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# **D0025 - Gen1B Stroke Detection Device Operator Manual**

Stroke Detection Project

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# 1. Introduction

## 1.1. Purpose

The purpose of this manual is to serve as a guideline for professionals trained by Openwater to operate the Openwater system, and to enable them to take measurements safely.

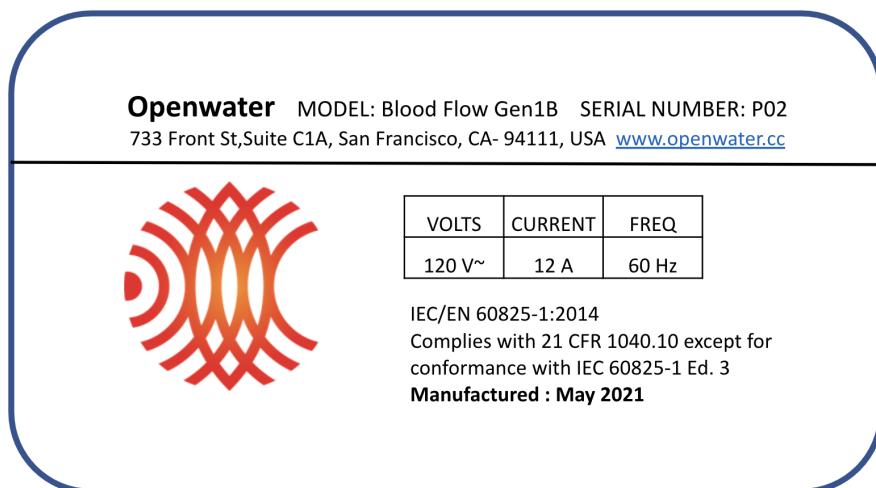


Fig 1: Title label of the product

## 1.2. Scope

This document covers day to day operation of the Openwater system, and is intended to be used as directed by the IRB protocol. This document does not cover system assembly or extensive troubleshooting, which shall only be performed by trained and qualified Openwater personnel.

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## 1.3. Definitions, Acronyms and Abbreviations

G1B: shorthand for Gen 1B, or Generation 1B of device.

TEC: Thermo Electric Cooler

TA: Tapered Amplifier

GUI: Graphical User Interface

PHI: Protected Health Information (HIPAA privacy)

## 2. Safety

CAUTION – USE OF CONTROLS OR ADJUSTMENTS, OR DEVIATION FROM INSTRUCTIONS AND CAUTIONS SPECIFIED HEREIN MAY RESULT IN HAZARDOUS RADIATION EXPOSURE, THAT MAY CAUSE EYE DAMAGE OR BURNS.



Fig 2: Laser label on the product

**The system emits invisible laser pulses (Class 3R) under normal operating conditions.**

**WARNING:** Please do not open/unplug any module without authorized Openwater personnel present.

**Please read all instructions first carefully before attempting to operate the laser.**

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**In case of any emergency, please press the red emergency stop button on the side of the tower (opposite to the handle), which turns off the laser.** The Emergency Stop Button is located on the right side face of the tower that also holds the wand. Pressing this button stops the laser firing.

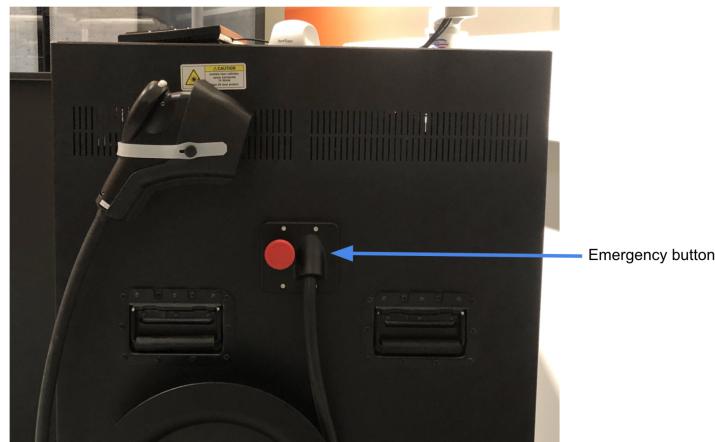


Fig 3: Location of the Emergency stop button

Observe the safety instructions AT ALL TIMES.

- Please ensure that the voltage for your AC mains supply is appropriate for the device (110 V, 20 A, 60 Hz outlet) before connecting. The supply must include a good ground connection.
- **All the people in the room need to wear the appropriate safety glasses (OD 3+), before powering on the laser.**
- **Always use the wand with the provided diffusing spacer tips for operator and patient safety, and follow proper instructions for its application.**
- Please follow the instructions provided in the manual, and read it thoroughly before operating.
- Position the tower close to the wall with an electrical outlet or cover the electric cable with the cable mat to minimize trip hazards.
- Lock the tower wheels after it is positioned.
- Do not under any circumstances open the source module or unplug the optical fibers without qualified personnel from Openwater present.
- **When the trained personnel are performing troubleshooting with the source module open, everyone in the room should wear laser safety glasses with OD 5+ at the wavelength of operation.**
- Do not point the wand directly at anyone's eyes when the system is operational/power ON.

