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October, 10, 2014

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

Re: ENSC 440 Functional Specifications for Influx Medicals Smart Abdominal Binder

Dear Dr. Rawicz,

Please accept the following document as our functional specifications for Influx Medical's Smart Abdominal Binder project. Influx Medical's aim is to design and implement a Smart Abdominal Binder that is targeted towards patients suffering from orthostatic hypotension due to spinal cord injury. Our goal is to increase the stroke volume and blood pressure of the patient by applying tolerable pressure to the abdomen region. Our design will consist of a programmable automated inflatable abdominal binder that provides controlled pressure.

The purpose of this document is to provide an overview of the functional aspects of the proposed project, without excessive design content. Furthermore, our group members will use this document to help implement the project, while considering its main aspects such as its process details, engineering standards, and sustainability.

Influx Medical consists of six talented and determined 4th and 5th year engineering students: Hamed Soltanishirazi, Kevin Liew, Simon Cheng, Shayan Gaeni, Jason Jiang, and Junyang Tao. If you have any questions, or concerns regarding our functional specifications enclosed within the document, please feel free to contact Shayan Gaeni at 604-728-4433 or by email at sga60@sfu.ca. We look forward to your feedback on our proposed project.

Sincerely,

Shayan Gaeni

Shayan Gaeni
Chief Executive Officer
Influx Medical

Enclosed: Functional Specifications for a Smart Abdominal Binder

FUNCTIONAL REQUIREMENTS

Smart Abdominal Binder

Company: InFlux Medical

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Executive Summary

There are many patients worldwide that suffer from complete/incomplete spinal cord injury, which deal with many hardships in everyday situations. They seek the help of health care providers in order to carry out simple and basic tasks that are common for normal human beings. There are currently more than 86,000 individuals living with spinal cord injury in Canada, with 4,300 new cases of spinal cord injured subjects each year [1]. There are numerous studies that have indicated the presence of orthostatic hypotension following spinal cord injury [2]. Not only is this condition apparent in the severe period post-injury, it has also continued to affect a significant number of individuals for many years after [2].

Thus InFlux Medical purpose is to eliminate one of the many hardships that spinal cord injured patient's deal with on an everyday basis, which patients are suffering from as a result of low blood pressure, also known as orthostatic hypotension. InFlux Medical plans to implement a smart abdominal binder that is placed around the abdomen area of the patient in order to disperse blood throughout the circulatory system. Utilizing a Bluetooth capable blood pressure sensor, if the blood pressure of the patient falls below a certain threshold the smart abdominal binder will start to contract. This in effect will cause blood to flow throughout the circulatory system, which is high in volume in the abdomen area. InFlux Medical will take the patient's safety into aspect while implementing the smart abdominal binder.

The development of the Smart Abdominal Binder is scheduled to be completed in three phases: two stages that consider the development of the product in order to obtain a proof-of concept and a third and final stage to obtain a final product ready for manufacturing. The development stages will be followed as such:

First development stage:

- Designing and/or implementing an inflatable abdominal binder, which is effective, and user friendly.
- Integrating a diaphragm pump and pneumatic valve to inflate and deflate the abdominal binder.

Second development stage:

- Additional features are added to the abdominal binder.
- Pressure transducer is used to detect the amount of pressure applied to the abdomen, used as a safety aspect.
- Bluetooth capable blood pressure sensor is used to detect the blood pressure of the individual.

A list of requirements will be created to outline the specification details needed at each phase. The abdominal binder should also comply with the specific engineering standards

and regulations, while serving its main functional purpose of dispersing blood throughout the circulatory system.

Within the enclosed document, detailed functional specifications will be outlined for the main system as well as subsystems. Various aspects of the device will be considered, which include the core electronic hardware components, the software aspect, power supply, user interface module, user manual, and its sustainability considerations. This document is intended for use by designers, developers and testers as a form of a system guideline.

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Glossary

APU	Air Pressure Unit
BPM	Blood Pressure Monitor
GUI	Graphical User Interface
MCU	Microcontroller Unit
OH	Orthostatic Hypotension
POC	Proof-of-concept
SAB	Smart abdominal binder
SCI	Spinal cord injured

1. Introduction

Influx Medical is creating a solution for patients suffering from orthostatic hypotension (OH), which is implementing by using a smart abdominal binder (SAB). Our companies aim is to create an automated inflatable abdominal binder that will increase an individual's blood pressure through the use of compression around the abdomen. There has been adequate research done to show that the use of an abdominal binder is one of the most efficient methods to increase the stroke volume of the individual, which in effect increases the individual's blood pressure (systolic/diastolic) [3]. The user of the SAB will be wearing a Bluetooth capable blood pressure monitor, which continuously measures the individual's blood pressure. In effect, the inflatable abdominal binder will cause compression around the abdomen region, which helps circulate blood throughout the body.

