CONTRACT BOOK

Andrew Lippe, Divyasree Sasi Kumar, Subhiksha Somanathan
EN.520.657.01 Design of Biomedical Instruments and Systems
Fall 2021

Table of Contents

Biographies 3
Abstract 4
Introduction 4
Design 5
Market Survey 5
  Competitor Analysis 6
Patent Survey 7
Regulatory Overview 8
Development Plan 9
Business Plan 9
Business Model 10
Marketing Strategy 10
SWOT Analysis 11
Recruitment Strategy 11
Financial Plan: 2 Year Budget 12
Valuation 12
Exit Strategy 13
Products in the pipeline 13
Summary 13
References 13
Appendix 15
  Production Cost Breakdown 15
Patent 15

Biographies

Andrew Lippe
Andrew is an Electrical and Computer Engineering Master's candidate at Johns Hopkins University. He graduated with a B.S. in Bioengineering from the University of Maryland. He previously worked at Loccioni USA on robotic automation solutions for two years. Andrew has prototyping experience including circuit and PCB design, microcontroller programming, CAD, and fabrication.

Subhiksha Somanathan
Subhiksha is a Biomedical Engineering Master's candidate at Johns Hopkins University. She graduated with a B.Tech in Biomedical Engineering from SRM Institute of Science and Technology, India. She has done several internships with renowned hospitals in India working directly with medical devices. She currently works in a systems Neuroscience lab at Johns Hopkins School of Medicine. Subhiksha has experience with PCB Design, microcontroller programming, electrical and electronic circuitry.

Divyasree Sasi Kumar
Divyasree is a Biomedical Engineering Master's candidate at Johns Hopkins University. She graduated with a B.E degree in Medical Electronics from Ramaiah Institute of Technology, India. She has interned in hospitals and organizations that integrate state-of-the-art technology and healthcare. She has previously worked at Infosys Limited, India on Azure Cloud integration. Divyasree has experience with Sensor integration and biomedical instrumentation, biomedical signal processing, and Azure Cloud technology.

Abstract

Auris, the smart earring, is the only FDA approved medical device that can continually monitor your SpO_2 levels accurately. Auris is a wearable continuous pulse oximeter earring that is a wellness tracker as well as a medical device. Not only will Auris have a technological leg up by measuring SpO_2 on the ear lobe, but there are no other health tracking earrings currently on the market, so Auris would fill a gap in the wearable market as well. Auris measures metrics such as fitness, stress levels, temperature, and personalized data analysis depending on the wearers need and supplies insights through a Bluetooth connect app. The need for monitoring SpO_2 levels is apparent: several million lives can be saved annually if hypoxia or hypoxemia is detected and reported to the clinician instantly, which can be done with Auris.

Introduction

Below is a personal anecdote from Auris cofounder Andrew Lippe.

“Last January my stepdad came down with a terrible cough. He refused to go to the hospital and claimed he could fight it off on his own. It wasn’t until my aunt showed up at his house with a pulse oximeter that he finally agreed to go. His blood O2 was 85%. If he had gone to the hospital sooner, he might have survived.”

