SacralSense System
By I-CUra Tech

Prevention of Pressure Ulcers in the Intensive Care Unit

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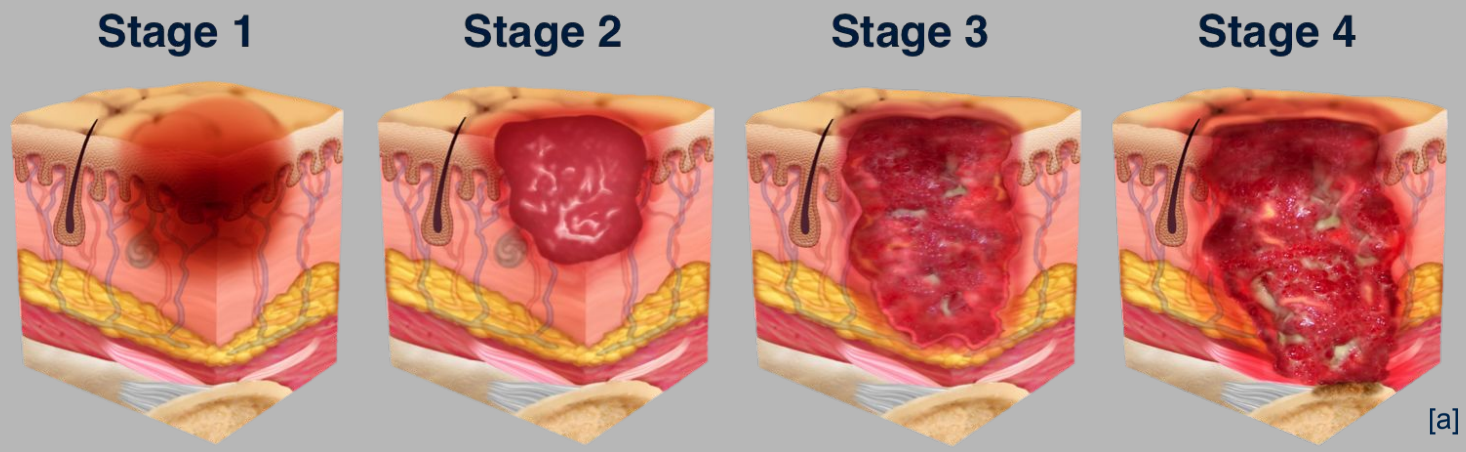
Making the Critical Simple

Pressure Ulcers

A pressure ulcer is a localized damage to the skin and underlying soft tissue usually over a bony prominence [1]



[a]

Clinical Case

Clinical Significance

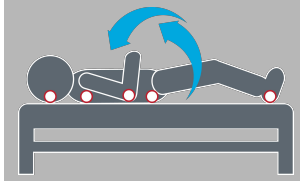
Incidence Rate: 3 - 30% in the ICU [2]

Average Additional Length of Stay: 4.3 days [3]

[b]

Medical Complications [4]

Infection, Vascular Damage, Increased Recovery Time, Mortality



[c]

Psychosocial Complications [4]

Social Isolation, Anxiety, Diminished Quality of Life

[d]

Financial Case - U.S.

Medical Costs

[5]

$11 Billion

2.5 Million Patients

Prevention: $55/day
Treatment:
Stage I/II: $2,770/day
Stage III/IV: $18,231/day

Litigations

[6]

$4 Billion

17,000 cases
87% patient favored

Medicare

[7,8,9]

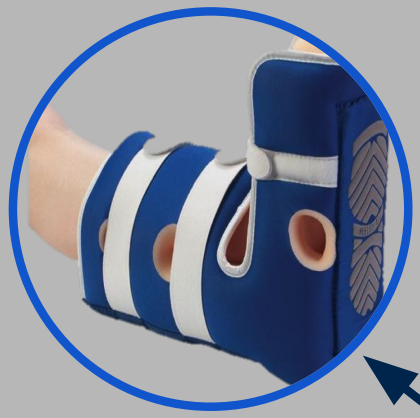
No Reimbursement for HAC

Lowest quartile -
1% penalty on all codes

Need Statement

A way to prevent development of Stage I Pressure Ulcers and progression of all stage pressure ulcers in the Intensive Care Unit upon patient admission and throughout hospital stay.

Current Preventative Methods

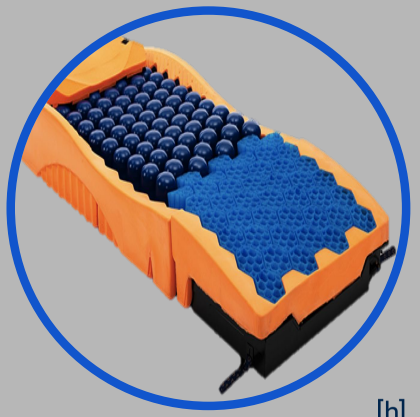


[f]

[g]

[e]

[i]



[h]

Physiological Indicators

External Factors

Internal Factors

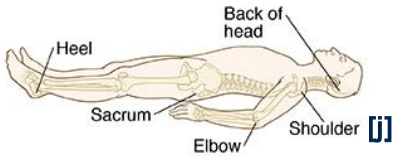
Physiological Indicators

External Pressure [10]

Normal Pressure Only **11.6 kPa**

Pressure + Shear Stress **8.7 kPa**

INCREASED RISK



[j]

Bioimpedance [11]

