

# Daily Diabetic Foot Risk Screening Device

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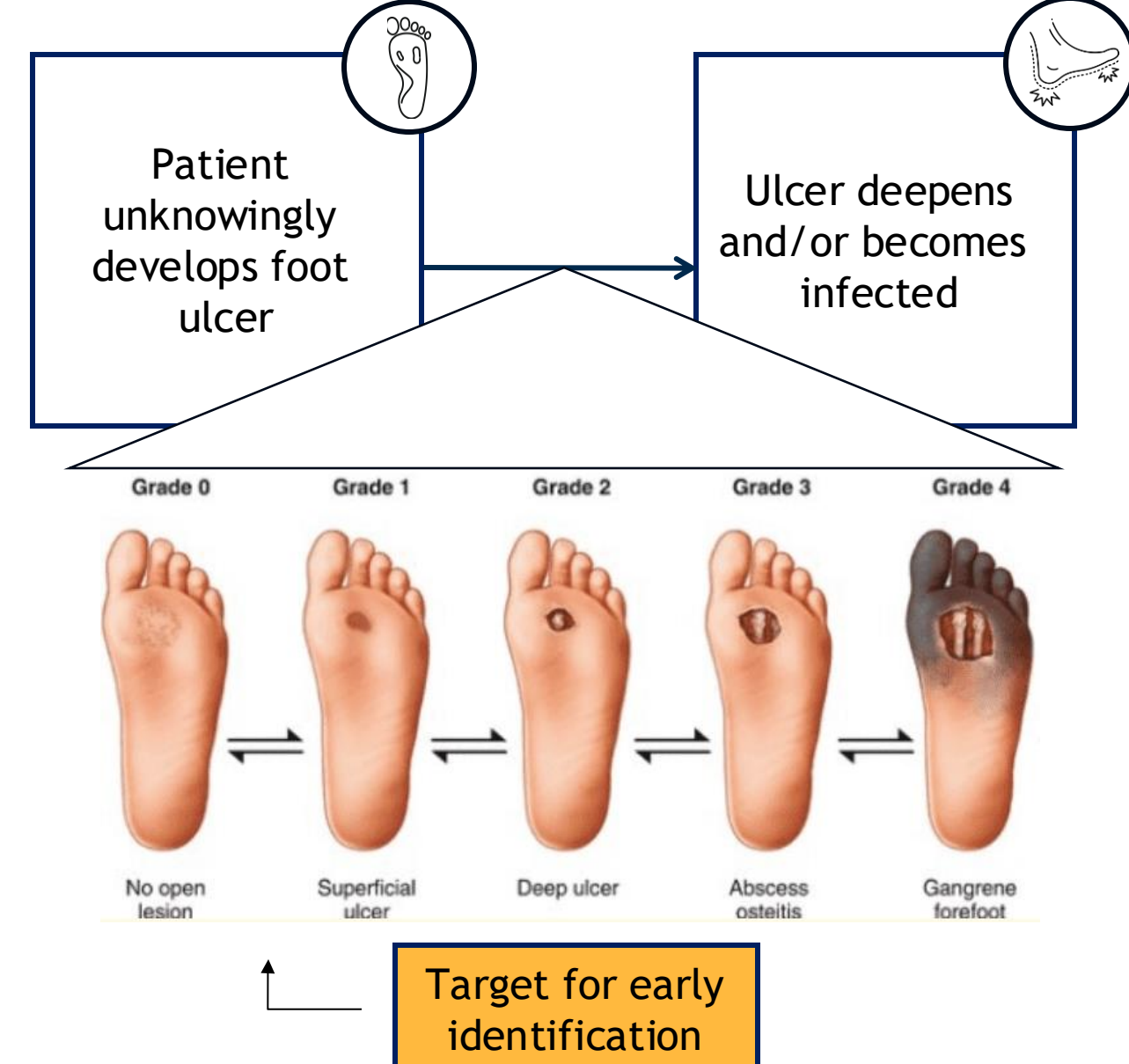


