



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 US¹
- 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, extravasations, and discomfort.

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

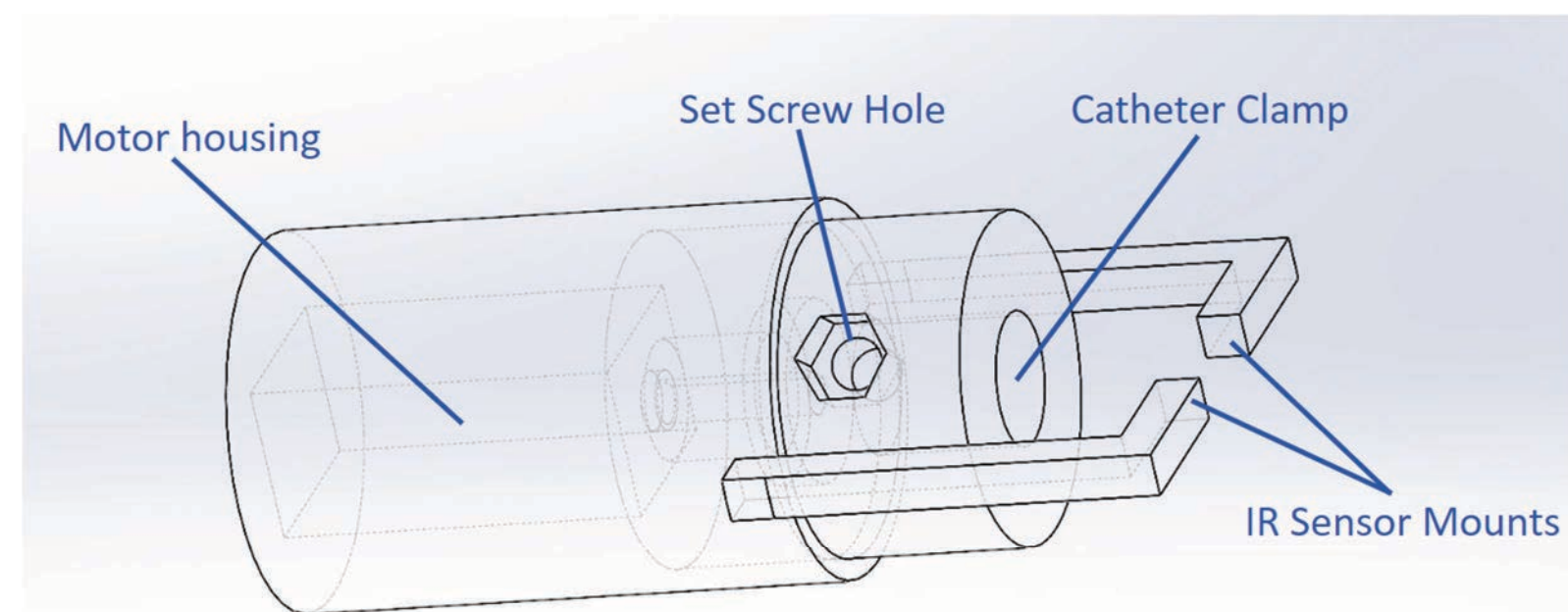


Figure 1: Housing Schematic

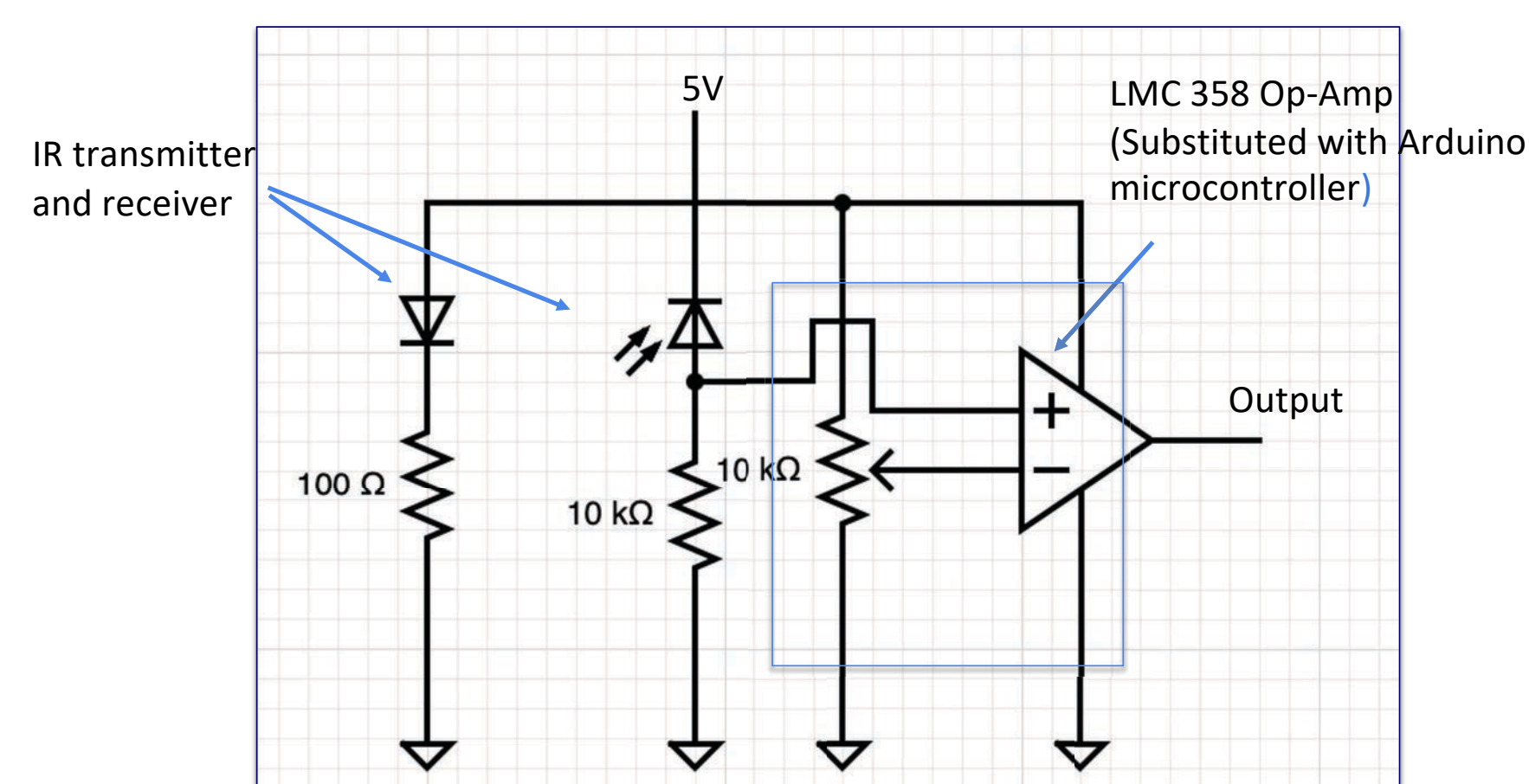


Figure 2: Preliminary Infrared Sensor Circuit Diagram

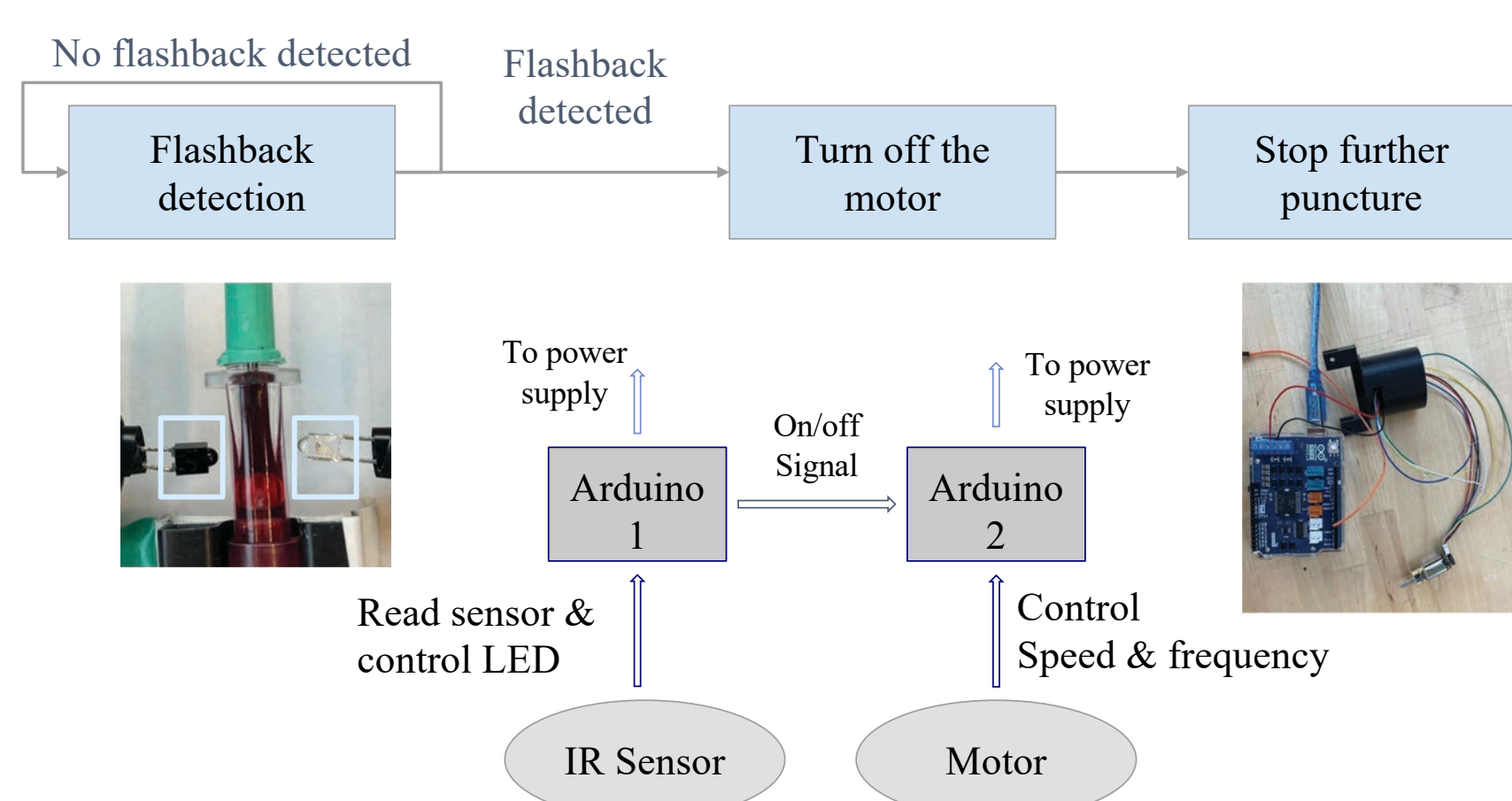


Figure 3: Integrated Device Operation Scheme

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±30 RPM: Motor stall in vein
- **700±30 RPM: 26.2% force reduction**
- 800+: 23.6% force increase

