

DialySafe

Making at-home dialysis easier and safer



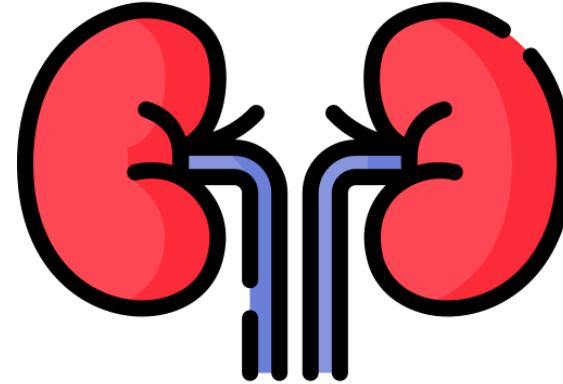
DialySafe



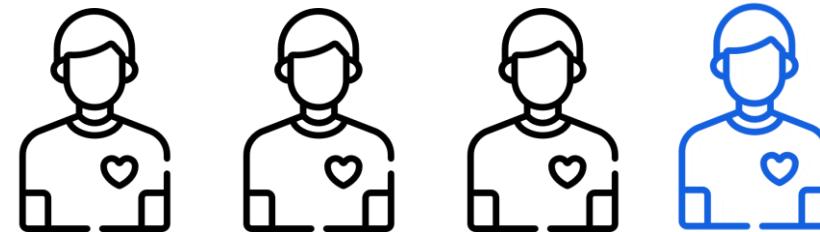
Over 9,000 patients in the
US like Jack



DialySafe

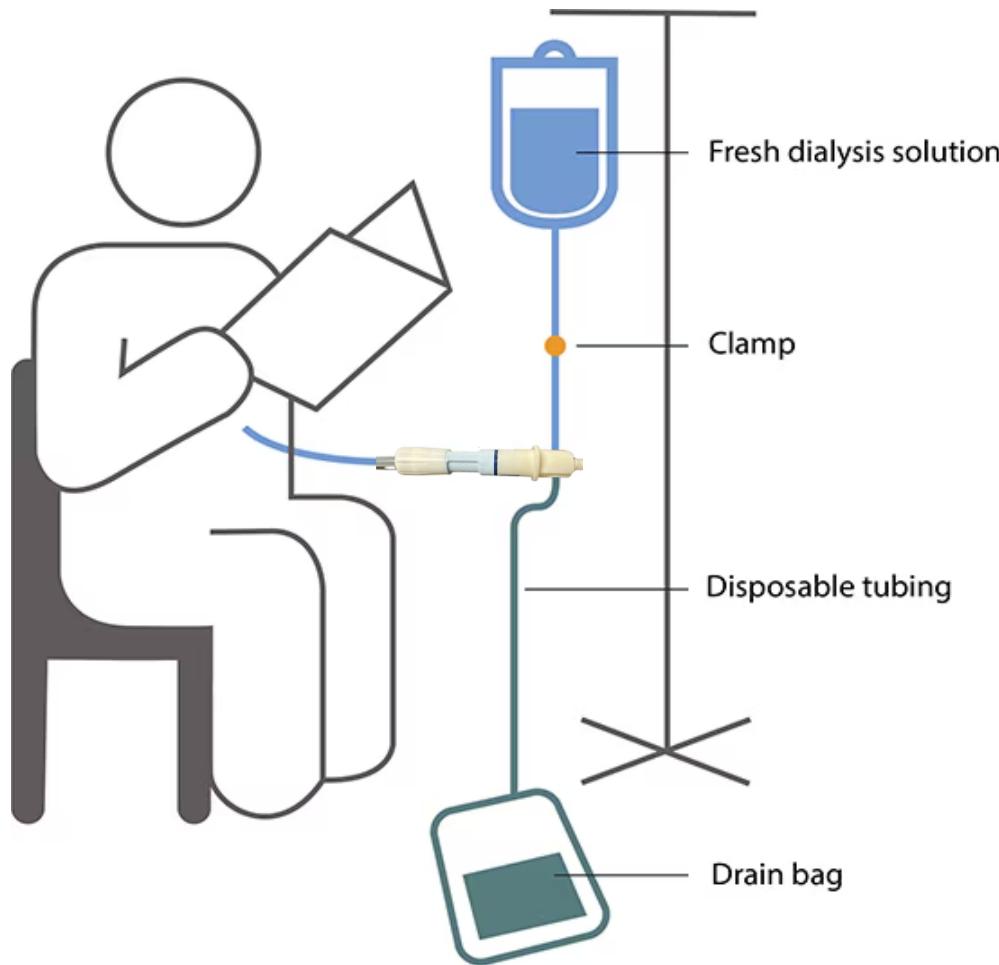


Kidney failure affects over
800,000 patients in the US per
year



1 in 4 peritoneal dialysis (PD)
patients get infections

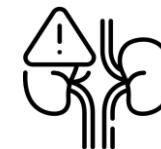
Peritoneal Dialysis (PD)



>90% of infections caused by touch contamination

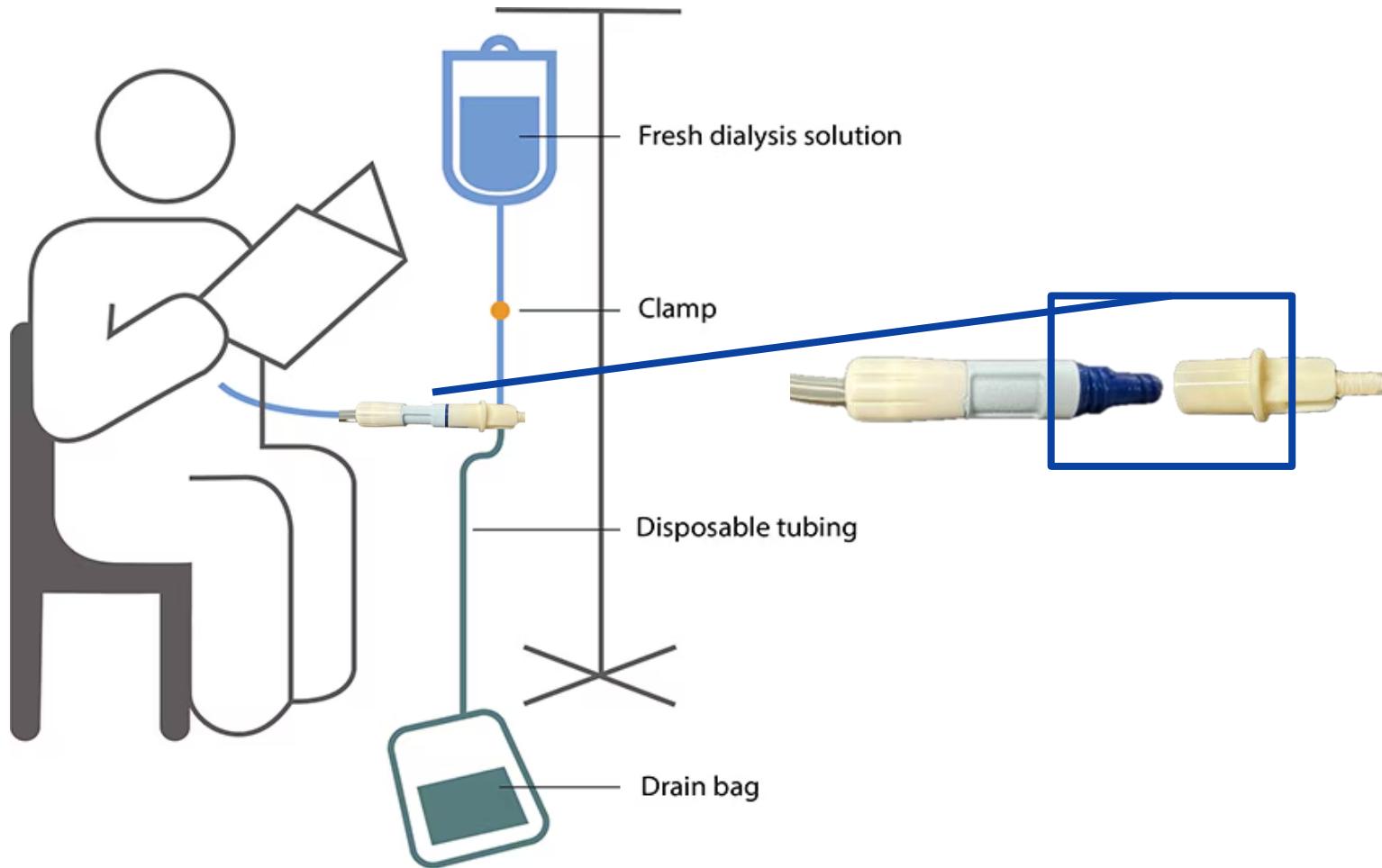


67% of infections result in hospitalizations



7% increased risk of PD failure or death for each hour in delay of treatment

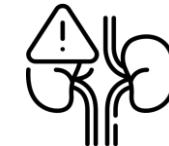
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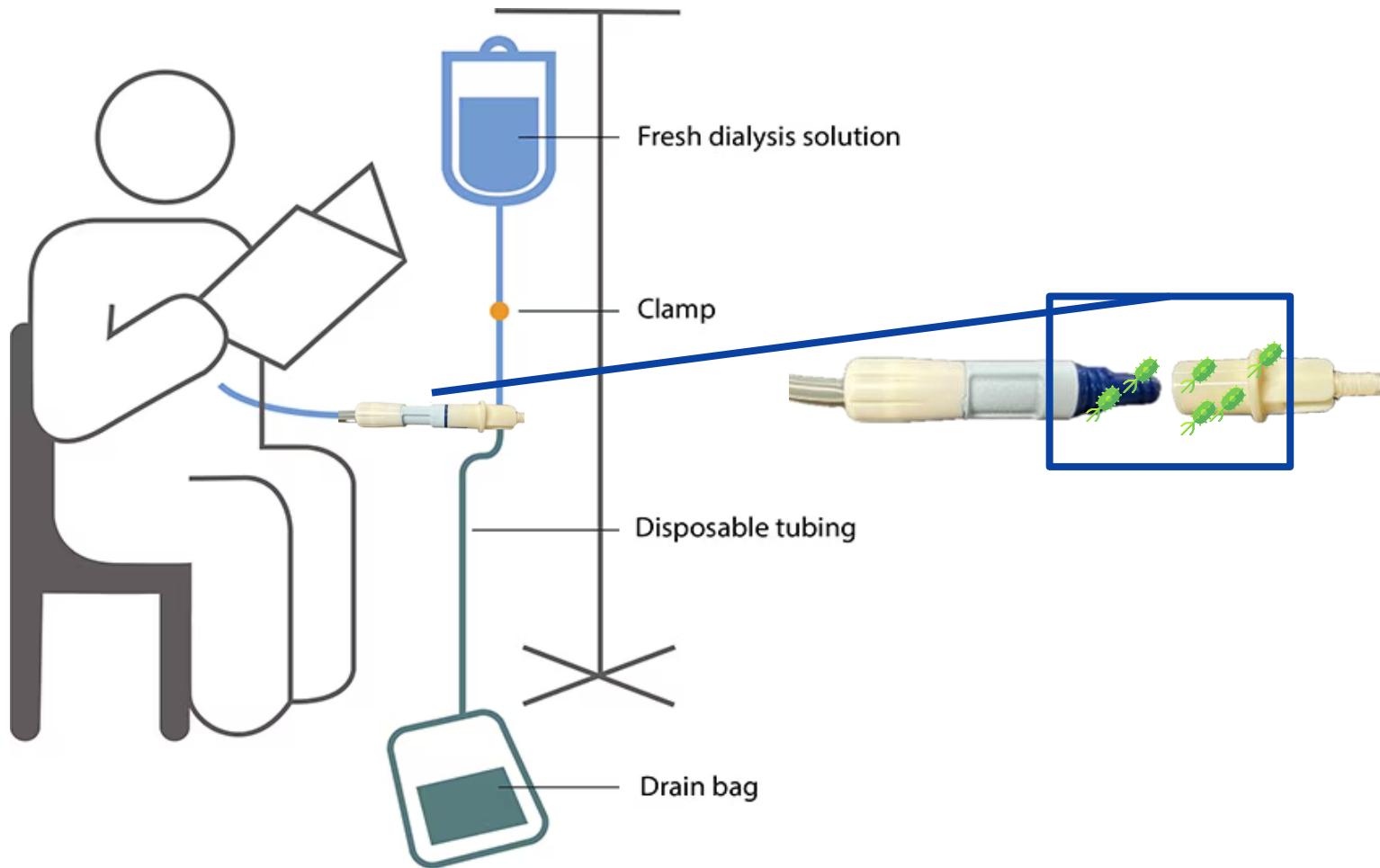


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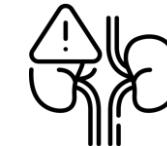
Peritoneal Dialysis (PD)



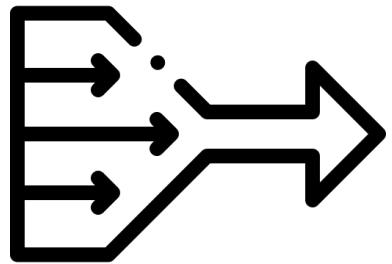
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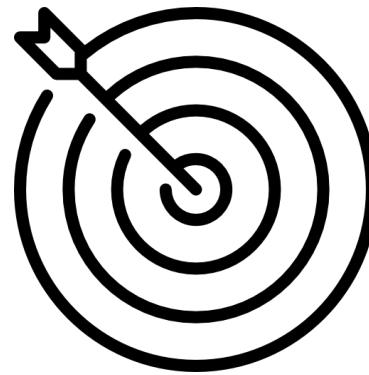
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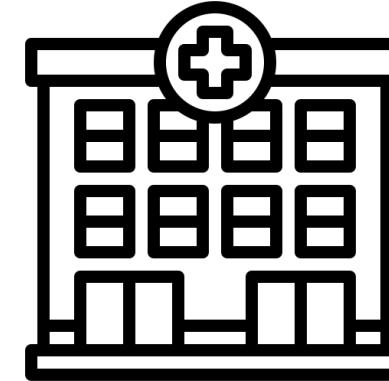
7% increased risk of PD failure or death for each hour in delay of treatment



Simplify
exchange process



Detect potential
infections



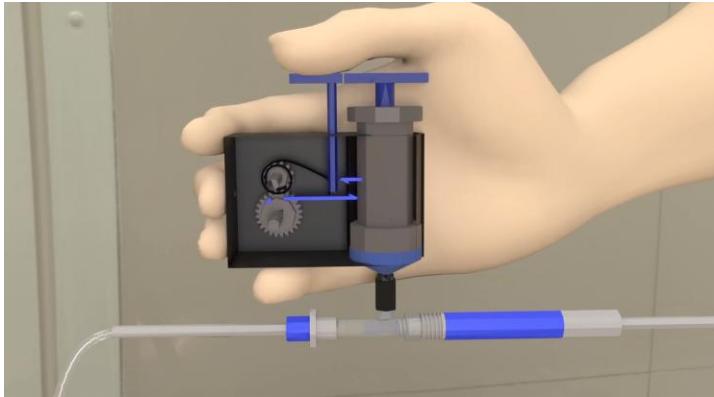
Compatible with
existing PD
procedure



Guarantee **low-**
cost

COMPETITOR LIMITATIONS

PeritoneX Disinfectant



Adds manual steps



Tedious process

Kaguya Automates PD



Expensive (\$50k)



Bulky, non-portable

CloudCath Optical Turbidity Infection Sensor



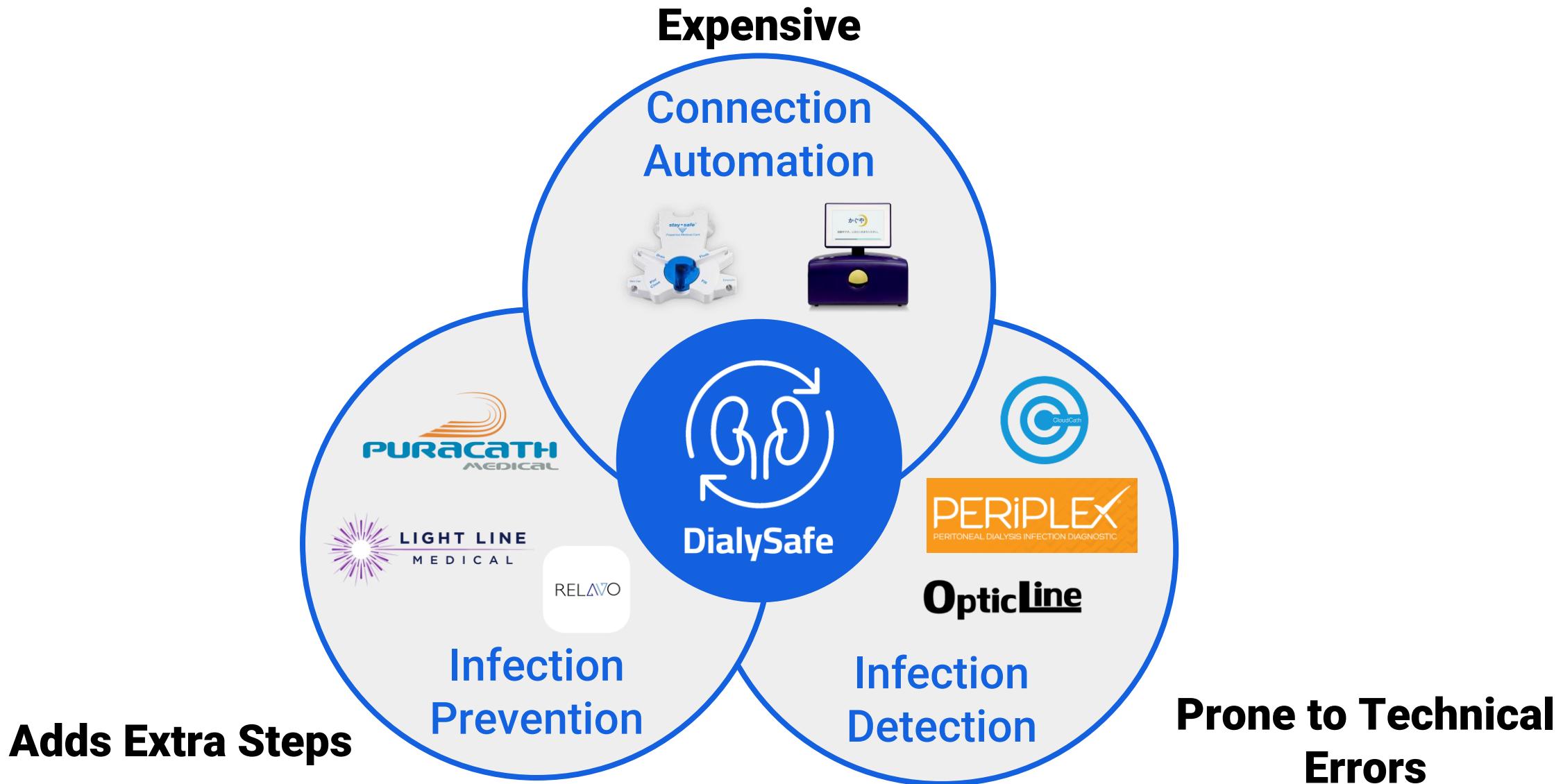
Long lag in detection time
(10% of cases took >1 day to detect)



Susceptible to occlusion



SUSTAINABLE COMPETITIVE ADVANTAGE



VALUE PROPOSITION

Patients/Caretakers



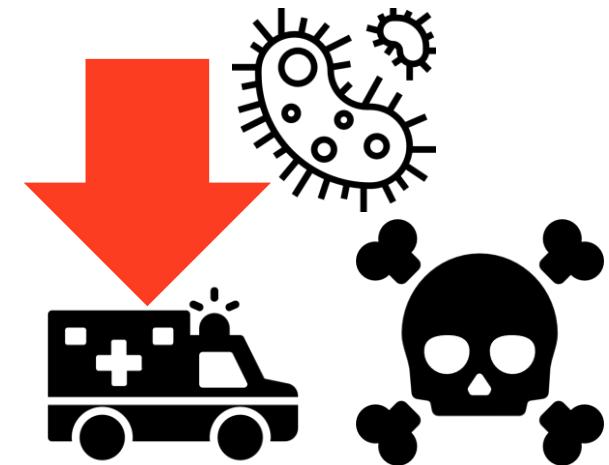
Saves Lives &
Catheters

Clinics



RPM Revenue
Stream

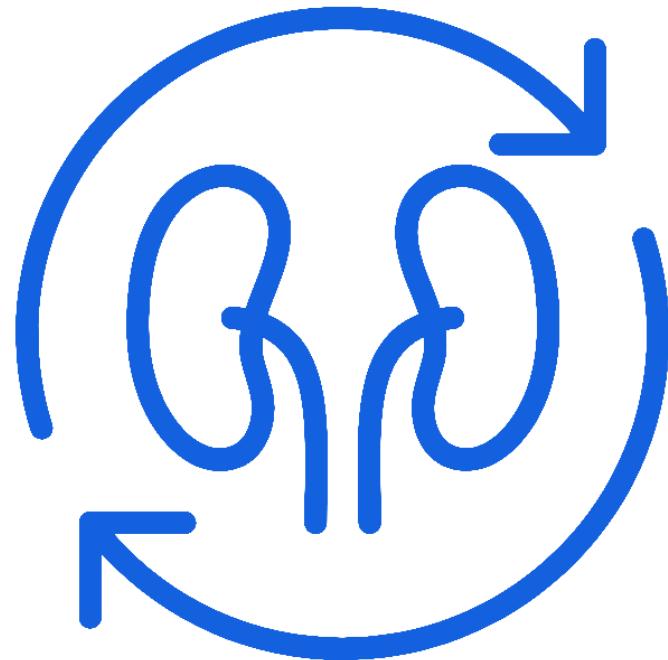
Payers



Reduced Complications
& Healthcare Costs



SOLUTION OVERVIEW



DialySafe



Automates connection procedure



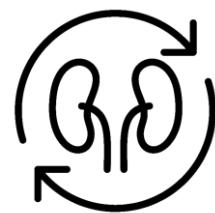
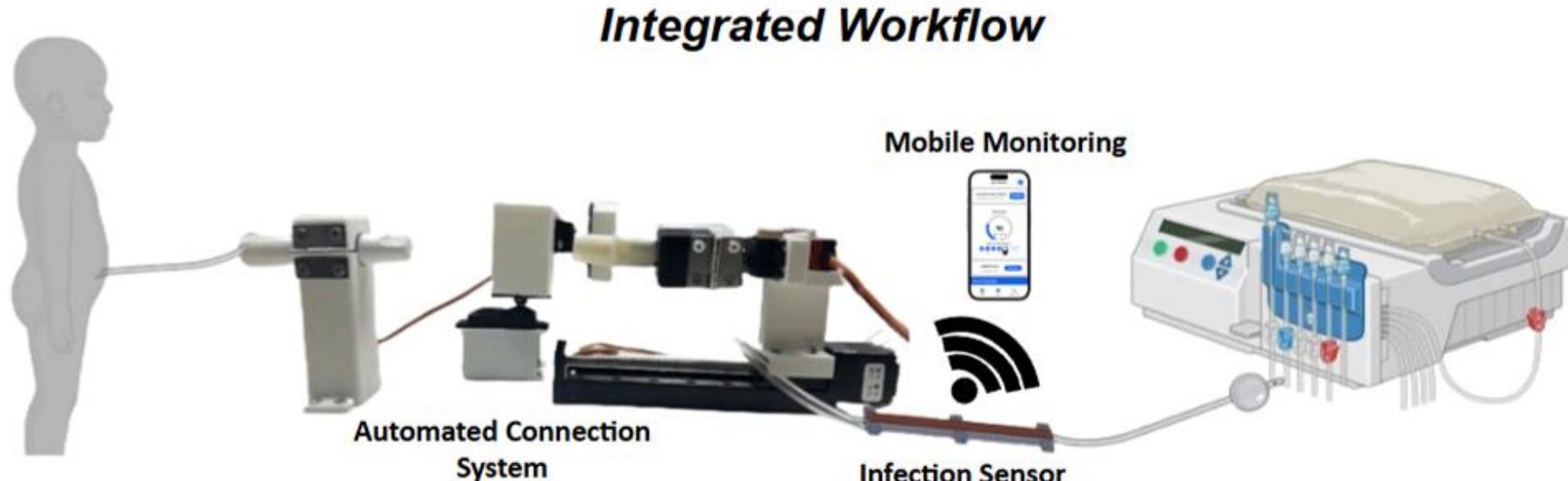
Detects infections for early treatment



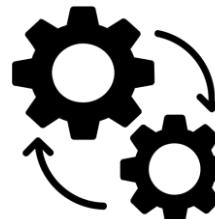
Seamless integration with market leader products



