# Gen2 Stroke Detection Device
# Operator Manual

Stroke Detection Project

Open Water Internet Inc.

# 1. Introduction

## 1.1. Purpose

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

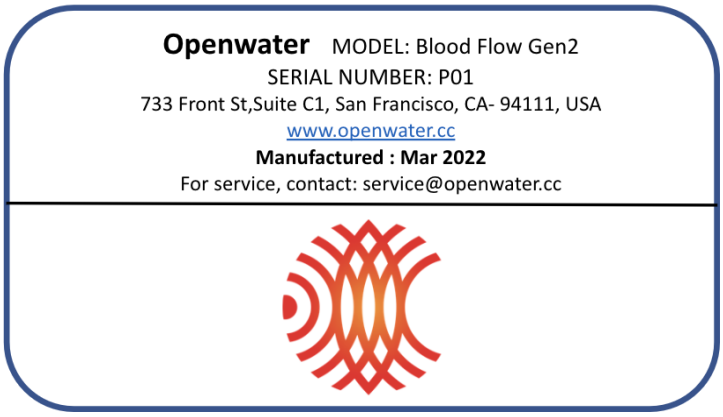



Figure 1: Example title label of the device.

## 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.

## 1.3. Definitions, Acronyms, and Abbreviations

Gen2: shorthand for Generation 2 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 LASER RADIATION EXPOSURE, THAT MAY CAUSE EYE DAMAGE OR BURNS.


Figure 2: Laser label on the product.

**The device emits invisible laser pulses (Class 1) 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 device.**

**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 to the upper left of the device's interactive display. Pressing this button stops the laser from firing.

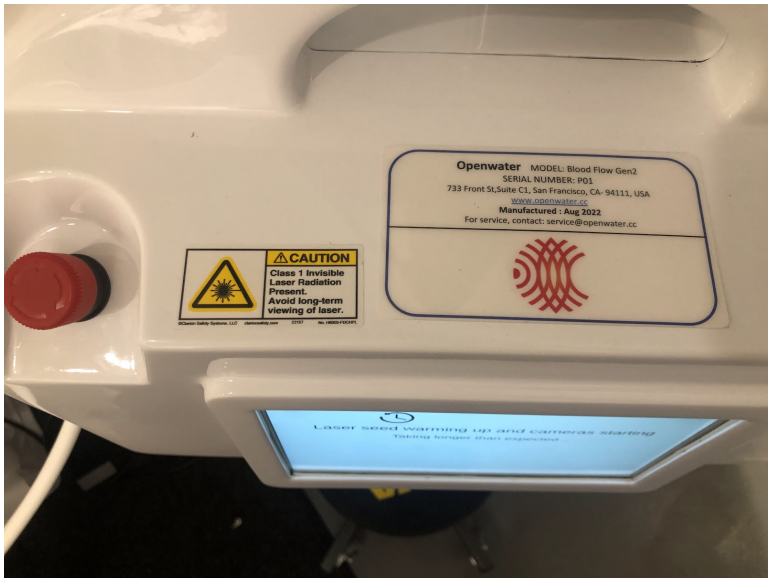



Figure 3: Top view of the console, showing the location of the emergency stop button.

**CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use**

Figure 4: Investigational device label (displayed on outside of the device).

This device is only intended to be used as an investigational device, and is not intended to diagnose, treat, cure, or prevent any disease.

Observe the following safety instructions AT ALL TIMES.

- **Please ensure that the voltage for your AC mains supply is appropriate for the device (120 V, 20 A, 60 Hz outlet) before connecting. The supply must include a good ground connection.**
- Please read this manual thoroughly before operating and follow all of the instructions provided within it.
- Position the device close to the wall with an electrical outlet or cover the electric cable with a cable mat to minimize tripping hazards.
- If the device is mounted on the IV pole, lock the IV pole wheels after it is positioned.

- **Do not under any circumstances open the console or unplug the optical fibers**.
- Do not point the modules directly at anyone's eyes when the system is operational and/or powered ON.
- Do not use any optics in front of the beam.
- This system is only intended to be operated by trained personnel.

