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February 16, 2011
Dr. Andrew Rawicz
School of Engineering Science
8888 University Drive
Simon Fraser University
Burnaby, British Columbia
V5A 1S6

Re: ENSC 440 Function Specifications for a Blood Speed Measurement Probe

Dear Dr. Rawicz,

The document included outlines the functional specification for our *Vivace*Flow blood flow measurement probe. Our team at VeloStream Technologies Incorporated is designing a blood flow measurement probe, which can be inserted into the atria of a patient to perform blood flow measurements.

Our functional specification document describes the high level requirements of our *Vivace*Flow device. This document will be used throughout the design process as a guiding resource, and it will direct the development and testing of our design process.

Our team is comprised of five undergraduate students from Simon Fraser University: Connie Drewbrook, Wyatt Gosling, Kaveh Naziripour, Jedsada Sahachaiwatana, and Elizabeth Steiner.

If you have any questions or concerns regarding our functional specifications, please do not hesitate to contact us at velostreamtech@googlegroups.com.

Sincerely,

E Steiner

Elizabeth Steiner
Chief Executive Officer
VeloStream Technologies Inc.
Suite 2106 - 8888 University Drive
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Enclosure: *Function Specifications for a Blood Speed Measurement Probe.*

VeloStream Technologies Incorporated

Functional Specifications for the

*Vivace*Flow Speed Measurement Probe

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Issued Date: February 16, 2011

Executive Summary

The percentage of the American population afflicted with coronary heart disease (CHD) due to obesity, family history, age and genetics is rising at an alarming rate. Six percent of the total population will suffer from a non-fatal heart attack due to CHD in the year to come (AHA, 2011). This disease is often treated through the placement of stents in the arteries that supply blood to the heart.

At VeloStream Technologies Incorporated, we are a group of five inspiring young engineers who are passionate and committed to developing novel medical technology, with the aim of improving the quality of human life. Our team has purposed the *Vivace*Flow (vee-VAH-chay-flow) speed measurement probe as a device to be used by medical specialists, in conjunction with external imaging, to increase the accuracy and efficacy of the placement of stents.

The *Vivace*Flow system has been split into three separate components:

- The User Interface: *Unisca*Suite™
- The Controller: *Genio*Box™
- The Sensor: *Piccolo*Probe™

The *Unisca*Suite will be a software package, available for download on any computer, which provides the user with a means to control the probe and collect processed data. Connection of the PC to the rest of the system will be facilitated by the use of a regular serial port cable, which will be provided with the system. The *Genio*Box, which consists of a processor and electronic components, will act as the connection between the PC and the sensor. The *Piccolo*Probe will be inserted into the heart for invasive blood flow measurements, and will transmit data back to the *Genio*Box for processing. The results will be then plotted on the computer screen.

The following document outlines the Functional Specifications for the entire *Vivace*Flow system, as well as each of the individual components. The document assumes that the user will be a health care professional using the device in an operating room, which must comply with medical standards. In addition, we also consider biocompatibility requirements and performance requirements specified by our investors. The document ends with a detailed system test plan for proving the functionality that has been specified.

Although our current goal is to develop a working “proof of concept” prototype, this does not mean we have lost sight of the additional functionality that is necessary for the final product; both concepts are included in this document.

Table of Contents

Glossary

17 French Catheter	A tube which can be inserted into the body having an inner diameter of 5.7 mm.
Biocompatibility	The ability to coexist with living organisms without harming them.
Cardiac catheter	A long catheter designed for passage, usually through a peripheral blood vessel, into the chambers of the heart.
CHD	Coronary Heart Disease
Coagulation	When blood solidifies or clots.
Coronary angiography	An invasive procedure used to examine the blood vessels of the heart.
Coronary arteries	Vessels that supply the heart muscle with blood rich in oxygen.
CSA	Canadian Standard and Administration.
FDA	US Food and Drug Administration
Femoral artery	A few large arteries in the thigh area which start at the femoral head and end just above the knee.
Fluoroscopy	An x-ray procedure that produces real-time images and motion on a screen.
IPA	Isopropyl alcohol; a chemical that is normally used as a disinfectant.
Invasive procedure	A procedure that involves entering the body through the skin or through a cavity or anatomical opening.
Percutaneous procedure	A procedure that is done through needle-puncture of the skin, as opposed to an approach using a scalpel.
Pulsatile	Beating, or pertaining to activity that is characterized by rhythmic pulsation.
Sheath	The cover on the opening of the body where the catheter is inserted.
Thrombogenicity	The tendency of a material in contact with the blood to produce a thrombus, or clot.
UI	User Interface

1 Introduction

The *Vivace*Flow is a blood speed measurement probe that will be capable of accurately measuring flow rates, while remaining small enough to be inserted into small enclosures, such as the heart. The development of the *Vivace*Flow is divided into two stages. The first is a proof of concept prototype that will be developed over a four-month period ending April 11th, 2011. After testing and analysis, a production ready system will be developed. This document outlines the functional requirements of the system.

