UNCLASSIFIED

Sempulse Halo: Operator Validation, HaloCRM Development, and Hemodynamic Status for Triage Integration across the SOF Community

K. Stump - Sempulse® Corporation, V. Convertino, PhD - USAISR | Abstract MHSRS-26-5485 | Session: New Sensor & Algorithm Technologies to Improve & Support Monitoring, Triage, & CCC

Sempulse Halo Platform

FDA-Cleared, Durable, Non-Invasive Vital Signs

FDA-Cleared for use in military field trauma settings:

SpO_2 | PR | RR | T_{core} | T_{skin} | Motion

Under FDA Review or In Development:

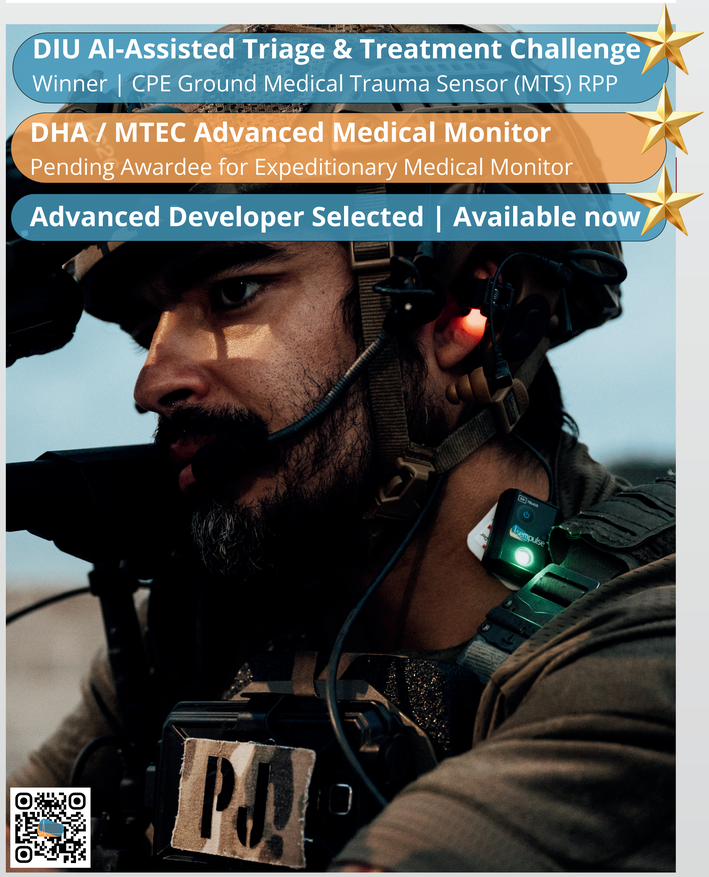
CRM | NIBP | ECG | SCG | Triage | AI

- 17 grams — fits in an IFAK
- Back of earlobe + neck over carotid
- IP67, MIL-STD-810, -40°F to 158°F operating temperature
- Up to 110 hour battery, Reusable, 1 Gbit storage for DDIL
- All Fitzpatrick skin types validated
- Compatible with helmets, Peltors, eyewear, armor, full kit
- Applies in under 10 seconds with a gloved hand

DIU AI-Assisted Triage & Treatment Challenge
Winner | CPE Ground Medical Trauma Sensor (MTS) RPP

DHA / MTEC Advanced Medical Monitor
Pending Awardee for Expeditionary Medical Monitor

Advanced Developer Selected | Available now



MASCAL 9-Line MEDEVAC via Sempulse Halo Comparison

28 min → 4.7 min

Naval Medical Forces Pacific (NMFP) MASCAL 9-Line MEDEVAC 3-casualty scenario
(n=22 NSW Level 3 TCCC medic exercise, Strategic Operations, San Diego; 9/4/2025; operationally timed)

Manual DD 1380	28.0 min avg	28 min
Halo + LiveCharts	4.7 min avg	4.7 min

NMFP has confirmed Halo data flowing bidirectionally between BATDOK-J and MHS Genesis.

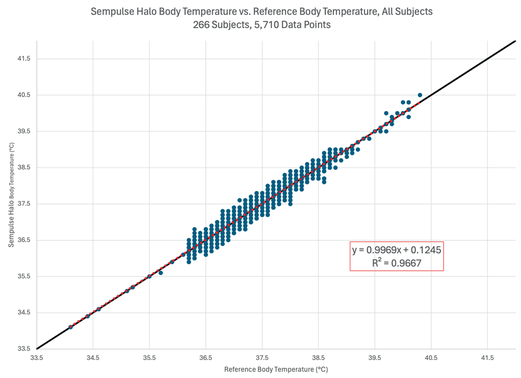
Operator Validation Across the SOF Community

Navy SEALs — Team 5 R&D design evaluation
Involved from early design stages. Guided ear sensor shape, sizing, fit, finish, and adhesive selection. Affirmed compatibility with Peltors, eyewear, and full kit with no interference to any issued equipment.

