The Development of a 4 DoF Robotic Manipulator for Automated Venipuncture

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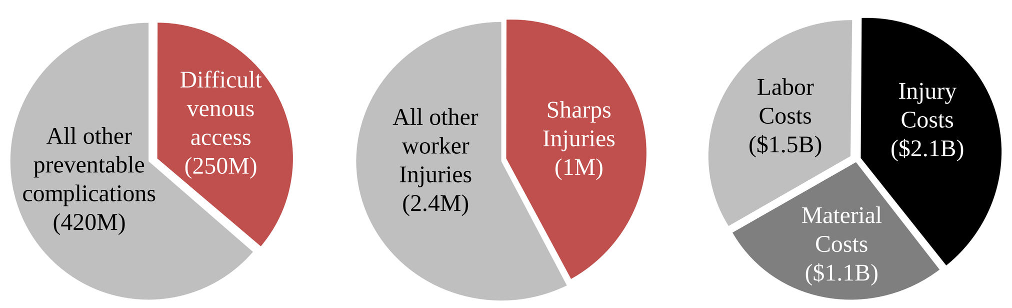
Clinical Problem

- Venipuncture is the most ubiquitous clinical routine practiced in the U.S. (**1.4 B/yr**[1]) and the leading cause of medical injury for both patients (**2 M/yr**[2]) and practitioners (**1 M/yr**[3]).
- First-stick failure rates are exacerbated (>60%)[4] in difficult populations, including pediatric, geriatric, obese, and chronically-ill patients. Repeated failures significantly increase the risks of tissue damage, contaminated sharps injuries, and bloodborne disease transmission[5]. In total, **venipuncture-related complications are estimated to cost the U.S. healthcare system close to $5 billion/year**[1].



- Current imaging technologies are unable to improve first-stick success, completion time, and practitioner safety[6,7].
- Robotic needle insertion systems are large, complex, and expensive; and none are fully automated nor miniaturized enough to be implemented for venipuncture.
- **Project goal: Develop an autonomous medical robot that improves venipuncture accuracy, speed, and safety by drawing blood and delivering IV fluids with >95% first-stick success in <2 min**[8,9]**.**

Current Venipuncture Methods

	Manual Phlebotomy	SonoSite	VeinViewer GS	Veinlite
User Needs				
Mode of operation	VIS light & palpation	Ultrasound	NIR light	Trans-illumination (VIS light)
Completion time	22.9 min[1]	16.1 min[4]	13.5 min[6]	11.75 min[7]
First-stick accuracy	50-80%[1]	74%[4]	65%[6]	60%[7]
Portable	✔	-	✔	✔
Automated intervention	-	-	-	-
Practitioner safety	-	-	-	-
US Market Share	97%	1.5%	1.0%	0.5%

