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Algorithms Embedded Personal Medical Device For Smart Healthcare

An Interactive Qualifying Project Report
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Abstract

This project studies various aspects of algorithm embedded personal medical devices including applications, regulations and social acceptance. Several products on market are investigated. FDA and FCC regulations and their impacts on lifecycle of product development are discussed. A survey was designed and distributed among different locations. The results provided insights on designing smart healthcare devices for product developers. Social acceptance of using algorithm embedded medical devices for health monitoring is also analyzed through survey responses.

Acknowledgement

I would like to acknowledge and extend my most sincere gratitude to the following persons who have made the completion of this Interactive Qualifying Project possible: Professor Hakim, who gave me the chance to propose my own topic for this Interactive Qualifying Project; All the other members of FIVOLTS: Yichao Joy Xu, Jun Wang, Zhongjie Wu, and Quanquan Ma, who put great efforts into our drowsiness control center project and help make this wonderful product real; Our project advisor, Professor Clancy, Professor Jarvis and Professor Huang, who guide our team for the Cornell Cup competition; And to all the 1054 people who answered my survey, they helped me finishing up the most important part of the project.

Table of Contents

List of Figures

List of Tables

1. Executive Summary

Healthcare is always one of the most important topics in our daily life. As wireless technologies are getting more and more popular, people start to think a way to reduce the cost of healthcare: wear wireless sensors for long-term health monitoring. As more algorithms for analyze different health conditions are being researched in many biomedical labs, it's time to bring those from research labs to daily life. For designing an algorithm embedded medical devices, several things needs to be considered. In this project, those things needed for such device is studied.

In the beginning of this report, the most important factors affecting new product development are discussed through literature review. Popular technologies used in wireless personal medical devices are also studied. After finish the above tasks, FDA and FCC regulations and requirements are also included because they are very important in a life cycle of medical devices. To design a new product for smart healthcare, investigate similar products under category of algorithm embedded medical devices on current market is also important, as well as the concerns and regulatory issues on FDA. After finishing these two tasks for the report, a survey is designed to collect various opinions on social acceptance and product design on a prototype device of algorithm embedded medical devices. In the last part of this project, results from all the survey responses are discussed and analyzed. The survey shows some interesting trends on people's opinions and they provide some useful insights for product developers.

2. Introduction

As wireless sensor technologies continue to develop, it has the potential to change our lifestyle. One highly possible application enables wireless sensor network is the combination of biomedical sensors and consumer electronics technologies which would allow people to be constantly monitored. Long-term monitoring will greatly increase early detection of emergency conditions and diseases for at risk patients and also provide wide range of healthcare services for people with various degrees of cognitive and physical disabilities [12]. Lots of different people could benefit from it. For example, for the elderly and chronically ill, the monitoring system could send emergency signals to the hospital when critical condition is detected. For the families in which both parents have to work, the system could monitor their babies and all the important information would send to them wirelessly.

Nowadays as more people start to care about their health conditions, various personal medical devices were designed and sold in the market. However, the functionalities of most of these devices are very simple: they only monitor uses' vital signals. Some of the heart monitoring devices might tell user if his or her heart rate is good, poor or normal, but this is not enough. It takes efforts for normal people without prior knowledge to learn how to interpret such signals or tell the correct health conditions based on them. Design algorithms that determine health conditions are one research area in many major universities. There are various research paper published on ways of interpreting vital signals and how to extract useful information from them and determine certain health conditions. Some of the signal processing techniques are mature enough so that actual device contains certain algorithms start to appear on the consumer electronics market.

In September of 2011, the first Cornell Cup USA[1] is announced and each team could design almost anything using embedded techniques. Team FIVOLTS was formed to compete for the Cornell Cup and our proposed project was selected to be one of the finalists. The idea of our design came from the Major Qualifying Project that two of our team members were doing: Design algorithms to determine fatigue or drowsiness levels based on heart rate variability. For the competition, we decided to design a wireless sensor with a target embedded computer to monitor driving drowsiness and if possible, extend the functionalities of this device and implement more algorithms into it and make it an ultimate personal health manager.

In this Interactive Qualifying Project, there are two major goals: investigate the applications, social acceptance, and regulations of algorithms embedded personal medical devices; provide design suggestions for Team FIVOLTS on developing the Drowsiness Control Center.

[1] Cornell Cup USA, presented by Intel, is a college-level embedded design competition created to empower student teams to become the inventors of the newest innovative applications of embedded technology. The inaugural competition will be held in May 2012 at Walt Disney World and will give teams the opportunity to win up to $10,000.

3. Background and Literature Review

3.1 Introduction

In this section, success factors of new product innovation and development are investigated through literature review. A series of different technologies used on algorithms embedded personal medical devices are reviewed. Regulations on personal medical devices are also discussed.

3.2 New Product Development

There are two most important things in new product development. The first is to do the right projects first, and the second is to do the project right [1]. Doing the right project is usually captured by external or environmental success factors include characteristics of the new product's market, technologies, and competitive situation. Doing projects right focuses on the process factors and they are usually the invisible ones. Studies of hundreds of different cases reveal the differences between successful and unsuccessful projects. Many of the factors are controllable. In the controllable factors, there are 8 common denominators of successful new product projects [2].

"Up-Front Homework Pays Off" is the first factor. There are many projects move from the idea stage right into development with little or no assessment or up-front homework. Result of this approach is usually disastrous. Research shows that inadequate up-front homework is a major reason for failure [2], and other studies show that solid up-front homework drives up new product success rates significantly. "Build in the Voice of the Customer" is the second factor. Successful teams usually have a slave-like dedication to the voice of the customer. New product projects that feature high-quality marketing actions almost double the success rates, and 70% higher in market share, than those projects with poor marketing actions. "Seek Differentiated, Superior Products" is the third one and it is also one of the top success factors [2]. Delivering a differentiated product with unique customer benefits and superior value for the user could lead to a superior product that has five times the success rate, four times the market share, and four times the profitability as one product that lacks this ingredient.

"Demand Sharp, Stable, and Early Product Definition" is the fourth factor. Early and stable product definition is consistently used as a key to success [2]. A successful project team should define the product's target market, the concept, benefits and positioning, requirement, features and specs before development. "Plan and Resource the Market Launch...Early in the Game!" is the fifth factor [2]. A strong market launch underlies a successful product and this factor is not surprising to us. A quality launch should be well planned, properly resourced, and well executed. “Build Tough GO/Kill Decision Points into Your Process - a Funnel, not a Tunnel" is the sixth factor. Sometimes when projects move deeply into development, there is very little change that it will ever be killed. Having tough go/kill decision points has a strong relation with the company's profit level. Tough go/kill decision points are the weakest ingredients of all process factors being studied [2]. Thus new project teams should pay extra attention to this factor.

The second last factor is "Organize Around True Cross-Functional Projects Teams" [2]. Many studies have shown that good organizational design (having accountable, dedicated, supported cross-functional teams with strong leaders) is strongly linked to success. The last factor is "Build an International Orientation into Your New Product

Process" [2]. This means an international orientation, which include international teams, multi-country market researches, and global/"glocal" products.

3.3 Technologies Used in Personal Medical Devices

3.3.1 Photoplethysmography (PPG)

Photoplethysmography (PPG) is a non-invasive optical measurement technique and it is widely used in pulse oximetry. It uses a light source and a photo detector to measure blood volume changes in the microvascular bed of tissue: a light source that illuminates the tissue, and then a photo detector would measure the amount of light that associated with changes in perfusion in the catchment volume. [10] For this project, an infrared LED is used as the light source and a photo diode is used as the photo detector. A diode is a device that has two electrodes and only allows current to flow in one direction. A light emitting diode (LED) is a P-N junction device that emits light when it is forward-biased. A photo-detector diode is a semiconductor light sensor that generates a current proportional to the light intensity it receives. Since the regular incandescent bulbs would emit light over a large range of bandwidth, an LED only emits light of a specific wavelength. For PPG measurement, a corresponding photo-detector diode with the matching wavelength as the LED is usually used.

When a PPG sensor (a light emitter diode and a photo detector) is placed on somewhere on a human body, for example, on a finger, the emitter emits light into the tissue and the detector will pick up the amount of light that reflected back from the tissue. There are many different factors that would affect the light after it is sent from the LED and before it gets reflected to the detector. The blood volume and the surrounding tissue such as the blood vessel wall have the largest impact on the light that gets reflected. The reflected light intensity decreases as the blood volume increases in the region where the diodes are placed. Therefore, as the blood volume varies according to the cardiac output, the reflected light intensity respectively gets affected. In addition, there is another steadier component that is due to the tissues and the average amount of blood volume that always remain in certain sections of the artery. As a result, the raw PPG wave contains an alternating current (AC) component that is superimposed onto a large, quasi-DC (direct current) component. [10] Usually the amount of AC component is much smaller than the DC component, so some amplification and filtering circuit is needed in order to extract the pulse rate from raw PPG waveform.

3.3.2 Bluetooth and ZigBee

Both Bluetooth and ZigBee are standards in Wireless Personal Area Network (WPAN). Bluetooth has been a boon to all devices in the IEEE 802.15 working group. ZigBee, as a technology within IEEE 802.15.4, was designed as a low-power, low-cost, and low-speed solution. Both Bluetooth and ZigBee operate in the unlicensed 2.4 GHz spectrum, but ZigBee only operate at reduced speeds at 915MHz and 868MHz. As for power consumption, ZigBee offers only 30mW but Bluetooth needs 100mW [11]. The new Bluetooth 2.1 can operate in a maximum range of 30m. On the other hand, ZigBee allows a maximum range of 75m since it was designed to enable "home and industry automation". For data transfer rate, Bluetooth reaches a maximum rate of 3Mbps. ZigBee sacrifices data rates for power savings and it only transmit 20-250Kbps [11]. As for the cost, ZigBee is about $1 cheaper than Bluetooth. To conclude, when a very high data transfer rate is necessary, Bluetooth is a good choice. When the need of data rate is very low and requires a longer battery life, ZigBee is obviously better choice over Bluetooth.

3.4 Regulation

U.S. Food and Drug Administration (FDA) regulate all the medical devices on the marketplace. All the medical devices have to be registered and approved by FDA before they can be put on sale. If the device uses radio frequency for wireless communication, it also needs to obey the rules made by the Federal Communication Commission (FCC). FDA regulates a broad range of medical devices, including complicated, high-risk medical devices, like artificial hearts, and relatively simple, low-risk devices, like tongue depressors, as well as devices that fall somewhere in between, like sutures [14]. FDA has the authority to regulate all the above medical devices before and after they reach the marketplace.

All the registered medical devices are classified into three different classes corresponding to their risks. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. Dental floss is an example of a Class I device. Class II devices are higher risk devices than Class I and they require greater regulatory controls to provide reasonable assurance of the device’s safety and effectiveness. Condoms are one example of Class II devices. Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control. Class III devices must typically be approved by FDA before they are marketed. Replacement heart valves are one example of Class III devices.

When FDA review is needed prior to marketing a medical device, FDA will either “clear” or “approve” the device. To be more specific, FDA "clear" the device after reviewing a premarket notification, and "approve" the device after reviewing a premarket approval (PMA) application that has been submitted to FDA. Other than that, the status is known as a 510(k) (named for a section in the Food, Drug, and Cosmetic Act), which means it has been filed with FDA. Whether a 510(k) or a PMA application needs to be filed depends on the classification of the medical device. To acquire clearance to market a device using the 510(k) pathway, the submitter of the 510(k) must show that the medical device is "substantially equivalent" to a device that is already legally marketed for the same use. To acquire approval of a device through a PMA application, the PMA applicant must provide reasonable assurance of the device's safety and effectiveness.

There are usually four types of medical devices: FDA-listed medical devices, 510(k) exempt medical devices, cleared medical devices, and approved medical devices. FDA-listed medical devices is a medical device is FDA-listed if the firm that manufactures or distributes the medical device has successfully completed an online listing for the device through the FDA Unified Registration and Listing System (FURLS). (While manufacturers are the entities that typically list medical devices, they are not the only entities responsible for doing so.) 510(k) exempt medical devices are medical devices that do not require FDA review before the devices are marketed are considered "510(k) exempt." These medical devices are mostly low-risk, Class I devices and some Class II devices that have been determined not to require a 510(k) to provide a reasonable assurance of safety and effectiveness. These devices are exempt from complying with premarket notification requirements subject to the limitations on exemptions; however, they are not exempt from certain general controls. For example, 510(k) exempt devices must be suitable for their intended use, must be adequately packaged and properly labeled, must have establishment registration and device listing forms on file with FDA, and must be manufactured under a quality system (with the exception of a small number of class I devices that are subject only to complaint files and general recordkeeping requirements).

Under all the categories of medical devices regulated by FDA, only two out of twelve categories are relative to FIVOTS' design project: health and consumer devices, and mobile medical applications. FDA regulates medical devices that consumers use themselves without professional medical assistance in the same way as other medical devices. But the agency also focuses on how people can use these devices safely and effectively. In addition to work done throughout the medical device approval process, the Home Health Care Committee reviews what has been done to address problems when devices are used in the home and recommends further actions to ensure consumers can use the devices safely and effectively.

The mobile medical applications category is a relatively new, and there are no formal FDA regulations on them yet. Mobile applications are software programs that run on smartphones and other mobile communications devices. Development of mobile medical applications is opening new and innovative ways for technology to improve health and health care. Consumers use mobile medical applications to manage their own health and wellness. Health care professionals are using these applications to improve and facilitate patient care. These applications include a wide range of functions from allowing individuals to monitor their calorie intake for healthy weight maintenance, to allowing doctors to view a patient's X-rays on their mobile communications device. The FDA encourages further development of mobile medical apps that improve health care and provide consumers and health care professionals with valuable health information very quickly. The FDA has a public health responsibility to oversee the safety and effectiveness of a small subset of mobile medical applications that present a potential risk to patients if they do not work as intended. In order to balance patient safety with innovation, it is important for the FDA to provide manufacturers and developers of mobile medical applications with a clear and predictable outlines of our expectations. Through draft guidance release on July 19, 2011 the FDA defined a small subset of mobile medical apps that may impact on the performance or functionality of currently regulated medical devices and as such, will require FDA oversight [16].

3.5 Conclusion

In this section, three areas of algorithms embedded personal medical devices are investigated: factors that affect new product development; key technologies used in this type of devices, and regulations and restrictions on developing such medical device. In the next chapter, a detailed look into the applications of algorithms embedded personal medical devices is offered, and one survey on product development of this kind of device is designed according to the eight factors mentioned in this chapter.

4. Methodology

4.1 Objectives

There are three objectives for this chapter: explore various applications on algorithm embedded personal medical devices, discuss problems and challenges facing the regulations on those devices, and investigate social acceptance of this kind of devices through survey and collect different opinions for the design of Drowsiness Control Center.

4.2 Tasks

4.2.1 Applications

As a relatively new member of personal medical devices and consumer electronics markets, not very many relative products that have their own algorithms can be found. In this section, several main competitors are discussed. One of the products is very similar to what FIVOTS' project, but not officially released yet; one of them is already on market, but with different uses; third one is on market as well. In addition, there is one app found on iPhone's app store and it seems to contain some similar algorithms with FIVOLTS. In the last part, a prototype design from FIVOTS is also described.

Figure 1 shows a multi-sensor health tracking wrist band called Basis. It is designed by a company called BASIS Science. It contains different sensors includes a pulse sensor, 3D Accelerometer (movement, including sleep patterns), temperature and Galvanic Skin Response (sweat). Data captured can be analyzed on the web or on mobile devices. There is no release date yet for this device and it is now available for pre-order at $199 [5]. The company says user's data is completely private but easy to share when you want to. Humorous examples provided include: see just how stressed out you are during the weekly project status meeting; show your husband exactly what time his snoring woke you up; make your friends jealous with how relaxed you were at the 19th hole. In the

Consumer Electronics Show of 2012, Basis was one of the Innovations Honorees under Health and Wellness category.

Figure 1 Basis Multi-Sensor Health Monitoring Watch

Figure 2 shows a product from ZEO, it is a comprehensive system to help user to improve his/her sleep. It's composed of a lightweight wireless headband, a bedside display, a set of online analytical tools, and an email-based personalized coaching program. This product is already available for order at $149. Several features of this product include: shows how well the user really sleep, and helps user find ways to improve sleep; SmartWake™Alarm system gently wakes the user up at the optimal point in the sleep cycle; never wake up late, always wake refreshed; mobile app available for iPhone and Android smartphones; ZQ Sleep Score summarizes the sleep quality in a single objective number; analyze user's sleep patterns using its mobile app, online tools and expert sleep coaching program; find and adjust factors that are stealing user's Deep, REM &total sleep time; 7 Steps to Sleep Fitness™coaching program included, giving every user a personalized guidance to help his/her sleep better. The rating on Amazon is 4 out of 5 starts.

Figure 2 ZEO Sleep Manager

Figure 3 is DSS system developed by a company called Seeing Machines. Some features of this product include manage driver fatigue; detect driver distraction, and real-time driver feedback. This is how it works: the DSS-IVS (in vehicle system) measures the eyelid opening of the driver, and based on this data derives the drowsiness state. No sensors need to be worn by the driver; a remote sensor on the dashboard observes the face of the driver and measures eyelid closure. There is also no calibration procedure required for new drivers. This means any driver can get behind the wheel without any time consuming calibration, annoying sensor attachment process, or any special knowledge about the system. A downside of this product is that when driver is wearing sunglasses, the facial detection no longer works.

Figure 3 Seeing Machines DSS

In addition to the above three products, there is one app found in IPhone's app store named "Stress Check". It has two versions: one for free but with advertisements, and one for $.99 without advertisements. Figure 4 shows two screen shots for this app. The first step is to enter user's birth date and sex information, and then stress level is measured by putting one finger on the camera. It can take quite long for the process to be completed. On my case, it took almost 3 minutes to finish a full calculation. The stress level estimate is pretty accurate according to all the ratings and feedbacks. The algorithm used in this app is definitely very good, but the disadvantage is it takes too long to finish one computing cycle and it's impossible for user to use it as a long term monitoring device.

Figure 4 Free Version of IPhone App "Stress Check"

Figure 5 shows a prototype picture of our design for Cornell Cup USA. It consists of a wireless sensor and a drowsiness level manager. The sensor must be touching the skin in order to get the heart pulse signals. PPG is the main technique used here and wireless transmission protocol used here is ZigBee. The look of the sensor will be customizable and used for different situations. Like the DSS system by Seeing Machines, Drowsiness Control Center is also able to determine driving drowsiness and give real-time feedback to the driver. The algorithms determine drowsiness levels are developed by correlating heart rate variability with fatigue levels using a cognitive task called N-back. This is probably the first project that does this. And we are very proud to be selected as one of the 20 finalists in the nation.

Drowsiness Control Center is only one of our goals as FIVOLTS. Our plan is to distribute many of our wireless sensors for free to a certain amount of people, and collect their vital signals to develop other useful algorithm that tells you other health conditions. Smartphones will be used as a data collect platform and all the physiological data will be stored in our database. This seems very similar to Basis, but we don't know them until 2 months ago when they appeared on the Consumer Electronics Show of 2012. One advantage of our product is that we make customizable sensors so that more people would like to use our product.

