Analysis of Mechanical Properties of Dialysis Sets

Klara Fiedorova[1], Martin Augustynek[1], Frantisek Fojtik[2] and Milada Hlavackova[2]

[1]*VSB Technical University of Ostrava, Faculty of Mechanical Engineering, Department of Cybernetics and Biomedical Engineering, Ostrava, Czech Republic*

[2]*VSB Technical University of Ostrava, Faculty of Mechanical Engineering, Department of Applied Mechanics, Ostrava, Czech Republic*

Keywords: Blood Dialysis Set, Haemodialysis, Mechanical Properties of PVC, Mechanical Tests.

Abstract: Dialysis sets are part of the dialysis circuit and are used every day. It is important to find out how the dialysis sets behave under load and whether they retain their typical properties, which are the strength and flexibility. Therefore, the mechanical properties of the dialysis sets are evaluated depending on the selected physical parameters. For this reason, the sets are subject to temperature changes and changes in the pressure of the peristaltic pump occlusion cylinders. To evaluate the mechanical properties of the dialysis sets, the sets were subjected to stress tests and subsequent tests. The results were processed and analysed.

1 INTRODUCTION

Work deals with dialysis sets. Set are used during blood dialysis. They ensure the transfer of blood flowing from the patient's body to a blood-purifying dialysis machine and to return the purified blood back to the patient's body. The material from which the dialysis sets are made is very important. Material biocompatibility is an important component for the success of hemodialysis. The set is not to produce thrombogenic, inflammatory, immune or toxic reactions. The dialysis sets must meet the criteria, such as mechanical strength of material and optical properties. Therefore it made of polyvinyl chloride. Due to their chemical composition today they are condemned. (Augustynek et al., 2014), (Neergaard et al., 1971), (Liao et al., 2003) Therefore, the products emerging from alternative materials. But the use of PVC medical devices is still very important, because some of the alternative materials do not have the necessary properties. (Kostic et al., 2017)

The result of the work should be an analysis of the mechanical properties of dialysis sets. These properties are dependent on physical parameters. Mechanical properties mean the behaviour of materials under the influence of external mechanical forces. Sets are exposed to deformation by pressure of occlusion cylinders and change in temperature of saline. Dialysis sets must be strength, elasticity and malleability to withstand stress tests. It is assumed that under optimal conditions the dialysis sets meet the standards. However, if the set goes through a series of loads, measurements should demonstrate the change of mechanical properties of dialysis sets. This work focus on a group of AV dialysis sets, which are most commonly used today. Because dialysis sets are used during blood dialysis, their properties may affect the quality of therapy. Therefore, in this work, the sets undergo a load and subsequent mechanical tests of physical properties. By analyzing the obtained data we are able to determine the limit of the mechanical load so as to avoid a malfunction. (Brugger, 1999), (Beisser and Oesterreich, 2018)

1.1 Properties of Dialysis Sets

Set should guarantee a safe path of blood from the patient's body and return cleaned blood back. It belongs to special medical supplies, which must meet certain characteristics. In order to be able to fulfil its function, set made from polyvinyl chloride. To ensure the necessary features of the sets, PVC is softened by the plasticizer during production. The most commonly used plasticizer is di-ethylhexyl phthalate (DEHP hereinafter). (Neergaard et al., 1971), (Kostic et al., 2017)

Another reason for using PVC in making dialysis sets is transparency and clarity. During the actual

Fiedorova, K., Augustynek, M., Fojtik, F. and Hlavackova, M.
Analysis of Mechanical Properties of Dialysis Sets.
DOI: 10.5220/0007555302280234
In *Proceedings of the 12th International Joint Conference on Biomedical Engineering Systems and Technologies (BIOSTEC 2019)*, pages 228-234
ISBN: 978-989-758-353-7
Copyright © 2019 by SCITEPRESS – Science and Technology Publications, Lda. All rights reserved

blood dialysis is very important to check it by eye, the nurse examines the blood. Thanks to these characteristics nurse can see harm of dialysis tubing or may capture a blood clot in the blood. (Di Landro et al., 2005), (Latini et al., 2010)