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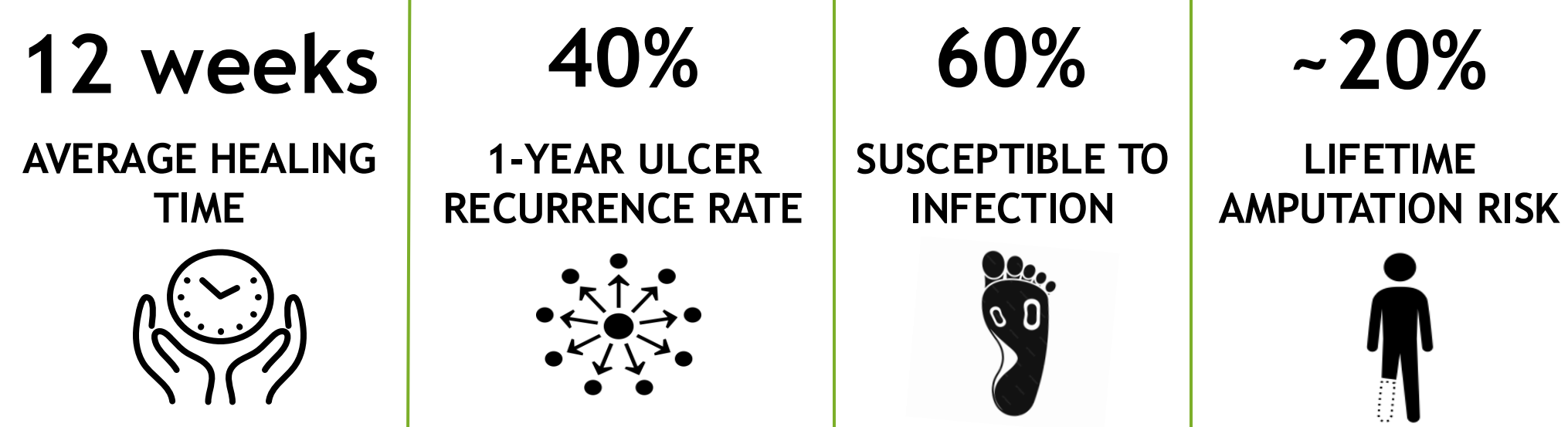
## BACKGROUND

- Due to loss of sensation, individuals with diabetic neuropathy may not notice pathological abnormalities on their feet. Calluses and injuries go undetected, eventually developing into open wounds called **ulcers**.
- Ulcers affect approximately **30% of diabetics in their lifetime**.

### Wagner Classification of DFU Stages



### Clinical Outcomes of Diabetic Foot Ulcers (DFUs)



### DFU Monitoring Technology Gap Analysis

	Smart Socks	Ulcer Monitoring App	RTM Mat	Biosensing Insoles
Early-stage ulcer detection	—	×	—	✓
Frequent measurements	✓	×	×	✓
Comprehensive bioanalysis	×	×	×	—
Convenient	—	×	—	✓

**Need Statement:** Diabetes patients need a convenient and effective method to monitor early-stage neuropathic ulcer development to minimize necessary invasive treatments.

### DESIGN INPUTS

#### Functional Requirements

Detect Early-stage Ulcers	Identify ≥ 90% of ulcers at or before Grade 1 on the Wagner scale
Alert Patients	≥ 3 different levels of risk severity are considered
Interface with Clinical Systems	Score > 4 on user-defined scale to assess provider perception of device data integration

#### Constraints

Convenient	Score > 4 on user-defined scale
Safe	User-defined scale and IEC 60601 for medical device electrical safety
Easy to Use	Score > 4 on user-defined scale
Equitable	Score > 4 on user-defined scale