Influx Medical is designing and implementing a unique product that will provide spinal cord injured (SCI) patients suffering from OH, a hassle free solution. Since our product has continuous blood pressure monitoring, the subject will not likely experience the effects of light-headedness or dizziness due to adequate circulation of blood throughout the circulatory system. This document provides the functional specifications of the SAB, such that it will be used as a reference during the creation of its proof-of-concept (POC) and later in the products development stage.

1.1 Scope

The scope of the following document is to outline the functional requirements of Influx Medical's SAB. The enclosed document describes the functionality of the system including the blood pressure monitor, microcontroller, air pressure unit, inflatable abdominal binder, Bluetooth capabilities and the overall system functionality. Additionally, within this document, detailed functional requirements will be discussed, which will be used a reference guide during the design, development and testing of the SAB. Furthermore, during the design process, some of the components may change so that they can meet performance standards and safety aspects set aside.

1.2 Intended Audience

The functional specifications is intended for use by all members of Influx Medical, which is created to be served as a reference in the development stage of the SAB to guarantee that the final product meets its functional requirements. Furthermore, development engineers should refer to this document for implementation purposes, and test engineers for test conditions.

1.3 Classification

The following convention used throughout the document lists each requirement and indicates its priority as shown:

[Rn-p]

Where “R” is an abbreviation for requirement, “n” is the functional requirement number and “p” correlates to one of the following three development phases:

I – Highest Priority; Proof-of-concept stage
II – Medium Priority; must meet both proof-of-concept and production model
III– Low Priority; Final production stage

2. System Requirements:

Within the following section you will find the general system requirements and specifications of the SAB described as a complete system.

2.1 System Overview

The following high-level system block diagram as illustrated in figure 1, represents the system overview of the SAB.