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- Do not look directly into the beam.
- **Do not use any optics in front of the beam.**
- The tower doors are to be kept locked at all times and only be opened by Openwater personnel if necessary for servicing.
- This system is only intended to be operated by trained personnel.

## 2.1. Laser Parameters

### 2.1.1. Embedded Laser Source Specifications (Class 3B)

The Openwater Gen 1B Stroke Detection Device is a class 3R laser product that outputs 5 mW average power under normal circumstances and utilizes a **Class 3B laser**, which is capable of producing Class 4 radiation if used in the wrong configurations by bypassing safety protocols and normal factory settings.

**Under no circumstances are the laser driver settings to be changed**, even for troubleshooting or servicing. Please exercise extreme caution with the handling of the fiber, follow safety instructions and do not gaze into the apertures or point the wand towards eyes. Do not open the tower doors and/or go inside the tower unless you are a qualified Openwater service personnel. **When the tower doors are open, there is CLASS 3B invisible radiation.**  
**AVOID EXPOSURE TO THE BEAM.**



Fig 4: Class 3B Laser warning on the source module

#### 2.1.1.1. Laser Output Specifications (Class 3R)

Wavelength	785 nm
Pulse duration	100 µs
Pulse Repetition Rate	14 Hz
Average Power	4.9 mW

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Peak Energy per pulse (at the delivery fiber tip)	350 uJ
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### 2.1.2. Laser Labels

Please note that the laser emission label (below) has been posted at the aperture to indicate the point from which the laser emission is intended to be emitted from the housing of the product. To avoid eye damage and corneal burns, please do not put your face or eye in front of the aperture.



Fig 5: Laser emission warning label, placed at potential access to emissions

Please be aware that there is **Class 3R laser radiation** from the tip (source fiber) of the wand, which is an **Invisible Laser Radiation**. **AVOID EXPOSURE TO BEAM**. Please adhere to the laser warning sign posted and **do not stare at the beam or point the wand towards the eyes**. **Only use the wand with the disposable diffusing spacer tips provided**, and use a new tip for each application.



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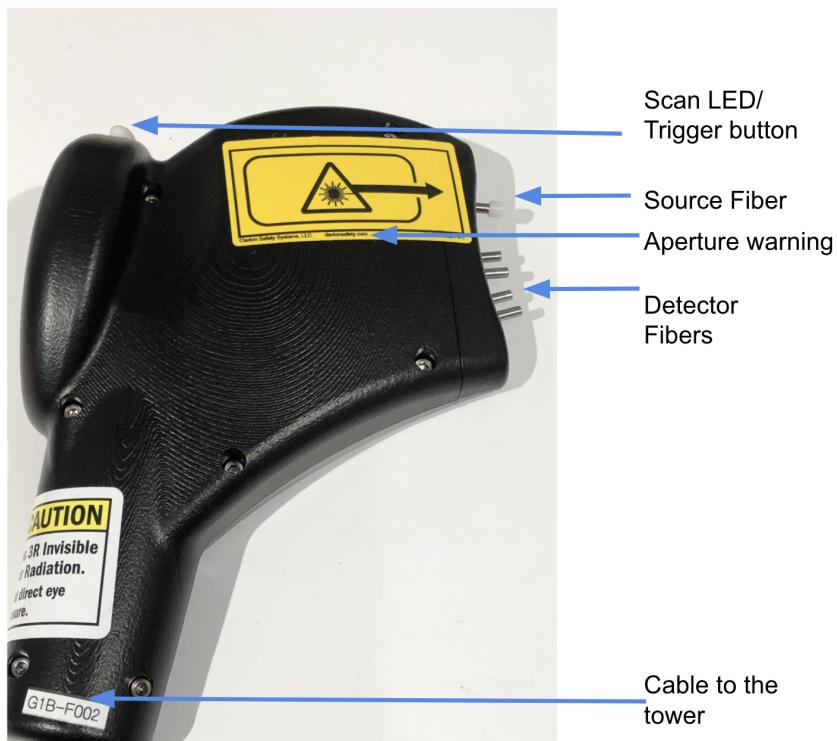


Fig 6: Laser emission warning label, placed at the source fiber aperture of the wand (the emission point of the system)

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Fig 7: Class 3R Warning & Advisory Label on exterior of tower door, and the detector module inside the tower.

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## 3. System set-up

### 3.1. List of items included in shipment

- OD 3+ Safety Glasses
- Patient Safety Glasses
- Tower with:
  - Source module
  - Detector module
  - Octopus
  - Isolator box
  - Computer
  - Wand
  - Wand holder
- Monitor
- Keyboard, mouse
- Articulate arm
- Calibration Phantom
- Diffusing spacer tips (disposable)

### 3.2. Tools & Equipment needed

- Openwater staff will complete assembly, and no in-house tools are required.