## PROPOSED SOLUTION: EZ STEPPER

### Pathophysiology of Early-Stage Ulcers

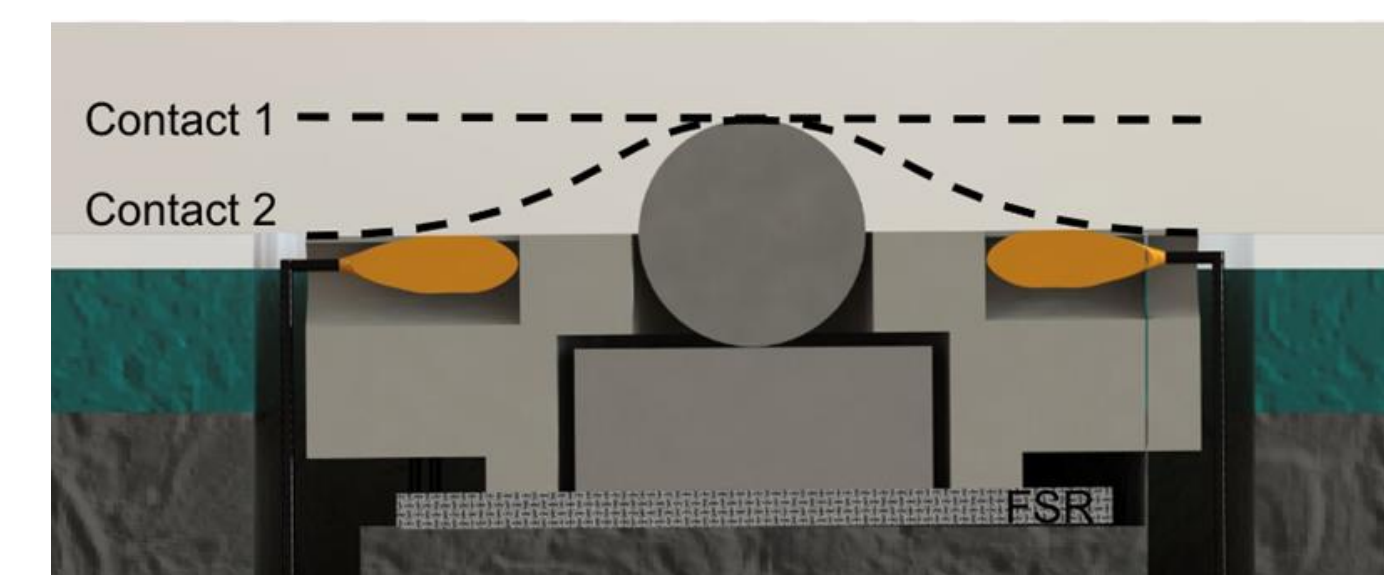


**Pre-Ulcer Skin**  
• Calloused skin is 2-3 times stiffer than normal skin.



**Inflammation**  
• DFU inflammation causes locally elevated skin temperature - 2.2°C is considered abnormal.

