Development of a Submersible Multi-modal Physiological Monitoring System for Enhanced Diver Safety and Mission Readiness

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Warfighter Exertional Illness & Operations in Extreme Environments

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Disclosures

- The presenter is an employee of NIRSense Inc. Product references do not imply federal endorsement. Investigational technologies have not been cleared or approved for clinical use unless otherwise stated.

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The Warfighter Problem: Coupled Stressors Underwater

- Military divers meet environmental and operational stressors **at the same time**
  - 83% of 263 U.S. Navy mishaps were decompression sickness or arterial gas embolisms [1,2]
  - 57% of U.S. Navy dives under 190 ft are training dives [1-3]
  - 5% of Navy SEAL (BUD/S) candidates developed exertional swimming-induced pulmonary edema [4]

Environmental		**Operational**		**Severe Events**
• Cold water • Depth/Pressure • Hypoxia/Hypercapnia	+	• Heavy exertion • High task loading • Negative static lung load	=	• Immersion Pulmonary Edema • Decompression sickness • Hypoxic Blackout

- Most military diving occurs in training
  - Realistic training reproduces the same couples stressors, same risks
- Diver physiology historically has been captured mainly pre- and post- dive
- Few systems can track and report signals in real time at depth

Photo by PO1 Almagissel Schuring / DVIDS (2024)

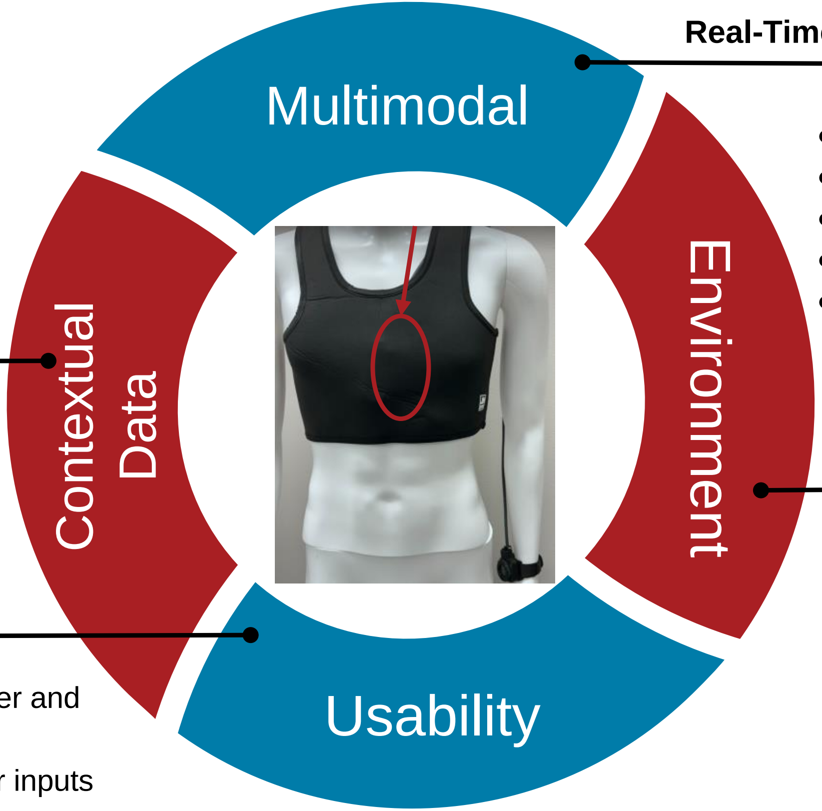
[1] Beatty et al., Physiological Monitoring to Prevent Diving Disorders, Front. Physiol. 2024 (10.3389/fphys.2024.1517361)
[2] O)'Connor et al, A methodology for identifying human error in U.S. Navy diving accidents, Hum. Factors. 2007 (doi:10.1518/001872007X312450)
[3] Colgary et al, An experimental study of one Atmosphere Diving Suites (ADS) and data analysis of military diving, MIT. 2026. (https://dspace.mit.edu/handle/1721.1/104301.)
[4] Adir et al., Swimming-induced pulmonary edema incidence: Incidence & Impact of SIPE on Navy SEAL Candidates, CHEST 2020 (doi:10.1378/chest.126.2.394)

The Capability Gap

Clinical Grade	COTS Dive Compatible
✔ Yields more valid and reliable metrics	✘ Non-validated metrics in dive setting
✔ Dependable in **clinical environment**	✘ Less reliable performance
✘ Often higher cognitive burden, raw data	✔ Lower burden, processed data output
✘ More complex and fragile	✔ Robust system
✘ Less robust	✔ Integrate with dive computer to provide context
✘ Limited context	✘ Not real-time (pre/post)
✔ Real-time	✘ Limited multimodal

How do you develop a real-time multimodal system that overcomes these limitations?