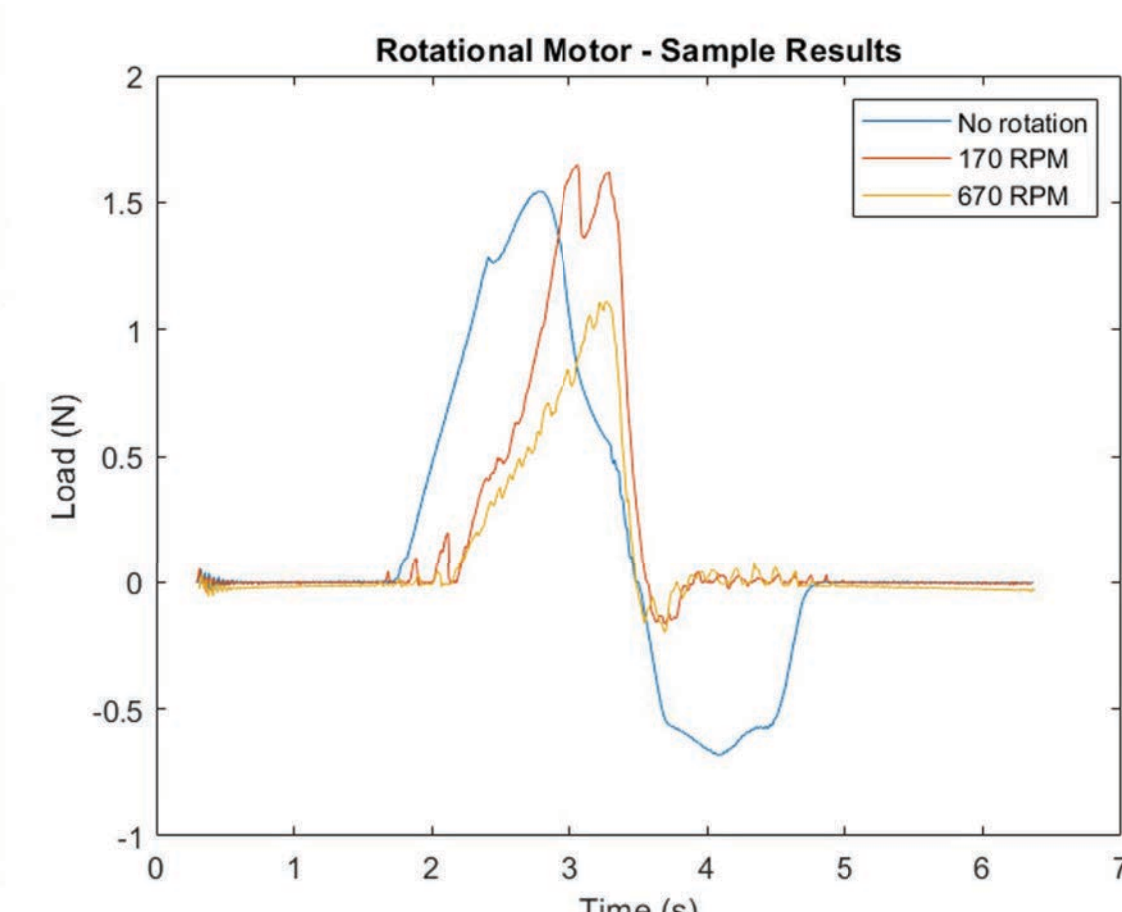


Figure 6: Sample results, showing decrease and stall

Vibrational

Stroke Length = 0.6mm, N=3

- Force Reduction:
- 50 Hz: 23.6%
 - 100 Hz: 7.7%
 - 166 Hz: 6.5%

Drawbacks:

