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Design development and evaluation of a wearable telerehabilitation system for segmental respiratory

Segmental solunum için giyilebilir bir telerehabilitasyon sisteminin tasarımı, geliştirilmesi ve değerlendirilmesi

***Yazar(lar) (Author(s))**: Fatma Betül DERDİYOK[1], Kasım SERBEST[2]*

ORCID[1]: 0000-0001-8027-7365

ORCID[2]: 0000-0002-0064-4020

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Design Development and Evaluation of A Wearable Telerehabilitation System for Segmental Respiratory

Highlights

- *A detailed conceptual design.*
- *A novel home-based telerehabilitation device with web interface.XXXXX*
- *A training device for segmental breathing.*

Graphical Abstract

In this study; a wearable device that supports segmental breathing exercise for the rehabilitation of people with respiratory system problems is designed using conceptual design concepts.

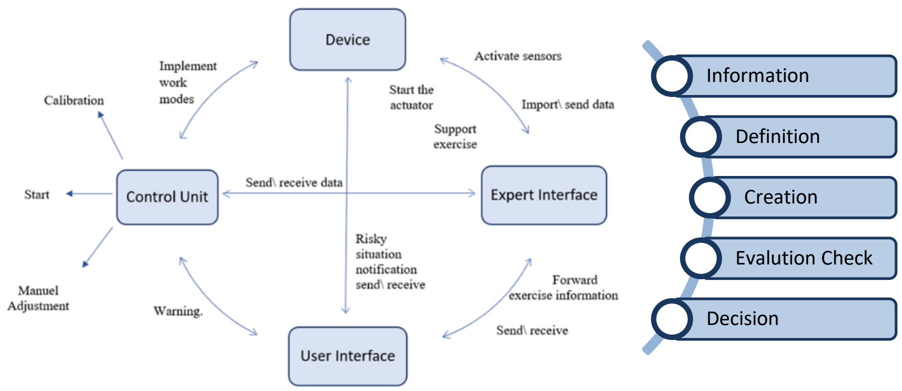

Figure. Conceptual design steps and workflow of the system.

Aim

In this study, it was aimed to support the patients to segmental breathing exercises in people with respiratory system disorders; easy to use, allowing for individual use. It is aimed to design a device integrated with telerehabilitation in accordance with engineering design and rehabilitation engineering design approaches.

Design & Methodology

Within the scope of conceptual design, a list of requirements for the design was created. Functional structures and solution principles of the device were determined. Design variants were created and were evaluated. Structures of the final solution variant and 3D drawings of the design were created.

Originality

The originality of the study is the design of the first wearable respiratory device specific to segmental breathing exercises for respiratory rehabilitation.

Conclusion

Our design has effective and appropriate equipment that can increase the respiratory capacity of patients and contribute to rehabilitation in the home environment thanks to telerehabilitation application.

Declaration of Ethical Standards

The authors of this article declare that the materials and methods used in this study do not require ethical committee permission and/or legal-special permission.

Design Development and Evaluation of A Wearable Telerehabilitation System For Segmental Respiratory

Araştırma Makalesi / Research Article

Fatma Betül DERDİYOK[1], Kasım SERBEST[2]
[1] Faculty of Technology, Departmant of Biomedical Engineering, Sakarya University of Applied Sciences, Turkey
[2 *]Faculty of Technology, Departmant of Mechatronic Engineering, Sakarya University of Applied Sciences, Turkey

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ABSTRACT

In this study, it was aimed to support the patients to segmental breathing exercises in people with respiratory system disorders; easy to use, allowing for individual use. It is aimed to design a device integrated with telerehabilitation in accordance with engineering design and rehabilitation engineering design approaches. Within the scope of conceptual design, a list of requirements for the design was created. Functional structures and solution principles of the device were determined. Design variants were created and were evaluated. Structures of the final solution variant and 3D drawings of the design were created. Our design has effective and appropriate equipment that can increase the respiratory capacity of patients and contribute to rehabilitation in the home environment thanks to telerehabilitation application.

Keywords: Pulmonary rehabilitation, Engineering design, Wearable technology, Patient-expert interface, Respiratory capacity

Segmental Solunum İçin Giyilebilir Bir Telerehabilitasyon Sisteminin Tasarımı, Geliştirilmesi ve Değerlendirilmesi

ÖZ

Bu çalışmada, solunum sistemi hastalığı olan kişilerde segmental solunum egzersizleriyle hastaların desteklenmesi; kullanımı kolay, bireysel kullanıma olanak sağlayan bir cihaz tasarlanması amaçlanmaktadır. Mühendislik tasarımı ve rehabilitasyon mühendisliği tasarım yaklaşımlarına uygun olarak telerehabilitasyon ile entegre bir cihaz tasarımı hedeflenmektedir. Kavramsal tasarım kapsamında, tasarım için bir gereksinim listesi oluşturulmuştur. Cihazın fonksiyonel yapıları ve çözüm prensipleri belirlenmiştir. Tasarım çeşitleri oluşturulmuş ve değerlendirilmiştir. Nihai çözüm varyantının yapıları ve tasarımın 3 boyutlu çizimleri oluşturulmuştur. Tasarımımız telerehabilitasyon uygulaması sayesinde hastaların solunum kapasitesini artırabilecek ve ev ortamında rehabilitasyona katkı sağlayabilecek etkin ve uygun donanıma sahiptir.

Anahtar Kelimeler: Pulmoner rehabilitasyon, Mühendislik tasarımı, Giyilebilir teknoloji, Hasta-uzman arayüzü, Solunum kapasitesi

1. INTRODUCTION

Respiratory exercises include practices to support more active use of the muscles that should play an active role in inspiration and to strengthen the muscles [1]. With these exercises, thoracic mobility increases [2] and respiratory mechanics are supported by using respiratory muscles more effectively [3]. Segmental breathing exercises are applied to use the intercostal muscles in the respiratory muscles more effectively.Segmental breathing exercises are manual applications that aim to increase the ventilation of the lung area under the chest wall by applying pressure to certain areas on the chest cage, creating proprioception stimulation and mechanical stimulation in those areas. The application is in the form of trying to inflate that part of the lung against the pressure applied by hand to the chest wall area, the projection of the area of the lung that is desired to be ventilated after expiration. The intercostal muscles under the chest wall are stimulated and the chest moves in that direction to ventilate the pressurized lung area. In this way, the patient's attention and awareness of that area increases and that chest area starts to work more actively. Segmental breathing is a key element in promoting respiratory health as it improves respiratory function, regulates respiratory mechanics, prevents secretions and fluid accumulation in the pleural space, increases thoracic mobility and reduces stress levels. Respiratory exercises constitute an important part of rehabilitation in people with respiratory system problems. However, in hospitals, rehabilitation services are not sufficiently accessible due to limited patient employment, limited time allocated to the patient, and lack of information about pulmonary rehabilitation practices by patients and problems in access to treatment [4]. In a study conducted in the United Kingdom, the number of hospitals conducting pulmonary rehabilitation programs

*Corresponding Author
e-mail : kserbest@subu.edu.tr

constituted 40% of the hospitals included in the study [5]. According to the review study by Milner et al., [6] reported, which examined 42 studies on the referral rate of COPD patients by healthcare professionals and the barriers to referral; 2-56% of patients are referred to pulmonary rehabilitation before intervention and 8-71% after intervention. The factors that prevent patients from being referred to pulmonary rehabilitation are generally lack of knowledge about pulmonary rehabilitation and its benefits. In addition, people who access pulmonary rehabilitation in clinics should perform breathing exercises within the home rehabilitation program as recommended by the specialist [7].