Dialysis sets are important parts of the dialysis device. There are two pressures on the dialysis set during blood dialysis. The external pressure is caused by the peristalsis pump. The effect of the occlusion cylinders is to inject blood into the device and further drive the circuit. Thus, a flow of a certain value is created. Blood flowing through the dialysis set produces internal pressure. During the measurement, the temperature of the solution is warmed to the temperature of the blood, ie it has a temperature of 37°C. Therefore, the effect of the temperature on the properties of the sets must be considered. Optimum physical parameters under which the dialysis is carried out, the temperature of the solution through 37°C and speed peristaltic pump 300 ml/min. (Rose et al., 2012), (Ronco and Levin, 2004), (Cihak and Augustynek, 2013), (Jeppsson and Losell, 1994), (Brugger et al., 1997)

1.2 The Important Mechanical Properties

The mechanical properties are evaluated in the work. During testing, the sets undergo stress. The dialysis set has to be characterized by basic features such as strength, elasticity, toughness, malleability. We use these properties in real use fatigue resistance. Temperature plays a role in the material properties; the influence of certain temperatures may cause a change in the material structure. (Pelleg, 2013), (Dowling, 2007)

The dialysis sets are produced from plasticized polyvinyl chloride. Due to this fact, they are characterized by strength, flexibility, elasticity, etc.

- Flexibility - elastic deformation before the breach, evaluated using the modulus of elasticity and stress.
- Strength - material resistance to deformation and breach of external forces.
- Plasticity - the material retains permanent deformation induced by external forces, assessed using the relative size of the permanent deformation prior to the breach.
- Toughness - resistant to high tension, this feature is dependent on the strength and plasticity. The measure of the work required to deform a violation.

(Pelleg, 2013), (Dowling, 2007)

1.3 Standards Applied

The standard EN ISO 8638 Cardiovascular implants and extracorporeal systems - Extracorporeal blood circuit for haemodialyzer, haemodiafilter and haemofilter deals with dialysis sets. The standard lists the requirements for dialysis sets and tests that test the dialysis sets. Tests are performed on the testing machine, which will assess the ability of a material to withstand the required stress. It records the force which must be exerted in order to break the material. Other values are modulus and elongation of the material. (ČS EN ISO 6838, 2014)

1.4 Testing of Mechanical Properties

According to the standard above, dialysis sets are subjected to a tensile test. This test is part of mechanical static tests. The tensile strength is performed on all materials because, thanks to the measured values, we can further count the structural elements and choose the appropriate material. The tensile strength test indicates the force exerted, variable elongation, elongation and material constriction.

2 TESTING OF DIALYSIS SETS

Measurements were measured in were school lab because the laboratory has a dialysis machine Fresenius 4008 and other essential components that are, dialysis sets Basic Line AV, dialyzers AV600S and dialysate. Dialysis apparatus with dialyzer and bag can be seen in Figure 1.

Figure 1: A – Bibag, B – Hemodialysis Fresenius 4008, C – Dialysator AV 600S (Cihak and Augustynek, 2013).

Measurements are divided into several series. The series differs in the used and set parameters. The combination and the values of these parameters are given in the following section. After the part of the measurement has been completed, tensile tests are carried out. The obtained data determine the mechanical properties of the dialysis kits. The assumed, that dialysis sets after a series of measurements when exposed to the highest pressure and the highest temperature should have the greatest degree of flexibility. Thus, there should be a greater extension and the equation:

$$F = \frac{E \cdot \rho_{\Delta} \cdot l}{l_{\Delta}} \quad (1)$$

where F is force, E is the modulus of tensile elasticity, ρ_{Δ} is tensile strength, l is original length, l_{Δ} is elongation length. We can deduce that it will increase the maximum force expended and the modulus of elasticity decreases as the module increases with stretching flexibility. (Pelleg, 2013), (Beisser and Oesterreich, 2018), (Rose et al., 2012)