1.1 Scope

This document lists the functional requirements of the upcoming *Vivace*Flow Blood Speed Measurement Probe System. It describes in detail the functionality required for a proof of concept model as well as a production model. The requirements within will be used to guide further development of the product.

1.2 Intended Audience

This document is intended for use by all engineers within VeloStream Technologies Incorporated. Design engineers will use it as a guiding document such that the final design will satisfy the requirements listed within, and test engineers will use the document to design test criteria. The team leader will use this document to monitor the overall progress of the engineering groups to ensure the team's progress.

1.3 Requirement Classification

Throughout this document, the following convention will be used to label requirements:

[FS-{module}-##-{rank}]

- **{module}** identifies which subsystem of the design the functionality is intended for. It will be set as one of:
  - **S** Describes requirements which apply to all components of the system
  - **P** Describes requirements of the *Piccolo*Probe™
  - **I** Describes requirements of *Unisca*Suite™
  - **B** Describes requirements of the *Genio*Box™
  - **D** Describes requirements of user documentation
- **{rank}** identifies for which milestone a requirement needs to be satisfied. It will be set as one of:
  - **A** Required for both proof of concept and production models
  - **B** Required for only proof of concept model
  - **C** Required for only production model

- An **Asterisk (*)** at the end of each code indicates that this requirement is a demand of our primary investor Kardium Inc. Based on our format it will look as follows:

[FS-{module}-##-{rank}]*

2 System Overview

The *Vivace*Flow™ flow speed measurement system has been split up into three main components: the User Interface (UI), *Unisca*Suite™, the controller, the *Genio*Box™, and the flow sensor, the *Piccolo*Probe™. The following section outlines the functionality of the entire *Vivace*Flow system and each of its separate components. In addition, it identifies the intended user, standard requirements, and biological effects, which must also be considered to ensure safe use of our product.

2.1 High Level Functionality

Our product will be placed in a liquid to perform real-time flow speed measurements. The flow measurement will be based on the movement of liquid past the tip of the probe. The system will have the ability to do invasive blood flow measurements within the chambers of the heart, either by direct access, or percutaneous navigation through the use of a 17 French guide catheter.

2.2 Intended User

The main drive for the development of the *Vivace*Flow is to provide health care professionals with a method, to be used in conjunction with a coronary angiography, to aid in the placement of stents for the treatment of CHD. As a result, the intended user of our device is a health care professional with specific knowledge and expertise in cardiac surgery. Generally, there are many different people present in an operating room during cardiac surgery, including, but not limited to: the surgeon, assisting surgeons, an anesthesiologist, scrub nurses and circulating nurses (Hill, 1999). Due to the fact that our device has a specific intention and that there are only a small number of people who will be required to know how to use the device, each person can be trained in proper use. On the other hand, because the device will be used in a medical setting, there must be redundant protection designed into the device in order to reduce the probability that the user accidentally harms the patient.

We also need to consider the space available to the user when deciding on functional requirements. Cardiac surgery, even one which is percutaneous, involves the use of multiple technological devices such as fluoroscopy machines, ultrasound imaging machines, vital sign monitors, and ventilators (Goldman, 2008). Many of these devices need to be located near the patient, so the space around the bed is extremely limited. Often, during these procedures, the computers for processing will be located on the opposite side of the room from the surgical team. In this regard we must consider the space taken up by the device, and the length of connection between different components of the device.

2.3 Unit Functionality

Presented in Figure 1 is a functional block diagram of the *Vivace*Flow system, identifying each of the components of the system, and how they communicate with each other during the flow speed measurement process. A list of each component's basic functionality is introduced below.

