School of Engineering Science, Burnaby, BC V5A 1S6

Feb 9th, 2015

Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
Burnaby, British Columbia
V5A 1S6

Re: ENSC 440 Functional Specification for Health Reporter

Dear Dr. Rawicz

Attached below is the functional specification for "Health Reporter", which is a health condition sensing device. The "Health Reporter" is a health condition monitoring device. We are designing a platform to provide diagnostic report and emergency notification to the clients about their health conditions. This device will give the possibility for clients to perform regular health check-up on their own instead of going to a clinic.

Our Functional Specification describes the Health Reporter system requirements in details, including intended capabilities, reliability, usability, sustainability and safety for both proof-of-concept and production phases of the development. All our team members will utilize this document as a reference for designing, developing and testing our product.

D-Health Solution Inc. is aiming to provide simple and convenient medical solutions to patients by developing Health Reporter system. We are formed of five engineering students: Jue(Carter) Chen, Simone Liu, Janice Mardjuki, Kai Geng, Xing Qiao. If you have any questions or concerns regarding to our project, please contact me at 604-728-7157 or by email at carterc@sfu.ca.

Yours Sincerely,

Jue Chen

Jue Chen
CEO
D-Health Solution Inc.

Functional Sepcification for Health Reporter

Project Team: Jue(Carter) Chen
Simone Liu
Janice Mardjuki
Kai Geng
Xing Qiao

Contact Person: Jue(Carter) Chen
carterc@sfu.ca

Submitted to: Dr. Andrew Rawicz
Steve Whitemore

Executive Summary

33% percent of patients wait for more than six days just for a clinical visit with family doctors in Canada [1]. Even though Canada is a developed country, it has a relatively high quality of medical service and low death rate compare to other countries on our mother earth. There are still a noticeable number of people who do not have a quick access to doctors. “Health Reporter” will be the ultimate solution for them. “Health Reporter” will also be the solution to patients in hospitals and elders in Nursing Houses. Doctors and nurses can perform quick responses to those patients according to our analysis.

Since “Health Reporter” is a real-world device, it will transfer the data and analysed result to the cloud. As long as family doctor has the permission from our clients, they can simply log into the clients’ account and perform regular analysis based on the data we sent. Then they can choose either it is necessary to contact with our clients or not. After introducing this procedure, our “Health Reporter” will not only be in home device, but also an information bridge that connects clients and doctors together in a more efficient way.

“Health Reporter” will capture the following human body data:

- Body Temperature
- Pulse
- Oxygen in Blood
- Skin condition (sweating rate)
- Air Flow rate
- Patient Position

After “Health Reporter” captured the above data or only part of them, it will transfer those data to our server in real-time. Because of the fact that a smart-phone application will be included in the delivery package for our clients, clients can also read their health condition data and analysed the result by using smart-phone. Last but not least, the data obtained from “Health Reporter” will also be available to family doctors as long as they have the permission from the clients.
More importantly, our “Health Reporter” will follow all related medical device standards and guidelines, including IEC and ASTM.

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Glossary

IEC	International Electrotechnical Commission
IOS	International Organization for Standardization
MTBF	Mean Time between Failures
CLSI	Clinical and Laboratory Standards Institute
"Health Reporter" Client	Client should have the following abilities ・Clients should not have Contact Dermatitis ・Clients should be psychologically fit to have additional electronic parts attached to their body.

D-Health Solution Inc.

1. Introduction

The Health Reporter is an integrated body monitoring system focusing on day-to-day health report and real time body condition analysis. The system has five sensors attaching to user's body to measure sweating, breathing, body temperature, body position and heart rate. At the end of each measuring period, the Health Reporter will generate a report for the user showing on our mobile and web application. The report will indicate the average, maximum and minimum records of the five dimensions. If the patient is in critical condition or needs immediate assistance, the system will send notifications to pre-registered accounts, such as hospitals and patient's relatives. All authorized parties can login to our website and view the patient's report. The corresponding requirements for the Health Reporter are listed in this functional specification.

