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(54) **Title**: AN INTEGRATED DEVICE TO CALCUTATE HEART RATE AND BODY ACTIVITY ACCURATELY

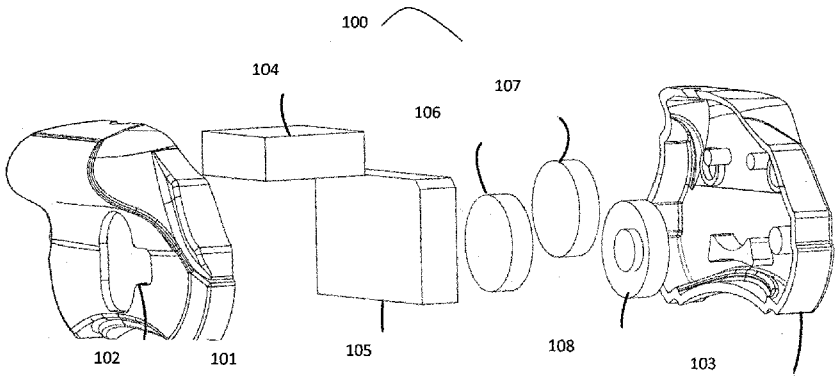

Figure 1

(57) **Abstract**: The main objective of the present invention is to design a compatible and a novel device (100) with reduced form factor to measure and monitor the biological conditions of a living body and communicate it to the remotely connected device. It monitors almost all crucial factors such as hear rate, calorie count, physical activity, sleep, tiredness, posture etc. The device comprises of components that are comfortably packed into a plastic shell that is separated as two lobes along with a pair of permanent magnets to help in firmly positioning the device on the ear. The main components of the device are heart rate monitor, accelerometer, microcontroller and a wireless communication module.

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AN INTEGRATED DEVICE TO CALCULATE HEART RATE AND BODY ACTIVITY ACCURATELY

FIELD OF THE INVENTION

The present invention relates to an ear based fitness and lifestyle device designed to suit people with varied activity levels and lifestyles by trying to provide them information on their quality of life and further to engage and inspire them to be more wellness conscious, by consciously and gradually altering their lifestyle by aiding them where possible.

BACKGROUND AND PRIOR ART

Fitness and health have an immense co-relation to the functioning of the heart, hence understanding the information from the heart in the form of heart rate is an important tool to improve one's wellbeing. It has been well documented, especially in the paper published as ***'Prognostic Significance of PVCS and Resting Heart Rate'*** by Gregory Engel et al. in A.N.E., 2007, which signifies how a higher heart rate reduces the quality of life as well as increases the chances of heart failure, myocardial infarction and other such cardiac disorders. Resting heart rate, as shown by Benetos A, et al., in a literature titled ***'Hypertension'*** (published in the year1999; 33:44-52) is an important indicator for the mortality of the person.

Heart rate is typically calculated using an ECG, pressure sensors near arteries or veins or by the use of pulse oximeters. **US2358992** entitled ***"Oxygen meter"***, which is one of the earliest mention of the pulse oximeter, demonstrated how shining light could be absorbed and reflected by the capillaries within the ear, which not only indicated heart rate but also the oxygen saturation of the blood.

US5513642 entitled ***"Reflectance sensor system"*** disclosed a form of reflected pulse oximeter, where the sensors were placed on the same plane as the light-emitting source, improved the earlier system. This would allow for a much smaller oxygen saturation and heart rate calculating device, and would avoid the need for clips. This patent formed the basis of many others that

followed; including **US20100113948** entitled ***"Heart Rate Measurement"*** which describes a device that calculated one's heart rate from around the ear. This patent also improves upon the earlier patents by detecting dark signal which may be derived during an off phase of a duty cycle of an emitter and a photoplethysmogram system arranged to select between a plurality of detectors, which would mitigate motion artefacts, thereby making the heart rate monitor more mobile.

Activity monitoring too forms an important part of the information that must be related to the user to improve his fitness and lifestyle. By placing piezoelectric MEMS (Microelectromechanical systems) sensors, such as accelerometers, allow us to view the activity of the individual. **US5425750** entitled "***Accelerometer-based multi-axis physical activity sensor for a rate-responsive pacemaker and method of fabrication***", which is one of the earliest patents which referred to the use of such sensors for calculation of physical activity, used film of a piezoelectric polymer adhered to each surface of an electrically conductive substrate to calculate physical activity.