The Integrated Monitoring System (IMS)



Real-Time Physiological Alerting

- PPG
- NIRS
- Single lead ECG
- Skin temperature
- Derived metrics: HR, PR, HRV, RR, SpO_2, StO_2, non-invasive core temperature, activity state.

Relevant Contextual Data

- Ambient pressure
- Ambient temperature
- Accelerometry

Training and Mission Environments

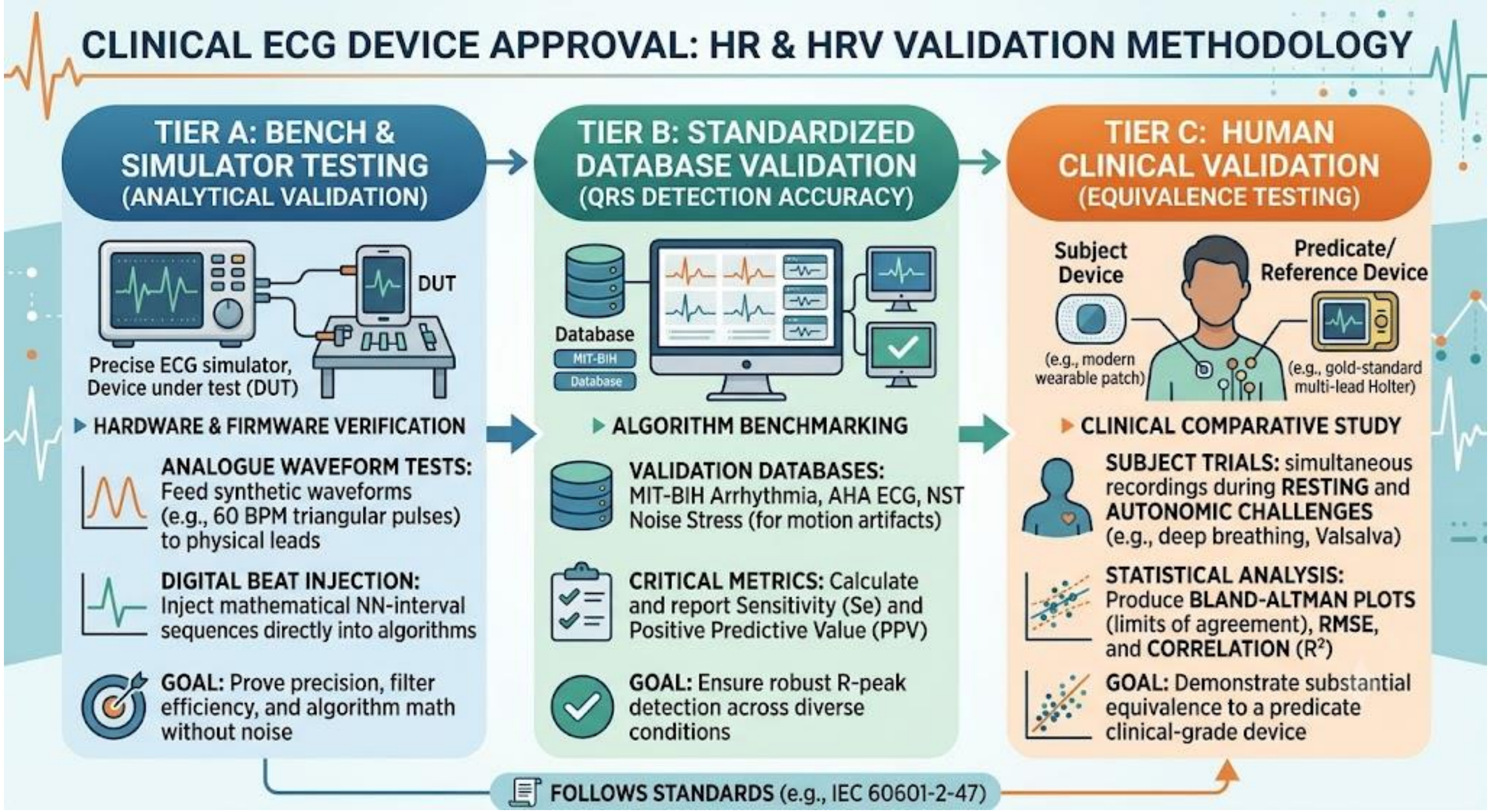
- Ruggedized
- Modular
- Low size/weight/power
- Wearable
- Chest worn sensor
- Companion app (out of water)
- Depth rated for extended range

