual parameters may one watches on HMI by means of graph.

IV. Experiments and Discussion

The purpose of experimental analysis was verification of suitability and quality of ventilation according to required standards. It is clear, that emergency ALV based on BVM, cannot achieve such results which are required from professional lung ventilators. The main aim of the experiments is to verify a time course of pressure in a test lung. We have tested the developed ALV with consideration of 5 cmH_20 for PEEP. Inspiration pressure will change from 17 up to 25 cmH_20. The inspiration time vary from t_i = 0.5 s up to t_i = 0.7 s and expiration time is set to be t_e = 1.5 s.
As can be seen from the Fig. 3, 4, 5, the controlled pressure (red colour) incoming to the respiratory tract of a patient, roughly tracks required pressure (blue colour). There can be also seen gradual decline of pressure during the expiration phase caused by PEEP valve, which is set to be 5 cmH_20 from the reasons mentioned above in theoretical section. Comparing the expiration pressure with and without PEEP valve can be seen in Fig. 6. The difference between case with and without PEEP valve is evident. Using PEEP valve the pressure decrease slowly. When PEEP valve is not present the pressure decrease almost immediately. However, disadvantage of PEEP-less version is decline of pressure under required low value of expiration pressure value, see Fig. 6. This state could be potentially dangerous for a patient. It has to be noticed, that problematic control of expiration pressure is caused especially due to the fact, that the ventilator is based on BVM in cooperating with pneumatic system of compressing.