Cell death

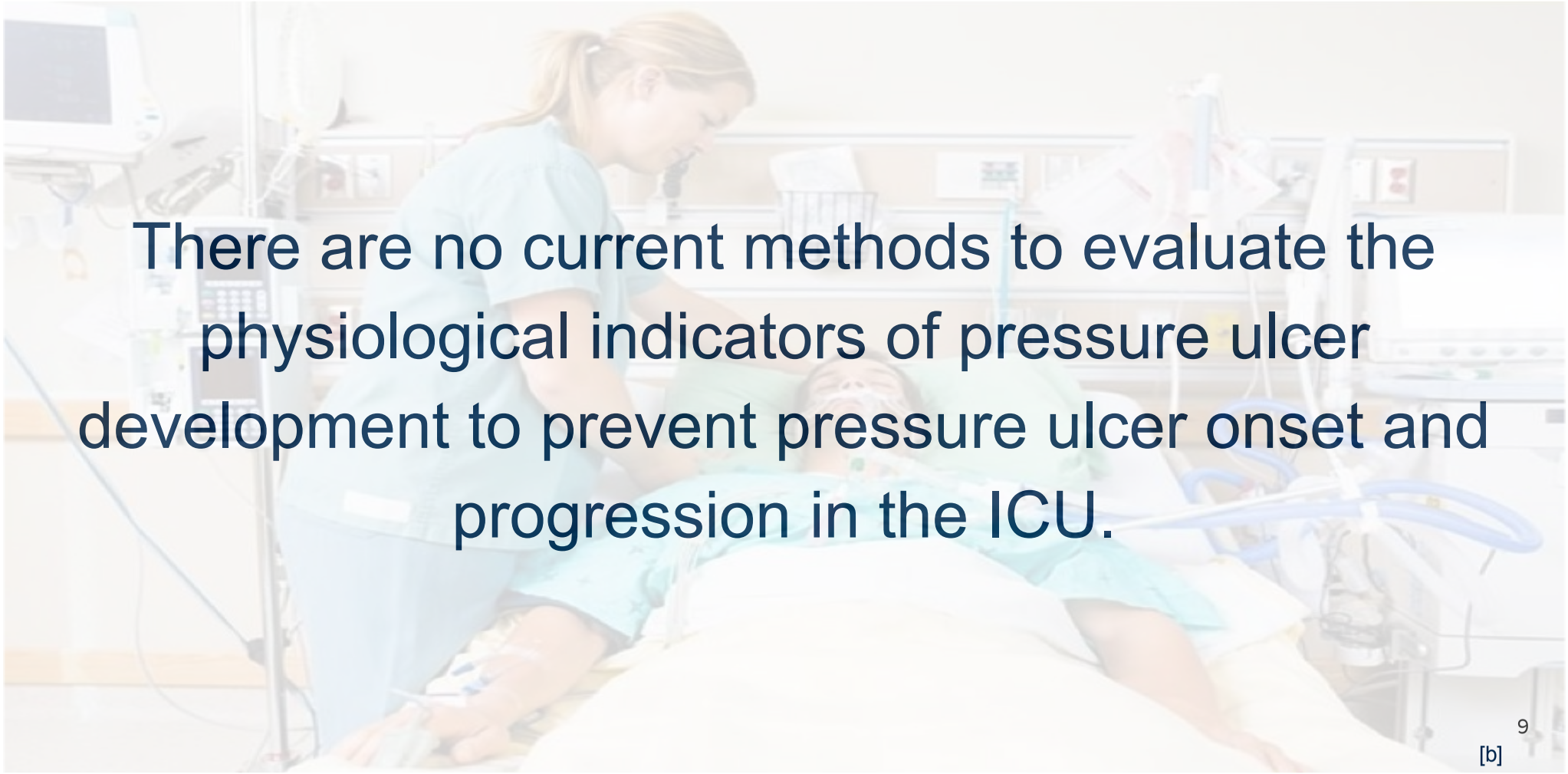
Edema

Fluid Leakage

Internal Moisture

HIGH CONDUCTIVITY

Current Clinical Problem

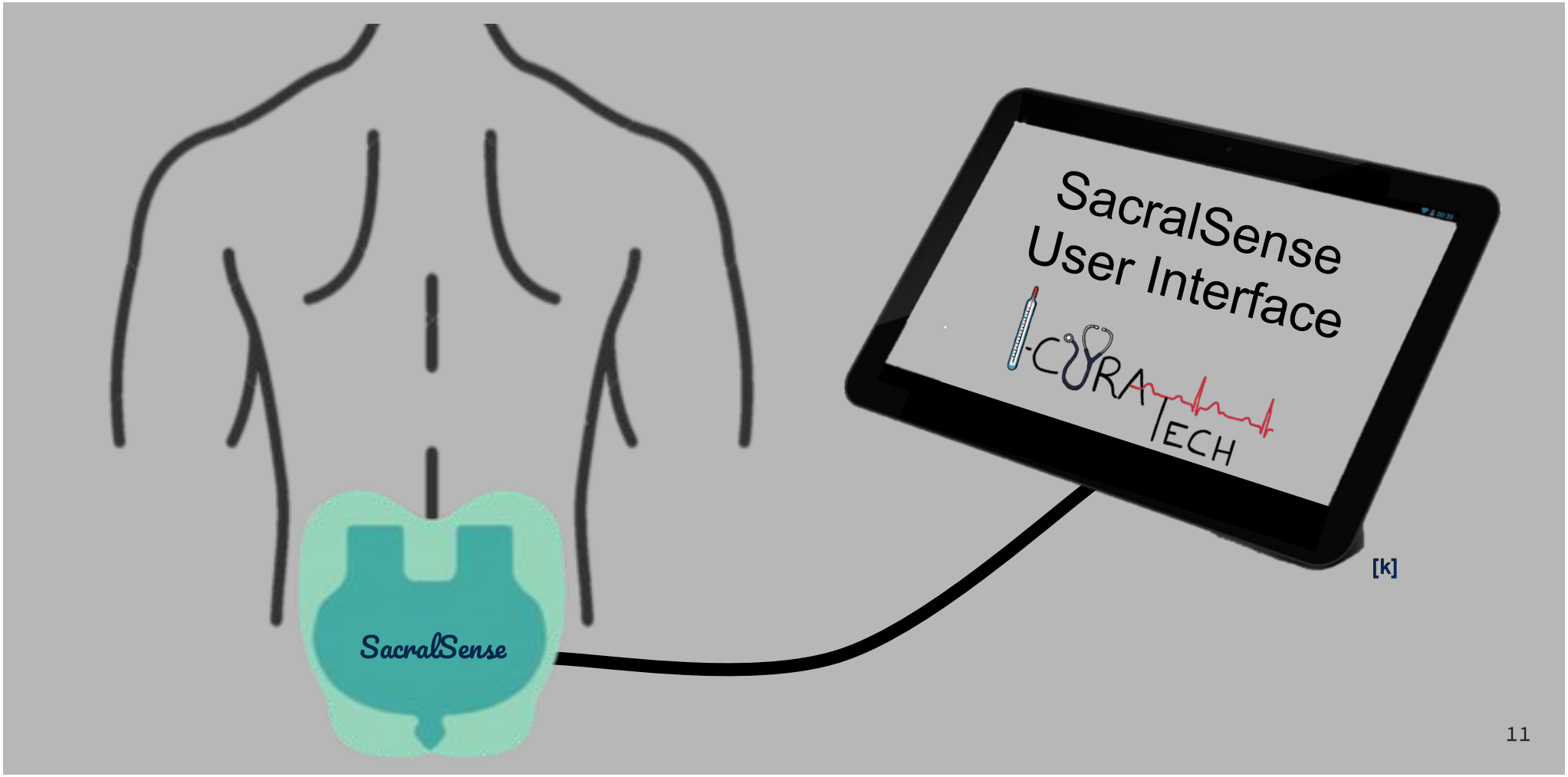


There are no current methods to evaluate the physiological indicators of pressure ulcer development to prevent pressure ulcer onset and progression in the ICU.

