D0011 - Gen 1 Stroke Detection Device Design Review

Stroke Detection Project

Introduction

The Generation 1 Stroke Detection Device is the first in a series of prototypes developed to measure blood flow in the brain of a human. Data from Generation 1 Stroke Detection Device testing in human studies will inform design changes to subsequent prototypes.

1. Overview

1.1 Purpose

The purpose of this document is to specify the design input requirements associated with the development of the Gen 1 Stroke Detection Device for clinical study and clinical trial after the study is complete.

1.2 Project Overview

The Gen 1 Stroke Detection Device enables direct noninvasive measurement of local cranial blood flow under continuous, direct, control by a trained operator.

1.3 Scope

The objective of Openwater Platform Gen 1 is to gather a baseline data set for the blood flow measurements in a clinical setting. The clinical study is separated into 3 phases.

1.3.1 Stage 0 - Pre-testing

Date: Dec 2020 - Jan 2021
Location: Openwater Facilities - San Francisco, CA
Objectives:

1.4.1 Verify that all components are working correctly, separately and together.
1.4.2 Verify that safety mechanisms function correctly.
1.4.3 Establish expectations for range of measurements on healthy volunteers.

1.3.2 Stage 1 - Healthy Participants

Date: Jan 2021 - Q2 2021
Location: Hartford Hospital - Hartford, CT
Objectives:
In healthy volunteers,

1. Assess blood flow measurement variability of right/left hemispherical differences, as well as for different spatial locations per hemisphere in non-stroke subjects.

2. Assess blood flow measurement variability of repeated measurements in Objective #1.

3. Assess whether the subject's position, lying supine versus sitting upright, produces any differences in the blood flow measurement variability of right/left hemispherical differences.

Full protocol: D0017 Openwater_Engineering Study Clinical Protocol 1_Gen 1 Stroke Detection Device

1.3.3 Stage 2 - Clinically Significant Participants

Date: Q2 2021 - Q3 2021
Location: Hartford Hospital - Hartford, CT
Objectives:
In patients with clinically significant from a stroke perspective,

1. Assess blood flow measurement variability of right/left hemispherical differences, as well as for different spatial locations per hemisphere in non-stroke subjects.

2. Assess blood flow measurement variability of repeated measurements in Objective #1.

3. Assess whether the subject's position, lying supine versus sitting upright, produces any differences in the blood flow measurement variability of right/left hemispherical differences.

Full protocol to be determined and informed by Stage 1

Definitions, Acronyms and Abbreviations

This section is to be used to capture and define acronyms and abbreviations.

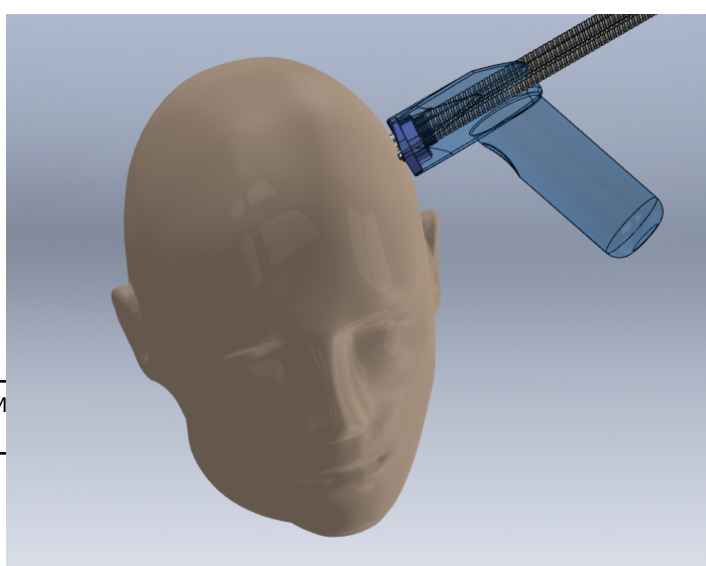
AOM - Acousto-Optic Modulator
G1 - shorthand for Gen 1, or Generation 1 of device
PLC - Programmable Logic Controller

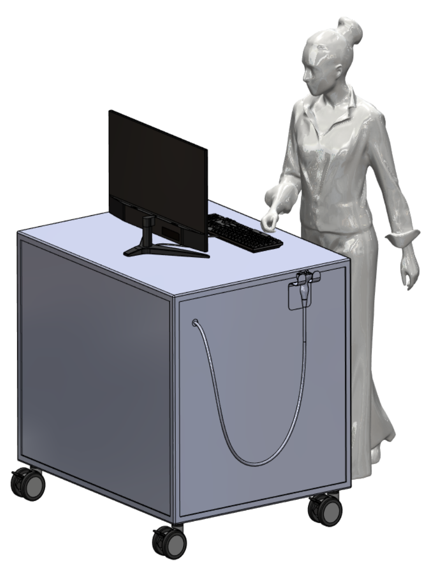
References

D0002	Gen1 Detector Module Specification
D0003	Gen1 Source Module Specification
D0004	Gen1 Wand Module Specification
D0005	Gen 1 Stroke Detection Cart Specifications
D0006	Gen 1 Stroke Detection Device, Customer Input Requirements
D0007	Gen1 Prototype Software Configuration Management
D0008	Gen1 Prototype Software Architecture
D0010	Photodiode Laser Safety Board
D0012	Gen 1 Stroke Detection Device Operator Manual
D0017	Openwater_Engineering Study Clinical Protocol 1_Gen 1 Stroke Detection Device

1. Intended Use

The Openwater Platform and its accessories are intended to provide measurement of local cranial blood flow and detect the difference of blood flow between the two hemispheres of the brain for stroke and post stroke detection and eventually diagnosis.