SOLUTION OVERVIEW



=



DialySafe System



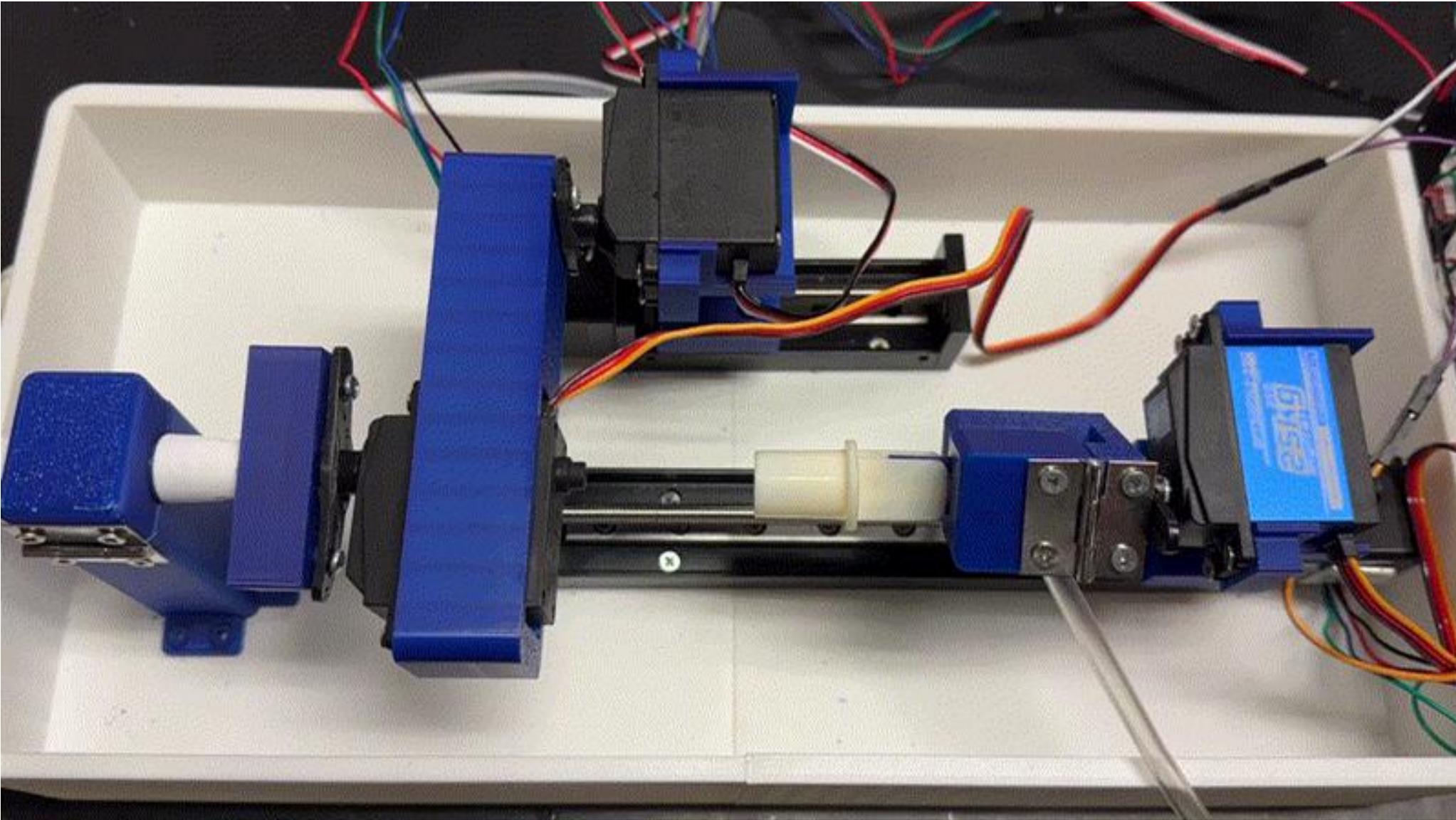
Automation



Infection Detection

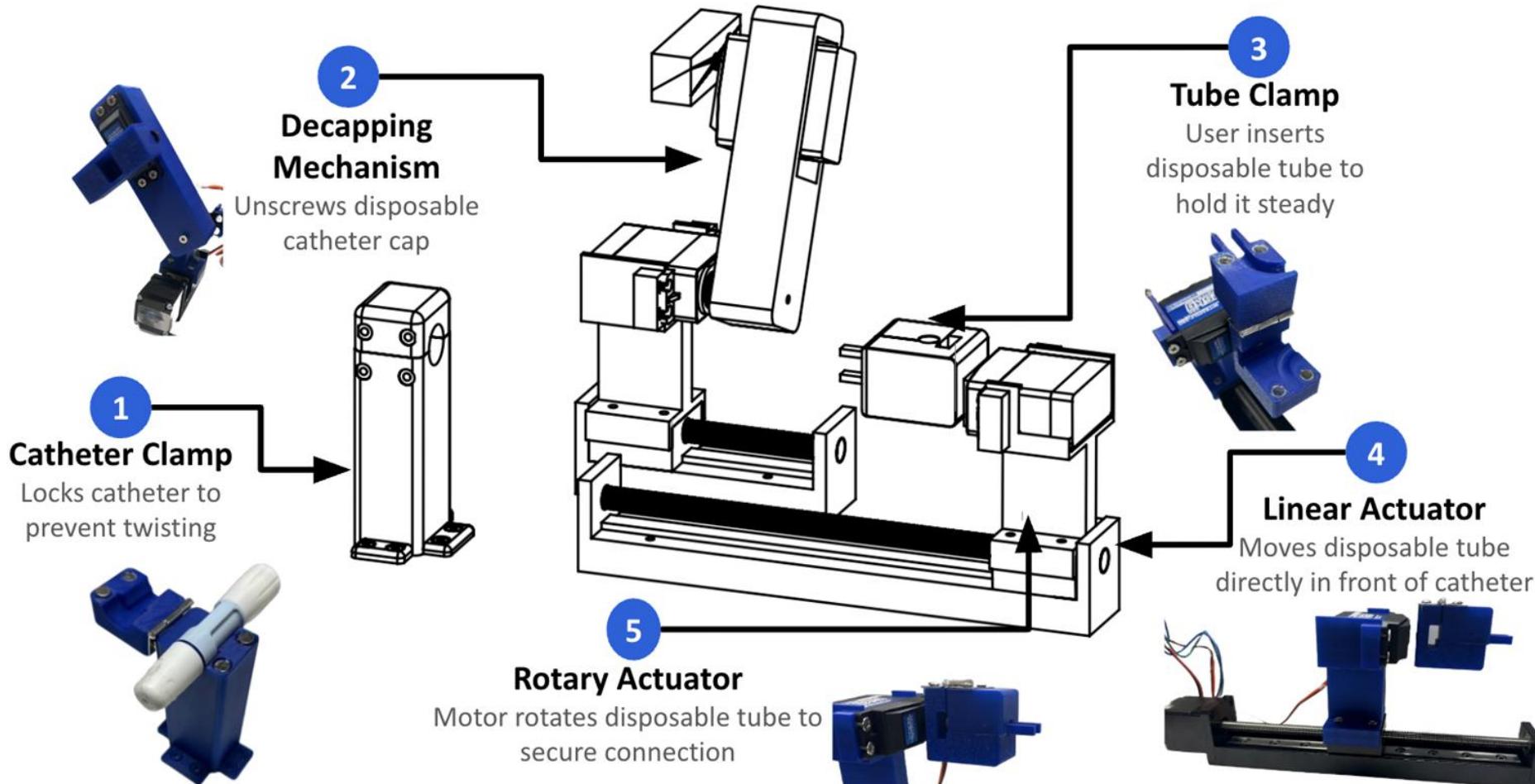


SOLUTION - AUTOMATION RIG





SOLUTION - AUTOMATION RIG

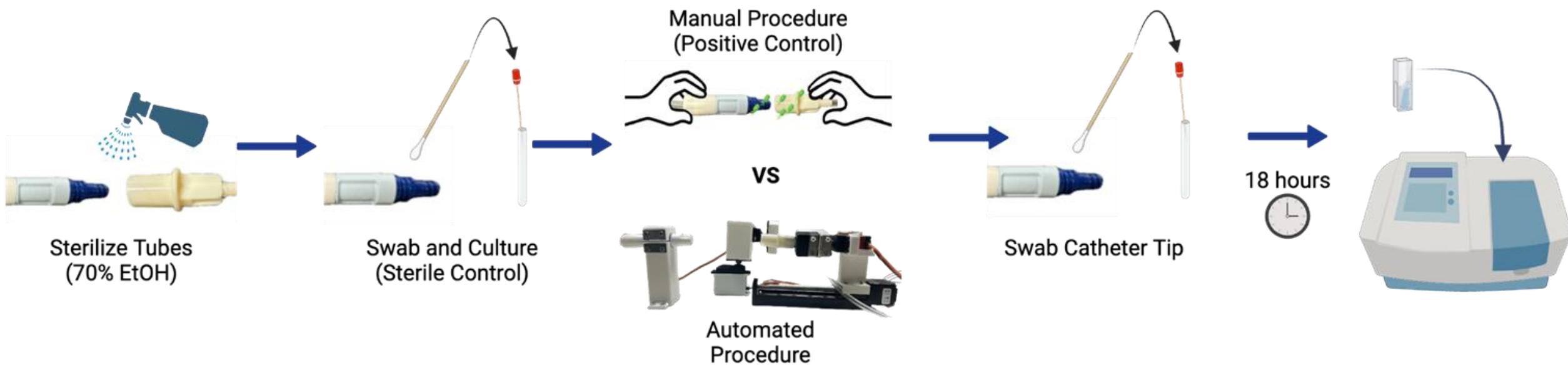


Reduces risk of contamination by

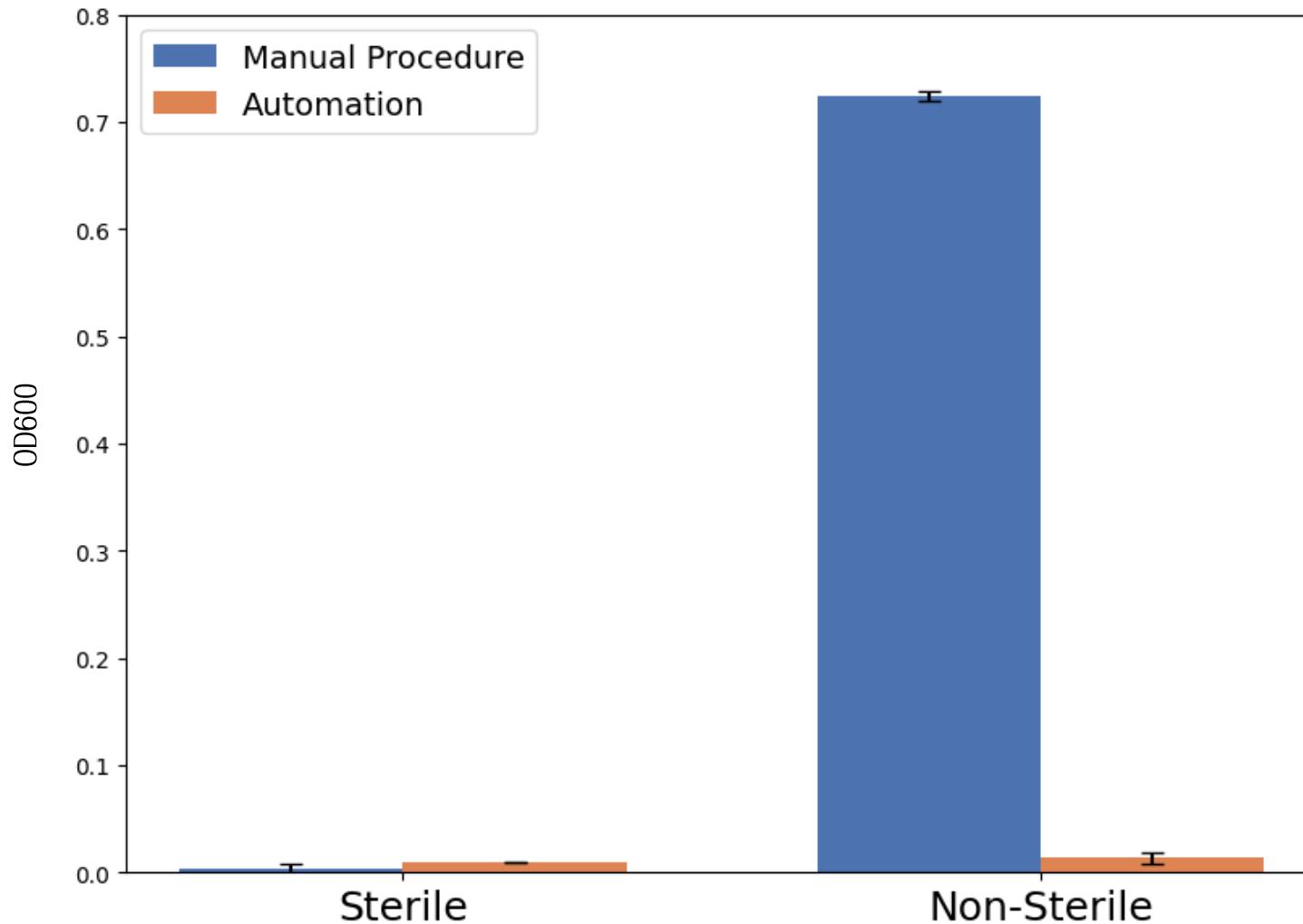
99%



AUTOMATION RIG EXPERIMENTAL METHODOLOGY

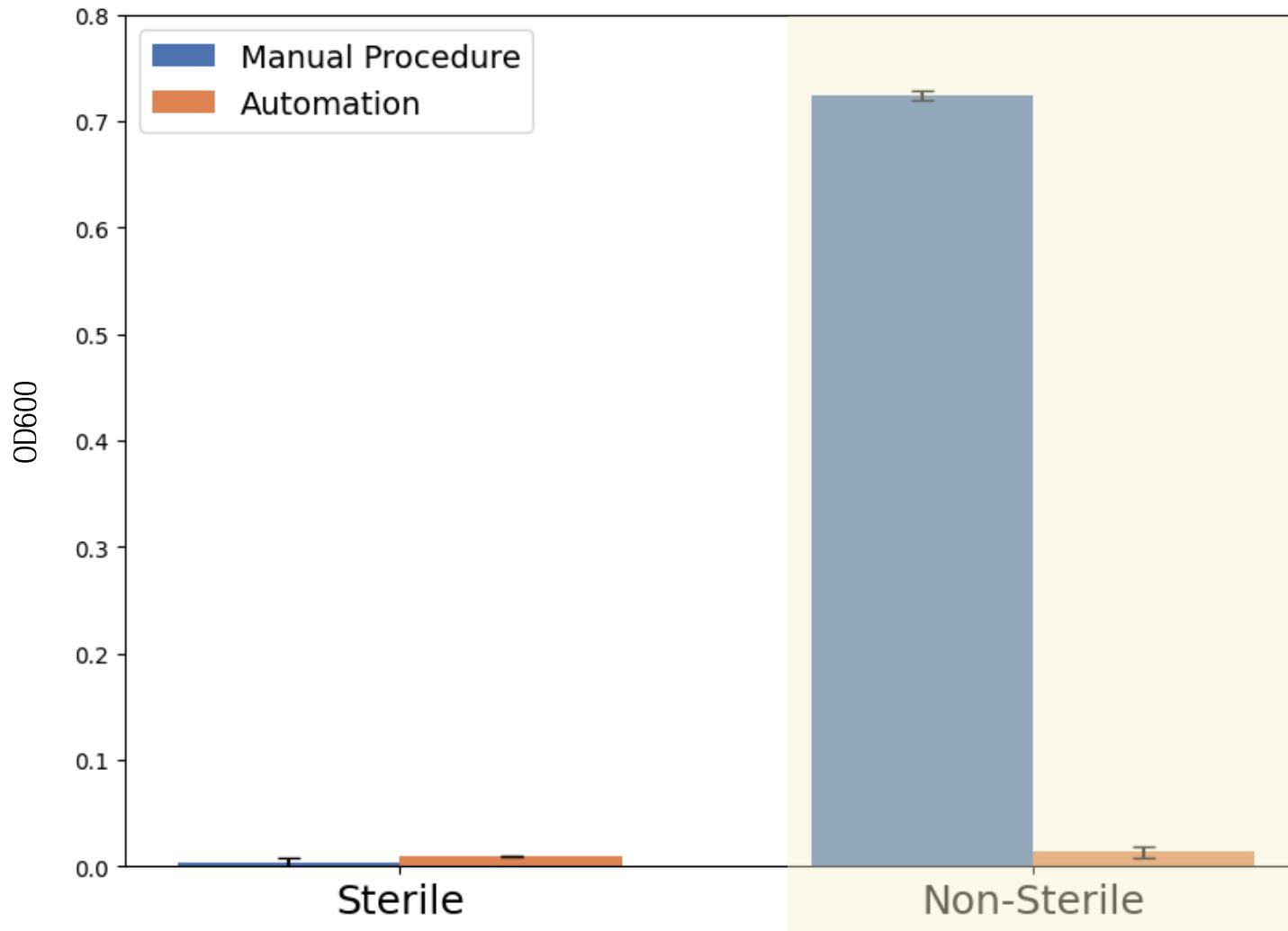


AUTOMATION RIG EXPERIMENTAL DATA



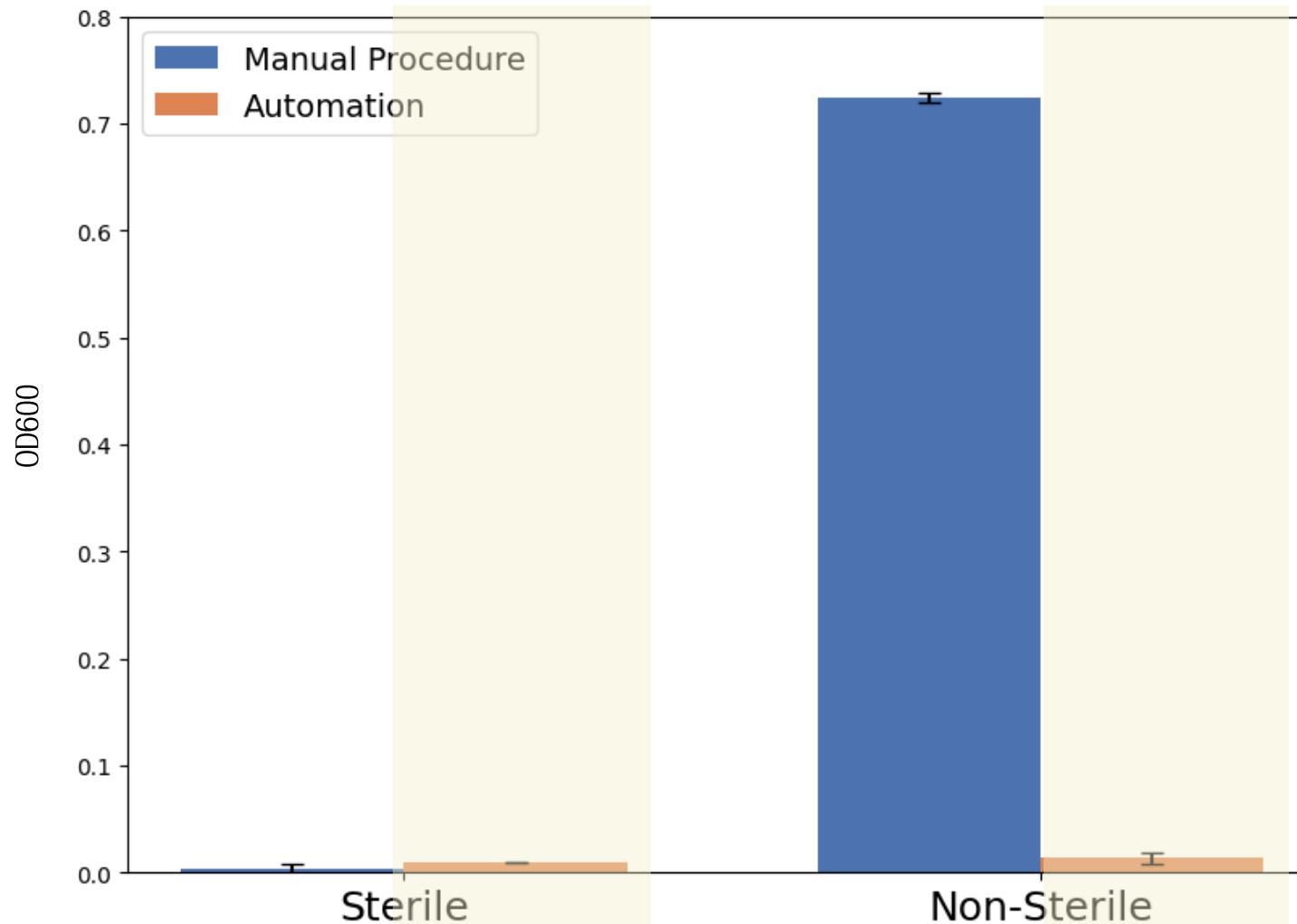
Reduces risk of
contamination by
99%

AUTOMATION RIG EXPERIMENTAL DATA



Reduces risk of
contamination by
99%

AUTOMATION RIG EXPERIMENTAL DATA



Reduces risk of
contamination by
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SOLUTION - INFECTION DETECTION

To detect infections, the standard is to:

- Wait for symptoms to develop
- Wait for effluent to become cloudy
- Measure bacteria level
- Measure WBC level

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 - Lab test comes back culture-negative in 40% of peritonitis cases
- Measure WBC level

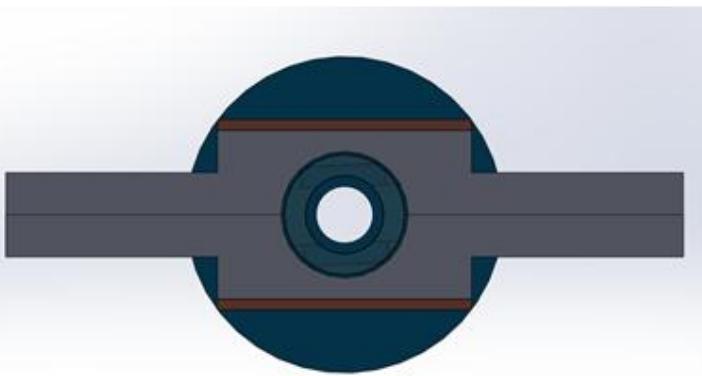
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- Measure bacteria level 
 - Lab test comes back culture-negative in 40% of peritonitis cases
- **Measure WBC level **
 - **Reliable marker, with 100 WBCs/ μ L used as clinical threshold**

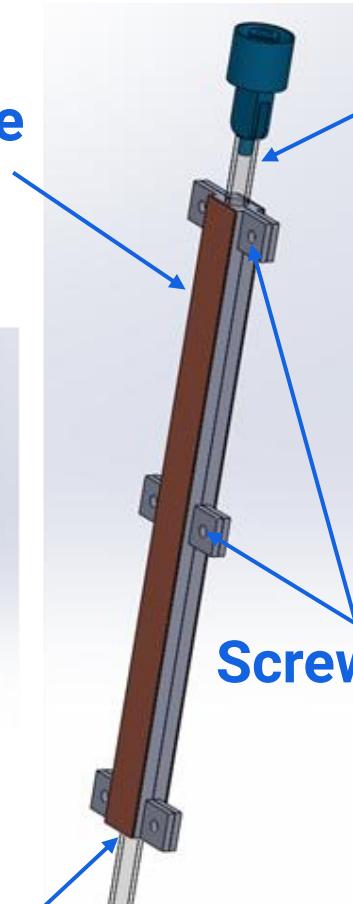


CONTACTLESS CONTINUOUS FLUID MONITORING

Copper Tape Electrode



Tubing

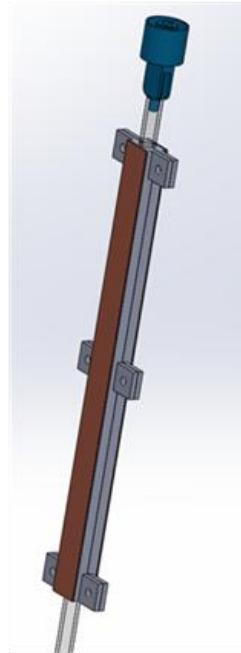
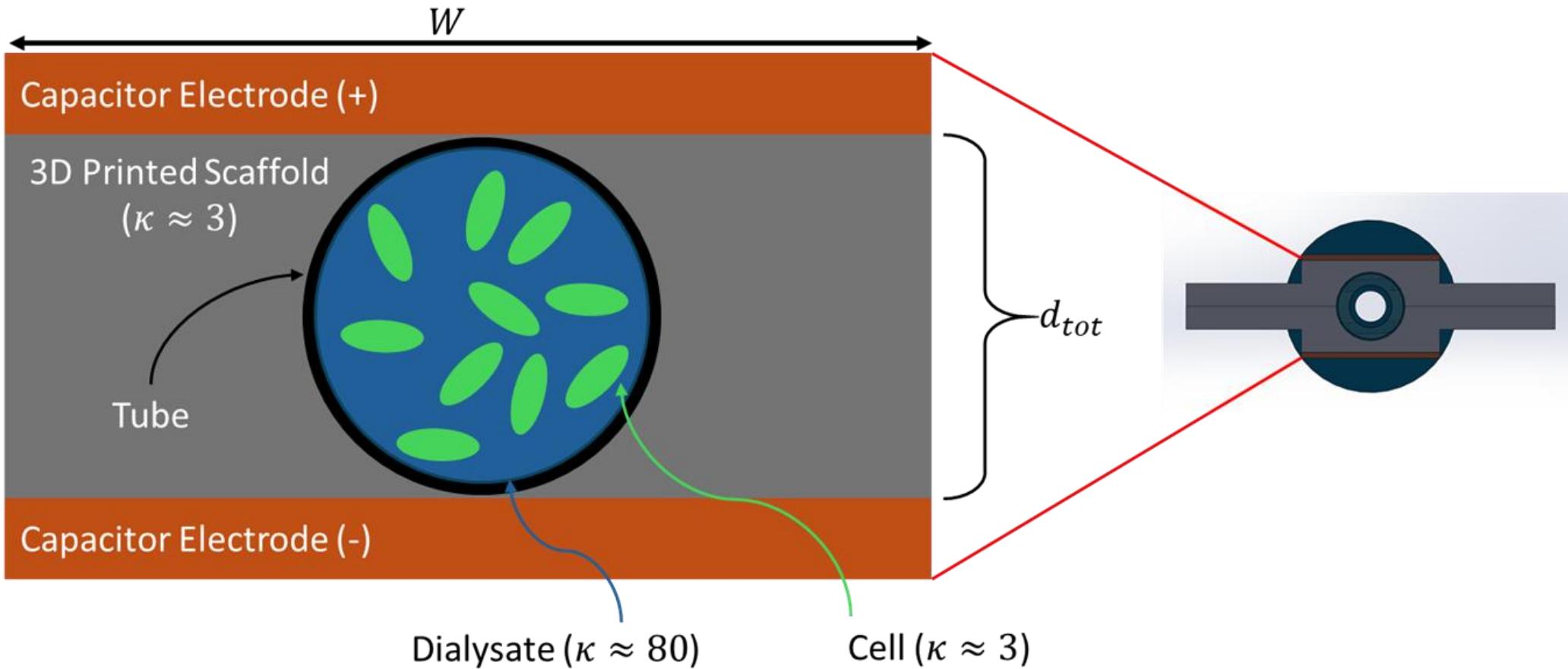


