TrueCycle

truecycle hormone tracker

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Motivation & Market Need

Motivation
- Only **7%** of healthcare focuses on women's conditions
- Only **5%** of global R&D funds are allocated to women's health

Unmet Clinical Need
- **Endometriosis:** affects 10% of women, ~10-year diagnosis delay
- **PCOS:** 70% remain undiagnosed worldwide
- **Gap:** no tools exist to continuously monitor estradiol and progesterone levels, leading to delayed diagnoses and ineffective treatment

Our Market

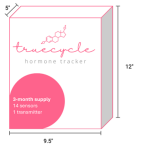
Women's health research labs at academic institutions → Women's health clinics and at-home consumers

Financial Analysis

A. Estimated Costs

Category	Period	$/yr
Development	Yr 1	$1,639,210.00
Capital	Yr 2	$624,313.73
Operational –Material	Yr 2-10	$30,000-8,300,000
Operational -Utility	Yr 2-10	$130,723
Business	Yr 2-10	$1,085,900.00

B. Key Assumptions
- Market Price: $600/unit
- Manufacturing Cost: $273.28/unit
- Tax Rate: 35%
- Discount Rate: 10%
- Revenue begins Year 2, grows each year
- Operating- Material costs increase annually
- Break-even (with TVM): Year 9
- Break-even (without TMV): Year 8.5



3-month supply (14 sensors, 1 electronic component)

C. Net Present Value (NPV) Over Time

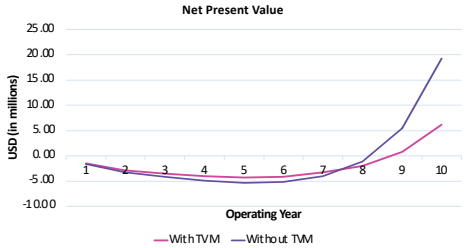
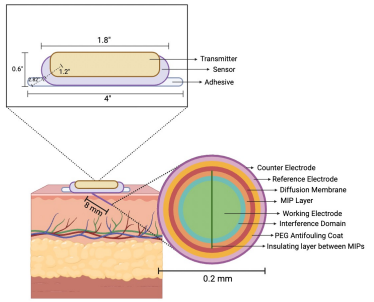


Figure 1. Financial Analysis of the Development and Manufacturing of TrueCycle. Panel A summarizes the estimated costs, Panel B outlines key assumptions, and Panel C shows NPV over time. Analysis indicates a positive NPV by Year 9.

Product Specifications



Filament Dimensions

Layer	Thickness
Counter Electrode	10 µm
Insulator (between electrodes)	20 µm
Reference Electrode	10 µm
Diffusion Membrane	5 µm
MIP Layer	15 µm
Interference Domain	15 µm
PEG Coating	15 µm
Insulator	20 µm
Working Electrode	90 µm

Hormone Detection Mechanism

Molecularly Imprinted Polymers (MIPs)
- Reversible due to moderate binding affinity
- Selective due to precise binding cavity
- Allows detection of analyte in low concentrations

Electrochemical Impedance Spectroscopy (EIS)
- Three-electrode system
- Detects interface changes during binding events
- Measures electron transfer at electrode surface
  - Increased binding → higher resistance → measurable signal
- Counter and reference electrode minimize electrochemical drift

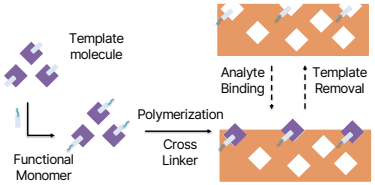


Figure 2. Formation of Molecularly Imprinter Polymers (MIPs). Creation of template molecule (analyte) followed by polymerization and cross linking. The template is removed and analyte can bind to MIP.

Technical Modeling

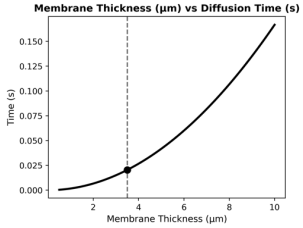


Figure 3. Membrane Thickness (µm) vs Diffusion Time. Diffusion is not a limiting factor in determining detection time as, no matter how thick the diffusion membrane is, the hormones can diffuse through the membrane in negligible time (<1s).