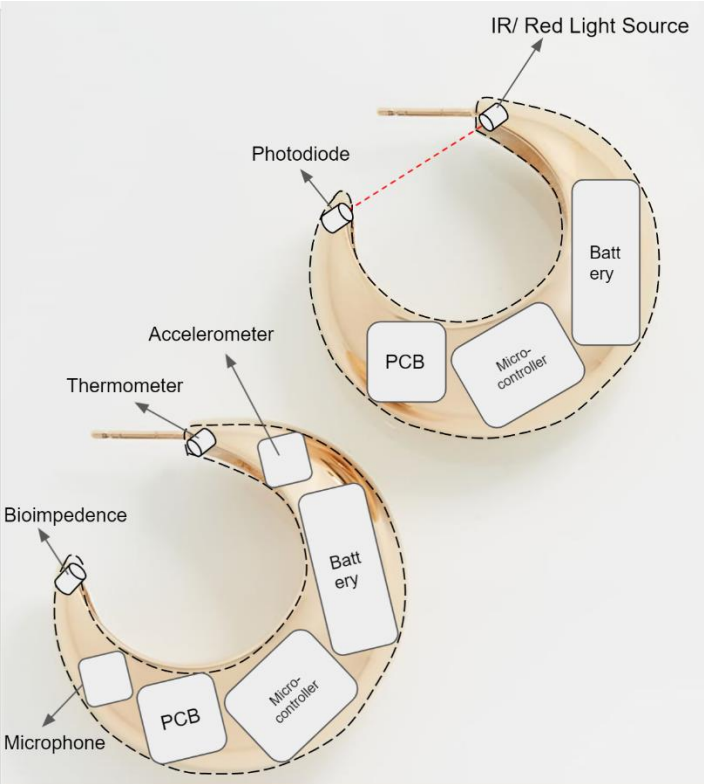
Unfortunately, his story is familiar to many individuals after the Covid19 pandemic, yet there is still no FDA approved continuous blood oxygen monitor.

While infected with Covid19, patients have a chance of developing hypoxia or hypoxemia, which is when blood O_2 levels fall below 95% for the former and 92% for the latter. “Silent Hypoxia” is when hypoxia advances without any symptoms and is common for Covid19 patients. Hypoxia from Covid leads to pneumonia and respiratory distress, which can lead to death. At home pulse oximetry before or after hospitalization is important for prevention and management of Covid19.

As a result of the Covid19 pandemic, the pulse oximeter market grew by 80% in 2020 alone [REF]. In an attempt to address the spike in demand, the new Apple Watch and Fitbit have pulse oximetry features, but these are NOT medical devices, they are essentially toys. They are not FDA approved and they are not accurate. Reliable pulse oximetry requires an extremity for the light to pass through, whereas a smartwatch attempts to reflect the light off dense bone and tissue which introduces error in the reading.

Aside from Covid, other respiratory ailments such as COPD, Asthma, or secondary infections arising from COVID like bronchitis require frequent pulse oximetry to monitor patient condition. COPD is the number 3 cause of death worldwide with 3.2 million people dying annually out of 65 million people who are affected. 80% of these deaths occur in low- and middle-income countries. For COPD, it is important to monitor SpO_2 for oxygen support intervention. The statistics show that there is a need for an accurate tool for continuous blood oxygen monitoring.

Design



Measurements:

- Heart Rate
- Respiratory Rate
- Temperature
- Physical Activity
- Skin Resistance/bioimpedance
- Sound dB exposure
- Blood O2

Sensors and Components:

- IR/Red LED
- Photodiode
- Galvanic Skin Resistance electrode
- Accelerometer
- Gyroscope
- Bluetooth capable Microcontroller
- Onboard memory
- Rechargeable battery

Market Survey

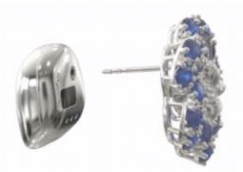
Auris will be penetrating 3 markets at once - wearable digital health, women's health, and the pulse oximeter market. Auris is the bridge between these 3 markets with the potential for exponential growth in revenue and sales.

Women's Digital Health Market: The women's digital health market is projected to reach 6.5 billion dollars by 2028. The biggest sectors for growth are expected to be mobile applications and wearable technology. It has been estimated that the wearable market experiences a loss of 50 billion dollars by not catering to women. All the estimates that drive most wearable digital technology is correlated with men's health data.

Pulse Oximeter Market: The pulse oximeter market is projected to reach $3.55 billion by 2026. It has been estimated that this market would see a 7.25% Annual Growth. This growth is attributed to the fact that continuous heart rate and dissolved blood oxygen monitoring is key for diagnosis and treatment of pulmonary and respiratory distress caused by conditions like COPD, COVID- 19 and Bronchitis.

