STRETCH

Sensor-based Tactical Response and Evaluation for Triage & Continuous Healthcare

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Disclosures

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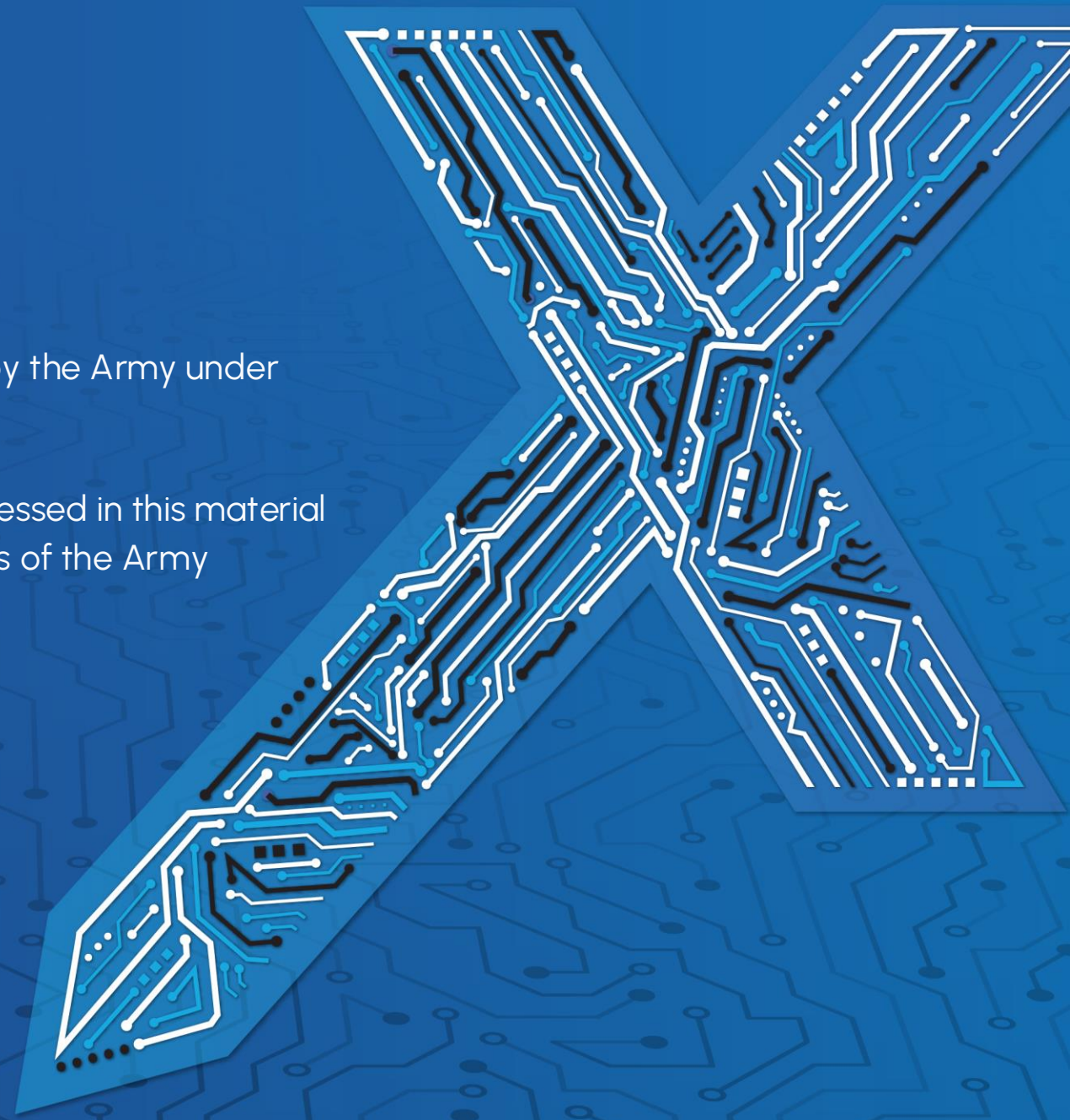
I have no financial or other conflicts of interest to report.