### Principle of Operation – Multimodal Biosensing

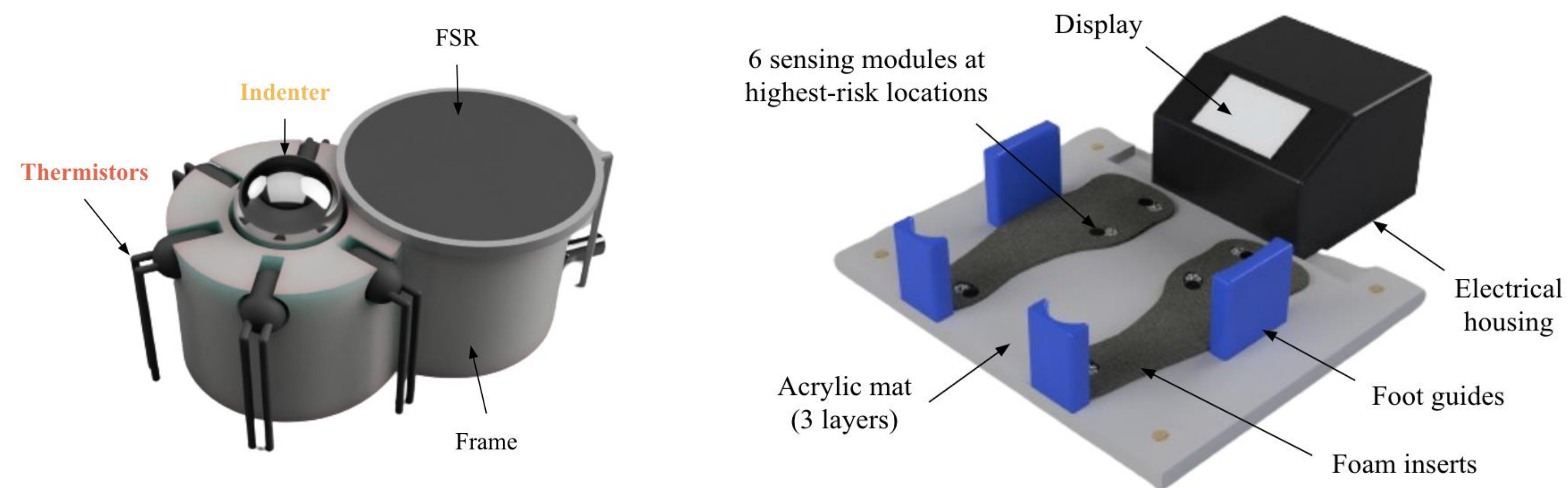


**Pre-Ulcer Skin**  
• Spherical indentation measures Young's modulus through Hertz Contact Theory

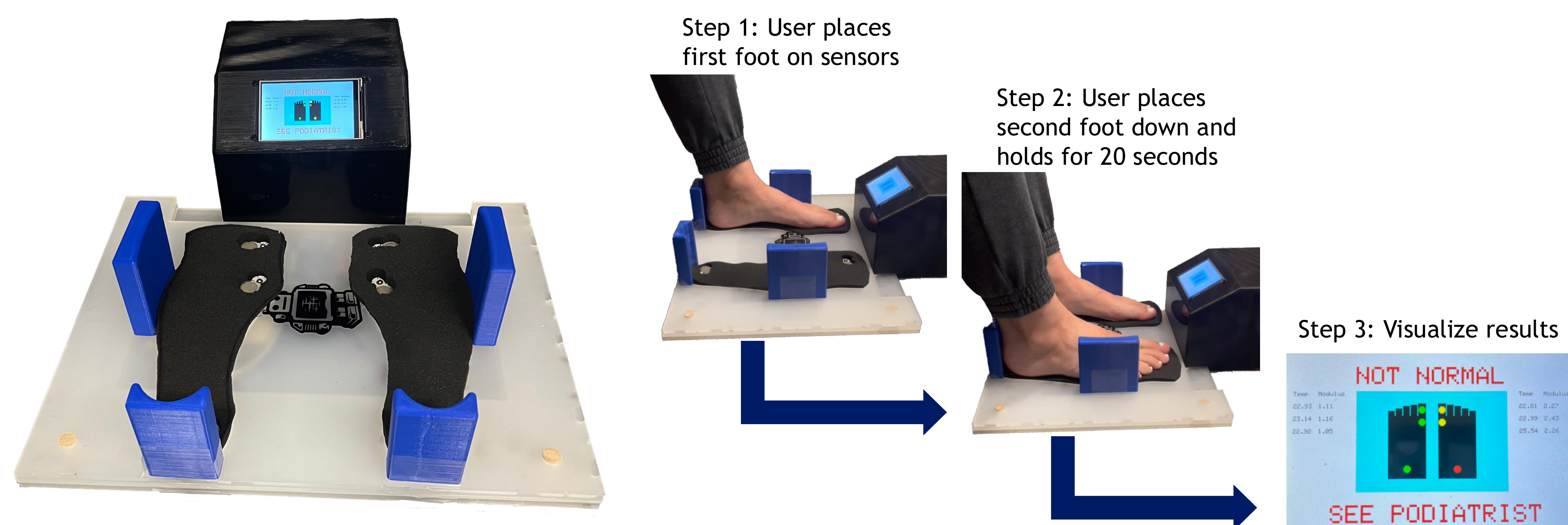
$$E = \frac{3F(1-\nu)}{4R^{1/2}\delta^{3/2}}$$

