The Advantages of the Ear for Monitoring Physiological Readiness in Dynamic Conditions: Blood Pressure and Blood Flow

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SESSION: OPTIMIZING THE HUMAN WEAPON SYSTEM: UTILIZING WEARABLE SENSOR DATA TO INFORM READINESS

Disclaimers & Financial Support

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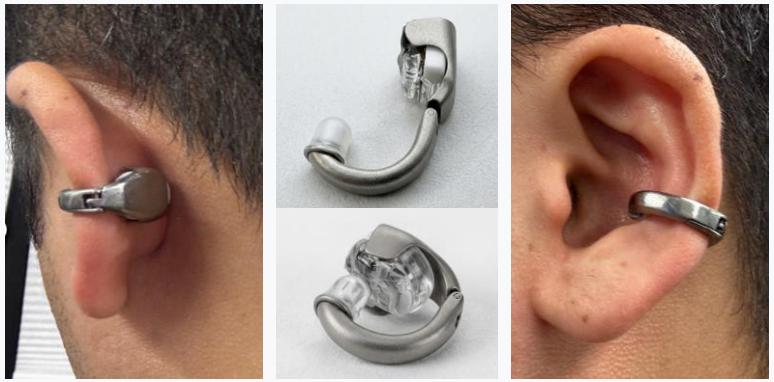
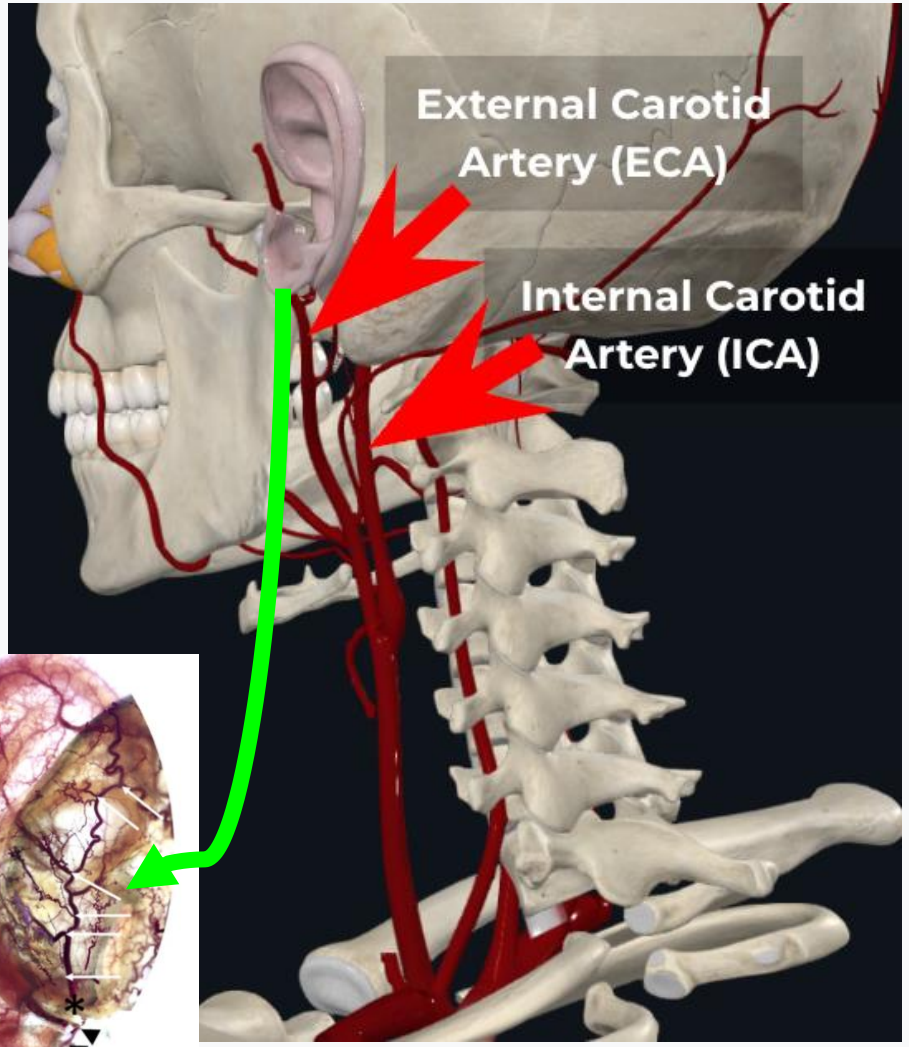
LUMIA™ MGH 1811 MASSACHUSETTS GENERAL HOSPITAL HARVARD MEDICAL SCHOOL AFWERX

Targeting External Carotid Artery via Behind-Ear Sensor

Lumia: Infrared optical sensing of blood flow in the External Carotid Artery (ECA)

As close as possible to the brain and heart, non-invasively.





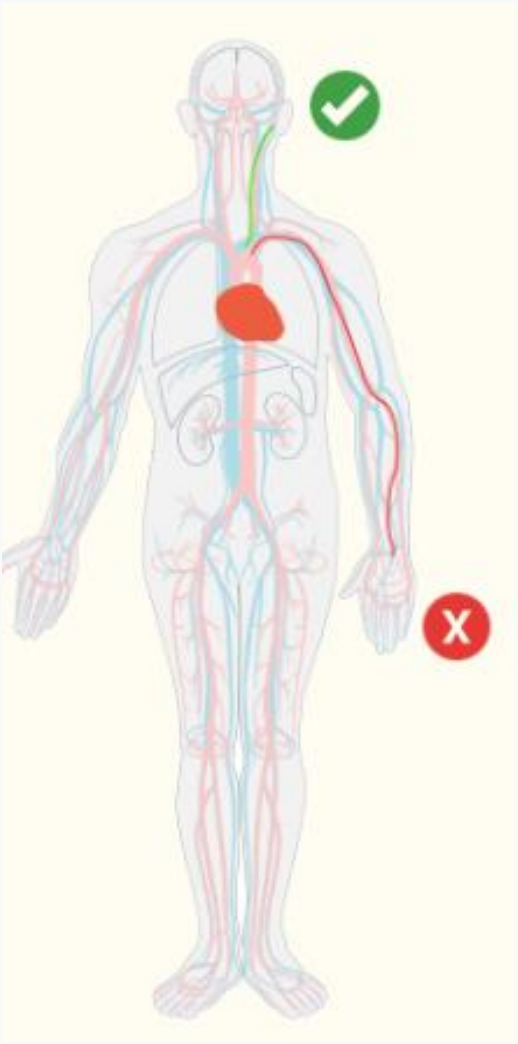
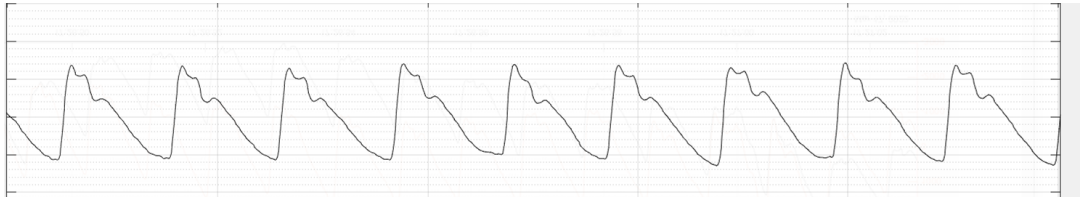


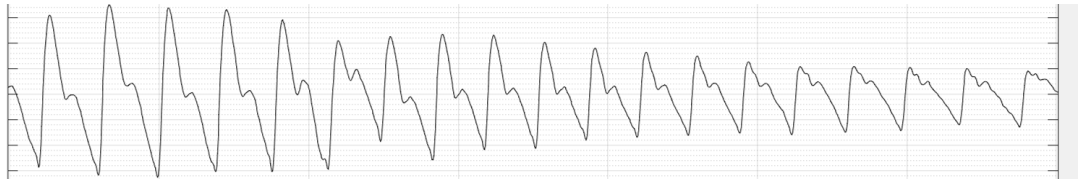
Image credit: Adapted from Zilinsky et al., 2016.

Shallow Ear Arteries Provide Unrivaled Cardiac Signal

Ear (Lumia Approach)

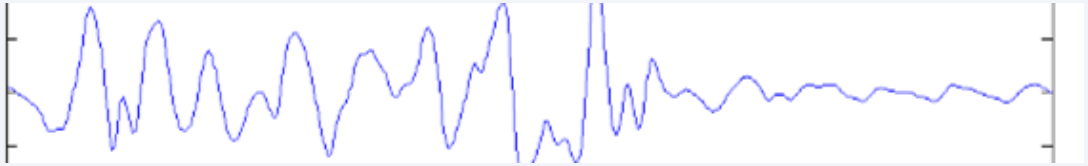
- **Arterial Signal** (Infrared)
- **Consistent Person-to-Person Quality**
- **Superior Data Continuity** (>95% Daily)
- **Information-Rich Signal (Blood Pressure, Blood Flow, etc)**