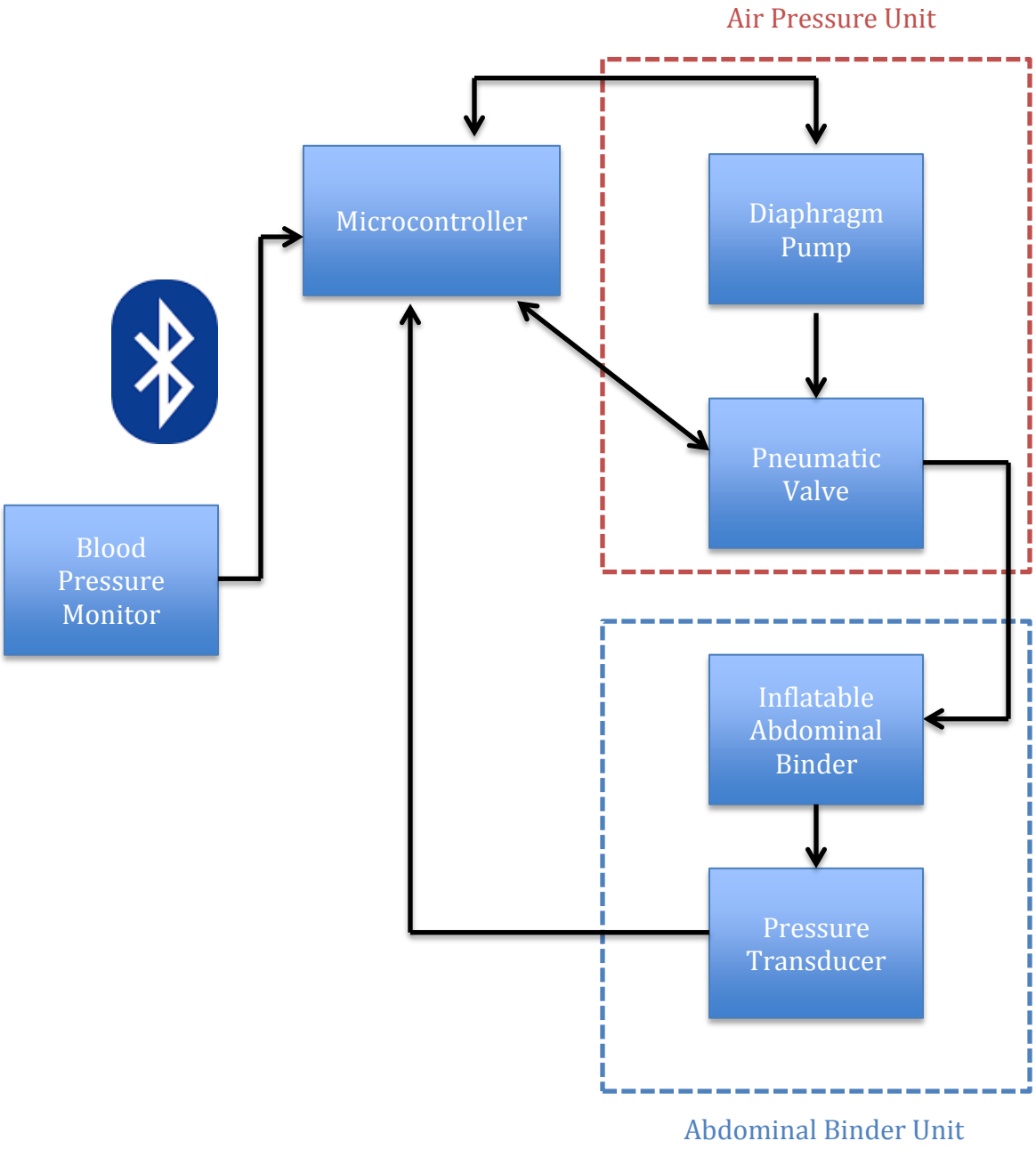

Figure 1: SAB system overview

The SAB has both a hardware device and a software package associated with the product. The hardware aspect includes electronic components that obtain information on compression pressure, and equipment used to inflate and deflate the abdominal binder itself. The software aspect requires real-time data readings from the blood pressure monitor (BPM), pressure sensor, and pressure associated with the pneumatic valve for assessment and device control. There will be certain safety thresholds which the software package will take into account, such that the user does not experience any harm.

2.1.1 Development Stage I

Influx Medical's goal is to replace the current solution to OH, medication and wearable pressure garments, with one that continuously monitors the patient and applies a compressive force through an inflatable abdominal binder before the patient experiences symptoms of syncope. Thus, the first stage of development requires our team to focus on implementing or designing an inflatable abdominal binder. This phase will require the implementation of the inflatable binder with the use of a miniature diaphragm pump to propel a fluid (air) and a pneumatic valve to start, stop, or change direction of compressed airflow. After doing extensive research we have determined that the optimal amount of sustained pressure required is around 40 mmHg, such that organs in the abdomen area do not get damaged [3]. The diaphragm pump which we require needs to supply at most 40 mmHg of pressure, and through the use of an electronic pneumatic valve the microcontroller can monitor the amount of compressed air being supplied to the abdominal binder. The abdominal binder will need to be inflated for approximately one minute; inflation to deflation should be approximately 30 seconds [3]. The frequency rate of inflation/deflation will be dependent on factors such as time (since blood pressure varies throughout the day) and severity in drop of blood pressure. The air belt unit will look similar to the lumbosacral belt as shown below in figure 2.

Figure 2: Air belt unit

At the end of this stage, the SAB should be able to inflate/deflate in response to compressed air flow supplied by the miniature air pump.

2.1.2 Development Stage II

After designing the main functionality of the SAB, the second development stage focuses on adding in a pressure transducer and a Bluetooth capable blood pressure sensor.

The pressure transducer is placed beneath the automated inflatable abdominal binder, such that it can detect the amount of pressure being applied to the abdomen region. This part of the design should be done with minimal wiring to the microcontroller, and is added to the system design for safety purposes such that organs in the abdomen area do not get damaged. The microcontroller will set a threshold of 40 mmHg (acceptable pressure to be applied to the abdomen region) to the associated signal obtained from the pressure transducer, which is used for safety purposes.

Furthermore, a Bluetooth capable blood pressure sensor will be used to obtain real-time data of the user's blood pressure, such that the microcontroller can start inflating the abdominal binder when the patient's blood pressure goes below a certain threshold. The normal blood pressure of an individual will be around 120 to 130 mmHg and when there is a drop of approximately 20 mmHg, the patient starts getting the symptoms of OH. Thus the blood pressure sensor will communicate with the microcontroller to prevent the user from experiencing syncope.