The use of accelerometers has hence been used for multiple physical activity indicating parameters, including gait analysis by G.Z. Yang et al., in the patent **CA2641474. EP1770368 entitled** ***"Pedometer device and step detection method using an algorithm for self-adaptive computation of acceleration thresholds"*** discloses a pedometer device for detecting and counting steps taken of a user on foot and an accelerometer sensor detects a vertical acceleration generated during the step. G.Z. Yang also placed the accelerometer onto the ear, which allowed them to gain far more body information.

US20120078119 titled ***"Method and apparatus for robust heart rate sensing"*** discloses fitness devices, which integrates both heart rate and physical activity sensing from the ear wherein the innovators place an optical heart rate sensing module and an accelerometer within an ear cuff. An ear cuff is designed by the innovators to ensure a stable hold of the device, even during much physical movement due to exercise. However, these add-ons to the device, not only increase the discomfort to the user, who has to tightly secure the device, but also increase battery consumption by adding additional sensors onto the device. The device also varies the gain of the

amplifiers based on the pressure applied when the cuff is clipped to the ear. Varying the gain of the amplifier of the product with the pressure placed (although an original thought) is also prone to other noises as lowering of the gain also lowers the common mode rejection ratio, allowing the device prone to other noises.

US20100016741 entitled ***"Heart rate monitor"*** is an innovative device, which is able to calculate heart rate and activity, which is completely waterproof for swimmers and other water-based athletes. This sensor is placed on the goggles or other headgear of the user, and is able to calculate the heart rate through the optical sensors placed near the temples of the user. Strapping the device onto swimming goggles can do this, however this makes it difficult for other users who do not use goggles while swimming, and do it as a leisure sport than as a professional one.

Other devices also offer the same functionality inside the aforementioned innovation as in **US20100113948** titled ***"Heart Rate Measurement"***, wherein the innovators place the optical ear sensor behind the ears. The device also includes a wireless transmitter to include the data to a wireless receiver. This prior art also continues to measure when the emitter is not emitting any radiation, so as to remove the ambient light noise artefacts. The design of such a device, which encompasses the entire area behind the ear, also makes the device indiscrete, and the placement without the support of a clip or other such holding mechanism would allow itself to dislodge from the ear easily.

As any means of monitoring heart rate, which has to produce low noise, requires it to be firmly fixed to the skin, the aforementioned methods that use cuffs or clips, add mechanical parts, thereby making the device uncomfortable, prone to wear and tear and non-waterproof.

Furthermore, the lack of proper affixation of the device to the body part, makes the accelerometer data inaccurate as well, which leads to wrong calculations of bodily activity of those who run, swim or do any form of cardiovascular exercises.

This inaccurate data is the reason why many activity trackers still depend on actigraphy to measure the calorie expenditure, rather than the more accurate means of measuring it using heart

rate. This becomes challenging for users who are more prone to muscle training than to hig motion cardiovascular training (such as jogging, aerobics).

Hence, there is a need for a device that: is discrete, accurate, comfortable to the user constantly, when he is exercising, relaxing or engaged in some other work; measures important parameters while ensuring a long battery life. The innovation must also work seamlessly, whereby it must function despite the surrounding of the user. This device has to be intelligent enough to use these vital sign data, to aid and inform the user, so that he may enhance his fitness and wellbeing. Therefore, there is a need not only for a fitness device, but one that alters the user's lifestyle to a more fitness oriented one.

SUMMARY OF THE INVENTION

The device is designed to provide greater accuracy in its heart rate and accelerometer calculation. The device primarily consists of an accelerometer and a heart rate monitor within a miniature device placed over the ear thereby ensuring the discrete usage of the device. Such placement over the ear is done by the use of magnets, which would ensure minimal user interaction, and no mechanically moving elements in the design.

The usefulness of not using mechanical parts, allows the entire device to be completely enclosed within a plastic enclosure, as the main means of charging would be through wireless induction charging, making the device completely waterproof. The device is further supported by gesture control, wireless communication and has an inbuilt memory.

The device as mentioned comprises of an accelerometer and a heart rate monitor, which is enclosed within a miniature device that is placed over the ear. The device includes a microcontroller, a vibrator and a wireless networking module, which allows it to communicate with other devices, such as smart phones, computers, etc. The invention is designed to extract heart rate using reflected photoplethysmography from behind the ear. The means of measuring this is done by the use of infrared (IR) LEDs and photodiodes. The portion of the IR light behind the LEDs, which is transferred through the skin of ear into the capillaries within it, is absorbed or

reflected by oxygenated or deoxygenated blood respectively. This absorption and reflection of light can be measured by the use of an IR photodiode, which is placed on the same side as IR LEDs, and hence allows the device to determine the frequency at which the heart is pumping blood to the capillaries, thereby determining the heart rate. The IR LEDs, which is not within the visible spectrum, allows the device to be unnoticeable top the external observer, thereby providing a greater amount of discretion.

