

Attentiv Medical

Kevin Ta
Jessica Bo
Gordon Yeh
Rio Nishida



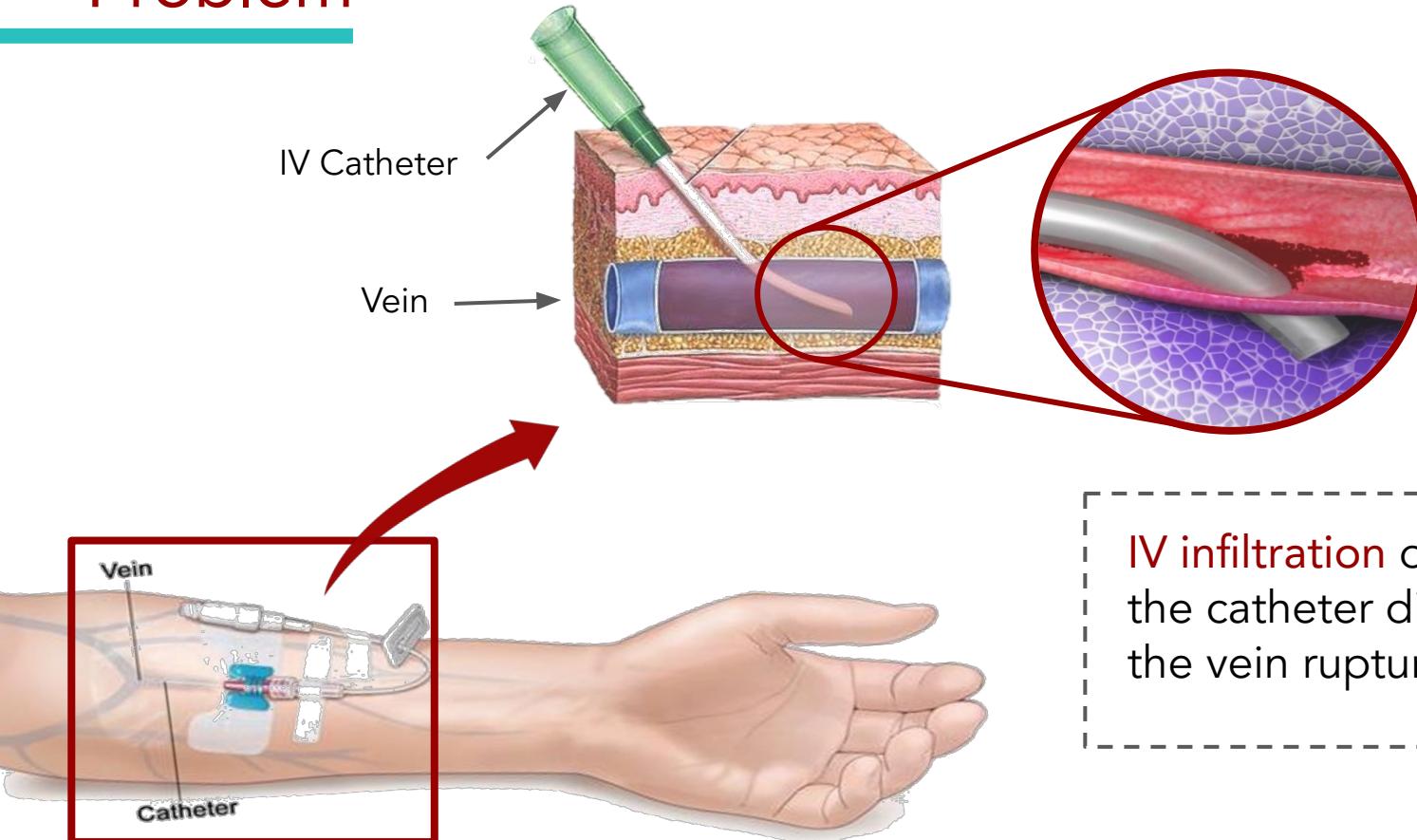
Baby Benny in the Newborn Intensive Care Unit



Baby Benny in the Newborn Intensive Care Unit



Problem



IV Infiltration

Consequences:

Blisters and necrosis (tissue death) that requires injections, surgery, and amputation



\$50,000 treatment costs/patient



\$500K - \$2.25M payout/lawsuit



70% of NICU babies

23% of adult patients

4-6% result in serious injuries

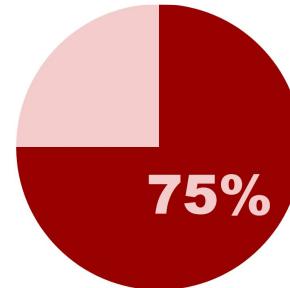
Validation



40 expert interviews

46 clinician surveys

2 interested NICUs



say infiltration needs to be solved

"The infiltration may not be immediately apparent or missed on assessment"

"If an IV gets infiltrated it can cause serious harm to the patient and loss of medication and time."



Infusion ongoing stopped

Infusion Condition

NORMAL

Patient Profile

Risk **High**

Medication **Dopamine**

Solution

Attentiv
Catheter



Monitor
Module



Transmitter
Module



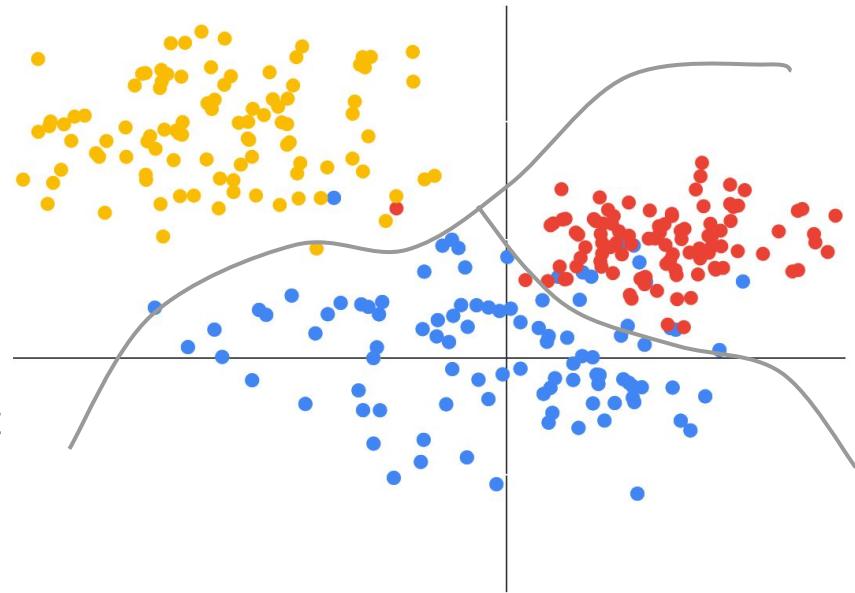
Leveraging AI

Objective: Use a *single* bioelectric sensor to infer blood vessel condition

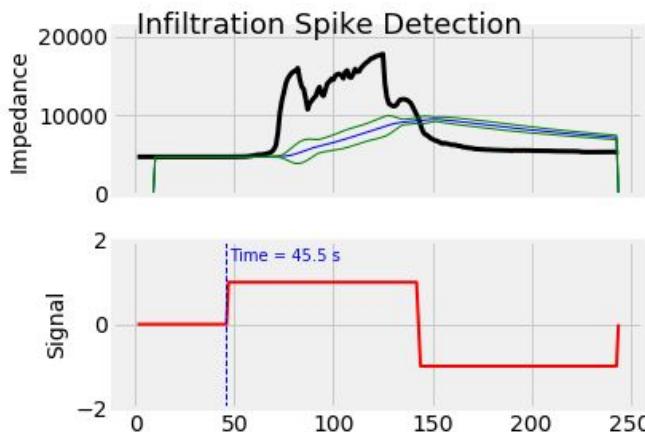
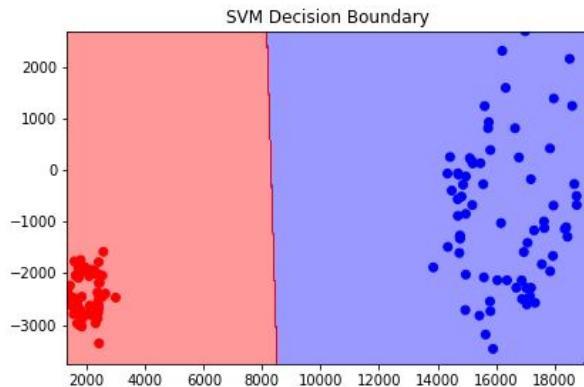
Why Use AI: In-vivo conditions dynamically varies with:

- Temperature
- Blood flow rate
- Dissolved nutrients
- Biological composition
- Applied sensor frequency
- ... and other patient specific conditions (disease, hydration)

AI & Machine Learning allows us to account for all the above factors in ways traditional classifications can't control.