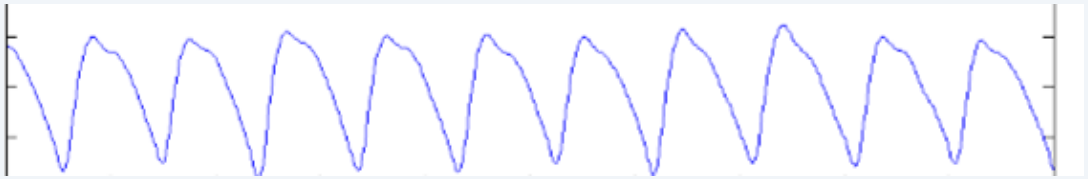




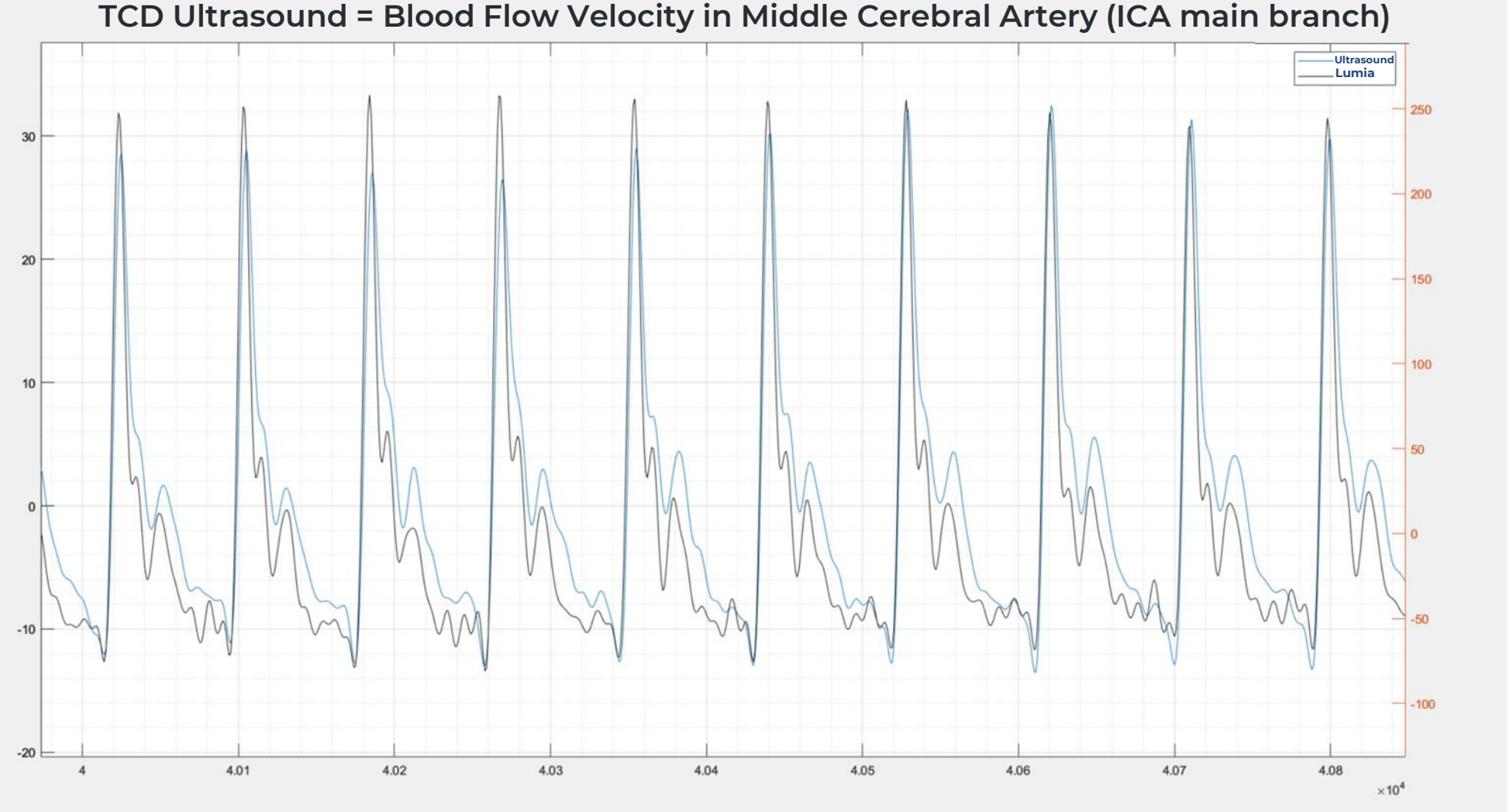
Wrist (Conventional)

- **Capillary Signal** (IR Unusable)
- **Variable Person-to-Person Quality**
- **Poor Data Continuity** (<50% Daily)
- **Limited-Information Signal (just HR/HRV)**

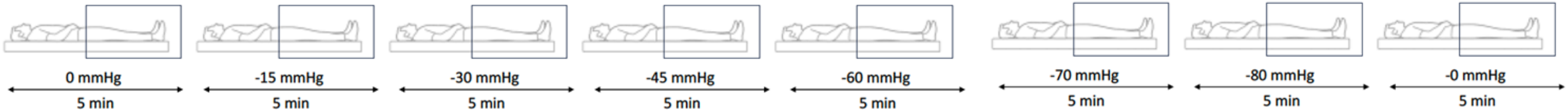




Ear ECA and Brain ICA Have Strikingly Similar Morphology

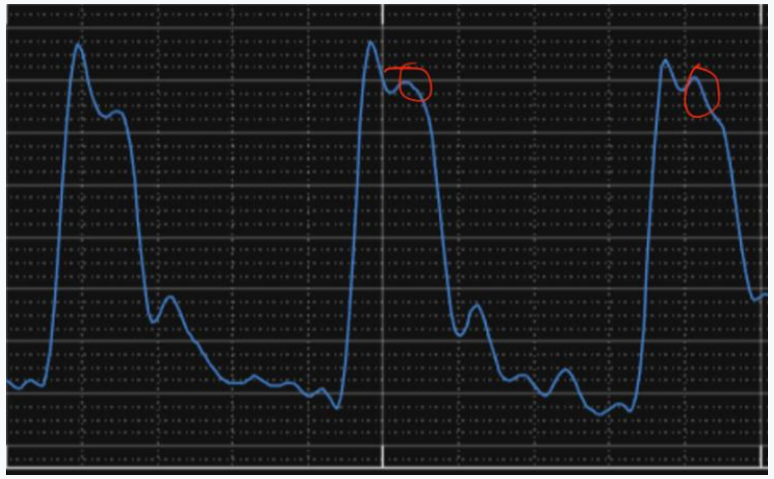


Study Design: Session 1



Primary Feature for Ear-Based Blood Pressure

High P2/P1 Ratio → Higher Systolic BP



Low P2/P1 Ratio → Lower Systolic BP

**Multiple Patents Granted & Pending*

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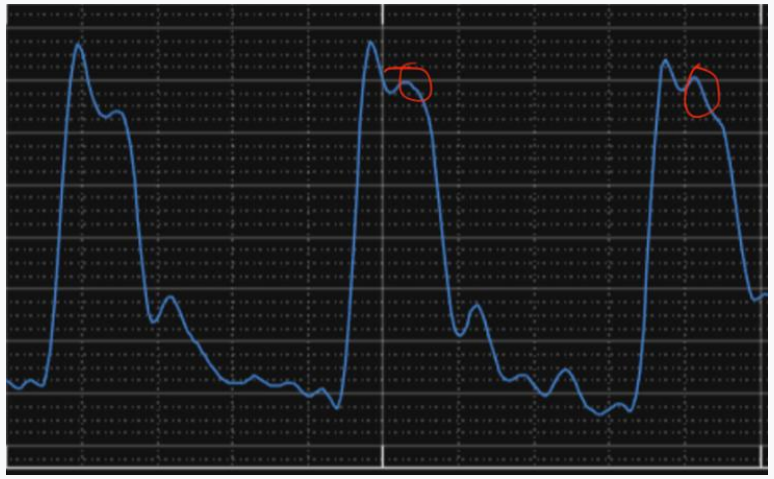

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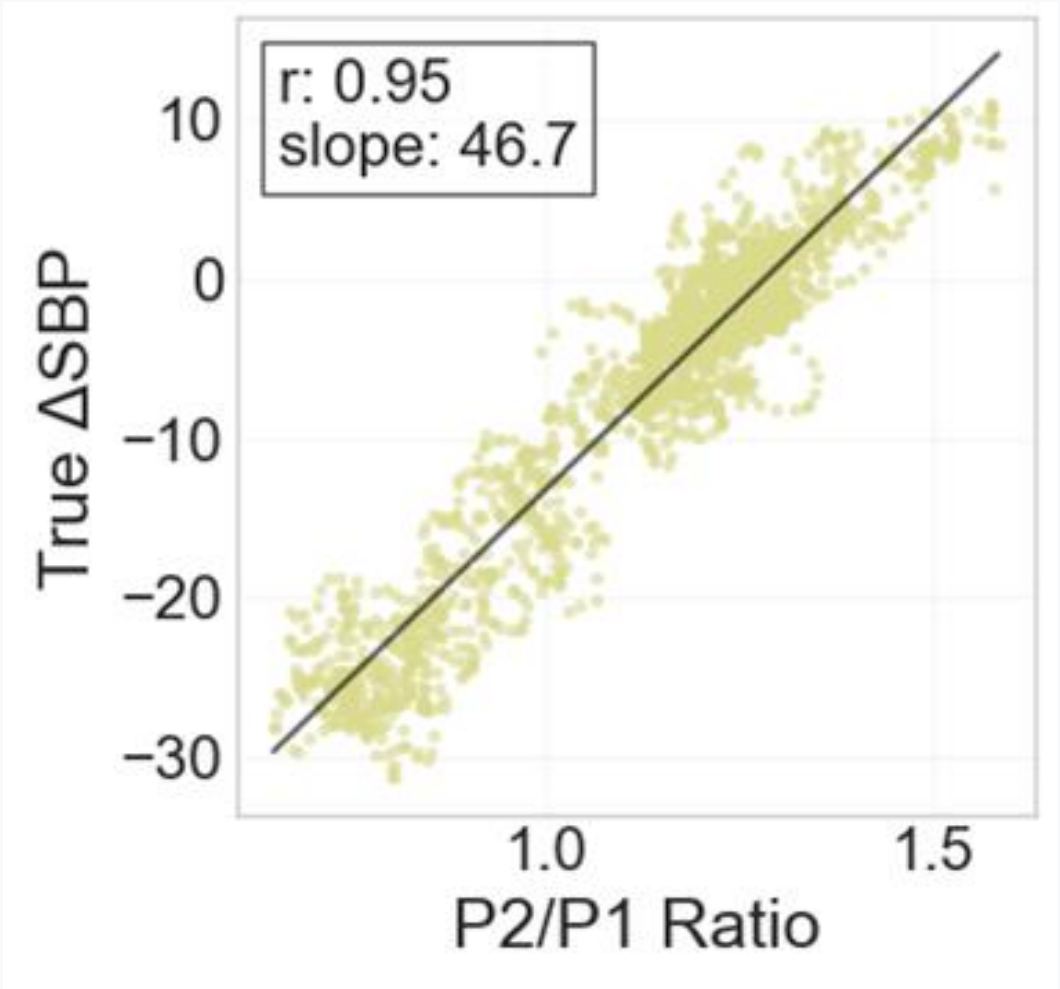