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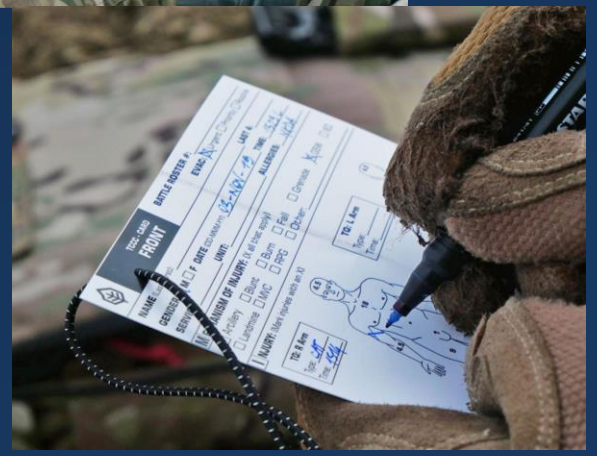
Modern Medic Reality

The "Golden Hour" is gone...

Current Technology

- **POI Capability**: *Buddy aid and Medic aid*
  - Initial assessment
  - Limited treatment
  - No logging
- **Role 2+ Capability**: Basic & Enhanced mobile treatment centers
  - Stabilizing care
  - 2-4 patients (2 per monitor)
  - Hand Notes

Estimated 25% of "Died of Wounds" casualties are potentially preventable [1]



Next Gen Technology

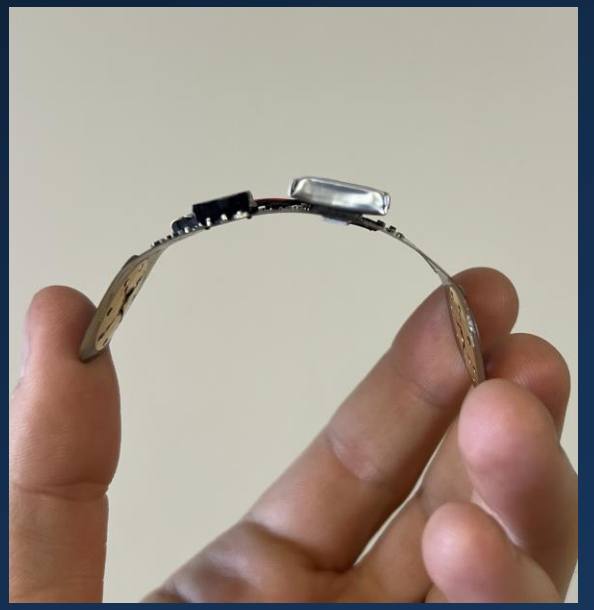
- Highly portable
- Long runtime (3+ days)
- Clinical-grade sensing
- Local processing, display, & logging
- Multi-patient monitoring
- Autonomous triage & documentation

Impact: *Drastically reduce the "Died of Wounds" rate by addressing the delayed recognition of fixable injuries.*

STRETCH Device

- *STRETCH* is a wireless, flexible, low-profile, wearable continuous physiological monitor.
  - 3+ days continuous runtime
  - Onboard processing and logging
  - Multi-patient dashboard
  - Live waveform streaming
  - Rechargeable and AMAL compliant

- **Metrics:**
  - HR
  - HRV
  - Skin & Core Temp.
  - RR
  - SpO_2



Sensor Operations in Extreme Environments

Proven effectiveness during MASCAL exercises in extreme and extreme cold.

