

Contract Book



Continuous Health Monitor System
Giving Families Peace of Mind

Design of Biomedical Instruments and Systems

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Bibliography



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Raphael Chernoff is a dual degree student at Johns Hopkins University getting both his undergraduate and master's degrees in Biomedical Engineering with a focus in medical imaging and instrumentation. His interests are in medical device product development and has experience both in product and circuit design.



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Abstract

The invention is a continuous health monitoring system that is worn around the chest with a breathable chest strap. The strap contains an SpO2 sensor, thermometer, heart rate monitor, ecg electrodes, and has some ability to detect blood pressure to enable the device to obtain health information about the patient. Care strap is meant to be continuously worn by the patient to continuously monitor and store health data in our application. This application allows for the user and user's family to observe and be alerted if the user's health changes and be advised if action should be taken.



Introduction

As the population is aging, the risk of elderly people living alone at home or at nursing homes is an extremely common and potentially devastating problem. Cardiovascular disease, cancer, diabetes mellitus, and dementia are the most common chronic diseases in elderly persons, leading to impaired physical function, dependence, high care costs, and shorter survival. Physiological data such as heart rate, blood glucose, blood pressure, and oxygen saturation (SPO₂), convey vital metabolic information of elderly people's health condition. Because prompt detection and proper management of chronic diseases can significantly alter their course especially within a remediable time of the occurrence, continuously monitoring devices with a sophisticated algorithm, which can determine the presence and extent of any abnormalities in elderly people's physiological data play important roles in the health management for older adults.

Continuous physiological data acquisition is conventionally achieved by integrated monitoring equipment in intensive care units (ICUs). However, until recently, these monitoring systems were bulky and expensive. Solutions are being demanded to upgrade and simplify the way to monitor patients on hospital wards and even for home-based scenarios. On the other hand, this brings commercial opportunities to propose our product.

Care Strap incorporates two main products. One is the wearable device that accommodates five types of biosensors in one kit. Biosensors continuously monitor the heart rate, respiratory rate, blood pressure, SPO₂, and body temperature of the elderly one, and are powered by two batteries. The sensor kit is mounted on an elastic band to make it comfortable to wear 24 hours a day. Besides, another unique aspect is that the device is connected to a mobile application that patients, their family members, and medical teams can have access to the physiological data and make actions.



Field Survey

Home-based healthcare is a fast-growing industry as a result of the fact of the aging of the population. Globally, health care spending on the elderly is substantially higher than for the population as a whole, due to the rising share of the population in this group and the fact that per capita health care spending for the elderly. There are over 800,000 people residing in America in assisted living facilities, with the national median expenditure of \$4,000 monthly and \$48,000 annually. China's chronic disease expenditure in 2016 was approximately 500 billion dollars, accounting for about 70% of the total health expenditure. The median length of stay in nursing homes is 22 months during which Medicare will not cover the cost, and the common condition is that elderly people suffer from chronic diseases such as high blood pressure, arthritis, Alzheimer's, etc. We recognized the urgency of the development of continuous health monitoring systems for the elderly.

The patient monitoring devices market is projected to reach USD 55.1 billion by 2025 from USD 36.4 billion in 2020, at a compound annual growth rate (CAGR) of 8.6% during the forecast period. Integration of monitoring technologies in smartphones and wireless devices is a key trend in patient care, resulting in the introduction of remote monitoring systems, mobile cardiac telemetry devices, mobile personal digital assistant (PDA) systems, ambulatory wireless EEG recorders, and ambulatory event monitors are the key factors supporting the growth of the market. The continuous health monitoring system for elderly people will combine the implementation of body-worn sensors with the transmission of physiological data in real time to an online platform.

There were 727 million persons worldwide aged 65 years or over in 2020, and the number of elderly people is projected to reach over 1.5 billion in 2050. In 2020, \$83.2 billion was spent in the U.S. on assisted living and is expected to expand at a CAGR of 5.3% from 2021 to 2027 (Fig.1). As the Chinese population ages, the market size of the Chinese silver economy almost doubled from 2015 to 2020. Based on research by the Forward institute, the CAGR of the silver economy in China is expected to be around 16% (Fig.2). These factors provide a huge market for continuous health monitoring systems for the elderly in nursing homes.



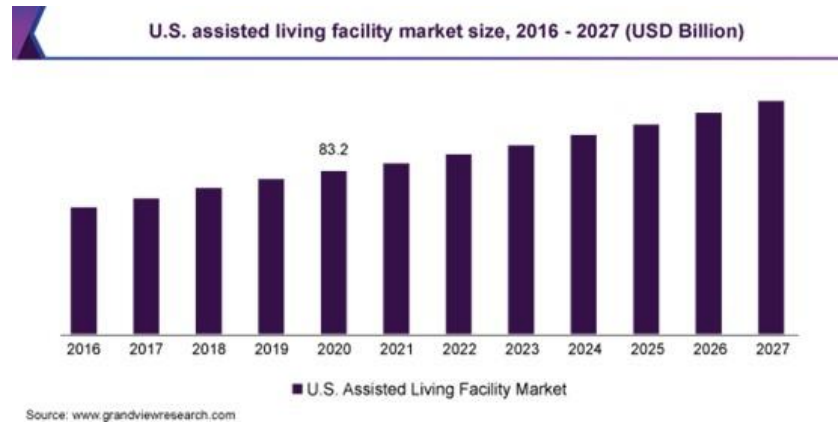


Figure 1: Assisted living facility market size in the U.S. (2016-2027)

