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PROTOTYPE MANUFACTURING OF A NEW DYNAMIC-BASED PRESSURE MEASUREMENT TEST DEVICE FOR MEDICAL AND TEXTILE APPLICATIONS

MEDİKAL VE TEKSTİL UYGULAMALARINA YÖNELİK YENİ BİR DİNAMİK TABANLI BASINÇ ÖLÇÜM TEST CİHAZININ PROTOTİP İMALATI

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ABSTRACT

Customers nowadays demand that their clothes be comfortable and suitable for their health in addition to the aesthetic features of the clothes they wear. Therefore, manufacturers following technological innovations to test their product capability are putting those devices on the market to measure the impact on health. The study describes the design, development, and prototype manufacturing stages of a new pressure measurement test device for measuring the pressure resulting from the interaction of human legs and stretch garments. The device can bend from the knee and move dynamically which has innovative aspects compared to the ones commercially available. After mass production of the device, it might be possible to measure the pressure levels of the garments to the human body, therefore, the effects of the fabrics on blood pressure in addition to body physiology can be evaluated with concrete values.

Keywords: Compression, medical textiles, pressure measuring device, dynamic pressure measurement, prototype test device

ÖZET

Günümüzdeki müşteriler giydikleri kıyafetlerin estetik özelliklerinin yanı sıra rahatlık ve sağlıkları ile uyumunu da önemsemektedirler. Bu yüzden imalatçılar, teknolojik yenilikleri takip ederek ürün yeterliliklerini test etmek ve ürünlerin sağlık üzerine etkilerini değerlendirebilmek için test cihazları imal etmekte ve pazara sunmaktadırlar. Çalışmada, insan bacakları ve streç giysilerin etkileşiminden kaynaklanan basıncı ölçmek için yeni bir basınç ölçüm test cihazının tasarım, geliştirme ve prototip üretim aşamaları anlatılmaktadır. Dizden bükülebilen ve dinamik olarak hareket edebilen bu cihaz piyasada bulunan cihazlarla karşılaştırıldığında yenilikçi özelliklere sahiptir. Cihazın seri üretime geçmesinin ardından giysilerin insan vücuduna uyguladığı basınç seviyeleri ölçülebilecektir. Böylelikle kumaşların vücut fizyolojisine etkisinin yanı sıra kan akışına/tansiyona etkileri de somut verilerle değerlendirilebilecektir.

Anahtar Kelimeler: Kompresyon, tıbbi tekstiller, basınç ölçüm cihazı, dinamik basınç ölçümü, prototip test cihazı

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INTRODUCTION

Blood circulation in a body is provided by arteries and veins. While arteries send oxygen-rich and clean blood from the heart to the farthest tissues of the body, dirty blood in the tissues is transported back to the heart by the veins. Contractions of the calf muscles also help this process. Thanks to dynamic movements such as walking and jogging, the muscles in the leg contract and pump blood into the heart by compressing the veins. The clothes worn to accelerate blood circulation should not slow the circulation, they should provide freedom of movement and comfort (Seyrek Kurban, 2017). The mechanical properties of the fabric and the suitability of the clothes made of these fabrics affect the comfort degree of the clothes. Versatile and random forces that occur as a result of the interaction between the human body in motion and the garment create a feeling of pressure in the relevant parts of the body. It has been stated that the disturbing level of garment pressure is between 60 and 100 g /cm2. Therefore, the pressure exerted by the garment is an important design criterion (Güney et al., 2016). Correct pressure application in the treatment is possible with a balanced pressure profile that decreases upwards from the ankle to the groin. Therefore, it should help the transport of dirty blood from the legs to the heart in one way in the lower body clothing such as stretch pants, tights, etc., which are very much preferred daily except for compression clothes for medical purposes (Seyrek Kurban, 2019).