Screw Terminals

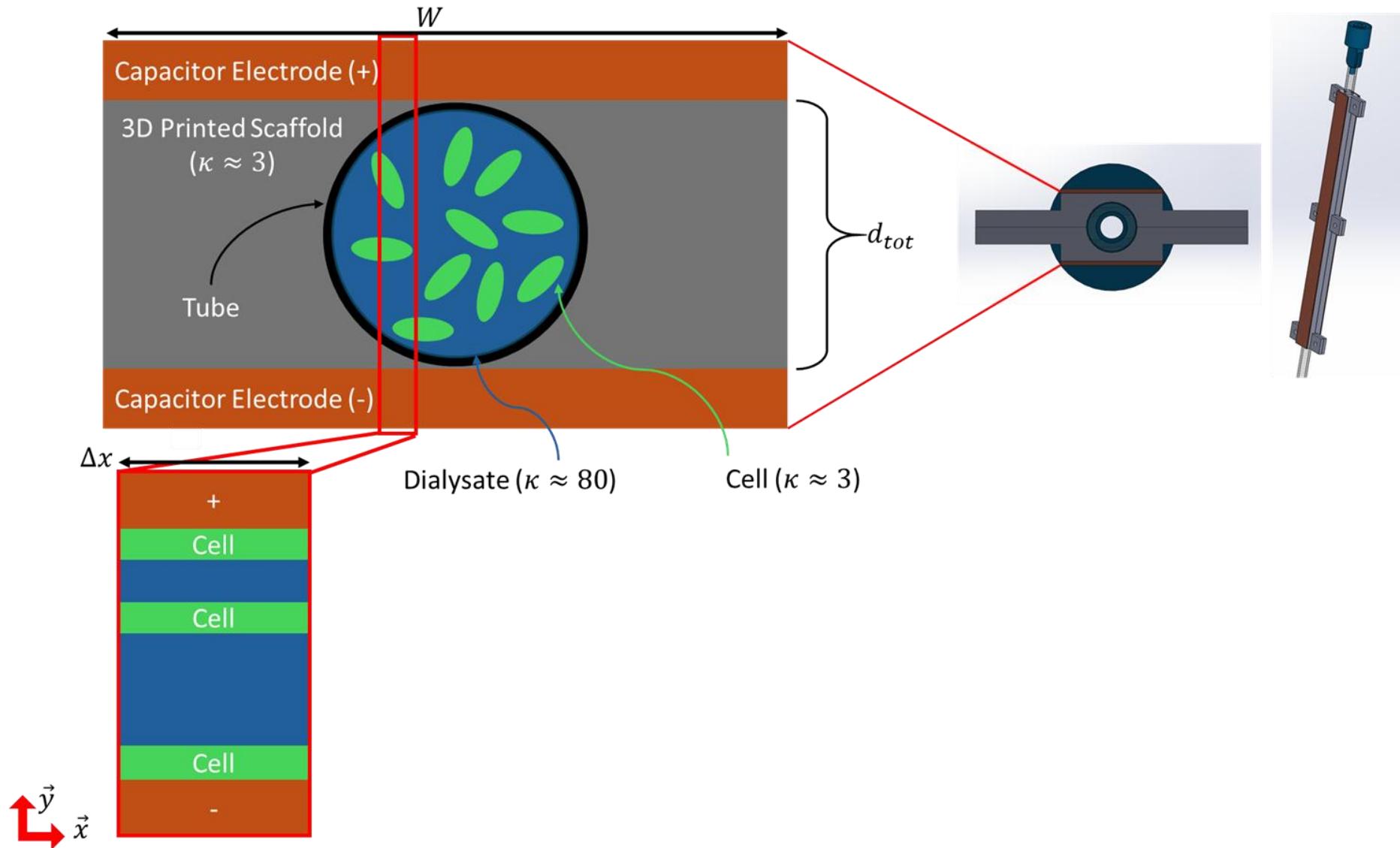
Scaffold



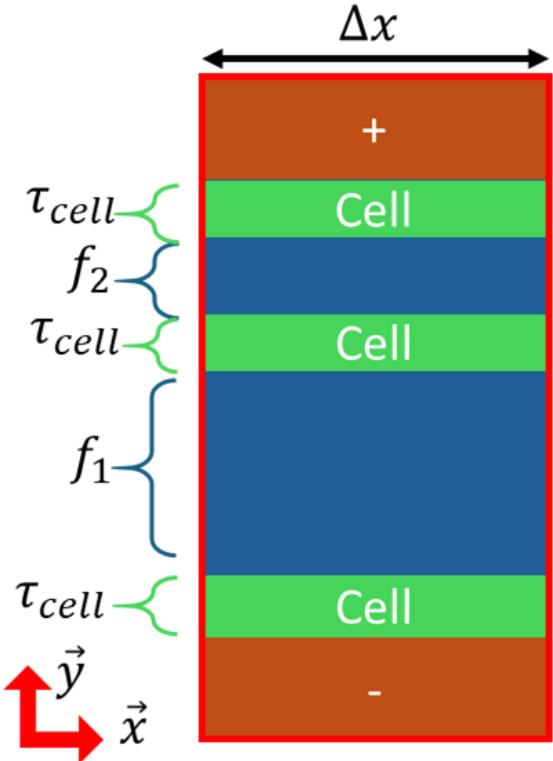
MEASUREMENT PRINCIPLE - CAPACITANCE



MEASUREMENT PRINCIPLE - CAPACITANCE DERIVATION



MEASUREMENT PRINCIPLE - CAPACITANCE DERIVATION

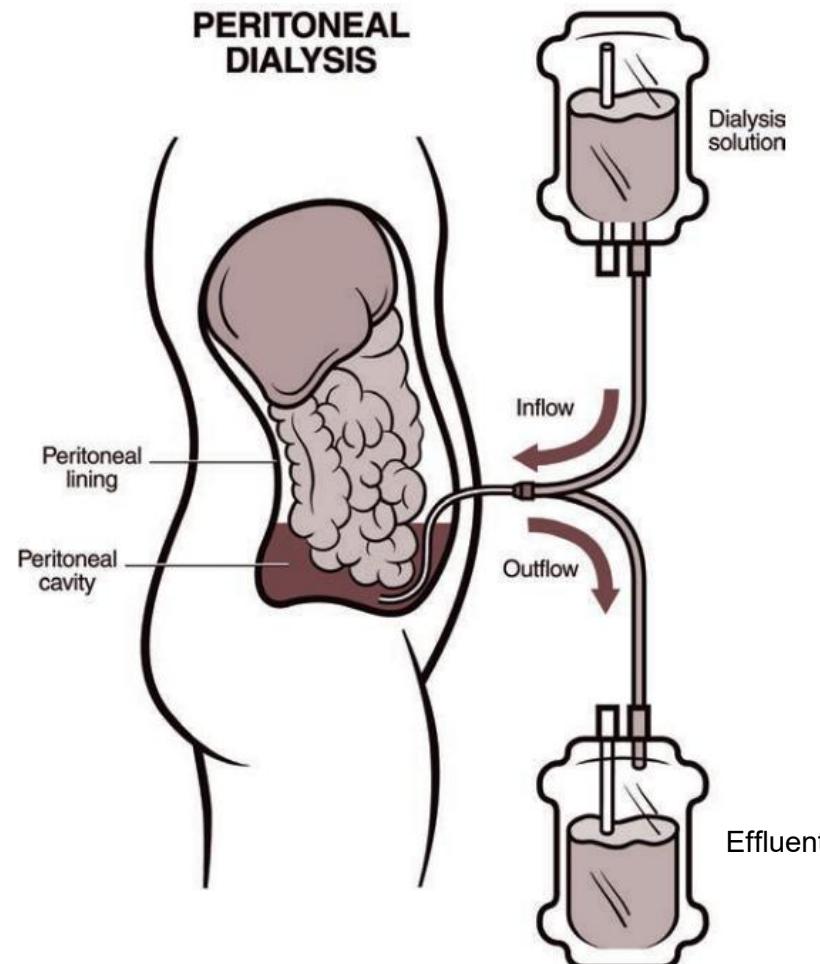


$$\frac{1}{C_{eq}} = \frac{n_{cells} \tau_{cell}}{\epsilon_0 \kappa_{cell} A_{electrode}} + \sum_i \frac{f_i (d_{tot} - n_{cells} \tau_{cell})}{\epsilon_0 \kappa_{fluid} A_{electrode}}$$

of Cells **Cell Size**
Physical Constant **Relative Permittivity of Cell (~3)** **Area of Electrode**
Space Occupied by Fluid
Relative Permittivity of Fluid (~80)

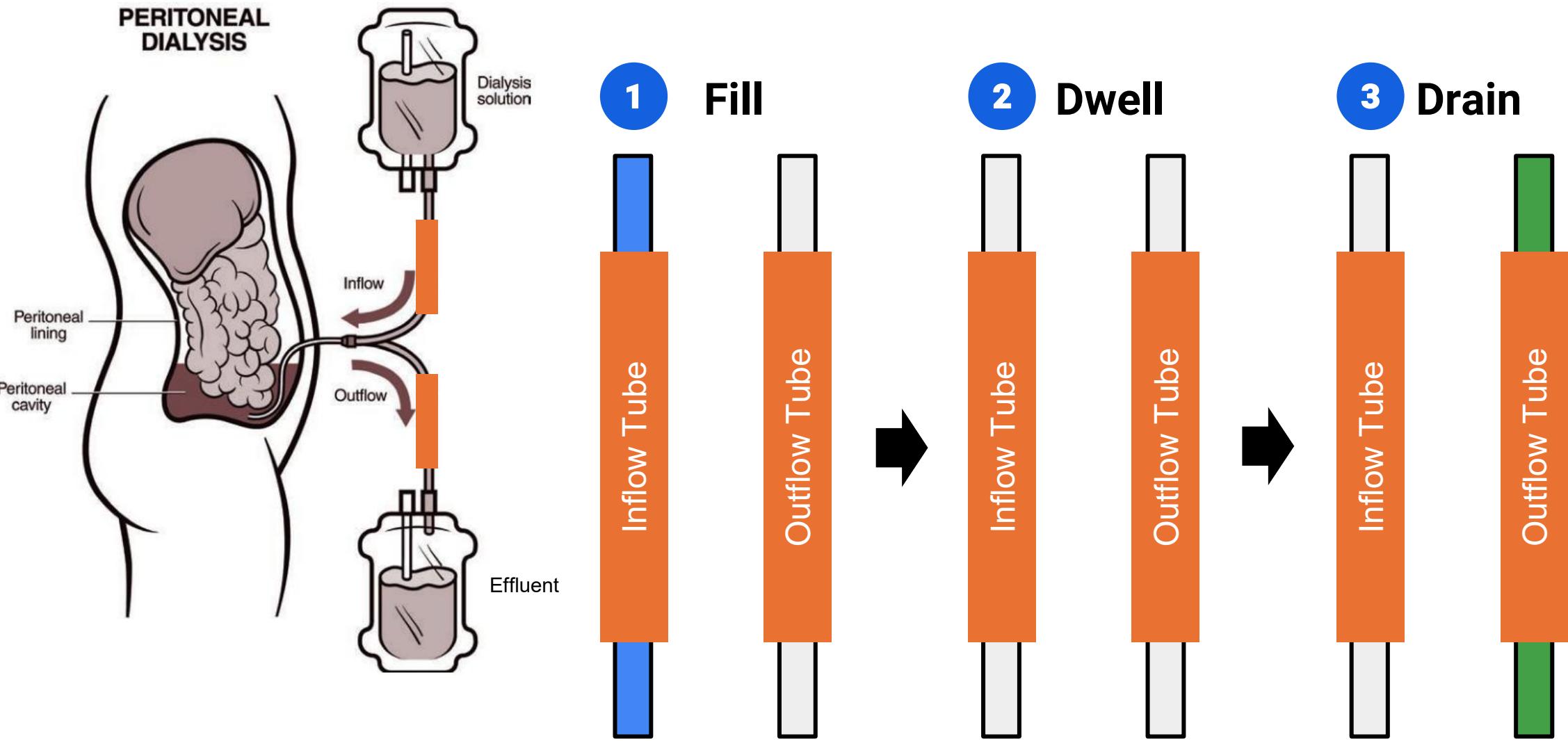
- Cell relative permittivity, cell size, and cell number are the factors impacting capacitance
- WBCs and K562 cells have same relative permeability, and similar sizes making good proxy for testing

MEASUREMENT PRINCIPLE

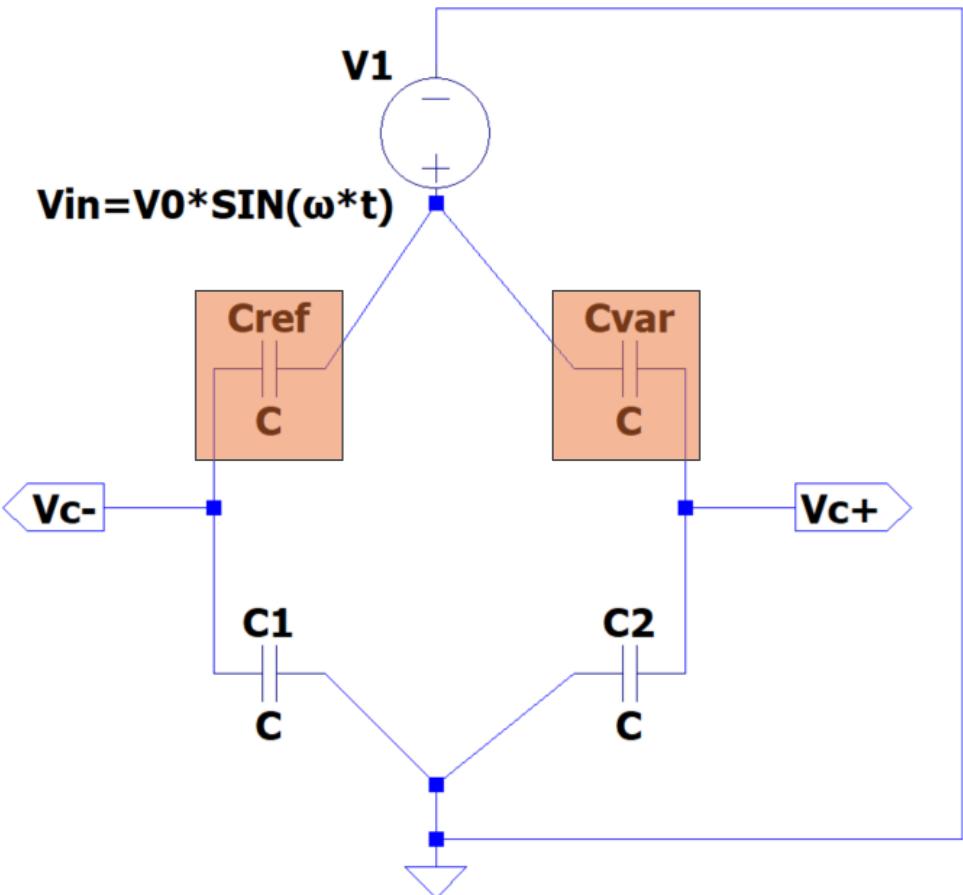


- 1 **Fill**
- 2 **Dwell**
- 3 **Drain**

MEASUREMENT PRINCIPLE



MEASUREMENT PRINCIPLE - BRIDGE CIRCUIT

Bridge Circuit

$$V_c = V_{in} \left(\frac{C_{var}}{C_2 + C_{var}} - \frac{C_{ref}}{C_1 + C_{ref}} \right)$$

1**Fill** C_{var}

Inflow Tube

 C_{ref}

Outflow Tube

3**Drain** C_{ref}

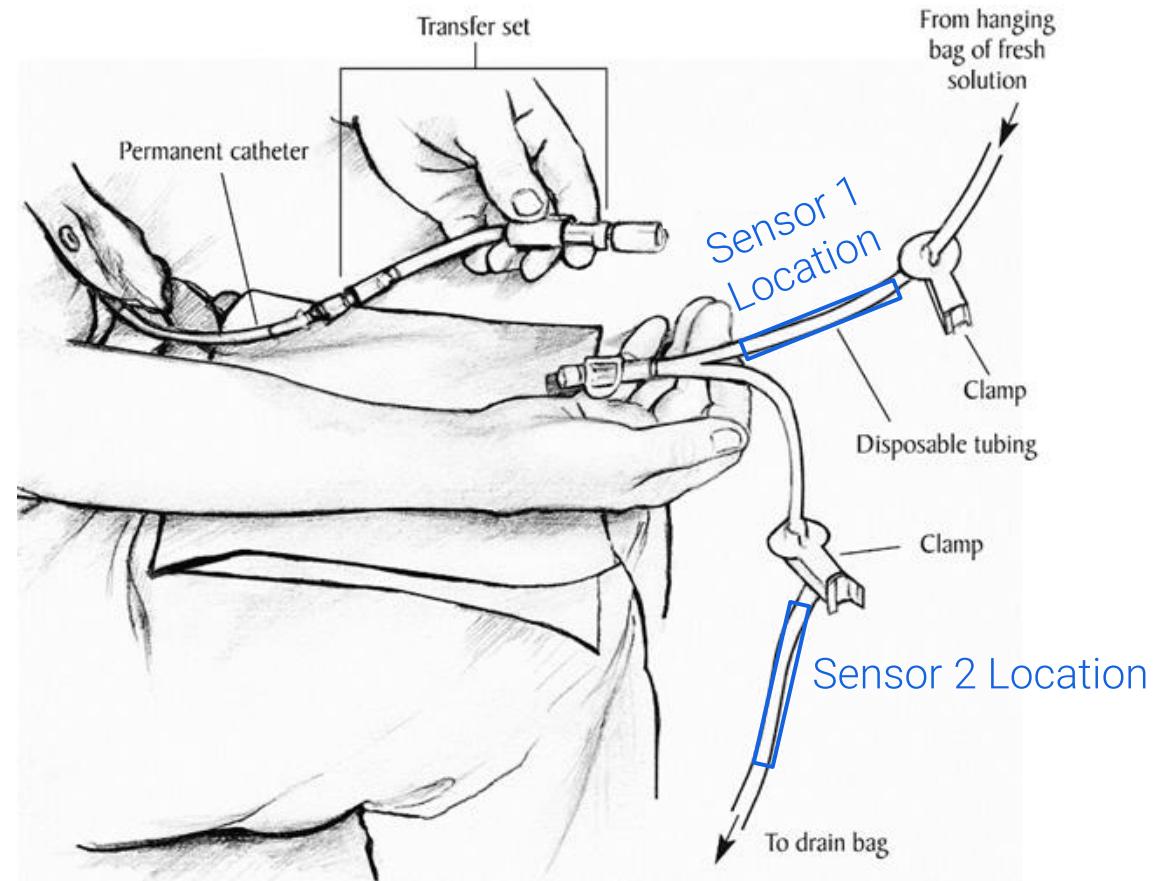
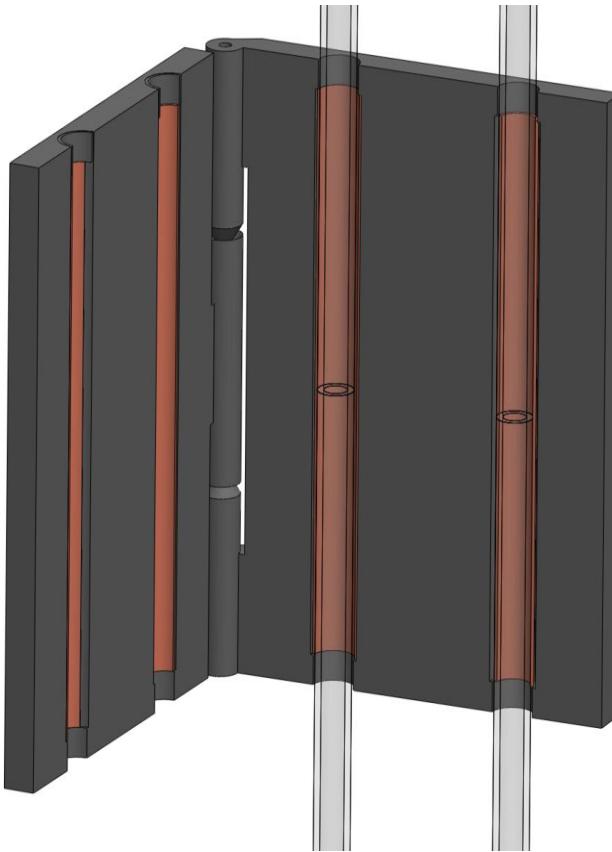
Inflow Tube