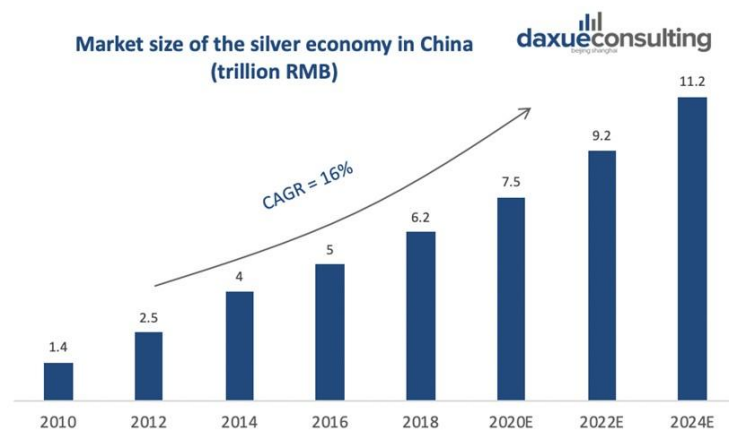
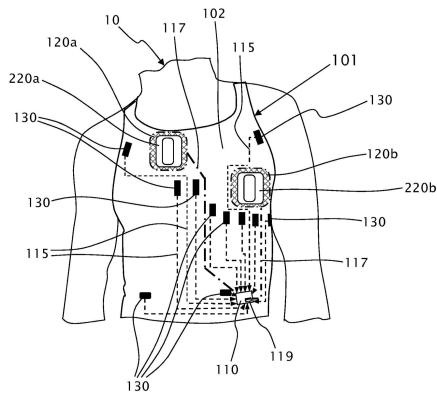


Figure 2: Market size of the silver economy in China

In the current market, several other companies have developed their health care or chronic diseases management platforms. Welldoc is a company that helps customers manage their chronic diseases such as diabetes, pre-diabetes, hypertension and heart failure. Its main product Bluestar is a diabetes health management platform approved by the FDA. Bluestar requests patients to upload glucose data to the platform. The main payers are insurance companies, and service is intended for people who purchase these insurances. Another company is Livongo which has a similar business model to Welldoc. It connects mobile applications with monitoring devices. And payers are companies that buy medical insurance for employees. Omada Health focuses on sub-healthy people with latent diabetes. Its business model also requires clients to buy certain medical insurance. The three companies and most other health related platforms request insurance purchase. For Care Strap, it has abilities to constantly monitor the data and a mobile interface for wireless communication. Moreover, it is open to every individual.

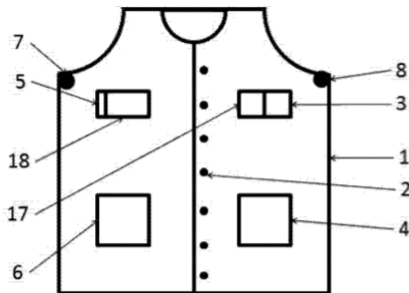
Patent Survey

The competitiveness within the health monitoring devices increases constantly. Several extensive patent searches have been conducted to understand the competitiveness, the lead manufacturers, the existing concepts and the opportunities for our design. The most relevant patents are listed as follows:



1. **WO2015056262** - Independent wearable health monitoring system, adapted to interface with a treatment device

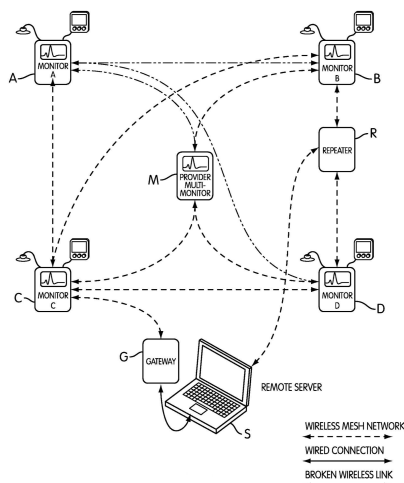
An independent wearable health monitoring system includes a knitted garment worn by the living being, a garment-processing device having a processor, and a multiplicity of sensors adapted to measure health parameters, wherein the knitted textile sensors include electrodes adapted to provide ECG data. The system further includes an interface adapted to operatively connect at least one external medical device to the garment-processing device.



2. **CN2013203441613U** - Elderly health monitoring vest based on wearable sensor

The elderly health monitoring vest based on the wearable sensor can monitor the blood pressure, the heart rate, the body temperature, and the blood glucose; and can communicate with a mobile communication terminal that performs functions of data storage, analysis, early warning and communication with the outside, and performs monitoring and early warning on the motion stage of

the user. The elderly health monitoring vest can be applied to most old people who need special monitoring.



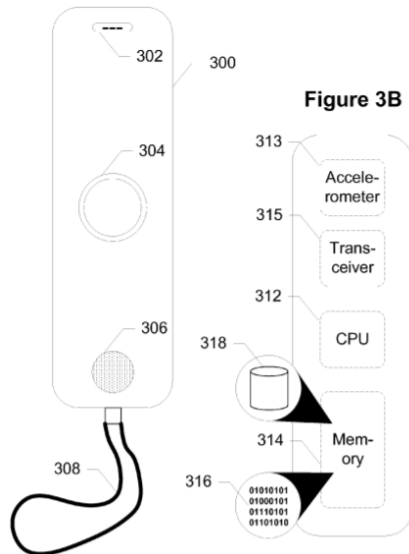
3. **WO2009036150** - Wearable wireless electronic patient data communications and physiological monitoring device

A patient data communication device that may be used as a wearable patient monitor. The devices are adapted to accept essentially any type of data from essentially any data source, and are reconfigurable, such that each device can determine which data inputs and outputs



should be active, and can reconfigure itself based on new configuration instructions. The devices include wireless transceiver units that allow them to form networks, and particularly mesh networks, with other devices.

4. **US20110092779A1** - Wearable health monitoring system



Devices, systems, and methods are disclosed which relate to remotely monitoring the health of an individual. The individual wears a health monitoring device, with an attached strap, capable of sensing voice level and tone, movements, blood pressure, temperature, etc. The device allows individuals to constantly monitor their health. Wireless communication allows measurements to be made and evaluated by a computerized healthcare service provider. For a more accurate evaluation, measurements are sent over the internet to a service.