## 2.1. Laser Parameters

### 2.1.1. Device Class 1 Laser Output Specifications

| | |
|---|---|
| Wavelength | 785 nm |
| Pulse duration | 100-400 µs |
| Pulse Repetition Rate | 40 Hz |
| Average Power | 12 mW |
| Energy per pulse (at the delivery fiber tip) | 300 uJ |

### 2.1.2. Embedded Class 3B Laser Source Specifications

The Openwater Gen2 Stroke Detection Device is a Class 1 laser device that outputs 12 mW of average power under normal operation and utilizes a **Class 3B laser**, which is capable of producing Class 4 laser radiation if used in the wrong configurations by bypassing safety protocols and modifying the 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 optics, follow safety instructions and do not look into the apertures or point the laser output towards your or anyone else's eyes. Do not open the console, headset, optical fibers, or modules unless you are a qualified Openwater service personnel. **When the console is open, there is Class 3B invisible laser radiation. AVOID EXPOSURE TO THE BEAM.**

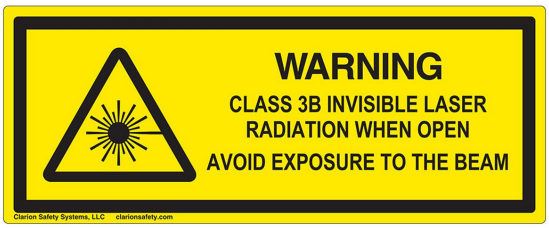
## 2.1.3. Laser Labels

Please be aware that there is **Class 1 laser radiation** emitted from the modules of the headset that is **not visible with your eyes. AVOID UNNECESSARY EXPOSURE TO THE BEAM.** Please adhere to the laser warning signs posted. **Do not stare at the beam, point the headset towards the eyes,** or use the device with any viewing optics. Use the headset only as intended. The below label (Figure 5) has been added to the outside of the device as a reminder to treat it with proper caution.


Figure 5: Class 1 laser warning on the device.

The label shown in Figure 6(A) is displayed on the console to warn the user of a higher class of laser embedded inside of it. The console should never be opened by the users, as the user will be exposed to Class 3B invisible laser radiation when the box is opened.

(A)




(B)


Figure 6: Class 3B warning labels (A) on the device and (B) inside the device.

The label shown in Figure 6(B) is displayed inside the console, on the source module to warn the user of a higher class of embedded laser.

It is also important to note that the cord connecting the headset to the console has **embedded optical fibers carrying Class 3B laser radiation.** Hence**, the cord should be treated gently.** Do not bend the cord excessively, or subject to pressure, or put under heavy objects. Laser radiation exposure from the cord may occur in the case of breakage, and any exposure to this laser radiation should be avoided.


Figure 7: Warning label on the exterior of the cord connecting the headset to the console.

# 3. Parts of the System

## 3.1. List of Items Included in Shipment

- Console
- Wearable headset
- Calibration phantom
- Electrical power cable
- IV pole cart
- Light-blocking veil

### 3.1.1. The Console

The console refers to the body of the device which consists of: electronics and optics inside, touchscreen, emergency button on the top, power cable, on/off switch on the side, and holder for the cord connecting to the headset. The device is mainly operated through this console; the touchscreen allows the user to start and take a scan measurement. The console should never be opened by anyone other than trained Openwater personnel, as it houses a Class 3B laser inside. Opening it could expose the user to harmful laser radiation which is capable of causing eye damage and skin burns.


Figure 8: Images of the console. (A) Interactive display screen, (B) emergency button, (C) USB slot for service use only, (D) on/off button and power cable receptacle, (E) ports for service use only, (F) holders for cord storage, (G) knob to secure the console to the IV pole.

#### 3.1.1.1. Console Mounting on the IV Pole

The console is generally kept mounted on an IV pole for easy transport. Please do not remove it from the pole without Openwater personnel. Please ensure that it is always mounted sturdily. It is advised that the console be mounted at or below the subject's bed height. Please ensure that the final placement is not such that the console is located directly over the subject's head; this is to avoid any injuries due to the console falling or the subject getting up and hitting their head.