## 4. Parts of the system

### 4.1. The Tower

The tower refers to the main body of the device which consists of: electronics and optics inside; the touchscreen, medical use grade monitor on a retractable arm and other computer accessories, along with the calibration phantom on top; the wand and emergency button on the side, as well as storage for the disposable diffusing spacer tips on the wand holder; the power cord and switch on the back; with handles and lockable wheels to enable movement between different locations.

**The body of the tower is locked and access inside is only intended for Openwater Service personnel, and need not and shall not be accessed for day to day use.** Keep the tower locked at all times, and keep the keys in a safe, predetermined location.

The tower can be moved to the required location and the wheels can be locked to prevent accidental motion.



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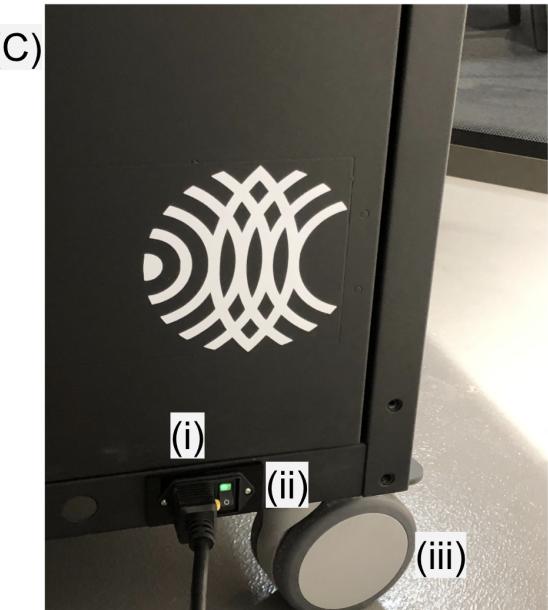
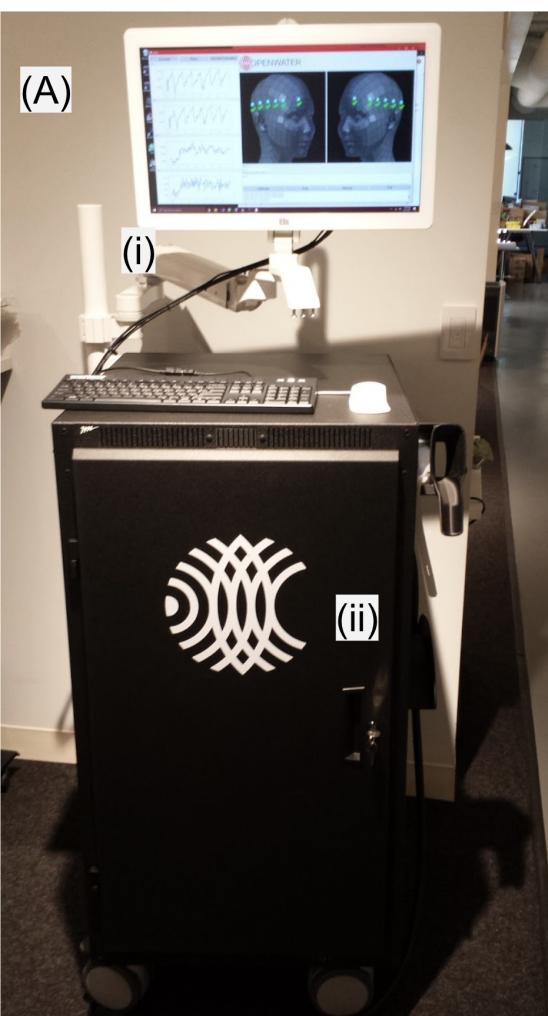


Fig 8: Images of the Tower. (A) Shows the front of the tower, specifically the (i) Monitor and other computer accessories, (ii) tower door and lock, (B) Shows the right side of the tower, specifically the (i) Wand, strapped in the wand holder, (ii) the Emergency stop button, and (iii) Tower handles, (C) shows the back side of the tower, zoomed in to show the (i) power cable, (ii) power switch and (iii) lockable wheels.

