Contract Book

Design of Biomedical Instruments and Systems

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1 Biographies

Benjamin Monteagudo
Benjamin "Benjy" Miguel Monteagudo is from New York City, NY. He is a Senior undergraduate at Johns Hopkins University studying Biomedical Engineering, with minors in Entrepreneurship & Management, and Mathematics. He is interested in the design of medical devices, and is driven by the prospect of one day developing or contributing to medical technology that can be beneficial to improving global healthcare.

Kevin Lee
Kevin Lee is a first year PhD student in the Department of Electrical and Computer Engineering at Johns Hopkins University. He graduated in 2020 from New Mexico State University with a Bachelor's in Physics as well as a Bachelor's in Engineering Physics (Electrical Engineering concentration). His research interests include semiconductor physics and renewable energy technologies.

Qihang Shi
Qihang Shi is from Beijing, China. He is a first year graduate in the Mechanical Engineering program at Johns Hopkins University. He graduated from University of California, Irvine with a Bachelor's degree in Applied Physics with a concentration on Engineering. He is interested in the development of medical instrumentations, aiming at design of high-tech medical devices to make expensive surgery and disease detection simpler and commonly affordable.

Benjamin Huang
Benjamin Huang is a fourth-year undergraduate student studying Electrical Engineering at Johns Hopkins University. He is interested in combining medicine and electrical engineering to make the former more safe, efficient, and accessible. In his spare time, he may be found running in nearby parks or fiddling with an electronics hobby-project.

2 Abstract

Vitalisation is a startup dedicated to bringing essential healthcare to everyone, anywhere. Its first product is the VitalCorder, an inexpensive, portable, easy-to-use vital-signs measurement and recording device. The VitalCorder measures five vital signs in one package: heart rate, blood oxygenation, ECG, temperature, and respiration rate. These vital signs are among the most-commonly used to diagnose, monitor, and treat patients. The VitalCorder is designed for use in consumer healthcare and field medicine. It distinguishes itself from the competition in its low cost, intuitive design, and integrated multi-functionality.

3 Introduction

Vital signs play an important role in the diagnosis, monitoring, and treatment of patients. The most common vital signs measured include Temperature, heart rate, blood oxygenation, respiration rate, and ECGs. Traditionally, physicians measure these signs using separate, large, dedicated devices in a hospital or other clinical setting. It is impractical or impossible to measure vital signs this way in many situations outside of a clinical setting. Such situations include medical emergencies on aircraft, medicine practiced in isolated locations far from a hospital, and at-home patient monitoring. The ongoing COVID-19 pandemic has also led to an increase in monitoring vital-signs at home as patients self-isolate or are discharged from hospitals. In short, there is a growing need and a market for portable vital signs measurement devices.

To meet this need, Vitalisation presents the VitalCorder, an inexpensive, portable, easy-to-use device that measures five aforementioned vital signs in one package. Powered by two AA batteries, the device is small enough to fit on one's hand and can quickly measure all five vital signs at once. Designed for use in consumer healthcare and field medicine, the VitalCorder is intuitive enough for people without medical training and sophisticated enough for medical professionals.

4 Field Survey

Our team realized that there is a market for portable medical devices (PMDs) based on research provided by the paper "Beyond Wearables: Experiences and Trends in Design of Portable Medical Devices" [1]. With the advent of smartphones and personal computing, it was only a matter of time before PMDs became commonplace in many households. Health products such as Fitbits and Apple watches are now ubiquitous in modern society. This paper emphasized the need for designers to "be aware of future design trends" and some of these trends are listed in Appendix A.

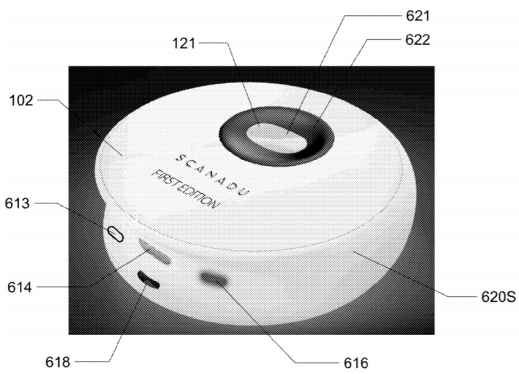
The paper believes that future changes on the nature of healthcare will learn towards more self-directed/self-diagnostics care [2]. Our company would like to take advantage of these shifting trends and we believe we have found a market space for PMDs that can be used for routine/daily healthcare checkups.