2.1 Determination of Possible Influence of Changes of Physical Parameters on Mechanical Properties of Dialysis Sets

The tensile test is performed during the production of the set. It is assumed that the sets will be used under standard conditions. Such a set must have certain features, such as flexibility, tightness, plasticity, according to the standard. Therefore, the aim of this work is to verify the effect of certain physical parameters on the properties of the set. (Hochman et al., 2015)

Work focuses on the influence of temperature and pressure. The effect of temperature on the mechanical properties of the set is derived from its structure. PVC is made up of linear or slightly branched chains. It is assumed that by varying the temperature, the internal structure of the set will expand or retract. At higher temperatures it will be more flexible. On the contrary, the strength of the set will fade. The effect of pressure on the mechanical properties of the set will only affect the place of direct action, not the length of the whole set. If the pressure is increased, the material will weaken at the point of application. This reduces the strength. (Hochman et al., 2015)

2.2 Workflow Proposal

Since we cannot work with the biological material in the laboratory, it is measured by with the physiological solution heated to the temperature of human blood, which is 37 °C. Instead of connecting to the vascular access use of circular bags, which join dialysis sets. The saline which flows through the circuit, it will drain back into the bag. The important part is ripper for determining the mechanical properties of dialysis sets, which we will evaluate.

Measurements must be carried out under steady conditions (pressure, temperature, humidity). Measurements on one set is always carried out only once because dialysis sets are used for single use. In the experimental measurement, two measuring parameters are changed, namely the temperature of the saline solution and the speed of the peristaltic pump, thereby achieving a change in pressure. Temperatures are used: 36.5ºC, 37ºC, and 37.5ºC and speed of the peristaltic pump: 200 ml/min, 300 ml/min and 450 ml/min. Each combination of measurement conditions shall be subjected to a four-hour measurement.

Figure 2 shows a dialysis device. Part of a dialysis machine belonging to the arterial part is marked by the letters B, C and D. Part of dialysis device marked with B is a peristaltic blood pump, this section includes the insulin pump segment. Under C is located the arterial blood pressure sensor to which the set up via the transmitter. The heparin pump is under D. The arterial part of the set also includes the arterial chamber is located under the letter E. The letters G, H, CH are the venous part of the set. Point G shows the air sensor, here is placed venous chamber. Below the H, there is a fuse in the circuit that interrupts the blood flow in case of an alarm. The pressure sensor can be found under the letter CH. Letter A indicates the monitor. Under the letter I, a physiological saline bag is found. Letter F denotes a part, to which the inlet and outlet hoses are attached, they are stored under the letter J. The dialysis solution is made up of chemicals, which are stored in parts marked K, L.

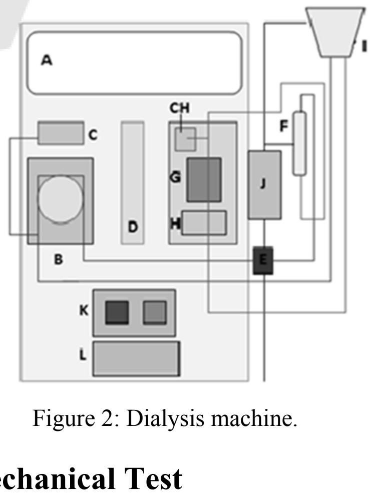

Figure 2: Dialysis machine.

2.3 Mechanical Test

Mechanical tests were carried out at VŠB-TUO at the Faculty of Mechanical Engineering. It was tested on the device Testometric M500-50CT (see Figure 3). Those parts that were exposed to stress were tested. In the case of experimental measurements, it is peristaltic pump segment. Sets is characterized by an inner diameter of 8 mm and an outside diameter of 12 mm measured. The length of the test sample was 6 cm. The sample was expanded at 100 mm/min. The samples were attached to the vice of the instrument, each side being held at 0.5 cm. The whole machine is controlled by software, where the computer sets up the appropriate parameters (length of the sample, the outer and inner diameter, speed). After setting the appropriate parameters, the machine starts.