The same LED and photodiode set-up also differentiates on the rate of oxygenation and deoxygenation, thereby indicative of the body's breathing rate. As the oxygen saturation increases steadily during an inhalation, and reduces steadily with exhalation, it is possible to decipher the respiration rate too from this data. By applying a low-pass digital filter below 0.7 Hz, it's possible to extrapolate respiration rate.

BRIEF DESCRIPTION OF THE DRAWNGS

The above-mentioned and other features and advantages of this present disclosure, and the manner of attaining them, will become more apparent and the present disclosure will be better understood by reference to the following description of embodiments of the present disclosure taken in conjunction with the accompanying drawings, wherein:

Figure 1 illustrates the internal components of the ear based device of the system such as shell, battery, PCB board, vibrator, magnets and an induction coil;

Figure 2 shows the means by which the device is mounted on the ear firmly and flexibly in detail;

Figure 3A shows the data of noise-free heart rate graph as acquired from the ear; **Figure 3B** shows the data of respiration rate extrapolated; and **Figure 3C** shows the data that is further filtered to a low pass frequency of 0.7 Hz to obtain a clean trace.

Figure 4 illustrates the monitoring of the posture of the user; and

Figure 5 illustrates the communication between the device and the charging dock, so that the user may understand whether the device is charged or charging.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference will now be made in detail to the exemplary embodiment(s) of the system. Before describing in detail embodiments that are in accordance with the present disclosure, it should be observed that the embodiments reside primarily in combinations of components of the device.

In this document, the terms "comprises," "comprising," or "including" or any other variation thereof, are intended to cover a non-exclusive inclusion, such that a system, method, article, device or apparatus that comprises a list of elements does not include only those elements but may include other elements not expressly listed or inherent to such system, method, article, device, or apparatus. An element proceeded by "comprises ...a" does not, without more constraints, preclude the existence of additional identical elements in the process, product, method, article, device or apparatus that comprises the element.

Any embodiment described herein is not necessarily to be construed as preferred or advantageous over other embodiments. All of the embodiments described in this detailed description are illustrative, and provided to enable persons skilled in the art to make or use the disclosure and not to limit the scope of the disclosure, which is defined by the claims.

It will be apparent to those skilled in the art that various modifications and variations can be made to the present invention without departing from the spirit and scope of the invention. Thus it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents.

In the following description, for the purpose of explanation, numerous specific details are set forth in order to provide a thorough understanding of the present construction of a novel device. It will be apparent, however, to one skilled in the art that the present invention can be practiced

without these specific details. In other instances, structures and devices are shown in block diagram form only in order to avoid obscuring the present invention.

Figure 1 illustrates the internal components of the ear based device which is covered by plastic shell (**101,103**) and creatively uses space by placing the battery **(104)** at a perpendicular angle to the PCB board **(105).** The PCB board comprises of an accelerometer, heart rate monitor, microcontroller, wireless communication module among others. A vibrator **(106)**, magnet **(107)** and an induction coil **(108)** are placed beside one another to reduce the size of the design. The front plastic cover **(101)** has a cut out/marking **(102)**, which will either be made of a transparent material or be affixed with a transparent material, so as to allow the LED and Photodiode to acquire the information from the ear.

Figure 2 highlights the means by which the device is affixed onto the ear **(109)**. The body contains a magnet **(107)**, the same body is also fixed to a flexible material **(111)**, which contains another magnet **(110)**. The magnetic force between the magnets will ensure the device is placed on the ear.

To place the device on the ear, the user would have to separate the two magnets, and place his ear between them. The use of magnets is a novel step in the design of the innovation, as it ensures a stable and constant contact between the ear and the device; additionally as the head and hence the ear, experiences minimal reverberations during walking or running, (as compared to any other body part) due to the torso and the abdomen acting as shock absorbers, the device experiences very minimal motion artifacts, and hence ensure that the signal that is received has much lesser noise than if it's placed elsewhere. The magnets placed on the ear, also ensure that the device doesn't succumb to motion due to its own weight, and ensure minimal movement of the device. As the heart rate sensor is reflective, i.e. the sensors are placed on the same side of the ear, placing the magnet directly opposing them on the other side of the ear, also reduces the noise that may interfere due to ambient infra-red light.

Additionally permanent magnets have a long life, and do not alter the functionality of the device, as well as ensure that there are no mechanical parts on the device. This combination of placing

the innovation on the ear using magnets will ensure the lowest noise possible during most form of high physical activity. While magnets have been used for the purposes of jewelry (US 3034320), it is for the first time used for the purposes of a medical health monitoring device.