Classification Algorithms



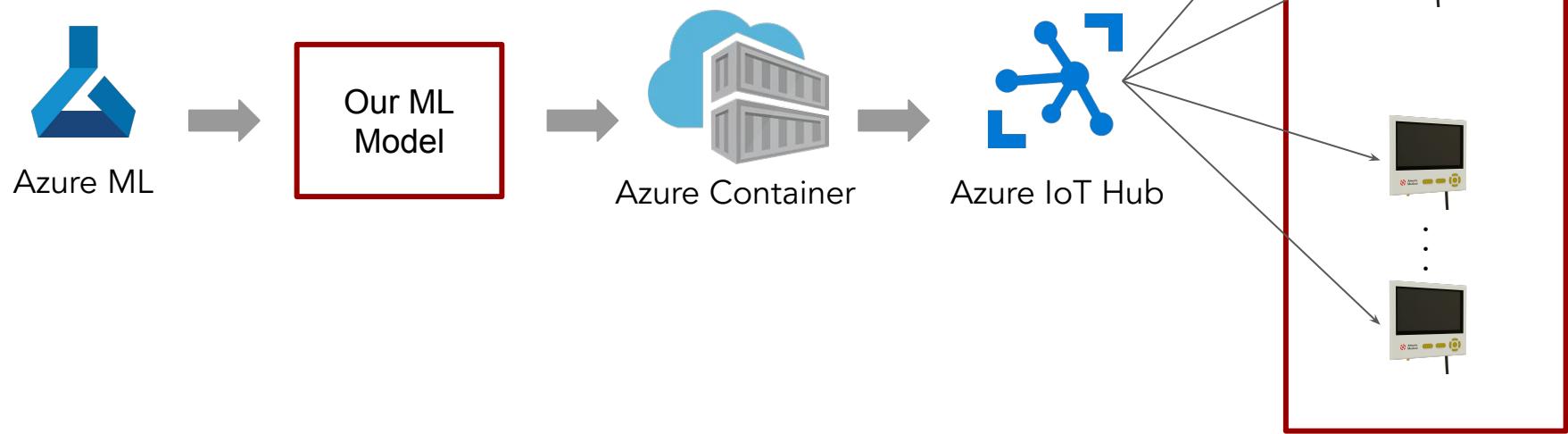
Classification:

- ✓ Achieved blood-fat differentiation on animal tissues with 100% accuracy using SVM model

Peak detection:

- ✓ Estimated time-of-infiltration from phantom testing using peak detection algorithm

Model Pipeline



DEMO

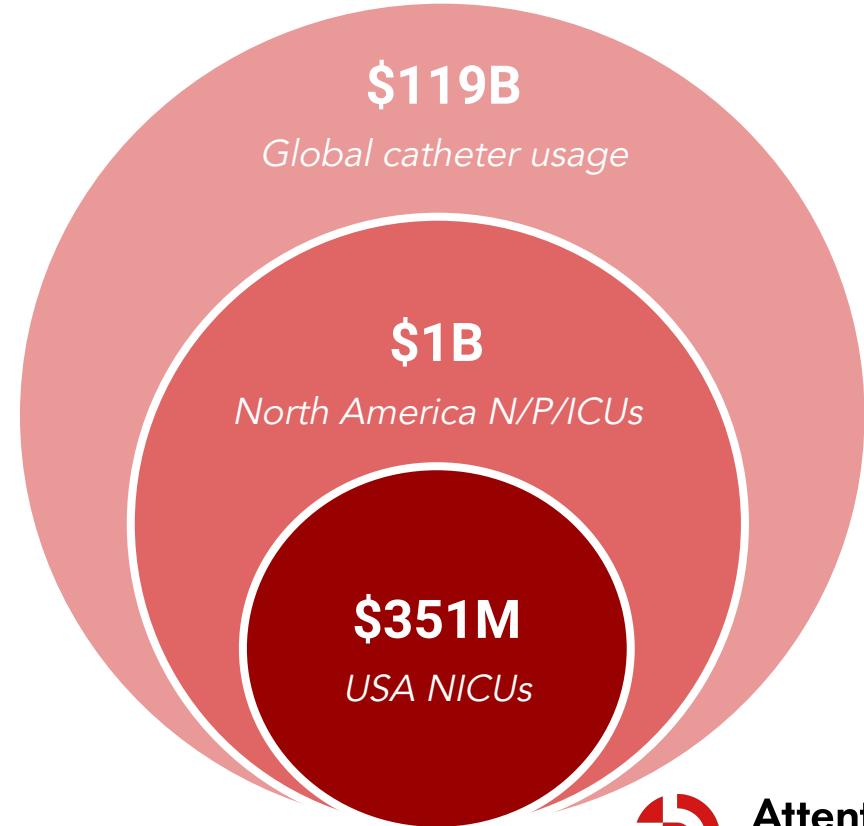
Market Size

IV market growing at **6.5%** annually

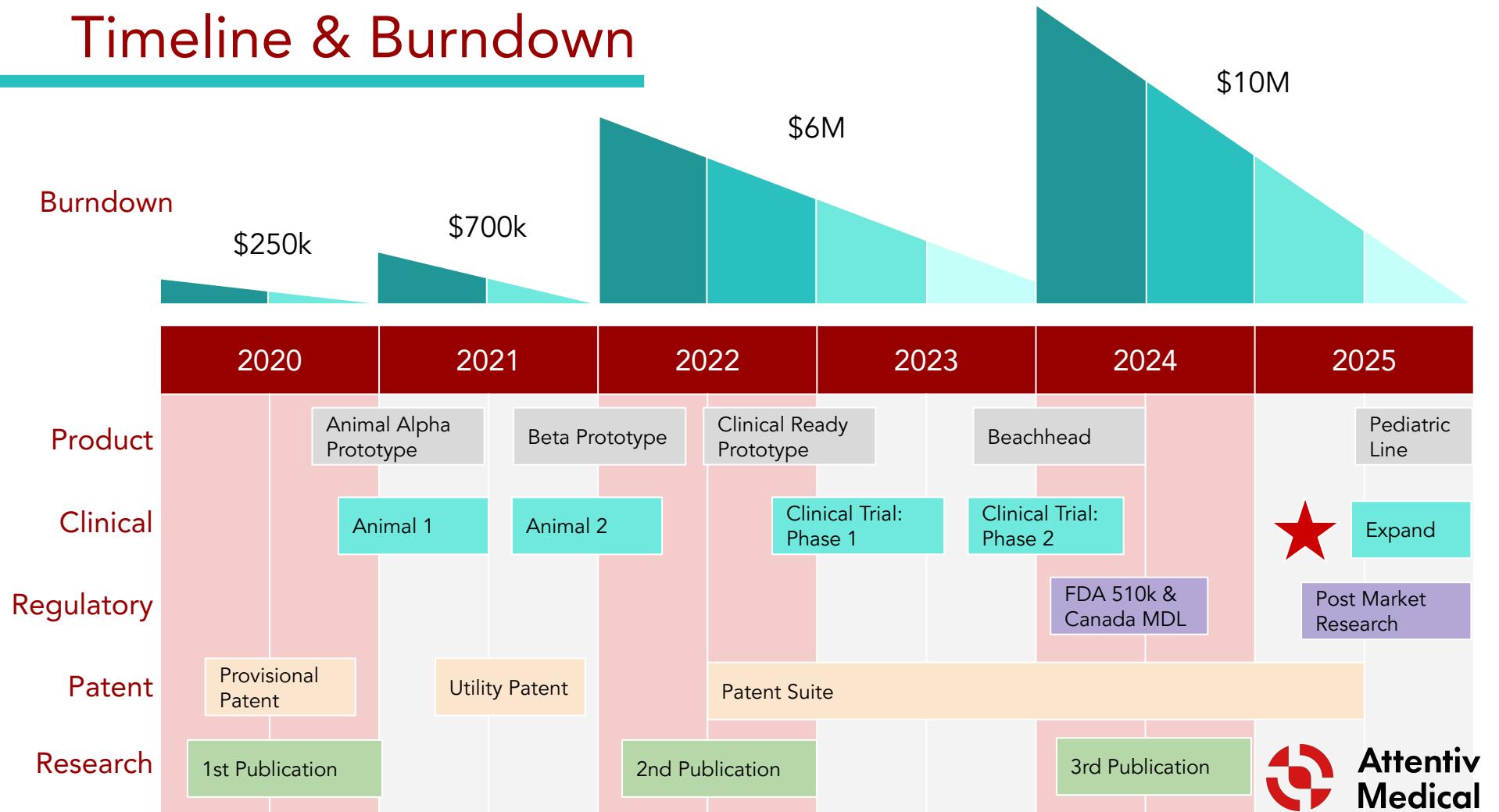
Average hospital spends **\$2.5M USD** per year on IV equipment

