Technical Concept Report

Technical Summary

CASI, the acronym for Cardiac Arrest Stress Indicator, is a routinely-disposable patch designed to detect, ergo, prevent any affliction, specifically cardiovascular diseases, using elementary chemical properties and contemporary technological concepts. These integrate to provide accurate insight to monitor the stress level of an individual

1. The relation between apocrine sweat and stress
    a) Apocrine sweat along with eccrine sweat are two major body fluids secreted from our skin. Since eccrine sweat is mostly secreted for thermal regulation, apocrine sweat functions as a doorway for release during anxiety & stress-inducing situations.
    b) Differentiating it with the rest of the body fluids is the amount of sweating one does, which widely varies for an individual. We instead focused on the relative increase in apocrine sweating, through this device, to arrive at conclusions and suggestions for the user.
    c) The principles of apocrine secretion show a direct relationship between the relative increase in the amount to stress levels for an individual, which is mapped by CASI.

2. Principle of detection of Cardiac Arrest in the context of Apocrine Secretion
    a) The premise of the device is based on the above statement. It has been shown that patients suffering from a history of cardiovascular diseases have had significant apocrine secretion preceding an oncoming cardiovascular attack.
    b) This presented the case for CASI to work as a Cardiac Arrest Indicator for a population demographics of people with heart history. For the rest of the demographics, the device would simply work as a stress indicator since the probability for these individuals would be too volatile for the working of a precise indicator.

3. Variance in Properties of Solution (Soapy Water) and Solvent (Apocrine Sweat)
    a. In the layer where the tests are conducted, the solution is that of soapy water, since it has a high pH value of around 12.
    b. Apocrine sweat pH value ranges from about 6-7.5 which would turn the soapy water solution relatively more acidic with a gradual increase in its volume.

4. Direct Link between Heart Attacks and Cardiac Arrests
    a. While Cardiac Arrests and heart attacks are different cardiovascular diseases, Cardiac Arrests are more serious since, at their occurrence, the

heart stops beating and doesn't pump blood, but in a heart attack, the artery gets blocked.

b. However, the most common cause of a cardiac arrest is a heart attack, and multiple heart attacks increase the risk of sudden cardiac arrest drastically.
c. Therefore, CASI is designed to determine the erratic functioning of the heart and therefore detect any such possible cardiovascular disease, like Cardiac Arrests and heart attacks.

5. Misc. Concepts & Principles
    a) Sensors such as MEMS density sensor & pH sensor assist in determining the apocrine sweat activity and sends the data to a Bluetooth device connected with CASI which categorizes it according to its relative increase.
    b) The data is saved to the local server and is used to chart out sweat channels and activity of the user over a period of time, thus increasing accuracy in identifying any unexpected peaks.

Need Statement

The fundamental problem Rearden aspires to solve is a central part of integrating technology with our evolutionary responses to quantify our psychological state using physiological systems, in turn creating an efficient and futuristic medical care system.

The body's fluidic waste is one such medium that has excessive accuracy in presenting data of our body, and utilizing sweat is one area that modern scientists have not reasonably addressed. CASI would raise the bar of the industry and facilitate in-depth research into integrating data from these fluids to create a system that could warn us of possible dangers to an individual with a very low delay. Such advanced medical equipment could seriously decrease the death rate and economize, as well as, make the industry more efficient and dynamic.

Cardiac arrest strikes almost 600,000 people each year, which makes it the leading cause of death in the US behind cancer and heart disease. Following a cardiac arrest, every minute decreases the likelihood of living through one without a disability. Detecting the probability of a cardiac arrest is the issue that CASI was primarily designed to avert. During the onset of a heart attack, which is a prevalent cause of cardiac arrests, profuse sweating occurs, in all regions, which is utilized by CASI to alert the user, relative, or concerned doctor about it. As 60% of cardiac arrests occur outside a hospital setting, with the help of CASI, this percentage would drastically decrease, therefore, helping a vast majority of people get golden hour treatment.

The importance of our proposed concept can be understood on two levels - two different time frames. The first involves the near future. The short term perspective relates to a stress indicating device which impacts both the general public and the cardiovascular demographic, albeit by different temporary attachments. This would represent a

significant jump in our ability to quantify our physiological processes and could decrease the number of ‘false alert’ cases coming to already overworked, understaffed hospitals so that people with actual definite problems be provided with prioritized care.