In addition to the conference paper, we have asked several members of the professional medical community for their opinion on PMDs. A questionnaire was submitted to ten doctors/nurses/medical students, it can be found in Appendix B.

The results of the survey show 10/10 participants agreeing that PMDs would be useful in general at home settings, and the average score among doctors for their perceived usefulness of portable vital signs monitoring devices is a 7.6. The results of the survey is summarized in Table 2 of Appendix B.

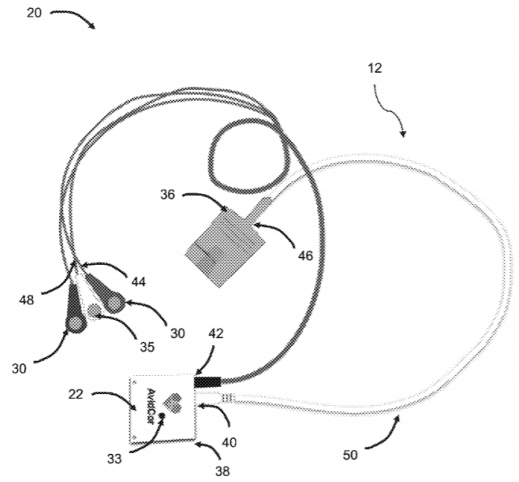
5 Patent Survey

A comprehensive patent search was conducted to determine the scope of the field of similar multifunctional sensing devices to detect various vital signs in portable systems. Of those investigated, the most relevant ones are listed below:



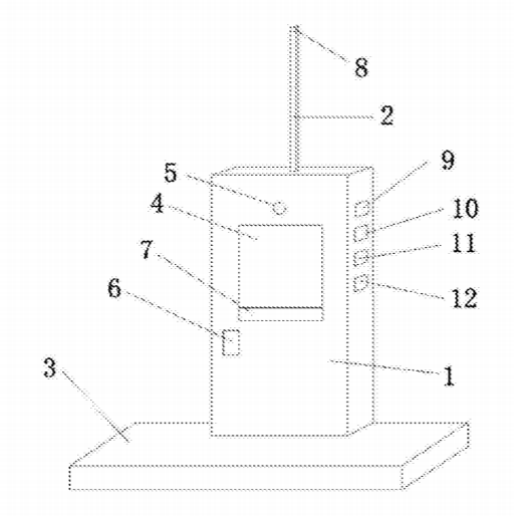
Systems, Methods, and Apparatus for Personal and Group Vital Signs Curves (US2019350535-A1)

This system provides an apparatus displaying vital signs (temperature, ECG, pulse oximetry) for at least one sign over a 24 hour period, a method of monitoring these signs by receiving and storing them internally in a server wirelessly, and a method of creating a personal vitals sign curve. The VitalCorder is different through the addition of respiration rate as a measured vital sign and through the lack of detachable sensors to place on the body.



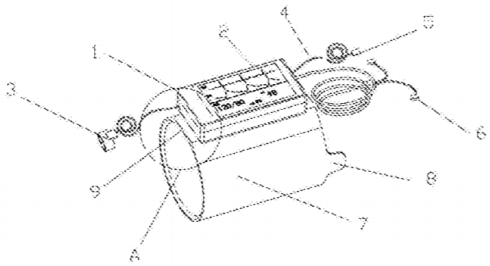
Vital Monitoring Device, System, and Method (US2019183359-A1)

This system provides a vitals monitoring device with a microsensor with numerous channels, several sensors with the purpose of measuring pulse oximetry, ECG, and temperature, all with wireless communication to a remote sensor, as well as a remote device to view these signals on a graphical user interface. The VitalCorder adds respiration rate and features no detachable sensors, all are contained internally within the shell.



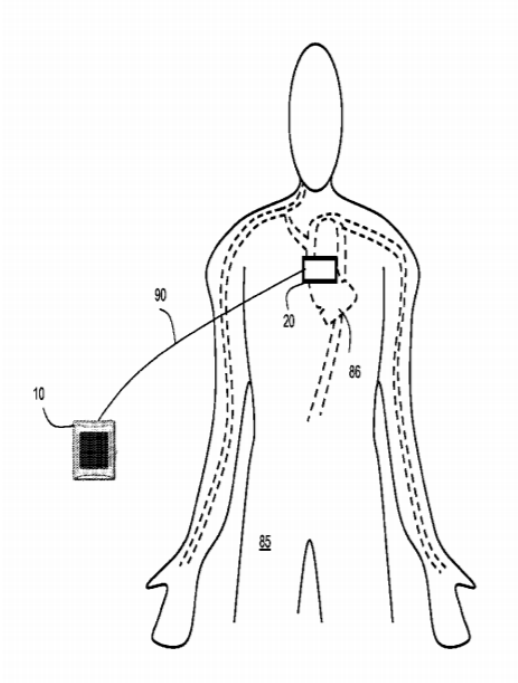
A kind of shared intelligent physical examination machine (CN107260144-A)