Low Cognitive Burden

- LED alerting scheme to diver and dive buddy
- Push-button/rotary dial user inputs
- Minimal diver interaction.

The Evaluation Criteria & Challenge

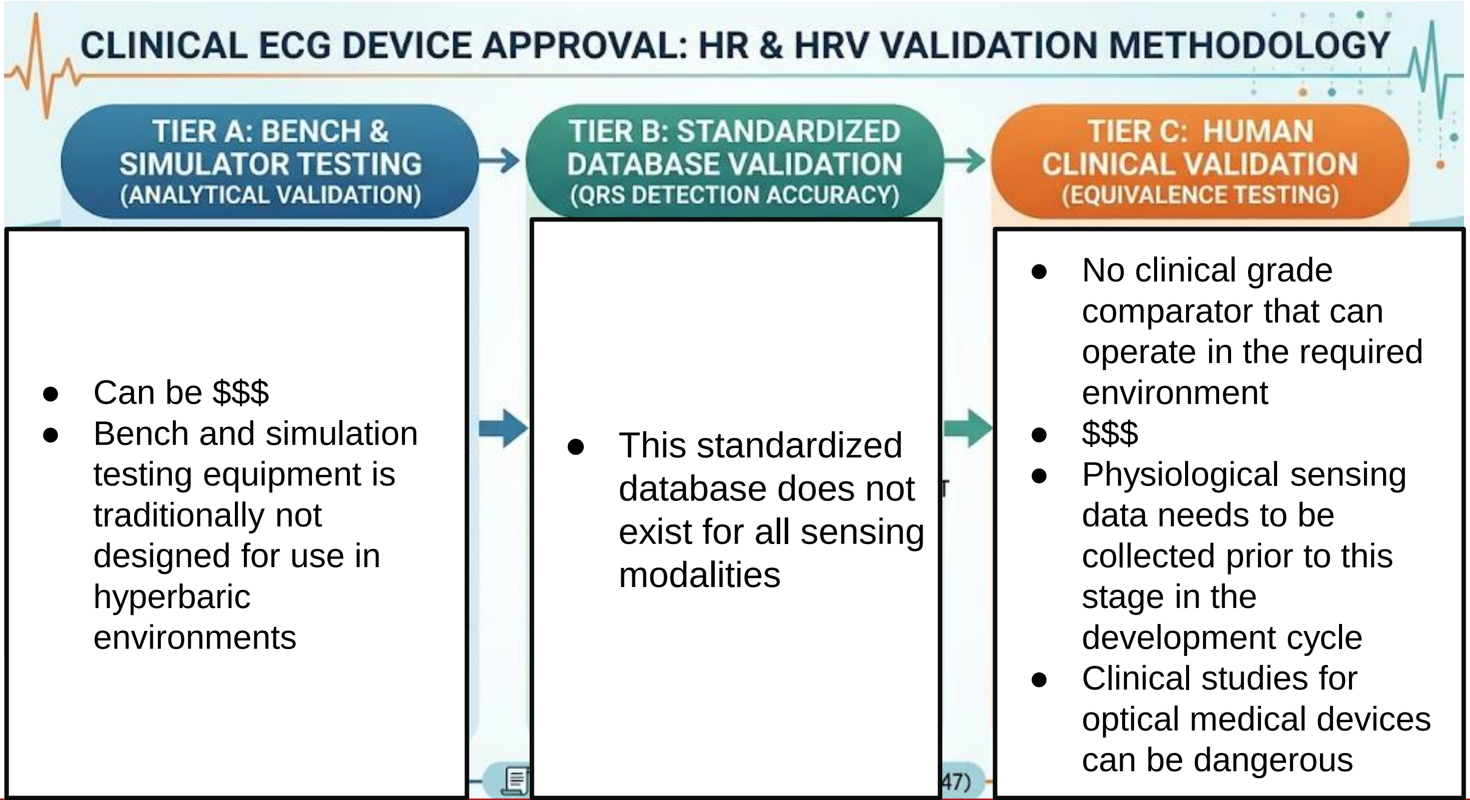
Goal = Clinical Grade Accuracy, Start with Clinical Standards