- Reduced precision at high RPMs
- Needle wear

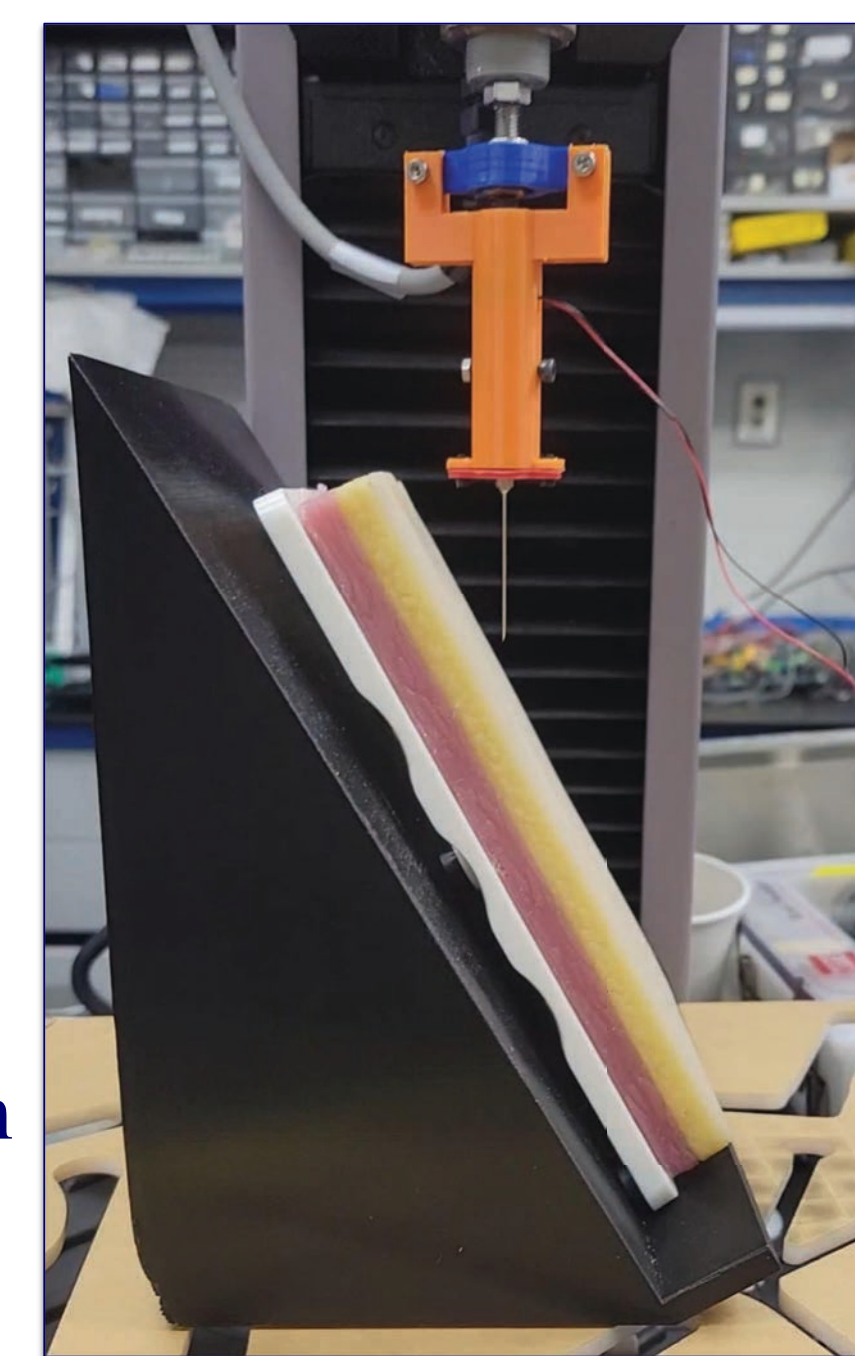


Figure 7: MTS Setup

IR Sensor System Testing

Methods

Flashback Detection

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

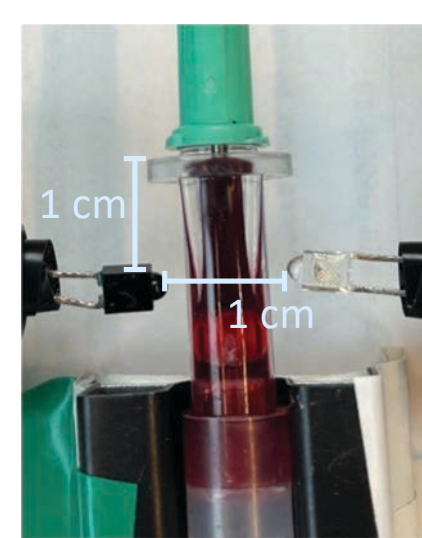


Figure 8: Flashback Detection Setup⁴

Used red food coloring to simulate blood

Results

Threshold Determination

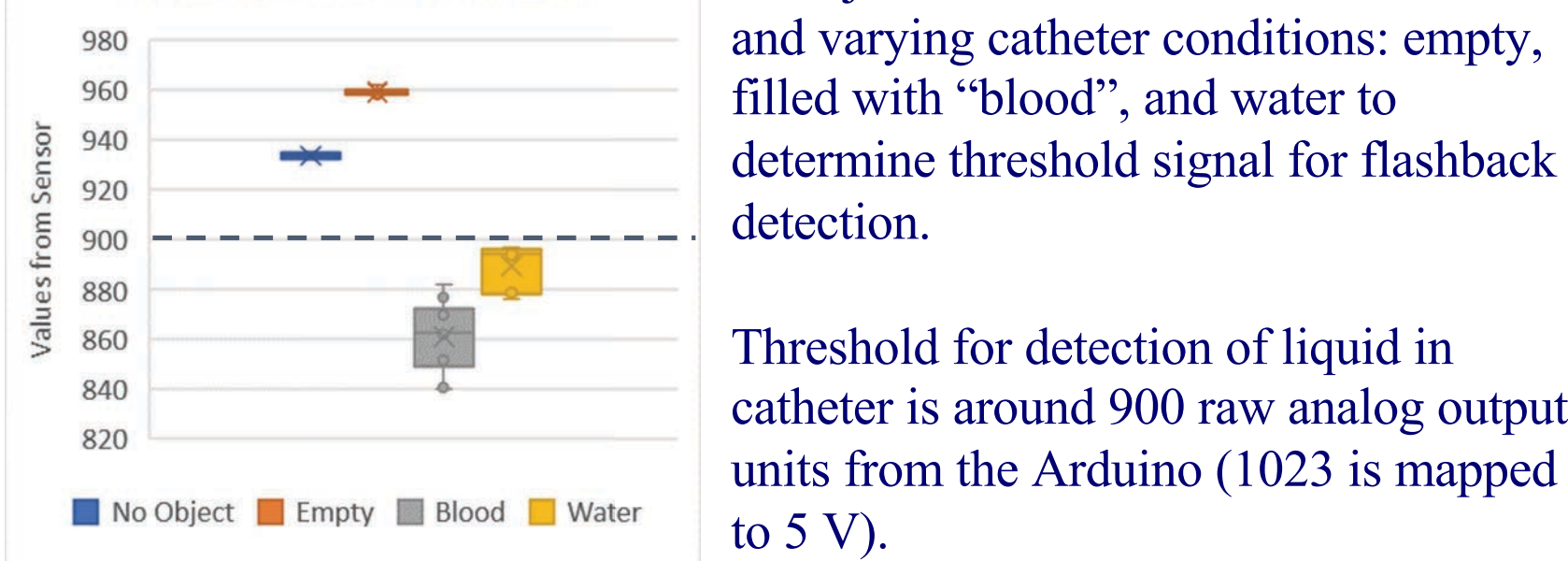


Figure 7: Signal from the IR sensor for no object between the sensor/transmitter and varying catheter conditions: empty, filled with "blood", and water to determine threshold signal for flashback detection.

Threshold for detection of liquid in catheter is around 900 raw analog output units from the Arduino (1023 is mapped to 5 V).

Table 1: Infrared Sensor Sensitivity Testing Data (Voltage)

Conditions	No Catheter		Empty Catheter		0.25mL Blood in Catheter	
	On	Off	On	Off	On	Off
Normal room (fluorescence light)	0.35-0.36	0	0.14-0.15	0	0.31	0
Bright room (~50 lumens)	0.35	0	0.15-0.16	0	0.31	0
Dimmer room	0.35-0.36	0				

The results tested 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.

Patent & Reimbursement

Patent

Compared to existing device

- Patents such as GentleSharp, (US-10219832-B2) utilize vibration to reduce insertion forces⁵

Novelty

- Sterility and suitability for human use
- IR sensor integration

Reimbursement

- Because IV insertions are covered under Medicare and Medicaid, we expect our device to be reimbursable
- There is no similar devices on the market for comparison but increasing first stick success rates would decrease expenses for the hospital (\$28-\$35 per IV needle stick)¹

Conclusion

- Reduced insertion forces by 6-26%
- IR sensor is compatible for detection of blood in the catheter and is insensitive to environmental light noises; thus, could be used for controlling the motor system
