Open-Motion 3.0 Specification v. 3.2

Product Summary

Open-Motion 3.0 is Openwater's diagnostic platform using low intensity near-infrared light to measure blood flow, blood volume, and micro-motions deep under the tissue surface. The platform is flexible, easy-to-use, and can interrogate many locations throughout the head and body. While Open-Motion 3.0 devices are ready to set up "out of the box", their open-source design allows customization and modification to support clinical research across diverse users and applications. At the same time, its controlled design features make it an effective solution for developing regulated medical devices that are portable and low-cost. By filling the gap between expensive research hardware available for proof-of-concept studies and commercially manufacturable hardware suitable for regulated medical devices, Open-Motion 3.0 greatly facilitates the translation of novel diagnostic devices from bench to bedside.

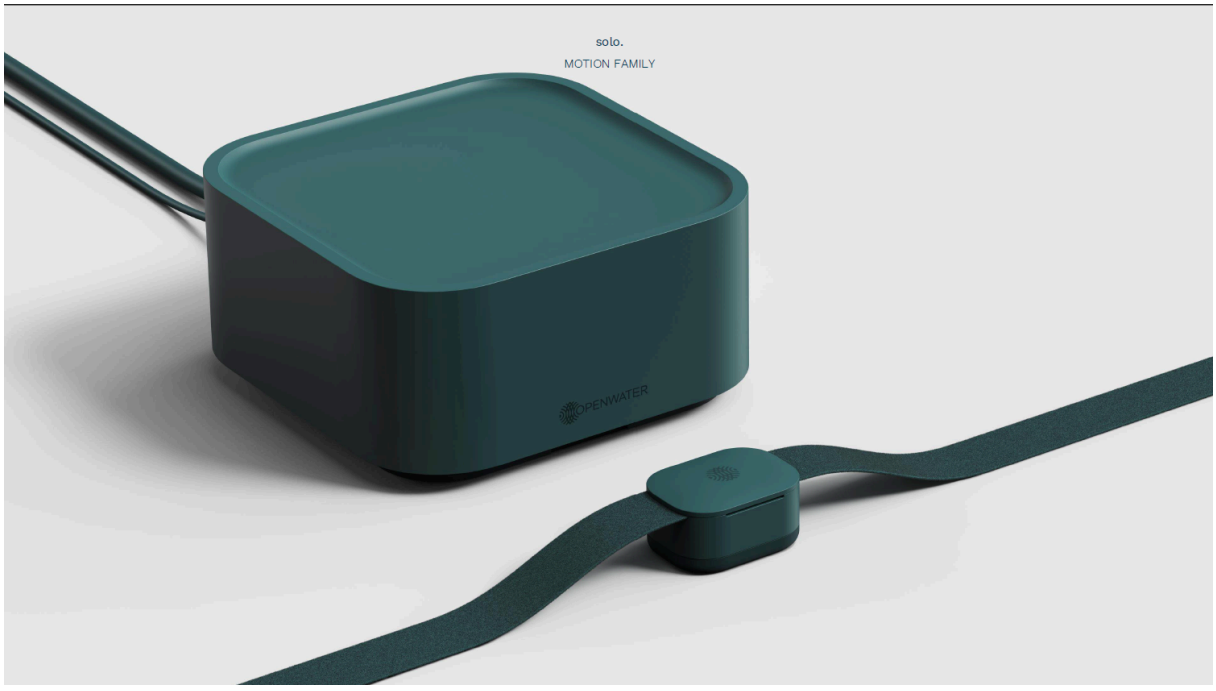


Figure 1: Industrial Design that enables use of one or more modules driven by a small console. The console with a single sensor module and its strap holder is pictured on the right. Each sensor module has a laser output and 8 camera chips. The console has inputs for 2 sensor modules.