[b]

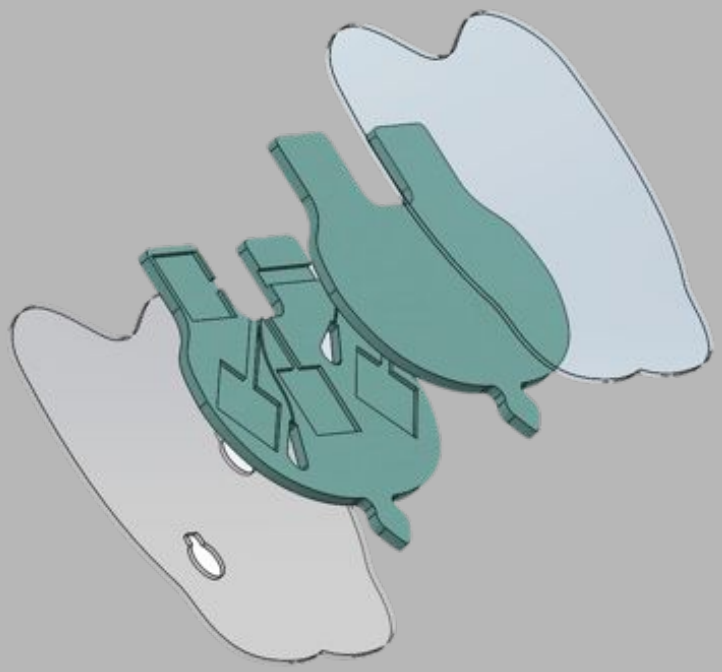
Clinical Solution

SacralSense System



[k]

SacralSense Dressing



Backing Layer
Tight seal to prevent moisture leakage
Polyurethane film

Compression Layers
Moisture retention and cushioning
Houses embedded sensors and wires
Polyurethane foam

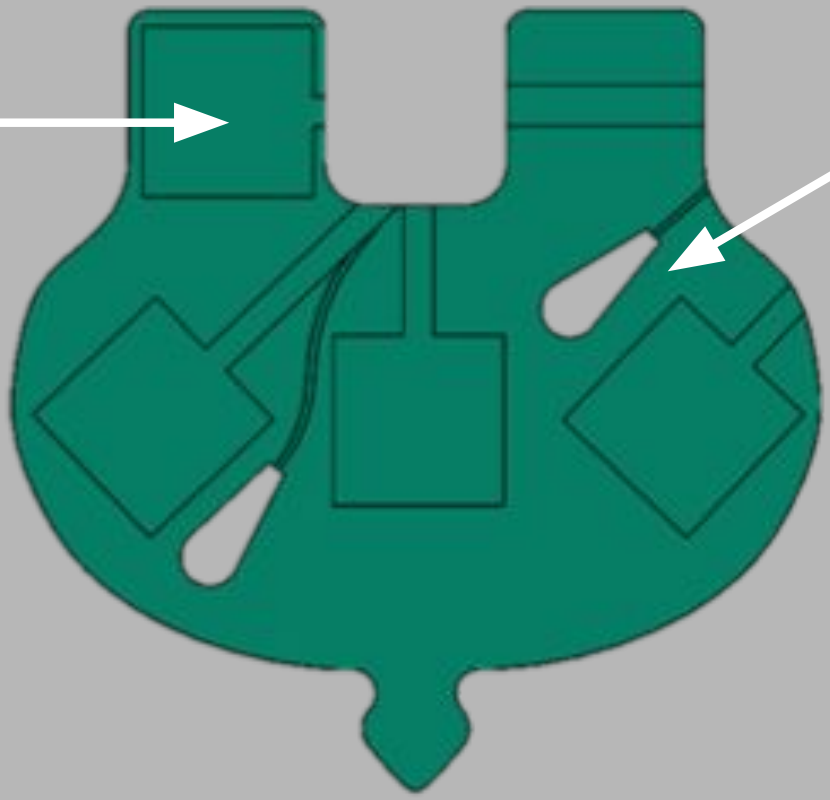
Skin-Contacting Layer
Protects the skin and re-distributes pressure
Houses embedded electrodes
Silicone adhesive film

SacralSense Dressing - Sensors

Force Sensitive Resistors (FSRs) + Electrodes

Reference FSR for Relative Differential Pressure

3 Sensor Array for Precise Detection



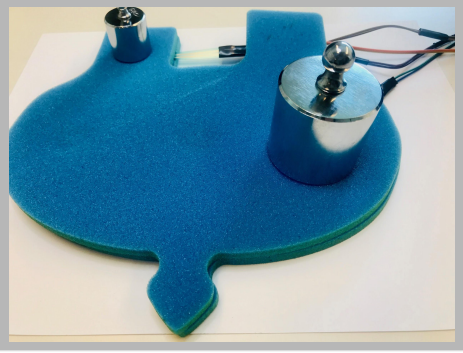
Diagonal Orientation Measures Across Spine