**Inflammation**  
• Thermistors measure Temperature.

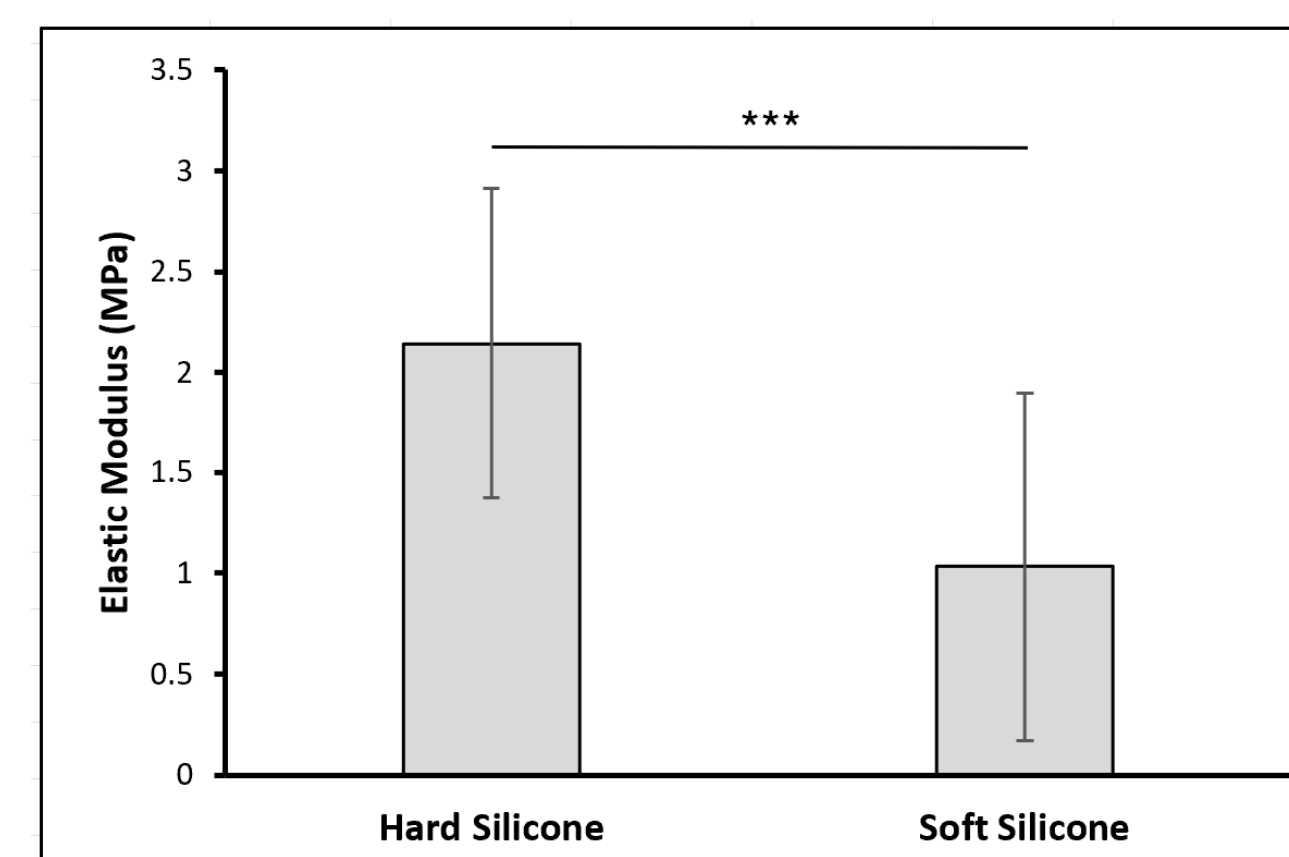