The Evaluation Criteria & Challenge

Goal = Clinical Grade Accuracy, Start with Clinical Standards

Expanding this beyond ECG



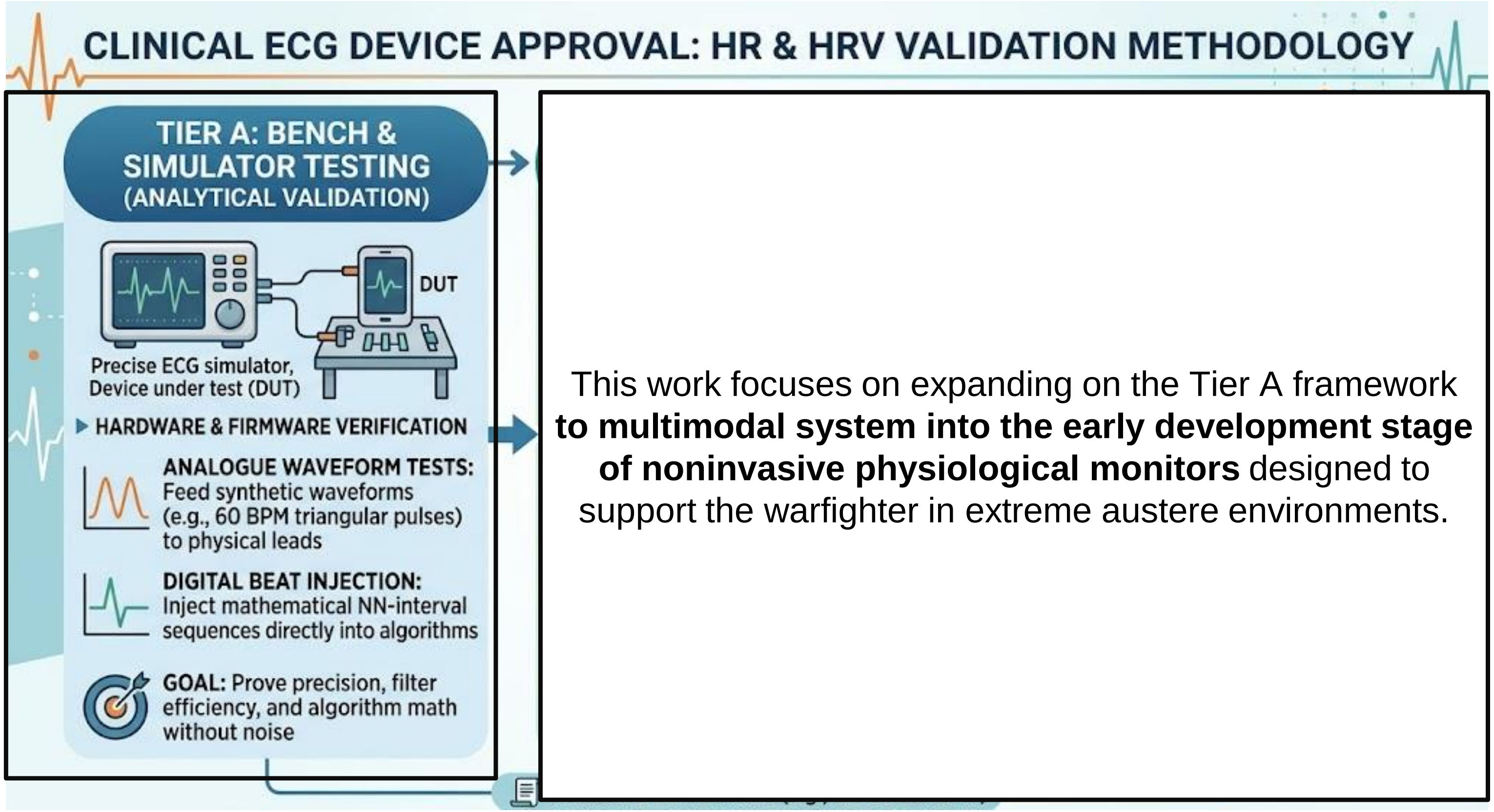
- Can be $$$
- Bench and simulation testing equipment is traditionally not designed for use in hyperbaric environments

