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## 1. Purpose and Scope

The purpose of this Hardware Architecture Design Document (HADD) is to provide a structured and comprehensive overview of the hardware architecture for the Openwater General Blood Flow device and confirm that User Needs are met. This document aims to communicate the high-level design and structure of the system to all stakeholders.

The document outlines the system's main components and their interfaces.

## 2. Definitions, Acronyms, and Abbreviations

- 2.1. Accessible emission limit (AEL): maximum accessible emission permitted within a particular class
- 2.2. Architecture: organizational structure of a system or component
- 2.3. Class 1 laser product: any laser product which during operation does not permit human access to laser radiation in excess of the AEL of Class 1 for applicable wavelengths and emission durations
- 2.4. Class 1m laser product: any laser product in the wavelength range from 302,5 nm to 4 000 nm which during operation does not permit human access to laser radiation in excess of the AEL of Class 1 for applicable wavelengths and emission durations
- 2.5. Compensating Controls: a safeguard or countermeasure deployed, in lieu of, or in the absence of controls designed in. These controls are external to the device design, configurable in the field, employed by a user, and provide supplementary or comparable cyber protection for a medical device.
- 2.6. Concurrent engineering: use of a multi-functional team in the development cycle of a product
- 2.7. Configuration item: entity that can be uniquely identified at a given reference point
- 2.8. Critical areas: portions of the software design or implementation which, in the hazard analysis, have a high level of impact on performance and/or hazard control functions.
- 2.9. Cybersecurity: the process of preventing unauthorized access, modification, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient.
- 2.10. Design control: the systematic process of conducting and documenting activities related to product design and development to assure that the finished product design meets all of the specified design requirements
- 2.11. Design History File (DHF): a chronology of the product development process. A DHF is required to be established and maintained for each type of device under design control. The DHF contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan. The DHF is maintained by the project leader and document control

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- 2.12. Design input: the physical and performance requirements of a device that are used as basis for device design, so that the device will perform to meet its intended use and the needs of the user/customer
- 2.13. Design output: the results of a design effort at each design phase and at the end of the total design effort. The design output documents contain or refer to acceptance criteria and ensure that those design outputs that are essential for the proper functioning of the device are identified. Finished design output is the basis for the Device Master Record (DMR). The total finished design output consists of the device, its packaging, labeling, and the DMR. The design output shall be documented, reviewed, and approved before commercial release of the device

### 3. Architecture Goals and Constraints

Openwater has designed the general blood flow system Gen 2.5 in accordance to SOP-01

This general blood flow detection system serves as a general measurement system, where all safety and verification of detection is proven in the general case with a general interface to human subjects in a hospital, research center or healthcare provider's office.

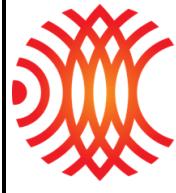
The tool Marix Requirements has been implemented to record and trace all:

- User needs
- Business needs
- Risks
- External regulations

See attachment 1

### 4. Architecture Presentation

#### 4.1. Design and System View



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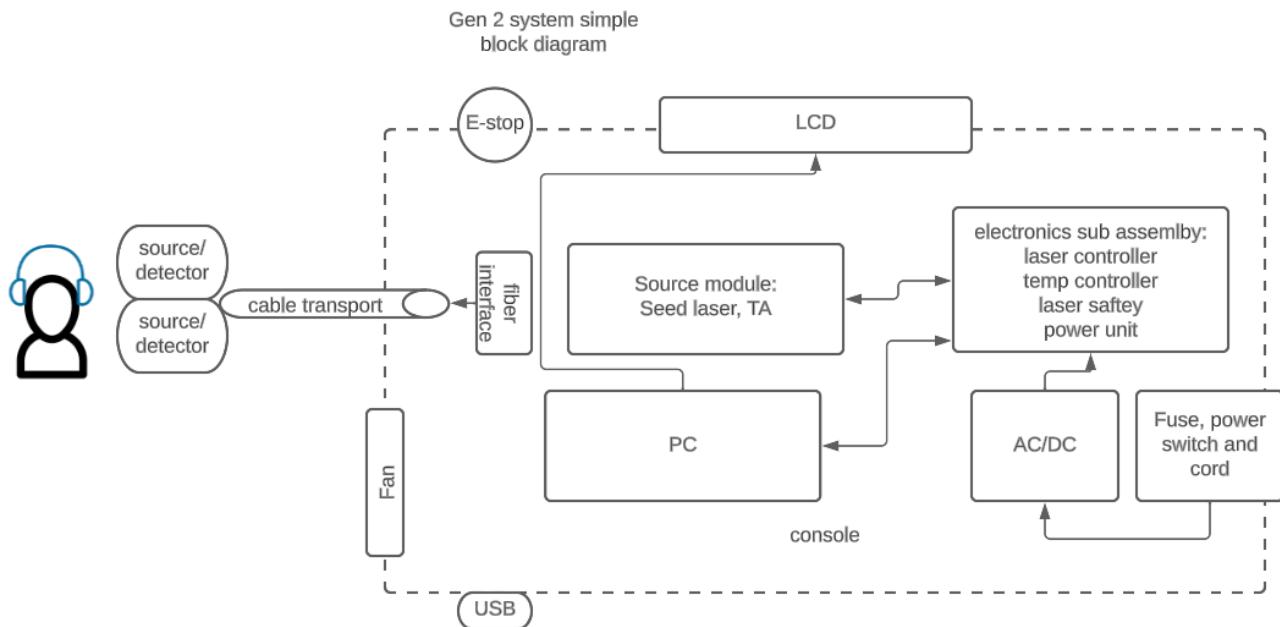
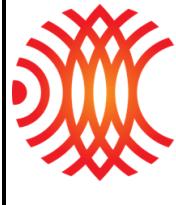


