

Collaborative Research in Medical Sensing: Wearable Wireless Sensor for Pressure Ulcer Prevention

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Disclosures

- **Grant/Research Support:**
 - **In-kind support, Boston Scientific**
- **Graphic content warning: Images of**
 - **Pressure ulcer wound**
 - **Porcine model animal experiment**

Development of Biomedical Collaboration

GREATEST ENGINEERING ACHIEVEMENTS OF THE 20TH CENTURY

1. Electrification
2. Automobile
3. Airplane
4. Water supply & distribution
5. Electronics
6. Radio & television
7. Agricultural mechanization
8. Computers
9. Telephone
10. Air-conditioning & refrigeration
11. Highways
12. Spacecraft
13. Internet

ENGINEERING'S GRAND CHALLENGES

Make solar energy economical.
Provide energy from fusion.
Develop carbon sequestration methods.
Manage the nitrogen cycle.
Provide access to clean water.
Restore & improve urban infrastructure.
Advance health informatics.
Engineer better medicines.
Reverse engineer the brain.
Prevent nuclear terror.
Secure cyberspace.
Enhance virtual reality.

- **General direction: NAE Grand Challenges**
 - **Health; Sustainability; Security**

Collaboration History

2011-12

- **MQPs: Wired / Wireless pressure ulcer prevention device**
Morianos, Jones, Gutierrez; Williams, Truhanovitch, Hause
Advisors: Mendelson (BME), Bitar (WPI ECE), Dunn (UMMS)

2015

- **McNeill, Dunn meet at UMMS/WPI Research Collaboration event**
- **\$20K + \$5K WPI/UMMS Seed Grant funding**
Partial support for MS student Matthew Crivello

2016-17

- **McNeill ½ sabbatical at UMMS**
- **TA support for PhD student Devdip Sen**
- **2 MQPs (ECE, BME)**
Agdeppa, Hussain, Kim, Loehle; Ooyama-Searls, Pachucki, Parent
Advisors: McNeill, Mazumder, Mendelson

2017-18

- **\$25K UMass Technology Commercialization (OTCV) funding**
- **\$10K Massachusetts Technology Transfer Center (MTTC)**

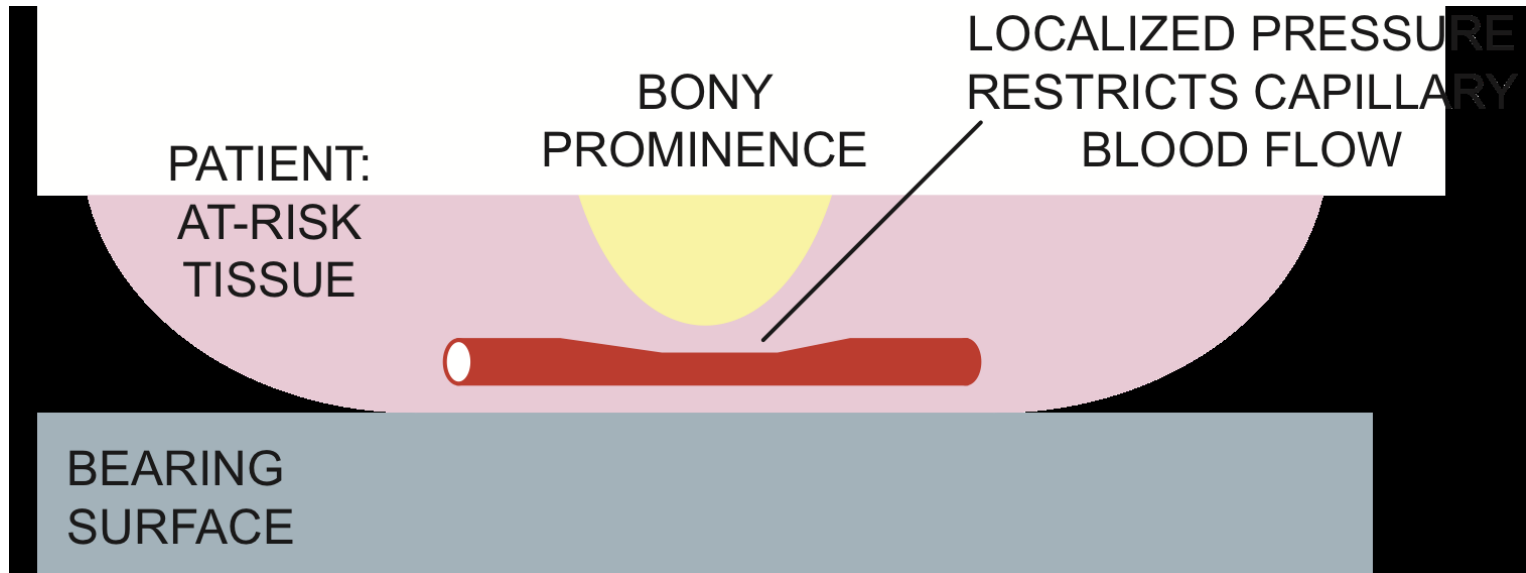
Motivation: Pressure Ulcer Prevention

- Painful
 - Increases risk for secondary infection
 - Wound healing takes up to several months
 - May not heal at all in compromised patients
 - Adds \$11B annually to US health care costs
 - Demographics: Increasing cost, incidence, prevalence
- *Need compact, low-cost prevention for patients:*
- In hospital setting
 - Confined to bed at home
 - With limited mobility in wheelchairs