Figure 5 Prototype of Drowsiness Control Center

4.2.2 New Product Development Concerns and Regulatory Issues

The lifecycle of a new medical product is shown in Figure 6. Concept of the product and the proof of concept are the earliest stages. As soon as product development starts, the FDA regulation should start and would continue all the way till the market release. Clinical trial design and FDA negotiations is the next step after product development and pre-clinical testing stage. There are many different types of product pre-clinical testing. Typical ones including component verification, electrical parameter testing, software validation, system integration testing, environmental testing, electromagnetic compatibility testing, biocompatibility testing, packaging verification, sterilization validation, human factors/usability testing, and animal studies. Radio Frequency Registrations with FCC and medical device regulatory submissions with FDA starts after finishing up the Clinical Trials. After finishing all the above steps, the product is ready for market release.

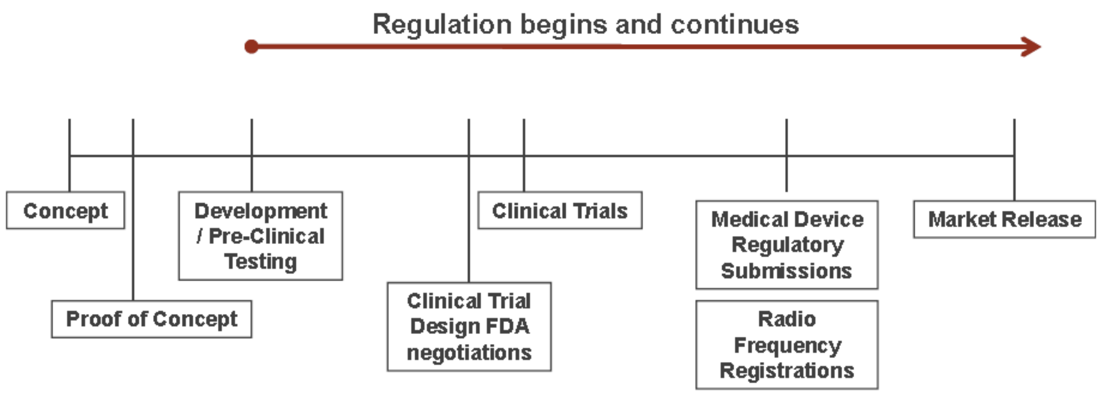

Figure 6 New Medical Technology Development Lifecycle [17]

As one of the relatively new area in medical devices, FDA put wireless healthcare devices under its "mission critical" applied research areas. In 2010, the Medical Device Innovation Council under FDA established two settings, wireless healthcare and home use of devices, to address the unmet public health need. Since patents covering wireless aspects of medical technology are growing at a much faster rate than other device patents, both of FDA and FCC are now working together to bring forward innovative wireless technologies for healthcare faster.

On the other hand, as the area of wireless healthcare grows faster and faster, state-of-art wireless devices may be so novel that there may be no prior similar device(s) to base on for the FDA approval process. FDA wants higher level of evidence for wireless devices since they believe wireless is inherently less reliable than wired communication. As for wireless monitoring devices, FDA believes that their diagnostic data is dangerous and they want to know what exactly is the device monitoring/measuring, how often, and most importantly what will the user do with the information. Proof of information is used in a correct way and clinical benefits in it are essential for FDA approval. To be more specific, for those medical devices with embedded algorithms, the paradigm for them is similar with diagnostic devices, which relies heavily on the intended usage. For example, if the device measures some physiological data and inaccurate information would only cause small risk to patients, this can be counterbalanced by some small benefits. If the algorithm inside the device can predict heart failure risk, then misdiagnosis can cause much greater risks to patients, thus larger benefits must be provided to the patients to counterbalance the risk.

Other than the standard safety and effectiveness considerations, FDA has some additional concerns for the wireless healthcare devices including wireless coexistence/performance, data integrity, security and electromagnetic compatibility. Since all the above concerns need to be considered in the product development stage, FDA recommends that they can be included in the product design requirement, verification, validation and risk management processes and procedures. If the device has wireless transmission of critical medical device alarms, continuous physiological waveform data, real-time or wireless control of therapeutic medical devices, time-critical medical telemetry, FDA would pay specific attention to the reliability of the wireless communication. This is because connections lost without warning, failure to establish connections, or even slight degradation of service/signal can have serious consequences. For the registration of radio frequency devices, different countries have different requirements. In some countries, U.S or Europe standard testing is accepted. In some countries, additional testing and certification may be required. Thus, approval times for different telecommunication authorities could vary from a few weeks up to four months.

4.2.3 Target Population and Data Collection

A survey consists of eleven questions is designed using Google doc and distributed among the internet as well as several communities in Worcester, Massachusetts and St. Louis, Missouri. I also contacted local hospitals in my hometown, Ningbo, China to participate in my survey since population there is much more dense than America thus it is faster to collect large amount of survey responses. A total response number of 1000 is expected to achieve.

4.2.4 Survey Description

A product survey is needed in order to collect more information on social acceptance on algorithms embedded medical devices as well as our product design. One goal of the survey is to see how many people would like to give their physiological signals to us for developing new algorithms. Another goal of this survey is to see for this kind of devices, what are the key things that people cares the most. The target population of this survey is middle-aged up, both males and females. Thus college student is not a good source for me to perform this task. Full version of the product survey is attached in the appendix section of this report. Following are the twelve survey questions: 1. Do you get tired when drive for a long time; 2. would you like to have a device that detect your drowsiness/fatigue level and prevent you from falling asleep while driving; 3. which one do you prefer to wear, baseball cap or sunglasses, to monitor your drowsiness level while driving; 4. Are you suffering from one of the following diseases; 5. would you like to wear this product for long-term as a health monitor system even when you're not driving; 6. which one of the following aspects would you concern the most about this product; 7. would you like to have one of those products for free if you share your physiological data with us for 6 months; 8. if possible, would you like to use your smartphone as your primary health monitoring device; 9. what's your age; 10. What's your sexuality; 11. If you have any other ideas or concerns about this product, please put them in the space below. Different answer options are provided and all the questions are required to answer, no skipping is allowed.

4.3 Conclusion

In this section, all three of the objectives are successfully achieved by looking into various personal medical products on the market, discuss various aspects facing the regulation problems, design challenges, and distributing a survey on algorithms embedded personal medical devices. In the next chapter, detailed analysis for the product survey is discussed.

5. Results and Analysis

A product survey with eleven questions was distributed in several different locations for about one month. A total of 1054 responses were received which successfully met my original goal of 1000. The responses helped FIVOTS's project on several design decisions and the social acceptance of this type of algorithm embedded medical device is studied. The results and analysis of this product survey is discussed in the following sections of this chapter.

5.1 Product Survey Results

From March 5th to April 8th, a total number of 1054 surveys were collected. Following are the number of responses received for each question:

For question 1 "Do you get tired when drive for a long time", 651 answered "Yes", 102 answered "No" and surprisingly, 301 answered "Does Not Apply". For question 2 "Would you like to have a device that detect your drowsiness/fatigue level and prevent you from falling asleep while driving", 651 answered "Yes", 156 answered "NO", and 247 answered "Does Not Apply". For question 3 "Which one do you prefer to wear, baseball cap or sunglasses, to monitor your drowsiness level while driving", 93 chose "baseball cap", 389 chose "sunglasses", 189 chose "both", 248 answered "does not apply", and 120 chose "other". For multiple choices question 4 "Are you suffering from one of the following diseases", "any Cardiac Disease" was selected 13 times, "Diabetes" was selected 39 times, "high blood pressure" was selected 66 times, "other chronic disease" was selected 45 times, and "none of the above" was selected 887 times. For question 5 "Would you like to wear this product for long-term as a health monitor system even when you're not driving", 561 answered "Yes" and 488 answered "No". For question 6 “Which one of the following aspects would you concern the most about this product”, 618 chose “accuracy of the drowsiness algorithm”, 106 chose “power consumption”, 180 chose “sizes”, and only 87 chose “appearance”. Figure 8 shows the percentage of total responses on different selections. In addition, there were 55 people chose “other” and left their opinions on the survey. For question 7 “Would you like to have one of those products for free if you share your physiological data with us for 6 months”, 678 answered “Yes” and only 372 answered “No”. For question 8 “If possible, would you like to use your smartphone as your primary health monitoring device”, 706 selected “Yes” and 342 selected “No”. For question 9 “what’s your age”, 102 answered “18-22”, 498 answered “23-34”, 382 answered “35-55”, and only 64 answered “56 and above”. For question 10 “what’s your sex”, 433 selected “male”, and the rest 617 all selected “female”. For the last question “other comments”, 13 people left their comments regarding this project, and all the rest did not leave any comments.

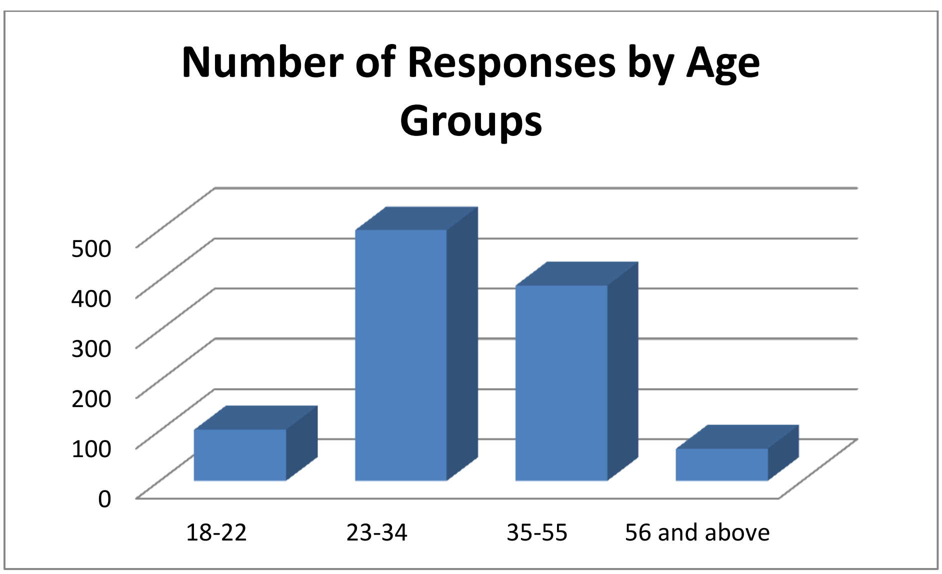

Figure 7 Number of Reponses by Age Groups

Among all the responses, almost 62% people want to have a device to monitor drowsiness levels when driving, 64% people want to have one of those devices for free by sharing their physiological data with us to developing new algorithms for six months, and 53% people want to use wireless sensors for long-term health monitoring. There are 311 out of 1054 want to have a device like the drowsiness control center, share their own physiological data for developing new algorithms, wear the wireless sensor for long-term health monitoring, and use their smartphone as a health monitoring platform. There are 13 people left some comments at the end of survey, and they can be found in the appendix section of this report.

Figure 8 shows the result of most important factors for FIVOLTS' drowsiness control center: 59% people chose accuracy, 17% people chose the size of the sensor, 10% people chose power consumption and 9% chose the appearance. In the following sections, all the responses from the product survey are divided into different subdivisions. Results and statistics are provided for each of the survey question.

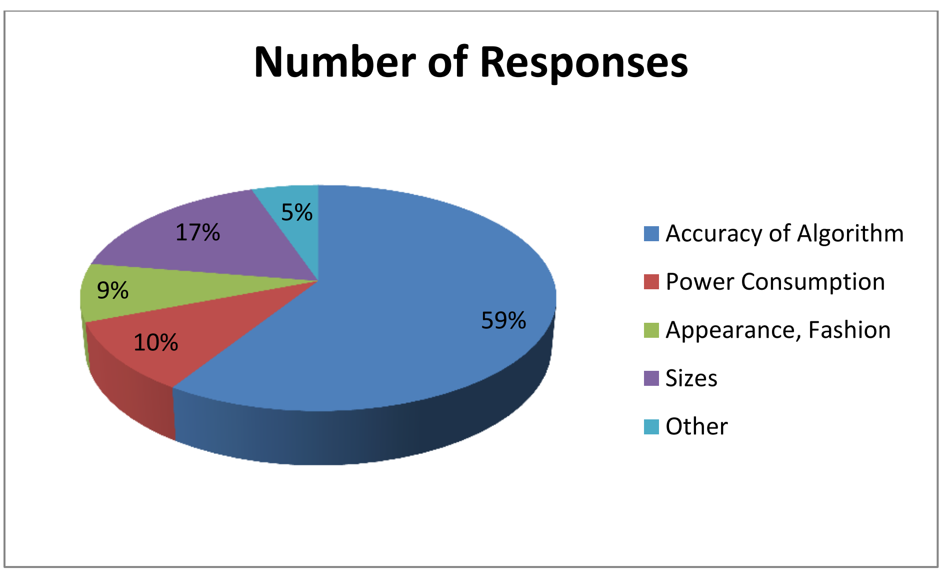

Figure 8 Factors People Concerns the Most on the Product

5.1.1 Statistics by Different Age Groups (Q9)

Survey results according to different age groups are shown in Table 1. Percentage of each answer selection is calculated and displayed under its corresponding number under specific age group.

Table 1 Survey Distribution for Different Age Groups

	Age Groups		18-22		23-34		35-55		56 up	
			number	%	number	%	number	%	number	%
Survey Results by Different Age Groups	Drowsy if driving for long time?	Yes	44	73.33	326	88.82	262	89.12	16	57.14
		No	16	26.67	41	11.17	32	10.88	12	42.86
		Not Sure	42	41.18	131	26.25	88	23.04	36	56.25
	Want a device to monitor your driving drowsiness?	Yes	58	87.88	348	85.09	225	75.25	18	62.07
		No	8	12.12	61	14.91	74	24.75	11	37.93
		Not Sure	36	35.29	89	17.84	83	27.76	35	54.69
	Appearance / Fashion	Baseball Cap	9	13.24	44	8.83	38	9.95	2	3.13
		Sunglasses	31	45.59	215	43.17	135	35.34	16	25.00
		Both	19	27.94	88	17.67	76	19.90	5	7.81
		Not Sure	34	33.33	91	18.27	83	21.73	35	54.69
		Other	9	13.24	60	1.81	45	11.78	6	9.38
	Long-Term Wear?	Yes	61	59.80	271	54.53	196	51.31	31	50.00
		No	40	39.22	226	45.47	186	48.69	31	50.00
	Most Important Factor for Algorithm Embed Device	Accuracy	57	57.00	311	62.4498	215	56.28	32	50.79
		Power Usag	12	12.00	41	8.23	42	10.99	10	15.87
		Fashion	11	11.00	45	9.04	27	7.07	3	4.76
		Size	15	15.00	83	16.67	70	18.32	11	17.46
		Other	5	5.00	18	3.61	23	6.02	7	11.11
	Donate Data for Developing New	Yes	69	69.7	335	67.27	238	62.30	35	55.56
		No	33	33.33	163	32.73	142	37.17	28	44.44
	Use Smartphone as Personal Health	Yes	71	70.3	352	70.68	245	64.14	37	57.81
		No	30	29.7	145	29.12	134	35.08	27	42.19
	Sexuality	Male	54	52.94118	180	36.14	160	41.88	38	59.38
		Female	48	47.06	318	63.86	222	58.12	26	40.63

5.1.2 Statistics by Different Sexualities (Q10)

Survey results according to different sexualities are shown in Table 2. Percentage of each answer selection is calculated and displayed under its corresponding number under specific sexuality group.

Table 2 Survey Distribution for Males and Females

			Males	%	Females	%
Survey Results by Sexuality	Drowsy if driving for long time?	Yes	294	87.50	**357**	**85.61**
		No	42	12.50	**60**	**14.39**
		Not Sure	97	22.40	**204**	**32.85**
	Want a device to monitor your driving drowsiness?	Yes	281	81.21387283	**370**	**80.260304**
		No	65	18.78612717	**91**	**19.739696**
		Not Sure	87	20.09	**160**	**25.76**
	Appearance / Fashion	Baseball Cap	48	11.09	**46**	**7.41**
		Sunglasses	157	36.26	**242**	**38.97**
		Both	94	21.71	**95**	**15.30**
		Not Sure	85	19.63	**163**	**26.25**
		Other	49	11.32	**75**	**12.08**
	Health Conditions	Cardiac Disease	4	0.92	**9**	**1.45**
		Diabetes	21	4.85	**18**	**2.90**
		High Blood Pressure	37	8.55	**32**	**5.15**
		Other Chronic disease	31	7.16	**14**	**2.25**
		healthy	340	78.52	**548**	**88.24**
	Long-Term Wear?	Yes	252	58.20	**311**	**50.08**
		No	181	41.80	**310**	**49.92**
	Most Important Factor for Algorithm Embbed Device	Accuracy	274	63.28	**344**	**55.39**
		Power Usage	53	12.24	**53**	**8.53**
		Fashion	31	7.16	**56**	**9.02**
		Size	53	12.24	**127**	**20.45**
		Other	22	5.08	**41**	**6.60**
	Donate Data for Developing New Algorithm?	Yes	296	68.36	**386**	**62.16**
		No	137	31.64	**235**	**37.84**
	Use Smartphone as Personal Health Platform	Yes	293	67.67	**416**	**66.99**
		No	140	32.33	**205**	**33.01**
	Age Groups	18-22	54	12.47	**48**	**7.73**
		23-34	180	41.57	**318**	**51.21**
		35-55	160	36.95	**223**	**35.91**
		56 up	38	8.78	**26**	**4.19**
		17 below	1	0.23	**6**	**0.97**

5.1.3 Statistics by Different Health Conditions (Q4)

Survey results according to different sexualities are shown in Table 3. Percentage of each answer selection is calculated and displayed under its corresponding number under specific sexuality group.

Table 3 Survey Results for Different Health Conditions

			Chronic Disease total: 166	Chronic disease %	Healthy total: 887	Healthy %
Survey Results by Different Health Conditions	Drowsy if driving for long time?	Yes	88	75.86	562	88.36
		No	28	24.14	74	11.64
		Not Sure	50	30.12	251	28.3
	Want a device to monitor your driving drowsiness?	Yes	77	62.60162602	573	83.89458
		No	46	37.39837398	110	16.10542
		Not Sure	43	25.9	204	23.00
	Appearance / Fashion	Baseball Cap	14	8.43	79	8.91
		Sunglasses	59	35.54	340	38.33
		Both	36	21.69	156	17.59
		Not Sure	45	27.11	203	22.89
		Other	12	7.23	109	12.29
	Long-Term Wear?	Yes	87	52.41	476	53.66
		No	79	47.59	411	46.34
	Most Important Factor for Algorithm Embbed Device	Accuracy	85	51.20	534	60.20
		Power Usage	35	21.08	71	8.00
		Fashion	11	6.63	76	8.57
		Size	29	17.47	151	17.02
		Other	6	3.61	55	6.20
	Donate Data for Developing New Algorithm?	Yes	98	59.04	583	65.73
		No	68	40.96	304	34.27
	Use Smartphone as Personal Health Platform	Yes	93	56.02	616	69.45
		No	73	43.98	271	30.55
	Age Groups	18-22	5	3.01	97	10.94
		23-34	37	22.29	460	51.86
		35-55	80	48.19	302	34.05
		56 up	40	24.10	24	2.71
		17 below	4	2.41	3	0.34
	Sexuality	Male	93	56.02	339	38.22
		Female	73	43.98	548	61.78

5.1.4 Statistics on Drowsiness Control Center (Q1-2)

Survey distribution for those answered question 2 "Would you like to have a device that detect your drowsiness/fatigue level and prevent you from falling asleep while driving" is shown in Table 4. For those people answered "Yes", "No" or "Not Sure", their responses on other questions were selected and displayed in the following table.