### 3.1.2. The Headset

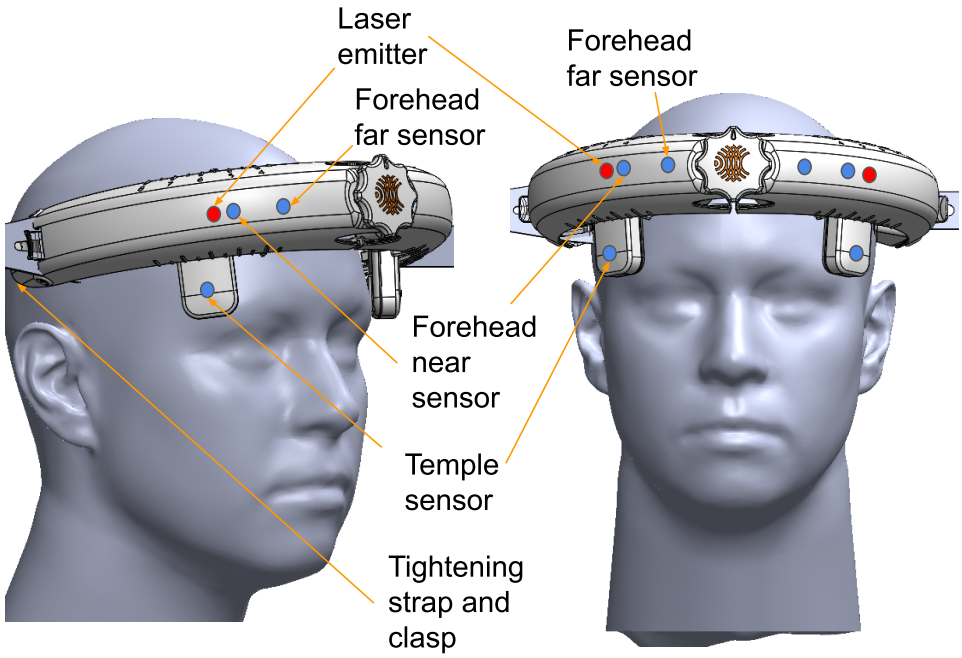



Figure 9: Parts of the headset.

#### 3.1.2.1. Description and Functionality of the Headset

- The headset interfaces the device with the subject, enabling the user to measure optical signals via the modules in the headset. The modules consist of optics for delivery of the laser light and detection of the optical signal from the measured subject.
- As the source fiber emits the laser beam it is important to treat this part of the device with caution. Please adhere to the laser warning signs posted and **do not stare at the beam or point the modules towards the eyes.** Please be aware that there is **Class 1**

**laser radiation** emitted from the module, which is an **invisible type of laser radiation. AVOID UNNECESSARY EXPOSURE TO BEAM.**

- Since the optics are made of glass, please do not mishandle (drop, crash, rub against an abrasive surface) them.
- Treat the cord connecting the headset to the console gently, and do not bend it excessively or subject it to undue force, as it contains optical fibers and electrical wiring.

### 3.1.2.2. Storage and Handling of the Headset

- The placement adjustment knob can be used to move the detection modules to fit the subject's head. Please adjust the knob gently.
- To ensure a secure and stable fit, the rear rubber strap can be tightened by pulling on either or both ends of it. To loosen the rubber strap, press on the clasps to release.
- Before and after each use, and after making sure that the device is off, wipe the headset with disinfecting alcohol wipe, followed by a dry wipe of the optical contacts with a non abrasive tissue paper to ensure there is no smearing or dirt on the sensors.
- The headset can either be stored by hanging it from the strap or placing it on the calibration phantom as shown in Figure 10 below.