- This prototype addresses original problem statement:
 - reduces risk of extravasation with flashback detection
 - reduces resticks with insertion force reduction
- Future considerations:
 - Integration of smaller motors with higher frequencies
 - Lower cost
 - Smaller circuit components for the IR sensor and microcontroller

Acknowledgments

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Manufacturing Cost & Market Analysis

Manufacturing Information

Item	Price	Units	Description
IR Sensor & receiver	\$0.59	1	IR sensor & receiver pair for flashback detection
IR Arduino module	\$1.98	1	Circuit to connect IR sensors to arduino
Rotational Motor	\$20.95	1	30:1 Micro Metal Gearmotor HP 6V with Extended Motor 1 Shaft
Encoder for Rotational Motor	\$7.95	1	Magnetic Encoder Pair Kit with Side-Entry Connector for Micro Metal Gearmotors, 12 CPR, 2.7-18V
Motor encoder wires	\$1.89	1	6-Pin Single-Ended Female JST SH-Style Cable 30cm used for connecting motor encoder to Arduino Motor Shield
Arduino Motor Shield	\$27.60	1	Arduino Motor Shield Rev3 used for testing rotational motor
Arduino Uno	\$28.50	1	Arduino UNO: one to control IR sensor and other for motor control
Ball Bearings	\$9.46	1	4575N31: Light Duty Mounted Ball Bearing with Two-Bolt Flange, Shielded, for 1/8" Shaft Diameter used for housing
Filament for 3D printing housing	\$20.99	1	OVERTURE PLA Filament 1.75mm PLA 3D Printer Filament, 1kg Cardboard Spool used for housing
Total Cost			\$149.36

Pathway

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

Market Analysis

- Geriatric patients and patients with sclerosed/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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