When looking at the clothes preferred by young and middle-aged people in recent years, it has been noticed that stretch clothes that mostly surround the body like a second skin stand out. Depending on the extreme preference of these clothes, they should not cause any problems in terms of human health and physiology. In addition, it is not desirable any restriction on body movements for life at an increasing pace. From this perspective, it is very important to know the interaction of stretch clothing with the human body is a crucial factor. Stretch garments, which are questionable in terms of health, should be interpreted with measurable concrete data/information that can interact with the human body/leg. There is a huge research gap in the literature in that regard and evaluations are considered purely subjective. From this point of view, a new pressure measurement test apparatus that can measure the interaction of the clothes with a human leg by pressure levels was designed, developed and its prototype manufactured (Seyrek Kurban, 2019). Before moving on to research the manufacturing process, many test apparatus, many of their applications (especially related to medical compression stockings) and a variety of scientific literature have been examined in advance (Pohlen, 2023; RAL-GZ 387/1, 2008; TS ENV 12718, 2006; TS ENV 12719, 2007; TSE CEN/TR 15831, 2010; Cansunar, 2014; Swisslastic MST MK IV and MST MK V and MST Professional 2 and MST MPT-4/MPT-7, 2023; Seyrek Kurban and Babaarslan, 2017; Seyrek Kurban et al., 2016, 2017; Kuenzli et al., 2007; Hohenstein, 2023; Filodoro Calze Spa, 2001; Oğlakçıoğlu, 2009; Oğlakçıoğlu and Marmaralı, 2010; Yıldız Varan, 2012; Wang et al., 2011). Some of these include individual leg moulds made of wood according to different stocking sizes. The circumference and length of the leg are adjusted using these moulds. Test probes are attached to these wood moulds and the values from the probes are measured using a control system. In such devices, pressure measurement is performed by a manometer with digital output operated by pneumatic principle, some of which allow pressure measurement from seven different points. At the same time, the measurement is conducted in a static (stationary) test environment. In this case, the pressure values which occur during different movements of the leg cannot be measured. Such devices have been developed for particular use in the pressure measurement of medical stockings. The Patent Application No. US2007/0012120A1 discloses a mechanical leg developed for allowing size change in a different test apparatus used for pressure measurement of medical stockings. In this test apparatus, circumferential size expansion is ensured electronically and unidirectionally. Since the leg allows for a unidirectional expansion in this apparatus, a proper measurement can only be made in a limited region. The Patent Application No. TR2010/01394 relates to a pressure measurement apparatus. It is stated in the said invention that pressure measurement at seven different points of the leg can be performed in different types (short, mid-calf, thigh high, and pantyhose) and various groups (primarily compression stockings; as well as regular, support, and work stockings) of stockings and the pressure profile can be detected before wearing. It was also stated that this apparatus is capable of determining pressure values of the cuff portion of regular socks, at the same time allowing a pressure measurement for any type of compression product (bandages, corsets, knee pads, wrist pads, etc.) by adjusting the mechanical mould form. However, this apparatus also performs a static measurement. Also, this test apparatus is quite different from human anatomy and the surface structure thereof carries many components that may affect the test results. A European patent application with the publication number EP1118851 A2 relates a device for measuring the compression that can be exerted by a stocking, pantyhose, or the like. The device disclosed in the document is capable of displaying and recording the compression data both in a static and a dynamic condition, and uses a detection system with two-dimensional sensors, each comprising a matrix arrangement of load cells. It appears that pressure measurement apparatuses worldwide are generally statically operating apparatuses. The moving apparatuses, on the other hand, have a limited capability of movement, but not a sufficient measurement precision (Seyrek Kurban et al., 2017).

As a result, there is a need for test apparatuses that are used for pressure measurement evaluation of textile products, especially for the end user. The dimensions must be changed by mimicking according to body movements dynamically, and the insufficiency of the existing solutions has made it obligatory to make a development in the related technical field. The present study relates to a pressure measuring test apparatus capable of performing dynamic and static measurements, which meets the mentioned requirements, eliminates all the drawbacks, and simultaneously provides additional advantages.

MATERIAL AND METHOD

Material of the Prototype Pressure Measurement Test Apparatus

The outer surface material of the prototype pressure measurement test apparatus consists of epoxy resin reinforced with fibreglass. Based on the prosthetic mould consisting of polyester material shown in Figure 1, the final mould was created by applying the measurement height values from the ground along with surrounding measurements of the points specified in the ENV 12718 standards. The operating area of the prototype pressure measurement test apparatus is a Polyester-based casting mould in full-leg format. The mould has high-strength features and is lightweight. It permits the interpretation of sanitary and comfort properties of textile products in using lower-body clothing before being presented. It is also easy handling usage and finally, its structure is compatible with the installation of the FSR (Force Sensing Resistor) type sensor. FSR-type sensors are used in pressure measurement points to measure between a range of 0-1 lb. With this sensor structure, which has a very sensitive measurement characteristic, modules have been created to provide a stable structure at the measurement points. The markings of the prosthetic mould according to ENV 12718 standards were made as in Figure 1. Then it was reduced to one leg and installed on the test device as in Figure 2.