Influx Medical's goal is to incorporate the following features listed while meeting the Health Canada's and FDA standards.

2.2 General Requirements

[R1 – I]	The user must be able to turn the device off manually.
[R2 – I]	The device must require minimal training for use.
[R3 - II]	The SAB must be compatible and adaptable to any wheelchair.
[R4 – II]	The SAB must be comfortable for wearing at prolonged periods.
[R5- II]	The SAB shall have minimal setup and wiring to the wheelchair.
[R6- II]	The SAB should not interfere with other electronic devices.
[R7 – II]	The SAB should be easy to put on and take off by the patient.
[R8 – II]	The SAB should not cause any damage to the individual using the device.
[R9 – II]	The SAB should have a modular design.
[R10 – III]	The SAB should have a retail price no more than $150.

2.3 Physical Requirements

[R11 – II]	The device shall be adjustable in size to fit almost all users.

[R12 – III] The SAB shall be lightweight.
[R13 – III] The SAB shall be waterproof.
[R14 – III] The device shall withstand impacts from free fall of 1.0 meter.
[R15 – III] The SAB should be breathable.
[R16 – III] The device shall look appealing to a broad range of users.

2.4 Electrical Requirements

[R17 – I] The power being provided to the system should sufficiently power all components of the SAB.
[R18 – I] The device must be powered by a medical battery pack.
[R19 – I] All electrical contact points must be covered from physical interactions.
[R20 – II] All components of the SAB must have an operating point of 3-12V.
[R21 – II] The device must have a power switch.
[R22 – II] The device must have a power rating no higher than 300W.
[R23 – III] The power supply in [R18] last for up to 24 hours.
[R24 – III] The power supply in [R18] must be rechargeable.

2.5 Environment Requirements

[R25 – II] The device shall be operable under ambient humidity between 10% and 40%.
[R26 – II] The device shall be operable outdoors.
[R27 – II] The device shall be operable at altitudes between 0m to 1000m above sea level.
[R28 – III] The SAB shall operate normally within a specific temperature range of -10 to 45 °C.

2.6 Standards and Safety Requirements

[R29 – I] The device must be electrically insulated from the user.
[R30 – I] The device must not create any electrical discharge.
[R31 – I] The device must not exert any force on the urinary bladder.
[R32 – I] The device must conform to CSA C22.2 NO 60601-1-08.
[R33 – II] The SAB should not interrupt and individuals breathing pattern.
[R34 – II] The SAB should apply minimal pressure when not in use.
[R35 – II] The device must conform to IEC 60601-1:2005-Ed.3.0 [4].
[R36 – II] The device must conform to IEC 60601-1-4:2000-Ed.1.1 [4].
[R37 – II] The device must conform to IEC 60601-1-6:2006-Ed.2.0 [4].
[R38 – II] The device must conform to IEC 60601-1-8:2006-Ed.2.0 [4].
[R39 – II] The device must conform to IEC 60601-1-10:2007-Ed 1.1. [4].
[R40 – III] The device must inform the user of a malfunction when detected.

2.7 Reliability and Sustainability Requirements

[R41 – I] The SAB shall not have any excessive heat dissipation.
[R42 – II] The SAB shall be made of recyclable material and eco-friendly components.
[R43 – II] The device must be capable of a minimum of 6 operational hours with a single charge of said battery in [R18].
[R44 – III] The SAB shall be relatively accessible to change the battery proposed in [R18].
[R45 – III] The device shall have a minimum lifetime of 3 years.

3. The Abdominal Binder and the Pressure sensor

The abdominal binder in this system is the key factor. Most of our interaction with the users, whom are the patients with spinal cord injuries, would use this binder. This binder should have the requirements suitable to the physics, health and the physical capabilities of the users. Since in our case we are targeting specific users for our device, our requirements would be very exclusive and detailed based on the medical health conditions of the patients with spinal cord injury and their interaction with our system. The pressure sensor would also need to be adaptable with the body.

3.1 General Requirements

[R46 – I] The binder needs to be able to deflate manually.
[R47 – I] The binder needs to have an input for the gas pipeline.
[R48 – I] The binder needs to be able to apply pressure on the patient body up to 40 mmHg.
[R49 – I] The binder needs to cover the abdomen of the user.
[R50 – I] The binder needs to be easy to put on and off.
[R51 – I] The pressure sensor needs to be able to communicate with the microcontroller unit.
[R52 – I] The pressure sensor needs to be able to measure the pressure applied by the binder.
[R53 – I] The pressure sensor needs to be able to detect the minimum pressure of 100 mmHg.
[R54 – II] The binder needs to be fitted in the patient's body in both inflated and deflated states.
[R55 – II] The temperature of the contact region of the binder with the skin of the user must be in the range of 20-30 centigrade while in use.

