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The Heat Elite
DESIGN SUMMARY

DESIGN PROBLEM

Core body temperature and heart rate are vital indicators of fitness and health during physical exertion. Exhaustion and cramps caused by overheating are problematic symptoms which may progress to heat stroke when thermoregulatory mechanisms become overwhelmed and fail, possibly leading to organ damage or death. The condition advances quickly, and signs can be subtle, making it hard to diagnose in time to treat, even though it is preventable. Heat stroke is the second leading cause of death among athletes in the United States, and is a significant cause of injury among firefighters and military personnel as well. Under conditions of high temperature and humidity, the body is unable to effectively dissipate heat, which is especially true for physically active people who wear helmets. Overexertion may cause heart rate to increase beyond a safe range, indicating the onset of heat illness. Immediate cessation of activity is necessary to avoid potentially harmful hyperthermia or exhaustion.

DESIGN BRIEF

A need exists for a temperature and heart rate monitor to alert physically active people or their trainers when hyperthermia or exhaustion is imminent. We propose a small, battery-powered, comfortably wearable, durable, and convenient device for use during physical exertion. Information acquired by the device will be sent to a receiver that processes the data and alerts the user to stop activity when temperature and/or heart rate deviates from a safe range. We envision a design that initially incorporates into the helmets worn by the aforementioned groups who are at highest risk of heat stress. Our device will eventually be developed to benefit a wide range of people who are at high risk of exertional heat illness due to their careers or physical activities.

References

http://techtransfer.gsfc.nasa.gov/TOP-SS-Ing-Thermom.html

http://www.medicinenet.com/heat_stroke/article.htm

A. PROBLEM SUMMARY

Our group intends to create a device to monitor the body temperature of athletes, soldiers, and firefighters and provide warnings of heat-related illness. These warnings would serve athletes, trainers, or medics by alerting them in advance of overheating, so that activity can be ceased and measures can be taken to avoid adverse affects.

There are several grades of heat stress or heat illness, which vary in severity. Some examples are heat cramps, heat syncope, heat exhaustion, and heat stroke. These heat stresses or heat illnesses affect athletes in a wide variety of sports. The greatest incidence of hyperthermia is among athletes in outdoor sports, particularly football players and runners. This section will cover the demographics, statistics, and details of heat illness.

Heat Illness

Heat illness is typically caused by overheating of the muscles and organs caused by a combination of a hot environment, dehydration, strenuous exercise, poor fitness, clothing that limits evaporation of sweat, inadequate adaptation to heat, and/or excess body fat. The negative consequences associated with overheating vary in severity; they are listed below in order of increasing danger. [2,3]

Heat Cramps

Heat cramps are painful cramps or spasms in the abdominal muscles and extremities caused by prolonged exercise in hot, humid conditions. Depletion of salt and water due to perspiration leads to cramping, usually resulting after several hours of exertion in the heat. Other symptoms include faintness or dizziness, weakness, and profuse sweating. [2,3]

Heat Syncope

Dizziness or fainting due to loss of water and salt in sweat due to exercise. Heat syncope predisposes athletes to heat stroke. [2,3]

Heat Exhaustion

A more severe form of the dehydration that causes cramps and syncope. Water depletion from prolonged periods of profuse perspiration results in excessive weight loss, reduced sweating, elevated skin and core body temperature, thirst, weakness, headache, and possible loss of consciousness. Heat exhaustion due to salt loss includes nausea, vomiting, muscle cramps, and dizziness. [2,3]

Heat Stroke

An athlete suffering from heat stroke shows all the outward symptoms of heat exhaustion, with the addition of severe disorientation. However, the extended duration of exercise or increased severity of conditions leading to heat exhaustion may cause heat stroke. Heat stroke is an acute medical emergency caused by failure of the body's thermoregulatory mechanisms. If untreated, besides experiencing the symptoms of heat exhaustion, a person with heat stroke may experience seizures, change in mental status (disorientation and confusion), or even unconsciousness or coma. However, while heat stroke may occur with a progressive worsening of the symptoms associated with heat exhaustion, heat stroke may also occur without any prior signs of heat stress in that athlete. [2,3]

Heat stroke is the most dangerous of the heat-related illnesses. As mentioned, it can result in coma or death if not treated immediately. Moreover, unlike heat exhaustion, it can sometimes strike without the obvious physical symptoms such as nausea or cramping, when core body temperature increases after failure of thermoregulatory systems. The telltale signs of heat stroke include body temperature at or above 105 degrees F, hot, dry skin, lack of sweating, elevated pulse, and disorientation.

Hyperthermia and Cardiovascular Function
Heat loss from the skin is dependent on perfusion of the superficial capillaries to the skin relies on a temperature gradient from the core to the skin. The body attempts to increase heat loss from the skin by redistributing cardiac output away from the internal organs and to the skin. At early onset of heat stress, cardiac output increases to account for this demand. However, during prolonged exercise, endogenous heat production may outpace the ability of the skin and sweat to dissipate heat, especially on hot, humid days. Also, increased core temperature causes the CNS to decrease cardiac output to produce fatigue in the athlete as a warning to cease exercise. Stroke volume decreases due to the combined effect of reduction in cardiac filling pressure due to decreased central blood volume during peripheral vasodilation, as well as shorter diastolic filling time that results in lower end-diastolic ventricular blood volume. These effects act to increase heart rate over and above the rate increase demanded by oxygen debt and acid production during exercise. [5,6]

During dynamic exercise in warm environments, heat is dissipated from the skin by increasing the flow of blood to the skin. Hot blood from the core of the body is able to release heat to the surrounding environment when it passes through vessels in the skin. The requisite increase in skin blood flow is in competition with the demands of perfusion of muscle tissue during exercise. Therefore, an integrated cardiovascular response is necessary to maintain circulation in both the skin and muscular circulations and maintain blood pressure homeostasis. [18]

To summarize, exercise causes the core to heat up, the body increases blood flow to the skin to improve heat dissipation, and the heart rate increases to meet this new demand. Therefore, it is possible to make a quantitative measurement of the body's thermoregulatory response by monitoring heart rate during exercise.

A1. DEMOGRAPHICS and STATISTICS

After exploratory research, our group has targeted physical activity (training, exercise, sports, etc). where heat stress is a significant factor. Specific groups of athletes to consider are football players, soccer players, and endurance athletes, such as runners and cyclists. Other groups were heat exhaustion poses a health risk are soldiers and firefighters.

Heat related illness is responsible for thousands of summer emergency room visits. In fact, heat stroke is the third most common cause of exercise-related death in high school athletes in the United States. Statistics show an average of 3 heat-related deaths of football players in the United States per year over the last 10 years. While this statistic may cause some to dismiss the idea of a heat stroke warning device for athletes, we believe that the fact that heat-stroke is an easily preventable cause of death is reason enough. Moreover, although statistics are not readily available to document it, many more than 3 high school athletes per year suffer from consequences of heat stroke that are less severe than death. These include muscular and mental fatigue, nausea, vomiting, debilitating cramps, severe headaches, and loss of consciousness, all of which, while not fatal, are very common forms of heat exhaustion that can be avoided by monitoring temperature and heart rate. [2,3,4]

Another group that is affected by heat illness is military personnel. During 2002, there were 1,816 heat-related injuries of active duty soldiers. Approximately 70% of all heat injury-related medical encounters were in June through September – and the highest rate was in July. Approximately one-sixth of all heat injury-related diagnoses were reported as "heat stroke." However, in general, the proportions of all diagnoses reported as "heat stroke" were inversely related to the overall heat injury rate—for example, approximately half of all heat injuries in December, but fewer than 10% in July and August, were reported as "heat stroke." This is probably due to the fact that less severe instances of heat illness are in fact more common in the summer months, but for heat illness to be cause for hospitalization in non-summer months, it is likely more serious. [33] The total number of injuries due to heat stress, primarily heat exhaustion, was 3,030 in 2005. [32]

Firefighters are another demographic at risk for heat stroke, due to the extreme conditions they encounter in their job. Statistics are difficult to find on injury or death characterized as heat stroke. However, one website shows 40 deaths in 2007 that resulted from "exertion/stress/other" or "sudden cardiac death." [34] Research revealed many individual reports or news stories of firefighters suffering heat illness/stroke. [35] Heat illness is more common during training exercises than in actual fire-fighting. This is because heat stroke results from prolonged exercise without proper hydration, and training is usually much longer than responding to a call.[36]

The case of football players is particularly illustrative of the risk factors that can cause heat illness. Practicing twice a day, or on successive days can predispose athletes to heat illness. The body needs "cool-down" time to recover from heat stress and dehydration after initial periods of exercise. Long, back-to-back training sessions that are common for football players increase the risk of heat illness. The football season in the United States coincides with late summer months when the temperature is at its highest. Football uniforms effectively insulate the athlete from the environment, slowing the rate of cooling from sweat evaporation.

Football is certainly one area of athletics where we think a temperature and heart-rate monitoring device would be useful. Other areas that we think our device would be applicable are endurance sports that take place in the heat. Specifically, we could target our device toward long-distance runners and cyclists. Prolonged physical exertion demanded by these sports can cause body temperature to rise, in some cases, to greater than 42 degrees C.

Based on team research, runners and football players are shown to be at highest risk of heat stress. The device would be less useful to the recreational user since they are least likely to push themselves to the point of heat illness. Based on interviews, we expect high school athletes to be a strong initial target because compliance at this level can be required by coaches or trainers, and in many cases this is a seriously competitive environment where athletes may exert themselves to the point of heat sickness. Also, younger athletes are less knowledgeable of the threat of heat illness and less prepared to handle a dangerous situation. The product will also be targeted towards military personnel, firefighters, and endurance athletes, modifying the design to ensure compatibility with the specific performance needs of each group.

A2. MEASUREMENTS

When core body temperature rises above a safe range (98-99 degrees F), the thermoregulatory mechanisms of the body act to dissipate excess heat and restore core body temperature to a safe level. Vasodilation of superficial capillaries in the skin allow for heat loss by radiation and conduction. Along with vasodilation, the other major heat dissipation mechanism is perspiration, where heat is lost in the evaporation of sweat. However, this causes loss of essential body water and salt. The symptoms of heat exhaustion and heat stroke result when the body is depleted of water and salt by sweating. The body is unable to sweat when salt and water are depleted. The physiological mechanisms involved in hyperthermia-induced fatigue involve several factors, but it mainly relates to changes in the central nervous system, called central fatigue, as well as impaired cardiovascular function causing decreased arterial oxygen delivery to the periphery of the body.

A2.1 Core vs. Shell Temperature

Core temperature in humans refers to the temperature of the abdominal, thoracic, and cranial cavities. It is regulated by the brain to be set around 36.8 degrees C during rest. Shell temperature is the temperature of the skin, subcutaneous tissue, and muscle, and is influenced more by blood flow and environmental factors than by endogenous heat production. Heat dissipation from the body relies on a temperature difference between the core and shell, and between the shell and the environment. During heat stress, skin blood flow increases, thereby increasing shell temperature and heat dissipation. While exercising, metabolic heat production can increase up to 20-fold, but more than 70% of the heat generated has to be dissipated to the environment. [1] Heat loss occurs by conduction, convection, and radiation, but more than 80% of heat is dissipated through evaporation of sweat.

When the mechanism of sweating is inhibited by high humidity or loss of water due to prolonged exercise, the core temperature will continue to increase. Our team needs to design a system for reliably obtaining measurements of core temperature. When temperature increases to around 102-103 degrees F, our device will warn the user to cease activity and cool down.

A2.2 Temperature Measurement

Our group needs to find a method of obtaining a reliable measurement of core temperature to predict when the cooling mechanisms of the body have failed and heat illness is likely. The "gold standard" for core temperature measurement is the temperature within the pulmonary artery. [1] Obviously intra-pulmonary arterial (IPA) temperature is impossible for our group to measure, as it is too invasive. Common non-invasive surrogate measurements for core temperature include the sublingual site (oral), the axilla (under armpit, near the brachial artery), and the tympanic membrane.

<u>Oral</u>- Oral temperature is easy to access, and is a good indicator of core temperature. However, it takes about 5 minutes to get a reliable reading using a mercury glass thermometer, and its accuracy may be influenced by breathing rate, which would normally be increased during exercise. Also, though non-invasive in a clinical setting, a sublingual thermometer in the mouth is impractical and unsafe for sports. See the section that considers a mouth guard sensor below.

Axilla- Also a non-invasive and practical, but its inaccuracy and instability makes it unreliable for clinical or research applications. Axilla temperature is too easily influenced by ambient temperature, sweat, humidity, and density of hair at the axilla, all of which are factors that would vary and cause error in our measurements during exercise.

Tympanic Temperature- Among non-invasive sites for core temperature measurement, temperature at the tympanic membrane probably has the strongest associate to core temperature. [1] The tympanic membrane receives blood from the internal carotid artery, which also supplies blood to the hypothalamus, which is the region of the brain that regulates temperature. Therefore, the blood perfusing the region of the tympanum is at the same temperature of the core.