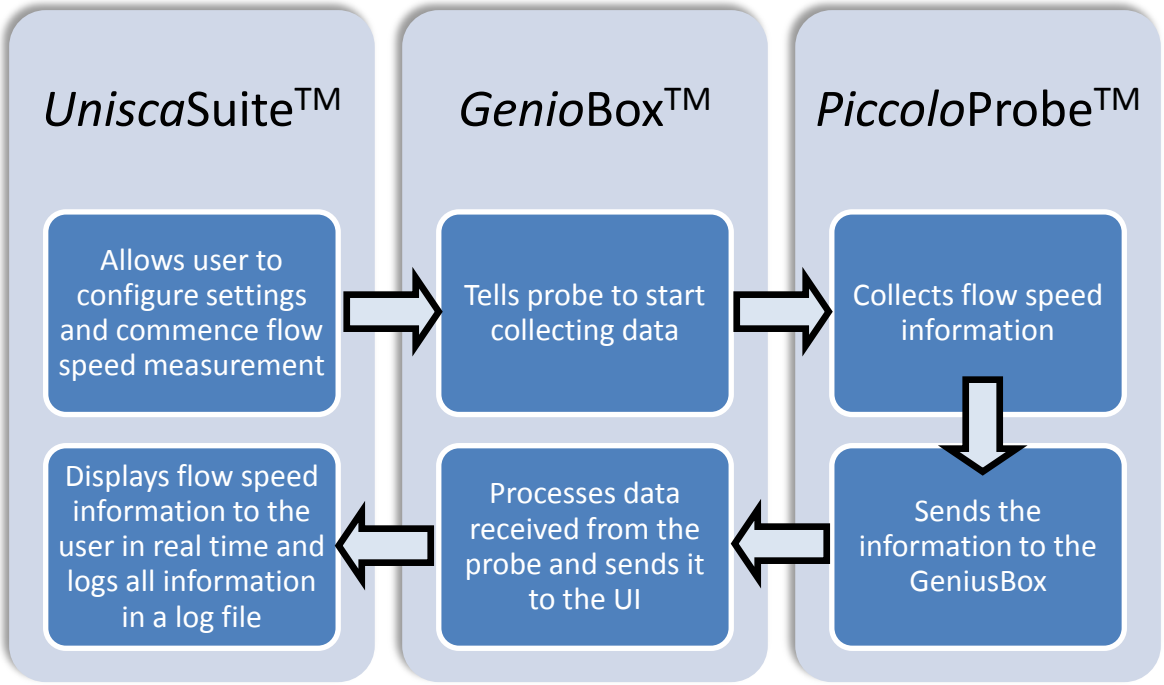

Figure 1 – High Level Functional Block Diagram for the *Vivace*Flow

The Sensor: *Piccolo*Probe™

The *Piccolo*Probe consists of four main parts: the head, the body, the probe steering control and the connector. The head acts as the sensor for flow detection, and the body which connects the head to the probe steering control. The probe steering control manages the movement of the probe head, and is connected to the *Genio*Box via the connector. The head is the part of the system that is inserted into the atria via a cardiac catheter, although a large portion of the body may also be in contact with the liquid given the nature of the setup. The probe will be disposable such that a new sensor is used for each patient. The probe will be able to:

- continuously provide real time information on flow speed to the *Genio*Box when instructed to, and
- curl the head in order to achieve access to small crevices inside the heart.

The Controller: *Genio*Box™

The *Genio*Box communicates between the probe and the UI. The *Genio*Box consists of a processor and electronic components that are capable of process data coming from the probe and the UI. It will also have its own power supply that will be used to power the probe. The box will have three electrical outlets: the first outlet is a plug that is connected to a power source, the second is a cable that links to a computer on which the UI is running, and the last is an outlet to which the probe will be connected. The *Genio*Box will:

- commence measurements at the probe given instructions from the UI,
- stop measurements at the probe given instructions from the UI,
- stop measurements at the probe given suspicious behavior, and
- process information received from the probe.

The User Interface: *Unisca*Suite™

Included in the *Vivace*Flow system is a software package, called *Unisca*Suite, which is to be run on any regular PC with a Windows operating system and serial port. The software package serves two roles: it will provide the user a means to control the probe and it will collect processed data from the *Genio*Box and present it to the user. The user interface will:

- provide controls to start and stop recording flow information,
- provide controls to change the liquid for which the probe is calibrated
- provide controls to initiate calibration,
- initiate calibration on its own, as necessary,
- collect data from the *Genio*Box and convert it into a human readable output in standard units presented in a self updating graph, and
- provide some auxiliary features such as per patient data storage, and a link to the current log file directory.

2.4 Standard Requirements

Our initial target market consists of hospitals and surgical clinics in the United States of America. As a result, it is essential that we follow the FDA standards (US Department of Health and Human Services, 2011). Moreover, we are interested in penetrating the Canadian market; therefore our product must follow the CSA standards (Health Canada, 2010). Since the concept of the blood flow meter already exists on the market, the approval process will be procedural. Upon the approval of the following protocols, we will be able to distribute our product into the market. This step will come after validation and the completion of the prototype. The most important standards for our device are as follows:

American Standards

- US Food and Drug Administration: 21CFR870.2100 which falls under class II category for blood flow meter.