Competitor Analysis

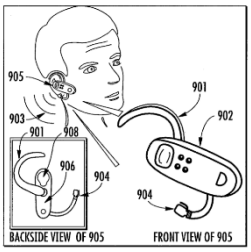
Women's and Alternative Digital Health Competitors

Ivy by Bellabeat	Joule Earring	Oura ring
		
$250	$120	$300
Appealing design Women Centered Brand	Fitness tracking	Sleep tracking Less bulky design
Heart rate, Respiratory rate, sleep, hydration, menstrual cycle, stress	Heart rate Calories burned Activity level	Heart rate Respiratory rate

Wearable Pulse Oximeter Competitors

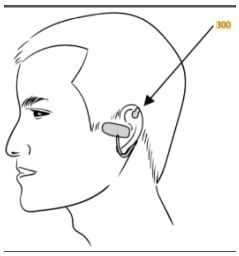
Apple Watch	Fitbit	Wellue O2 ring
		
$400	$300	$165
Activity tracker + heart rate	Activity tracker + heart rate	Sleep monitor Vibrates when SpO2 low
No FDA approval for SpO2	No FDA approval for SpO2	"FDA Registered"

Patent Survey



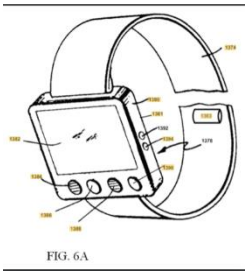
US20150126825A1 - Physiological Monitoring Apparatus

- Real-time and noninvasive wearable sensors wirelessly transmit physiological data
- Explicitly includes pulse oximetry on the earlobe
- Status: Abandoned following worldwide litigation



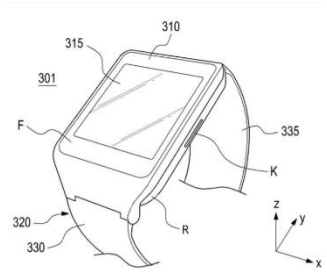
US20180042496A1 - System and Method for Measuring Vital Signs

- Portable and wearable sensing and computing device for wireless transmission of patient vital signs
- Explicitly includes pulse oximetry worn as an earpiece
- Status: Abandoned



US8764651B2 - Fitness Monitoring

- Wearable sensor on or near skin for wireless transmission of fitness data
- Status: Active - Expires 2026



CN105930631B - Method for measuring bio-signals and wearable electronic device thereof

- Use of a motion sensor to start measurement of a biological signal with a different sensor when no motion is detected
- Status: Active - Expires 2036

<u>Patentable aspects of the Auris</u>

Integrated sensors for spo2 measurement, body temperature, heart rate, intensity of activity is integrated in the earring wire for more accurate measurements and increased compactness of the wearable health monitoring earring.
Auris would be a unique solution that would track spo2 and heart rate monitoring in one earring and health parameters in another earring.

Regulatory Overview

The FDA Listing pathway for Auris is outlined below. The Regulation 21 CFR Part 870 highlights guidelines to list a medical device which defines a device as: The term "device" includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act; Device Specification and intent to be clearly defined; The registration details of the establishment to clearly updated; The premarket notification submission should be done 90 days before the establishment proposes to begin the introduction of a device intended for human use. This information of device name and the classification based on section 513 of the act to be included above - Auris - would be a class II device. Proposed labelling and unique labels to identify the device in market. Information about a predicate device - Joule earrings - and describe our product features that are similar and different from this.

The pathway for FDA approval for Auris pulse oximeter is outlined below. The classification controls of our device would be in Class II. FDA has released a guidance document to assist in preparing premarket notifications (510(k)s) for pulse oximeters. The scope of that document is limited to the Class II devices and the regulations for ear oximeter is 21 CFR 870.2710 – Ear Oximeter which includes the regulation for Oximeters (21 CFR 870.2700). A clinical evaluation of a new intended use of a legally marketed device may require an Investigational Device Exemption (IDE) under 21 CFR Part 812 before the clinical study is initiated.