Figure 1. Marked Prosthetic Mould According to ENV 12718 Standard

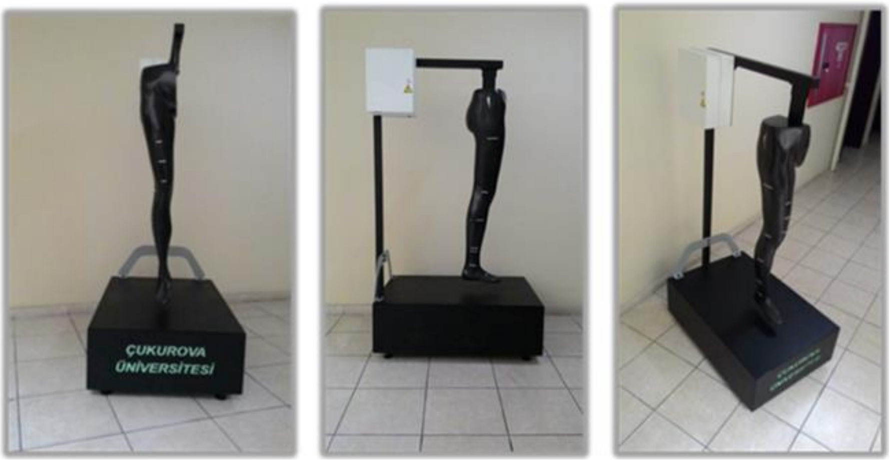


Figure 2. The State of the Prosthetic Leg on the Device Before Cutting

Method for Pressure Measurement on the Prototype Test Apparatus

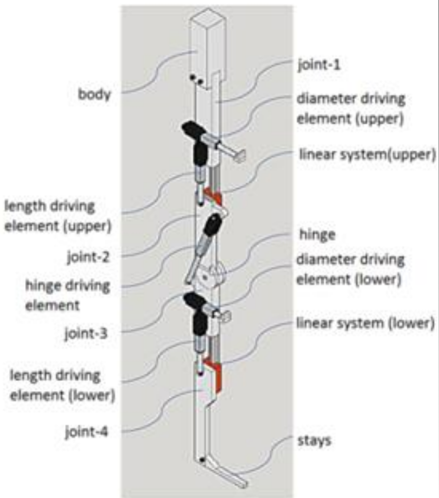
In the design and developing stages of creating the dynamic-based prototype test device, the measurement points (C, G, etc.) were identified along the human leg by the standard titled ENV 12718 Medical Compression Hosiery. The circumference measurements of these points with measurement height values were taken into consideration. Given the fact that the cost of the device, the prototype device has been designed and manufactured so that measurements can be taken from 3 regions using 4 different sensor points. Those regions are located under the knee (C region), above the knee (G region), and upon the knee.

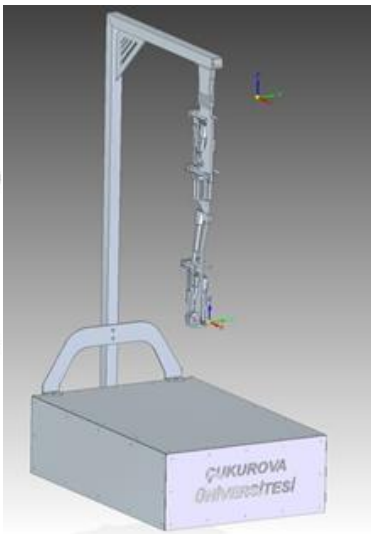
The force values obtained through the FSR sensors used in the developed device enable the pressure value to be obtained directly because the measurement surface areas of the sensors are known. The information received from the sensors is transferred to the computer by filtering through the PCB converter, which will convert the analogue data to digital, before being transported to the computer environment in the form of raw data. The values read by the sensors can be viewed numerically from the computer. The dimension/size control of the prototype device can also be adjusted on the computer. In addition, linear actuator control and sensor value reading software have been installed on the system. The methodology for the manufacturing process of the dynamic-based pressure measurement device is examined under 4 steps as follows.

