THE HEAT ELITE

Business Proposal:
The ThermaTracker

Group Members:
Jeff Chiang
Hayley Dirscherl
Philip Kemp
Sara McArdle
Leah Petersen

Biomedical Engineering Senior Design
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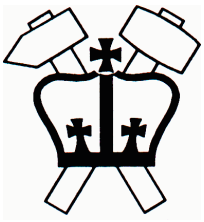
Columbia University, School of Engineering and Applied Science



Executive Summary: The Heat Elite and The ThermaTracker

Our company intends to develop a novel product that can be used by physically active people to predict and prevent heat stroke. It will be mounted inside the padding or straps of a protective helmet and include a reflectance photoplethysmography sensor at the forehead for measuring heart rate, as well as an in-ear infrared thermometer to monitor temperature. The physiological data will be sent wirelessly to a monitoring station, where a trainer or medic can monitor the health of multiple users. The ThermaTracker will have the competitive advantage of being the only product available to monitor the early indicators of heat stroke amongst physically active people who wear protective helmets.

During prolonged strenuous physical activity in hot, humid environments, the protective thermoregulatory mechanisms of the body may fail, and heat stroke may result. Heat stroke's common symptoms are dangerously high core temperature, rapid heart rate, muscle cramps, dizziness, confusion, headache, nausea, and vomiting. More severe outcomes, such as loss of consciousness or even death are possible.

Increased core temperature and heart rate are easily measurable indicators of imminent heat stroke, but they are often not checked until a heat stroke incident has occurred. While a number of products on the market today measure heart rate and temperature, no device exists for measuring both in a single, wearable, rugged design that wirelessly tracks multiple users. The market for such a product is as of yet untapped, and is ready to embrace a solution that warns the user of heat stroke before it strikes.

The ThermaTracker will initially be focused toward football players, firefighters, and military personnel as they all have many risk factors for heat stroke, can be monitored by a supervisor, and wear helmets. There are 1.58 million high school and college football players in the United States, 1.1 million military personnel, and 1.1 million firefighters. If we are able to capture a modest 1% of each of these three markets --38,000 units sold, at retail price of $50 per unit-- we stand to make a gross revenue of $1.9 million.

We expect to develop a prototype of the ThermaTracker by May 2009. We will seek FDA approval beginning in 2009, and expect to receive approval by the end of 2011. During this time period, we will continue to develop the ThermaTracker, including a design for personal use, begin advertising, and establish sales agreements with vendors and distributors. Following FDA approval, we will begin selling the ThermaTracker.

Our projected costs include research and development, cost of manufacturing each unit, marketing, salaries of sales staff and executive board, and cost of leasing a workspace. We expect revenue from sales of the ThermaTracker to exceed these costs by 2013.

The Heat Elite executive team is comprised of five senior biomedical engineering students at Columbia University in New York City. As athletes as well as biomedical engineers, the officers of The Heat Elite are familiar with both the conditions that lead to heat exhaustion and current technologies for monitoring its physiological symptoms.

Company Overview

The Heat Elite is dedicated to providing a product that monitors early signs of heat exhaustion in football players, soldiers, and firefighters. The device, called the ThermaTracker, warns the user that heat stroke may result unless they cease activity. As a person exerts him or herself at length in a hot, humid environment without properly rehydrating, their core body temperature rises and heart rate increases. To monitor core body temperature, the ThermaTracker will use an in-ear thermometer that detects infrared radiation from the tympanic membrane. The ThermaTracker will also monitor heart rate with a reflectance photoplethysmography (PPG) sensor at the forehead or temple. Similar in theory to pulse oximetry, but simpler, PPG technology uses infrared light to measure the volume of subcutaneous vasculature, which oscillates with each heart beat. The information collected by the ThermaTracker will be sent wirelessly to a monitoring station on the sideline, where coaches and trainers can keep track of the heart rate and temperature data of their players and be alerted if any are at risk for heat stroke.