Ethical consideration

The ethical consideration involved is interlinked with the regulatory pathway as the guidelines for FDA approval ensures clear documentation of the clinical data provided to support the need of the medical device. For this pathway, all sensors/ instrumentation testing should be according to the ISO 80601-2-61:2011 Medical Electrical Equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment or equivalent method. Also, the guidelines for pulse rate and SpO_2 testing is given in Clause 201.12.1 of the above-mentioned ISO. The software involved according to the guiding policy document by the FDA for medical software would have the controls based on the device it is integrated to.

Development Plan

Develop the Auris smart earring health tracker, with one earring focusing on tracking SpO2 levels while the other tracks everyday vitals.

Launch the Auris with an FDA listing and sell direct to consumer.

Invest the profits Auris into the process of getting full FDA approval for SpO2 measurements.

Launch a simplified clip-on version of Auris that only measures SpO2 and has FDA approval.

Expand our platform for clinical Spo2 monitoring by physicians, opening a revenue stream from physician prescribed and insurance covered continuous Spo2 monitoring.

Business Plan

The Auris Smart Earring will be sold at a price of $120 dollars, which is priced relative to other similar wearable technology. At this price point, the profit per unit is about $24. As we proceed with development and gauge interest in the market, it is possible the sale price of Auris will increase to increase our profit margins.

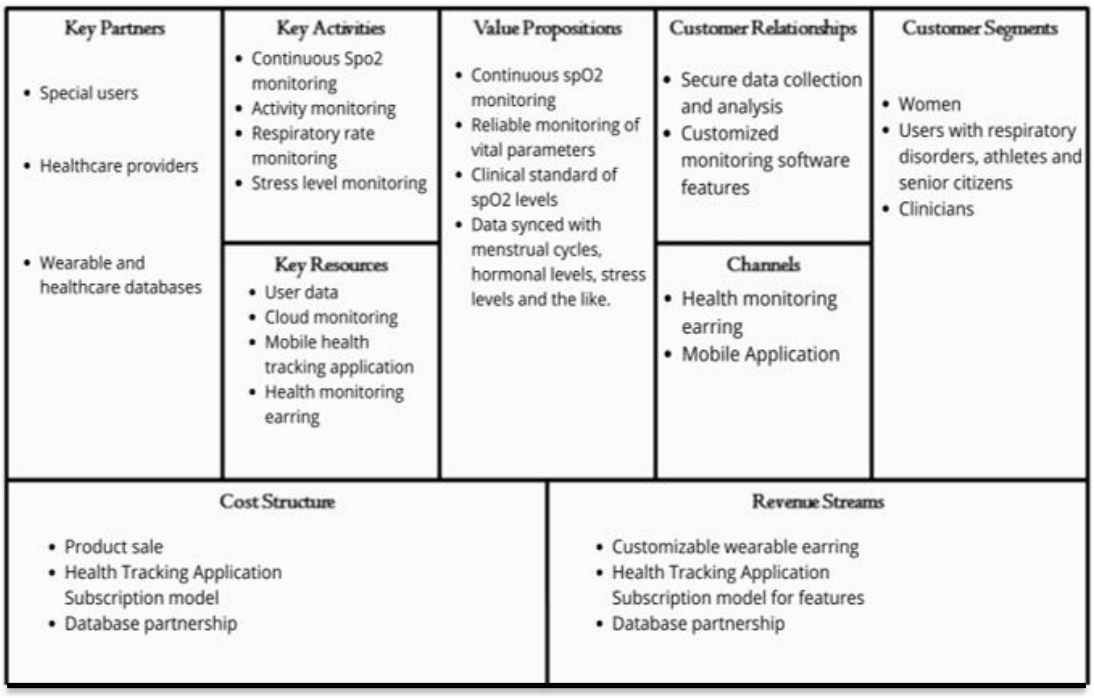
Our second revenue stream will be from a monthly subscription service to our premium software. This software will include some of the more advanced metrics that we saw earlier and will be customizable by the user as which features to include in their subscription. This will provide Auris recurring revenue.