Infiltration in the NICU can cost a hospital **~\$2M USD** per year

Based on **\$100** per catheter and **\$1000** equipment rental:



Timeline & Burndown



Team



Kevin Ta

Technical Lead



Rio Nishida

Hardware Developer



Jessica Bo

Research Lead



Gordon Yeh

Software Developer



Manon Ranger

Clinical Advisor (UBC)



Megan Bolton

Clinical Advisor (BCCH)

Thank you!



Questions & Answers

What is our business model canvas?

What is our revenue model?

What does our system design look like?

What is the science behind our sensor?

What prototyping have we done?

Tissue Classification, Signal Detection, Catheter Fabrication, Video

How did we perform our tests on biological models and phantom models?

What are the different types of catheter treatments that can result in infiltration?

What is the economic impact of infiltration?

How did we price the Attentiv catheter?

How did we calculate the market size?

How does medical device procurement work (USA)?

How does medical device procurement work (Canada)?

What is our growth plan?

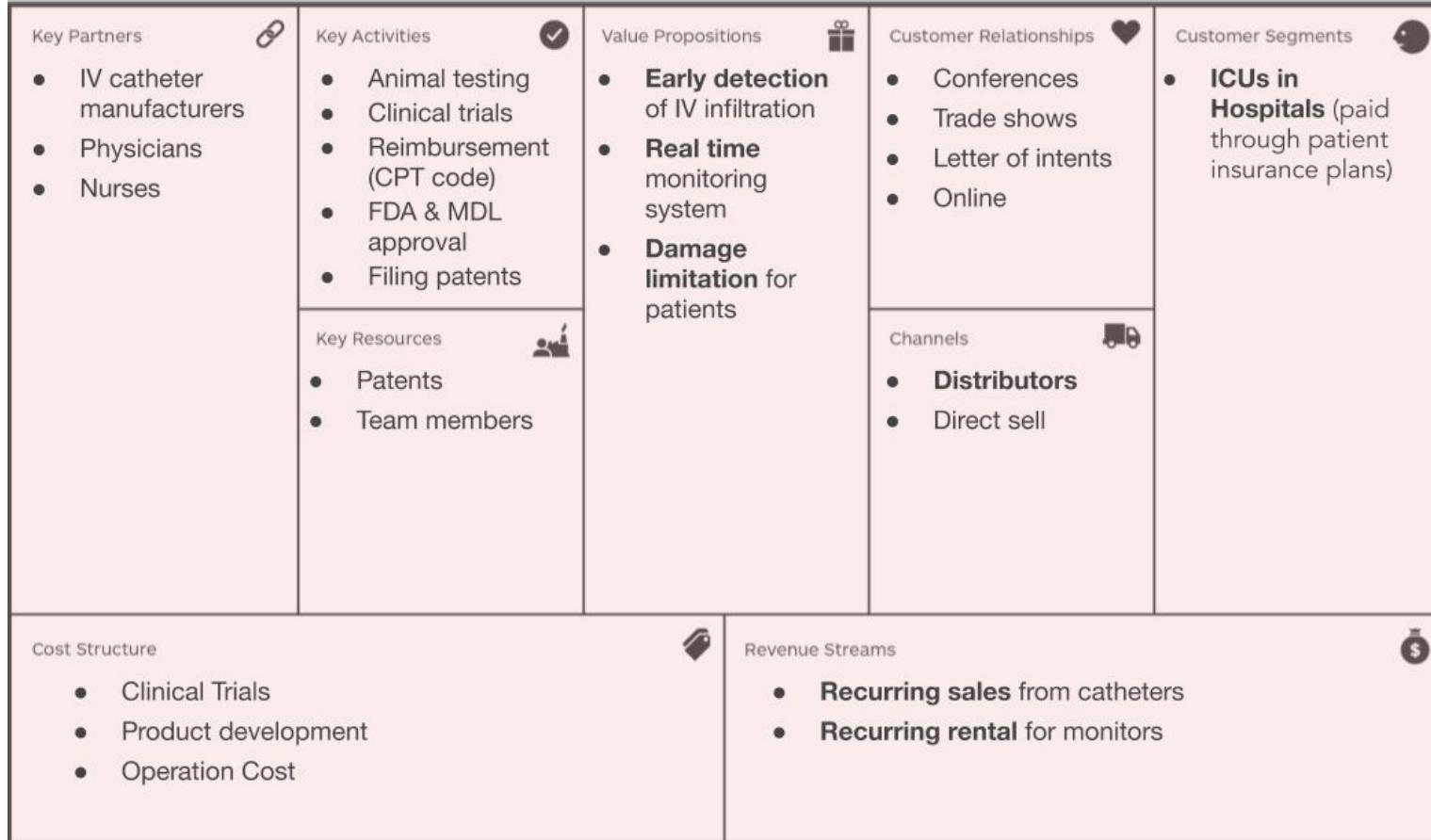
What is our patent landscape overview?

What is our IP strategy?

What does our competitive landscape look like?

What is the regulatory environment?