After running a device the test material is tensioned. The material to be tested should break with a certain extension. The whole course of testing is recorded in a graph of force versus extension.

Figure 3: Testing of dialysis kits.

3 DATA PROCESSING

Data obtained from material testing on mechanical tests, calculations and measurements will be processed and evaluated using tables and graphs. Prolongation will depend on selected physical quantities (flow and temperature).

The following variables (shows in Table 1) are used in the work.

Table 1: Overview of the variables.

Quantity:	Unit:
Temperature of saline solution	[°C]
Speed peristaltic pump blood	[ml/min]
Mechanical tests are extension	[mm]
Maximum developed force	[N]
Young's modulus	[MPa]
Length is expressed	[mm]

3.1 Dependence of Extension on Temperature

The chart (Figure 4) shows the dependence of the extension on the saline temperature. Three temperatures were set for each used speed. On the X axis the values of the saline temperature [°C] were plotted, and an extension [mm] was recorded on the Y axis. When the peristaltic pump speed was set at 200 ml/min, the largest extension from the 60 mm sample was 367.071 mm, this sample was recorded at 37°C. For 300 ml/min was the largest extension 414,57 mm (37°C) and for 450 ml/min it was 350,573 mm. We can see that prolonging varies with temperature, which satisfies the assumption. It is apparent from the graph that the least elongation has 200 ml/min samples and gradually increase with an increasing flow. At a speed of pump 450 ml/min, the extension does not change much. In this graph, we can see that at the temperature of 37 °C, the test sample is most prolonged.

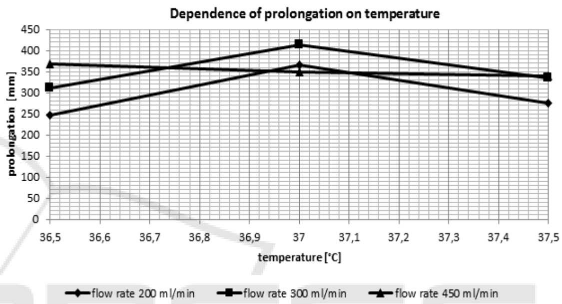

Figure 4: The dependence of prolongation on temperature.

3.2 Dependence of Maximum Force on Temperature

The graph (Figure 5) shows the dependence of maximum force on the temperature of the saline. Values were obtained by the same procedure as in the previous chapter. On X axis, the saline temperature [°C] is showed, and the maximum force [N] is recorded at Y axis. From the values in the graph it is evident that as the temperature of the solution increased, the force that was needed to break the test sample decreased. In the sample obtained from the measurement at 200 ml/min, the smallest applied force was 407.9 N at 37.5°C. For 300 ml/min is the smallest applied force 458.9 N at 36.5°C and for 450 ml/min is force 458,3 N at 37.5°C. The force applied to the test sample was the smallest in the sample test at a pump speed of 200 ml / min. However, the maximum force applied to the samples at a speed of the pump 450 ml/min is less than the maximum force that was applied to the samples measured at 300 ml/min. It can be seen in this figure (Figure 5) that the samples measured at 37 ° C are the most stable.

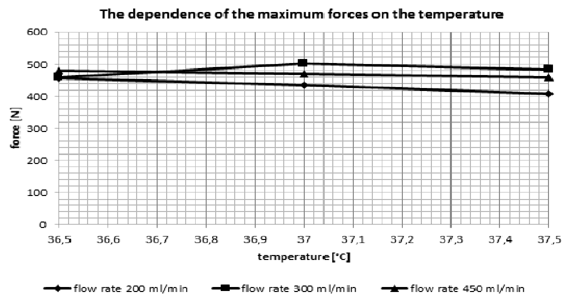

Figure 5: The dependence of the maximum forces on the temperature.