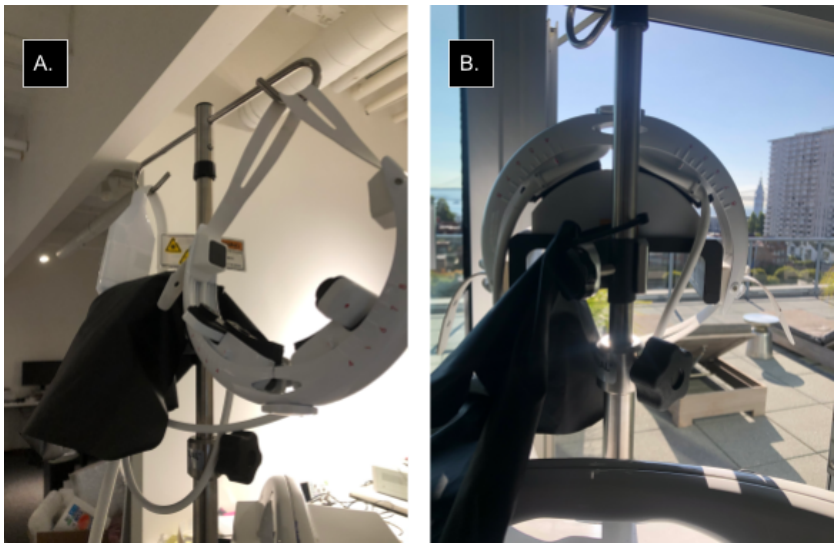



Figure 10: The correct way to store the headset on (A) the IV pole or (B) the phantom.

- Replace the headset to its original holder after each use.

# 4. System Operation

## 4.1. Everyday Scanning Operation

### 4.1.1. Scanning Subjects

To operate the system, please follow these directions, in the order that they are mentioned, and follow the prompts on the screen for a smooth operation.

1. Positioning and starting the device:
    - Place the IV pole and console close to the subject, making sure the subject is within the reach of the device.
    - Plug the electrical power cable into a nearby power supply (ensure the ratings match that of the device, as mentioned at the beginning of the document), making sure there are no tripping hazards.
    - Press the power button located on the left side of the console.
    - Wait for the device to start up.The GUI screen will be displayed when the system is ready.
    - If the system is unresponsive, please wait for at least 5 min before restarting the device.
    - On the GUI, using the alphanumeric touchscreen keyboard that is activated when the “Patient ID” field is touched, enter the patient ID and then press start (refer to Figure 11).

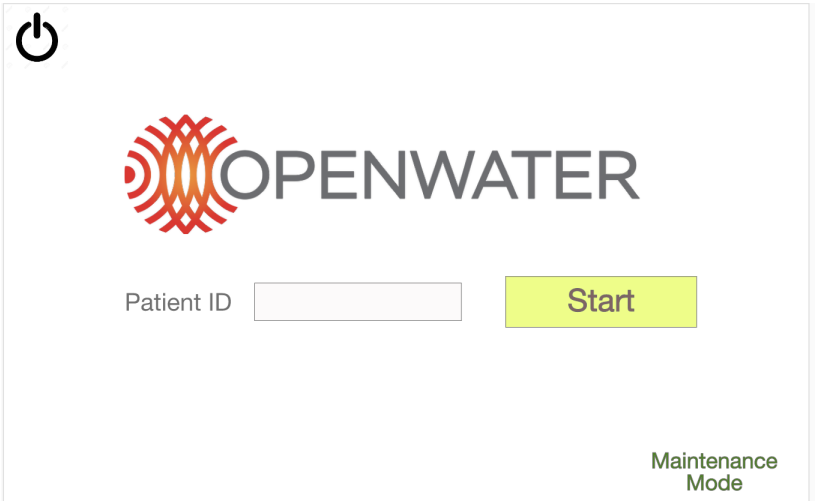



Figure 11: Home screen of GUI.

2. Placing the headset on the subject:
    - Wipe the subject's forehead with alcohol wipes before placing the headset.
    - Pull the subject's hair back from their forehead (use a hairband if needed).
    - Slide the strap on the back of the headset over the subject's head.
    - Place the headset over the subject's forehead, ensuring good contact between the modules and the subject's skin, with no hair in between the two.
    - Snugly tighten the two ends of the straps evenly to secure the headset to the subject.
    - The placement guide can also be opened by clicking the 'Open Placement Guide' button on the top right corner of the GUI screen as indicated in Figure 12, and it can be exited by pressing the 'Exit Guide' button on the bottom right corner of the screen.