Table 4 Survey Results for Q2 (Yes, No and Not Sure for Drowsy Device)

			Yes for Q2	Yes for Q2 %	No for Q2	No for Q2 %	Not Sure on Q2	Not Sure for Q2 %
Survey Distribution for chosing YES and NO on Question 2	Drowsy if driving for long time?	Yes	537	91.02	105	72.92	9	3.64
		No	53	8.98	39	27.08	10	4.05
		Not Sure	61	9.37	12	7.69	228	92.3
	Appearance / Fashion	Baseball Cap	80	12.29	14	8.97	1	0.40
		Sunglasses	331	50.84	54	34.62	16	6.48
		Both	131	20.12	46	29.49	12	4.86
		Not Sure	29	4.45	8	5.13	211	85.43
		Other	80	12.29	34	21.79	7	2.83
	Health Conditions	Cardiac Disease	7	1.08	3	1.92	3	1.21
		Diabetes	16	2.46	11	7.05	12	4.86
		High Blood Pressure	27	4.15	23	14.74	19	7.69
		Other Chronic disease	27	4.15	9	5.77	9	3.64
		healthy	574	88.17	110	70.51	204	82.59
	Long-Term Wear?	Yes	403	61.90	60	38.46	99	40.08
		No	248	38.10	96	61.54	148	59.92
	Most Important Factor for Algorithm Embbed Device	Accuracy	446	68.51	62	39.74	111	44.94
		Power Usage	46	7.07	25	16.03	36	14.57
		Fashion	48	7.37	20	12.82	20	8.10
		Size	96	14.75	31	19.87	54	21.86
		Other	15	2.30	18	11.54	26	10.53
	Donate Data for Developing New Algorithm?	Yes	493	75.73	76	48.72	110	44.53
		No	158	24.27	80	51.28	137	55.47
	Use Smartphone as Personal Health Platform	Yes	514	78.96	76	48.72	118	47.77
		No	137	21.04	80	51.28	129	52.23
	Age Groups	18-22	58	8.91	8	5.13	36	14.57
		23-34	348	53.46	61	39.10	89	36.03
		35-55	225	34.56	74	47.44	83	33.60
		56 up	18	2.76	11	7.05	35	14.17
		17 below	2	0.31	2	1.28	4	1.62
	Sexuality	Male	281	43.16	65	41.67	87	35.22
		Female	370	56.84	91	58.33	160	64.78

5.1.5 Statistics on Long-Term Health Monitoring (Q5, 7-8)

Survey distribution for those answered question 5 “Would you like to wear this product for long-term as a health monitor system even when you're not driving?” is shown in Table 5. For those people answered “Yes”, “No”, their responses on other questions were selected and displayed in the following table.

Table 5 Survey Results for Q5 (Yes and No for Long Term Monitoring)

			Yes for Long Term Monitoring	%	No for Long Term Monitoring	%
Survey Distribution for chosing YES and NO on Question 5	Drowsy if driving for long time?	Yes	374	86. 77	277	86. 02
		No	57	13. 23	45	13. 98
		Not Sure	131	23. 31	170	34. 55
	Want a device to monitor your driving drowsiness?	Yes	403	87. 04	248	72. 09
		No	60	12. 96	96	27. 91
		Not Sure	99	17. 62	148	30. 08
	Appearance / Fashion	Baseball Cap	58	10. 32	35	7. 11
		Sunglasses	228	40. 57	171	34. 76
		Both	129	22. 95	60	12. 20
		Not Sure	98	17. 44	150	30. 49
		Other	49	8. 72	71	14. 43
	Health Conditions	Cardiac Disease	6	1. 07	7	1. 42
		Diabetes	18	3. 20	21	4. 27
		High Blood Pressure	34	6. 05	35	7. 11
		Other Chronic disease	28	4. 98	17	3. 46
		healthy	476	84. 70	412	83. 74
	Most Important Factor for Algorithm Embbed Device	Accuracy	367	65. 30	259	52. 64
		Power Usage	40	7. 12	66	13. 41
		Fashion	44	7. 83	43	8. 74
		Size	100	17. 79	80	16. 26
		Other	11	1. 96	44	8. 94
	Donate Data for Developing New Algorithm?	Yes	486	86. 48	193	39. 23
		No	76	13. 52	299	60. 77
	Use Smartphone as Personal Health Platform	Yes	473	84. 16	237	48. 17
		No	89	15. 84	255	51. 83
	Age Groups	18-22	62	11. 03	40	8. 13
		23-34	271	48. 22	227	46. 14
		35-55	196	34. 88	187	38. 01
		56 up	31	5. 52	33	6. 71
		17 below	2	0. 36	5	1. 02
	Sexuality	Male	252	44. 84	181	36. 79
		Female	310	55. 16	311	63. 21

Survey distribution for those answered question 7 “Would you like to have one of those products for free if you share your physiological data with us for 6 months?” is shown in Table 6. For those people answered “Yes”, “No”, their responses on other questions were selected and displayed in the following table.

Table 6 Survey Results for Q7 (Yes and No for Sharing Data)

			Yes for Sharing Data	Yes for Sharing Data %	No for Sharing Data	No for Sharing Data %
Survey Distribution for chosing YES and NO on Question 7	Drowsy if driving for long time?	Yes	460	87.95	191	83.04
		No	63	12.05	39	16.96
		Not Sure	158	23.20	143	38.34
	Want a device to monitor your driving drowsiness?	Yes	493	86.49	158	66.67
		No	77	13.51	79	33.33
		Not Sure	111	16.30	136	36.46
	Appearance / Fashion	Baseball Cap	74	10.87	19	5.15
		Sunglasses	285	41.85	114	30.89
		Both	139	20.41	50	13.55
		Not Sure	112	16.45	136	36.86
		Other	71	10.43	50	13.55
	Health Conditions	Cardiac Disease	7	1.03	6	1.61
		Diabetes	23	3.38	16	4.29
		High Blood Pressure	36	5.29	33	8.85
		Other Chronic disease	32	4.71	13	3.49
		healthy	582	85.59	305	81.77
	Long-Term Wear?	Yes	485	71.32	76	20.60
		No	195	28.68	293	79.40
	Most Important Factor for Algorithm Embbed Device	Accuracy	441	64.95	177	48.23
		Power Usage	45	6.63	61	16.62
		Fashion	61	8.98	26	7.08
		Size	114	16.79	66	17.98
		Other	18	2.65	37	10.08
	Use Smartphone as Personal Health Platform	Yes	581	85.32	128	34.50
		No	100	14.68	243	65.50
	Age Groups	18-22	69	10.13	33	8.85
		23-34	335	49.19	163	43.70
		35-55	240	35.24	143	38.34
		56 up	36	5.29	28	7.51
		17 below	1	0.15	6	1.61
	Sexuality	Male	296	43.47	137	36.73
		Female	385	56.53	236	63.27

Survey distribution for those answered question 8 “If possible, would you like to use your smartphone as your primary health monitoring device?” is shown in Table 7.

For those people answered “Yes”, “No”, their responses on other questions were selected and displayed in the following table.

Table 7 Survey Results for Q8 (Yes for Using Smartphone)

			Yes for Using Smartphone as health platform	Yes for Using Smartphone as health platform %	No for Using Smartphone as health platform	No for Using Smartphone as health platform %
Survey Distribution for chosing YES and NO on Question 8	Drowsy if driving for long time?	Yes	481	88.91	167	79.90
		No	60	11.09	42	20.10
		Not Sure	166	23.48	134	39.07
	Want a device to monitor your driving drowsiness?	Yes	513	87.10	136	63.26
		No	76	12.90	79	36.74
		Not Sure	118	16.69	128	37.32
	Appearance / Fashion	Baseball Cap	76	10.76	17	5.01
		Sunglasses	297	42.07	102	30.09
		Both	146	20.68	42	12.39
		Not Sure	117	16.57	130	38.35
		Other	70	9.92	48	14.16
	Health Conditions	Cardiac Disease	10	1.41	3	0.87
		Diabetes	22	3.11	17	4.96
		High Blood Pressure	35	4.95	35	10.20
		Other Chronic disease	27	3.82	18	5.25
		healthy	613	86.70	270	78.72
	Long-Term Wear?	Yes	472	66.95	89	26.18
		No	233	33.05	251	73.82
	Most Important Factor for Algorithm Embbed Device	Accuracy	473	67.09	143	42.43
		Power Usage	51	7.23	55	16.32
		Fashion	61	8.65	25	7.42
		Size	101	14.33	78	23.15
		Other	19	2.70	36	10.68
	Donate Data for Developing New Algorithm?	Yes	579	81.90	100	29.15
		No	128	18.10	243	70.85
	Age Groups	18-22	71	10.04	30	8.75
		23-34	352	49.79	145	42.27
		35-55	246	34.79	135	39.36
		56 up	37	5.23	27	7.87
		17 below	1	0.14	6	1.75
	Sexuality	Male	293	41.44	137	39.94
		Female	414	58.56	206	60.06

5.1.6 Survey Result for those answered YES on all of Q2, Q5, Q7 and Q8

Out of 1054 survey responses, 311 of them answered YES on Question 2, 5, 7 and 8. This means there is about 29.5% percent of all the survey participants support the idea of FIVOTS’ drowsiness control center and algorithm embedded medical devices. Their opinions on other survey questions are displayed in Table 8.

Table 8 Survey Distribution for those answered YES on Q2, 5, 7 and 8

			Number	%
Survey Distribution for those answered YES on Q2, Q5,Q7, and Q8				
	Drowsy if driving for long time?	Yes	252	81.03
		No	33	10.61
		Not Sure	26	8.36
	Appearance / Fashion	Baseball Cap	40	12.86
		Sunglasses	161	51.77
		Both	73	23.47
		Not Sure	10	3.22
		Other	27	8.68
	Health Conditions	Cardiac Disease	4	1.29
		Diabetes	11	3.54
		High Blood Pressure	13	4.18
		Other Chronic disease	17	5.47
		healthy	265	85.21
	Most Important Factor for Algorithm Embbed Device	Accuracy	225	72.35
		Power Usage	15	4.82
		Fashion	21	6.75
		Size	46	14.79
		Other	4	1.29
	Age Groups	18-22	37	11.90
		23-34	150	48.23
		35-55	115	36.98
		56 up	9	2.89
		17 below	0	0.00
	Sexuality	Male	151	48.55
		Female	160	51.45

5.2 Analysis and Discussion

In this last section, all the statistics and results are displayed. In this section, a more detailed analysis and comparisons between different groups of people is provided. The analysis and statistics on certain questions show some interesting insights. Some of them make great sense, and some of them do not make any sense at all. The survey statistics provide some useful advices for further product development on FIVOTS' drowsiness control center and algorithm embedded smart healthcare devices.

5.2.1 Analysis and Discussion by Different Age Groups (Q9)

Survey responses for different age groups on question 1 and 2 are shown in Figure 9. As we can see, people from 18-34 and 35-55 groups have higher rate of driving drowsy.

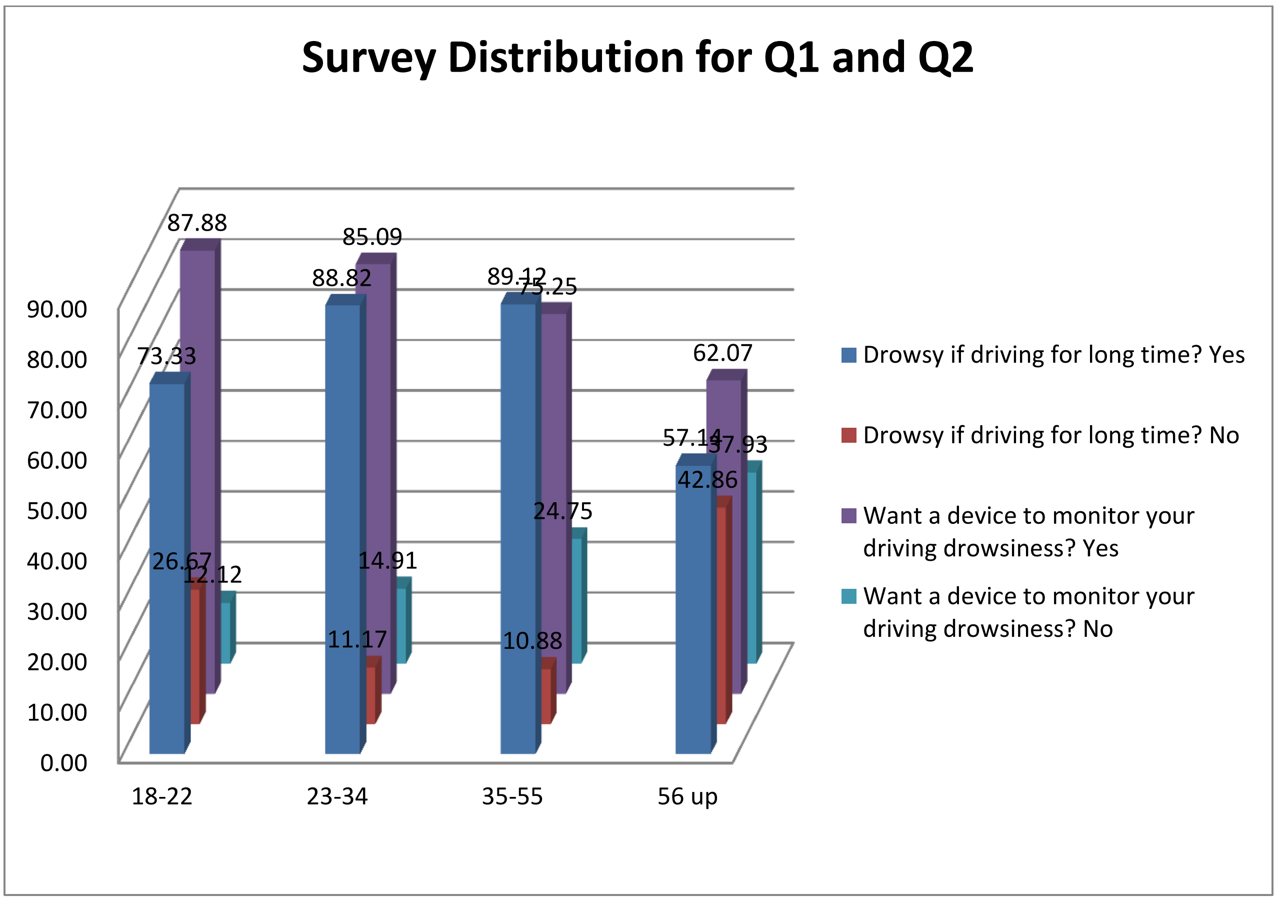

Figure 9 Survey Distribution for Question 1 and 2 According to Age Groups

People from 18-22 groups also have a pretty high rate of getting drowsy when driving for a long time. People from 56 years old and up seems to have lower rates of getting drowsy when driving. One reason for this could be that people at their age are very experienced drivers and they can control themselves well when driving and won't get drowsy.

Another interesting statistics from the survey is that younger people tend to like the idea of drowsiness control center and willing to have on device like that even they don't have the highest rate for answering YES on driving drowsy question. The purple bar on Figure 9 shows the percentage from each age group who answered YES on 2nd question. As we can see, 18-22 years old people have the highest rate, and people who are older than 56 years old have the lowest rate.

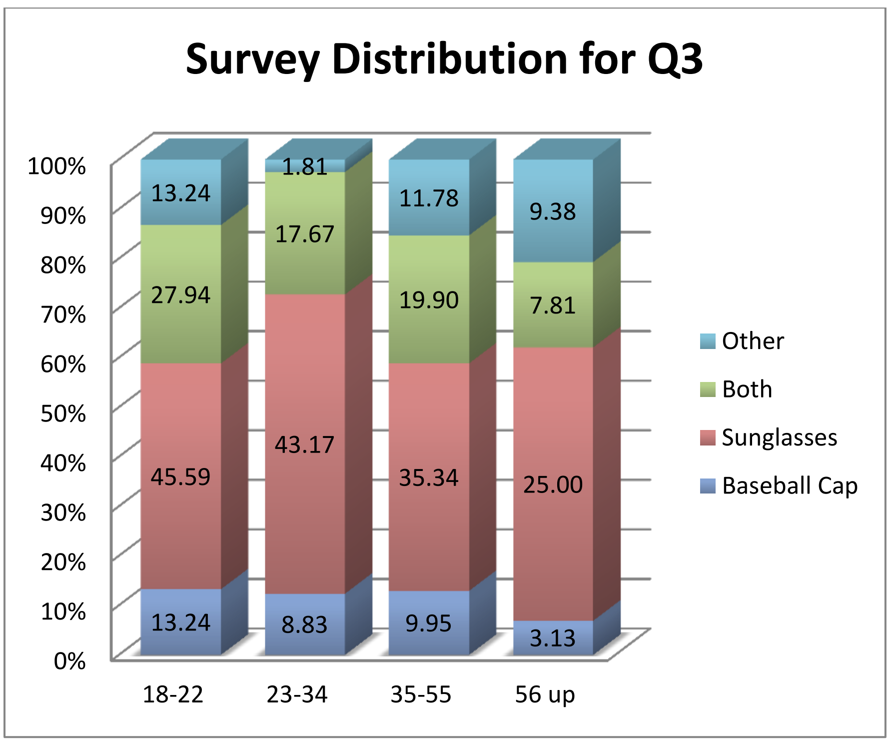

Figure 10 Answer Distribution for Question 3 According to Age Groups

The above figure shows the answer distribution on the 3rd question for different age groups. Sunglasses are the top choice among all the age groups. Baseball cap has the highest rate among young people (18-22), and lowest rate among old people (56 up).

Figure 11 shows survey distribution for question 6 “Which one of the following aspects would you concern the most about this product”. Accuracy of the algorithm was the top choice for all the age groups. Size of the sensor was the second top choice among all the age groups.