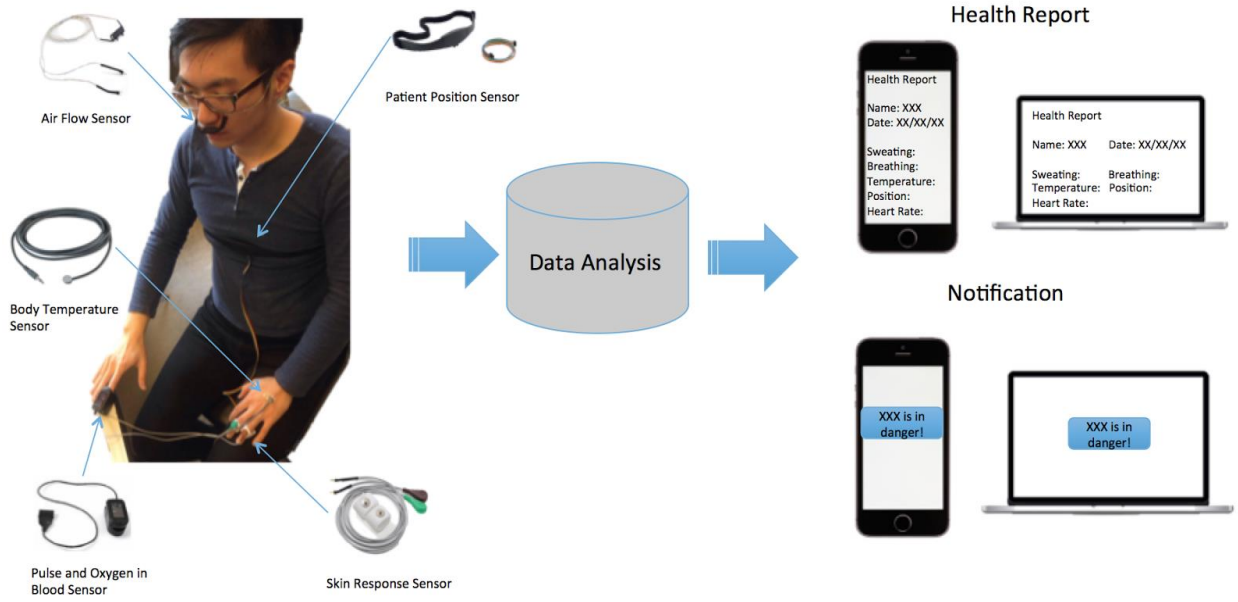

Figure 1: High-level design of Health Reporter [2].

1.1 Scope

The functional specification defines the functional requirements that the Health Reporter must adhere to. The document clarifies the proof-of-concept device and final production device. The design and development of the device will address the requirements listed in this document.

1.2 Intended Audience

The functional specification is intended for use by all members of D-Health Solution Inc during the design and development of the Health Reporter device. Development Engineers shall follow the requirements as product design goal. Quality Assurance Engineers shall use this document as a guidance for creating test plan.

D-Health Solution Inc.

1.3 Classification

In order to make it easier to cross reference and prioritise the functional requirements, the following convention is applied throughout this document:

[Rn-p] A functional requirement.

Where **R** denotes the functional requirement, **n** contains the heading number of the components followed by the functional requirement number, and **p** indicates the priority of the requirement specified by three levels below:

I The requirement applies to the proof-of-concept system.
II The requirement applies to the prototype system.
III The requirement applies to the final production system.

2. System Requirements

This section demonstrates general system requirements to the Health Reporter.

2.1 System Overview

The Figure 2 below illustrates the high-level system block diagram for the Health Reporter.