A future revenue stream will come with FDA approval of the pulse oximeter earring. This will allow insurance reimbursement to the patient under code 94761.
With the wearable market growing exponentially, the sky is the limit as to potential revenue. Last year, 154 million wearable device units were sold alone in the last quarter. The pulse oximeter market saw a growth of 80.2% in just one year when the need was felt.

This figure is projected to continue growing. In addition, Auris is inclusive of women’s health, and we will be tapping into all 3 markets at once. This gives Auris an opportunity to experience

exponential growth in terms of sales and revenue after the initial market penetration, which would further increase following FDA approval. By just focusing on the wearable market alone, a market penetration of 0.01% would give an annual sale of 50,000 units for a profit of 1.2 million USD in a single year.

Business Model



Marketing Strategy

The marketing strategy will initially focus on video advertisement, newspaper advertisements and pamphlets and handouts at pharmacies, clinics, and hospitals. The advertisements will rely heavily on storytelling to convey the need for the product while also raising awareness about various pulmonary disorders. In the second stage after successful market penetration, users will be privy to premium subscriptions on the mobile application that will focus on delivering user specific stats and analysis.

The users using the mobile application will also have an option to subscribe to monthly newsletters that will be delivered via email that will inform them about new products and provide incentives for future purchases. Following this, a more targeted advertisement strategy will be used based on the users' browsing history, cache, and cookies. Social media will also be used for advertising.

Following FDA approval, marketing efforts would focus more on a direct relationship between clinicians and the user.

SWOT Analysis

Strengths What do you do well? What unique resources can you draw on? What do others see as your strengths?	**Weaknesses** What could you improve? Where do you have fewer resources than others? What are others likely to see as weaknesses?
Development of wearable health tracking earring that would monitor SpO2 and heart rate on one ear and vitals like body tempertaure, skin impedance on the other. Health Tracking earring that focuesses on women menstrual health with the personlized app	Affect of body temperature variance on vital monitoring Specialization of algorithms which will be dynamic in nature to ensure that analysis of vital parametrs are customizable
Opportunities What opportunities are open to you? What trends could you take advantage of? How can you turn your strengths into opportunities?	**Threats** What threats could harm you? What is your competition doing? What threats do your weaknesses expose you to?
Only FDA approved wearable Spo2 measuring device Become a key player in customized women centric health tracking solution	Navigating the pathway of FDA approval supported by clinical trials that follows stringent ISO guidelines in terms of algorithm specialization.

Recruitment Strategy

Auris will focus on key aspects of Research and Development and prototyping in the initial stages and the recruitment strategy will reflect this focusing on Biomedical R&D and Product

Manufacturing specialized recruitment. The regulatory pathway to FDA approval would involve IP and legal professionals whilst strategically involving market analysts and digital marketing experts focusing on digital health and monitoring solutions.

Financial Plan: 2 Year Budget

Embedded Electronics Engineer:	$120,000
Software Engineer:	$140,000
Manufacturing Engineer:	$100,000
Designers:	$120,000
Biomedical R&D:	$130,000
FDA Listing and Fees:	$12,000
IP and Legal:	$50,000
Marketing:	$50,000
Manufacturing Prototype:	$25,000
Manufacturing:	$200,000
Office space rent:	$100,000
Equipment:	$20,000
Other expenses:	$15,000
Total:	**$1,038,000**

Valuation

Based on the wearable market penetration and annual bulk unit sales of 1,082,000 USD and an anticipated increase of earnings of about 5% for a period of five years, Auris is valuated at $6,095,268.

Exit Strategy

Since Auris will be FDA approved and meet all the compliance and regulatory requirements, the suitable and most profitable exit strategy for Auris would be Initial Public Offering (IPO) and will be listed on the stock market. This will allow for Auris to have a more profitable turnover and a to fund Auris as a long-term venture with scope of future improvement and deployment of various other product lines under the company's brand name. Hence, this strategy will be a long-term goal with planning and documentation and would help increase the horizon of Auris and related wearable health products.