3.2 Physical Requirements

[R56 – I] The pressure sensor needs to be able to fit under the binder.

[R57 – II] The binder needs to be fitted for various sizes of the abdomens.
[R58 – II] The binder must not cover the bladder of the user.
[R59 – II] The binder must not cover the respiratory system of the user.
[R60 – II] The material of the binder in contact with the skin of the user must be comfortable enough to not irritate the skin (in order to prevent Autonomic Dysreflexia).
[R61 – III] The pressure sensor needs to be flexible and be able to curved on human body.

3.3 Safety Requirements

[R61 – I] The pressure sensor must be compatible and have the safety requirements for medical usage.
[R62 – II] The pressure sensor must have error of less than 5%.

4. The Air Pressure Unit

The Air Pressure Unit is the inflation air supplier to the abdominal binder which consists of a miniature diaphragm pump and a miniature pneumatic solenoid valve. The miniature diaphragm pump shall constantly deliver inflation air to the abdominal binder through the solenoid valve and it is turned on or off by the MCU. The miniature pneumatic solenoid valve is also controlled by the MCU. It guarantees the air flow directly into the binder for inflation work and allows the air to flow out for deflation; moreover, it controls the speed of air flow from the pump to the binder by adjusting exhaust mufflers on it.

4.1 General Requirements

[R63 – I] The APU parts must be compatible with the MCU.
[R64 – I] The diaphragm pump shall be turned on or off by the MCU .
[R65 – I] The diaphragm pump shall constantly deliver air flow once it turns on.
[R66 – I] The maximum continuous pressure of the air flow shall be no more than 2.0 Psi (103.42 mmHg).
[R67 – I] The pneumatic solenoid valve shall be able to inflate and deflate the binder.
[R68 – I] The pneumatic solenoid valve shall operate according to the MCU.
[R69 – I] The pneumatic solenoid valve needs to have exhaust port(s).

4.2 Mechanical and Physical Requirements

[R70 – I] A set of suitable gas pipelines shall be applied to internally connect the pump and the valve, and externally connect the valve and the binder.

[R71 – I] The gas pipelines shall have compatible ports to all the parts it connects to.
[R72 – II] The APU parts shall have low noise level.
[R73 – I] The APU parts shall be light weighted.
[R74 – I] The APU package shall be as smaller as better in order to avoid any inconvenient issues since it is a carry-on device.

4.3 Electrical Requirements

[R75 – I] The diaphragm pump shall apply an individual battery power supply
[R76 – I] The pneumatic solenoid valve shall operate with a voltage of 24V DC.
[R77 – I] The diaphragm pump shall operate with a nominal motor voltage of 3-6V DC.
[R78 – II] The battery must to be rechargeable and last for 12 hours for one cycle use.
[R79 – II] The air flow and pressure shall be controlled by adjusting the input motor voltage from zero to maximum rated voltage.

4.4 Environmental and Safety Requirements

[R80 – I] All components of the APU must conform to IEC 60601-2-34 [5].
[R81 – I] All components of the APU must not inflict any physical harm to users.
[R82 – II] All components of the APU shall operate normally under a temperature range of -10°C to 50°C.
[R83 – II] The input and output ports of the pump, the valve, and the binder needs to be connected tightly by the gas pipelines.
[R84 – III] All components of the APU shall operate normally under 10%-90% relative humidity.

5. Automatic Blood Pressure Monitor

The automatic blood pressure monitor (BPM) measures the user's systolic and diastolic pressures at regular intervals that are determined by the user. The normal blood pressures vary with the time of day [6]. The BPM consists of an arm cuff attached by a wire to a display unit. Wrist-mounted BPMs are not suitable as inaccuracies may occur if the wrist is not at heart level during measurements [7]. The BPM functions by inflating a cuff over the brachial artery in the upper arm to take pressure readings. The BPM will send real-time BP readings to the microcontroller for processing.

5.1 General Requirements

[R85 – I] The BPM will take readings at regular intervals as set by the user.
[R86 – I] The BPM will have a pressure range including 50 mmHg to 250 mmHg.