Pre-gelled, Adhesive Backed

Verification Testing

Verification Testing - Sensors

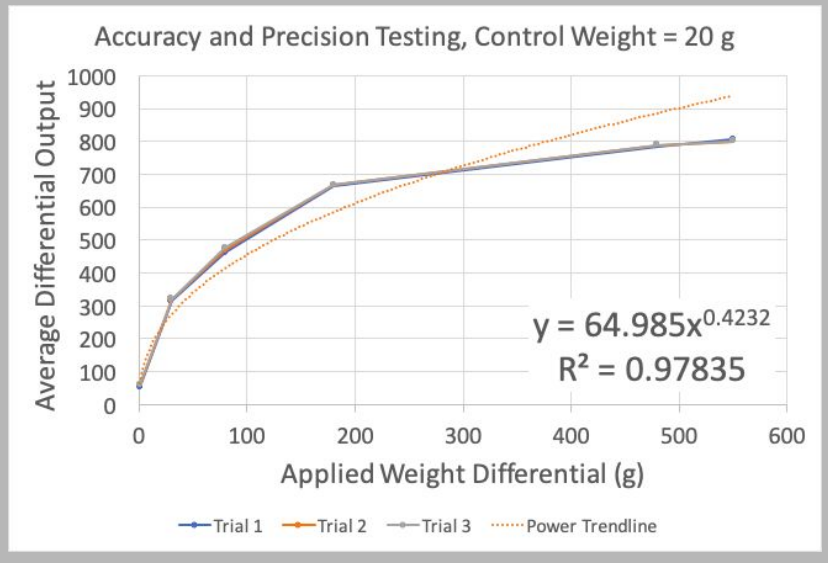
Calibration of Pressure



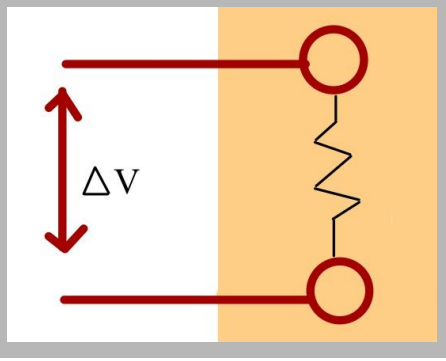
Dynamic Ranges

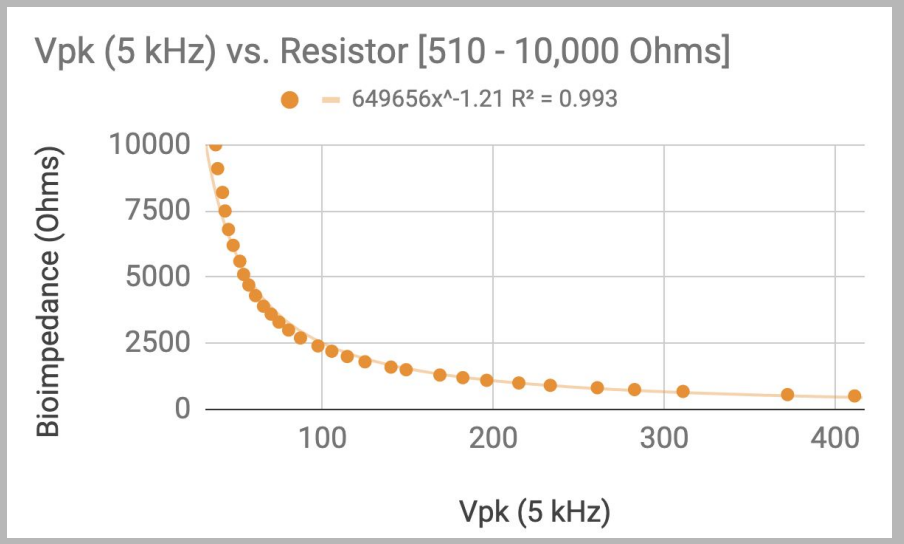
0 - 18 kPa

0 - 470 kΩ



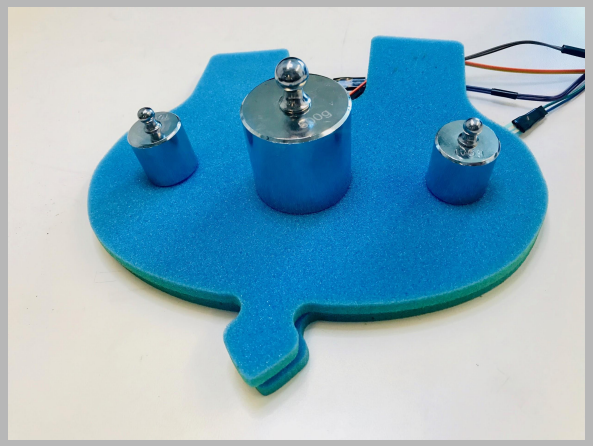
Calibration of Bioimpedance





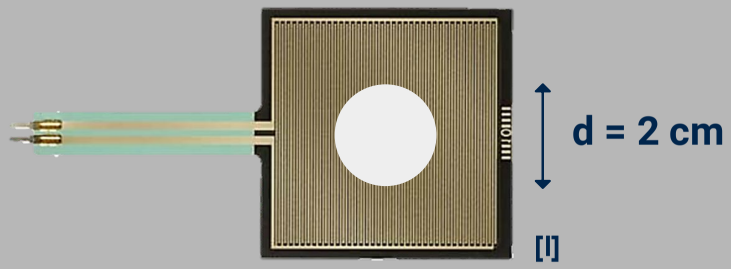
Verification Testing - Pressure

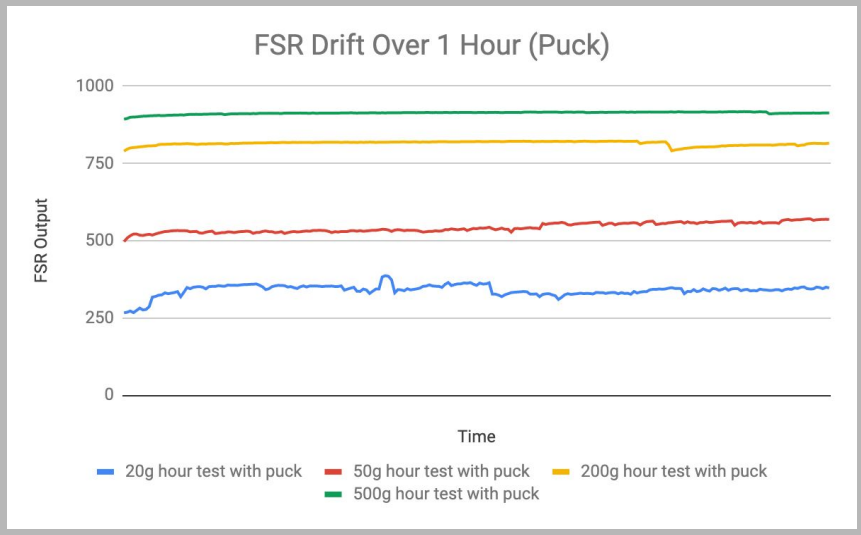
Accuracy of Pressure Differential



	Left (100g)	Center (500g)	Right (100g)
Average Differential	831.2	956.7	799.3
Standard Deviation	3.9	2.4	4.3