Products in the pipeline

A simplified clip-on version with rechargeable case will be developed that focuses on pulse oximetric measurement to track heart rate and dissolved blood oxygen which would be connected via Bluetooth to the mobile application for personalized analysis of vitals.

Summary

Auris will redefine the way we look at wearable healthcare; a step closer to merging conventional diagnostic tools and non- invasive health monitoring. Auris is a wearable continuous pulse oximeter earring that is also a medical device. Not only will Auris have a technological leg up by measuring on the ear lobe, but there are no other health tracking earrings currently on the market, so Auris would fill a gap in the wearable market as well. From measuring fitness, stress levels, temperature, and personalized data analysis depending on your need, to clinically reliable oxygen monitoring; Auris does it all.

References

1. Google. (n.d.). *US20150126825A1 - physiological monitoring apparatus*. Google Patents.
2. *Biomedical engineering: FDA Regulations*. Research Guides. (n.d.).
3. Center for Devices and Radiological Health. (n.d.). *Policy for device software functions and mobile medical applications*. U.S. Food and Drug Administration.
4. *Tax management real estate journal - morganlewis.com*. (n.d.).
5. Center for Devices and Radiological Health. (n.d.). *Pulse oximeters - premarket notification submissions [510(K)s]*. U.S. Food and Drug Administration.
6. Center for Devices and Radiological Health. (n.d.). *Device advice*. U.S. Food and Drug Administration.
7. FDA. (2001, December 8). *510(k) summary IM2001 pulse oximeter 2002*. Accessdata.FDA.
8. Stamford, C. (2021, January 12). *Gartner forecasts global spending on wearable devices to total $81.5 billion in 2021*. Gartner.

9. Centre for Disease Control and Prevention. (2021, June 14). *CDC - data and statistics - chronic obstructive pulmonary disease (COPD)*.
10. World Health Organization. (2021, June 21). *Chronic obstructive pulmonary disease (COPD)*.
11. Thomas, J. (2020, July 2). *COPD: Facts, statistics, and you*. Healthline.
12. Grand View Research, I. (2021, June 16). *Women's digital health market size worth $6.5 billion by 2028: Grand View Research, inc*.
13. Mellor, M. (2019, November 27). *Fitness trackers and wearables are ignoring a $50bn market: Women*. WIRED UK.
14. Grand View Research, I. (2021, August 24). *Fitness tracker market size worth $138.7 billion by 2028: CAGR: 18.9%: Grand View Research, inc.*
15. McCarthy, J. (2021, November 20). *One in five U.S. adults use health apps, Wearable Trackers*. Gallup.com.
16. Dublin. (2018, September 20). *Global $6.5 billion women's digital health markets to 2028: Reproductive Health, pregnancy & nursing care, Pelvic Care, General Healthcare & Wellness*. "Global Women's Digital Health Market 2021-2028.
17. Gunja, M. Z. (2018, December). *What is the status of Women's Health and health care in the U.S. compared to ten other countries? What Is Status of Women's Health? U.S. vs. 10 Other Countries*. Commonwealth Fund.
18. Elflein, J. (2021, July 6). *Ongoing health issues women by age U.S. 2020*. Statista.
19. Benoist, B. de. (2008, July 9). *Global anaemia prevalence and number of individuals affected*. World Health Organization.
20. Zhu, Z., Barnette, R. K., Fussell, K. M., Rodriguez, R. M., Canonico, A., & Light, R. W. (2005, May 5). *Continuous Oxygen Monitoring-a better way to prescribe long-term oxygen therapy*. Respiratory Medicine.

Appendix

Production Cost Breakdown

Components	Price per unit ($)
Microcontroller	$6.95
Thermistor	$1.43
Galvanic Skin Resistance Sensor	$2.95
IR LED	$1.00
Red LED	$0.60
Phototransistor	$2.67
Accelerometer	$17.50
Battery – Rechargeable Lithium	$8.40
Polycarbonate sheets	$3.53
Carbon Steel	$1.20
Manufacturing + Fabrication costs	$30.00 appr.
Total	$76.23

Patent

United States

Patent Application Publication

Title: Earring wire integrated with spO2 sensor.