- This standardized database does not exist for all sensing modalities

- No clinical grade comparator that can operate in the required environment
- $$$
- Physiological sensing data needs to be collected prior to this stage in the development cycle
- Clinical studies for optical medical devices can be dangerous

The Evaluation Criteria & Challenge

Goal = Clinical Grade Accuracy, Start with Clinical Standards

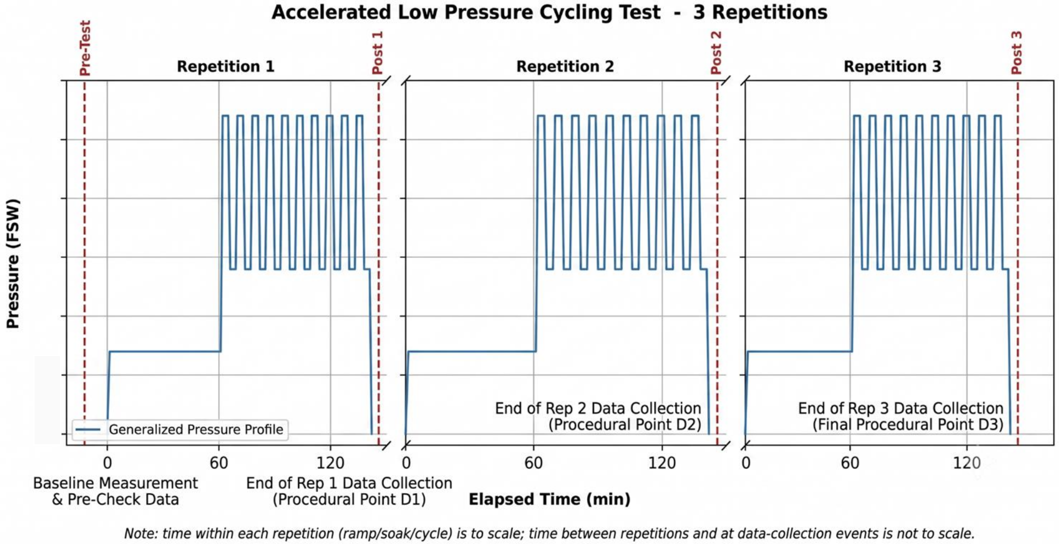


This work focuses on expanding on the Tier A framework **to multimodal system into the early development stage of noninvasive physiological monitors** designed to support the warfighter in extreme austere environments.

IMS Hyperbaric Battery Testing

- Is the IMS device safe?
- Battery P/N: RJD3048HPPV30M (UL 1624 and UN 38.3 Compliance)
- NEWARE Battery Testing System
  - Battery Temperature and Thickness provide insight into pressure experienced inside the housing
  - DCIR and Charge Cycling are key indicators of a battery’s health
- Unmanned testing (compliance and safety) are also critical in the early development of dive monitoring systems

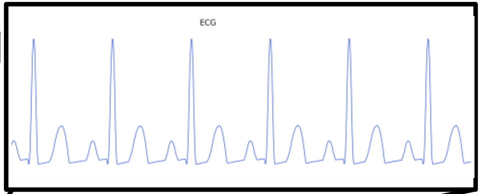
Test	Acceptance Criteria
Battery Thickness	<5.7mm <266 °F (130 °C)
Battery DCIR Test	<700mΩ
Battery Capacity	>285 mAh total capacity <5% change