Canadian Standards

- IEC 60601-1:1988-Ed.2.0
  - Medical electrical equipment – Part 1: General requirements for basic safety
- IEC 60601-1:1988-Ed.2.0 /Amd.1:1991
- IEC 60601-1:1988-Ed.2.0 /Amd.2:1995
- IEC 60601-1:1988-Ed.2.0 /Cor.1:1995
- IEC 60601-1:2005-Ed.3.0
  - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1:2005-Ed.3.0 /Cor.1:2006
- ISO 10555-1:1995 Sterile, single-use intravascular catheters – Part 1: General requirements ISO 10555-1:1995/Amd.1:1999 ISO 10555-1:1995/Amd.2:2004
- ISO 10555-3:1996 Sterile, single-use intravascular catheters – Part 3: Central venous catheters ISO 10555-3:1996/Cor.1:2002

2.5 Biological Effects

Due to the nature of the device, it is expected that the device will remain in contact with tissue and blood for lengthy periods of time. As a result, there are a series of biocompatibility issues which must be considered when designing for functionality. Presented below is a table, indicating temperature effects on biological tissue. As you can see from the table, coagulation occurs above 47°C. Coagulation can also occur if blood remains stagnant, which may occur if it is allowed to pool in crevices of the device.

Table 1 - Effect of Temperature on Biological Tissues (Habash, Bansal, Krewski, & Alhafid4, 2006)

Temperature Range	Time Requirements	Physical Effects	Biological Effects
< -50	> 10 minutes	Freezing	Complete Cellular Destruction
0-25	> 10 Minute	Decreased Permeability	Decreased blood perfusion, decreased cellular metabolism, hypothermic killing
30-39	No Time Limit	No Change	Growth
40-46	30-60 Minutes	Change in Optical Properties of Tissue	Increased perfusion, thermotolerance

			induction, hyperthermic killing
47-50	> 10 Minutes	Necrosis, Coagulation	Increased perfusion, thermotolerance induction, hyperthermic killing
> 50	After ~ 2 Minutes	Necrosis, Coagulation	Cell Death
60-140	Seconds	Coagulation, Ablation	Protein denaturation, membrane rupture, cell shrinkage
100-300	Seconds	Vaporization	Cell shrinkage and extracellular steam vacuole

3 System Requirements

The following section identifies the functional requirements for the entire system, based on the system overview presented in Section 2. These requirements are those which are shared by all components of the *Vivace*Flow system.

3.1 General Requirements

[FS-S-01-A] The system must have an "off state", irrespective of the state of the UI, when the power to the GenioBox and *Piccolo*Probe is off.

[FS-S-02-A] The system must have a "ready state", when the power to the *Genio*Box is on and the UI is connected, but there is no power being fed to the *Piccolo*Probe.

[FS-S-03-A] The system must have a "hold state", when the power to the *Genio*Box is on, the UI is not connected, and there is no power being fed to the *Piccolo*Probe because measurement has not been initialized.

[FS-S-04-A] The system must have a "running state", when the power to the *Genio*Box is on, the UI is connected, and there is power being fed to the *Piccolo*Probe for measurements.

[FS-S-05-A] The system must have an "error state", when the power to the *Genio*Box is on, the UI is connected, but the power to the *Piccolo*Probe has been shut off due to the detection of abnormal/hazardous conditions at the *Piccolo*Probe.

[FS-S-06-A] The retail price of the system must be less than $600.

3.2 Physical Requirements

[FS-S-07-A] The system must be capable of being transferred from one location to another by a single able bodied person.

[FS-S-08-C] The distance achievable between the *Genio*Box and the head of the *Piccolo*Probe must be greater than four meters in order to provide appropriate distance between the catheter insertion location and the foot of the bed.

[FS-S-09-B] The distance achievable between the *Genio*Box and the head of the *Piccolo*Probe must be greater than two meters.

[FS-S-10-C] The distance achievable between the Computer and the *Genio*Box must be greater than 26.5 feet, or eight meters, given an approximate OR size of 600-

700 square feet. (Cantrell, 2008)

[FS-S-11-B] The distance achievable between the Computer and the *Genio*Box must be greater than one meter.

3.3 Electrical Requirements

[FS-S-12-A] The electronic components must not interfere with other medical devices in use (IEC 60601).

[FS-S-13-A] The system must not be susceptible to interference from other electrical systems (IEC 60601).

[FS-S-14-A] All electronic components must be concealed from physical interference.

[FS-S-15-A] The system , excluding the PC, must not require for operation more than a single wall outlet with a supply of 110V, 60Hz AC.