The advancement of technology has led to the production of various devices aimed at providing treatment and support for patients. Telerehabilitation systems are also being utilized to enable patients to receive treatment outside of a hospital environment, thereby increasing their access to healthcare and ensuring safer patient follow-up.

1.1. Devices for Respiratory Rehabilitation Research

One of the previous study conducted by Loubet et al., [8] to examine thoracic volume change. In the study, the thoracic volume template is monitored through the MATLAB program with the data obtained from the magnetic sensor placed at anatomical points such as around the scapula, lower ends of the costae, spinal cord and trachea. The thoracic volume values obtained are compared with the parameters measured with the spirometer device and it is seen that the spirometer data and the data obtained from the vest are compatible. With this study, an innovative approach for thoracic volume change monitoring is presented. Another respiratory monitoring device design was made by Puranik & Kanthi, [9]. The device consists of a belt with a pulse sensor positioned at the lower end of the torso and a sensor worn on the wrist. There is an acceleration sensor on the belt to determine the thoracic volume change with the expansion of the lower costae. There is also a flex sensor on the back to monitor the postural change of the person. In addition to respiratory monitoring, the device aims to teach the user deep controlled breathing techniques by taking yogic breathing as an example. In this context, it warns the user with a vibration actuator in case of a deviation in the parameters received from the sensors during respiratory monitoring. Another study of a device for teaching controlled breathing is the pneumatic system design by Choi et al., [10], which is designed as a system that can be easily attached to a belt or a harness. The system includes air bladders, an actuator array and a structure that monitors respiration. In the system, respiration is monitored with Bioharness device for respiratory rate monitoring and electrodermal activity is monitored with Qsensor. Pneumatic actuators provide tactile stimulation to the person by inflating the air sacs on the pneumatic actuators in order to direct the respiratory type of the person. The order of inflation of the air bladders can be controlled via the mobile device. When the system is tested, it is stated that by inflating the balloons in order, people adapt to the breathing pattern more easily, thus regulating their breathing.Another study of a wearable device design that can stimulate this type of breathing with mechanical stimuli is presented by Tsaknaki et al., [11]. Based on the fact that vocal artists improve their phonetic abilities by controlling their breathing, the system focuses on the design of a device that allows them to experience respiratory control. In the study, both the experience and teaching of breathing types and awareness during breathing are included. For this purpose, first, respiration types are taught with the guidance of voice trainers, and then respiration is monitored with the help of sensors. A strain sensor is used for respiratory monitoring, and a belt sensitive to strain change is modified to be a stiffer and tighter belt and presented in the device design. There is also wearable equipment that examines the activity of the rectus abdominus muscles with EMG sensors mounted on a tight dress used by dancers. In addition, a system called "respiratory shell" consisting of a sensor-actuator cushion system was created to feel breathing, stimulate and train correct breathing with tactile stimulation. These pillows are positioned anterior, lateral and posterior to the thorax. The cushions inflate and exert pressure on the thorax of the person like a hand from the outside, concentrating the breathing in that area. Likewise, when exhaled, the air in the cushions is released to support expiration. The design has been tested and evaluated as effective and remarkable in respiratory monitoring, support and awareness. For future studies of the system, it is evaluated that comprehensive, detailed evaluation and more effective support of people's breathing can be provided by tracking physiological signals.

1.2. Related Patents

In addition to studies involving monitoring and training for the respiratory system, there are also patented designs. While examining the patent studies on this subject, patents suitable for similar purposes were examined by searching the keywords "respiratory device", "breathing exercises device", "segmental breathing" etc. on Google patent, Espacenet and Turkish Patent websites. Table 1 analyzes patents that are similar to our study in terms of goal and approach.

1.3. Commercial Products

There are many commercially available designs that support breathing exercises that capture respiratory system data. Commercial products for the respiratory system and their features are shown in Table 2. When the commercial products shown in the table for respiratory monitoring are examined; although the primary purpose of the devices examined is mostly to evaluate exercise performance, many studies in the literature show that they can also be used for monitoring respiratory diseases. When studies, commercial products and patents are examined, designs for the respiratory system can be divided into groups focusing on respiratory monitoring, respiratory training and both respiratory monitoring and training. These designs include examples of systems

Table 1. A Summarise of Related Patents.

Patent no	Feature
US4602643 (Dietz, [12])	It pneumatically senses and monitors the volume increase and decrease in the chest, abdomen and back during ventilation.
US20040224822A1 (Verheem, [13])	It is an electronic timer device design that provides audio, visual and sensory signals such as pressure and electric current to guide breathing exercises.
US20070203433A1 (Murphy, [14])	It is a wearable device that provides tactile feedback with electronic transducers with electromechanical sensors that measure respiratory rate and respiratory depth with ventilation monitoring.
US20080142004A1 (Wasnick, [15])	The key is the indicator system, activated by the chest strap and chest expansion to train deep breathing.
WO2008139380A2 (Baruers, [16])	The system is a device that provides visual, audible and tactile warning to guide breathing exercises with sensors mounted on the respiratory belt and textile fabric, to monitor the intensity of inspiration and expiration and to guide it in a way that is integrated with the exercise.
WO2009036327A1 (Amurthur et al., [17])	It consists of wearable respiratory monitoring (bioimpedance sensor) and sensors that receive physiological data (pulse oximeter) and motion information for posture (accelerometer) to study breathing patterns in sleep, and a wireless monitoring processor that can monitor the data remotely.
WO2012117376A1 (Dijk et al., [18])	Device design proposals consisting of sound, light and physiological sensors that measure motion (accelerometer), respiration rate, respiration pattern, sound, light and physiological sensors to guide and manage breathing, especially during physical activity.
US20130289431A1 (Gavish & Doron, [19])	Microphone and loudspeaker system design to analyze respiratory period, inspiration and expiration time.
US8663126 (Al Thalab, [20])	It is a wearable chest strap with an acoustic sensor for monitoring the respiratory sounds of the pediatric group and a device with a microprocessor for monitoring respiratory sounds and collecting data.
US20150342518A1 (Persidsky & Ahlund, [21])	It is a wearable breath training system that includes a microcontroller to monitor (displacement sensor), guide and evaluate breathing (displacement sensor) and monitor posture (angle sensor) according to breathing exercises; receive, process and transmit signal data.
CA2896498C [(Roy et al., [22])	It is a wearable device that can measure a person's physiological parameters, respiratory rate, tidal volume, minute ventilation by measuring the plethysmogrophic signal.
US20170071506A1 (Dwarika, [23])	It is a wearable device consisting of acoustic sensors (accelerometer, microphone, vibration sensor, etc.) for monitoring physiological parameters and respiration, with a warning system for worsening progression, where data can be transferred and collected via bluetooth.

integrated with telerehabilitation. In addition to respiratory diseases, it focuses on respiratory exercises and stress management. Most of the devices designed for respiratory training focus on diaphragm breathing.Examples of studies where respiratory system devices are supported by telerehabilitation Among these studies, there are few studies that meet respiratory monitoring and training together, but there is only one study that focuses on segmental respiration. In addition, there are no examples of systems in which telerehabilitation is integrated. It is evaluated that the lack of study examples that combine all these features may be insufficient to support pulmonary rehabilitation. The aim of the paper is to design a device integrated with telerehabilitation in accordance with engineering design and rehabilitation engineering design approaches, which is easy to use, portable, allows individual use, compatible with the anthropometric characteristics of adult

Table 2. Commercial wearable products for respiratory monitoring and education.

