February 15, 2016

Dr. Andrew Rawicz
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Burnaby, British Columbia
V5A 1S6

RE: ENSC 440 Functional Specifications for ETA VitalTAG

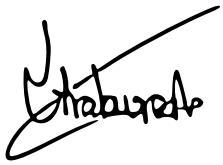
Dear Dr. Rawicz

The enclosed document is the functional specifications for our SFU engineering capstone project VitalTAG. The team of ETA (Emergency Technological Applications) gathered inspiration for this project by investigating the severe lack of support that first responders can provide for paramedics. VitalTAG is designed to be a standalone device that any first responder can use on any victim. The device would measure and log the key vitals required by paramedics. Once at the scene, paramedics would be able to view the vitals of all victims in the vicinity on a pair of Recon Jet smart eyewear. All data logged can be retrieved from a VitalTAG via Bluetooth communication to a monitor or printer for further analysis if required. Our goal is to improve the capabilities of the first responders such that it reduces the time required by the paramedics to gather the essential vitals and would allow them to administer care near immediately.

In our functional specifications, we provide the system requirements detailing intended functions, constraints, reliability, sustainability, and safety for proof-of-concept and production phase of development. Our team will be referencing this document during the design, development, and testing phases of our product.

The founders of ETA are Andre Chang, Jeetinder Ghataurah, Richard Chen, and Tony Yuen. We thank you in advance for your time and interest in our functional specification. For any reason, please contact us at jghataur@sfu.ca or (778) 997-JEET.

Sincerely,



Jeetinder Ghataurah, CEO
Emergency Technological Applications

Enclosure: Functional Specifications for ETA VitalTAG

wearable vital sensor

VitalTAG

Functional Specifications

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Executive Summary

Paramedics and other first responders are one of the most important functions in modern day cities. They save hundreds of lives around the world every year. Despite their importance, they are equipped with outdated technologies. In specific, equipment's used to acquire heart rate, SPO2 and blood pressure dates back to as old as the late 1800's. Paramedics are forced to rely on time proven techniques, such as checking radial pulse using their fingers and a stopwatch. In a modern era of technologies, paramedics and first responders should be equipped with safe, robust and smart devices which can automate the measurement and logging of vitals, allowing them to focus on more important tasks. ETA is aiming to optimize the process with VitalTAG, a platform which would allow paramedics to see the victim's vitals in a glance.

VitalTAG is a device that would be donned on a victim's index finger. Once VitalTAG is deployed, it would estimate the victim's blood pressure, heart rate and SPO2 through photoplethysmogram. These metrics would then be displayed to the first responder through a pair of smart eyewear. In addition, all vitals are logged on the device for future reference. Moreover, VitalTAG does not limit paramedics to one-to-one operations. By tagging multiple victims with VitalTAG, paramedics can monitor all their vitals at the same time.

This document provides a high-level overview of our objectives and market research for the project. Specifically, we define the scope including potential benefits and risks that come with this project. We also outline the timeline and cost breakdown for the development of this product.

Our team consists of electronics, systems, computer and biomedical engineers with at least 1 year of industry experience. We are a multi-disciplinary team well suited to tackle the task of providing paramedics and first responders with a robust and unified platform to obtain vitals.

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Glossary and Acronyms

ACP – Advanced Care Paramedics
CCP – Critical Care Paramedics
CPR - Cardiopulmonary resuscitation
DCF – Discounted Cash Flow
EMR – Emergency Medical Responders
First Responders – any personnel first on scene prior to paramedics
GCS – Glasgow Coma Scale
HUD – Heads Up Display
IP – Ingress Protection
NPF – Net Present Value
PCP – Primary Care Paramedics
PoC – Proof of Concept
PPG – Photoplethysmography
SPO2 – Saturation of Peripheral Oxygen

1. Introduction

In a job where every second can change the odds of survival, paramedics optimally spend over 2 minutes measuring vital signs per victim. Paramedics resort to rudimentary tools such as stethoscopes, watches, blood-pressure cuffs and their refined abilities in order to assess the severity of the situation. When using these tools, both hands are needed, which prevents the aider from attending other matters or patients. Furthermore, responders who arrive first are not trained to measure specific vitals, limiting their assistance towards the paramedics and patients. Precious seconds are consistently being wasted. The technology to help is readily available, but they unfortunately lack the capability to fit a paramedic's demand for accuracy, simplicity and robustness. Our solution is VitalTAG (Figure 1).