Healing of pressure ulcer over several months



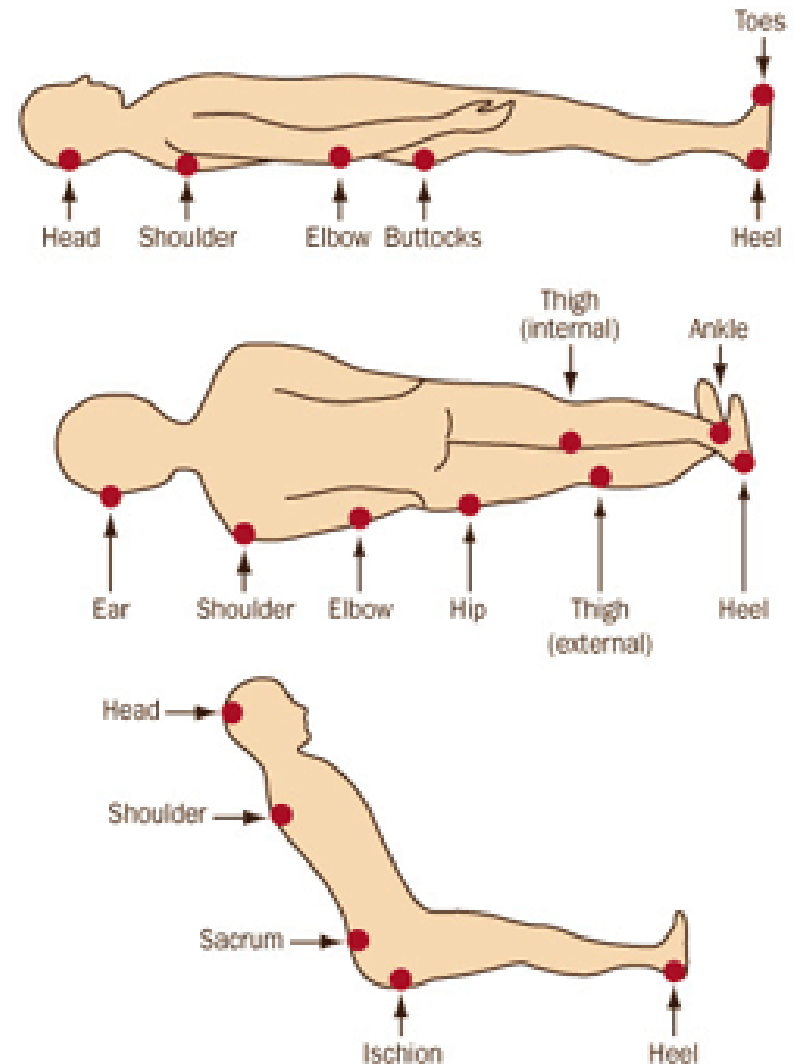
Cause: Localized Pressure



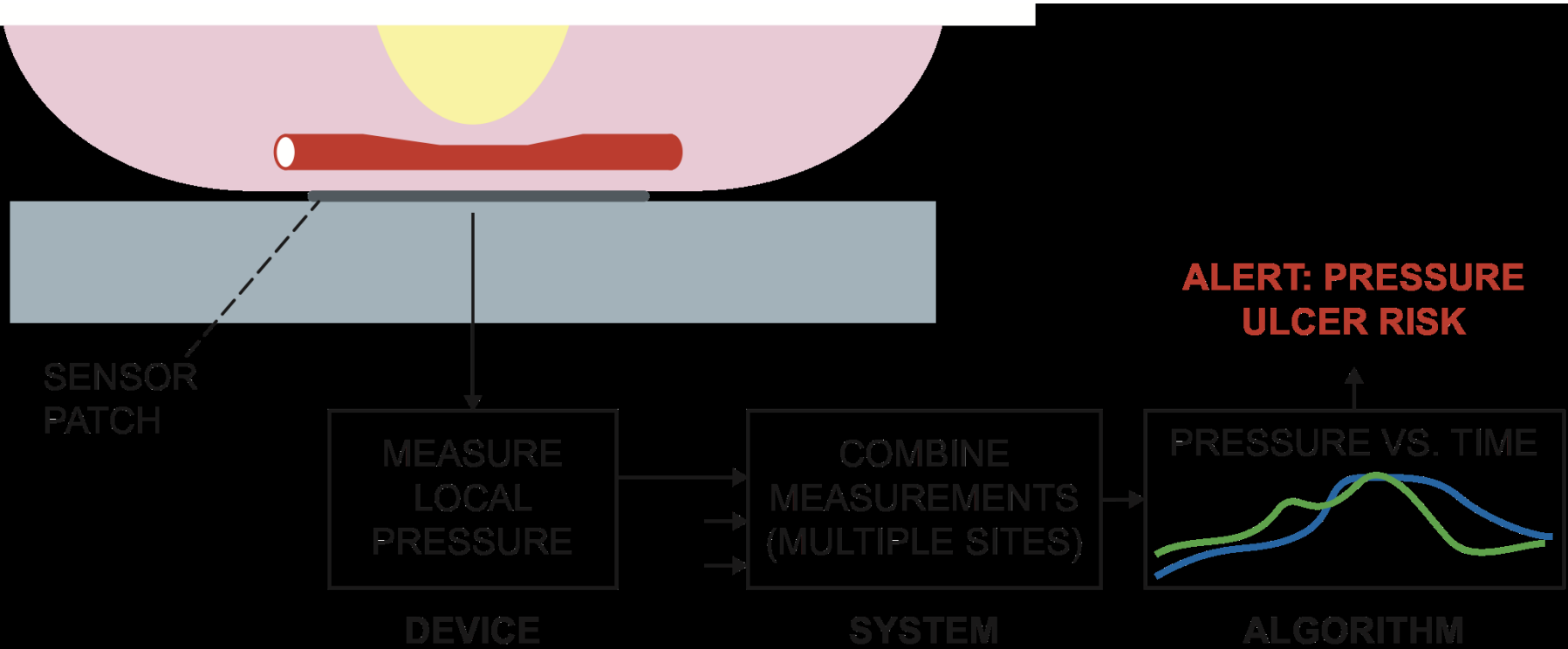
- **External pressure over ~30mmHg restricts blood flow**
- **Ischemia; tissue deprived of oxygen**
- **Can lead to tissue necrosis**