Product Description

We applied continuous health monitoring, which is widely used in ICU to continuously track patients' physiological data, into our daily life. Care Strap is a wearable chest strap with a sensor array to monitor user physiological data, such as heart rate, blood pressure, respiratory rate and SPO2. The mobile app receives data from the product via a wireless communication system and continuously monitors the health of the user by processing and analyzing data. These data and results will be displayed on our mobile app and shared to the user's family members or personal care provider for further interpretation of the user's health and early detection of potential health risks. The Care Strap workflow is demonstrated in the following flow diagram:

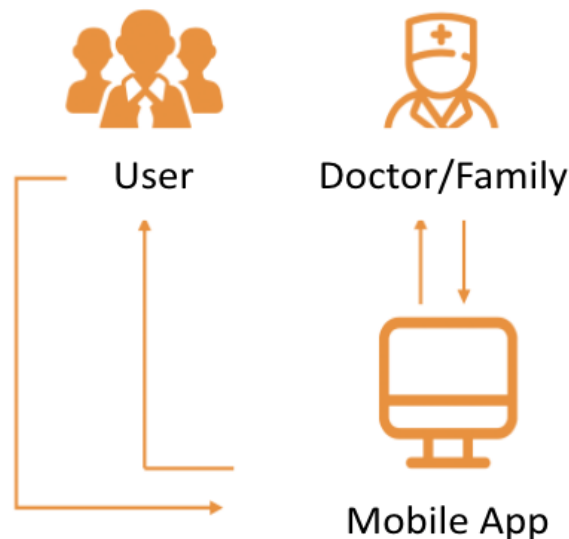


Figure 3: Data and information flow diagram

As shown in the flow diagram above, the mobile app will first collect data from users. After data is processed and analyzed, data and results will be shared to doctors or family members. If doctors or family members give any feedback, the mobile app will also inform users, Which forms a closed loop among users, platform, doctor and family. Care Strap offers affordable, comprehensive and continuous care to your loved ones.

Product Design

Care strap is a wearable sensing device that is wrapped around the chest to continuously monitor the user's physiological data, such as heart rate, blood pressure, respiratory rate and SPO2. These recorded physiological data will be subsequently transmitted to a mobile application for data processing and analysis via a wireless communication module. The mobile application will employ machine learning methods



to translate recorded physiological data into the diagnosis of potential health risks, such as sleep apnea, seizures, epilepsy, breathing cessation, etc. If any potential health risks are detected by our algorithm, the mobile application will send alerts to the user or contact hospitals and family members in case of extreme conditions.



Figure 4: Display of included sensors

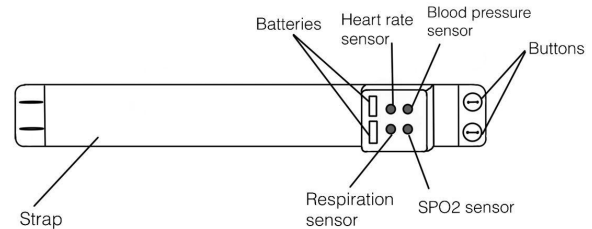


Figure 5: Care Strap product sketch

As shown in the diagram above, we are combining several commercial health measurement devices into one wearable device. This device is designed to be worn comfortably through the day and help the user stay healthy and safe.

The strap is made of a breathable fabric material that will not irritate the skin when worn directly on it. The strap is also composed of an elongated configuration to fit under the chest of the user, for comfortable wear during day and night.

A sensor array is directly installed on the strap. This sensor array is composed of five different sensors including heart rate sensor, blood pressure sensor, respiratory rate sensor, SPO2 sensor, and temperature sensor. When the device is wrapped around the user with proper contact, the sensor array will start to continuously record physiological data, which will form a comprehensive health check of the user.

A mobile application receives recorded physiological data from the device via a wireless communication module. The mobile application will employ machine learning methods to process and analyze these received data for interpretation of health and early detection of potential health risks. All data and analysis results are displayed on the application mobile. Users can use our mobile application to check his or her health status and also authorize family members and care providers access to the same information. If any potential health risks are detected, the mobile application will send alerts to the user or family members and care providers once authorized. If some extreme conditions, such as seizure, sleep apnea, etc, happen to the user and the user can't rescue himself or herself, our mobile application will inform family members and hospitals automatically for help.



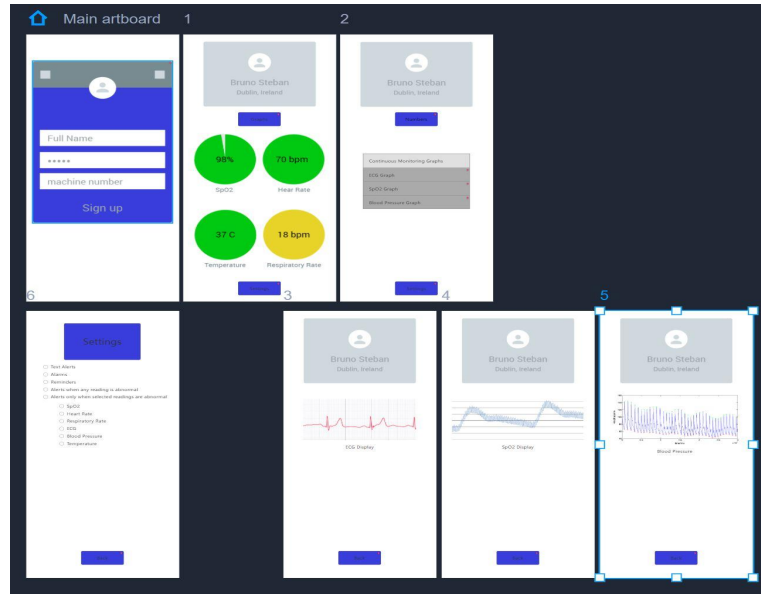


Figure 6: Diagram of Care Strap mobile application

As shown in the figure above, it is the interface of our mobile application. Recorded physiological data from the user is displayed on the screen via lists and plots. Considering the user may not understand numbers of different physiological data, we use different colors to indicate meanings of them. Green color of the physiological data means it is within a healthy range, yellow color means the user needs to pay attention and may go to hospital for further check, and red color means this physiological data is abnormal and potential health risk is detected.

Intended Use

Care Strap is intended to function as a continuous monitoring device to keep the elderly safe and healthy. Our targeted customers are elder people over 60 who live alone or have certain chronic diseases that need to be monitored continuously. Our device can be used to continuously monitor the user's important physiological data for interpretation of health and early detection of potential health risks. The mobile application can be used as an interface among users, family members and care providers. The user can use our mobile application to check his or her health status, and family members can also use our mobile application to check the health status of the significant one remotely. If some extreme conditions, such as seizure, sleep apnea, etc, happen to the user and the user can't rescue himself or herself, our mobile application will inform family members and hospitals automatically for help.

In the future, we hope to connect our product to the hospital system and provide some critical physiological data on a daily basis to help doctors to make better diagnoses.