Figure 1 - Prototype of VitalTAG made in SolidWorks

VitalTAG will unify heart rate, SPO2 and blood pressure sensors into a compact, standalone device donned on a victim's index finger. By *tagging* multiple victims with this device, responders can focus on containing the situation, and attend to as many victims as possible. In addition to logging the information, vitals are displayed on a smart eye-wear HUD. Our aim is to extend the abilities of a paramedic where time is crucial, and potentially decrease the time spent measuring vitals.

This document presents an overview of our product and an outline of our functional specifications.

1.1 Background

Although the technology exists for measuring the four main vital signs [1], there exists no unified solution to accurately measure and log the data without an operator. Not only so, additional equipment is avoided by all emergency medical personnel. From our market research, we learned the rudimentary techniques paramedics use to obtain vitals and the lack of accuracy it produces. Our main driving force, however, is that the first people to attend to these victims, the

firefighters, are unqualified to measure certain vitals and cannot further prepare the victims before the paramedics arrive.

First responders will apply basic first aid which includes checking: 1) the airway, 2) for breathing, and 3) if they have blood circulation (pulse). These basic first checks are commonly referred to as the First Aid ABC's. If no immediate aid is required for resuscitation (e.g. CPR), first responders are unable to further assist paramedics. In 2014, the 90th percentile response time for paramedics in the Greater Vancouver Regional District was 33.3 minutes for all calls and 13.3 minutes for life-threatening calls [2].

Upon the paramedic's arrival, standard ABC is reassessed, followed by 9 major vital checks: 1) Glasgow Coma Scale (GCS), 2) heart rate, 3) blood pressure, 4) respiration rate, 5) SPO2, 6) blood glucose, 7) pupil response, 8) core temperature, and 9) response to pain. Optimally, paramedics will spend the majority of the time measuring circulation-related vitals, leaving an opportunity for technology to not only assist in the measurements, but to provide a better scope of the situation.

1.2 Scope

The scope of this document covers the functional specifications for sensors, microcontroller, Bluetooth communications, and the smart eyewear. Additionally, factors such as safety and sustainability will be the building blocks for our testing plan.

1.3 Intended Audience

The intended audience of the functional specifications is the entire team of ETA. Management would use the requirements to keep the project on task during design and development. Quality systems would reference the requirements for consistency among future documentation. Design engineers would utilize the requirements when constructing the design specifications. Testing shall be done using the test protocols laid out to verify the product functionality.

1.4 Classification

For the entirety of the functional specification the following convention will be used to denote functional requirements:

[Rn-p] A generic functional requirement

n is the functional requirement number
p is the functional requirement priority denoted by:

I. The requirement applies to the proof-of-concept/prototype device only.
II. The requirement applies to both the proof-of-concept/prototype device and the final product.
III. The requirement applies to the final product only.

2. System Requirements

A high level overview of VitalTAG will be shown followed by the system requirements in this section.