The long term concept of CASI involves integrating multiple approaches to further physiological readings of the individual. Moreover, with the onset of space travel, the device could be used to monitor the well-being of spacefarers. With CASI, the monitoring of astronauts and other people invested in similar jobs which can take a toll on the mind of the individual would help considerably in red-flagging any probable cases of stress-induced diseases like severe anxiety, gastrointestinal problems, or even Alzheimer’s.

Another problem that CASI addresses is, as the patch concomitantly acts as a storage unit for the sweat, it helps in the social, hence indirectly, psychological upliftment of patients who have axillary hyperhidrosis, a condition which leads to abnormally excessive sweating in the armpit region. Patients with hyperhidrosis have reported an extremely significant low Quality Of Life. A few colleagues noted that Hyperhidrosis Disease Severity Scale (HDSS) and the 36-item Short Form test results showed that axillary hyperhidrosis, compared with hyperhidrosis of other regions, most severely impacted patients QOL.

Most importantly, CASI addresses the problem that every single person faces. By measuring stress, CASI would provide people with an immeasurable quantity. This reading would help the user recognize, and plan accordingly, what are stressful activities and which are not. Since apocrine sweat is a direct byproduct of stress, it is an accurate measurement of the psychological condition of the person, too.

To provide countermeasures to deal with this huge problem, there is an application compatible with the device connected through Bluetooth. The application helps alleviate stressful conditions and situations by providing therapeutic approaches for calming down, like listening to a song, reducing caffeine intake or spending time with relatives and friends. Furthermore, the application will be connected to the user’s therapist or doctor or even relative (can be chosen) and this data will further help improve prescriptions and doctors' suggestions, as they will be per the patients’ mental state.

Additionally, hospitals conduct sweat tests, mainly to detect the build-up of mucus in the lungs and other vital organs, largely to detect cystic fibrosis. To help in this assessment of eccrine sweat, in this case, the CASI-ß was designed to fundamentally separate both types of sweat which can be used for further experiments. This type of patch would also help in further research on the premise of sweat.

Current stress indicators mostly consist of watches built by tech companies. These watches measure stress by calculating the difference between regular heartbeats through photoplethysmography or PPG or simply, by optical means. Since PPG helps in measuring the variability in time intervals, it is an inaccurate measurement of the stress level of an

individual. This begs the need to come up with an innovative, practical, yet cheap and simple idea to alleviate one of humanity's daily troubles, and hence CASI.

Background Technology

CASI is a concept based on a number of different design paradigms, combining them to achieve a standard system of analyzing natural stress indicator, i.e. apocrine sweat. While there exist excellent devices and interfaces utilising key body indicators, CASI uses apocrine sweat as an indicator to make the overall process much more accurate and precise.

Existing Technology

CASI makes use of the following currently existing technologies:

1.Sensors: CASI uses several different sensors in order to-

a) Determine the pH of the solution in the patch, to assist in determining the concentration of Apocrine sweat. With a pH range of 2.22 to pH 11.81, a MEMS water quality assessment chip was used.
b) Measure apocrine sweat concentration at all times, using a MEMS density and viscosity sensor, working on resonance. The sensor has a range of 750 - 1350 kg/m^3 and viscosity range of 1 - 40mPas.
c) Measurement of heartbeat and oxygen saturation levels by a pulse oximetry sensor in the CASI-ß patches' pouch.

2. Bluetooth Connectivity: In order to make the entire user experience much more satisfactory and pleasant, the patches will be connected to your phone through a Bluetooth transmitter. The transmitter will be a part of the permanent rim attachment.

3. Microchannel Transportation: This technology too will be used in the CASI-ß patch, for the collection of sweat from the skin's surface, that will direct it into the central tubule of NASA's patented microfluidic channel.

Relevant Patents

While a product like CASI is entirely unique on its own, there is other similar research, to either, achieve the same results by different methods, or similar techniques for different purposes.
The most comparable patents relevant in the context of CASI are mentioned below:

- Devices and methods for treating psychological disorders - US20110245633A1
    - The patent was filed by a researcher at MIT in Brain and Cognitive Sciences; Robert Goldberg and associate, Shailendra Yadav, in the name of Neumitra LLC. The procedure of determining someone's stress level was through electrodermal activity, which is an inaccurate way to measure stress levels as EDA can vary for different causes, like temperature and humidity.