This device includes a touch screen display, camera and speaker, and the body is connected to an oximeter, glucometer, blood pressure meter and an ECG. It also contains an ultrasonic probe provided with a top end of a telescopic rod, containing an internal pressure sensor in the base. This device is different in that the VitalCorder does not include a touch screen display, and has a different array of signs to measure. Though similar in intent, the items actually measured are different.



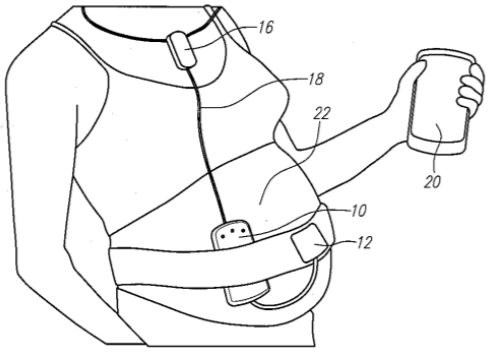
A Kind Of Portable Multi-Function Patient Monitor (CN108714024-A)

This device presents a unique cuff design containing sensors including a finger oximeter, an electrocardiogram monitoring device, body temperature probe, blood pressure measuring pneumatic unit, a Bluetooth communication unit, and a backup power source. While incorporating similar sensors, its formulation is more of a cuff as opposed to a single device, and it relies on bluetooth connections to show its findings, whereas ours are readable on the device itself.



Hand-held vital signs monitor (US20140235964A1)

This system presents a hand-held vital signs system with a touch screen providing operation controls for the system on an icon-driven graphical user interface, at least two electrodes to measure an electrical signal providing an ECG waveform, a sensor operably to measure heart valve operation, and a sensor to measure an optical waveform. The VitalCorder has no touch screen, and is a singular device with no detachable parts, as well as more than just ECG wave monitoring.



HWireless fetal monitoring system (KR101902594B1)

This system presents a wireless fetus and maternal monitoring system, a fetal sensor unit provides a signal indicative of a fetal heartbeat, a contraction sensor provides a signal indicative of a uterine contraction of the mother during uterine contraction, a microphone including a heart rate sensor and a processor adapted to eliminate erroneous measurements by comparing a first sensed heartbeat period to a second sensed heartbeat period, as well as using an external app on a smart device to view data. This system focuses more on monitoring fetal systems as opposed to patient health in general, while the VitalCorder takes these concepts and applies them to a more broad scope, and also does not depend on a smartphone app to see data.

6 Intended Use

The VitalCorder portable vital sign monitor is meant to provide users an estimation of their oxygen saturation, ECG, respiration rate, and body temperature. The VitalCorder is a general-purpose device: it can be used in at-home settings as well in the field/remote locations such as mines, sewers, and airplanes. In either case, the VitalCorder is NOT a replacement for a professional diagnosis and is only meant to assist users in assessing their general health condition. This product aims to offer additional health information to people experiencing symptoms or problems related to physiological health. It is designed to be used by individuals aged 18 and up. Individuals under 18 should use this device with an accompanying adult.

A growing body of research shows that portable medical devices such as ours can improve patient outcomes and medical adherence. It is with this evidence in mind that we have designed the VitalCorder for daily at home use. In addition, when being used in emergency situations, such as in-flight emergencies, it is expected that the VitalCorder will be used alongside the guidance of a medical professional. In these scenarios, the VitalCorder was designed to perform functions normally done by large hospital machines. In situations such as in-flight emergencies, however, such machines are usually not accessible, and the VitalCorder is a temporary alternative that fills the roles of these machines. It is important to note that the VitalCorder does NOT have an IP rating and should not be used underwater or in overly humid environments. This device has an operating temperature of -25°C to +70°C.

7 Regulatory Issues

Because the VitalCorder is effectively a combination of numerous existing vital sensors, it will not pose significant risk to its users. It uses noninvasive means to measure each sign. Although minimal, the use of infrared light does pose minor risks if shined directly into the eye. A warning shall be administered for this. Because we will not be seeking reimbursement from insurance companies and we will be directly selling to customers, we do not expect to deal with FDA regulation. However, if this ever changes, we expect VitalCorder to be classified as a Class II medical device, with no need for a 501k form to be filled out.