Camp Lejeune, NC

Twentynine Palms, CA

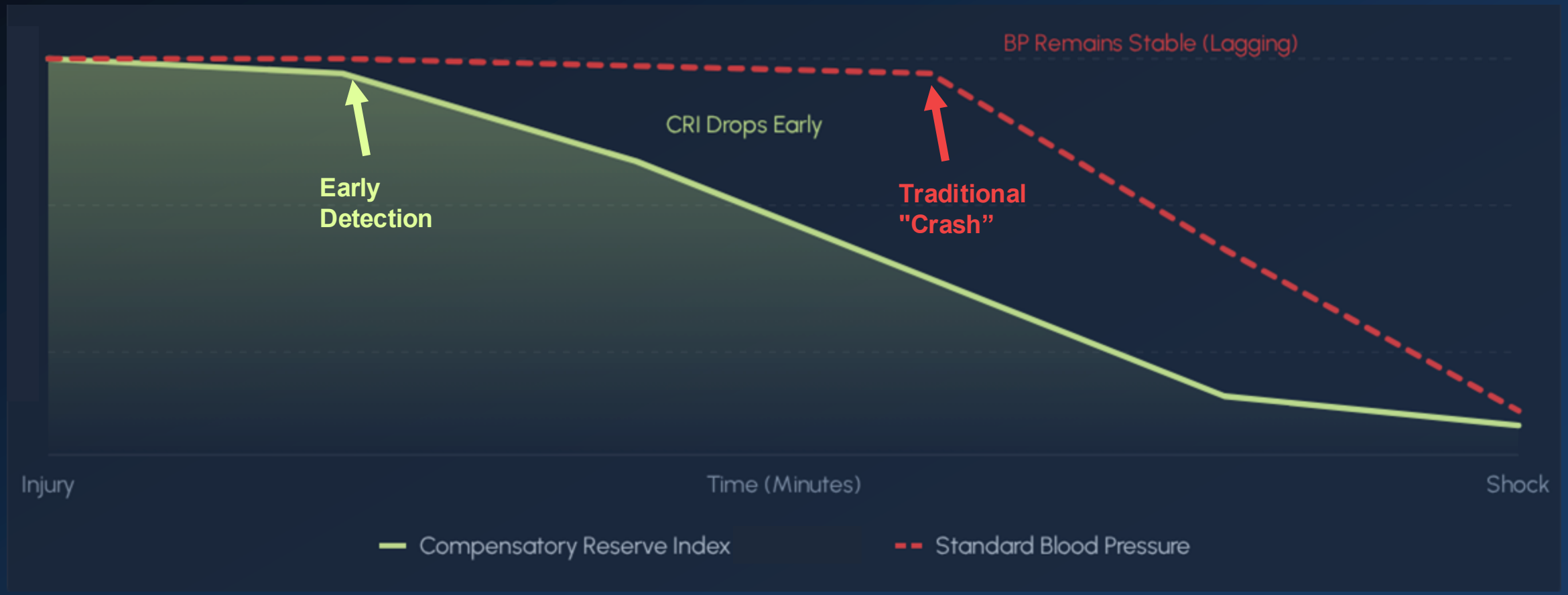
Anchorage & Fairbanks, AK

STRETCH Interface

Blood Pressure & Critical Reserve Index (CRI)

USAISR studies show CRI predicts decompensation **20 to 40 minutes before** hypotension occurs