 C_{var}

Outflow Tube



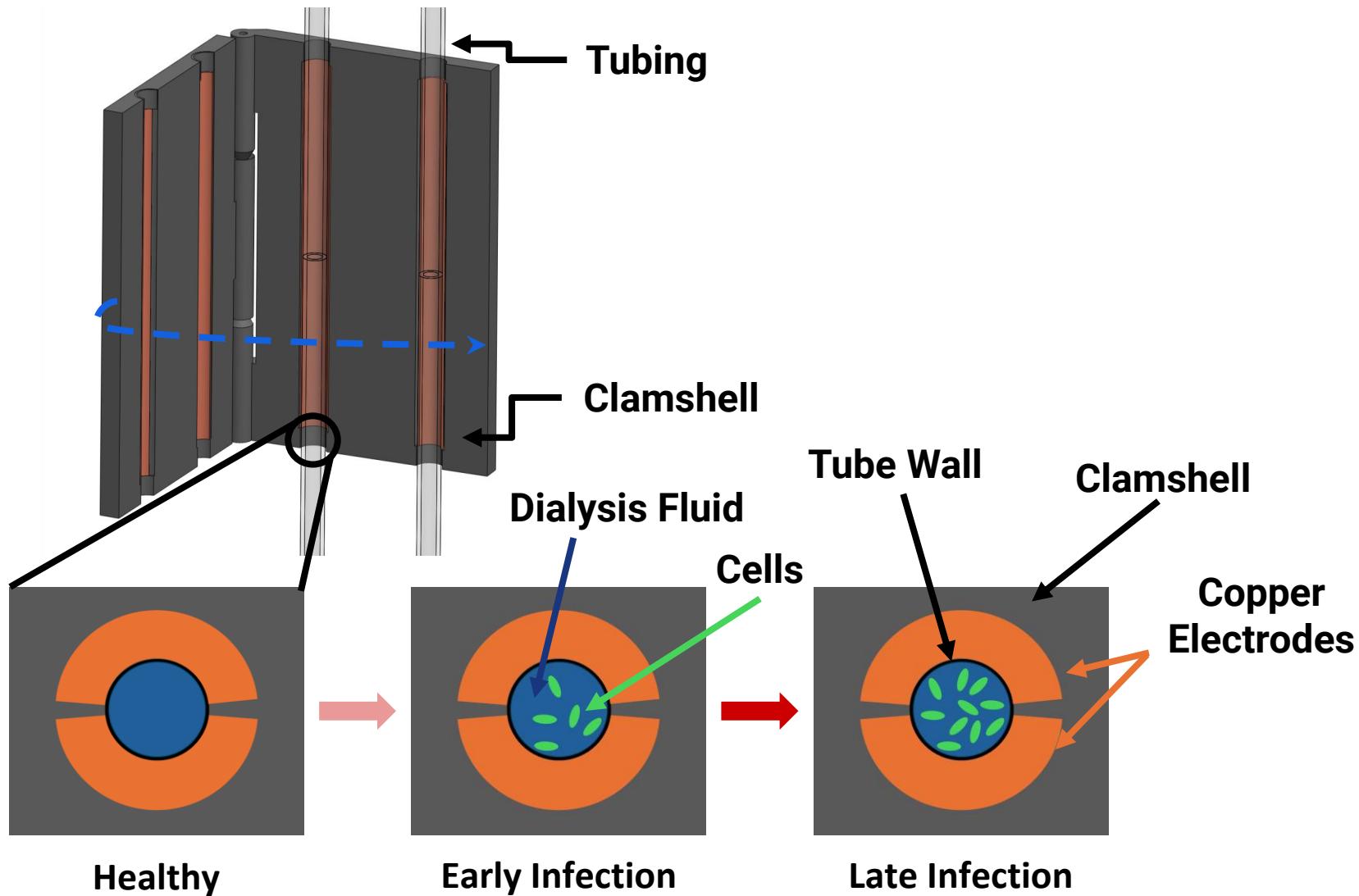
SOLUTION - INFECTION DETECTION



33X more sensitive than clinical standard

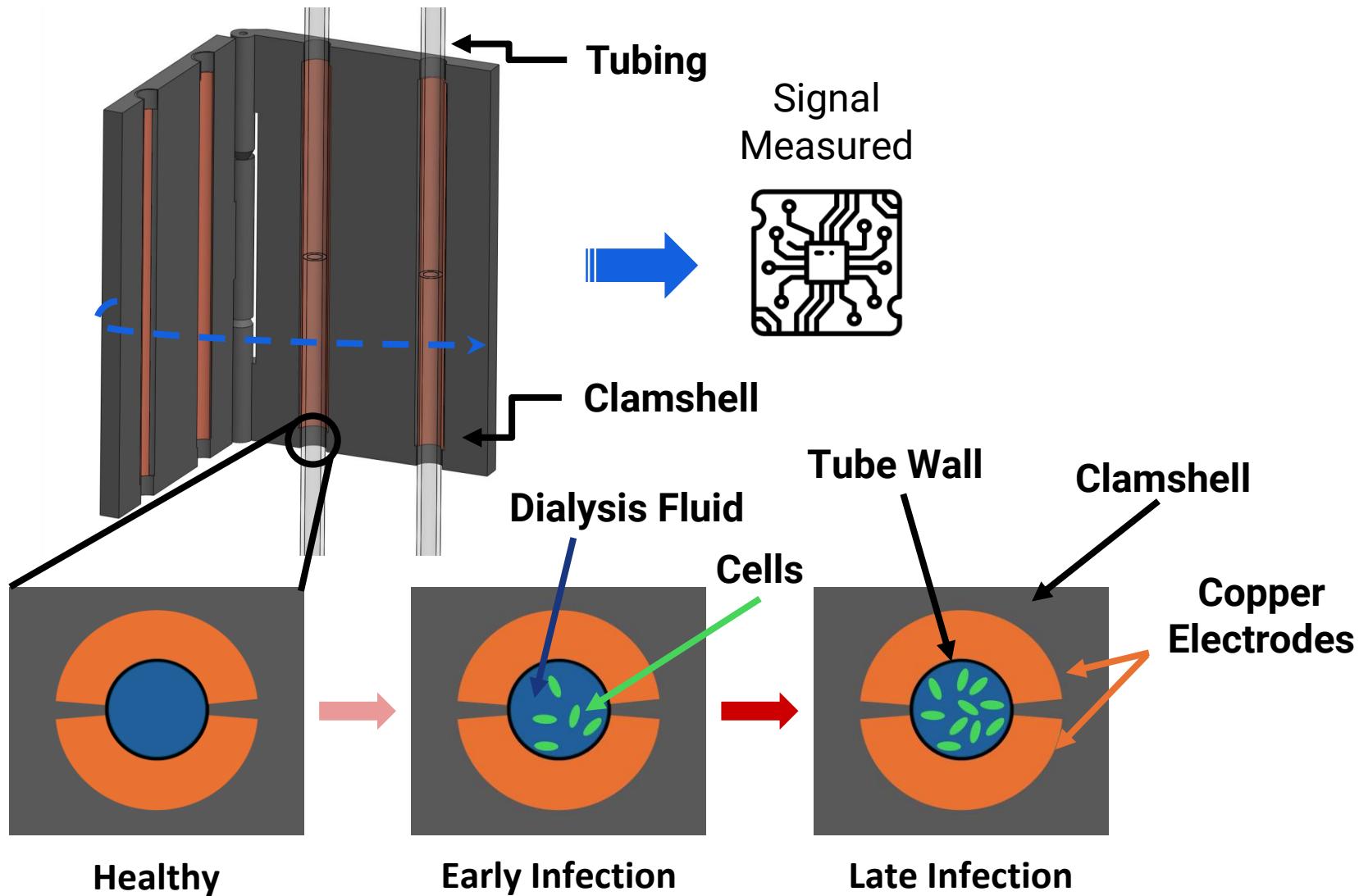


SOLUTION - INFECTION DETECTION



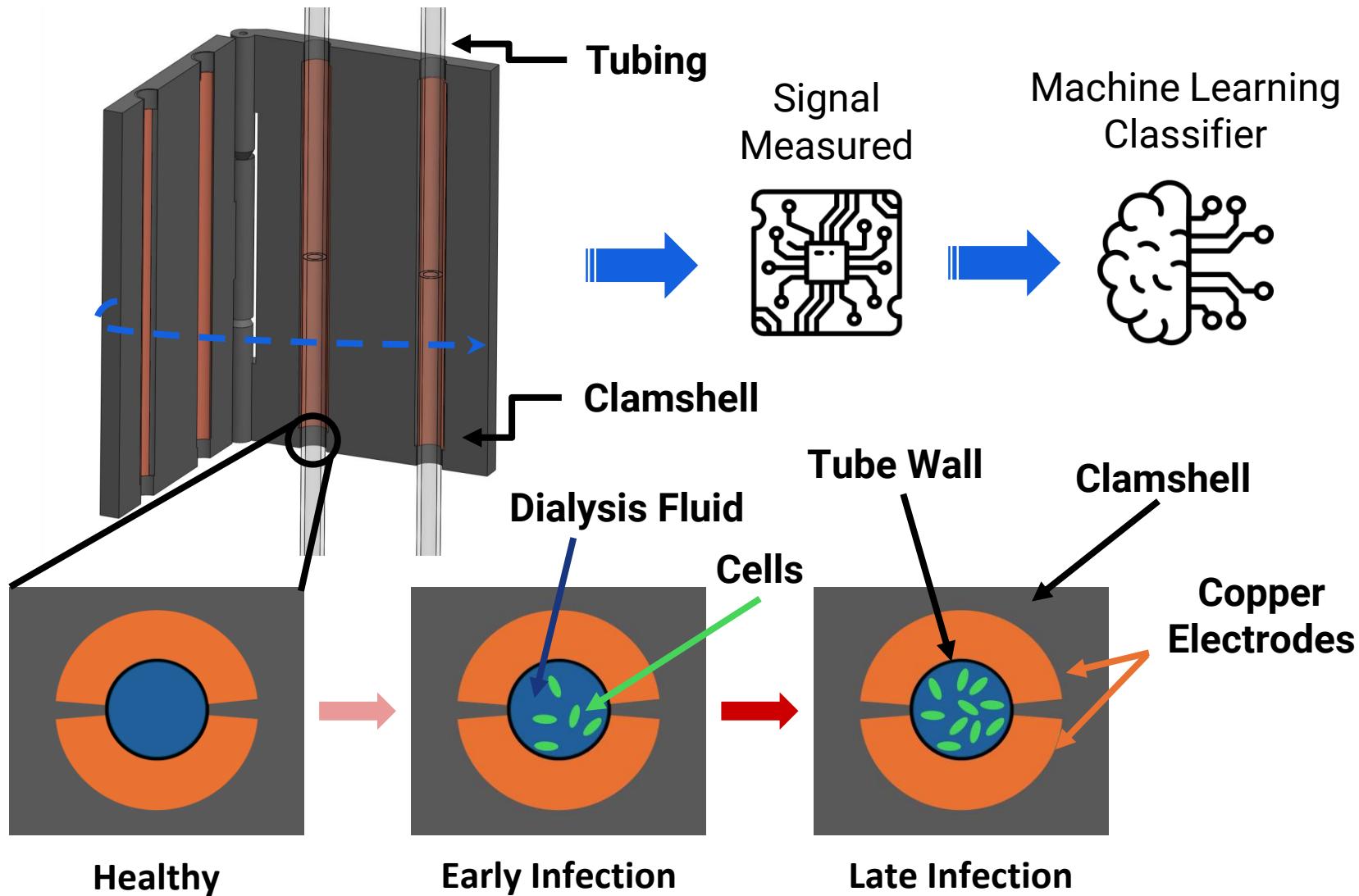


SOLUTION - INFECTION DETECTION



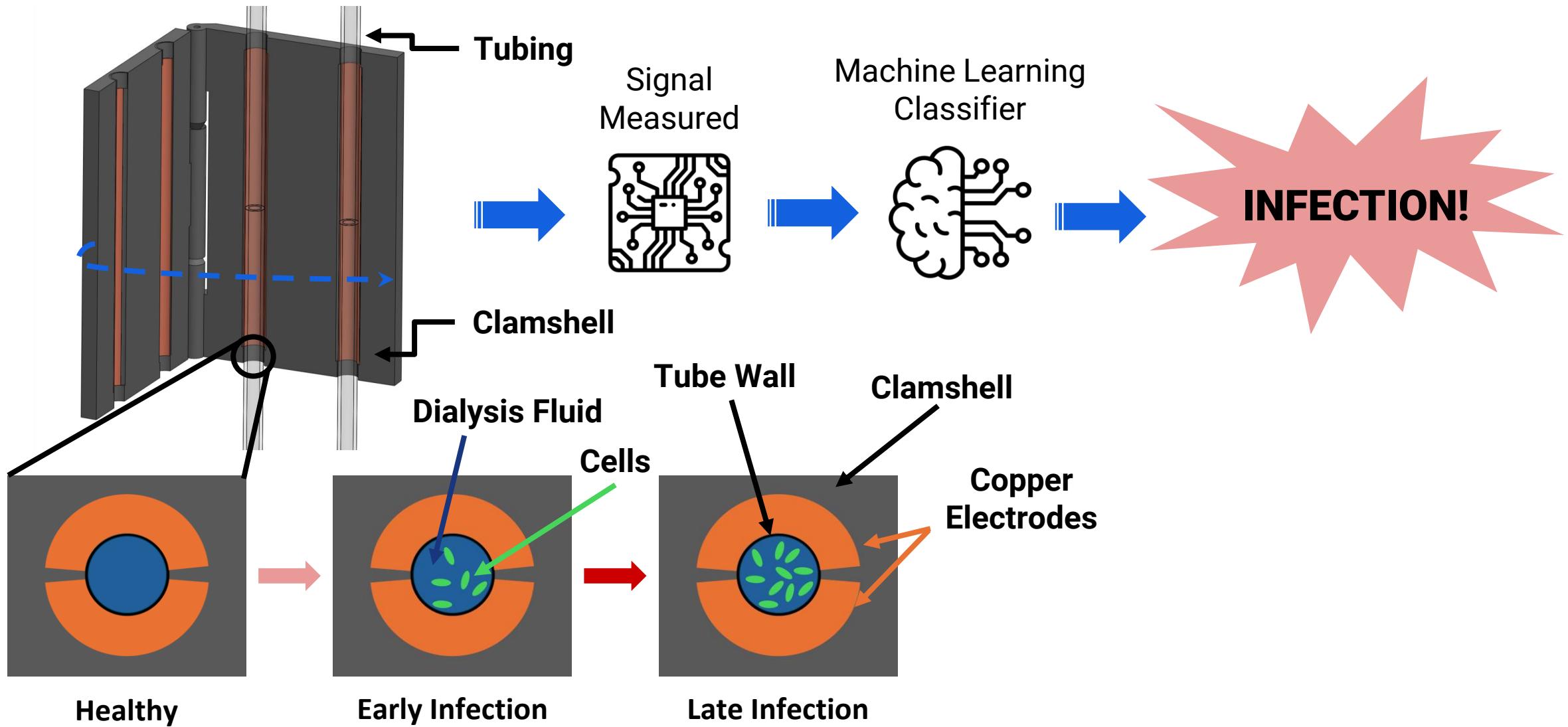


SOLUTION - INFECTION DETECTION





SOLUTION - INFECTION DETECTION

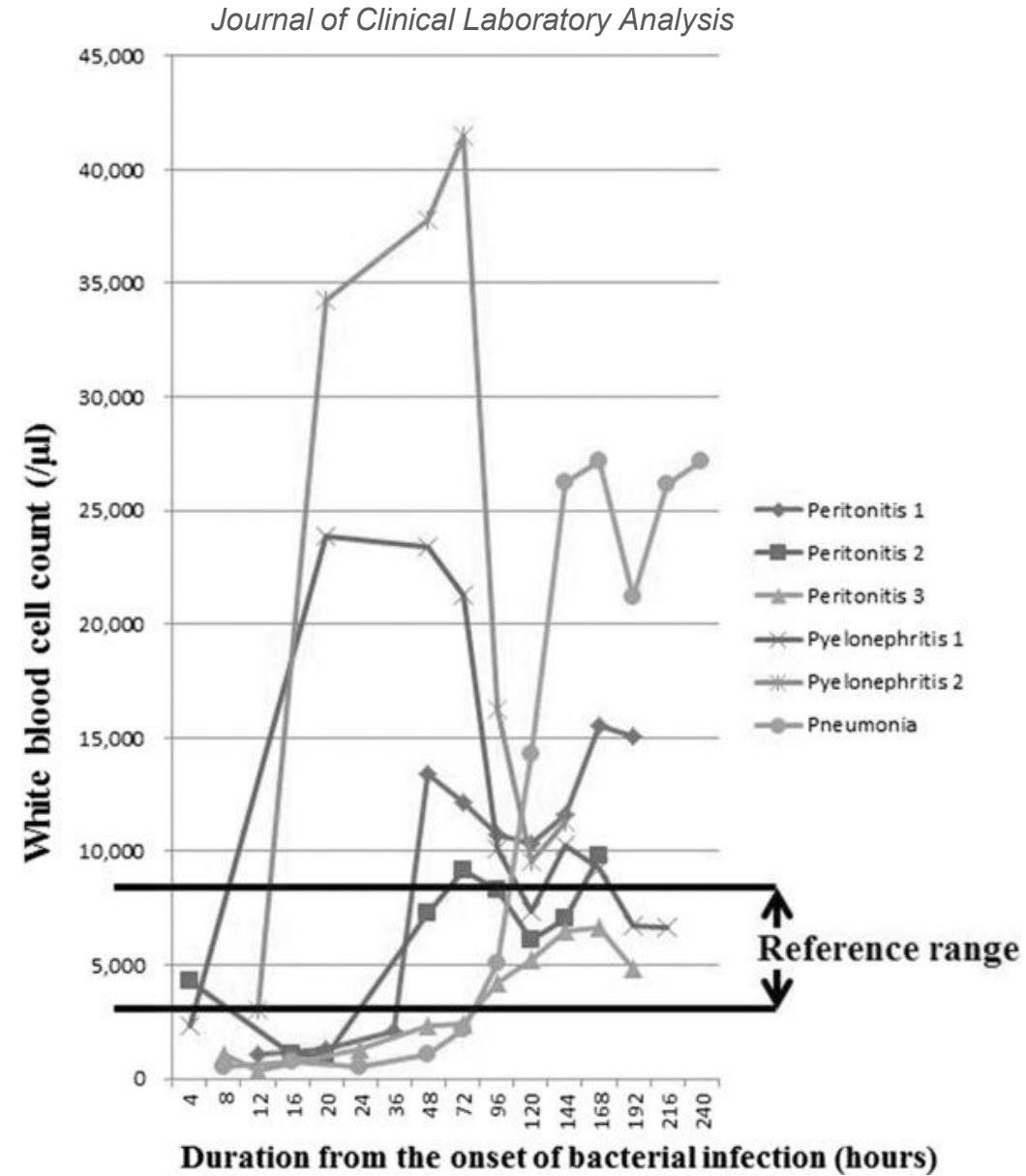


SENSOR EXPERIMENTAL METHODOLOGY

White Blood Cell (WBC) count is most reliable method

Treatment within 24 hours reduces hospitalizations by 80%

Earlier detection can half the duration of the hospital stay

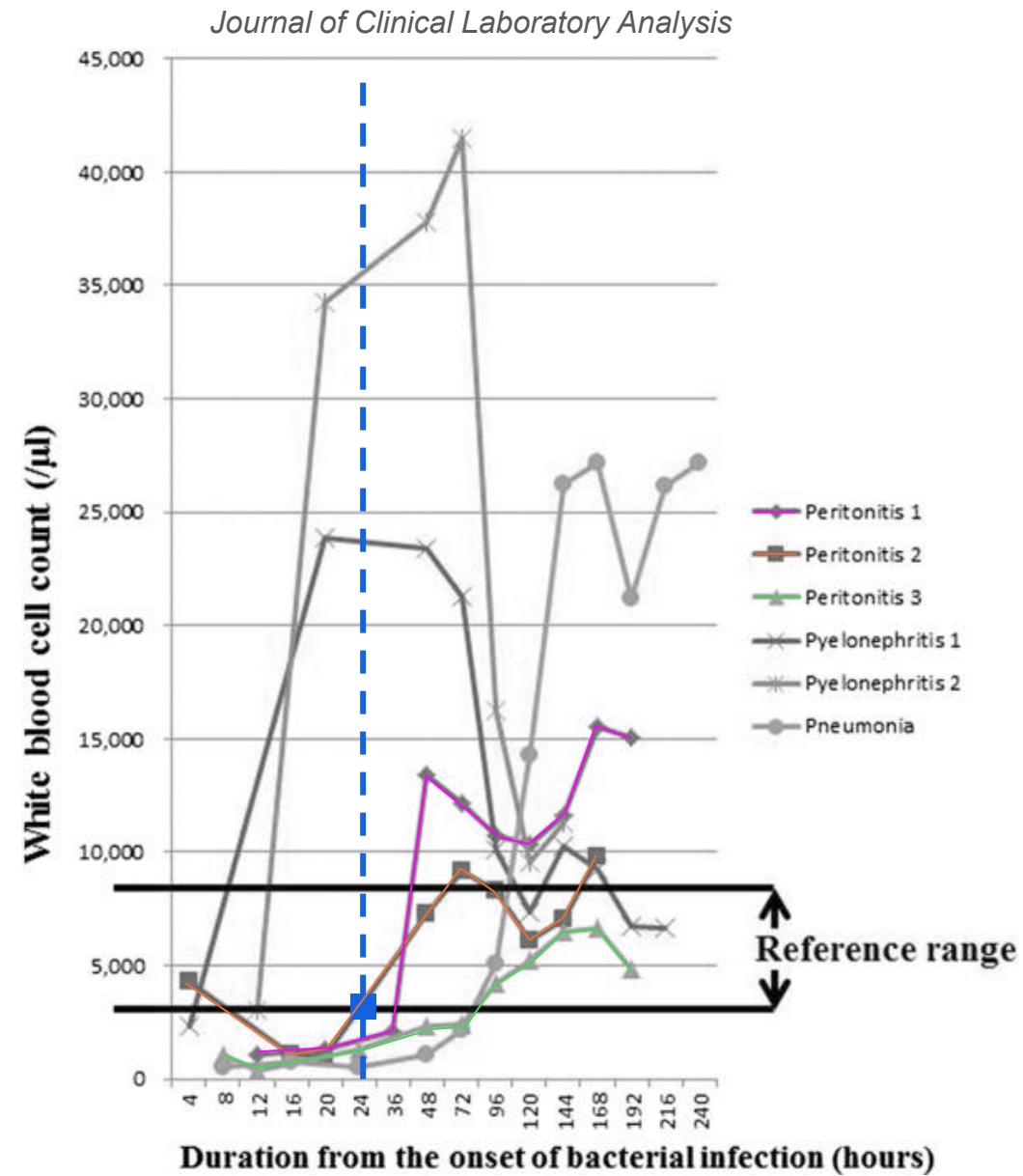


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SENSOR EXPERIMENTAL METHODOLOGY

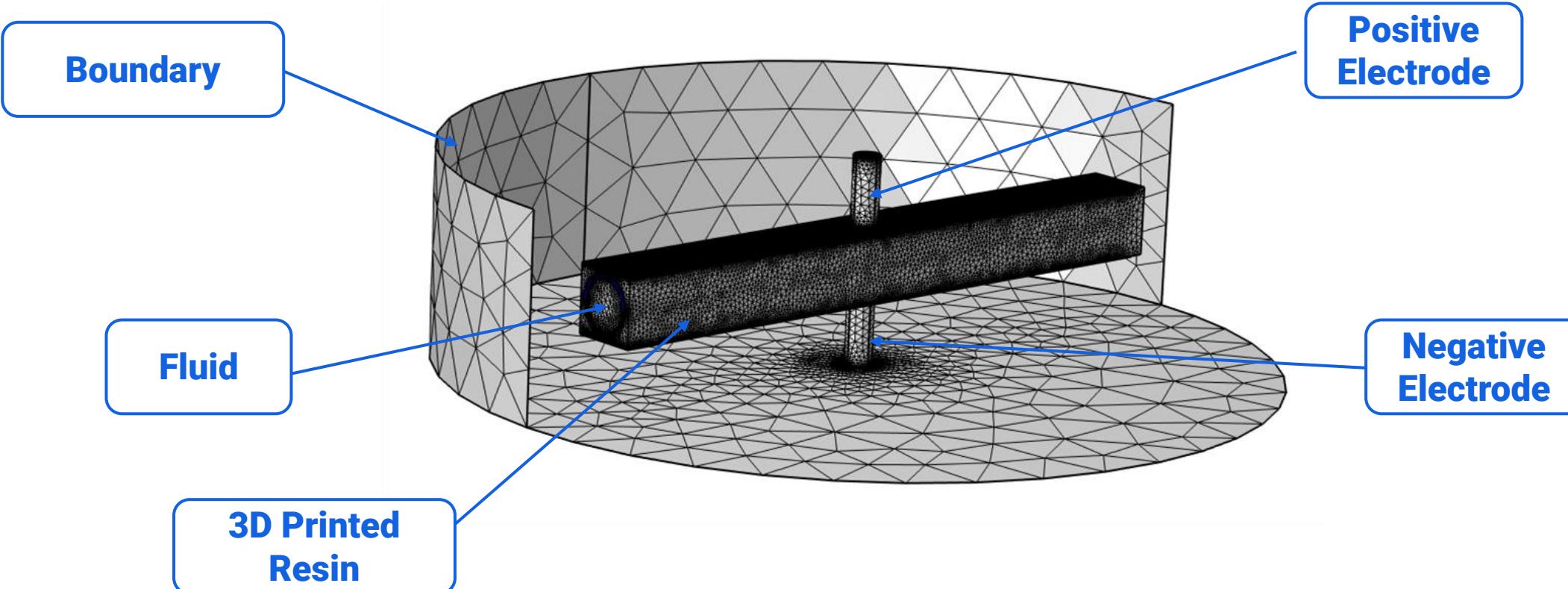
Duration from Onset of Bacterial Infection	WBC Concentration	Equivalent K562 Cell Concentration
<24 hours	100 WBCs/ μ L	100k cells/mL
24 hours	3,000 WBCs/ μ L	3M cells/mL
48 hours	10,000 WBCs/ μ L	10M cells/mL

SENSOR PHYSICS SIMULATION - SETUP

Sensor Mesh and Boundary Created

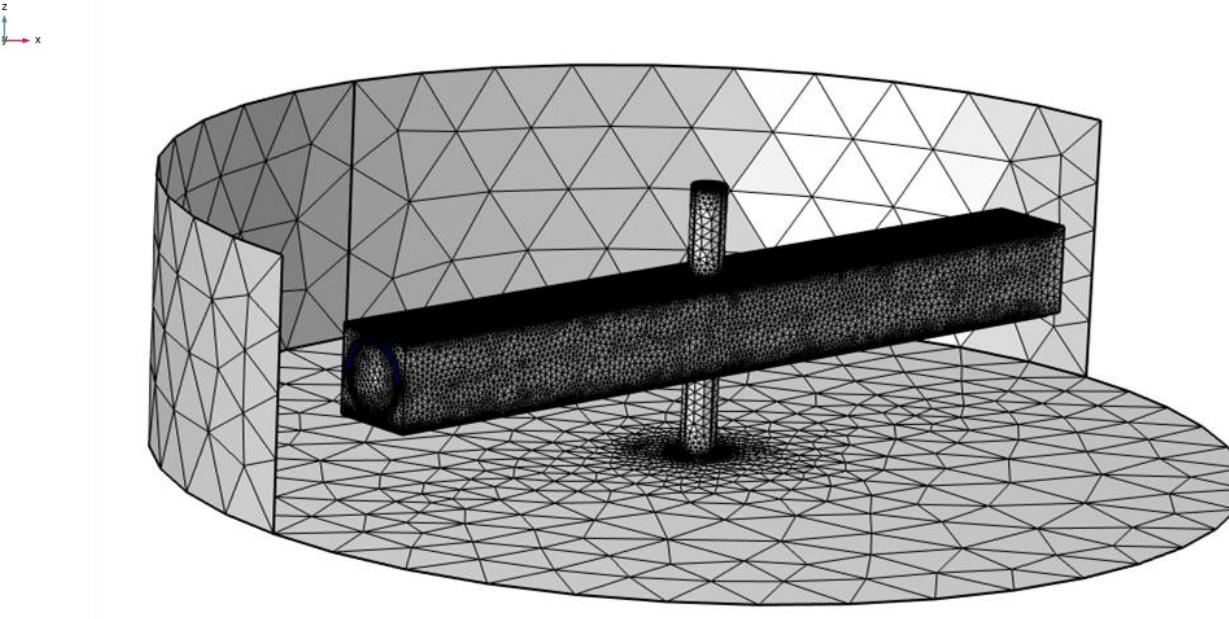
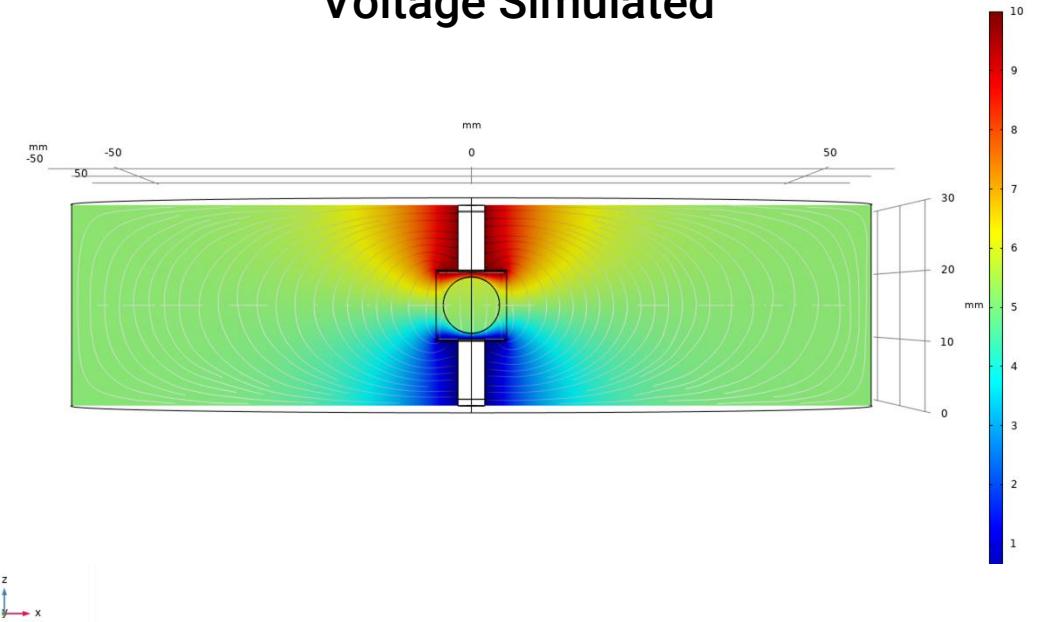
+