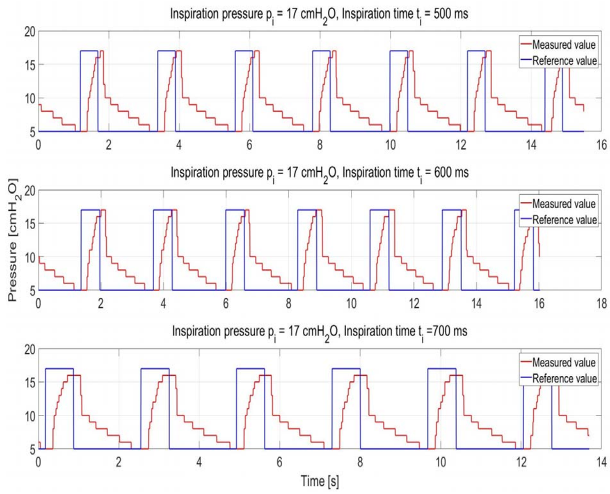

Fig. 3. Time course of pressure, reference pressure p_i=17 cmH_20

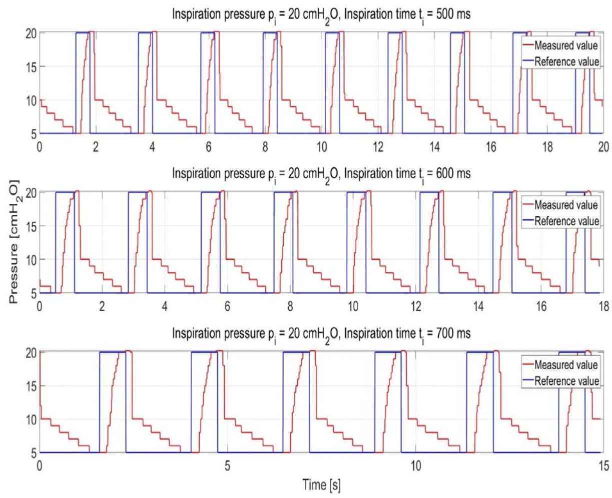

Fig. 4. Time course of pressure, reference pressure p_i=20 cmH_20

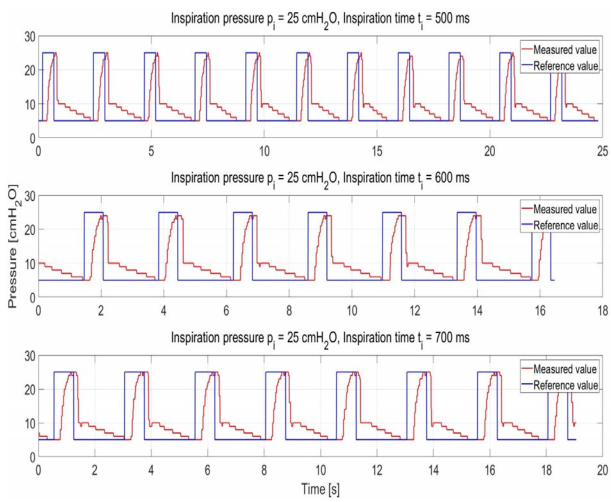

Fig. 5. Time course of pressure, reference pressure p_i=25 cmH_20

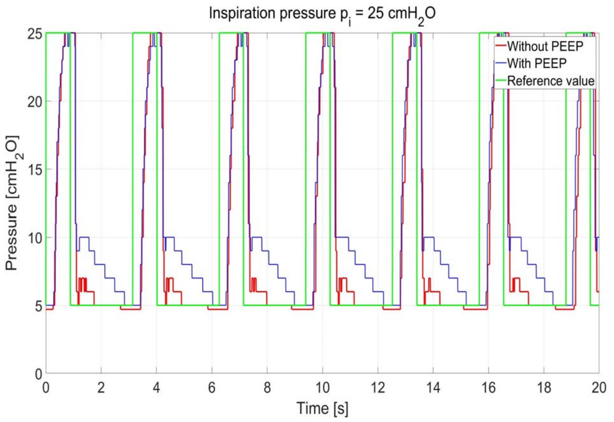

Fig. 6. Time course of pressure with and without PEEP valve

By gradual compression of BVM by pneumatic cylinder extension the pressure before test lung increases gradually. On the other hand, by very low insertion of cylinder, the pressure before test lung decreases rapidly and from this reason it is problematic issue from the view of control. This point is critical and it is caused by character of BVM.

V. Conclusion and Future Work

The paper describes BVM-based mechanical ventilator. Our requirements to development of low-cost mechanical ventilator were: simplicity, robustness, portability, fast reproducibility, and utilization in hospitals, in field hospitals and in households. The character of IoT is the next significant element of our developed ventilator. Mechanical side of ventilator is designed to be fast reproducible in the case of critical situations, where shortage of professional ventilators would occur. The ventilator has the potential to be used also in households for patient without pulmonary pathology. The developed mechanical ventilator is designed especially for the patients with light course of lung disease.

From the experimental results can be seen usability of developed low-cost mechanical ventilator. On the other hand has to be noted, that the main disadvantage of designed concept is the use of BVM, which is problematic from the view of precise pressure control.

Our future work in developed ventilator is focused on fully assisted ventilation, where ventilator would be able to set a frequency of the inspiration and expiration phase in cooperation with patient breathing.