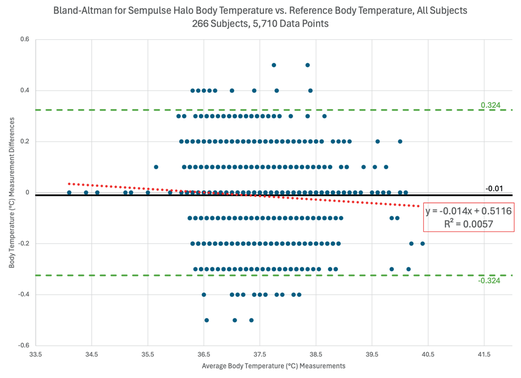
RDAX 2023 — multi-domain field evaluation (n=266, 3 phases)

- 266 subjects across 3 phases, including naturally febrile subjects.
- Running, obstacle courses, surf operations, CBRNE triage scenarios.
- Core body temperature: A_{RMS} 1.89 vs FDA-cleared CorTemp ingestible thermometers.
- Improved SpO_2 + pulse rate efficacy vs. reference Garmin watch general wellness devices.
- US Army field evaluation data provided to Sempulse; accepted under FDA 510(k) K232495.

All Subjects (266 Subjects, 5,710 Data Points): Sempulse Halo Body Temp vs. Reference Body Temp



Bland-Altman Plot for Sempulse Halo Body Temp vs. Reference Body Temp for All Subjects



Sempulse Halo Core Body Temperature vs. Reference Core Body Temperature (°C)

# pts	5,710	Max diff	0.6
		Min diff	-0.6
A_{RMS}	1.89	LR Slope	0.997
Stand Dev	0.324	Y-Int	0.125

Sempulse Halo Core Body Temperature vs. Reference Core Body Temperature (°C)

# pts	5,710	Max diff	0.6
Mean Error	-0.010	Min diff	-0.6
Upper Limit	0.324	LR Slope	-0.014
Lower Limit	-0.324	Y-Int	0.512

PC-C5 — multi-unit evaluation
- Advantages: compact size, multi-vital capability, novel acquisition sites, multi-platform integration.
- Areas improved: application consistency, adhesive in high-sweat environments — all addressed.

Ivy Mass, Sword 2026, PC-C6 — soldier demonstration exercises
- HaloCRM and NIBP demonstrated with soldiers (both under FDA review).
- LiveCharts, BATDOK-J, NGC2, Rune TyrOS, Anduril Lattice Mesh and Army Edge integrations shown live.

CRM Algorithm

CRM is the only hemodynamic status metric with clinical utility.

Metric (n=191)	Youden's J Index
CRM	**0.62 - 0.73**
Pulse Pressure Variability	0.47
SpO2	0.40
Heart Rate	0.18
Systolic BP	0.03

HALO CRM®

Source: Convertino et al., Sensors 2020. Clinical utility threshold = >0.50 J Index.

Real-time CRM provides an average early prediction time of 18.3 minutes (±7.94 min) for hemodynamic decompensation.

Source: Ortiz et al., Experimental evaluation of a real-time implementation of compensatory reserve measurement in a human model of hemorrhagic shock. Front Bioeng Biotechnol. 2026 Apr 15. Validated on PPG-based pulse oximeter; Halo validation ongoing.

Sempulse Halo Integrations

- Sempulse Halo is now integrated into the current and future EUD systems in use and being tested by the DoW today.
- Average DoW System Integration Project Duration: 1.6 weeks
- Sempulse Halo is now integrated into legacy, current, and development medical, C2, and AI systems.
- Halo to NGC2 data flow confirmed.
- Halo to MHS Genesis data flow confirmed.

Conclusions

- Sempulse Halo improved the average time for a 3-casualty 9-Line MEDEVAC TCCC exercise from 28 to 4.7 minutes by eliminating manual processes.
- Sempulse Halo demonstrated clinically equivalent or better vital signs performance across active, diverse SOF operator populations.
- CRM is the only hemodynamic status metric with clinical utility, based upon Youden's J index scores.
- Halo data has been confirmed end-to-end from POI through simulated Role 4.
- Hemodynamic status, vital signs, cuffless blood pressure, and Class VIII resupply real-time data to C2 has been demonstrated and confirmed at multiple exercises.

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To learn more, visit:
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