The invention is designed to extract heart rate using reflected pulse plethysmography from behind the ear. The means of measuring this is done by the use of infrared (IR) LEDs and photodiodes. The portion of the IR light behind the LEDs, which is transferred through the skin of ear into the capillaries within it, is absorbed or reflected by oxygenated or deoxygenated blood respectively. This absorption and reflection of light can be measured by the use of an IR photodiode, which is placed on the same side as IR LEDs, and hence allows the device to determine the frequency at which the heart is pumping blood to the capillaries, thereby determining the heart rate. The IR LEDs, which is not within the visible spectrum, allows the device to be unnoticeable top the external observer, thereby providing a greater amount of discretion.

The same LED and photodiode set-up also differentiates on the rate of oxygenation and deoxygenation, thereby indicative of the body's breathing rate. As the oxygen saturation increases steadily during an inhalation, and reduces steadily with exhalation, it is possible to decipher the respiration rate too from this data. By applying a low-pass digital filter below 0.7 Hz, it's possible to extrapolate respiration rate. **Figure 3A** shows the data that is acquired form the ear, where a noise free heart rate graph is noticed, which allows for extrapolation of respiration data as shown in **Figure 3B**, which can be further filtered to a low pass frequency of 0.7 Hz to obtain a clean trace as shown in **Figure 3C**.

Respiration rate or the breathing rate, may be co-related to multiple health and wellness information, including Stress onset, sleep onset, Apnea, and Asthma. Respiration rate information is also useful in the determination of certain exercises, such as Yoga, which relies heavily on breathing, and ensuring that the user breathes constantly. Hence a device that measures both heart rate and breathing rate, can aid the user by informing them about their performance in such exercises.

Physical activity and pedometer calculations can be acquired from the accelerometer placed around the ear. This forms the most optimal position to ascertain the physical activity of the user as the ear moves in tandem with the head, and the head moves in tandem with the whole body. Placement on the ear, removes much of the body movement noise, and focuses on the force acting on the head due to normal human gait, as the body behaves as a shock absorber for the neck, the head and the ear.

The accelerometer placed on the ear, may also determine head movement (like moving up and down and tilting sideways) which can be characterized in technical terms as pitch and roll angle rotation respectively as shown in **Figure 4**. The information hence gathered from the pitch information, may also provide information of the person's neck posture, thereby also providing information to the user to improve his/her sedentary state. The device is able to determine proper posture **(302)**, which maintains the angle of the head rotation to the normal axis (301), as well as poor or improper posture in terms of either concave neck and spine bend (304), which would make the ear's axis shift to the left of the normal axis **(303)** and poor convex posture **(305)** makes the ear's axis shift to the right of the normal axis **(306)**.

As mentioned previously, the invention does not exist in isolation, but has the ability to connect and work in tandem with smart devices through the use of wireless communication, such as Bluetooth. Taking advantage of this communication, the device is able to determine more about the user's behavior and hence be of more assistance to the wellbeing of the user. Using the GPS on the phone, which is connected to the innovation, we can determine whether the means of travel of the user. The speed of his travel, as well as his attention levels, that are interpolated through the means of heart rate variability and respiration rate, allows the innovation to ensure that the user is active and alert, especially at moments when he's driving the vehicle. As almost 15% of all road accidents occur due to weariness or a lack of focus, the device will ensure the user is safe and secure even when he's behind the wheel.

The same communication may also aid the user in precarious situations. As the device monitors heart rate accurately, it allows the innovation to have an understanding of Heart Rate Variability (HRV), which is a frequency transformation of the time difference between two consecutive

heart rate values. Research has shown that HRV and respiration rate, can indicate the user's mood. This is helpful in terms of safety, especially for women. In a crisis situation, when the user is in danger, the ability to have lucid thoughts is a rarity. The innovation may then determine the state of panic in the user through HRV and respiration, and trigger an emergency call or SMS to all the user's emergency contacts, along with the information of the user's location through the paired communication device. This would allow help to reach the user, even if the user doesn't have the ability to call out for help.

The device is also built in with gesture control by the use of touch capacitive sensors in front of the ear as well as behind it, to allow continuous engagement with the user. This gesture control (taps, double taps, flips, etc.) can be used to control the music player on the smart device and also trigger an emergency, whereby a beacon is sent to the emergency contacts to help in the case of trouble. The information that will be relayed in case of an emergency, to the emergency contact will be the vital sign information of the user as well as location information, which can be granted from the smart device.