8 Design

The VitalCorder has four sensors that sense five different vital signs: Temperature is sensed using an infrared temperature sensor that shines infrared light to the body to tell its temperature, which is then processed. Respiration rate is measured through the use of a pressure sensor embedded in a tube that the user breathes into, when the sensor senses spikes in pressure as the user breathes in, these spikes are interpreted and calculated into a rate. For ECG, heart rate, and pulse oximetry, two fingers are placed in holes on the side of the device, where a pulse oximeter is present in one hole to take this reading, and ECG leads are present in both holes, which process the signals and are used to calculate heart rate as well. All of the sensors are attached to a microcontroller, which processes all of these signals, and then sends them to a display monitor on the front of the device so the user can see the measured vital signs. The

device is powered by a 9V battery placed in the back of the device. The design can be viewed in Appendix C.

9 Instructions

We have provided a set of instructions for using the VitalCorder below.

1. Before powering on the VitalCorder, insert a 9V battery in the detachable slot on the back of the device. To power on the VitalCorder, press and hold the red button on top that reads "ON". Wait up to five seconds for the device to power on, which is signified by the red light on the top right corner of the device, and for the monitor to display an image of a heart and the words "WELCOME" before displaying the interface. To turn it off, repeat the same process, the light will turn off and the screen will say "GOODBYE" before fading.

2. To activate one of five vital signs to measure, press one of the five green buttons on top of the device. For heart rate, press the button with the heart on it, for ECG, press the button with the waveform on it, for oxygen saturation, press the button with "O2", for temperature, press the button with the thermometer on it, and for breathing rate, press the button with the air symbol.

3. For heart rate, place either your left index finger into the left hole on the side and hold until it displays the number in the top left corner of the monitor.

4. For ECG, place both fingers into the side holes and hold, in the center of the screen, the waveform will appear.

5. For oxygen saturation, insert your right index finger into the right hole on the side and hold, the number will appear in the lower left corner of the screen.

6. For temperature, open the hatch on top that will start emitting the infrared light. Take caution not to shine this light into your eyes. Shine it at any piece of skin and the temperature in fahrenheit and celsius will display on the top right corner of the monitor.

7. For respiration rate, attach the breathing tube that comes with the device into the large hole in the center of the device below the monitor. Put it up to your mouth and begin breathing into it, the rate will appear in the bottom right corner of the screen. Discard the breathing tube and attach a new one after using.

10 Business Model

For the first two years, Vitalisation will have the four founders as the only full-time employees. We will manufacture and sell units on our own until more employees can be hired. We will sell VitalCorder units at an MSRP of $150. Our key targets will be to sell and advertise at stores such as CVS and Walgreens to reach our target market much easier. In addition, we will offer breathing tubes for the respiration rate sensor sold separately, using the razor blade

model. Furthermore, we will offer volume sales to buyers who will purchase many units, our key targets for these sales will be places like assisted living, nursing homes, airplanes, boats, mines, and the military. We will also provide tech support and repair services on our website to help people with troubleshooting their devices.

11 Market Research

The global vital signs monitoring devices market size valued at 4.7 billion USD in 2018 and is expected to grow at a compound annual growth rate (CAGR) of 8.7% from 2019 to 2026 [3]. Market details are summarized in the table below and in the figures provided in Appendix D. Constant innovation in products, increasing demand for home healthcare services, rising number of healthcare settings primarily hospitals, and rising prevalence of chronic disorders are key drivers responsible for the lucrative growth of the market.

Market size value in 2020	USD 5.1 billion
Revenue forecast in 2026	USD 9.1 billion
Growth Rate	CAGR of 6.5% from 2019 to 2026
Base year for estimation	2018
Historical Data	2015-2017
Forecast period	2019-2026
Quantitative Units	Revenue in USD million and CAGR from 2019 to 2026
Report coverage	Revenue forecast, company ranking, competitive landscape, growth factors, and trends
Segments covered	Product, end-use, region
Regional scope	North America; Europe; Asia Pacific; Latin America; MEA
Country scope	US; Canada; UK; Germany; China; Japan; Mexico; Brazil; South Africa; Saudi Arabia
Key companies profiled	Koninklijke Philips N.V.; Medtronic; Nihon Kohden Corporation; GE Healthcare; Masimo; Omron Healthcare; Contec Medical Systems Co. Ltd; A&D Company Ltd.; Nonin Medical Inc.; SunTech Medical, Inc.