- Method and system for assessing mental state - WO2016201499A1
    - Licensed to MediBio, this idea is an outstanding way to assess mental health, albeit, it focuses on key aspects which can be affected due to multiple reasons. This helped us understand, and eventually incorporate, that focusing on a few things which have direct correlations to the result we desire provides accurate and precise objective data.

- Methods for treating psychiatric disorders using light energy - US20130211183A1
    - Invented by Fredric Schiffer, this method uses light therapies by subjecting the individual to light energy to treat psychiatric disorders other than depression. Light energy specifically refers to NIR or near-infrared light. However, this method fails to detect any psychological ailment with the device and tries to deal with severe disorders, with ways that themselves have been reported as causes of mild. exasperating issues like headaches, irritation, nausea, or headache.

- Method and apparatus for measuring acute stress - WO2003084402A1

- Wafer Level Microchannel fabrication process for Lab-on-a-Chip devices
    - NASA's patented mechanical and fluid systems, designed to collect and separate amino acids allowed us to incorporate this into our own design. Different species of analyte molecules will take a longer time to travel along the tube as they have a longer retention time due to interaction with the columnar chemistry.

Competing Technologies

Current industry standards for cardiac arrest devices are nearly non-existent at a wearable device level while stress indicators work on smartwatches from tech companies like Apple, Samsung, Garmin, Muse & Fitbit among others, and work on either of the two major premises, both of which do not match the expected standards of the contemporary technology.

Garmin uses the Firstbeat algorithm to monitor the time interval between each heartbeat. This is called heart rate variability (HRV), which tracks any changes in your heart rate between physical activities. Other trackers such as Apple Watch, use your heart rate information to calculate the resting heart rate. In addition, it also calculates how long it takes you to recover after your workout. These two pieces of information combine to predict where your heart stands and an increase in the heart rate would help confirm stress levels.

Any mechanism, especially in the healthcare industry, is judged based on the likelihood of it being right. Several medical industries experts have corroborated the fact that heart rate

variability is an accurate measure of the health of our autonomic nervous system. In theory, HRV as a system accounts for all variables. In practical applications, like the smartwatches mentioned above, variables & discrepancies appear in the medium through which the data is entered. Moreover, Elite HRV, affiliated with the Harvard Medical School, has further confirmed that most smartwatches are not reliable for accurate HRV readings, stating that even watches which are 'ECG accurate' do not specify on what parameters these are true. Since watches detect HRV through heart rates, consumer reviews have informed that many a time, one can 'feign stress' by breathing rapidly, hence accelerating the heartbeat.

Muse, on the other hand, works as a light headband with EEG sensors which detect brain activity, in some format, and compares stress levels. Without going into details, the complications occur due to its high energy requirements, since one can only wear the headgear for 6-7 minutes at a stretch, making it not an indicator but rather a device one wears to calm down or meditate.

Multiple products and companies were analysed to see what functions they can perform while at the same time keeping in mind the ease of use and purposefulness in mind and compared in relation to CASI. The factors considered were; real-time analysis, Stress analysis, sweat storage, realtime cardiac prevention/analysis, wearability, consumer base, and cost-effectiveness. CASI is designed to fulfil all these basic requirements one would expect from a product with a similar premise. One more thing that was noticed, is because CASI works on a simple yet elegant principle, it is the only product which is cost-effective and the most accurate one too.

Concept Details

Conceived Function

CASI was, above all, designed to discern and mitigate cardiovascular diseases, which are introduced at their onset with a significant increase in sweating, and stressful sweating too. As stress sweat is different in chemical properties and can be separately analysed by differentiating it from the normal thermoregulatory sweating, we devised a way to measure the apocrine or stress sweat by utilising a few simple scientific concepts. The means of gathering this data need not be limited to density and pH sensors and can further be extended to ECG readings on the chest in the future.