Inventor: Auris

Corresponding Address: 3400 N Charles Street

Appln No: 580,771

Filed: Dec 9, 2021

Drawing:

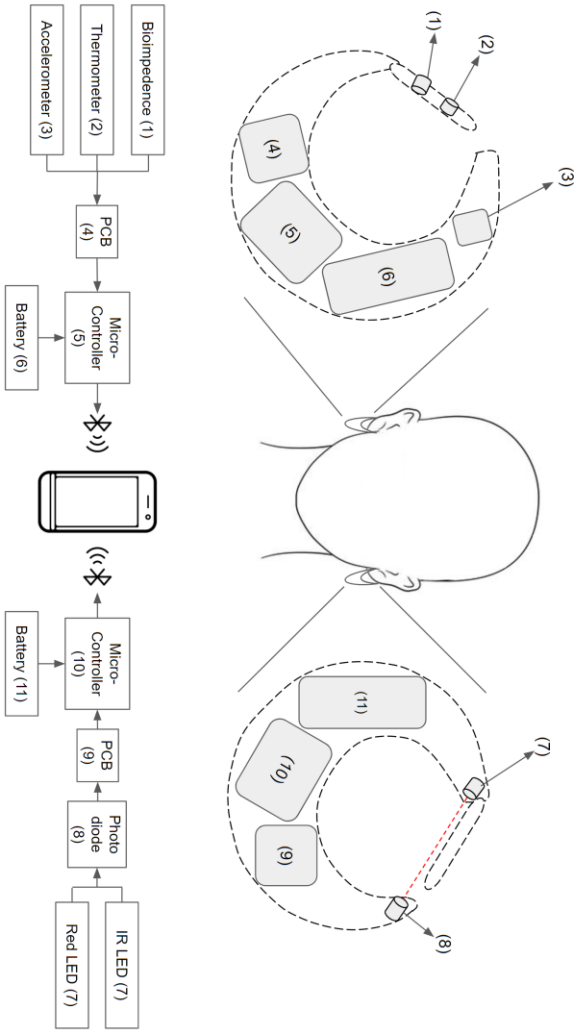


FIG 1.

Abstract

A device used to continuously detect spo2 levels while also monitoring everyday vitals such as movement, steps walked, stress levels, activity level and temperature was designed. This device is packaged to resemble an earring that can be worn continuously on both ears. The sensors used to detect everyday vital parameters include thermistors, galvanic skin resistance sensors and an accelerometer. To continually monitor spO2 levels, the principle of pulse oximetry is employed. These sensors are integrated into the wire of the earring that goes into the piercing.

The proximity of these sensors to the skin in the lobe of the ear enable accurate, reliable readings.

Health monitoring earrings where the sensing element is integrated in the wire of the earring.

BACKGROUND ON THE INVENTION

[0001] Clinical Need
[0002] Activity Monitoring
[0003] This invention is related to a device that can continually monitor SpO2 levels along with everyday activity monitoring.
[0004] There is a need to continually monitor spO2 levels with great accuracy for it to be used at a clinical scale. The need for continuous SpO2 monitoring arises due to various health conditions such as Covid19, COPD, etc. which are both leading causes of death worldwide. Continuous spO2 monitoring results in getting the right treatment when the need arises for emergency oxygen supplement treatment.
[0005] Taking advantage of the nature of the earring's wire enables this. The earring wire is in direct contact with the lobe of the ear and multiple sensors integrated into this would enable accurate, motion artifact free readings for monitoring everyday vital parameters.

[0006] All recorded data will be sent to a mobile based application for continuous analysis and future reference.

PRIOR INVENTIONS

[0007] The common parameters for monitoring fitness and stress levels include intensity of physical activity in terms of steps taken heart rate, respiratory rate and body temperature. Spo2 levels are monitored to measure the efficiency of the respiratory system in patients with COPD, Covid and other respiratory disorders.