3.3 Dependence of Modulus on Temperature

The graph (Figure 6) shows the dependence of the modulus on the temperature. The temperature of the saline [°C] was plotted on the X axis and a modulus of elasticity [MPa] was recorded on the Y axis. Considering that the modulus of elasticity is the greater the stronger the test material, in theory, in our case, this modulus of elasticity should decrease. Because sets that have been exposed to more stress become more flexible. For samples generated at 200 ml/min, the maximum modulus of elasticity is 91.166 MPa at 37°C. For speed 300 ml/min, the highest elasticity model was 54.7 MPa at 37°C. The highest modulus for 450 ml/min is 53.773 MPa at 36.5°C. This chart (Figure 6) we confirm assumption, namely the gradual decrease of the modulus of elasticity with the increasing stress of the set. Only the values listed on the sets measured at 36.5°C, are different.

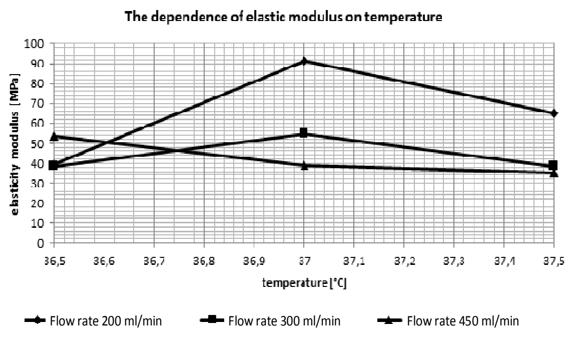

Figure 6: The dependence of elastic modulus on temperature.

3.4 Dependence of Extension on Flow Rate

The graph (Figure 7) shows the dependence of the elongation on the speed of the peristaltic pump. At each temperature, each measured speed was used. Flow rates [ml/min] were plotted on the X axis, the elongation [mm] was plotted on the Y axis. The increasing flow rate should result in prolongation of the test specimens. Because the material becomes more flexible. We can see, that for samples measured at 36.5°C, the longest extension is 368.106 mm at 450 ml/min. The largest extension for samples with a temperature of 37°C is 414.579 mm at a pump speed of 300 ml/min. The largest extension for samples with a temperature of 37.5°C is 339.464 mm at a pump speed of 450ml/min. The graph shows that the sets exposed to 37 ° C are out of the assumption.

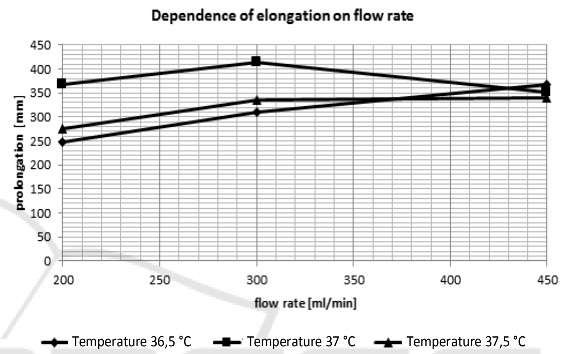

Figure 7: Dependence of elongation on flow rate.

3.5 Dependence of the Maximum Force on Flow Rate

The graph (Figure 8) shows the dependence of the maximum applied force on the flow rate. The flow velocity values [ml/min] were plotted on the X axis, and a maximum force [N] was recorded on the Y axis. Higher blood pump speeds should result in a weakening of the material. We can see, that for samples measured at 36.5°C, the maximum force is 479.6 N at 450 ml/min. The maximum force for samples with a temperature of 37°C is 501.1 N at a pump speed of 300 ml/min. The maximum force for samples with a temperature of 37.5°C is 483.2 N at a pump speed of 300 ml/min. We can see that the effect of flow does not have such an effect on the maximum force used, because the measured values are quite similar. The data of samples measured at 37°C and 300 ml/min are again different.