Products	Features
Spire [24]	Respiratory data and Physiological data (Heart rate etc.) monitoring. Monitoring with mobile application.
Oxa [25]	Respiration (Plethysmography), Heart Rate and body temperature (Infrared sensor) monitoring. Training tracking (Accelerometer).
Prana [26]	Respiratory training with diaphragmatic breathing monitoring, posture control and tactile stimulation. Providing visual feedback and entertainment with mobile game.
Eq lifemonitor [27]	Monitor Respiration Rate, Heart Rate and body temperature (Thermometer). Training tracking (3-axis accelerometer).
BioHarness Zehr [28]	Respiratory monitoring, data analysis.
Hexoskin [29]	Respiratory rate and volume (Plethysmography), Heart rate monitoring; fatigue and stress level monitoring. Training movement tracking (accelerometer).
RESPeRATE [30]	Respiratory rate (strain sensor), providing audible feedback to stimulate relaxation.

individuals, and supports the patient to perform segmental breathing applied within the scope of pulmonary rehabilitation in people with respiratory system disorders correctly and effectively. The aim of the device to be developed is to increase the respiratory capacity of people with respiratory symptoms and to support respiratory rehabilitation.

2. MATERIALS AND METHODS

In this section, engineering design processes are presented in accordance with the conceptual design stages. As a result of these stages, design specification are identified, solution proposals are presented, and the final design is presented by evaluating the proposals. Conceptual design, with its systematic approach, enables the design process to shift from an intuitive process to systematic techniques [31]. In this concept, it is defined as a detailed solution definition that creatively identifies important problems, elaborates functional structures, explores appropriate solutions and integrates them into a working structure [32]. In the first stage of conceptual design, the product to be created should be examined in a general framework. In this framework, the needs for the problem are sorted according to their characteristics and priorities are determined [33]. With the determined features, the main and sub-functions of the system are shaped [32]. Demands (D) are the features that are expected to be met under all conditions. Features specified as Wishes (W) are not essential wants for all conditions. The features specified as needs are scored between 1 and 3 points according to their importance in the design. The scores are interpreted as 1 point "low", 2 points "medium", 3 points "high" importance, respectively. The design specification was classified into ten categories. These are geometric features, energy, materials, safety, cost, sensors, telerehabilitation, data monitoring, respiratory muscle groups, notifications (See Table 3).

2.1. Identifying Function Structures

In the design process, function is defined as expressing the inputs and outputs in the system in accordance with the needs. The function structures of the device to be designed are examined in two groups. These are overall functions and sub-functions [32].

Table 3. Requirements List.

Category	Content	D/W	Score D (1-3)	Unit	Scale	Value
Geometric features	Body anthropometric characteristics	D	3			for adults
	Length	D		50- 80	cm	
	Width	D		50-80	cm	
	User weight	D		60-100	kg	
Terms of use	Ergonomic	W				
	Easy to use	D	2			
	Home use	D	3			
	Individual use	D	3			
Evaluation parameters	Heart rate	D	2	40-220	bpm	
	Blood pressure/ Saturation	W		0-200 70-100	mmHg %	SpO2
	Respiratory rate/ Respiratory rhythm/ Thoracic volume change/ chest wall movement	D	3	0-24	dk s	

Table 3.(Cont). Requirements List Continue.

Telerehabilitation	Wifi connection	D	3			
	Bluetooth connection	W				
	Simple user interface	D	3			
	Simple expert interface	D	2			
	Data security	D	2			
Respiratory muscle groups	Intercostal muscles	D	3	MVC	%	40-100(75)
	Diaphragm	W		MVC	%	20
	Accessory respiratory muscles	W		MVC	%	5
Respiratory monitoring	EMG	W				
	Accelerometer/ Pressure meter/ Strain gauge	W				
Notifications	Mechanical stimuli (vibration, pressure, etc.)	W				
	Auditory stimuli	W				
	Visual stimuli	W				
Energy requirement	Electric Energy	D	3	220	volt	
	Battery	W				3 hours usage
	Low voltage	W		12-48	volt	
Material	Lightweight	D	2			
	Skin compatibility	W				
	Resistant	D	2			
	Recyclable	W				
Safety	User safety	D	2			
	Device safety	D	2			
Cost	Be competitive	W	1			
	Low cost of sales	W	2			350-3500 $
	Low maintenance cost	W	2			

2.1.1. Overall functions

In the Figure 1, the system is delimited by axis lines. Energy input in the system: E, energy output: E'. The energy input of the developed segmental respirator consists of electrical energy, battery and muscle power. The device supports the filling of the battery and the operation of the system with electrical energy. Electrical energy is used for signal collection, transmission and mechanical stimulation. The system will convert electrical energy into mechanical energy by means of mechanical actuators. In addition, the respiratory muscle activity of the user also supports the mechanical energy. Here, the user uses the respiratory muscle power to change the intensity of the mechanical stimulus (See Figure 1).

2.1.2. Function structure of sample design

In the system, M is defined as an individual who cannot perform segmental breathing and M' is defined as an individual who has learned segmental breathing and has been rehabilitated The signal input S refers to the operation of the system through the control unit, while the signal output S' refers to the mechanical actuators and data monitoring (See Figure 2). When developing the design, it is necessary to present defined design problem solution options suitable for all known and proven functions and sub-functions. For this purpose, solution options are presented in the form of a design catalogue corresponding to each function. This catalogue can contain various types of data such as basic solutions, solution principles, device elements and different solutions at the shaping level (See Table 4).

2.2. Combining Solution Principles

While developing the design, the most appropriate solution options that can meet the needs of the design are brought together by considering the functions (Pahl et al., [32]) (See Table 5).

Design solutions are reassessed using the selection card's table of alternatives (see Table 6). At this stage, an objectives tree is developed, incorporating evaluation criteria aligned with the design specifications. Each objective is weighted based on its importance, with assigned values summing to 1 (see Figure 3). In accordance with the VDI 2225 guidelines prepared by the German Society of Engineers (as cited in Pahl et al., [32]), solution principles are evaluated based on objectives and weighted criteria, using a scoring system

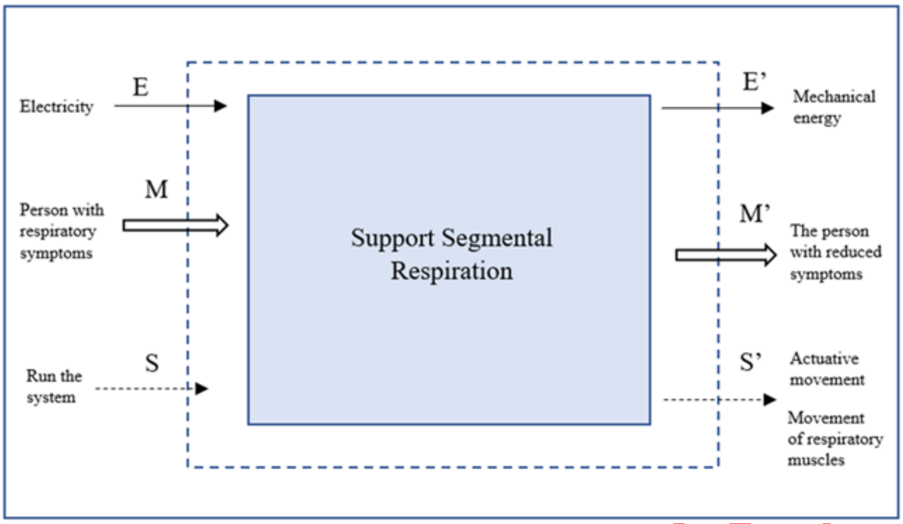

Figure 1. Overall function of the segmental respiratory system.