[0008] Wearable bands and jewelry have monitored activity levels and fitness parameters. One band measures heart rate, respiratory rate, and monitors sleep, hydration, menstrual cycle and stress. One earring tracks fitness and measures heart rate, calories burned, and steps taken. One ring tracks sleep and alerts when Spo2 is low.

SUMMARY OF THE INVENTION

[0009] The clinical need is to provide a means of continually monitoring clinical grade spo2 levels to provide required emergency and assistance as required. In order to do this accurately, the sensor needs to be in close proximity to areas of the body with high vasculature.

[0010] **s**po2 monitoring goes hand in hand with monitoring other vital activity parameters such as temperature, steps count, activity rate, movement and stress levels. These parameters are often subjected to motion artefacts due to insufficient contact with the body or movement due to incorrect placement of the monitoring device. Integrating these sensors into the wire of the earring which is subject to little to no movement would allow for accurate measurement of the aforementioned parameters.

BRIEF DESCRIPTION OF THE FIGURES

[0011] Figure 1 provides the overall representation of the earring to be used for blood oxygen level monitoring and activity rate monitoring by integrating sensors into the earring casing and earring wire as appropriate. It also depicts the sensors integrated into the wire of the earring. One earring will be used for spo2 monitoring, which includes the LED for transmission of light. The other earring's wire will be used for activity monitoring and is complete with accelerometer, bioimpedance sensor and a thermistor. A block diagram represents the major components in the design.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0012] The Spo2 sensing is implemented using a Red LED and an IR LED [7] coupled with a photodiode in one earring's wire. [8] Along with the 5V microcontroller [10] and a printed circuit [9] in one earring's casing. The photodiode would detect the changes in LED transmittance by capillaries in the proximity of the ear and would transmit it to the microcontroller.

[0013] The other earring's wire also contains a thermistor [2], galvanic skin resistance sensor [1] along with an accelerometer [3], the 5V microcontroller [5] and a printed circuit board [4] in the earrings casing. Skin Resistance is measured by the bioimpedance sensor at the surface of the earlobe [1]. The device has the thermistor making direct contact with the user's skin, at the earlobe. The thermistor will monitor the temperature at this location [2]. The integrated accelerometer would record the steps taken [3].
The above data is preprocessed by the 5 V microcontroller and sent via Bluetooth to the mobile application.

What is claimed is:
1. Integration of spo2 sensing elements within a thin wire wherein
a. The wire is in close contact with the extremities of the body where there is high vasculature.
b. The device transmits and senses visible light and/or IR light to take these measurements.
c. The wire is disguised as an accessory that can be worn in a piercing on the ear, finger, nose, and the like.
d. The device can monitor spo2 levels at a clinical grade and report the recorded data on a mobile application and to the user's desired physician.
2. A miniaturized sensing element wherein
a. The sensing element is disguised as the wire of an earring, nose ring or any similar piercing.
b. Multiple sensors are coupled to the sensing wire for every day vital parameter monitoring.

3. The device as claimed in claim 1 wherein the spo2 measurements are taken continuously.
4. The device as claimed in claim 1 and 2, wherein
a. The sensor is powered by a rechargeable battery such as but not limited to LiPo.
b. The sensor is controlled by a microcontroller housed in a casing in close contact with the sensing wire.
5. The device as claimed in claims 1 and 2, wherein the device is a wearable jewelry or accessory.
6. The device as claimed in claim 5, wherein
a. The power source for the sensor is housed in a casing that is also a part of the wearable jewelry.
7. The device as claimed in claim 1 wherein,
a. The monitoring of respiratory rate and heart rate occurs at the site of a piercing where the sensing wire is housed in the piercing.
8. The device as claimed in claim 2 wherein,
a. The sensors used are designed to track every day vital parameters such as temperature, steps walked and the like.
b. The sensors used can detect movement, light, temperature changes all while being encased in the accessory's wire.