2.1 System Overview

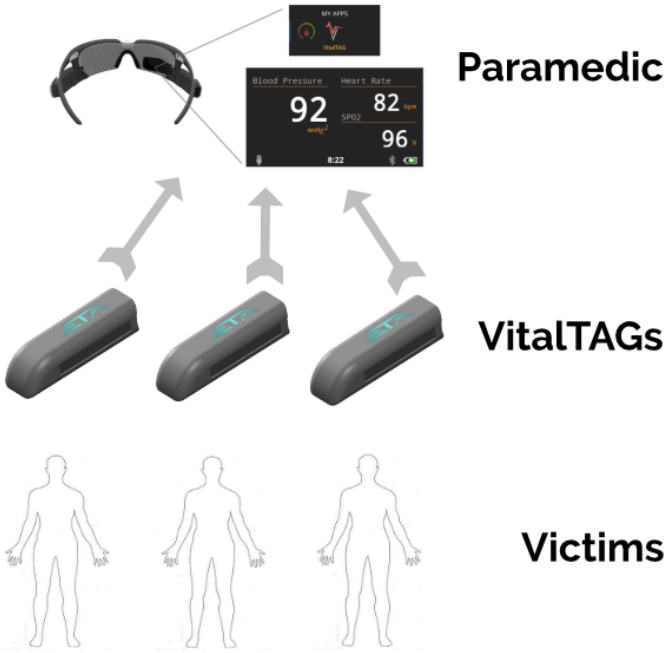

Figure 2 - High level system block diagram

VitalTAG was designed to be a standalone, automatic device that requires no training yet can measure and log the essential vitals required by paramedics and physicians. Initially the design was focused on a glove that paramedics could wear to assist in vital checks. Although this design would satisfy most of our functional requirements, further market research indicated its faults: 1) the glove could be soiled, 2) the operator's hands would be occupied during measurements, and 3) only one victim could be assessed at a time. With the information obtained, the VitalTAG finger apparatus (Figure 2) was designed to provide more features with less implications.

The importance of data-logging was noted through market research, but to increase the usability of the device by emergency responders, we needed to implement a non-intrusive monitoring system to display only the necessary information. A HUD was chosen to accomplish these sets of requirements. Using the Recon Jet, the operator will be able to monitor the current situation of a victim. The graphic interface as seen in Figure 3 is non-intrusive and does not require continuous attention.

Figure 3 - Graphic interface as seen through the Recon Jet

In the development of VitalTAG, rapid prototyping will occur first to ensure functionality before moving to final production. To detect heart rate and SPO2 the Pulse Sensor Amped and Maxim Integrated MAX30100EFD+T have been chosen for its simplicity and compact design. These sensors both utilize LEDs and photodetectors to measure the light intensity of the blood flow. The firmware will be rapidly prototyped using the Arduino Genuino 101 with an Intel Curie chip due to its ease of use, performance, and sufficient I/O (input/output) pins. The vital measurements will be verified by the CMS 50D+ Finger Pulse Oximeter. Blood pressure is projected to be derived from the PPG signal timing intervals. The blood pressure measurement will be verified using an automated blood pressure monitor. For production of the final product, a PCB will be constructed using the Intel Curie chip. It has been chosen for its compact size, performance, and on-chip Bluetooth Low Energy communication. The proposed design will allow the vital information to be logged, processed, and also transferred to a pair of Recon Jet smart eyewear.

2.2 General Requirements

[R00-I]	The cost should be under $1400
[R01-III]	The cost should be under $500
[R02-III]	The system should be water resistant according to IP53
[R03-II]	Each VitalTAG should connect easily to the smart eyewear within 30 seconds
[R04-II]	The system is designed to operate between -20˚C to 45˚C
[R05-II]	The system sensors should be minimally invasive to the user
[R06-III]	The VitalTAG should be able to detect if no finger is inserted

2.3 Physical Requirements

[R07-III]	The VitalTAG should fit most finger widths (16mm – 25mm)
[R08-III]	The VitalTAG should weigh under 120 grams
[R09-III]	The VitalTAG should look sleek
[R10-III]	The system should be able to be cleaned with 70% IPA
[R11-III]	The system should be able to withstand a 1m drop
[R12-III]	The VitalTAG should have an outer width and height less than 2”
[R13-III]	The VitalTAG should have a length less than 1.5”

2.4 Electrical Requirements

[R14-III]	The battery should last for at least 1 hour
[R15-II]	The charger should connect to a standard 120V outlet
[R16-II]	The DC current on-board should be below 300 mA to prevent atrial fibrillation
[R17-III]	The system should sleep when no finger is detected for a set amount of time to conserve battery (approx. 10 minutes)

2.5 Mechanical Requirements

[R18-III]	The VitalTAG should be constructed of a strong and mildly elastic material
[R19-III]	The smart eyewear should be constructed of durable material

2.6 Environmental/Sustainability Requirements

[R20-II]	Any batteries should be removable for proper disposal
[R21-I]	Recycled material should be used whenever possible
[R22-III]	Minimalistic packing material should be used to prevent excess waste
[R23-III]	The system should be durable and provide long term usage to reduce waste
[R24-II]	The system should have no lead-based components
[R25-II]	The system should be repairable
[R26-II]	The system should be easy to disassemble for recycling

2.7 Standards Requirements

[R27-III]	All connections will conform to the CSA Canadian Electrical Code
[R28-III]	The system should comply with FDA 21 CFR 820
[R29-III]	The system should comply with FCC wireless regulations
[R30-III]	The system should comply with ICS 11.040.01
[R31-III]	The system should comply with IEC 60601-1-1
[R32-III]	The system should comply with ISO/IEC Guide 51:2014