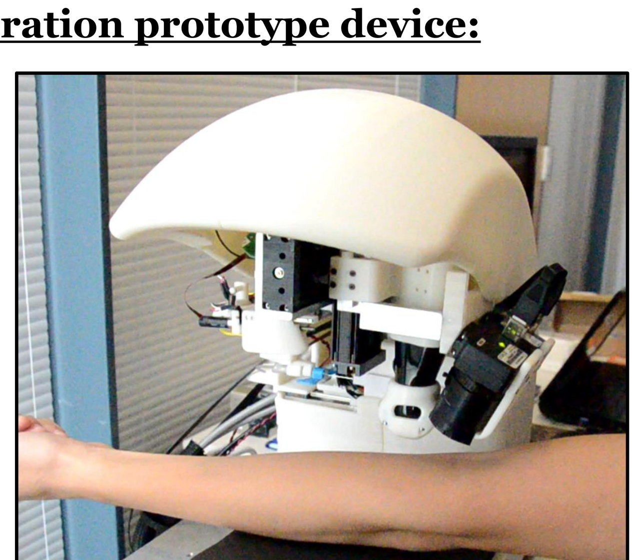
Device Design

a. **Engineering design requirements:**

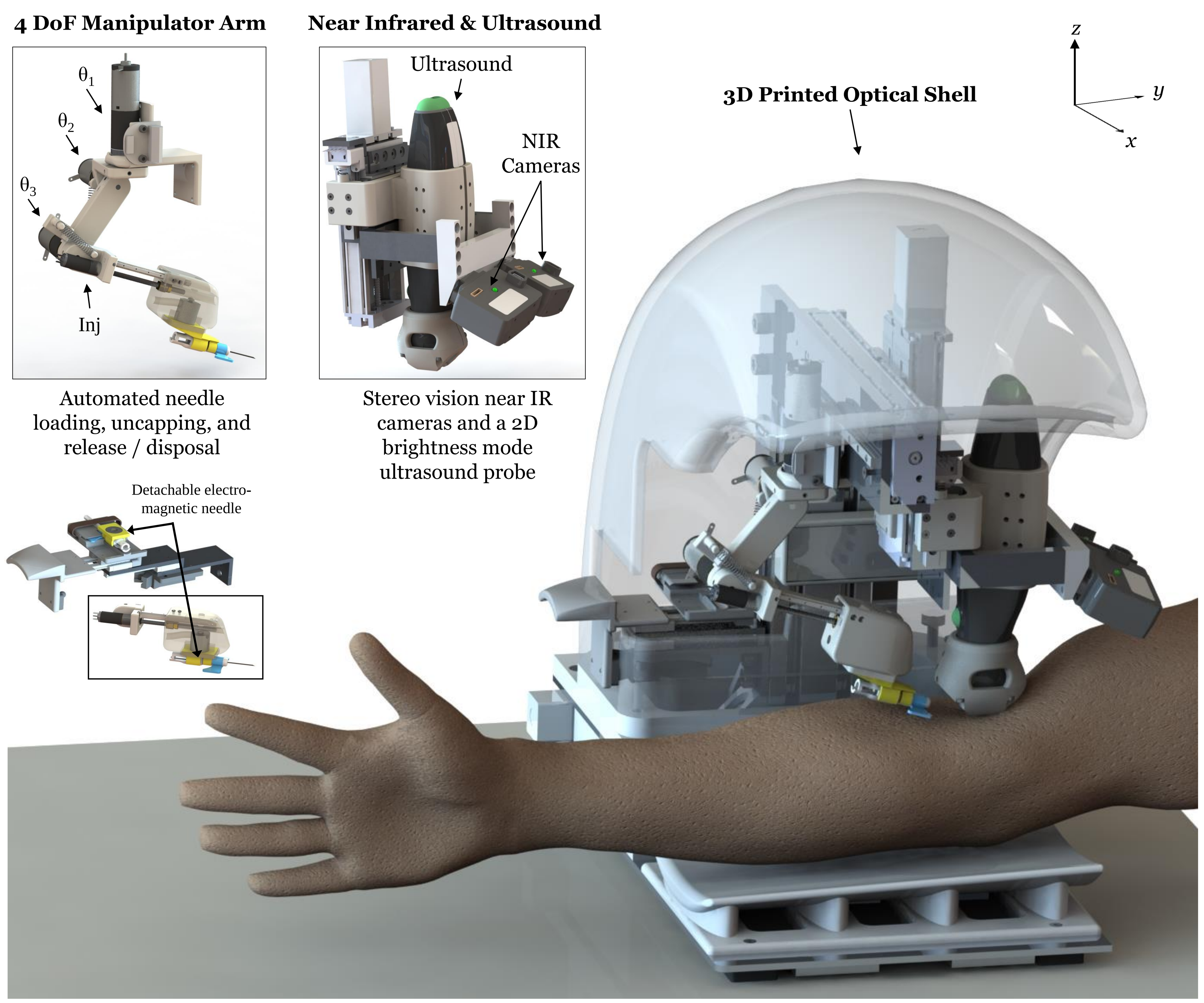
Design Criteria	Engineering Constraint
Accuracy	Cannulate ø1.0–3.5 mm veins
Imaging	Image veins up to 10 mm deep
Real-time tracking	Segment and track veins at >15 Hz loop rate
Size & weight	Portable (<30x30x30 cm) & lightweight (<10 kg)
Time of procedure	Perform the venipuncture in <5 min
Cost	Total device materials cost <$6000