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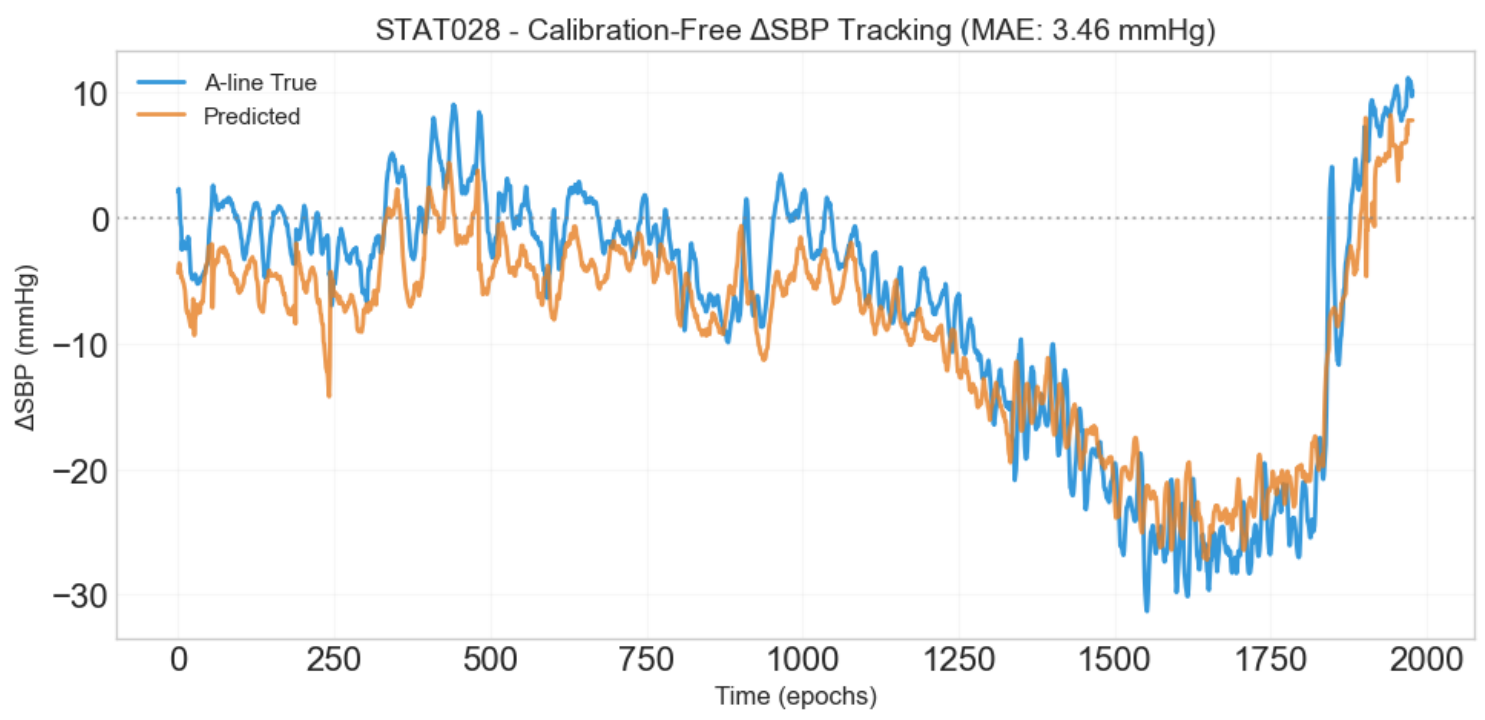
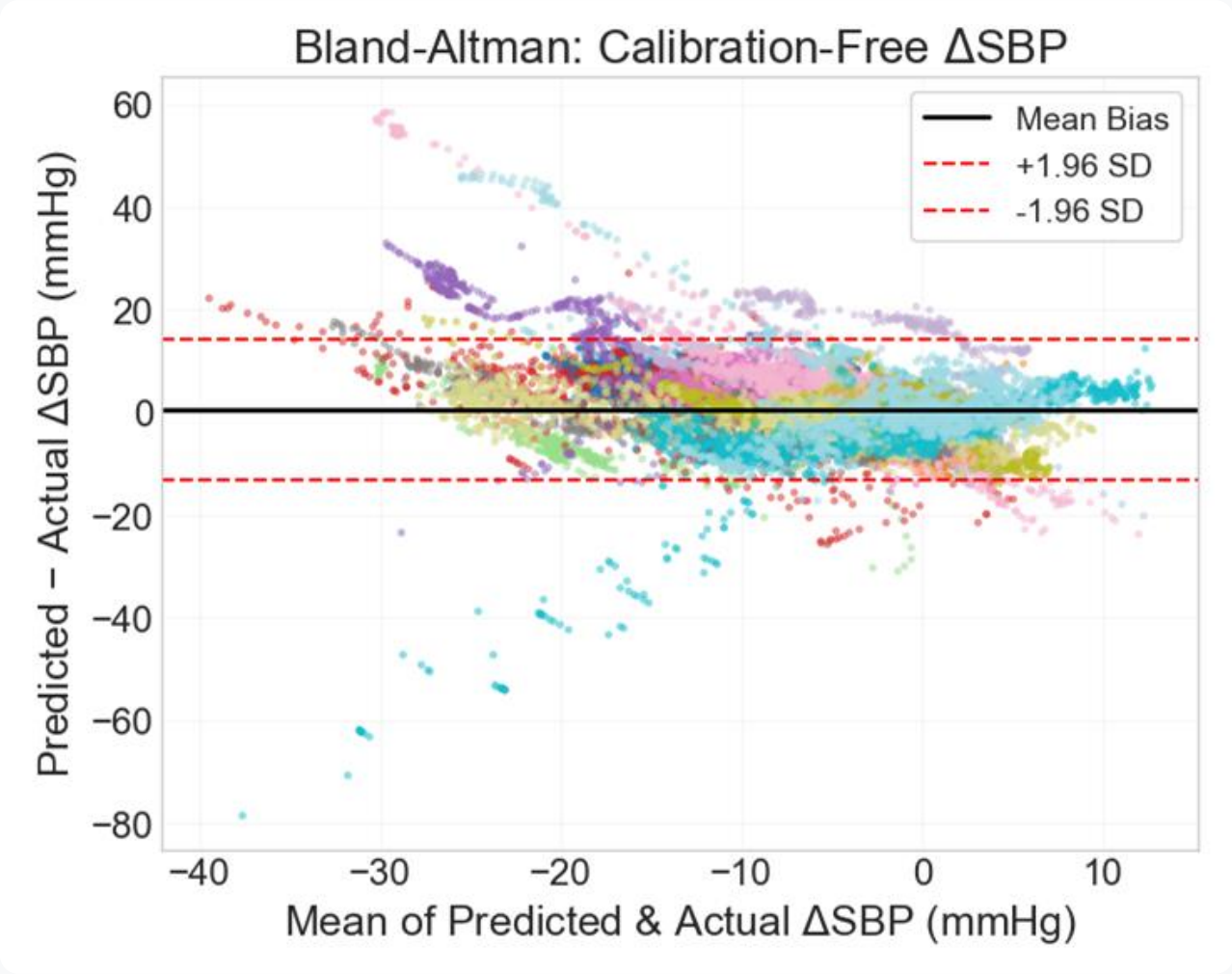
Real-Time ΔSBP Tracking: Representative Subject



- Continuous, beat-to-beat ΔSBP prediction tracks arterial line ground truth throughout the full LBNP protocol
- Subject MAE: 3.46 mmHg
- Demonstrates the clinical utility of a calibration-free, wearable-ready algorithm for continuous hemodynamic monitoring