Sixty percent of the heat dissipated by the body is lost via electromagnetic waves in the form of infrared radiation. The tympanic membrane emits infrared waves in proportion to its temperature.[7] The hypothalamus and tympanic membrane both receive blood from the internal carotid artery, with blood whose temperature is close to core temperature.

Weaknesses of this method are concerns that infrared temperature scanners are not adequate for healthcare standards, and they cannot measure temperature continuously. Ear wax can cause a false low reading. Also, danger of tympanum perforation during sports poses a significant barrier to implementing this strategy for a device used in athletic activities. [7] Non-contact infrared emission detection (IRED) thermometers would avoid the problem of contacting the ear drum, and do not require temperature equilibration with the tissue but instead gather infrared emission in proportion to the temperature. Clinical studies have demonstrated the validity of IRED thermometry by showing correlation between IRED temperature at the ear drum and temperatures taken with thermistors or mercury thermometers and the rectral, sublingual, axillary and pulmonary arterial sites.

The method for measuring temperature at the eardrum involves inserting a thermopile sensor into the external acoustic meatus and measuring the infrared radiation emanating from the drum. The ear canal is a readily accessible, curvilinear tube. Design of a thermometer probe must consider the geometry of the canal, and the probe might be built with a curve or turn in order to face the ear drum. Using tympanic thermometers in a clinical setting, the pinna of the ear is pulled back and the non-contact lens on the probe of the thermometer is pointed towards the eye. The positioning of an in-ear thermometer in our design is important. The thermopile sensor must be directed towards the eardrum so that IR radiation can be detected. The sensor must have a small diameter so that it can fit far enough into the ear to collect radiation from the eardrum. Please refer to the "Existing Products" section for information on an existing in-ear thermometer similar to the design we envision. Like this product, our ear-piece must be able to conform to the ear canal and fit snuggly so that it can hold the thermometer securely in place to gather temperature readings.

Whatever the method of measuring temperature, important criteria are that it is accurate, safe, easy to perform in a short while, and tolerable for the subject.

A2.3 Mouthguard Thermometer

One proposed idea for measuring temperature is a thermometer embedded in a mouth guard. While this idea has already been pursued by some (http://www.freepatentsonline.com/6491037.html), there is little scientific evidence supporting the validity of temperature measurement in the mouth during exercise. Most mouth guards used in contact sports such as football are designed to cover only the top row of teeth, and research was unable to reveal instances of reliable temperature measurement at the top of the mouth. Placing mouth guard at the bottom row of teeth is one option, to measure the temperature under the tongue. However, placing a thermometer under the tongue (the normal spot for thermometer placement in the mouth) is unsafe and impractical during sports. Such a device would inhibit breathing, swallowing, and communication, all of which are clearly necessary in athletic competition. Also, another practical concern is whether breathing through the mouth or drinking water would affect the accuracy of temperature measurement.

Our device involves the use of wireless telemetry of temperature data to a monitoring station, and fitting a transmitter into a mouth guard would be impractical because of size considerations and the functional considerations of a mouth guard. These functional considerations are the need for the mouth guard to fulfill its primary role of dampening the pressure between the top and bottom rows of teeth during a blow to the head and thereby absorbing some of the force of the blow. The size of a mouth guard also limits what can be embedded inside it. Mouth guards are only a few millimeters thick, making it difficult to place any electronic thermometer or wireless transmitter inside the mouth guard. For this reason, other mouth guard thermometer designs indicate temperature by changing color as temperature changes. Monitoring the color change of mouth guards of a whole team of athletes is impractical for a trainer, since it would require constantly interrupting practice or competition to observe the color of the mouth guard of a large number of players. These considerations lead us to reject a mouth guard thermometer design, especially when other viable options such as in-ear thermometers are available for measuring core temperature. An additional advantage of the in-ear thermometer is that it can be connected to a wire, so that it is not necessary to include a wireless transmitter in the in-ear component.

A2.4 Hyperthermia and Cardiovascular Function

Due to the heart rate increase that occurs at the onset of heat stress (see description above), it is necessary for our group to measure the heart rate of athletes as another indicator of heat illness. Since our device will most likely be situated on the upper body, head, or neck, our options are limited to this area. Pulse can be taken at the temples, neck, or ear.

A3. Pulse Oximetry and Photoplethysmography

A3.1 Light Absorbance in Pulse Oximetry

Pulse oximetry is a common method of detecting the pulse. Red and near infrared light is transmitted through a relatively thin tissue bed , such as the ear or finger, and the ratio of red (760nm> λ >610 nm) to infrared (λ>760nm) light transmitted or reflected is a measure of the relative amounts of hemoglobin and oxyhemoglobin in the blood. The light absorbance of oxygenated hemoglobin (HbO_2) and deoxygenated/reduced hemoglobin (Hb) is different at these wavelengths. At the isobestic wavelength, close to 805nm for infrared wavelengths, the extinction coefficients for Hb and HbO_2 are identical. For measurements performed at the isobestic wavelength, the signal should be largely unaffected by changes in blood oxygen saturation. For this reason, IR wavelengths are ideal for PPG heart rate detection. The pulsatile nature of arterial blood results in a waveform in the transmitted signal that allows the absorbance effects of arterial blood to be identified from those of nonpulsatile venous blood and other tissues. With adequate light intensity, scattering in blood and tissue will illuminate enough arterial blood to allow for reliable detection of a pulsatile signal. Scattering allows for a transmittance path around the bone in the finger, as well as the path of backscattered light in reflectance mode. [10, 25, 31]

Most pulse oximeters on the market feature a photoplethysmograph, which is derived from the same waveforms used to calculate oxygen saturation. The arteries contain more blood during systole than during diastole, and therefore their diameter increases and decreases in one heart beat. The PPG waveform consists of a "pulsatile" or AC component that oscillates due to this cardiac synchronous change in blood volume with each heartbeat. [10, 25, 31] The basic form of PPG technology is simpler than pulse oximetry, requiring only a few components and less complicated control of the driving circuitry. Only one light source is needed (as compared to two for pulse oximetry), as well as a photodetector to measure the back-scattered or transmitted light. PPG uses a red or infrared light, and the photodetector measures small changes in the absorbance properties of the tissue associated with changes in perfusion in the tissue volume. In practice, the AC component of the PPG signal is superimposed over a slowly oscillating DC signal, which is the "background noise" that results from respiratory activity, sympathetic nervous activity such as vasomotor or vasodilatory waves, and thermoregulation. [10]

A3.2 PPG sensor location

Pulse oximeters typically gather data from a finger tip, as this is a thin area with blood vessels, capable of transmitting light from a source on one side of the finger to a detector on the other side of the finger. However, the light need not be transmitted only through thin body parts; reflectance sensors may also be used to gather data at areas where light will clearly not be transmitted to the other side, such as the forehead or temple.[9] Although reflectance mode offers more versatility in terms of probe site, the reflected PPG have generally lower amplitudes, as compared to transmittance mode.[26] This disadvantage can be overcome by compensating with increased photodetector size, novel LED arrangement, and signal processing, as will be discussed later. Pulse oximeters normally consist of a computer or processor to process the acquired signal, receiver and transmitter modules connected to a data acquisition platform, and a voltage source. [8]

Some of our design ideas involve a temperature sensor apparatus on the head, so we would like to include the heart rate sensor on the head as well. On the head, transmission PPG can be used at the ear to gather PPG data, or reflectance PPG sensors can be used at the forehead above the eyebrow or at the temple. The nature of transmission mode PPG limits the number of available sites for this type of PPG, since a thin section of tissue is required. For the purposes of this design, we are not too concerned with measuring oxygen saturation with pulse oximetry, but rather just pulse. Therefore, we have more latitude in selecting possible sites for measuring pulse with a PPG sensor. Several candidate sites for a device used in athletic activities are the wrist, finger, hand, ear, shoulder, or temple. See Figure 1, taken from Nilsson et al., for several possible designs and locations of PPG sensors. Note that the sensors have infrared LEDs (λ=806nm or λ=880nm) adjacent to or surrounded by photodetectors (abbreviated PD).

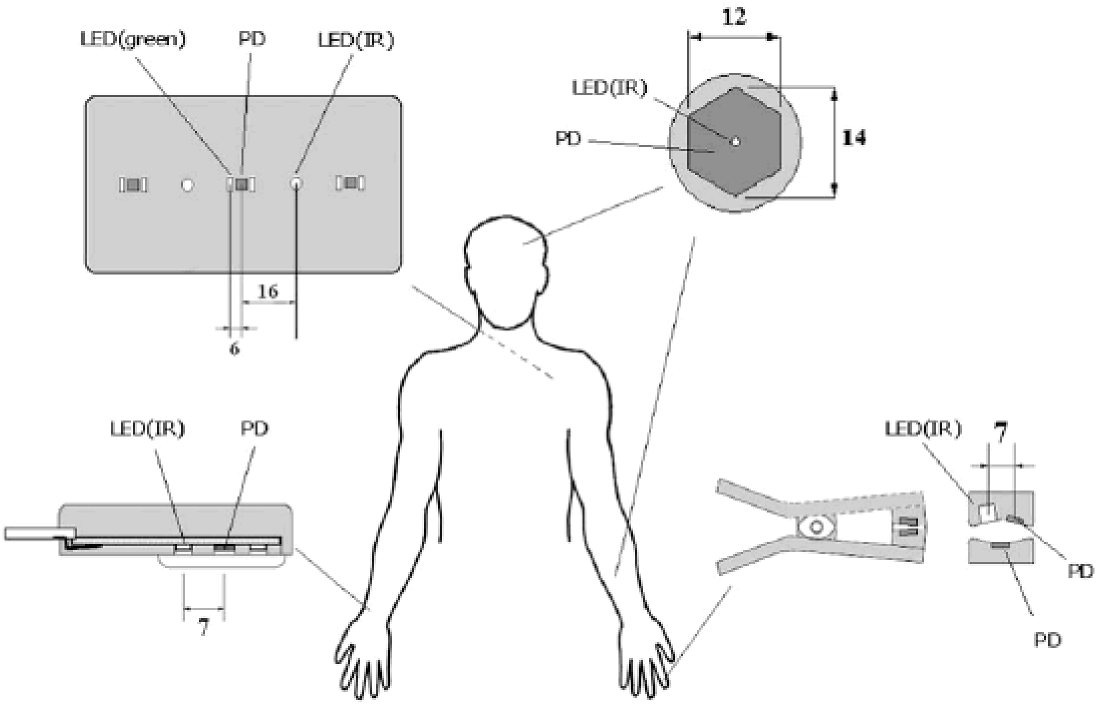

Figure 1. Four photoplethysmographic (PPG) sensors, including LEDs emitting infrared (IR) or green light and photodetectors (PD). Image is from Nilsson et al.

A3.3 The Photoplethysmography Waveform

The pulsatile component of the PPG waveform is often referred to as the "AC" component, and it usually has a frequency around 1 Hertz, depending on heart rate. [10] As in pulse oximetry, this AC component is superimposed onto a large DC component, which is generated by the average blood volume in the tissue over the course of the measurement time period. Due to the relative weakness of the AC signal compared to the DC component, electronic filtering and amplification are necessary to extract the pulsatile signal for further analysis. Please see Figure 2 below for characteristic PPG waveforms from the various locations studied in the paper by Nilsson et al. Note that reflected mode PPG is used at the finger, forearm, forehead, wrist, and shoulder. The traces on the left show the two frequencies contained in the PPG signal: the lower frequency slow wave for the respiration-synchronous variation, and the higher frequency pulse-synchronous component. To extract the pulse-synchronous component from the composite signal and equalize its amplitudes, the slow wave content can be extracted and subtracted to yield only the higher frequency waveform. [10, 24, 25]