This wireless connectivity, will also allow the user to be notified when his/her smart device is out of reach from the innovation. The innovation, which has an electronic vibrator built into it, will gently vibrate to alert the user that his/her smart device is out of reach or has disconnected. The vibrator may be switched off by the use of a gesture. The vibrator may also be used to inform the user of any alerts, such as medication reminder or an important phone call that is being received by the smart device. Additionally the vibrator may also be used to determine when the user has reached his exercise goal.

The device and the smart device is connected to calculate sleep as well as calorie expenditure, however the means of calculation is far different from the norm. The calculation of sleep and calories by the device is not done by using the accelerometer alone (which only highlights the physical activity) but also by calculating the heart rate. By integrating an algorithm within the device, which can calculate the rise of heart rate as well as the physical activity, the device will be able to calculate with a much higher accuracy. The device will provide the smart phone with information with a much lower frequency, thereby preventing power consumption. And when the

smart device is disconnected or is not connected to the device, it will store the information on an inbuilt memory, and once connected to the smart phone will provide the information to the smart phone for analysis and calculation. This will ensure that the device is functional and useful even without the smart device.

Sleep too is not calculated only by the use of accelerometers, which is highly faulty and can be greatly wrong in many circumstances. By measuring the heartrate variability of the individual as well as the body position (i.e. lying down), the device can reasonably estimate to a much higher level of accuracy the stage of sleep the individual is in, and also the efficacy of it. The placement behind the ear, with a small form factor and a soft exterior, will ensure the device is comfortable even while sleeping.

The device further provides personalized mannerisms to help an individual improve his activity levels based on their BMI (Body Mass Index) and Body Fat. Both professional athletes and laymen can also use the device for multi-dimensional purposes. The device provides wireless connectivity (such as Bluetooth) such that the information collected by it can be transmitted to the mobile phones or other devices. Through the use of BMI and Body Fat, the innovation may then determine the body type of the user, and hence provide the correct work-out regiment to the user, thereby optimizing the user's exercise routine. This will allow for a much more individual goal setting than other devices, as it would allow people with a high BMI (*e.g.* obese people) a much lower goal, which it would increase regularly based on the number of times that goal has been achieved, and for people with lower BMI it would set a much higher goal, which would increase systematically. The goals may alter from a cardiac oriented exercise to weight training depending on the user's body type.

As mentioned earlier, the innovation will be charged using wireless induction charging, through the means of a very small and low inductance coil. Doing so, reduces the efficiency of the power transfer, and hence communication through the induction coil becomes difficult. Hence an innovative technique of using an IR LED to communicate to the dock, of when the device is charging and when the device is full charged is devised as shown in **Figure 5**. The dock on the other side has a photodiode that will placed at the correct position so as to ensure that the

communication occurs. As the innovation has no screens or open parts, the dock will have the LED indicator to indicate whether the device is charged or not. The dock will have an input port for a USB cable.

The LED on the device **(401)** will indicate the charging level of the battery, and convey the information to the Photodiode on the dock **(402)**. This photodiode will appropriately control the display unit **(403)**, informing the user of the charging status of the innovation.

CLAIMS

1. A compatible miniature device **(100)** for measuring biological condition of a user accurately, the said device includes: a pair of flexible permanent magnets **(107, 110)** to place the device stably mounted on to the ear **(109)**; a heart rate monitor to measure and monitor the heart rate; an accelerometer to calculate the physical activity and pedometer measurements; a battery **(104)** that is charged using a wireless induction charging through the induction coils **(108)**; an electronic vibrator **(106)** to alert the user when the remotely connected device is out of reach and in case of any emergency to the contacts of the user; infrared LEDs **(401)** and photodiodes to measure the reflected photoplethysmogram, oxygenation rate among others from behind the ears; a microcontroller including a processor and inbuilt memory to receive the data and store; a wireless networking module to communicate the data received to a remote device where the data is processed; and touch sensors to control the usage of the device and to control the remotely connected system through touch, tap and gesture control.

2. The device as in Claim 1 wherein it is covered by a plastic shell **(101, 103)** and separated as two lobes by means of which user's ear can be inserted to fix the device.

3. The device as in Claim 1 wherein the photo plethysmogram is measured by transferring IR light behind the LEDs **(401)** through the skin of ear in to the capillaries; and measuring the absorbed and reflected light by oxygenated and deoxygenated blood with the help of IR photodiodes.

4. The device as in Claim 1 wherein it is used to calculate and alert the user about hear rate, heart rate variability, photoplethysmogram, physical activity, breathing rate, BMI, body fat, calorie count, pedometer measurements, body posture and tiredness of the body/ sleep.

5. The devices as in Claim 1 wherein the signal that is measured is 99% accurate and is devoid of any noise and interruptions.