3.4 Environmental Requirements

[FS-S-16-A] The system must operate as expected under the expected temperature and humidity conditions inside an OR of 18-24°C and 50-60% Humidity (Hamlin, Richardson-Tench, & Davies, 2009).

3.5 Reliability/Durability Requirements

[FS-S-17-A] The system must not overheat with continuous usage.

[FS-S-18-A] The system performance must not degrade with normal use.

[FS-S-19-C] Any part of the system which is not disposable must have an expected life of over ten years with regular maintenance due to the simplicity of the system.

3.6 Safety Requirements

[FS-S-20-A] The system must be equipped with an emergency stop which cuts off all electronic power to the *Piccolo*Probe.

[FS-S-21-A] The system must be designed to react appropriately and turn off the power to the *Piccolo*Probe if the PC, which the software is running on, crashes or is

turned off.

[FS-S-22-A] Any part of the system in contact with tissue or blood must not exceed in temperature of 46°C (Habash, Bansal, Krewski, & Alhafid4, 2006).

[FS-S-23-A] The system must have electrostatic shock resistance for discharge levels of at least ±6KV (IEC 60601).

[FS-S-24-C] The system must provide a warning to the user given detected improper use at the *Piccolo*Probe.

3.7 Performance Requirements

[FS-S-25-A]* The range of liquid flow speed able to be detected by the probe must be between 0 to 1m/s.

[FS-S-26-A]* The system must have a flow speed measurement accuracy of the smaller of ± 10% or 2.5cm/s.

[FS-S-27-A]* The system must be able to be calibrated for blood and saline.

[FS-S-28-A] The system must have a reasonable boot time of less than 60 seconds, considering surgical operation time restrictions.

[FS-S-29-A]* The system must have a temporal resolution of 10ms or less.

3.8 Usability Requirements

[FS-S-30-A] The user must not require personal protection equipment to operate the system.

[FS-S-31-A] The user must be aware at all times if speed measurements are being made.

[FS-S-32-A] The system must be usable by one person.

[FS-S-33-C] The system must have a first run wizard for new users.

4 *Piccolo*Probe™ Requirements

Presented below are the requirements for the *Piccolo*Probe, consisting of the sensor, mechanical components for steering, and connection to the *Genio*Box. Due to the environment in which the probe will be used, there are many considerations we must take into account to ensure safe and effective functioning of the probe. The *Piccolo*Probe also inherits the requirements of the system as described in Section 3.

4.1 General Requirements

[FS-P-01-C] The *Piccolo*Probe must have the ability to be inserted into the heart via a 17 French cardiac catheter (5.7 mm diameter).

[FS-P-02-B]* The probe must have the ability to be inserted into the heart via a sheath having an inner diameter of 15.3mm.

4.2 Physical Requirements

[FS-P-03-C] The *Piccolo*Probe must be small enough to fit in coronary arteries, which range from 15 mm^2 to 25 mm^2, without interfering with blood flow or stent placement. (Sheifer, Canos, Weinfurt, Arora, & Weissman, 2000).

[FS-P-04-B]* The head of the *Piccolo*Probe over which we will take the measurements must be less than 4 mm by 4 mm in area.

[FS-P-05-A] The *Piccolo*Probe body must not be porous, have tangles of wire, or loose parts in order to be minimally throbogenic.

[FS-P-06-A] The body of the probe must be less than 1.0 cm diameter.

[FS-P-07-A]* The head of the *Piccolo*Probe must be able to bend back on itself to a distance of 10mm from the body to ensure the probe can access the majority of the cavity into which it is placed.

[FS-P-08-A]* The *Piccolo*Probe must be visible under fluoroscopy and ultrasound.

[FS-P-09-A] The *Piccolo*Probe must create a haemostatic seal with the sheath.

[FS-P-10-C] The *Piccolo*Probe steering control must have a spring lock mechanism.

[FS-P-11-C] The knob must have a controlled release to limit the recoil speed of the *Piccolo*Probe connecting body.

[FS-P-12-C] The length of the *Piccolo*Probe body must be at least 3 m to ensure sufficient length for percutaneous access.

[FS-P-13-B] The length of the *Piccolo*Probe body must be at least 2 m for direct access to the atria through the ribs.

4.3 Electrical Requirements

[FS-P-14-A] The *Piccolo*Probe must have two conductive electrodes on the outside for voltage location sensing.

[FS-P-15-A] The bulk of the *Piccolo*Probe‘s exterior (besides the conductive electrodes described above) must not be electrically conductive.

4.4 Environmental Requirements

[FS-P-16-A]* The *Piccolo*Probe must be functional within a temperature range of 37-39 C° (Kalat, 2009).