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## 4.2. The Wand

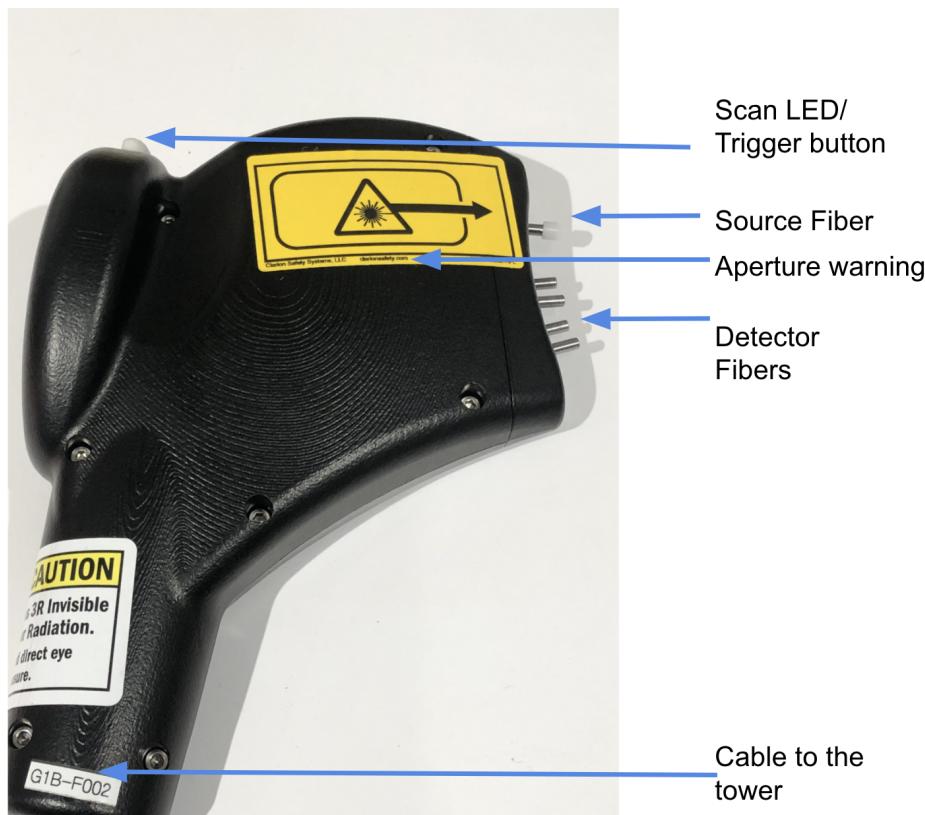


Fig 9: Parts of the wand

### 4.2.1. What is the wand

- The wand interfaces the system with the subject, enabling the user to control the delivery of the laser (via source fiber) and detect the optical signal (via the detector fibers) from the measured subject. As the source fiber emits the laser beam it is important to treat this part of the device with extreme caution. Please adhere to the laser warning signs posted and **do not stare at the beam or point the wand towards the eyes**. Please be aware that there is **Class 3R laser radiation** from the tip of the wand, which is an **Invisible Laser Radiation. AVOID EXPOSURE TO BEAM**.
- Since the fibers are made of glass, please do not mishandle (drop, crash, rub against an abrasive surface) them.

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#### 4.2.2. Storage and handling of the wand

- The wand is stored on the right side of the tower on a dedicated holder, and secured with a rubber strap. This is also how the wand should be stored any time that it is not being used, and especially when the tower is being moved from one location to another. Please be careful to not crash the wand into walls while moving the tower.
- The wand holder has a sliding cover which should always be kept in a position that covers the face of the wand for safety of the wand.
- The wand holder also provides a small storage for the disposable fiber spacers, which should be replenished as required.
- **Please only use the wand with the disposable fiber spacers provided for your safety** (instructions for the same are in the following subsection). After use, dispose of these spacers, and sanitize the wand.
- After each use, replace the wand in its original holder and secure it well with the rubber strap.

##### 4.2.2.1. Putting the diffusing spacer tips on the wand

It is crucial to put the diffusing spacer tips on the wand before using it for patient and user safety. Please follow these steps to securely place a tip on the wand before each use.

1. Ensure that the scanner app is closed.
2. The diffusing tips are stored in a plastic jar in the wand holder. Take a diffuser from the jar (with sanitized, gloved hands), then close and replace the jar in its position.
3. Remove the wand from its holder and locate the source fiber (it is at one end of the wand, separated from the other fibers, as indicated in the picture below). You can also use the Aperture label to identify the source fiber.
4. Put the diffusing spacer on the source fiber hollow side first, such that the tapered side is pointing outward, and ensure it is firmly attached to the fiber.
5. Continue using the wand as instructed (if doing a scan, the instructions will ask the user to put Tegaderm on the wand face after this step).
6. After completing the scan, remove this tip and dispose.