Business Model Canvas



Revenue Model

Catheter Sales

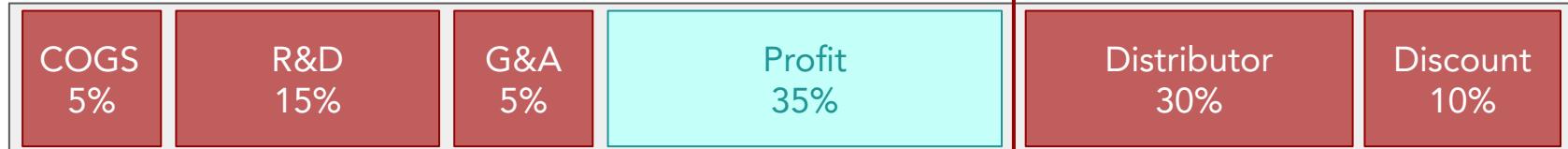


per catheter

Monitor + Transmitter Subscription

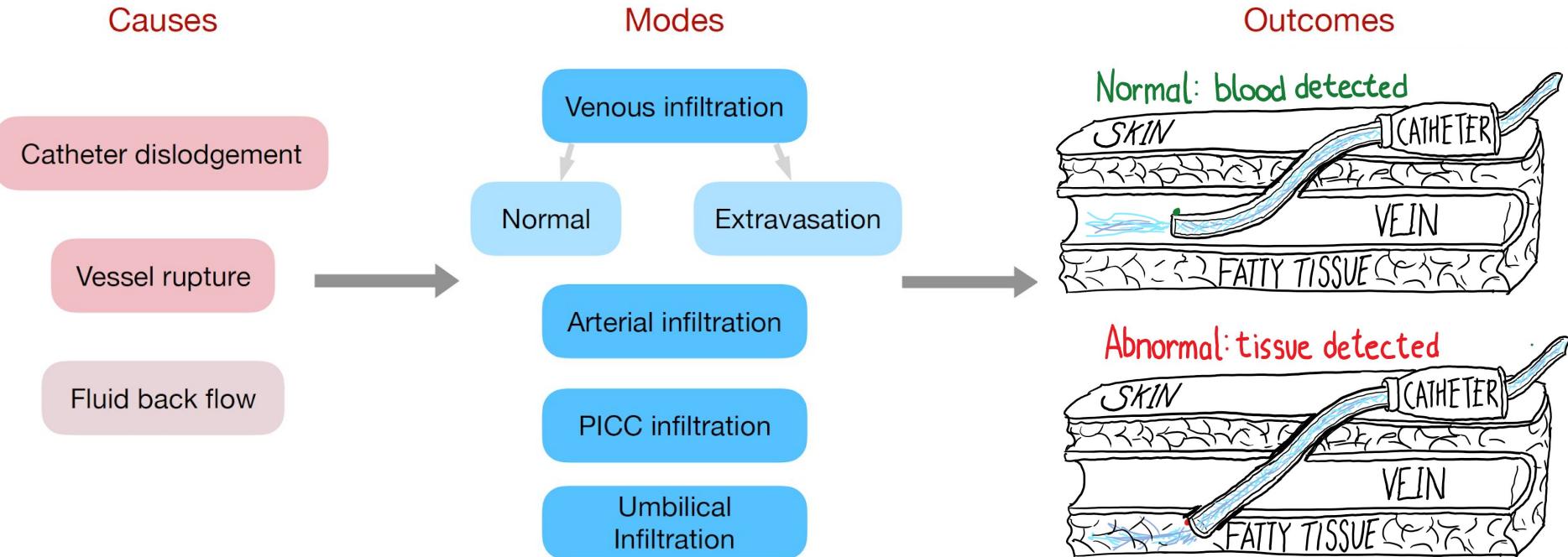


per bed per year



* assuming we are going to market

Types of Infiltration



Bioimpedance

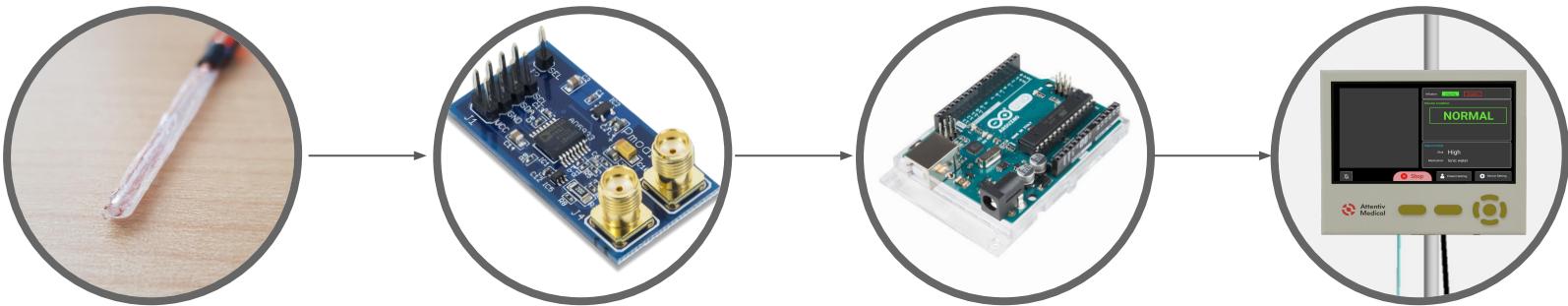
Overview:

- Veins are surrounded by fatty connective tissue, which has a much higher bioimpedance value than blood inside the vein

$$Y = \frac{1}{Z} = \sum_{i=1}^n [(\sigma_{ci} + \sigma_{di}) + jw(\varepsilon_{ci} + \varepsilon_{di})] V \frac{A}{d}$$

- When infiltration occurs, the sensor will read a spike in impedance value as the catheter enters the tissue, but the signal's transient response will decrease to the original value
- Our algorithm is able to discriminate between tissue and blood and also detect the signal spike when infiltration occurs

Design Overview



Catheter
[Sensor]

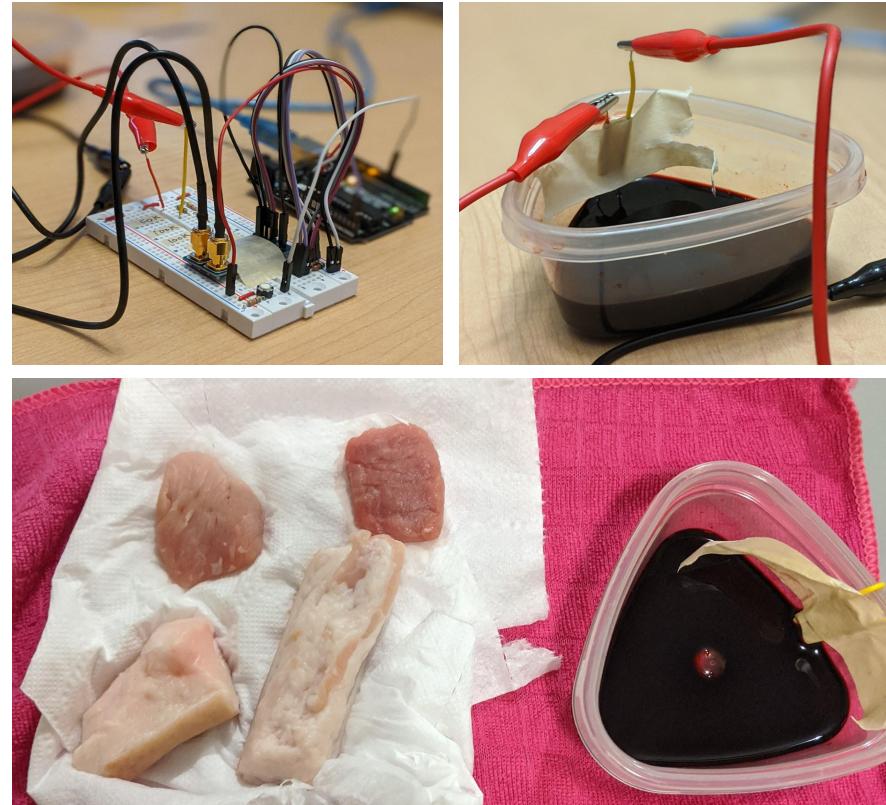
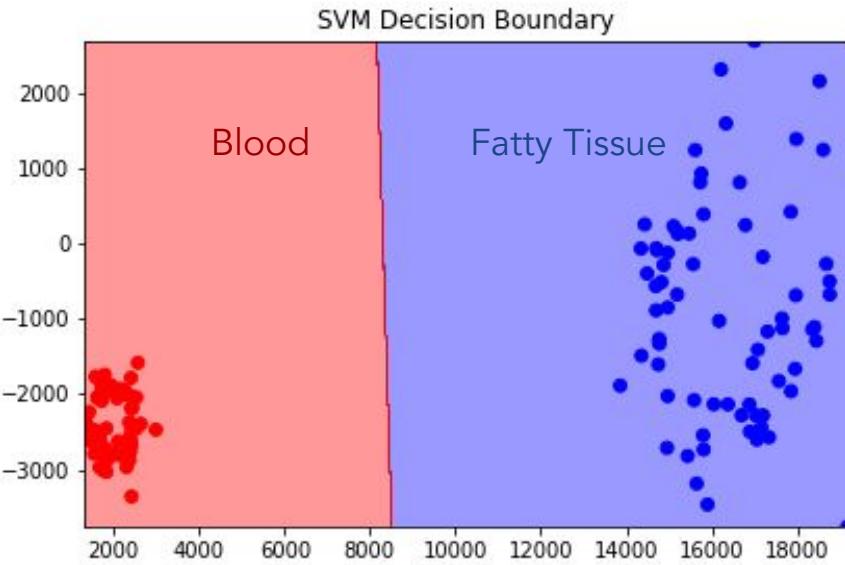
Impedance Analyzer
[Generate Signal]

Microprocessor
[Signal Processing]