Table 1: The global patient monitoring devices, homecare market through 2023 ($ Millions) according to BCC Research [4].

Vital signs monitoring devices have evolved over a short duration of time from individual devices measuring blood pressure (BP), pulse, and temperature to a combined all-in-one device. In addition to this, there has been an increasing number of innovations in this product category which is fueling the growth of products in this category.

The rising global prevalence of lifestyles associated with chronic disorders is expected to positively impact the market. With increasing awareness, the demand for personalized and accurate vital sign monitoring devices is expected to grow lucratively in recent years. According to the Global Health Observatory data, in 2015, 70.0% of the deaths were due to non-communicable diseases (NCD). The major NCDs are cardiovascular diseases (CVD) which caused 45.0% of all NCD deaths, cancer which caused 22.0% of all NCD deaths, and chronic obstructive pulmonary disease (COPD) which causes 10.0% of all NCD deaths, and diabetes which caused 4.0% of all NCD deaths.

Blood pressure monitors (sphygmomanometer) held lucrative shares of more than 41.1% in 2018 and are also anticipated to grow at a healthy CAGR of 8.9% from 2019 to 2026. This can be attributed to increasing BP monitoring due to the rapidly rising prevalence of hypertension. Additionally, with the increasing awareness, patients today are keeping an eye on blood pressure as a precautionary or preventive measure. This further led to an increase in demand for self-operational digital blood pressure monitors.

Homecare Market accounted for about 34.7% ($6.7 billion) of the Patient monitoring devices end-user market as of 2017 and is expected to grow at a CAGR of 8.8% from 2017 to 2023 to nearly $11.2 billion in 2023 from $7.3 billion in 2018 [4]. North America is the largest segment of the market. In 2018, it has already reached more than 3 billion dollars. The global CAG rate is about 8.5% on average. Asia-Pacific is a huge potential market due to its population and it has a growth rate of 9.4% from 2018 to 2023.

12 Financial Model

Based on our projected financials, we are asking for $1,040,000 for our first two years of operation. We will start our salaries at $38/hour and work eight hour, five day work weeks. The parts needed to make the VitalCorder total at about $100, we plan to make about 100 units to start, and then increase to 400 by the end of the year, and repeat for the next year. We plan to purchase computers, 3D printers, soldering equipment, and electronic parts. We will rent an office space in Baltimore with an annual rent of $41,250 [5]. We plan to spend at least $1,000 in marketing every year on advertisements to run in drug stores such as CVS and Walgreen's. We will allocate about $20,000 to distribution and shipping costs, and $10,000 a year to manufacturing costs. For our patent, we will need to pay a fee of $20,000, as well as $1,000 yearly, and allocate $12,000 a year to legal fees, and $12,000 a year to a CPA.

	Year 1	Year 2
Salary ($38/hr, 4 employees, 5 day work weeks, 8 hour work days)	$320,000	$320,000
Device Parts ($100 per device parts, make 100 to start, plan for at least 300 more per year)	$40,000	$40,000
Equipment (Computers, soldering parts, 3D printer parts)	$5,000	$2,000
Office Space [5]	$41,250	$41,250
Marketing ($1,000 per month)	$12,000	$12,000
Distribution (Shipping, packaging, storage)	$20,000	$20,000
Patent (Fees, utility patent)	$20,000	$1,000
Legal Fees (Lawyer, consultant)	$12,000	$12,000
CPA (Accountant fees)	$12,000	$12,000
Manufacturing	$10,000	$10,000
Contingency	+8%	+8%
Total	$530,000	$510,000

Table 2: An overview of the budget for the first two years.

13 Reimbursement

We will not be seeking reimbursement through insurance for the VitalCorder due to the device's relatively low price, so as to avoid increasing production cost or time spent to bring it to market.

14 Pitch

Hello, we are Vitalisation,

In the uncertain times of the COVID-19 pandemic, portable medical devices are increasingly becoming a necessity, as not everyone has access to key technology found in hospitals. In particular, vitals measuring devices, which are critical to monitor in a hospital setting to keep track of a patient's health during a health crisis. These are typically big, stationary, and expensive. While useful in hospitals, there is potential to innovate a similar device that is portable and usable outside of hospitals. With a portable and affordable device, monitoring a patient's health when not in a hospital would be far easier. Fortunately, we have created a device that can accomplish this task and fulfill this need.