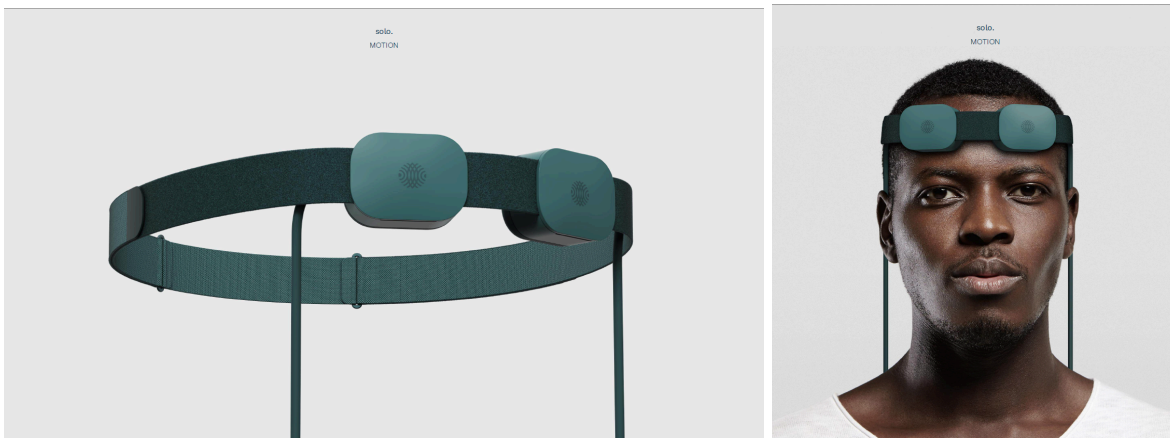


Figure 2: On the left depicted: how to add more sensor modules to the strap (extra modules and cables can be purchased separately). On the left - how this can look on a head.

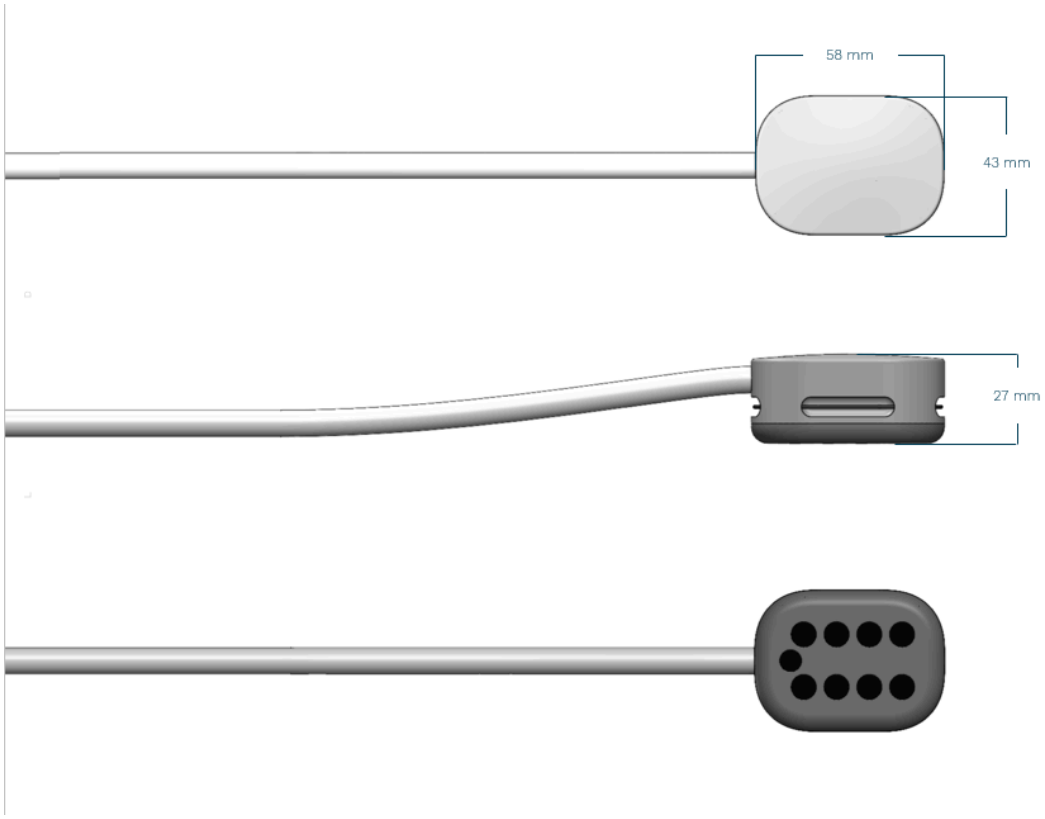


Figure 3 Depiction of the top, bottom and side of the sensor modules with estimated dimensions