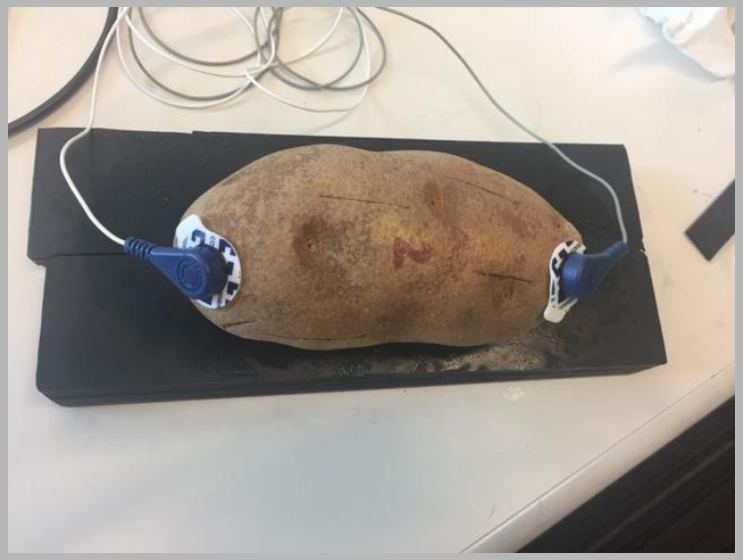
1 Hour Drift Test





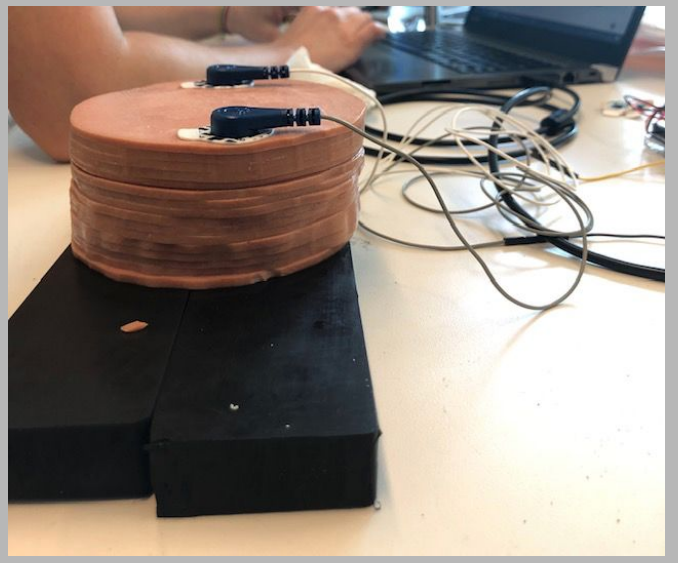
Verification Testing - Bioimpedance

Frequency and Voltage Study



Conclusion: **100 kHz** and **2 Vpk** gave minimal variation in bioimpedance and optimal for human measurements

Depth Test



Conclusion: Bioimpedance electrodes can measure up to **12 mm** in depth

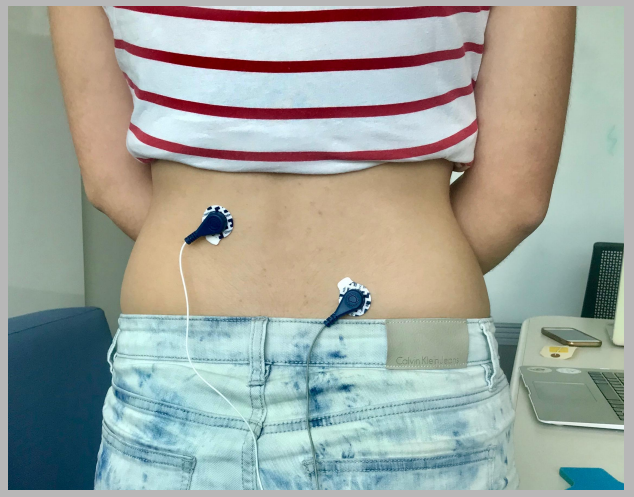
Verification Testing - Bioimpedance

Selectivity Test

Frequency = 100 kHz Vpk = 2 V	
Sample	Reduction
Potato 1	48.49%
Potato 2	71.56%

Conclusion: **Measurable reduction** in bioimpedance after saline bath

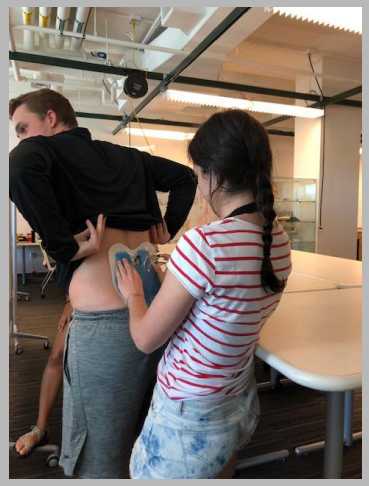
Human Subject Test



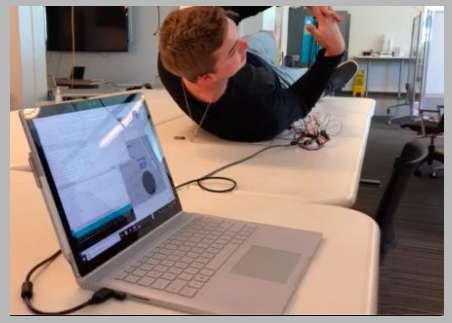
Conclusion: Bioimpedance values were **variable yet consistently in the healthy range**