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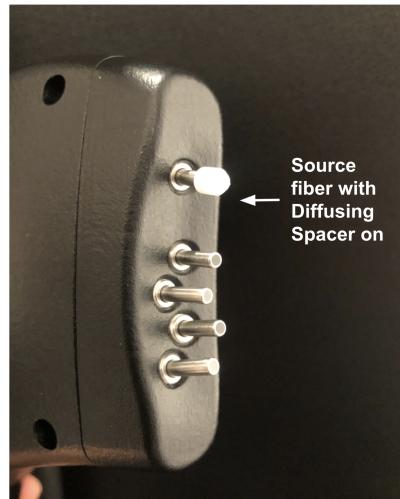
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### 4.2.3. Using the wand

- The wand shall always be used with the Diffusing Spacer on the source fiber.
- The Trigger button is the white plastic protruding from the top, as indicated by the figure above (Fig 9). Depressing the trigger button when the system is ready to emit light (when in calibrate/scan mode) initiates the emission of light from the source fiber, and releasing it stops the emission. The trigger switch also serves as an indicator to display the status of the system, via the Scan LED.
- The different statuses indicated by the LED are:

LED color	System status
OFF	System not ready to emit light
ON- Green	System ready to emit light
ON- Red	System currently emitting light

- Use the wand such that the fibers are perpendicular to the surface being scanned (subject's head or the calibration phantom). Grip the wand well using the palm and fingers, and use your fingers to depress and release the trigger button. Keep the grip firm and stable during a measurement.
- Please press the trigger button firmly as releasing the pressure results in the laser shutting off, causing bad measurements.

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## 4.3. The Scanner App

The Scanner App is the app that allows the user to interface with the system and take measurements. It enables the system to be set and operated in the predesigned way to enable timely laser emissions and acquisition, among other things. Closing the Scanner App stops laser emission.

The Scanner App is launched via the desktop shortcut (Fig 10 below) and it generates two windows: the Scanner GUI and the Powershell window.

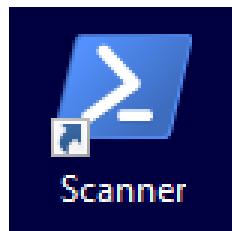


Fig 10: Desktop shortcut for the Scanner App

### 4.3.1. Scanner GUI

The Scanner GUI is the interface which the user most actively uses that enables all the functions necessary to run a scan.

Referring to Fig 11, which shows the GUI:

- The left side of the screen displays the chosen variable from the current scan. This variable can be chosen by the user by clicking the desired variable from the options on the top left corner of the Scan GUI before starting the scan.
- The central part of the GUI displays a graphic of a human head and the scan locations and indicates the ongoing scan position, as well as the completed positions (with tick marks).
- Just below this display are fields to enter the subject ID (without any PHIs) and any relevant information or notes. Please do not note any PHI in these fields.
- Below the 'notes' field are clickable buttons that allow you to 'Calibrate', 'Scan', 'Backup' or 'Exit'. Depending on the chosen action, the application starts the process and displays distilled system messages in the message box below these buttons.

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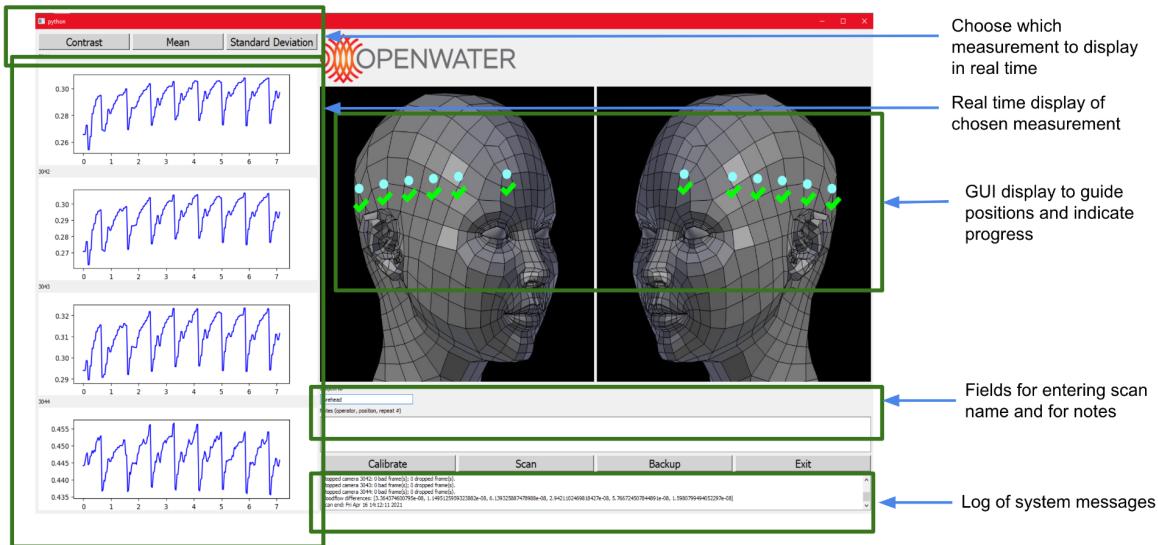