Regulatory Issues

Care Strap is a Class II medical device according to the guidelines by the Food and Drug Administration (FDA). As a wearable medical device that will make contact with skin and tissue of the user and include several different sensors, Care Strap needs to provide substantial evidence that all sensors have a good insulation cover to prevent potential electric shock or other damages from the circuitry. Since functions of Scare Strap have a substantial equivalence to other commercial medical devices, such as blood pressure monitor, thermometer, oximeter, etc, we will try to get 510(k) approval by FDA. Our mobile application will be regulated by FDA and Federal Communications Commissions (FCC). In order to connect our mobile application to the hospital system, we will apply to become HIPAA compliant to ensure the security and safety of users' information.



Elevator Pitch

Personal story of grandmother

I want to share a story about my grandma. When my grandma got old, we decided to pay for a personal care provider to take care of her. We thought this would ensure her health and safety. However, tragedy still struck. One day, the care provider just went out for a walk, but she forgot to bring the key. So when she came back and knocked at the door, she thought my grandma would open the door for her, but nobody replied. So She called my uncle to open the door. When he eventually came and they got into the home, they found my grandma lying on the ground in the bathroom. My grandma was sent to the hospital and diagnosed with a stroke. The doctor said she already had a stroke for hours and had missed the best timing of treatment. So she sadly passed away in a few days. This is not a single occurrence as over half a million people 65 and older in the US have a stroke, and I really don't want this tragedy to happen to any other families again, so we designed this product called "care strap". We hope this product will keep your elderly loved ones safe.

Product (Care Strap)

So what do we do? We applied continuous health monitoring, which is widely used in ICU to continuously track patient's physiological data, into our daily life. Our product is a wearable chest strap with a sensor array to monitor heart rate, respiratory rate, SpO2, blood pressure, and more. The health of the user will be continuously monitored by gathering, processing and analyzing data from our product. These results will be displayed for the user and family members on our platform and can be further used for interpretation of an individual's health and early detection of diseases.

We give families peace of mind, helping ensure your loved one's are safe while allowing the loved one a longer time being independent.

Market size

The nursing home industry in the US is a \$169 billion dollar industry and by 2030 it is estimated that 1 in 5 Americans will be above the age of 65, and more than this the continuous health monitoring devices market is estimated to grow to \$73.46 billion by 2028. This shows how the market is clearly there for a device to monitor elderly health and keep loved ones safe

Competitors

Currently on the market there are a number of devices that monitor parts of the patient health, whether that be SpO2, heart rate and ekg, or temperature, but no device both monitors all these different factors and connects to a downloadable application on any smart phone or computer to give access to this information to a loved one to ensure the health and safety of the user at all times.

With our device you no longer need to worry about your loved ones health and situations like trends never have to happen again because with the care strap you know.



Logo

Our product is named “Care Strap.” The name is simple and clear stating to the user that our product is a strap that will ensure correct care of the user.

Our logo:



The logo includes the name of our product, but also the recognizable medical cross in the palm of a hand.

Our short slogan:

Giving Families peace of mind.



Business Model

After looking at different business models and the models of devices with features similar to our own, we found that the business model that best suits us is a recurring revenue business model and specifically the sunk money consumable model. With Care Strap the model works by the consumer having a one time purchase of the Care Strap device and then needing to pay a monthly subscription to use our application to be able to see and save data. Prices below:

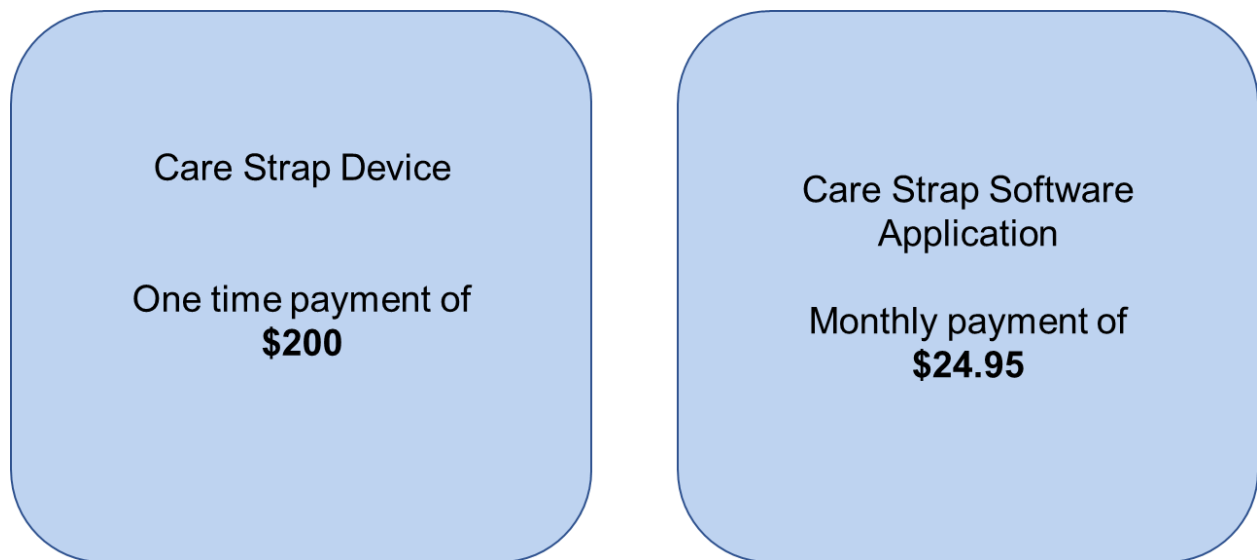


Figure 7: Plan for subscription and sale of product

We are hoping that after getting FDA approved, our device and service will be able to be subsidized or completely covered by medical insurance, just as a few of our data collecting competitors are.

Market Size

Looking into the potential market for Care Strap, we focused on two locations. The first being the market in the United States as that is where our company is based and we have affiliations to Johns Hopkins University who can help with research and initial customer and physician acceptance of our product. The second is China where two of our team members are from and have personal ties and affiliations with organizations there, as well as China currently has and is expected to continue having a steady increase in market size. For our main market, we are focusing on the people 65 years of age and older. In the United States in 2020 there \$910.22 million spent on health monitoring systems for people aged 65 and older and currently has a CAGR (compound annual growth rate of 5.7%. More than this, 17% of Americans of this age, or about 9.2 million Americans 65 years and older, used wearable monitors, and this number is expected to grow both in percent of the population and in number of people, as it is expected that by 2030 1 in 5 americans will be age 65 and older. Looking at the Chinese market there are a total of 191 million people 65 years of age and older, but the health monitoring device market is still in its infancy. Therefore the statistics are not yet available of the breakdown of the total market, but currently there is a \$4.2 billion total market with the expected total market to reach \$36 billion by 2025. This with the fact that China has been increasing its investments in supporting chronic disease management, which in 2020 had an expenditure of over \$800 billion, shows that the market exists and is ready for products like Care Strap.