In-ear thermometry, photoplethysmography, and wireless data transmission are already widely used, and there is a large amount of information available on how to construct devices that use these technologies. Therefore, it will be relatively easy to implement these technologies in our product. This will reduce the time needed to develop our product and deliver it to market; we expect to have a functional prototype by May 2009. Reflectance PPG may have decreased signal quality as compared to transmittance mode PPG. However, this limitation can be overcome by using a photodetector with a larger sensing area or by arraying the photodetectors around the light source to detect as much reflected light as possible. Moreover, reflectance PPG is better suited to our application because the LED-sensor apparatus can be safely embedded in the padding or straps in the front of a helmet and will be flush with the forehead. Future versions of this design will be developed for use with a headband, hat, or visor. On the other hand, a transmittance PPG sensor clipped to the ear would not be secure enough for use in a helmet. Devices that transmit data wirelessly are also widely used; examples are cell phone earsets and computer keyboards. This technology is readily adaptable to our product. Following the development of a prototype we will seek FDA approval. Once approved, we will begin advertising and selling our product, as well as developing new products.

Other companies have products similar to the ThermaTracker. Polar is the leading brand in producing heart rate monitors for runners. Sports equipment companies, such as Nike, Garmin, and Reebok, also sell heart rate monitors to runners and other endurance athletes. While these devices are commonly used for monitoring heart rate, there is currently no device available for monitoring other indicators of potential heat stroke, such as temperature. Additionally, the current heart rate monitors are not intended for use in a contact sport like football. The ThermaTracker will offer football athletes and others experiencing heat stress during physical activities involving a helmet a better option than other companies' products with its ability to track not only heart rate but temperature as well. It will be able to withstand the physical rigors of tackles, bumps, or falls. Its compatibility with many types of helmets is another key advantage. In a market with no known products for monitoring heat exhaustion for groups of people who wear protective helmets, the Heat Elite will have the advantage of being the sole producer of such a device.

MARKET ANALYSIS

Our addressable market consists of organized groups of physically active people who wear protective helmets. Specifically, we will target football players, military personnel, and firefighters. Because these groups perform in a controlled, supervised environment, the coaches, trainers, or officers who have an obligation to maintain the well being of each member will be able to monitor the conditions of multiple individuals simultaneously. Because these groups make up a healthy, physically fit population, it is believed that heat stroke can be prevented.

Within the U.S., there are approximately 1.58 million football athletes, 1.1 million military personnel (U.S. and territories), and 1.1 million working firefighters. All three groups are at exceptionally high risk of suffering from heat illness for similar reasons. All groups frequently perform in high temperature, high humidity settings for extended durations. Poor acclimation and dehydration can result from such conditions, heightening the risk of heat exhaustion. Each group uses multiple layers of gear and equipment, which add weight and trap heat, increasing physical stress during activity. Additionally, members are expected to perform with a self-sacrifice, "team-player" mentality. Thus, concern for one's own physical condition and welfare becomes a very low priority and can result in signs of heat illness being ignored.

Since 1995, 35 football players have died from heat stroke, 5 occurring in 2006 alone. The number of injuries and incidences due to heat exhaustion is much greater, but not sufficiently recorded.[1] It is a fact that troops in the field are at the greatest risk from heat stroke since they may not be in a position to evacuate nor near a water source. In 2002, approximately one-sixth of all heat injury-related diagnoses of military personnel were reported as "heat stroke."[2] From 1980-2002, the US Army recorded 5246 hospitalizations and 37 deaths due to heat illness. Heat stroke hospitalization increased five-fold over the 22 yr. period, and in 2002 alone over 320 incidences were recorded.[3] For firefighters, statistics are difficult to find on injury or death specifically characterized as heat stroke. However, the 2008 Annual Fatality Report shows 45 deaths (42.4%) resulting from "Exertion/Stress" while many individual reports indicate incidences and deaths due to heat stress.[4] Thus, the need for preventing heat stroke in these populations is not being met.