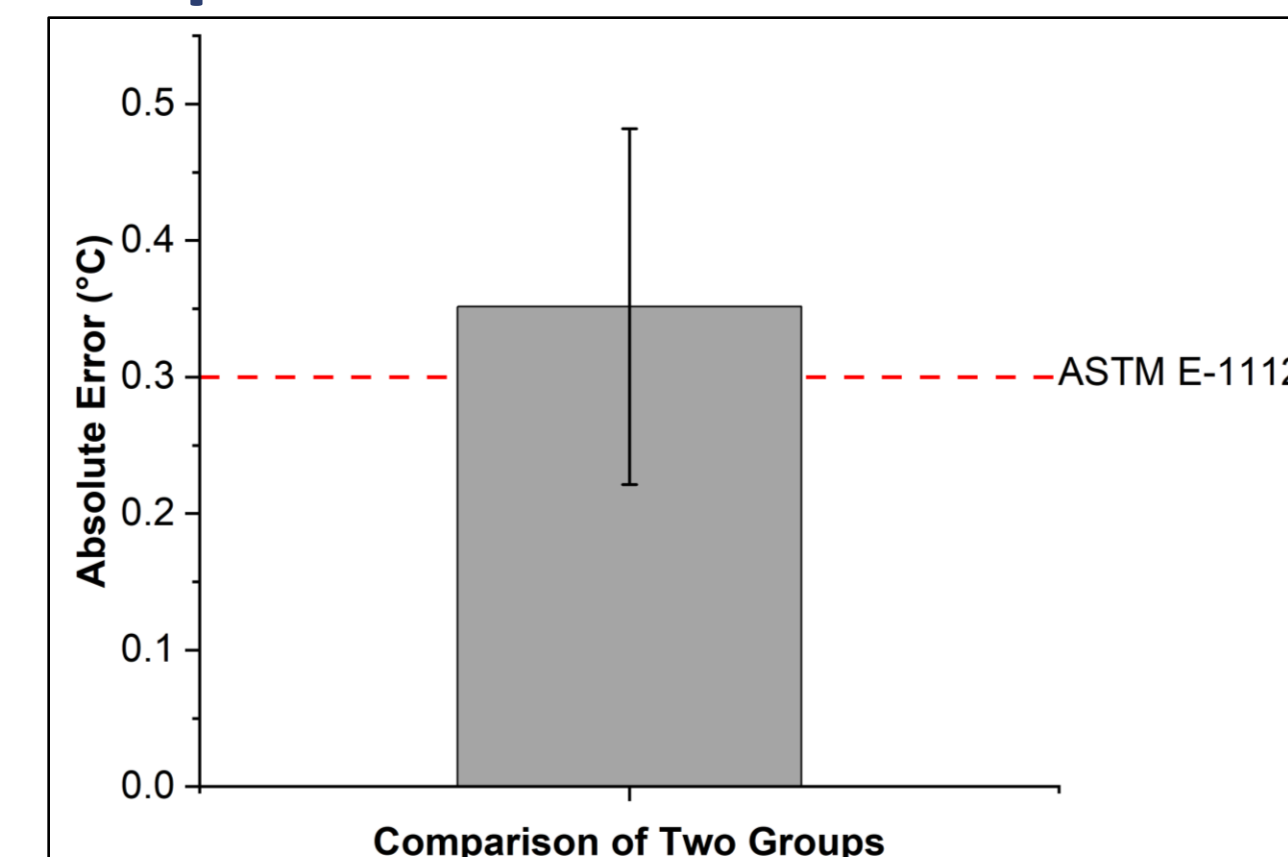
### Solution Visualization