Bland-Altman Analysis: FDA/AAMI Criterion 1 — PASS



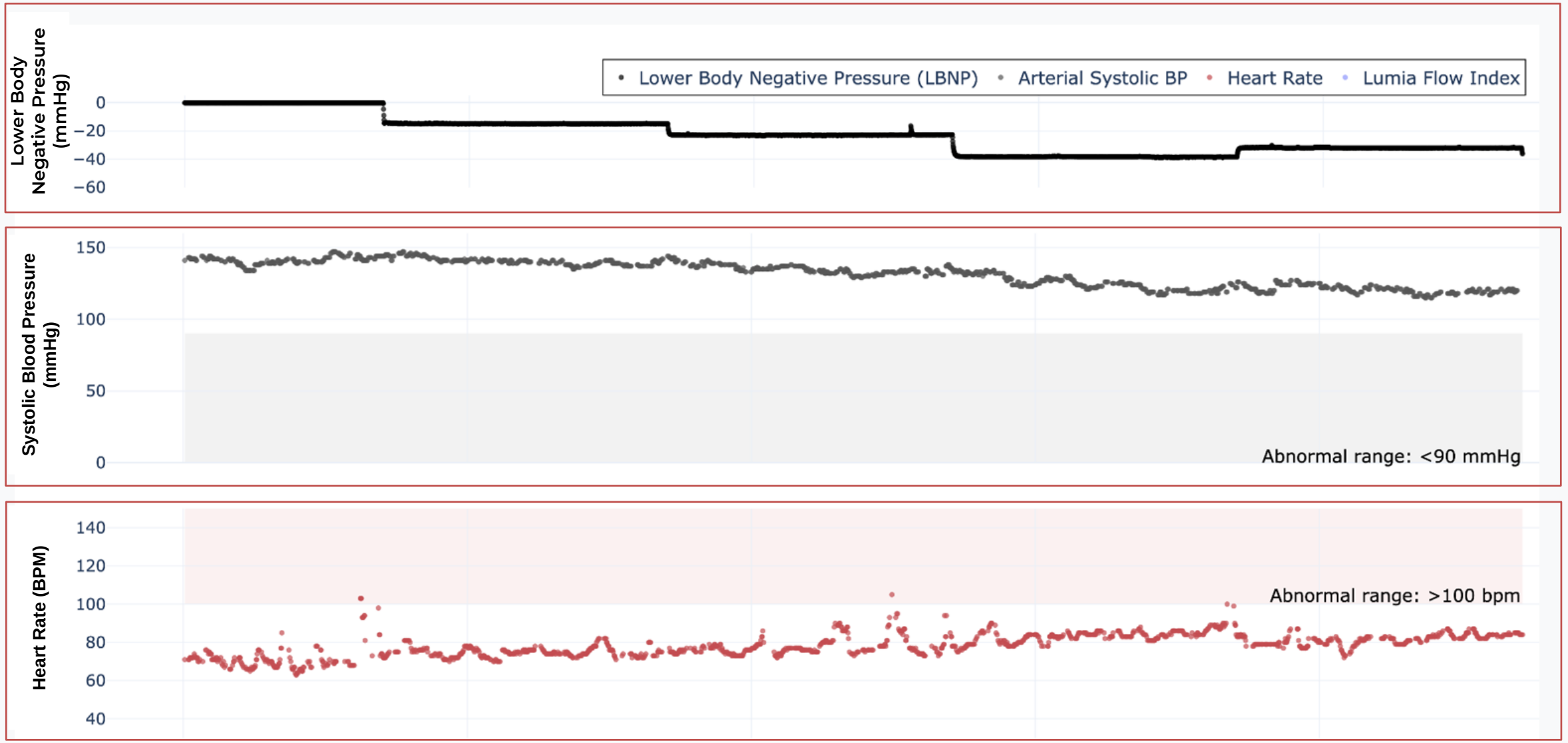
KEY VALIDATION RESULTS

Mean Bias: +0.42 mmHg ✓

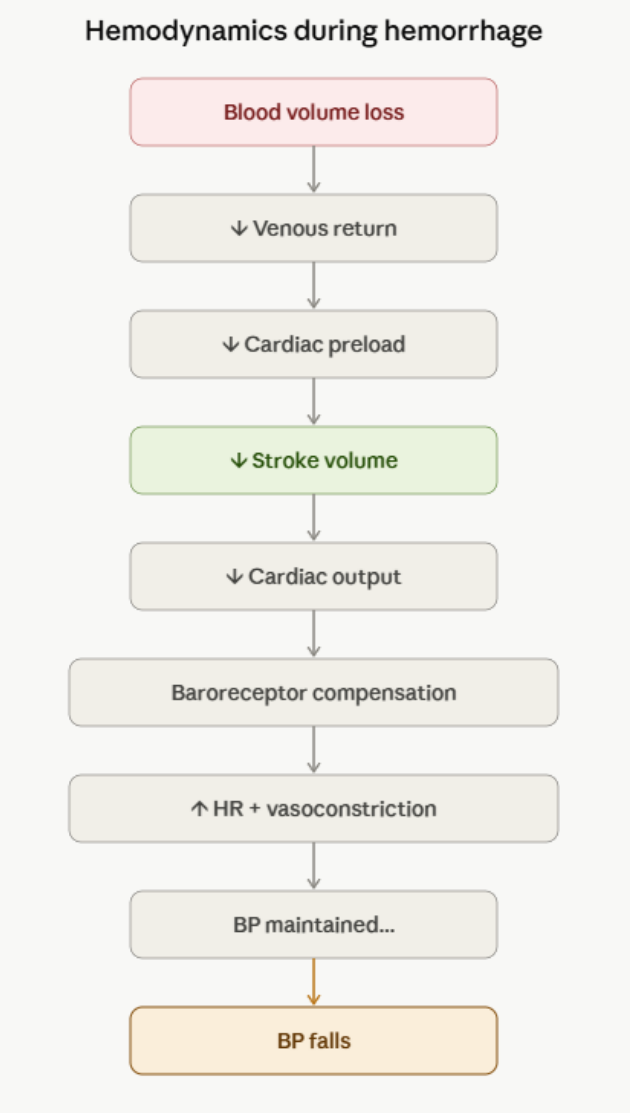
SD of Bias: 6.99 mmHg ✓

- Limits of Agreement: [−13.29, +14.13] mmHg
- No systematic proportional bias observed (uniform scatter across range)
- Meets ANSI/AAMI/ISO 81060-2 statistical accuracy thresholds
- Validated in a proof-of-concept cohort ensuring high reliability

No Clinically Significant Drop in Blood Pressure?!



What Happens During Hemorrhage?



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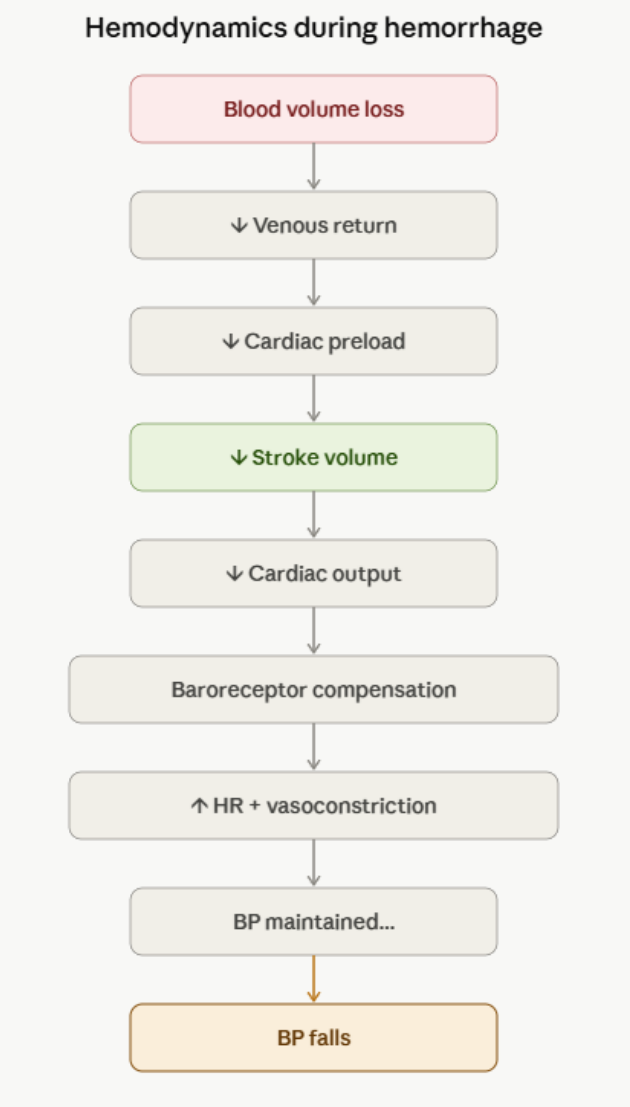

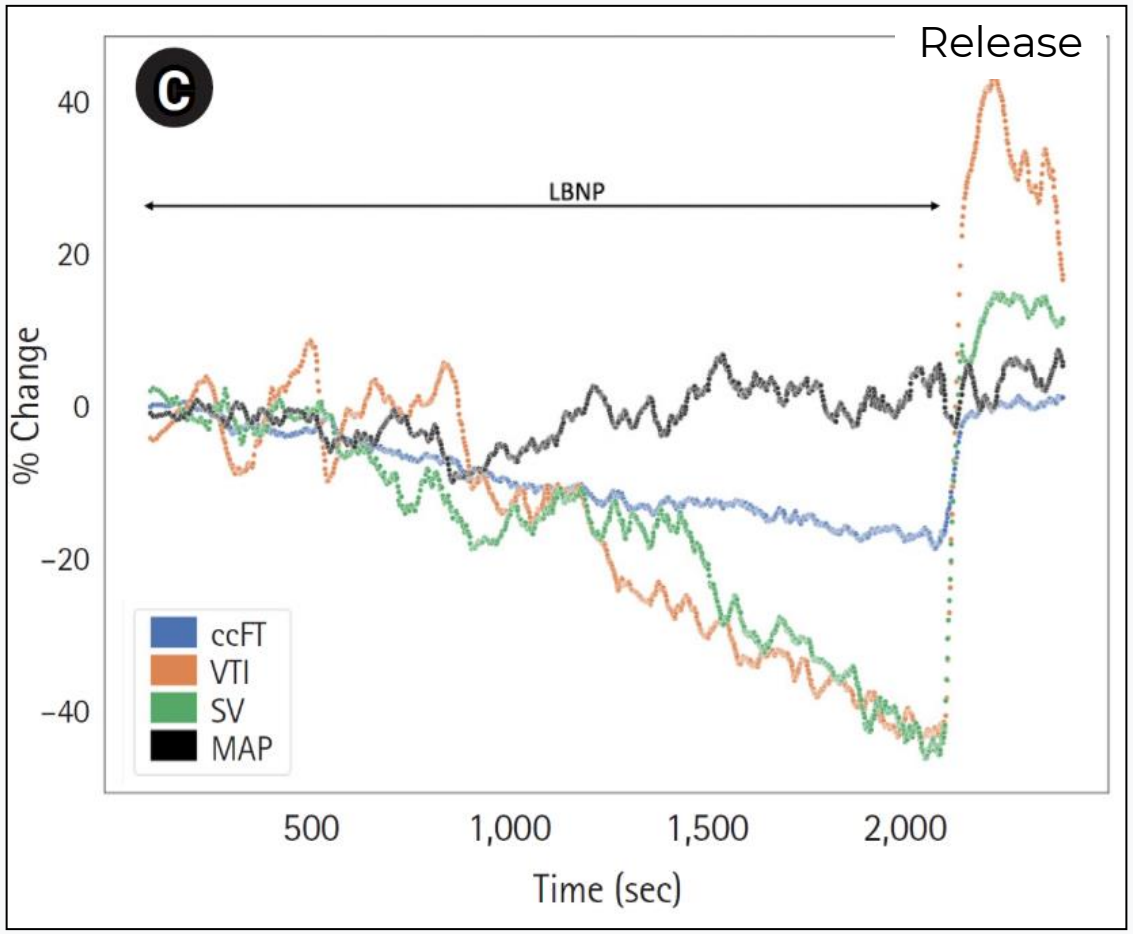

Mean Arterial Pressure (MAP) is a lagging indicator of hemorrhage compared to flow time

Photo Credit: Reproduced from *Acute and Critical Care*, 2024;39(1):162-168. DOI: https://doi.org/10.4266/acc.2023.01095