6. The device as in Claim 1 wherein the proper posture of the user is determined by verifying the rotation of the neck and monitoring the position of the ear with that of neck and torso.

7. The device as in Claim 1 wherein gesture control such as taps, double taps, flips etc. is used to control the device itself and also the remotely connected device through wireless mode.

8. The device as in Claim 1 wherein the calculation of sleep and calories is done accurately by integrating a mechanism to calculate the rise of heart rate as well as the physical activity at the same time.

9. The device as in Claim 1 wherein IR LED is used to communicate to the charging dock which has a USB cable and photodiode regarding the status of the charge in the battery of the device.

10. An efficient system for measuring biological condition of a living body accurately comprising an ear mountable device to measure the biological conditions of a living body; and a remotely connected device to which the measured the data is communicated through wireless network for further processing.

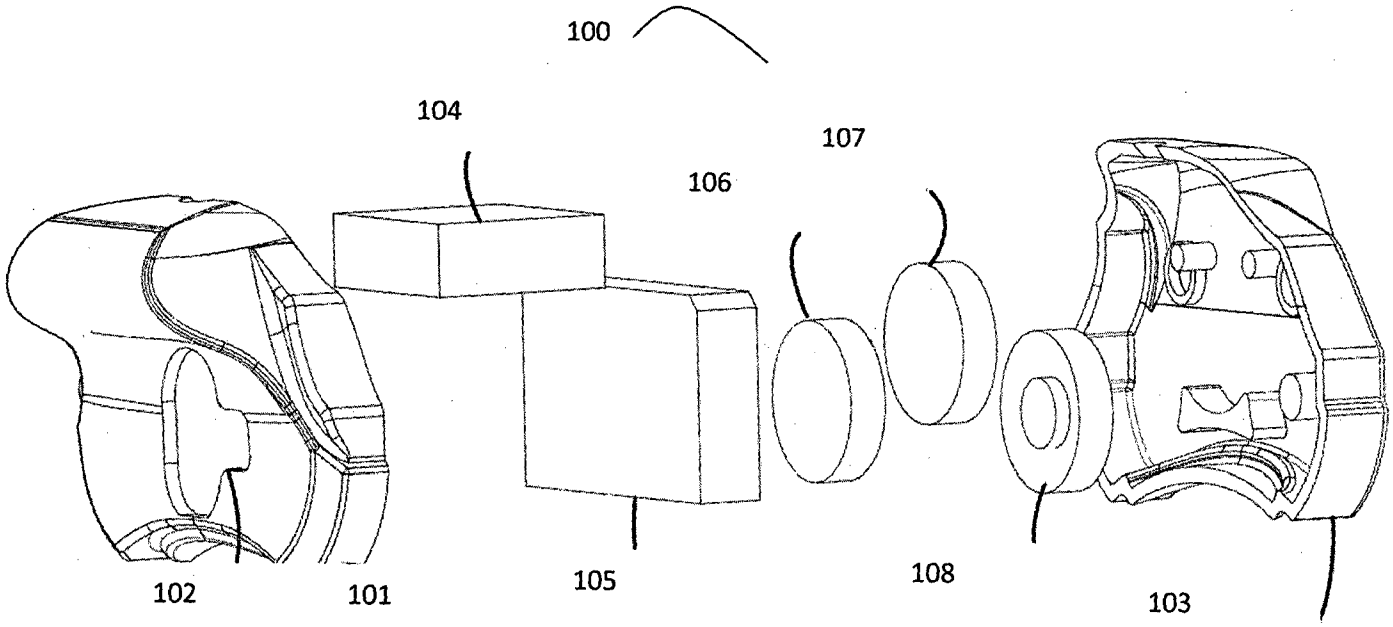


Figure 1

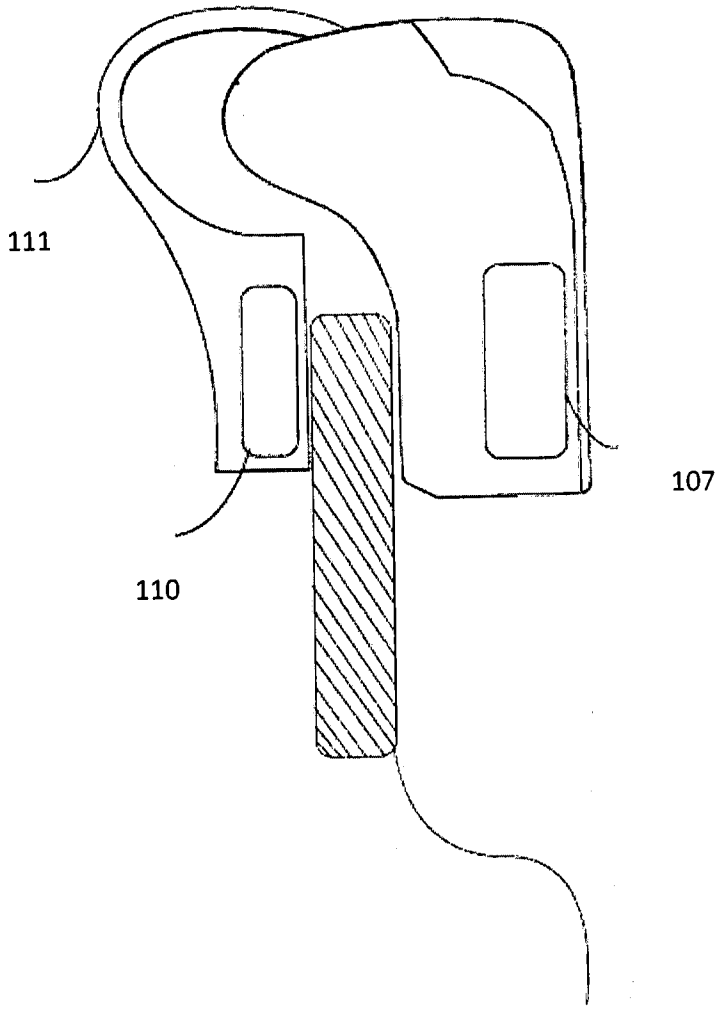


Figure 2

Figure 3A

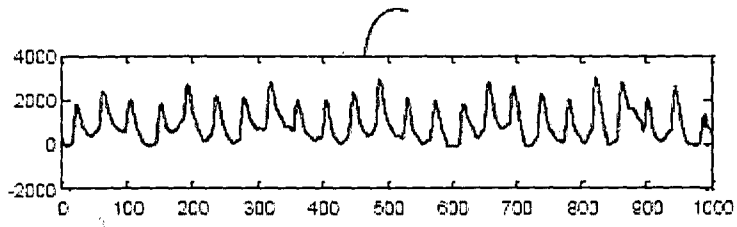


Figure 3B

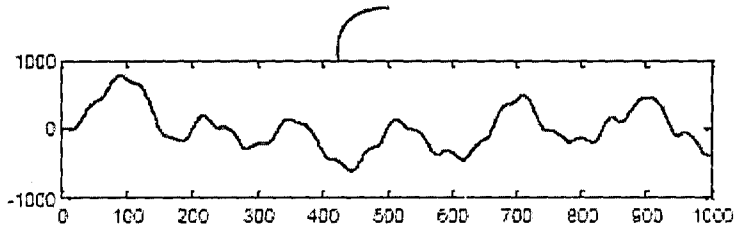
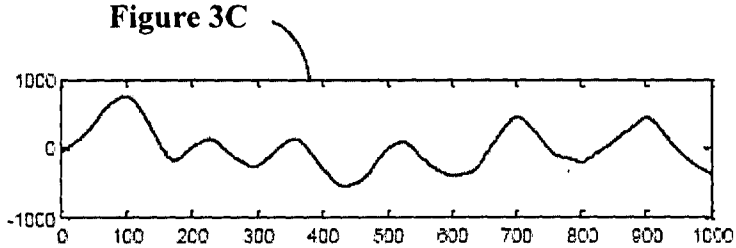