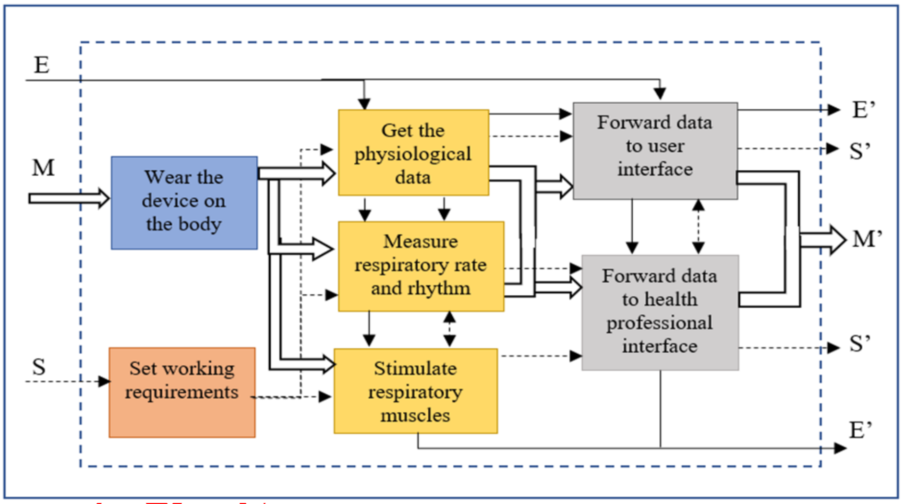

Figure 2: Function structure of sample design.

Table 4. Morphological Chart to Possible Solutions.

	Subfunctions		**1**	**2**	**3**	**4**	**5**	**6**
1	Wearing the device on the body	Wearability	Vest	Chest belt	Strap with sensor pendant	T- shirt	Shoulder body belt	Prototype strap
2	Working conditions	2.1. Energy	Electric E.	Lithium Ion Battery	Nickel Cadmium Battery			
		2.2. Data collection	Physiologic	Respiration	Demographic			
		2.3. Evaluating data	Expert assessment					
3	Physiological data		Heart rate (Pulse meter)	Blood Pressure (Pressure sensor)	Saturation (pulseoximeter)			

Table 4. Morphological Chart to Possible Solutions Continue.

4	Respiration data	4.1. Feature			Respiration rate	Breast enlargement amount	Respiratory muscle activity	Respiratory rhythm	Breathing pattern	Chest wall movement
		4.2. Sensor			Accelerometer	EMG	Acoustic sensor	Pressure sensor	Strain gauge	Flex sensor
5	Stimulate the respiratory muscles	5.1. Warning type			Vibration	Linear actuator	Electrical stimulation	Electronic timer	Soft actuator	
		5.2. Muscle group			Intercostal muscles	Diaphragm	Accessory respiratory muscles			
6	Communicating data to the user	6.1.Alert			Voice alert	Visual alert	LED allert			
		6.2./ 7.1. Telerehabilitation	6.2.1. /7.1.1. Receiving notifications	6.2.1.1./7.1.1.1. Type	Email	Mesage				
7	Forward data to the health professional	6.2./ 7.1 Telerehabilitation	6.2.1. /7.1.1. Receiving notifications	6.2.1.2./7.1.2. Feature	Allert	Forwarding	Motivation			
			6.2.2./7.1.3. Data storage		External Disk	SSD	USB	Cloud storage		
			6.2.3. /7.1.4. Connection		Wifi	Bluetooth				

Table 5. Solution Variants and Characteristics.

Solution Variants (SV)	Characteristics
SV1	1.1.2 - 2.1.2 – 2.2.1 – 2.2.2 - 2.3.1 - 2.4.1 - 3.1- 4.1.2 - 4.2.5 – 5.1.1 – 5.2.2 – 6.1.1 – 6.2.1.1.1 – 6.2.1.2.1 – 6.2.2.1 – 6.2.3.1
SV2	1.1.3 – 2.1.3 – 2.2.2 – 2.2.3– 2.3.1 – 2.4.1 – 4.1.4 – 4.2.3 – 5.1.2 – 5.2.1 - 6.1.2 – 6.2.1.1.2 – 6.2.1.2.1 – 6.2.1.2.2 – 6.2.2.4 – 6.2.3.1
SV3	1.1.1 + 1.1.5 – 2.1.1 – 2.2.1 – 2.2.2 – 2.2.3 – 2.3.1 – 2.4.1 – 2.4.2 – 3.1 – 3.3 – 4.1.1 – 4.1.4 – 4.1.5 – 4.1.6 – 4.2.1 – 5.1.5 – 5.2.1 – 5.2.2 – 5.2.3 – 6.1.1 – 6.1.2 – 6.2.1.1.2 – 6.2.1.2.1 – 6.2.1.2.2 – 6.2.1.2.3 – 6.2.2.4 – 6.2.3.1 – 6.2.3.2
SV4	1.1.4 – 2.1.1 – 2.2.1 – 2.2.2 – 2.3.1– 2.4.2 – 3.1 – 3.3 – 4.1.3 – 4.2.2 – 5.1.3 – 5.2.1 - 5.2.3 – 6.1.2 – 6.1.3 – 6.2.1.1.1 – 6.2.1.2.1 – 6.2.2.3 – 6.2.3.1
SV5	1.1.3 – 2.1.1 – 2.2.1 – 2.2.2 – 2.3.1 – 2.4.1 – 2.4.2 – 3.1 – 4.1.1 – 4.1.4 – 4.2.1 – 5.1.1 – 5.2.1 – 5.2.3 – 6.1.2 – 6.2.1.1.2 – 6.2.1.2.2 – 6.2.2.1 – 6.2.3.1
SV6	1.1.1 – 2.1.2 – 2.2.1 – 2.2.2 – 2.3.1 – 2.4.1 – 3.1 – 3.3 – 4.1.4 – 4.2.5 – 5.1.2 – 5.2.1 – 5.2.2 – 5.2.3 – 6.1.1 – 6.1.2 – 6.2.1.1.1 – 6.2.1.2.2 – 6.2.2.2 – 6.2.3.1

to quantify design solutions. A score of 0 represents an inadequate solution with significant structural or functional deficiencies that fail to meet user needs. A score of 1 indicates a medium solution that offers some utility but has structural deficiencies. Solutions scoring 2 are considered adequate, possessing essential structural elements despite minor shortcomings. A score of 3 represents a good solution that is efficient and well-structured, while a score of 4 signifies a very good solution with optimal suitability and maximum utility. This systematic approach ensures consistent assessment of design alternatives (see Table 7).

2.3. Fixing Solution Variants

Physical models facilitate understanding and transfer of design features and structure by simulating them during the design process. In this way, more original works can be created in design [34].