[R87 – I] The BPM will be Bluetooth capable within at least 10 feet.
[R88 – I] The BPM will provide real-time blood pressure data by Bluetooth.
[R89 – I] The BPM readings must be accurate to within 3%.
[R90 – I] The BPM must display the current systolic and diastolic blood pressure measurements on a screen.
[R91 – III] The BPM must have a life expectancy of at least 2 years.
[R92 – III] The BPM must be a commercial product which can be replaced by the user in case of failure.
[R93 – III] The BPM must have replaceable arm cuffs.

5.2 Software Requirements

[R94 – I] The BPM must boot up within five seconds.
[R95 – I] The user can view the current measurement interval.
[R96 – I] The user may select at least three interval options between 2 minutes and 2 hours from which the BPM will take regular measurements.
[R97 – II] The BPM can store at least the fifty previous measurements in memory.
[R98 – II] The BPM can transfer previously made measurements by Bluetooth.
[R99 – III] The BPM can erase stored measurements.

5.3 Physical Requirements

[R100 – I] The BPM will be non-invasive.
[R101 – I] The BPM will consist of a measurement cuff and a display module connected by a wire.
[R102 – I] The arm cuff can fit an adult patient.
[R103 – I] The arm cuff can fit a larger adult patient.
[R104 – I] The different size arm cuffs must be interchangeable and replaceable.
[R105 – II] The BPM display module can be mounted on a wheelchair or armrest.
[R106 – II] The BPM must withstand a 3-foot drop.
[R107 – III] The BPM will weigh less than 1kg.
[R108 – III] The display module will be less than 25cm x 20cm x 15cm.

5.4 Electrical Requirements

[R109 – I] The BPM will last for over 24 hours on one set of batteries.
[R110 – I] The BPM will display a warning on low-battery.
[R111 – II] The BPM can be shut down by a button.
[R112 – III] The BPM will have an optional AC adapter.

5.5 Environmental Requirements

[R113 – I] The BPM will function from 0°C to 40°C.
[R114 – I] The BPM will function from 20% to 80% relative humidity.

5.6 Safety and Reliability

[R115 – I] The BPM warns the user before taking a measurement and inflating the arm cuff.
[R116 – I] The BPM can be shut down with one button-press.

6. General Bluetooth Requirements

[R117 – I] The BPM, phone and microcontroller's Bluetooth transmitters will operate to IEEE 802.15.1 standards [8].

[R118 – I] The BPM, the android phone and the microcontroller will maintain minimum connection of at least 4 feet.

[R119 – I] Communication between BPM, phone and microcontroller must not perturb one another.

[R120 – I] The system will maintain a consistent and steady connection at all times.

[R121 – I] All Bluetooth connections operate at a baud rate of 115,200.

[R122 – III] The Bluetooth data transferred will be encrypted for security.

7. Microcontroller

The microcontroller (MCU) will receive signals in analog and digital form. It will be using Bluetooth to transmit the digital signals to various parts in the system.

7.1 General Requirements

[R123 – I] The MCU will have at least 2 digital outputs.

[R124 – I] The MCU will have a minimum of 3 analog inputs with digital to analog converters. The inputs will be used for the diaphragm pump, pneumatic valve and pressure transducer.

[R125 – I] The MCU will have a Bluetooth transmitter.

7.2 Electrical Requirements

[R126 – I] The MCU will lower power consumption and use less than 100Ma.

[R127 – II] The MCU will use the same power source as the whole system.

[R128 – III] The MCU will not require heatsinks on any internal components.

7.3 Software Requirements

[R129 – I] The MCU needs to be able to handle high real-time refresh rate at 10 microseconds.

[R130 – II] The MCU must have boot up time of less than 5 seconds.

[R131 – III] The MCU must have recovery plan/data restoration/shock resistance.

[R132 – III] The MCU must be able to receive and send data to at least 6 adjacent users.

7.4 Performance Requirements

[R133 – I] The MCU ADC inputs will have a resolution of 10 bits.

[R134 – I] The MCU will have digital filtering capabilities.

[R135 – I] The MCU will analog to digital conversion capabilities.

[R136 – I] The MCU will receive and transmit digital data from and to an android phone.
[R137 – I] The MCU will actuate the abdominal binder when the patient's blood pressure crosses a threshold value.
[R138 – I] The MCU will receive the patient's blood pressure readings by Bluetooth at regular intervals.
[R139 – I] The MCU will adjust to the new targets.