*Design specifications determined from market research of 13 U.S. hospitals, 2 diagnostic labs (Quest and LabCorp), 140 healthcare professionals, 256 parents, and 50 children.

b. **4th-generation prototype device:**

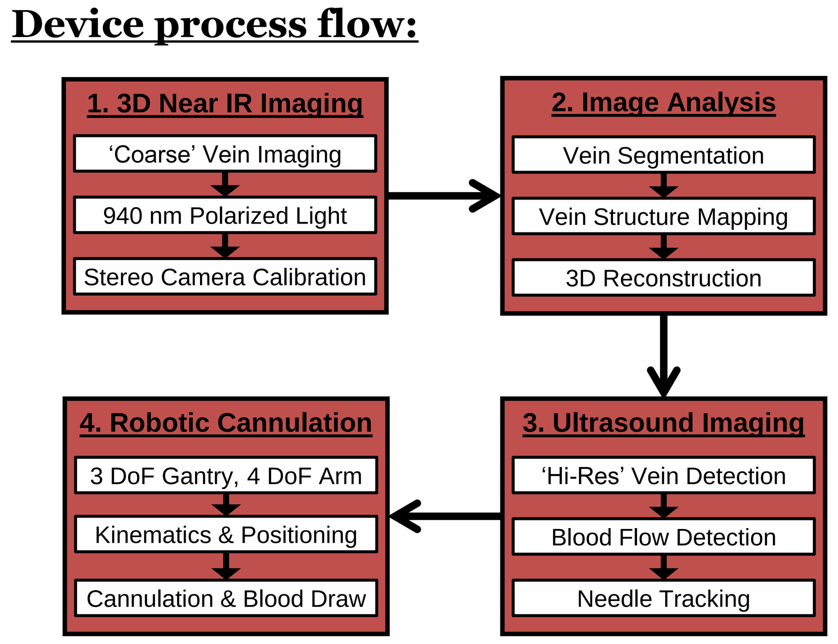


7 DoF Image Guided Venipuncture Robot

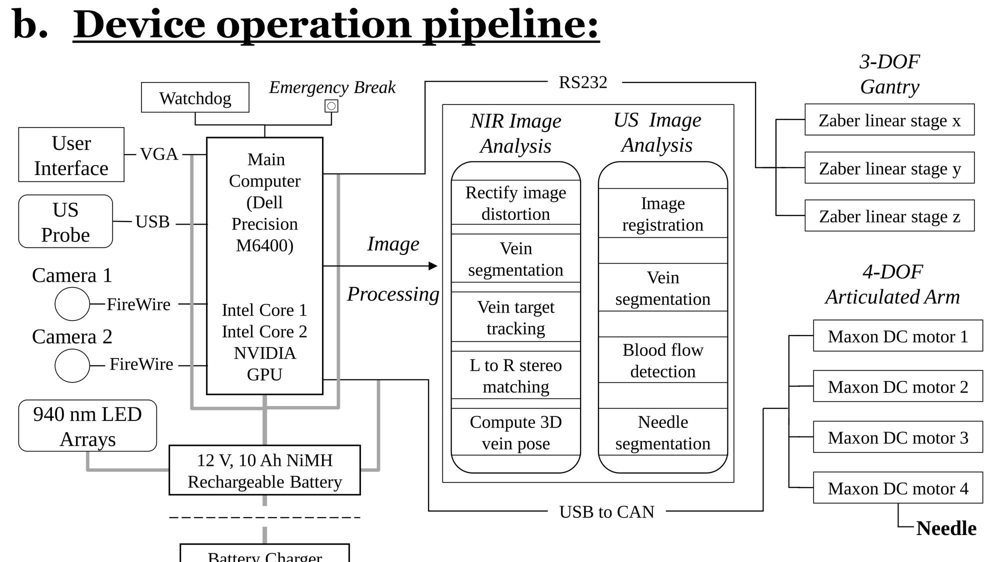


System Architecture

a. **Device process flow:**



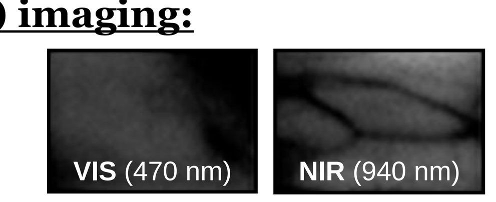
b. **Device operation pipeline:**



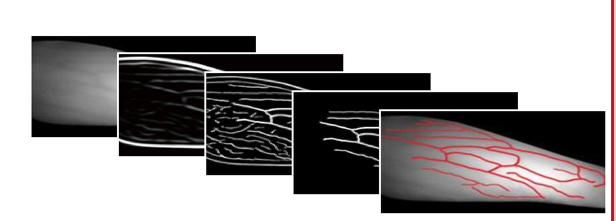
Computer Vision Algorithms

a. **Near-infrared (NIR) imaging:**

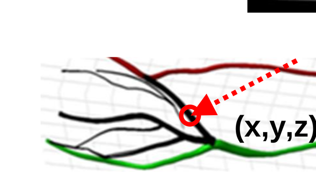