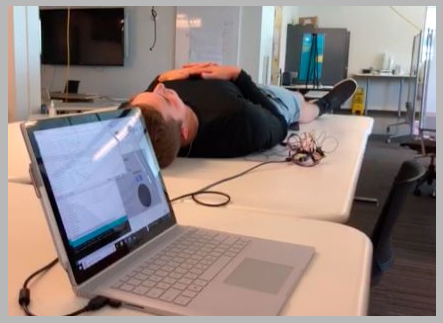
Average (n = 8): 2792 ± 700.2 Ω

Verification Testing - SacralSense System



```
Impedance: 1736.97 - Healthy. Good Job! :-)
Impedance: 1736.97 - Healthy. Good Job! :-)
Impedance: 1741.03 - Healthy. Good Job! :-)
Impedance: 1730.92 - Healthy. Good Job! :-)
Left Pressure Sensor reading = 581 - Large Pressure
Center Pressure Sensor reading = 650 - Large Pressure
Right Pressure Sensor reading = 615 - Large Pressure
Force being applied on spinal column
Left Pressure Sensor reading = 471 - Medium Pressure
Center Pressure Sensor reading = 641 - Large Pressure
Right Pressure Sensor reading = 473 - Medium Pressure
Force being applied on spinal column
```





Conclusions:

- System **alternated** between collecting pressure and bioimpedance data
- System detected localized pressure due to **shifts in weight**

User Interface

SacralSense User Interface

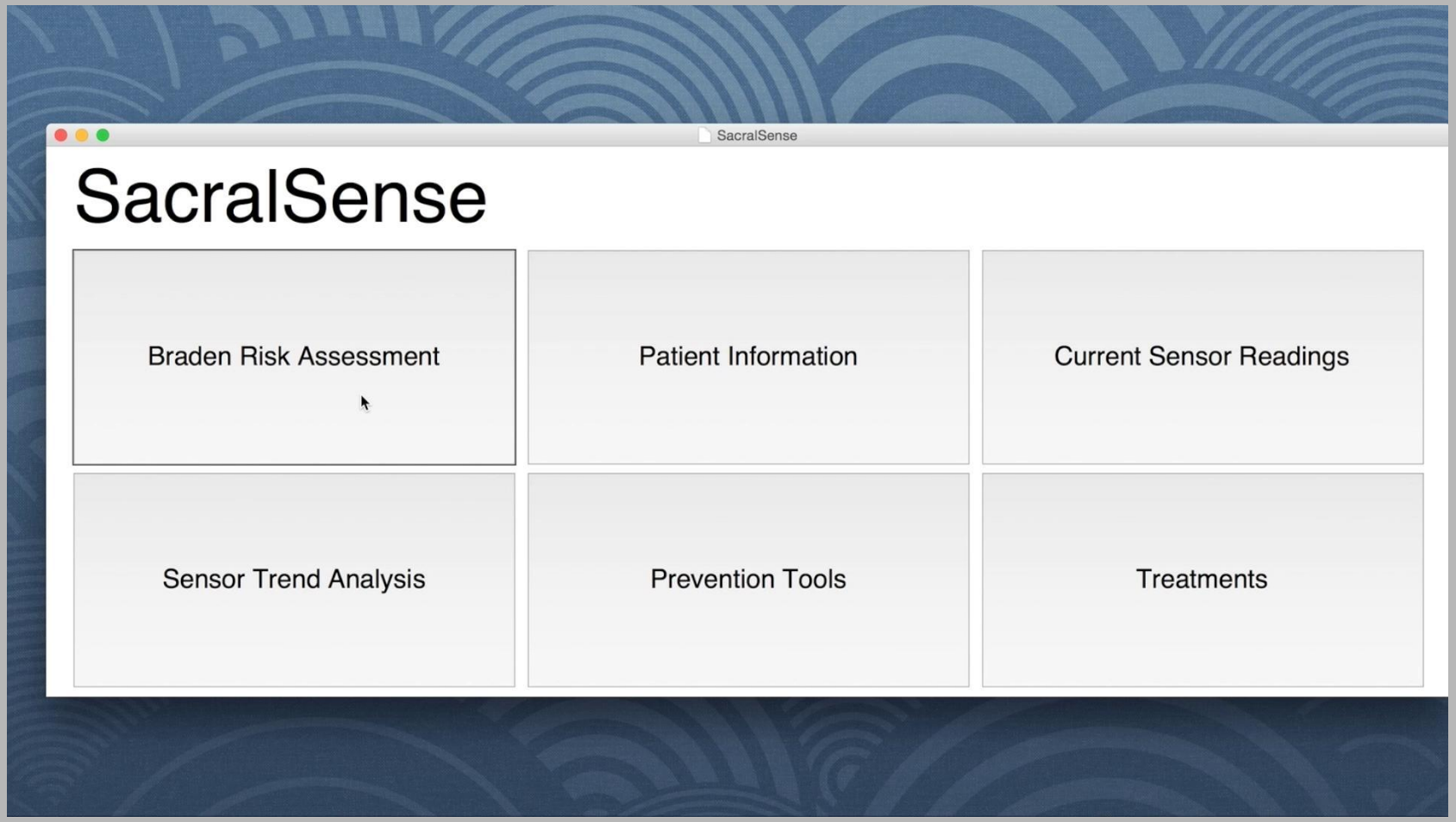
Accessibility of Data

Trend Analysis

Automatic Alerts

User Friendly

SacralSense User Interface



Usability Tests

Threshold Alarms
Alarms are easy to notice and beneficial

Concerns
Recurring audible alarms can distress patient

Future Design Ideas
Solely visual alarm (flash) in patient's room
Include audible alarm in telemetry system

Usability Tests

Hydrofoam Dressing
Comparable to current dressings
Reference sensor location is accurate