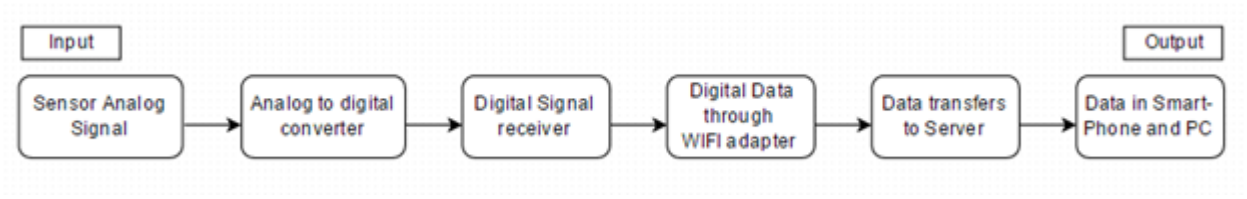

Figure 2: High-Level System Block Diagram

The concept of the Health Reporter is to collect human body information and provide health related feedback to the user. Because of the limitation on budget and time, only six sets of information will be collected from user's body. Those information are Body Temperature, Pulse, Rate of Oxygen in Blood, Skin Condition (Sweating/Dry), Air Flow Rate through nose and Body Position (Standing/Falling). User can read those data along with the analytic feedback through mobile application or our website.

The user of the Health Reporter should be psychologically comfortable with sensors attached to their body according to the glossary.

Additionally, the user should be able to move and adjust the sensor to the appropriate location of the human body. The general usage of all sensors are listed below.

- Body Position Sensor should be attached to the chest of human body
- Temperature Sensor should be attached to the position where the temperature is less affected by surrounding environment.
- Pulse and Oxygen in Blood Sensor should be attached firmly on any of the finger.

- Air Flow Rate Sensor should be attached right at the nares.
- Galvanic Skin Sensor should be attached to two adjacent fingers.

Not all sensors are need to be attached to the human body. User can choose to attach one or several of the provided sensors to their body according to their personal needs. Once sensors are attached correctly, user can power up the device and data along with the analytic feedback will be displayed on mobile application or our website.
Note that we will only support five sensors with 6 set of information in the prototype. The maximum number of sensors that can be attached to our device will be limited to ten.

Figure 3: The completed set of the Health Reporter without Sensors Attached

Figure 3 illustrated the base layout of the Health Reporter. Because of the confidential issue of three boards, we will not provide the schematic graphs of boards in this document.

2.2 General Requirements

[R2.2.1-III] The retail price of the Health Reporter including five sensors and the platform board shall be less than CDN$200.
[R2.2.2-III] According to Figure 2, the set of device much be kept away from any general source that can lead to the damage of electronic components.
[R2.2.3-III] The device must require minimal training time to use.
[R2.2.4-II] The device shall be easy to assemble and disassemble.

2.3 Physical Requirements

[R2.3.1-I] Sensors must be able to remain functionality in regular human body movement.
[R2.3.2-II] The outer case of the Health Reporter shall be water and heat resistance.
[R2.3.3-III] The size of outer case shall be relatively small in order to be portable.

2.4 Electrical Requirements

[R2.4.1-II] The wall adaptor shall be working properly with 110V at 60Hz.
[R2.4.2-II] All sensor and boards should be remain functionality under regular temperature range(-10 ℃ to 60 ℃).

[R2.4.3-II] The analog input pins shall be accessed easily in order to perform measurements when problems happen.
[R2.4.4-I] The input voltage of the device must be less than 9 V.
[R2.4.5-II] The USB ports of the Health Reporter shall be compatible with USB2.0/3.0.
[R2.4.6-I] The Wifi adapter of the Health Reporter shall be able to transfer information under the standard functionality range indicated by IEEE 802.11[3].
[R2.4.6-III] The device should enter sleeping mode when the device has been idle for more than 30 minutes.

2.5 Standards

[R2.5.1-II] The Health Reporter shall conform IEC 61010-1:2001-Ed.2.0[4].
[R2.5.2-II] The Health Reporter shall conform ISO 10993-11:2006[5].
[R2.5.3-II] The Health Reporter shall conform CLSI EP24-A2:2012[6].

2.6 Reliability and Durability

[R2.6.1-II] The Health Reporter shall be able to keep functionality with daily usage.
[R2.6.2-III] The Health Reporter shall be able to collect and analyse data for at least 48 hours continuously.
[R2.6.3-III] All sensors' lifetime shall be more than three years.
[R2.6.4-III] Regular software update shall be easily done with minimal technical knowledge.
[R2.6.5-III] The MTBF (mean time between failures) of the Health Reporter shall be no less than 2,400 hours.
[R2.6.6-III] The mobile and web application shall be bug free under regular daily usage.