SCITEPRESS SCIENCE AND TECHNOLOGY PUBLICATIONS

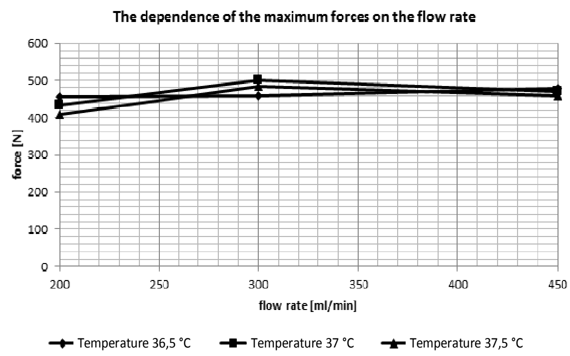

Figure 8: The dependence of the maximum forces on the flow rate.

3.6 Dependence of Modulus on Flow Rate

In the graph (Figure 9) we can see the evaluation of the dependence of the modulus on the flow rate. The flow velocity values [ml/min] were plotted on the X axis and the modulus of elasticity [MPa] on the Y axis. For samples generated at 36.5°C, the maximum modulus of elasticity is 53.773 MPa at 450 ml/min. Samples measured at 37°C and 37.5°C using a different flow rate meet the theory that the elastic modulus decreases with increasing effort. The values of all measured samples shows (Figure 9) that the values for the samples exposed at 37°C, again stands out. We can see that the model flexibility is diminished with increasing temperature.

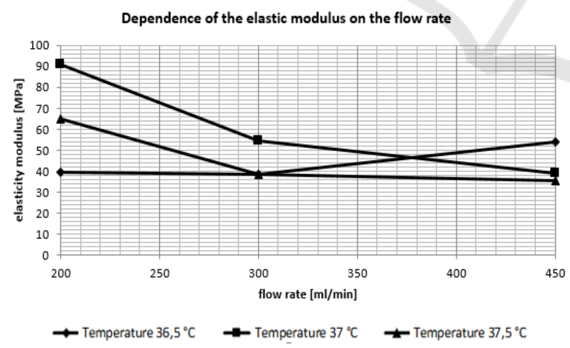

Figure 9: Dependence of the elastic modulus on the flow rate.

4 DISCUSSION

All combinations of temperatures and flows were tested, one by one. A part of the dialysis sets that was exposed to peristaltic pumps was tested. Considering the assumptions set, the samples obtained at temperature 37°C do not meet the requirements. But the remaining samples confirm the assumptions. These fluctuations can be justified by the fact that hemodialysis is normally used at 37°C and this temperature influences the production of sets.

The elongation of the sample and the applied force applied to the specimen increases with the load, ie the flow temperature and the flow rate. In addition, the elastic modulus of test samples which were subjected to increased strain gradually decreases. Expansion between 200 - 400 mm was recorded, with increasing expansion increasing the maximum applied force, which was measured in the range of 400 - 500 N. The range of 40 to 100 MPa include modulus of elasticity.

Said modulus could not be verified by calculation, as Hook's law applies only to a small linear part that cannot be deducted from the chart. Beyond this, there is a large deformation of the material.

5 CONCLUSION

From the analysis of the experimental measurements it is possible to confirm the assumptions that the change of the physical parameters (temperature of the physiological solution and the flow) affects the properties of the dialysis sets. Changing the mechanical properties of dialysis sets is not so significant as to affect the safety of the use of sets. The sets proved to be a very solid and durable material on mechanical tests. Situations that may occur in health care facilities under the supervision of professional staff will not expose a set of conditions to fatal failure of the material.

ACKNOWLEDGEMENTS

The work and the contributions were supported by the project SV4508811/2101Biomedical Engineering Systems XIV'. This study was also supported by the research project The Czech Science Foundation (GACR) 2017 No. 17- 03037S Investment evaluation of medical device development run at the Faculty of Informatics and Management, University of Hradec Kralove, Czech Republic. This study was supported by the research project The Czech Science Foundation (TACR) ETA No. TL01000302 Medical devices development as an effective investment for public and private entities.