1. Enhanced visibility of veins in the NIR spectrum.



2. 'Coarse' segmentation of veins as curvilinear features

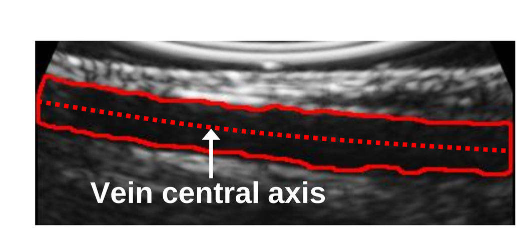


3. 3D reconstruction and selection of cannulation site

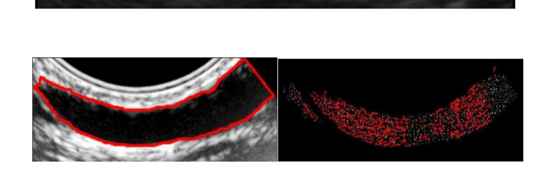


b. **Ultrasound imaging:**

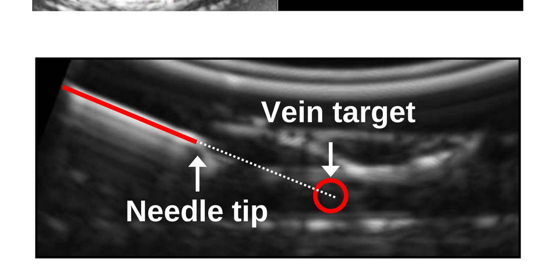
1. 'Hi-Res' B-mode vein segmentation via region grow formula



2. Blood flow detection via optical flow feature tracking



3. Needle tracking and tip position estimation via Gabor filter and Hough transform



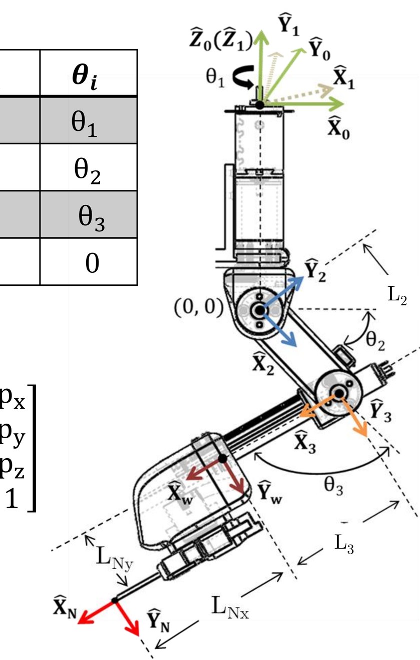
Serial Arm Kinematics and Motor Control System