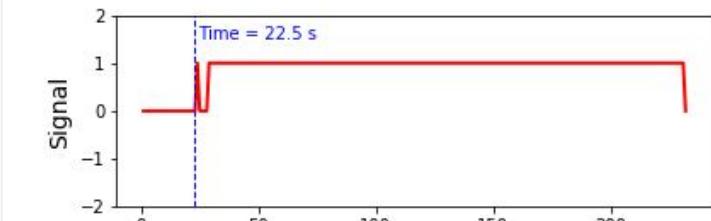
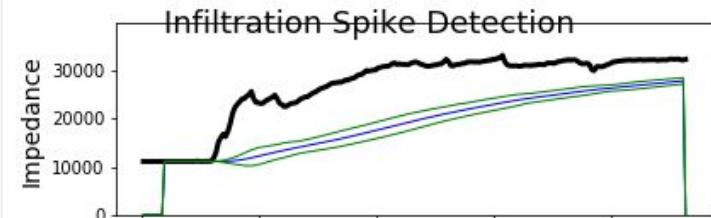
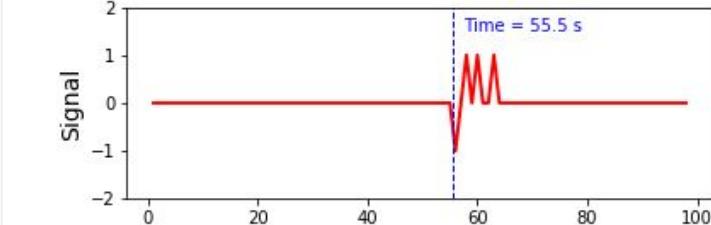
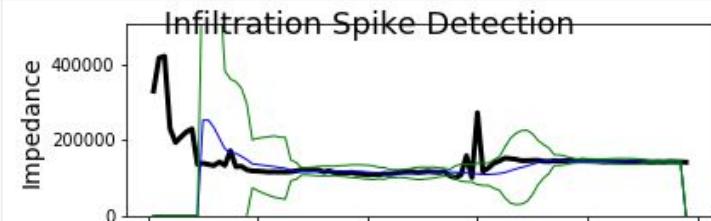
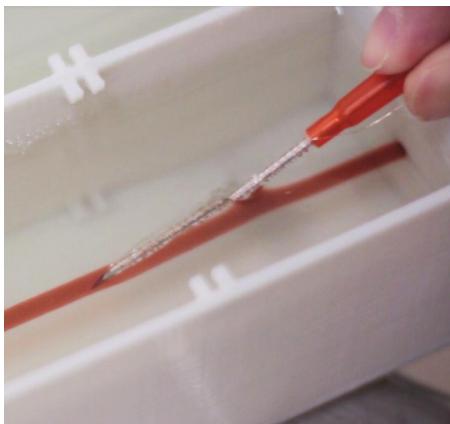
Display / Alarms
[UI/UX]

Tissue Classification

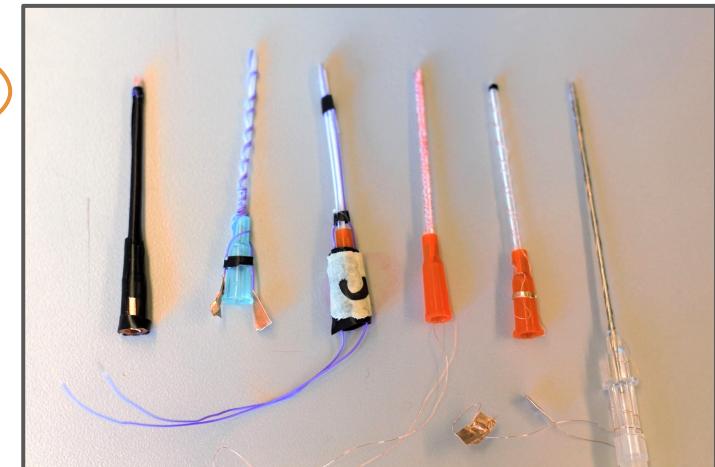
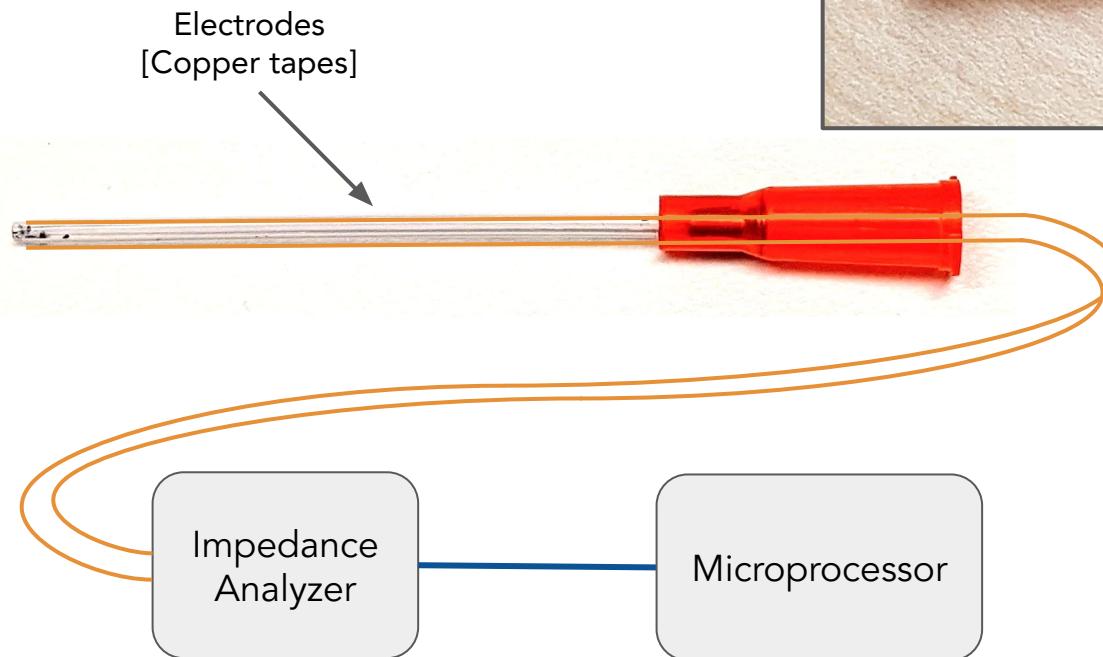
Tissue Characterization
100% classification accuracy



Infiltration Peak Detection



Prototype Results III



Prototype Video



Biological Models

[✓] Pork meat, fat, blood discrimination

[✓] Round I animal testing

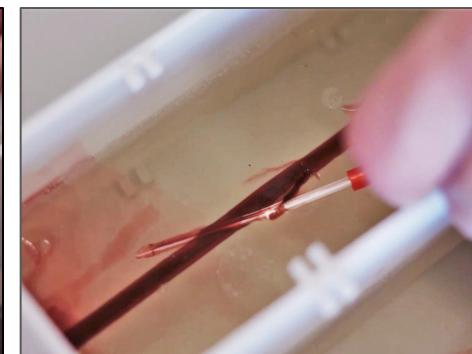
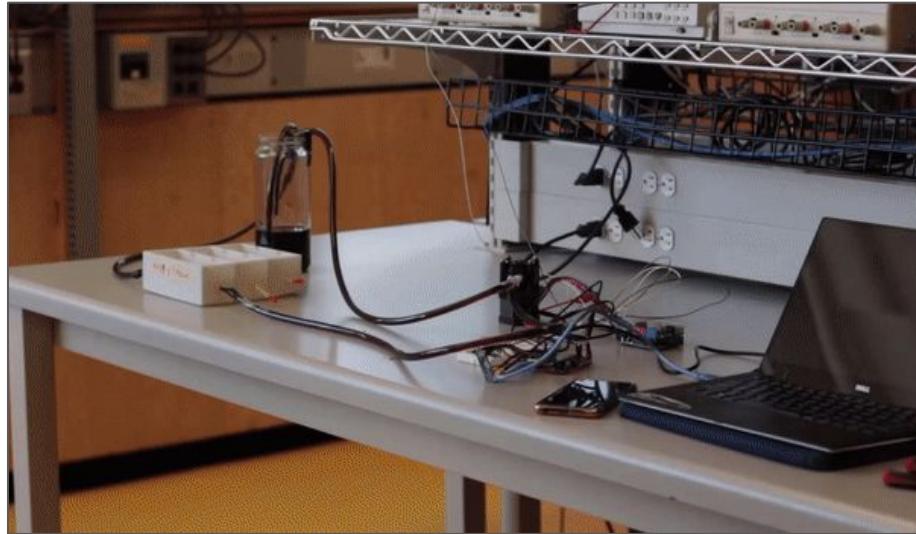
- Tissue discrimination (pig cadaver)
- Catheter insertion testing

[✗] Round II animal testing (Covid-19 Delays)



Phantom Models

- [✓] Replicates biological environment
- [✓] Captures dynamic impedance measurements
- [✓] Simulated blood flow and pulsations



Economic Impact

From: Lim, R., Cheng, M.Y., Damalerio, R. and Chen W. *Simulation Analysis of a Conformal Patch Sensor for Skin Tension and Swelling Detection*. IEEE 2017.