Fig 11: Scanner GUI

### 4.3.2. Powershell window

The Powershell Window (Fig 12) is the window where the application displays all the system messages in real time. Please go through the status messages to see the current state of the system in case there is an issue. Error messages are also displayed in this window.

```

Scanner
System ready for trigger
Waiting for frames, camera 3041
(capturing for 8 secs)
Enabletimer: pin (8) out of range.
Stopped camera 3041: 0 bad frame(s); 0 dropped frame(s).
Stopped camera 3042: 0 bad frame(s); 0 dropped frame(s).
Stopped camera 3043: 0 bad frame(s); 0 dropped frame(s).
Stopped camera 3044: 0 bad frame(s); 0 dropped frame(s).
Capture complete. Let up the trigger.
cam 3041: mean 74.9084, contrast 0.289137
cam 3042: mean 60.8099, contrast 0.278373
cam 3043: mean 59.8355, contrast 0.253157
cam 3044: mean 13.7159, contrast 0.244991
Bloodflow: 1.7035e-07
Enabletimer: pin (8) out of range.
Stopped camera 3041: 0 bad frame(s); 0 dropped frame(s).
Stopped camera 3042: 0 bad frame(s); 0 dropped frame(s).
Stopped camera 3043: 0 bad frame(s); 0 dropped frame(s).
Stopped camera 3044: 0 bad frame(s); 0 dropped frame(s).
Bloodflow differences: [3.364374600795e-08, 1.1495125959323882e-08, 6.139325887478988e-08, 2.9421102469818427e-08, 5.766724505794489e-08, 1.598079944052297e-08]
Scan end: Fri Apr 16 14:12:11 2021

```

Fig 12. Scanner Powershell window with status messages

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## 5. System operation

The system operation consists of the following steps, to be followed in the given order, which are detailed in the following subsections:

1. Positioning and starting the system
  - This includes setting up the device in a feasible and safe manner, and powering it on to enable scans.
2. Launching the app
  - This includes launching the GUI after every system power up, the user interface for the scanning process.
3. Calibration
  - This is necessary each time the app is launched. The system doesn't allow scanning until a successful calibration is executed after the app launch. If you close the app, you will have to recalibrate before taking a scan.
4. Scanning
  - This includes the actual scanning process wherein you can make blood flow measurements on the subjects with the device. This includes the automatic process of starting up the laser, cameras and other control electronics, and turning them off after the scan is done.
  - It is recommended that after the scan, the app be shut down if there are no other immediate scans scheduled.
5. System shutdown
  - This refers to the process of shutting down the system safely, including sanitization procedure, and moving it to a safe storage location if necessary.

### 5.1. Setting up and starting the system

1. Make sure that the wand is strapped in and sitting in its holder, and the power cable is not plugged into the wall.
2. Unlock the wheels by lifting up the lock on the wheels (Fig 8.C.iii) and carefully move the tower to the desired location by gripping the side handles (Fig 8.B.iii), avoiding any collisions that could damage the equipment.
3. Ensure that the tower is placed in a way that you can easily reach the patient with the wand, without creating unsafe tripping hazards.
4. Lock the tower wheels to prevent the tower from rolling.
5. Connect the tower power cable to the electric outlet, taking care to keep the tower close to the wall.
6. Ensure that you have enough sanitized safety goggles for every person in the room, and the patient safety glasses as well.
7. Ensure you have the head scan guide (the plastic frame used to indicate scan locations and ensure symmetric placement of the wand).

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8. Turn on the power switch located at the back of the tower module.
9. Once the computer powers up, log into the 'Hartford Healthcare clinician' account (login details are provided in Attachment 1).

## 5.2. Launching the Application

1. Double-click the *Scanner* icon on the desktop to start the scanner.
2. The app tests the configuration of the device and is loaded after these tests are complete, ready for the next steps.
3. The app opens two windows: the Scan GUI (which is what the operator mostly uses) and a Powershell window (that looks like the command prompt)- where the system displays status and error messages in real time.
4. In case there are any issues with the scan, please navigate to the Powershell window for error and warning messages and take corrective actions if necessary.
5. The GUI has all the control buttons necessary to run a scan. Please go through section 4.3 for details on the Scanner App.
6. If in the app startup process any issues are encountered, please look up the error code and take necessary steps to correct the issue referring to Section 7. (Often a simple reload or restart helps with app issues).

## 5.3. Calibration procedure

After launching the Scanner App, run a calibration test to enable taking scans with the device. To do so, please follow these steps:

1. Ensure that everyone present in the room has the proper protection goggles on.
2. Remove the wand from its holder (on the right side of the tower, as displayed in Fig 8.B.i) by unstrapping the rubber cord.
3. **Apply the disposable diffusing spacer tips provided on to the source fiber. Make sure it fits snugly ; it must not feel loose.** Refer to section 4.2.2.1 for instructions.
4. Apply the Tegaderm film on to the wand face.
5. Place the wand firmly onto the Calibration phantom (white rectangular plastic block) located on the tower.
6. Click on the 'Calibrate' button on the app. The LED on the wand will glow green, indicating it is ready to take measurements.
7. Press and hold the trigger **firmly** on the wand for about 8-10 seconds to take the calibration data. During this time the Scan indicator LED on the wand should turn red until the measurement is complete. Refer to Fig 9 to see the labelled parts of the wand.
8. Once the measurement is done, you will hear a chime indicating that the measurement is done, and the red Scan LED on the wand turns off, at which point you can release the

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trigger button. Do not release the button before the measurement is complete (while the wand LED is still ON).