2. Mechanical Hardware

The Gen1 Device will be a Cart that contains all of the major subsystems, detailed below. The cart will be grounded. This version of the cart will not be designed to meet IEC 60601-1.

The Cart will have a door with a keyed handle that can be used to access the internals, un-trained users will not have access to the modules.

The Cart will have fans to help cool the internals.

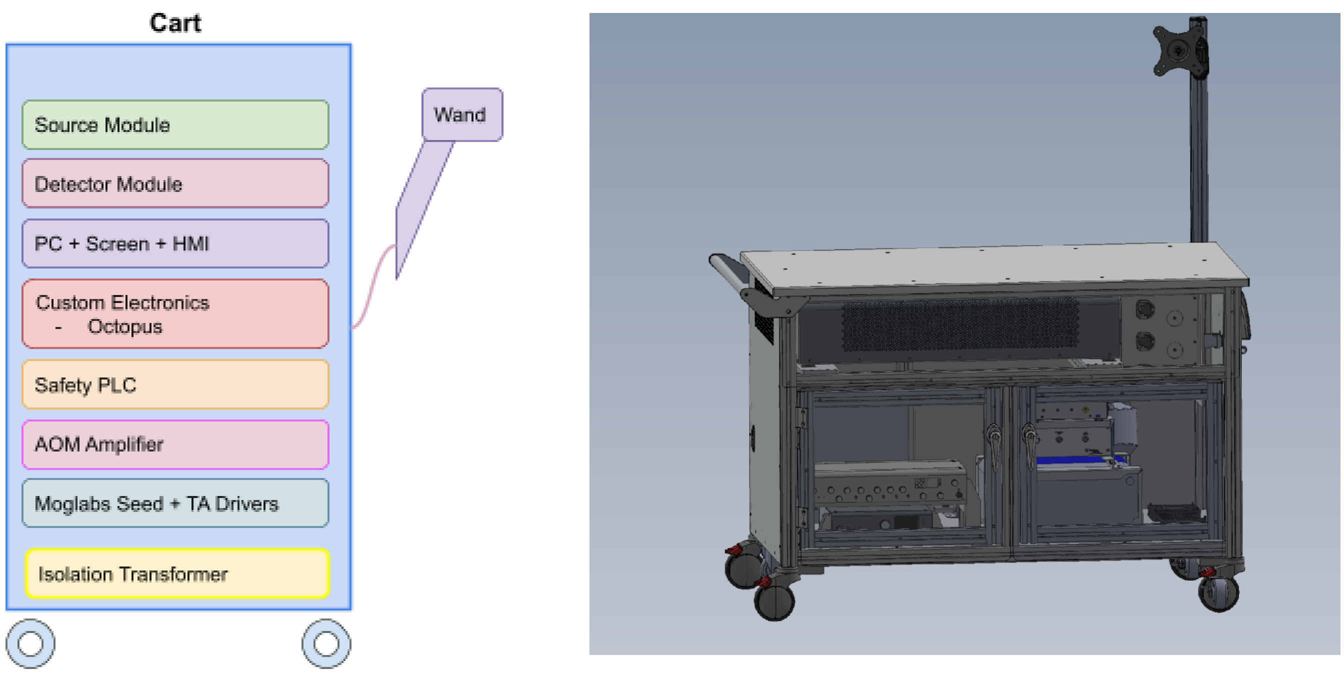


Figure 1. Gen1 Stroke Detection Prototype Cart w included Sub-Systems

2.1. Source Module

The source module will provide laser light to the wand. It incorporates an off the shelf laser module by Moglabs. The laser beam path is shown in Figure 2. It will pass through a few mirrors so it can be aligned to pass through an AOM (Acousto Optical Modulator). The modulator will send the light to a beam blocker or “beam dump” normally. When triggered the AOM will deviate the light toward the fiber output, it essentially works like a normally closed shutter. After the AOM, the beam will go through a few more mirrors to align it to the output fiber coupler. Before the beam exits the source module, it will be sampled by sending a small percentage into two photodiodes which monitor to assure laser power is not above the set safe threshold.