Opportunity for Prevention

- **Well-known locations on body at risk for pressure ulcer formation**
- **Location depends on patient environment:**
 - **Hospital setting**
 - **Confined to bed at home**
 - **With limited mobility in wheelchair**

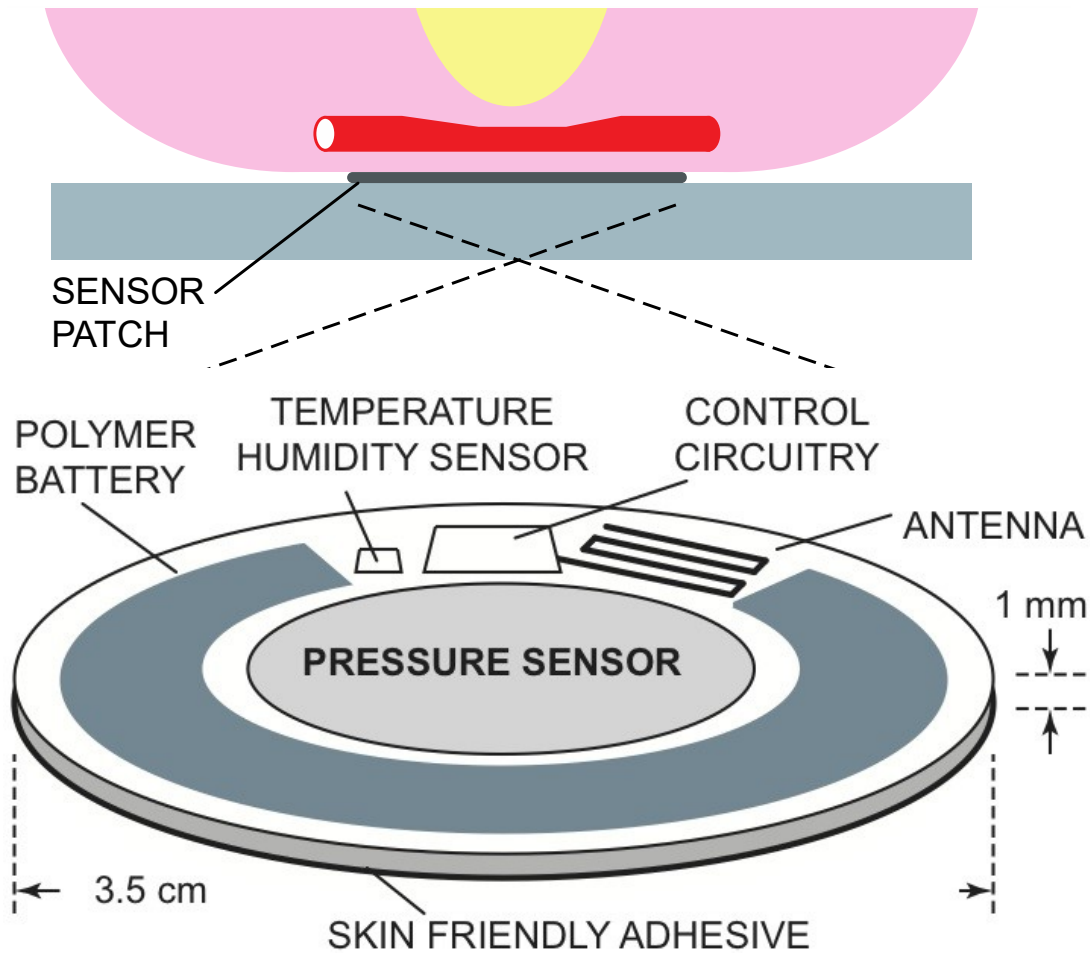


System Approach: Pressure Ulcer *Prevention*



- **Device:** Low-cost, disposable, wearable sensor patch
- **System:** Wireless data collection from multiple at-risk sites
- **Algorithm:** Assess risk from pressure vs. time profile

Device



- **Low-cost, disposable, wearable sensor patch**
- **Measure local pressure, temperature**
- **Small size, comfortable to wear for long duration**

