# OxiWear: FDA-Cleared Ear-Worn Pulse Oximeter for Military Clinical Decision Support

OxiWear
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**FDA-cleared ear-worn continous $SpO_2$ and pulse rate measurements during motion for military operational and clinical environments.**

## BACKGROUND

**THE CHALLENGE**

- Military personnel frequently experience hypoxia and physiological deterioration during:
  - High-altitude operations
  - CASEVAC
  - En Route Care
  - Prolonged Field Care
  - Combat casualty care
- Current fingertip pulse oximeters are often unreliable because they are affected by:
  - » Motion
  - » Peripheral vasoconstriction
  - » Cold exposure
  - » Extremity injury
  - » Limited hands-free operation

## Why the Ear?

**FINGER VS EAR**



**Finger**

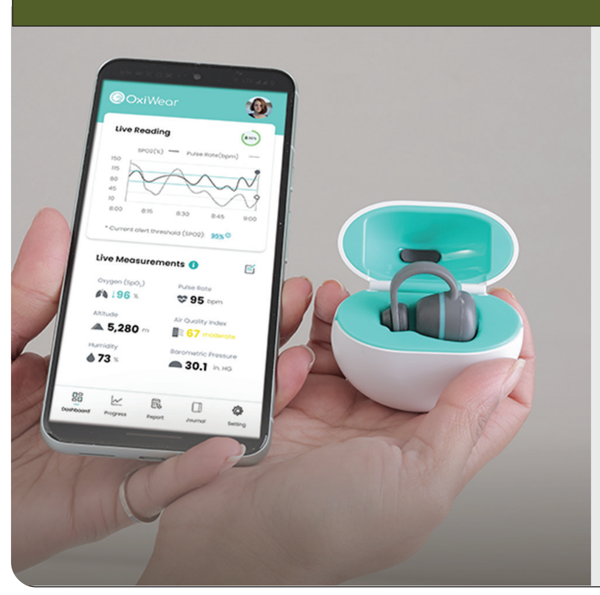
High motion artifact
Vasoconstriction
Hands occupied
Extremity injuries



**Ear**

Stable blood flow
Less affected
Hands-free
Preserved measurement

## OXIWEAR SOLUTION



- **FDA-cleared Class II medical device**
  - Continuous $SpO_2$ measurements
  - Continuous Pulse Rate measurements
  - Ergonomic ear-worn form factor
  - Ultra-lightweight (5.3 g) wearable
  - Real-time physiological alerts
  - Tactical platform interoperability
  - Validated across all skin tones

## VALIDATION

### Clinically Validated Performance

**ISO 80601-2-61 VALIDATION**

Workflow → → → → Role Study

**Desaturation Study**

UCSF Hypoxia Laboratory

- 24 healthy participants
- Arterial Blood Gas (ABG) reference
- $SpO_2$ Range: 70–100%

**Motion Study**

- 30 participants
- Rigorous Walk / Jog protocol
- Compared directly against Nellcor PM10N

### Results

| $SpO_2$ Accuracy | |
|---|---|
| No Motion $A_{RMS}$ | Motion $A_{RMS}$ |
| 3.42% | 1.74% |

| Pulse Rate Accuracy | |
|---|---|
| No Motion $A_{RMS}$ | Motion $A_{RMS}$ |
| 1.14 BPM | 3.62 BPM |

**VALIDATED ACROSS ALL FITZPATRICK SKIN TYPES**

## MILITARY APPLICATIONS

- **Point of Injury :** Continuous physiological assessment
- **CASEVAC :** Uninterrupted monitoring during transport.
- **En Route Care :** Supports critical medical decision-making
- **High Altitude Operations :** Earlier detection of hypoxia
- **Diverse Force :** Validated across all skin tones.
- **Low-Light Operations :** Objective $SpO_2$ measurement when cyanosis cannot be visually assessed.

## FUTURE INTEGRATION

OxiWear → BATDOK → CDP → JOMIS → Medical Command

## DEVELOPMENT STATUS

FDA Cleared → Commercial Deployment → TRL 6 → MIL-STD-810 Hardening → IP65 → Military Integration

## KEY TAKEAWAYS

**CONTINUOUS MEASUREMENTS**
Unlike spot-check pulse oximeters

**MOTION VALIDATED**
Reliable and resilient during movement and transport.

**EAR-WORN DESIGN**
Measurement integrity is preserved when hands or extremities are compromised.

**OPERATIONAL READINESS**
Seamlessly supports monitoring from point of Injury through en route care.

**CLINICALLY VALIDATED**
ISO 80601-2-61 compliant, FDA Cleared, and commercially available.