Advanced Recovery Solutions: PrecisionFit Analyzer

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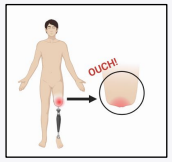
Clinical Problem



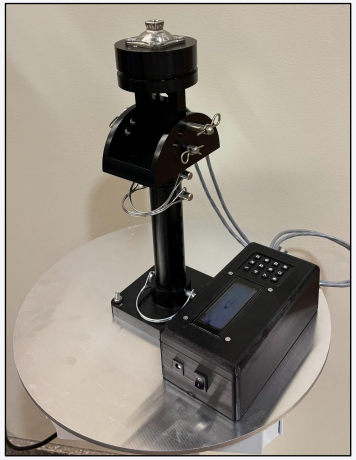
$35.55 Million

- **Clinical Problem:** Difficulty identifying high pressure areas on lower leg amputees.
  - ⅓ unhappy with fit, 50% due to contact related pain, 30% of that pain due to high pressure areas. [1,2]
- **Current Solutions:** Prosthetic socks and vacuum/inflatable sockets.
- The US market for lower limb prosthetics is $0.711 billion dollars [3]
- Estimated $35.55 million market value related to issues involving prosthetic fit.

Our Solution

PrecisionFit Analyzer:

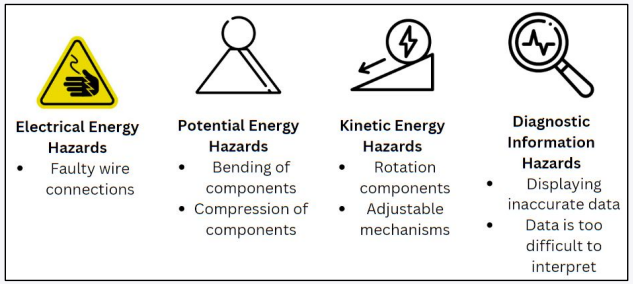
- Diagnostic tool to identify high pressure regions in lower limb prosthetics.
- Attaches to variety of prosthetics with universal pyramid adaptor.
- Adjustable for diverse patient heights and weights, analyzes fit throughout gait.
- LCD displays directional loading data for easy clinician interpretation during fittings.



Regulatory Information

- **Device Class:** 2
- **Predicate Devices:** Tekscan F-Socket, Rincoe Socket System, Tactilus Tactile Pressure System
- **Reference Standards:** ISO 14971:2019, ISO 10012:2003, ISO 24971:2020

Risk Management



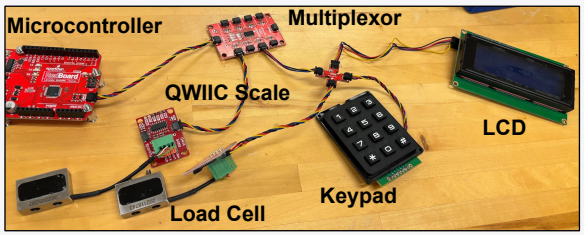
Mitigations:

- Safety-rated power cord, secured electrical components
- High-strength steel screws & pins
- Clear/simple user interface & display

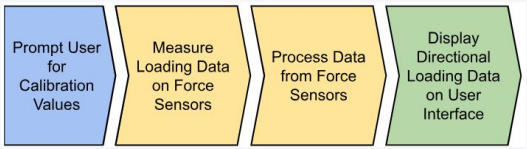
Design and Manufacture

- **3D Device Component Design:**

- **Electronic Components:**



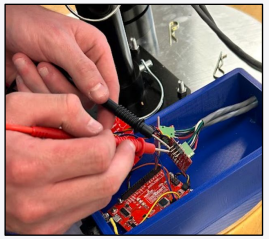
- **Software Design:**

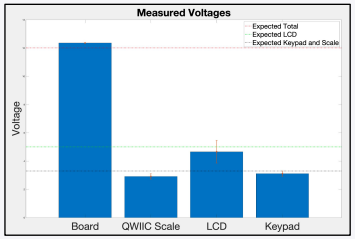


- **Prosthetic Docking with Device:**

Verification and Validation

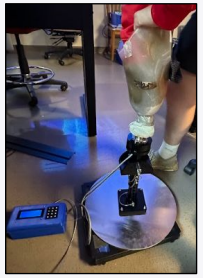
- **Device Voltage Testing with Multimeter:**

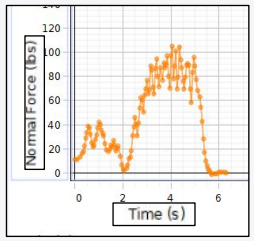




Proper supply of voltage to each electronic component. Overload is not likely and lifetime should not be reduced.

- **Device Stability and Integrity with Applied Forces in all Directions:**

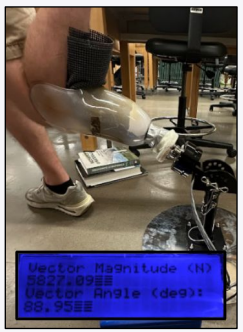


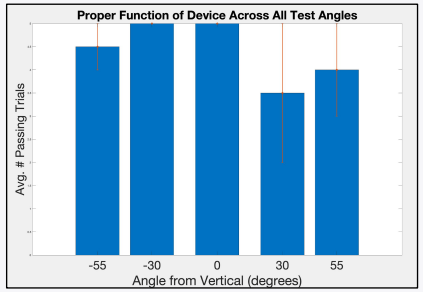


Force Applied (lbs)	Result
0	Pass
10	Pass
20	Pass
30	Pass
40	Pass
50	Pass
60	Pass
70	Pass
80	Pass
90	Pass
100	Pass
110	Pass

Device maintained structural integrity and balance across all loading directions.

- **Device Function Testing Across All Angle Adjustments:**





Proper function of device for each angle within maximum of 2 attempts.

Acknowledgements and References

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[1] Dillingham, T., Kenia, J., Shofer, F., & Marschalek, J. (2019) [2] Baars, E. C., Schrier, E., Dijkstra, P. U., & Geertzen, J. H. B. (2018)[3] *Limb Prosthetics Market Size, Share | Growth Analysis [2030]*