Benefits of Our Approach

- **Low cost: \$10 / sensor**
- **7-day wearable; disposable**
- **Meet needs for multiple populations:**
 - **Caregiver: Reduces workload**
 - **Doctor: Detailed pressure-time information**
 - **Patient: Improved independence**

Drawbacks of Existing Techniques:

- **2-hour turn protocol**
 - **Workload, injury risk for caregivers**
 - **Not supported by controlled trials**
- **Offloading beds**
 - **Expensive (> \$10K), fixed location**
- **Pressure mapping pad**
 - **Expensive (> \$1K), caregiver interpretation**

Commercial Impact

\$11B annual cost in US for pressure ulcer treatment

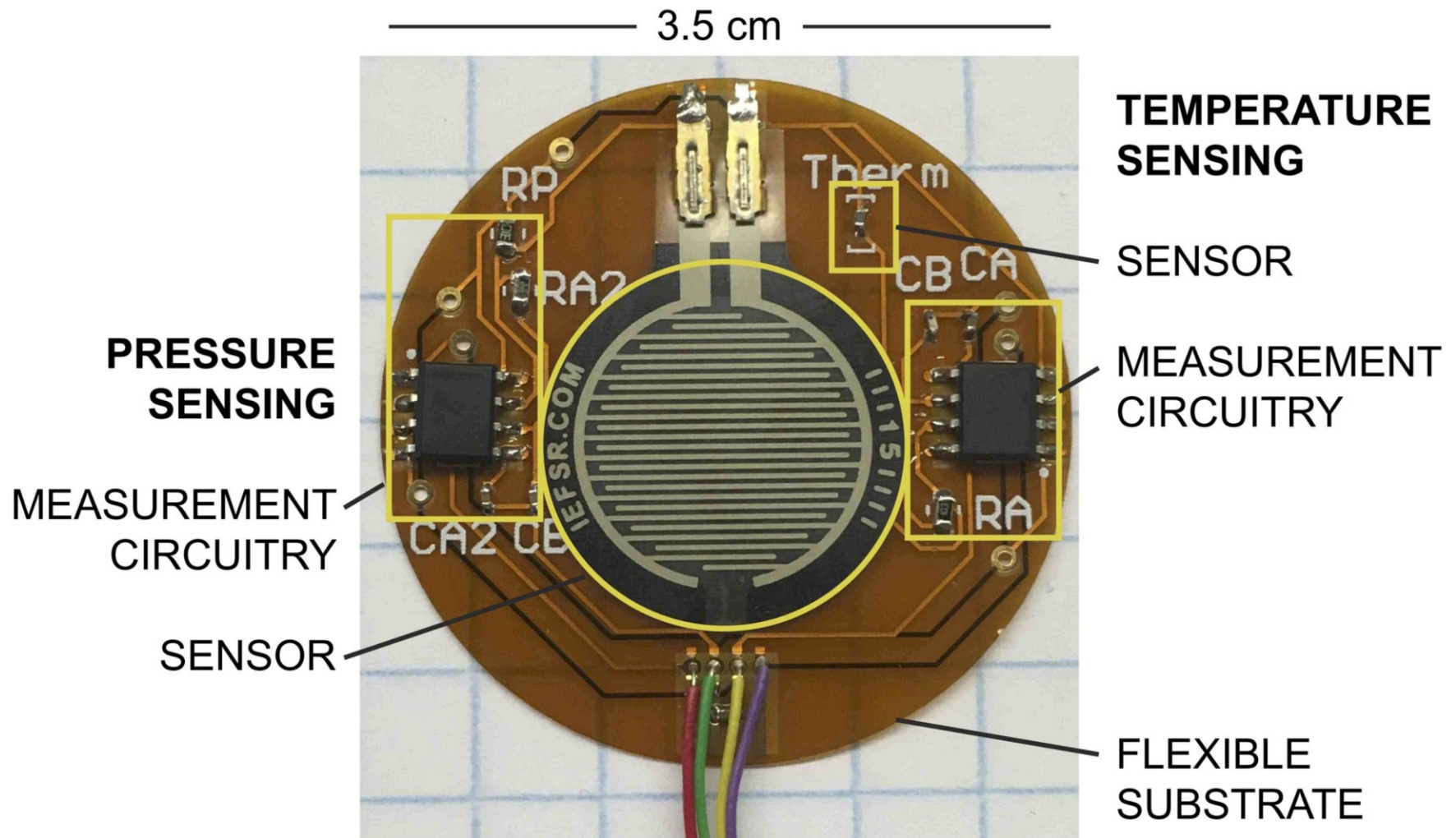
- **Potential annual market population:**

– Hospitals	35.1 million
(2014: No Medicare reimbursement)	
– Nursing homes	1.4
– Long term / residential care	1.0
– In-home care	5.3

Potential Population (5% at risk)	2.1 million
Estimated Gross Annual Market	> \$120 million