2.8 Reliability Requirements

[R33-I]	Vital measurements should be repeatable with errors similar to current portable electronic devices within 20% tolerance
[R34-II]	The VitalTAG should be able to be used multiple times before needing service
[R35-II]	The system should only be serviced by trained technicians
[R36-II]	The system should only need calibration yearly

2.9 Performance Requirements

[R37-II]	All vital accuracies should be comparable with current portable electronic measurement devices
[R38-II]	The smart eyewear should be able to connect to multiple VitalTAGs
[R39-II]	The VitalTAG should reliably store the collected vitals

2.10 Safety Requirements

[R40-III]	All electrical connections should be sealed or recessed to prevent shock
[R41-II]	Surfaces and seams should be smoothed to prevent cuts and abrasions
[R42-II]	The system should cause no permanent damage to the user
[R43-III]	All enclosed components should be secured to prevent damage or short circuiting

3. Smart Eyewear Requirements

The required vital metrics heart rate, SPO2 and blood pressure should be streamed to the smart eyewear through Bluetooth Technology displayed in Figure 4 below. These metrics would then be displayed to the user in a non-distracting fashion. In specific, the display would be in the bottom right hand corner of the user's vision. The UI design is shown in Figure 4 below, providing the user a clean interface to the vital metrics. These functions justify the following requirements.

Figure 4 - Smart eyewear block diagram

3.1 General Requirements

[R44-II]	The eyewear should be foldable to conserve space during storage
[R45-II]	The eyewear should not disturb the user's normal field of view
[R46-III]	The eyewear should be stylish
[R47-III]	The eyewear should be comfortable
[R48-II]	The eyewear should be Bluetooth compatible
[R49-II]	The eyewear should have an intuitive design

4. Microcontroller/Circuitry Requirements

The Arduino Genuino 101 Microcontroller is a crucial component for signal processing, storage, and transfer. It will collect the raw data from the MAX30100 and process it. The data will be stored and transmitted to the smart eyewear via Bluetooth. Upon completion of prototyping with the Arduino Genuino 101, the Intel Curie chip will be custom fitted on a PCB board to simplify the design and better integrate into the enclosure. On the PCB design, the MAX30100 will be surface mounted close to the Intel Curie chip to avoid crosstalk and parasitic capacitance in the high frequency I2C communication.

4.1 Electrical Requirements

[R50-III]	The microcontroller should be enclosed to prevent environmental damage
[R51-II]	Processing time should not vary drastically
[R52-II]	PCB traces will be a minimum of 6mm apart
[R53-II]	PCB trace width will be a minimum of 6mm
[R54-II]	Data sampling will be within 50-1000 samples
[R55-II]	Resolution will be no lower than 13 bits

5. Software Requirements

The software should be able to obtain the SPO2 values and the PPG from the MAX30100 sensor. It will then translate the PPG into heart rate and blood pressure. Furthermore, the software should manage the data storage and transfer it to the smart eyewear through Bluetooth technology illustrated in Figure 5 below. These functions justify the following requirements.