[FS-P-17-A] The *Piccolo*Probe must be submersible in liquids without leakage.

[FS-P-18-C] The *Piccolo*Probe must be biocompatible.

[FS-P-19-B]* The exterior of *Piccolo*Probe must be smooth to ensure that no blood can leak through the seal of the sheath.

4.5 Safety Requirements

[FS-P-20-A] The *Piccolo*Probe must have a current leakage of 10 μA or less (Lobato, Gravenstein, & Kirby, 2008).

[FS-P-21-A] The *Piccolo*Probe must not have sharp edges.

4.6 Durability Requirements

[FS-P-22-B]* The *Piccolo*Probe must be reusable and cleanable with isopropyl alcohol.

[FS-P-23-C] The head and body of the *Piccolo*Probe must be disposable, and the remainder of the probe must be reusable and sterilizable.

5 *GenioBox™* Requirements

Presented below are the functional requirements for the *Genio*Box, consisting of the processor, electronic components, power supply and housing container. The *Genio*Box also inherits the requirements of the system as described in Section 3.

5.1 General Requirements

[FS-B-01-A] The *Genio*Box must have an ON/OFF switch.

[FS-B-02-C] The *Genio*Box must be stable and not move around while the *Piccolo*Probe is in operation.

[FS-B-03-C] The *Genio*Box must have smooth surface for easy cleaning.

[FS-B-04-C] The *Genio*Box must be water resistant.

[FS-B-06-C] The *Genio*Box must have a light on the top to indicate error.

5.2 Performance Requirements

[FS-B-07-A] The *Genio*Box must be able to collect data at a frequency of 100Hz.

[FS-B-08-A] The *Genio*Box must be able to send data at a frequency of 100Hz.

[FS-B-09-A] The *Genio*Box must be able to power the *Piccolo*Probe.

5.3 Reliability Requirements

[FS-B-10-A] The *Genio*Box must be able to run continuously without downtime.

5.4 Safely Requirements

[FS-B-11-C] The *Genio*Box must be able to detect abnormality of the *Piccolo*Probe.

[FS-B-12-A] The *Genio*Box must be able to power off immediately with delay.

[FS-B-13-A] The *Genio*Box must be able to block electromagnetic interference.

[FS-B-14-C] The *Genio*Box must be protected from power surges.

6 *Unisca*Suite™ Requirements

Presented below are the functional requirements for the *Unisca*Suite software package, which acts as the user interface. The *Unisca*Suite also inherits the requirements of the system as described in Section 3.

1.1 General Requirements

[FS-I-01-A] The software must display speed to the user via a graph.

[FS-I-02-A] The software must have a control allowing the user to initialize and cease flow measurements.

[FS-I-03-A]* The software must log speed data to a log file.

[FS-I-04-A] Only one instance of the software suite will run at a time. Reason: Multiple instances can send contradictory data to the *Piccolo*Probe.

[FS-I-05-C] The software must be able to separate data based on different patients.

[FS-I-06-A] The software must provide a control allowing the user to select the liquid to measure.

[FS-I-07-B] The software must support Windows XP.

[FS-I-08-C] The software must support Windows XP, Vista, 7; Mac OS X; and Linux.

1.2 Performance Requirements

[FS-I-09-A] The software must be able to collect data at a frequency of 100Hz.

[FS-I-10-A] The software must be able to log data at a frequency of 100Hz.

[FS-I-11-A] The software must be able to update visual display of flow at a frequency of at least 10Hz. A 10Hz refresh rate should be sufficiently fast enough to not appear choppy. Higher rates would stress the host computer more without being a noticeable difference for most people.

1.3 Usability Requirements

[FS-I-12-B] The software must provide a control to initiate calibration.

[FS-I-13-C] The software must initialize calibration as necessary, without user input.

[FS-I-14-A] The software must inform user when calibration is taking place.

[FS-I-15-A] The software must clearly show which fluid the system is currently calibrated for.

[FS-I-16-A] The software must be able to open the current log file directory.

1.4 Reliability Requirements

[FS-I-17-A] The software must not corrupt current log file during a crash.

[FS-I-18-A] The software must not use administrator or root privileges.

[FS-I-19-A] The software must not crash if it receives erroneous data from the *Piccolo*Probe.

[FS-I-20-A] Software must not introduce instability to other software.

[FS-I-21-A] Software's one instance mechanism must not break in case of a crash.

7 User Documentation Requirements

The user documentation is a manual that will be provided with each unit of *Vivace*Flow. The users of the device will also be able to access this information online in case of damage, loss, or more important updates. Users will be enabled to use *Vivace*Flow appropriately and effectively after educating themselves with the user documentation.