Technical Calculations of the System, Mechanical Initial Designs and Creation of Automation Algorithm

At this stage, literature information, preparation of patent data for the protection of the device, etc. primary data were created, necessary technical calculations were made and theoretical findings were obtained. Units with material and dimensional properties that will meet the dynamic qualifications obtained by technical calculations have been designed in the computer environment before manufacturing, and their dimensional analysis, study simulations, and numerical models have been completed. Mechanical sections along with the intervention of the integrated system to the preliminary algorithm of the communication network in the drive section are also shaped under this title. Final designs of the system were created with CAD (Computer Aided Design) support.

The illustration of the internal mechanism and components of the pressure measurement test device is shown in Figure 3(a). The installation of the internal mechanism on the test device is also given in Figure 3(b).





(a) (b)

Figure 3. The Illustration of the Internal Mechanism; (a) Components of the Pressure Measurement Test Device, (b) The Installation of the Internal Mechanism on the Test Device

The circumferential diameter change of the measurement areas of the developed system has been realized with linear actuators and additional mechanical parts that will provide axial direction change. The requirement of dimensions by the standards was made with sensor controls. The diameter change takes place simultaneously with the length change by the size selection from the control computer. The length change made by the length change actuators is shown in Figure 4(a). Also, a CAD image of the knee bending process performed by the bending actuator in the knee region is shown in Figure 4(b).

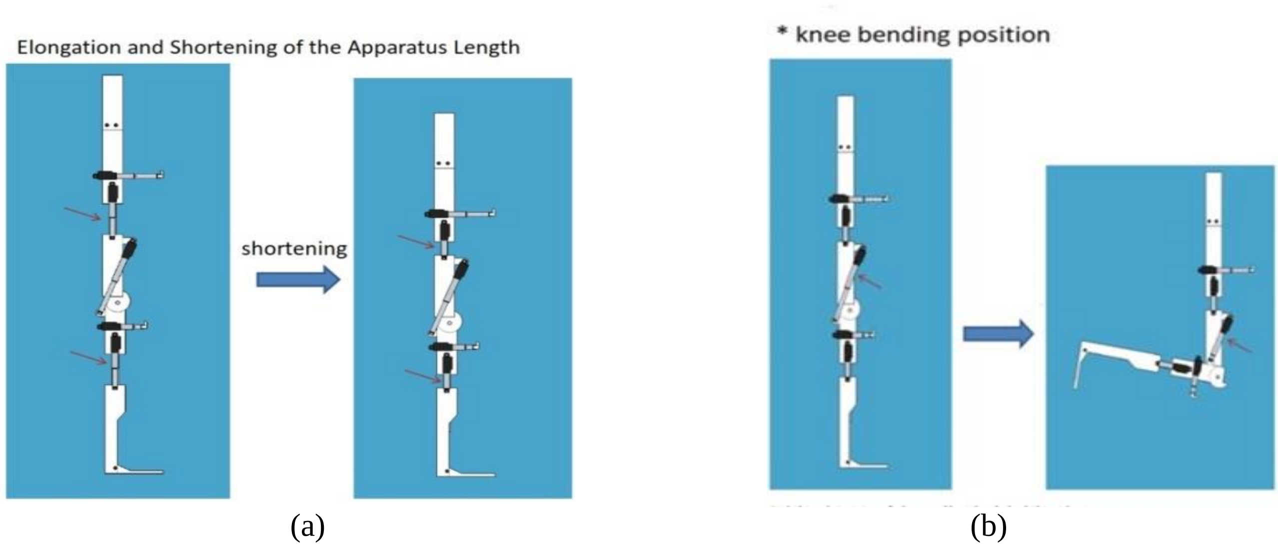


Figure 4. (a) Dimensional Change by Length Change Actuators; (b) Knee Bending Process Performed By Knee Bending Actuator

The leg structure is integrated at the shortest measuring distances obtained from the test standard and based on the software. The leg form is separated from each other at increasing measurement distances. The distance between the B-G points which is identified with the ENV 12718 standard can be adjusted to the desired length in the range of 65-83 cm with the help of linear actuators. This adjustment allows different sample sizes to be examined with the same test apparatus. The necessary settings for the required size change can be made through the computer control interface. Electromechanical motion that occurs in size/size changes is controlled simultaneously by the sensors. This control will provide millimetric precision in dimensional changes. CAD images of the removable portion of the leg form covering the internal mechanism and CAD drawings of the final version of the pressure measurement device are shown in Figure 5.