Table 6. Solution Selection Card

SELECTION CARD

SELECTION CRITERIA
(+) Yes
(-) No
(?) Lack of information
(!) Check requirements list

DECISION
(+) Purse Solution
(-) Eliminate solution
(?) Collect information
(!) Check requirements list for changes

A. Direct provision to all functions.
B. Providing the requirements list.
C. Allowable cost.
D. Providing safety requirements.
E. Sufficient and secure access to data.
F. Suitability of usage features and conditions.
G. Effectiveness and adequacy of the warning system.
H. High compliance with telerehabilitation.
I. Ease of adaptation

ENTER SOLUTION VARIANTS (SV)	A	B	C	D	E	F	G	H	I	REMARKS (İndications, Reasons)	DECISION
SV1	-	?	+	+	?	+	?	?	+	The system does not fulfill its main function.	-
SV 2	+	!	?	+	?	+	+	+	+	It does not take physiological data.	-
SV 3	+	+	+	+	+	+	+	+	?		+
SV 4	+	+	?	-	?	?	+	?	+	More information is needed on user safety, ease of use, breadth of user profile.	-
SV 5	?	+	+	+	+	+	?	?	+		+
SV 6	?	+	+	+	?	+	+	+	?		+

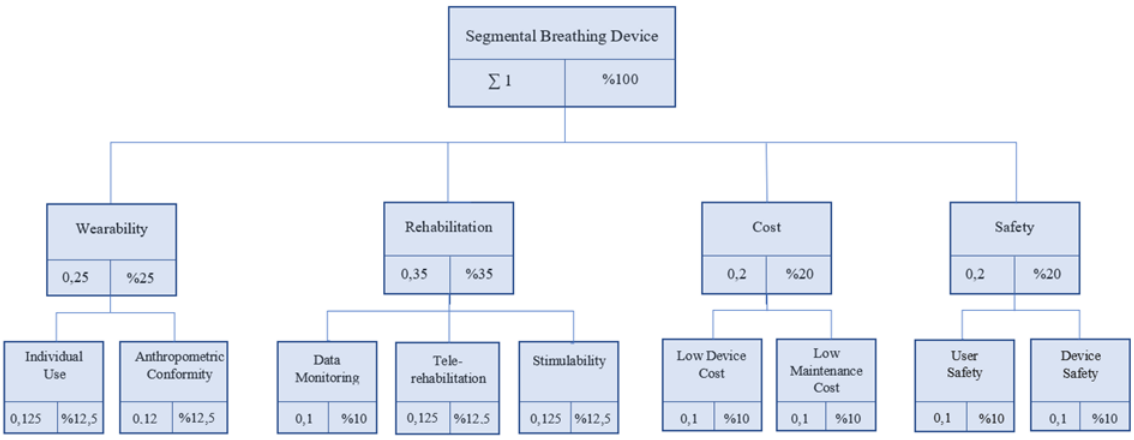

Figure 3: Objectives Tree.

2.3.1. Solution variant (SV) 6

The design consists of sensors and stimulating structures placed on the inner surface of the vest (See Figure 4). The design includes a pulseoximeter (1) that can be measured from the earlobe to obtain heart rate and saturation information from physiological parameters. Respiratory rhythm data from respiratory parameters is obtained with strain sensor (5). It was considered to use a linear actuator as a stimulus factor in respiratory training (3). The inner structure of the vest is covered with Velcro lining (7) and provides displacement and fixation with the apparatus (2) that provides attachment to the Velcro under the sensors and actuators. At the same time, these elements can be adjusted in diameter with the belt (6) and apparatus (4) in order to adapt more to the body size of the person.

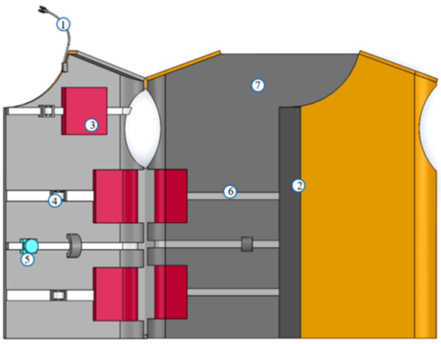

Figure 4: Solution Variant 6 front view.

2.3.2. Solution variant (SV) 5

This design consists of a strap with a sensor (See Figure 5). The straps can adapt to the body size of the person with the Velcro connection (1). In order to adjust the change in the chest diameter, a connection is provided with a buckle structure (2) on the front belt. When the interior of the design is examined in detail, there is a pulse sensor (4) positioned on the chest to correspond to the heart rate data as the physiological data of the person. Among the respiratory parameters, respiratory rate and respiratory rhythm data are obtained with the acceleration sensor (5). A vibration actuator (3) was added to stimulate segmental respiration.

2.3.3. Solution variant (SV) 3

This solution variant received the highest score in the evaluation and was determined to be the optimal solution. The parts of this solution proposal are; vest, shoulder chest strap, smart watch and control module. If the vest design is examined (See Figure 6.a); the number 1 part in the design is the Velcro strap. When the internal view of the design is examined in detail, the structure shown with number 3 is the soft actuator and the structure number 6 is the ventilation channels. The soft actuator is a balloon-like actuator that has the appearance of an airbag and can inflate with the formation of positive pressure.

Table 7. Evaluation of the principle solution variants.

		Solution Variants											
		SV1		SV2		SV3		SV4		SV5		SV6	
Criteria	**Rate**	V 1	w1	V 2	w2	V 3	w3	V 4	w4	V 5	w5	V 6	w6
Individual Use	0,125	2	0,25	2	0,25	3	0,375	1	0,125	3	0,375	3	0,375
Anthropometric Conformity	0,125	2	0,25	1	0,125	3	0,375	1	0,125	2	0,25	3	0,375
Data Monitoring	0,10	1	0,10	1	0,10	3	0,30	3	0,3	3	0,30	2	0,20
Telerehabilitation	0,125	1	0,125	2	0,25	3	0.375	1	0,125	2	0.25	1	0.125
Stimulability	0,125	1	0,125	2	0,25	3	0.375	2	0,25	2	0,25	3	0,375
Low Device Cost	0,1	3	0,3	1	0,1	2	0,2	1	0,1	3	0,3	2	0,2
Low Maintenance Cost	0,1	3	0,3	1	0,1	2	0,2	1	0,1	3	0,3	2	0,2
User Safety	0,1	2	0,2	2	0,2	3	0,3	1	0,1	3	0,3	3	0,3
Device Safety	0,1	2	0,2	2	0,2	3	0,3	1	0,1	3	0,3	3	0,3
Total (∑)	∑=1		1,85		1.57		2,80		1,325		2,625		2,45

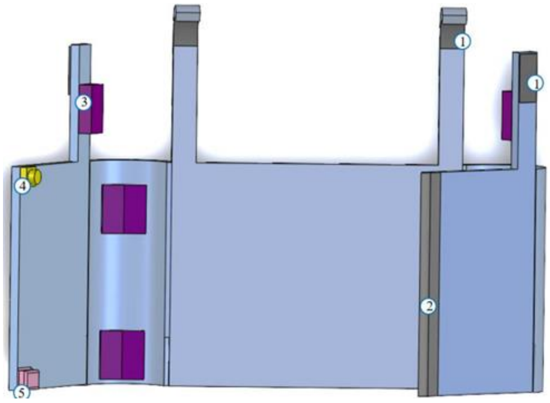

Figure 5: Solution Variant 5 front view.