Currently, our main competitor is the HQ Inc. CorTemp Ingestible Thermometer Pill and Monitoring System. The ingestible pill uses a crystal quartz temperature sensor and wirelessly sends a signal to a monitoring device, where the core body temperature of multiple users is tracked. The ThermaTracker will have an advantage over CorTemp Thermometer Pill by simultaneously measuring heart rate, an important indicator for preventing heat exhaustion. *BioShirt,* an athletic shirt that contains two electrodes for measuring heart rate and a sensor for measuring surface temperature, was introduced at a National Sports Festival in South Korea in October 2006, but has yet to be introduced commercially. If this product becomes available, it will also be a competitor. However, the ThermaTracker will remain distinct in its ability to measure core body temperature, a more accurate reading for anticipating heat stroke than surface temperature.

In the future, as we develop a design for personal use, our market competitors will include companies that sell heart rate monitors such as Polar, Garmin, Timex Ironman, and Nike.

However, these products only measure heart rate, primarily for training purposes. Our design will remain unique in its ability to protect the user from heat illness by warning the user when heart rate and/or temperature fall outside the preset range.

Current economic hardships leading to budget constraints could detain growth in the short term if the ThermaTracker is not deemed a priority item to be purchased, but we anticipate that the need for such a device will sustain growth in the long term. We also suspect a change in market trends as global warming becomes increasingly problematic. It is predicted that the incidences of heat stroke cases and fatalities will become more prevalent as climate temperatures increase, as evident during the heat wave of 1980 (record year for heat) when 1700 deaths were attributed to heat in the U.S., compared to only 148 deaths attributed to heat in the previous year.[5] Thus, we expect the demand for our product to increase as heat stroke prevention becomes a more vital concern.

References:

1. http://medicineworld.org/cancer/lead/8-2007/middle-high-school-football-players.html

2. http://www.usfa.dhs.gov/downloads/pdf/08-fatality-summary.pdf

3. Carter III, Robert, Samuel N. Cheuvront, Jeffrey O. Williams, Margaret A. Kolka, Lou A. Stephenson. "Epidemiology of Hospitalization and Deaths From Heat Illness in Soldiers." *Medicine and Science in Sports and Exercise*. 2005;37(8):1338-1344. ©2005 American College of Sports Medicine, http://www.medscape.com/viewarticle/512284.

4. http://www.usfa.dhs.gov/downloads/pdf/08-fatality-summary.pdf

5. http://www.emedicine.com/MED/topic956.htm

Business Model

Our company has the potential of developing a novel product with the ability to predict and prevent heat stroke. The ThermaTracker will initially be focused toward football players, firefighters, and military personnel as these groups all have many risk factors for heat stroke, can be monitored by a supervisor, and wear helmets. As such, our device will be built into foam padding that can replace the existing padding in multiple helmet types. Our main revenue stream will come from selling the device at $50 per unit to users who can then easily install it themselves.

A secondary source of income will come from the sale of a yearlong warranty. The warranty will cost $15 dollars and will ensure that the device will be repaired or replaced by our company free of charge. It will not cover any damage due to misuse or loss. In the future, we hope to expand both our market and our product line. An endorsement by a well-known football player or by the Department of Defense could help to convince recreational users that they need our product to ensure their safety during strenuous physical activity. We could also sell accessories such as a long-range monitoring system that may be most applicable to users within the military.

The main costs to our company will include raw materials, research and design, salaries, and marketing. We plan to market our device in catalogues that sell football gear, on websites that distribute goods to the different groups in our market, and through workshops with football coaches and other potential customers. During the early stages, we will send out videos to these customers demonstrating both the need for and value of our product. Eventually, after sales have begun, we will be able to afford to send salesmen to deal directly with potential buyers. If our market were expanded to include recreational users, we would also benefit from a television commercial endorsing our product.