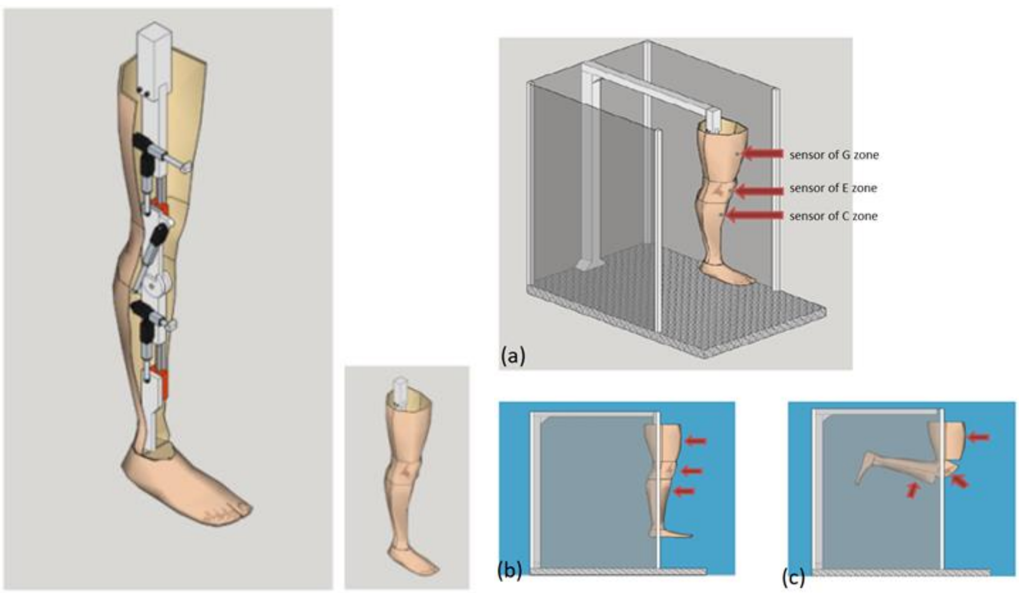


Figure 5. Internal Mechanism Covered by Leg Form, and Final Version of the Pressure Measurement Device (a) General View, (b) Side View, (c) View When the Knee is Bent

Production of Prototype Pressure Measurement System Components, Manual Tests and Creating Technical Algorithms

CAD drawings are modelled and verified in the previous title. The manufacturability stage with industrial production techniques has been explained in this section. Since the test device has a high precision capability with a low tolerance mechanism, this study needs to work with a verification method focused on the transition process from product design to manufacturing. Sensitive mechanical structures in the system were produced with high precision capacity by adding appropriate structures to CAM-computer-aided manufacturing methods. Figure 6 shows the internal mechanism structure of the device.

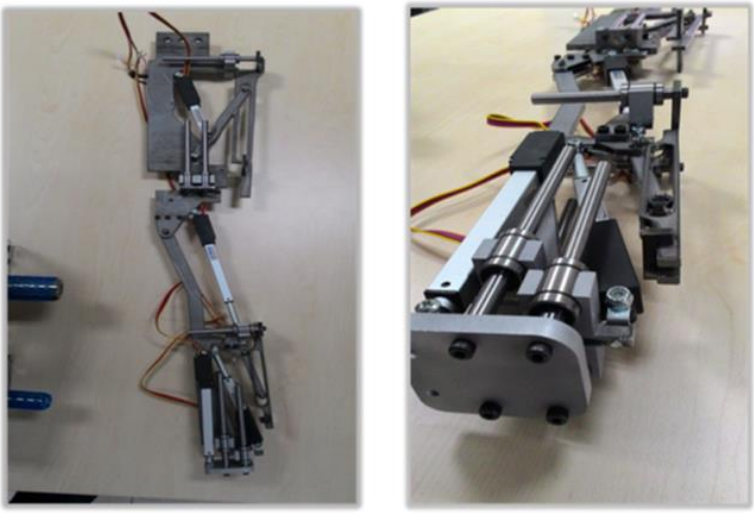


Figure 6. Internal Mechanism of the Pressure Measurement Test Device

Mechanical components with CAD designs were completed by the appropriate manufacturing methods, and have been produced with pre-design values for geometric dimensions in terms of surface quality through using machining techniques. In the production process, all parts have been manufactured under constant size control, and the risk of faulty parts is minimized by purchasing services from outside. This section is critical in the manufacturing process of the pressure measurement test device due to fact that the risk of dimensional differences between manufactured parts and their technical calculations. The components were assembled with the system chassis and other installation parts. Then, the prototype frame was created as in Figure 7(a), and the outer surface (shell) installation was carried out as in (b) in Figure 7.