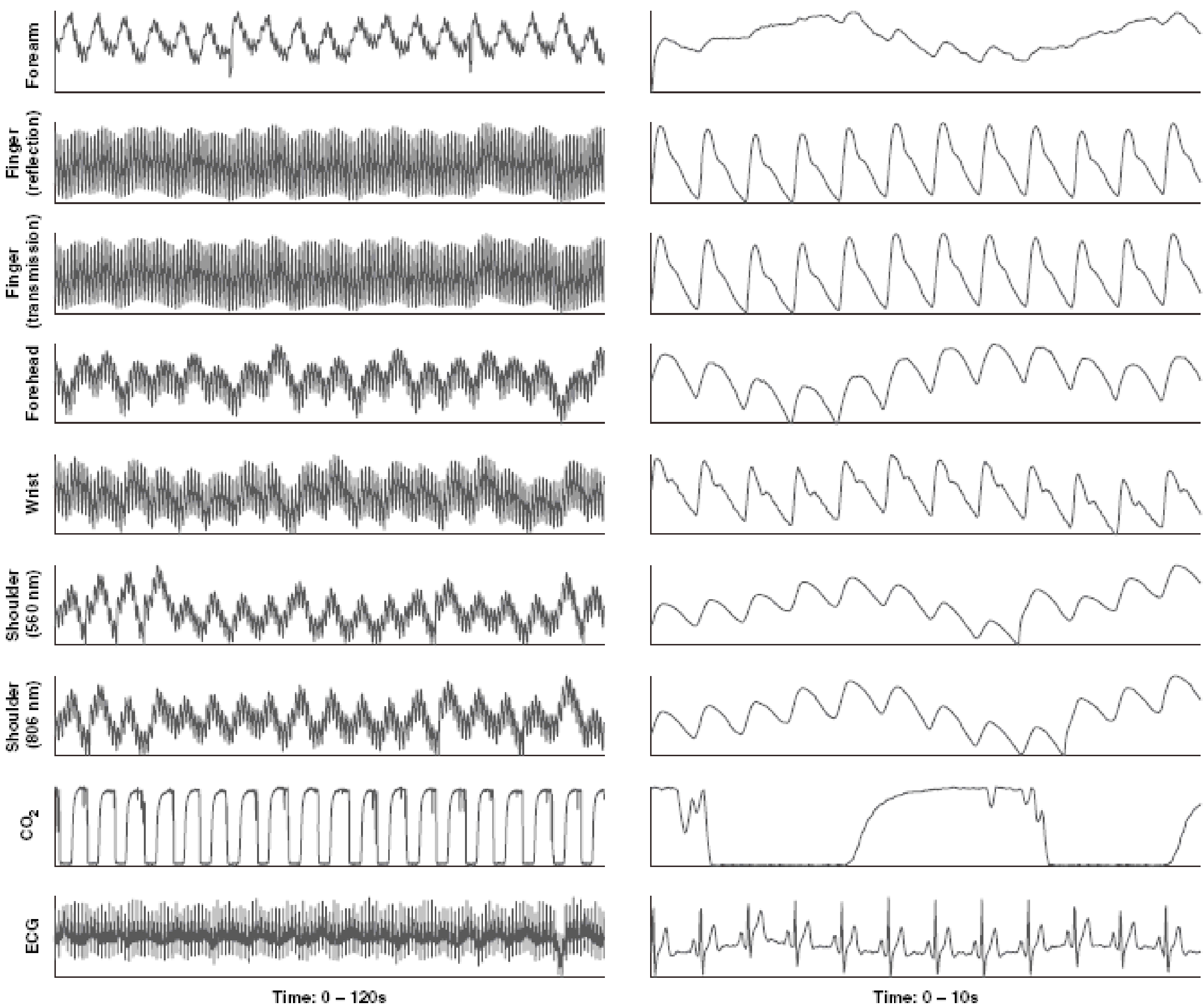

Figure 2. Typical examples of recorded PPG signals.

A3.4 Photoplethysmography and Exercise

Pulse oximeters may fail to provide valid saturation data in situations that produce low signal-to-noise ratio, such as exercise. A number of researchers have concerned themselves with this problem: Gaskin et al. , Martin et al., Comtois et al., Barker et al., Powers et al. Johnston et al. The main cause of decreased accuracy during exercise is motion artifact, which results from the relative movement of the sensors and the skin at the measurement site. Football players, soldiers, and firefighters often engage in activities that cause their head and helmet to undergo may forms of abrupt motion, shock, and vibration. Another suggested cause of poor results during exercise is the high level of catecholamines in the circulation, which restrict cutaneous blood flow.[15] Nonetheless, studies generally conclude that pulse oximetry, and photoplethysmography by extension, are valid under the conditions of exercise.[14,15, 16, 20, 29] Especially relevant to this project, Johnston et al. showed that forehead measurements remained stable through a number activities, suggesting that the forehead region is a good choice for sensor placement for wireless physiological monitoring.[16]

Signal Processing

Several measures can be taken to improve the PPG signal during exercise. Comtois and Mendelson have developed adaptive noise-canceling algorithms for minimizing motion artifact in forehead reflectance pulse oximeters, quantifying errors by utilizing accelerometers. Their study revealed that processing motion-corrupted PPG signals by least mean squares and recursive least squares algorithms effectively reduces saturation and heart rate errors during jogging, with the degree of improvement depending on filter order.[14] Johnston and Mendelson investigated three signal processing algorithms as potential methods for measuring heart rate based on infrared PPG. Without going into detail here about each method, they are: 1.) varying-width adaptive window to locate individual pulse peaks in the PPG, 2.) two-point derivative of the PPG to identify pulse peaks by zero-crossing, and 3.) power spectral density analysis and discrete Fourier transform of the PPG data in one-minute increments.

Signal quality may be decreased in our application for two reasons. Firstly, motion artifact, the error introduced by relative motion between the probe and skin surface, is more common in exercise than in static monitoring. To compensate for this error, the probe must be securely affixed to the monitoring location by a headband or some other means. Some signal processing algorithms have also been developed to deal with this problem.[10, 14, 16] Another source of weak signal is the fact that we plan to use reflectance mode PPG rather than transmittance mode. Transmittance mode works well because it relies on light passing through the tissue, which is more likely to occur than the backscattering that is necessary for reflectance pulse oximetry or PPG. This weakness can be compensated for by increasing the active area of the photodetector used, or by strategically positioning an array of photodetectors around the light source so the maximum amount of light is detected.

Other Pulse Detection Methods

Pulse can also be determined from other methods, such as an electrocardiogram (ECG), which uses electrodes spaced over the body to detect the electrical activity of the heart. Heart rate monitors used by long-distance runners are employ electrodes mounted via chest strap in order to gather electrical data from the chest. The human heart generates an electrical signal that can be measured on the skin. The heart rate monitor transmitter developed by Polar (see "Existing Products") contains two electrodes to detect the electrical signal on the skin. The electrodes are mounted on a transmitter attached to an elastic belt. The Polar transmitter detects the voltage differential on the skin during every heart beat and sends the signal continuously and wirelessly using an electromagnetic field to the wrist receiver. [11] While this is possible to implement for runners, it would not be useful for football players because of the nature of the sport, where tackles and falls would likely damage the system or tear it off. Also, the market for this type of products for runners is fairly saturated, and we don't plan on improving on the ECG technology, but rather combining heart rate measurement with temperature measurement, a task we feel we can complete without ECG.

A4. Design Components

A4.1 Light Emitting Diodes*

Specifications and Packaging

An LED is an optoelectronic semiconductor which produces light by electroluminescence. LEDs are a good choice for our design because of the high efficiency and specific wavelength of emission, compared to other methods of light emission. Light is created in the p-n transistor junction of the LED when an excited electron that has crossed the energy gap into the conduction band decays to the lower energy level of the valence band. This decay is accompanied by the release of energy as light. The wavelength of light emitted depends on the energy gap of the diode, which is a property of the materials and manufacturing. Most LEDs are made from gallium arsenide phosphide (GaAsP), gallium phosphide (GaP), and gallium aluminim arsenide (GaAlAs). GaAsP and GaP diodes emit light in the visible spectrum, and GaAs diodes emit IR radiation.

Most LED packaging is made of resin to provide mechanical strength and the ability to withstand vibration and shock, making them ideal for use in a "rough and tumble" design that will be used in harsh conditions. The LEDs themselves are flat squares with sides approximately 0.25mm in length. Some pulse oximeter probes have packaging containing multiple LEDs to increase light output. The important message is that there is no wrong choice of LED packaging as long as the size is small enough for the application at hand, and the intensity of light is not compromised. See figure 2 for an image of a LED.

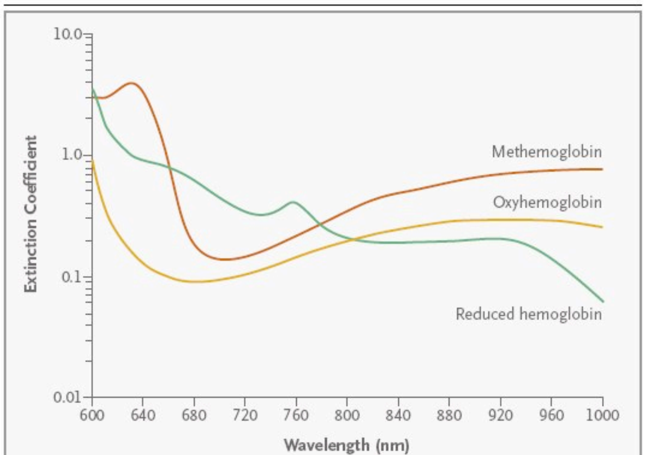

Figure 1. Extinction Curves for Various Hemoglobin Species.
Oxyhemoglobin and reduced hemoglobin have different absorptions at 660 and 940 nm, whereas methemoglobin has similar absorption at the two wavelengths. The extinction coefficient is shown on a logarithmic scale.

Figure 3. See caption above.

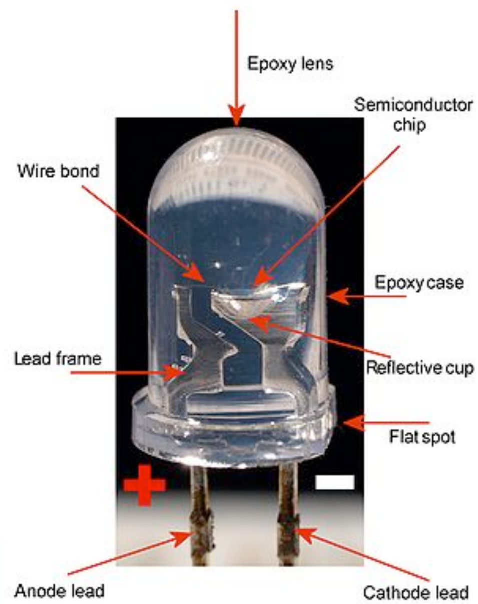

Figure 4. Common configuration of a LED

* Much of the information for the discussion on LEDs is taken from Webster J.G, Design of Pulse Oximeters. (see reference 31)

Voltage and Current

The forward voltage is the potential drop across the p-n junction of the diode from anode to cathode. The forward voltage for LEDs ranges from 0.9V to 2.5V. LEDs with a smaller energy gap have smaller forward voltages, and emit a lower energy, longer wavelength light. Thus, IR LEDs have smaller forward voltages than red LEDs. The forward current is what causes the LED to emit light. Radiated power, to a first approximation, varies linearly with forward voltage. Forward current has a large range; 2 to 50mA.

Reverse voltage is also known as the breakdown voltage. As with all diodes, under reverse bias very little current flows across the p-n junction until the breakdown voltage is reached. The current that flows after breakdown voltage will damage the LED and so this situation should be avoided. This is more of a problem for pulse oximeter probes, where multiple LEDs are wired in parallel, and the switching between them required for the photodetector to sample each wavelength individually causes polarity to reverse across the "OFF" LED. For PPG, since only one LED is used, switching is unnecessary and reverse voltage will likely not be an issue.

Power Dissipation and Operating Temperature

Our device will not be used in a stationary environment where power is available from an outlet. Therefore minimizing power consumption of our electronic components is an important design feature. LEDs can be responsible for much of the power dissipated in a pulse oximeter or PPG sensor. [27] Power is a function of three parameters: ambient temperature, rate maximum junction temperature, and the increase in junction temperature above ambient per unit of power dissipated for the given LED's packaging and mounting configuration. LEDs are usually 2% to 10% efficient, meaning that most of the power becomes heat. The optical power absorbed by tissue also becomes heat. Power ratings for LEDs range from 20 to 300mW. IR LEDs, with lower forward voltages, require greater forward current to dissipate the same amount of optical power as red LEDs, an important consideration of the design of the LED driver circuit.

As mentioned, most of the energy dissipated by LEDs is in the form of heat. In order to prevent burns on the user's skin, the FDA requires that the contact region of the LED and the skin not exceed 41 °C. Most LEDs on the market have a maximum operating current around 50mA, which is sufficiently large to provide adequate light for the photodetector, and sufficiently small to prevent dangerous heating.

Cost

Disposable PPG/pulse oximeter sensors have some advantages over reusable probes in terms of convenience and sterility. However, cost may be a prohibitive factor in a disposable design. Luckily, both red and IR LEDs can be purchased in bulk for just a few cents, from suppliers such as Digi-Key, Mouser, or Jameco.

Wavelength and Bandwidth

As mentioned, in pulse oximetry, red and IR wavelengths are used due to the different extinction coefficients of oxyhemoglobin (HbO_2) and reduced (deoxy-) hemoglobin (Hb) at these wavelengths. See Figure 3 above. At red wavelengths, there is a large difference in extinction coefficients, and at IR wavelengths the extinction coefficients are relatively similar.

LEDs have a characteristic bandwidth associated with them, which describes the range of possible wavelengths emitted. This is due to imperfections that occur in the manufacturing process. Usually this bandwidth is given as the center, or "peak wavelength," plus or minus some bandwidth range, into which the emitted wavelengths may fall, although with less intensity than the peak wavelength. Typical LEDs have a spectral bandwidth in the range of 60nm to less than 20nm. The extinction coefficient curve vs. wavelength shows a relatively steep slope for HbO_2 and Hb in the red wavelength region. In the IR region, however, the curves are relatively flat. Because of the steep slow in the red region, it is important that the red LEDs used in pulse oximeter probes have a peak wavelength exactly at the chosen wavelength in order to minimize error in the saturation readings. The extinction coefficients will change a lot as wavelength changes in this region, and so the calculations that assume a constant extinction coefficient will be in error. Error in the peak wavelength of the IR LED is less important for accuracy due to the relative flatness of the curve in this range. For this reason, IR LEDs are a better choice for PPG heart rate monitoring, since only one type of LED is needed. [31]

A4.2 Photodetectors[*]

The photodetector is the main input device of the pulse oximeter or PPG system. They sense the intensity of light emitted by the LED after the light passes through or is reflected by the tissue. Various photodetectors are available, such as photocells, photodiodes, phototransistors, and integrated circuit sensors. Most current pulse oximeters use silicon photodiodes.