Material Properties Defined

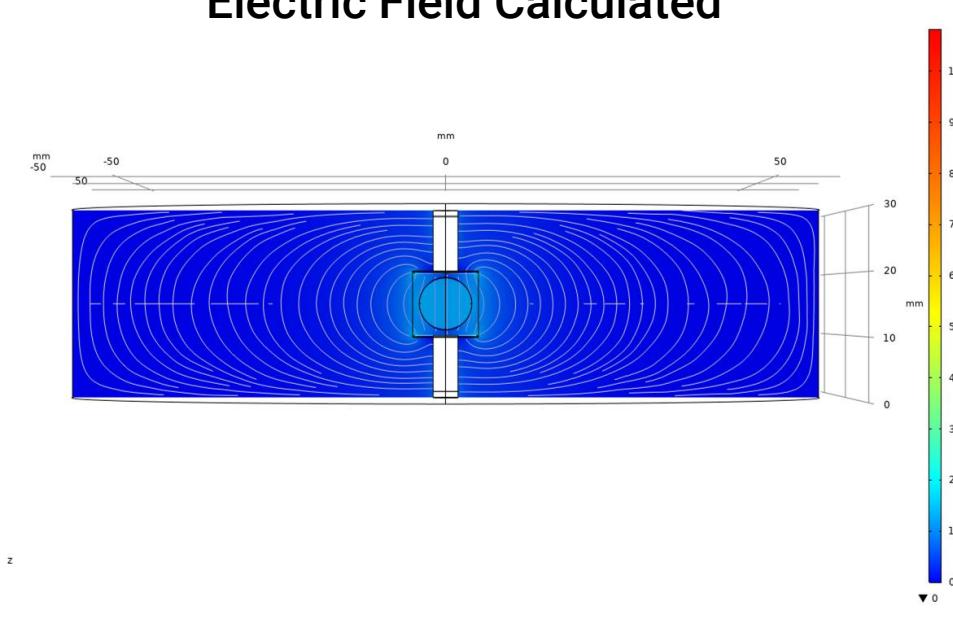


SENSOR PHYSICS SIMULATION - RESULTS

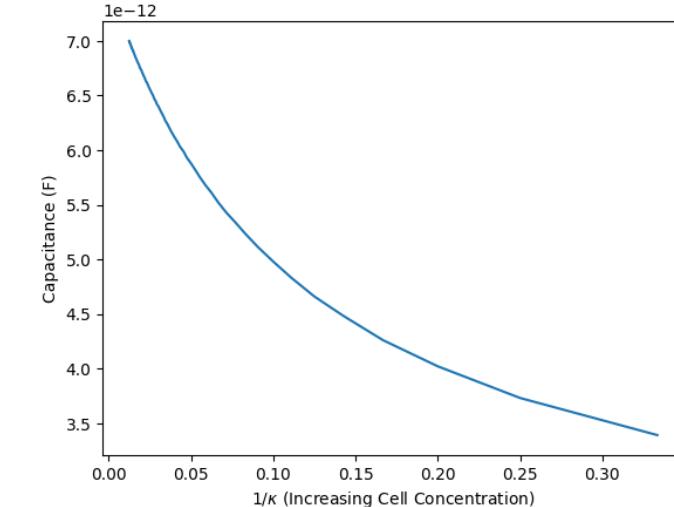
Voltage Simulated

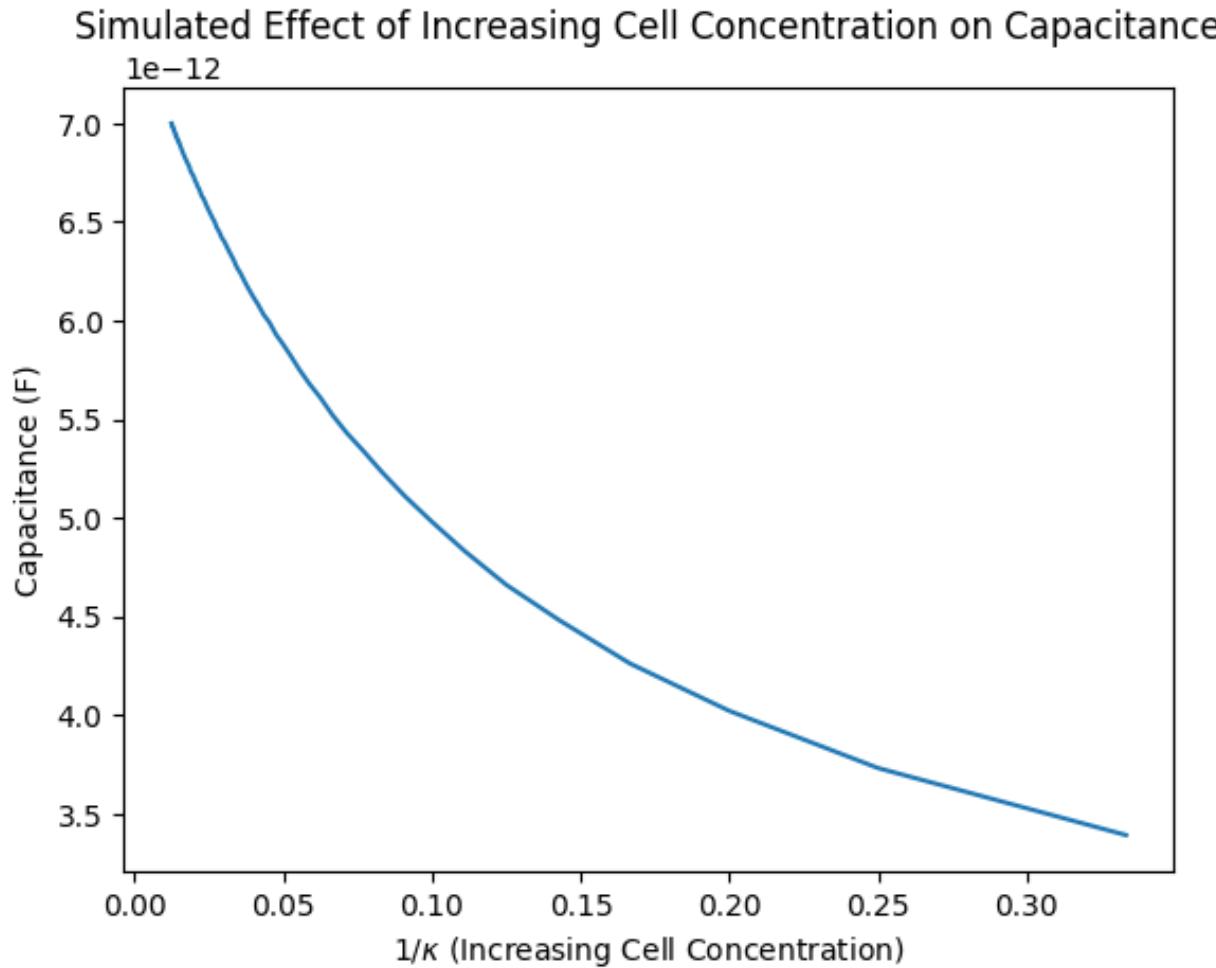


Electric Field Calculated



Simulated Effect of Increasing Cell Concentration on Capacitance

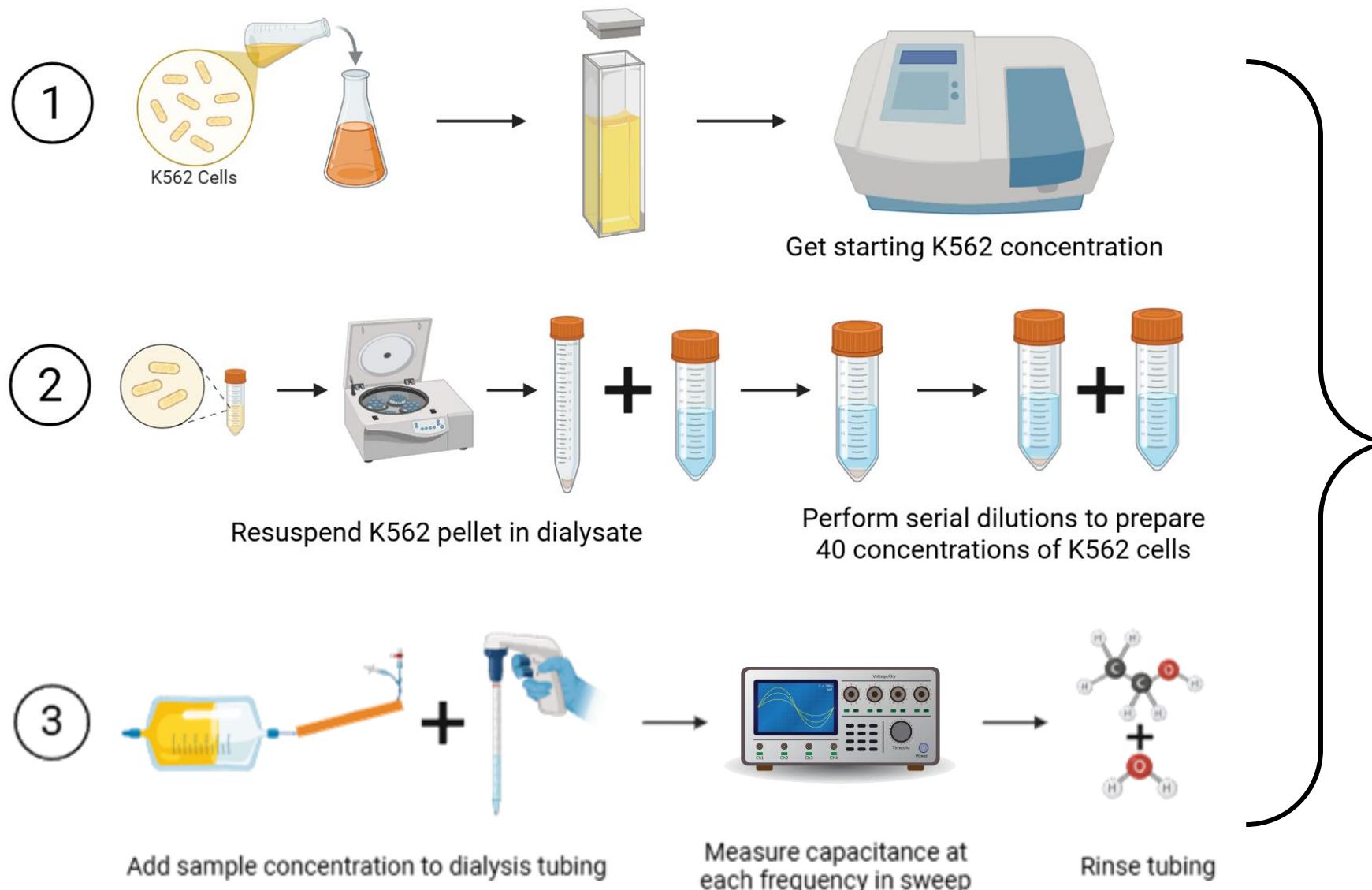




Main Findings

- **Validated inverse cap-conc relationship**
- **Expected max of 7 pF (0% cells)**
- **Expected min of 3.5 pF (100% cells)**

SENSOR EXPERIMENTAL METHODOLOGY



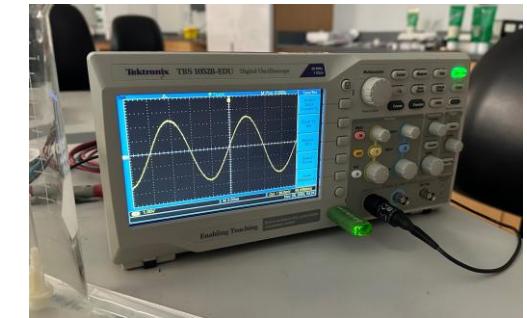
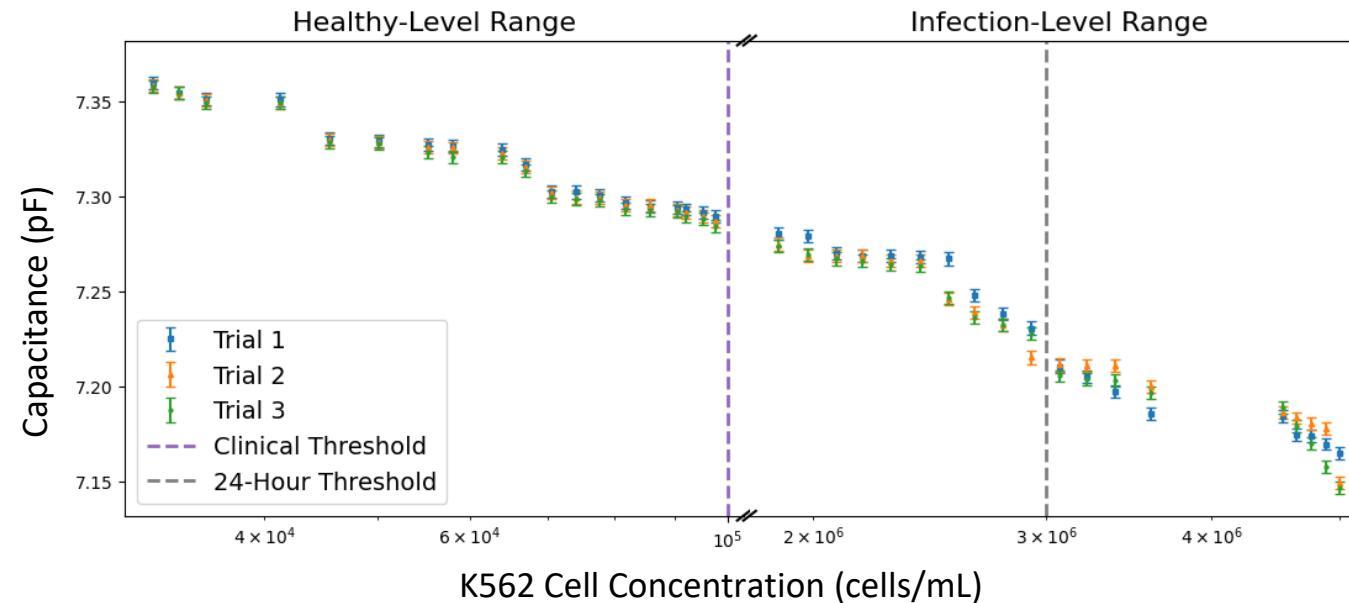
40 Concentration Values

3 Biological Replicates per Concentration

480K Points in Dataset

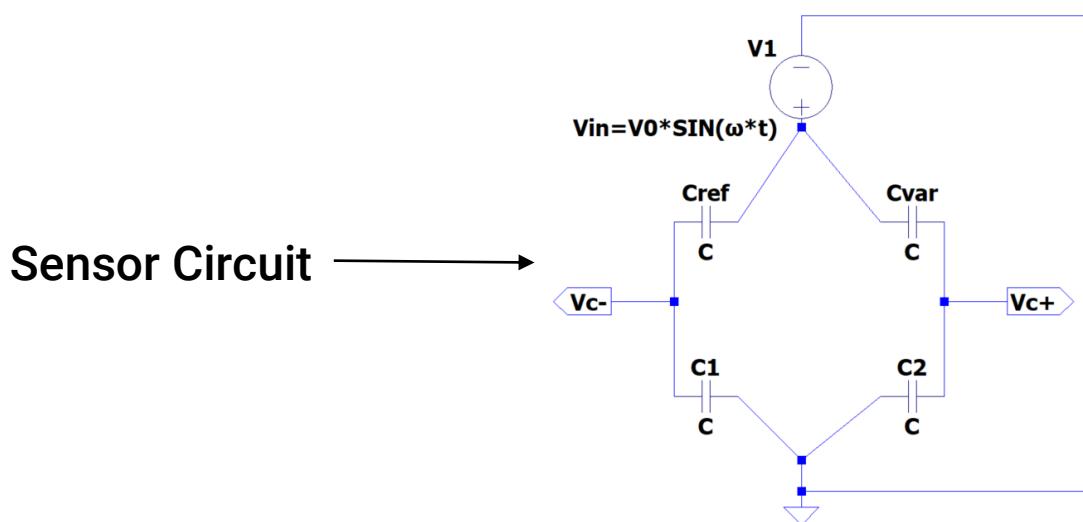


SENSOR ACCURACY EXPERIMENTAL DATA



Sensor Voltage Output

Sensor Prototype



Capacitance Bridge Equation

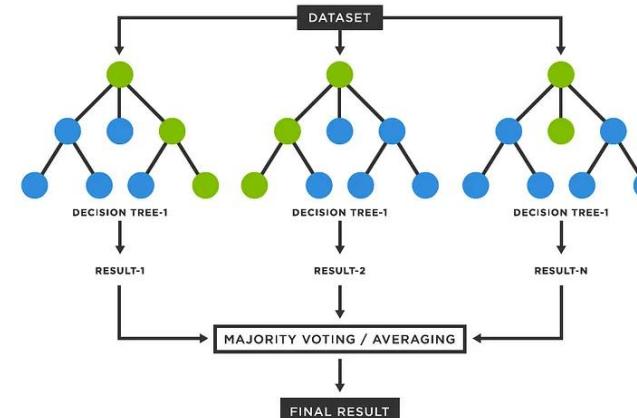
$$V_c = V_{in} \left(\frac{C_{var}}{C_2 + C_{var}} - \frac{C_{ref}}{C_1 + C_{ref}} \right)$$

Input Vector

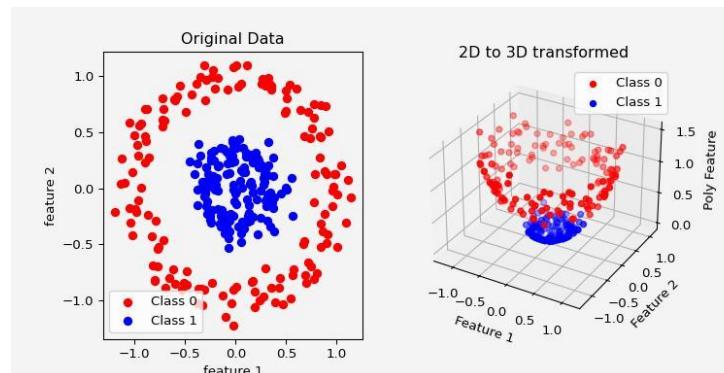
- Voltage
- Voltage StdDev
- Capacitance
- Capacitance StdDev
- Phase Shift
- Phase Shift StdDev
- Frequency
- Temperature
- Humidity

Classifier Models

Model 1: Random Forest



or
Model 2: Support Vector Machine

**Binary Classification Output**

Anomaly/Infection Detected

or

Healthy

SENSOR ACCURACY EXPERIMENTAL DATA

ML Model	Accuracy	Sensitivity	Specificity	F1-Score
Random Forest	98.8%	100%	97.6%	98.8%
Support Vector Machine (RBF Kernel)	98.3%	96.7%	100%	98.3%
Support Vector Machine (Poly Kernel)	96.7%	100%	93.3%	96.8%
Support Vector Machine (Linear Kernel)	81.7%	63.3%	100%	77.6%



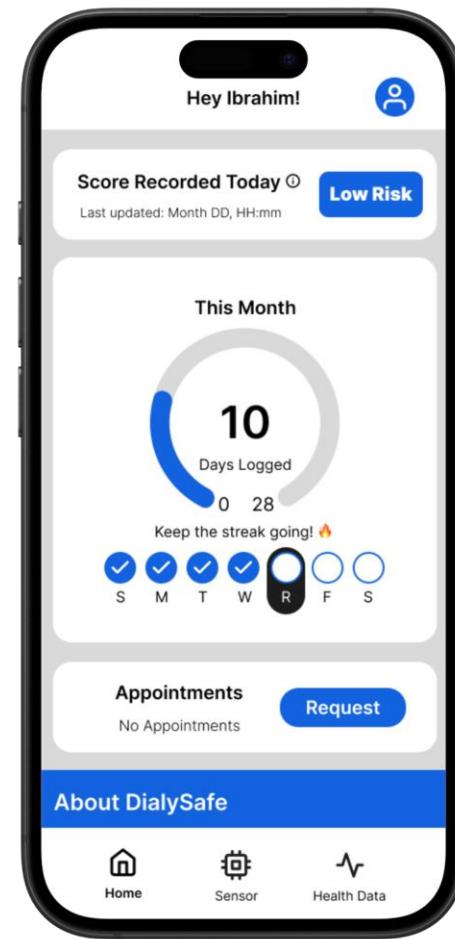
REMOTE PATIENT MONITORING (RPM SOLUTION)

Clinical Dashboard

The Clinical Dashboard displays the following information:

- CLINIC DASHBOARD**: Wednesday, January 23, 2025.
- Patient Overview**: Patient Name: John Doe, Assigned Caretaker: John Doe, Sensor UUID: 740412ef-eb0b-4056-b53e-
eff07cf01a8, Join Date: 12/29/2024, Insurance Provider: Medicaid.
- Latest Exchange Sensor Data**: Capacitance vs. Frequency graph showing Pure Dialysate (blue dots) and Effluent (black dots) levels over time.
- Sensor Data History**: Calendar view for Wed, Jan 23, 2025, showing daily sensor data collection status (green checkmark or red X).
- Patient Data Summary**: Total Exchanges: 360, Exchanges This Year: 360, Exchanges This Month: 360, Total Infections Detected: 1, Average Monthly Chat Minutes: 60.
- User Profile**: Hey Ibrahim!, Low Risk.

Mobile Application



Doctor



Nurse



Caregiver



Patient

REMOTE PATIENT MONITORING (RPM SOLUTION)

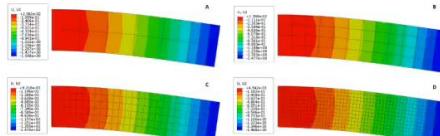
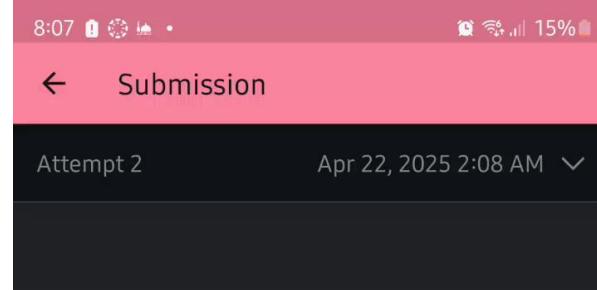
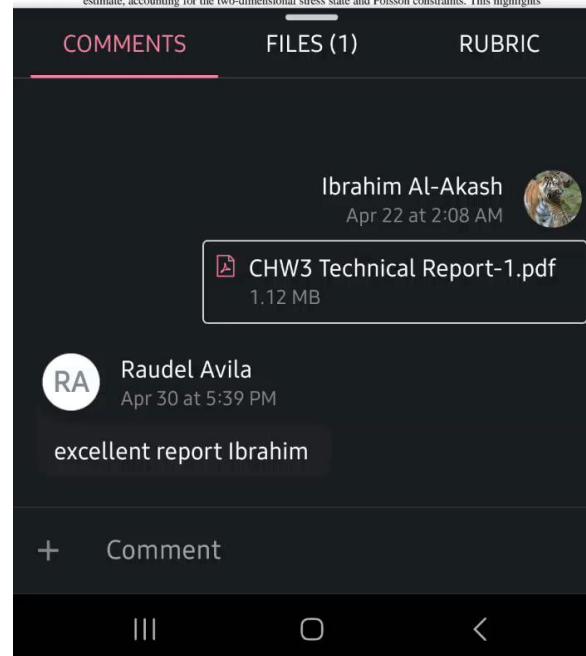


Figure 4. Vertical displacement fields for meshes with 12 (A), 48 (B), 162 (C), and 612 (D) CPE4 elements.

Looking at the trend in the displacement as the number of elements increases, the displacement converges around -1.462 inches (Figure 5). The classical engineering beam solution under pure shear predicts a significantly smaller vertical displacement at point A (on the order of 0.03 inches). However, this theoretical value neglects the effects of plane strain and nearly incompressible behavior. As a result, it severely underestimates the true response of the structure. The converged FEM value from the fine mesh with CPE4 provides a more accurate estimate, accounting for the two-dimensional stress state and Poisson constraints. This highlights



A mobile application interface showing a list of interactions. The top navigation bar includes "COMMENTS", "FILES (1)", and "RUBRIC".

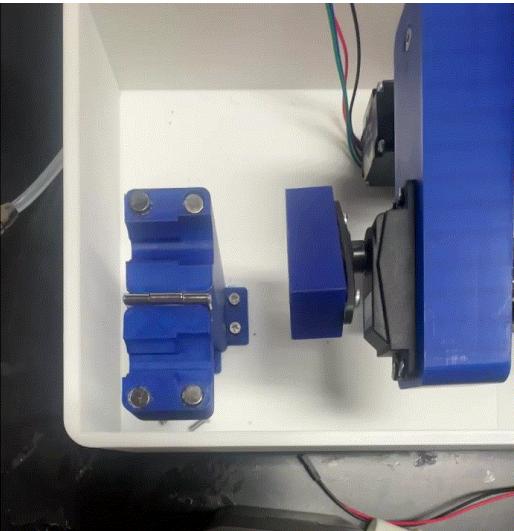
- Ibrahim Al-Akash** (Profile picture of a tiger) - Apr 22 at 2:08 AM
CHW3 Technical Report-1.pdf
1.12 MB
- Raudel Avila** (Profile picture of a person) - Apr 30 at 5:39 PM
excellent report Ibrahim

At the bottom, there is a button labeled "+ Comment".

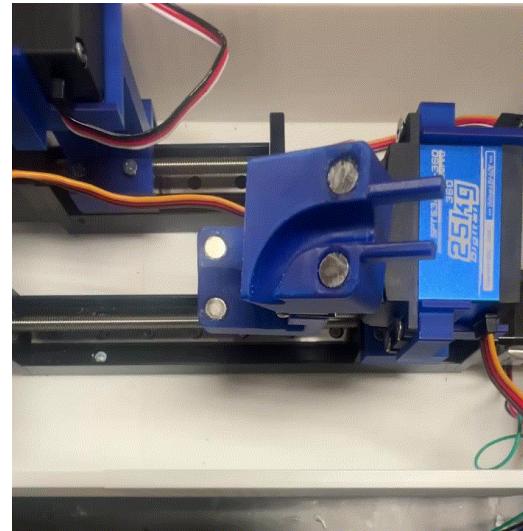


SYSTEM SIMPLIFIES SETUP

1. Transfer Set to Clamp and Decapper



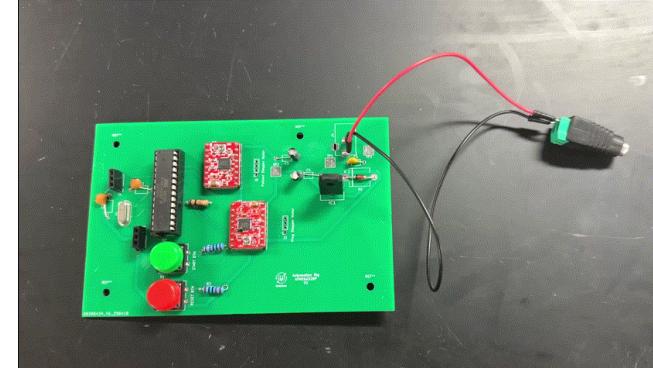
2. Disposable Tube to Clamp



3. Fill/Drain Tubes to Sensor



4. Start Button is pressed



Cuts Procedural Steps in Half



Without DialySafe	Result
8-13 manual steps	4 manual steps



NEXT STEPS - 15 WEEKS

Automation Rig

Transfer breadboard to PCB
(2 weeks)

Optimize human factors
(2 weeks)

Perform accelerated failure testing
(1 week)

Sensor

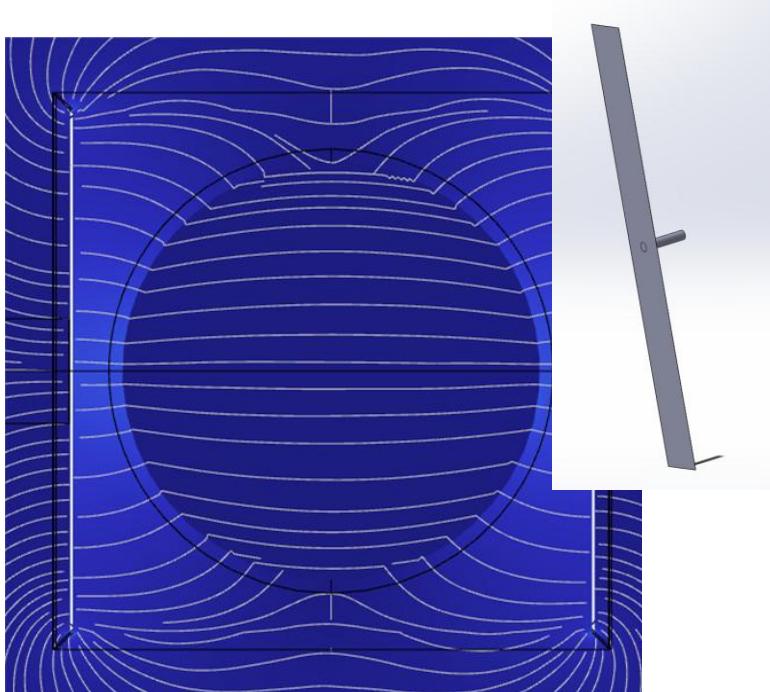
Optimize hardware and circuitry
(5 weeks)

Train ML models on more data
(3 weeks)

Perform validation experiments
(2 weeks)

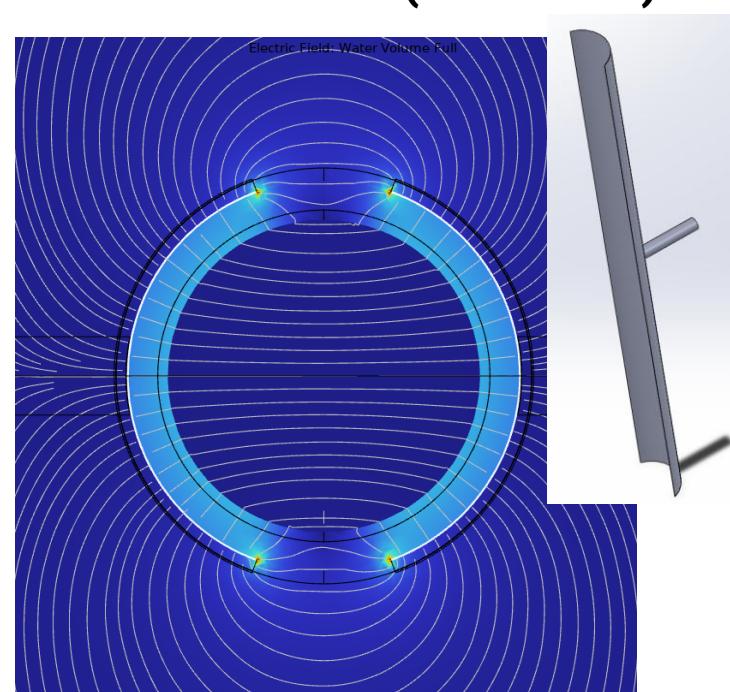
SENSOR OPTIMIZATIONS - ELECTRODE GEOMETRY