Figure 7 - Depiction on wrist

Figure 4: “x-ray” view of sensor module internals + detail of externals

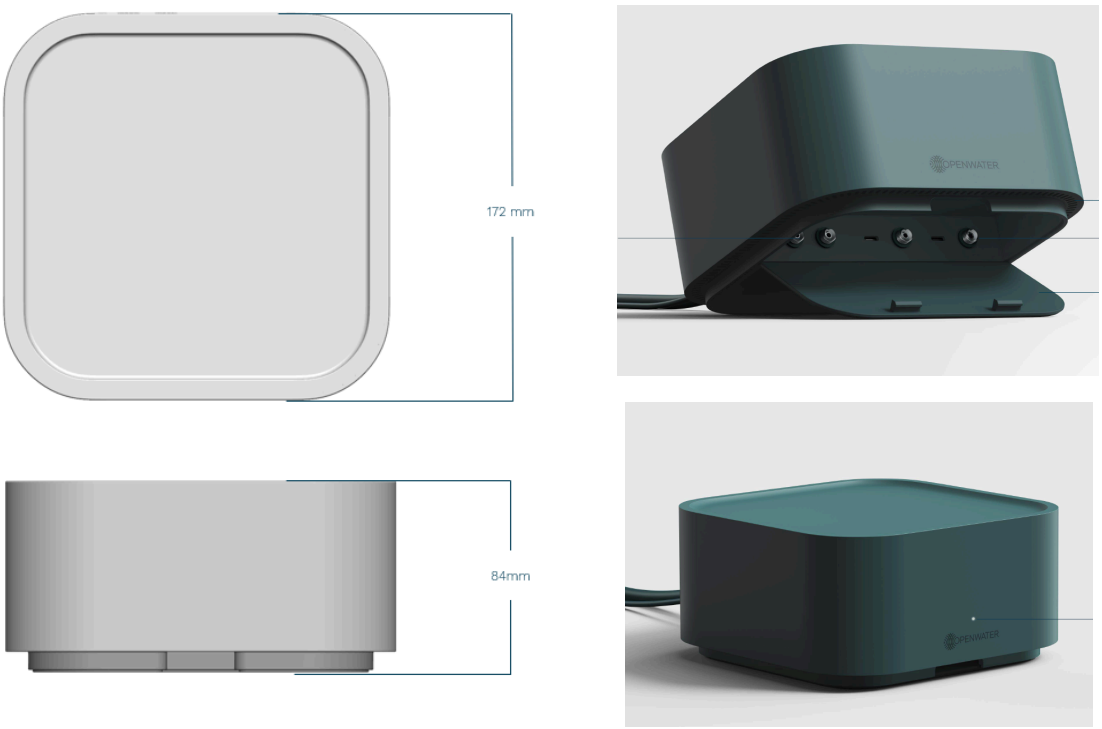


Figure 5: Dimensions of the Open-Motion console and depiction.

Target Specifications

Category	**Parameter**	**Value**
Product Classification	Blood flow and hemoglobin concentration meter	
Configuration	Major components	1 console,1 measurement module, and software
Light Source:	Center Wavelength Peak Power Bandwidth Pulse Length Classification	795 ± 5 nm 5 Watts < 15 MHz 250 µs Class 1 emissions per IEC 60825
Detectors	Type Number Shutter Format Pixel Size Frame Rate	CMOS 16 Global 1920 x 1280 2.2 µm 40 fps
Terminals and I/O signals	Electrical Optical DC Power Supply Laser TTL Sync	3 × USB-C 2 × 200 um fiber optics 1 × Barrel Jack 1 × SMA
Mechanics	Dimensions Weight	W: 250 mm, H: 75 mm, D: 160 mm Approx. 2.5 kg
Software Requirements	Operating System Memory Storage Connections	Windows 10, version 22H2 or later or Apple macOS 12 or later 8 GB of RAM 100 GB of free storage 1 available USB-C port (at least USB 3.0)
Others	Power Supply Power Consumption Operation Environment Storage Environment	AC 100 - 240V, 50/60 Hz 72 Watts (Maximum) 15°C - 30°C, 20% RH - 80% RH -0°C - 40°C, 20% RH - 80% RH
Compliance	IEC standards ISO standards	60601-1, 60825-1, 62304 13485, 10993

Intended Use Statement

Open-Motion 3.0 is intended to help qualified researchers study the use of optical blood flow and blood volume monitoring in laboratory, pre-clinical, and clinical research settings. The system is designed to be flexible and re-programmable so that a wide variety of tissue types can be explored, while also enabling researchers to configure constrained operation modes so that trained operators can use the system to complete specified workflows, and entities seeking regulatory approval for specific indications can use realizations of the platform in commercial products. Open-Motion 3.0 has not been evaluated by the FDA and is intended for research use only.