Being considerate and having a penetration rate of about 6% due the need and expanding market of our product, we made the following calculations:

$$\begin{aligned}\text{Market Volume} &= \text{Number of customers} \times \text{Penetration rate} \\ &= (9.2\text{M(Americans)} + 21\text{M(Chinese)}) \times .06 \\ &= \mathbf{1.812M}\end{aligned}$$

If we consider the average value of a customer per month is \$24.95

$$\begin{aligned}\text{Market Value} &= \text{Market Volume} \times \text{Average Value} \\ &= 1.812 \times (24.95 \times 12) \\ &= \mathbf{\$542M}\end{aligned}$$



Care Strap

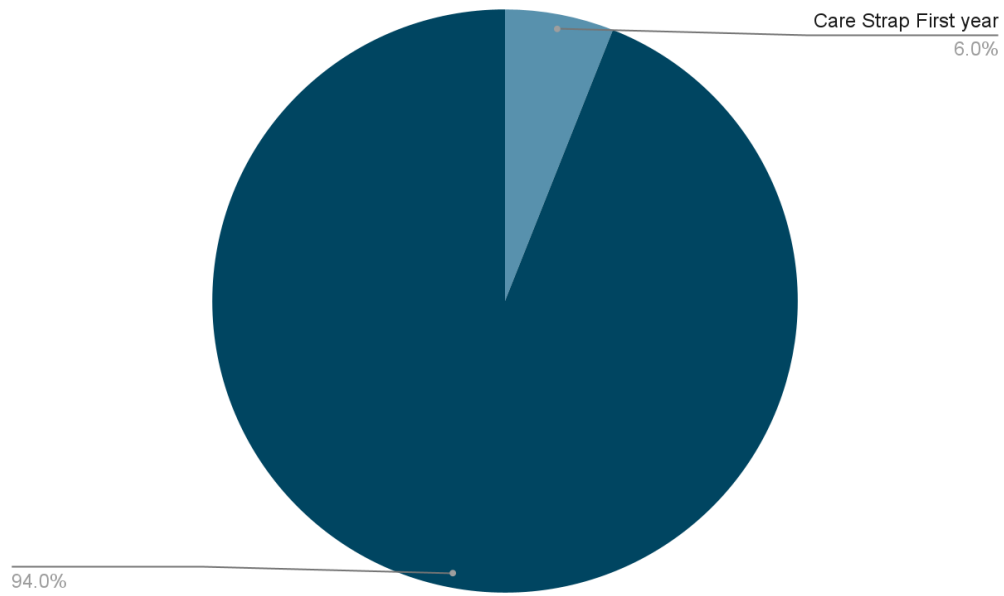


Figure 8: Market share of Care Strap compared to the Industry in the first year of sales.

Financial Plan and Budget

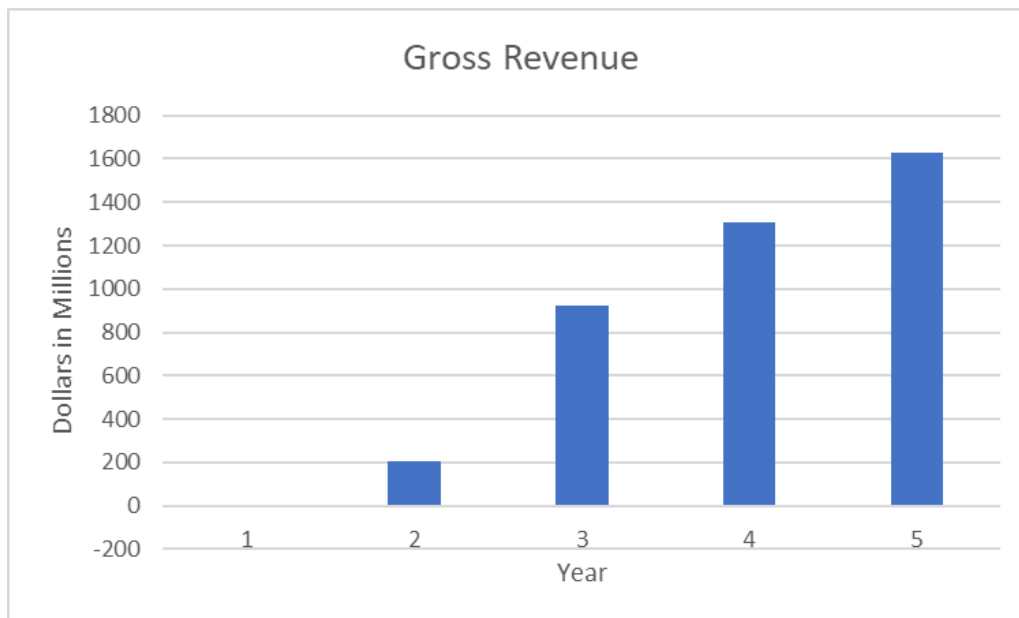


Figure 9: Net revenue projections over the next five years

	Orders	Gross Revenue	Net Revenue
2022	0	\$0	-\$0.345M
2023	1.81M	\$474.8M	\$202.74M
2024	1.92M	\$1.21B	\$921.5M
2025	2.05M	\$1.615B	\$1.31B
2026	2.18M	\$1.96B	\$1.63B

Figure 10: Revenue projections over the next five years



Financials Expense sheet:

	Price	Year 1	Year 2	Year 3	Year 4	Year 5	
Equipment	\$100,000	\$100,000	\$100,000	\$15,000	\$15,000	\$15,000	
Cost per unit	\$150		\$150(1.81M)	\$150(1.92M)	\$150(2.05M)	\$150(2.18)	6% increase
Engineer Salary	\$100,000	\$100,000	\$300,000 (software, electrical, and mechanical)	\$309,000	\$318,270.00	\$327,818.10	Increase 3%
Business Consultant Salary	\$90,000	\$45,000 (add half way through the year)	\$90,000	\$92,700	\$95,481.00	\$98,345.43	Increase 3%
Office Space	\$25,000	\$10,000	\$25,000 (move to bigger space when start to sell product)	\$26,250.00	\$27,037.50	\$27,848.63	Increase 3%
Office Supplies	\$20,000	\$10,000	\$20,000	\$21,000.00	\$22,050.00	\$23,152.50	Increase 5%
Patent	\$25,000	\$10,000	\$30,000	\$1,000	\$1,000	\$1,000	
FDA	Initial fee \$12,700, annual \$5,600	\$0	\$12,700	\$5,600	\$5,600	\$5,600	
Testing and R&D	\$50,000	\$60,000	\$50,000	\$50,000	\$50,000	\$50,000	
Advertisement	\$25,000	\$10,000 (start advertising later in the year)	\$25,000	\$27,500.0	\$30,250.0	\$33,275.0	Increase 10%
Total Expenses		\$335,000	\$272,152,700	\$288,548,050	\$308,064,689	\$327,582,040	
Profit/Revenue			\$474,898,750	\$1,210,000,000	\$1,615,000,000	\$1,960,000,000	
Net Revenue		-\$345,000	\$202,746,050	\$921,451,950	\$1,306,935,312	\$1,632,417,960	

Figure 11: Balance sheet

Taking into account the critiques and advice from the investor pitch, CareStrap has pushed back the expected date to sell the product by a full year. Care Strap will use the year 2022 to fully develop, research, and test the product to ensure its success in the



market, as well as do user testing to further validate the product. In this year, Care Strap will start to hire engineers, business consultants, and advertising agencies to ensure we have a viable and well built product that consumers will be ready and willing to start to pay for when the product begins to be sold in 2023.

Funding

Regardless of how good of a product or profitable Care Strap may be, one of our largest hurdles to getting Care Strap on the market is getting the needed funding to both develop the product and bring it to the market. To get this funding there are multiple routes and types of investors to go to, but most of them require business plans, pitch decks, market size, expected returns, and other documents. Many of these documents the team has begun to lay out in this contract book, but as Care Strap progresses these documents will need to be updated and become more robust.

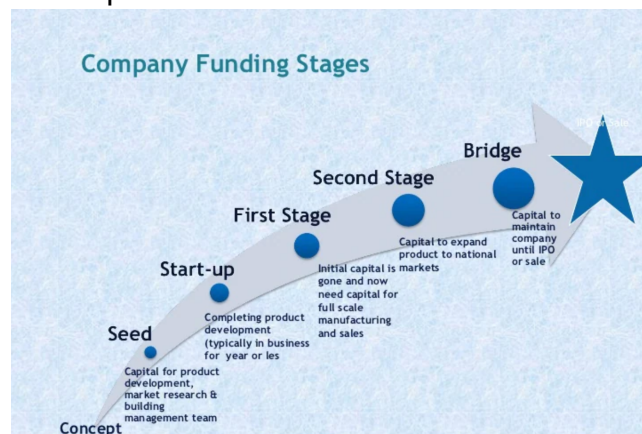


Figure 12: Stages of funding for a business

Looking in the figure above one can see there are a number of different stages in the funding process that can start from the very beginning when a business is just an idea all the way to when a company is ready to go public or be sold. Currently, Care Strap is in the stage where it is transitioning from a concept to seed stage. Funding is now required for further research and development of a prototype and continued market research. In the next stage, the start-up stage, funding will be used to rent a space for operations, acquire needed manufacturing equipment, start hiring employees, and finish creating the final product and version of the Care Strap. Once the final product has been created, the team will start to look for first stage funding, which will be used to complete clinical trials and begin the commercialization of Care Strap. The next stages of funding come after this and currently Care Strap is too early to know exactly what we intend to do at that point.

To get this funding, the team plans to look into Venture Capital funding, angel investors, borrow from banks through loans, and even other corporations. Each one of these



investor types has different benefits and costs to the business. To get funding from venture capitalists and angel investors, Care Strap will need to pitch our idea and likely give up equity for the needed capital. As for banks, there are many different offers for startup loans that we will receive money that later we will have to pay back with interest, but no equity will be lost in the transaction. Then for corporations and corporate investors getting funding from one will increase our companies credibility, but at the same time they often invest to obtain all distribution rights or to be the first to have the chance to acquire the company. Corporate investors help set up a path to selling the business and liquidity, but due to their nature will discourage other buyers and investors.

Reimbursement

Once FDA approved the ability for patients to get reimbursed for the product is key to the ability for Care Strap to gain traction and grow its sales. To get the reimbursement and approval from the FDA, Care Strap will need to meet the standard of both the FDA and CMS, and have the proper clinical requirements from them to gain approval and reimbursement.

One of the needs for reimbursement is to have the proper coding of our product. Due to the nature of the Care Strap, we are hoping to be able to file a 510k and be a class II device, which will require proving that existing devices are substantially equivalent to our own through research and approved patient trials. One code that we will be looking to be listed under is code 99454, which reimburses for remote monitoring devices with daily recording and programmed alerts.



Future Work

Care Strap is still in its very early stages, and therefore there is still a lot of work to be done before it can become a viable company and product. The future work we have, and which is laid out throughout this contract book, can be broken into multiple categories:

Research and Development of the Care Strap

- The Team must begin to build the actual strap portion of our device with the embedded sensors. This will require circuit design and building as well as integration of the multiple sensors that will be used in the device
- Along with the physical prototyping, the team will need to develop the application that will securely and efficiently store the data from the sensors and then through algorithms help assist in alerting patients of changes in their health.
- The team will also seek IRB approval for an initial patient survey to ensure the Care Strap meets all patient needs as well as later getting IRB approval to test the product itself on patients for continuous monitoring.

IP and Regulatory

- After the initial development and testing of the device the team plans to patent certain features of it to ensure our ability to operate and protect our invention. After acquiring a patent and further development of the device, we will require regulatory approval due to the product being a medical device, and therefore we will need FDA approval to be sold in the United States. Afterwards, we will try for NMPA, the chinese agency for medical device regulation, to then be able to sell in china a key market in the continuous monitoring device field.