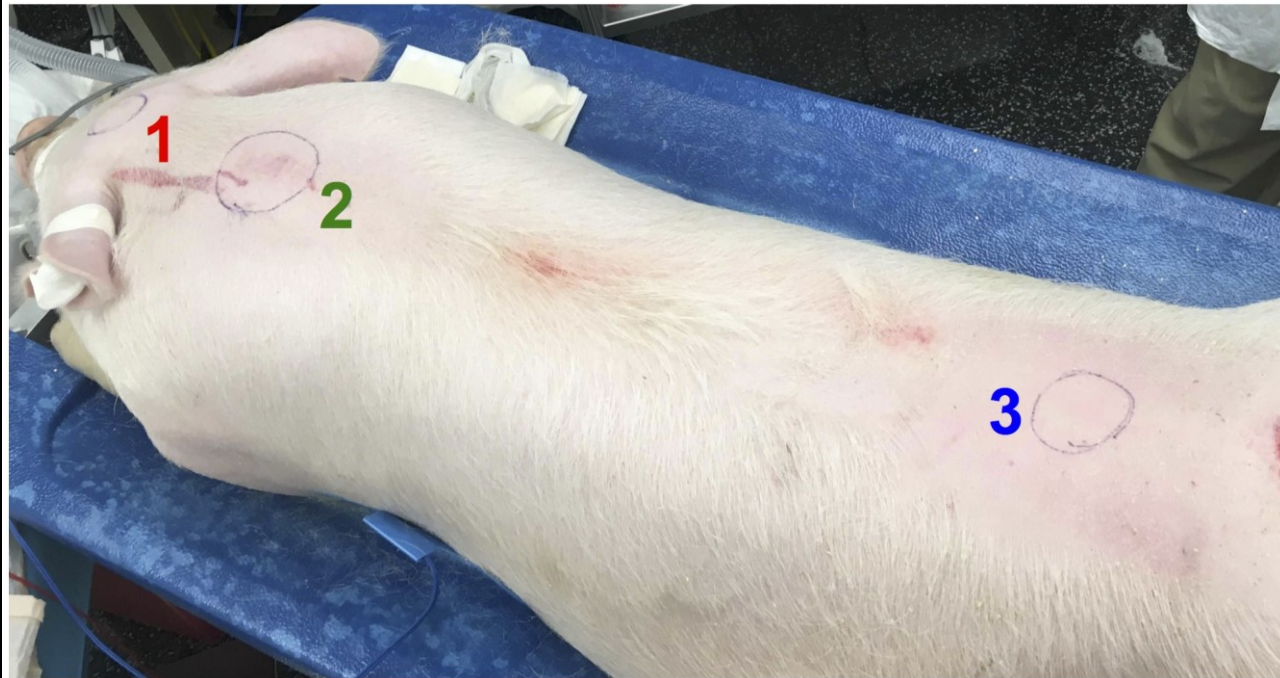
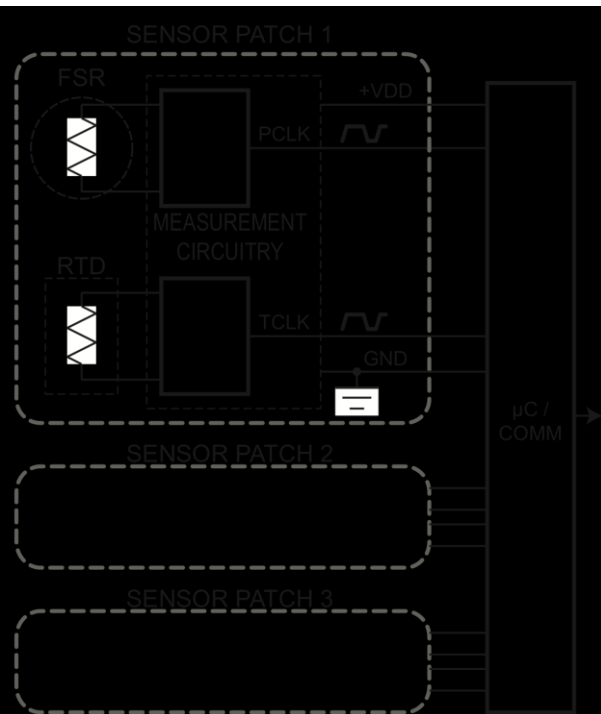
- **Demographic demand accelerating**
 - **Aging, longer lived population**