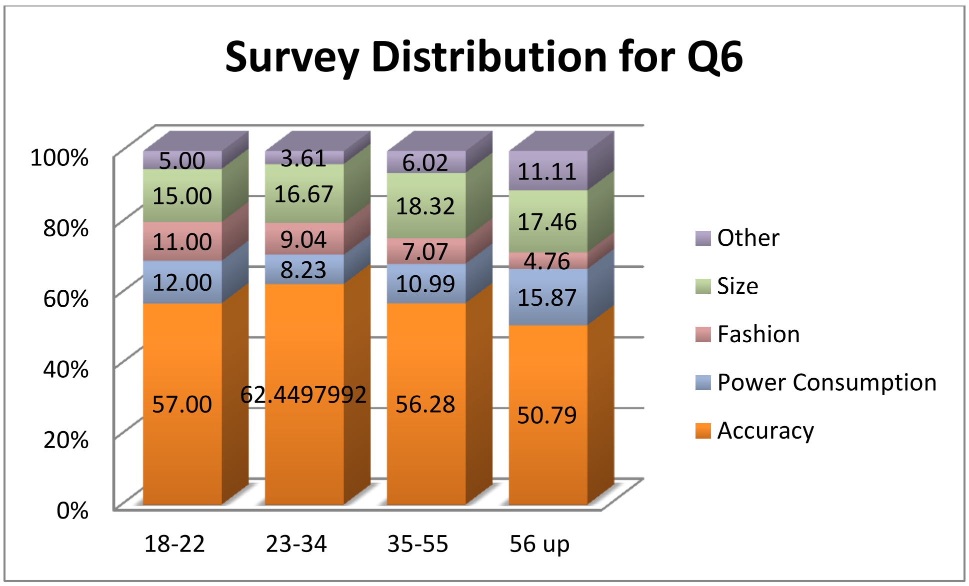

Figure 11 Survey Distribution for Question 6 According to Age Groups

Figure 12 shows survey distribution for question 5, 7 and 8 for all age groups. The trends of all 3 questions are very obvious from the graph: 18-22 years old people have the highest rate for answering YES on all three questions and 56 years old and above people have the highest rage for answering NO on all of the three questions. 23-34 years old people have higher rate for answering YES on the three questions than 35-55 years old people.

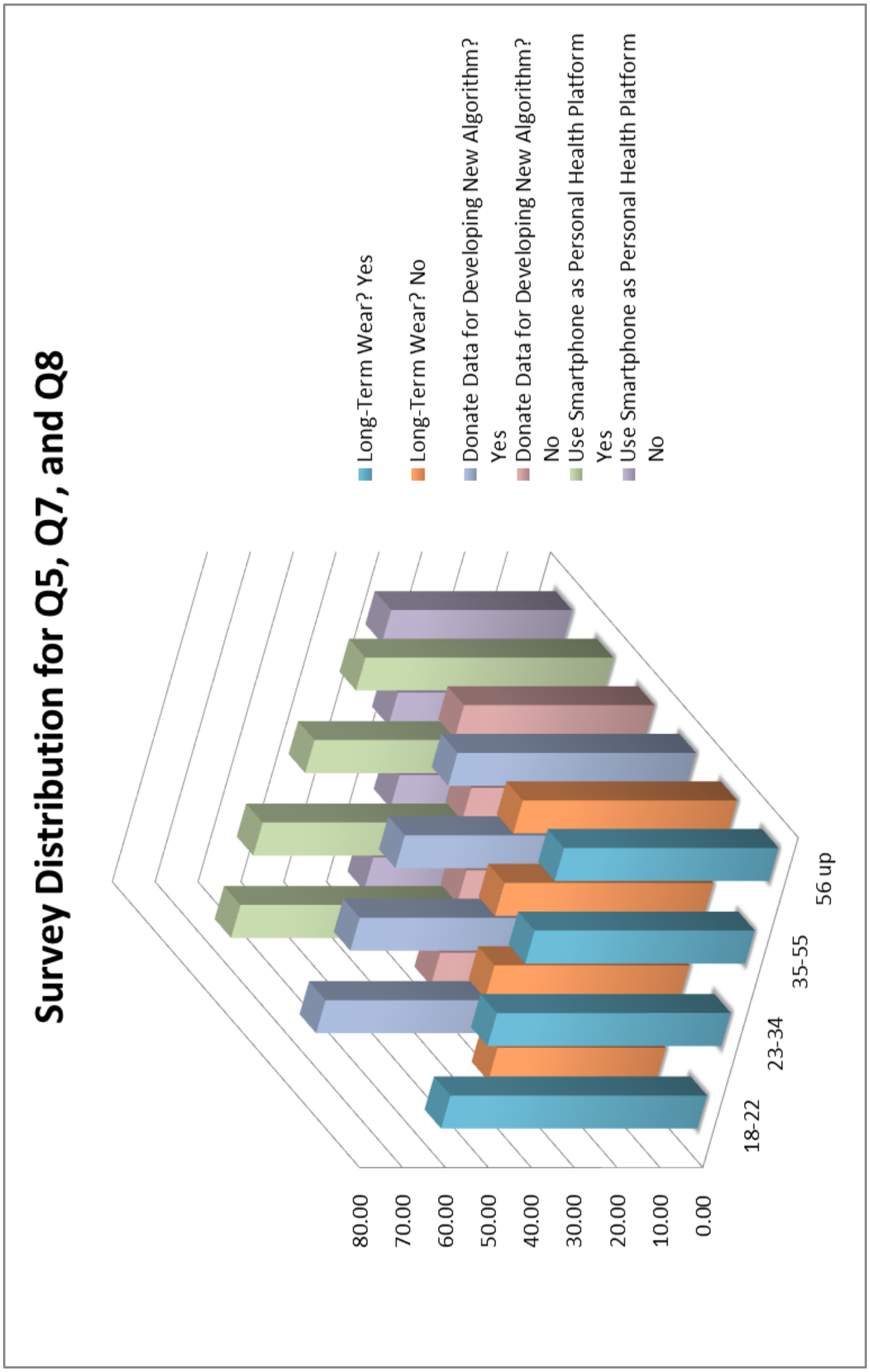

Figure 12 Survey Distribution for Question 5, 7 and 8 According to Age Groups

5.2.2 Analysis and Discussion by Different Sexualities (Q10)

In this section, survey responses for males and females are discussed. Following figure shows the responses for question 1 and 2. As we can see, both males and females have relative high rate selecting YES on both questions. Thus, there is no clear difference between males and females for driving drowsy and their opinions for using a device monitoring their drowsiness levels.

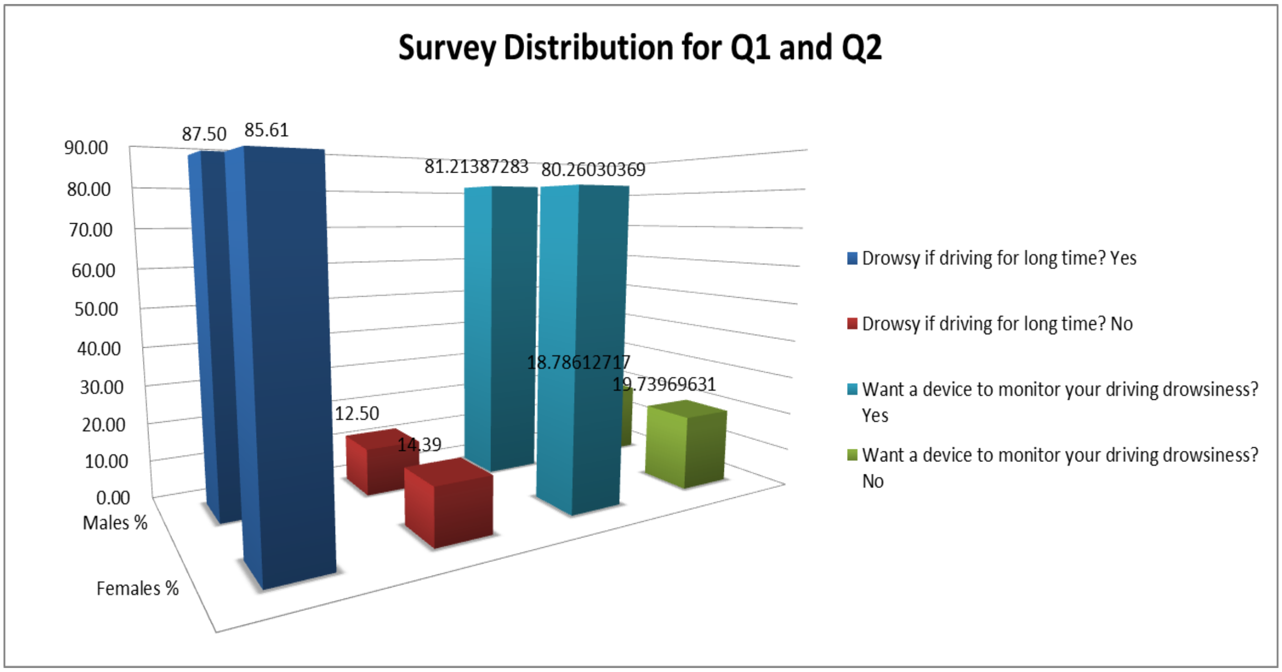

Figure 13 Survey Distribution for Question 1 and 2 According to Sexuality

Figure 14 shows survey distribution on the appearance/fashion of the wireless sensor for drowsy control center. Sunglasses again are the top choice for both males and females. More males selected baseball caps than females. There are 11-12 percent from each group selected "other" for the appearances. Some popular comments from females are "watches", "pendant" and "earrings", and some popular comments from males are "Bluetooth headsets", "watches" and "somewhere in the car".

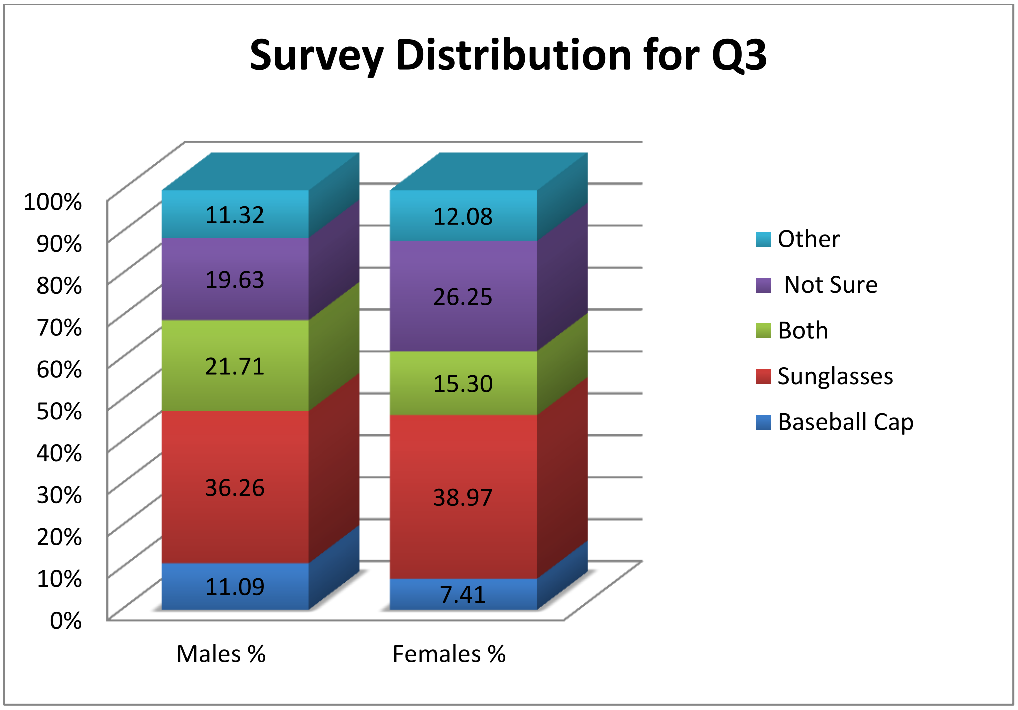

Figure 14 Survey Distribution for Question 3 According to Sexuality

Figure 15 shows survey distribution on question 6 "most important factor for algorithm embedded medical devices". Although accuracy is being selected the most times, we can see that more males care about this feature than the females. The second popular choices for males are "power usage" and "size". However, on females' side, a lot more people selected "size". Although "Fashion" has similar percentages for males and females, 9.02% for females is still more than 7.12% for males. To conclude, males care most about accuracy, sizes and power usage while females care most about accuracy (less than males), sizes and fashion.

Figure 16 shows survey distribution on question 5, 7 and 8, for their opinions for using wireless sensor for long-term monitoring and smartphones as the algorithm embedded medical platform. Males have higher rates for selecting YES for long-term monitoring and share data with developers for new algorithms. For smartphone usage, both males and females have similar rates for different selections.

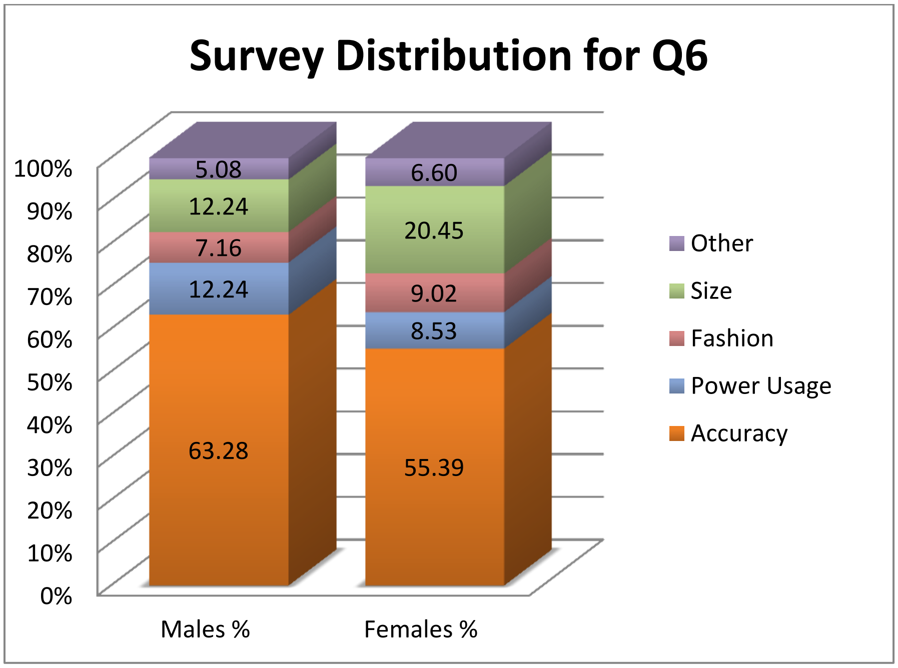

Figure 15 Survey Distribution for Question 6 According to Sexuality

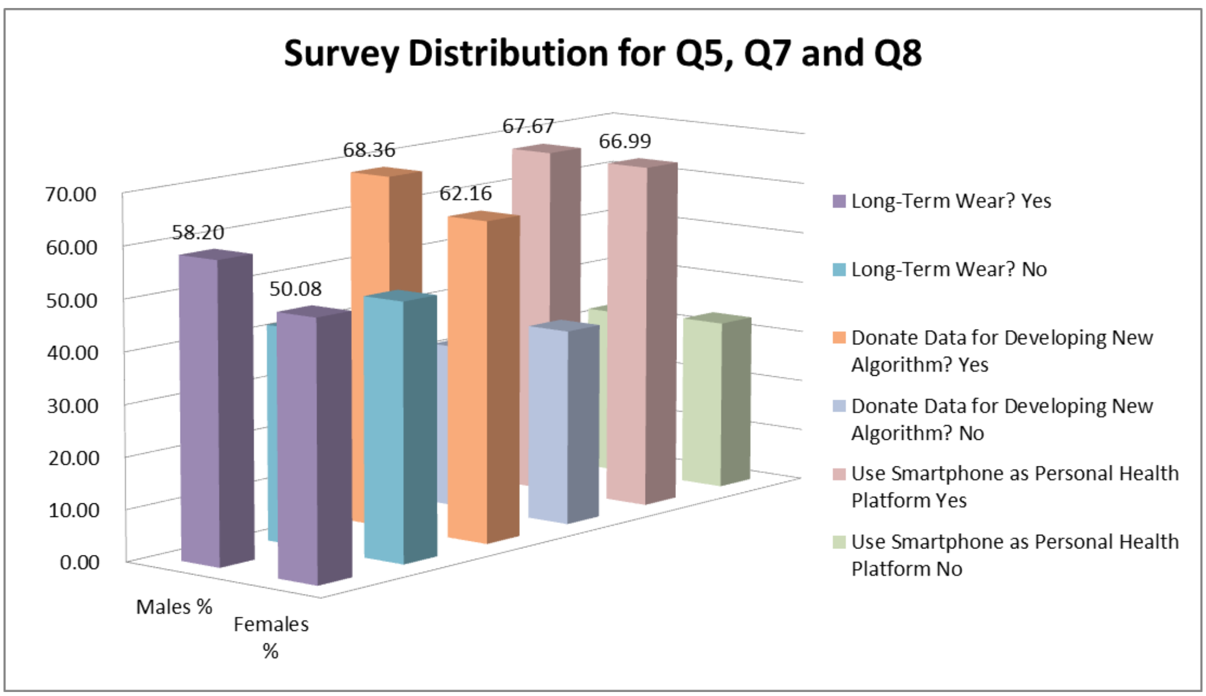

Figure 16 Survey Distribution for Question 5, 7 and 8 According to Sexuality

5.2.3 Analysis and Discussion by Different Health Conditions (Q4)

Figure 17 shows survey distribution on question 1 and 2 for people with different health conditions. Since most people answered this survey selected "healthy", not much useful data can be taken from those suffering from chronic diseases. Thus I combined different groups of people into 2 categories: healthy and not healthy. In the following figure, we can see that there are more healthy people answered YES on the driving drowsy question than the unhealthy people. Also, healthy people who select "Yes" for willing to have a device for drowsiness monitoring is much higher than the unhealthy people. This is different than what I believed before: people who are unhealthy would like to have this type of medical device more than healthy people. But from the survey result, my presumption was wrong. Obviously, more healthy people are willing to have a drowsy control device.

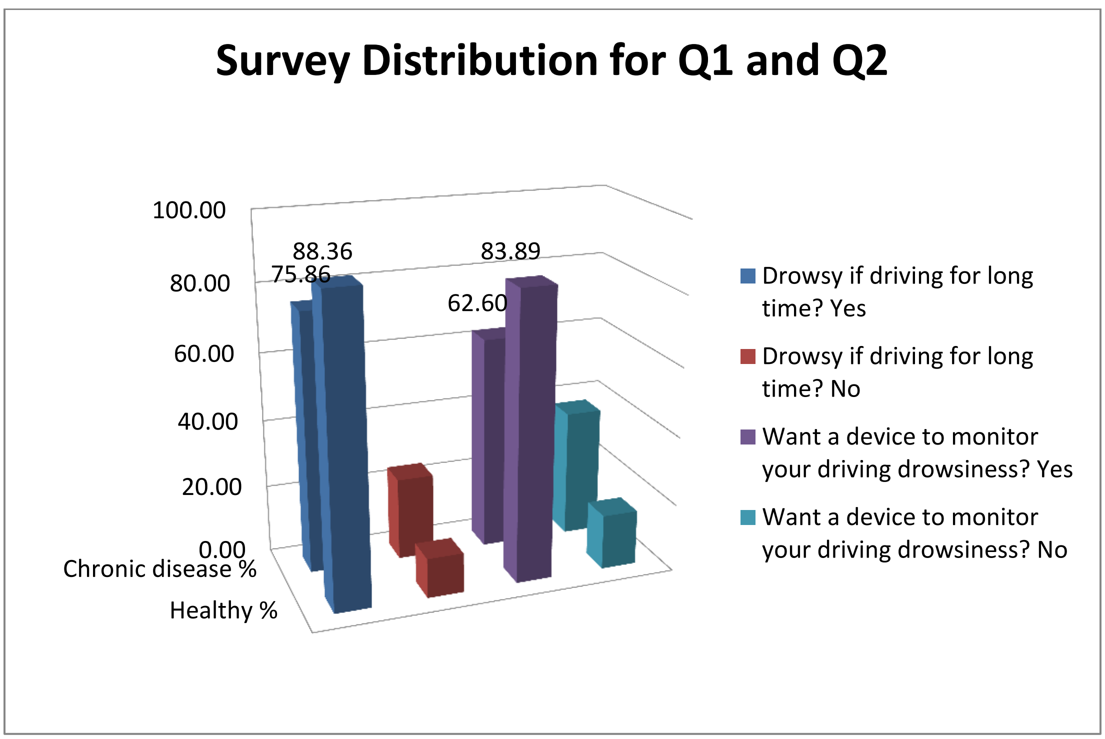

Figure 17 Survey Distribution for Question 1 and 2 According to Health Condition

Figure 18 shows survey distribution on question 3 for healthy and unhealthy people. As the figure shows, there is no obvious difference between the two groups of people. Sunglasses are still the top rates appearance. Unlike males and females, the percentages on different appearances are very close for the healthy group and unhealthy group of people.