Straight Electrodes



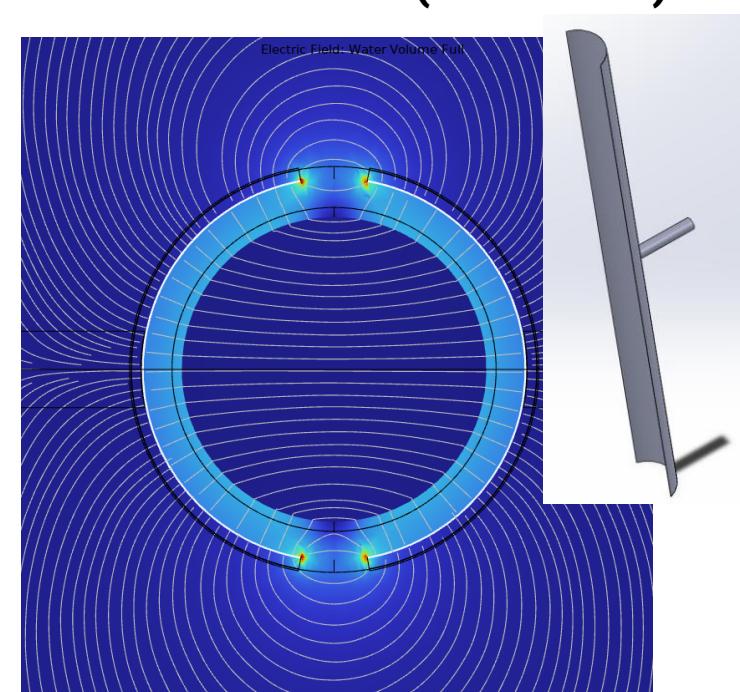
7.6713 pF

Curved Electrodes (20° Offset)



13.6800 pF

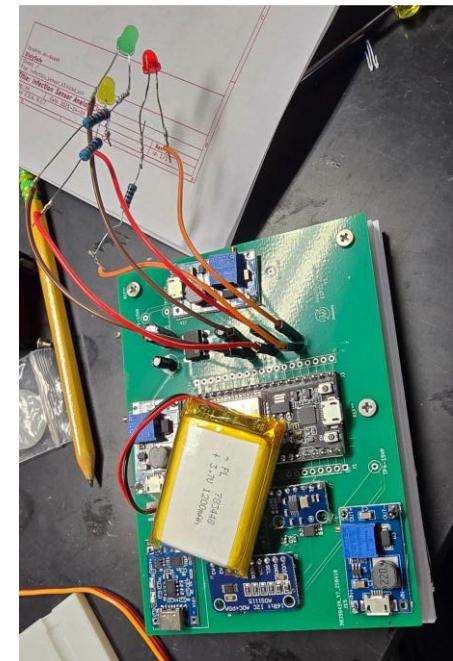
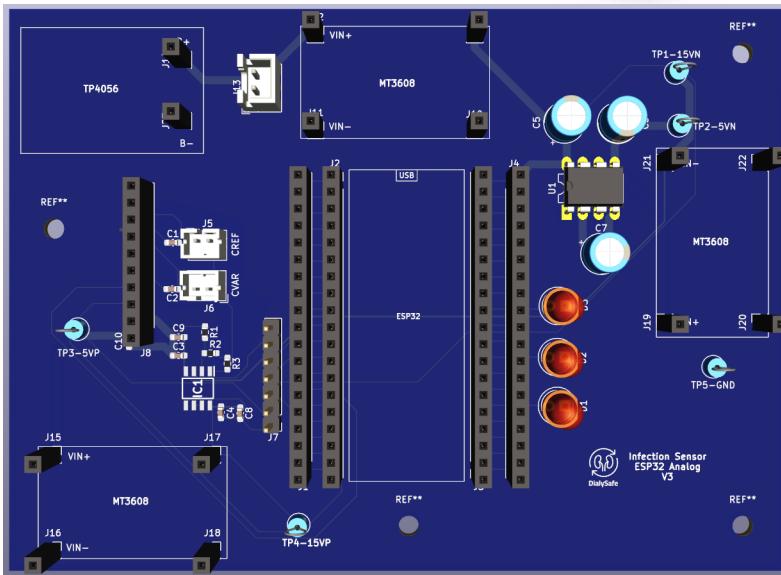
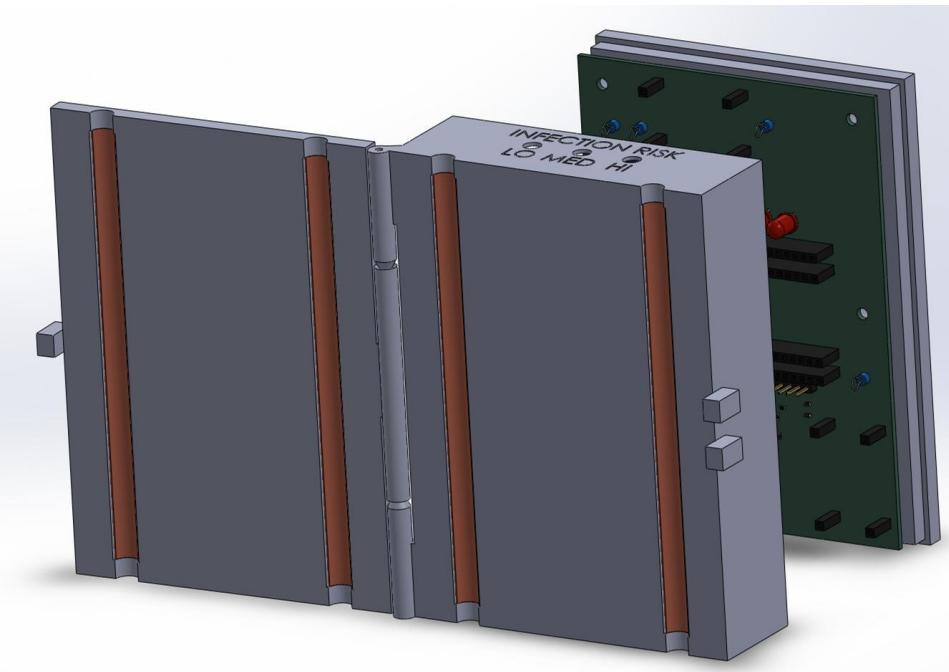
Curved Electrodes (10° Offset)

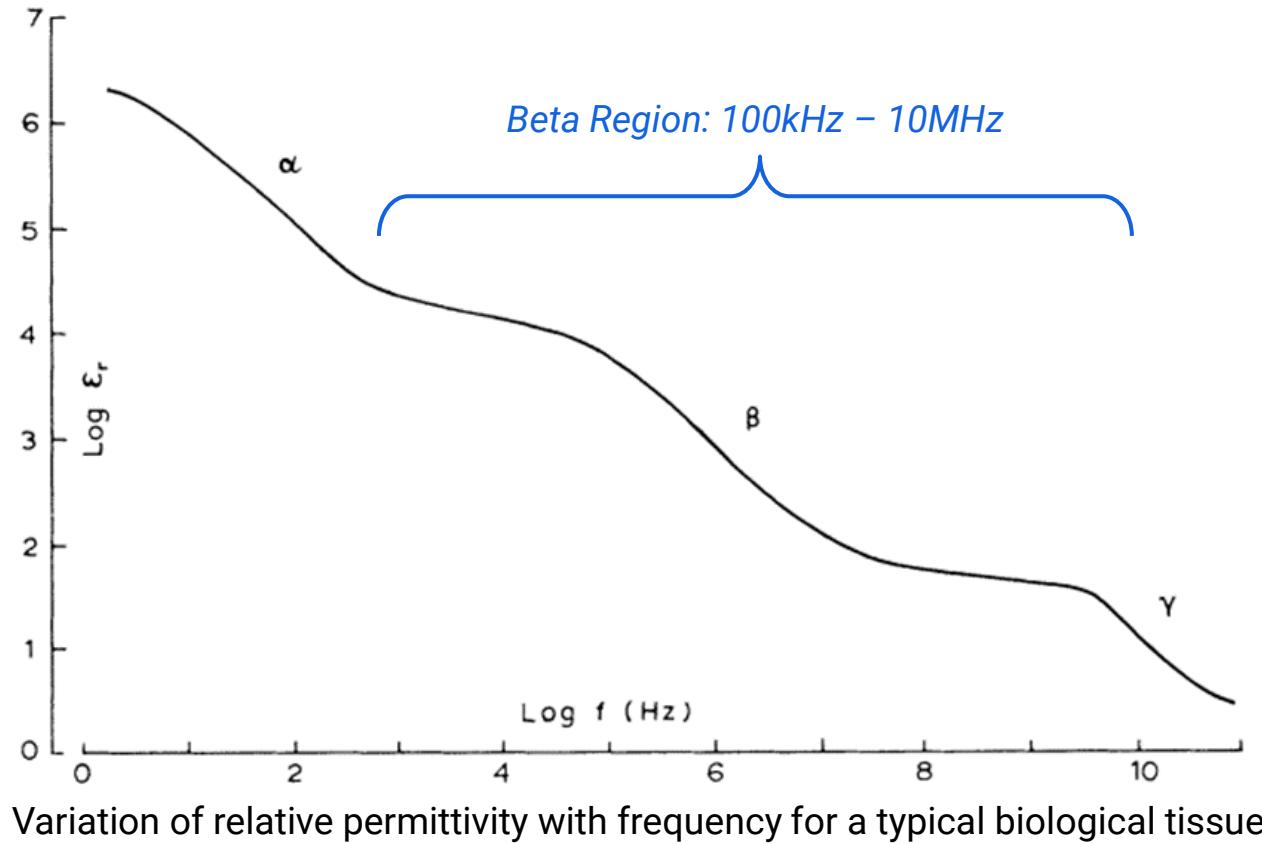


15.9200 pF



SENSOR OPTIMIZATIONS - FABRICATION





Test differentiation between different cell types (T, B, M, G):

- Wet lab tests with patient-collected effluent samples
- Variation and cross-contamination testing between different interferents
- Cycle testing to quantify drift or hysteresis that may be present

TABLE 2 Blood cell dielectric parameters

Cell type	Number	Radius (μm)	C_{mem} (mF/m^2)	σ_{int} (S/m)	ϵ_{int}
T-lymphocytes	91	3.29 ± 0.35	10.5 ± 3.1	0.65 ± 0.15	103.9 ± 24.5
B-lymphocytes	49	3.29 ± 0.26	12.6 ± 3.5	0.73 ± 0.18	154.4 ± 39.9
Monocytes	43	4.63 ± 0.36	15.3 ± 4.3	0.56 ± 0.10	126.8 ± 35.2
Granulocytes	33	4.71 ± 0.23	11.0 ± 3.2	0.60 ± 0.13	150.9 ± 39.3

UN SUSTAINABLE DEVELOPMENT GOALS

3 GOOD HEALTH
AND WELL-BEING



10 REDUCED
INEQUALITIES



8 DECENT WORK AND
ECONOMIC GROWTH





KEY PERFORMANCE INDICATORS

Infection Rate Reduction

Current Standard: 0.5-0.6 episodes per patient-year

TARGET

Lower than 0.4 episodes per patient-year

PD Failure Rate Reduction

Current Standard: 70-80% PD survival for 3 years of treatment

TARGET

Maintain 90% PD survival rate for 3 years of treatment

PD Prevalence Rate Improvement

Current Standard: 10-12% PD prevalence rate

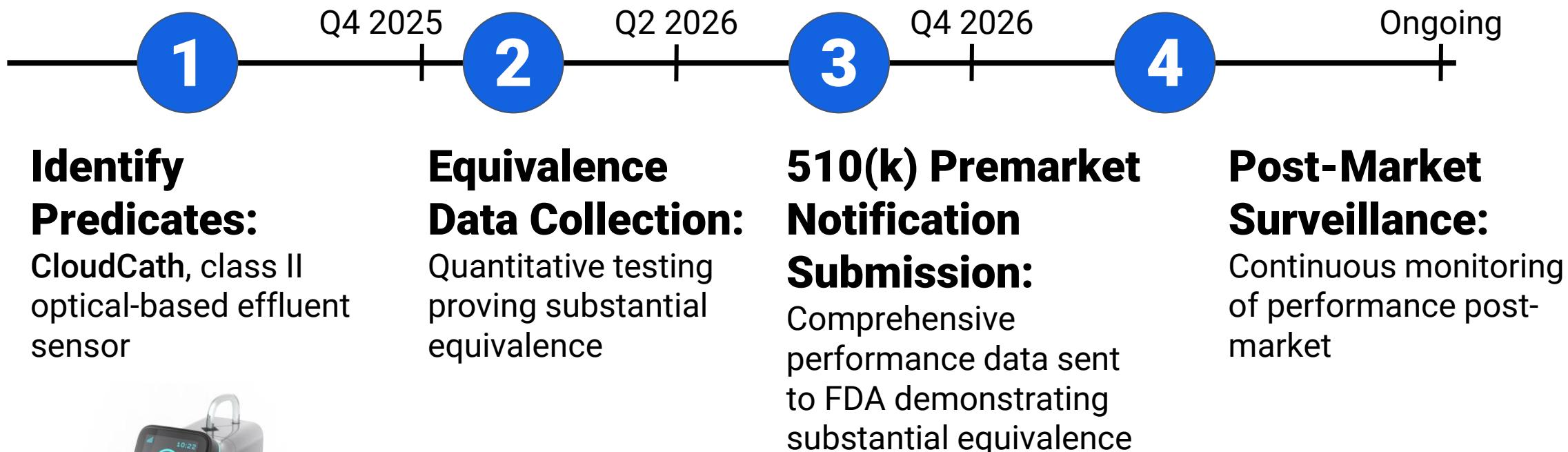
TARGET

Achieve 70% PD prevalence

Targets defined by International Society for Peritoneal Dialysis (ISPD)

Target defined by Advancing American Kidney Health Initiative

Class II Medical Device 510(k) Pathway



COST TO MANUFACTURE

**Cost of V1 Prototype
(Current)**

\$250

**Cost of V2 Prototype
(Next)**

\$160

**Cost @ Scale
(Final)**

\$100





REVENUE MODEL

No upfront patient costs



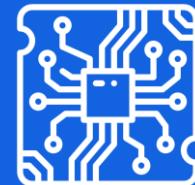
Minimum of **\$1,061/patient MRR**

Automation Hardware



\$31/use (1 use/day)

Infection Sensor Hardware



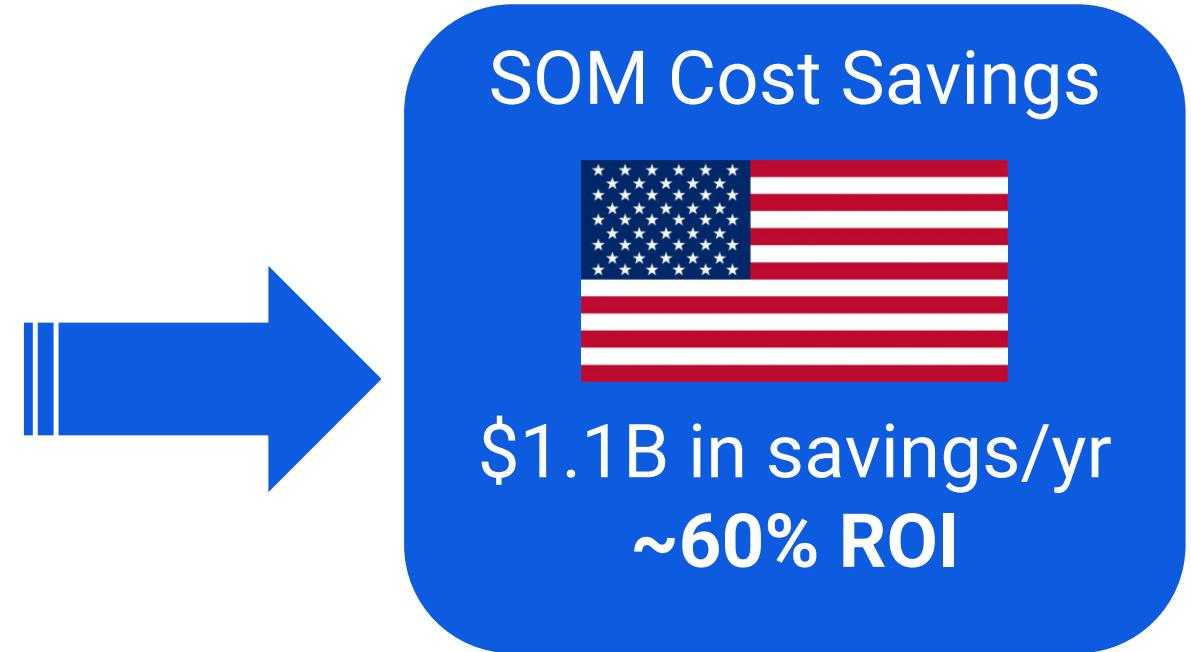
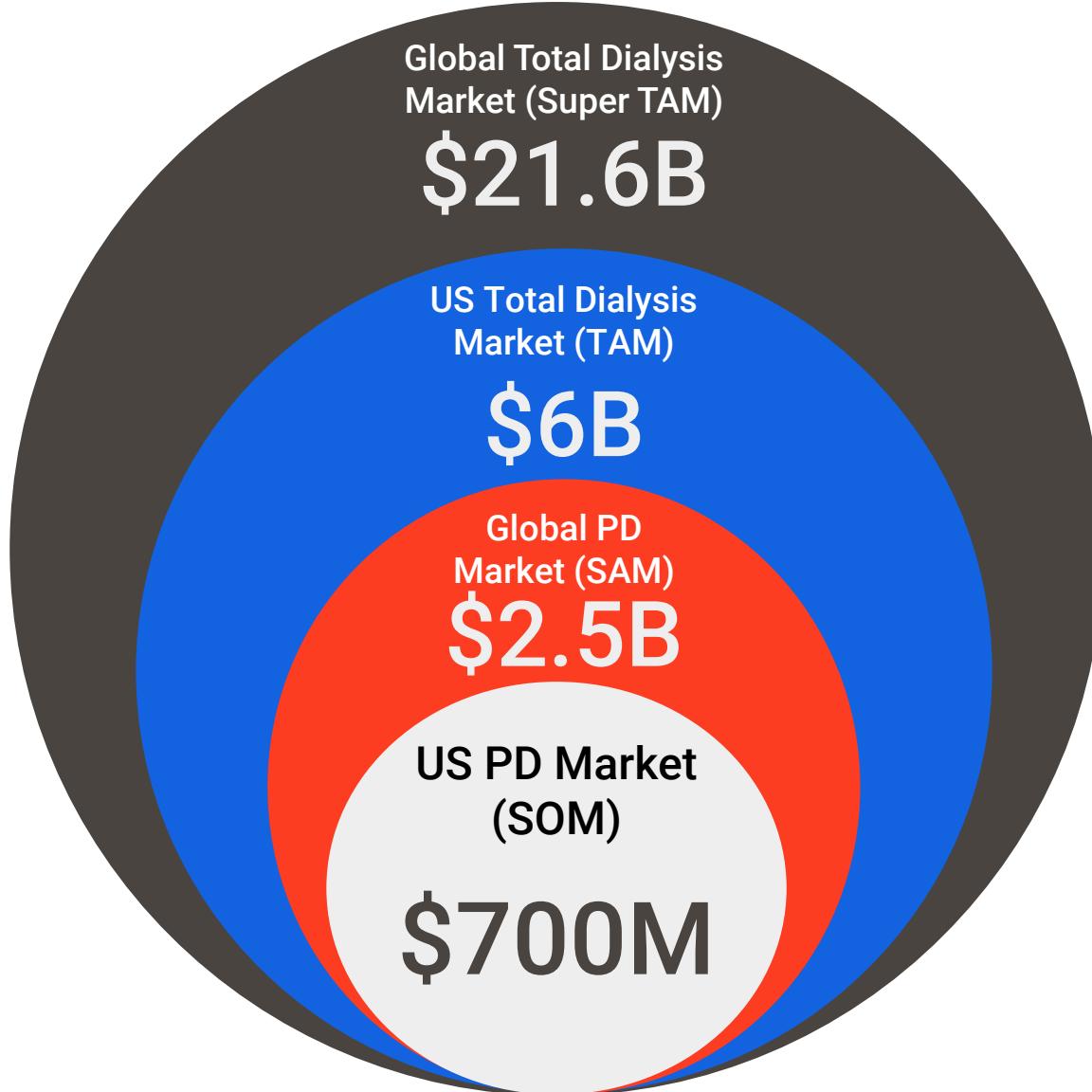
\$20 one-time fee

Remote Patient Monitoring (RPM)



\$62 per monthly report
\$49 per 20 min of phys. int.

MARKET SIZE





TREATMENT COST COMPARISON

PD without DialySafe

\$87k

PD with DialySafe

\$99k

In-Clinic HD

\$110k



UNIT ECONOMICS

COGS + CAC

ARR per Patient

Patient LTV



\$250 +
\$270

\$12k

\$36k-60k

Annual Savings per
Patient (for Insurance)

Lifetime Savings per
Patient (for Insurance)

\$20k

\$60k-100k



Medicaid &
Medicare



INTELLECTUAL PROPERTY



RICE UNIVERSITY

Rice owns the IP

Provisional patent was filed Jan. '25,
will convert to 2 non-provisionals

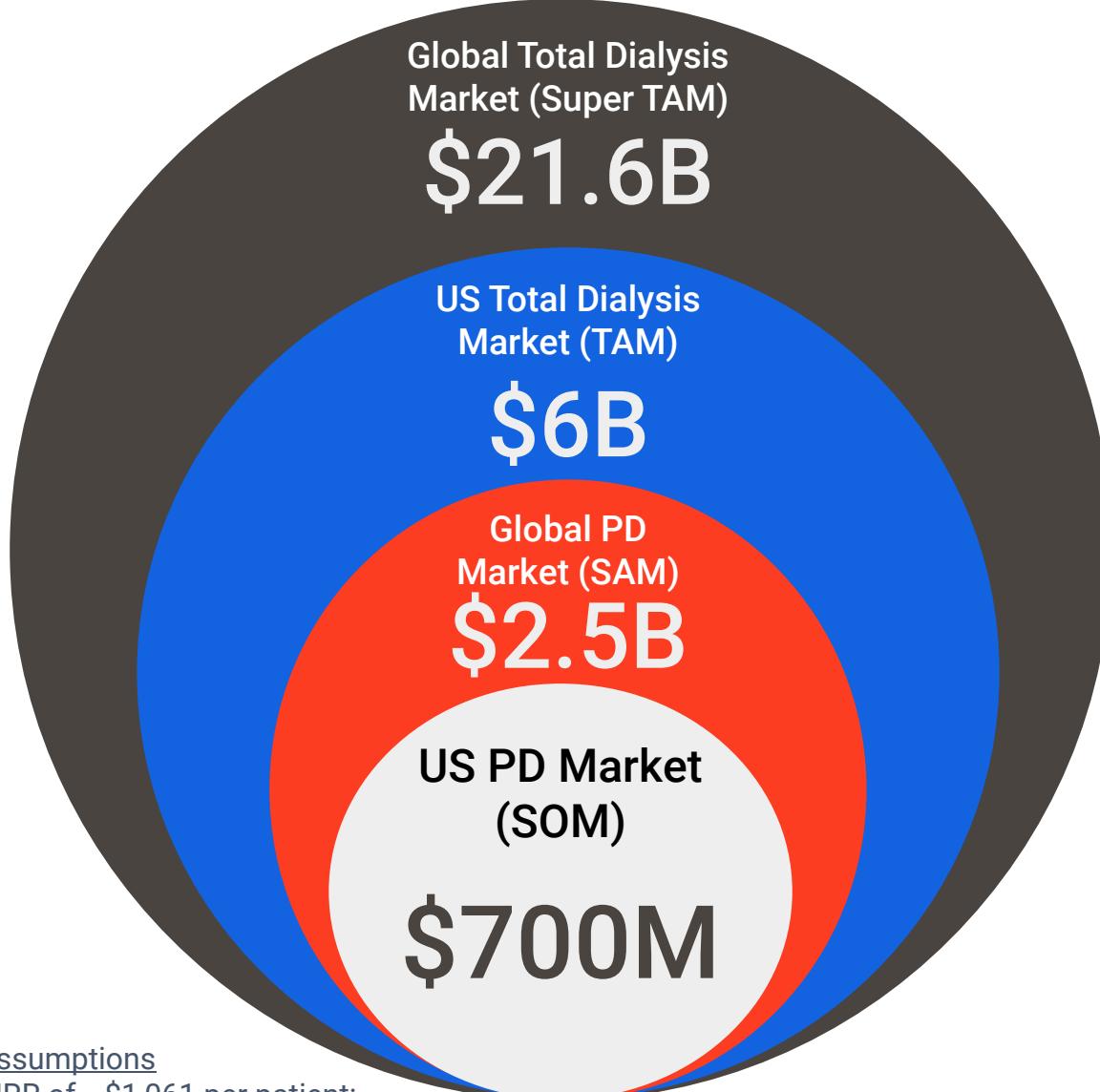


Thank You

DalySafe's mission is saving lives and creating a healthier future for patients everywhere

Contact us @ dialysafe@protonmail.com

MARKET SIZE

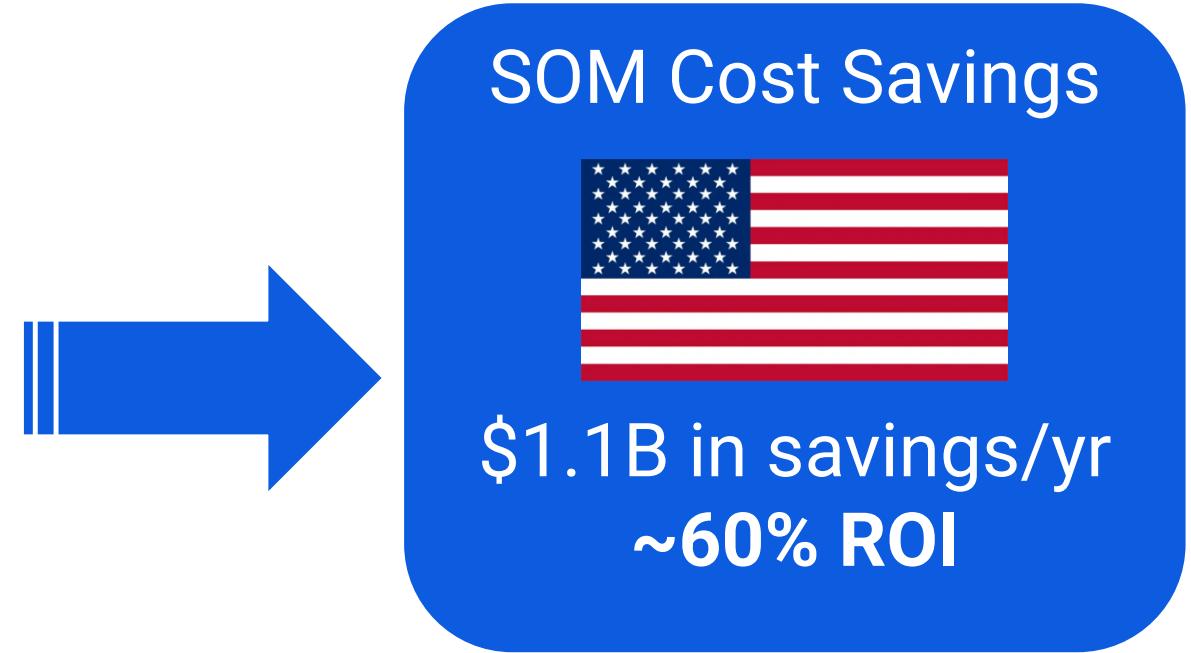
Assumptions

MRR of ~\$1,061 per patient:

5K Pediatric PD patients in US

55K Total PD patients in US (550K Total PD+HD)

200K Total PD patients worldwide (2M Total PD+HD)

Assumptions

Reduced infections saves \$300M/yr

Reduced hospitalizations saves \$88M/yr

Reduced PD failure saves \$52M/yr

Shortened hospital stays saves \$55M/yr

Increased PD adoption saves \$615M/yr



REVENUE MODEL

No upfront patient costs



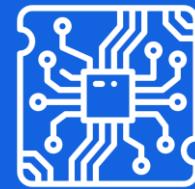
Medicare/Medicaid covers all dialysis costs:
Minimum of **\$1,061/patient MRR**

Automation Hardware



Insurance billing code A4913
(Miscellaneous dialysis supplies):
\$31/use (1 use/day)

Infection Sensor Hardware



Insurance billing code 99453 (initial
patient setup + training):
\$20 one-time fee

Remote Patient Monitoring (RPM)



Insurance billing codes 99454 (monthly report),
and 99457/99458 (physician interpretation):
\$62 per monthly report
\$49 per 20 min of phys. int.