We have created a device called the VitalCorder - a portable vital signs monitor capable of measuring heart rate, blood oxygen saturation, body temperature, respiration rate, and even ECG. This device is small, portable, and usable outside of hospitals. The idea came out of inspiration when one of its creators' father was hospitalized with COVID-19, not realizing the severity of his symptoms until arriving in the hospital. Following his return home, to monitor his symptoms, he purchased a pulse oximeter and breathing monitor separately, wishing that he could have one device for everything. Then, with some notes taken from the Tricorder, a fictional handheld medical device from the Star Trek franchise that collects medical data easily, the VitalCorder was born. Though not intended as a replacement for hospital vitals measuring technology, the VitalCorder is instead an affordable means of vital signs monitoring in at-home or in public settings.

Our product has several uses, and therefore several potential markets: Our device could be used to help monitor patients at home if monitoring for COVID-19 symptoms, or on a plane if experiencing in-flight medical emergencies. For a person who fears they may be infected with COVID-19, the ability to measure vital signs at home easily is incredibly important so they can monitor their conditions and determine if they need to visit the hospital. Often times, early detection of symptoms can be critical in peoples' treatment and recovery from diseases, so such a device would be incredibly useful. Furthermore, hospital vital sign devices may not always be available in places like airplanes, boats, and passenger trains, where medical emergencies are harder to deal with and it could be beneficial to monitor vitals before medical professionals are able to give treatment.

Portable vital sensing devices are a growing market - currently valued at $5.1 billion and expected to grow to $9.1 billion by 2026. We intend to sell this device at a much lower cost than most other vital signs devices. Many of these devices retail for several thousand dollars, whereas we hope to sell our device at about $200 to maintain affordability and accessibility.

The VitalCorder has a chance to become an essential piece of medical technology and it will be beneficial to millions of people in a post-pandemic world, allowing people to be more aware of their health at any given time.

15 Logos

We have designed two logos for our project. One company logo (Vitalisation) and one product logo (VitalCorder).

16 Website

Our website can be found at: `https://bmonteagudo98.wixsite.vitalisation.com/`

17 Summary

With the COVID-19 pandemic ongoing, there is a need for people to be able to monitor their vital signs while outside of a hospital setting. Few have access to the advanced medical technology found in hospitals, so the ability to have something similar in your pocket is incredibly important. Vitalisation promises to bring the VitalCorder forward as an option for people to have at home as an option to keep track of their health before making an informed decision about seeking medical care. The VitalCorder's size, ability to measure five distinct vital signs, and portability all make it a great possibility to help people monitor themselves at home. It can truly help make a difference in our ever changing world today.

18 Appendix

A Table of Future Design Trends

Distance to body	External	Wearable	Internal
Interface	Tangible, graphical user interface (GUI)	Tangible, GUI	Intangible, GUI
Device response condition	Responds primarily to patient input	Responds to patient input and context	Responds to internal condition of patient
Experience potential	Can mediate experience	Can mediate experience	Can medicate and control experience
Patient awareness	Conscious device interaction	Interaction fades into subconscious	No longer aware of device interaction
Patient control	High degree	Some degree	Minimal to none

Table 3: Portable medical device experience according to PMD changes [1].

B Questionnaire for Medical Professionals

Dear Dr. <Name>,

My name is Benjamin Monteagudo, and I am currently a student at JHU taking the course "Design of Biomedical Instruments and Systems." I am emailing to ask if you could please take a brief 3-minute survey that will be useful for my class.

1. On a scale of 1-10, how useful do you think a portable vital sign monitoring device would be for the general public? This device would measure vital signs such as heart rate, body temperature, ECG, respiration rate, and oxygen saturation.

2. Do you think that any portable vital sign monitoring device would be useful for potential patients to use at home to monitor themselves regarding symptoms of diseases such as COVID-19? (yes/no)?

3. Would you purchase such a device if it was available to you? (yes/no)

Name	Profession	Question 1	Question 2	Question 3
Dr. Felipe Tudela	Perinatology	6	Yes	Yes
Dr. Yvette Cordoba	Perinatology	7	Yes	Yes
Dr. Carmen Tudela	Perinatology	8	Yes	Yes
Dr. Mario Velez	Gastroenterologis	8	Yes	Yes
Dr. Peter Volsky	Otology	10	Yes	No
Dr. Ana Monteagudo	OB-GYN	10	Yes	Yes
Dr. Ilan Timor	OB-GYN	10	Yes	Yes
Dr. Carolinna Garcia	Pediatric ER	5	Yes	No
Dr. Sarah Doe	Resident	7	Yes	No
Dr. Cecelia Smith	Resident	5	Yes	Yes

Table 4: Results of the survey summarized.