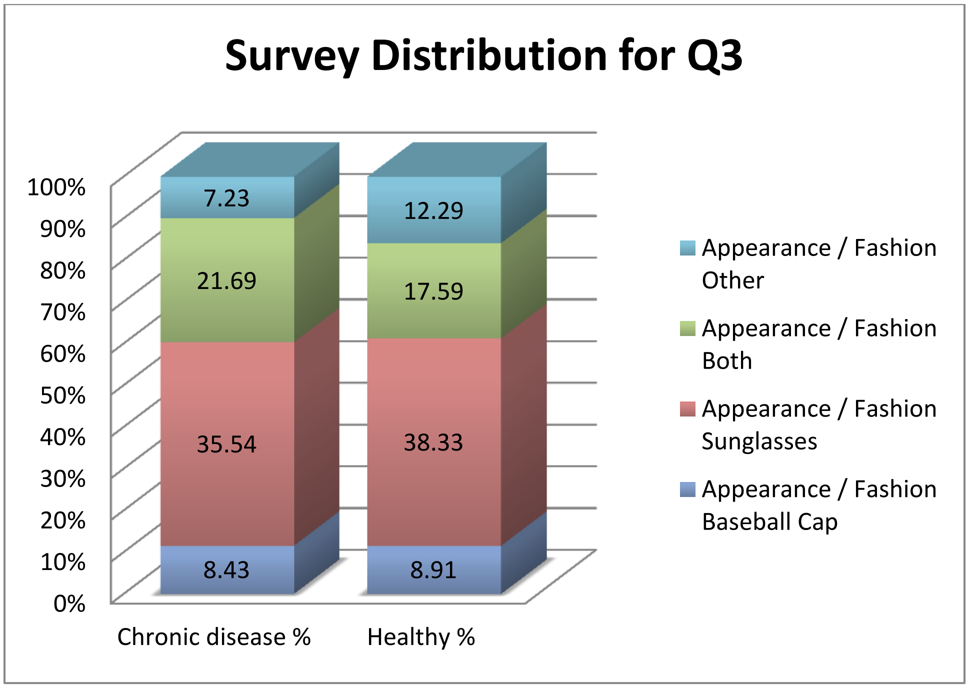

Figure 18 Survey Distribution for Question 3 According to Health Condition

Survey distribution for question 6 is shown in Figure 19. As we can see, healthy people have higher rates for selecting accuracy than unhealthy people. This is again very different than I expected before. Also, people suffering from chronic diseases have a much higher rate on power usage compare with healthy people. One reason for this could be that they need to wear the sensor for longer time because of their health conditions. As for the option "size", both groups have almost same rate, and people from the healthy group have slightly higher rates on fashion.

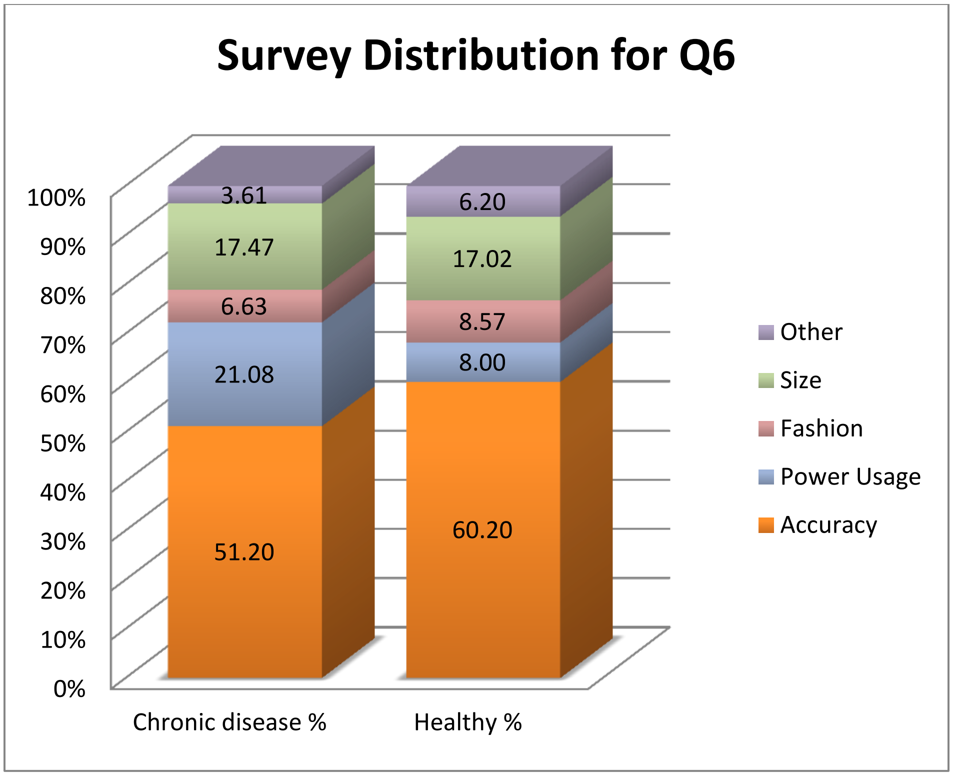

Figure 19 Survey Distribution for Question 6 According to Health Condition

Survey Distribution for question 5, 7, and 8 is shown in Figure 20. For question 5 “Would you like to wear this product for long-term as a health monitor system even when you're not driving?” survey is almost half and half for both groups. There are slightly over 50% people from both groups selected “YES”. But for question 7 and 8, more people from the healthy group answered YES compare with the other group. More healthy people tend to like the idea “sharing physiological measurements for developing new algorithms”, and “use smartphone as main health monitoring platform”.

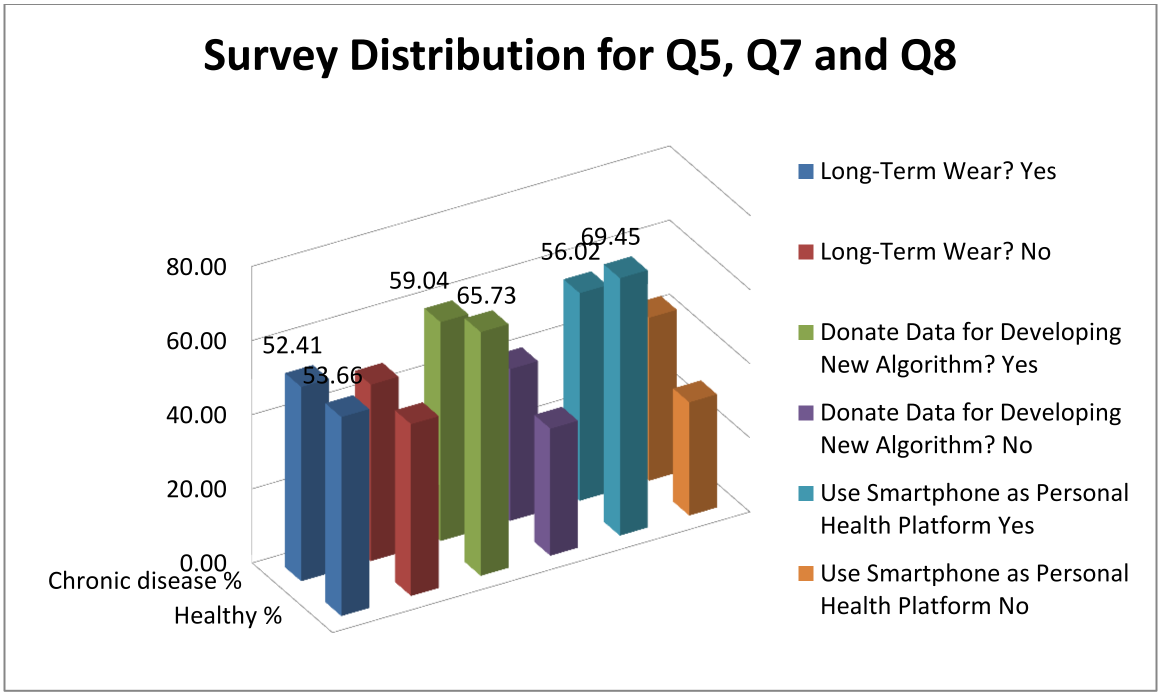

Figure 20 Survey Distribution for Question 5, 7 and 8 According to Health Condition

5.2.4 Analysis and Discussion on Drowsiness Control Center (Q1-3)

To better collect people's opinion on FIVOTS' drowsiness control center, those who answered "YES", "NO" and "Not Sure" on question 2 "Would you like to have a device that detect your drowsiness/fatigue level and prevent you from falling asleep while driving?" are separated from other people. Among all the survey responses, 62% answered "YES", 15% answered "NO" and the rest answered "Not Sure" on this question. Their answers on other survey questions are discussed in this section in order to provide better ideas for FIVOTS design project.

Figure 21 shows survey distribution for question 1 "Do you get tired when drive for a long time" for those answered "YES", "NO", and "Not Sure" on question 2. Over 90% people who answered "Yes" on question 2 also answered "Yes" on the first question. Similarly, over 90% people who answered "Not Sure" on question 2 also answered "Not

Sure" on the first question. However, for those answered "No" on second question, over 70% people still selected "Yes" on the first question, which means they get tired when driving for a long time, but do not want a device to monitor their drowsiness level while driving.

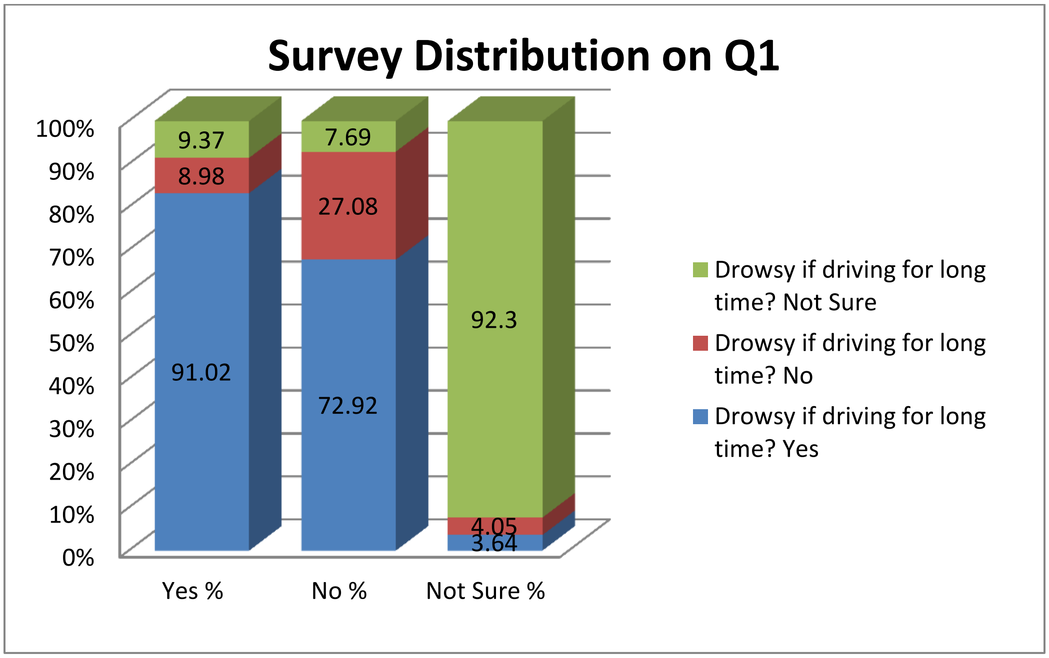

Figure 21 Survey Distribution on Q1 for Question 2

Figure 22 shows survey distribution for question 3 "Which one do you prefer to wear, baseball cap or sunglasses, to monitor your drowsiness level while driving?" for those answered "YES", "NO", and "Not Sure" on question 2. For those answered "Yes" on question 2, almost half of them selected "Sunglasses" and their ratings for "baseball cap" and "other" are the same. For those answered "No" on question 2, ratings for "sunglasses" are much lower and "other" has much higher ratings compare with other groups. Again, for those answered "Not Sure" on questions 2, most of them still selected "not sure" on question 3.

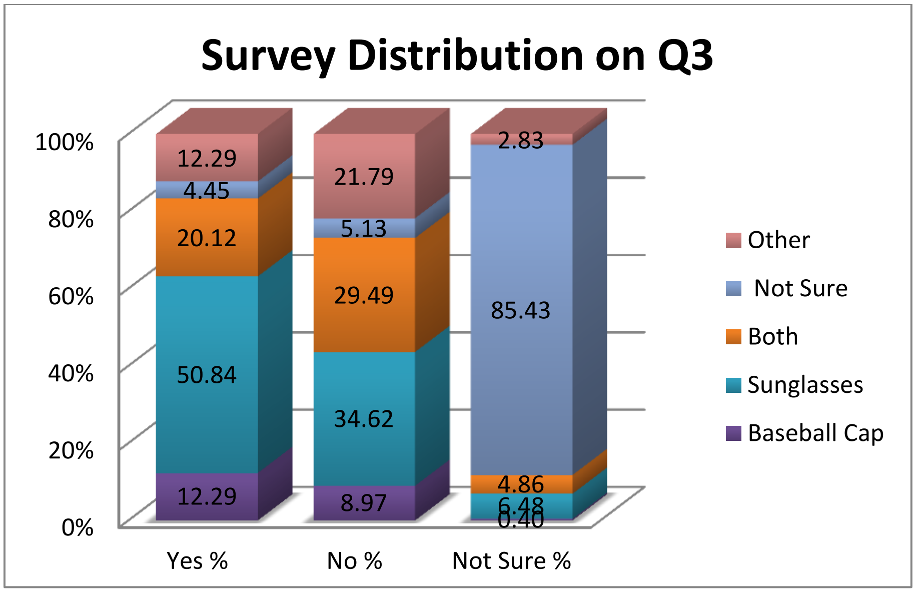

Figure 22 Survey Distribution on Q3 for Question 2

Figure 23 shows survey distribution on opinions for wearing wireless sensor for long-term health care and share information for developing new algorithms, as well as using smartphones as main health monitoring platform. As we can see from the graph, those who answered "Yes" on question 2 have much higher rates for answering "Yes" on all of the three questions. For those answered "No" on question 2, there are still 39% people answered "Yes" for long-term health monitoring (question 5), 49% people answered "Yes" for sharing information for developing new algorithms (question 7), and 49% people answered "Yes" for using smartphones as main health monitoring platform. This is good because although there are people who do not like the idea of driving drowsiness control devices, many of them would still support the idea of long-term monitoring and sharing information for developing new algorithms on health monitoring platforms.

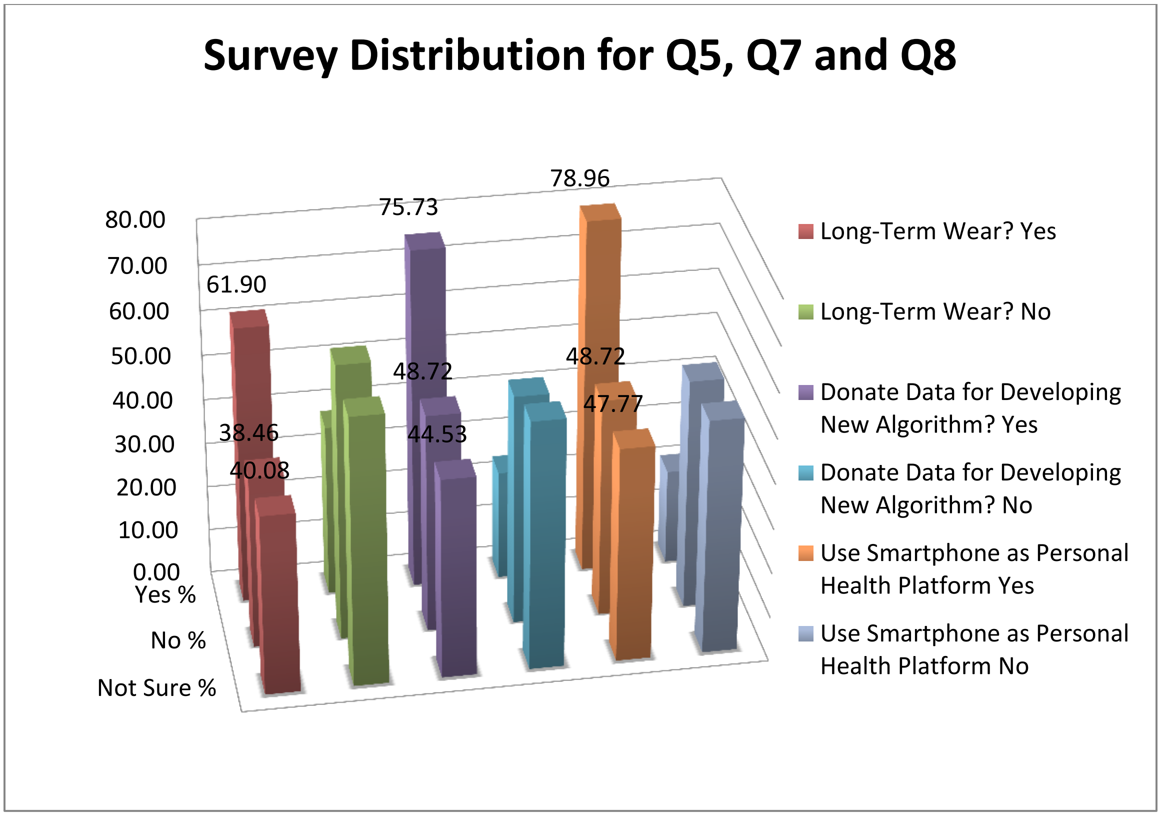

Figure 23 Survey Distribution on Q5, Q7 and Q8 for Question 2

Figure 24 shows survey distribution on question 6 “Which one of the following aspects would you concern the most about this product” for those answered “Yes”, “No”, and “Not sure” on question 2 “Would you like to have a device that detect your drowsiness/fatigue level and prevent you from falling asleep while driving”. Accuracy is again the top choice among all the three groups, and “size” again is the second top choice for all the three groups. For those answered “No” and “Not sure” on question 2, their ratings on “other” and “power usage” are much higher than those answered “Yes” on question 2.