Photodiode Characteristics

A photodiode produces an output current or voltage that is proportional to the intensity of the incident light. The p-n junction photodiode absorbs photons, creating electron hole pairs, which are filled by electrons from the p-side, causing a current. Photodiodes operate in one of two modes. Photovoltaic mode generates a light induced voltage by an open-circuit photodiode. This voltage is not a linear function of incident light. The photoconductive mode generates a light induced current, and the photodiode voltage is zero or constant with varying light intensity. Current is linearly proportional to the level of incident light, making it a good mode for detecting light without the need for complex calculations by microcontrollers.

Photodiodes have a spectral response that are relatively insensitive to temperature variations, have response times on the order of 20 microseconds, radiant sensitive areas of 1 to 7 mm^2, and price around $1.

Junction Capacitance

Junction capacitance is an important parameter of photodiodes and is proportional to junction area. The response speed of the photodiode to changes in light intensity depends on the RC time constant of the junction capacitance and load resistance of the circuit.

[*] Much of the information about photodetectors taken from Webster J.G, Design of Pulse Oximeters. (see reference 31)

Sensitivity

The output current of the photodiode is linear, so the sensitivity is normally expressed as the output current level for a known incident light level and a given temperature. In some cases, the sensitivity is determined with an LED optical source and its associated peak wavelength and switching frequency (which is not considered in single LED PPG). Photodiodes have a specific spectral response which should be considered when selecting one. Manufacturers usually indicate this response by specifying the wavelength of peak sensitivity.

Photodiode Packaging

In the can package, the photodiode chip is mounted on a metallic stem and is sealed with a cap that has a window to allow incident light to reach the semiconductor surface. Ceramic stem packaging has the photodiode chip mounted on a ceramic stem, and is coated with resin. In resin mold packaging, the chip is mounted on a lead frame and molded with resin. Some of these devices use molding that is transparent only to certain wavelengths of light.

Optical Filtering and Interference

It is important to minimize the effects from light other than the optical signals of interest. Unwanted incident light can be minimized by placing a light filter over the photodiode, allowing light of the desired wavelength to pass through, and keeping out other wavelengths. Companies like Kodak manufacture external filtering that can be used to eliminate the flickering effect of fluorescent light. Many photodiodes are built with clear plastic filters to absorb UV light.

Placement of the LED and photodiode in a thoughtful manner is necessary to prevent interference of light that hasn't passed through the tissue. Light impervious barriers should be placed between the LEDs and photodiode in reflectance sensors. Decreasing the angle of incidence of the photodiode will also decrease interference. Another method is is coating the housing around the photodiode with a material that does not scatter or reflect light.

Optical interference can come from two sources. The first is excessive ambient light from fluorescent lights or direct sunlight. This type of interference will usually saturate the photodiode so that no pulse can be distinguished. Therefore, this should be considered in the probe design, although placement inside a helmet will likely decrease the amount of ambient light. The second type of interference is called optical cross-talk, which occurs when multiple probes or LED/photodiode combinations are used in close proximity. Light from one LED is sensed by the photodiode of another probe.

A4.3 Amplifiers

Photodiodes in photoconductive mode generate an output current in response to incident light. An amplifier must be used to translate that current into a voltage for use by the pulse oximeter or PPG machine. The common type used is a transimpedance amplifier, or current-to-voltage converter. This configuration involves a resistor, op amp, and possibly a capacitor. See figure 5 below for a circuit diagram of this amplifier.

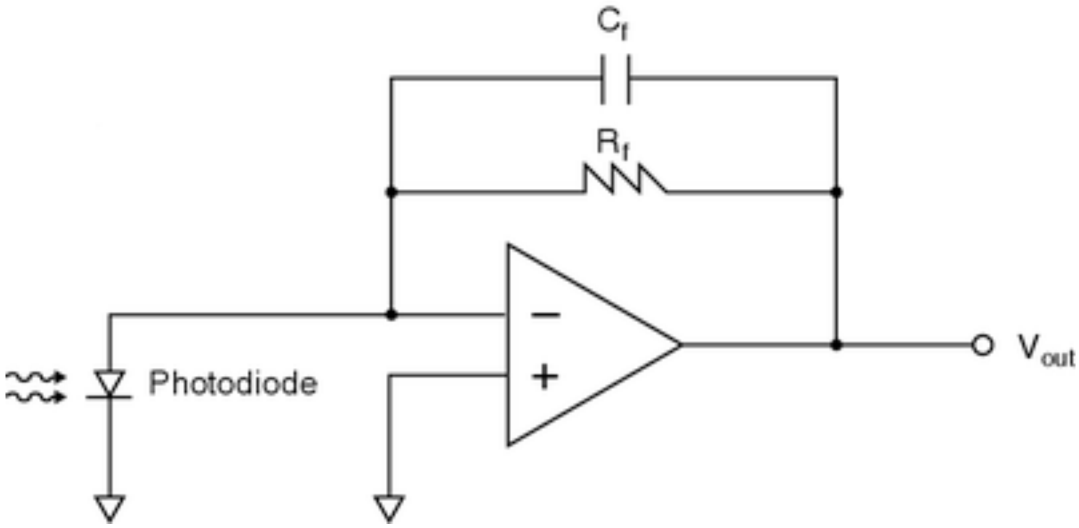

Figure 5. Typical transimpedance amplifier used with a photodiode

The FET op amp maintains zero voltage across the photodiode. Current flows through the feedback resistor and creates a voltage at the output (V_{out}) that is proportional to the light intensity. The transimpedance gain is equal to the value of the feedback resistor.

Photodiode junction capacitance should be kept as low as possible because it can affect noise and bandwidth of the circuit. The feedback resistor should be as large as possible to minimize noise. The feedback capacitor minimizes gain peaking and improves stability of the amplifier.

Other possible circuits are differential transimpedance amplifiers and zeroing circuits to removed coupled noise and noise from ambient light. [31]

A4.4 Probes

Transmittance Probes

Light from an LED is transmitted through tissue in an extremity. Pulse oximeters employ two LEDs with emission peak wavelengths 660nm and 940nm, which are powered alternated so that light of only one particular wavelength will pass through the tissue at a given time. The intensity of the light emerging from the tissue is attenuated by the amount of blood present, and varies with pulse. The photodiode is placed in line with the LEDs so that the maximum amount of the transmitted light is detected. Increasing the distance between the LEDs and the detector decreases the amount of light detected. Normally these probes are placed on the finger, toe, ear, or nose. [31]

Reflectance Probes

These probes are used to measure oxygen saturation or pulse where transmittances probes cannot be used. Oxygen saturation is measured by detecting reflected light. The intensity of backscattered light from the skin depends on the optical absorption spectrum of the blood and the structure and pigmentation of the skin. The LEDs and photodiode are placed on the same side of the skin surface. It is usually placed on the forehead or temple, but is not restricted to only those places.

A trade-off exists between signal quality and power consumption. Using large driving currents for the LEDs improves light penetration of the tissue, illuminating a larger portion of the vasculature and increasing the amount of light available for the photodiode to detect. However, large current for the LED can dissipate too much power for battery powered sensors to have a long battery life. Placing the photodiode close to the LEDs can improve signal quality, but placing them too close together can cause the photodiode to saturate as a result of a large DC component from multiple scattering events, covering the pulsatile information in the signal.

Using multiple photodiodes placed symmetrically with respect to the LED allows for a larger fraction of the backscattered to be detected. Therefore, larger PPGs will be obtained. This has been demonstrated by several researchers. [12,13, 22, 26, 27, 31]

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B. EXISTING PRODUCTS THAT MEET THE SAME NEED

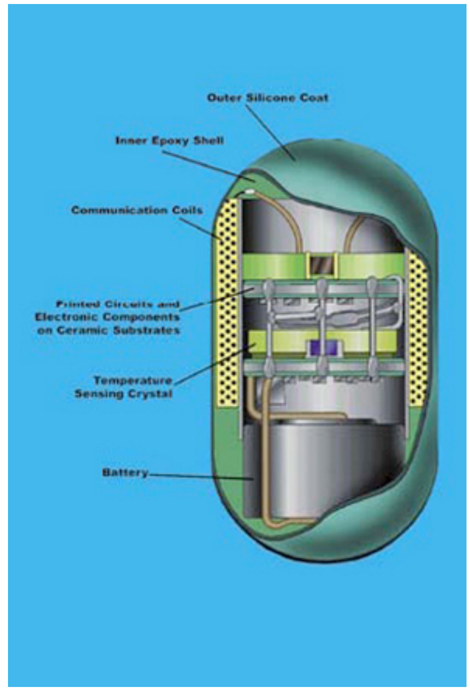
Summary

No products we found on our market measure both core body temperature and heart rate. The only device that currently targets our specific market is HQ Inc's Core Body Temperature Monitoring System (see below). Many other devices that are available monitor either heart rate or temperature, but not both. Most of the heart rate monitors target athletes *in training* and claim an "EKG-accurate" method for obtaining measurements, which means the method used is equivalent in its level of accuracy as compared to that of an EKG. Some are strapless designs, but do not output continuous measurements. Others require chest straps that send the signal to a wrist-worn device. For our design, rather than measuring the signal received between electrodes, we are looking into using a pulse-oximeter for obtaining heart rate alone, since we are not worried about obtaining %SO2. We are focusing on implementing a *forehead* pulse-ox design, which would allow our product to be a more comfortably worn than the EKG or "EKG-accurate" methods while maintaining accuracy. Additionally, this design will be easily compatible with helmets, a common feature among our target-market groups.

As for monitoring temperature, there are different thermometers available for measuring core temperature but most are meant for taking static measurements and not for users who are concurrently engaging in physical activity. The ingestible pill thermometer can be used during physical activity, but does not measure heart rate. We did not come across a product that encompasses both, a thermometer and a heart rate monitor, to track a user's vital information continuously and comfortably during physical activity

Jeff Chiang•Hayley Dirscherl•Philip Kemp•Sara McArdle•Leah Petersen

HQ, Inc.'s Core Body Temperature Monitoring System



SUMMARY

HQ, Inc.'s Core Body Temperature Monitoring System — consisting of the Ingestible Core Body Thermometer Pill and Data Recorder — reveals core body temperature for the prevention and treatment of heat-related illnesses. At three-fourths of an inch, the thermometer Pill wirelessly transmits core body temperature as it travels through the human digestive tract. A sensor within the pill sends a signal that passes harmlessly through the body to the CorTemp Data Recorder outside of the body. Athletic trainers can retrieve athletes' core temperatures right from the sidelines, and also away from the playing field, since it can be transmitted wirelessly to a PDA or a PC in real time. The ingestible "thermometer pill" has a silicone-coated exterior, with a microbattery, a quartz crystal temperature sensor, a space-aged telemetry system, and microminiaturized circuitry on the interior.

COMMENTS

While this ingestible pill seems to offer an accurate measurement of core-body temperature, and has a proven track record of development by NASA, testing such a product would be difficult with our resources. The separate hand-held data processor/monitor is beneficial for a supervisor to monitor athletes' conditions on the sidelines of an event and could be applied in other field applications, such as military and fire fighting use. However, the pill does not measure heart rate, an important indicator for detecting the onset of heat illness.