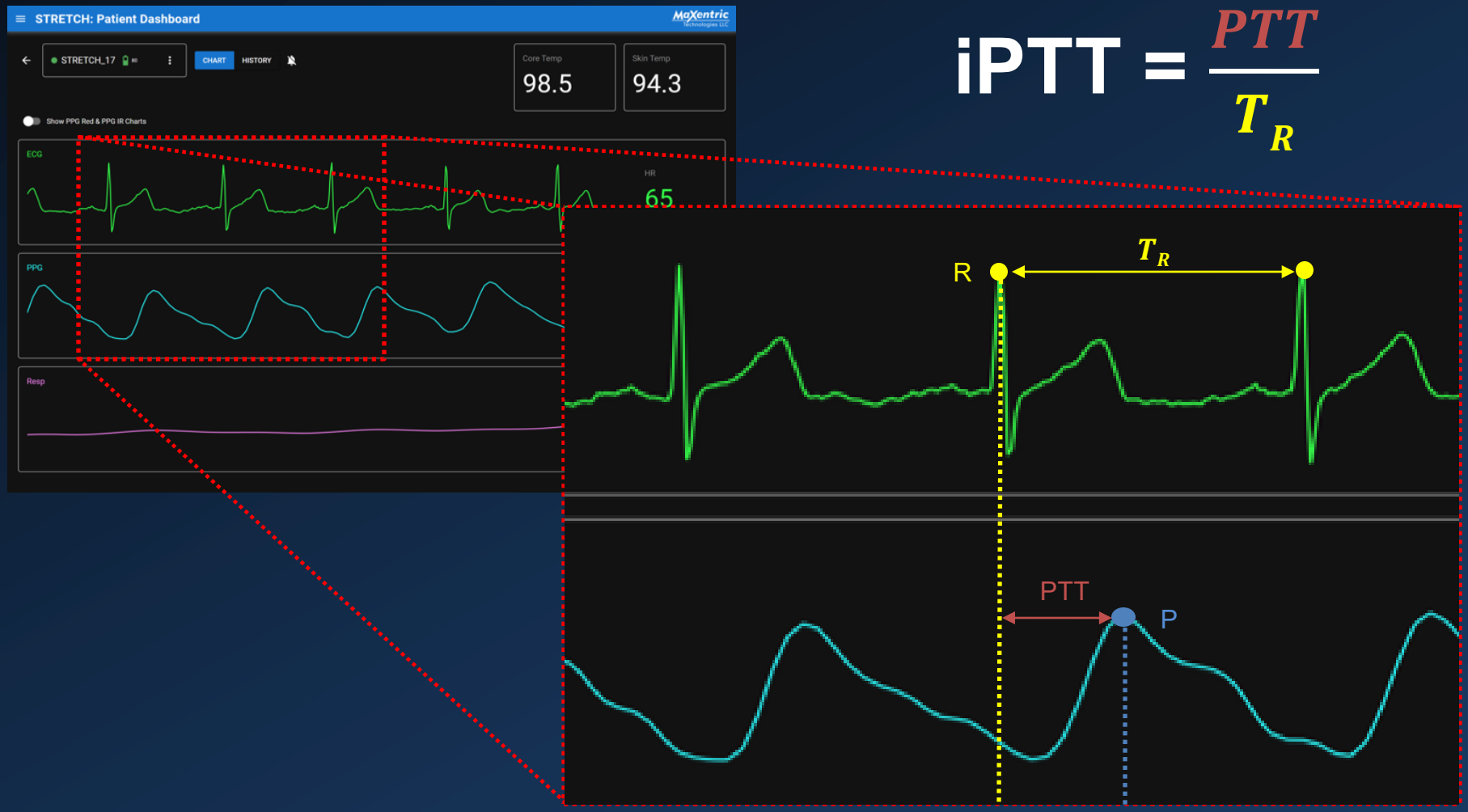
(93% sensitivity, 91% specificity for detecting blood loss)[2,3]



Blood Pressure & Critical Reserve Index (CRI)

Blood Pressure & Critical Reserve Index (CRI)

$$iPTT = \frac{PTT}{T_R}$$



Algorithm Architecture

1. Signal Acquisition

Raw sensor data and timestamps.

2. Feature Extraction

Filtering, motion removal, and waveform feature extraction.

3. Phys. Metrics

Physiological metrics are determined (HR, Temp, etc.).

4. Edge ML Triage

Machine Learning models are applied for BP and CRI triage scores.

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Thank you!

Questions?

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Citations

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5. Additional citations upon request…

Appendix 1: Physiological Validation

STRETCH maintains high fidelity compared to the *ProPaq* monitor in live field exercises:

Biosignal / Metric	Device Component	Validation Error Margin	Tactical Relevance
Heart Rate (HR)	ECG / PPG	< ± 5 bpm	Baseline tracking
Respiration Rate (RR)	ECG derived	< ± 3 bpm	Early stress indicator
Core Body Temp	Thermal Sensor	< ± 1˚F	Hypothermia prevention
Blood Oxygen (SpO2)	Optical PPG	< ± 2% MAE	Tissue perfusion proxy

Appendix 2: FDA Clearance

Phase	Activities	Duration	Deliverables
Phase 1: Regulatory Planning & FDA Pre-Sub	Identify predicate, conduct risk assessment for hemorrhagic alert feature, submit Q-Sub, and hold Pre-Sub meeting.	Months 0–3	Pre-Sub meeting minutes and FDA feedback summary
Phase 2: Non-Clinical Verification	Conduct biocompatibility, electrical safety, EMC, software, and algorithm verification.	Months 4–8	Verification and validation reports
Phase 3: Clinical Validation	Execute clinical study per FDA-reviewed protocol.	Months 9–14	Clinical validation report with performance metrics for alert functionality
Phase 4: 510(k) Preparation and Submission	Compile 510(k) submission, including all technical and clinical data.	Months 15–17	510(k) submission to FDA
Phase 5: FDA Review and Clearance	Address AI requests, finalize labeling.	Months 18–22	FDA 510(k) clearance letter
Phase 6: Post-Clearance	Implement post-market surveillance plan.	Months 23–24	Post-market surveillance plan