REFERENCES

R. J. Rose, M.J. Priston, A.E. Rigby□Jones, J.R. Sneyd, 2012. The effect of temperature on di (2□ethylhexyl) phthalate leaching from PVC infusion sets exposed to lipid emulsions. In *Anaesthesia*, 67(5), 514-520.

Z. Liao, C.K. Poh, Z. Huang, P.A. Hardy, W.R. Clark, D. Gao, 2003. A numerical and experimental study of mass transfer in the artificial kidney. In *Journal of biomechanical engineering*, 125(4), 472-480.

C. Ronco, N.W. Levin, 2004. Hemodialysis, Vascular Access, and Peritoneal Dialysis Access. In *Karger Medical and Scientific Publishers*, (Vol. 142).

J. Cihak, M. Augustynek, 2013. Infuzní technika a hemodialyzační technika a technologie. In *Ostrava: VŠB - Technická Univerzita Ostrava, p. 373*, 2013, ISBN 978-80-248-3100-8.

J. Pelleg, 2013. Mechanical properties of materials. In *Springer, c2013. Solid mechanics and its applications,* ISBN 978-94-007-4341-0.

N.E. Dowling, 2007. Mechanical behavior of materials: engineering methods for deformation, fracture, and fatigue. In *Upper Saddle River: Prentice Hall*, 3rd ed. 2007. ISBN 0-13-186312-6.

ČSN EN ISO 8638 Kardiovaskulární implantáty a mimotělní systémy: Mimotělní krevní okruhy pro hemodialyzátory, hemodiafiltry a mofiltry, 2014.

V. Hochman, J. Cihak, M. Augustynek, 2015. Interaction of Infusion Set and Volumetric Infusion Pump and Their Impact on the Quality of Treatment. In *Springer International Publishing*, Ifmbe Proc, pp. 645-648. (2015)

M. Augustynek, J. Sterba, J. Cihak, 2014. Hemodynamic diagnostics shunt for hemodialysis. In *Biomedical Engineering and Environmental Engineering* 145, 163 (2014)

J.B. Jeppsson, I. Losell, 1994. Set of tubes for peritoneal dialysis. *U.S. Patent No. 5,338,293. 16 Aug. 1994.*

J. Brugger, K. J. Manica, W.G. Palsulich, 1997. Dialysis blood tubing set. *U.S. Patent No. 5,693,008. 2 Dec. 1997.*

J. Brugger, 1999. Technique for using a dialysis machine to disinfect a blood tubing set. *U.S. Patent No. 5,948,251. 7 Sep. 1999.*

L. Di Landro, C. Capone, F. Inzoli, P.E. Malacari, 2005. Coextruded PVC tubes for biomedical application. In *Journal of Vinyl and Additive Technology*, 11(3), 111-118.

J. Neergaard, B. Nielsen, V. Faurby, D.H. Christensen, O.F. Nielsen, 1971. Plasticizers in PVC and the Occurence of Hefatitis in A Haemodialysis Unit: A Preliminary Communication. In *Scandinavian journal of urology and nephrology*, 5(2), 141-145..

I. Kostić, T. Anđelković, D. Anđelković, A. Bojić, T. Cvetković, D. Pavlović, 2017. Quantification of DEHP into PVC components of intravenous infusion containers and peritoneal dialysis set before and after UV-A treatment. In *BULGARIAN CHEMICAL COMMUNICATIONS*, 49(2), 360-365.

N. Beisser, S. Oesterreich, 2018. Heating apparatus for heating dialysis liquid, dialysis liquid tube set, set, medical apparatus and methods. *U.S. Patent Application No 15/879,656, 2018.*

G. Latini, M. Ferri, F. Chiellini, 2010. Materials degradation in PVC medical devices, DEHP leaching and neonatal outcomes. In *Current medicinal chemistry,* 17.26 (2010): 2979-2989.

SCITEPRESS SCIENCE AND TECHNOLOGY PUBLICATIONS