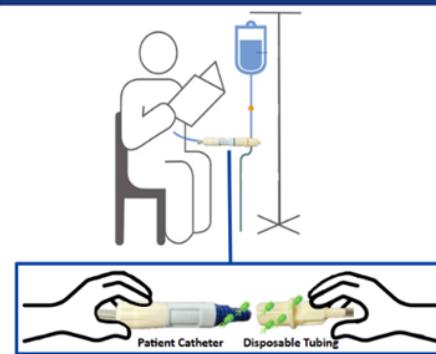
Automated Catheter Connection System and Infection Sensor for At-Home Dialysis Patients

Ibrahim Al-Akash¹, Marc De Guzman^{1,2}, Shereena Johnson¹, Leora Maksoud², Vedha Penmetcha²
¹Rice University Department of Bioengineering, ²Rice360 Institute for Global Health Technologies

Peritoneal Dialysis is Underutilized

- Convenient at-home treatment for end stage renal disease (ESRD), when kidneys can no longer filter blood
- Around 550,000 patients on dialysis in the US, but less than 7% use peritoneal dialysis
- Patient set up at-home: 8-13 sterile manual steps resulting in high contamination risk

Peritoneal Dialysis Infection Risk



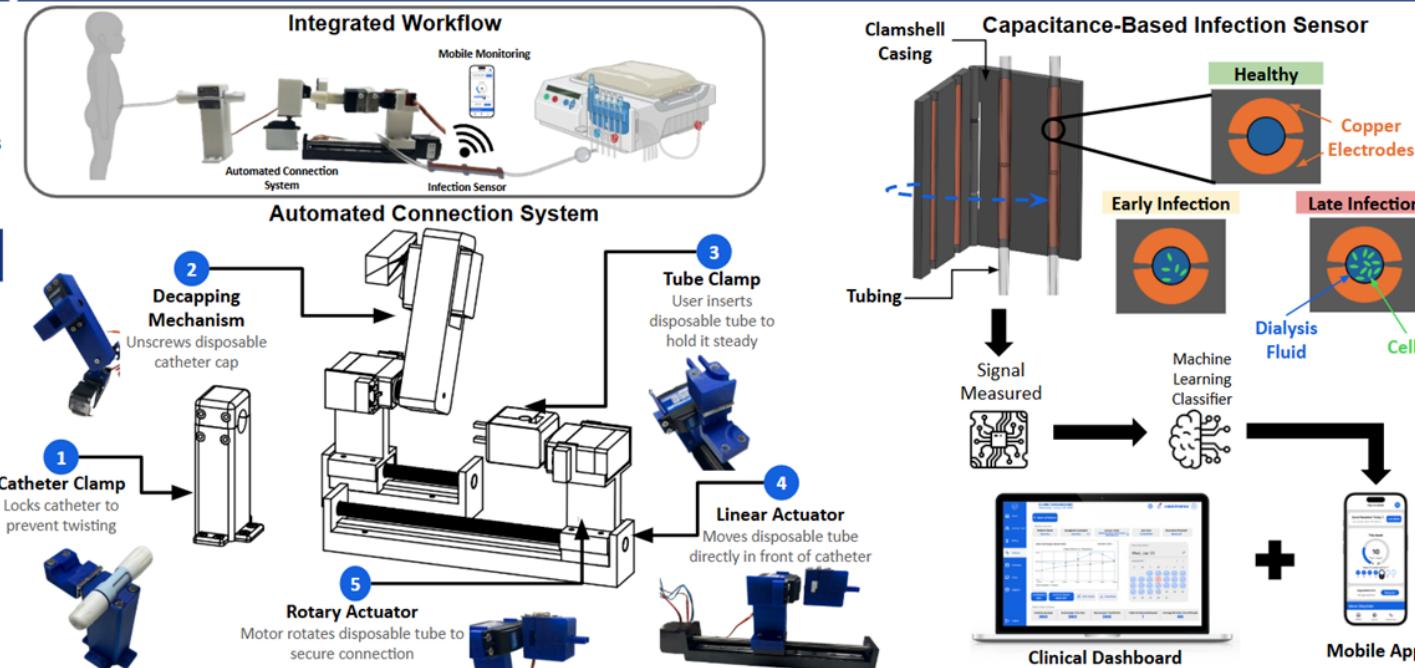
- Complex manual PD procedure leads to **burnout and fatigue** for caretakers
- 1 in 4** patients undergoing PD develop infections typically from **touch contamination**
- 2/3** of infections lead to hospitalization from lack of standardized infection detection method

Design Objectives

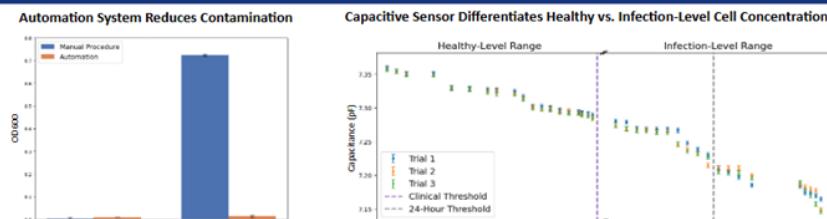
Develop a solution for making at-home PD exchanges for ESRD patients easier, cleaner, and safer by:

- Automating tube connections
- Reducing risk of contamination
- Detecting potential infections

DalySafe Automation and Infection Detection System



Evaluation of DalySafe System



ML Model	Accuracy	Sensitivity	Specificity	F1-Score
Random Forest	98.8%	100%	97.6%	98.8%
Support Vector Machine (RBF Kernel)	98.3%	96.7%	100%	98.3%
Support Vector Machine (Poly Kernel)	96.7%	100%	93.3%	96.8%
Support Vector Machine (Linear Kernel)	81.7%	63.3%	100%	77.6%

Description	Clinical Dashboard (n=3)	Mobile App (n=7)
Ease of Navigation	4.67	5
Visual Design and Readability	4.67	5
Data Visualization	4.33	5
Mean UDS Score (1-5)	4.56	5

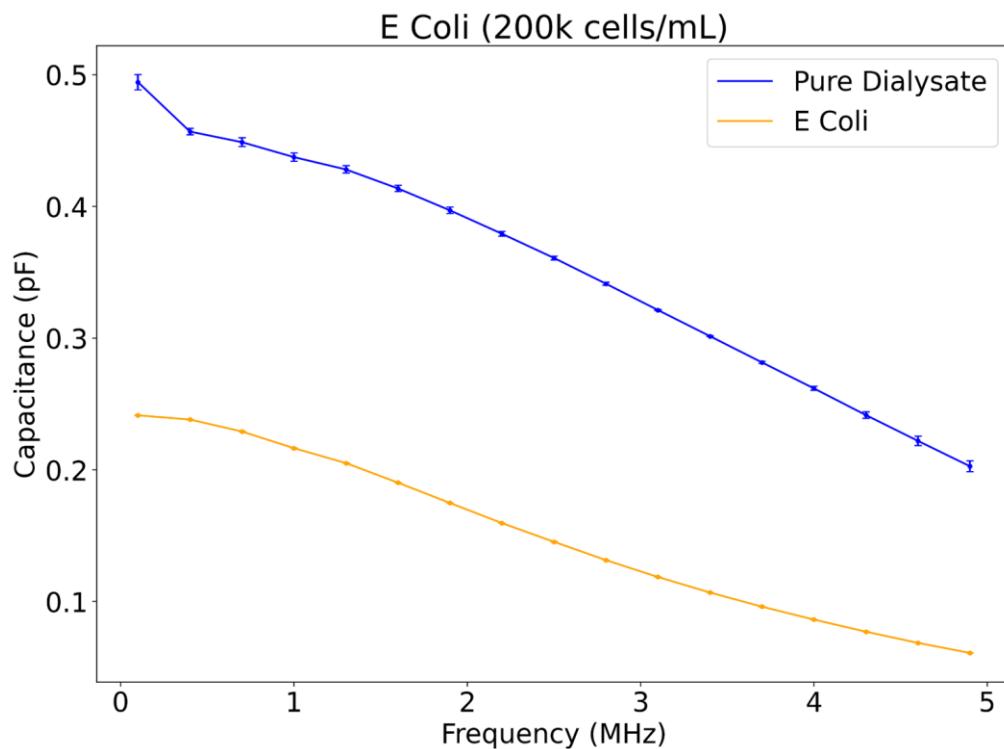
Advantages of DalySafe

- Reduces bacteria concentration by **99%** compared to touch contaminated samples
- Reduces setup process to **3-4 steps** from **8-13 steps**
- Sensor is **>33X more sensitive than clinical threshold**
- Detects infection-level cell concentrations **within 24 hours of contamination onset**
- System is low-cost to manufacture at **\$250**

Acknowledgements

We thank our sponsors Dr. Joseph and Dr. Thadani; our instructors Dr. Abidi, Dr. Woods, Dr. Ghosh, and Dr. Lee; and our design mentor Sahana Ramaswamy for their assistance and guidance in this project. We also thank the OEDK staff for their resources and prototyping space.

SENSOR SENSITIVITY EXPERIMENTAL DATA

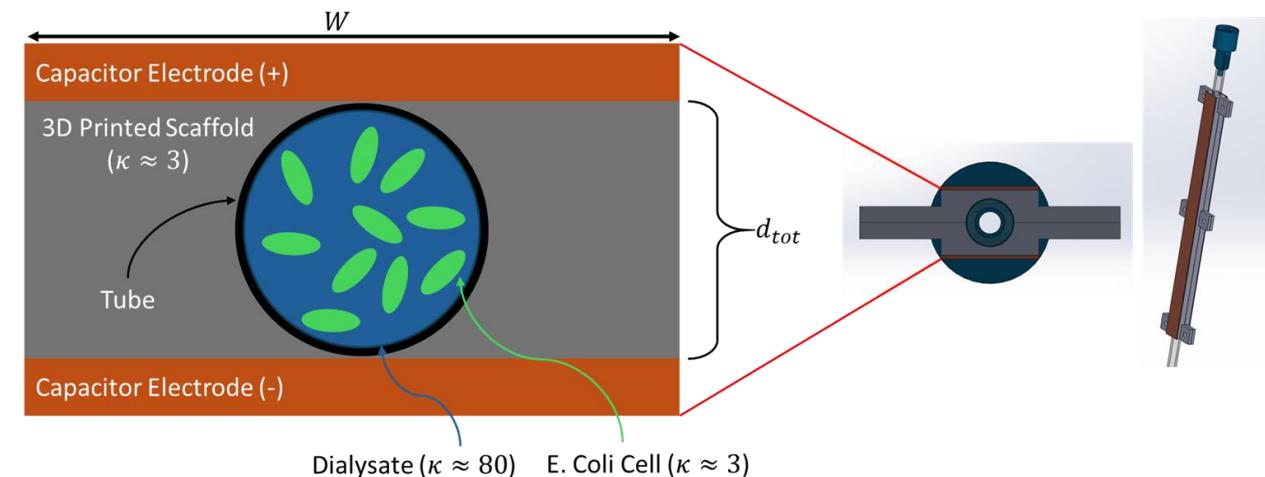


Prototype Sensor E. coli Experiment Data

$$\frac{1}{C_{eq}} = \frac{\# \text{ of Cells}}{\varepsilon_0 \kappa_{cell} A_{electrode}} + \frac{\text{Cell Size}}{\varepsilon_0 \kappa_{fluid} A_{electrode}} + \sum_i \frac{f_i(d_{tot} - n_{cells} \tau_{cell})}{\varepsilon_0 \kappa_{fluid} A_{electrode}}$$

of Cells
Cell Size
Space Occupied by Fluid

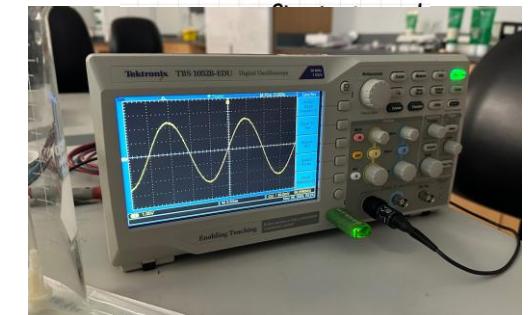
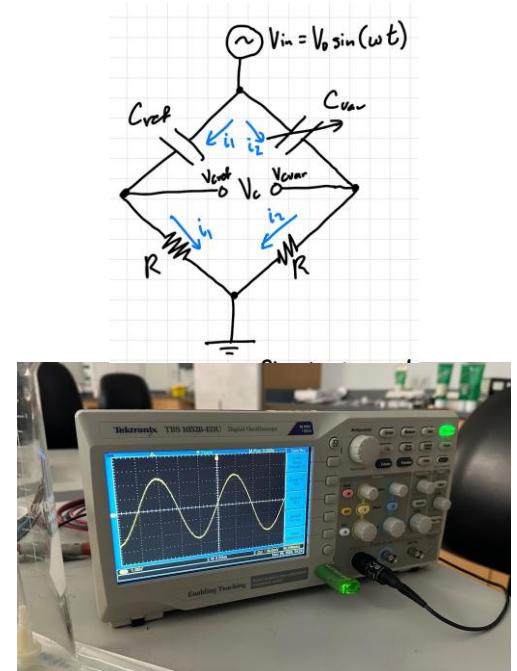
Capacitance Derivation (E. coli lowers capacitance)



Sensor Cross-Section



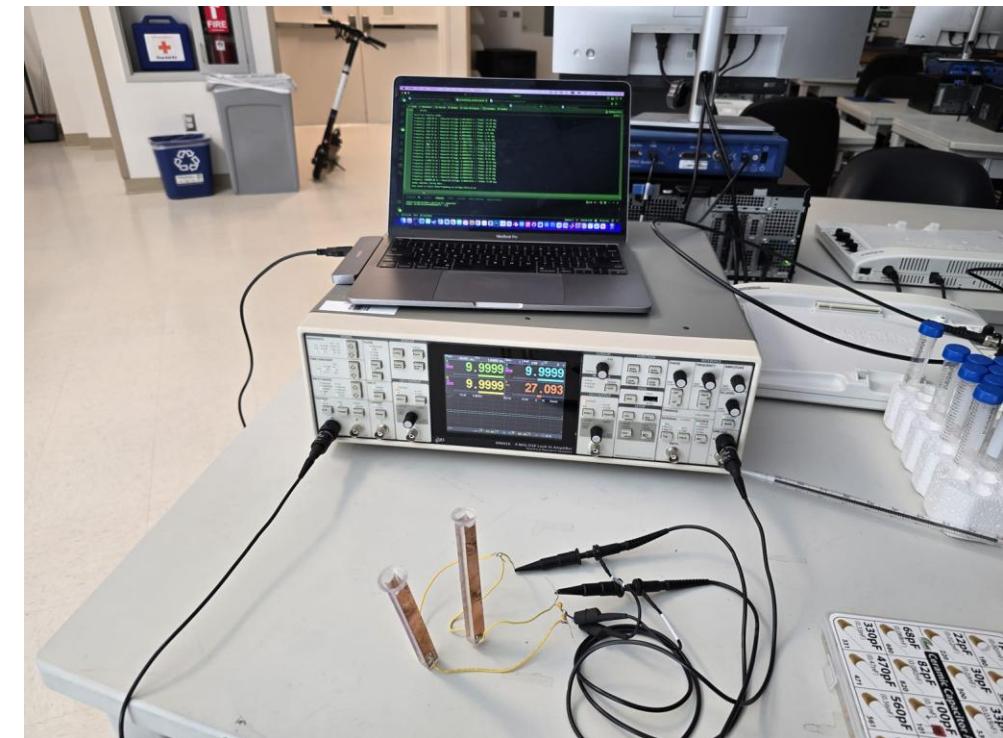
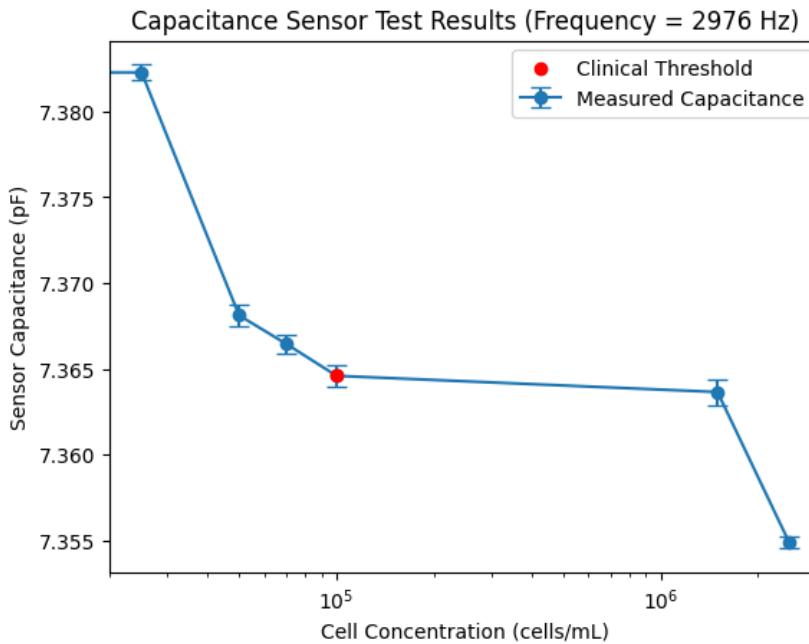
Sensor Prototype



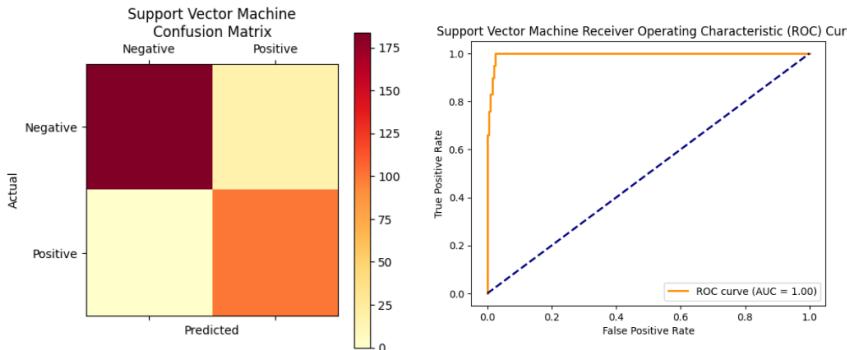
Sensor Voltage Output



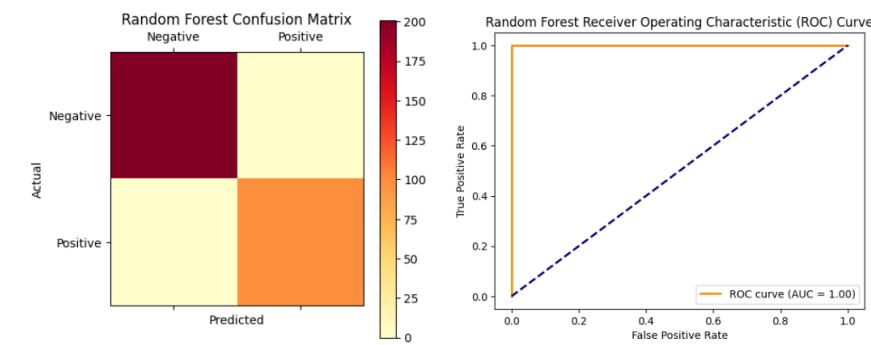
SENSOR ACCURACY EXPERIMENTAL DATA



Prototype Sensor Mammalian Cell Experiment Data



ML Model V1 Data - Support Vector Machine



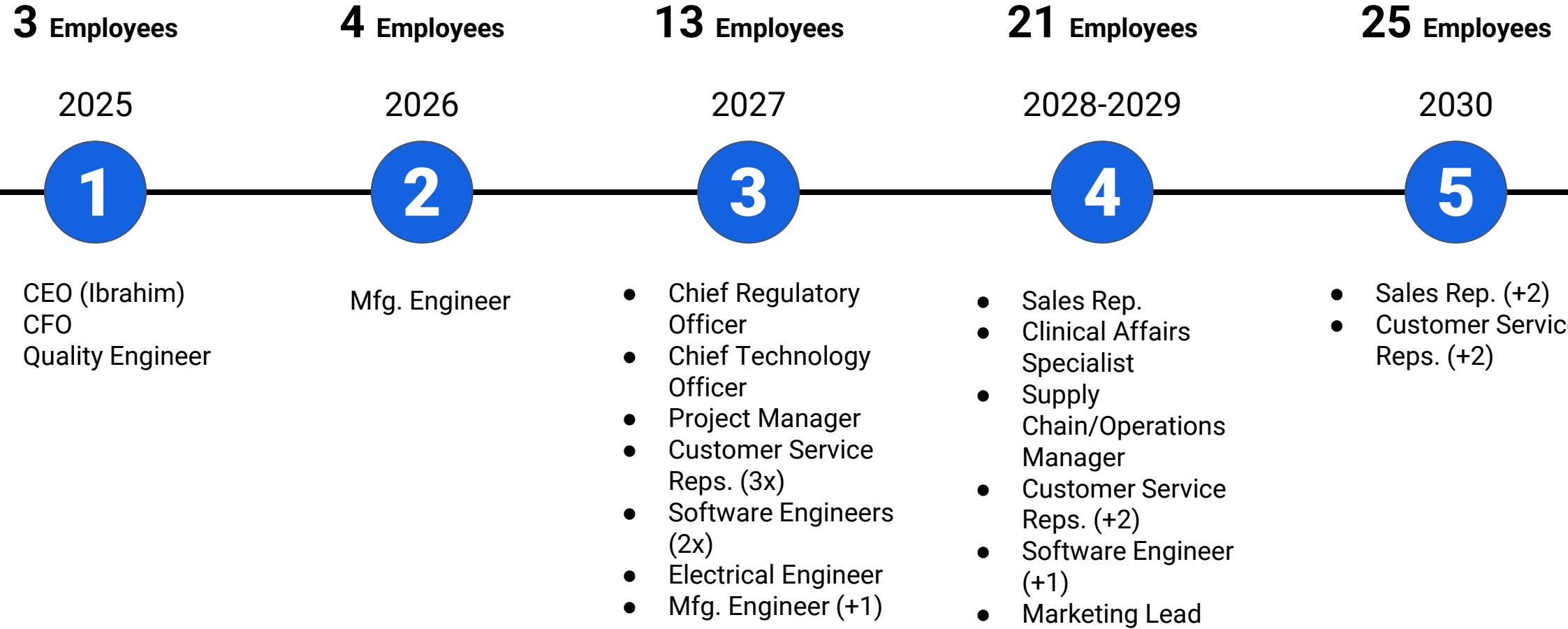
ML Model V2 Data - Random Forest



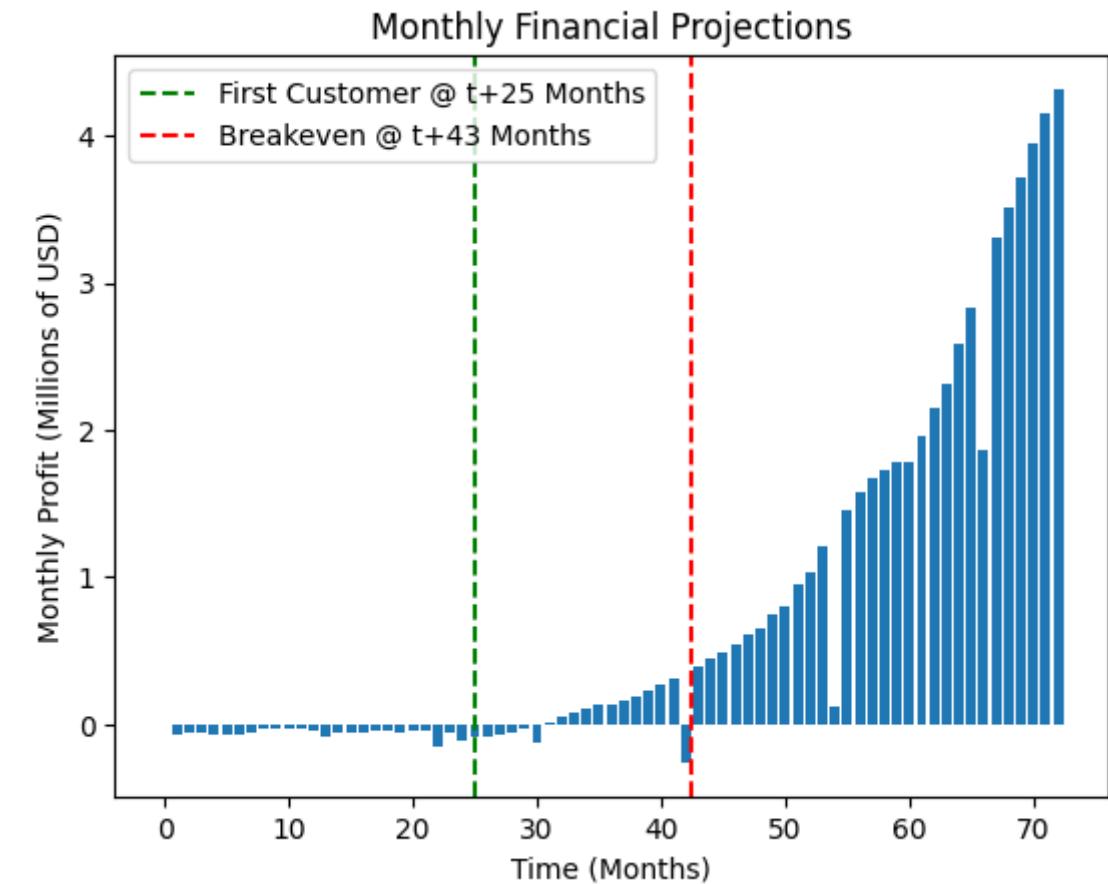
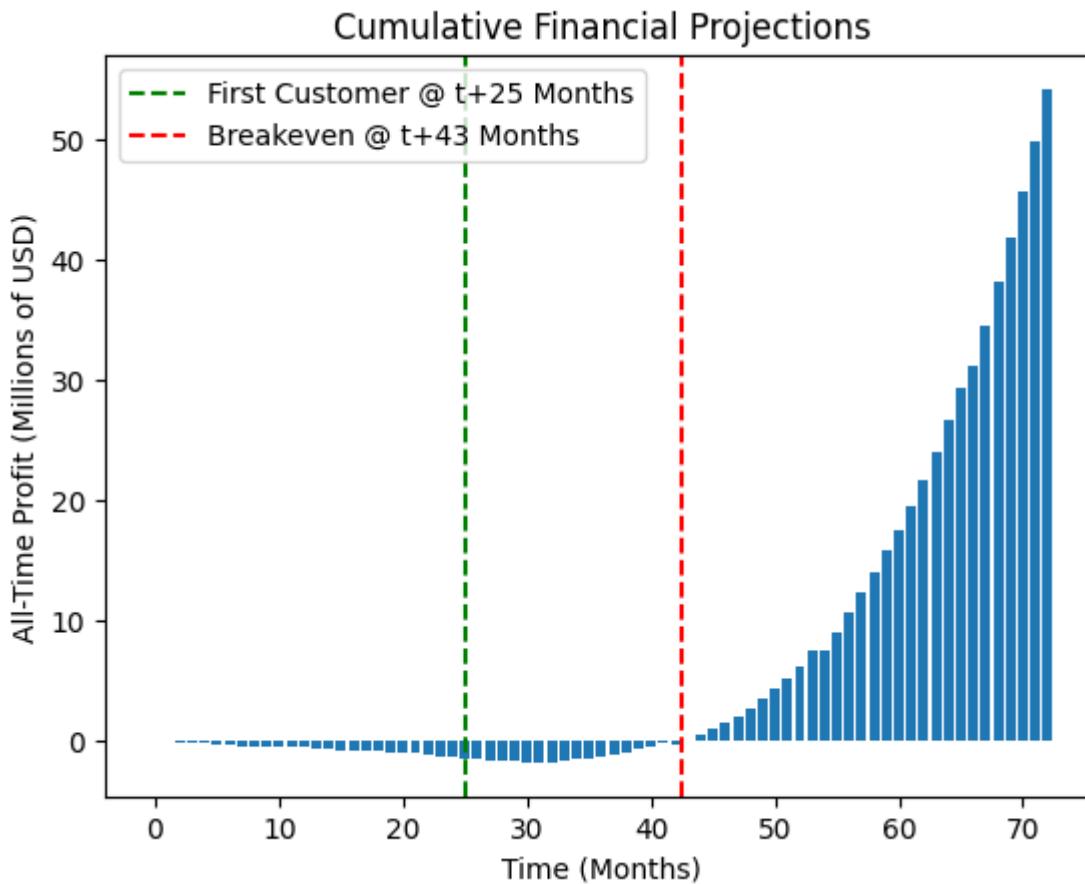
SOFTWARE TEST RESULTS