In the inner structure of the vest, there are belt structures (2) and connection apparatus (4) that allow these belts to be adjusted in accordance with the body size of the person. The inner lining of the vest is designed to have a velcro (5) structure in order to ensure that the structures in the vest remain fixed while moving in the desired direction.If the shoulder-chest belt design is examined (See Figure 6.b), the design consists of three belt structures (2, 3, 4) for the shoulder, upper chest and lower chest and their belt connections (5) and connection apparatus (6) to adjust the belt size. In addition, there is an acceleration sensor (1) on each belt.Heart rate and saturation information can be seen on the smart watch (See Figure 6.c). The received data is transferred to the control module via the connection cable.The control module (See Figure 6.d) has (1) switches for switching on the device and starting the exercise. The connection of the device with the pneumatic system on the vest is made with the inlet number 2 and the air outlet is made through the channel number 3. At the same time, the data received from the sensors can be temporarily stored in the microprocessor inside the device. The connection with the sensors is made via cable connection and the web interface is connected via Bluetooth with the connection input number 4.

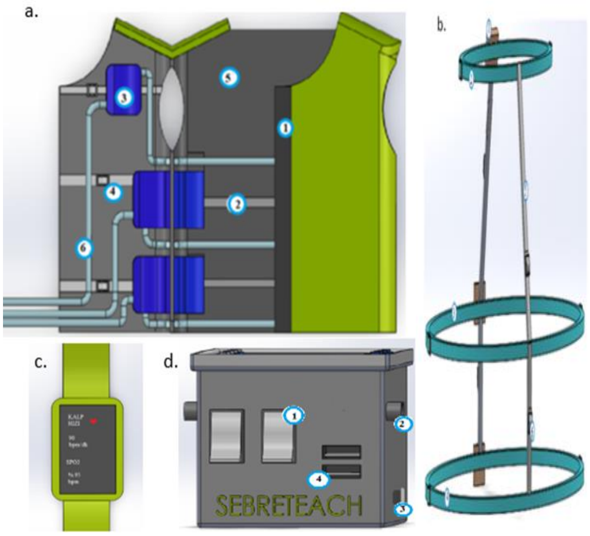

Figure 6: Solution Variant 3 front view.

2.4. Web Interface

In the treatment of the disease with pulmonary rehabilitation, the patient's developmental status should be monitored by a healthcare professional by monitoring respiratory data and kept under control against possible complications. Remote rehabilitation can be provided with telerehabilitation in patient follow-up. In order to take advantage of these opportunities and provide more patients with access to pulmonary rehabilitation, we included telerehabilitation feature in the device we designed. To achieve this, we created a web interface that transmits patient data and provides communication with the specialist. The respiratory monitoring web interface provides separate login options for patients and specialists. Once logged in, users can view key metrics, including heart rate, respiratory rate, and saturation during exercise. A dedicated respiratory menu provides details on respiratory rhythm, rate, pattern, and chest expansion. Patients can customize exercise parameters, such as duration, rest time, and targeted thoracic regions, while also accessing notifications and reporting adverse effects (See figure 7). The specialist interface offers a patient information menu with individual tabs for each patient, displaying demographic details (See figure 8) and submenus for tracking exercise, physiological data, and respiratory metrics to monitor therapeutic progress (See figure 9)

2.5. Device Workflow

The user who wants to use the device first opens the control module after putting on the device elements. When the device is turned on, there is a warning to calibrate the sensors on the screen and a button to start the calibration process right next to it. Then the system checks the correct positioning of the sensors, the full contact of the sensors and whether data can be received from the sensors.In the second stage of calibration, physiological (heart rate, saturation, etc.) and respiratory data (respiratory rate, rhythm, pattern; chest wall movement) are collected from the person with the help of sensors. This data is transmitted from the control module to the web interface of the mobile device's healthcare professional. After examining the patient's data and exercise performance, the healthcare professional organizes the patient's daily/weekly exercise program from the "prescribe exercise" menu in the system. On the window that opens, the user enters information such as

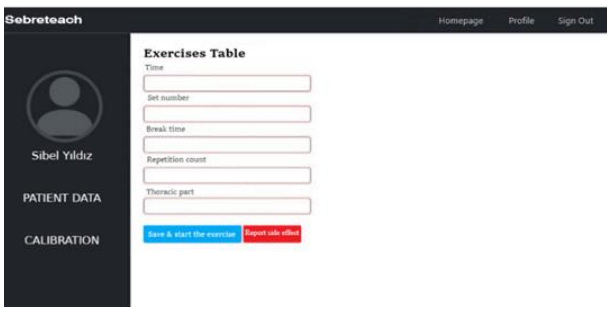

Figure 7: Patient interface exercise table view

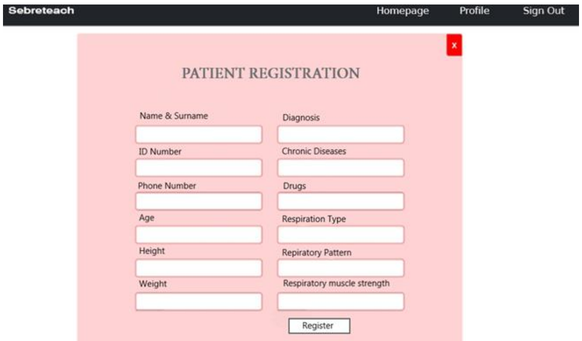

Figure 8: Healthcare professional web interface patient registration menu.

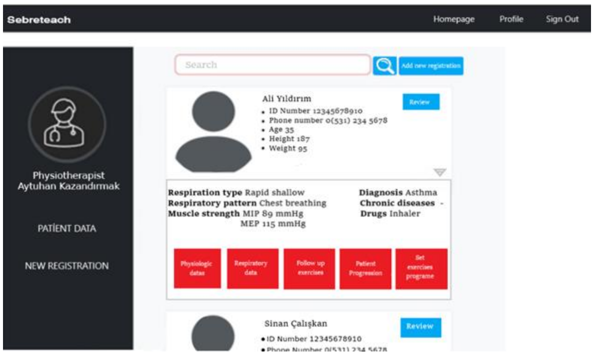

Figure 9: Health expert web interface view.

the duration, number of repetitions, rest time and thoracic regions to be exercised. There is also a tab at the bottom of the screen for messages to be sent to the patient. After completing the exercise program and writing a message, the specialist transmits the information to the patient by clicking the forward to patient interface button. In the user interface, the respiratory exercise program transmitted by the healthcare professional when notified can be set manually on the control module or via the web.In the event of technical faults or malfunctions in the device or deviations from normal physiological data (heart rate, saturation) while the person is performing the exercise, the display shows a warning of an abnormal situation. If the deviation continues to increase, the device stops the exercise system to shut down. If the exercise progresses smoothly, the system pauses when the person completes the exercise set and automatically starts a new set when the rest is completed. The system stops the device after the sets and rest are completed. The data received during exercise and rest on the user screen is transmitted to the patient and healthcare professional interface. Depending on the health status of the patient, the specialist provides the user with warnings, guidance and motivational messages about what to pay attention to during exercise. In addition, it transmits the decision that the exercise program should be modified and new exercise program information as a message (See Figure 10).

2.6. Specifications of Device Components

The device basically consists of four components. The first component is the torso belt elements. The torso belt structure with sensors consists of three belts on the clavicle, upper and lower part of the chest. On each belt there is a "MPU6050" accelerometer to measure respiratory data, chest wall movement and indirect respiratory rate and rhythm.