Figure 25 shows survey distribution on question 9 “what’s your age” for those answered “Yes”, “No”, and “Not sure” on question 2 “Would you like to have a device that detect your drowsiness/fatigue level and prevent you from falling asleep while driving?". For those answered "Yes", there are more people from age group 23-34 than 35-55. For those answered "No", there are more people from age group 35-55 than 23-34. For those answered "Not Sure", amount of people from 23-34 and 35-55 age groups are very close to each other.

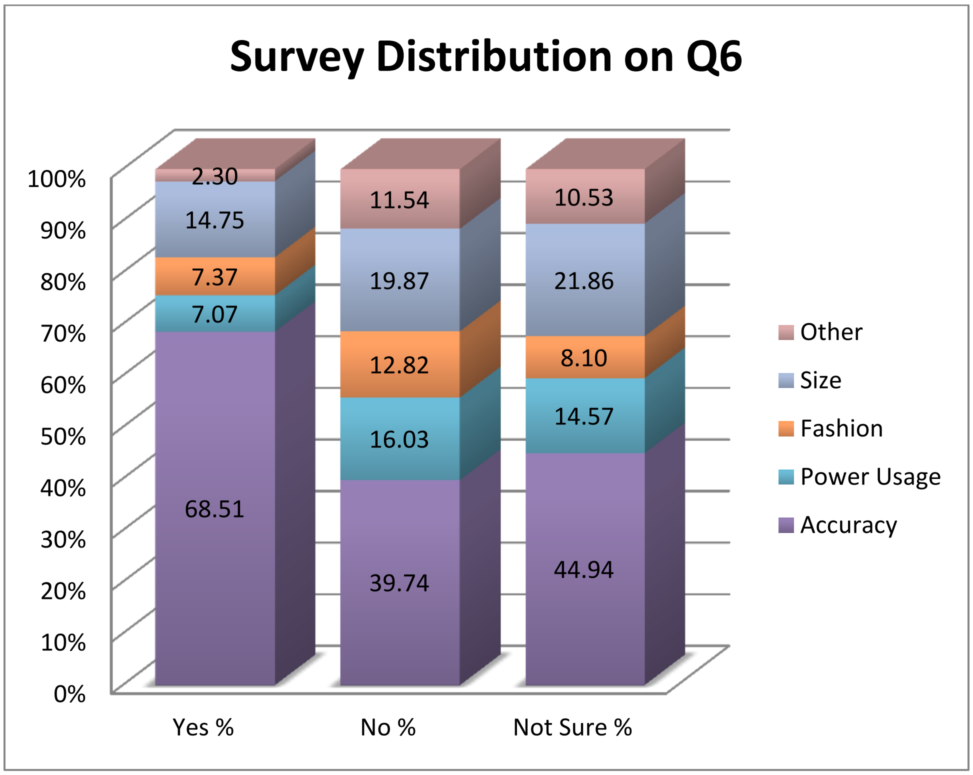

Figure 24 Survey Distribution on Q6 for Question 2

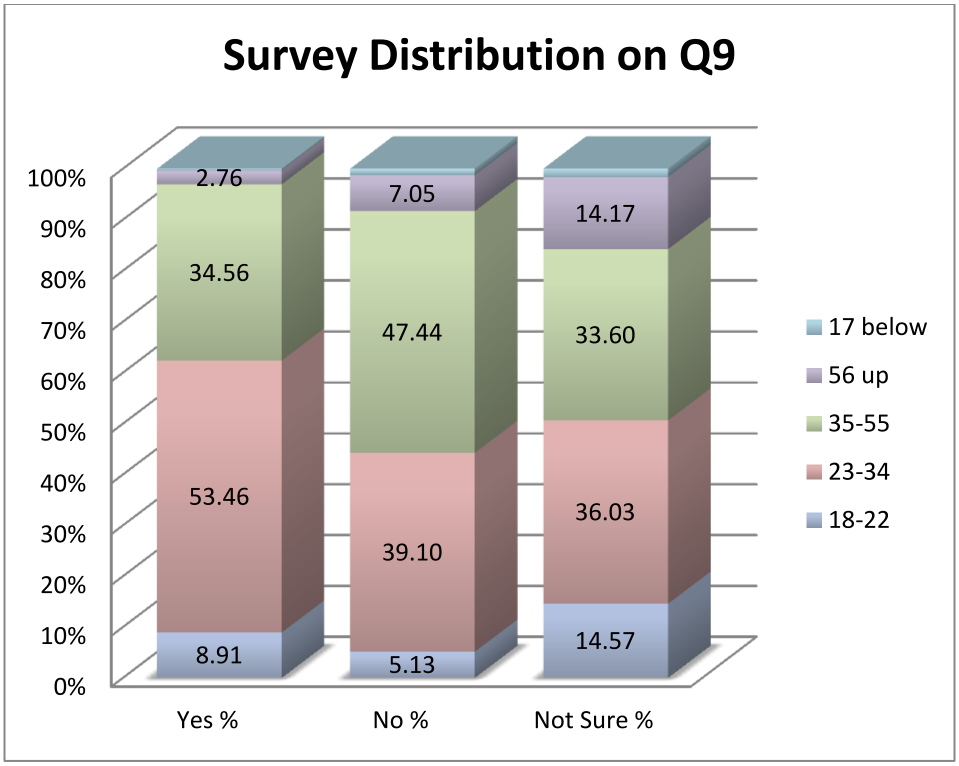

Figure 25 Survey Distribution on Q9 for Question 2

5.2.5 Analysis and Discussion on Long-Term Health Monitoring (Q5, 7-8)

In this section, people who answered “Yes” on question 5 “Would you like to wear this product for long-term as a health monitor system even when you're not driving”, question 7 “Would you like to have one of those products for free if you share your physiological data with us for 6 months”, and question 8 “If possible, would you like to use your smartphone as your primary health monitoring device” are separated and for different answers for each, the responses on other questions are discussed.

Figure 26 shows survey distribution on question 1 and 2 for those answered “Yes” on question 5. For question 1, 87% of those answered “Yes” also answered “Yes”, and 86% of those answered “No” answered “Yes” as well. Similar data is also found for question 2 where 87% of those answered “Yes” also answered “Yes” and 72% of those answered

"No" answered "Yes". From those data we can see that although only 53% people of this survey are willing to wear sensors for long-term monitoring, but majority of those who do not want long-term monitoring still want a device for monitoring the drowsiness levels when driving.

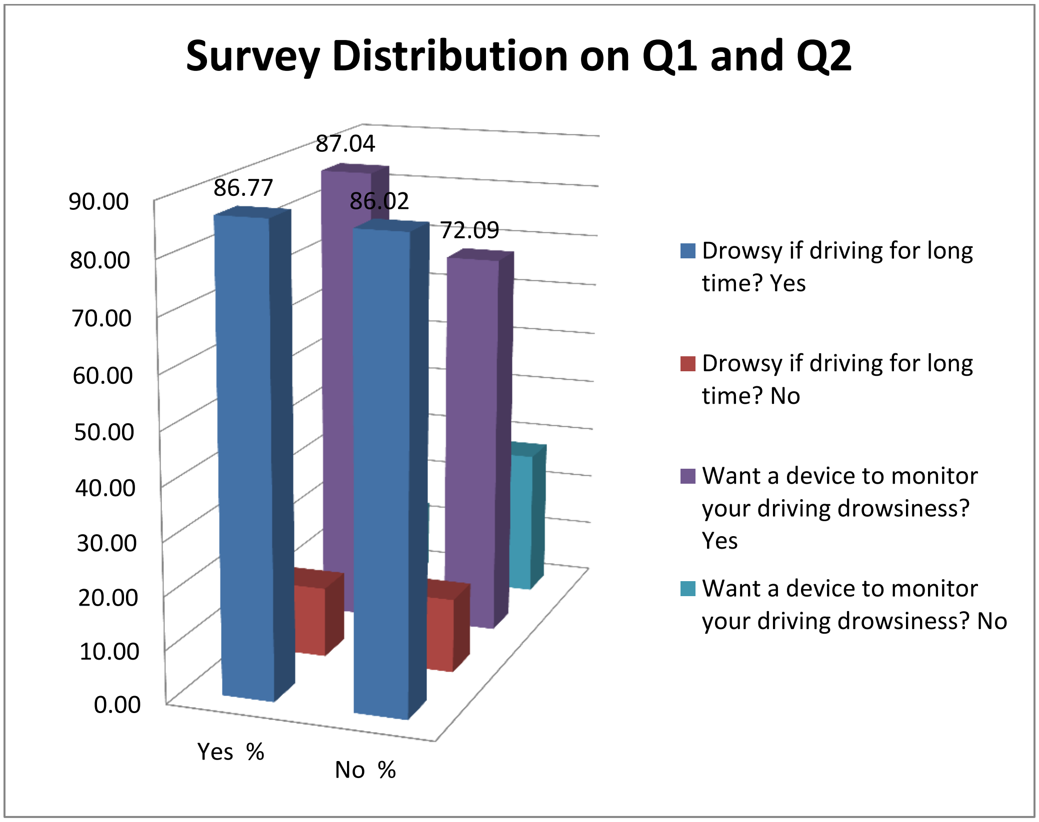

Figure 26 Survey Distribution on Q1 and Q2 for Question 5

Figure 27 shows survey distribution on question 6. The same trends are found here again: algorithm accuracy and sensor sizes are the top 2 factors for both answered "Yes" and "No" on question 5. Ratings for "accuracy" are more than 10% higher for "Yes" group comparing with the "No" group. Ratings for "size" are almost same for both groups. However, "power usage" has higher ratings in "No" group comparing with the "Yes" group.

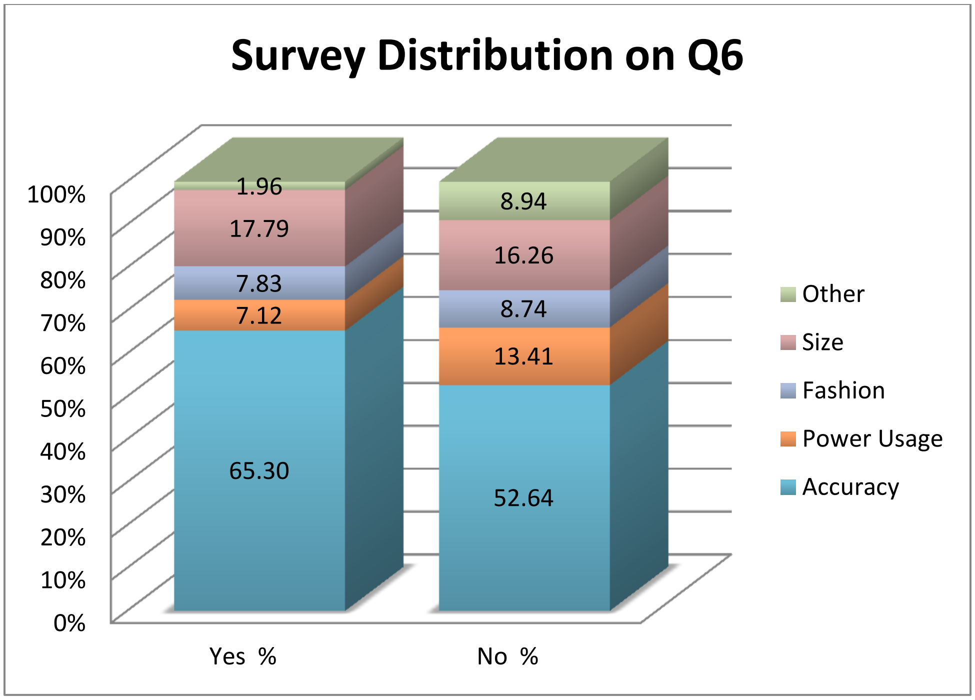

Figure 27 Survey Distribution on Q6 for Question 5

Figure 28 shows survey distribution on question 7 and 8 for opinions on sharing data for new algorithm development and using smartphone as main health monitoring platform. For those answered “Yes” on question 5, 86% answered “Yes” on question 7 and 84% answered “Yes” on question 8. For those answered “No” on question 5, 60% answered “No” again on share data for developing new algorithms. On question 8, only 52% of those who answered “No” on question 5 answered “No” again and 48% answered “Yes”. This means even though they don’t support the idea of long-term monitoring, half of them still want to use their smartphone to manage their health information. Figure 29 shows the age groups for “Yes” and “No” groups on question 5. 48% of those answered “Yes” are 23-34 years old and 35% of them are 35-55 years old. For 18-22 years old group, there are more answered “Yes” than “No” for question 5. 46% of those answered “No” on question 2 are 23-34 years old and 38% are 35-55 years old. Thus there are no clear relationships we can see for different age groups on question 5.

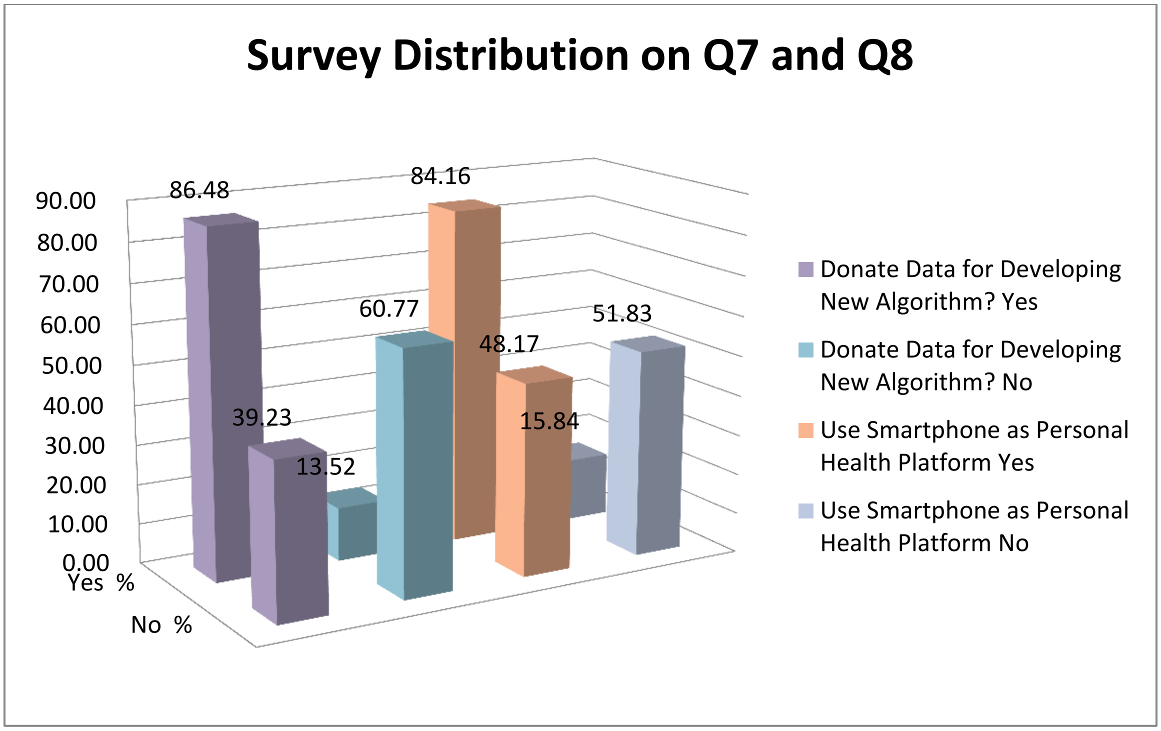

Figure 28 Survey Distribution on Q7 and Q8 for Question 5

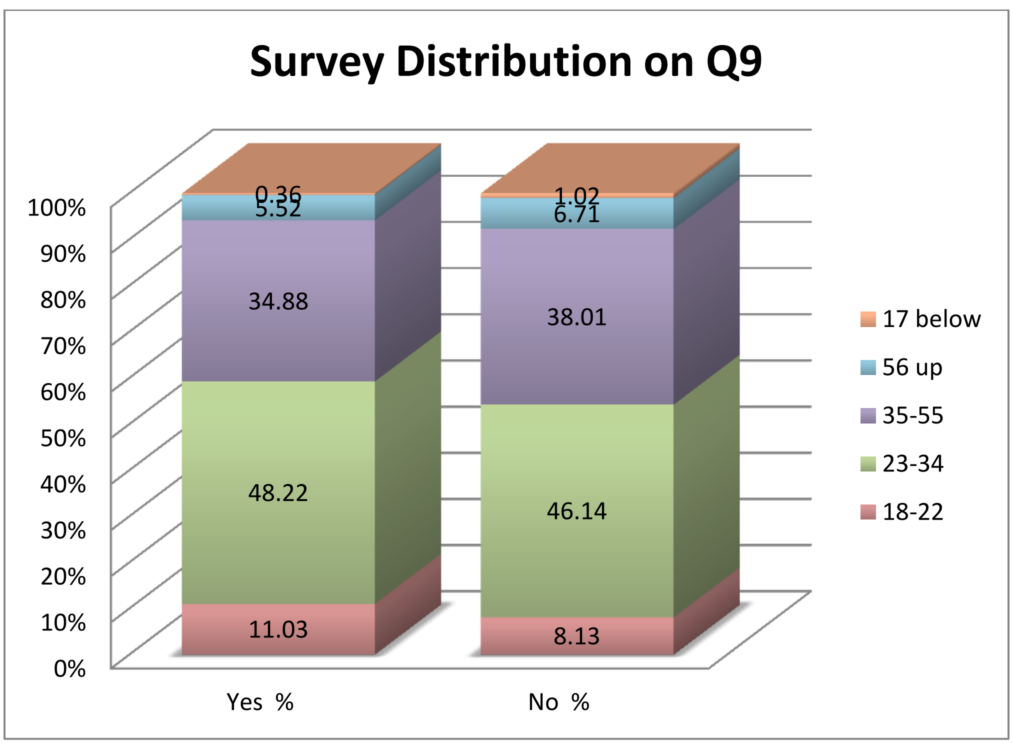

Figure 29 Survey Distribution on Q9 for Question 5

Figure 30 shows survey distribution on question 1 and 2 for those answered “Yes” and “No” on question 7 “Would you like to have one of those products for free if you share your physiological data with us for 6 months”. For question 1, 88% of those answered “Yes” also answered “Yes”, and 83% of those answered “No” answered “Yes” as well. Similar data is also found for question 2 where 87% of those answered “Yes” also answered “Yes” and 67% of those answered “No” answered “Yes” here. From those data we can see that although only 64% people of this survey are willing to share their physiological data for developing new algorithms, but majority of those who do not want to share their physiological data for developing new algorithms still want a device for monitoring the drowsiness levels when driving.