a. **Needle manipulator kinematics:**

Correlate joint angles with 3D Cartesian coordinate of needle tip.

i	α_{i-1}	a_{i-1}	d_i	θ_i
1	0	0	0	θ_1
2	90°	0	0	θ_2
3	0	L_2	0	θ_3
W	0	L_3	0	0

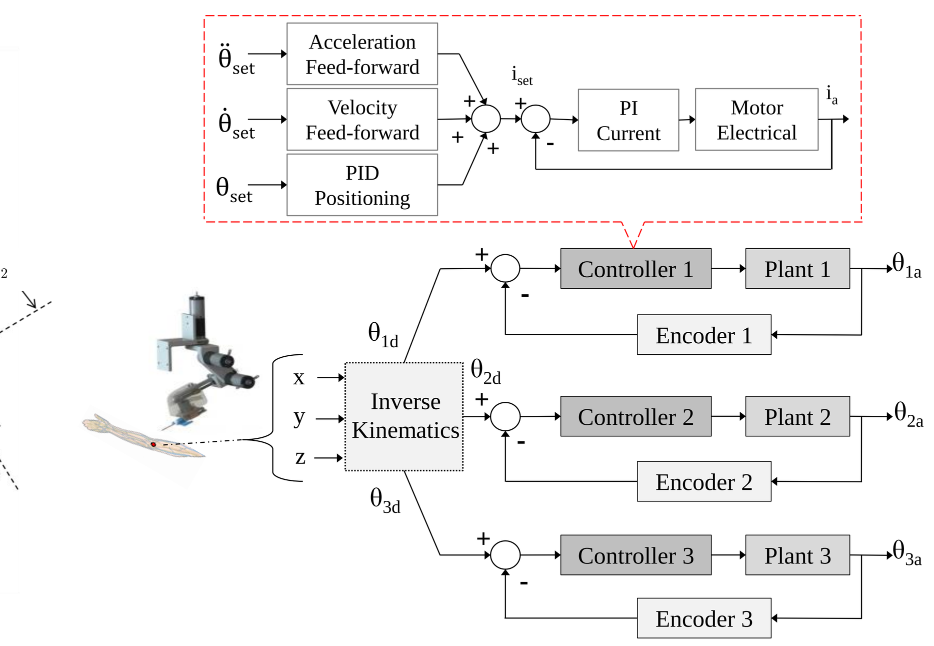
$$ {}^0_N T = \begin{bmatrix} r_{11} & r_{12} & r_{13} & p_x \\ r_{21} & r_{22} & r_{23} & p_y \\ r_{31} & r_{32} & r_{33} & p_z \\ 0 & 0 & 0 & 1 \end{bmatrix} $$



$$ {}^0_N T = {}^0_1 T(\theta_1) * {}^1_2 T(\theta_2) * {}^2_3 T(\theta_3) * {}^3_W T(L_3) * {}^W_N T\left(L_{N_x}, L_{N_y}\right) $$