BioShirt

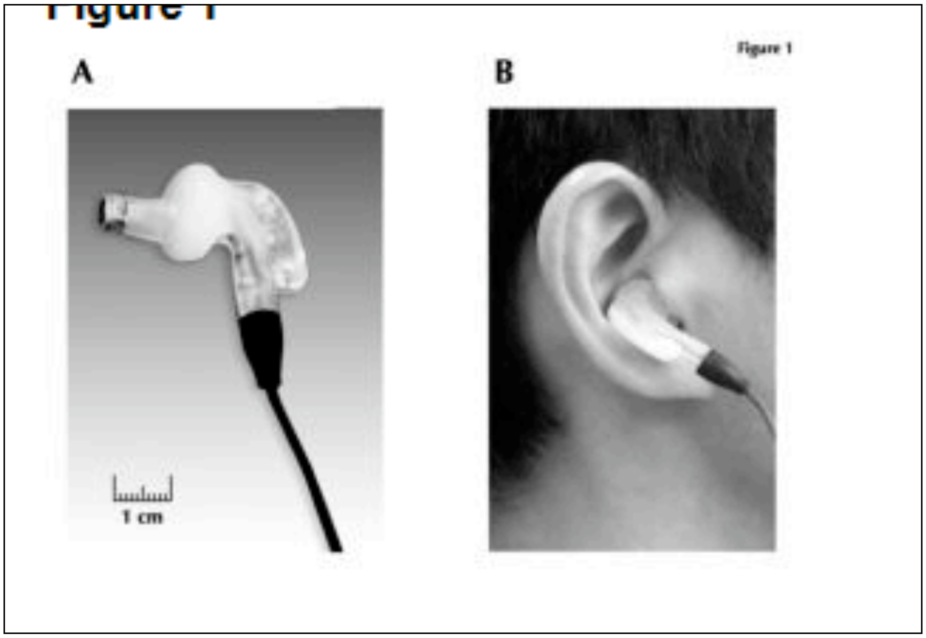
SUMMARY

BioShirt was introduced to the National Sports Festival in South Korea in 2006, with hope to be on the market in 2007, but no records show it is currently available. It is specifically designed with athletics in mind and monitors the runner's temperature, heart rate and speed; it then sends that data to a wrist-worn monitor via Bluetooth. Kim Seung-hwan, the leader of the Electronics and Telecommunications Research Institute team that built the BioShirt, believes the shirt could also have similar applications as a monitoring system for elderly or infirmed patients who need constant attention. The battery life is about 3.5 to 5 hours, and the shirt must be tight-fitting to maintain skin contact

COMMENTS

Skin/surface temperature is not an accurate reading of core body temperature, since sweat, wind, and ambient temperature would all affect the sensor. The speed measuring device is not necessary for detecting heat exhaustion. Conclusively, BioShirt is essentially just an EKG chest strap added inside a shirt. Unless the user owned more than one, it would be inconvenient to have to wash the shirt every time he or she wanted to use it.

Infrared In-Ear Thermometer

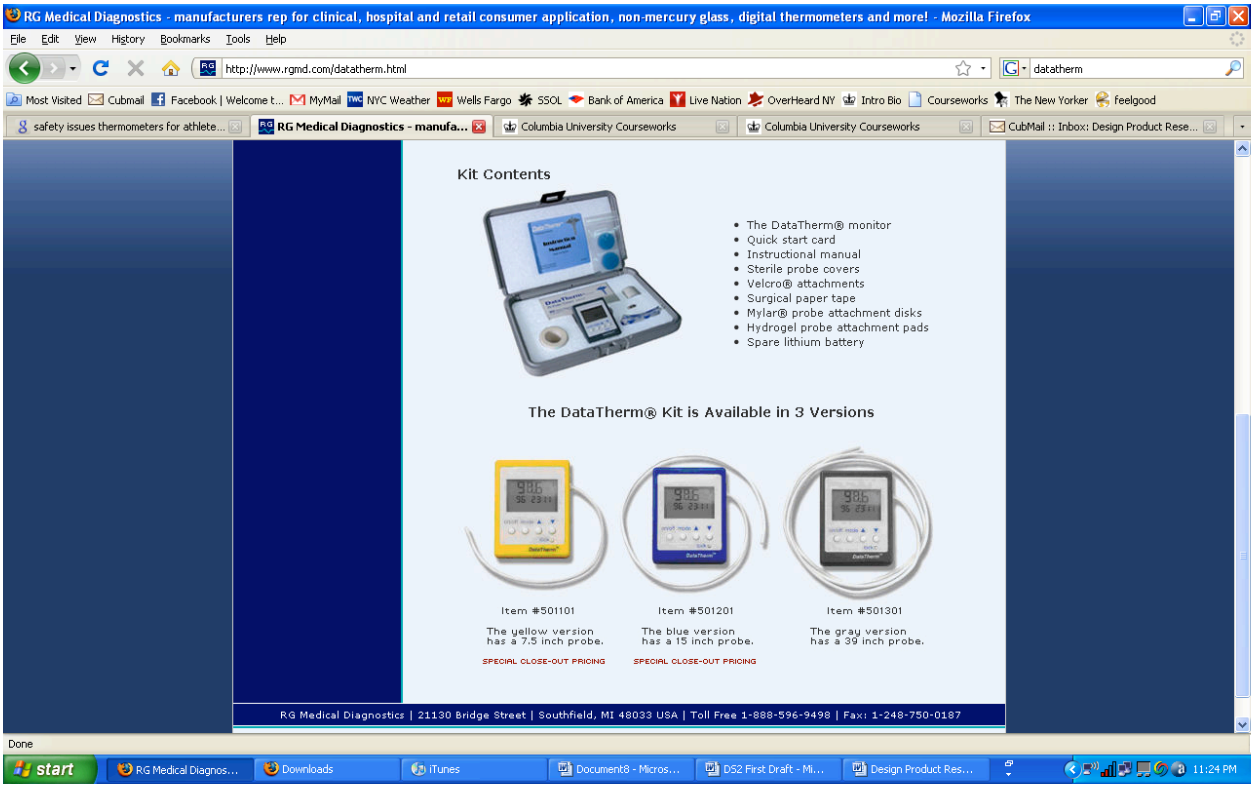


SUMMARY
This product is almost identical to our design idea for core temperature sensing. It is an IR thermometer that fits in the ear for continuous tympanic membrane temperature measurement. It was developed in a medical school in Japan to be used during surgery to monitor the hypothermic effects of anesthesia. It was shown in clinical trials to be just as accurate as the current methods of measuring temperature during surgery. This product is not a direct competitor, however, because it is not available on the market and not designed for physical activity.

COMMENTS
This proves that our idea is feasible. As the authors state in the paper: “First, we succeeded in manufacturing a prototype earphone-type temperature sensor with a miniaturized infrared ray measurement component. Moreover, by using an appropriate algorithm, we succeeded in continuous measurement of infrared rays from the tympanic membrane at 1-s intervals with no drift in measured values (± 0.1°C, 32°C–34°C).” However, it does not say how long it took them to build their device, or how much it cost, both of which are concerns for us.

T Kiya, M Yamakage, T Hayase, J Satoh, A Namiki. “The Usefulness of an Earphone-Type Infrared Tympanic Thermometer for Intraoperative Core Temperature Monitoring” *Anesthesia and Analgesia* 105(6) (2007).

DataTherm



SUMMARY

The DataTherm is a diagnostic device which has FDA approval for measuring temperature. It has a probe which comes in varying lengths for different areas of application: esophygeal, axillary, rectal, topical. It is targeted towards athletes who are at risk for exertional heat illness and for patient transport. It takes the user's temperature in every 4 seconds and has an alarm if the user's temperature leaves a pre-defined range. Price: $225 for kit, $5.50 for extra probes

COMMENTS

This product is highly invasive and simply cannot be as comfortable as an earphone. It is hard to imagine that anyone would want to work with a probe inserted into their rectum or esophagus. The applications of it which are noninvasive (axillary and topical) do not measure core temperature. It is not very convenient, as it must be attached by Velcro or medical tape. Also, testing our device would be very difficult if we chose to use a rectal or esophygeal probe.

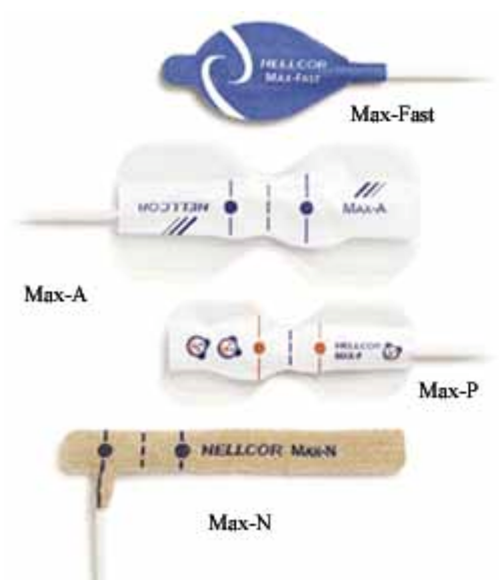
Prestige DT-22 Digital Infrared Ear Thermometer

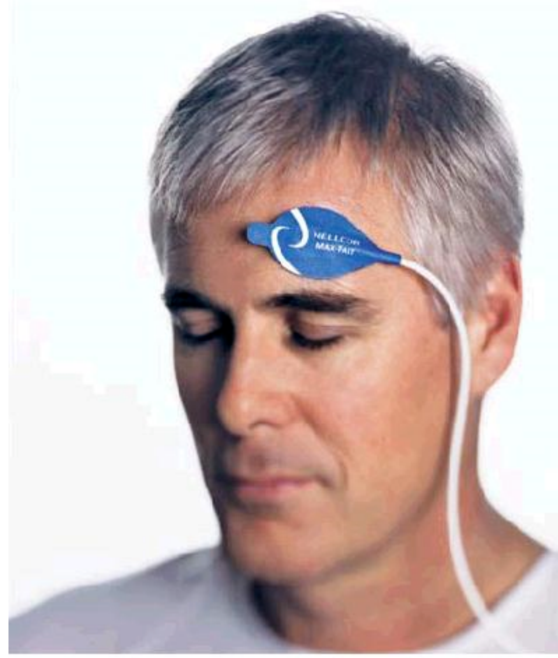
Measuring range 34^{O}C - 43^{O}C (93.2^{O}F - 109.4^{O}F)
Measuring accuracy +/- 0.2^{O}C(0.4^{O}F)
Fast response time: reading is obtained in 0.1 second
Audio-visual fever alarm (beeper and symbol warning)

SUMMARY
This uses a thermopile to measure temperature through detection of infrared from the tympanic membrane. The functional range is 34^{O}C - 43^{O}C +/- 0.2^{O}C and can read in 0.1 seconds. It has a display and an alarm goes off if it detects a fever. Unlike most IR thermometers, no probe cover is needed for this one.

COMMENTS
These thermometers are readily available on the market. We can take one apart to obtain parts that are small and accurate enough for our application, while also studying the circuitry. We may or may not include probe covers for hygiene.

OxiMax Max-Fast Forehead Sensor





The MAX-FAST Adhesive Forehead Sensor alerts clinicians to hypoxemic events earlier than digit sensors

http://www.nellcor.com/prod/product.aspx?S1=POX&S2=SEN&id=246

SUMMARY

Designed for use clinical use, to be worn on the patient's forehead, a site closer to the heart, the Max-Fast forehead sensor responds to changes in arterial oxygen saturation typically one to two minutes sooner than digit sensors for patients with weak pulses. The Max-Fast forehead sensor provides an effective monitoring option when digit sensors fail to obtain an SpO_2 signal. Unlike ear sensors, which may cause pressure necrosis and are subject to vasoconstriction, the Max-Fast sensor maintains stronger signal integrity. The Max-Fast sensor is more accurate than all other ear, nose and forehead sensors. A digital memory chip is embedded in the sensor itself that contains all the calibration and operating characteristics for that sensor design. This gives the monitor the flexibility to operate accurately with a diverse range of sensor designs

COMMENTS

We will not need to measure SpO_2 signal, however this forehead pulse-oximeter could offer a convenient method and location for obtaining heart rate if incorporated with a helmet or head-gear design. Whereas the product website does not address accuracy of measurement during movement, we have found many scholarly journal articles that provide evidence of successful use of forehead pulse-oximeters during exercise. This product uses disposable forehead sensors, but a more permanent design that could directly insert a pulse-ox to some kind of padding applied to the forehead, such as in a helmet, sweat band, or visor.

Polar RS100 Heart Rate Monitor

SUMMARY

Polar is one of the leading brands of current heart rate monitors used by endurance athletes today. The chest strap monitor transmitter contains two electrodes to detect the electrical signal on your skin. The electrodes are mounted on a transmitter attached to an elastic strap. The Polar transmitter detects the voltage differential on the skin during every heart beat and sends the signal continuously and wirelessly using an electromagnetic field to the wrist receiver. This method is based on ultra low power consumption, due to the unique insertion molded electronics module and circuitry to pick up the electrical signal of the heart. Readings obtained simultaneously by Polar monitors and by electrocardiogram (ECG) monitors are almost identical, thus, like many other heart rate monitor companies, they claim it is “ECG Accurate”.

COMMENTS

A “Heat Elite” group member, who is has used the chest strap design, complains that the strap is constrictive to breathing, especially during intense physical activity. Loosening of the band results in the transmitter slipping off the chest during exercise, preventing consistent measurement. The Polar RS100 does not measure core body temperature and is meant for personal training purposes. Therefore, it will not be a direct competitor to our heat exhaustion-prevention device. However, in the future, we look to expand to the “personal user” market, so a wrist-worn monitor like this one will be a plausible design for our product. MSRP: $119.95

http://www.polarusa.com/us-en/products/running_multisport/RS100

Power Glove Basic Strapless Heart Rate Monitor

SUMMARY
BodyTronics and Impact Sport's PowerGlove is a strapless, continuous heart rate monitor which uses EKG accurate technology, involving two light-emitting diodes and microchip technology to detect pulse from the thumb. Worn on the wrist and over the thumb, there is a large display on the back which indicates user's pulse in real time.