The survey includes the data on annual IV cannulation procedure being carried out in hospital, the estimated the incident rate and complication cost incurred for extended hospitalization due to extravasation incident. There is an estimated annual incident rate up to 6% in North America and EU, which correspond to an estimated up to 3.8 million and 5.1 million cases respectively. For China, there is an approximation annual incident rate up to 10% which is 5.6 million cases.

The extended hospitalization stay and cost incurred per case was approximately up to USD \$50,000 for North America, Euro €30,000 for EU and USD \$15,000 for China.

$$\begin{array}{l} \$50,000 \times 3.8 \text{ million} + \$33,000 \times 5.1 \text{ million} + \$15,000 \times 5.6 \text{ million} = \$442B \text{ USD} \\ (\text{North America}) \qquad \qquad \qquad (\text{Europe}) \qquad \qquad \qquad (\text{China}) \qquad \qquad \qquad (\text{Globally}) \end{array}$$

Product Pricing

50/50 Method of Pricing:

- 1700 NICU babies/year at BC Children's Hospital, requiring on average 8.66 catheters in their treatment → **14,718 catheters** used in the NICU/year
- 90% of patients require an IV and 4% result in serious injuries → 61.2 babies/year * \$50,000 USD treatment cost = **\$3.06 million/year**
- We can sell our system at 50% of the cost, which is **\$1.53 million/year**
- $\$1.53 \text{ million} / 14,718 \text{ catheters} = \sim \$100/\text{catheter}$

Market Sizing

Total Available Market - \$119B

- \$1000 rentals * 2.705 hospital beds/1000 people worldwide * 7B population = **\$18.9B**
- \$100/catheter * 1B catheters used worldwide/year = **\$100B**

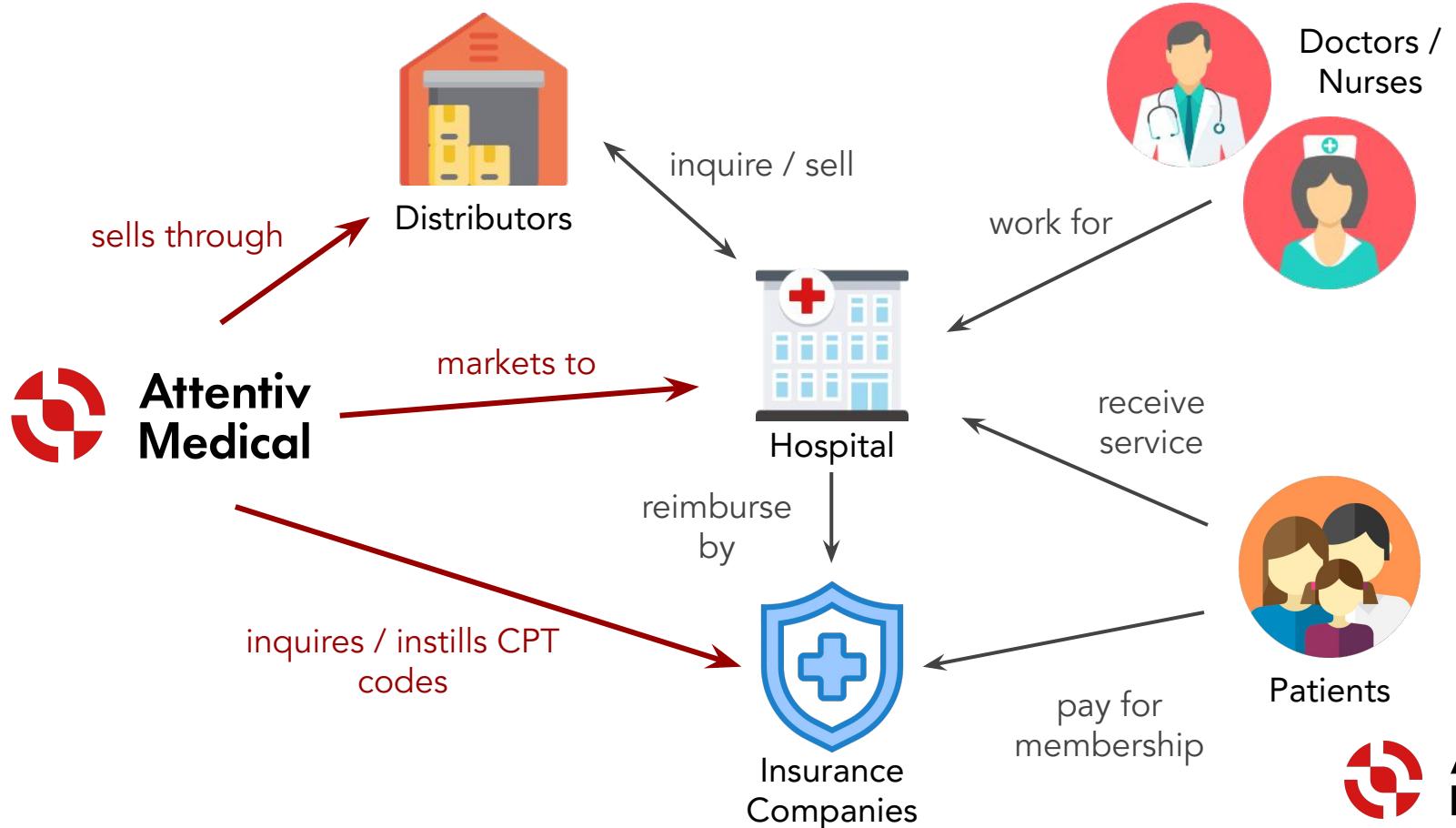
Serviceable Available Market - \$1.0B

- \$1000 rentals * [950k N/P/ICU beds in the USA + 5k in Canada] = **\$100M**
- \$100/catheter * [# catheters used in NICU (3.3M USA + 370k Canada) + PICU (735k USA + 83k Canada) + ICU (4.2M + 475k Canada)] = **\$917M**