7.1 General User Documentation

[FS-D-01-C] The user instruction manual must be provided in English, French, and Spanish.

[FS-D-02-A] The user instruction manual must have exact and real images or snap shots.

[FS-D-03-A] The user instruction manual must use a clear and non-technical language as much as possible.

[FS-D-04-C] The user instruction manual must be accessible via VeloStream's website.

[FS-D-05-C] The user instruction manual must have a service and maintenance contact number.

[FS-D-06-C] The user instruction manual must have a 24 hours technical support contact number.

[FS-D-07-C] The user instruction manual must have the company fax number.

7.2 Physical User Documentation

[FS-D-08-C] The user instruction manual must be laminated or hard-cover to increase durability.

[FS-D-09-C] The user instruction manual must be thin and space efficient.

[FS-D-10-C] The user instruction manual must get updated regularly.

[FS-D-11-C] The user instruction manual must enable the user to remove and insert new sheets for updated sections.

7.3 Usability User Documentation

[FS-D-12-A] The user instruction manual must be intuitive.

[FS-D-13-A] The user instruction manual must not necessarily be for an individual with technical background.

[FS-D-14-A] The user instruction manual must provide a “quick-start” section for easy set-up and installation.

[FS-D-15-C] The user instruction manual must have a page tab for easy find of different sections or topics.

[FS-D-16-A] The user instruction manual must have a table of contents.

[FS-D-17-C] The user instruction manual must have an index section for convenience.

[FS-D-18-C] The user instruction manual must have notes page at the end, in case users would like to add extra hand written note at the end.

8 System Test Plan

To prove the functionality of our system we will test our product in several stages. First, we will ensure that each component of the entire system works as specified. Second, we will test that the components are compatible once integrated. Last, we will test the overall system and perform failure testing to ensure that the device fails safely.

Due to the environment in which our device will be used, the heart chambers, it is necessary to test our device under similar conditions. We have decided to build a pulsatile flow machine that will mimic the blood flow in the heart and enable us to accurately judge whether our device can operate as desired in these conditions. This flow machine will consist of a regulated pump and electronic parts that control the speed of the regulator. The fluid regulator will be able to accurately measure the flow speed. The probe will be inserted into the flow and the accuracy will be determined by comparing the flow speed output to the regulated flow speed.

The major problem presented is the inability to test our device in the media for which it is intended - blood. Instead, we will be testing the device in a fluid with similar physical properties. This fluid should have a similar specific heat capacity and viscosity to blood to ensure that the properties of blood which affect the flow speed measuring process are adequately represented. The specific heat capacity of blood is 3.78 J/g·K, and its viscosity is approximately 3.5 mPa·s. We have two options: buy a blood mimicking fluid, or synthesize our own fluid. Blood mimicking fluids are available on the market, but are quite expensive for the quantities we require. Therefore, we will synthesize our own fluid to test our device, whose physical properties, which are relevant to our system, will be sufficiently similar to those of blood.

Figure 2 demonstrates the testing process. We will also test the compliance of our device with necessary standards.

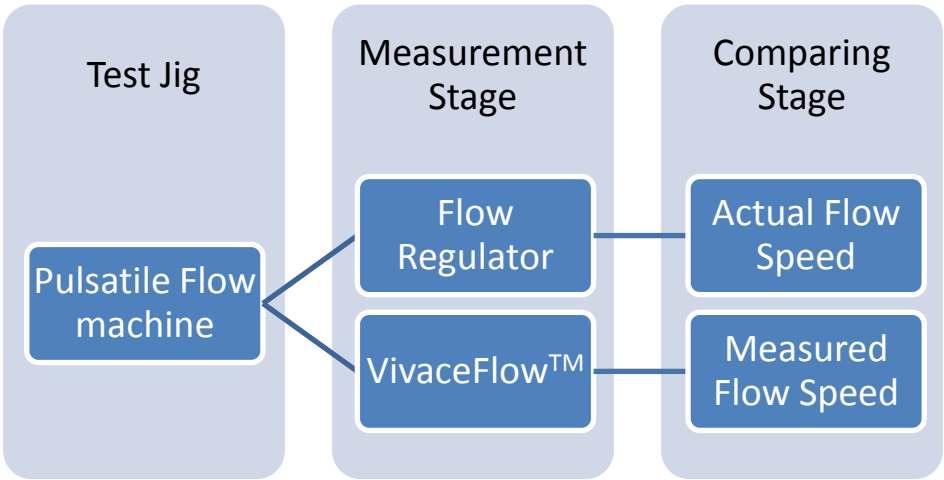

Figure 2: System Test Plan

8.1 Individual Component Testing

PiccoloProbe

- Ability to measure signal from fluid accurately over a range of speeds
- Ability to measure flow speed accurately within different types of fluid
- Ability to reach within everywhere within a 50 mm sphere except a 10 mm radius around the entry orifice