Additionally, as we are analysing a byproduct of stress, we can, therefore, quantify the degree of stress an individual is facing by measuring the volume and concentration of apocrine sweat through density and pH sensors. This will help in the general public deal and cope with stress as relative 'values' of stress will be provided through the app on the user's personal device.

Besides these two key functions, CASI will also help in research through the additional function of separation in the CASI-ß patch. As both eccrine and apocrine sweat will be

separated, with the user's approval, the sweat can be collected and can be subjected to natural biological sweat tests or even pheromonal research, where sweat is given the most attention.

CASI would side by side also act as a way to curb stress levels of an individual through the connected application, as was mentioned earlier.

Operations

CASI is essentially a butterfly-shaped patch which will be placed under the armpit of the wearer. The permanent rim attachment has a slot for the temporary patches, with a sticky adhesive on the inside to prevent loose fit.

First Layer Functioning: In the CASI-α patch, the first layer is made of a semipermeable membrane with a valve. This valve prevents the backflow of the water solution into which the sweat dissolves. The semipermeable membrane, too, prevents the entering of any unwanted denser substance like mucus to enter into the patch. Both types of sweat in this variant move into a layer of soapy water.
In the CASI-ß patch, the first layer consists of small microchannels that lead to the central tube. The central tube has NASA's patented technology of microfluidic separation of chemicals by reaction with columnar chemistry.

Second Layer Functioning: In the generalised patch, or CASI-α, the solution of soapy water and sweat are then subjected to pressure by secretions of further apocrine sweat (or eccrine) from the skin. As the solution is followed by another semipermeable membrane which allows the passage of only relatively less dense substances (in this case eccrine sweat), eccrine sweat passes onto the next layer while apocrine sweat is left in the soapy water solution. Here the stress sweat is subjected to tests and is sensed accordingly by the sensor which fits perfectly into the slot in the slot of the temporary patch.
In the specialised patch, CASI-ß, however, the sweat has to pass through the straight tube which has a semipermeable membrane along the length of the curved surface. The retention time of amino acidic substances, hence, eccrine sweat is greater. This allows for apocrine sweat to pass directly into the third layer. Due to larger retention time of eccrine sweat, it slowly diffuses through osmosis into the surrounding, layer i.e. the second layer with water.

Third Layer Functioning: In CASI-α eccrine sweat passes through the semipermeable membrane from the second to the current, and third layer for storage and disposal.
In CASI-ß, however, apocrine sweat reaches the third layer through the microchannel and is dissolved in a soapy solution. Here this apocrine sweat too is subjected to pH and density & viscosity tests.

Additionally, in the specialised patch, there is a pulse oximetry sensor on the strap of the

permanent rim. This will help determine the heartbeat and the oxygen saturation levels in the blood of the patient.

Proposed Development

Though CASI may be used as it is, we propose certain options for the development of the product in different stages of its future. This development varies from changes in the firmware to changes in its very function:

1. The first modification we conceived for CASI was in widening its application at a certain time in the future when enough CASI units would be in use in the general public.
    A. Since sudden spikes in stress levels would be reflected on the app, and in the server, the majority of cases of accidents and emergencies, there would be an expected spike in stress levels of the people in the immediate vicinity, which could be monitored by an algorithm and be used to contact first responders.
    B. Similarly, through the application users would be given real-time data of, say, a road in general with high-speed lanes, leading people to be very stressed out on the road. Using a map to indicate such information and presenting it to the user would prove to be highly simplified data which could help the individual in multiple ways.
    C. Obviously, it would take a certain amount of data to identify cases of actual accidents and emergencies and differentiate them from other cases of surprises, etc. It would also require a certain level of calibration in the server, to identify such spikes.
    D. Its relation to data privacy would play an interesting role. Preliminarily, we will give people the option of choosing whether to use their information for the above cause, offering minor incentives such as discounts or special features.

2. We also propose developments in the firmware and the server, with the usage of machine learning and neural networks, to improve the accuracy of predictions and inferences and optimize CASI as a whole.

3. Other modifications would be in regard to specific components. With the development in density and pH sensing equipment, CASI would, post-experimenting, modify and change its sensors for future batches.