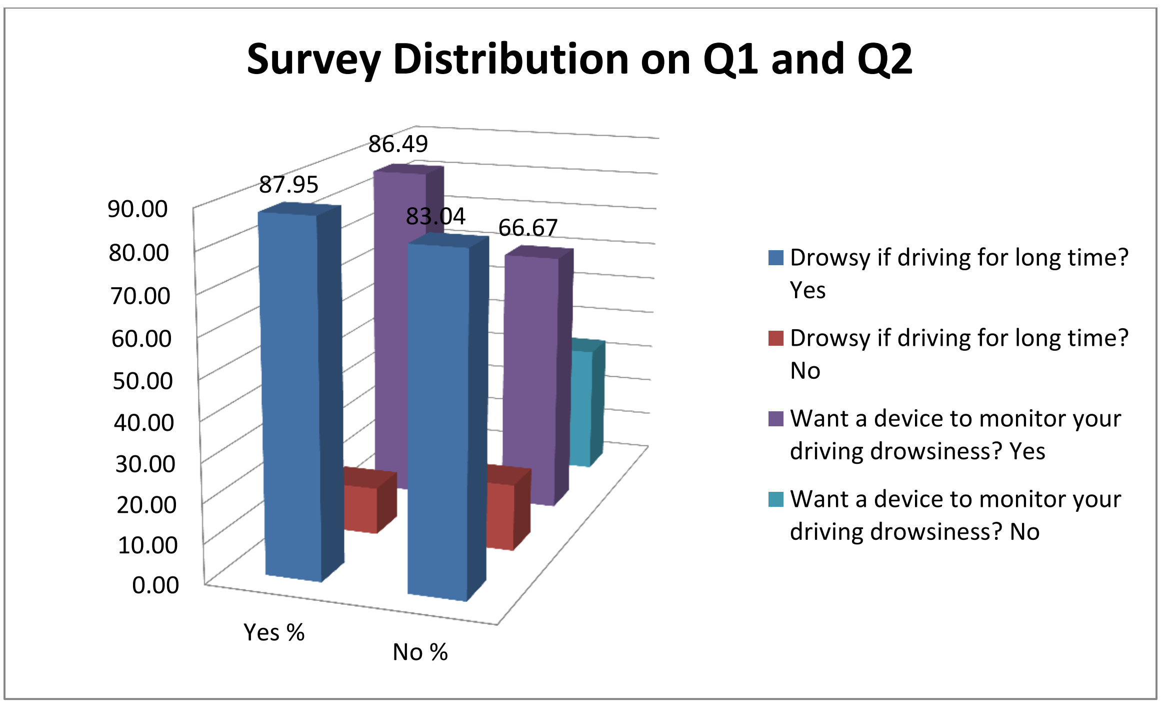

Figure 30 Survey Distribution on Q1 and Q2 for Question 7

Figure 31 shows survey distribution on question 6. The same trends are found here again: algorithm accuracy and sensor sizes are the top 2 factors for both answered “Yes” and “No” on question 7. Ratings for “accuracy” are more than 15% higher for “Yes” group comparing with the “No” group. Ratings for “size” are almost same for both groups. However, “power usage” has 10% higher ratings in “No” group comparing with the “Yes” group.

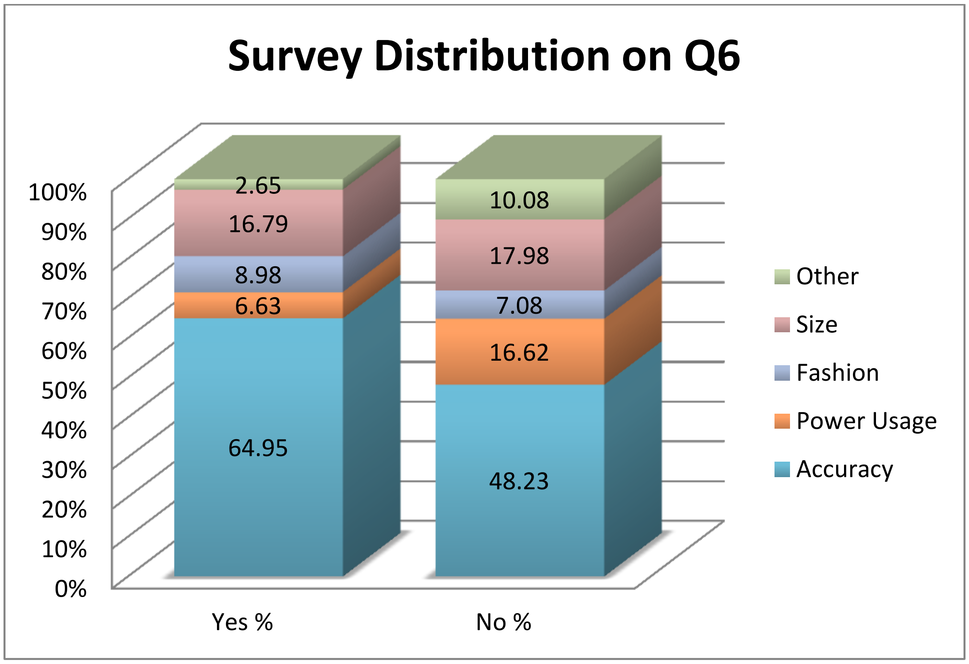

Figure 31 Survey Distribution on Q6 for Question 7

Figure 32 shows survey distribution on question 5 and 8. For those answered “Yes” on question 7 “Would you like to have one of those products for free if you share your physiological data with us for 6 months”, 71% answered “Yes” again for long-term monitoring and 85% answered “Yes” for using smartphones as health monitoring platform. For those answered “No” on question 7, majority of them answered “No” again on question 5 and question 8.

Figure 33 shows the age groups for “Yes” and “No” groups on question 7. The result plot is very similar with previous plot for those answered “Yes” and “No” on question 5. 50% of those answered “Yes” are 23-34 years old and 35% of them are 35-55 years old. For 18-22 years old group, there are slightly more answered “Yes” than “No” for question 7. 43% of those answered “No” on question 2 are 23-34 years old and 38% are 35-55 years old. Thus there are no clear relationships we can see for different age groups on question 7.

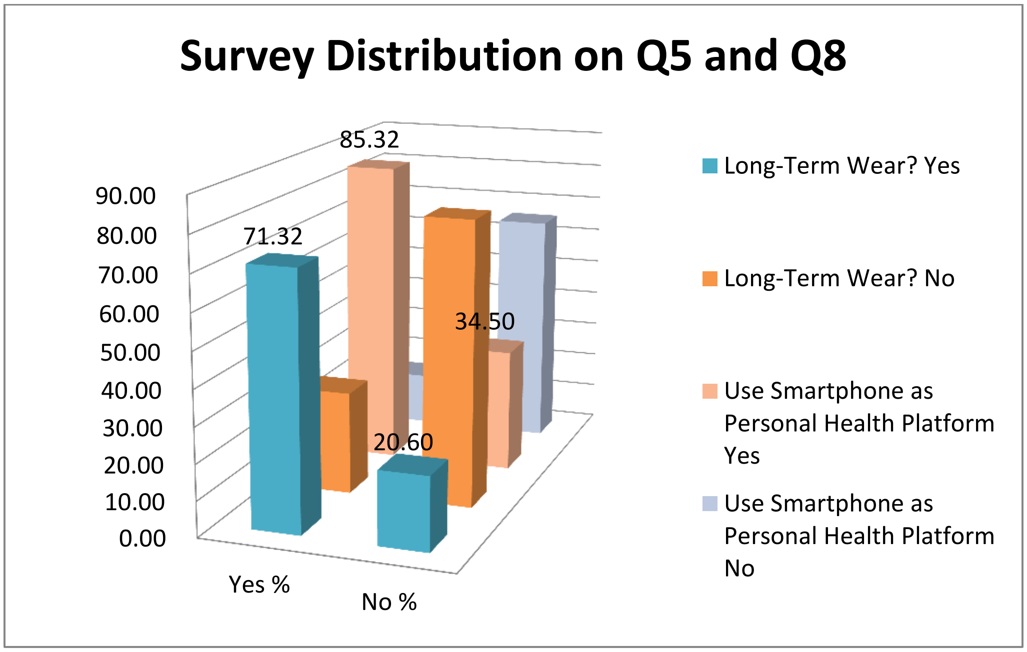

Figure 32 Survey Distribution on Q5 and Q8 for Question 7

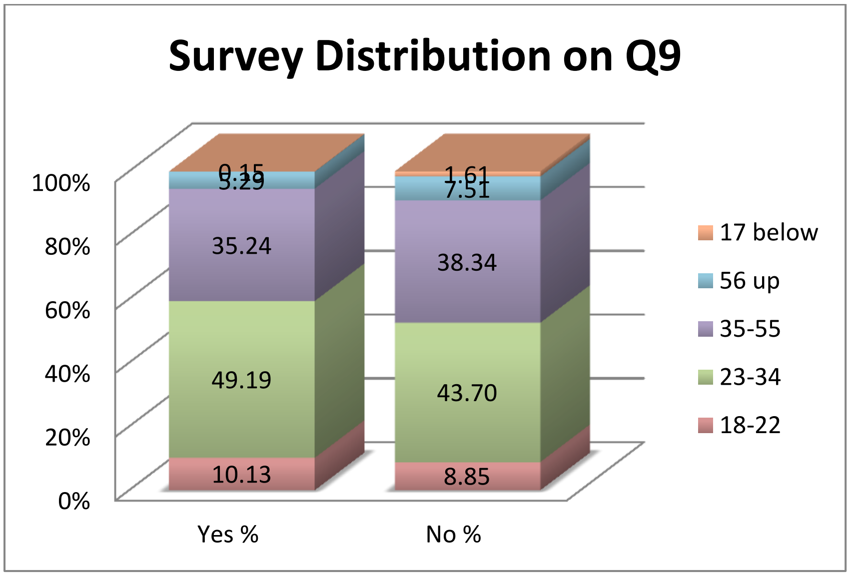

Figure 33 Survey Distribution on Q9 for Question 7

Figure 34 shows survey distribution on question 1 and 2 for those answered “Yes” and “No” on question 8 “If possible, would you like to use your smartphone as your primary health monitoring device”. For question 1, 89% of those answered “Yes” also answered “Yes”, and 80% of those answered “No” answered “Yes” as well. Similar data is also found for question 2 where 87% of those answered “Yes” also answered “Yes” and 63% of those answered “No” answered “Yes” here. From those data we can see that out of 67% people of this survey are willing to use smartphones as main health monitoring platform. For the rest 37% people who do not want to use smartphones for health monitoring purpose, majority of them still want a device for monitoring the drowsiness levels when driving.

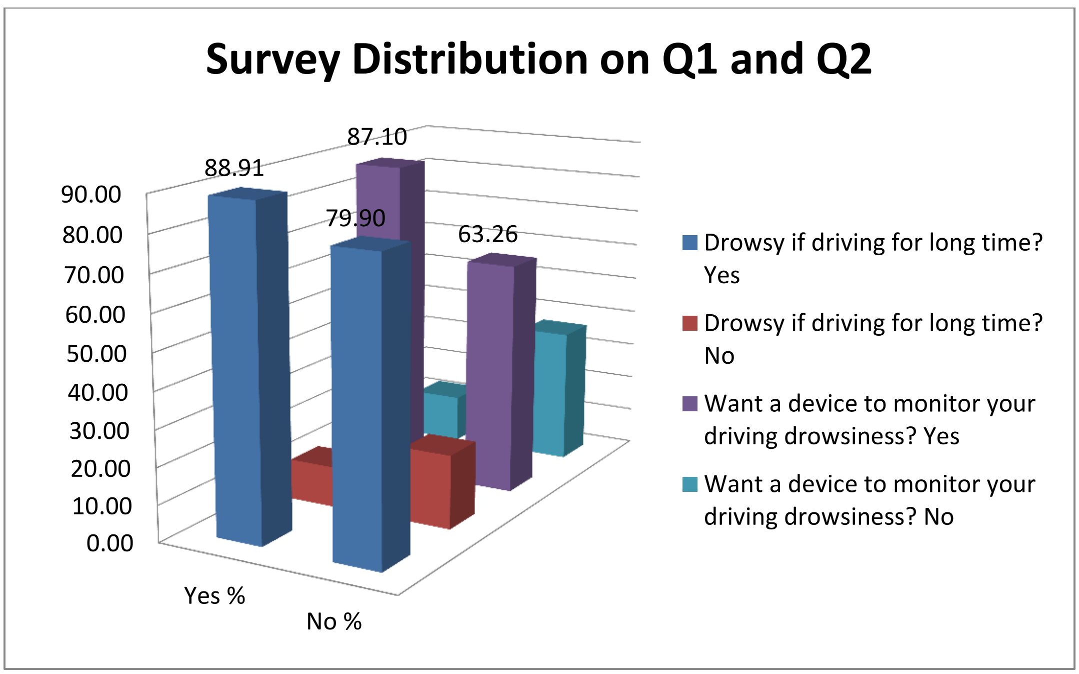

Figure 34 Survey Distribution on Q1 and Q2 for Question 8

Figure 35 shows survey distribution on question 6. The same trends found in previous survey groups are found here again: algorithm accuracy and sensor sizes are the top 2 factors for both answered “Yes” and “No” on question 8. Ratings for “accuracy” are more than 25% higher for "Yes" group comparing with the "No" group. Ratings for "size" are more than 7% higher for "No" group than the other one. However, "power usage" has a rating of 16% among "No" group which is higher than the rating of "size" among the "Yes" group and it is also much higher comparing with the "Yes" group for the same option.

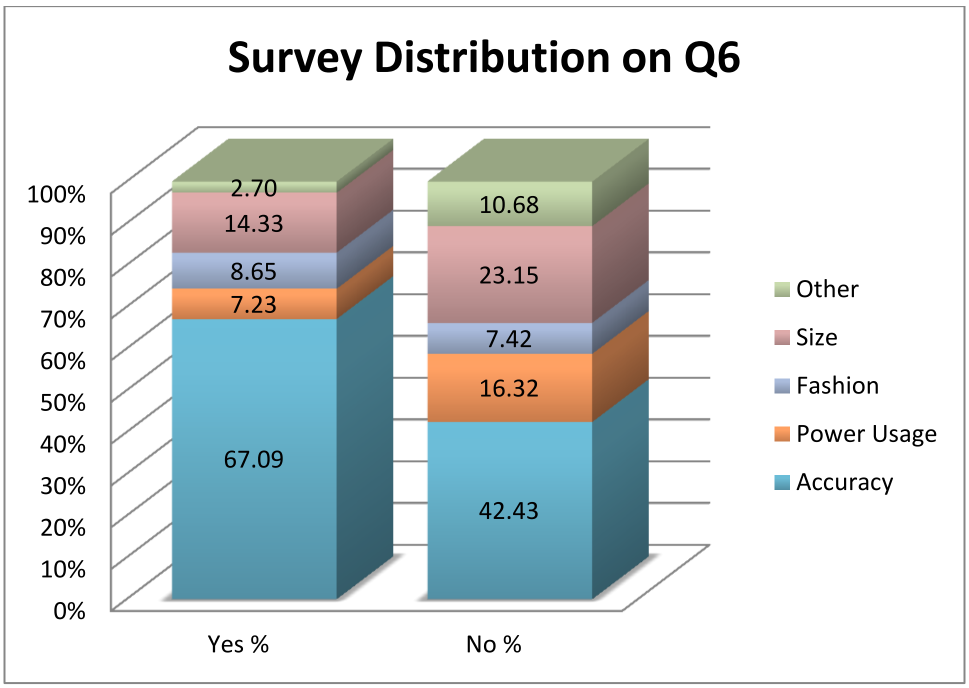

Figure 35 Survey Distribution on Q6 for Question 8

Figure 36 shows survey distribution on question 5 and 7. For those answered "Yes" on question 8 "If possible, would you like to use your smartphone as your primary health monitoring device", 67% answered "Yes" again for long-term monitoring and 82% answered "Yes" for using smartphones as health monitoring platform. For those answered "No" on question 7, majority of them answered "No" again on question 5 and question 7. Ratings for "YES" are lower comparing with those answered "Yes" on question 5 and 7. Although 67% people are willing to use smartphones as health monitoring platform, there are still almost 30% of them do not like long-term monitoring or sharing their physiological data for developing new algorithms.

Figure 37 shows the age groups for “Yes” and “No” groups on question 7. The result plot is again very similar with previous plot for those answered “Yes” and “No” on question 5 and question 7. 50% of those answered “Yes” are 23-34 years old and 35% of them are 35-55 years old. For 18-22 years old group, there are slightly more answered “Yes” than “No” for question 7. 42% of those answered “No” on question 2 are 23-34 years old and 49% are 35-55 years old. Thus there are no clear relationships we can see for different age groups on question 8.