Flexible Wired Prototype

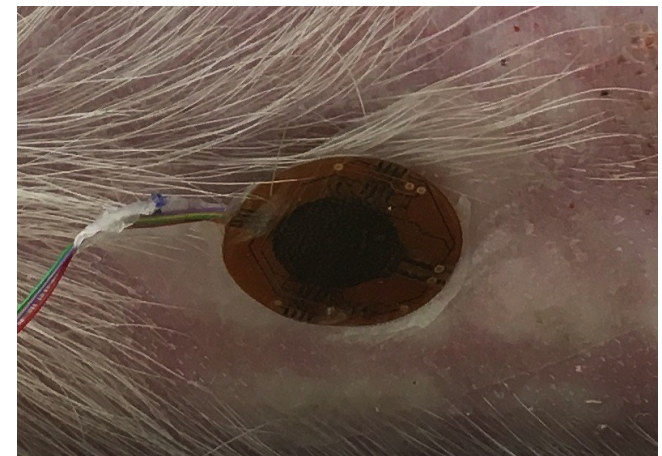


- Implement sensors, measurement circuitry on flexible substrate

Animal Experiment Data Acquisition

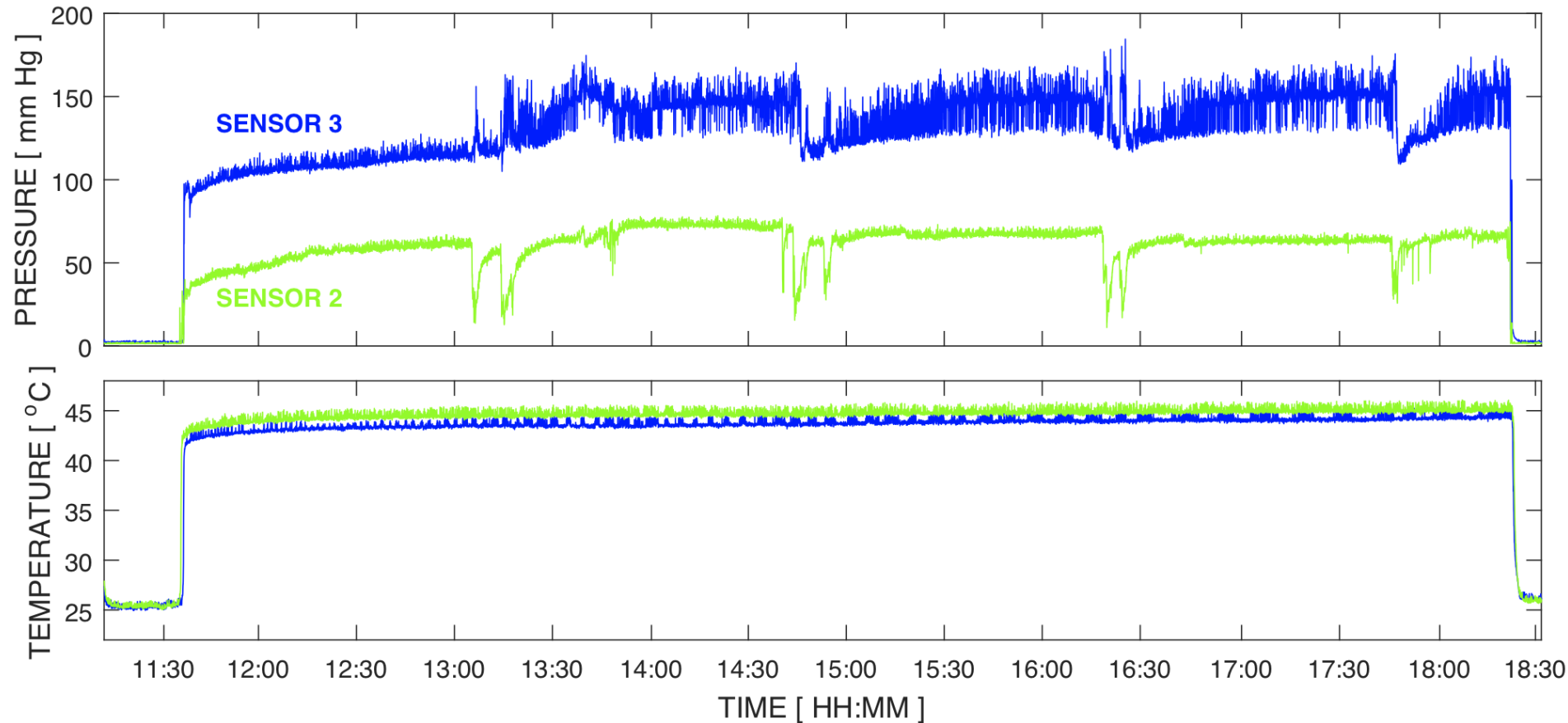


- **Surgical protocol: Anesthetized pig immobile on back for ~ 7 hours**
- **Identified at-risk sites for placement of wired sensors**
- **Acquire data from multiple sites**