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References

[1] Hoehl, S. et al. Evidence of SARS-CoV-2 infection in returning travelers from Wuhan, China. N. Engl. J. Med . https://doi.org/10.1056/NEJMc2001899 (2020).
[2] Available: https://www.worldometers.info
[3] Available: https://coronavirus.jhu.edu/map.html
[4] Gattinoni, L., Caironi, P., Cressoni, M., Chiumello, D., Ranieri, V.M., Quintel, M., Russo, S., Patroniti, N., Cornejo, R., Bugedo, G., Lung recruitment in patients with the acute respiratory distress syndrome. N Engl J Med. 2006 Apr 27;354(17):1775-86. doi: 10.1056/NEJMoa052052. PMID: 16641394.
[5] Dostál, P., Základy umělé plicní ventilace, ISBN 80-7345-059-3, 2004, T.A.V.A. books s.r.o.
[6] Das, A., Menon, P. P., Hardman, J. G., Bates, D. G., Optimization of Mechanical Ventilator Settings for Pulmonary Disease States, IEEE Transaction on Biomedical Engineering, Vol. 60, No. 6, 2013
[7] Esteban, A., Anzueto, A., Frutos, F., Alia, I., Brochard, L., Stewart, T. E., Benito, S., Epstein, S. K., Apezteguia, C., Nightingale, P., Arroliga, A. C., Tobin, M. J., Characteristics and outcomes in adult patients receiving mechanical ventilation: A 28-day international study, J. Amer. Med. Assoc., vol. 287, pp. 345–355, 2002.
[8] Esteban, A., Ferguson, N. D., Meade, M. O., Frutos-Vivar, F., Apezteguia, C., Brochard, L., Raymondos, K., Hurtado, J., Tomicic, V., Elizalde, J., Nightingale, P., Abroug, F., Pelosi, P., Arabi, Y., Moreno, R., Jibaja, M., D'Empaire, G., Sandi, F., Matamis, D., Montanez, A. M., Anzueto, A., Evolution of mechanical ventilation in response to clinical research, Am. J. Resp. Crit. Care, vol. 177, pp. 170–177, 2008.
[9] Khoury, A., Hugonnot, S., Cossus, J., De Luca, A., Desmettre, T., Sall, F. S., Capellier, G., From Mouth-to-Mouth to Bag-Valve-Mask Ventilation: Evolution and Characteristics of Actual Devices—A Review of the Literature, BioMed Research International, dx.doi.org/10.1155/2014/762053
[10] Islam, M. R., Ahmad, M., Hossain, M. S., Islam, M., Uddin Ahmed, S. F., Designing an Electro-Mechanical Ventilator Based on Double CAM Integration Mechanism, 2019 1st International Conference on Advances in Science, Engineering and Robotics Technology (ICASERT), Dhaka, Bangladesh, 2019, pp. 1-6, doi: 10.1109/ICASERT.2019.8934562.
[11] Acho, L., Vargas, A.N., Pujol-Vázquez, G., Low-Cost, Open-Source Mechanical Ventilator with Pulmonary Monitoring for COVID-19 Patients. Actuators 2020, 9, 84.
[12] Al Husseini, A. M., Lee, H. J., Negrete, J., Powelson, S., Servi, A., Slocum, A., Saukkonen, J., Design and Prototyping of a Low-cost Portable Mechanical Ventilator, Proceedings of the 2010 Design of Medical Devices Conference, 2010.
[13] Castro-Camus, E., Ornik, J., Mach, C., Hernandez-Cardoso, G. G., Savalia, B., Taiber, J., Ruiz-Marquez, A., Kesper, K., Konde, S., Sommer, C., Wiener, J., Geisel, D., Huppe, F., Kraling, G., Nguyen, J., Wiesmann, T., Beutel, B., Koch, M., Simple ventilators for emergency use based on Bag-Valve pressing systems: Lessons learned and future steps, DOI https://doi.org/10.1101/2020.04.29.20084749, medRxiv The preprint server for health sciences (2020).
[14] Petsiuk, A., Tanikella, N. G., Dertinger, S., Pringle, A., Oberloier, S., Pearce, J. M., Partially RepRapable automated open source bag valve mask-based ventilator, HardwareX (2020), Vol. 8, DOI https://doi.org/10.1016/j.ohx.2020.e00131.
[15] Dreyfuss, D., Saumon, G., Ventilator-induced lung injury. Lessons from experimental studies. Am J Respir Crit Care Med. 1998;157:294–323.
[16] Oten, R., de Figueiredo, R. J. P., Adaptive alpha-trimmed mean filters under deviations from assumed noise model, in IEEE Transactions on Image Processing, vol. 13, no. 5, pp. 627-639, May 2004, doi: 10.1109/TIP.2003.821115.
[17] Virgala, I., Kelemen, M., Prada, E., Lipták, T., 2015. Positioning of Pneumatic Actuator Using Open-Loop System. AMM 816, 160–164. https://doi.org/10.4028/www.scientific.net/amm.816.160
[18] Prada, E., Virgala, I., Granosik, G., Gmiterko, A., Mrkva, S., Simulation Analysis of Pneumatic Rubber Bellows for Segment of Hyper-Redundant Robotic Mechanism, Applied Mechanics and Materials 611 (August 2014): 10–21. https://doi.org/10.4028/www.scientific.net/amm.611.10.