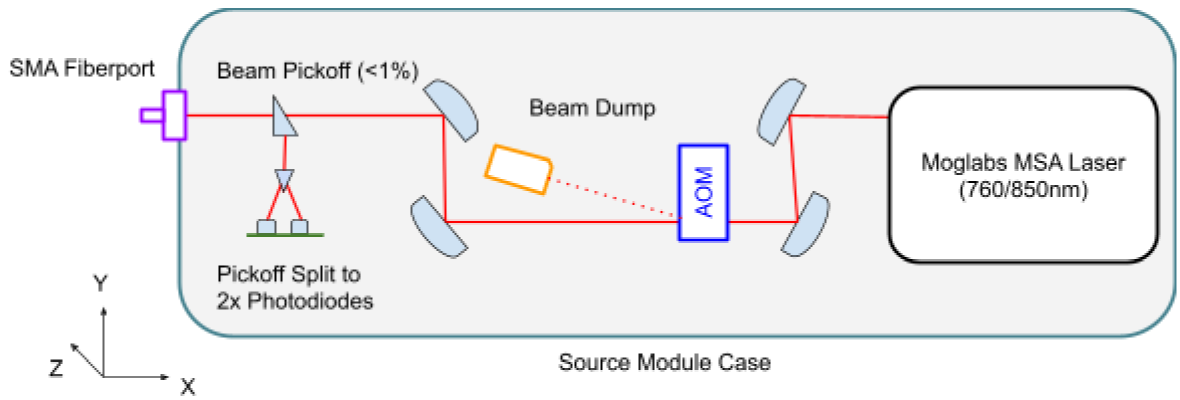


Figure 2. Optical Layout of Source Module bock diagram

Figure 3 shows the source module mechanical layout as designed by Openwater. It includes a safety interlock switch to assure if the cover is attached. This switch is defeatable for factory alignment, but the source module cover cannot be accessed without the deliberate use of tools by a trained technician.

The Moglabs laser is controlled by a seed driver, and TA (tapered amplifier) driver which are also mounted on the cart. Three cables connect the Moglabs laser to these drivers, and pass through an Icotek cable manifold in the Source Module.

The AOM (which is an off the shelf part from IntraAction) is controlled by a custom Openwater PCB. This custom PCB is called the “octopus board”, it is connected to the AOM Amplifier.

The Source Module case is designed to be light tight.

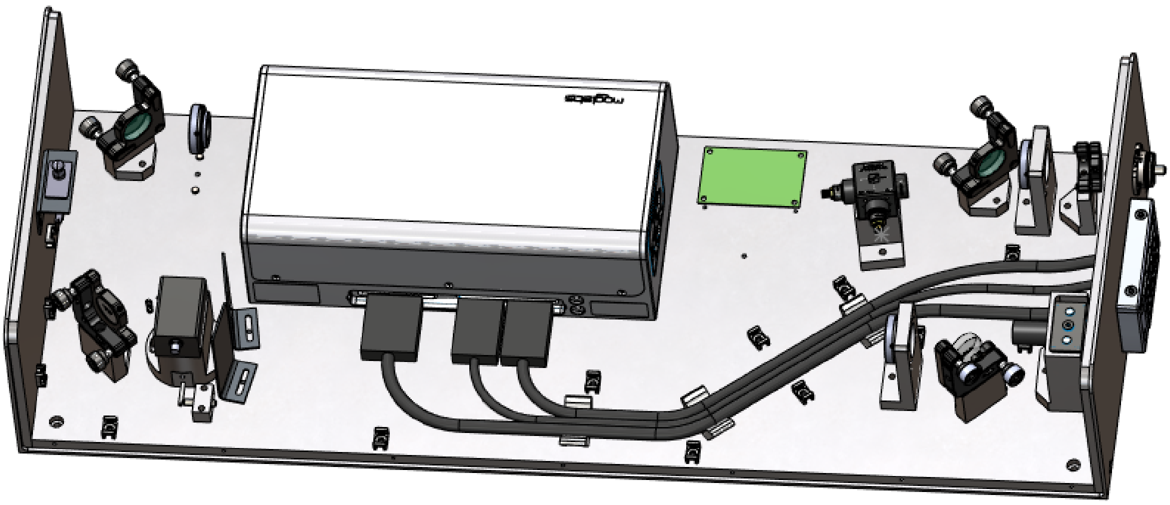


Figure 3. Source Module

2.2. Moglabs Seed & TA Drivers

Figure 4.

Figure 5. Moglabs TA Driver

Both Moglabs laser drivers are off the shelf parts. Both drivers require a key to turn on. Openwater is submitting a CDRH laser filing.

The Moglabs laser is a class 4, and is embedded into the source module and can not be accessed without the use of tools.
The laser has the following features:

- It has two stages to turn on - 1st) power button 2nd) key switch
- Has a cover with and interlock switch
- See Laser Safety Board board confirming output level (see section below)
- Labels instructing all persons to wear provided laser safety goggles per D0012 Operator Manual

Embedded Laser Source Specifications (Class 4)

The Openwater Gen 1 Stroke Detection Device utilizes a Class 4 Moglabs laser as its light source. The Class 4 CW laser is shuttered to create short pulses that produce a Class 3R laser output. See the system output specifications in the next section.

Wavelength	850 nm

Power	3.5 W
Seed input power	10 mW to 30 mW

System Laser Output Specifications (Class 3R)

Wavelength	850 nm
Pulse duration	100 µs
Pulse Repetition Rate	14 Hz
Average Power	1.8 mW