7.5 Usability Requirements

[R140 – I] The MCU is easy to program and is easy to use.
[R141 – II] The MCU can be powered by batteries.
[R142 – II] The battery must be easily accessible for replacement, detachable and changeable.
[R143 – II] The battery fully charged must be able to last 24 hours of continuous operation.
[R144 – III] The MCU will not exceed 800 grams in weight.

7.6 Safety and Reliability Requirements

[R145 – I] The MCU will be in an enclosure.
[R146 – I] The MCU will have no exposed circuitry.
[R147 – I] The MCU in the enclosure will be grounded properly.
[R148 – II] The enclosed MCU will be able to sustain repeated drops from waist height.
[R149 – III] The MCU will be protected in high humidity environments by using silicone conformal coating.
[R150 – III] The MCU enclosure will have warning labels over the assembly screws.

8. Mobile Application Requirements

The mobile application displays blood pressure information in an easy to read number format from the MCU as the blood pressure monitor sends the data to MCU. The application will determine if the information is below a set threshold and it will display a graphical indication with an option to enable sound or vibration as well to let the user know the belt is about to be activated. The application will send and receive information via Bluetooth from the MCU. The graphical interface (GUI) will be simple for any user to use.

8.1 Performance Requirements

[R151 – I] The application will be able to send and receive data to and from the MCU via Bluetooth.
[R152 – I] The application will be able to receive data from the blood pressure monitor via Bluetooth.

[R153 – I] The application can detect abnormal blood pressure changes within 5 seconds.
[R154 – II] The application will be able to detect when the blood pressure has exceeded its set threshold.
[R155 – I] The application will send a signal to the MCU to start the belt action within 5 seconds once the threshold is exceeded.
[R156 – I] When the user enters new blood pressure targets, the targets will be adopted within 3 seconds.
[R157 – II] The application will not have a big impact on the battery life of the phone (<10 % battery life decrease with the application running).
[R158 – II] The application will have a maximum 2 second start up time from a cold launch.
[R159 – II] The application must not consume excessive processing and memory resources on the phone.
[R160 – III] The application will follow the standard android performance guidelines [9].

8.2 User Interface Requirements

[R161 – I] The GUI will be intuitive and user friendly.
[R162 – I] The GUI will have clear and obvious buttons for interaction.
[R163 – I] The GUI will have clear instructions to lead users.
[R164 – I] The GUI will not have any hidden features.
[R165 – I] The GUI will have an apparent visual indication when the system will start performing its belt contraction function.
[R166 – I] The GUI will have an easy to read permanent blood pressure text in numerical values which cannot be toggled off.
[R167 – II] The GUI will be easy to read from 4 feet away.
[R168 – II] The GUI will have text reminders for users when the blood pressure is close to the threshold.
[R169 – III] The GUI will display a graph for blood pressure which can be toggled off or on.
[R170 – III] The GUI will follow the standard android visual design and user interaction guidelines [9].
[R171 – III] The GUI will allow the user to view the threshold targets for day and night.
[R172 – III] The GUI will allow the user to set threshold targets for day and night.

8.3 Reliability and Safety Requirements

[R173 – I] The abdominal binder must have a safe maximum pressure of 60 mmHg
[R174 – I] The application allows margin of error in measurement no more than 5%.

[R175 – I] The application will be able to handle bad received data without crashing.
[R176 – I] The application will have a confirm dialog to prevent accidental exits.
[R177 – I] The application will have a very low chance of false starts of the belt (<1%).
[R178 – I] The application will read and display blood pressure reading accurately 99% of the time.

[R179 – I] There will be an easily accessible emergency stop button to shut down the binder.

[R180 – I] The abdominal binder will not be triggered from low blood pressure readings when the user takes off the BPM arm cuff.

[R181 – I] The user will be warned if the MCU is not receiving any data from the MCU or BPM.

[R182 – III] The application will follow the standard android reliability guidelines [9].

[R183 – III] The application will require minimum permissions from the user to function.

[R184 – III] The application must prevent the user from entering unreasonable BP threshold targets.

9. User Documentation

[R185 – III] An instruction Manual with an installation guide will be provided.

[R186 – III] A Quick Start guide in English, French and Chinese will be provided.

[R187 – III] The User manual will be written for a general audience with minimal use of technical terms.

[R188 – III] The user manual includes company website which includes a FAQ section

[R189 – III] The user manual includes warranty, contact information and terms and conditions

10. System Test Plan

Individual component testing is an integral part of the system test plan. The project is separated into software and hardware modules. Hardware and software must pass the tests for system integration to occur. Integration testing will involve using the entire system in its working state and tests cases will be developed to discover and fix any problems that may arise in a specific scenario.