### Prototype, Workflow, and Testing



### Is Temperature Detection Accurate? ✓ Is Modulus Detection Accurate? ✓ Can we Detect Ulcer Risk? ✓

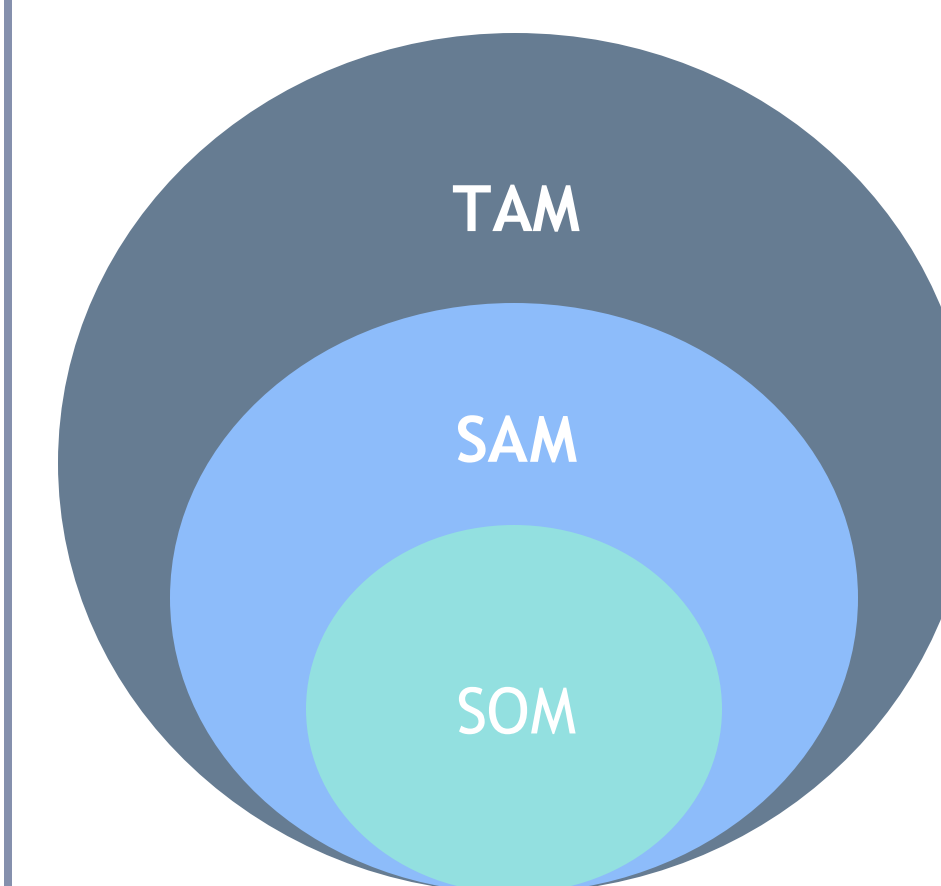


	Low Modulus	High Modulus
Low Temperature	100%	100%
High Temperature	87.5%	87.5%

## BUSINESS PLANNING

<b>Regulatory Pathway</b>	<ul style="list-style-type: none"> <li>Attain Class I (low risk) clearance from the FDA</li> <li>No 510(k) required, as the CFR predicate is also 510(k) exempt (21 CFR 890.5050)</li> </ul>
<b>Reimbursement</b>	<ul style="list-style-type: none"> <li>Device will be prescribed by podiatrists</li> <li>Coverage by payer mix of Medicare and commercial insurance (CPT Code 99454)</li> </ul>