COMMENTS
This product is related to our design idea in that it is an alternative to the traditional chest strap based heart rate monitoring technology. The PowerGlove also inspired a thumb-worn pulse-ox design as a possible product for monitoring the heart rate of endurance athletes. A disadvantage to this idea is it would make our product into two separate pieces, a hand-worn heart rate monitor and head-worn in-ear thermometer, which takes away from a single, less cumbersome device.
MSRP $69.94
http://www.bodytronics.com/page/bodytronics/PROD/Heartrate_Monitors/PGBASIC

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ePulse Strapless Heart Rate Monitor

SUMMARY
The ePulse strapless, continuous heart rate monitor uses "EKG accurate" technology, via "sophisticated integration of light-sensor and micro-chip technology (like that used in hospital heart rate monitors)" to accurately read the pulse from the forearm. The device has a large display that indicates the user's pulse in real time. It requires no programming to immediately display heart rate and with a simple input of personal data, it will also calculate calories burned and target exercise zones. http://www.impactsports.com/technology.php

COMMENTS
This product is another alternative to the traditional chest strap heart rate monitor design that we are trying to get away from. The ePulse inspired us to use look into technologies other than the use of electrodes, such as PPG technology, as a way of measuring heart rate of physically active people. MSRP $119.95

Reebok Heart Touch Strapless Heart Monitor

SUMMARY
The Reebok strapless heart rate monitor uses two electrodes that the user must touch with two fingers to get a reading of their heart rate. While this design does allow Reebok to provide a product that does not use the traditional chest strap, it does not give a continuous heart rate reading.

COMMENTS
This product is again an alternative to the traditional chest strap design incorporated into modern athletic heart rate monitors. We have decided not to incorporate this technology into our design due to the non-continuous monitoring of heart rate that would be required for our design objectives. The Reebok monitor demonstrates that strapless technology does not necessarily equate to useful technology for our design goals. MSRP $49.99

C. ALTERNATIVE, RELATED PRODUCTS

The following products demonstrate different ideas we can use to package the separate components that will make up our device, such as a forehead sensor, an in-ear thermometer, a Bluetooth-like device, etc. One key idea that is necessary to include in our design for our target market is showing compatibility with different helmets, thus different types are shown below. We also investigated other technologies that could compliment the use of an in-ear thermometer and wireless signal transmitter for relaying the data to an outside source.

Football Helmets

SUMMARY
Helmets, such as this one from Schutt, all features a some kind of pad liner system, which distributes the force of an impact then immediately returns to its original shape. Schutt advertises that the pad liner system makes it easy to get a custom fit for each player. All of the interior parts are interchangeable and replaceable, ensuring a completely custom fit that maximizes protection and comfort. This model also features a third chinstrap snap location – perfect for players who don't fit or don't like the standard setup.

COMMENTS
The inner lining pads shown here has great potential for incorporating a forehead device using PPG technology for measuring heart rate. The interchangeable and replaceable feature of the padding is ideal for allowing our device to be easily inserted by simply exchanging or adding a forehead pad. This should also ensure user-friendly application if the user will be installing the device to the helmet themselves. One concern in this design will be making sure the padding we use is comparable to that used in these helmets, so as not to take away from the original quality.

Military Helmets

SUMMARY

MSA Gallet is a company that provides a large line of combat helmets for military use worldwide. Many other military supply companies make similar helmets. Helmet styles can vary, depending on the intended purpose, such as for those for paratroopers, Air Force pilots, or special force units. A commonality among all designs we researched includes inner padding to provide comfort and shock absorption. Additionally, most designs mentioned compatibility with a variety of accessories, such as communication systems, protective goggles, breathing masks, and adjustable straps.

COMMENTS

The inclusion of inner padding could allow easy insertion of sensors or the addition of a forehead pulse-oximeter. It will be necessary to ensure that the addition of devices to the helmet will not cause harm, or hinder the user when removing or putting the helmet on. It is promising that other devices can be connected to the helmets, meaning addition of a device for preventing heat exhaustion is feasible.

Military GI Style Sweatband for GI Pot Helmet

SUMMARY
This product comes from the company Army Nany Shop. No description or product details were given except that it uses clips to attach to the helmet.

COMMENTS
A headband such as this could provide an alternative method for incorporating a forehead pulse-oximeter into a helmet of any kind. MSRP $8.00

Firefighter Helmets

The TL-2 (Traditional Leather) Fire Fighting Helmet

SUMMARY
The TL-2 weighs approximately 55 ounces, is ergonomically correct, and fits comfortably and lower on the head. The inside dome is made of injection molded thermo-plastic, designed for durability. The "Impact Cap" along the inside is a closed-cell foam comparable to the foam inside football helmets, designed to take hit after hit. The chinstrap is Nomex Webbing with a

standard Postman's slide buckle. Optional chinstrap choices are a quick release style or a combination of both. The earlaps are detachable and made from black Nomex and black fire retardant cotton. The optional sewn-in earlaps are made from the same materials and must be requested, if desired.

COMMENTS
The foam padding that makes up the "Impact Cap" could possibly provide a means for inserting a small forehead pulse-oximeter. The feature of "fitting lower on the head" would be ideal for maintaining skin contact with a forehead pulse-ox. This could be an obstacle with other designs that nay not fit low enough, and therefore prevent a proper signal from being obtained. The optional earflaps could help protect a temperature sensor positioned inside the ear.

Nike + iPod Sport Kit

Transform your iPod nano or iPod touch (2nd generation) into a personal workout coach with the Nike + iPod Sport Kit. This wireless sensor and receiver combination works exclusively with your Nike+ shoes and iPod nano or iPod touch to give you real-time feedback during workouts and let you track your performance on your Mac or PC.




Overview

Thanks to a unique partnership between Nike and Apple, your iPod nano or iPod touch (2nd generation) becomes your coach. Your personal trainer. Your favorite workout companion.

Tune

Insert the wireless sensor inside the custom, built-in pocket beneath the insole of your Nike+ shoe, then plug the receiver into the Dock connector on your iPod nano. The iPod touch (2nd generation) includes built-in support for the system — no receiver necessary.

Run

Now start your workout. As your run or walk, the sensor sends information to your iPod, tracking your time, distance, pace, and calories burned. If you choose, real-time, spoken feedback can even alert you to milestones throughout your workout.

Sync

Back at your computer, sync your iPod to transfer your workout data to iTunes and nikeplus.com. There, you can evaluate your performance history, set goals, and even challenge other runners to a virtual race.

What's in the Box

- Wireless sensor for Nike+ shoes
- Wireless receiver for iPod nano
- Printed documentation

Requirements

- iPod nano or iPod touch (2nd generation)
- Nike+ shoes
- iPod nano software v1.2 and iTunes 6.0.5 or later (available via free download)
- A Mac with a USB 2.0 port and Mac OS X version 10.3.9 or later; or a PC with a USB 2.0 port and Windows 2000 (SP4) or XP Home or Professional (SP2)
- Internet access and a free Nike.com account

Specifications

Sensor*

- Size: 1.37 x 0.95 x 0.30 inches
- Weight: 0.23 ounce
- Broadcast frequency: 2.4GHz

Receiver

- Size: 1.03 x 0.62 x 0.22 inches
- Weight: 0.12 ounce
- The sensor's battery is not replaceable. Battery life will vary considerably based on use and other factors.

SUMMARY

This is an example of a sports equipment company (Nike) coming together with an electronics company (Apple) to make a product for athletes as a training tool. The product is designed to fit into the shoe easily, so that the user can install it. It monitors time, distance, pace, and calories burned. It also easily interfaces with a computer.

COMMENTS

This product is the result of a true partnership. Nike had to develop a shoe with a small hole specifically for this product. Our device will fit into a helmet without the helmet manufacturer having to change anything. It will monitor vital signs, not performance.

Sony Fontopia MDR-ED21LP - headphones

SUMMARY
The Sony in-ear headphones fit snuggly and comfortably inside the user's ears. This ergonomic design helps both seal out ambient noise as well as maintain its position inside the ear during physical activity. An anti-bacterial material makes the outer covering safer to wear as well. These earphones are stylish and unobtrusive.

COMMENTS
This product reflects the design principles on which we hope to base our in-ear thermometer. Ergonomics must be considered in our product in order for it to stay put as well as seal out ambient temperature in order to capture accurate real-time data monitoring. If we were designing a product for endurance athletes or recreational users, aesthetics of the thermometer would also be a factor. MSRP $13 - 25

Motorola Bluetooth Active Headphones

SUMMARY
The Motorola Active Blue Tooth Headphones are both stylish and practical. Giving athletes the ability to listen to their music wirelessly allows them to focus more on their endeavors rather than getting tangled up in a wired mess.

COMMENTS
These headphones exemplify an ergonomic, compact, and cost-efficient method of wireless delivering information between ear pieces and a control unit. This technology can be integrated into a ThermaTracker for endurance athletes who would normally wear headphones while exercising, providing them with a quick and tangle-free way to monitor their health.
MSRP $54 - $125

Sensor worn behind the ear

Home > Technology & Science

Improving Athletic Performance

A Sensor Worn Behind the Ear Could Monitor a Person's Movements

By Brittany Sauser
Oct. 4, 2007

Researchers at the Imperial College London have developed a sensor worn behind the ear that can measure an individual's biomechanical data, such as his or her posture and gait, during an activity. The data is then wirelessly transmitted to a computer so that the wearer's performance can be measured and assessed in real time.

The sensor could be used to both optimize athletic performance and help monitor changes in movement in people recovering from surgery or suffering from neurodegenerative diseases. According to Guang-Zhong Yang, a professor in the department of computing at Imperial College and the project leader, the device works and could be mass-produced within 12 to 18 months.

sensor worn behind the ear of an athlete can measure posture, stride length, step frequency, and...
(Imperial College London)

There are a number of technologies that are looking toward providing this kind of information about an athlete's performance, says Peter Vint, a senior sports technologist for the United States Olympic Committee. "But what distinguishes it [the sensor] from others is it is very small and worn on a place in the body that is stable in noncontact sports."

The sensor is about the size of a cuff link and measures the posture, stride length, step frequency, and acceleration of an individual. In addition to being used in applications for

http://abcnews.go.com/Technology/Story?id=3688357&page=1

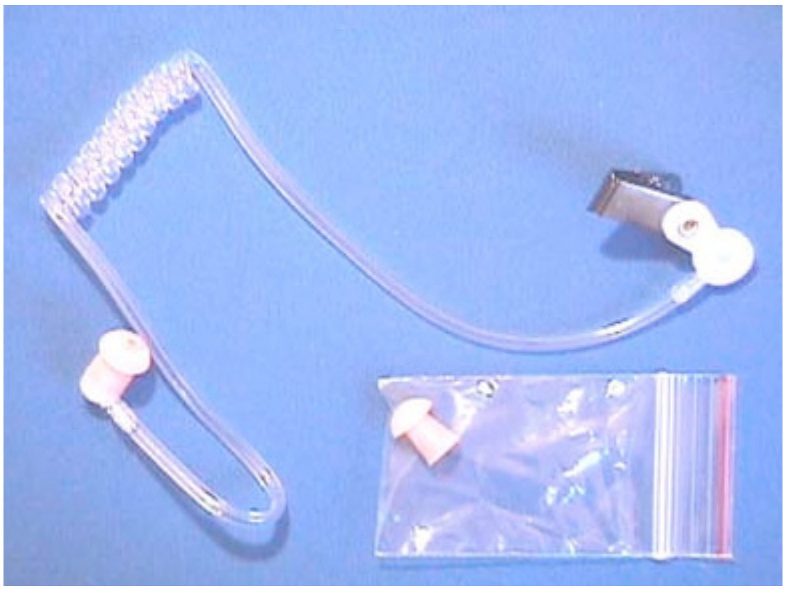
SUMMARY

This is a device worn behind the ear of athletes to monitor posture and gait. It measures posture, stride length, step frequency, and acceleration to gauge athletic performance. It can also be used to monitor changes in patients with neurodegenerative diseases. It transmits the data wirelessly to a computer that analyzes the information and displays the results in real time. They are looking into incorporating heart rate and finding a way of transmitting data more than 10m.

COMMENTS

It is very interesting to see a device meant for athletic training as well as a true medical need, like ours. This device is very small but still contains a sensor and a wireless transmitter, showing that our design is feasible. However, these researchers are also having trouble extending the range of the wireless data transmission, so it is likely that we will have trouble there too. It does not say how much this device will cost because it is not on the market yet.

VestGuard UK Earpiece



SUMMARY
This clear, two-wire earpiece is perfect for discreet use. Used by security personnel around the world, it has a push to talk clip-mike that can easily be attached to a shirt cuff.

COMMENTS
If attached to our in-ear thermometer, this small, plastic coil design could be an easy way for the user to remove the device while it stays attached to the helmet and remains accessible for reinsertion.

D. INTERVIEWS

Interview 1. A semi-professional tri-athlete who is also a Columbia University graduate student studying nutrition, responded to the following questions to provide feedback from a user's perspective:

Have you had any experience with heat stroke/heat exhaustion?

If yes: what happened?

How did you know they/you had heat exhaustion?

How did you treat it?

Can you think of a way that it could have been prevented?

If no: Have you heard any stories of other people having problems?