Concerns
Wiring could increase external pressure and added inconvenience

Future Design Ideas
Consider wireless/portable design

Usability Tests

Input of Data
All necessary patient information is included

Concerns
Repetitive inputs are a waste of time

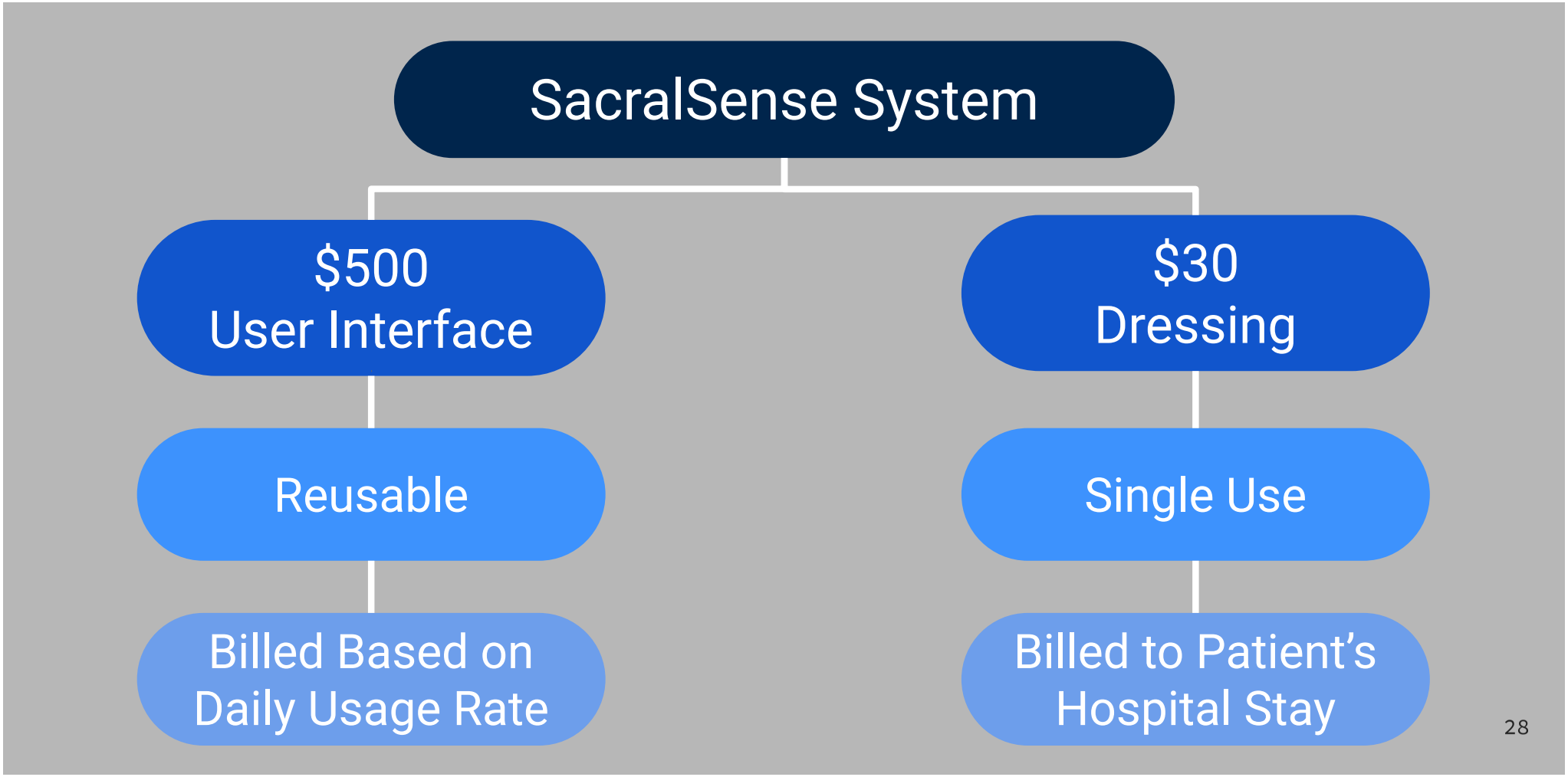
Future Design Ideas
Automatic transfer of information between EMR and user interface

Commercialization

Regulatory Landscape

Regulatory Classification	Environment of Use	Patient Population	Indications for Use
Class II 510(k)	Intensive Care Unit	Age 15+	ICU Patient at Risk for a Pressure Ulcer

Value Brief - Pricing Strategy



Value Brief - Healthcare Economics

Case Study: 9.49% Market Penetration, +20% Prevention Rate

Time Savings

101.8 days/yr
10 bed ICU

Treatment Savings

$206,785/yr
Emory ICU unit [12]