2.7 Safety Requirements

[R2.7.1-I] The sensors must not cause harmful interference to any user.
[R2.7.2-I] The device must have sufficient insulation to prevent user from direct contact with electronic components.
[R2.7.3-II] The device shall have self-diagnose and alarming system. Once a failure is detected, it shall give a warning to the user indicating an unexpected error occurred in the Health Reporter system. It shall also advise the user to shutdown the device and remove all the sensors from the user's body.
[R2.7.4-III] The power connections and electronic components shall be enclosed and shall not be opened during operation.
[R2.7.5-II] The electronic components of the Health Reporter shall not be interfered with other regular electronic devices.

2.8 Usability Requirements

[R2.8.1-I] The method of using each sensor must be easily understood by the user.
[R2.8.2-II] The medical analytic function shall be based on the correctness of collected data from sensors.
[R2.8.3-III] The Health Reporter's firmware shall be updated by specialized technician.
[R2.8.4-III] All functions built in the Health Reporter shall be based on the proper performance of sensors.
[R2.8.5-III] The weight of the device shall be less than 500 g in order to be comfortably carried by the user.

2.9 Environmental Requirements

[R2.9.1-II] The Health Reporter should be working properly from sea level to 5000m above sea level.
[R2.9.2-II] The Health Reporter should be working properly from -20 ℃ to 70 ℃.
[R2.9.3-III] The Health Reporter should be remain functionality under relatively normal humidity (40%).

2.10 Performance Requirements

[R2.10.1-II] The Health Reporter shall have data shown on mobile or web application within 1 minute after booting up.
[R2.10.2-III] The system shall analyze and transfer data in real-time.
[R2.10.3-I] The system shall send notification within 30 seconds after an emergency condition is detected.

3. Sensors

3.1. Body Temperature Sensor

Body Temperature Sensor is used to measure user's body temperature by attaching to user's skin. The system monitors body temperature statistics sent from body temperature sensor. Once the body temperature is above or below certain normal region, the system will send notifications to pre-registered user, such as associated doctor in order to initiate the medical treatment is required.

3.1.1. Electronic Requirements

[R3.1.1-I] The working voltage of body temperature sensor shall be in range of 3.0 V to 5.5 V DC[7].
[R3.1.2-II] The data provided by the body temperature sensor shall be within ±0.5 ℃ accuracy.
[R3.1.3-III] The working range of the body temperature sensor is -55 ℃ to 125 ℃.

3.1.2. Physical Requirements

[R3.1.4-II] The body temperature sensor should be waterproof.
[R3.1.5-I] The sensor shall not cause any uncomfortableness to the user.

3.2 Pulse and Oxygen in Blood Sensor

Pulse and Oxygen in Blood Sensor measures two sets of data.

1. Heart rate. If the heart rate is falling or rising into unexpected region without any unusual physical movement of user's body, the user will get an immediate alert and a corresponding notification will be sent to other pre-registered users.
2. Percentage of oxygen in blood. The sensor measures the arterial oxygen saturation of functional hemoglobin. When the rate of oxygen dissolved in blood is lower than regular condition, the user will get an immediate alert and a corresponding notification will be sent to other pre-registered users.

3.2.1. Electronic Requirements

[R3.2.1-I] The working voltage of the pulse and oxygen in blood sensor shall be in range of 3.0 V to 5 V DC.
[R3.2.2-III] Power consumption of the pulse and oxygen in blood sensor shall be at 8 mA at 5 V.

3.2.2. Physical Requirements

[R3.2.3-II] The pulse and oxygen in blood sensor should be attached to the finger of any user easily.
[R3.2.4-II] The weight of the pulse and oxygen in blood sensor should be less than 50g in order to make the user feel relatively comfortable when performing the measurement.