C Schematic View of the VitalCorder

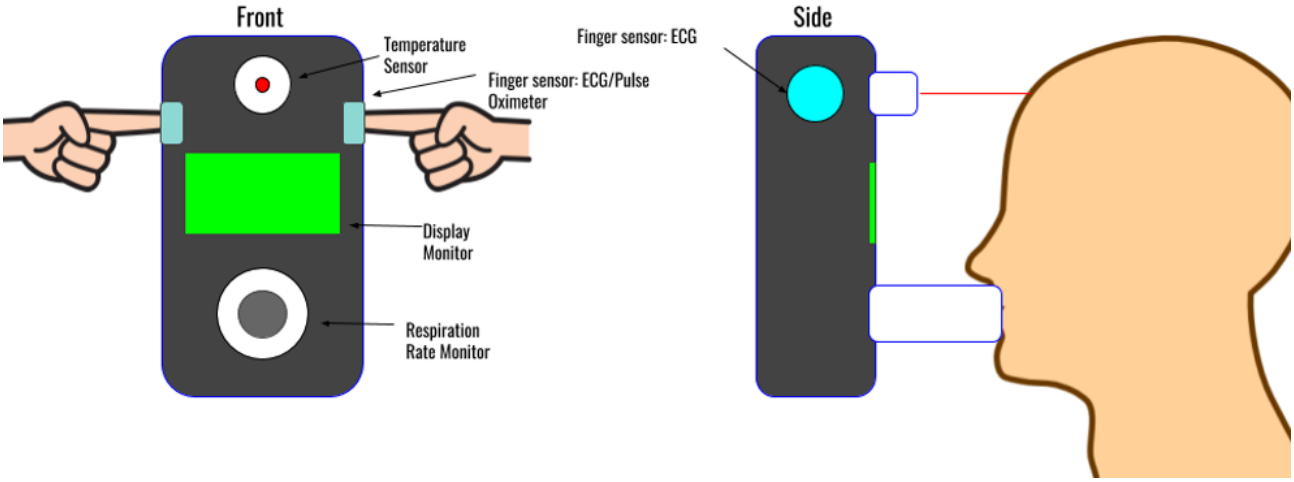


Figure 1: An illustration of the VitalCorder system.

D Figures of the Vital Signs Monitoring Market

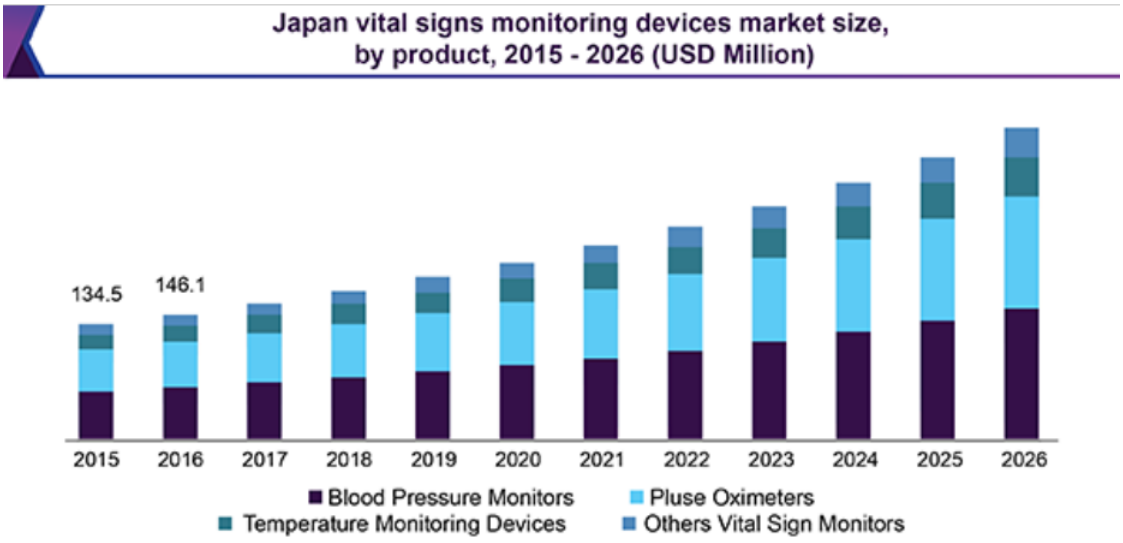


Figure 2: The Japanese vital signs monitoring market [3].

