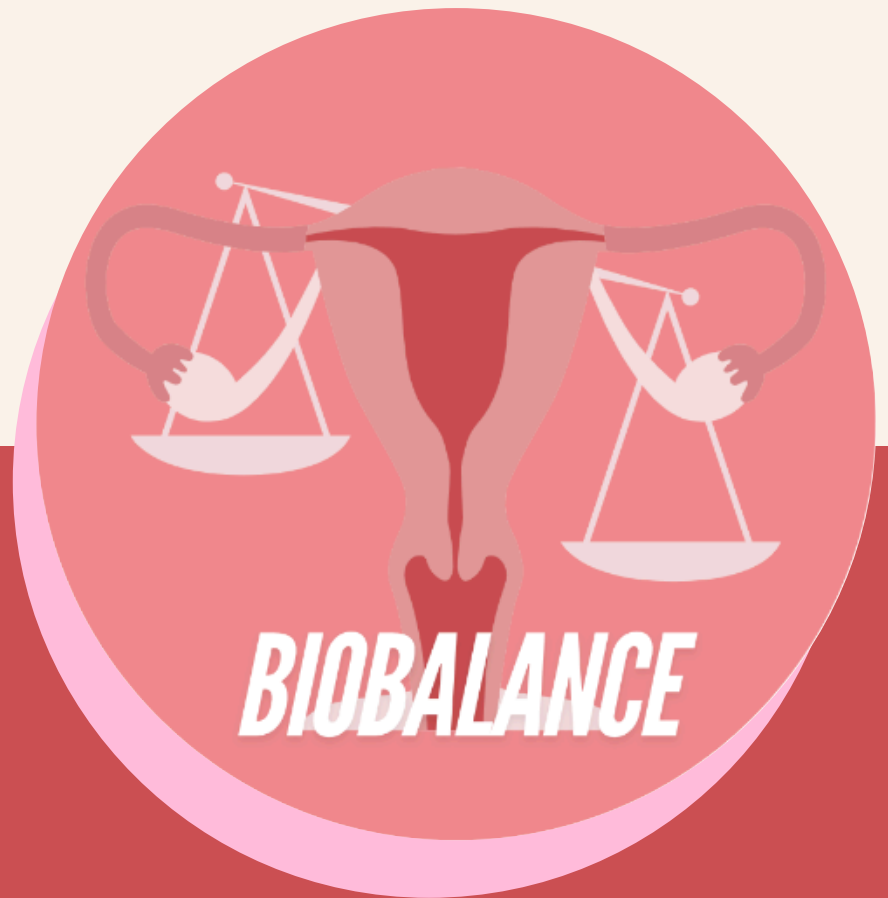


BME CAPSTONE TEAM 2

BIOBALANCE

SOFIA ANDRADE
RUHI DHARAN
ASHLEY HILL
SHEETAL JHA
LILLIAN MOFFATT



Continuous intervaginal cervical mucus monitor for cycle tracking and diagnostics research

FACULTY MENTORS & ACKNOWLEDGEMENTS:

JENNIFER BLAIN PH.D.
JENNA CLARK BSN, RN
DANIEL GULICK PH.D.
ROOHIE GUPTA B.S.
SARAH STABENFELDT PH.D.

SBHSE

School of **Biological and
Health Systems Engineering**

ASU Ira A. Fulton Schools of
Engineering
Arizona State University



UNDERSTAND YOUR CYCLE

BEYOND FERTILITY TRACKING

ABSTRACT

CLINICAL NEED & MARKET

01

80% of U.S. women experience imbalance of their reproductive hormones often causing conditions such as endometriosis, PCOS, PID, chronic yeast infections and chronic bacterial vaginosis. 1 in 6 women globally also experience infertility and 1.3 million women in the U.S. are experiencing menopause annually. The aim of BioBalance is to advance female reproductive healthcare and empower women by developing research and diagnostic models using cervical mucus qualitative metrics and quantitative hormone analytics. By doing this BioBalance hopes to be able to detect conditions resulting from hormonal imbalance such as those aforementioned.

The device will be marketed for anyone with female reproductive organs who seek a personalized understanding of their menstrual cycle. Currently, the market for cycle-tracking or fertility-tracking devices is experiencing a compound annual growth rate of ~10.8% by 2032 with a current market size of around \$475 million USD.

The competition in this market is not significant especially for BioBalance's unique design concept that goes beyond fertility tracking.



DESCRIPTION OF CONCEPT

02

BioBalance proposes a final design concept similar in shape to existing vaginal ring technologies made of ethylene vinyl acetate to ensure flexibility for insertion. The device sits in the vagina near the cervix, held in place by the pelvic bone. The device uses three sensors to qualitatively monitor cervical mucus. It has silicone-encased circuitry which processes information from the integrated sensors. Three separate sensors will detect and analyze the pH levels, basal body temperature, and the viscosity of the fluids in the cervical mucus for each phase of the cycle. BioBalance's wearable device will address user needs such as ease of use, comfortability, minimal-invasivity, and discreteness for continuous or daily cycle tracking.



DESIGN FOR MANUFACTURING & ASSOCIATED COSTS

03

The first component for our device will be the material necessary for easy insertion will be approximately 4.16 cm³ ethylene vinyl acetate (EVA) foam with the approximate cost being \$55 for each product unit. The three combined sensors - pH, viscosity, and temperature - will be approximately 5x5x2 mm with the cost varying from \$50-\$80. The power source for these sensors will be a lithium polymer battery that has dimensions 2.9x16.5x15.5 mm. The cost of this battery for each device will be around \$8 to \$12. Additionally, to incorporate the circuitry a 2x2 mm microcontroller will be implemented with the cost ranging from \$1 to \$3. The circuit will also depend on printed circuit board (PCB) strips that would cost about \$70 each. Lastly, Because the circuit will be encased in water-proof medical-grade silicone, the final cost will be dependent on the necessary encasing determined post-prototyping but will likely be around \$36 per unit. The total final manufacturing cost of the product will be around \$250-\$260 which is similar to other fertility/cycle-tracking products on the market indicating that the competitive advantage of BioBalance is its unique sensor implementation.