Description	Clinical Dashboard (n=3)	Mobile App (n=7)
Ease of Navigation	4.67	5
Visual Design and Readability	4.67	5
Data Visualization	4.33	5
Mean UDS Score (1-5)	4.56	5

Head Count



FINANCIAL PROJECTIONS



Year	Revenues	Expenditures	COGS	Profits	Gross Margin	Operating Margin
1	\$0	\$609,150	\$0	-\$609,150	N/A	N/A
2	\$0	\$774,184	\$0	-\$774,184	N/A	N/A
3	\$1,527,840	\$1,474,840	\$34,001	\$53,000	97.77%	3.47%
4	\$6,779,790	\$2,747,900	\$102,003	\$4,031,890	98.50%	59.47%
5	\$18,540,975	\$3,698,650	\$238,007	\$14,842,325	98.72%	80.05%
6	\$41,219,850	\$4,589,900	\$544,016	\$36,629,950	98.68%	88.86%

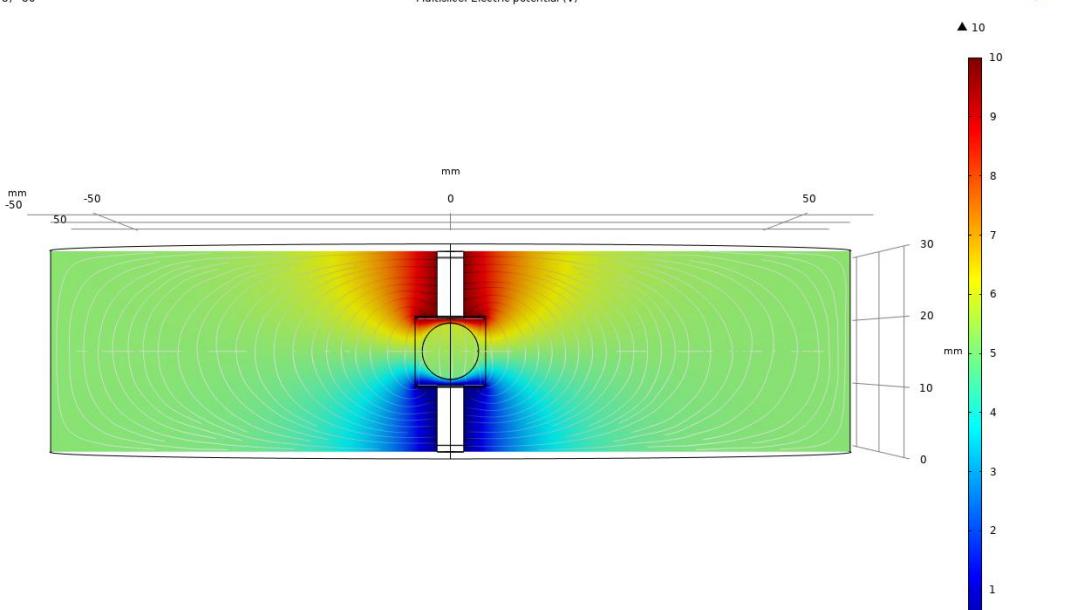


SENSOR SIMULATION

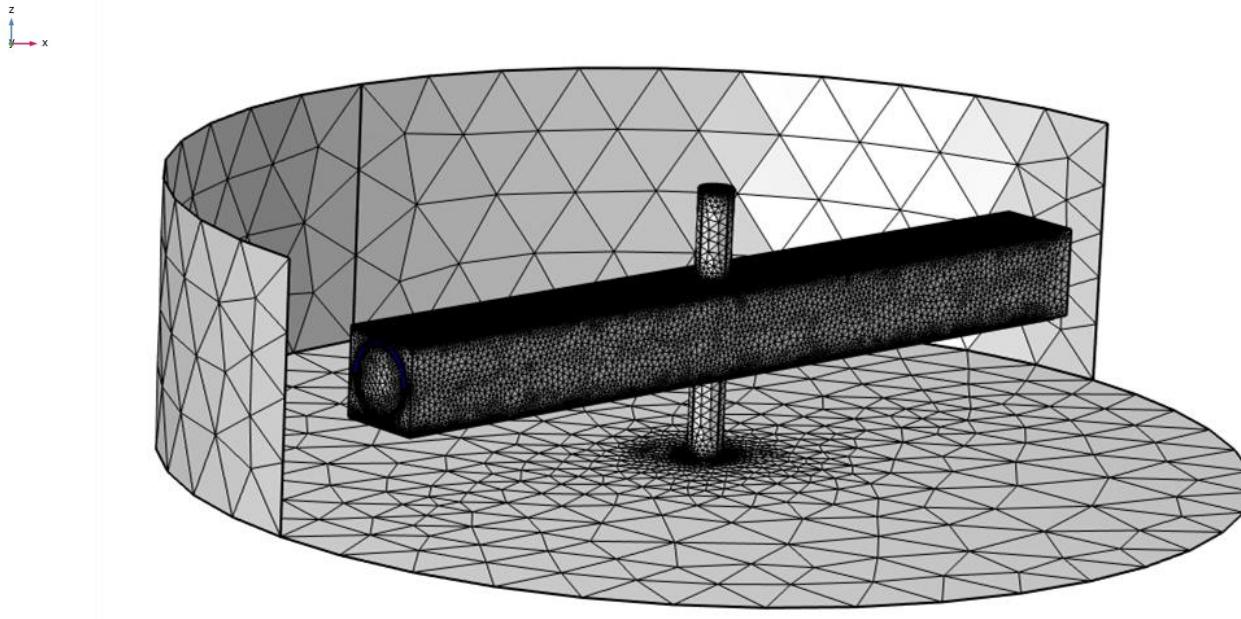
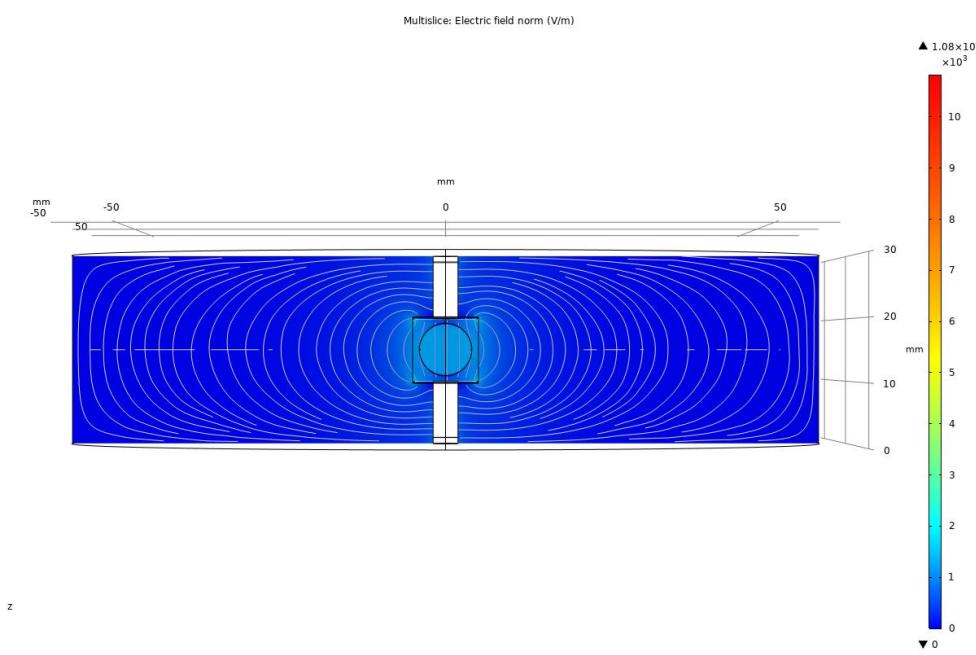
DialySafe

eFluid(78)=80

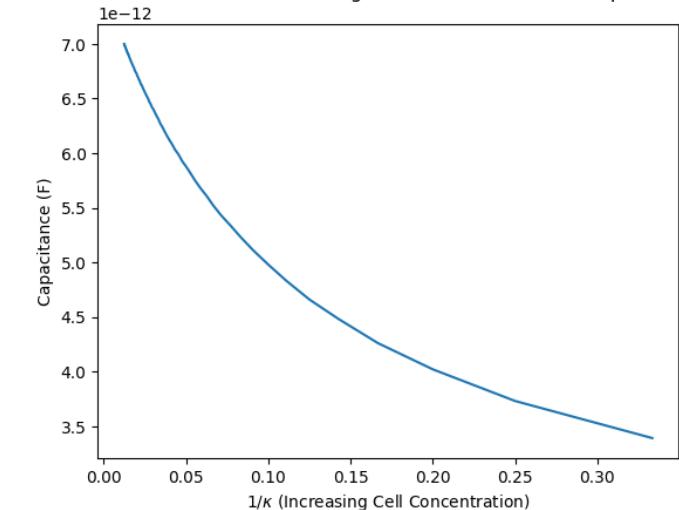
Multislice: Electric potential (V)



Multislice: Electric field norm (V/m)

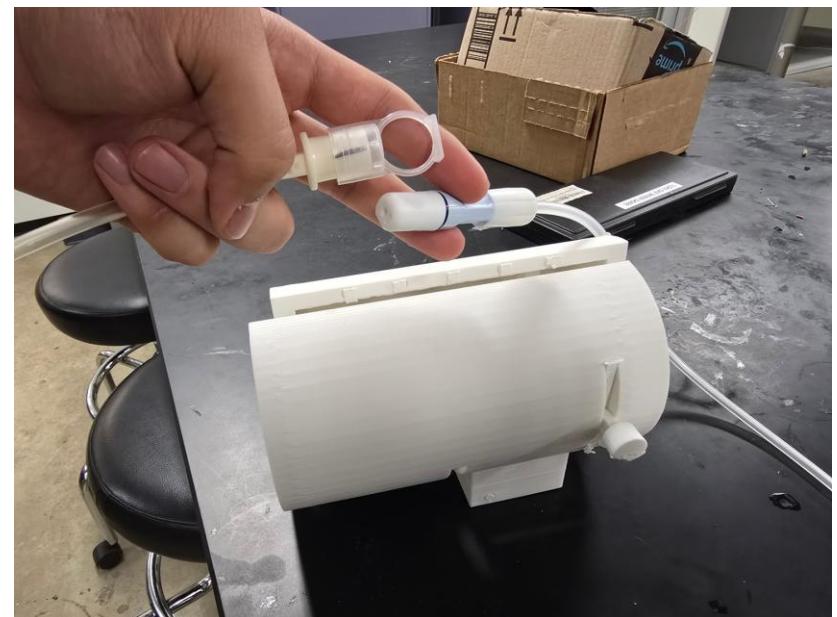
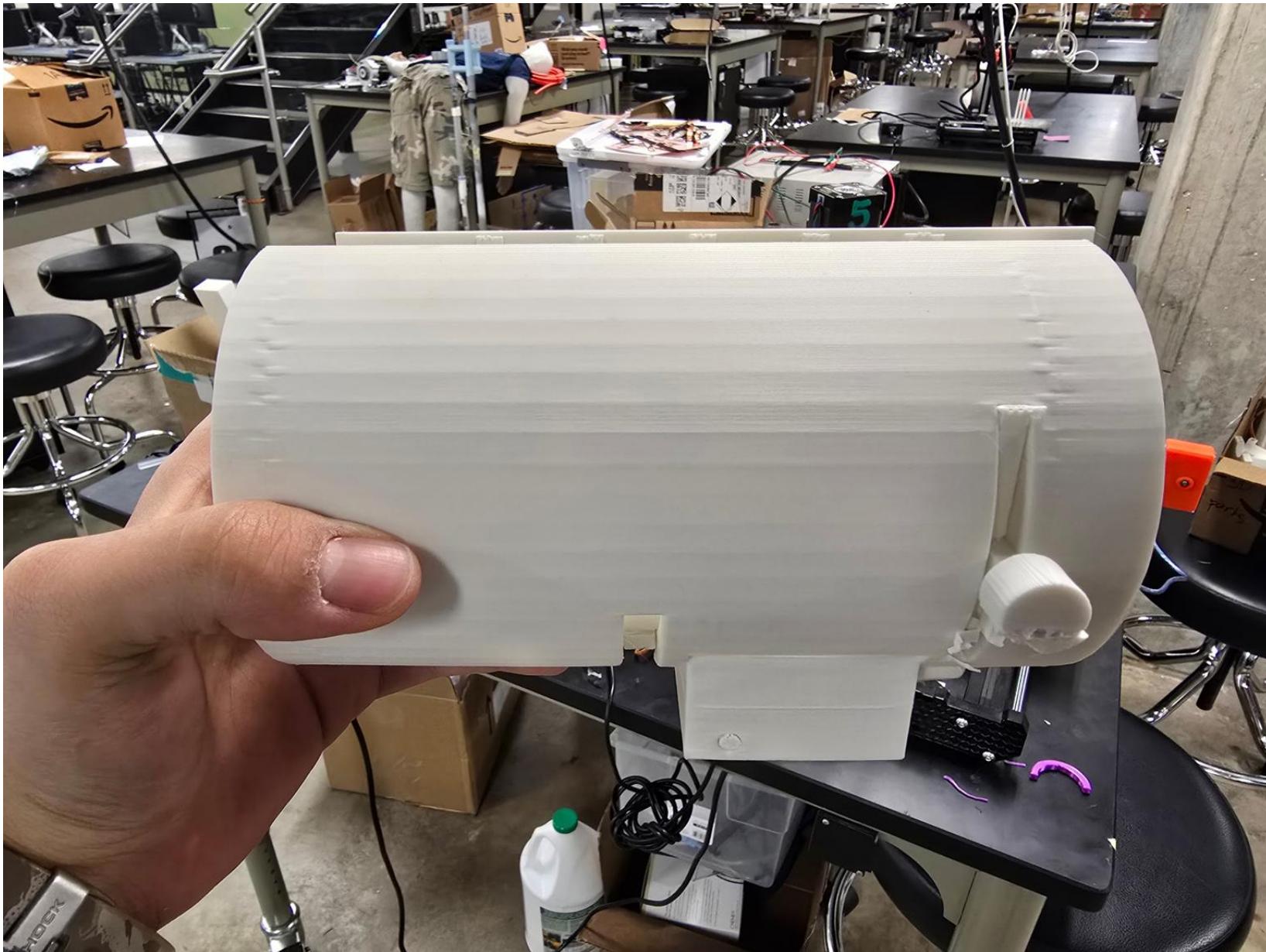


Simulated Effect of Increasing Cell Concentration on Capacitance



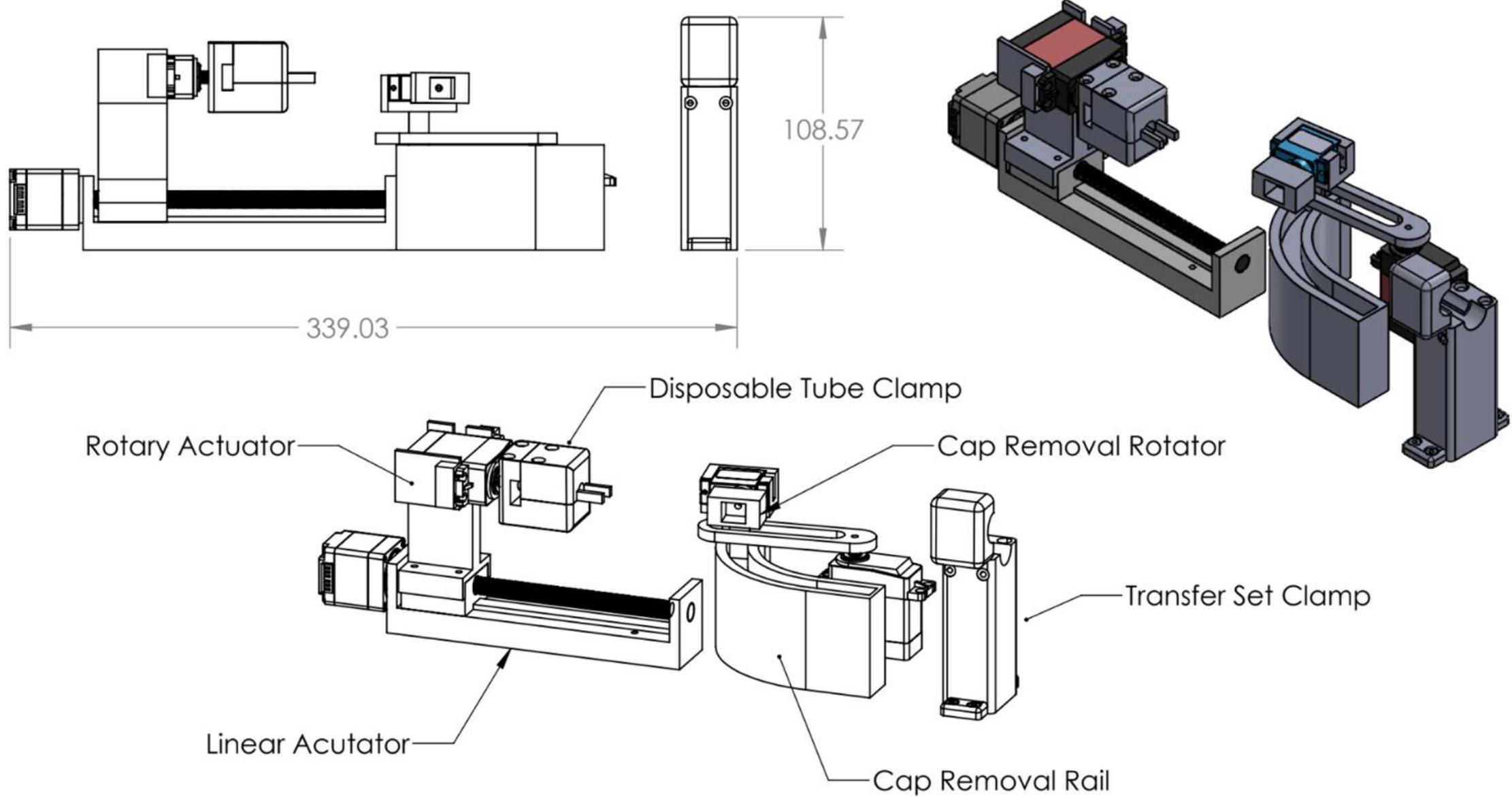


MECHANICAL DESIGN PROTOTYPE



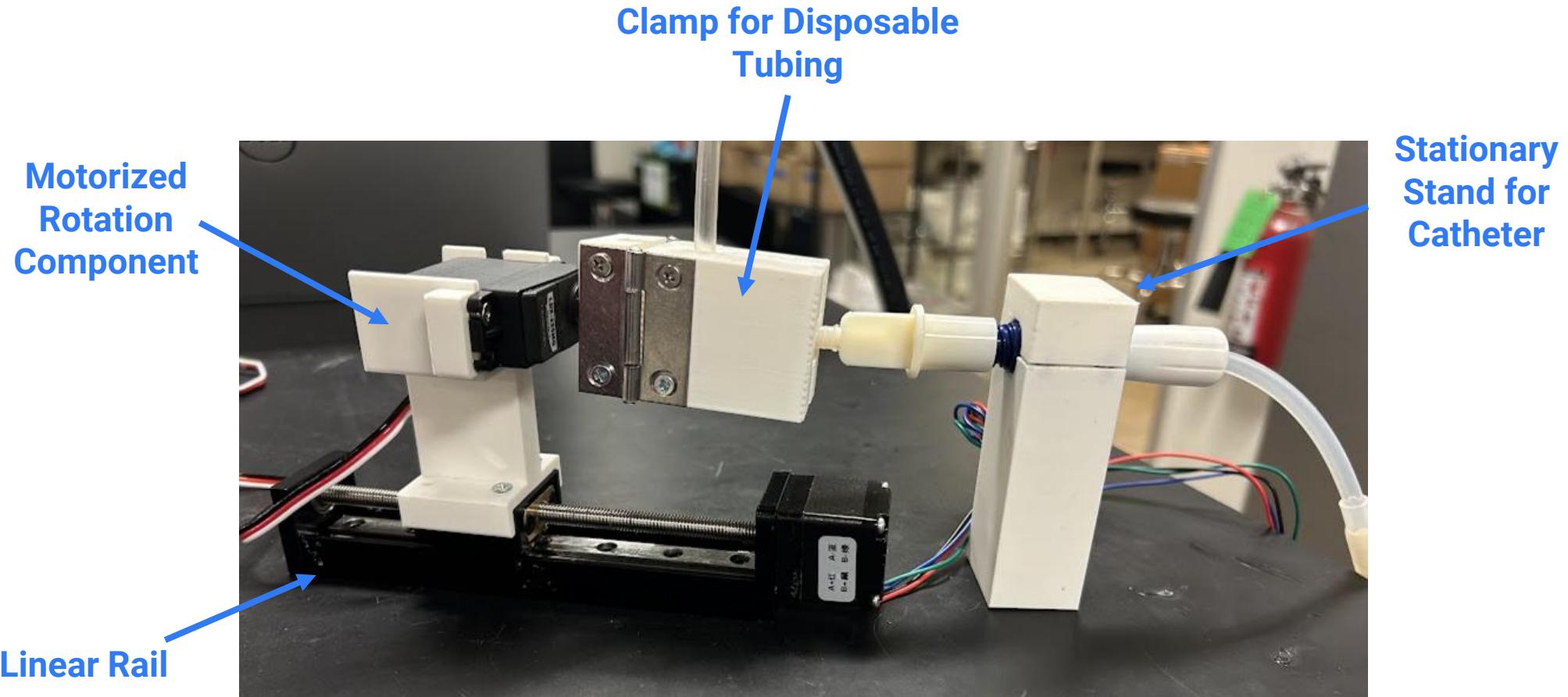


MOTORIZED AUTOMATED DESIGN PROTOTYPE (IN PROGRESS)

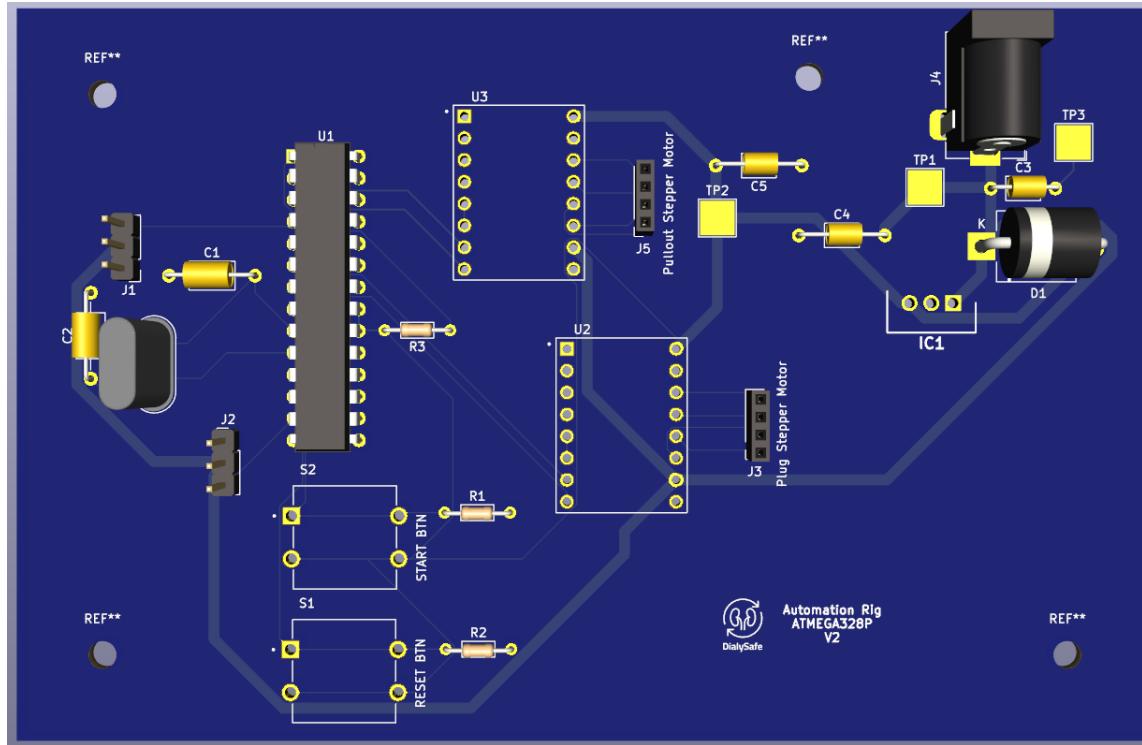




MOTORIZED AUTOMATED DESIGN PROTOTYPE (IN PROGRESS)



AUTOMATION



SENSOR