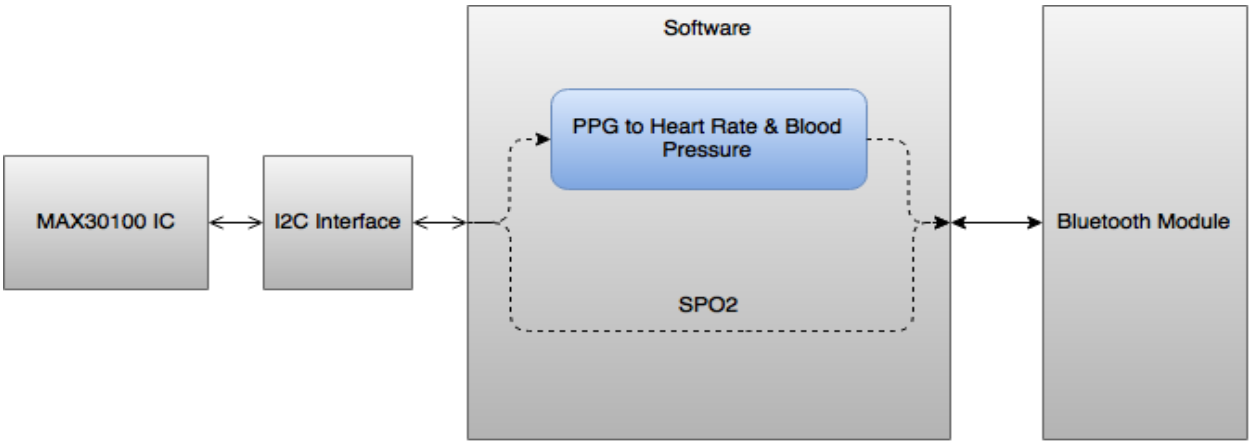

Figure 5 - Software block diagram

5.1 General Requirements

[R56-II]	The software should convert the raw data from the MAX30100 and produce the Heart Rate, SpO_2, and Blood Pressure
[R57-II]	The software should store the processed data in static memory
[R58-II]	The software should transfer vital data via Bluetooth
[R59-II]	The software should have high and low limits for Heart Rate (50-110 bpm)
[R60-II]	The software should have high and low limits for Blood Pressure (Systolic 90-119mmHg, Diastolic 60-79mmHg)
[R61-II]	The software should have low limits for SpO_2 (less than 90%)

6. User Manual Requirements

6.1 General Requirements

[R62-III]	The user manual should be easy to follow and include diagrams
[R63-III]	The user manual should list all safety precautions
[R64-III]	The user manual should clearly state the intended use of the device

7. Sustainability/Safety

The entire team of ETA employed safety and sustainability tactics throughout the creation of VitalTAG. Safety, health and the welfare of both the users and the public were held at the highest priority. Furthermore, by basing our product life cycle on the Cradle-to-Cradle logic we can minimize the impact on the environment.

From research and development to product production we use efficiency and optimization to reduce our environmental footprint. For the prototype, the majority of the components will be used to reduce the need to purchase new goods. Vigorous testing will be performed using breadboards before creating a PCB. All electronic components will be lead free to prevent environmental contamination. In addition, the final product will be constructed of non-toxic plastic. Using these measures we can reduce the environmental impact during the creation of VitalTAG.

Although VitalTAG is a Class I medical device, which intrinsically shows a low risk, safety factors will be implemented throughout the system. The enclosure will be water resistant to prevent electrical shock during use. Low current DC voltage will be used for all vital measurements as to reduce the chance of atrial fibrillation due to an electric shock during catastrophic failure or misuse. All edges and mating surfaces will be smoothed to prevent the chance of any cuts or abrasions.

8. System Test Plan Overview

Our system test plan is used to verify all vital measurements along with fundamental functional specifications for usability and operation.

8.1 SpO_2 Measurements

SpO_2 measurements will be verified using a Contec Medical CMS 50D+ Blue Finger Pulse Oximeter. Multiple repetitions with multiple subjects will be performed to verify the data.

8.2 Heart Rate Measurements

Heart Rate measurements will be verified using a Contec Medical CMS 50D+ Blue Finger Pulse Oximeter. In addition, we will compare the Heart Rate with radial pulse measurements and a stopwatch by a paramedic. Multiple repetitions with multiple subjects will be performed to verify the data.

8.3 Blood Pressure Measurements

Blood Pressure measurements will be verified using two different electronic portable blood pressure monitors. In addition, blood pressure measurements will be compared to an inflatable cuff and stethoscope used by a paramedic. Multiple repetitions with multiple subjects will be performed to verify the data.

8.4 Data Storage

Data storage will be verified by interrupting power during use and then accessing the memory to ensure the data was not lost. Multiple repetitions will be performed to verify no data loss.

8.5 Bluetooth Connectivity

Multiple VitalTAGS will be connected to a single smart eyewear to verify that several VitalTAGS can communicate seamlessly. Multiple repetitions will be performed to verify the data.

8.6 Smart Eyewear Data

The smart eyewear will be used while navigating a vehicle in a closed circuit to verify it does not obstruct the users field of view. Additionally, the vitals will be verified for clarity and ease of view.

9. Conclusion

This document covers the functions specifications of VitalTAG entirely. The requirements for the system and highlighted individual components were sectioned into 3 categories being proof-of-concept/prototype, final product, and both. The proof-of-concept/prototype are well under way in the development process. The final product is projected to be completed by mid April 2016.

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