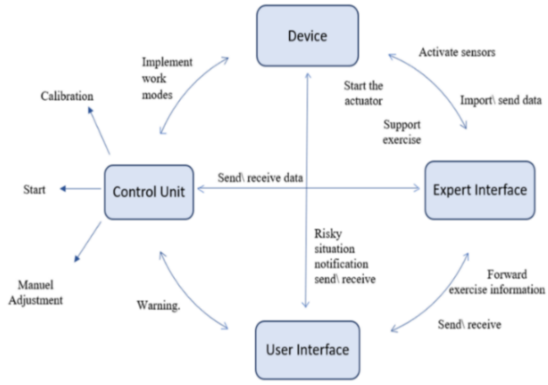

Figure 10: Schematic representation of device operation flow.

The vest elements include a soft actuator balloon, ventilation ducts and pressure sensors located on the soft actuators. The soft actuator balloons are connected to the control module located outside the vest via ducts. The pneumatic actuator system inside the control module provides air inlet and outlet into the soft actuators through the ducts. The pneumatic system includes a DC motor, turbine, solenoid valve, microprocessor, switch and ventilation ducts for connection to the vest. There are two ventilation ducts connected to the turbine for the inflation and deflation of the soft actuator balloons and solenoid valves controlled by electrical energy for the passage of air flow in these ducts. When the turbine is operated, the balloons inflate when the air flow is realized in the duct-balloon direction, and the air in the balloons is discharged when the cross switch direction is changed and the air flow is changed in the balloon-channel direction. During this process, the solenoid valve on the first channel remains open during air supply to the balloons, while the solenoid valve connected to the first channel is closed and the solenoid valve connected to the second channel is opened during air intake. The "RP-L 400" thin film pressure sensor on the soft actuator balloons is included in the system to monitor the response of the chest wall via pressure.

The sensor wristband has a MAX3010 sensor that allows to track pulse and saturation information together. It has a connection with the Arduino in the sensor control module to receive data from the sensor.

The control module includes pneumatic system structures (motor, solenoid valve, switch), control unit, display, flow shut-off keys, buttons, connection inputs and speaker for voice notification. It was determined to use "Arduino UNO" to receive data from the sensor structures on the vest, chest-body belt and sensor wristband and to control all these elements, including soft actuators. The connection between the sensor structures and the Arduino is provided with the help of a cable. In addition, it includes "ESP8266" Wi-Fi module to provide connection with web interface and data transfer and

"HC05" Bluetooth module to provide data transfer without internet connection.

3. RESULTS and DISCUSSION

According to the results of the study, the design we proposed to regulate the respiratory rhythm and teach the respiratory pattern, as determined in the objectives of the study, includes an actuator system that can monitor the person's breathing and provide directional warnings accordingly. The actuator system in our design; As stated in other studies, it supports the respiration of the person, it is evaluated that it can be used for the treatment of respiratory system diseases in regulating the rhythm and creating awareness of the respiratory pattern. In addition, in the system we designed to stimulate the muscles active in segmental respiration with stimulating actuator systems, it creates a more effective treatment awareness by providing a guiding message notification warning to the person. Another goal is that the device design supports telerehabilitation. In our proposed study, which includes telerehabilitation application in respiratory system designs; it is ensured that the data obtained is received, transferred to a mobile device and monitored by an expert. With the web system we designed, the data received from the person is collected in a storage area and transferred online to the healthcare professional. This data can be viewed by the user and the specialist through the website interface. Thanks to these features, the treatment of the person is supported and it enables intervention without putting the person at risk from adverse situations and conditions.

This study presents the design of a wearable device suitable for individual use that can support patients while performing segmental breathing exercises and facilitate exercise training. In addition, a system design integrated with telerehabilitation to support patient-expert communication is designed within the framework of conceptual design. The device is a device that can be used in the home respiratory rehabilitation program of adult individuals who show symptoms due to respiratory system problems. With this design supported by telerehabilitation, individuals can perform a safe and efficient exercise program in the home environment. Thanks to telerehabilitation, the healthcare professional can monitor patient data, progression, interventions to be made to the patient, the treatment program to be given and the effectiveness of the treatment.

3.1. Evaluation from the User Perspective

To ensure safety compliance, a device must reliably perform its technical functions while protecting users and the environment. The German industry standard DIN 31 004 provides guidance for selecting safety-compliant solutions (as cited in Pahl et al., [32]). Effective electrical insulation is essential to prevent direct contact, and the integration of fuse elements safeguards the system against high current draw. To enhance safety, the device should display visual and audible warnings on the user interface if operational disruptions occur due to issues like electrical failures or leakage. For technical challenges, such as inaccessible notifications or difficulties in initiating programs, users are advised to seek support from the technical team.

Commercial Potential of Design

The cost analysis for mass production of the device, with a target of 300 units per month (10 units per day, 3,600 units annually), reveals a reduction in unit cost. Initially, the unit cost is $130.71 for a single device. With mass production, the price decreases by 25%, lowering the unit cost to $98 for 300 units per month, and further to $65.30 for 1,000 units per month. After incorporating additional costs such as web services, employee expenses, depreciation, and operational overhead, the projected selling price is $230.When similar devices are analysed, "Spire" [24], which receives respiratory data and transfers it to the mobile application, costs 129 $. "Oxa" [25], which takes both respiratory and physiological data, costs 435 $. "Hexoskin" [29], which monitors respiration and transfers data to the mobile application, costs 648 $, while "Eq Lifemonitor" [27], which also measures fatigue and stress levels, costs 1649 €. "Prana" [26], a mobile app-supported device that receives respiratory data and supports respiratory training using a single stimulus, costs $199, while "RESPeRATE" [30], which includes audio and video alerts, costs $349.The design includes features with elements of data tracking, alerting system and telerehabilitation. Compared to other commercial products, SV3 design includes advanced and multiple features. However, it is seen that it is lower than the cost of other devices.

3.2. Comparison of Design with Similar Studies

There are many studies on the respiratory system in the literature. While there are many products that contribute to the diagnosis of disease by tracking data for the respiratory system, there are also studies in which physiological data are monitored. In addition to these, devices that warn against deviations in respiratory data and provide guidance to support controlled breathing are also included in the literature. In Table 8, the features of the studies in the literature and the designed devices are examined in detail and allow comparison with our design Solution Variant 3 our optimal design we created within the scope of the study, scientific studies, patents and commercial products were compared according to their purposes. The focus of our study on the purpose of respiratory rehabilitation and its specialization with segmental respiration constitute the originality of our study. In our proposed design, heart rate and saturation among physiological parameters and respiratory rate, rhythm and depth of breathing among respiratory parameters are evaluated among the data we examined. Venegas et al. [39], in their technical review of respiratory monitoring systems, showed that 60% of the studies examined chest wall movement in respiratory data. The final design in our study utilizes chest wall motion tracking, which is highly preferred for examining

Table 8. Respiratory device studies and their features.