b. **Control system**

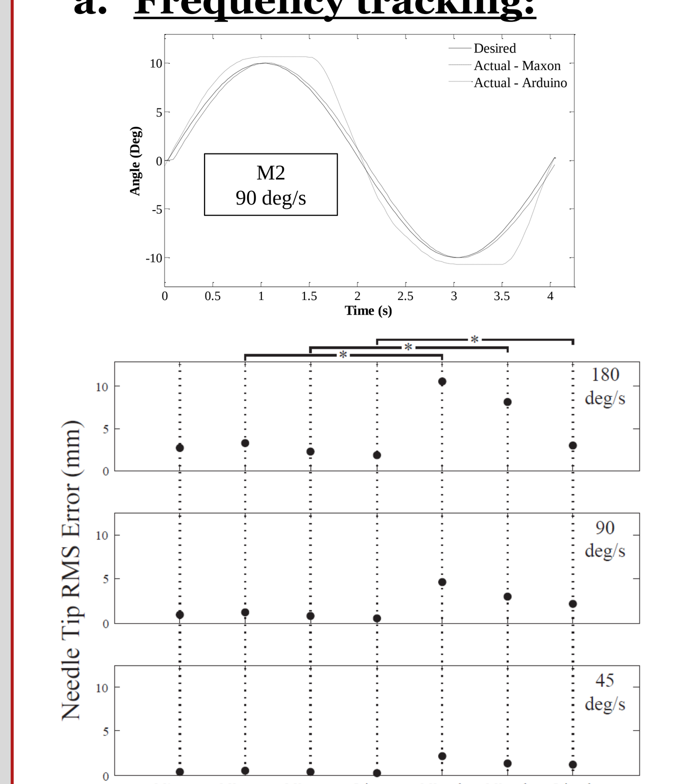
Each joint angle enters a negative feedback control loop based on PID positioning to minimize errors between the desired and actual positions.



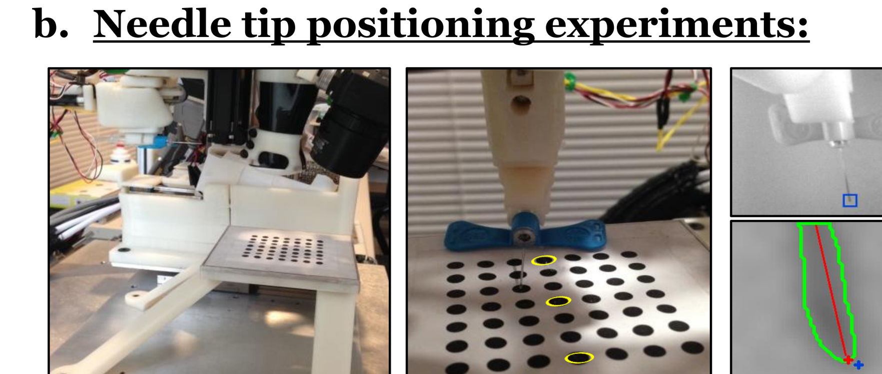
$$ \text{Plant} = \frac{K_t * V}{s^3(LI^2_\eta + IJ\eta) + s^2(Lb_M\eta + RI^2_\eta + RJ\eta) + s(Rb_M\eta + K_t K_e)} $$