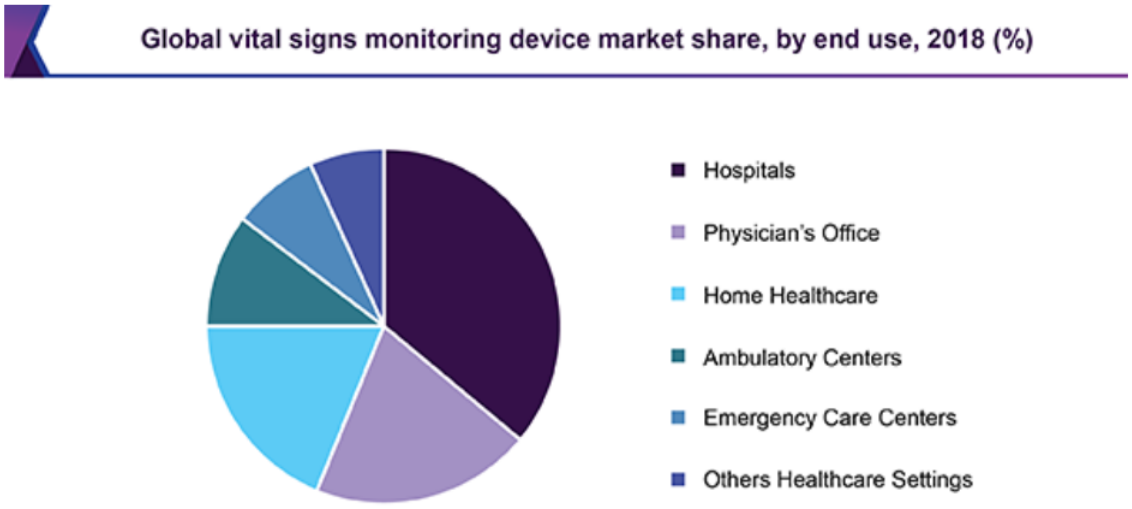


Figure 3: The global vitals monitoring market share sorted by end use [3].

Region	2017	2018	2023	CAGR% 2018-2023
North America	2928.3	3181.3	4784.7	8.5
Europe	1941.0	2116.8	3245.6	8.9
Asia-Pacific	1296.2	1419.4	2219.5	9.4
RoW	550.7	598.7	903.4	8.6
Total	6716.2	7316.2	11153.2	8.8

Table 5: The global patient monitoring devices, homecare market through 2023 ($ Millions) according to BCC Research [4].

E Competition Analysis Table

	AriaTele	Life Scope G3	PG S10	Waveline Nano	TEMP Vital Sign Monitor	Checkme Pro	BT-720	PC100-A	Recobro VIGILE	SureSigns VS2+	VitalCorder
Brand	SPACELABS	NIHON KOHDEN	PROGETTI	Avante	idottmed	Viatom	bistos	UN-MEDICAL	Clarity	PHILIPS	Vitalisation
Portable	-	Y	Y	Y	Y	Y	Y	Y	-	Y	Y
Wireless	Y	Y	-	-	-	Y	-	-	Y	Y	Y
BP	-	-	Y	-	Y	-	Y	Y	Y	Y	Y
SpO2	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
ECG	Y	Y	Y	-	-	Y	-	-	Y	-	Y
HR	Y	Y	Y	-	-	Y	-	Y	Y	-	Y
RESP	-	-	Y	-	-	-	-	-	Y	-	Y
TEMP	-	-	Y	-	Y	Y	-	Y	Y	Y	Y

Table 6: Comparison of various vital sign monitoring devices on the current market (2020).

References

[1] R. Gomez and A. Harrison, "Beyond wearables: experiences and trends in design of portable medical devices," in *International Conference of Design, User Experience, and Usability*, pp. 261–272, Springer, 2014.

[2] H. Greenspun and S. Coughlin, "mhealth in an mworld how mobile technology is transforming health care," Deloitte Center for Health Solutions, 2019.

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[4] "Patient monitoring devices: Global markets," BCC Research, 2018.

[5] "1601-1611 bush st baltimore, md 21230 - office property for lease." `https://www.showcase.com/1601-1611-bush-st-baltimore-md-21230/3965745/`. Accessed: 2020-12-22.