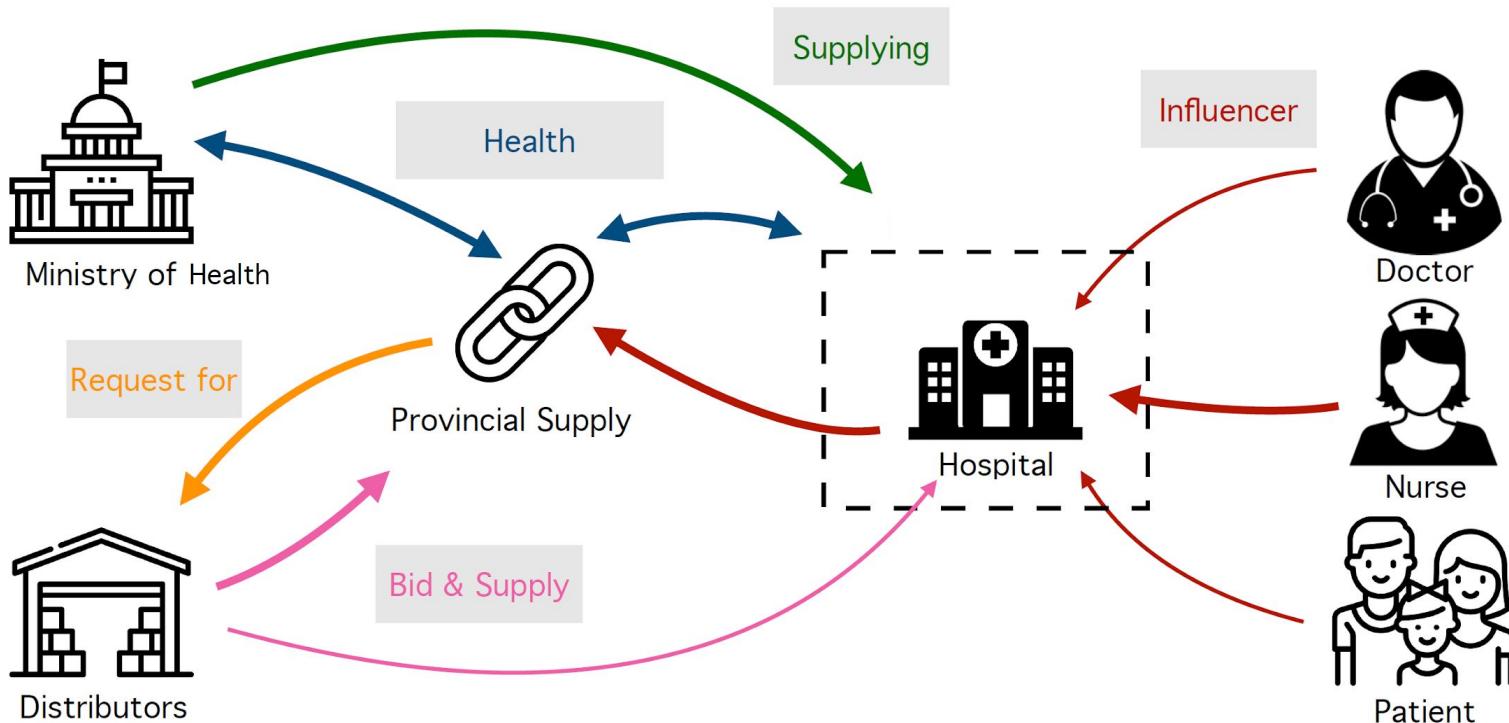
Serviceable Obtainable Market - \$351M

- \$1000 rentals * 23k NICU beds in the USA = **\$22.3M**
- \$100/catheter * [# catheters used in NICU (3.3M)] = **\$329M**

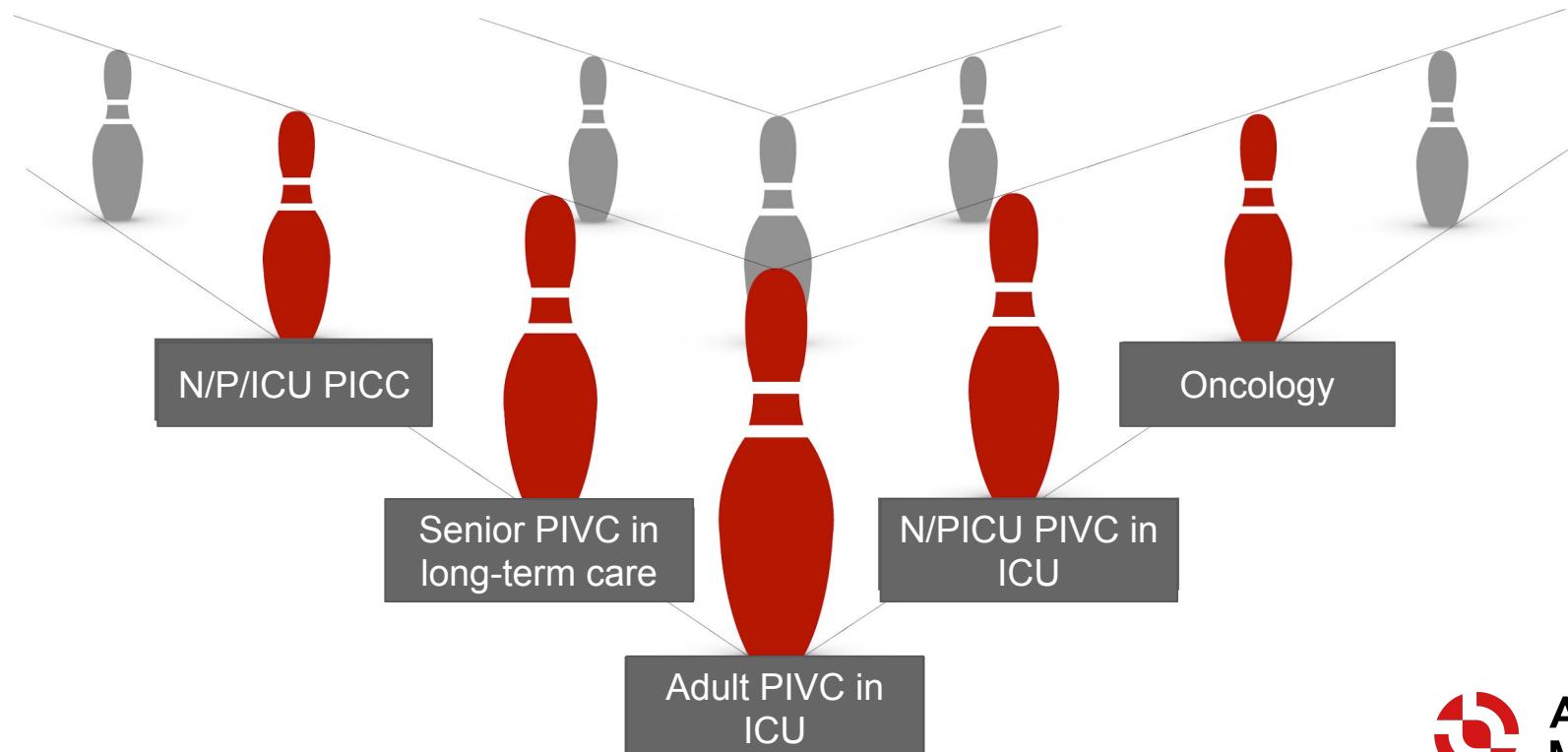
Medical Device Procurement (US)



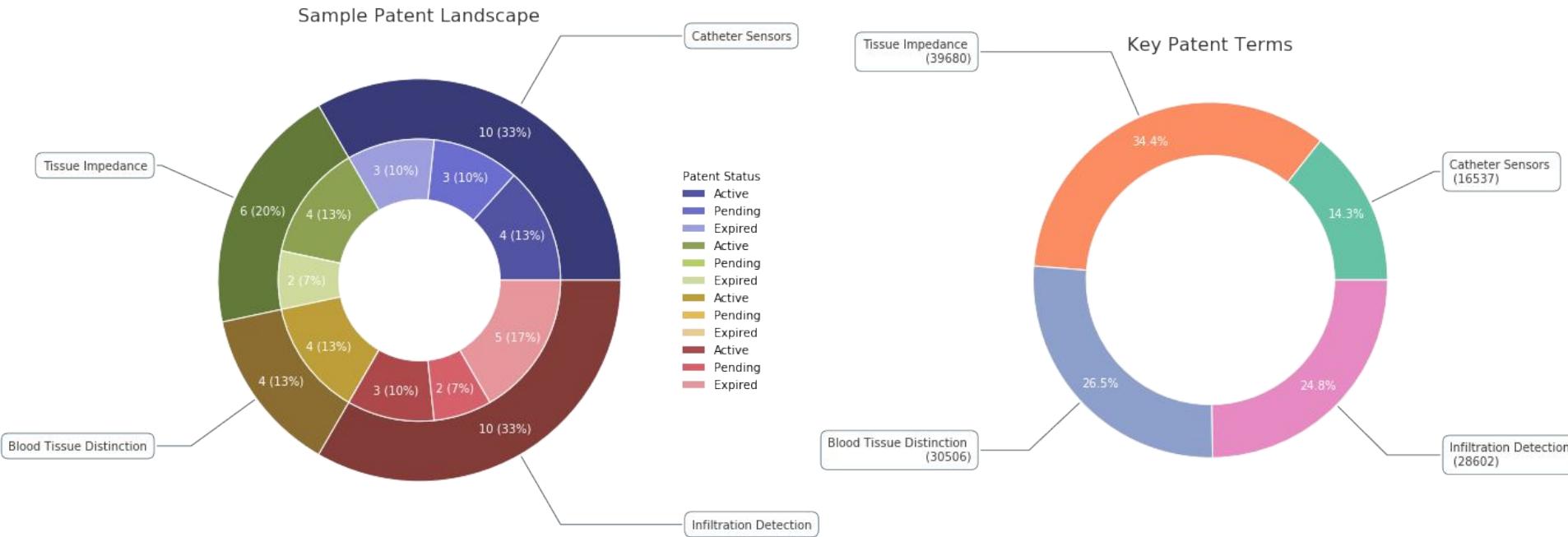
Medical Device Procurement (Canada)