Figure 1- simplified block diagram of system 7000-0246 ASM, BLOOD FLOW



Figure 2 - blood flow system view



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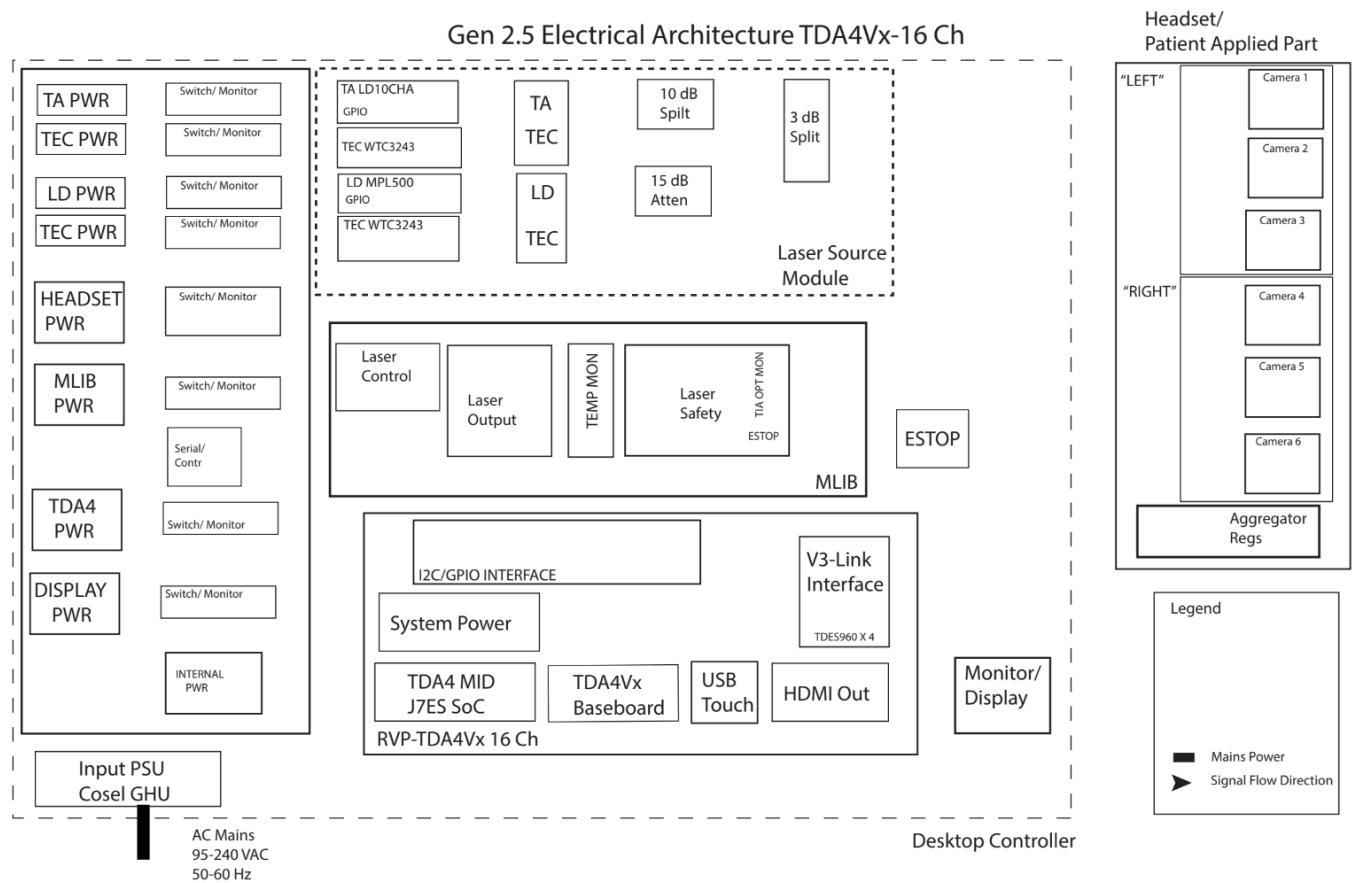