9. After successfully taking the calibration data, the UI will indicate 'calibration done', after which point you may proceed with actual patient measurements.
10. In case of an incomplete or bad measurement, the UI displays a 'Bad Calibration' message. If this happens, please look at the accompanying error message, refer to the troubleshooting section and take any steps necessary to correct the issue, and retake the measurement by repeating steps 2 through 4.
11. If the 'Bad Calibration' message persists after six attempts, please contact Openwater for further maintenance.
12. After a successful calibration, you can proceed to the *Scanning Procedure* to take measurements.
13. Replace the wand in its holder.

## 5.4. Scanning procedure

1. Ensure that everyone present in the room has the proper protection goggles on.
2. Enter the specifics of the measurement (user ID number, and other notes). Each group of scans will be associated with its respective calibration scan by the most recent successful calibration data before the scan).
3. Note down any patient/subject vitals that you might need.
4. Remove the wand from its holder (on the right side of the tower) by unstrapping the rubber cord.
5. If not already done,
  - a. **Make sure that the source fiber has a disposable diffusing spacer tip on. If not, apply the disposable diffusing spacer tip provided on to the source fiber. Make sure it fits snugly, and does not feel loose.**
  - b. **Cover wand face with Tegaderm:** Apply Tegaderm onto wand face/fibers, press it around the fibers with your fingers as much as possible to allow the fibers to make it through hair
6. Place the head scan guide on the patient's head as indicated by the UI. The placement guide should be centered on the patient's head.
7. Place the wand tip on the patient's head firmly (scalp/temples/forehead) at the location indicated by the UI Guide.
8. At this point, the app should have been launched and a successful calibration must have been completed prior to starting a scan.
9. The top left corner of the Scan UI allows the user to choose which scan value to display during the scan in real time (speckle contrast, STD, image mean). You can choose which parameter to display here (refer to Fig 11).
10. Press the *Scan* button on the UI (refer to Fig 11).
11. For each of the scan locations (watch the circled prompts on the head model pictures in the UI),

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- a. **Wand placement:** Hold the wand to the corresponding location on the subject's head, taking care to place the wand such that all fibers are in contact with skin, and there's no hair between scalp and fibers. Part the hair if necessary with a comb.
    - i. Follow the GUI's instructions and place the wand on the subject's forehead at different locations as indicated, taking care to orient the laser fiber (indicated by yellow triangular sticker in Fig 4) as directed by the GUI.
    - ii. The wand face and fibers should be as perpendicular to the surface of the skin/scalp as possible, with all fibers in contact with the skin/scalp. Press the wand into the skin if some fibers are not in contact with the skin, taking care not to cause too much discomfort to the patient. The fibers are retractable, making contact possible even with slightly curved tissue surfaces.
  - b. **Gently massage fibers through hair:** Gently make small pea-sized circles with the wand to massage fibers through any hair should there be any locations that fall within the hairline.
  - c. The Scan LED should be green, indicating that the system is ready to take a scan. Depress the scan Trigger button on the wand for 7-10 s. While taking the measurement, the Scan LED turns Red. Please hold the wand as still as possible during this time.
  - d. **Repeat or move to next position:** When the acquisition is complete the light on the wand will turn off and you can release the trigger subsequently, after a second or two the data will be analyzed and either a wind chime sound will indicate to move onto the next position or a digital bell sound will indicate the scan needs to be redone (after 4 tries the wind chime will always play indicating to move onto the next position)
  - e. Release the button only after you hear the cue. Please note that releasing the button before the cue might result in incomplete measurements. In case of such incomplete measurement, please repeat steps c-d, and redo the measurement, depressing the button till you hear the cue.
  - f. After each successful measurement, move to the next location as indicated by the UI.
12. When the scan is complete (after measurements at all locations are done), the system flashes a 'Scan Complete' sign on the UI, you will see a numerical display of blood flow, and lateral differences thereof.
13. **Remove the tegaderm and the disposable diffusing spacer tips from the source fiber and dispose.** Place the wand back in its holder.
14. At this point, click the '**Backup**' button to backup the data. Please wait until the output to the shell window stops, to allow backup to complete before shutting the computer down. The GUI will also show "Done" in the status area.