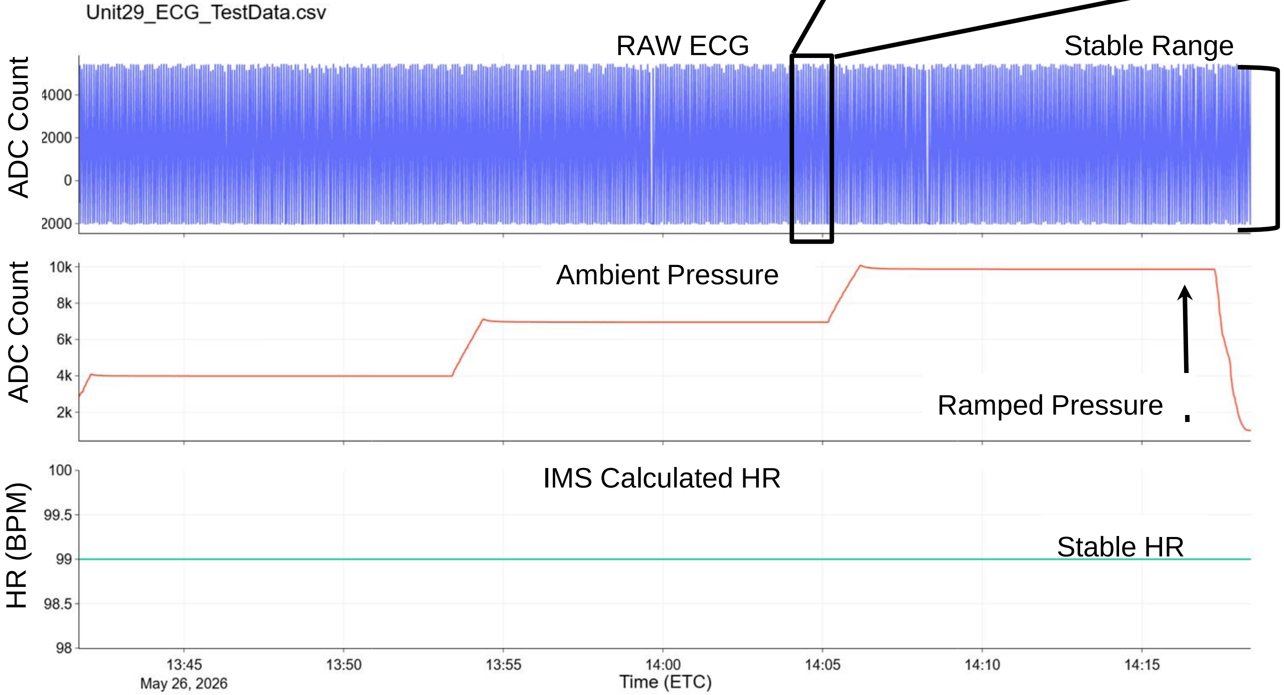


IMS Hyperbaric ECG Testing

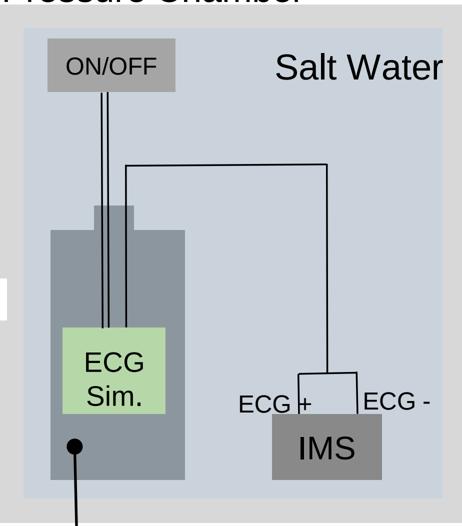
- IMS on-board data, retrieved post test