Fick's Second Law

$$\frac{\partial C}{\partial t} = D\frac{\partial^2 C}{\partial x^2}$$

Diffusion Time

$$\tau = \frac{L^2}{2D}$$

Binding Affinity

$$K_D = \frac{k_{off}}{k_{on}} = \frac{[M][E2]}{[ME2]}$$

Observable on-rate

$$k_{on}^{obs} = c \cdot k_{on} + k_{off}$$

Fractional Site Occupancy

$$\theta = \frac{[E2]}{(K_D + [E2])}$$

Association Time

$$\tau_{on} = \frac{1}{k_{on}^{obs}}$$

Dissociation Time

$$\tau_{off} = \frac{1}{k_{off}}$$

L	diffusion membrane thickness (m)
D	diffusion coefficient (m^2/s)
K_D	binding affinity (nM)
k_{off}	dissociation rate constant (s^{-1})
k_{on}	association rate constant (s^{-1})
θ	fractional site occupancy
$[E2]$	estradiol concentration (nM)

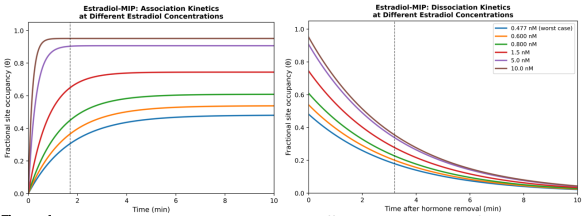


Figure 4. Association and Dissociation Kinetics at Different Concentrations of Estradiol in the Interstitial Fluid. At the lowest Estradiol concentration, the time of association of hormone to MIP is 1.7 mins, while the time of dissociation is 3.2 mins.

Manufacturing

Manufacturing Block Flow Diagram

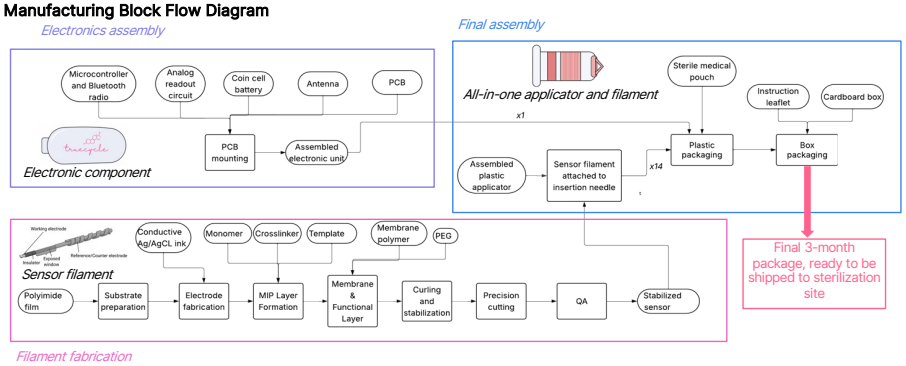


Figure 5. Detailed In-House Manufacturing Steps for Filament Fabrication, Electronics Assembly, and Applicator Fusion and Packaging.

Outsourced manufacturing steps
- Electronic component manufacturing
- Sterilization
- Plastic applicator manufacturing

Production capacity (per technician)
- 9.6 sensor per hour
- 20,000 sensors per year

Manufacturing scale up
- **Year 1:** 1/7 technician (contracted labor)
- **Year 9:** 18 technicians
- **Year 10:** 36 technicians

References

Conclusion

The Problem: Limited access to continuous hormone data restricts research and delays understanding of conditions like PCOS and endometriosis

Our Solution: A wearable device that continuously measures estradiol and progesterone in interstitial fluid using an electrochemical sensor

Strategy: Begin with research institutions to generate validated datasets, then expand to clinical and consumer markets

Impact & Value: Will create continuous hormone datasets to support research and improve the understanding of hormone-related conditions

Acknowledgements

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