Figure 3 overall Electrical hardware block diagram

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Link to detailed overall electrical block diagram below

See attachment 2- D0074 Gen 2.5 Architecture diagram 1.0-1

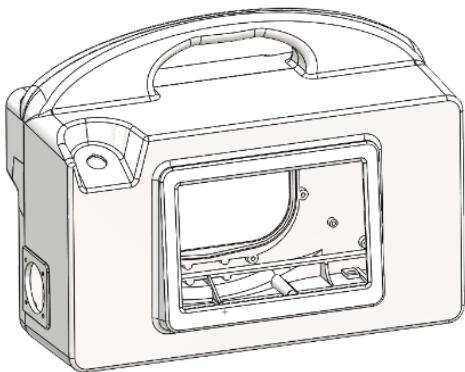
One of the key subsystems from both the component cost and safety perspective is the laser source module a link with the detail of this subsystem is below:

See attachment 3 D0075 Laser source module electrical specification



Figure 4 7000-0242 Source Module Gen 2.5

#### 7300-0145 master model



3000-0472	CASE, FRONT
3000-0473	CASE, REAR
3000-0474	CASE, CABLE BLOCK
3000-0475	CASE, FAN PANEL
3000-0476	CASE, EXHAUST PANEL
3000-0477	FIBER RACK

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figure 5 -console housing

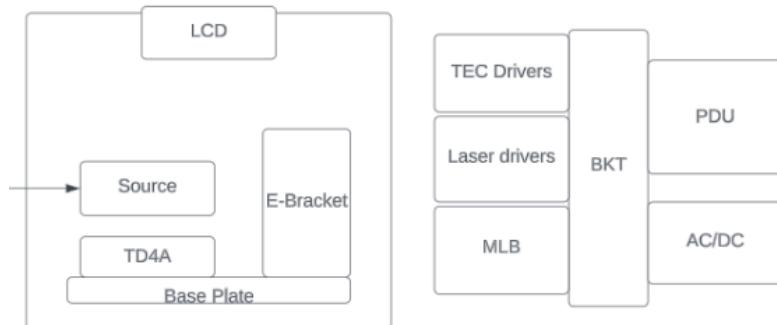
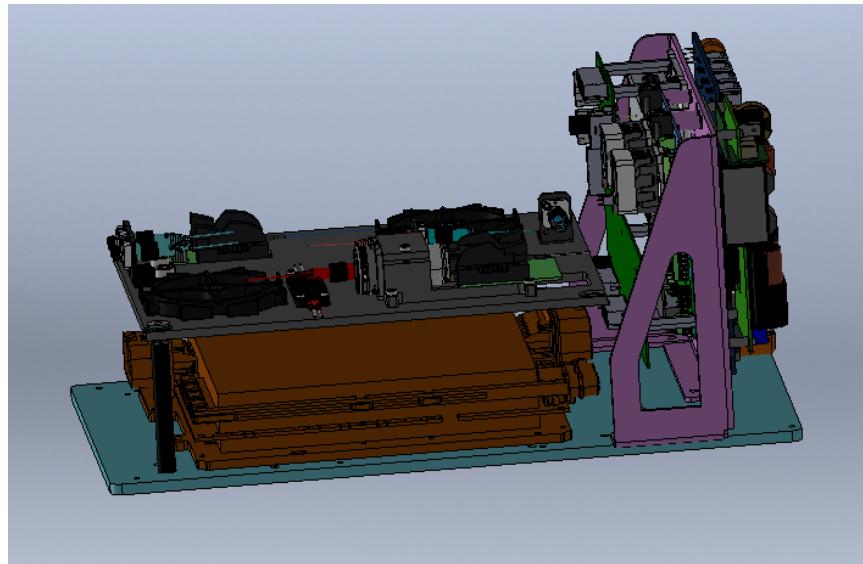