### Foot Ulcer Sensors Market Size

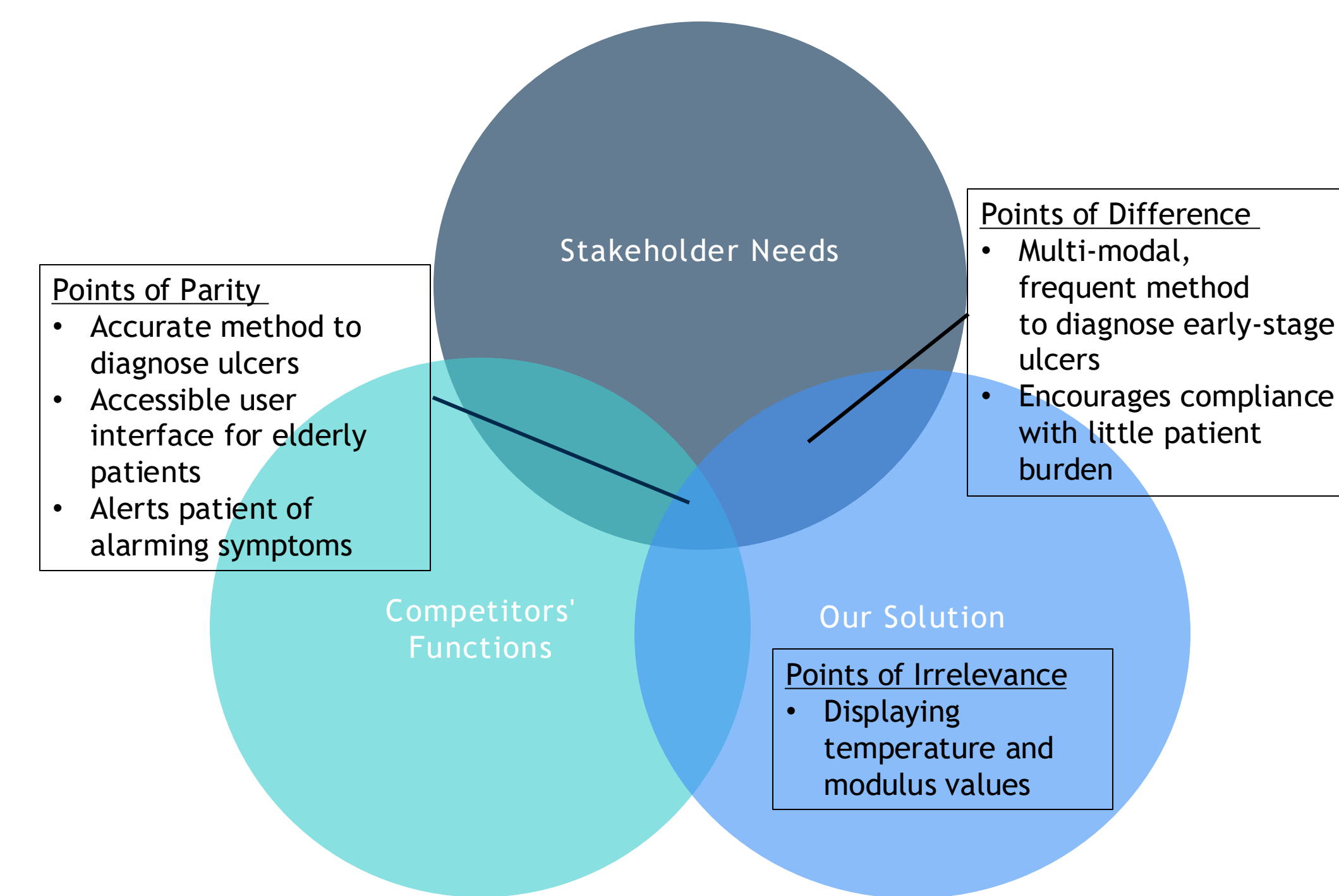


**Total Addressable Market**  
18.6 million people worldwide  
\$163 million with CAGR of 3.7%

**Serviceable Available Market**  
1.6 million people in the U.S.  
\$44.6 million per year

**Serviceable Obtainable Market**  
5-year projection: 100,000 patients  
\$2.8 million per year

### Value Proposition



## CONCLUSIONS

Our multi-modal solution monitors tissue stiffness and local temperature fluctuations as early indicators of DFU formation.

- Next steps:
  - Establish protocol to interface with clinical systems
  - Design for manufacturability and adaptability
  - Obtain approval as a Class A medical device
  - Go to market as a competitor with the Podometrics mat

## REFERENCES

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- Armstrong, D. G., Tan, T.-W., Boulton, A. J., & Bus, S. A. (2023). Diabetic foot ulcers. *JAMA*, 330(1), 62. <https://doi.org/10.1001/jama.2023.10578>
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