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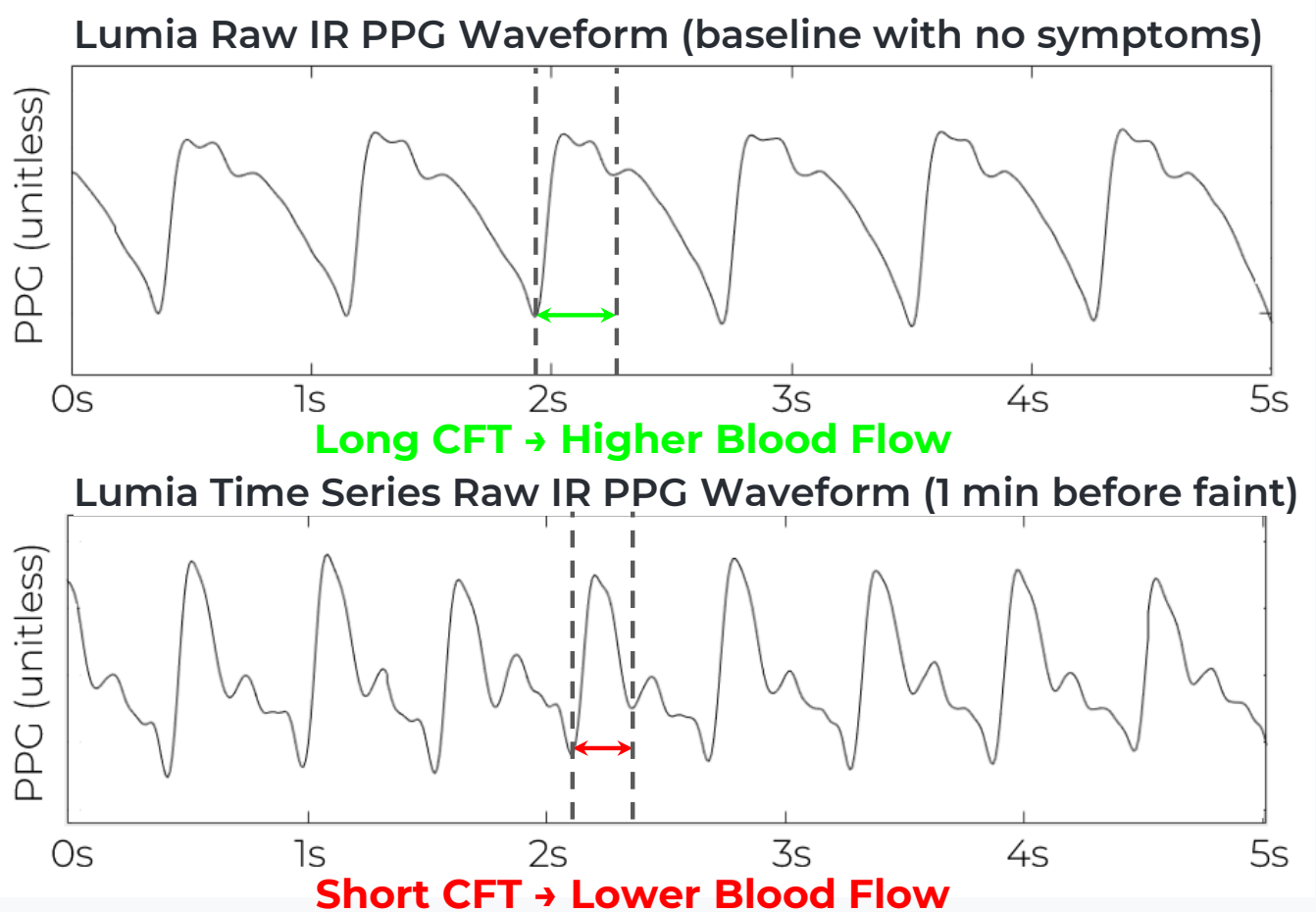

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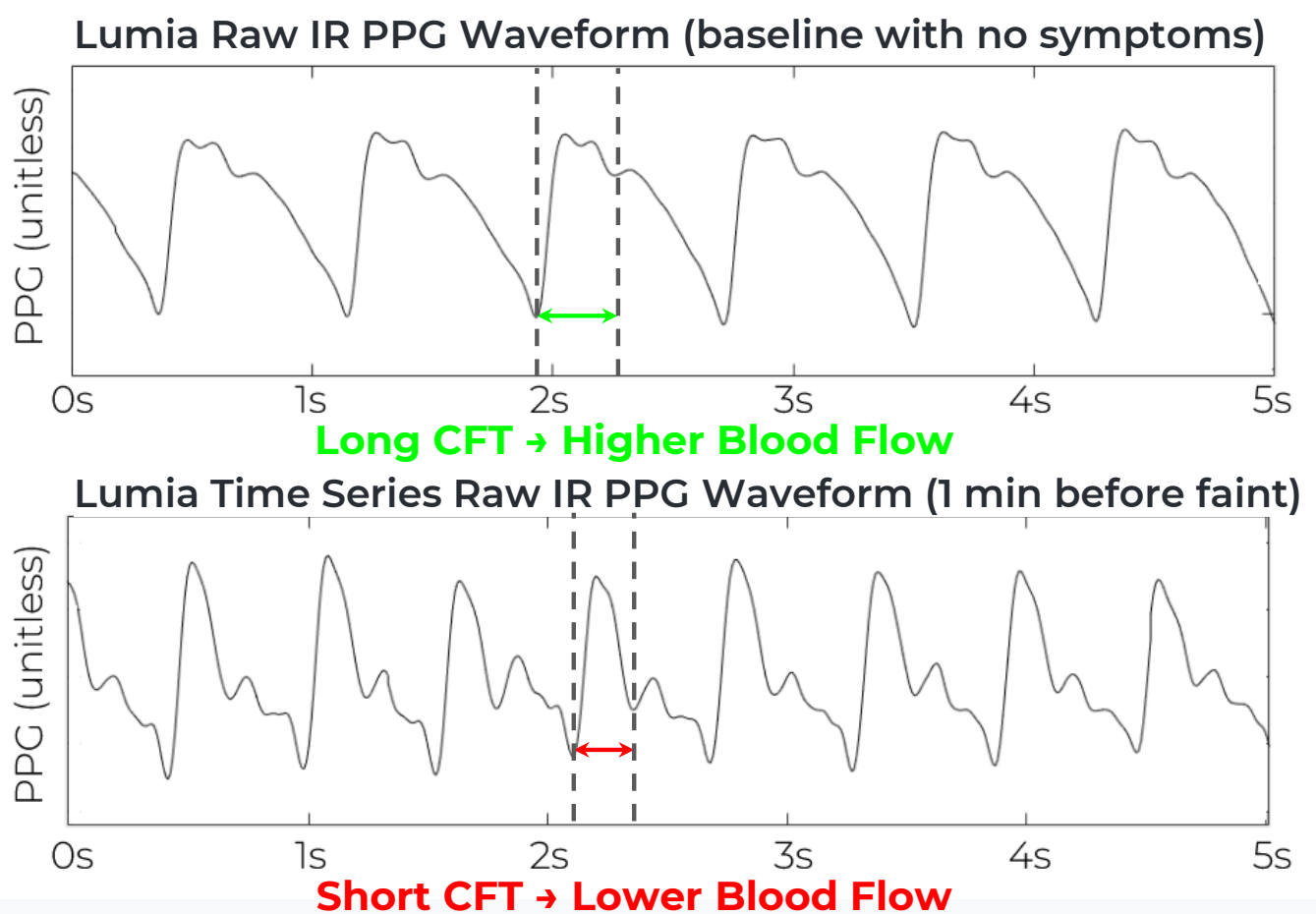