Clear QRS

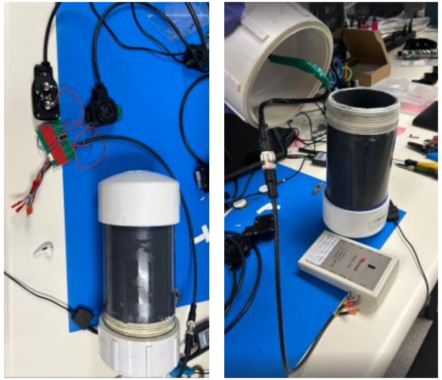




Pressure Chamber



PVC Pressure Housing



IMS Hyperbaric Optical Testing

- SR200 spectrometer (pre/post pressure exposure)
  - Spectral shape
  - Peak wavelengths and bandwidth
  - Power and irradiance levels
  - Stability over time and temperature
- Custom Fixture
- 8 Hour Pressure Soak, 10 cycles

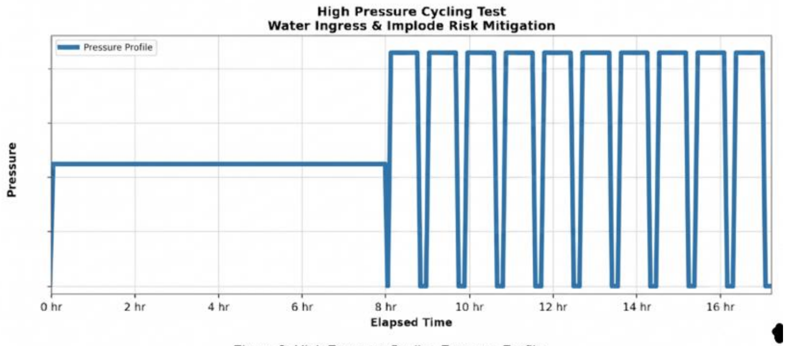
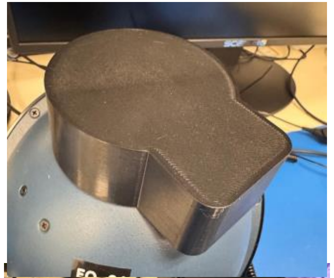


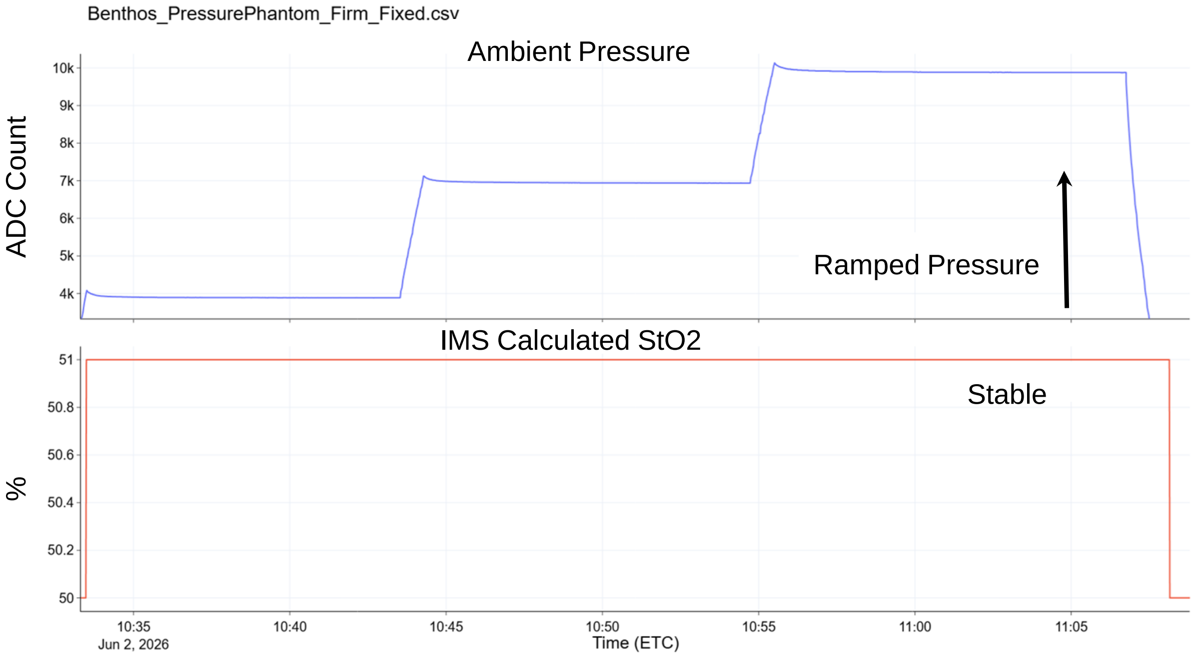
Figure 3: High Pressure Cycling Pressure Profile