***To ensure proper data capture:***

A. Headset modules must make contact with the skin below the hairline
B. Headset should be placed symmetrically left to right
**C. Laser & sensors must be flush to the skin (*no hair or air-gap between the two*)**
D. Subject should be as still as possible and avoid talking during the scan

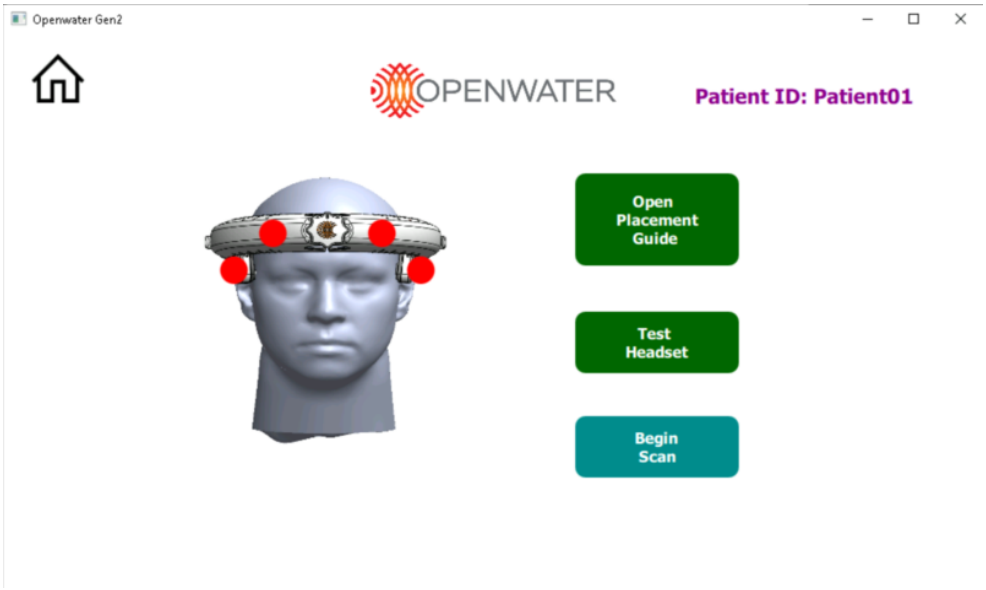



Figure 12: Choose placement guide or test headset.

3. Placing the light-blocking veil:
    - After the headset is correctly placed, drape the light-blocking veil on the headset by attaching the two end holes in the veil to the hooks near the headset strap tightening mechanism, making sure the veil covers the headset well enough to isolate the modules from any ambient room light or sunlight.

- This step is very important to obtain good quality results.

4. Testing the contact:
   - After placing the headset, the user needs to test its fitment at least once in order to enable the ability to take full scans.
   - Test the fitment by pressing the ‘Test Headset’ button on the touchscreen as displayed in Figure 12.
   - A countdown will be displayed, indicating the approximate time that the user will need to wait until the test scan is completed.
   - After completion, a green indicator near each module on the display indicates good contact, while a red indicator indicates poor contact. Attempts should be made to achieve proper fitment for any modules displaying a red indicator.
   - If time permits, the test can be repeated to ensure good contact on all four modules.
   - After achieving good contact on all modules, the user can proceed to scanning.

5. Scanning:
   - To begin the scan, press the ‘Begin Scan’ button on the lower right side of the touchscreen, as shown in Figure 12. This initiates the automatic process of starting up the laser, cameras and other control electronics, and turning them off after the scan is done.
   - While the scan is in progress, avoid any motion from the device or subject.
   - A countdown indicating the approximate time that the user will need to wait until the scan is completed will be displayed. The screen below is displayed until the scan is completed, approximately 90 seconds.