Figure 5- inside hardware of console

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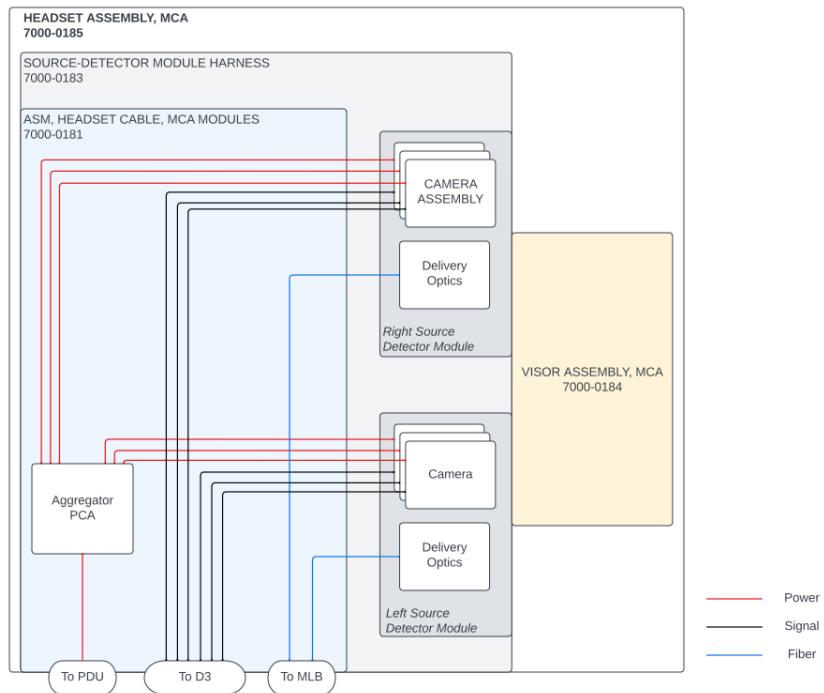


Figure 6 patient contact block diagram

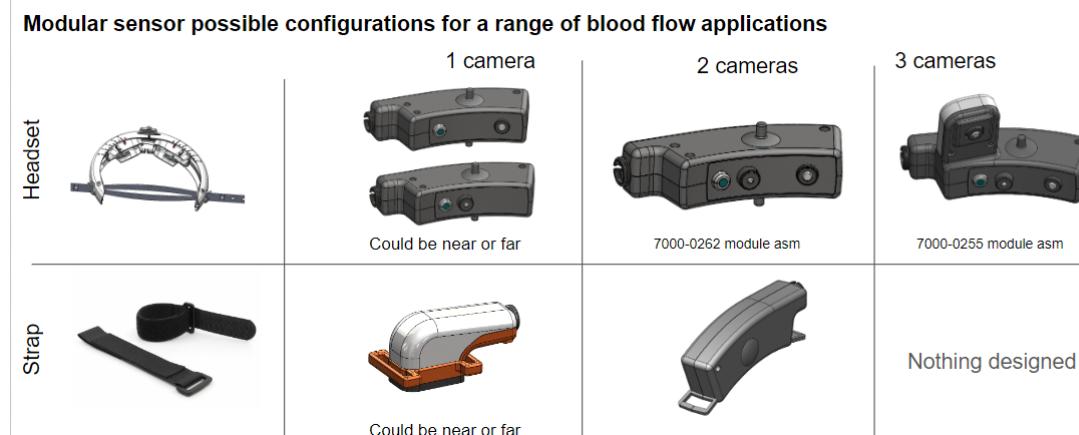


Figure 7- patient contact options

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Figure 8 sensor module

#### 4.2. Use Case View-detect below surface blood flow

4.2.1. This release of the general blood flow detection system intent is to serve for multiple use cases. Initial use cases included a neural or headset interface to detect blood flow beneath the scalp of a patient. In the general case Doctors or Researchers can interface with any part of a patient's anatomy. A series of sensor modules and straps have been developed and tested to meet this goal.

#### 5. Testing- safety and essential performance

- 5.1. Test systems have been developed to assure safety and essential performance of sub systems and final system.
- 5.2. sub-system test results during production will be recorded and retained in the device history record for each produced unit at each step of production.
- 5.3. Essential performance
  - 5.3.1. The detection system relies on mean light intensity from an absorbing and scattering media testing on representative static phantoms
  - 5.3.2. Engineering and clinical testing have been performed to determine the light level needed to produce acceptable signal to noise waveforms showing the dynamics of pumping blood inside the human arterial structure.
  - 5.3.3. Liquid flow Phantom have been developed to show non-human depth and flow dynamics.
  - 5.3.4. Dynamic clinical testing has been developed to show typical waveforms produced on a live subject.
  - 5.3.5. Testing has been performed to show ambient light threshold levels

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- 5.4. Testing for equipment Safety will be performed as part of design verification described in SOP-001.
- 5.4.1. medical safety IEC-60601
  - 5.4.2. laser safety IEC-60825
  - 5.4.3. general system robustness

## 6. Quality Records

The Hardware Architecture document will be retained as a quality record and referenced in the Design History File per SOP-001.

### Attachments:

1. D0073-Arch goals Gen 2.5
2. D0074-Gen 2.5 Architecture diagram 1.0-1
3. D0075-Laser source module electrical specification

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### Revision History

Revision	Date	DCO	Description of Change
01	11/2/2023	00001	Initial release