Major Subsystems

Console

The Console contains electronics and laser components. The laser components contained within the Console include the laser itself, laser driving electronics, and safety circuits that ensure safe operation of the device. The Console also contains electronics to split out the single USB line coming from the PC into electrical connections to each of the individual sensor modules. In addition, the console contains the necessary optical components to divide out the laser output to each of the sensor modules.

	Terminal	**Signal**
Host PC Connection	USB-C (Host PC)	Data
Device Power	Barrel Jack	24V, 3A DC Power
Sensor Module Connections (with 8 cameras connected to each sensor module)	USB-C (sensor module)	Data, synchronization triggers
	USB-C (sensor module)	Data, synchronization triggers
Auxiliary	SMA (sensor module)	External TTL laser synchronization

Sensor Modules

Each sensor module connects to the console with a USB cable and fiber optic for laser light delivery, and contains 8 sensors that measure the light coming out of the tissue. The sensor modules will be mechanically attached to the subject, and potentially to each other depending upon the desired configuration. Additional sensor modules can be added as shown.

Software

The device is configured by a computer program on a PC. The software has modules that are available for flexible and direct control of the hardware by users, as well as applications that guide users through a controlled workflow. A PC connects to the console through a USB-C connection. Device software, instruction manual and additional documentation will be available on the Openwater website (www.openwater.health).

Open Source

All hardware and software will be released under an aGPLv3 open-source license, the Creative Commons Attribution-ShareAlike 4.0 International (license available at https://creativecommons.org/licenses/by-sa/4.0/legalcode), or equivalent licensing terms.

Safety

This notification serves as a safety disclosure for our Open-LIFU 2.0 and Open-Motion 3.0 medical components intended exclusively for research purposes. Openwater acknowledges that, as of January, 2024 the device has not undergone review and clearance or approval by the U.S. Food and Drug Administration (FDA) for commercial distribution and use.

Research-Only Purpose: The devices discussed on this site are exclusively intended for research purposes and are not cleared or approved by the FDA for clinical use or commercial distribution. It is solely available to researchers and research institutions.

Lack of FDA Review: The safety and effectiveness of these components have not been established through the FDA's formal review process. Researchers should be aware that the device has not undergone the regulatory scrutiny required for general medical use.

Risk Awareness: The potential risks associated with these components are not fully known. Researchers and research institutions are advised to exercise caution and fully inform all involved parties about the investigational nature of the device and the uncertainties surrounding its safety and efficacy.

Informed Consent: Researchers using these components are responsible for obtaining informed consent from participants, clearly communicating the experimental nature of the device and any potential risks associated with its use.

Monitoring and Reporting: Researchers are urged to closely monitor the use of these components during research activities and promptly report any adverse events or unexpected side effects to Openwater safety@openwater.cc. This information is crucial for ongoing evaluation and refinement of these devices.

Restricted Use: These components should be confined to research settings and not used in clinical practice or commercial applications. Their use should be limited to researchers and research institutions with the expertise to manage and monitor the investigational nature of the device. For inquiries or additional information, please contact safety@openwater.cc

Note: the specification is nearing finalization, We are seeking comments from the community prior to finalizing to give you the best system we can.
Send your comments to community@openwater.health

Appendix

Previous Work with this Technology:
Open-Motion 3.0 is designed to enable researchers to study hemodynamics in pre-clinical and clinical settings. A previous generation of the device using the same core technology was used in clinical studies that led to two peer reviewed publications. The first publication (Favilla et al., Neurophotonics, 2024) demonstrated a strong correlation between optics and transcranial doppler ultrasound, a clinical gold standard for measuring cerebral blood flow. The second publication (Favilla et al., Journal of NeuroInterventional Surgery, 2024) demonstrated the ability of the optical blood flow measurements to detect large vessel occlusion in suspected stroke patients.