2.3. Detector Module

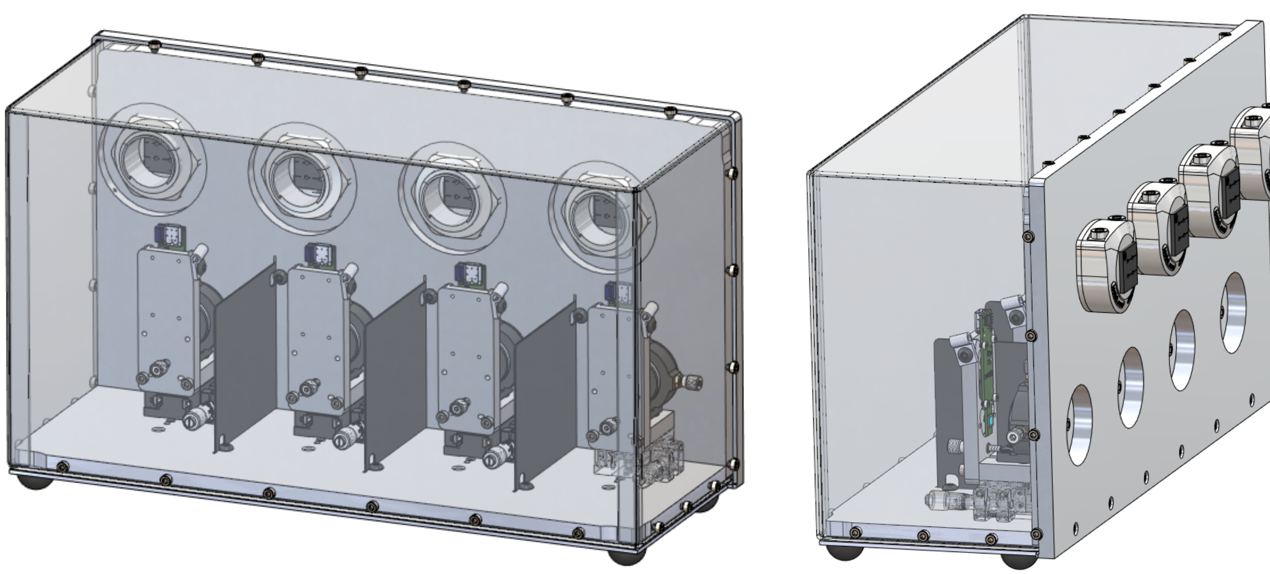


Figure. 6 Detector Module

The detector module incorporates four cameras that are coupled to fibers that are collecting light from the wand.

The cameras are mounted on manually-adjustable stages to allow for some adjustment to help couple the fibers to the camera sensor. All stage are also lockable after alignment

The cameras are connected to the Dell XPS system via 4x USB-C (camera) to USB-A (dell) cables. The cameras are also connected to the Octopus PCB via 4x custom cables.

All cables pass through an Icotek gland manifold that is rated to IP54 (at least).

The Detector Module case is designed to be light tight.

2.4. Octopus, custom PCB

Octopus is a custom designed PCB used to control the timing of the entire system.

The Octopus connects 2x BNC TTL out signals to each camera in the Detector Module.

The Octopus connects 1x SMA analog out signal to the AOM Amplifier, which then connects to the AOM in the Source Module.

The Octopus connects to the Dell XPS computer with a USB-C (Octopus) to USB-A (Dell) cable.

The Octopus is powered by USB for basic timing functions, and a 12V barrel jack for driving the AOM amplifier.

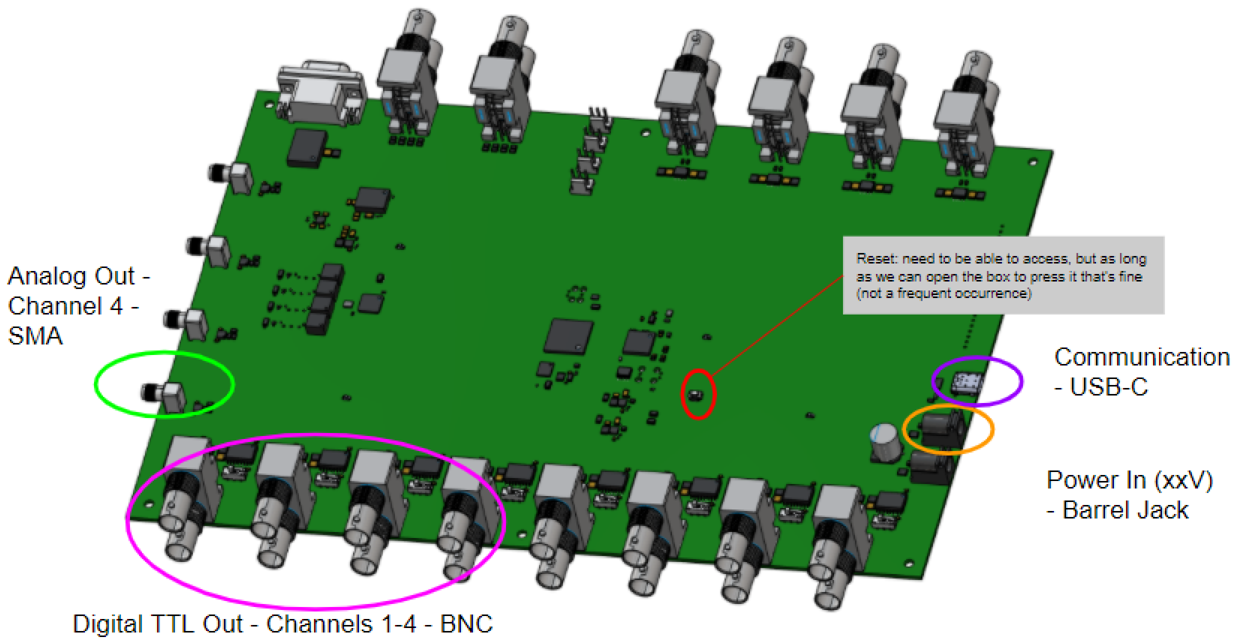


Figure 7. Openwater Octopus PCB

The Octopus PCB will be packaged in its own metallic case, which is then mounted in the Cart.