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15. Use caution to not bend/kink the cord of the wand too tightly as this could break the fiber optics inside it, when not using the wand please store and secure it in its holder on the side of the tower or in a secure location where it won't accidentally fall to the ground (hanging over the keyboard/mouse tray tends to work well)

#### 5.4.1. Canceling a scan before it finishes

If needed, the scan can be cancelled midway before it has completed taking data from all locations by pressing the 'Exit' button on the bottom right corner of the scanner GUI (refer to Fig. 11). This causes the system to shut down the laser immediately, but the operator will be required to press the trigger after pressing 'Exit' to successfully quit the scan and the app.

### 5.5. System shutdown process

1. Make sure that the data is backed up.
2. Close the app by clicking 'Exit' or the 'X' on the Scan GUI window.
3. Remove and dispose of the head scan guide.
4. Sanitize the device with the following *Sanitization Procedure*:
  - a. The wand surface, the laser safety glasses, the calibration puck, computer accessories (keyboard, mouse, monitor, keyboard table/stand), tower surface, and any other part of the system that might have been touched should be thoroughly wiped down with CaviWipes following its instructions (keeping all surfaces wet for at least 60 seconds). The laser safety glasses should be cleaned with 70% alcohol and a soft tissue residue exists afterward.
  - b. If CaviWipes are unavailable, use any one of the approved cleaning solutions (Hydrogen peroxide, Quaternary ammonium, IPA, Sodium hypochlorite solutions), to sanitize the wand (handle, front face, wand holder), computer accessories (keyboard, mouse, monitor, keyboard table/stand), tower door handles, and any other part of the system might have been touched.
  - c. Clean the fibers with the fiber cleaners provided- take a sheet from the fiber cleaning strip dispenser, fold it in half, pour a few drops of 70% IPA (isopropyl alcohol) on it, and drag this folded strip across the face of the optical fibers gently in a single direction, taking care not to scratch the surface of the optical fibers.
  - d. Please sanitize the system frequently, and sanitize after each patient's measurements.
5. Place the wand securely back in the wand holder provided on the side of the tower.
6. If no more measurements are planned in the next few hours, follow all the following instructions:
  - a. Shut down the PC via the Start menu (i.e., in the usual way).
  - b. Shut off the power to the system by turning 'off' the power switch on the backside of the Tower on the bottom right corner.

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- c. Unplug the main power cord (grasping the plug, not the cord) and stow it safely back onto the holder at the side of the tower.
- d. Stow the keyboard and mouse safely by lowering the articulate arm.
- e. Move the tower to its designated storage space where it can be stored till it is next used, without it being a tripping hazard.

## 6. Accessing the data

To access the data, go to the data folder and sort through it to get to the folder with the correct patient ID. Each folder is also date and time stamped. Each folder contains a log of error messages, and data files for the raw data of the scan.

## 7. Troubleshooting

At any point after the App starts, if the system does not operate correctly, or has errors, please look at the Powershell window to read any error messages displayed.

Restarting the app usually solves most of these issues, but if the issue persists, please refer to the section below for information on error codes displayed on the GUI, and the recommended steps to be taken. If you face issues not mentioned in the guide, please contact Openwater personnel for service.

The following list discusses some errors displayed by the laser module (inside the tower) or the laser safety board, and the recommended steps to correct these errors.

### 7.1. System Errors

Error/ Error message	Cause	Solution
Loss of signal	No light on some or all of the frames	Could be because of loss of pressure on the trigger button. Retake data with firm pressure on the trigger button throughout the scanning duration.
Data check for camera XXXX failed	Low light on cameras	Retake data and ensure good contact and that there are no hair between the fibers and the scalp.

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Bad frames	Camera issue detected	Retake data.
No octopus detected	Cannot establish communication with octopus	Restart the computer/device.
App freezes/ does not launch GUI		Restart the app. Ensure there are not too many other processes running.
Camera init failed		Restart the app. If that fails, restart the computer/device.
Scanner init failed		Restart the computer.
Wand Scan LED does not turn on after starting a scan, system keeps waiting for a trigger		Relaunch the app.
Insufficient data for camera XXXX	Camera connection issue detected	Report to Openwater personnel
Thorlabs laser could not be turned on, connection disabled	Laser connection issue detected or key is turned off or driver/s are off	Report to Openwater personnel

## 8. Operator Training Checklist

- I am aware of where the emergency safety shut off switch is on the device.
- I am aware that the device should not be operated without use of the included laser safety glasses for both the operator and subject.
- I am aware that the device should be operated with the diffusing spacer tip on the source fiber at all times - and I am familiar with the proper process of putting a diffusing spacer tip on the correct fiber.
- I am aware that the device should never be pointed directly at anyone's eyes.
- I am aware that only personnel trained directly by Openwater are allowed to operate the device.

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- I am aware that under any circumstances, I should not modify any of the hardware as a part of the device.
- I am aware the PC component of the scanner is a special-purpose device and is not to be used for anything except for the research study; no additional software should be downloaded or installed on the computer.

Trainee: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

Openwater Trainer: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

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## Appendix 1

### 9. Login credentials

Username: HartfordHealth

Password: <provided by voice>