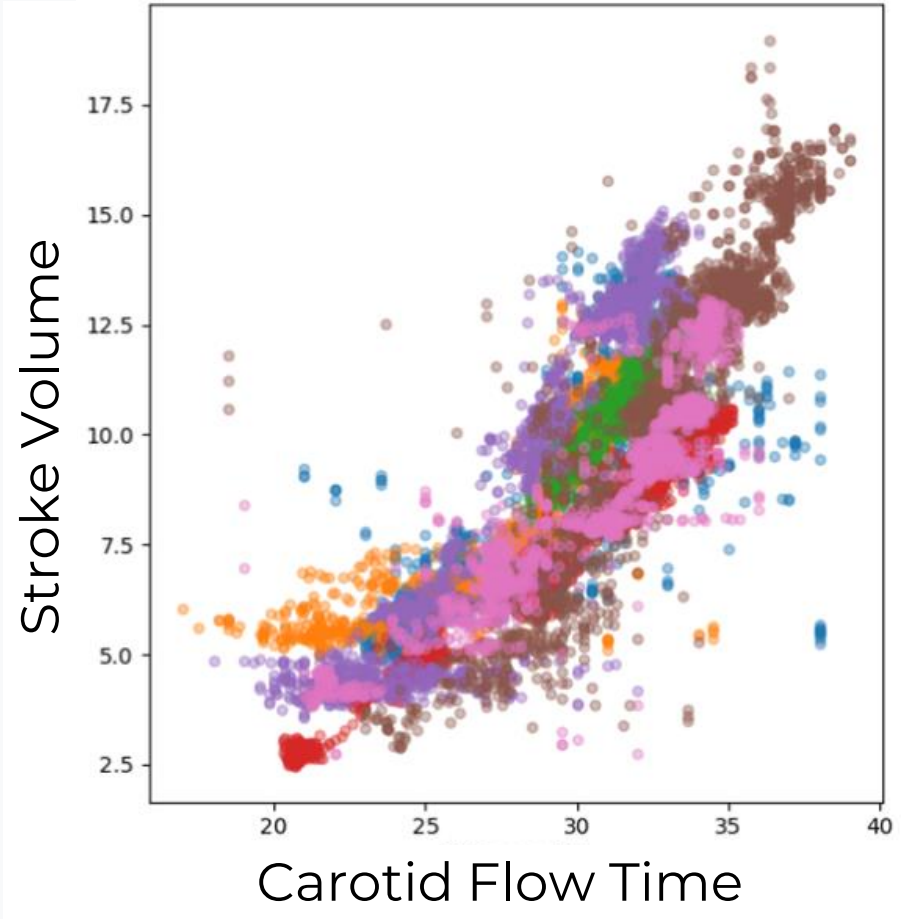

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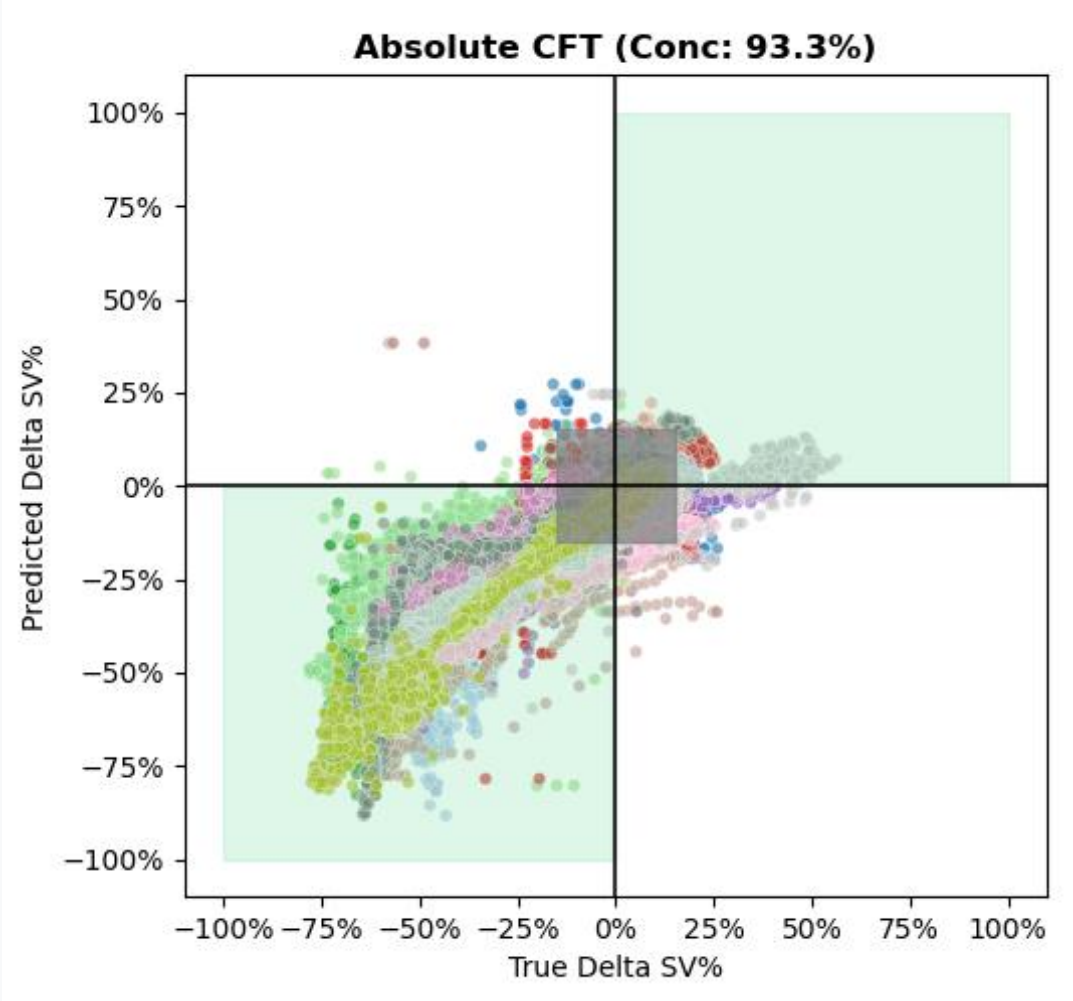
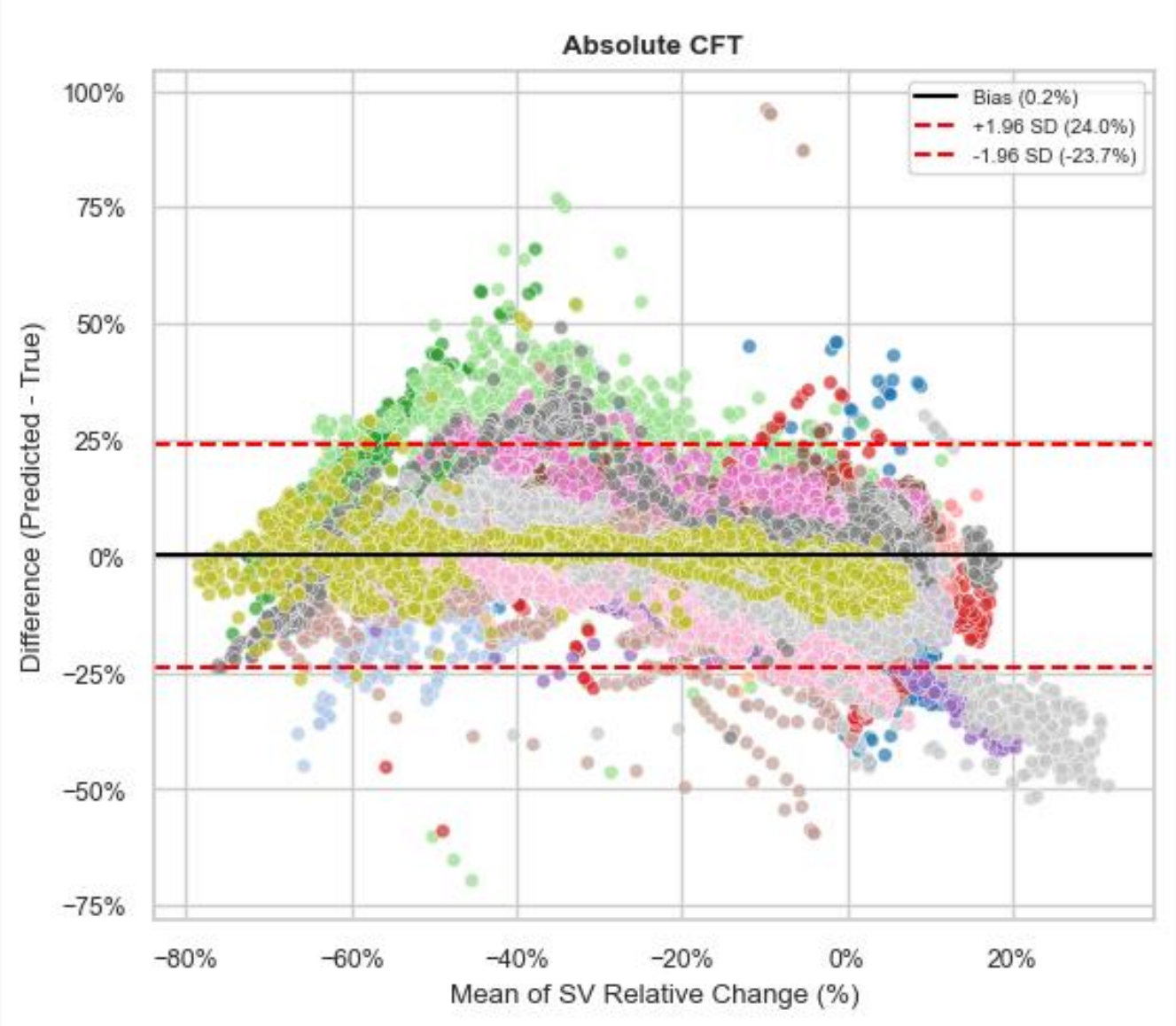
CFT is a Strong Predictor of Reduced Stroke Volume

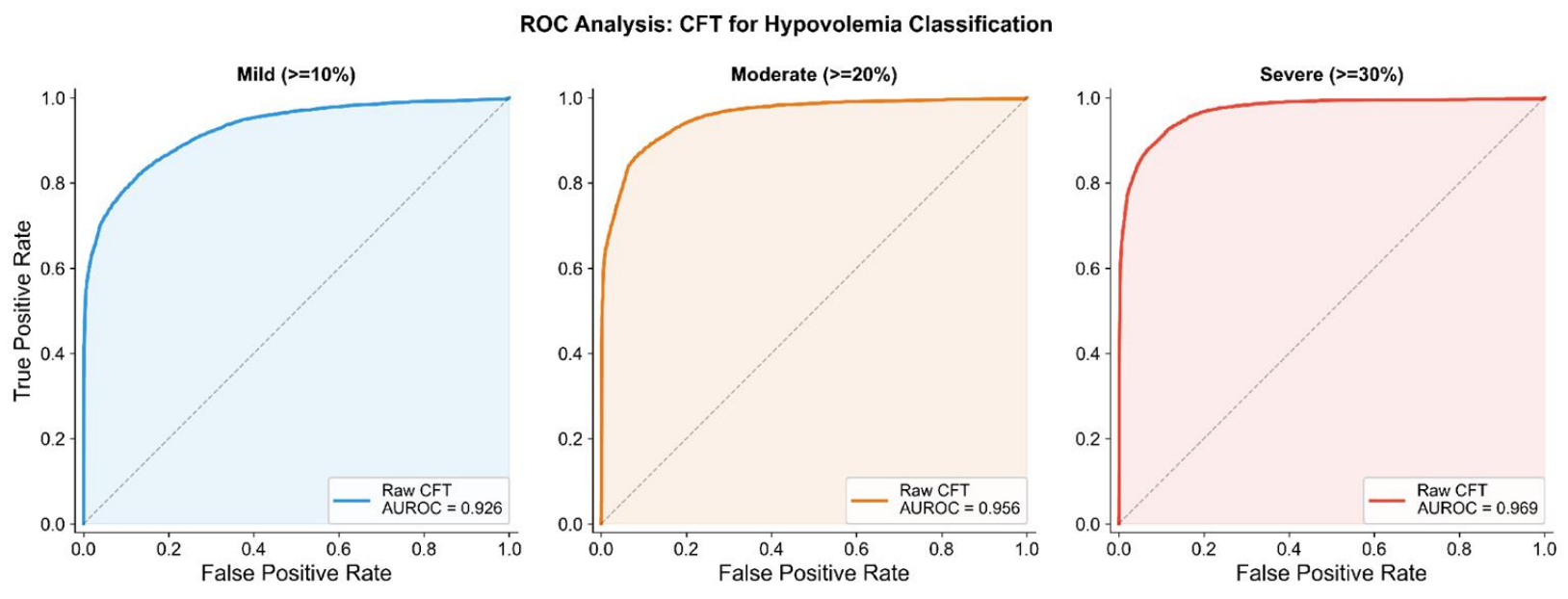
4-Quadrant Concordance Tracking
(15% Exclusion Block)