It's hard for me to extract the role of "heat exhaustion" per se with other factors such as over training (i.e. total miles), dehydration, and electrolyte imbalance. My summer I Chicago, I did not have an air conditioner, and it was obvious that my body was not recovering overnight properly when I didn't own an air conditioner. I guess overall, I have not had acute symptoms heat exhaustion due to heat alone, usually symptoms of dehydration/electrolyte or calorie balance present first. I do remember heat exhaustion being a big concern for younger children (i.e. the hot summer days when I played soccer), not sure if certain age groups are more prone?

Do you currently use a heart rate monitor?

If yes: What do you think of current heart rate monitors?

Any improvements you would like to see?

If no: Why not?

Is there anything that could change about it that would make you use it more?

I own a polar RS200, but currently rarely use. When I started training for my first triathlon, oh, about 7 years ago, I primarily used it during training and races to find a pace at which I could push myself but not burn out (I was always terrible at that in high school track and cross country). I quickly correlated that heart rate with a perceived exertion, and got a "feel" for my ideal pace. For years I haven't been using it, but now that I plan on training more seriously, I can see it becoming more an integral part of my training plan. In terms of my thoughts about current products, I guess I should preface by saying I'm a mac person. I like sleek in simple design. The most respected and reliable heart rate monitors come from Polar, but using them is like fighting with Vista, its not intuitive. In addition, the wrist watch of all the heart rate monitors that I know of are too bulky and pretty ugly, nothing that I could feasibly wear throughout the day, so I guess when I go for my run, I just simply don't want to take the extra time to switch my watch. Making a sleek design would be a big plus (fyi, I have the "timex ironamn sleek 50-lap", product code T542819J and couldn't imagine wearing anything else).

What would you think of a product that can monitor both the temperature and heart rate of an athlete?

I think I could be a very useful tool….but would have to be completely convinced. If it is strictly a tool to avoid heat exhaustion, I probably wouldn't buy it, since I've never really had it before. However, if it could somehow be correlated with sweat production, and subsequently help people with their hydration needs, I think you would have a HUGE market. It took my 5 years to figure out my caloric and electrolyte/water balance in an ironman, and still not 100% confident with it. If it was comfortable enough to wear all day, and could be correlated with recovery, that could also be extremely useful.

Would you use it or recommend it?
What would be your specific considerations?

Depends on the specific design and extended applicability

Where would you want it on your body?

I suppose either chest, or cuff around the upper or lower arm, or ankle.

How would you want the information to be displayed?

On wristwatch, I guess just ºF or ºC

What features would make you want to use it?

Save/display data from entire workout. Could outside ambient temperature also be taken? I would be nice to correlate the data.

What would keep you from using it?

Irritation, uncomfortable and/or bulky

How much would you pay for a combination temperature/ heart rate monitor?

Depending on the features, I suppose upward of $175 -/+ $20

Do you have any other idea for what would be useful to monitor on athletes?

Hydration/electrolytes, maybe blood glucose to learn calorie balance and avoid bonking.

Any other thoughts?

Good start, it would be interesting to know more what is feasible.

Interview 2. Kelly Webb, the athletic trainer for a high school in Florida, answered our questions, offering input from a sports trainer's (possibly the customer and/or user) perspective.

1) *Have you had any experience with heat stroke/heat exhaustion*? Heat stroke: No, Heat Exhaustion: Yes
If yes: what happened? Multiple incidents: mostly football players (practices and games) and a few incidents at cross country meets

How did you know that they/you had heat exhaustion? Signs/symptoms: dizziness, nausea, profuse sweating, pale skin, history taken of food ingested/beverages consumed, previous illness/fever

How did you treat it? Rest in shade, remove pads/helmet/excess clothing, drink water/electrolyte replacement (if available), heat illness prevention education given

Can you think of a way that it could have been prevented? Proper nutrition/hydration, wearing appropriate (light colored, light weight) clothing, better conditioning

2) *Do you currently use a heart rate monitor?* No

If yes: What do you think of current heart rate monitors? Any improvements you would like to see?

If no: Why not? Cost prohibitive

Is there anything that could change about it that would make you use it more? Funds to make use available

3) What would you think of a product that can monitor both the temperature and heart rate of an athlete? Would you use it or recommend it?

Great idea. Yes, I would use/recommend it if it was available to me.

4) What *would be your specific considerations- Where would you want it on your body? How would you want the information to be displayed?*
It probably wouldn't matter too much where on the body it would be located…wherever it would be most effective. Display of information: as easily readable/accessible as possible would be best.

5) What *features would make you want to use it? What would keep you from using it?*
Ease of use and cost effective would be the best features. The opposite would be true for keeping me from using it :)

6) *How much would you pay for a combination temperature/ heart rate monitor?*
Good question…I am unaware of baselines for cost of this type of item. I have no budget for any items outside of the county bid-list for supply items, so it would have to be purchased through outside funding somehow (donation, bulk district purchase).

7) *Do you have any other ideas for what vital signs would be useful to monitor on athletes? Any other thoughts?* BP might be nice? :)

E. SAFETY CONSIDERATIONS & FDA

The main safety issues include:

1. Sweat + Electricity =Electric shock: Perspiration during performance often drains around the ears, thus can could cause electric shock if the device is not water-proof

2. External – If during athletic performance, the athlete falls/is hit on or around the ear, where the temperature sensor device will be worn, the device could potentially cause outer or inner ear injury

3. Medical safety – If the heart rate and temperature output report numbers lower than the athlete's actual measurements, the athlete could reach the dangerous/fatal range without the trainer or athlete knowing. In this case, proper steps may not be taken to prevent heat stroke/over exhaustion, or even death. How can we prevent failure and liability?

    a. If during testing, we find the measurements are consistently lower or higher than actual measurements, we can provide a calibration method to accurately measure the athlete's temperature and heart rate.

According to the FDA, Heart rate monitors, oximeters for monitoring heart rate during exercise, and electric thermometers are all Class II devices subject only to performance standards. Since our product will be equipped with an alarm for warning the user when the heart rate or temperature falls outside preset upper and lower limits, it will function as a diagnostic tool and not be used for recreational purposes. See FDA details below.

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2008]
[CITE: 21CFR870.2300]

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 870 -- CARDIOVASCULAR DEVICES

Subpart C--Cardiovascular Monitoring Devices

Sec. 870.2300 Cardiac monitor (including cardiotachometer and rate alarm).

(a) *Identification.* A cardiac monitor (including cardiotachometer and rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.

(b) *Classification.* Class II (performance standards).

Database Updated April 1, 2008

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=870.2300

Others at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=870.2300
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=880.2910

DS3: Constraints and Specifications

Portability
The device must be able to communicate wirelessly with a receiver monitored by a supervisor.

Accuracy
The device must be able to take accurate measurements while the user is in motion. A calibration and check method should be included to provide accurate temperature and heart rate readings.

Ergonomics
The device must be comfortable to wear as to not hinder normal performance.

Price
The device should be affordable so that groups can buy multiple devices. The price should be comparable to or less than that of current heart rate monitors.

Appearance
The device should be inconspicuous so as to not be distracting.

Regulation
Our product must conform to the performance standards of the FDA for Class II devices.

Training
Minimal training should be required to use the device. An instruction manual should suffice to explain the operational procedure.

Data Output
The receiving device, whether worn on the user or monitored by a supervisor, must clearly alert the user of potential heat exhaustion.

Advantage Over Similar Products
The device must be able to measure both temperature and heart rate in order to predict heat stroke since other commercially available devices only serve as athletic training tools by monitoring heart rate.

Power
The device should be battery powered in order to maintain portability. The battery life should be at least as long as the event being monitored, e.g. a football game or a combat training session.

Safety
The device needs to be water-resistant to prevent electric shock caused by sweat or rain penetrating the electric component.

Customer
The customers should include the departments in charge of football teams, the Department of Defense, and Fire Chiefs or Commissioners.

User
The users should include football players, military personnel, and firefighters.

Testing
The device should be able to be tested by anyone engaging in an activity where heart rate and body temperature are elevated, and the results should be compared to alternate modalities of heart rate and body temperature monitoring.

Technology
The heart rate should be measured using photoplethysmography at the temporal artery. Core body temperature should be measured using a thermopile to detect infrared radiation from the tympanic membrane of the eardrum.

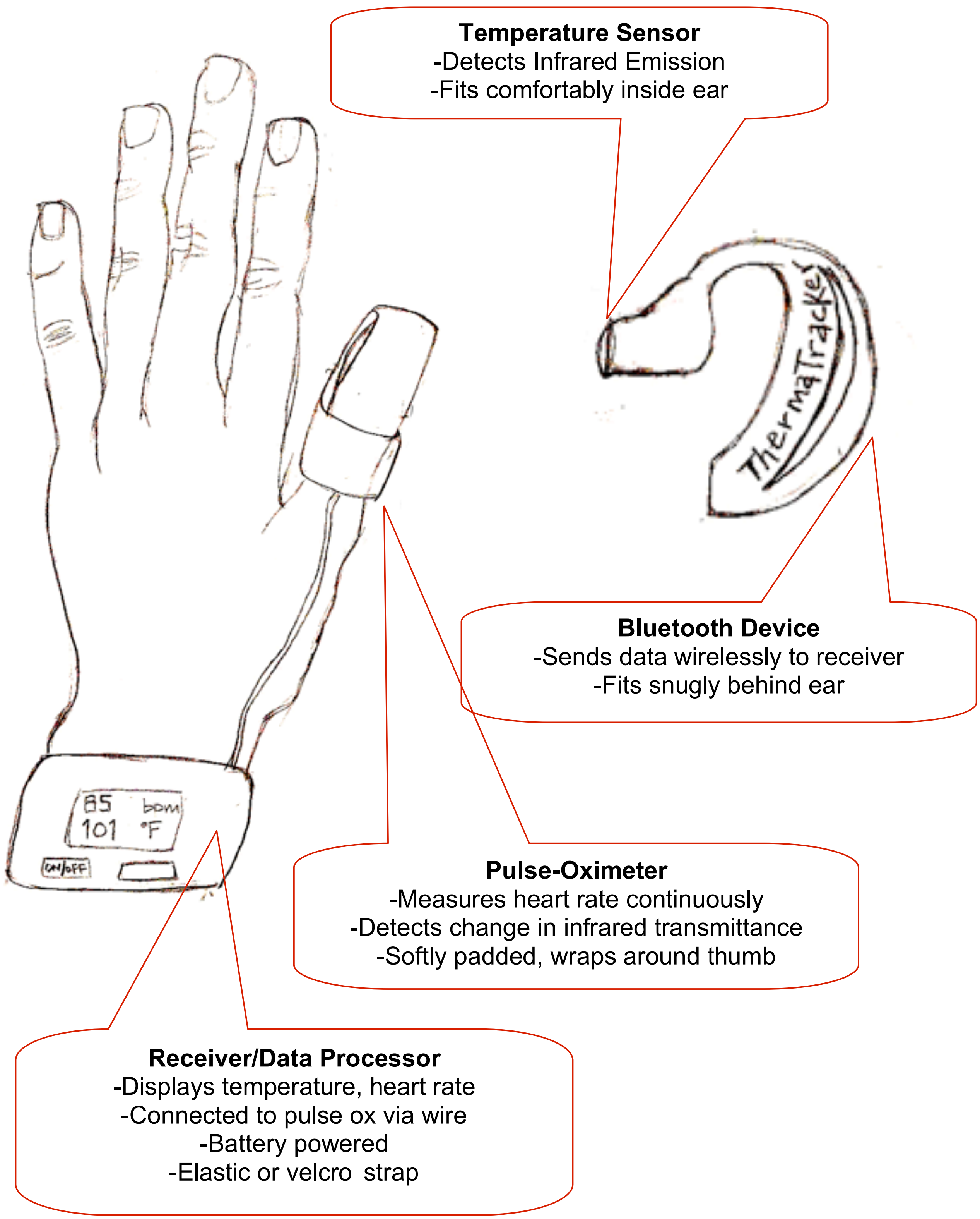
Life of the Product for the User
The device should be able to last between one and two years even when subjected to high impact environments.

Warranty
The device should have a yearlong warranty to account for the possibility of faulty manufacturing.