We hope that our company can get its start with a Small Business Innovation Research (SBIR) grant from the Department of Defense. Our company qualifies for the SBIR program since we are a technology company with fewer than 500 employees and are ready to enter the early stages of research and development. Also, our product could serve a Department of Defense need and has the potential for commercialization. The ThermaTracker could be applicable to the research solicitation for an assessment of return-to-duty status (topic number OSD09-H04). The desired system must be able to provide easily interpreted measurements of physical performance. In the case of the ThermaTracker, the measurements would be heart rate and core body temperature.

The SBIR grant provides up to $850,000 and does not have to be repaid. This is divided into $100,000 for six months of project feasibility testing and $750,000 for two years of project development and prototyping. At the end of those two-and-a-half years it would be necessary to find another source of funding in order to commercialize the technology in either a military or private sector market. At that point it would be easier to convince investors to fund our company since a working prototype would already exist.

Purchase orders will be made in large-quantities to supply entire departments. As such, our device will be kept in stock at all times in order to expedite distribution to our customers. No training will be necessary to use our product, but customers will receive either an instruction

manual or a demo video with their purchase that should answer any questions they may have. After our product is on the market for two years, we will evaluate the need to bring out a new and improved model based on any changes in technology or customer complaints.

Design and Development plan

The ThermaTracker is composed of 3 main elements: a heart rate monitor, thermometer, and separate data display. All three of these components employ proven technology, confirming the feasibility of the design. The implementation of the technology must be optimized for use by football players, firefighters, and soldiers.

The heart rate monitor uses reflectance photoplethysmography to monitor changes in the volume of blood under the skin of the forehead. We will optimize the placement of the light sources and detector on the forehead and design a circuit to condition the signal, by amplifying the wave and removing noise. To achieve this, we will purchase LEDs and photodiodes and build a circuit with the parts, adjusting important parameters as necessary until we develop a system that is able to output a usable signal.

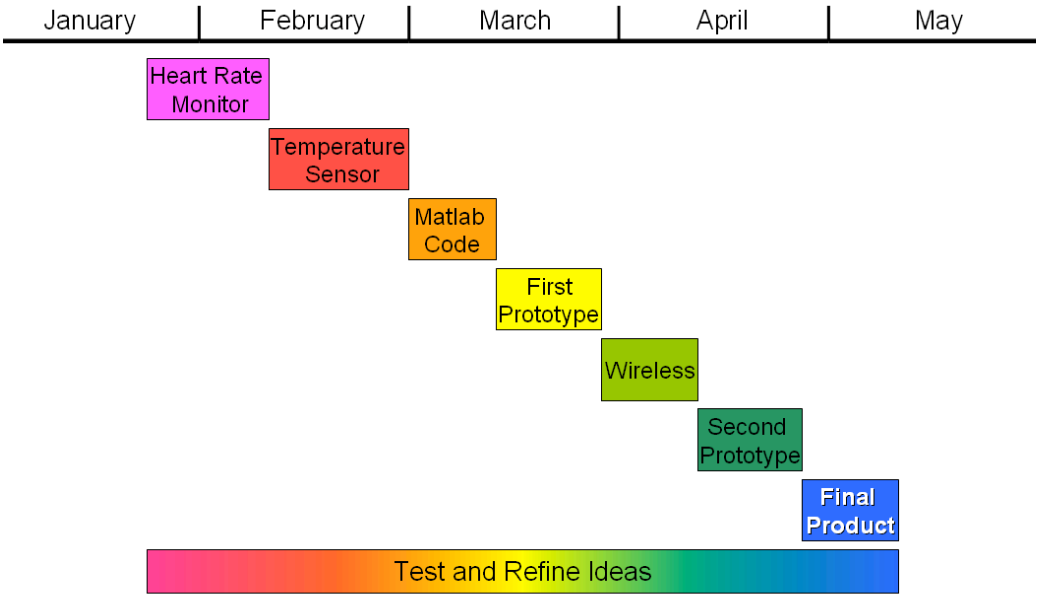
The temperature sensor will detect infrared emissions from the tympanic membrane. We will reverse engineer a commercially available in-ear thermometer for infants by studying the circuitry and then modify the components to fit the needs of our device. It will be necessary to design a circuit to amplify and denoise the signal from the IR detector. Additionally, we will study current earbuds to design an enclosure for the detector that will keep it in place properly, pointed directly at the tympanic membrane where it is most accurate.