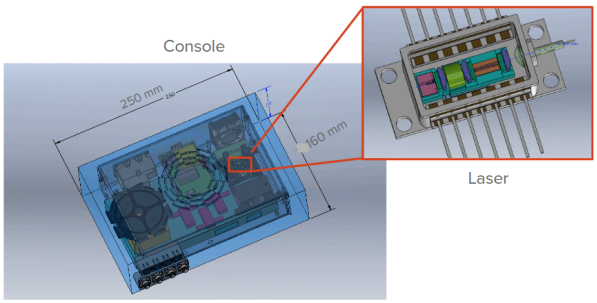
Theory of Operation:
The technology underlying Open-Motion 3.0 utilizes light to measure and quantify blood flow within tissue. The technology utilizes highly refined pulses of laser light consisting of an extremely narrow range of wavelengths. As this specific type of light passes through tissue, its properties can be altered by the flow or movement of blood. Once the light exits the tissue, detecting and quantifying the small changes in flow is achieved by illuminating the transmitted light onto sensors with numerous tiny yet highly sensitive pixels. To accomplish this all, the technique employs low cost, yet very sophisticated lasers and sensors originally designed for the mass market consumer electronics supply chain. This ultimately allows the device to be scaled down in cost dramatically compared to other medical devices, while providing unique and important biological information. Additional details on this technology and its application to stroke diagnosis can be found on our website.

On-Camera-Chip Histogram Processing:
Two of our goals in the development of the next-generation Open-Motion 3.0 platform are making the system modular to enable many applications, and making it low in cost. Integrated conversion of the raw images to histograms within each individual camera makes these two goals possible. In the previous generation, the entire camera images were sent back to the console for processing on its computer. This meant quickly transfering an incredible amount of data over the cable and processing it on a single general-purpose computer. This limited the number of possible cameras that could be used at once, as well as requiring a console computer with significant processing power. In the new design, a specialized processor called an FPGA (Field Programmable Gate Array) is incorporated into every camera board, and each raw image is converted to a histogram such that the amount of data transferred back to the console per image is a tiny fraction (<0.1%) of the data in the raw image. Since each camera has its own FPGA, the number of cameras can be increased without substantially increasing the data transfer capability of the cable or processing power of the computer. In fact, the next-generation console does not even have a computer, and the data is easily transferred to the user's computer. A significant amount of engineering goes into making this data pipeline work. We outline some of the details below.

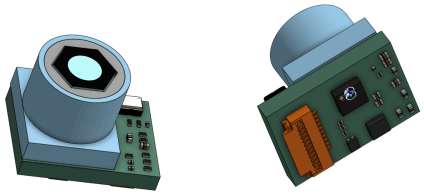
The raw 10-bit image packets are sent from the camera sensor directly to a 2.5×2.5 mm FPGA that is on the same camera board. This FPGA converts the large raw images into much smaller histograms (over 1000 times smaller in size). Reading and writing to the camera sensor's registers is also done via this FPGA. For debugging purposes, this FPGA is also able to pass full-size raw images to the console, albeit at a much slower frame rate.

After the histograms are generated, they are sent to the aggregator boards, where data streams from eight cameras are combined in order to be passed over USB-C to the Console Board. In terms of the data pipeline, the Console Board mostly acts as a USB hub. It takes the data stream from up to 2 aggregator boards and merges them into a single USB-C connection that interfaces with the host computer. The host computer converts the histograms into blood flow and blood volume data using its CPU.

MOPA Laser Performance:
Open-Motion 3.0 employs what is commonly called a Master Oscillator Power Amplifier (MOPA) laser system. In the first stage, a master oscillator (sometimes called a seed laser) generates a highly-coherent laser beam. This optical illumination is then amplified by the power amplifier, which increases the power of the laser with the desired pulse shape and length. This technology enables precise control over the pulse width and frequency, which is crucial for our application. In a typical laser system, pulsed operation is obtained by pulsing the current to the laser cavity. For short pulses the laser cavity does not have time to stabilize resulting in phase and wavelength fluctuations. In our system, the seed laser is run at low power in continuous mode, and as a result emits stable narrow bandwidth light. High power pulses are obtained by pulsing the current to the amplification stage. We use a tapered amplifier (TA) in our system due to its ability to output high power.



Blown up view of console showing size of our fully-custom MOPA laser within.



Camera sensor assembly sub-modules.