CFT-derived SV Changes Have Strong Agreement with Invasive A-line

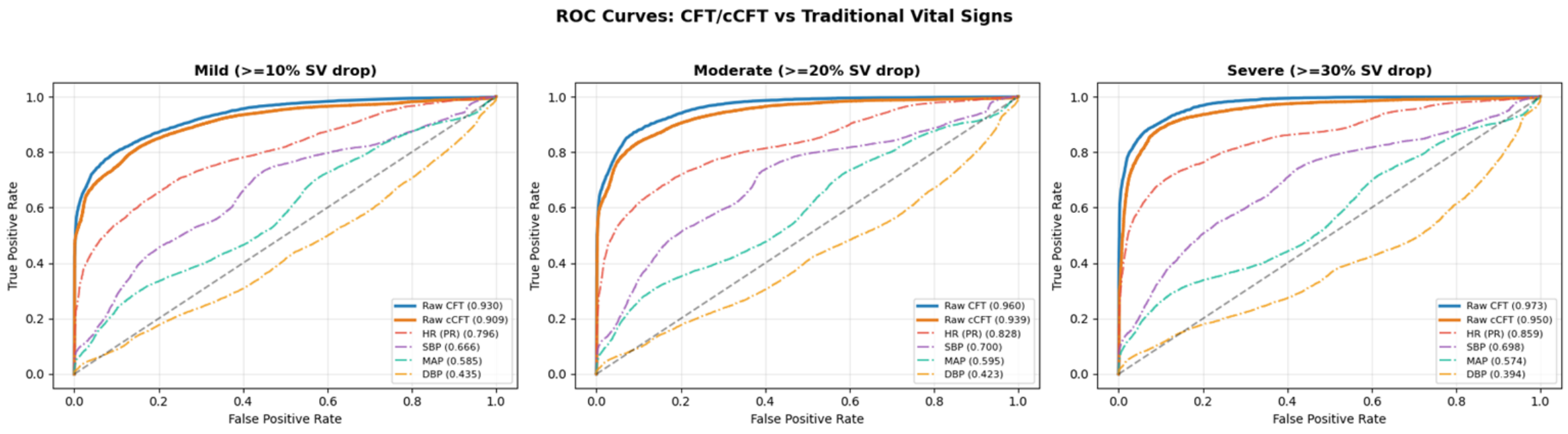


Initial Results: CFT Discriminates Hypovolemia Severity with High Accuracy

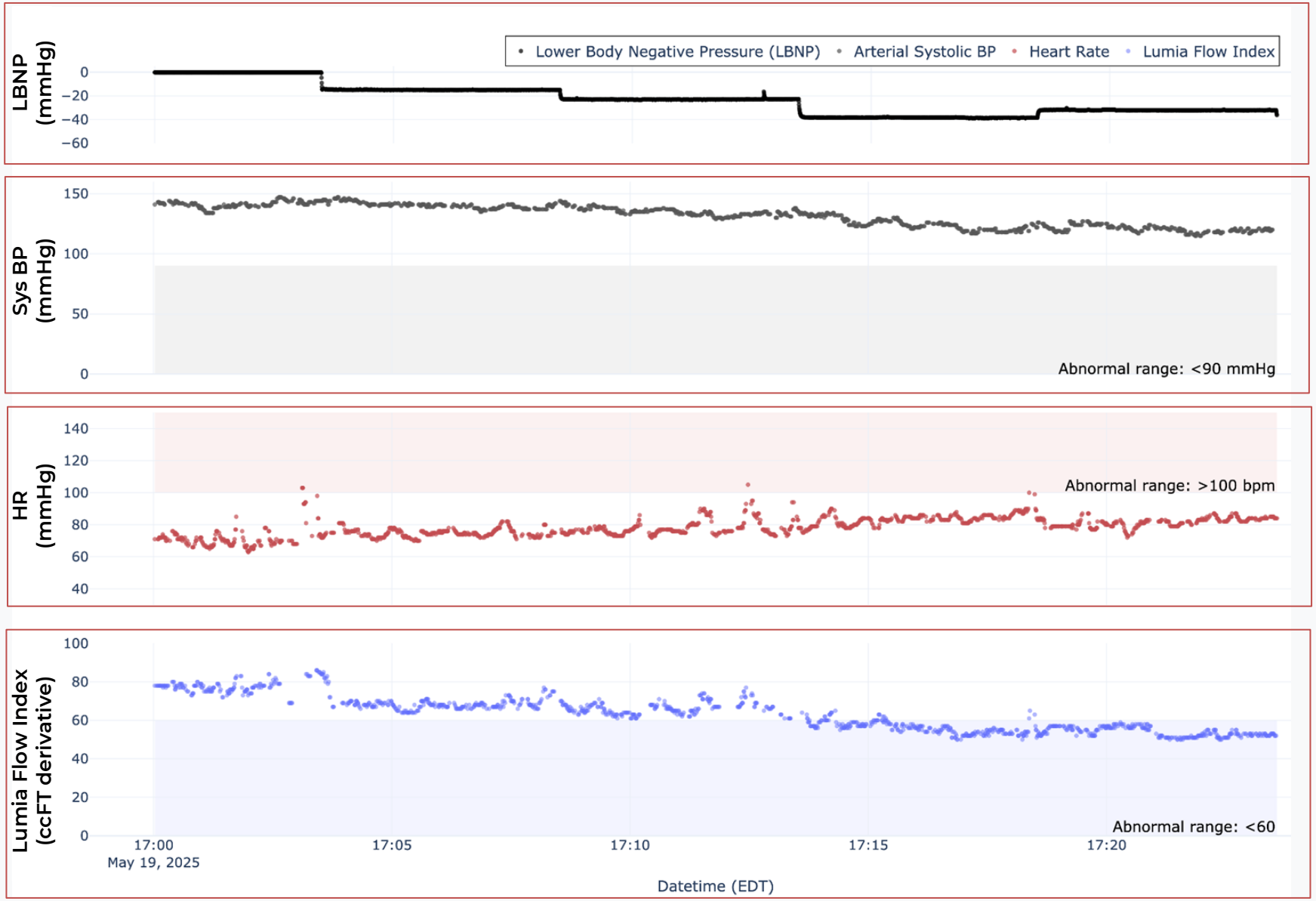


Metric	Severe (≥30%)
Sensitivity	88.4%
Specificity	93.0%
AUROC	0.969
Concordance	91.4%

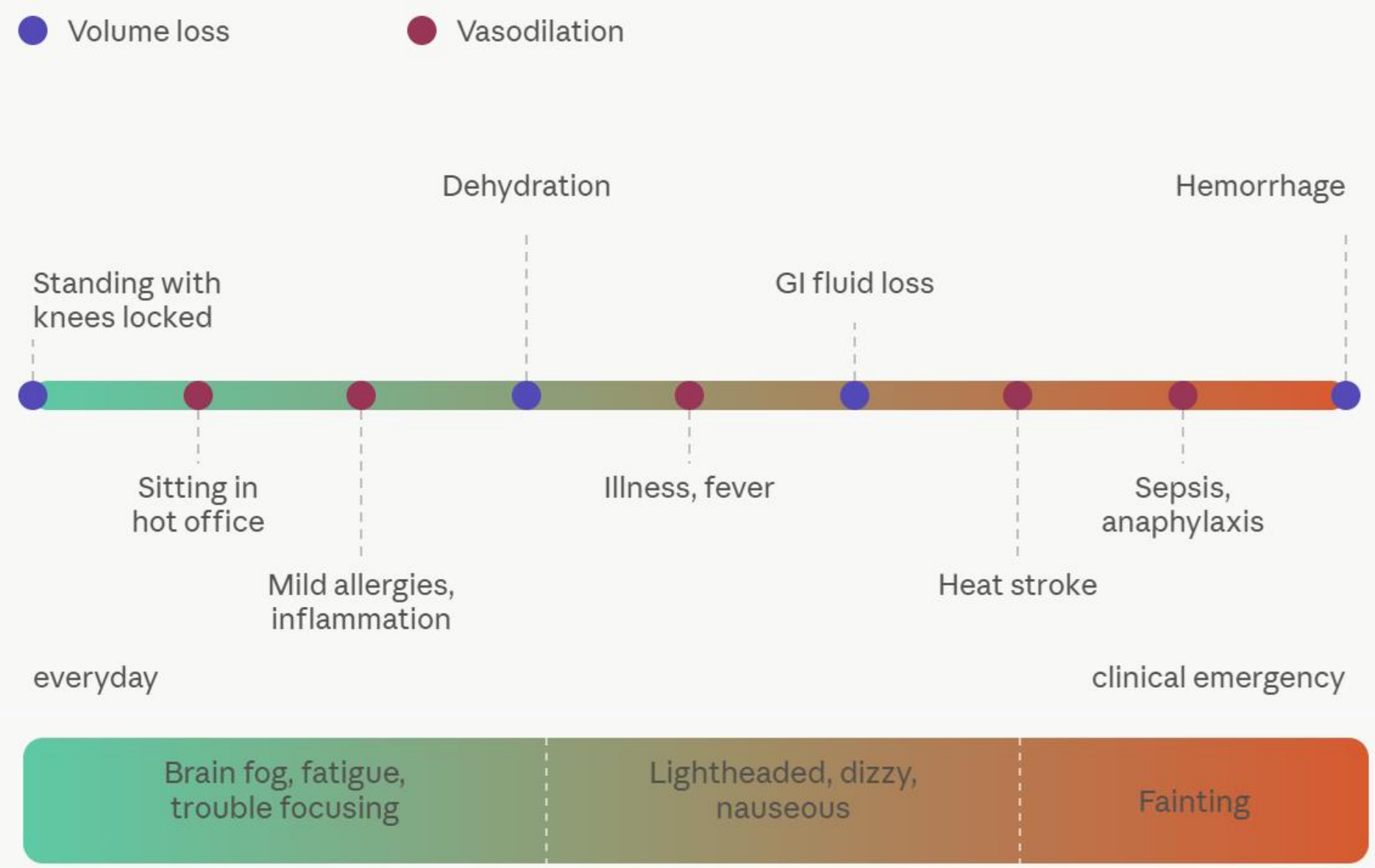
Initial Results: CFT Outperforms Standard Vital Signs for Hypovolemia



Lumia Flow Index Detects Simulated Hemorrhage Before Standard Vitals

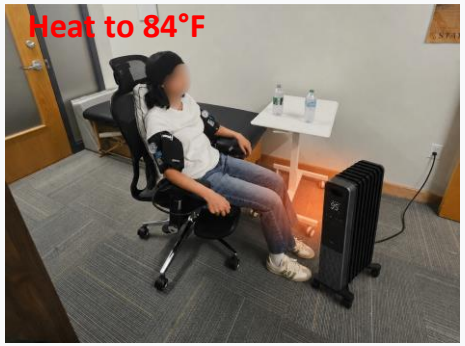


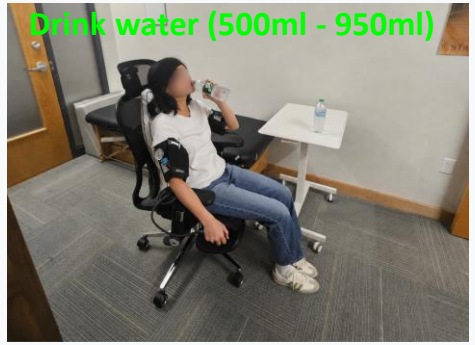
Bleeding Out Isn't the Only Cause of Compromised Blood Flow