Data collected from the heart rate monitor and temperature sensor will be sent via Bluetooth or other means to a nearby receiver, such as a laptop, which will be monitored by a team coach or trainer. The first step after developing the appropriate circuits for the heart rate and temperature sensors will be to write a program in Matlab to extract useful information from the signals and display the temperature and heart rate of each player. If any player's heart rate or temperature deviates from a safe range, an audio or visual alarm will be activated. In our second prototype, the outputs from the heart rate monitor and temperature sensor will be transmitted to the computer through Bluetooth or similar technology. We will develop a system for transmitting both pieces of information either simultaneously or alternately and modify the program to use inputs from the receiver.

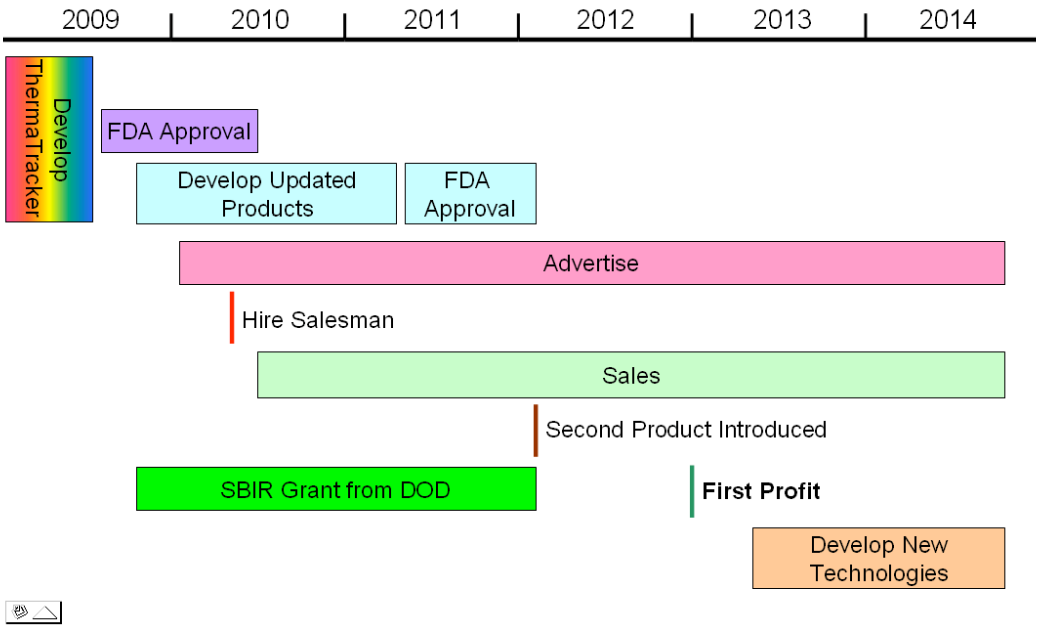
The ThermaTracker is intended to be able to attach to multiple types of helmet with minimal modifications by the user. We will model an example helmet and the sensors and transmitters in Solidworks and use this to design a method to attach the electronic components to the helmet so that they are secure and do not interfere with normal function.