3.3 Galvanic Skin Sensor

The Galvanic Skin Sensor detects the sweat levels and stress levels by measuring skin conductance. Diseases, such as diabetes and epileptic attack, may cause the patients to produce more sweat. The data collected by the Galvanic Skin Sensor may help the user understand their stress level, and also help the medical professionals to understand the state of illness of their patients. By combining the sweat of the hands with body temperature and pulse data, it is possible to detect potential disease in early stage [8].

3.3.1. Electronic Requirements

[R3.3.1-I] The working voltage of the galvanic skin sensor shall be in range of 3.0 V to 5 V DC.
[R3.3.2-III] Current flow in Galvanic Skin Sensor shall be under 200 μA.

3.3.2. Physical Requirements

[R3.3.3-I] The Galvanic Skin Sensor should be waterproof.
[R3.3.4-II] The Galvanic Skin Sensor shall be attached to the two adjacent fingers firmly.

3.4 Air Flow Sensor

The Air Flow Sensor detects the respiratory rates of the user. Abnormal respiratory rates and changes in respiratory rates could be an early indicator of major physiological instability. Once the respiratory rate drops below the standard rate, the system will provide an early warning of hypoxemia and apnea to both the user and the corresponding guardian.

3.4.1. Electronic Requirements

[R3.4.1-I] The working voltage of air flow sensor shall be in range of 3.0 V to 5 V DC.

3.4.2. Physical Requirements

[R3.4.2-III] The air flow sensor shall be light.
[R3.4.3-II] The air flow sensor shall be able to attached to user's nares with minimal support materials.
[R3.4.3-III] The material of Air Flow Sensor shall be smell free and not cause any uncomfortableness to the user.
[R3.4.4-I] The air flow sensor shall be water resistance.

3.5 Patient Position Sensor

The Patient Position Sensor detects several specific human body positions: standing/sitting, supine, prone, left and right. This function can help nurses to have a quick response when the user or the patient need emergency help, specially in nursing homes.

3.5.1. Electronic Requirements

[R3.5.1-I] The working voltage of the patient position sensor shall be in range of 3.0 V to 5 V DC.

3.5.2. Physical Requirements

[R3.5.2-III] This type of sensor should be water resistance.
[R3.5.3-III] Because this type of sensor is attached to the chest, the band attached to the sensor should be adjustable in size.
[R3.5.4-III] The material used for the sensor should not causing allergy.
[R3.5.5-III] The material used for the sensor should be smell free.

4. User Application Requirements

4.1 General Requirements

[R4.1.1-I] The user shall be able to access the application on different application platform such as mobile and web at anytime.
[R4.1.2-II] The application shall be easily operated for user with minimal technical knowledge requirement.
[R4.1.3-III] The application shall allow the user to quickly search relative information.

4.2 Performance Requirements

[R4.2.1-I] The application must be able to collect and show received data in real time.
[R4.2.2-I] The application must show data and send notification correctly to designed end user within 30 seconds upon request.
[R4.2.3-III] The text size in the application shall be adjustable.
[R4.2.4-II] The application shall have graphical representation for user's data.

4.3 Safety Requirements

[R4.3.1-I] The application must not provide user data to any unauthorized party.
[R4.3.2-I] The application must not use the user data for any commercial purpose.

4.4 Software Requirements

[R4.4.1-I] The application must be compatible with multiple browsers, such as Chrome, Firefox, Internet Explorer.
[R4.4.2-II] The application must be compatible with Android 4.3.

5. User Documentation

[R5.1-I] User documentation shall include a user manual, written in English.
[R5.2-I] User manual shall be written for people with minimum knowledge of sensor, ergonomics and application usage.
[R5.3-I] User documentation shall be provided in English, French, Spanish, German, Traditional Chinese, Simplified Chinese, Japanese, and Korean in order to satisfy the requirements for international markets
[R5.4-II] User manual shall provide the installation guide for technicians and vendors.
[R5.5-III] User documentation shall provide the information for warranty
[R5.6-III] User manual shall provide guide for troubleshooting and contact information

6. Sustainability Consideration

For modern aspect, countries and public associations are putting more effort to maintain the percentage of green color shown on the world map. In other words, people are more concerning about the environment issues in recent decades [9].