Control System Testing

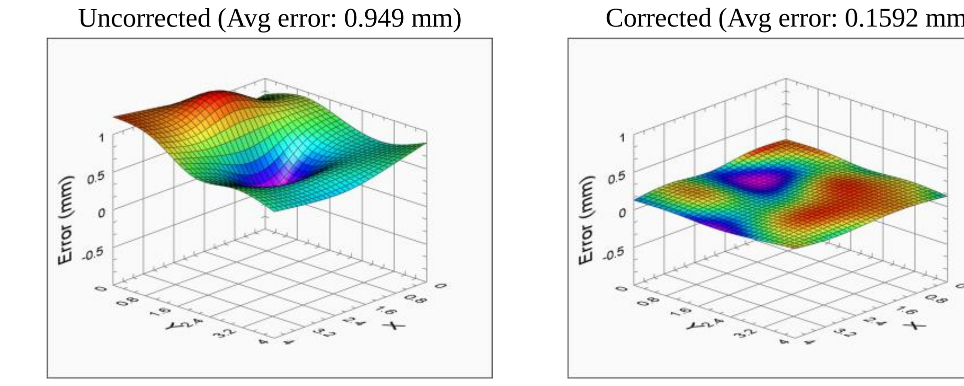
a. **Frequency tracking:**



b. **Needle tip positioning experiments:**



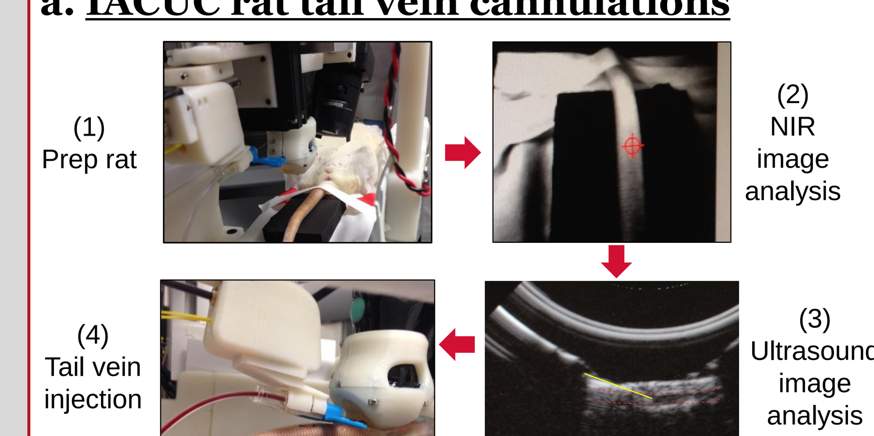
Repeatability testing (n = 50; far, mid, near circle in yellow) – StDev = **0.018 mm**



- All joints were controllable and repeatable in frequency tracking experiments using Maxon drivers.
- Needle manipulator exhibited average 3D positioning error of 0.16 ± 0.03 over grid area.

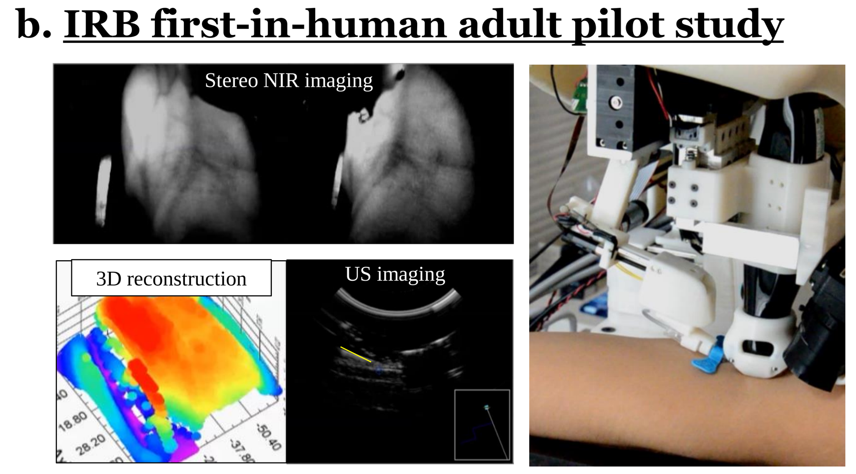
Ongoing *In Vivo* Device Evaluation (Animals and Humans)

a. **IACUC rat tail vein cannulations**



- **Justification:** Rat tail vein diameter ≈ pediatric vein diameter (1 mm)
- **Test model:** 30 anesthetized 10-wk-old rats using 3 sticks per tail (2 automated, 1 manual)
- **Benchmarks:** First-stick %, completion time; collection of 0.5 mL of blood

b. **IRB first-in-human adult pilot study**



- **Justification:** Provide preliminary human evidence in preparation for FDA clinical filing
- **Recruitment:** 40 adult patients recruited at UMDNJ; cover broad range of demographics
- **Benchmarks:** First-stick %, completion time; collection of 2 mL of blood; patient safety

References

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