References	Objective	Data	Sensor	Stimulatory system
Stafford et al., [35]	To design a virtual game to increase the participation of patients with respiratory problems in respiratory exercises.	Respiratory rate, amount of chest expansion	Acoustic sensor, Advanpro chest strap (includes acceleration sensor)	Mobile game with visual notifications
Puranik & Kanthi, [9]	To investigate the design of a wearable device to assess yogic breathing and technical practice performance.	Heart rate Posture Respiratory rhythm and pattern	Pulse sensor Flex sensor Gyroscope and accelerometer (MPU 6050)	Vibration actuator Visual monitoring
Siering et al., [36]	To design a wearable device integrated with a mobile game that increases the motivation and focus of children to support breathing education in children with respiratory problems.	Respiratory rhythm and depth	Reflexible textile	Visual feedback LED light
Tsaknaki et al., [11]	To design a device that can support the detection of different breathing patterns.	Respiratory muscle movement Amount of breast enlargement	EMG, strain sensor (Pressure sensor)	Pneumatic pillow actuator
Choi et al., [10]	Creating a wearable device that regulates respiratory rhythm with feedback method for stress management.	Respiration rate	Bioharness chest strap	Pneumatic actuator
Kulkarni et al., [37]	Designing a device that can support breathing exercises.	-	-	Vibration motor Voice warning piezoelectric buzzer)
Zhang et al., [38]	To design a device to support inspiratory and expiratory breathing patterns by mimicking respiration.			Vacuum actuator
Suggestion Study (Solution Variant 3)	To design a device integrated with telerehabilitation to support segmental respiration.	Respiratory rate, rhythm, depth Heart rate, saturation	Acceleration sensor (MPU6050) Heart rate and saturation (MAX30100)	Visual feedback (telerehabilitation web interface); Tactile warning (Soft actuator); Audible warning (Control module)

respiration. This data allows for indirect assessment of respiratory parameters, and therefore chest wall motion, respiratory rate, respiratory rhythm and depth are evaluated within the respiratory data.The device we designed receives physiological data as well as respiratory parameters. Cao et al. [40], evaluated the reliability and adequacy of the use of wearable sensors to monitor information such as respiratory pattern and respiratory rate, including vital signs of the patient for the progression and follow-up of COPD disease. Within the pulmonary rehabilitation program; respiratory pattern, respiratory exercise training, 6MWT (6 Minute Walk Test) and 24-hour physiological follow-up were performed and the participants use the SenseEcho device, a wearable belt respiratory tracking device. Participants were divided into two groups with and without COPD and these groups were included in the 6MWT: ECG, oxygen saturation (spO2), heart rate, respiratory rate; in the 24-hour monitoring: physiological values (including body temperatures, blood pressures), sleep quality, sleep disturbance detection, etc.; in respiratory pattern: chest breathing and diaphragmatic breathing are evaluated. According to the results of the study, the device can provide a detailed assessment of physiological and respiratory parameters and provide more detailed and useful information about patient compliance and the effects of respiratory rehabilitation; the use of wearable sensors is important for the follow-up of respiratory patients and can be a guide for pulmonary rehabilitation. The results of the study suggest that information from electronic health records should be tracked together with physiological data by wearable systems to provide comprehensive information for data analysis and confounding factor correction. In accordance with this purpose, in addition to respiratory data, heart rate and saturation information from physiological parameters are included in the data monitored by the device. In our final design, pulse meter and oximeter devices were included in the system to monitor pulse and heart rate among the included sensors, and acceleration sensor was included in the system for respiratory data. Venegas et al. [39] also demonstrated the sensors used for respiratory data tracking and stated that the top three most preferred sensors are optical sensor, resistance sensor, acceleration sensor 120 respectively. In our proposed design, the acceleration sensor is included in the design due to its high frequency of use in respiratory monitoring and its ability to measure changes in chest movement more precisely. Karpashevich et al. [41], evaluated the design of a soma corset with a shape-changing stimulus system for respiratory exercises; a pneumatic system that gives tactile stimuli compatible with the respiratory rhythm was established. The system activates the warning system in accordance with the respiratory cycle of the person in a way that is specific to the respiratory rhythm of the person. As a result of the study; it is evaluated that this stimulus system is an effective way to learn breathing exercises by improving the muscle nervous system reaction.When the effectiveness of the tactile stimulation is examined, it is evaluated that adding tactile stimulation to the system with the soft actuator we used in our design can play an important role in respiratory training. It is evaluated that arrangements can be made regarding this situation in future studies. Most of the studies on respiratory monitoring offer interface systems such as applications that can be accessed via mobile devices to provide visual feedback to the user. However, many of these devices do not have remote monitoring features that allow patient follow-up and feedback to the patient, although this is mentioned in the future goals of the studies. When respiratory monitoring devices integrated with telerehabilitation are examined in the literature, it is seen that studies on cloud computing systems are included in the studies. WELCOME, one of these systems, can perform patient assessment with a wearable sensor structure and cloud computing system for respiratory monitoring. To evaluate the effectiveness of the system, [42] remotely monitored patient data and progress of COPD patients using the WELCOME system and wearable sensor vest. The study included 17 patients with symptomatic COPD (GOLD level 2-4) who were hospitalized. The patients are followed up with the WELCOME system during hospitalization. As a result of the study, it is evaluated that the remote monitoring system can evaluate patient data and provide a better understanding of the underlying disease states. At the same time, with the ability to communicate with other health professionals, it can support collaboration between specialists in examining patients with multiple comorbidities; with this collaboration, it can provide a very high situational awareness of the disease status and quality of life of its patients and the recognition of subtle details in disease-related variables.

4. CONCLUSION

This study presents a comprehensive conceptual design for a wearable telerehabilitation device aimed at supporting segmental breathing exercises in individuals with respiratory system disorders. The innovative aspects of this device lie in its integration of telerehabilitation with personalized, home-based respiratory care, allowing patients to engage in targeted breathing exercises with real-time monitoring and feedback from healthcare professionals. By including features such as real-time data collection on respiratory parameters, remote monitoring capabilities, and customizable exercise programs, this device has the potential to enhance the accessibility and effectiveness of pulmonary rehabilitation outside traditional clinical settings.

The proposed device design emphasizes simplicity, usability, and compatibility with adult anthropometric standards, making it adaptable to various user needs. Additionally, by including a combination of tactile, visual, and auditory feedback, the device is intended to provide an immersive and engaging user experience that promotes adherence to respiratory exercises and reinforces correct breathing patterns. This user-centered design approach is supported by a modular system of sensors and actuators that provide physiological monitoring and targeted stimulation, ultimately aiming to improve the respiratory function and quality of life of patients.

Furthermore, the integration of telerehabilitation extends the reach of healthcare providers, enabling the development of tailored treatment plans and close follow-up, which are critical in managing chronic respiratory conditions. As this design progresses towards prototyping and testing, future research will focus on validating the device's functionality, safety, and user satisfaction, as well as assessing its effectiveness in improving clinical outcomes over time.

Finally, the proposed device has been registered as a utility model with the registration number 2023/004603, following the application submitted to the Turkish Patent and Trademark Office [43].

In future studies, a prototype of the device we designed can be produced and its suitability and efficiency can be evaluated in patients with respiratory system

DECLARATION OF ETHICAL STANDARDS

The authors of this article declare that the materials and methods used in this study do not require ethical committee permission and/or legal-special permission.

AUTHORS' CONTRIBUTIONS

Fatma Betül DERDİYOK: The researcher was involved in the processes of idea finding, literature research, idea development, design creation and writing the study.

Kasım SERBEST: The researcher was involved in the processes of idea finding, idea development, design creation and guiding the writing of the study.

CONFLICT OF INTEREST:

This study has no conflict of interest.

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