In order to make our mother earth a better place to live, we need to think about sustainability of every single part in our lives, which rises several considerations for the material selection of Health Reporter.

Health Reporter is a modern electronic device with complicated silicon chip built inside. Also, Health Reporter comes along with several sensors which mostly made from soft plastic and other rubber material.

For the main platform of Health Reporter, we need to consider the fact that modern electronic device always are sealed in the plastic case. Therefore, during our Health Reporter Case design, we need to make sure that the plastic case shall be easily opened in order to recycle the main electronic platform inside. Apart from that, the case should also be waterproof. Detachable and waterproof are two main goals for designing the case of electronic platform.
Furthermore, we need to make sure that every electronic component on the board is necessary not just an add-on. This will gives the promise that we only use the electronics we need instead of wasting components.

From the sensor aspect, there are more plastic and rubber materials included in making sensors. We need to think about the detachability of non-electronic and electronic components in sensors. Also, the selection of rubber and plastic material should be taken into account. Those materials need to be smell free and can be easily recycled by a third party recycling institution.
As long as we take the considerations which demonstrated above, it will have a dramatic decrease in the waste in each production of Health Reporter and we can pass these techniques for improving sustainability to other companies in order to have a noticeable evolution in the waste control industry. Last but not least, more effort we put into the sustainability issues, the earth will become a better place to live and our human civilization can continue evolving before we are surrounded by the waste created by ourselves.

7. System Test Plan

In order to make sure the positive feedback from the user after putting the Health Reporter into production. There are several test procedures need to be done before final release, including individual module testing and system testing.

The first section will be the physical characteristics of our sensors. Due to the fact that all sensors are needed to be attached to the human body, we need to make sure that all materials for making sensors should not causing allergy in general cases. We first make sure the materials we utilized are generously accepted by public and then we will have some patients carry those sensors for a specific period of time and report whether there are unexpected feeling or not.

Additionally, all sensors are required to be waterproof. Those sensors will be putting into several level of watery condition in lab situation. After we have reached the pre-set level of waterproof for our sensors, we will need actual human to carry those sensors in raining or swimming condition. This procedure gives us the feedback of waterproof ability in excess physical motion of our sensors.

Because of the fact that wires are coming up with the design of our sensors, we will need to proceed to the strength test of different wires according to sensors individually. This test will be in performed in lab condition because it is easier to test the upper limit of the strength which can be exerted on our wires.

For our main platform which is the analysis platform. We will add the outer case for it when we enters into final production. Also, the case will be conducted to have three type of testing, which includes waterproof testing, bearing capacity testing and physical motion testing. However, before all those testing, we need to make sure the design of our outer case is outstanding over our competitors like Apple and Garmin. We will have our mechanical design team and marketing team carry out this task. After our case has positive feedback from users, we will carry out the waterproof testing and physical motion testing first because those two are general day-to-day usage cases. For physical testing, we will need to shake the platform which is sealed inside our case randomly in different orientations and still remain functionality. Waterproof testing is straightforward as its name. We will put the device under water with sensors attached to it and our device should perform as usual without any out-of-range failure. We will also carry out the bearing capacity testing for our cases in order to simulate some edge cases when users accidentally sit on our device or put some excessive mass on it. The bearing capacity should at least be 100kg in order to put Health Reporter into production.

After all those individual tests have been passed successfully, we need proceed to the system testing. There will still be same sorts of testing areas demonstrated above including waterproof testing, bearing capacity testing and physical motion testing. But in this testing level, we will put the whole system together both in our lab or carries by users. This procedure will make sure that our whole system will perform properly in daily usage with some edge cases included.
Because of the fact that the self-error handling system is integrated in our Health Reporter, we will also create some dummy error cases in our testing procedure in order to make sure that the self-error handling system works as expected.

8. Conclusion

The documentation of function speculations represents the information of the overall project including the request proposal, client and user notes, and research. It also brings the issue of the ideal user and the minimal requirements of the user. The development of the project will follow the functional specification as close as possible. With further development of the test plan, we ensure that the function requirements are fully fulfilled.

9. Reference

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