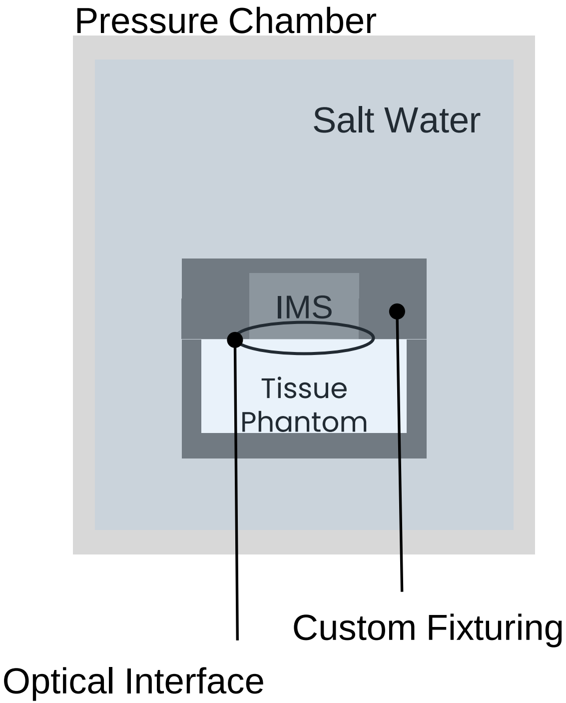
Peak Wavelength				
Device/Test	**Pre-Test Values**	**Post-Test Values**	**Acceptable/ Expected Range**	**% Change from Baseline**
DUT1: High Pressure Cycling	522.79 657.015 726.285 846.955 946.372	527.201 657.016 731.71 847.595 945.77	**OSRAM 535**: 520-540 **OSRAM 660**: 650-670 **Ushio 735**: 725-745 **Ushio 850**: 840-860 **OSRAM 940**: 930-950	-0.84% 0.00% -0.75% -0.08% 0.06%
Peak Irradiance				
Device/Test	**Pre-Test Values**	**Post-Test Values**	**Acceptable/ Expected Range**	**% Change from Baseline**
DUT1: High Pressure Cycling	229.286 337.187 141.075 123.465 165.709	216.767 350.058 132.192 120.627 163.996	<25% decrease from baseline	-5.46% 3.82% -6.30% -2.30% -1.03%



IMS Hyperbaric Optical Testing

- IMS on-board data, retrieved post test





Testing Summary

Additional Testing

- Expand the range of static simulator and phantom outputs
- Repeat in a temperature chamber

Limitations

- Static simulator and phantom outputs
- ECG Tissue/Electrode Interface
- Static environment

Testing Goals and Takeaways

➤ Integrate this testing as early in the IMS development cycle as possible, implementing traditional and inexpensive characterization methodologies where possible

➤ The development of these devices in extreme austere environments requires additional engineering efforts beyond the sensor design itself

➤ Isolate device-level performance from physiological confounds

➤ De-risk the development of this device

Why It Matters to the Warfighter

Environmental

- Cold water
- Depth/Pressure
- Hypoxia/Hypercapnia

+

Operational

- Heavy exertion
- High task loading
- Negative static lung load

=

Severe Events

- Immersion Pulmonary Edema
- Decompression sickness
- Hypoxic Blackout

- The IMS is designed to collect, process, and store accurate, quantitative physiological metrics to provide a holistic view of a diver's physiological state.
- Such monitoring could provide insight into the triggers of these diving mishaps, enable the prediction of the onset of dangerous and potentially fatal complications, and potentially provide an early warning to the diver, diving buddy, or topside personnel before mishaps occur.
- The IMS advances the **state of the art in ruggedized multimodal subsea physiological monitors**
  a. With a development goal of maintaining **measurement fidelity throughout representative hyperbaric and thermal stress**
- Engineered for **low cognitive burden and minimal obtrusiveness** in austere environments

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Thank You

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