(a) (b)

Figure 7. a) Installing the Main Frame on the Test Pressure Measurement Apparatus b) Arranging The Electrical Connection of the Pressure Measurement Test Apparatus and the Outer Surface (Shell) on the Frame

The mechanical model for the pressure measurement test device and most of the necessary engineering studies for the installation process were completed in this chapter. Controls of all components were carried out and manual tests were implemented in this chapter as well. After a series of manual tests were carried out, the amplitude motions were moved by manually the final version of the moving parts of the computer-controlled device and were followed. Manual test movement images and expansion /contraction of the frame of the prototype pressure measurement test device are shown in Figure 8.

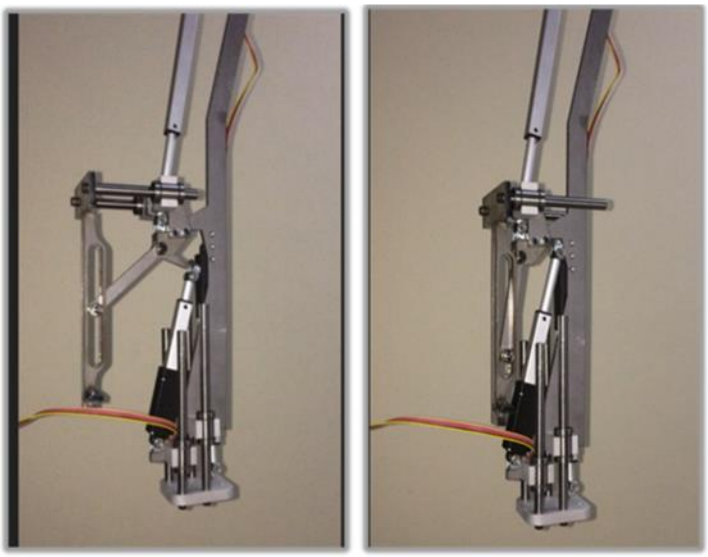


Figure 8. Manual Test Images, Expansion/Contraction of the Frame of the Prototype Pressure Measurement Test Device

Design and Manufacturing Phase of the Control Section

A whole system has been designed to work in harmony with the independent units by checking the operation desired from it in case of predetermined situations. In addition to being independent of the drive systems of different mechanisms, they are being driven by motors. In this context, electronic systems have been created to provide communication and control technics between sensors and drive systems in automation activities.

System Control Software and Calibration Studies

Since the units creating the structure of the measurement test device are based on the electric/electronic principle, they can be calibrated very quickly before each measurement phase therefore the measurement accuracy level is kept maximized. Remote access and control of the prototype manufactured device by a standard computer is important in terms of system flexibility and commercial success. Therefore, software was created with the electronic card which is installed inside the system providing a connection between the test device and the computer. This software is associated with the interface structure to provide easy control by the operator. Instant measurement test values can be directly viewed and recorded on the screen with a C# --based interface program on the computer. Also, it can be provided in the desired dimensional changes in the measurement test device with the same interface program. After the successful completion of the software in the computer and its integration with the system, the production of the prototype pressure measurement test device has been completed.

RESULTS AND DISCUSSION

The prototype stage of the pressure measurement test device, which has a dynamic movement that can be used in the textile and medical sectors, has been completed successfully. The final state of the device is shown in Figure 9.

Before placing the sample of lower-body clothing to be tested on the device, device positioning must be done according to the desired size. After the test device has reached the desired position, the sample clothing must be placed on the apparatus as shown in Figure 10, and then no position must be adjusted.

The measurement test is started by entering the appropriate values of the clothing size inside the software interface of the computer. The device is arranged in the knee-bending position as shown in Figure 11 and then becomes static, and the pressure values are read by sensors.