Funding

- To be able to do all we want to and develop our device for sales, the team will need funding to be able to acquire needed materials and manufacturing and later funds to apply for a patent and to the regulatory bodies. We are looking to get around \$1 million to be able to pay for our operation, especially in our first year when there will be no sales and only research and development of our product. These Funds will come from business competition, investors, and loans.



Summary

Care Strap is a novel concept that will build up a care system for the safety and health condition of the elderly among the current health care monitoring devices market. It has unique capabilities to continuously monitor several types of biological signals simultaneously by wearable sensors and connect to family members or medical teams through mobile applications. Our product is presumably designed for elderly people living alone or in assisted living facilities, to have a better understanding of their health condition, to alleviate the burden of care costs and make prompt actions when accidents happen. With more care and attention on health care for older adults, our product can have a promising and sustainable market.



Appendix

SWAT

Strength	Weakness
<p>Comprehensive: Integrated several biological sensors in a single product</p> <p>Convenient: Home-based, easy to use</p> <p>Connective: Communication with family members and medical teams wirelessly</p> <p>Consistent: Continuously monitoring in 24h</p>	<p>Lack of reputation: Have not established as a reputable health monitoring device provider</p> <p>Lack of precision: One body site for all signals</p>
Opportunities	Threats
<p>Aging population: Elderly Care Services market size exceeded \$976.2 billion in 2020, growing at a CAGR of over 10% between 2021 and 2027.</p> <p>New information age: The arrival of 6G is expected to be in 2030.</p>	<p>Competition: Other elderly care products</p> <p>Data Security: Unauthorized access may appear during the transmission process</p>



Patent

A CARE SYSTEM COMPRISING A MONITOR DEVICE AND A MOBILE APPLICATION TO MONITOR HEALTH

Inventors: **Trent Tang**, Baltimore, MD(US);
Raphael Chernoff, Baltimore, MD (US);
Runyu Tang, Baltimore, MD (US);

Assignee: **Care Strap**

Appl. No.: **2,518,817**

Filed: **December 06, 2021**

References Cited

PATENT DOCUMENTS

WO2015/056262	7/2015	SENTMAN, Charles, L.
CN2013203441613U	6/2013	Gangfeng yan et.al
WO2009/036150	10/2008	KNEISSEL, Michaela et.al

ABSTRACT

A care system of the present disclosure consists of a wearable monitor device and a mobile application. The wearable monitor device continuously records the user's vital signs and transmits the data wirelessly to a mobile application for further data processing and analysis. The monitor device consists of a strap with various sensors that can be worn around the chest. The strap is made of a breathable fabric material that will not irritate the skin when worn directly on it. Various sensors around the strap will continuously monitor different physiological data of the user and transmit that data to a mobile application via a wireless communication module. The mobile application serves as an interface among users, family members, and care providers, which employs machine learning methods to process and analyze transmitted data and help visualize the data and analysis results. If any potential health risks are detected, the mobile application will send alerts to the user or family members and care providers.

9 Claims, 3 Drawing Sheet



Care Strap

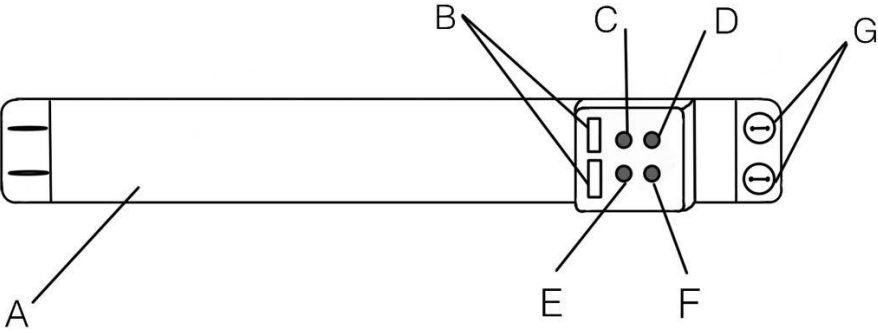


FIG. 1

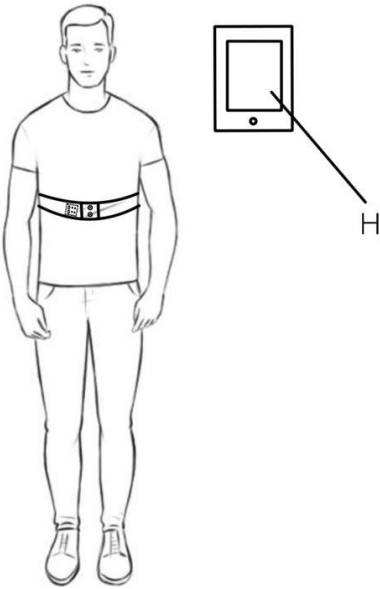
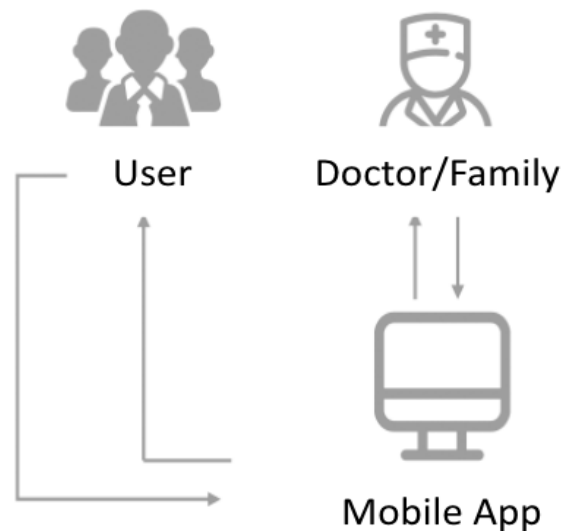


FIG. 2

**FIG. 3****FIELD OF THE INVENTION**

[0001] The present invention pertains to continuously monitoring health systems, and more specifically the present invention pertains to a wearable monitoring system worn by the person being monitored in a way that does not interfere with the person's daily life.

BACKGROUND

[0002] The world, and specifically The United States of America, has an aging population. There are estimates that by the year 2030, one in five Americans will be 65 years of age or older, and currently, 28% of older adults live alone. Published in the New England Journal of Medicine there was found to be an annual rate of 31.6 per 1000 people 65 or older who lived alone having emergency medical services personnel being called to assist after being found in their homes in need of emergency attention, and ten percent of the people found were estimated to have been unable to summon help for at least three days. In 23 percent of cases the person was found dead and in another 5 percent

of cases the person died in the hospital. This rate of occurrence has caused fear and a need to have elderly people's health continuously monitored to ensure tragedies like this do not happen.