Figure 3C



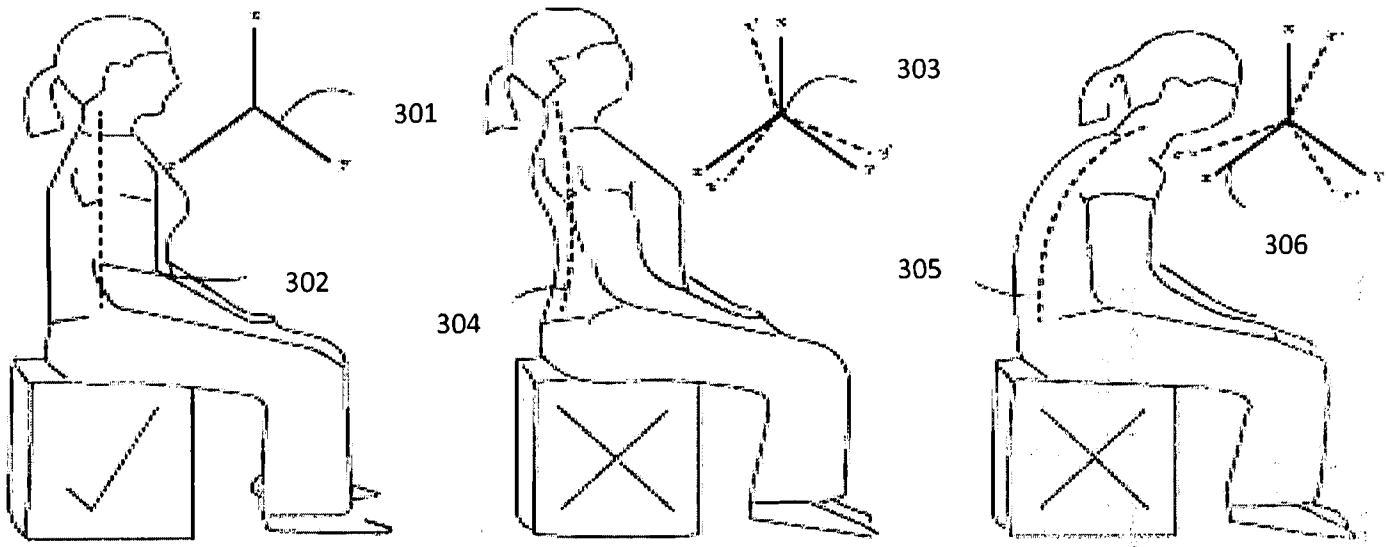


Figure 4

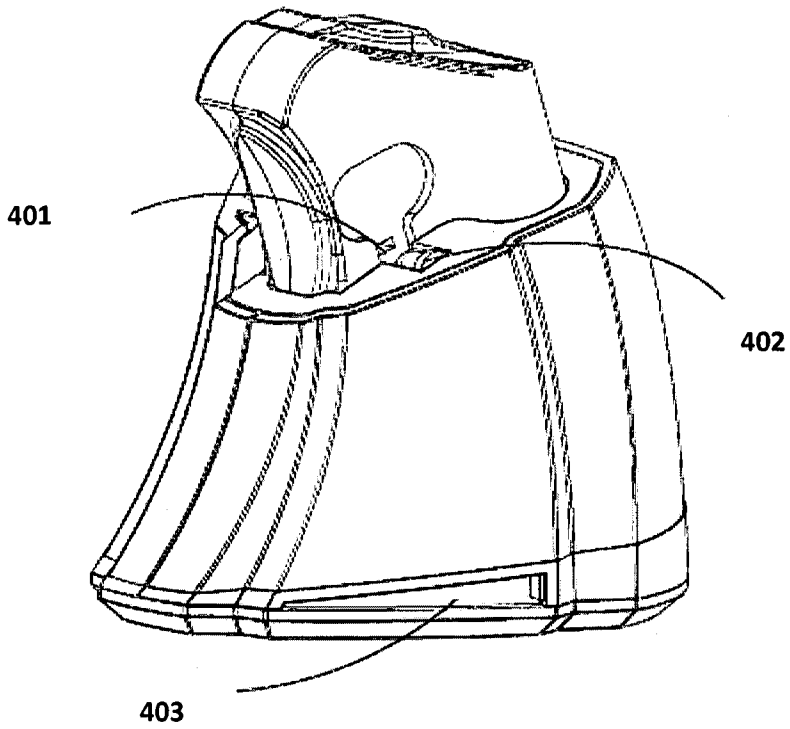


Figure 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2015/000928

A. CLASSIFICATION OF SUBJECT MATTER
A61B5/02,A61B5/0205 Version=2015.01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DATABASES: PATSEER ,IPO INTERNAL.
SEARCH TERMS: VITAL PARAMETER,CONTROLLER,EAR,MINIATURE,HEART RATE.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2094152 A1 (VALENCELL, Inc.) 02 Sep 2009 (02-09-2009) Abstract, Figures 1-20 and Paragraphs 0050-0162.	1-10
X	US 20070100666 A1 (STIVORIC JOHN M et. al.) 03 May 2007 (03-05-2007) Abstract, Tables 1-3, Figures 1-34 and Paragraphs 0090-0231.	1-10
X	WO 2008098346 A1 (HONGYUE LUO) 21 Aug 2008 (21-08-2008) Abstract, claims 1-31,Paragraphs 31-44 and Figures 1-6.	1-10
X	US 20060084878 A1 (TRIAGE WIRELESS, Inc.) 20 Apr 2006 (20-04-2006) Abstract, Claims 1-20, Paragraphs 31-50 and Figures 1-6B.	1-10

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22-09-2015	22-09-2015

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IB2015/000928

Citation	Pub.Date	Family	Pub.Date
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