GenioBox

- Ability to connect to computer
- Ability to process signal received from probe
- Ability to meet power requirements
- Ability to be used for long durations of time without failure

UniscaSuite

- Ability to display programmed UI
- Ability to display relevant information
- Ability to graph data in real-time

8.2 System Integration Testing

PiccoloProbe

- Ability to receive data from the GenioBox
- Ability to output data to the GenioBox for processing
- Ability to respond to changes in parameters provided by the user

GenioBox

- Ability to connect to the computer and *Piccolo*Probe
- Ability to transfer data between the computer and *Piccolo*Probe
- Ability to process data as necessary

UniscaSuite

- Ability to receive feedback from the *Genio*Box
- Ability to plot the data in real-time
- Ability to prompt the user for input parameters
- Ability to set device parameters based on user input

8.3 Typical Usage Scenario

The typical usage scenario is designed to mimic the use of *Vivace*Flow so that we can test the overall functionality of the system. To test the accuracy of our system, we will follow the typical usage scenario outlined below:

1. Start the software.
2. Power up the *Genio*Box.
3. *Genio*Box and *Unisca*Suite indicate a ready to use signal.
4. The user sets the type of fluid being used.
5. The user inserts the *Piccolo*Probe in to the fluid.
6. The user presses start to commence flow speed measurements.
7. Speed of the flow is plotted in real-time, and logged and saved automatically by the software.
8. After the user has gathered enough data, the stop button is pressed.
9. The user removes the *Piccolo*Probe.
10. The user turns off the GenioBox
11. The user terminates the software

To ensure that our system provides accurate values, we will test this in a circuit featuring a pulsatile pump following the test scheme outlined above. We will compare the values logged from the *Unisca*Suite software to values obtained from a commercially available flow measurement device.

8.4 Improper Use

As with all medical equipment, safety is of paramount importance. As such it is necessary that we have sufficiently tested improper usage and failures to ensure that the system does not produce potentially dangerous outputs. This section should be considered living: it will be added to and refined as we discover new potential failures.

Case 1: *Piccolo*Probe is disconnected

During normal operating procedure, while the system is running and the probe is sending and receiving data from the *Genio*Box, the *Piccolo*Probe is accidentally disconnected. In this case, the *Genio*Box detects that the *Piccolo*Probe has been disconnected and the warning LED on the *Genio*Box lights up. *Unisca*Suite then shows a warning that the *Piccolo*Probe has been disconnected.

Case 2: GenioBox loses connection to the UniscaSuite

During normal operating procedure, while the system is running the *Genio*Box loses its connection with the *Unisca*Suite software package. This could occur from a disconnected cable, a software crash, or the user could close the software. The *Genio*Box detects the connection loss and its warning LED lights up. The *Genio*Box stops sending power to the *Piccolo*Probe. If the *Unisca*Suite is still running, it will display a warning, which indicates that there is no connection to the *Genio*Box.

Case 3: The GenioBox loses power.

During normal operating procedure, the *Genio*Box loses power. The *Piccolo*Probe will necessarily lose power, as the GenioBox powers it. The *Unisca*Suite will display a warning indicating that there is no connection to the *Genio*Box.

Case 4: The PiccoloProbe is placed in a fluid at or above 46 degrees Celsius.

Due to how the human body reacts to heat, it is necessary that the system does not operate above a particular temperature. If the user places the *Piccolo*Probe in liquid above 46 degrees Celsius, the system will assume the *Piccolo*Probe is at risk of causing bodily harm and will stop providing power to the *Piccolo*Probe. The *Unisca*Suite will display a warning to the user to alert them of their mistake.

Case 5: The user tries to steer the probe at unsafe speeds.

Due to the spring, it is possible that the probe may recoil quickly from a bent position to its fully extended position, where the angle between the head and body is 180 degrees. Uncontrolled recoil could potentially cause harm to a patient. As such, the probe will be designed to prevent the user from unintentionally initiating recoil.

9 Conclusion

The functional requirements of this document describe the *Vivace*Flow flow measurement probe. This document provides a complete and precise outline of the features available in the *Vivace*Flow system. A proof of concept prototype is being developed at this time. It is expected that the prototype will satisfy all the requirements categorized in this document as A or B by April 11, 2011.

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