[0003] Health issues that can lead to or are signs that there may be a sudden need for help include increased heart rate, temperature increases, blood pressure changes, a drop in SpO2, and many others. So a need to monitor these signs in a continuous way without interfering with the daily life of an individual exists and many devices exist on the market to try to monitor these health signs, but they are cumbersome, uncomfortable, and inaccurate. Therefore, a need for a product that comfortably can be worn and continuously monitor a patient's vitals and that can analyze the data to alert the patient, family, or doctor of changes and issues is needed.

[0004] Below are some systems that incorporate some health monitoring aspects into their wearable devices. A wearable health monitoring system that is incorporated into a wearable

garment is disclosed in International Publication No. WO 2015/056262. A wearable health monitoring vest-based wearable sensor, which monitors blood pressure, heart rate, temperature, and blood glucose is disclosed in Application No. CN2013203441613U. A patient data communication device that may be worn is disclosed in International Publication No. WO 2009/036150. A wearable health monitoring device that constantly senses voice level and tone, movements, blood pressure, temperature, etc, with a computer evaluation system, is disclosed in United States Application No. US 2011/0092779 A1.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is an extended front view of the present device of the invention. The monitor device incorporates a stretchy strap (A), batteries (B), heart rate sensor (C), blood pressure sensor (D), respiratory sensor (E), SPO2 sensor (F), and two buttons (G).

FIG. 2 is a front view of the present invention in use with a mobile interface (H).

FIG. 3 is the complete workflow of the invention between the monitor device and the mobile application.

DESCRIPTION OF THE INVENTION

In figure 1, the strap (A) is preferably composed of an elastic and resilient material, such as but not limited to polyester. The strap (A) is also preferably composed of an elongated configuration to fit under the chest of a user, for comfortable wear during day and night. Buttons (G) are designed for easy wear-on and take-off. Sensors (C - F) measure biological data consistently and are supplied by batteries (B).

In figure 2, Physiological data recorded by the monitor device will be transmitted wirelessly to

a mobile application(H). The mobile application will employ machine learning methods to process and analyze transmitted data. Both data and analyzed results will be displayed on the mobile application. Users can check their health status through the mobile application interface, and authorize family members and care providers access to the same information. In order to help understand the meaning of recorded physiological data, Different colors are utilized to indicate various conditions. Green color of the physiological data means it is within a healthy range, yellow color means the user needs to pay attention and may go to the hospital for a further check, and red color means this physiological data is abnormal and potential health risk is detected. If any potential health risks are detected, the mobile application will send alerts to the user or family members and care providers once authorized. If some extreme conditions, such as seizure, sleep apnea, etc, happen to the user and the user can't rescue himself or herself, our mobile application will inform family members and hospitals automatically for help.

In figure 3, a complete workflow of the invention is illustrated. The monitor device will first record physiological data from the user and transmit them to the mobile application via a wireless communication module. After transmitted data is processed and analyzed by the mobile application, both data and analyzed results will be displayed on the mobile application and shared with family members and care providers. If family members and care providers give any feedback, the mobile application will inform the user, which forms a closed-loop among the invention, user, family members, and care providers.

SUMMARY OF THE INVENTION

The present invention is a care system comprising a wearable monitor device and a



mobile application. The monitor device is wrapped around the chest to continuously monitor the user's physiological data, subsequently transmit collected physiological data to a mobile application. The mobile application is an interface among users, family members, and care providers, which employs machine learning methods to process and analyze transmitted data and help visualize the data and analysis results. The care system is designed to continuously monitor the user's physiological data throughout the day and ensure the user's health and safety.

The monitor device in its current form consists of a strap with a sensor array that will continuously monitor the user's physiological data, such as heart rate, blood pressure, respiratory rate, and SPO₂. The strap is made of a breathable fabric material that will not irritate the skin when worn directly on it. Various sensors will be directly installed on the strap. When the device is wrapped around the user with proper contact, it will start to record physiological data and transmit recorded data to a mobile application for further data analysis. The mobile application will employ machine learning methods to process and analyze transmitted data. Both data and analyzed results will be displayed on the mobile application. Users can check their health status through the mobile application interface, and authorize family members and care providers access to the same information. To help understand the meaning of recorded physiological data, Different colors are utilized to indicate various conditions. If any potential health risks are detected, the mobile application will send alerts to the user or family members and care providers once authorized.

CLAIMS

We claim:

1. A novel care system comprising
a wearable monitor device wrapped around the chest that can continuously monitor user's physiological data, such as heart rate, blood pressure, respiratory rate, and SPO₂, subsequently transmit collected physiological data to a mobile application, comprising of:
 - a. Heart rate sensor
 - b. Blood pressure sensor
 - c. Respiratory rate sensor
 - d. SPO₂ sensor
 - e. Wireless communication module
 a mobile application that is an interface among users, family members, and care providers, which employs machine learning methods to process and analyze transmitted data and help visualize the data and analysis results.
2. A monitor device as defined in claim 1, wherein all components and parts are installed on a strap, including but not limited to a breathable fabric strap.
3. A monitor device as defined in claim 1, wherein heart rate sensor, blood pressure sensor, respiratory rate sensor, and SPO₂ sensor, including but not limited to these physiological sensors, continuously monitors the user's physiological data.
4. A monitor device as defined in claim 1, wherein wireless communication module transmits recorded physiological data to a mobile application from various sensors from claim 3.
5. A mobile application as defined in claim 1, in which transmitted physiological data is processed and analyzed based on machine learning methods for



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interpretation of user's health and early detection of potential health risks.

6. A mobile application as defined in claim 1, in which both transmitted physiological data and analysis results from claim 5 are displayed on the mobile application and shared with the care providers or family members.
7. A mobile application as defined in claim 1, in which the mobile application will use different colors to indicate various healthy conditions of transmitted physiological data from said monitor device.
8. A mobile application as defined in claim 1, in which the mobile application will send alerts to uses in case of any potential health risks, such as abnormal

breathing, incidences of apnea, etc, detected by the mobile application.

9. A mobile application as defined in claim 1, in which the mobile application will contact care providers or family members in case of any extreme life risk detected by the mobile application.