Figure 9. The Final Version of the Prototype Pressure Measurement Device

Figure 10. Positioning the Device and Dressing the Lower Body Clothing to be Measured on the Device

Figure 11. Knee Bending Position of the Pressure Measurement Test Device

If the pressure measurement process measured by the device is explained with an example; dressed in such a way that the marked parts of the sample shown in Figure 12 are on the sensor points on the device.

The screen setting values suitable for the sample size worn on the device and the motion motor are selected and then the test button is pressed. The device begins to bend at the knee and the test is completed when the leg form returns to its original state. The interface of the device is in Turkish. The Turkish language screenshot that appears after the pressure measurement test is completed is as in Figure 13.

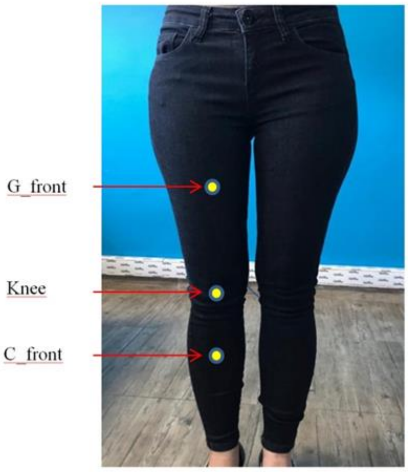


Figure 12. Sensor Points on Stretch Trousers Selected as Sample

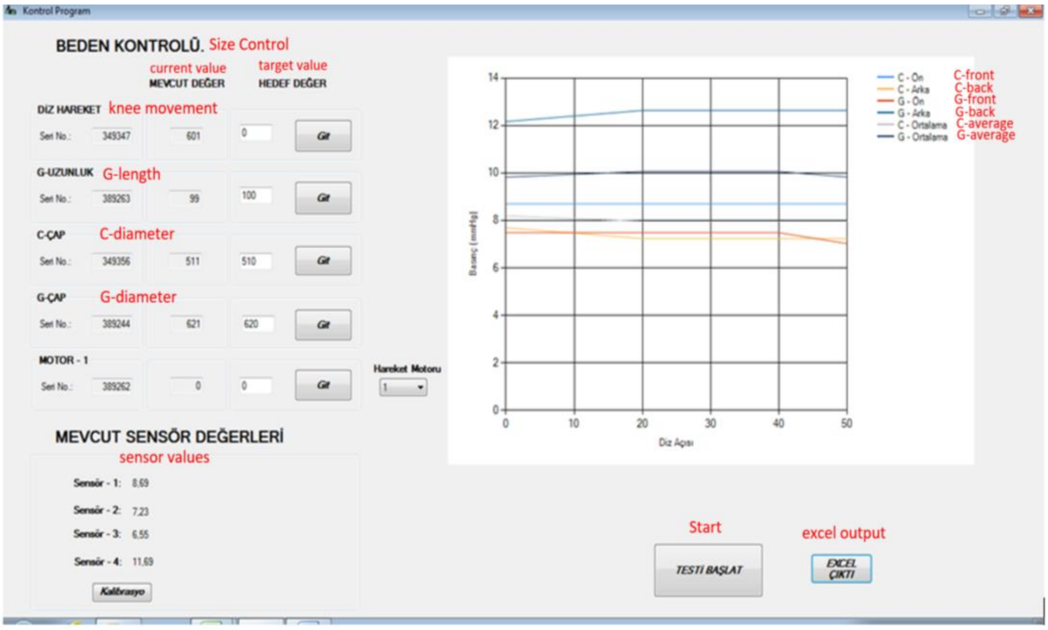
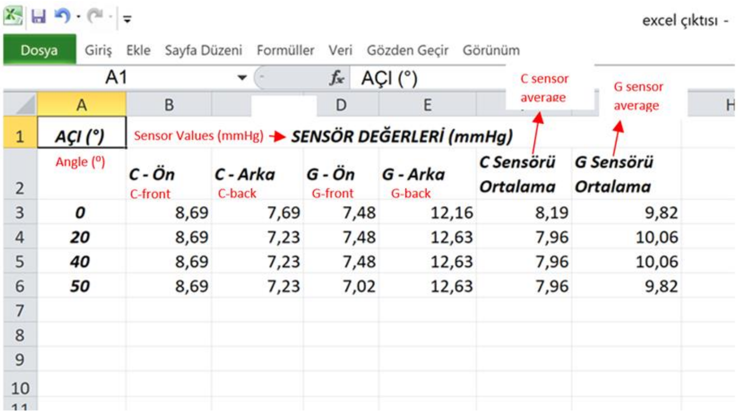


Figure 13. The Final State of the Pressure Values Applied by the Trouser Sample When the Device Becomes Static

If the user wants, the numerical values of the test can also be taken as Excel output. The interface of the device is in Turkish. Pressure values measured by the sensors according to knee bending angles are shown in Excel format in Figure 14.



