**Vein Access: Improving IV Insertion**

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**Introduction**

- Difficult Intravenous Access (DIVA) is failure to insert a needle into the vein with one attempt
- Affects 60 million peripheral IV catheter placements annually in the US
- Leads to complications such as extravasations (needle passing through vein)

Need for a solution to address difficulty in needle insertion for patients with poor vascular access in order to prevent resticking, extrusions, and discomfort.

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**Proposed Solution**

- Device uses a motor to add vibrational motion to the needle, thus decreasing force of insertion
- Infrared (IR) sensor detects blood flashback, indicating successful entry into the vein
- Vibration automatically stopped by IR sensor
- Components are contained within handheld housing

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**Vibrational Motor Testing**

**Methods**

A Material Testing System (MTS) was used to insert needles at 5mm/s into a Phantom skin model angled at 30 degrees

**Rotational**
- Rotation from 0-900 RPM, N=3
- 200±3 RPM: Motor stall in vein
- 700±3 RPM: 26.2% force reduction

**Vibrational**
- Stroke Length ~ 0.6mm, N=3
- 50 Hz: 23.6% force increase
- 100 Hz: 7.7%
- 166 Hz: 6.5%

**Drawbacks:**
- Reduced precision at high RPMs
- Needle wear

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**IR Sensor System Testing**

**Methods**

**Flashback Detection**
- Tested impact of environmental light spectrum on the sensor
- Evaluated signal threshold for flashback detection

Used red food coloring to simulate blood

**Results**

Threshold for detection of liquid in catheter is around 800 raw analog output units from the Arduinos (1023 is mapped to 5 V).

The results based on the preliminary IR circuit show that the IR sensor/transmitter pair is insensitive to environmental light. “On” = IR transmitter is on, “OFF” = IR transmitter is off.

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**Manufacturing Cost & Market Analysis**

**Pathway**

- The device falls under Class II
- It requires FDA review through premarket notification (PMN)/510(k)

**Market Analysis**

- Geriatric patients and patients with scleroder/ed hard veins is target market
- Market size of 2.4 billion people (bariatric, infant, emergency care) may benefit from product as well

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**References**