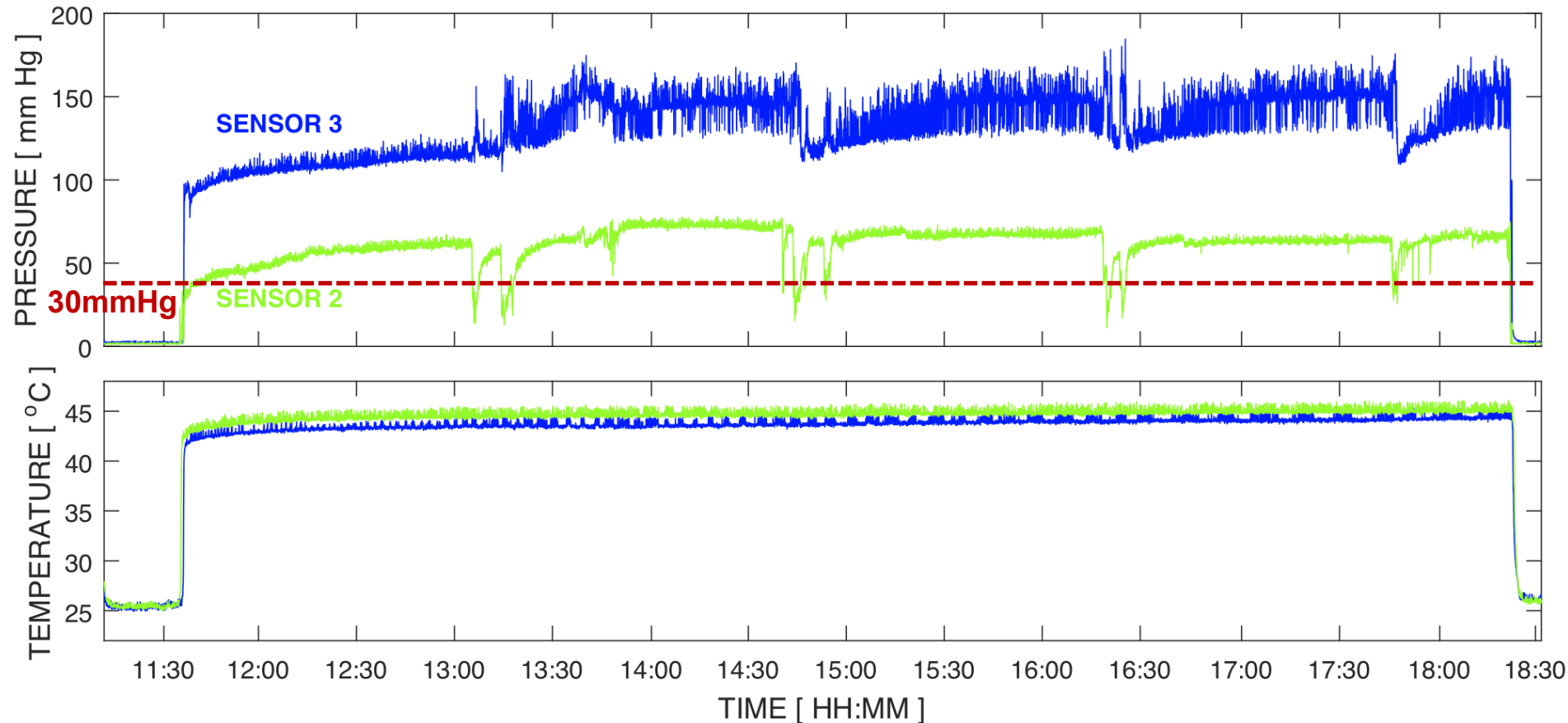
Closeup of attachment site

Experimental Results



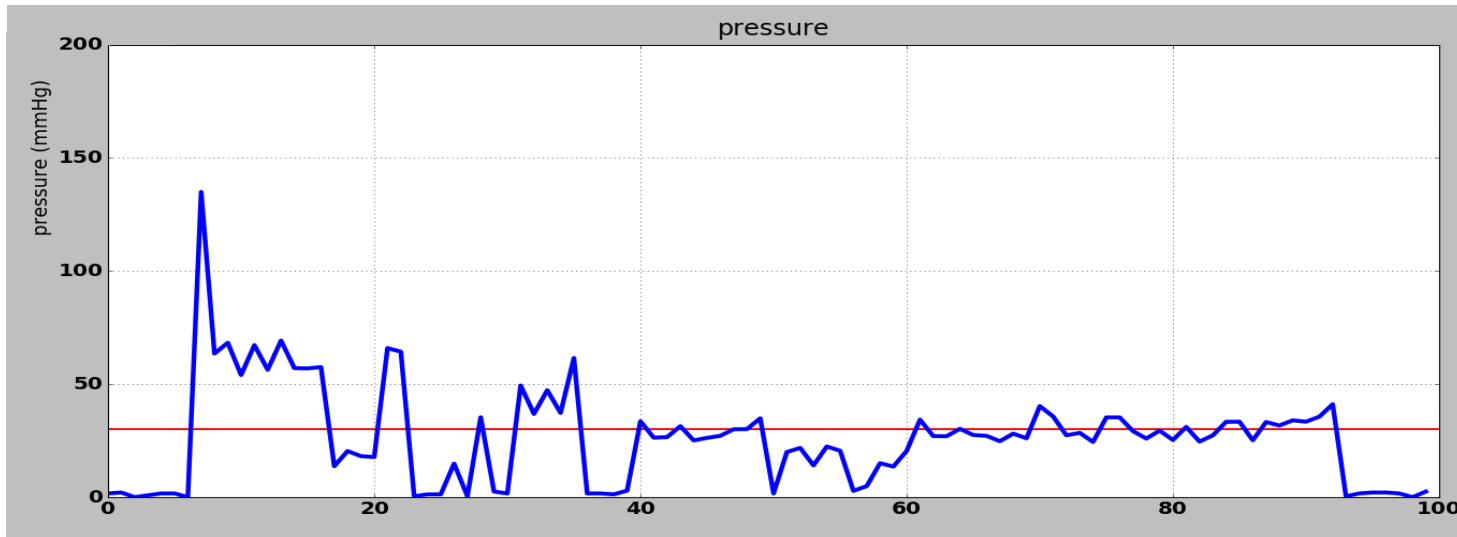
- **Pressure, temperature vs. time over 7 hour duration**
- **Surgical protocol: Animal repositioned every 90 minutes**