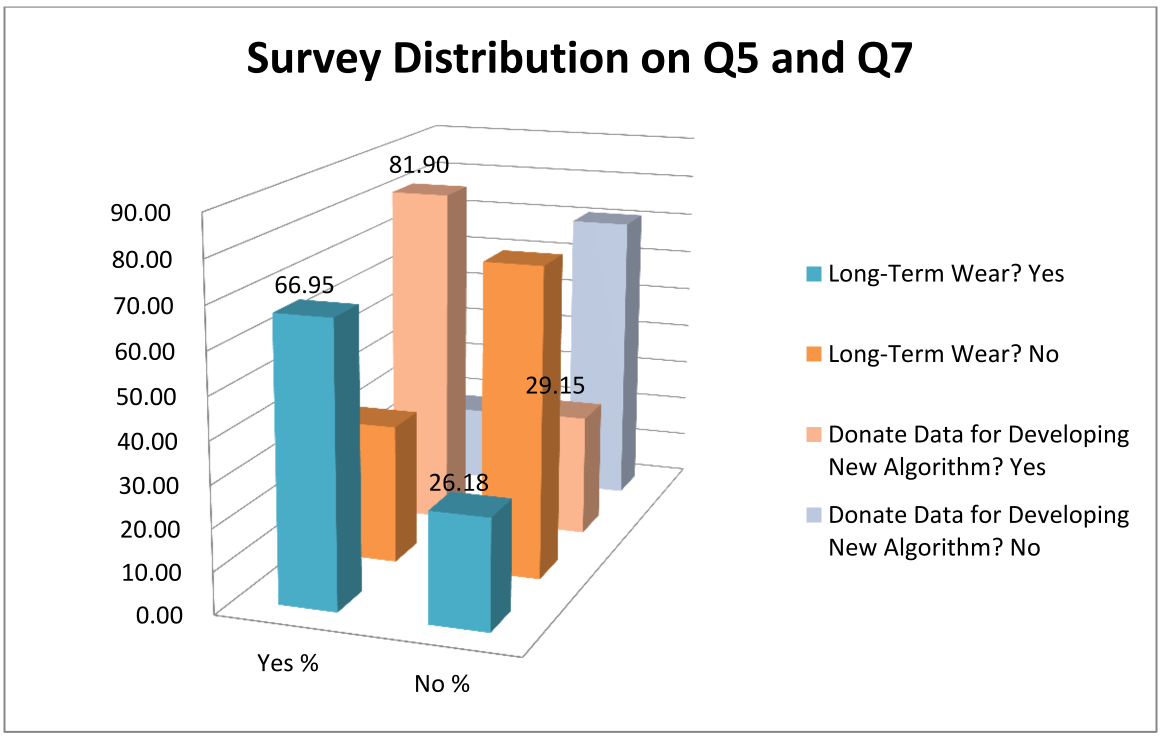

Figure 36 Survey Distribution on Q5 and Q7 for Question 8

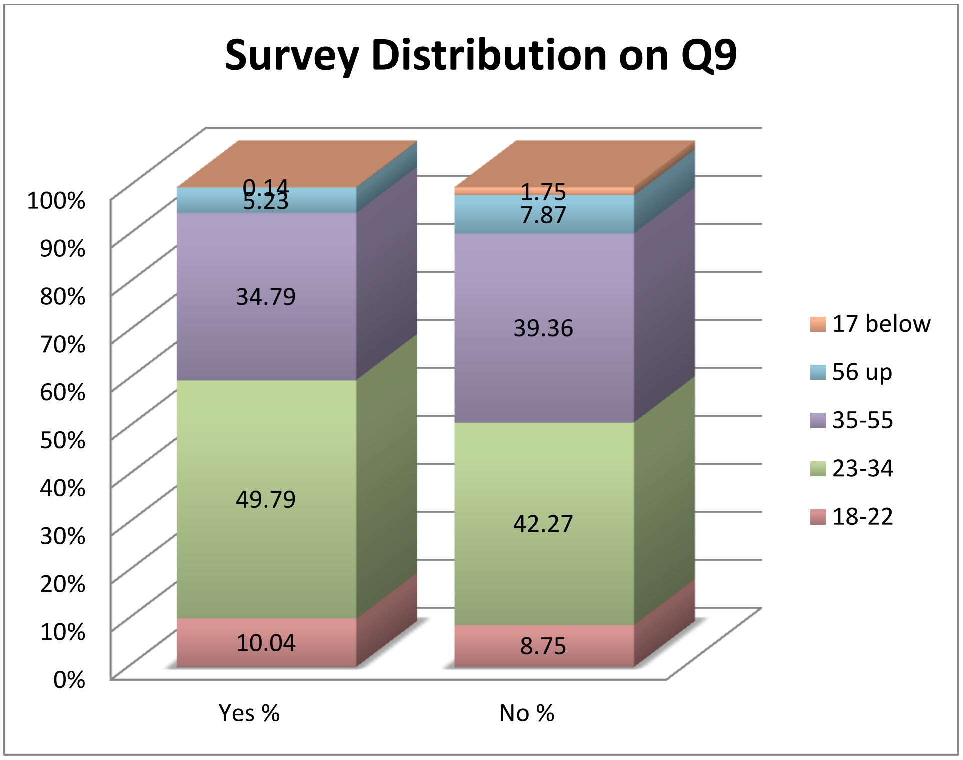

Figure 37 Survey Distribution on Q9 for Question 8

5.2.6 Analysis and Discussion for those answered YES on all of Q2, Q5, Q7 and Q8

In the last section of analysis and discussion, for those answered “Yes” on question 2 “Would you like to have a device that detect your drowsiness/fatigue level and prevent you from falling asleep while driving”, question 5 “Would you like to wear this product for long-term as a health monitor system even when you're not driving”, question 7 “Would you like to have one of those products for free if you share your physiological data with us for 6 months” and question 8 “If possible, would you like to use your smartphone as your primary health monitoring device” are grouped together and their responses on other questions are discussed.

As shown in Table 1, there are 311 people, which is almost 30% of all the responses answered “Yes” on all the above four questions. Among the 311 people, 51% are females and 49% are males. 11.9% from them are 18-22 years old, 48.32% are 23-34 years old, 37% are 35-55 years old, and only less than 3% are older than 56. There are 81% answered “Yes” for getting drowsy when driving for long time, 10.6% answered “No”, and the rest answered “Not Sure”. Sunglasses again are the top choice for the appearance for the sensor. Out of these 311 people, 85% are healthy and 15% are suffering from various chronic diseases. “Accuracy for the algorithm” again is being rated for the most important factor for algorithm embedded medical devices. “Size” and “fashion” are rated the 2nd and 3rd most important factor.

5.3 Conclusion

In general, young people like the idea of "algorithm embedded medical device" better than the older people. Males care more on "accuracy" than females and females cares more about "sizes" and "fashion" than males. More males are willing to use this wireless sensor for long-term monitoring than females and willing to share/donate data for developing new algorithms. People suffering from chronic diseases have much higher requirement for power usage than healthy people. More healthy people are willing to share their physiological information for developing new algorithms and use smartphone as health monitoring platform. For those answered "Yes" on Q7, they have the highest ratings for answering “YES” on question 2, 5 and 8. There are about 30% of total responses answered “Yes” on question 2, 5, 7 and 8. Sunglasses are the most rated appearances for the drowsiness sensor among all groups of people. “Algorithm accuracy” and “sizes” are the top 2 rated factors people care about for algorithm embedded medical devices.

6. Conclusions and Recommendations

6.1 Conclusions

In this project, the goals of study various aspects of embedded medical devices for smart healthcare is successfully achieved. In background and literature review chapter, general ideas of new product development are discussed; popular technologies used in wireless personal medical devices are provided, and FDA and FCC regulations and requirements on this kind of devices are investigated. In the methodology chapter, several current applications on market for algorithm embedded medical devices are discussed, concerns and regulatory challenges on wireless, algorithm embedded personal medical devices are mentioned, and a survey on social acceptance and product design on a prototype device is designed. The survey was distributed among several different locations in about one month and a total number of 1054 responses were received. In the result and analysis chapter, details of the survey results are discussed. The original objective of this project: investigate the applications, social acceptance, and regulations of algorithms embedded personal medical devices; provide design suggestions for Team FIVOLTS on developing the Drowsiness Control Center are successfully completed.

6.2 Recommendations

There are several things in this project could be done for further improvements: Longer time period and more locations for distributing the survey. Balance of data from different age groups, as well as male and females so that the survey is more controlled. In addition, if more data on those has chronic diseases can be collected it would help us to decide which type of algorithms to research first.

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Appendices A: Full Product Survey

https://docs.google.com/spreadsheet/viewform?formkey=dGhpNEpkRW51QmNnYzNOUjlvMWpIaGc6MQ#gid=0

Drowsiness Control Center (Algorithm Embedded Medical Device) Survey

Hello Everyone, we are FIVLOTS and our team is participating in the Cornell Cup Embedded System Design Competition. Our project is to design a medical device that would monitor users' heart rates, predict drowsiness/fatigue levels and give feedback to them . We'd like to collect different opinions from all of you for the design and use of our product. Your ideas and opinions would be extremely important to us and we would like to incorporate them in our project if possible.

* Required

Do you get tired when drive for a long time? *

- Yes
- No
- Does Not Apply (for non-drivers)

Would you like to have a device that detect your drowsiness/fatigue level and prevent you from falling asleep while driving? *

- Yes
- No
- Does Not Apply (for non-drivers)

Which one do you prefer to wear, baseball cap or sunglasses, to monitor your drowsiness level while driving? *

- baseball cap
- sunglasses
- both
- Does Not Apply (for non-drivers)
- Other:

Are you suffering from one of the following diseases? *

- any Cardiac Disease
- Diabetes
- High blood pressure
- other chronic disease
- no, I'm not suffering from any kind of chronic disease

Would you like to wear this product for long-term as a health monitor system even when you're not driving? *

we can calculate your chance of getting diabetes and heart problems

- Yes
- No

Which one of the following aspects would you concern the most about this product? *

- 1. performance on determining correct drowsiness level
- 2. power consumption
- 3. appearance/looks of the product
- 4. physical size of the product (I want this to be as small as possible to carry around)
- Other:

Would you like to have one of those products for free if you share your physiological data with us for 6 months? *

- Yes
- No

If possible, would you like to use your smartphone as your primary health monitoring device? *

use smartphone as an end device for receiving your physiological data through wireless transmission

- Yes
- No

what''s your age? *

- 18 to 22
- 23 to 34
- 35 to 55
- 56 and above
- none of the above

what's your sexuality? *

- male
- female
- not to answer

If you have any other ideas or concerns about this product, please put them in the space below

Appendices B: Comments from the Survey

Three questions from the survey provided space for "other" or "comments" option. All the comments from the survey result are included in this section.

Comments on Appearance/fashion:

- Car Key
- Earrings
- Earphones
- Auto-sensing in the car
- Pendant
- Pendant
- Pendant
- Pendant
- Ring
- Put in the pocket
- Some sort of auto-sensing
- Button on the shirt
- Something light and small
- Jewelry
- Jewelry
- Watch
- Watch
- Watch
- Watch
- Watch
- Watch
- Watch, Bluetooth Headset
- Watch, Earrings
- Something like watch or brooch
- Bracelet
- Cellphone
- Somewhere in the car
- Somewhere in the car
- On ECG Probes
- Watch
- Watch
- Bracelet
- Cellphone or GPS
- Cellphone
- Cellphone
- Cellphone style
- Watch
- Watch
- Watch
- Watch
- Watch
- Watch
- Bluetooth Headset
- Steering wheel
- Earphones
- I don't want it
- I don't want them
- I don't want them
- Somewhere on the shirt

- Cellphone
- Some sort of bracelet
- Necklace
- Necklace
- Necklace，Earring
- Something lightweight and small
- Brooch
- Eye Glasses
- Eye Glasses
- Collar
- Key ring

Comments on Most Important Factor for the Device:

- Price and accuracy
- Safety
- I don't care
- All of the above options
- Fashionable
- Do not care
- Type of device
- Safety
- Safety

Other Comments for the Product:

- 2 things, 1. Accuracy, 2. Lightweight and small size
- Put the drowsiness display somewhere close to the rearview mirror
- Minimal Radiation for body
- Continuous wearing for one-two months sounds fair, six months is too long
- I will buy it if it looks good and can benefit for my family
- Why don't use music to remind the driver
- Does the wireless sensor have radiation? How much radiation?
- I hope it's free
- Can you make them like those Bluetooth Headset?
- Accuracy is most important, and it should stay on body easily for long-term monitoring
- Accuracy is most important, and I hope it will be on market soon and we can try it!
- Appearance and accuracy, two important things
- I hope your project will be successful

Appendices C: Team Summary for Cornell Cup

Daytime drowsiness and fatigue lead to decreased driving reliability, lower working efficiency and fatal accidents. According to recent research, heart rate variability can be robustly calculated from the photoplethysmogram (PPG) to indicate parasympathetic nervous activity and classify drowsiness level. Concurrently, part of our group will conduct biomedical research on correlations between any available physiological signals from the PPG sensor, including: heart rate variability, respiration rate, oxygen saturation (SPO2) and blood pressure dynamics during fatigue-inducing cognitive experiments.

As a solution, we will design a control center using the Atom board to receive PPG from a wireless headband using the ZigBee protocol, then processed the PPG to classify drowsiness levels. Along with a built-in alarm, we also provided customizable response commands to peripheral devices such as track switching on a music player or flashing the vehicle's emergency lighting. Not only efficiency and reliability can be ensured, but lives will be saved. Furthermore, the control center will be able to connect multiple channels of wireless PPG sensors to reduce cost. Our product could also be used as a consumer health monitor to provide low cost remote health care and synchronize physiological data to a server.

Appendices D: Outline for Design of Drowsiness Control Center

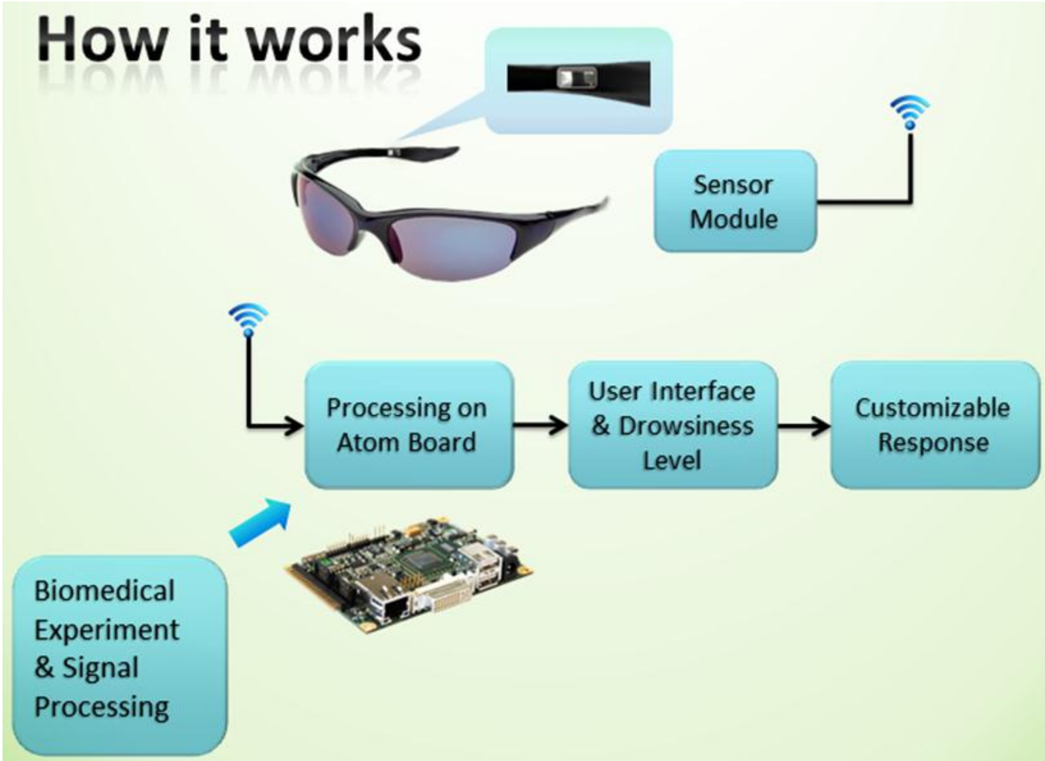

Figure 38 Top Level Diagram for Drowsiness Control Center*

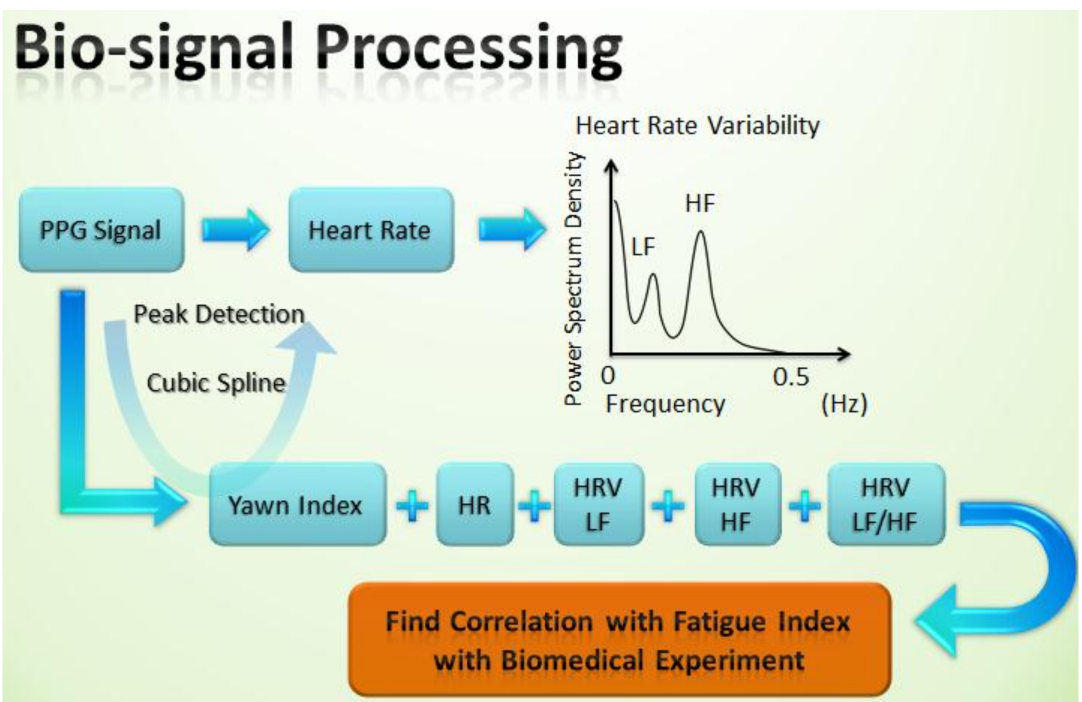

Figure 39 Algorithm behind Drowsiness Control Center*

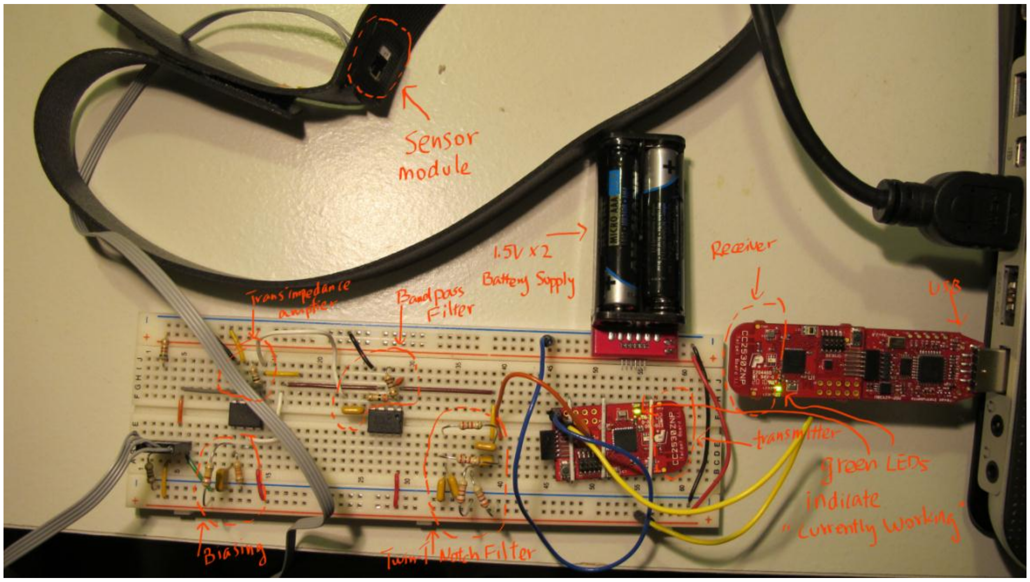

Figure 40 Physical Implementation of the wireless sensor on breadboard

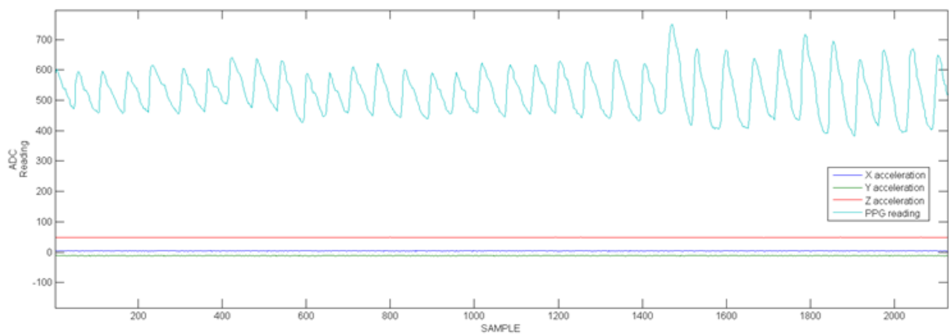

Figure 41 Sample Output Data Plot

**Pictures prepared by FIVOTS.*