Growth Plans



IP Landscape Analysis



IP Strategy

Our patenting strategy leverages our novel method for root cause detection:

1 Manufacturing Methodology

2 System Architecture

3 Apparatus Design

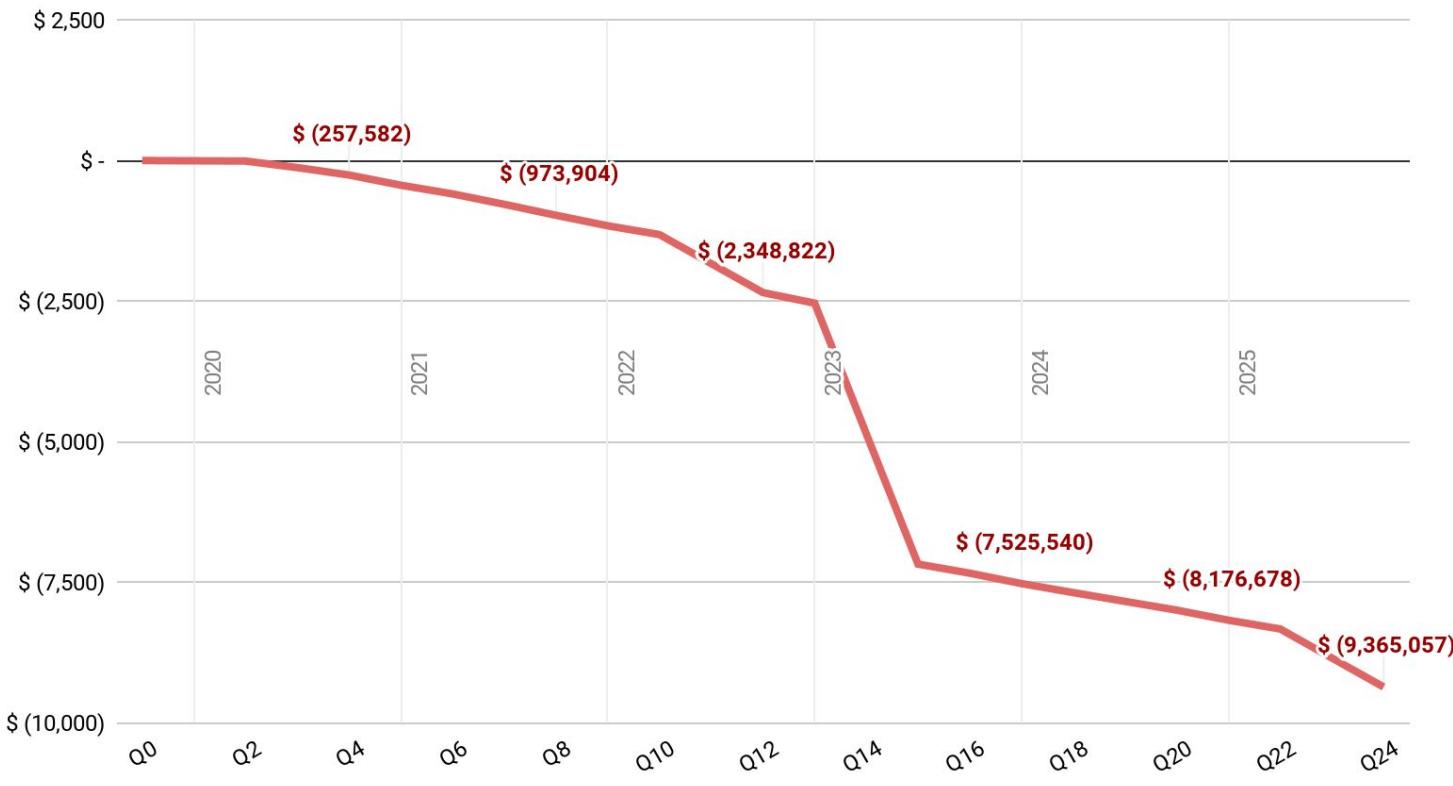


Competitive Landscape

| |  Attentiv Medical |  ivWatch® |  Lineus Medical | Infusion Pump | Manual Inspection |
|----------------|--|--|---|---------------|-------------------|
| NICU Suited | ✓ | ✗ | ✓ | ✓ | ✓ |
| Seamless | ✓ | ✗ | ✓ | ✓ | ✓ |
| Fast Detection | ✓ | ✓ | ✓ | ✗ | ✗ |
| High Accuracy | ✓ | ✓ | ✗ | ✗ | ✗ |
| Root Cause | ✓ | ✗ | ✗ | ✗ | ✗ |
| All Catheters | ? | ✗ | ✓ | ✗ | ✗ |
| Low Cost | ? | ✗ | ✓ | ✓ | ✓ |

Financial Projection

5 Years Cash Balance (Starting Q1 of 2020)



Financial Projection: Assumptions

- Animal trials
 - First (Pilot): \$13,000
 - Second (Full): \$55,300
- Patent
 - \$60,000 / patent
- Clinical trials
 - Phase 1: \$600,000
 - Phase 2: \$3,600,000
- Salaries
 - Initially: 4 Engineer, 1 Business
 - Eventually: 6 Engineer, 2 Business

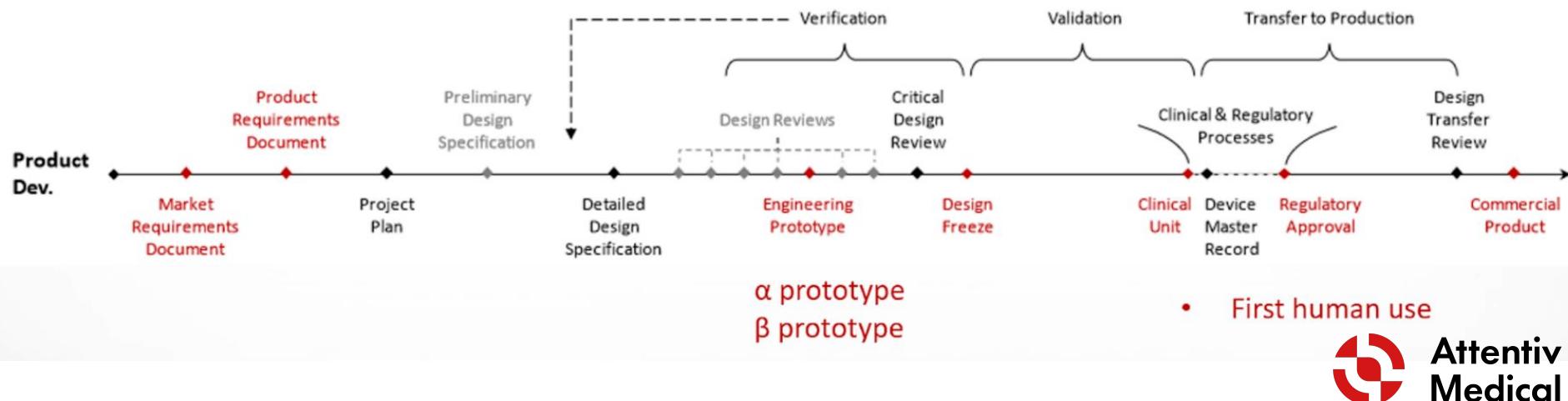
Regulatory

Medical Device Class:

- Health Canada: active, invasive device with no significant hazards → **Class II**
- FDA: substantially equivalent to other catheters & monitoring devices → **Class II**

Regulatory Pathway:

- Health Canada: QMS ISO 13485 certification, Medical Device License, Establishment License
- FDA: Investigational Device Exemption (clinical trials), 510k premarket notification, Quality System Regulations, Establishment License, CPT codes for insurance



Channel Economics

- **COGS** - IV catheters can be manufactured at low cost ^[1]
- **R&D** - typically 15% of sales ^[2]
- **SG&A** - ratio to R&D is typically 1:3 ^[2]
- **Distributor** - applies 20%~30% markup ^[3]



[1] <https://www.alibaba.com/showroom/iv-cannula-price.html>

[2] Biodesign: The Process of Innovating Medical Technology

[3] <https://www.medicaldevicesgroup.net/medical-devices/what-is-the-average-markup-that-a-distributor-adds-to-the-cost-price-for-medical-consumables/>

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