2.5. AOM Amplifier

The AOM Amplifier is an IntraAction PA-704 amplifier. It is used to amplify the analog signal from the Octopus to the AOM inside the Source Module.

Figure 8. AOM Amplifier

2.6. Wand

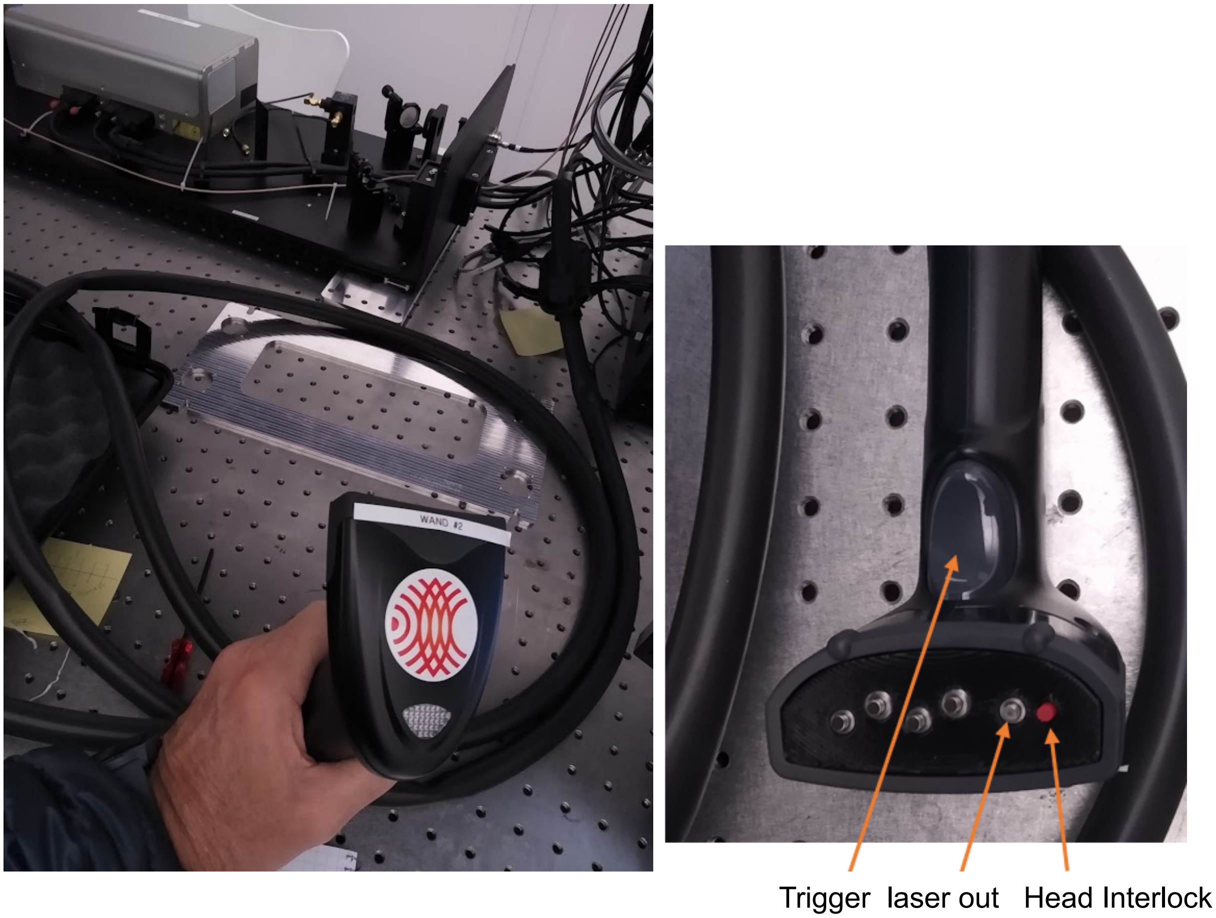
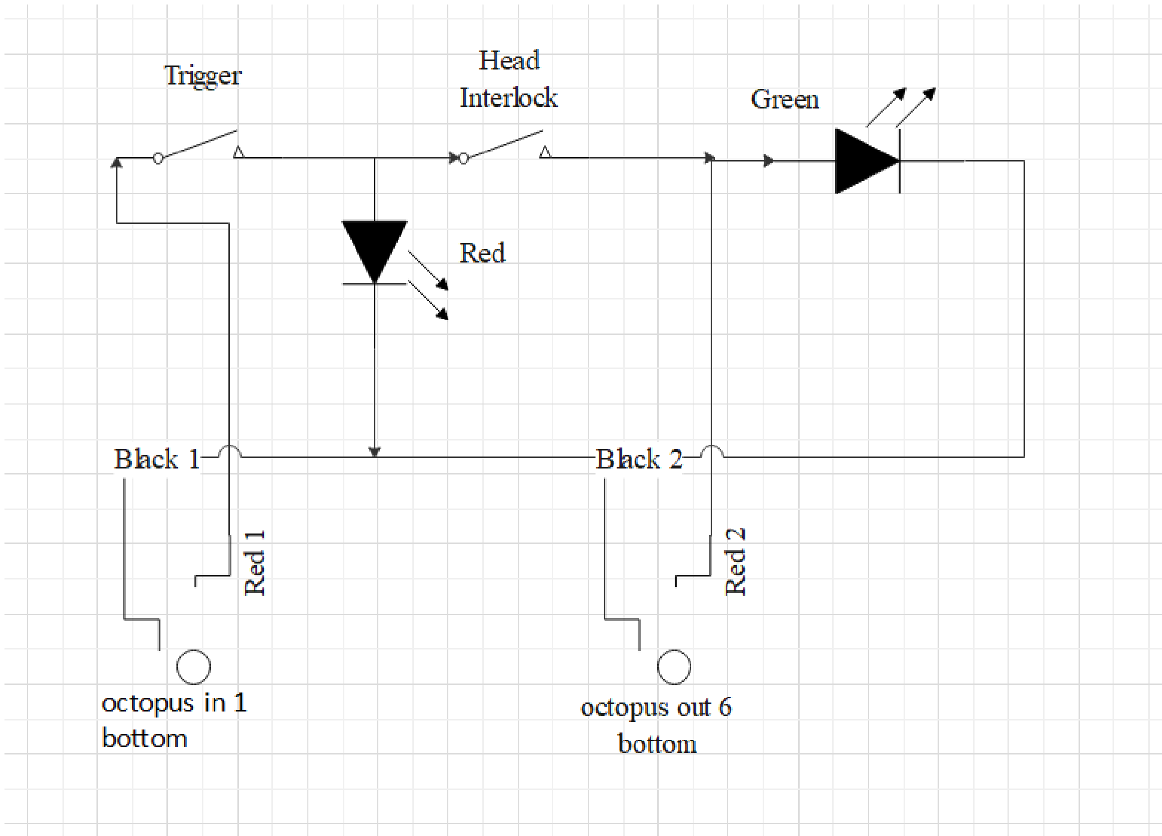