4. Additionally, further ways of determining physiological changes can be added and connected to the tying strap. As the entire patch is tied with a strap on the shoulder, further expansion could add sensors directly to the heart. For example, ECG sensors directly on the chest would significantly improve results and conspicuously, aid in better detection of cardiac arrests. It would further help in the collection of

more data. Similarly, many more body secretions and physiological biological processes can be studied in a similar way to quantify further mental and health processes, helping Rearden grow.

Experiments Required:

Several components of CASI's design is used in the industry while some have been theoretically proven to function properly, whose combination may be tested by experiments, which we describe below. These also include certain experiments required to obtain certain values for calibrating and establishing relations in our product:

1. Definite Relation between Critical Apocrine Sweat Amount with various variables
    a. The algorithm utilised by CASI works on a general principle, depending upon the anomalies in apocrine sweat secretion, as cited in several medical papers such as the Harvard Health Letter which gives a general proportion in a certain specific case and is thus likely to work as desired.
    b. It is still in need of verification, though. A detailed study could give a base for a relation between the critical secretion amount and how it depends on variables such as Age, Body Mass Index, Temperature, Presence of health issues all of which may cause anomalies in blood pressure, cortisol and adrenaline levels.

2. Increased Accuracy in Density & pH range of Apocrine Sweat
    a) Even though CASI has a base range of average density & pH, which would be used in all its functions, the range has been calculated by taking the average protein composition and its density from different experiments & sources, which themselves have not been used in the industry that often.
    b) So, experiments in the specific case of apocrine sweat, instead of its constituents, would result in a more accurate and realistic, which CASI can use, resulting in optimal functioning.

3. Quantifying Probability of Cardiac Arrest with Anomalies in Apocrine Sweat Secretion
    a) Various sources, such as Ms Catherine J.Ryan of University of Illinois, Chicago, have conducted various experiments to deduce relations between these anomalies and heart attack, also making credible a relationship between these anomalies and Cardiac Arrest.
    b) An experiment of similar sorts, with a focus on Cardiac Arrest, would help us to better quantify the same, and utilise it in CASI.

4. Quantifying Stress at Objective Levels through Apocrine Sweat
    a. Users will be asked to rate how their day went on a scale ranging from stressful to happy or cheerful. If their day were to go stressful, they would be asked to describe their day, however briefly they want to, with the

promise that their information will be kept confidential. Using machine learning, a software will determine an absolute amount of apocrine sweat secretion and the type of stress the individual went through, like daily stressors, major life events, or work-related stress to name a few.

b. This kind of study would better help the application to suggest better and more innovative and appropriate countermeasures to help the individual deal with their stress

Technical and Scientific Merits

1. What sets CASI apart from other systems is that it uses a new premise of a stress indicator by analyzing stress-induced apocrine sweat over common industry usage of variants of Heart Rate Variability (HRV). Consider the operation of CASI. Every step works on the basis of algorithms and natural body responses, thus making it nearly impossible to manipulate or by mistake corrupt data, something which could be easily done in current industry standards of stress indicators. This design takes into account chemical properties of sweat and using NASA's patented technology in the CASI-ß patch, and semipermeable membranes in the CASI-α patch efficiently monitor the eccrine and apocrine sweat levels based on their chemical composition, using a passive natural process, and in one case, separate them too.

2. A major point in CASI's favour is its temporary attachments. Since the rim is ideally always attached, to a region representing a sweat hotspot of our body, and requires no charging and the patches are changed within a span of seconds, the amount of live time data which CASI uses, beats the amount of data that, say, a Garmin or an Apple watch obtains. More data results in more accurate inferences and allows easy predictions of the body norms. This is of particular help in finding anomalies.

3. Another advantage is the ease with which one can use CASI. While an Apple Watch requires an iPhone, Garmin and Fitbit often get damaged easily with many interface parts causing problems in the device. Since the user would only interact with CASI when it is inserted in the rim, and due to the general elasticity of CASI, the same problems would not appear in this product.

4. Further advantages of using CASI include the fact that CASI has negligible impact on the environment due to the material selection. The permanent attachment along with the sensors would only be disposed of in a month, while the temporary patch of CASI-α is completely biodegradable.

5. Possibly the biggest advantage of a product like CASI is the goals it achieves in a price that is affordable to everyone. This allows for a wide consumer base and is not restricted to the richer market segment, unlike Neumitra's Bandu watch, to state an example.