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Need

3 million adults develop tissue pressure injuries each year. Incidence rates of **38% in hospitals**, **23.9% in nursing homes**.

2008 CMS Never Event prohibits medical reimbursement for hospital acquired conditions, including pressure injuries

Hospital acquired pressure injury treatment can cost the health industry up to **26.8 billion dollars**. 59% of these costs arise from DTI's that have reached stage 3/4

No current clinically accepted technology to detect PI prior to irreversible injury

Objective

Using **Diffuse Correlation Spectroscopy** to measure blood flow to **detect and diagnose DTI upon admission before it reaches an advanced state**. A probe will be placed on a patient's sacral region to detect any signs of ischemia.

Market Analysis

Population

Annual cases of pressure injury	3M
% Advancing to late stage	~30%
Total	~900,000

Potential savings estimate

Cost per patient:
10,708



of patients:
900,000



Total Savings
~9.6 B

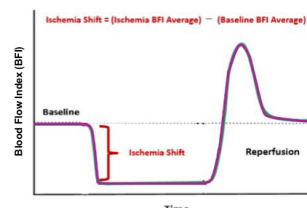
Design Inputs

Constraints

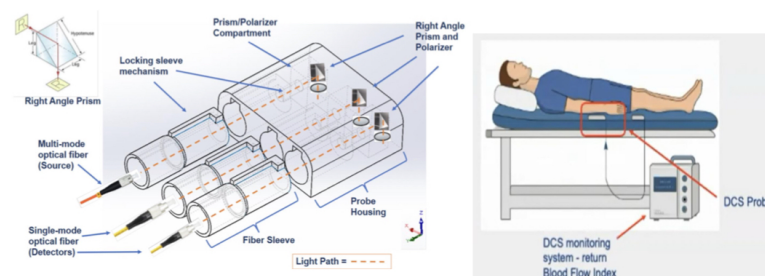
- Biocompatibility
- Max Laser Power: 5mW/mm²

Requirements

1. Assembly tolerance $\pm 0.15\text{mm}$
- 2a. 8-20 mm Source-Detector Separation
- 2b. $\geq 60\%$ decrease in BFI
3. Tensile strength $\geq 13.3\text{N}$
4. Application at sacrum



Prototype



- Probe compatible with DCS system to measure sacral blood flow
- Attach to sacral region using Tegaderm
- Flexible material



POTENTIAL RISK

- Sensor-induced skin irritation
- Application of additional pressure
- Eye irritation or injury
- Heat-induced skin burns

Medical-grade material (biocompatible per ISO-10993-10), **antiseptic protocol** for sensor, individual **pt. risk assessment**

Limit use of sensor to 15 minute periods; re-apply when necessary

Low-powered laser source mitigates possibility of inadvertent visual damage

Low-powered laser source avoids dangerous increases in temperature

OUR SOLUTION

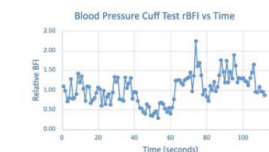
Verification/Validation

Test

1. Assembly Fit
2. Function/Flow
3. Lock Strength
4. Sacrum Function

Outcome

TBD



TBD

TBD

Existing Solutions/Limitations

Device	SacraFlow Probe	MRI (GE, Siemens)	Scanning Laser Doppler (Moor Instruments)	Ultrasound (GE, Siemens)	Thermal Imaging (FLIR Systems)
Capabilities	Detects early ischemia before skin breakdown; Ideal for ICUs, ERs, surgical teams where perfusion monitoring is critical	Measures blood oxygenation and perfusion, expensive, time consuming	Monitors microcirculation, low depth penetration	Measure blood flow velocity, highly operator dependent	Monitors temperature changes as proxy for tissue perfusion, rapid results, low depth penetration
Quantifies blood flow	✓	✓	✓	✗	✗
Portable System	✓	✗	✓	✓	✓
Depth of measurement	4-10 mm	Several cm	1-2 mm	1-2 cm	Surface-based (~0.5mm)

Conclusion and Impact

- Enhances patient care through early DTI detection, **reducing complications** and **accelerating recovery**
- **Lowers hospital costs** by preventing late-stage injuries and reducing readmissions
- **Portable, non-invasive**, and **easy-to-use**—fits seamlessly into existing clinical workflows



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Padula WV, Delarmente BA. The national cost of hospital-acquired pressure injuries in the United States. Int Wound J. 2019 Jun;16(3):634-640. doi: 10.1111/iwj.13071. Epub 2019 Jan 28. PMID: 30693644; PMCID: PMC7948545.