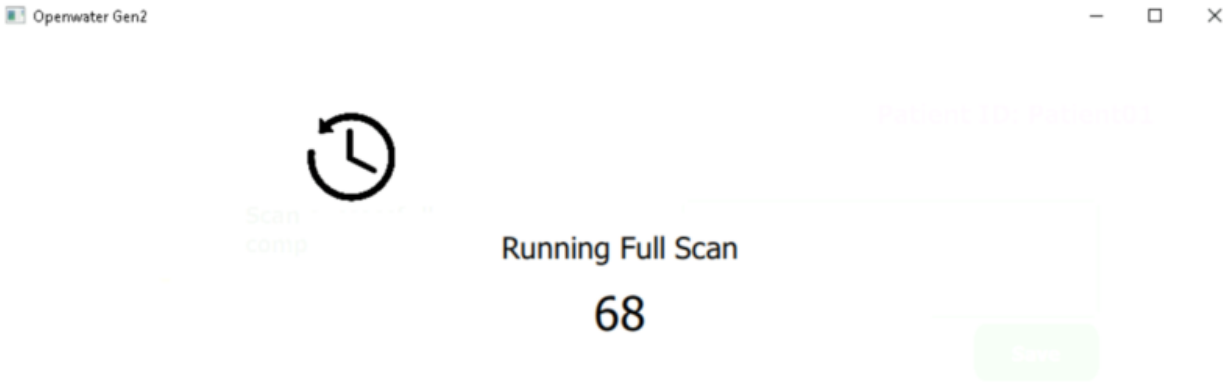



Figure 13: Scan in progress display.

   - Once the scan is complete, the screen shown in Figure 14 is displayed, giving the user the option to take and save any notes regarding the scan, or displays an error message if an error was encountered during the scan. This screen also

gives the user the option to repeat the scan, the headset test, or go back to the home screen.

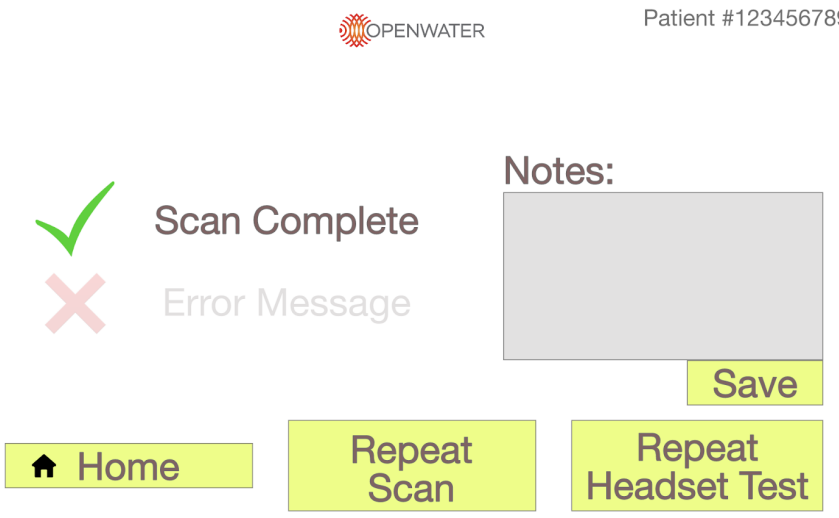



Figure 14: Post-scan screen.

- After the scan, please sanitize the system in accordance with section 4.2.

6. System shutdown:
   - The system can be turned off by pressing the power button.
   - If not intended to be reused within the next few minutes, the system should be properly stowed away and kept at its designated location.

### 4.1.2. Scanning the Calibration Phantom

The user is provided with a calibration phantom that is mounted on the IV pole and that should be scanned regularly to ensure proper system function. This provides a baseline for the system performance and can help Openwater personnel identify any potential issues. To scan the calibration phantom, please follow these steps:

1. Following instructions from the previous section, turn the system on.
2. Turn the headset adjustment knob to bring the modules to position 4 (confirm with the marker on the top of the headset).
3. Place the headset securely on the calibration phantom provided, and cover the headset with the light-blocking veil attached to the headset.
4. Click the ‘Test headset’ button in the GUI window displayed in Figure 12, or if scanning after a scan, click on ‘Repeat headset test’ button as shown in Figure 14.

## 4.2. System Shutdown Process

1. Make sure that the data is backed up, **follow instructions in section 4.3.2 to backup the data.**
2. Press the home button and turn off the system by pressing on the power button on the top left corner of the screen as shown in Figure 11.
3. After the system has shutdown, power off the device by pressing the on/off power switch on the side of the console as shown in Figure 8(D).
4. Sanitize the device with the following Sanitization Procedure*:*
    a. Using Caviwipes or any one of the approved cleaning solutions (hydrogen peroxide, quaternary ammonium, 70% isopropyl alcohol, sodium hypochlorite solutions), wipe the headset, calibration phantom and any other part of the system might have been touched.
    b. Take a dry lens cleaning wipe and wipe off the optodes in the sensor.
    c. Please sanitize the system after each subject's measurements.
5. Place the headset securely back on the IV pole hook or on the phantom.