After the ThermaTracker is fully designed and built, it will need to be submitted to the FDA approval (Class II), which should take approximately 1 to 2 years, because we are implementing already proven technologies. During that time, we will start developing new products to target other markets. Our first step will be to redesign the device so that it is incorporated into a visor or hat that will be suitable for runners. This will be an easy transition since the technology will be the same, only the packaging will be different. Once we begin to profit, in approximately 2013, we can look into new technologies to improve our product, such as monitors for environmental conditions or dehydration. In this way, we will be constantly progressing the ThermaTracker to stay on top of the market.

Short Term Timeline

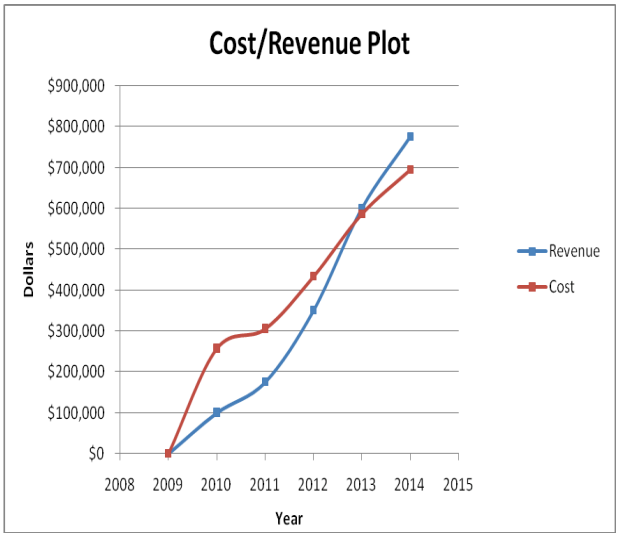


Long Term Timeline



Financial Projections

Revenue: 1.58 million American males participate in high school and collegiate football each year. We expect our product to be released by Q1 2010. We hope to capture about 1% of the market share within our first four years of release, at $50 MSRP to consumers, 15,800 units sold would bring in gross revenue of about $0.79 million from football. Military and firefighters are demographics of approximately 1.1 million each. Capturing a 1% market share within the first four years of product release would translate to 22,000 units sold at $50, bringing in additional gross revenue of $1.1 million for a total of $1.89 million. In 2012 we will release our version 2 of the ThermaTracker and we anticipate a jump in sales. Our projected break-even point is just before 2013.



Costs: As a start up, the five original founders of the company would work with minimum compensation until the product is on the market. Manufacturing costs would be one of our largest. Being associated with a large research university, much of our initial design and testing can be performed in university labs using provided materials and equipment saving some costs. Manufacturing is estimated to cost $30 per unit and possibly lower when returns to scale are taken into consideration during bulk processing. A sales representative would be hired to reach potential buyers. Also to be factored in are costs of leasing a workspace for our company along with associated costs such as utilities. Research and marketing costs are factored in as well.

Funding: Initial manufacturing expenses can be covered by loans. As product sales increase, the money can be used to repay loans and re-invested in manufacturing more products. Since our product has apparent application for military use, it is feasible that we apply for government grants to cover some initial expenses before our product is on the market.

	2009	2010	2011	2012	2013	2014
Units Sold	0	2000	3500	7000	12000	15500
Price	$50	$50	$50	$50	$50	$50
Total Revenue	$0	$100,000	$175,000	$350,000	$600,000	$775,000
COGS	$0	$60,000	$105,000	$210,000	$360,000	$465,000
R&D Costs	$500	$1,000	$2,000	$3,000	$4,000	$5,000
Marketing Costs	$0	$2,000	$4,000	$6,000	$8,000	$10,000
Salary Costs	$0	$120,000	$120,000	$140,000	$140,000	$140,000
Other Costs	$0	$75,000	$75,000	$75,000	$75,000	$75,000
Total Costs	$500	$258,000	$306,000	$434,000	$587,000	$695,000
Net Income	($500)	($158,000)	($131,000)	($84,000)	$13,000	$80,000