Litigation Savings

$75.9 million/yr
in USA

Future Directions

Testing

Cadaver Tissue
Healthy vs. Unhealthy

Animal Studies
n = 30, Porcine

Clinical Studies
n = 100, Safety & Efficacy

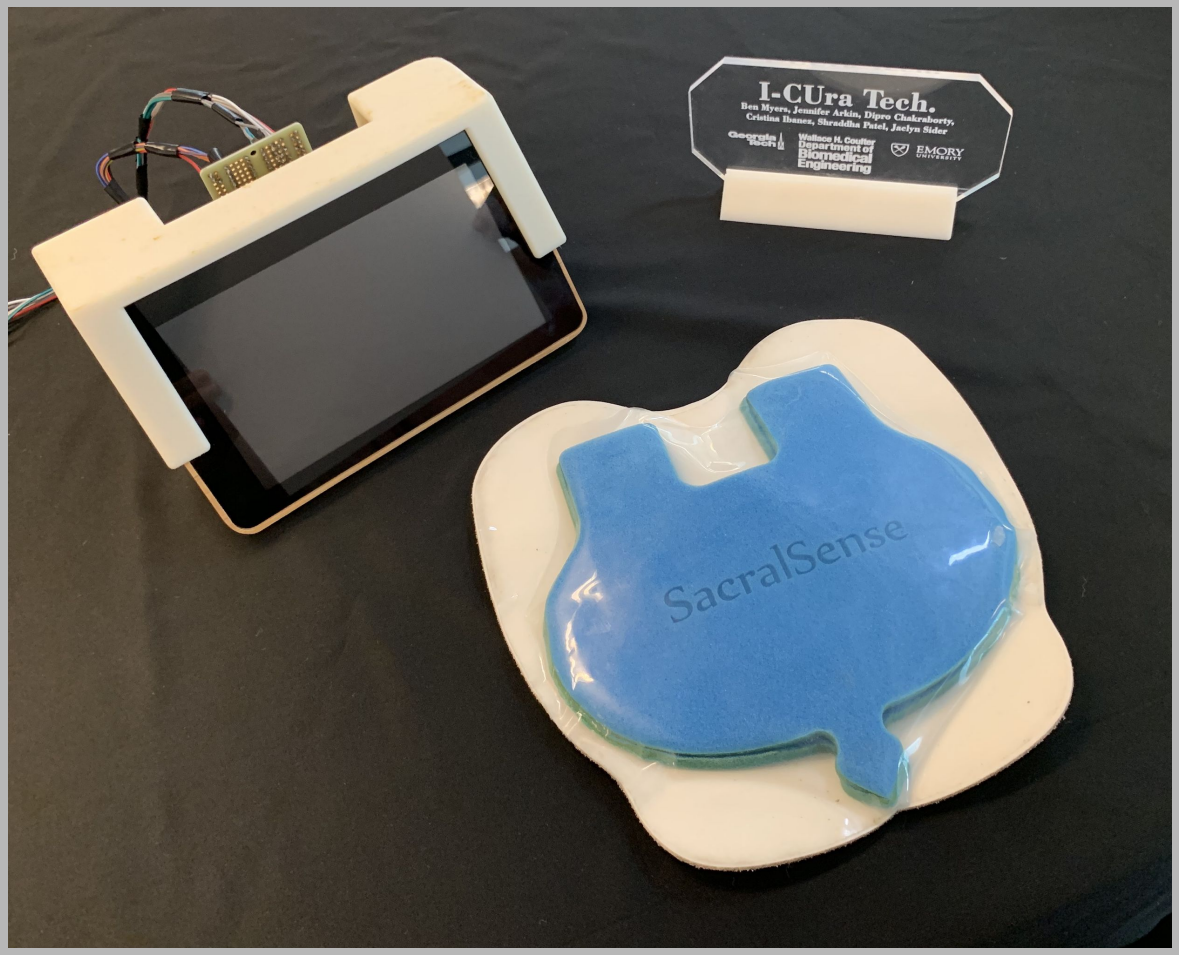
Design

Design for Manufacturing

Portable System

Expand Product Portfolio

SacralSense System



Acknowledgments

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Thank You!

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Team Captain

Jennifer Arkin
Regulatory

Dipro Chakraborty
Quality

Cristina Ibáñez
R&D

Ben Myers
Clinical

Shraddha Patel
Financial

References

[1] NPUAP Pressure Injury Stages. (n.d.). Retrieved from http://www.npuap.org/resources/educational-and-clinical-resources/npuap-pressure-injury-stages/

[2] Geriatric Medicine Gerontology Hopkins Medicine Chapter 3 - Pressure Ulcers. (n.d.). Retrieved from https://www.hopkinsmedicine.org/geriatric_medicine_gerontology/_downloads/readings/section8.pdf

[3] Graves, N., Birrell, F., & Whitby, M. (2005). Effect of Pressure Ulcers on Length of Hospital Stay. Infection Control & Hospital Epidemiology, 26(03), 293-297.

[4] Terekeci, H. M., Top, C., Kucukardali, Y., & Oktenli, C. (2009, August). Risk assessment study of the pressure ulcers in intensive care patients. Retrieved from https://www.researchgate.net/publication/26289972_Risk_assessment_study_of_the_pressure_ulcers_in_intensive_care_patients

[5] Boyko, T. V., Longaker, M. T., & Yang, G. P. (2018). Review of the Current Management of Pressure Ulcers. *Advances in wound care*, *7*(2), 57-67.

[6] Are We Ready for This Change? Preventing Pressure Ulcers in Hospitals: A Toolkit for Improving Quality of Care. April 2011. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/systems/long-term-care/resources/pressure-ulcers/pressureulcertoolkit/putool1.html

[7] Page, L. (n.d.). 5 Most Common Hospital Acquired Conditions Based on Total Costs. Retrieved from https://www.beckershospitalreview.com/hospital-management-administration/5-most-common-hospital-acquired-conditions-based-on-total-costs.html

[8] Hospital-Acquired_Conditions. (2018, August 30). Retrieved from https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitalacqcond/hospital-acquired_conditions.html

[9] HAC-Reduction-Program. (2018, July 30). Retrieved from https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program.html

[10] The Relative Contributions of Interface Pressure, Shear Stress, and Temperature on Tissue Ischemia: A Cross-sectional Pilot Study. (n.d.). Retrieved from https://www.o-wm.com/article/relative-contributions-interface-pressure-shear-stress-and-temperature-tissue-ischemia-cross

[11] Batchu, S., & Taco, K. (n.d.). Design of a Bio-Impedance Analyzer and Tissue Phantom for Prevention of Pressure Ulcers. Retrieved July 23, 2019.

[12] Emory University Hospital surgical/transplant ICU recognized with Beacon Award for high nursing standards. (2017, May 03). Retrieved July 15, 2019, from https://news.emory.edu/stories/2017/05/5e_icu_euh_receives_beacon_award_for_nursing/index.html

References

[a] Pressure Injury Staging Illustrations. (n.d.). Retrieved from http://www.npuap.org/resources/educational-and-clinical-resources/pressure-injury-staging-illustrations/
[b] Our journey towards Outstanding Care, Always The Last 5 Years. (n.d.). Retrieved from http://www.kgh.on.ca/kgh-journey/
[c] Digital Health Solutions. (n.d.). Retrieved from http://digitalhealths.com/
[d] Psychologist clipart transparent ~ Frames ~ Illustrations ~ HD images ~ Photo Designs. (n.d.). Retrieved from https://kathleenhalme.com/explore/psychologist-clipart-transparent/
[e] Sheridan Sheridan Outlet Fresh Loft Pillow. (n.d.). Retrieved from https://www.sheridanoutlet.com.au/sheridan-outlet-fresh-loft-pillow-t2069-b100-c200-na-white.html
[f] Heelift® AFO. (n.d.). Retrieved from https://www.alimed.com/heelift-afo.html
[g] 3M Wound Care Solutions. (n.d.). Retrieved from https://www.3m.com/3M/en_US/company-us/all-3m-products/~/All-3M-Products/Health-Care/Medical/?N=5002385 8707795 8707798 8709679 8711017 3294857497&rt=r3
[h] Explore this Stryker Patient Care Offering. (n.d.). Retrieved from https://patientcare.stryker.com/en/products/surfaces/powered-surfaces/isolibrium
[i] A Wrong Turn: Fraudulent Documentation. (n.d.). Retrieved from https://www.medscape.com/viewarticle/896932
[j] Pressure Injuries: Common Sites. (n.d.). Retrieved from http://poc.select.kramesstaywell.com/Content/healthsheets-v1/pressure-ulcers-common-sites
[k] Graphical User Interface - Unlimited Download. Kisspng.com. (n.d.). Retrieved from https://www.kisspng.com/png-handheld-devices-user-interface-design-tablet-comp-2904443/
[l] Adafruit Industries. (n.d.). Square Force-Sensitive Resistor (FSR). Retrieved from https://www.adafruit.com/product/1075