10.1 Hardware Test

The functionality of the abdominal binder can be tested by doing an examination of inflation and deflation of the binder, and by testing it on a manikin model. The binder must be put on the manikin model to do a simulation of the inflation of the abdominal binder on a patient. The pressure must be monitored by the pressure sensor put on the manikin abdomen to make sure the pressure applied on the manikin body matches the pressure applied from the diaphragm pump, and also to check the range of the pressure applied.
The physicality of the binder must be checked on various human bodies with different sizes when the binder is disconnected from the pump. The pressure sensor could be tested by applying a known pressure using a calibrated and precise pressure source. This could be also checked with another type of a pressure sensor to make sure the methodology of the collection of data does not make any difference in the result collected. All of these data would be collected in the microcontroller unit and the result could be compared to ensure the functionality of the device.

The diaphragm pump can be tested when it only connects to the MCU and its individual battery power supply. The most primary thing to check is to make sure the pump can be turned on and off properly by the MCU. Once it is turned on, a pressure sensor can be attached to the output port of the pump to check if it constantly delivers the inflation air, and as well as to monitor the air pressure value; the supplied motor voltage is adjustable and as a result, the output air pressure can be tested and adjusted to a desired value.
The pneumatic solenoid valve can be tested as a further step of the diaphragm pump test. Once the air pressure meets the expectations, we will connect the pump output port to the valve input port by a gas pipeline. Firstly, the function of controlling the airflow speed needs to be checked by screwing the mufflers into the exhaust ports put a hand to the output side to feel the air speed change. Secondly, we will connect the valve to the binder to check if it is able to inflate and deflate the binder. Lastly, we will connect the valve to the MCU to ensure the two behaviors of the valve are controllable by the MCU.
The BPM will be tested by comparing the BPM measurements against the simultaneous results of a mercury manometer for five subjects. The results should be accurate to within 3% of the mercury manometer reading. The results from the BPM display screen should match the data sent to the microcontroller.

10.2 Software Test

The Bluetooth communication between the Arduino and the BPM will be tested by pairing the BPM to the Arduino. The test will ensure that data can be sent and received from the Arduino to the BPM and vice versa. The same test is applicable between the phone and the Arduino as well and will be done using the Arduino software. The software developed for the Arduino will be tested for its ability to differentiate and act on several inputs from various hardware modules such as the pneumatic valve. A basic mobile application will be developed to communicate with the Arduino Bluetooth module before more advanced functionality is developed. The mobile application will be tested for its blood pressure reading from the Arduino and be verified against the BPM's physical display to confirm its accuracy. The mobile application will be tested for its ability to respond to a specific reading by displaying colors, sound alerts and vibration.

10.3 Integrated System Test

As the whole system is integrated, many test cases will be developed to verify functionality.

The BPM will send a reading to the Arduino and from the Arduino to the phone application and the reading on the phone must be tested to correspond with the physical display on the BPM.
The user wearing the prototype will sit stationary and is expected to move their arms and legs as well as torso and upper body movement to ensure there is no movement restriction, discomfort and hazards.

The mobile application's ability to set new BP targets will be tested by white-box testing different input targets, ensuring that the microcontroller adopts the new targets and the abdominal binder behaves correctly in each case.
When the user sets new targets and their actual BP is below the target threshold, the abdominal binder actuates within 10 seconds. When the user sets new targets and their BP is above the new threshold, the abdominal binder does not actuate. When their BP drops below the threshold, the abdominal binder actuates.

To ensure functionality of the abdominal binder when the mobile app is not running, the microcontroller will be cold-launched while the mobile app is not running. The abdominal binder should continue to actuate and de-compress according to the last known target threshold. For the case when the mobile app shuts off during different states of operation, the microcontroller will continue to obey the last known targets. The states that will be considered are decompressed, and compressed abdominal binder, and standby.

11. Conclusion

InFlux is in the early development stages for the development of the Smart Abdominal Binder which will greatly aid wheelchair patients who regularly experience faintness from prolonged sitting. The functional specification document outlines the current necessities to show the objectives and may be further expanded and adapted from continuous research and development. The most important functional requirements I and II will be developed for the prototype. If time permits, good to have functional requirements III will be added to further expand its functionality. The functional prototype is expected to be completed by the end of November 2014.

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