AÇI (°) Angle (°)	C - Ön C-front	C - Arka C-back	G - Ön G-front	G - Arka G-back	C Sensörü Ortalama (C sensor average)	G Sensörü Ortalama (G sensor average)
0	8,69	7,69	7,48	12,16	8,19	9,82
20	8,69	7,23	7,48	12,63	7,96	10,06
40	8,69	7,23	7,48	12,63	7,96	10,06
50	8,69	7,23	7,02	12,63	7,96	9,82

Figure 14. Excel Screenshot Showing the Instant Pressure Values Applied by the Trouser Sample According to the Knee Angles

When the scientific literature and the catalogues of the previously produced test devices were examined, it was found that the devices measured the pressure values and their compliance with the standards worked statically, but the moving devices reflected the body movement in a limited way. It has been observed that the impression test apparatuses available in the market are produced for medical compression stockings. Pressure measurements of stretch bottom garments were carried out with the device for which a prototype was produced. These results will be published as a different research article. The certification process was not included in this academic study program because it was difficult to provide the necessary budget for the calibration and certification of this prototype device. The device has been patented as EP 3417286B1. Patent validation procedures have been completed in 6 different countries (Germany, Switzerland, Italy, Spain, Netherlands, and Turkey). Necessary certification processes will be carried out to ensure data security and reproducibility during the commercialization process. However, the SWISSLASTIC Company in Switzerland which has proven its reliability worldwide, was contacted to compare the data. It was learned that eight companies they sell to in Turkey. Data comparison was made using the MST MK IV device from Beksel Sağlık Gerecleri in Istanbul, one of these companies. Since the certified devices in the Turkish market can only measure pressure in a static state, static pressure results could be compared. These results were found to be in similar pressure classes. In summary, the pressure measurement test device described in the study examines the pressure values while in motion, is in the form of a 3-dimensional body leg, and contains a technological structure that provides the desired leg circumference and lengths. Therefore, it contains important innovations compared to equivalent test apparatus available in the market.

CONCLUSION

It is important to make evaluations in medical technical textile products such as compression garments, and compression/support socks that regulate blood flow in our body and to realize production in this direction. In the medical treatments applied with medical compression stockings/garments, the correct pressure application is possible with a balanced pressure profile that decreases upwards from the ankle to the groin. Therefore, it is expected that both daily clothes and medical clothes will help to pump up the deoxygenated in other words dirty blood from the legs to the heart in one direction. Thanks to the measurement of the pressure levels of the dressed stretch garments on the body, the decision-making ability to accept daily use purposes (preventing varicose veins, facilitating blood circulation) is also gained.

After the prototype device production will be transformed into the mass production stage. This device can also be utilized for pressurized garments, which are often used in the fields of textile, medical, and health/astronomy. This device will bring a new approach to increasing product quality and technical standards. Within the scope of the study, the design of the prototype pressure measurement tester that can mimic the human leg movements and be bent from the knee, dynamically expanding / contracting, shortening/extension has been realized for all stretch lower body clothing besides compression stockings. Especially for big textile companies, it is very important to be able to embody and analyze the functional and aesthetic properties of the fabric. At this point, there is a huge gap in the literature and assessments come out purely subjective. Therefore, the design, development, and production process has been realized for a test device that can demonstrate the interaction of garments with the human leg with concrete and measurable data. Therefore, the pressure measurement tester in the study is of great importance.

With the start of mass production, stretch fabric/clothing manufacturers will gain the ability to numerically report the effects of the fabrics offered to their customers on human physiology and biology. By measuring the pressure levels that the garments will apply to the body, the effects of the fabric on blood pressure and body physiology will be able to determine. With this capability, companies will be able to support their product under the positive effects of stretch fabrics by releasing presentations with written documents.

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