Experimental Results

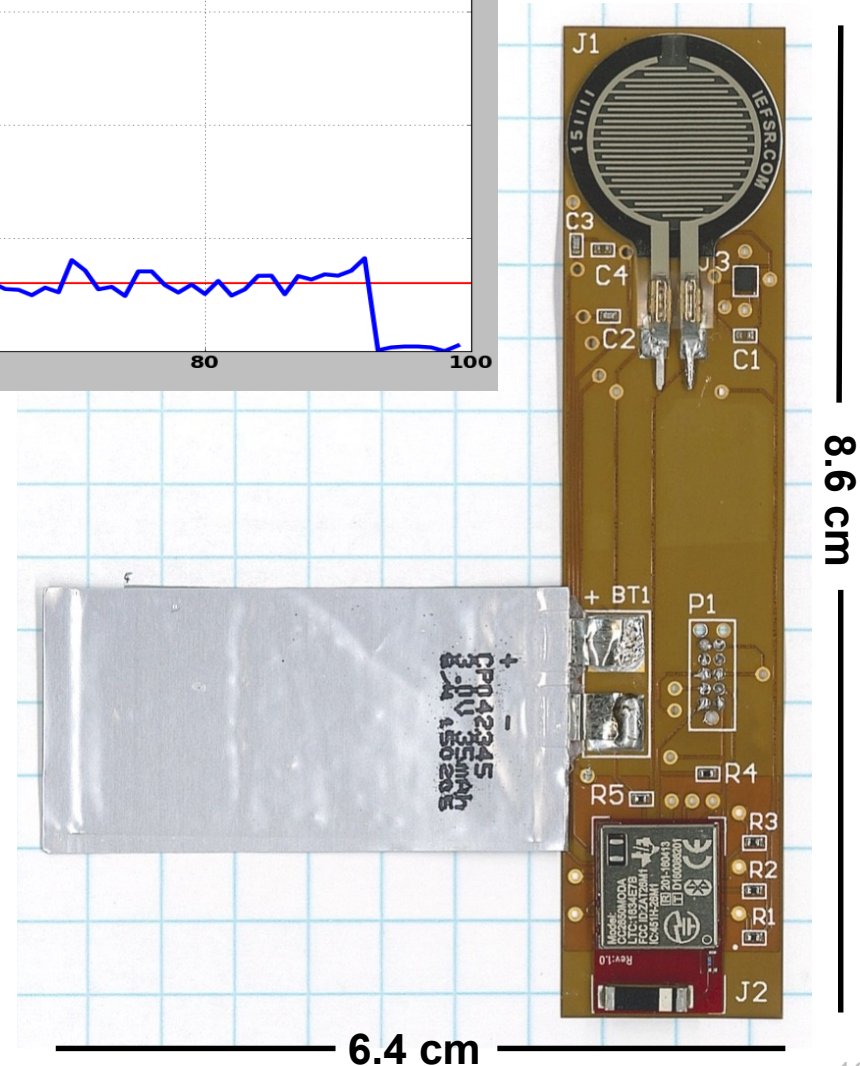


- **Pressure, temperature vs. time over 7 hour duration**
- ***Verified ability to resolve threshold, pressure relief events***
- ***Importance of multiple sensors for each at-risk point***

Current Status



- **Wireless prototype verified**
MS: Matt Crivello
PhD student: Devdip Sen
WPI Undergraduate project:
ECE MQP: Amanda Agdeppa
Ali Hussain
David Kim
Victoria Loehle



Development Plan Status

TIME ↓	Measure pressure, temperature, moisture	Verified
	Wireless self-powered measurement	
	Human wearable, biocompatible sensor	IN PROGRESS (OTCV, MTTC, M2D2)
	Animal model trials	
	Evidence based algorithm	FUTURE FUNDING (NIH, NSF, SBIR, STTR, PARTNERS)
	Human trials (Class 2)	
	Clinical use	

- **Licensing most likely path to commercialization**
- **IP Status: Provisional patent application filed June 2016**

Potential Partners

- **Boston Scientific: Wearable sensors**
- **Johnson & Johnson: Managing diabetes, surgery recovery**
- **Convatec, Acelity, Smith & Nephew, Medtronic, GE, ...**

➔ ***M2D2 support: Preliminary results for future funding***
Technology: Disruptive shift in pressure ulcer prevention

Interdisciplinary Development Team

UMMS Division of Plastic Surgery

Raymond Dunn, M.D.	Chief; P.I.	Head, Wound Care
Kelli Hickie, M.D.	Resident	Surgical resource
Heather Tessier	Lab Director	Animal model resource

WPI Electrical & Computer Engineering

John McNeill, Ph.D	Professor	Sensor electronics
Xinming Huang, Ph.D	Professor	Internet of Things
Devdip Sen	Student	Prototype fab / test

WPI Biomedical Engineering

Yitzhak Mendelson, Ph.D.	Professor	Skin-friendly materials
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Acknowledgments

- **Supported by a grant from the UMMS/WPI Collaborative Seed Funding Initiative.**
- **William Appleyard [WPI]**
 - **Assistance with sensor fabrication**
- **Heather Tessier [UMMS]**
 - **Access to experimental resources**
 - **Compliance with the IACUC-approved protocol**

Summary: Lessons Learned

- **Find an important problem: Listen to practitioners**
 - Reduce cost, improve quality of care
 - Meets needs for majority of patient populations
 - Reduce workload on caregivers
- **Clinical partner a must**
- **Engineers:**
 - Interdisciplinary team
 - Different experimental constraints
 - Rapid prototyping
- **Need credible plan for entire development cycle**
 - Bring in partner resources (business, IP, ...)
- **Multiple funding sources**
 - Get out of your comfort zone