## 4.3. Maintenance Mode

The maintenance mode can be accessed and used by any user with the system password to limit access maintenance features. The maintenance mode can be used for system calibration, troubleshooting and routine system logging.

### 4.3.1. Entering Maintenance Mode

- To enter the maintenance mode, click on the ‘Maintenance Mode’ button on the lower right corner of the Home Screen as displayed in Figure 11.
- Enter the password provided to the user (not included in this document) when prompted on the next screen and press ‘Enter’ (Figure 15).

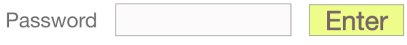



Figure 15: Entering the maintenance mode.

- This takes the user to the next screen (Figure 16), where they can choose to Calibrate System, Backup to USB, Measure Laser energy, Update Main Firmware, or Update Touchscreen.

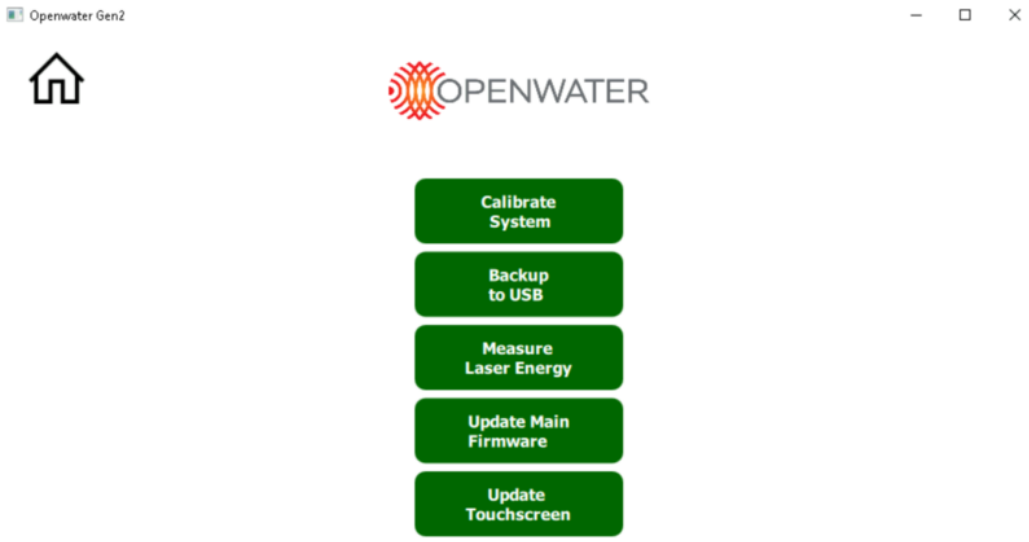



Figure 16: Choosing maintenance action in maintenance mode.

- The user can click on the appropriate button to proceed to the next step.

### 4.3.2. Backup Data to USB

- Insert a USB drive in the slot labeled USB on the side of the console.
- Enter the maintenance mode and click on the ‘Backup to USB’ button to backup data to USB.
- **This process can take several minutes**, depending on the amount of data and the USB device speed. The display will indicate when the data transfer is complete. Please wait until then before removing the USB stick or shutting down the device.
- Backing up the data should be done frequently.

# 5. Troubleshooting

At any point after the device starts up, if the system does not operate correctly or has any errors, please restart the device. Restarting the device usually solves most issues, but if the problem persists, please refer to any information or errors displayed on the GUI, and take the

recommended steps. If you face issues not mentioned in the guide, please contact Openwater personnel for service. The following section discusses some common errors and the recommended steps to correct them.

## 5.1. System Errors

| **Error/ Error Message** | **Cause** | **Solution** |
|---|---|---|
| System taking longer than expected to start up | N/A | Please wait for at least 5 minutes, and if the issue isn't resolved, restart the device by switching the on/off button. |
| Emergency stop triggered | The emergency stop system was activated either by out of specification laser pulses or by the emergency stop being pressed | 1. Ensure that the E-stop is not engaged and then restart the device as usual.<br>2. If the issue persists, place the headset on the phantom to avoid harm from any errant laser pulses. |

# 6. 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 never be pointed directly at anyone's eyes.
❏ I am aware that only personnel trained directly by Openwater are allowed to operate the device.
❏ 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 module 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: __/__/____