Figure 9. Wand, with close up of source and detector fibers.

The wand is what will be used to couple our 5 fibers (1x source, 4x detector) to the sample to be measure



The wand has two buttons and a two color LED for user feedback.
The head interlock button assures that the laser source output is in contact with the patient's skull and the trigger is used to start the measurement. If either button is not closed,the laser is turned off.

The LED shows green if the system is ready to measure and amber when the measurement is being taken (the laser is on)

Figure 10. Depiction of how the wand will be used

The wand housing is made from PCABS, the fibers are silica or borosilicate glass, 353ND epoxy, 4310 cyanoacrylate adhesive and 304 steel SMA housings.

2.7. Isolation Transformer

The isolation transformer is from Toroid, Inc., model AN170411. It provides isolation between the host electrical environment and all the electronics in the cart. The larger loads plug directly into three of the four sockets on the transformer. The smaller loads (12VDC and 24VDC power-supplies etc.) plug into a medical-grade power strip, which in turn occupies the fourth socket on the transformer.

3. Electrical block diagram

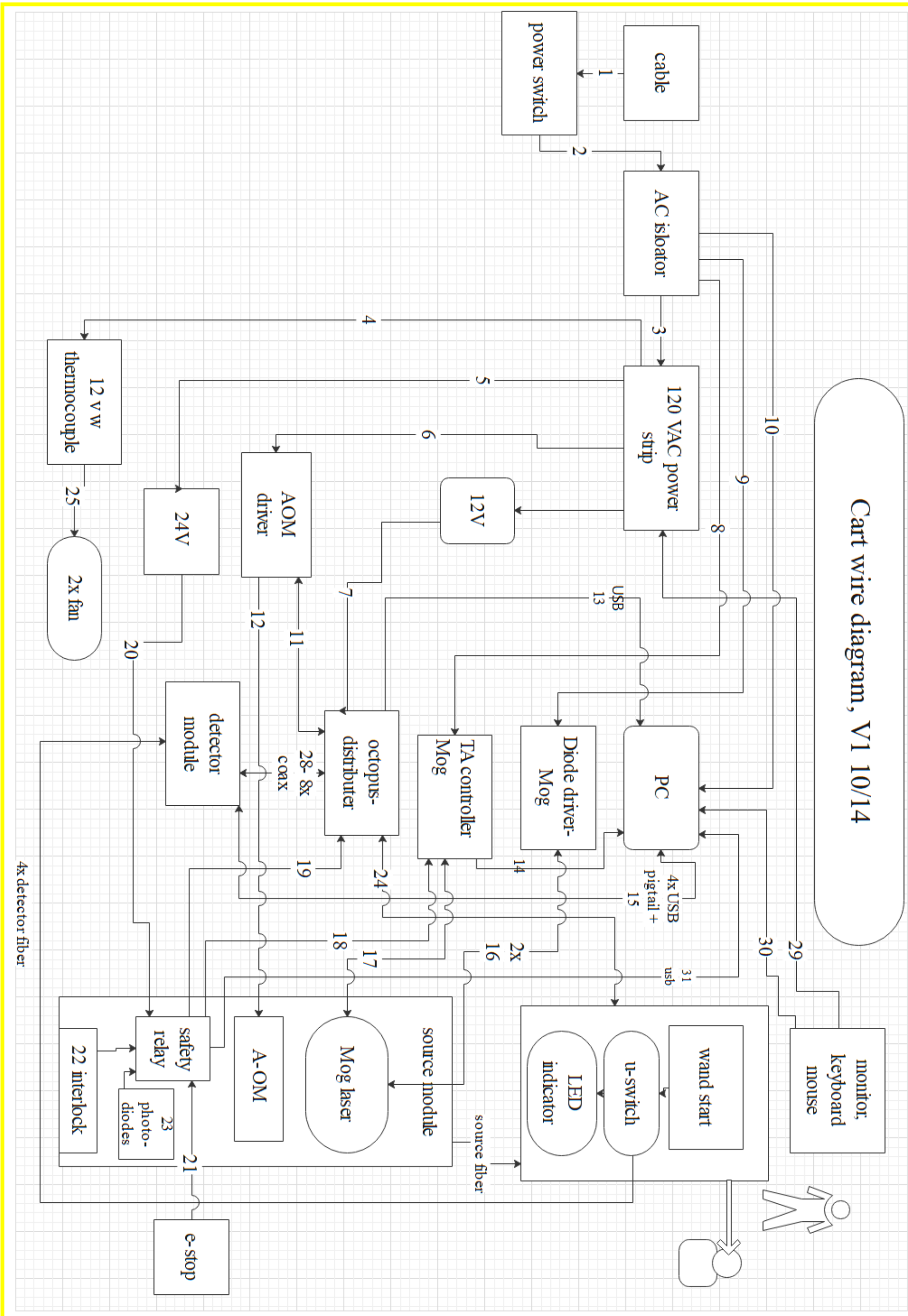


Figure 11 Full Electrical Block diagram of the cart

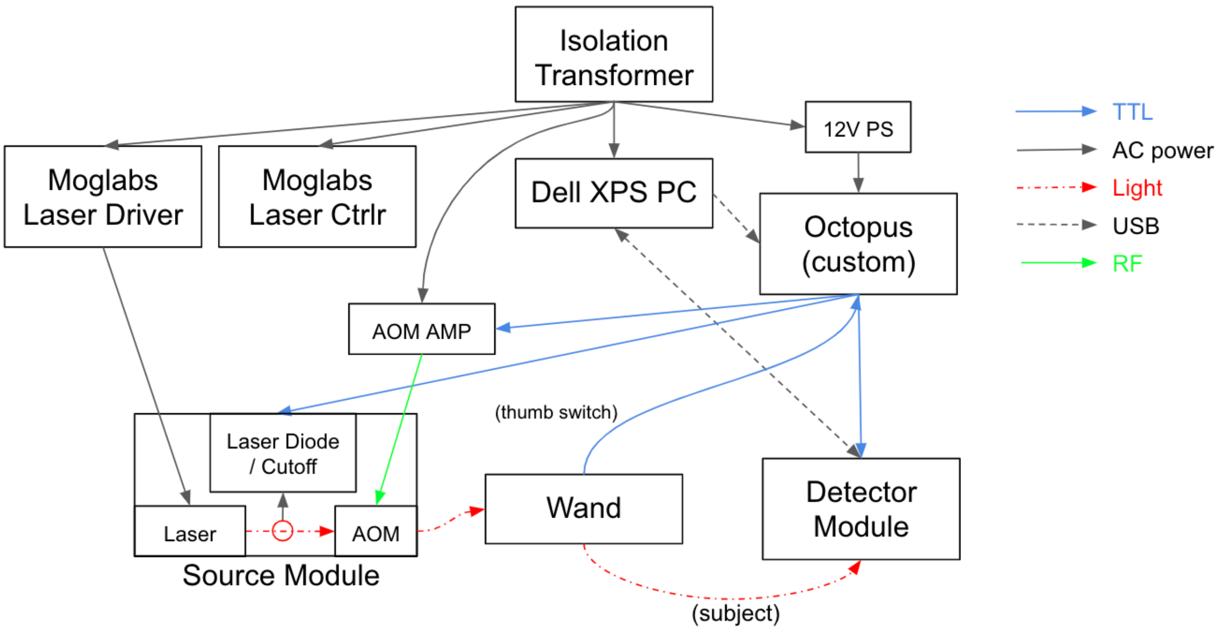


Figure 11. Electrical safety block diagram.

Isolation of wand: The wand does not convey significant current (4V, 1.6 mAmp), and is only connected to isolated components

- The radiated emissions and EMI susceptibility reports will be added as an addendum.

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3.1. Laser Safety Board

There is a laser safety board that will monitor multiple TTL signals for the emergency switch, door interlock, wand trigger, wand interlock and laser power. The safety board cuts power laser power by sending a signal to the AOM to stop all light from coming out.

This is represented in the diagram below:

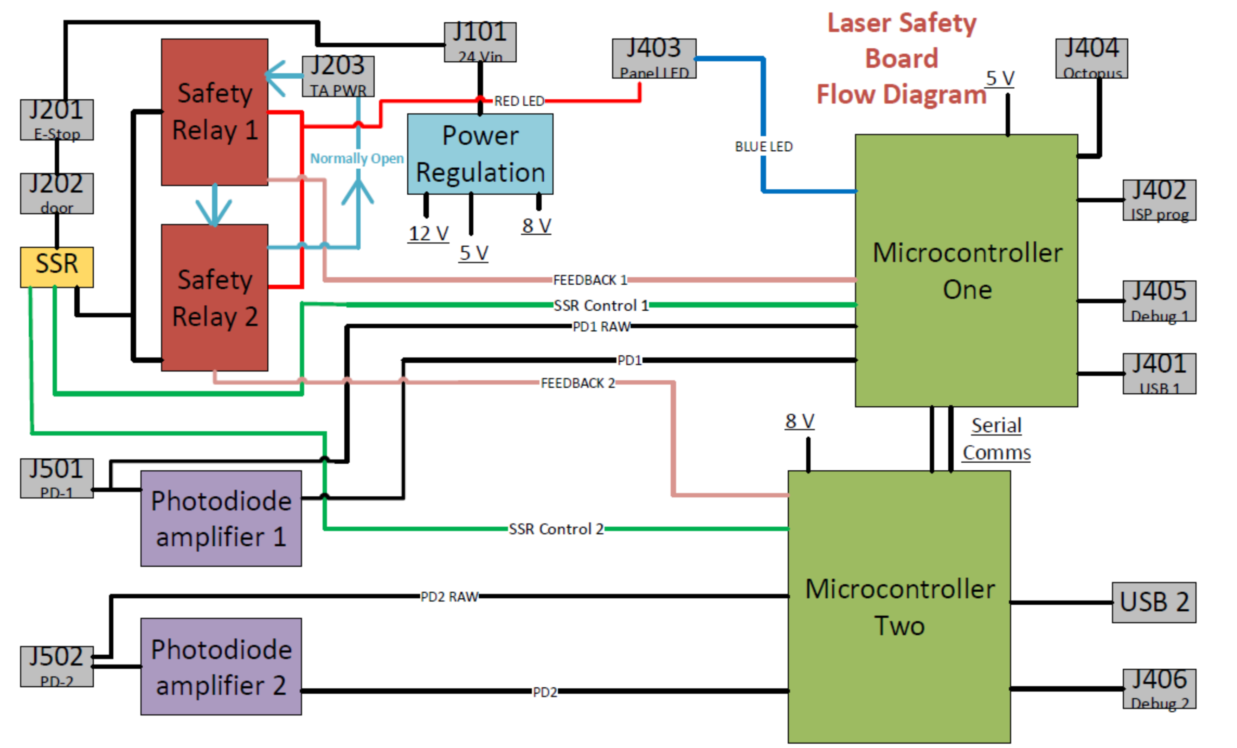

Figure 12: safety board block diagram

The Laser Power measurement will be made from a custom PCB internal to our Source Module that will look at readings from two photodiodes, and will trip if a set laser 1.5 W power threshold is exceeded. The Photodiodes will monitor instantaneous energy as well as pulse duration. Photodiodes have a rise time of 10ns and will need to be calibrated.

4. Software

The following is a digest of [D0008, Bloodflow Scanner Software Architecture], updated with a current breakdown of modules and workflows.

4.1. Software Architecture

The blood-flow prototype app is constructed using Python, with PyQt for user interface, and the Python *ctypes* package as a link to a plug-in containing C++ code for communicating with Octopus and camera sensors, and processing image pixels. The user interface provides three basic modes of operation:

- Align: for checking alignment of optical fibers to sensors, and checking whether laser light is reaching the sensors
- Scan: for acquiring data from a test subject
- Backup: for backing up PHI-free data to the cloud

4.2. Software Modules

4.2.1. App (in Python, except where noted)
- 4.2.1.1. scanUI: the main driver for the app
- 4.2.1.2. aligner: alignment module
- 4.2.1.3. cameras.json: configuration information such a per-camera gains, sensor-to-detector spacing, etc.
- 4.2.1.4. speckle_fcns: calculation of bloodflow index from laser speckle measurements
- 4.2.1.5. flat_field_fcns: calibration of cameras for varying intensity across sensors (may go away)

4.2.2. Component (in C++, except where noted)
- 4.2.2.1. rcam: interface to Gumstick camera sensors, via fx3
- 4.2.2.2. fx3: interface to Cypress CX3 via USB
- 4.2.2.3. octopus: low-level interface to Octopus, via fx3
- 4.2.2.4. execnode: base class for camera processing chain
- 4.2.2.5. stddev: statistics calculation for input to bloodflow index calculation

4.2.3. Plugin (in C++, except where noted)
- 4.2.3.1. scan: interface between Python and C++ code
- 4.2.3.2. CameraManager: aggregate interface to multiple cameras
- 4.2.3.3. OctopusManager: high-level interface to octopus for timing signals
- 4.2.3.4. VoxelSave: output from accumulated data in memory to CSV files

The C++ plug-in is built to binary form using bazel, an open-source build manager. It relies on having Microsoft Visual C++ installed, but does not use Visual Studio.

4.3. Software Operation

In operation, the software is fairly simple:

- Align: captures images at low frame rate from the camera sensors and displays them with basic statistics
- Scan: captures images at full frame rate, calculates statistics on each frame, calculates blood flow index from per-frame statistics, and outputs to a series of CSV files, displaying summary values in the U.I.
- Backup: syncs files of captured data to a private cloud (currently AWS S3)

4.4. Software Testing

Our scanner software is built on demand using continuous integration (CI) on a cloud server, on both Windows and Linux. All software is peer-reviewed. Flaws are detected prior to merging new versions by triggering builds when a change is first proposed for review. Unit tests cover some, but not all, of the Python and C++ code. By-hand testing is used to validate new versions of the software by running Align, Scan and Backup workflows prior to shipping.

5. Other Materials

Operator manual D0012