Jeff Chiang•Hayley Dirscherl•Philip Kemp•Sara McArdle•Leah Petersen

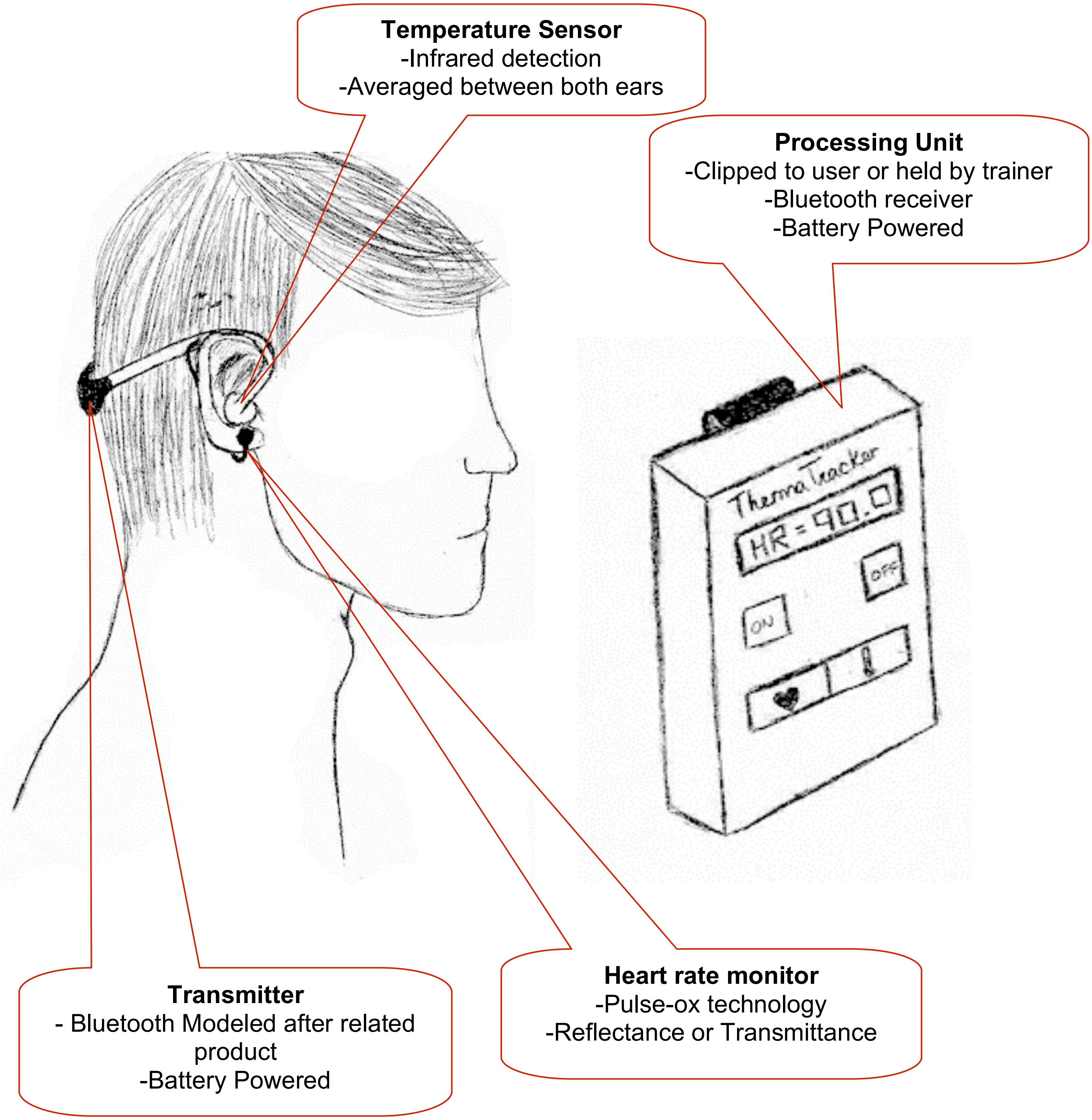
DESIGN IDEA 1

Intended User: Endurance athletes of non-contact sports, self-monitored



DESIGN IDEA 2

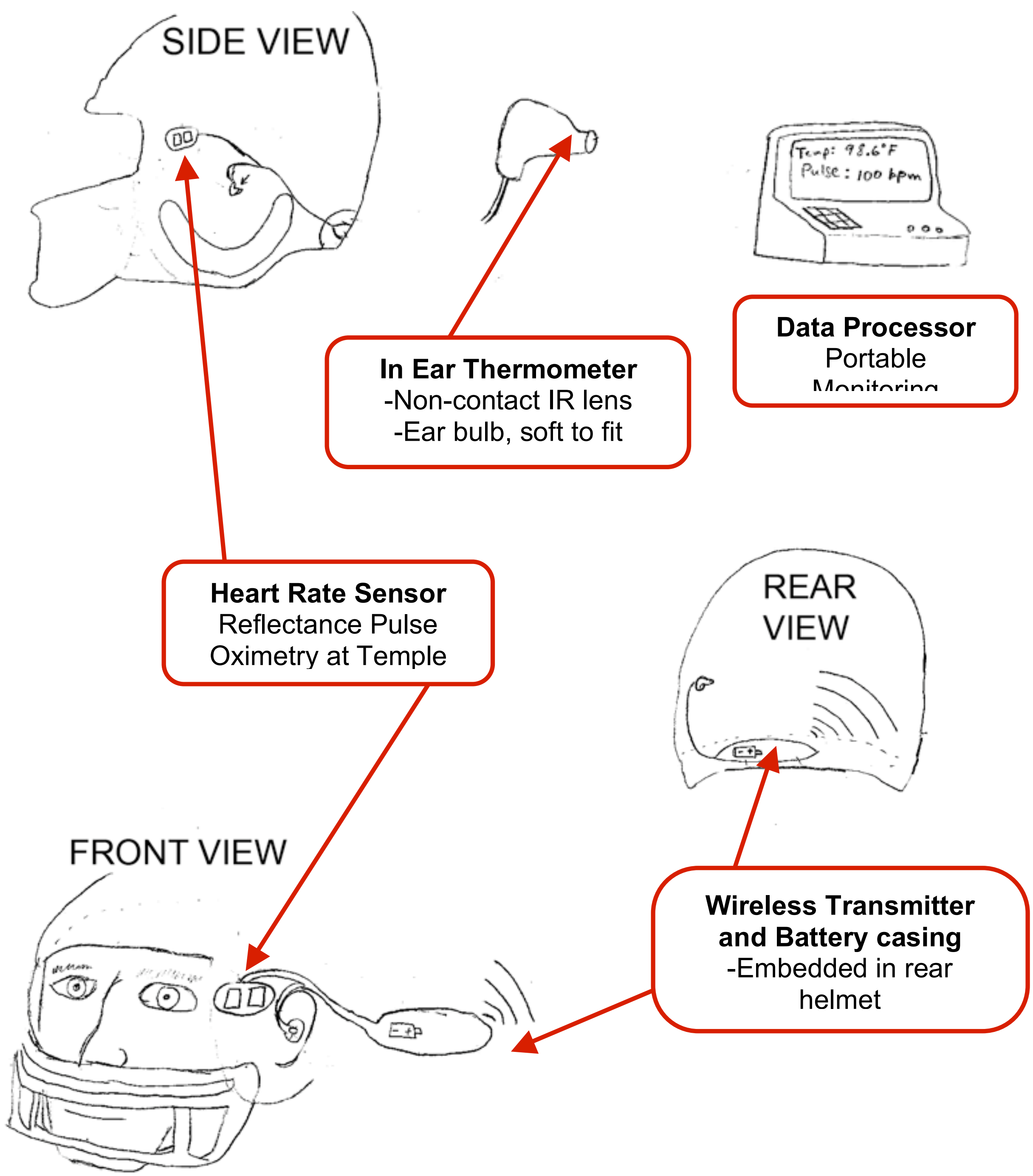
Intended User: Physically active people, self or trainer-monitored



Columbia BME Senior Design 2008
Jeff Chiang•Hayley Dirscherl•Philip Kemp•Sara McArdle•Leah Petersen

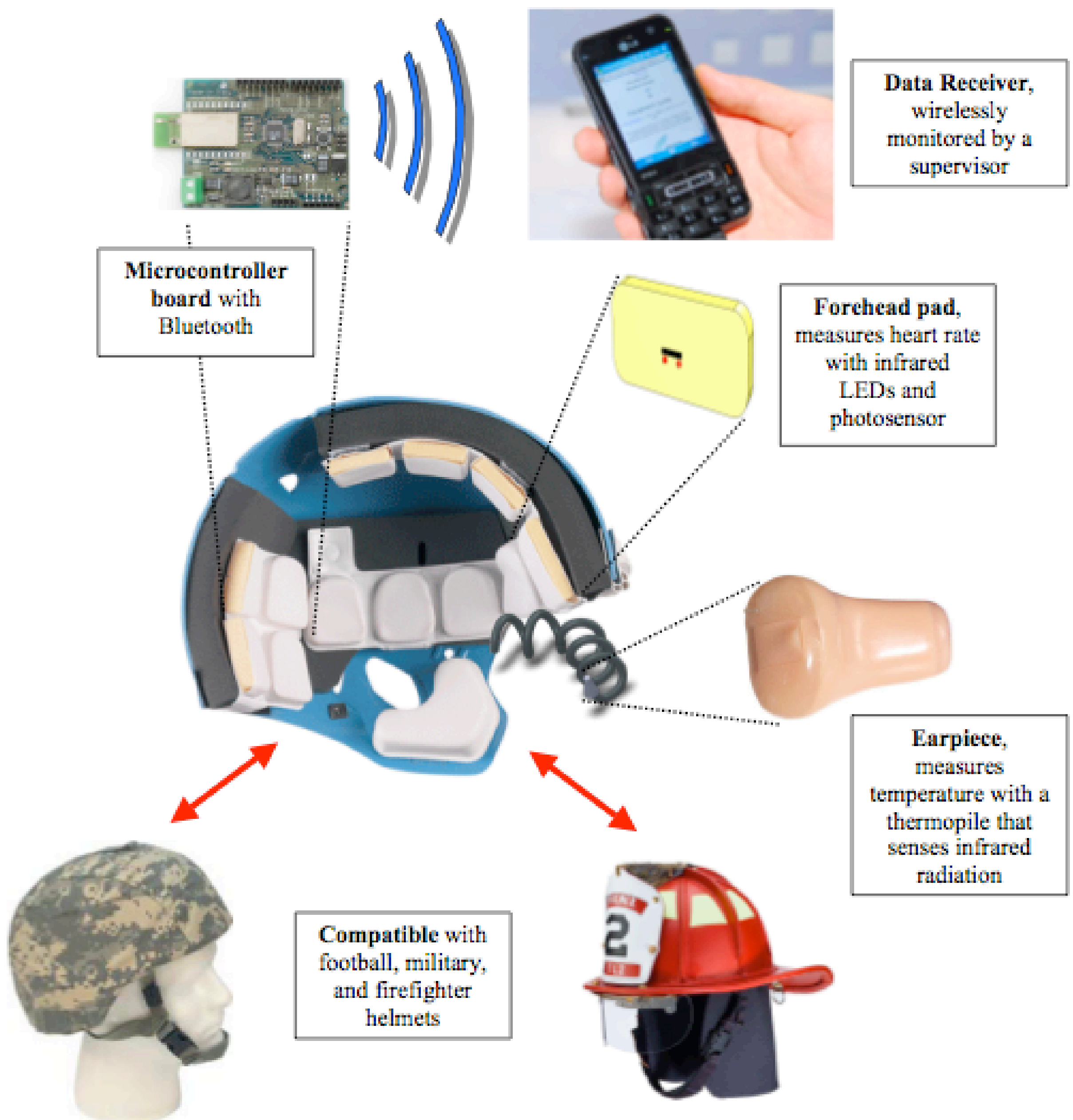
DESIGN IDEA 3

Intended User: People who use protective helmets, monitored by a trainer



DS5: Chosen Idea Development

Our chosen idea is a heart rate and temperature sensor that is incorporated into the padding of the helmets used by football players, military personnel, and firefighters. The device uses photoplethysmography technology to measure heart rate at the temporal artery and measures temperature by detecting infrared radiation from the eardrum.



Jeff Chiang•Hayley Dirscherl•Philip Kemp•Sara McArdle•Leah Petersen

DS6: Prototype Manufacture Plan

Our prototype development will occur in three stages: 1) construction of a core body temperature sensor, 2) construction of a heart rate sensor, and 3) writing the necessary MATLAB code to process the signals from these sensors.

Stage 1 will be done by ordering an in-ear infrared thermometer from Fischer Scientific and deconstructing it. This will help us to understand what parts, other than a thermopile, will be necessary to include in our circuit to detect infrared radiation from the eardrum.

Stage 2 will be done by ordering a phototransistor from Digikey and obtaining infrared LEDs, op amps, and other circuit elements from the Biomedical Engineering Department of Columbia University. After much research, we have found several articles and even a book on designing devices that use photoplethysmography to detect heart rate.

Stage 3 will draw from the practice design project we did at the beginning of the semester in which we modified a graphical user interface (GUI) through MATLAB in order to acquire data from both digital and analog inputs. We will initially attempt to acquire the signals from our heart rate and temperature sensors by modifying this same GUI, and then apply other filters and data processing algorithms as necessary.

Prototype Budget:

COMPONENT	TYPE	COMPANY/SUPPLIER	Order #	AMT	UNIT PRICE	TOTAL
Arduino		SparkFun.com (Keith)		1	borrow	$0.00
In-ear Infrared Thermometer		Fisher Scientific		2	$25.00	$50.00
Battery		Fisher Scientific		3	$3	$9.00
Football Helmet		Columbia Athletic Dept		1	borrow	$0.00
Computer		Columbia		1	borrow	$0.00
LEDs		Columbia		5	borrow	$0.00
Silicon NPN Phototransistor	SFH 309 PFA	Digikey	475-1442-ND	10	$0.36	$3.60
Op-amp		Columbia		5	borrow	$0.00
					TOTAL	**$62.60**

Prototype Diagram