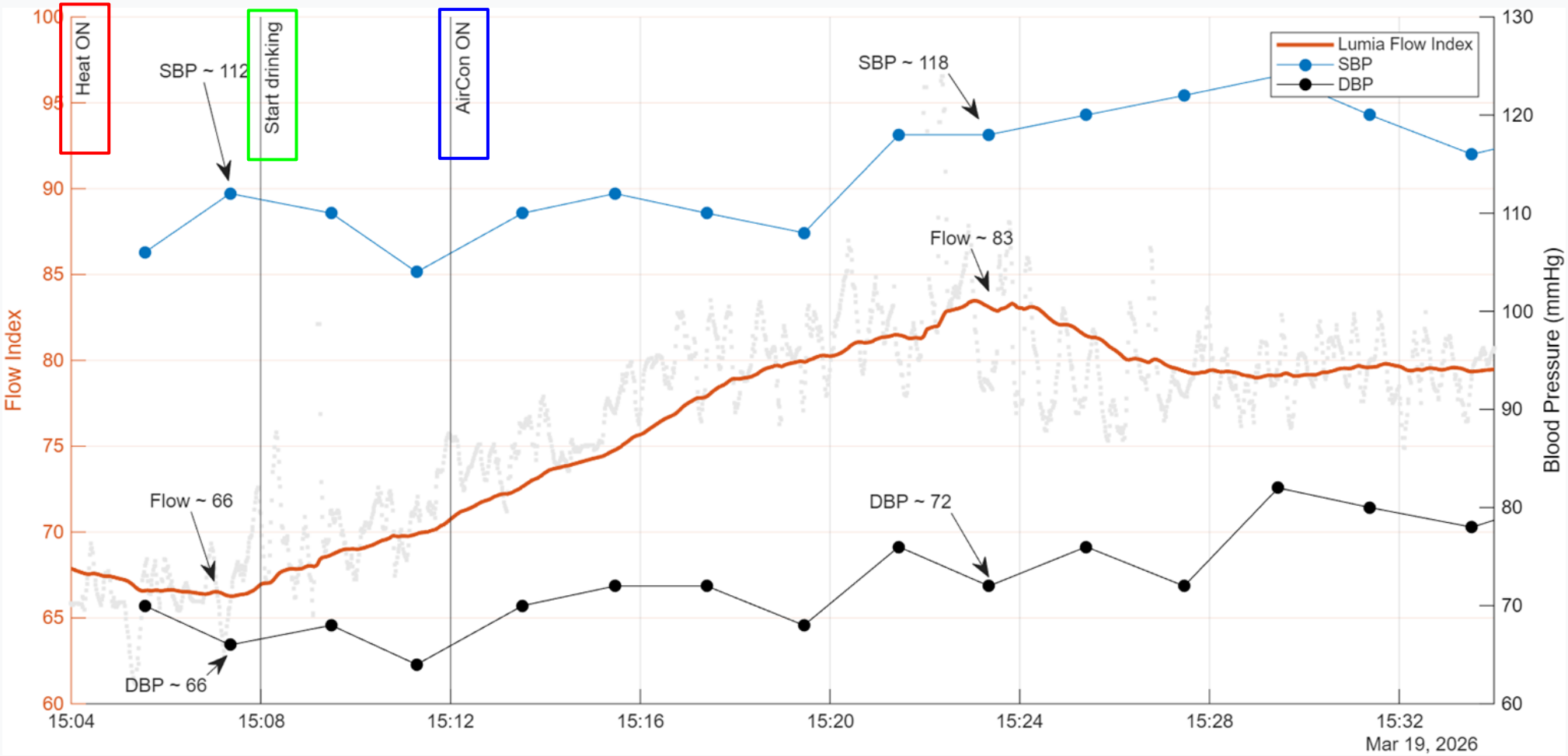


Everyone Experiences Reduced Blood Flow Every Day

Session 2 of Study Design



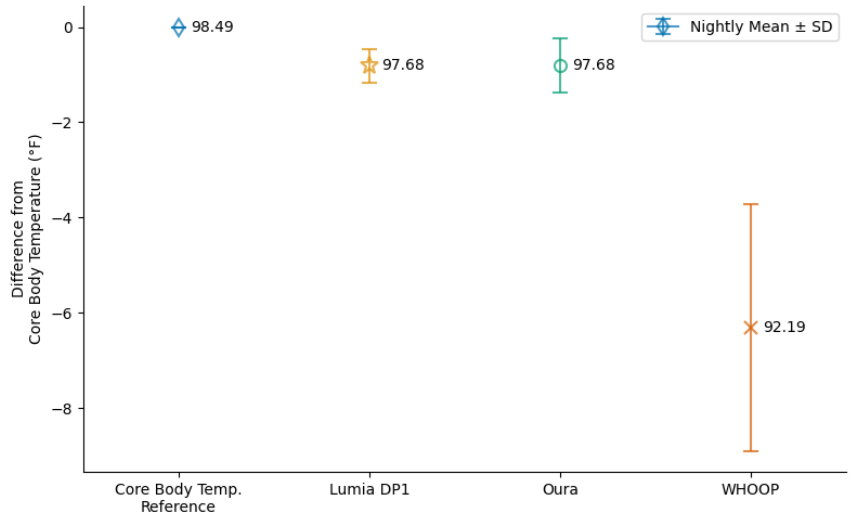




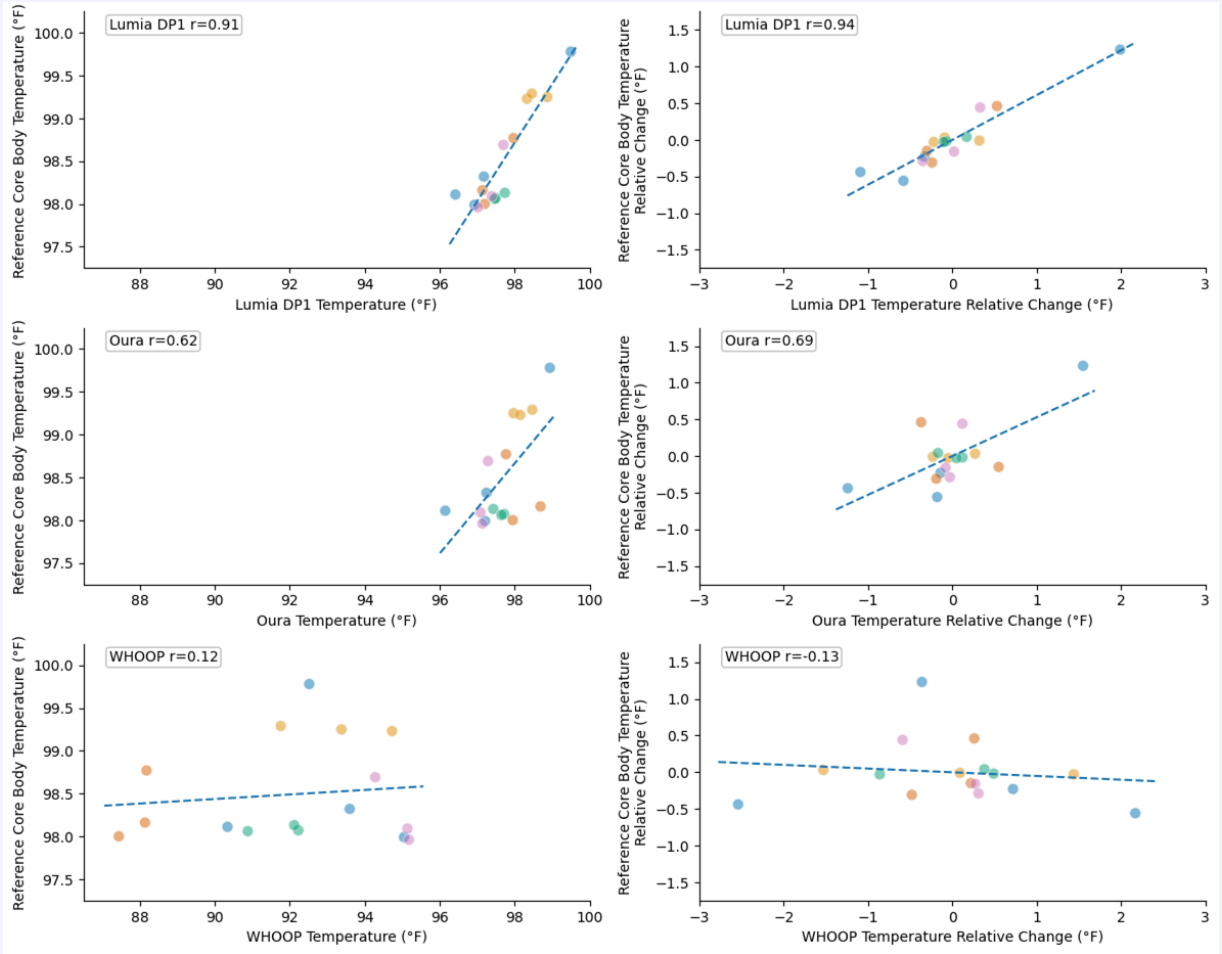
Other Lumia Data: Temperature Sensing

Lumia Ear/Neck temp tracks Core Body Temperature more closely than Oura, Whoop, and Apple Watch

Relative Accuracy Comparison



Night-to-Night Temperature Correlations



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Poster 1

Comparison of an Ear-Worn Wearable Against Commercial Wearables in Overnight Relative and Absolute Temperature Tracking

Session: Optimizing the Human Weapon System: Utilizing Wearable Sensor Data to Inform Readiness

Poster 2

Improved HRV Accuracy and Signal Stability Using an ear-based Photoplethysmography Wearable Compared to Finger-Based Sensors

Session: The Key to Medical Readiness

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